NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of bioresorbable stent implantation to treat coronary artery disease

The coronary arteries supply blood to the heat muscle. In coronary artery disease, they become narrowed with fatty material. This can cause chest pain on exertion and increases the risk of heart attacks. In this procedure, a stent (small tube) is implanted into a narrowed artery to widen it. Unlike permanent metal stents, bioresorbable stents dissolve over a few months. The aim is to increase blood flow to the heart, while reducing the risk of longer term complications.

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Appendix

Abbreviations

Word or phrase	Abbreviation
Acute coronary syndrome	ACS
American College of Cardiology	ACC
American Heart Association	AHA
Academic Research Consortium	ARC
Bioresorbable stents	BRS
Bioresorbable vascular scaffold	BVS
Coronary artery disease	CAD
Coronary artery aneurysm	CAA
Coronary heart disease	CHD
Confidence interval	CI
Drug-eluting stents	DES
Device-oriented composite endpoint	DOCE
Everolimus-eluting stent	EES
Hazard ratio	HR
Health technology assessment	HTA
Intravascular ultrasound	IVUS
Left circumflex artery	LCX
Left anterior descending artery	LAD
Major adverse cardiovascular event	MACE
Magnesium-based bioresorbable scaffold	MgBRS
Myocardial infarction	MI
Optical coherence tomography	OCT
Odds ratio	OR
Percutaneous coronary intervention	PCI
Patient-oriented composite endpoint	POCE
Randomised controlled trials	RCTs
Risk ratio	RR
Reference vessel diameter	RVD
Scaffold thrombosis	ScT
Sirolimus eluting stent	SES
ST elevation myocardial infarction	STEMI
Target vessel revascularisation	TVR
Target vessel failure	TVF

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Target lesion failure	TLF
Target lesion revascularisation	TLR

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and professional opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in August 2021.

Procedure name

- Bioresorbable stent implantation to treat coronary artery disease

Professional societies

- British Cardiovascular Intervention Society (BCIS)
- British Cardiovascular Society (BCS).

Description of the procedure

Indications and current treatment

Stenosis of the coronary arteries is usually caused by deposition of atherosclerotic plaque. This reduces blood flow to the heart muscle and is usually progressive. Symptoms of CAD typically include angina (chest pain that is exacerbated by exertion). A critical reduction of the blood supply to the heart may result in MI or death.

The symptoms from a stenosed artery may be treated medically. This includes modifying risk factors (for example, smoking, hyperlipidaemia, obesity, hyperglycaemia) and treatment with medicines (for example, beta blockers, nitrates, calcium-channel blockers, antiplatelet agents, statins).

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If medical management fails or is inappropriate, the usual options are coronary artery bypass grafting, or percutaneous transluminal coronary angioplasty followed by stent insertion to maintain the patency of coronary artery.

What the procedure involves

BRSs are designed to be absorbed by the body over time. One aim is to reduce the risk of late complications such as thrombosis, which may occur after the use of metal stents. The other is to reduce the need for long-term anti-platelet medicines, with their risk of bleeding complications.

The procedure is done under local anaesthesia. A guidewire is passed into the target coronary artery, usually from the radial or femoral artery under fluoroscopic image guidance. A balloon angioplasty catheter passed over the guidewire is used to dilate the coronary artery stenosis. A bioresorbable stent mounted on a balloon catheter is passed over the guide wire into the relevant segment of the artery. Then, it is expanded by inflation of the balloon within it. The balloon is then deflated and removed with the guide wire. The stent acts as a scaffold to hold the vessel open. Additional imaging, such as IVUS and OCT, is sometimes used to guide the procedure. This is to optimise positioning and deployment of the stent in the target coronary artery.

BRSs are absorbed over time. Most BRSs are also drug-eluting, with a view to reducing the risk of restenosis. Antiplatelet medicines such as aspirin and clopidogrel are usually prescribed for at least 6 months after the procedure.

Efficacy summary

Device and procedure success

In an RCT of 150 patients with STEMI, there was no statistically significant difference in device success between a magnesium-based SES BRS (n=74) and a metallic SES (n=76; 99% compared with 100%, difference 1.4%, 95% CI -1.3 to 4.0, p=0.493). There was also no statistically significant difference in procedural success (96% compared with 96%, difference 0.2%, 95% CI -6.2 to 6.4, p=1.000). Device success was defined as successful implantation with less than 30% residual stenosis of the target lesion and thrombolysis in MI [TIMI] flow grade 2 or more. Procedural success was defined as device success and no in-hospital cardiac events (Sabaté 2019).

In an ASORB UK registry of 1,005 patients with new coronary lesions who had BRS, there was device success in 99% and procedure success in 97% of patients. Device success was defined as successful implantation of 1 or more scaffolds with a final in-scaffold diameter stenosis of less than 50%, without BRS device deficiency. Procedure success was defined as successful implantation of

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1 or more scaffold with a final in-scaffold diameter stenosis of less than 50%, without TVF within 3 days of the index procedure (Baumbach 2018).

In an ISAR-ABSORB registry of 419 patients who had BRS, there was procedure success in 97% of patients. Procedure success was defined as residual stenosis of less than 30% and thrombolysis in MI [TIMI] grade 3 flow (Wiebe 2021).

MACE and POCE rates

In an HTA of BRS for treating CAD, a meta-analysis of 4 RCTs including 3,200 patients and with a maximum 5-year follow up found statistically significant higher rates of MACE with Absorb BRS (n=1,962) compared with permanent metal DES (n=1,238; RR 1.36, 95% CI 1.06 to 1.73, p=0.01; 0% heterogeneity). MACE comprised cardiac death, all MI and ischaemic-driven TLR. In the same study, a meta-analysis of 5 RCTs including 5,449 patients and with 5-year maximum follow up found statistically significant higher rates of POCE with Absorb BRS (n=3,153) compared with permanent metal DES (n=2,296; RR 1.36, 95% CI 1.06 to 1.73, p=0.01; 0% heterogeneity). POCE comprised of all death, all MI and all revascularisations (IAMEV 2019).

In an individual patient data meta-analysis of 4 RCTs, including 3,384 patients with CHD and with at least a 5-year follow up, reported that POCE rate was higher with BRS (n=2,161) than with EES but not statistically significantly so (n=1,223; 26% compared with 23%, HR 1.15, 95% CI 0.99 to 1.33, p=0.07). POCE comprised of all-cause mortality, all MI or all revascularisations. The increased risk of POCE with BRS compared with EES between 0 to 3 years (20% compared with 16%, HR 1.23, 95% CI 1.04 to 1.46) was not evident between 3 to 5 years (9% compared with 9%, HR 0.97, 95% CI 0.76 to 1.24, p=0.10; Stone 2019).

In the ABSORB UK registry of 1,005 patients, MACE rate was less than 1% in hospital, 1% (12/992) at 30-day follow up and 3% (34/992) with BRS at 1-year follow up. MACE rate was defined as cardiac death, all MI and ischaemia-driven TLR (Baumbach 2018).

In the ISAR-ABSORB registry of 419 patients, the 5 year rate of composite endpoint of death, MI and ischemia-driven TLR with BRS was 33% (Wiebe 2021).

In the RCT of 150 patients with STEMI, after 1 year, the POCE was higher, but not statistically significantly so, with magnesium-based SES BRS than with metallic SES (23% [17/74] compared with 15% [11/76], difference 8.5%, 95% CI -20.9 to 3.9, p=0.182), POCE comprised of all-cause death, any recurrent MI, or any revascularisation (Sabaté 2019).

TLF

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In a meta-analysis of 10 studies (n=6,383), TLF was statistically significantly higher with BRS (n=3,573 than with DES group (n=2,810; OR 1.46, 95% CI 1.20 to 1.79, p=0.0002; I^2=0%; Ni 2020).

In the individual patient data meta-analysis of 4 RCTs, TLF rate was statistically significantly higher with BRS than with EES (15% compared with 12%, HR 1.26, 95% CI 1.03 to 1.54, p=0.03). TFL rate was defined as the composite of cardiac death, target vessel MI and ischaemia-driven TLR. At 0- to 3-years follow up, TLF occurred in 12% of patients with BRS and 8% with EES group (HR 1.42, 95% CI 1.12 to 1.80). At 3- to 5-year follow up, TLF occurred in 4% with BRS group and 5% (with EES (HR 0.92, 95% CI 0.64 to 1.31, p=0.046; Stone 2019).

In a meta-analysis of 91 RCTs, pairwise meta-analysis of 6 RCTs in patients with stable or unstable angina (4 studies), STEMI (1 study) or with all types of CHD (1 study) showed that TLF rates were not statistically significantly different between BRS (n=3,179) and CoCr EES (n=2,239) at 1 year (OR 1.26, 95% CI 0.99 to 1.61, p=0.059, I^2=0%). However, they were statistically significantly higher with BRS than CoCr EES at follow up of over than 1 year (OR 1.39, 95% CI 1.15 to 1.67, p<0.001, I^2=0%; Kang 2018).

In the ABSORB UK registry of 1,005 patients, TLF rate was less than 1% in hospital, 1% at 30 days and 3% at 1 year. TLF rate was defined as the composite of cardiac death, target vessel MI and ischaemia-driven TLR (Baumbach 2018).

In a case series of 184 patients with new lesions and stable or unstable angina or documented silent ischemia, TLF occurred in 6% of patients at 2 years after resorption of a magnesium-based SES BRS and in 6% at 3 years (Haude 2020).

TVF

In the ABSORB UK registry of 1,005 patients, TVF (including cardiac death, all MI and ischaemia-driven TVR) was reported in 1% of patients at 30 days and 4% (at 1-year follow-up (Baumbach 2018).

TLR/TVR

In the HTA of BRS for treating CAD, a meta-analysis of 8 RCTs including 5,827 patients at maximum follow-up found a statistically significant higher rate of TLR with Absorb BRS (n=3,342) compared with permanent metal DES (n=2,485; RR 1.36, 95% CI 1.08 to 1.71; p=0.009; 0% heterogeneity). In a meta-analysis of 8 studies after a maximum length of follow-up, the rate of TVR was significantly higher in the Absorb BRS group than in the DES group [RR 1.18 (95% CI 0.98–1.41); p=0.08; I^2=0% heterogeneity] (IAMEV 2019).

In the meta-analysis of 91 RCTs, pairwise meta-analysis of 6 RCTs comparing BRS and CoCr EES found that there was no statistically significant difference in

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TLR at 1 year between the groups (OR 1.28, 95% CI 0.91 to 1.80, p=0.150). However, there was a statistically significant difference at follow up of over a 1 year (OR 1.46, 95% CI 1.12 to 1.85, p=0.004). A network meta-analysis of 91 RCTs showed similar performance with BRS and other DES, and statistically significantly better than BMS in terms of TVR and TLR (Kang 2018).

In the individual patient data meta-analysis of 4 RCTs, there were statistically significantly increased rates of ischemia-driven TLR (8% with BRS compared with 6% with EES, HR 1.41, 95% CI 1.06 to 1.87, p=0.02) and ischemia driven TVR (13% compared with 20%, HR 1.32, 95% CI 1.06 to 1.65, p=0.01). Between 3 and 5 years, the rates were not statistically significantly different between the groups (Stone 2019).

In the ABSORB UK registry of 1,005 patients, TLR was 1% at 30 days and 3% (with BRS at 1-year follow up. TVR rate was 1% at 30 days and 4% at 1-year follow up. All coronary revascularisation rate (based on the ARC definition) at 1 year was 14% (Baumbach 2018).

In the ISAR-ABSORB registry of 419 patients, the incidence of TLR with BRS at 12 months was 10% and increased to 20% between 1 and 5 years (Wiebe 2021).

In the RCT of 150 patients with STEMI, ischaemia-driven TLR at 1 year was statically significantly higher with magnesium-based SES BRS compared with metallic SES (16% [12/74] compared with 5% [4/76], difference 11%, 95% CI -20.7 to -1.2, p=0.030). TVR at 1 year was also higher with magnesium-based SES BRS compared with metallic SES (20% [15/74] compared with 8% [6/76], difference 13%, 95% CI -23.4 to -1.4, p=0.029; Sabaté 2019).

In the case series of 184 patients, clinically driven TLR was reported in 3% (6/174) of patients and clinically driven TVR in 5% (9/174) of patients at 3-year follow up with magnesium-based SES BRS (Haude 2020).

Reduced need for long-term anticlotting medicines

In the case series of 184 patients, 53% of patients were on dual antiplatelet therapy at 12 months, 19% at 2 years and 16% at 3 years with magnesium-based SES BRS (Haude 2020).

Angina status

In the case series of 184 patients, angina status in all patients (either stable or unstable angina, or documented silent ischemia) improved from baseline to follow up with magnesium-based SES BRS. In all, 93% of patients were symptom-free 2 years after scaffold resorption and 92% were symptom free at 3 years (Haude 2020).

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Safety summary

All cause death and cardiac deaths

In the HTA, mortality because of bleeding or stroke was reported in 2 patients across all Absorb BRS groups in 11 studies (n=1,402) between 6- and 60-month follow up (IAMEV 2019).

The individual patient data meta-analysis of 4 RCTs found similar rates of death between BRS and DES (all-cause mortality 6% compared with 6%, HR 1.02, 95% CI 0.75 to 1.38, p=0.92; cardiac deaths 2% compared with 3%, HR 0.79, 95% CI 0.50 to 1.25, p=0.31; Stone 2019).

In the meta-analysis of 10 studies, cardiac death was statistically significantly higher with BRS than with DES (OR 2.19, 95% CI 1.17 to 4.07, p=0.01; I^2=0%; Ni 2020).

In the meta-analysis of 91 RCTs, pairwise meta-analysis of 6 RCTs showed that the risk of cardiac death was similar both at 1 year (OR 1.13, 95% CI 0.57 to 2.24, p=0.717) and after more than 1-year follow up (OR 0.86, 95% CI 0.55 to 1.33, p=0.498) between BRS and CoCr EES. Network meta-analysis showed that BRS was associated with an increased risk of all cause death and cardiac death compared with DES (Kang 2018).

In the ABSORB UK registry of 1,005 patients who had BRS, 1 cardiac related death was reported at 30 days and 6 cardiovascular and non-cardiovascular deaths were reported at 1 year (of these 3 were cardiac related; Baumbach 2018).

In the ISAR-ABSORB registry of 419 patients who had BRS, the rate of all-cause death was 14% and cardiac death was 8% at 5-year follow up (Wiebe 2021).

In the RCT of 150 patients, reported deaths at 1 year (all of which were cardiac deaths) were similar between magnesium-based SES BRS and metallic SES (1.4% compared with 1.3%, difference 0.1%, 95% CI -3.7 to 3.6, p=0.985; Sabaté 2019).

In the case series of 184 patients who had magnesium-based SESBRS, deaths (cardiovascular and non-cardiovascular) were reported in 5% (9/174) patients at 3-year follow up (4 of these were cardiac related; Haude 2020).

Stent thrombosis

In the HTA of BRS for treating CAD, a meta-analysis of 6 RCTs (including 5,450 patients, there was a statistically significant increased risk in the rate of ScT after at least 1 year with Absorb BRS (n=3,152) compared with permanent metal DES

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(n=2,298; RR 5.09, 95% CI 1.97 to 13.17, p=0.0008; 0% heterogeneity; IAMEV 2019).

In the meta-analysis of 10 studies, stent thrombosis was statistically significantly higher with BRS than with DES (OR 2.70, 95% CI 1.57 to 4.66, p= 0.0003; I^2 = 0%; Ni 2020).

In the individual patient data meta-analysis of 4 RCTs, BRS was associated with higher rates of device thrombosis than DES-EES (3% compared with less than <1%, HR 2.87, 95% CI 1.46 to 5.65, p=0.002). At 0- to 3-year follow up, device thrombosis (definite/probable) occurred in 2% of patients who had BRS and less than 1% who had DES (HR 3.86, 95% CI 1.75 to 8.50) and at 3- to 5-year follow up, it occurred in 0.1% with BRS and 0.3% with DES (HR 0.44, 95% CI 0.07 to 2.70, p=0.03; Stone 2019).

In the network meta-analysis of 91 RCTs (including 105,842 patients with CHD), pooled results from 84 trials (n=99,112) showed that patients who had BRS had a statistically significantly higher risk of long-term (definite or probable) ScT compared with those who had metallic DES. The risk of very late (after 1 year) definite or probable ScT was statistically significantly higher for BRS than any other comparator group. BMS showed a lower very late stent thrombosis risk than DES and BRS (Kang 2018).

In the same study, pooled results from pairwise meta-analysis of 6 RCTs found that the risk of (definite or probable) ScT with BRS was high compared with CoCr EES across all time points (less than or equal to 30 days, OR 2.01, 95% CI 1.05 to 3.85, p=0.034, I^2=0%; 31 days to 1 year, OR 3.87, 95% CI 1.15 to 13.0, p=0.029, I^2=1.3%; more than 1 year, OR 5.09, 95% CI 1.94 to 13.3, p=<0.001, I^2=0%; Kang 2018).

In the ASORB UK registry of 1,005, at 1 year, definite ScT occurred in 1% of people who had BRS (acute 0.1%, sub-acute 0.7%, late 0.6%). In the multivariable analysis, only the use of the smallest scaffold size of 2.5 mm remained statistically significantly correlated to ScT (OR 3.27, 95% CI: 1.28 to 8.37, p=0.014; Baumbach 2018).

In the ISAR-ABSORB registry of 419 patients, at 5 years, the rate of definite stent thrombosis was 5% with BRS. Most events occurred within 2 years after implantation (2% to 4%) and rates were stable between 2-5 years (4% to 5%; Wiebe 2021).

In the RCT of 150 patients with STEMI, the rate of definite device thrombosis at 1 year was similar between magnesium-based SES BRS and metallic SES (1.4% [1/74] compared with 2.6% [2/76], difference 1.2%, 95% CI -3.2 to 5.7, p=1.000; Sabaté 2019).

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Target vessel MI

In the meta-analysis of 91 RCTs, pairwise meta-analysis of 6 RCTs showed that the risk of target vessel MI was statistically significantly higher with BRS at both 1-year follow up (OR 1.59, 95% CI 1.16 to 2.18, p=0.004) and in the long term (OR 1.67, 95% CI 1.28 to 2.18, p<0.001) compared with CoCr EES. Network meta-analysis showed that BRS was associated with an increased risk of MI compared with DES (Kang 2018).

The individual patient data meta-analysis of 4 RCTs found that BRS compared with DES through 0 to 3 years and at 5 years resulted in increased rates of all MI (0 to 3 years: 9% compared with 6%, HR 1.56, 95% CI 1.18 to 2.06; 5 years: 11% compared with 8%, HR 1.30, 95% CI 1.02 to 1.66, p=0.03) and target vessel MI (0 to 3 years: 8% compared with 4%, HR 1.76, 95% CI 1.28 to 2.43; 5 years: 9% compared with 6%, HR 1.55, 95% CI 1.16 to 2.06, p=0.003). Between 3 and 5 years, rates were not statistically significantly different between the groups (Stone 2019).

In the ABSORB UK registry of 1,005 patients who had BRS, MI rate was less than 1% in hospital, 1% at 30 days and 2% at 1 year. MI was defined as based on a protocol definition of symptoms and development of a Q wave and non Q wave MI (Baumbach 2018).

In the ISAR-ABSORB registry of 419 patients who had BRS, the rate of all MI was 6% at 5-year follow up (Wiebe 2021).

In the RCT of 150 patients with STEMI, the rate of MI at 1 year was similar between magnesium-based SES BRS and metallic SES (1.4% [1/74] compared with 3.9% [3/76], difference 2.5%, 95% CI -2.5 to 7.7, p=0.620; Sabaté 2019).

In the case series of 184 patients who had magnesium-based SES BRS, target-vessel MI was reported in 1 patient at 3-year follow up (Haude 2020).

Vessel perforation

Vessel perforation (at the side of the vessel likely because of fatigue and fracturing of the scaffold struts) after implantation of a BRS for coronary stenting within a mechanically stressed region was reported in a case report of 1 patient with restenosis after prior stenting in the LAD. This was successfully treated by positioning a balloon across the ruptured region and then implanting a covered stent graft within the scaffold, sealing the perforation. Restenosis of the previous LAD stent were treated with additional implantation of DES (Schinke 2015).

CAA

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CAA (defined as an in-scaffold diameter more than 1.5 times the RVD) 18 months after the procedure, over the BRS at the middle LCX was reported in a case report of 1 patient. OCT revealed absence of strut continuity and complete endothelialisation of sturt remnants at the aneurysm site, in the middle of the BRS. The patient did not have further intervention but dual antiplatelet therapy was given to prevent thrombus formation. The patient had no further adverse events during 1-year follow up. In addition, further literature review identified 11 cases of CAA after BRS implantation, which occurred between 2 and 32 months. Most patients did not have further intervention but long-term dual antiplatelet therapy and early follow up were adopted (Chua 2017).

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, professional experts are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, professional experts listed no anecdotal adverse events and theoretical adverse events.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to bioresorbable stent implantation to treat coronary artery disease. The following databases were searched, covering the period from their start to 11-08-2021: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The inclusion criteria were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

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Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with coronary artery disease.
Intervention/test	Bioresorbable stent implantation.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 140,584 patients from 1 HTA, 1 RCT, 3 systematic reviews with meta-analysis, 5 case series and 2 case reports. Of these 31,605 patients had BRS. There is some overlap of primary studies between the systematic reviews and meta-analyses and HTA[1-4].

Other studies that were considered to be relevant to the procedure but were not included in the main summary of the key evidence are listed in the appendix.

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Summary of key evidence on bioresorbable stent implantation to treat coronary artery disease

Study 1 IAMEV, SNSPMPDSB 2019

Study type	HTA
Country	Europe, New Zealand, USA, Australia, Japan, Singapore, Egypt, India
Search period	Search period -inception to 2018
Study population and number	n=53 studies of 22295 adult patients with CAD, including stable angina, unstable angina, and/or MI, who require and are eligible for myocardial revascularisation. [8 RCTs with 5863 patients covered across 18 articles and 45 uncontrolled cohort trials with 16432 patients covered across 71 articles]
Age and sex	RCTs: mean age range 57-67 years, 70-80% male Uncontrolled cohort studies: mean age range 54-66 years, 60-90% male
Study selection criteria	Inclusion criteria: Randomised clinical trials, prospective non-RCTs; prospective (single-arm) observational studies (e.g., case series), and registries with at least 50 patients involving PCI with implantation of a fully bioabsorbable, biodegradable or bioresorbable vascular scaffold or stent (BRS) Exclusion criteria: No primary study included in paper, no full-text publication available, no relevant outcomes, in language other than English/German/French/Spanish, cohort study not prospectively planned, cohort study <50 patients
Technique	RCTs: Patients were randomly assigned to ABSORB everolimus-eluting PLLA bioresorbable vascular scaffold (BVS) system (Abbott Vascular, Santa Clara, CA, USA) or metallic drug-eluting stents (DES) and the corresponding scaffold was implanted. Uncontrolled cohort trials: Patients were implanted with one of the following bioresorbable vascular scaffolds (BVS) depending on the study: ABSORB everolimus-eluting PLLA BVS system (Abbott Vascular), DESolve novolimus-eluting PLLA BVS (Elixir Medical Corporation), DREAMS 2G (commercial name Magmaris) sirolimus-eluting magnesium bioresorbable scaffold (Biotronik AG), Fantom sirolimus-eluting BVS (REVA Medical).
Follow-up	RCTs: 6 months-4 years Uncontrolled cohort trials: average follow-up 12-24 months, maximum reported follow-up 5 years
Conflict of interest/source of funding	This study was funded by a grant from the European Commission. No conflicts of interest reported.

Analysis

Follow up issues: Follow-up varies across studies and data was analysed as reported by individual studies.

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Study design issues: The HTA Core Model Application for Rapid Relative Effectiveness Assessment (REA; 4.2) was the primary source for selecting assessment elements.

To identify primary studies containing information about efficacy and safety within the scope of the HTA, systematic literature searches were conducted using Medline, PubMed, Embase and the Cochrane Central Register of Controlled Trials. In addition, authors searched the Cochrane Database for Systematic Reviews for topic-related review articles. References from relevant original articles and reviews were hand-searched to identify additional primary studies. A search for relevant ongoing studies was also conducted using clinical trial registries ClinicalTrials.gov and World Health Organisation (WHO)-International Clinical Trials Registry Platform (ICTRP). Two researchers independently screened entries, and in the case of disagreements, a third researcher was involved to resolve the differences.

Risk of bias at the study level and endpoint level for RCTs was assessed using the Cochrane risk of bias tool. Risk of bias at the study level for the single-arm studies was assessed using the Institute of Health Economics (IHE) 20-Criteria checklist. Two reviewers performed the risk of bias assessment independently and disagreements were resolved by consensus.

The quality of the body of evidence was assessed using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methodology in which “high” = further research is very unlikely to change confidence in the estimate of effect, “moderate” = further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate, “low” = further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate, and “Very low” = extreme uncertainty about the estimate.

Study population issues: Patients in the included studies (RCTs and single-arm studies) were predominantly male with and aged 60 to 70 years - generalisability to females and other age groups is limited. Most of the included study population had relatively simple lesions in contrast to patients with more complex lesions frequently encountered in daily practice.

Other issues: All effectiveness data and the majority of safety data reported in this HTA comes from studies using Absorb BVS; there are few studies related to other BVS devices included. Only 3/53 studies analysing 1.5% of the total patient population (345/22295) included in this HTA report outcomes relating to the DESolve BVS, 2/53 studies and 0.8% of the patient population (184/22295) report Magmaris BVS outcomes, and 1/53 studies and 1.1% of the patient population (184/22295) report Fantom BVS outcomes.

There is some overlap of primary studies between the systematic reviews and meta-analyses and HTA[1-4].

Key efficacy findings

Number of patients analysed: 5863 (across 8 RCTs comparing Absorb BVS with DES; 3362 Absorb versus 2502 DES)]

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Summary of mortality and MI outcomes

Outcome	Anticipated absolute effects (95% CI)		Relative effect (95% CI)	P-value	Number of participants across studies reporting outcome	Quality of studies according to GRADE
	Risk with DES	Risk with Absorb BVS				
All-cause mortality (2-4 years follow-up)	38 per 1000	32 per 1000 (24-43)	RR 0.84 (0.63–1.11)	0.22	5645	Moderate[a]
All-cause mortality (≥3 years follow-up)	41 per 1000	34 per 1000 (26-46)	RR 0.82 (0.62–1.10)	0.19	5001	Moderate[a]
Cardiac mortality (6 months-4 years follow-up)	16 per 1000	15 per 1000 (10-23)	RR 0.91 (0.60–1.39)	0.68	5830	Moderate[a]
Cardiac mortality (≥3 years follow-up)	18 per 1000	16 per 1000 (11-25)	RR 0.89 (0.58–1.38)	0.61	5185	Moderate[a]
MI (1–4 years of follow-up)	49 per 000	73 per 1000 (60-91)	RR 1.49 (1.21–1.84)	0.0002	5845	High
MI (≥3 years follow-up)	53 per 1000	77 per 1000 (62-96)	RR 1.44 (1.16–1.80)	0.001	5001	High

a = Imprecision was downgraded by 1 point because of a non-significant effect estimate with wide CI

All MI

Meta-analysis including results from the maximum length of follow-up in 8 RCTs showed statistically significant higher rates of MIs for patients who had Absorb BVS compared with patients who had permanent metal DES [RR 1.49 (95% CI 1.21-1.84); p=0.0002; 0% heterogeneity]. Limiting analysis to studies with at least 3 years of follow-up (5 RCTs) did not change the significance of the results [RR 1.44 (95% CI 1.16–1.80); p=0.001; 0% heterogeneity].

Angina

Angina as an endpoint was reported in 3 RCTs. In 1 study, the percentage of patients reporting angina after 1 year of follow-up was 18.3% in the Absorb BVS group and 18.4% in the permanent metal DES group. In the other 2 RCTs, the percentage of patients free of angina was assessed using the Seattle Angina Questionnaire,

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with no difference between the study groups (74% versus 73% after 3 and 91.4% versus 91.7% after 6 months, respectively).

MACE

Meta-analysis including results from the maximum length of follow-up in 4 RCTs (including 3,200 patients with a maximum 5-year follow-up) showed statistically significant higher rates of MACE (comprised of cardiac death, all MI, and ischaemic-driven TLR (ID-TLR)) in patients who had Absorb BVS (n=1,962) compared with patients who had permanent metal DES [n=1,238; RR 1.36 (95% CI 1.06–1.73); p=0.01; 0% heterogeneity].

POCE

Meta-analysis including results from the maximum length of follow-up in 5 RCTs (n=5,449 patients and with 5-year maximum follow-up) showed statistically significant higher rates of POCE (comprised of all death, all MI, and all revascularisations) in patients who had Absorb BVS (n=3,153) compared with patients who had permanent metal DES [n=2,296; RR 1.36 (95% CI 1.06–1.73); p=0.01; 0% heterogeneity].

TLR

In a meta-analysis for all-TLR after a maximum length of follow-up in 8 RCTs, the rate of TLR was significantly higher in the Absorb BVS group than in the DES group [RR 1.36 (95% CI 1.08–1.71); p=0.009; 0% heterogeneity].

TVR

In a meta-analysis for all-TVR after a maximum length of follow-up in 8 RCTs, the rate of TVR was significantly higher in the Absorb BVS group than in the DES group [RR 1.18 (95% CI 0.98–1.41); p=0.08; I^2=0% heterogeneity].

Other efficacy findings

1 RCT (Absorb II) reported outcomes linked to 'physical limitation' (as defined by the Seattle Angina Questionnaire), which increased in both study groups from baseline (75 patients versus 72 patients; p=0.77) to 1-year follow-up (87 patients versus 86 patients; p=0.48) and remained constant for the following 2 years (at 3-year follow-up: 87 patients versus 86 patient; p=0.54). There was no significant difference between patients in the Absorb BVS group and patients in the DES group.

2 RCTs reported that there was no significant difference in quality of life outcomes (as defined by the Seattle Angina Questionnaire) between the Absorb BVS and DES groups after 1, 2 or 3 years (76 pts vs 74 pts; p=0.47) and 1 year (87 patients versus 86 patients; p=not reported), respectively.

Key safety findings

Number of patients analysed: 22,295

Absorb BVS safety outcomes

Summary of Absorb safety findings – across all studies

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Outcome	Number of studies reporting outcome (n=patients)	Anticipated absolute effects		Relative effect (95% CI)	P value	Quality of studies (according to GRADE)
		Risk with DES	Risk with Absorb BVS			
Periprocedural MI	7 (n=5503)	60 per 1000	73 per 1000 (49-109)	RR 1.22 (0.82–1.82)	0.32	Moderate[a]
Mortality as a result of bleeding or stroke (6–60 months follow-up)	11 (n=1402)	2 deaths across all Absorb groups – absolute and relative risk not calculated				Very low[b]
Very late ScT (after at least 1 year of follow-up)	6 (n =5549)	7 per 1000 (3-17)	1 per 1000	RR 5.09 (1.97 to 13.17)	0.0008	Moderate[a]

a = Imprecision was downgraded by 1 point because of a non-significant effect estimate with wide CI

b = Risk of bias was down-graded by 2 points because of study design and study quality (observational single-arm studies with predominantly moderate to high risk of bias

Frequency and severity of adverse events in ABSORB RCTs

RCT	AIDA		TROFI II		Everbio II			Hernandez	
Adverse events	**Absorb BVS (n=924)**	**EES (n =921)**	**Absorb BVS (n=78)**	**EES (n=80)**	**Absorb BVS (n=78)**	**EES (n=80)**	**BES (n=80)**	**Absorb BVS (n=100)**	**EES (n=100)**
Very late (after ≥1 year) ScT and/or stent thrombosis and its consequences, n (%)	1.5 (14/294)	0.3 (3/921)	-	-	0	0	0	-	-
Periprocedural MI	1.0 (9/924)	0.7 (6/921)	0	0	-	-	-	-	-
Total SAEs % (n)	-	-	-	-	-	-	-	-	-

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Total deaths % (n)	4.4 (41/924)	5.3 (49/921)	2.1 (2/78)	5 (4/80)	3 (2/78)	5/(4/80)	1 (1/80)	1 (1/100)	1 (1/100)

- not reported for study

RCT	**Absorb II**		**Absorb III**		**Absorb Japan**		**Absorb China**	
Adverse events	**Absorb BVS (n=335)**	**EES (n = 166)**	**Absorb BVS (n=1322)**	**EES (n=686)**	**Absorb BVS (n=266)**	**EES (n=134)**	**Absorb BVS (n=241)**	**EES (n=239)**
Very late (after ≥1 year) ScT and/or stent thrombosis and its consequences, n (%)	**1.8 (6/335)**	**0**	**0.8 (10/1322)**	**0**	**1.6 (4/266)**	**0**	**0.4 (1/241)**	**0**
Periprocedural MI	**4 (13/335)**	**1 (2/166)**	**3.1 (41/1322)**	**3.2 (22/686)**	**1.1 (3/266)**	**1.5 (2/134)**	**1.3 (3/241)**	**0.4 (1/239)**
Total SAEs % (n)	-	-	30.1 (398/1322)	28,9 (198/686	-	-	18.7 (45/241)	19.3 (46/239)
Total deaths % (n)	3.2 (11/335)	4.7 (8/166)	3.1 (40/1322)	3.4 (23/686)	1.5 (4/266)	0	0.8 (2/241)	2.6 (6/239)

- not reported for study

Meta-analysis of periprocedural MI

In a meta-analysis of 7 RCTs, there was no statistically significant increased risk in the rate of periprocedural MI in the Absorb BVS groups compared with permanent metal DES [RR 1.22 (95% CI 0.82–1.82); p=0.32; 0% heterogeneity].

Meta-analysis of very late ScT (>1 year)

In a meta-analysis of 6 RCTs (including 5,450 patients), there was a statistically significant increased risk in the rate of ScT that occurred after at least 1 year of follow-up (very late ScT) in the Absorb BVS group(n=3,152) compared with permanent metal DES [n=2,298; RR 5.09 (95% CI 1.97–13.17); p=0.0008; 0% heterogeneity].

Subgroup analysis of late ScT in different patient groups (stable CAD vs ACS)

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A subgroup analysis on very late ScT (≥1 year follow-up) comparing RCTs where most of the included patients (60% or more) had stable angina and those in which most patients had ACS (60% or more) showed no statistically significant subgroup difference.

Safety outcomes for all other devices

Outcome	Device		
	DESolve (n=345 across 3 studies)	**Magmaris (n=184 across 2 studies)**	**Fantom (n=117 across 1 study)**
Periprocedural mortality % (n)	0 (0/345)	0 (0/184)	0 (0/117)
Periprocedural MI % (n)	0.29 (1/345)	0 (0/184)	0.85 (1/117)
Mortality as a result of bleeding or stroke	0 (0/219) across 2 studies*	0 (0/184)	0 (0/117)
Very late ScT (after at least 1 year of follow-up)	0 (0/126) across 1 study*	0 (0/123) across	Not available (only 6-month follow-up)

*Outcome not reported in all studies

Quality of evidence according to GRADE assessment was deemed “very low” for all safety outcomes outlined above for DESolve, Magmaris and Fantom devices due to very low event rates in the studies and/or a high risk of bias.

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Study 2 Ni L (2020)

Study details

Study type	Systematic review and meta-analysis
Country	China
Search details	Search period; from inception to October 2018; databases searched: PubMed, Springer, EMBASE, Wiley-Blackwell, and Chinese Journal full-text database. In addition, reference list of each article retrieved were also reviewed.
Study population and number	10 studies with 6383 patients with CHD. 3573 with bioresorbable stents (BRS) versus 2810 with drug-eluting stents (DES).
Age and sex	Age range- mean 56.7 to 64.3 years; sex not reported.
Study selection criteria	Inclusion criteria: RCTs or prospective controlled clinical trials; comparing treatment between BRS and DES. Exclusion criteria: observational studies, studies on other treatments other than BRS or DES, other indications, studies lacking outcome measures or comparable results, duplicate and incomplete studies.
Technique	PCI with stents (Absorb BRS or DES).
Follow-up	Varied across included studies (30 days to 5 years), mean 3 years.
Conflict of interest/source of funding	Authors declared that they do not have any conflicts of interest; no funding available.

Analysis

Follow-up issues: varied across studies.
Study design issues: Comprehensive searches were done; studies were selected by 2 reviewers and any disagreements were resolved by a third reviewer; the risk of bias in each study was assessed by using the criteria for evaluating design-related deviations in Review Manager 5.3. The risk of bias was high for blinding of participants and personnel in all studies. Outcomes assessed were risk of TLF, stent thrombosis and cardiac death. Meta-analysis was done to assess differences in clinical efficacy between BRS and DES.

Studies were conducted in different countries, published between 2010-2018, with largely small sample sizes. Most of the studies assessed 'Absorb BRS' device. There is little evidence of publication bias.

Study population issues: significant differences were found in patient characteristics between BRS group and DES group.

There is some overlap of primary studies between the systematic reviews and meta-analyses and HTA[1-4].

Key efficacy findings

Number of patients analysed: 3573 BRS versus 2810 DES

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TLF, n=10 studies

Pooled analysis of 10 studies showed statistically significant differences in TLF between BRS and DES. TLF of the BRS group was significantly higher than that of DES group with no heterogeneity among studies (OR = 1.46, 95% CI 1.20 to 1.79, p = 0.0002; p heterogeneity = 0.68, I^2 = 0%).

Key safety findings

Cardiac death (n=10 studies)

Pooled analysis of 10 studies indicated that the cardiac death in BRS was significantly higher than that of DES group with no heterogeneity among studies (OR = 2.19, 95% CI 1.17 to 4.07, p = 0.01; p heterogeneity = 0.93, I^2 = 0%).

Stent thrombosis (n=10 studies)

Pooled analysis of 10 studies indicated that stent thrombosis in BRS group was significantly higher than that of DES group with no heterogeneity among studies (OR = 2.70, 95% CI 1.57 to 4.66, p = 0.0003; p heterogeneity = 1.00, I^2 = 0%).

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Study 3 Stone GW (2019)

Study details

Study type	Systematic review and meta-analysis
Country	International group
Search period	Search date up to 21 July 2019; databases searched: MEDLINE and the Cochrane database.
Study population and number	n=4 studies of 3384 patients with non-complex CAD BRS (n=2161) versus DES (n=1223)
Age and sex	Mean age 62.8±11 years, 72.5% male
Study selection criteria	Inclusion criteria: RCTs of the ABSORB everolimus-eluting PLLA bioresorbable vascular scaffold (BRS) system (Abbott Vascular) compared with a metallic DES in which at least 5-year clinical follow-up has been reported. Exclusion criteria: observational or non-randomised study design, with less than 5 years of follow-up data, lack of interval data between 0 to 3 years and 3 to 5 years, use of non-ABSORB BRS, use of metallic DES with bioabsorbable polymers, editorials, letters, expert opinions, case reports/series, studies with duplicated data, and non-human studies.
Technique	Patients were randomly assigned to BRS or metallic EES and the corresponding scaffold was implanted during PCI.
Follow-up	5 years
Conflict of interest/source of funding	This study and the 4 trials included were all funded by Abbott Vascular. Authors reported receiving institutional research grants, personal fees, and speaker fees from Abbott Vascular and other companies. Authors also reported acting as consultants for Abbott Vascular and other companies, and 1 author is an employee of Abbott Vascular. One author reported past membership of an Abbott Vascular advisory board.

Analysis

Follow up issues: A total of 5 patients (3 randomised to BRS and 2 randomised to EES) withdrew consent immediately after enrolment in ABSORB China trial and were de-registered. These patients are not included in the study population. Follow up after 5 years was 80% (401/501), 93.8% (375/400), 96.4% (458/480) and 86.7% (1742/2008) in the 4 studies included.

Study design issues: comprehensive searches were done and 2 reviewers abstracted data. The review protocol was developed in accordance with PRISMA (preferred reporting items for systematic reviews and meta-analyses) reporting guidelines, and the Cochrane risk of bias tool was used to assess all included studies. Three of the eligible studies were single blind and 1 was open label study. The primary outcomes of interest were TLF cardiac mortality, target vessel–MI, or ischemia-driven TLR and definite or probable device thrombosis. Individual patient data from the 4 trials were pooled, and summary-level meta-analysis was performed.

Study population issues: Diabetes was present in 30.2% (1020/3384) of patients.

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There is some overlap of primary studies between the systematic reviews and meta-analyses and HTA[1-4].

Key efficacy findings

Number of patients analysed: 3384

Clinical outcomes up to 3 years and between 3 years and 5 years

Clinical outcome	Patients with outcome up to 3 years			Patients with outcome at 3-5 years**			P-value for interaction
	BRS % (n = 2161)	EES % (n = 1223)	HR (95% CI)	BRS % (n = 1984)	EES % (n = 1121)	HR (95% CI)	
TLF^	11.6 (245/2161)	7.9 (95/1223)	1.42 (1.12-1.80)	4.3 (82/1984)	4.5 (48/1121)	0.92 (0.64-1.31)	0.046
POCE*	19.9 (422/2161)	15.8 (190/1223)	1.23 (1.04-1.46)	9.4 (180/1984)	9.3 (100/1121)	0.97 (0.76-1.24)	0.10
All-cause mortality	2.6 (54/2161)	3.0 (35/1223)	0.84 (0.55-1.29)	3.4 (65/1984)	2.7 (29/1121)	1.22 (0.79-1.90)	0.23
Cardiac mortality	1.1 (22/2161)	1.1 (13/1223)	0.94 (0.47-1.88)	1.2 (22/1984)	1.7 (18/1121)	0.68 (0.36-1.26)	0.48
Non-cardiac mortality	1.5 (32/2161)	1.9 (22/1223)	0.79 (0.46-1.35)	2.3 (43/1984)	1.0 (11/1121)	2.11 (1.09-4.10)	0.02
All MI	9.0 (190/2161)	5.5 (66/1223)	1.56 (1.18-2.06)	2.0 (38/1984)	2.6 (28/1121)	0.71 (0.44-1.16)	0.004
TV-MI	7.6 (161/2161)	4.1 (49/1223)	1.76 (1.28-2.43)	1.4 (27/1984)	1.4 (15/1121)	0.96 (0.51-1.81)	0.05
Non–TV-MI	1.9 (39/2161)	1.8 (21/1223)	1.01 (0.59-1.73)	0.7 (12/1984)	1.3 (14/1121)	0.44 (0.20-0.95)	0.08
All revascularisation	14.3 (299/2161)	11.6 (138/1223)	1.20 (0.98-1.47)	5.7 (108/1984)	6.3 (67/1121)	0.86 (0.63-1.17)	0.08
ID-TLR	6.6 (137/2161)	4.3 (51/1223)	1.48 (1.07-2.04)	2.3 (43/1984)	1.8 (19/1121)	1.20 (0.70-2.06)	0.52

* POCE comprised of all-cause mortality, all MI, or all revascularisations.

** The 3-year to 5-year landmark period includes all randomised patients at 3 years except those who died before 3 years. Thus, there may be some patients with a non-fatal event within 3 years who have a second event between 3 years and 5 years.

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^ TFL rate was defined as the composite of cardiac death, target vessel MI and ischaemia-driven TLR.
The increased risks of TLF, POCE, all MI, TV-MI, and ID-TLR present with BRS compared with EES between 0 and 3 years were not evident between 3 and 5 years. Non-cardiac mortality was increased in BRS-treated patients between 3 and 5 years.

Cumulative clinical outcomes up to 5 years:

Clinical outcome	Patients with outcome up to 5 years			
	BRS % (n = 2161)	EES % (n = 1223)	HR (95% CI)	P value
TLF	14.9 (308/2161)	11.6 (135/1223)	1.26 (1.03-1.54)	0.03
POCE	26.4 (550/2161)	22.7 (267/1223)	1.15 (0.99-1.33)	0.07
All-cause mortality	5.9 (119/2161)	5.6 (64/1223)	1.02 (0.75-1.38)	0.92
Cardiac	2.2 (44/2161)	2.8 (31/1223)	0.79 (0.50-1.25)	0.31
Noncardiac	3.8 (75/2161)	2.9 (33/1223)	1.23 (0.81-1.85)	0.33
All MI	10.7 (221/2161)	7.9 (92/1223)	1.30 (1.02-1.66)	0.03
TV-MI	8.8 (184/2161)	5.5 (64/1223)	1.55 (1.16-2.06)	0.003
Non-TV-MI	2.5 (51/2161)	3.1 (35/1223)	0.78 (0.51-1.20)	0.26
All revascularisation	18.4 (378/2161)	16.3 (189/1223)	1.10 (0.92-1.31)	0.28
ID-TLR	8.4 (172/2161)	5.8 (67/1223)	1.41 (1.06-1.87)	0.02
ID-TVR	13.1 (268/2161)	19.8 (112/1223)	1.32 (1.06-1.65)	0.01

Key safety findings

Device thrombosis outcomes up to 3 years and between 3 years and 5 years

Clinical outcome	Patients with outcome up to 3 years			Patients with outcome at 3-5 years			P-value for interaction
	BRS % (n = 2161)	EES % (n = 1223)	HR (95% CI)	BRS % (n = 1984)	EES % (n = 1121)	HR (95% CI)	
Device thrombosis, definite/probable	2.4 (51/2161)	0.6 (7/1223)	3.86 (1.75-8.50)	0.1 (2/1984)	0.3 (3/1121)	0.44 (0.07-2.70)	0.03

Clinical outcome	Patients with outcome up to 5 years			
	BRS % (n = 2161)	EES % (n = 1223)	HR (95% CI)	P value
Device thrombosis, definite/probable	2.5 (53/2161)	0.8 (10/1223)	2.87 (1.46-5.65)	0.002

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Definite	2.3 (48/2161)	0.7 (8/1223)	3.14 (1.48-6.64)	0.003
Probable	0.2 (5/2161)	0.2 (2/1223)	1.73 (0.33-9.09)	0.52

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Study 4 Kang SH (2018)

Study details

Study type	Systematic review and network meta-analysis
Country	Republic of Korea
Search details	Search period: inception to October 2017; databases searched: PubMed, Embase, Cochrane Central Register of Controlled Trials, and relevant websites. In addition, manual review of reference lists of included articles, recent reviews, editorials, and meta-analyses were also examined.
Study population and number	n= 91 RCTs with 105,842 patients having PCI (comparing 2 or more coronary metallic stents or biodegradable scaffolds).
Age	Median 66 years (range 30 to 88); 23 to 89% male
Patient selection criteria	Inclusion criteria: studies comparing 2 or more coronary metallic stents or biodegradable scaffolds, reporting outcomes at more than 2 years with no restrictions on study period, sample size, publication status, patient or lesion criteria. Exclusion criteria: studies with follow-up less than 2 years, comparison of stents within the same category, no specification of stent types in study protocol, duplicate studies and publications in a language other than English.
Technique	PCI using Absorb BRS, contemporary DES and bare metal stents (BMS). 12 stents were compared: 1. Absorb bioresorbable vascular scaffold (BRS, 7 trials, n=3,257) 2. Bare metal stents (BMS, n=9,070) 3. paclitaxel-eluting stents (PES, n=14,956) 4. sirolimus-eluting stents (SES, n=22,101) 5. Endeavor zotarolimus-eluting stents (E-ZES, n=9,261) 6. cobalt-chromium everolimus-eluting stent (CoCr-EES, n=22,885) 7. platinum-chromium everolimus-eluting stents (PtCr EES, n=3, 105) 8. biodegradable polymer everolimus-eluting stents (BP-EES, n=940) 9. Resolute™ zotarolimus-eluting stents (R-ZES, n=5,546) 10. BP Biolimus A9-eluting stents (BP-BES, n=9,764) 11. Orsiro hybrid sirolimus-eluting stents (H-SES, n=2,622) 12. polymer-free sirolimus and probucol-eluting stents (Dual SES, n=2,335)
Follow-up	mean follow-up of 3.7 years (range 2 to 10 years)
Conflict of interest/source of funding	authors have no conflicts of interest to declare.

Analysis

Follow-up issues: follow-up varied across studies and was limited in BRS studies.

Study design issues: study registered on the PROSPERO database of systematic reviews. Comprehensive searches were done; studies were selected and data extracted by 2 reviewers and any disagreements were

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resolved by consensus. Direct and indirect evidence from multiple trials were combined and multiple treatment comparison network meta-analysis (using hierarchical Bayesian random effects meta-analysis models) was performed to give a comprehensive estimate. Also, pairwise meta-analyses was done for trials comparing BRS with cobalt-chromium everolimus-eluting stents (CoCr-EES) to provide better understanding of stent thrombosis risks according to follow-up period.

Studies had limited sample size and comparisons were available for certain type of stents (BP-EES, H-SES, dual SES, PtCr-EES, BRS; 7 trials tested the Absorb BRS, 6 with CoCr-EES, and 1 with PtCr-EES and BP-BES). There were 7 trials with a 3-arm design and 1 trial with a 4-arm design.

Key safety endpoint was the long-term risk of definite or probable stent/ScT defined according to the ARC criteria. Thrombosis rates were classified as early (≤30 days), late (31 days – 1 year), and very late (>1 year) according to the time of onset after the index procedure. The key secondary endpoint was definite stent/ScT defined according to the ARC criteria. Secondary endpoints of network meta-analysis included all-cause death, cardiac death, and MI, TVR and TLR. Secondary endpoints of frequentist conventional meta-analysis were TLF, cardiac death, target vessel MI, and ischaemia-driven or clinically driven TLR.

There was little evidence of publication bias. Most of the evidence was from direct comparison of BRS with CoCr-EES. Indirect evidence from network meta-analysis was weak.

BRS trials had stringent inclusion and exclusion criteria. The ABSORB II (n=501), ABSORB III (n=2,008), ABSORB Japan (n=398), and ABSORB China (n=475) trials enrolled stable or unstable angina patients, and excluded clinically or angiographically high-risk patients. ABSORB-STEMI TROFI II (n=192) exclusively enrolled patients with ST-segment elevation MI, and the EVERBIO II (n=238) and AIDA (n=1,845) trials had an “all-comers” design.

Study population issues: trials included had patients with different characteristics and medication protocols.

There is some overlap of primary studies between the systematic reviews and meta-analyses and HTA[1-4].

Key efficacy findings

- Number of patients analysed: n=99,112 (84 trials)

TLF (pairwise meta-analysis)

Pooled analysis of 6 RCTs, in patients with stable or unstable angina (4 studies), STEMI (1 study) or with all types of CHD (1 study) showed that TLF rates were not significantly different between the BRS group (n=3,179) and CoCr EES group (n=2,239) at 1 year (OR 1.26, 95% CI 0.99 to 1.61, p=0.059, I2=0%), but was significantly higher with BRS than CoCr-EES when the follow-up was extended to over than 1 year (OR 1.39, 95% CI 1.15 to 1.67, p<0.001, I^2=0%).

Study	BVS		CoCr-EES		OR (95% CI)	P value, I^2
	Events	Total	Events	Total		
TLF (≤ 1 year)						
Absorb II	16	335	5	166	1.62 (0.58 to 4.49)	

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Absorb Japan	11	265	5	133	1.11 (0.38 to 3.26)	
Absorb China	8	238	10	237	0.79 (0.31 to 2.04)	
Absorb Stemi Trofi II	1	95	0	96	3.06 (0.12 to 76.2)	
Absorb III	102	1322	41	686	1.32 (0.90 to 1.91)	
AIDA	60	924	48	921	1.26 (0.85 to 1.87)	
Overall (fixed effects model)	**198**	**3179**	**109**	**2239**	**1.26 (0.99 to 1.61)**	**0.059, I^2=0%**
Random effects model					**1.26 (0.99 to 1.61)**	**0.063**
TLF (> 1 year)						
Absorb II	37	335	9	166	2.17 (1.02 to 4.60)	
Absorb Japan	23	265	7	133	1.71 (0.71 to 4.10)	
Absorb China	13	238	11	237	1.91 (0.52 to 2.71)	
Absorb Stemi Trofi II	3	95	3	96	1.01 (0.20 to 5.14)	
Absorb III	229	1322	86	686	1.46 (1.12 to 1.91)	
AIDA	91	924	78	921	1.18 (0.86 to 1.62)	
Overall (fixed effects model)	**396**	**3179**	**194**	**2239**	**1.39 (1.15 to 1.67)**	**<0.001,I^2=0%**
Random effects model					**1.38 (1.15 to 1.66)**	**<0.001**

Ischemia driven TLR (pairwise meta-analysis)

Pooled analysis showed that TLR did not differ significantly at 1 year (OR 1.28, 95% CI 0.91 to 1.80, p=0.150) between the BRS and CoCr EES groups and but showed a statistically significant difference at long-term follow-up (OR 1.46, 95% CI 1.12 to 1.85, p=0.004) with BRS compared to CoCr EES group.

Study	**BRS**		**CoCr-EES**		**OR (95% CI)**	**P value, I^2**
	Events	**Total**	**Events**	**Total**		
TLR (≤ 1 year)						
Absorb II	4	335	3	166	0.66 (0.15 to 2.97)	
Absorb Japan	7	265	3	133	1.18 (0.30 to 4.62)	
Absorb China	6	238	5	237	1.20 (0.36 to 3.99)	
Absorb Stemi Trofi II	1	95	0	96	3.06 (0.12 to 76.2)	
Absorb III	40	1322	17	686	1.23 (0.69 to 2.18)	
AIDA	38	924	27	921	1.42 (0.86 to 2.35)	
Overall (fixed effects model)	**96**	**3179**	**55**	**2239**	**1.28 (0.91 to 1.80)**	**0.150, I^2=0%**
Random effects model					**1.28 (0.91 to 1.79)**	**0.155**
TLR (> 1 year)						
Absorb II	22	335	3	166	3.82 (1.13 to 12.9)	
Absorb Japan	18	265	5	133	1.87 (0.68 to 5.14)	
Absorb China	10	238	6	237	1.69 (0.60 to 4.72)	
Absorb Stemi Trofi II	2	95	1	96	2.04 (0.18 to 22.9)	
Absorb III	92	1322	39	686	1.24 (0.84 to 1.83)	

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AIDA	60	924	45	921	1.35 (0.91 to 2.01)	
Overall (fixed effects model)	**204**	**3179**	**99**	**2239**	**1.46 (1.12 to 1.85)**	**0.004, I^2=0%**
Random effects model					**1.43 (1.10 to 1.82)**	**0.007**

A network meta-analysis of 91 RCTs showed similar performance with BRS and other DES, and statistically significantly better than BMS in terms of TVR and TLR.

Key safety findings

Device thrombosis ≥2 years (84 trials, n=99,112 patients, mean follow-up 3.7 years)

Pairwise meta-analysis: pooled results of trials directly comparing BVS versus CoCr-EES, n=6 RCTs)

Pooled results of 6 studies showed that the risk of (definite or probable) ScT with BRS was high compared to CoCr-EES (contemporary second-generation DES) across all time points (early [OR 2.01, 95% CI 1.05 to 3.85, p=0.034, I^2=0%]; late [OR 3.87, 95% CI 1.15 to 13.0, p=0.029, I^2=1.3%] and very late [OR 5.09, 95% CI 1.94 to 13.3, p=<0.001, I^2=0%]).

Study	**BRS**		**CoCr-EES**		**OR (95% CI)**	**P value, I^2**
	Events	**Total**	**Events**	**Total**		
Early stent thrombosis (≤ 30 days)						
Absorb II	2	335	0	166	2.50 (0.12 to 52.3)	
Absorb Japan	3	265	1	133	1.52 (0.16 to 14.7)	
Absorb China	1	238	0	237	3.00 (0.12 to 74.0)	
Absorb Stemi Trofi II	1	95	0	96	3.06 (0.12 to 76.2)	
Absorb III	14	1322	5	686	1.46 (0.52 to 4.06)	
AIDA	13	924	5	921	2.61 (0.93 to 7.36)	
Overall (fixed effects model)	**34**	**3179**	**11**	**2239**	**2.01 (1.05 to 3.85)**	**0.034, I^2=0%**
Random effects model					**2.01 (1.05 to 3.82)**	**0.036**
Late stent thrombosis (1 year)						
Absorb II	1	335	0	166	1.49 (0.06 to 36.9)	
Absorb Japan	1	265	1	133	0.50 (0.03 to 8.06)	
Absorb China	0	238	0	237		
Absorb Stemi Trofi II	0	95	0	96		
Absorb III	6	1322	0	686	6.78 (0.38 to 121)	
AIDA	8	924	1	921	8.03 (1.00 to 64.4)	
Overall (fixed effects model)	**16**	**3179**	**2**	**2239**	**3.87 (1.15 to 13.0)**	**0.029, I^2= 1.3%**
Random effects model					**3.13 (0.93 to 11.8)**	**0.092**

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Very late stent thrombosis (≥1 year)						
Absorb II	6	335	0	166	6.57 (0.37 to 117)	
Absorb Japan	5	265	0	133	5.64 (0.31 to 103)	
Absorb China	1	238	0	237	3.00 (0.12 to 74.0)	
Absorb Stemi Trofi II	1	95	1	96	1.01 (0.06 to 16.4)	
Absorb III	10	1322	0	686	11.0 (0.64 to 188)	
AIDA	10	924	2	921	5.03 (1.10 to 23.0)	
Overall (fixed effects model)	**33**	**3179**	**3**	**2239**	**5.09 (1.94 to 13.3)**	**<0.001, I^2=0%**
Random effects model					**4.50 (1.67 to 12.1)**	**0.003**

Definite or probable stent thrombosis (comparison between different stents: network meta-analysis -ORs and credible intervals for each pair of comparisons were derived from the Bayesian random effects model).

Network meta-analysis showed that patients treated with the Absorb BRS had a significantly higher risk of long-term (definite or probable) ScT compared to those treated with metallic DES (R-ZES, E-ZES, BP-BES, dual DES, CoCr-EES, H-SES, and BP-EES). The risk of very late definite or probable (>1-year) stent thrombosis was significantly higher for BS than any other comparators except PtCr-EES and BP-EES . BMS showed a lower very late ST risk than SES and PES as well as BRS.

The probability of the rank of each device

The probability rank of each device was (BP-EES ≥ H-SES ≥ CoCr-EES ≥ dual DES ≥ PtCr-EES ≥ BP-BES ≥ E-ZES≥ R-ZES) > (SES ≥ BMS ≥ PES) > BVS.

Cardiac death (pairwise meta-analysis)

Pooled analysis of 6 studies showed that the risk of cardiac death was similar both at 1 year (OR 1.13, 95% CI 0.57 to 2.24, p=0.717) and at the extended follow-up to the long-term (OR 0.86, 95% CI 0.55 to 1.33, p=0.498) between the BRS and CoCr EES groups.

Study	**BRS**		**CoCr-EES**		**OR (95% CI)**	**P value, I^2**
	Events	**Total**	**Events**	**Total**		
Cardiac death (≤ 1 year)						
Absorb II	0	335	0	166	-	
Absorb Japan	0	265	0	133	-	
Absorb China	0	238	3	237	0.14 (0.01 to 2.73)	
Absorb Stemi Trofi II	0	95	0	96	-	
Absorb III	8	1322	1	686	4.17 (0.52 to 33.4)	
AIDA	12	924	11	921	1.09 (0.48 to 2.48)	
Overall (fixed effects model)	**20**	**3179**	**15**	**2239**	**1.13 (0.57 to 2.24)**	**0.717**

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Random effects model					**1.12 (0.30 to 4.26)**	**0.866**
Cardiac death (> 1 year)						
Absorb II	5	335	4	166	0.61 (0.16 to 2.32)	
Absorb Japan	1	265	0	133	1.51 (0.06 to 37.4)	
Absorb China	1	238	3	237	0.33 (0.03 to 3.19)	
Absorb Stemi Trofi II	1	95	0	96	3.06 (0.12 to 76.2)	
Absorb III	18	1322	8	686	1.17 (0.51 to 2.70)	
AIDA	18	924	23	921	0.78 (0.42 to 1.45)	
Overall (fixed effects model)	**44**	**3179**	**38**	**2239**	**0.86 (0.55 to 1.33)**	**0.498**
Random effects model					**0.86 (0.55 to 1.34)**	**0.496**

Target vessel MI (pairwise meta-analysis)

The pooled risk of target vessel MI (from 6 studies) was significantly higher with BRS at both 1 year follow-up (OR 1.59, 95% CI 1.16 to 2.18, p=0.004) and in the long term (OR 1.67, 95% CI 1.28 to 2.18, p<0.001) compared to CoCr EES group.

Study	**BRS**		**CoCr-EES**		**OR (95% CI)**	**P value, I^2**
	Events	**Total**	**Events**	**Total**		
Target vessel MI (≤ 1 year)						
Absorb II	15	335	2	166	3.84 (0.87 to 17.0)	
Absorb Japan	9	265	3	133	1.52 (0.41 to 5.72)	
Absorb China	4	238	2	237	2.01 (0.36 to 11.1)	
Absorb Stemi Trofi II	1	95	0	96	3.06 (0.12 to 76.2)	
Absorb III	79	1322	31	686	1.34 (0.88 to 2.06)	
AIDA	34	924	20	921	1.72 (0.98 to 3.01)	
Overall (fixed effects model)	**475**	**3179**	**58**	**2239**	**1.59 (1.16 to 2.18)**	**0.004, I^2=0%**
Random effects model					**1.57 (1.14 to 2.14)**	**0.005**
Target vessel MI (> 1 year)						
Absorb II	24	335	3	166	4.19 (1.24 to 14.1)	
Absorb Japan	14	265	4	133	1.80 (0.58 to 5.58)	
Absorb China	6	238	2	237	3.04 (0.61 to 15.2)	
Absorb Stemi Trofi II	2	95	3	96	0.67 (0.11 to 4.08)	
Absorb III	112	1322	40	686	1.49 (1.03 to 2.17)	
AIDA	48	924	30	921	1.63 (1.02 to 2.59)	
Overall (fixed effects model)	**206**	**3179**	**82**	**2239**	**1.67 (1.28 to 2.18)**	**<0.001,I^2=0%**
Random effects model					**1.64 (1.25 to 2.14)**	**<0.001**

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Network meta-analyses for all-cause death, cardiac death, MI, TVR, and TLR

Network meta-analysis showed that BRS was associated with an increased risk of all cause cardiac death, cardiac death, MI compared to DES (SES, BP-BES, CoCr-EES, R-ZES, E-ZES, dual DES, PtCr-EES, and H-SES). BRS showed similar performance as compared with other DES, and significantly better than BMS in terms of TVR and TLR.

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Study 5 Baumbach A (2018)

Study details

Study type	Prospective case series (ABSORB UK Registry)
Country	United Kingdom (24 centres)
Recruitment period	2014-2015
Study population and number	n=1,005 patients with *de novo* coronary lesions Target vessel: 54% LAD, 27% RCA, 18% LCx. Mean RVD 3.16±0.46mm, mean lesion length 23.3±13.3 mm.
Age and sex	Mean age 52±11 years, 75% male
Patient selection criteria	Inclusion criteria: Adults aged over 18 years with previously untreated *de novo* coronary lesions (prior treatment of lesions in a non-target vessel was permitted), willing to have all follow-up visits and data collection. Exclusion criteria: Inability to give informed consent or comply with protocol.
Technique	ABSORB everolimus-eluting PLLA bioresorbable vascular scaffold (BRS) system (Abbott Vascular) was implanted into patients. The technical recommendation was for appropriate lesion preparation with low residual stenosis prior to implantation of the scaffold, sizing according to angiographic vessel size with avoidance of under-sizing, and routine post-dilatation with high-pressure non-compliant balloons. The use of online QCA was explicitly encouraged in order to size the scaffold appropriately. The vessel size range was governed by the available scaffold sizes and the limited capacity for further expansion after implantation. Adjunctive imaging with IVUS or OCT was not specifically recommended but encouraged for complex lesions. Selection, dosing, and duration of antiplatelet therapy was left to individual operators' discretion, but the majority of centres opted for a prescribed DAPT duration of 12 months.
Follow-up	12 months
Conflict of interest/source of funding	Study was supported by institutional grant from Abbott Vascular. Several authors reported receiving institutional research grants, research support and speaker fees from Abbott Vascular, and 1 author is a consultant for Abbott Vascular.

Analysis

Follow-up issues: High follow-up (98.7% after 12 months), 13 patients were lost to follow-up.
Study design issues: Prospective observational post-market registry analysis. Recommendations for patient selection and implantation technique were not binding. Primary endpoint of the study was TLF at 12 months and primary patient-related outcome was MACE. An independent clinical events committee, consisting of experienced and unbiased cardiologists, adjudicated all serious adverse events and protocol endpoints.

Study population issues: 28.9% smokers, 49.9% hypertension, 56.5% dyslipidaemia, 17.4% diabetes. 24.3% prior MI, 20.9% prior PCI, 1.3% prior CABG, 31.9% NSTEMI, 13.8% STEMI.

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Key efficacy findings

Number of patients analysed: 1,005

Device success (defined as successful implantation of 1 or more scaffolds with a final in-scaffold residual diameter stenosis of <50%, without BVS device deficiency): **98.7%**

Procedure success (defined as successful implantation of 1 or more BVS with a final in-scaffold diameter stenosis of <50%, without TVF within 3 days of the index procedure): **97.3%**

Clinical outcomes

Clinical outcome		**In-hospital % (n=1,005)**	**30 days % (n=992)**	**12 months % (n=992)**
TLF		0.9 (9/1,005)	1.2 (12/992)	3.2 (32/992)
MACE*		0.9 (9/1,005)	1.2 (12/992)	3.4 (34/992)
TVF		1.0 (10/1,005)	1.4 (14/992)	4.3 (43/992)
All death		0 (0/1,005)	0.1 (1/992)	0.6 (6/992)
Cardiac death		0 (0/1,005)	0.1 (1/992)	0.3 (3/992)
MI outcomes				
MI (protocol definition)	**All MI**	0.8 (8/1,005)	1.0 (10/992)	2.1 (21/992)
	Q-wave MI	0.5 (5/1,005)	0.7 (7/992)	0.8 (8/992)
	Non-Q-wave MI	0.3 (3/1,005)	0.3 (3/992)	2.1 (21/992)
MI (third universal definition)	Type 1	0.2 (2/1,005)	0.4 (4/992)	1.5 (15/992)
	Type 2	0.2 (2/1,005)	0.2 (2/992)	0.4 (4/992)
	Type 3	0 (0/1,005)	0 (0/992)	0.1 (1/992)
	Type 4a	1.5 (15/1,005)	1.5 (15/992)	1.7 (17/992)
	Type 4b	0.6 (6/1,005)	0.8 (8/992)	1.3 (13/992)
	Type 5	0 (0/1,005)	0 (0/992)	0 (0/992)
Revascularisation outcomes				
TLR	**All**	0.6 (6/1,005)	1.0 (10/992)	2.5 (25/992)
	ID-TLR	0.6 (6/1,005)	0.9 (9/992)	2.3 (23/992)
	CABG	0 (0/1,005)	0 (0/992)	0.1 (1/992)
	PCI	0.6 (6/1,005)	0.9 (9/992)	2.2 (22/992)
TVR	**All**	0.8 (8/1,005)	1.3 (13/992)	3.8 (38/992)
	ID-TVR	0.8 (8/1,005)	1.2 (12/992)	3.6 (36/992)
	CABG	0 (0/992)	0 (0/992)	0.4 (4/992)
	PCI	0.8 (8/1,005)	1.2 (12/992)	3.2 (32/992)
All revascularisation	PCI	1.9% (19/1,005)	3.8 (38/992)	14.3 (143/992)
	CABG	0 (0/1,005)	0 (0/992)	0.6 (6/992)

*MACE rate was defined as cardiac death, all MI and ischaemia-driven TLR

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^TVF including cardiac death, all MI and ischaemia-driven TVR

Key safety findings

Clinical outcome	In-hospital % (n=1,005)	30 days % (n=992)	12 months % (n=992)
Stent thrombosis (definite/probable)*	0.2 (2/1,005)	0.9 (9/992)	1.7 (17/992)

***Core lab adjudicated**

At 12 months, the overall definite stent thrombosis rate was 1.4% (14/992); (acute 0.1%, subacute 0.7%, late 0.6%).

In all definite stent thrombosis cases, average vessel diameter was 2.62±0.41mm. In 5 of these cases, the core lab identified the target vessel to be less than 2.3 mm in diameter (range: 1.8-2.25 mm) by QCA, and in 2 cases there was a marked size mismatch (scaffold undersized >0.2 mm).

In multivariable analysis, only the use of the smallest scaffold size of 2.5 mm remained significantly correlated to stent thrombosis (OR 3.27, 95% CI: 1.28-8.37; p=0.0136).

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Study 6 Cakal S (2021)

Study details

Study type	Retrospective case series
Country	Turkey
Recruitment period	2014-2016
Study population and number	n=110 patients with CAD. Clinical diagnosis: stable angina (84%), ACS (16%) and heart failure (11%). Vessels diseased per patient 1.6. mean grade of stenosis was 80%, lesions RVD 3.13 mm; median length of the scaffold per patient was 28 mm (IQR: 17mm).
Age and sex	Mean age 60±11.3 years, 80% male
Patient selection criteria	Inclusion criteria: patients >18 years with myocardial ischemia, stable CAD and ACS, with a RVD ≥2.50 mm, stenosis of >50% in the native coronary arteries were included. Exclusion criteria: left main coronary artery lesion, a saphenous vein graft lesion, or the presence of a lesion requiring stents >4.0 mm or 2.5 mm.
Technique	150 Absorb BRS were implanted using pre-dilation (in all), proper sizing, and post-dilation (in 95%). Lesions treated were in the anterior descending coronary artery (51%,n=77), right coronary (30%, n=45) and circumflex (19%, n=28) arteries. Mean number of Absorb BRS implanted per patient was 1.4±0.6. 51% of the patients had at least 2 scaffolds implanted. Mean number of BRS per lesion, 1.18±0.4. Long-segment lesions (>28 mm) that could not be covered with a single BRS needed overlapping stents. 2 BRSs were overlapped in 19 patients/lesions, and an overlapping of BRS and a DES was performed in 30 patients (31 lesions). The implanted stent length did not differ significantly between the DES-BRS group (55.2 mm) and the BRS-BRS group (49.3 mm). Decision to implant an Absorb BRS was left to the operator. Routine angiography and imaging modalities during follow-up were not performed. All patients were anticoagulated, treated with DAPT for at least 12 months after the procedure. Quantitative coronary angiography (QCA) was performed in all.
Follow-up	median 53 months (range: 46–59 months)
Conflict of interest/source of funding	None; no funding available.

Analysis

Follow-up issues: long term follow-up.

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Study design issues: small sample from a single centre; data were collected retrospectively from medical records and through hospital visits and telephone consultations. The overlap patients had more complex lesion morphologies. The rate of MACE was studied using QCA.

Study population issues: 38% patients had diabetes mellitus; hypertension, hyperlipidaemia, and a smoking history were reported in 62%, 65%, and 42%.

Key efficacy findings

Number of patients analysed: 110 BRS and 40 overlapping (2 BRSs in 19 patients/lesions, and BRS and DES in 30 patients (31 lesions)

The **device success was 99%** (149/150) and the **procedural success** (defined as angiographic success in the absence of in-hospital death, MI, or revascularisation) was **98%** (108/110).

Clinical outcomes

	Total (n=110)	DES-BRS (n=30)	BRS -BRS	p value
1 year % (n)				
All-cause death	1.8 (2)	0	5.2 (1)	NA
Cardiac death	1.8 (2)	0	5.2 (1)	NA
TV-MI	4.5 (5)	3.3 (1)	15.7 (3)	1
Definite ScT	2.7 (3)	3.3 (1)	5.2 (1)	NA
TVR	8.2 (9)	10 (3)	10.5 (2)	0.95
TLR	7.3 (8)	6.7 (2)	10.5 (2)	0.64
MACE*	10 (11)	10 (3)	15.7 (3)	0.67
4 years % (n)				
All-cause death	4.5 (5)	3.3 (1)	5.2 (1)	NA
Cardiac death	2.7 (3)	3.3 (1)	5.2 (1)	NA
TV-MI	8.2 (9)	13.3 (4)	15.7 (3)	0.81
Definite ScT	5.5 (6)	10 (3)	10.5 (2)	0.36
TVR	18.2 (20)	26.6 (8)	21 (4)	0.74
TLR	18.2 (20)	26.6 (8)	21 (4)	0.74
MACE	5.5 (6)	26.6 (8)	16.7 (5)	0.97
Complete follow-up % (n)				
All-cause death	4.5 (5)	3.3 (1)	5.2 (1)	NA
Cardiac death	2.7 (3)	3.3 (1)	5.2 (1)	NA
TV-MI	8.2 (9)	13.3 (4)	16.7 (3)	0.81
Definite ScT^^^	5.5 (6)	6.7 (2)	5.2 (3)	0.3
TVR^	21.8 (24)	30 (9)	21 (4)	0.48
TLR^^	21.8 (24)	30 (9)	21 (4)	0.48
MACE	23.6 (26)	30 (9)	16.7 (5)	0.78

*defined as a composite of cardiac death, target vessel MI, and clinically-driven TLR.
^defined as repeat PCI or coronary artery bypass graft in the target vessel.
^^defined as any revascularisation within 5 mm of the scaffold.
^^^according to ARC.

The 4-year Kaplan-Meier estimate of MACE was 20%
Cox regression analysis indicated that a small BRS diameter (2.5 mm) was a risk factor for the development of a MACE during follow-up (HR: 2.23; 95% CI: 0.97 to 2.23; p=0.05)

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Key safety findings

Procedural complications

1. Slow-flow periprocedural MI (n=1)
2. Scaffold rupture (managed with prolonged balloon inflation) n=1

Study 7 Costa JR (2019)

Study details

Study type	Prospective case series (ABSORD EXTEND study- NCT01023789)
Country	multicentre study outside USA
Recruitment period	2010-2013
Study population and number	n=812 patients with low to moderate complexity CAD. Clinical diagnosis: stable angina 461 (56.8%), unstable angina 215 (26.5%), non ST elevation MI 136 (16.7%) Multiple vessel disease in 17.5% (n=142); single target lesion in 92.4% (n=750) Target artery, n (%): LAD 395 (45.2%), LCX 228 (26.1%), RCA 250 (28.6%), LM 1 (0.1%).
Age and sex	Average age 61 years, 74.3% male
Patient selection criteria	Inclusion criteria: target arteries with a maximum lesion length 28 mm, lesion RVD 2.0 – 3.8 mm, diameter stenosis ≥50% and <100%, 2 de novo native coronary artery lesions, each located in a different major epicardial vessel. Exclusion criteria: recent MI (less than 72 hours before the index procedure) and target lesions located in the left main or within an arterial or saphenous vein graft.
Technique	Absorb BVS implanted using a pre-dilation (in all), proper sizing, and post-dilation (in 68.8%). Single lesion was treated in 92.4%, the target vessel was LAD in 45.2%. Lesion stenosis, 58.7 ± 10.6%; overlapping was required in 10.5% of the procedures. Mean RVD and lesion length were 2.64 ± 0.39mm and 12.5 ± 5.3mm, respectively.
Follow-up	3 years
Conflict of interest/source of funding	Study was funded by the manufacturer.

Analysis

Follow-up issues: complete follow-up.

Study design issues: prospective study with large sample from 56 centres; outcomes assessed were 3 year MACE rates, TVF and ScT.

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Study population issues: 26.5% (n=215) patients had diabetes mellitus; 71.4% (580) had hypertension, 71.9% (584) had hypercholesterolemia; prior stenting in 27.6% (n=224).

Key efficacy findings

Number of patients analysed: 812

Procedure outcomes

Device success, % (n)	98.9 (861/874 lesions)
Procedure success, n (%)	97 (785/874 lesions)
Adequate scaffold implantation (pre-dilatation, sizing, post-dilatation), % (n)	14.2 (115/874)

Need for “bail out” scaffold/stent (use of additional, unplanned device to treat a complication related to the implant of the BVS) occurred in 4.2% of the procedures, 2.2% were performed with the implant of an additional BRS.

Clinical outcomes

	30 days	**1 year**	**3 years**
MACE, %	2.6	5.1	9.2
TVF, %	2.6	5.5	10.6
Ischemia driven TLR	0	1.4	3.1
Use of DAPT	98.8	79	40.1

Most of the in-hospital MACE was also driven by peri procedure MI.

Independent predictors of MACE were hypertension (OR 2.26, 95% CI: 1.18 – 4.32, p=0.01) and use of “bail out” stent (OR 3.32, 95% CI:1.37, 8.05, p= 0.008).

Clinical outcomes

	30 days	**1 year**	**3 years**
ScT (definite/probable), %	0.6	1.0	2.2^
Cardiac death, %	0.2	0.7	2.1
MI, %	2.3	3.0	4.0
Q-wave MI %	0.6	0.7	1.0
Non Q-wave MI	1.7	2.3	3.0

^of the 8 cases of very late ScT, 7 occurred among patients who did not fulfill the PSP criteria.

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Study 8 Wiebe J (2021)

Study details

Study type	Case series (ISAR-ABSORB registry)
Country	Germany (2 centres)
Recruitment period	2012-2014
Study population and number	n=419 symptomatic patients with de novo lesions having PCI with BRS lesions treated: n=527 (according to ACC/AHA lesion morphology 49% were complex and 13.1% were bifurcation lesions). Clinical diagnosis: CAD (n=256), unstable angina (n=48), non ST evaluation MI (n=80), ST evaluation MI (n=35). Baseline angiographic outcomes: RVD 2.89 mm, minimum lumen diameter 0.91 mm, stenosis 68.6%, lesion length 15.8%.
Age and sex	Mean age 67 years, 77% male
Patient selection criteria	Inclusion criteria: symptomatic patients with de novo lesions.
Technique	PCI-implantation of everolimus-eluting BRS (Absorb, Abbott Vascular) at the discretion of the interventional cardiologist. Modification in implantation (post-dilatation) was done after early experience. Pre-dilation was done in 97.7% and post-dilation in 71.5% lesions. Peri-procedural unfractionated heparin or bivalirudin and a loading dose of aspirin and ADP receptor antagonist was administered in all patients. 95.5% patients were given aspirin indefinitely and all patients had an ADP receptor antagonist.14.1% were given oral anticoagulation therapy at the operator's discretion. Post intervention lumen diameter was 2.60 mm and diameter stenosis was 13.7%. Mean of 1.2±0.4 BRS per lesion with a mean length of 26.9 ±13.2 mm were implanted. 17.9% (75/419) patients had BRS overlap, of these 41 patients had for treatment of long lesions and 34 patients had because of dissection.
Follow-up	Median 4.9 years
Conflict of interest/source of funding	3 authors received consulting or lecture fees and research grants from Biotronik and other companies.

Analysis

Follow-up issues: . Routine angiographic follow-up was done at 6 to 8 months, further clinical telephone follow-up was done at 1 and 12 months and annually up to 5 years.

Study design issues: prospective non-randomised study with good sample size; the primary outcomes assessed were the composite of death, MI and TLR, and definite ScT according to ARC criteria. There is lack of data on long-term DAPT.

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Study population issues: there were 39% patients with ACS, 31.5% (n=132) had diabetes mellitus, 86.2% had hypertension, 76.1% had hypercholesterolemia.

Key efficacy findings

Number of patients analysed: 419

Procedure outcomes

Procedural success	96.8%
Angiography results (at 6 – 8 months for 71% [374/527] of lesions)	
In-stent late lumen loss	0.27 ± 0.51 mm
In-segment diameter stenosis	27.7 ±16.1%.
Binary restenosis	8.0%

Clinical outcomes

Composite of death, MI, TLR, %	**1 year (n=348)**	**2 years (n=317)**	**3 years (n=286)**	**4 years (264)**	**5 years (217)**
	14.0	20.0	26.5	29.6	33.1
TLR, %	**1 year (n=351)**	**2 years (n=322)**	**3 years (n=289)**	**4 years (266)**	**5 years (225)**
	9.9	14.4	17.2	18.8	20.3

In the multivariate analysis, the incidence of the primary composite endpoint (of death, MI and TLR) was significantly associated with higher age (HR 1.29; 95% CI, 1.04-1.58; p = 0.02), female sex (HR 0.54; 95%CI, 0.33-0.90; p = 0.02), the number of treated lesions (HR 1.40; 95%CI, 1.14-1.74; p < 0.01), and BRS overlap (HR 1.39; 95%CI, 1.01-1.91; p < 0.05). The only predictor of TLR was the number of lesions treated (HR 1.64; 95%CI, 1.22-2.21; p < 0.01).

Key safety findings

Clinical outcomes

All-cause death, %		**1 year (n=392)**	**2 years (n=373)**	**3 years (n=350)**	**4 years (n=329)**	**5 years (n=274)**
		3.6	5.6	9.5	11.9	14.0
Cardiac death, %		2.2	2.9	5.1	5.9	7.5
MI, %		**1 year (n=386)**	**2 years (n=363)**	**3 years (n=344)**	**4 years (315)**	**5 years (305)**
		3.6	4.9	5.4	5.9	6.2
Death or MI, %		6.5	9.5	13.6	16.0	18.4

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Definite stent thrombosis^, %	**30 days (n=419)**	**1 year (n=390)**	**2 years (n=364)**	**3 years (n=348)**	**4 years (n=318)**	**5 years (n=309)**
	1.9^^	2.4	3.7	4.2	4.4	4.7

^^all patients were on DAPT except 1. ^None of the patients with late ScT (1-5 years) were on DAPT. OCT in 4 of these patients showed scaffold discontinuation with mal-apposed struts in 3 cases, of which 1 also had evidence of restenosis and a tissue bridge possibly related to chronic mal-apposition. In 1 patient an aneurysm in the BRS region was seen. Most definite ScT occurred within 2 years after BRS implantation.

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Study 9 Sabaté M (2019)

Study details

Study type	Randomised controlled trial (NCT03234348)
Country	Spain
Recruitment period	2017-2018
Study population and number	n= 150 ST-STEMI patients. mgBRS (n=74) versus DES (n=76)
Age and sex	Mean age 59.0±10.4 years, 89.3% male
Patient selection criteria	Inclusion criteria: patients >18 years with STEMI having primary PCI, at least 1 target lesion suitable for either MgBRS or SES implantation. Exclusion criteria: STEMI secondary to stent/ScT, target lesions with a RVDof <2.75 mm or >3.75 mm, and tortuous or calcified vessels that in the opinion of the investigators would result in suboptimal MgBRS implantation.
Technique	Patients were randomised 1:1 to have either MgBRS (Magmaris, Biotronik AG) or SES (Orsiro, Biotronik AG) following successful lesion preparation by either manual thrombectomy or predilatation, with opening of the vessel, thrombolysis in MI ≥2 and residual stenosis <20%. SES implantation technique was left to the discretion of the operator. However, a dedicated implantation technique according to the guidelines provided in the BVS-STEMI STRATEGY study was implemented for MgBRS. In particular, predilatation was mandatory when residual stenosis was >30% and full expansion of the predilatation balloon was required to allow Mg-BRS implantation. Post dilatation was also mandatory in all patients randomised to Mg-BRS stent, by using a noncompliant balloon of up to 0.5 mm more in diameter than the scaffold implanted. Periprocedural anticoagulation and the use of glycoprotein IIb/IIIa were left to the discretion of the operator. Dual antiplatelet therapy, preferably ticagrelor (90 mg bid) or prasugrel (10 mg/day) was prescribed in both study groups for 1 year with aspirin (100 mg/day).
Follow-up	12 months
Conflict of interest/source of funding	Study funded by the Spanish Heart Foundation. No authors disclosed links to Biotronik, but several authors report receiving speaker fees, personal fees and research grants from other companies.

Analysis

Follow-up issues: Good follow-up; clinical outcomes were obtained in all patients at 12 months.

Study design issues: Device success was defined as implantation of the intended device with attainment of <30% residual stenosis of the target lesion and thrombolysis in MI ≥2. Procedural success was defined as device success and no in-hospital cardiac events: death, repeat MI, TVR or stent/ScT. POCE is defined as combined (hierarchical) of all-cause death, any recurrent MI, or any revascularisation.

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Revascularisation was considered ischemia-driven if associated with any of the following: non-invasive positive functional ischemia study (e.g., exercise testing or equivalent tests) or invasive positive functional ischemia study (e.g., fractional flow reserve or coronary flow reserve); ischemic symptoms and an angiographic minimal lumen diameter stenosis ≥50% by on-line QCA; or diameter stenosis ≥70% by on-line QCA without either ischaemic symptoms or a positive functional study

Study population issues: 56% (84/150) current smokers, 16% (24/150) diabetes mellitus, 43.3% (65/150) hypertension, 58.0% (87/150) hypercholesterolemia, 14% (21/150) family history of CAD, 5.3% (8/150) previous MI, 3.3 % (5/150) previous PCI, 5.3% (8/150) COPD, 2% (3/150) cardiac arrest at presentation.

Key efficacy findings

Number of patients analysed: 150

Clinical events and outcomes at 1 year

	SES % (n=76)	MgBRS (n=74)	% Difference (95% CI)	P value
Device success	100 (76/76)	98.6 (73/74)	1.4 (-1.3, 4.0)	0.493
Procedural success	96.1 (73/76)	95.9 (71/74)	0.2 (-6.2, 6.4)	1.000
POCE	14.5 (11/76)	23.0 (17/74)	-8.5 (-20.9, 3.9)	0.182
DOCE	6.6 (5/76)	17.6 (13/74)	-11.0 (-21.3, -0.7)	0.038
All-cause death	**1.3 (1/76)**	**1.4 (1/74)**	**0.1 (-3.7, 3.6)**	**0.985**
Cardiac death	1.3 (1/76)	1.4 (1/74)	0.1 (-3.7, 3.6)	0.985
MI	**3.9 (3/76)**	**1.4 (1/74)**	**2.5 (-2.5, 7.7)**	**0.620**
Related with device thrombosis	2.6 (2/76)	1.4 (1/74)	1.2 (-3.2, 5.7)	1.000
Spontaneous MI	1.3 (1/76)	0 (0/74)	1.3 (-1.3, 3.9)	1.000
TLR	**5.3 (4/76)**	**16.2 (12/74)**	**-10.9 (-20.7, -1.2)**	**0.030**
TLR (ischaemia driven)	5.3 (4/76)	16.2 (12/74)	-10.9 (-20.7, -1.2)	0.030
TVR	7.9 (6/76)	20.3 (15/74)	-12.4 (-23.4, -1.4)	0.029
Non-TVR	3.9 (3/76)	2.7 (2/74)	1.2 (-4.5, 7.0)	1.000

Key safety findings

	SES % (n=76)	MgBRS (n=74)	% Difference (95% CI)	P value
Definite device thrombosis at 1 year	2.6 (2/76)	1.4 (1/74)	1.2 (-3.2, 5.7)	1.000
Definite or probable device thrombosis at 1 year	2.6 (2/76)	1.4 (1/74)	1.2 (-3.2, 5.7)	1.000

The 1 case of definite device thrombosis in the MgBRS group occurred (0 minutes after implantation and was resolved by thrombectomy and new balloon post dilatation. In the SES arm, this adverse event occurred in 2 patients (1 acute and 1 subacute definite stent thrombosis).

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Study 10 Haude M (2020)

Study details

Study type	Pooled case series (BIOSOLVE-II and BIOSOLVE III studies)
Country	Belgium, Brazil, Denmark, Germany, Singapore, Spain, Switzerland, the Netherlands
Recruitment period	2014-2015
Study population and number	n=184 patients
Age and sex	Mean age 65.5±10.8 years, 63.6% male
Patient selection criteria	Inclusion criteria: Stable or unstable angina, documented silent ischemia, a maximum of 2 single *de novo* lesions in 2 separate coronary arteries ≤21 mm in length. Exclusion criteria: MI within 72 hours prior to the index procedure, unprotected left main disease, 3-vessel CAD, heavily calcified lesions, unsuccessful pre-dilatation.
Technique	Patients were implanted with DREAMS 2G (Magmaris by Biotronik AG) sirolimus-eluting magnesium bioresorbable scaffold. Pre-dilatation with a balloon ≤0.5 mm smaller than the RVD, but not exceeding the vessel diameter, and a ≤ lesion length was mandatory. Post-dilatation was performed according to the discretion of the investigator. DAPT was recommended for at least 6 months.
Follow-up	3 years
Conflict of interest/source of funding	Study was funded by Biotronik. Authors reported receiving study grants, personal fees, and speaker fees from Biotronik and other companies.

Analysis

Follow-up issues: 2 patients recruited did not have device implanted due to insufficient pre-dilatation. 2 patients missed follow-up visit and were subsequently not included in further analyses, and 6 patients were lost to follow-up. Overall 5.4% (10/184) of study population not included in 3 year follow-up.

Study design issues: Pooled case series combining data from BIOSOLVE-II and BIOSOLVE III studies. Endpoints at 3 years were TLF, a composite of cardiac death, target-vessel MI, coronary artery bypass grafting, and clinically driven TLR, and ScT.

Study population issues: 25% had diabetes, 23.4% with prior MI, 41.4% with previous coronary interventions.

Key efficacy findings

Number of patients analysed: 184

Clinical outcomes up to 3 years

Clinical outcome	2 years % (n = 180)	3 years % (n=174)

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TLF	5.5 (10/184)	6.3 (11/174) [95% CI: 3.2;11.0]
All mortality*	3.9 (7/184)	5.2 (9/174)
Cardiac mortality	2.2 (4/184)	2.3 (4/174)
Target-vessel MI	0.6 (1/184)	0.6 (1/174)
Clinically driven -TLR	2.7 (5/184)	3.4 (6/174)
Clinically driven-TVR	4.3 (8/184)	5.2 (9/174)
CABG	0 (0/184)	0 (0/174)

*1 death at day 2 was probably due to a ventricular arrhythmia caused by a large infarction area after an ST-elevation MI that had occurred prior to the index procedure (autopsy confirmed the absence of ScT), 2 unwitnessed deaths occurred on day 134 and 395, and 1 non-arenaria died on day 574 of pre-existing chronic heart failure.

Angina status up to 3 years

Clinical outcome	Baseline % (n=184)	12 months % (n=176)	24 months % (n=173)	36 months % (n=165)
No pathological findings	0	85.8	92.5	91.5
Stable angina	75	13.1	7.5	8.5
Unstable angina	12.5	0.6	0	0
Documented silent ischaemia	12.5	0.6	0	0

53% of patients were on dual antiplatelet therapy at 12 months, 19% at 2 years and 16% at 3 years with magnesium-based SES BRS.

Key safety findings

No probable or definite ScT was reported throughout both studies.

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Study 11 Chua SK (2017)

Study details

Study type	Case report and review
Country	Taiwan
Recruitment period	2010-2013
Study population and number	n= 1 patient with angina and severe stenotic lesions in the middle LAD artery and LCx.
Age and sex	55 year old man
Patient selection criteria	Not applicable
Technique	PCI for the middle LCx with a 3.0 x 18mm and 3.5 x 28mm BRS that were post-dilated with 3.5mm and 3.75 mm non-compliant balloons. IVUS was used to confirm optimal expansion and good apposition of the 2 stents.
Follow-up	18 months
Conflict of interest/source of funding	Not reported.

Analysis

Study population issues: patient had hypertension and hyperlipidaemia.

Key safety findings

Number of patients analysed:1

Coronary artery aneurysm (CAA defined as in-scaffold diameter more than1.5 times the RVD)

18 months after the procedure, coronary angiography showed lumen dilatation and ectatic change with aneurysm formation over the BRS at the middle of LCx (50% increase in diameter compared to reference vessel) . OCT revealed absence of strut continuity and complete endothelialisation of sturt remnants at the aneurysm site, in the middle of the BRS. No further intervention for the aneurysm was done but DAPT was given to prevent thrombus formation. Patient had no further adverse events during 1 year follow-up.

In addition, further literature review identified 11 cases of CAA after BRS implantation (5 in the LAD, 3 in RCA, and 3 in LCx) which occurred between 2- 32 months. Patients did not have further intervention but long-term DAPT and early follow-up were adopted. One patient with in-scaffold restenosis in the middle of an aneurysm had subsequent implantation of a self-expanding DES. Another patient had a covered stent implantation for a CAA that had significantly increased in size at 1-year after BRS.

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Study 12 Schinke K (2015)

Study details

Study type	Case report
Country	Taiwan
Recruitment period	2010-2013
Study population and number	n= 1 patient with CAD and prior bare-metal stenting of the LAD had both de-novo-stenosis and in-stent restenosis within the LAD stent and presented with recurrent exertional angina.
Age and sex	45 year old man
Patient selection criteria	Not applicable
Technique	PCI after pre-dilatation with a completely expanded 2.5 x 20-mm balloon, a BRS (Abbott, Absorb, 2.5 x 28 mm) was positioned in the region of the de-novo-stenosis distal of the former stent and inflated stepwise to an end-pressure of 12 atm which was held for 30 seconds to achieve optimal expansion.
Follow-up	During implantation
Conflict of interest/source of funding	None.

Key safety findings

Number of patients analysed:1

Vessel perforation

Post-inflation angiography revealed a large extravasation caused by a broad perforation at the convex side of the vessel, likely due to fatigue and fracturing of the scaffold struts leading to a broad laceration. To prevent pericardial tamponade a 2.5 x 20 mm balloon was positioned across the ruptured region and inflated. Afterwards a covered stent graft, (2.5 x18 mm) was implanted within the scaffold sealing the perforation successfully. Finally, both the proximal de-novo-stenosis and the restenosis of the former LAD stent were treated with additional implantation of a 2.5 x 28mm XIENCE everolimus-eluting metallic stent with an excellent final result.

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Validity and generalisability of the studies

- The design, composition and features of different types of BVS vary significantly and may have an impact on clinical outcomes. They vary in the degradable material used [polymer such as poly-l-lactic acid-PLLA or magnesium alloy], thickness, eluting drugs used [everolimus, sirolimus, novolimus], and reabsorption time [within 1-4 years after implantation].
- Most of the studies included in systematic reviews were assessing the first-generation Absorb BVS. There is very little evidence on second generation absorb BVS or new generation scaffolds.
- Most of the RCTs included in the systematic reviews and HTA compared Absorb BVS with DES (CoCr-EES). Only 1 RCT compared MgBRS with DES-SES (Sabate 2019).
- The RCTs included in the systematic reviews had a variety of patient characteristics, medication and follow-up.
- Techniques of implantation are not standardised and evolved over time.

Existing assessments of this procedure

2018 European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS) guidelines on myocardial revascularisation does not recommend BVS for use in clinical practice outside of clinical studies (class III recommendation, level of evidence C).

Section 16.1.3 on bioresorbable scaffolds in the guideline states that *'bioresorbable scaffolds (BRS), which degrade to predominantly inert end products after fulfilling their scaffold function in the lesion site of the coronary vessel, have been developed with the goal of reducing or eliminating stent-related adverse events at long-term follow-up. Current scaffold platforms to have reached clinical testing are based on two different technologies: bioresorbable, polymer-based scaffolds (resorption up to 3–4 years) and resorbable, metallic (magnesium) scaffolds (resorption up to 1 year). Although a number of devices have received approval for use in Europe, randomized trial data are available only with the Absorb bioresorbable vascular scaffold (BVS) (Abbott Vascular)'.*

'The safety and efficacy profile of the Absorb BVS has been compared with contemporary DES in several trials. Findings of these trials as well as meta-

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analyses consistently indicate the inferior efficacy and safety of Absorb BVS compared with contemporary DES during long-term follow-up. Specifically, the Absorb BVS is associated with a significantly increased risk of target lesion revascularization and device thrombosis, with numbers needed to harm of 40–60. Of note, commercial use of the Absorb BVS was stopped in 2017'.

'Available evidence on the magnesium scaffold is limited to small observational studies. Initial results appear encouraging, but further evaluation is needed. Therefore, the Task Force endorses the recommendation of the recent ESC/European Association for Percutaneous Cardiovascular Interventions (EAPCI) document on bioresorbable scaffolds (Byrne RA 2018) that any BRS should not be used outside well-controlled clinical studies. In patients who have been treated with BRS, prolonged-duration DAPT for 3 years or longer may be considered' (Neumann FJ 2019).

A previous Task Force of the European Society of Cardiology (ESC) and European Association of Percutaneous Cardiovascular Interventions (EAPCI) provided a report on recommendations for bioresorbable scaffolds (BRS). It concluded that:

- *Five BRS have CE-mark approval for use in Europe, and only one device (the Absorb bioresorbable vascular scaffold) has published randomized clinical trial data and this data show inferior outcomes to conventional drug-eluting stents (DES) at 2–3 years. For this reason, at present BRS should not be preferred to conventional DES in clinical practice.*

- *On-going trials should be closely monitored for adverse events and data should be made available at regular intervals in the public domain, irrespective of the initial analysis plan.*

- *It is not recommended to use BRS in patients who cannot tolerate or are unlikely to be compliant with extended duration DAPT or who require oral anticoagulants.* (Byrne RA 2018).

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

- Intravascular lithotripsy for calcified coronary arteries during percutaneous coronary. NICE interventional procedure guidance 673 (2020). Available from http://www.nice.org.uk/guidance IPG673

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- Percutaneous insertion of a temporary heart pump for left ventricular haemodynamic support in high-risk percutaneous coronary interventions. NICE interventional procedure guidance 633 (2018). Available from http://www.nice.org.uk/guidance IPG633
- Bioresorbable stent implantation for treating coronary artery disease. NICE interventional procedures guidance 492 (2014). Available from http://www.nice.org.uk/guidance IPG492
- Optical coherence tomography to guide percutaneous coronary intervention. NICE interventional procedures guidance 481 (2014). Available from http://www.nice.org.uk/guidance IPG481
- Percutaneous laser coronary angioplasty. NICE interventional procedures guidance 378 (2011). Available from http://www.nice.org.uk/guidance IPG378
- Intraoperative fluorescence angiography for the evaluation of coronary artery bypass graft patency. NICE interventional procedure guidance 98 (2004). Available from http://www.nice.org.uk/guidance IPG98

Technology appraisals

- Rivaroxaban for preventing major cardiovascular events in people with coronary or peripheral artery disease. NICE technology appraisal 607 (2019). Available from www.nice.org.uk/guidance/TA607
- Drug-eluting stents for the treatment of coronary artery disease. NICE technology appraisal 152 (2008). Available from: www.nice.org.uk/guidance/TA152
- Guidance on the use of coronary artery stents. NICE technology appraisal 71 (2003). Available from www.nice.org.uk/guidance/TA71

Medical technologies

- HeartFlow FFRCT for estimating fractional flow reserve from coronary CT angiography. NICE medical technologies guidance 32 (2017, updated 2021). Available from:

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- http://guidance.nice.org.uk/MTG32
- MiraQ for assessing graft flow during coronary artery bypass graft surgery. NICE medical technology guidance 8 (2011) Available from:
- http://guidance.nice.org.uk/MTG8
- SeQuent Please balloon catheter for in-stent coronary restenosis. NICE medical technology guidance 1 (2010). Available from:
- http://guidance.nice.org.uk/MTG1

NICE guidelines

- Cardiovascular disease: risk assessment and reduction, including lipid modification. Clinical guideline 181 (2014, updated 2016). Available from http://www.nice.org.uk/guidance/cg181
- Acute coronary syndromes. NICE guideline 185 (2020). Available from http://www.nice.org.uk/guidance/NG185
- Myocardial infarction: cardiac rehabilitation and prevention of further cardiovascular disease. NICE guideline 172 (2013). Available from http://www.nice.org.uk/guidance/NG172
- Myocardial infarction with ST-segment elevation: acute management. Clinical guideline 167 (2013). Available from http://www.nice.org.uk/guidance/NG167
- Stable angina. NICE clinical guideline 126 (2011). Available from http://www.nice.org.uk/guidance/cg126
- Chest pain of recent onset: assessment and diagnosis NICE clinical guideline 95 (2010, updated 2016). Available from http://www.nice.org.uk/guidance/cg95
- Unstable angina and NSTEMI. The early management of unstable angina and non-ST-segment-elevation myocardial infarction. NICE clinical guideline 94 (2010). Available from http://www.nice.org.uk/guidance/cg94
- MI – secondary prevention: Secondary prevention in primary and secondary care for patients following a myocardial infarction. NICE guideline 48 (2007). Available from http://www.nice.org.uk/guidance/cg48

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Diagnostics guidance

- New generation cardiac CT scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash) for cardiac imaging in people with suspected or known coronary artery disease in whom imaging is difficult with earlier generation CT scanners (2012, updated 2017) NICE diagnostics guidance 3

Additional information considered by IPAC

Professional experts' opinions

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by professional experts, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. 2 professional expert questionnaires for bioresorbable stent implantation for treating coronary artery disease were submitted and can be found on the NICE website.

Patient organisation opinions

Patient organisation submissions for bioresorbable stent implantation for treating coronary artery disease were not received.

Patient commentators' opinions

NICE's Public Involvement Programme sent questionnaires to NHS trusts for distribution to patients who had the procedure (or their carers). When NICE has received the completed questionnaires, these will be discussed by the committee.

Company engagement

A structured information request was sent to 4 companies who manufacture a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

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Issues for consideration by IPAC

- Ongoing studies

NCT02601781: A prospective evaluation of a standardised strategy for the use of bioresorbable vascular scaffold in ST-segment elevation myocardial infarction: the BVS STEMI STRATEGY-IT registry. Procedure: primary percutaneous coronary intervention (PPCI); Device (BVS ABSORB); single group assignment; n=500, primary outcome: device oriented composite end-point (DOCE) at 30 days; location: Italy; start date October 2015, completion date December 2021.

NCT03112707: Performance of bioresorbable polymer-coated everolimus-eluting synergy® stent in patients at high bleeding risk having percutaneous coronary revascularisation followed by 1-month dual antiplatelet therapy. Single group assignment; n=1023 patients, primary outcome: MACE rate 1 year; location: Italy; start date April 2017, completion date May 2020.

NCT01761578: First in man safety evaluation of the ART18Z bioresorbable stent for the treatment of single de novo lesion of a native coronary artery. Device: ART18Z bioresorbable stent; n=30; single group assignment; primary outcome: MACE rate at 6 months; location: France; start date June 2012, study completion date not available.

NCT02067091: Performance of bioresorbable scaffold in primary percutaneous intervention of ST Elevation Myocardial Infarct (BVS in STEMI). Randomised clinical trial; n=120; Absorb BVS versus DES; primary outcome: coronary stent healing index at 12 months; location Denmark, Norway; start date August 2014, study completion date August 2020.

- First-generation Absorb BVS is the only device that has FDA approval but has been withdrawn from the market since September 2017.However,long-term follow-up associated with this device have been published. A second-generation Absorb BVS and other new polymer-or magnesium based scaffolds

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(with thinner strut profiles, advanced mechanical properties and faster reabsorption) are under development.

- Following current ESC guidelines, Magmaris BVS has only been used in clinical trials in the UK (BIOSOLVE VI).

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6. Cakal S, Cakal B, Karaca O et al. (2021) Long-term outcomes of Absorb bioresorbable vascular scaffold using predilation, sizing, and postdilation protocol in a real-world patient population. Turk Kardiyol Dern Ars; 49(1):40-50.
7. Costa JR, Abizaid A, Whitbourn R et al. (2019) Three-year clinical outcomes of patients treated with everolimus-eluting bioresorbable vascular scaffolds: final results of the ABSORB EXTEND trial. Catheter Cardiovasc Interv, 93 (1), pp.E1-E7. https://doi.org/10.1002/ccd.27715.
8. Wiebe J, Hoppmann P, Cassese S et al. (2021) Outcomes after complete dissolution of everolimus-eluting bioresorbable scaffolds implanted during routine practice. Rev Esp Cardiol. 74(7):584–590.
9. Sabate M, Alfonso F, Cequier A et al. (2019) Magnesium-based resorbable scaffold versus permanent metallic sirolimus-eluting stent in patients with ST-segment elevation myocardial infarction the MAGSTEMI randomized clinical trial. Circulation.140:1904–1916.
10. Haude M, Ince H, Kische S et al. (2020) Sustained safety and performance of the second-generation sirolimus-eluting absorbable metal scaffold: pooled outcomes of the BIOSOLVE-II and -III trials at 3 years. Cardiovascular Revascularization Medicine 21, 1150–1154.
11. Chua SK and Cheng JJ (2017) Coronary artery aneurysm after implantation of a bioresorbable vascular scaffold: case report and literature review. Catheterization and Cardiovascular Interventions 90:E41–E45.

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12. Schinke K, Langwieser N, Laugwitz KL et al. (2015) A potential life-threatening complication after implantation of a bioresorbable scaffold for coronary stenting within a mechanically stressed region. Clin Res Cardiol (2015) 104:366–367.

13. Neumann FJ, Saousa-Uva M, Ahlsson A et al. (2019) 2018 ESC/EACTS Guidelines on myocardial revascularization. Eur Heart J. 40 (2):87 –165.

    Sousa-Uva M, Neumann F-J, Ahlsson A, Alfonso F, Banning AP, Benedetto U et al. (2019) 2018 ESC/EACTS Guidelines on myocardial revascularization. Eur J Cardiothorac Surg; 55:4–90.

14. Byrne RA, Stefanini GG, Capodanno D, et al. Report of an ESC-EAPCI Task Force on the evaluation and use of bioresorbable scaffolds for percutaneous coronary intervention: executive summary. EuroIntervention. 2018;13:1574–1586.

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Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	11/08/2021	Issue 8 of 12, August 2021
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	11/08/2021	Issue 8 of 12, August 2021
International HTA database		
MEDLINE (Ovid)	09/08/2021	1946 to August 06, 2021
MEDLINE In-Process (Ovid) & MEDLINE ePubs ahead of print (Ovid)	09/08/2021	1946 to August 06,2021
EMBASE (Ovid)	09/08/2021	1974 to 2021 August 06

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search
- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

MEDLINE search strategy

The MEDLINE search strategy was translated for use in the other sources.

Strategy used:

1 coronary disease/ or coronary artery disease/ or coronary occlusion/ or coronary stenosis/
2 ((coronar* or heart*) adj4 arter* adj4 (diseas* or stenos* or occlusi* or narrow* or block* or restrict* or lesion* or atheroscler* or atherioscler*)).tw.
3 CAD.tw.
4 or/1-3 260,
5 Absorbable Implants/

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6 (bioresorbable* or bioabsorbable* or absorbable* or biocompatible* or biodegradable* or temporar*).tw.
7 5 or 6 134
8 stents/ or drug-eluting stents/
9 (stent* or tube* or graft* or scaffold* or implant*).tw.
10 Angioplasty, Balloon, Coronary/
11 angioplast*.tw.
12 Percutaneous Coronary Intervention/
13 (percutaneous adj1 coronary adj1 intervention*).tw.
14 PCI.tw.
15 (Percutaneous adj1 Transluminal adj1 Coronary*).tw.
16 PTCA.tw.
17 (Sirolimus* or Everolimus*).tw.
18 or/8-17
19 7 and 18
20 4 and 19
21 limit 20 to ed=20190701-20210831
22 animals/ not humans/
23 21 not 22
24 limit 23 to english languag

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Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the summary of the key evidence. It is by no means an exhaustive list of potentially relevant studies.

Additional papers identified

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in summary of key evidence section
Ali ZA, Serruys PW, Kimura T et al. (2017) 2-year outcomes with the Absorb bioresorbable scaffold for treatment of coronary artery disease: a systematic review and meta-analysis of seven randomised trials with an individual patient data substudy. Lancet; 390:760−72.	Systematic review and meta-analysis of randomised trials n=5583 patients assigned to Absorb BVS (n=3261) or metallic EES (n=2322) and followed up for 2 years.	BVS had higher 2-year relative risks of the DOCE than did EES (9·4% [304 of 3217] vs 7·4% [169 of 2299]; RR 1·29 [95% CI 1·08-1·56], p=0·0059). These differences were driven by increased rates of target vessel MI (5·8% [187 of 3218] vs 3·2% [74 of 2299]; RR 1·68 [95% CI 1·29-2·19], p=0·0003) and ischaemia-driven TLR (5·3% [169 of 3217] vs 3·9% [90 of 2300]; 1·40 [1·09-1·80], p=0·0090) with BVS, with non-significant differences in cardiac mortality. The cumulative 2-year incidence of device thrombosis was higher with BVS than with EES (2·3% [73 of 3187] vs 0·7% [16 of 2281]; RR 3·35 [95% CI 1·96-5·72], p<0·0001).	Large and recent studies included.
Ali ZA, Gao R, Kimura T et al. (2018) Three-year outcomes with the Absorb bioresorbable scaffold: individual-patient-data meta-analysis from the ABSORB randomized trials. Circulation; 137:464−79.	Meta-analysis of 4 RCTs assigning patients to an Absorb BVS (n=2164) or a DES (n=1225).	Individual-patient-data meta-analysis of 3 year outcomes of ABSORB versus Xience from the ABSORB RCTs showed higher rates of TLF (11.7% versus 8.1%; RR, 1.38; 95% CI, 1.10–1.73;P=0.006), driven by greater target vessel MI (7.8% versus 4.2%; RR, 1.72; 95% CI, 1.26–2.35; p=0.0006) and ischemia-driven TLR (6.6% versus 4.4%; RR, 1.44; 95% CI, 1.05–1.98; P=0.02), with comparable cardiac mortality (1.1% versus 1.1%; RR,	Large and recent studies included.

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		0.93; 95% CI, 0.47–1.88; P=0.85). Device thrombosis rates through 3 years were also higher with BVS (2.4% versus 0.6%; RR, 3.71; 95% CI, 1.70–8.11; P=0.001).	
Alfonso F, Cuesta J, Pérez-Vizcayno MJ et al. (2017) Bioresorbable vascular scaffolds for patients with in-stent restenosis: the RIBS VI study. JACC: Cardiovascular Interventions. 10: 1841-1851.	Prospective multi-centre study RIBS VI n=141 patients treated with BVS for either BMS-ISR or DES-ISR.	The study suggested that the use of BVS in patients with ISR was effective and safe. In this challenging anatomic scenario, BVS obtained late angiographic and clinical results similar to DEB but inferior to EES.	Large and recent studies included.
Anadol R, Lorenz L, Weissner M, et al. (2017) Characteristics and outcome of patients with complex coronary lesions treated with bioresorbable scaffolds: three years follow-up in a cohort of consecutive patients. Eurointervention;03:03.	Observational study (registry) (NCT02180178) n= 657 patients with BRS implantation in complex lesions. Median follow-up was 1,076 (762-1,206) days.	BRS implantation in complex lesions is, as expected, associated with higher incidence of events as compared to simple ones. The technique used at the time of the implantation, however, reduces the incidence of adverse outcomes.	Larger studies included.
Aaroyo D, Gendre G, Schukraft S et al. (2017) Comparison of everolimus- and biolimus-eluting coronary stents with everolimus-eluting bioresorbable vascular scaffolds: Two-year clinical outcomes of the EVERBIO II trial. International Journal of Cardiology 243; 121–125.	RCT EVERBIO II trial N=240 patients (1:1 e (Comparison of DES with ABSORB BVS) Follow-up 2 years	The current analysis shows no significant differences with regard to clinical outcomes at 2 years between BVS and the best-in-class metallic DES. Event rates were numerically higher in BVS-treated patients. However, when BVS were compared to BES alone, the occurrence of device related adverse events was significantly increased.	Included in systematic reviews and HTA.
Azzi N, Shatila W (2021) Update on coronary artery	Review	In this review, we discuss the	Review

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bioresorbable vascular scaffolds in percutaneous coronary revascularization. Rev. Cardiovasc. Med. 22(1), 137-145.		clinical procedural and technical evidence on BVS, with emphasis on their clinical impact. We finally tackle the future directions on device and procedural improvement while asking: is the bioresorbable technology still the way to the future?	
Abizaid A, Ribamar Costa J, Bartorelli AL, et al. (2015) The ABSORB EXTEND study: preliminary report of the twelve-month clinical outcomes in the first 512 patients enrolled. EuroIntervention; 10: 1396-1401.	Registry ABSORB EXTEND study N=512 Follow-up 12 month.	12-month MACE 4.3 showed that minor routine oversizing of the BVS followed by high pressure post-dilatation was safe with a low rate of MACE and no reported stent thrombosis.	Larger and more recent studies included.
Abizaid A, Costa RA, Schofer J et al. (2016) Serial multimodality imaging and 2-year clinical outcomes of the novel desolve novolimus-eluting bioresorbable coronary scaffold system for the treatment of single de novo coronary lesions. JACC: Cardiovascular Interventions; 9: 565-574.	Case series N=126 treated with 150 lm thickness pBRS.	The first series of the DESolve showed a LLL at 6 months of 0.19 ± 0.19 mm, which was similar to that seen with contemporary DES. The second series of the DESolve was assessed in the DESolve Nx trial. LLL at 6 months was 0.20 ± 0.32 mm; MACE rate at 24 months was 7.4%. No definite ScT were seen.	Larger and more recent studies included.
Bennet J, Hemptinne QE, McCutcheon K et al (2019) “Magmaris resorbable magnesium scaffold for the treatment of coronary heart disease: overview of its safety and efficacy” Expert review of medical devices. 757-769.	Review of sirolimus-eluting resorbable magnesium scaffold Magmaris	The first clinical studies testing this device in a small number of patients have shown promising results with good clinical and safety outcomes up to 3 years’ clinical follow-up, supporting the use of Magmaris in simple CAD.	Large and recent studies included.

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Bennet J, McCutcheon K (2020) "The coronary resorbable magnesium scaffold Magmaris: What we've learnt (so far...)" Minerva Cardioangiologica 69(2):215-221.	Review	Review focuses on the resorbable magnesium scaffold Magmaris® the only metallic bioresorbable scaffold currently available, providing an evaluation of the most up to date clinical data whilst also briefly highlighting learning points regarding the ideal patient and lesion choice and optimal implantation technique.	Large and recent studies included.
Banach M, Serban MC, Sahebkar A et al. (2016) Comparison of clinical outcomes between bioresorbable vascular stents versus conventional drug-eluting and metallic stents: a systematic review and meta-analysis. EuroIntervention;12: e175-e189.	Systematic review and meta-analysis. 10 studies with 5,773 subjects With BRS and conventional stents Follow-up in the included studies was up to 13 months.	Our meta-analysis suggests a significantly higher risk of TVMI with BRS compared with conventional stents and no significant differences in the rates of occurrence of the other outcomes during 1-year follow-up. Further studies with larger samples sizes, longer follow-up, different clinical scenarios and more complex lesions are required to confirm or refute our findings	More recent comprehensive studies included.
Baquet M, Hoppmann P, Grundmann D et al. (2019) Sex and long-term outcomes after implantation of the Absorb bioresorbable vascular scaffold for treatment of coronary artery disease. EuroIntervention;15:6 15-622	Pooling the individual patient data of the ISAR-ABSORB and KUM-ABSORB registries. of 1,032 patients, 259 (25.1%) were women. Follow-up 2 years.	BVS used in a routine setting tend to perform better among women compared to men, which might be partially related to the lower complexity of their CAD.	Larger studies included.
Bruining N, Tanimoto S, Otsuka M et al. (2008) Quantitative multi-modality imaging analysis of a bioabsorbable poly-L-lactic acid stent design in the acute phase: a comparison between 2- and 3D-QCA, QCU and QMSCT-CA. Eurointervention 4: 285-291.	Case series N = 16 Follow-up: Post-procedure only	Authors conclude that non-invasive multi-slice computed tomography coronary angiography could be used to quantify luminal dimensions in PLLA biodegradable stents.	Sub-study. Focus on imaging outcomes.

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Bruining N, de Winter S, Roelandt JRTC et al. (2010) Monitoring in vivo absorption of a drug-eluting bioabsorbable stent with intravascular ultrasound-derived parameters. A Feasibility study. JACC: Cardiovascular Interventions 3 (4): 449-456.	Case series N = 12 Follow-up: 2 years	Authors conclude that quantitative differential echogenicity can be useful for monitoring the absorption process of semi-crystalline bioabsorbable stents.	Sub-study. Focus on imaging outcomes.
Brugaletta S, Radu MD, Garcia-Garcia HM et al. (2012) Circumferential evaluation of the neointima by optical coherence tomography after ABSORB bioresorbable vascular scaffold implantation: Can the scaffold cap the plaque? Atherosclerosis 221: 106-112.	Case series N = 58 Follow-up: 12 months	Authors conclude that the neointimal thickness did not differ between 6 and 12 months but thickness was more symmetric at 12 months.	Sub-study. Focus on imaging outcomes.
Brugaletta S, Gori T, Low AF et al. (2015) Absorb bioresorbable vascular scaffold versus everolimus-eluting metallic stent in ST-segment elevation myocardial infarction: 1-year results of a propensity score matching comparison: the BVS-EXAMINATION Study (bioresorbable vascular scaffold-a clinical evaluation of everolimus eluting coronary stents in the treatment of patients with ST-segment	Propensity score matching comparison n=290 STEMI patients treated by BVS, compared with either 290 STEMI patients treated with EES or 290 STEMI patients treated with bare-metal stents (BMS) from the EXAMINATION trial. Follow-up 1 year.	At 1-year follow-up, STEMI patients treated with BVS showed similar rates of DOCE compared with STEMI patients treated with EES or BMS, although rate of scaffolds thrombosis, mostly clustered in the early phase, was not negligible. Larger studies with longer follow-up are needed to confirm our findings.	Large and recent studies included.

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elevation myocardial infarction). JACC Cardiovasc Interv; 8: 189–197.			
Brugaletta S, Gomez-Lara J, Garcia-Garcia HM et al. (2012) Analysis of 1 year virtual histology changes in coronary plaque located behind the struts of the everolimus eluting bioresorbable vascular scaffold. International Journal of Cardiovascular Imaging 28: 1307 – 1314.	Case series N = 17 Follow-up: 1 year	Authors conclude that there was an increase in plaque area with a reduction in necrotic core and dense calcium content.	Sub-study of ABSORB Cohort B2. IVUS-VH outcomes.
Brugaletta S, Gomez-Lara J, Serruys PW et al. (2011) Serial in vivo intravascular ultrasound-based echogenicity changes of everolimus-eluting bioresorbable vascular scaffold during the first 12 months after implantation. Insights from the ABSORB B trial. JACC: Cardiovascular Interventions 4 (12): 1281-1289.	Case series N = 63 Follow-up:12 months	Authors conclude that there was a 15% and 20% decrease in hyper echogenicity at 6 and 12 months respectively. No difference in hyper echogenicity changes were seen between the proximal, medial, or distal part of the scaffolded segment.	Sub-study. Focus on imaging outcomes.
Brugaletta S, Garcia-Garcia HM, Garg S et al. (2011) Temporal changes of coronary artery plaque located behind the struts of the everolimus eluting bioresorbable vascular scaffold. International Journal of cardiovascular Imaging 27: 859 – 866.	Case series N = 15 Follow-up: 6 months	Authors conclude that there was progression of necrotic core and fibrous tissue content of plaque behind the struts in those having a BVS.	Sub-study. Focus on imaging outcomes.

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Brugaletta S, Gomez-Lara J, Bruining N et al. (2011) Head to head comparison of optical coherence tomography, intravascular ultrasound echogenicity and virtual histology for the detection of changes in polymeric struts over time: insights from the ABSORB trial. EuroIntervention 8 (3): 352-358.	Case series N = 35 Follow-up:12 months	Authors conclude that changes in the BVS struts were detectable by OCT, echogenicity and IVUS virtual histology although there was poor correlation.	Sub-study. Focus on imaging outcomes.
Brugaletta S, Cequier A, Alfonso F, et al. Magnesium-based bioresorbable scaffold and vasomotor function in patients with acute ST segment elevation myocardial infarction: The MAGSTEMI trial: Rationale and design. Catheter Cardiovasc Interv. 2019 Jan 1;93(1):64-70.	RCT N=148 in ST-STEMI patients SES versus BRS	This trial will shed light on the vascular vasomotion following BRS implantation in the complex scenario of STEMI.	Rationale and study design.
Brugaletta S, Garcia-Garcia HM, Diletti R e al. (2011) Comparison between the first and second generation bioresorbable vascular scaffolds: a six month virtual histology study. EuroIntervention 6: 1110-1116.	Comparative case series N = 28 (BVS 1.0) versus 32 (BVS 1.1) Follow-up: 6 months	Authors conclude that BVS 1.1 was more durable than the BVS 1.0.	Sub-study. Focus on imaging outcomes.
Brugaletta S, Gomez-Lara J, Diletti R et al. (2012) Comparison of in vivo eccentricity and symmetry indices between metallic stents and	N= 242 patients (BVS 1.0: *n* = 28, BVS 1.1: *n* = 94, XIENCE V: *n* = 120). Follow-up: 6 months	In 28 patients with (BVS 1.0; MACE 3.5%), 94 (BVS 1.1; MACE 4.2%) versus 120 (DES; MACE 1.9%). No differences in MACE were detected between the groups according to their geometrical parameters. No	Sub-study. Comparative study of mainly imaging outcomes.

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bioresorbable vascular scaffolds: insights from the ABSORB and SPIRIT trials. Catheterization and Cardiovascular Interventions 79: 219-228.		further analysis on clinical outcomes was reported. Authors conclude that the BVS had a lower eccentricity index and a higher symmetry index but that these differences did not generate clinical events.	
Brugaletta S, Heo J-H, Garcia-Garcia HM et al. (2012) Endothelial-dependent vasomotion in a coronary segment treated by ABSORB everolimus-eluting bioresorbable vascular scaffold system is related to plaque composition at the time of bioresorption of the polymer: indirect finding of vascular reparative therapy? European Heart Journal 33: 1325-1333.	N= 26 Follow-up: 2 years	Authors report that vasodilatory response of a BVS segment was associated with decreased echogenicity over time, and a low amount of necrotic core.	Sub-study. Focus on imaging outcomes.
Capodanno D, Gori T, Nef H, et al. Percutaneous coronary intervention with everolimus-eluting bioresorbable vascular scaffolds in routine clinical practice: early and midterm outcomes from the European multicentre GHOST-EU registry. EuroIntervention. 2015; 10: 1144-1153	GHOST-EU registry N=1189 patients who had angioplasty with the Absorb BVS	The only independent predictor of TLF was diabetes (HR 2.41, P = 0.006) and TLF occurred at a rate of 4.4% at 6 months. The cumulative incidence for definite or probable ScT was concerning with 1.5% at 30 days and 2.1% at 6 months. Independent predictors in this registry included ostial lesions (P = 0.049) and impaired left ventricular ejection fraction (P = 0.019).	Large and recent studies included.
Chevalier B, Cequier A, Dudek D, et al. (2018) Four-year follow-up of the	RCT Absorb BVS II N=501 (335 versus	TLF (or the DOCE) increased from 10.5% to 11.5% in the Absorb arm and from 5% to 6% in the XIENCE arm, with 1% and 0.7% absolute difference,	Included in systematic reviews and HTA added.

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randomised comparison between an everolimus-eluting bioresorbable scaffold and an everolimus-eluting metallic stent for the treatment of coronary artery stenosis (ABSORB II Trial). Eurointervention; 13(13):1561–4.	166) Everolimus-eluting BRS/Absorb® versus DES/Xience® Follow-up 4 years.	respectively (p=0.3). No statistically significant difference could be seen (p=0.063). 2 patients in the Absorb arm and 1 in the XIENCE arm died between 3 and 4 years. The POCE was seen in 23.6% in the Absorb arm and 26.7% in the XIENCE arm (p=0.47). No case of additional very late scaffold/stent thrombosis was noted in either arm between 3 and 4 years, with a 4-year rate of 3% versus 0.0% (p=0.035). DAPT slightly decreased from 29.8% to 25.9% in the Absorb arm and from 27.7% to 21.1% in the XIENCE arm, with no significant difference between the 2 arms.	
Chevalier B, Onuma Y, van Boven AJ, et al. Randomised comparison of a bioresorbable everolimus-eluting scaffold with a metallic everolimus-eluting stent for ischaemic heart disease caused by de novo native coronary artery lesions: the 2-year clinical outcomes of the ABSORB II trial. Eurointervention 2016;12(9):1102–7.	RCT Absorb BVS II 501 (335 versus 166) Everolimus-eluting BRS/Absorb® versus everolimus-eluting permanent metallic stent/Xience® Follow-up 4 years.	At 2 years, the PoCE for the Absorb and XIENCE arms was 11.6% and 12.8% (p=0.70) and the DoCE/TLF was 7.0% and 3.0% (p=0.07), respectively. The hierarchical ID-MACE rate was 7.6% versus 4.3% (p=0.16) and the rate of TVF was 8.5% versus 6.7% (p=0.48). The definite/probable thrombosis rate was 1.5% in the Absorb arm versus 0% in the XIENCE arm (p=0.17). Thirty-six percent and 34% of patients remained on DAPT at 2 years, respectively.	Large and longer follow-up studies included.
Cassese S, Byrne RA, Ju¨ni P et al. (2017) Mid-term clinical outcomes with everolimus-eluting bioresorbable scaffolds versus everolimus-eluting metallic stents for percutaneous coronary interventions: a meta-	Meta-analysis 5583 included patients had BRS (n = 3261) or EES (n= 2322). Median follow-up was 26.6 months.	Patients treated with BRS versus EES showed higher risk for TLFOR (95% CI) = 1.35 (1.14–1.61), P = 0.005] due to a higher risk of target vessel MI [OR 1.68 (1.21–2.33), P= 0.008] and ischaemia-driven TLR [OR 1.42 (1.14–1.78), P = 0.008]. Patients treated with BRS versus EES showed a higher risk for definite/probable stent/ScT [OR 3.24 (2.34–4.50),	Large and recent studies included.

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analysis of randomized trials. EuroIntervention; pii: EIJ-D-17-00492. Doi: 10.4244/EIJ-D-17-00492		P= 0.0001], most marked in the period beyond 1 year after implantation [OR 4.03 (2.11–7.68); P = 0.003]. Both in-device and in-segment late loss are significantly higher for the Absorb BRS compared with metallic EES.	
Collet C, Asano T, Sotomi Y et al. (2017) Early, late and very late incidence of bioresorbable scaffold thrombosis: a systematic review and meta-analysis of randomized clinical trials and observational studies. Minerva Cardioangiologica; 65: 32-51.	Systematic review n=16,830 patients treated with ABSORB.	There was 1.8% overall rate of definite or probable stent thrombosis, and the residual diameter stenosis percentage was the only factor associated with stent thrombosis.	More recent studies included.
Collet C, Asano T, Miyazaki Y et al. (2017) Late thrombotic events after bioresorbable scaffold implantation: a systematic review and meta-analysis of randomized clinical trials. European Heart Journal; 38: 2559-2566.	Systematic review meta-analysis of 1730 patients. 24 months follow-up.	There was a higher incidence of DT in patients treated with Absorb BVS compared to those treated with EES, with 92% of the very late ScT occurring in the absence of DAPT. They also had a higher tendency for TLF (OR 1.48; P = 0.09) driven by a greater risk of TVMI and ischemia-driven TLR. No difference was found for cardiovascular mortality.	More recent studies included.
Cortese B, Ielasi A, Romagnoli E, et al. Clinical comparison with short-term follow-up of bioresorbable vascular scaffold versus everolimus-eluting stent in primary percutaneous coronary interventions. Am J	Italian ABSORB Prospective Registry N=563 patients with STEMI (comparing 122 with BVS-RAI and 441 PCI with EES) median of 220-day follow-up.	In this direct prospective comparison, BVS was associated with similar clinical results compared to EES in the STEMI setting. Larger and adequately powered randomised trials are needed to fully assess the potential clinical benefit of BVS versus the current standard of care in patients with STEMI.	Large studies included.

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Cardiol 2015;116(5):705–10.			
Danzi GB, Bernelli C, Cerrato E. (2020) Outcomes of Optimised Implantation Technique with Bioresorbable scaffolds: A Pooled Analysis of ABSORB-IV and COMPARE-ABSORB Trials. Cardiovasc Revasc Med; 21:559−61.	2 RCTs Pooled analysis of ABSORB-IV and COMPARE-ABSORB trials.	Pooling together data from ABSORB-IV and those of the COMPARE-ABSORB, showed that the scaffold was still associated with a statistically significant increased risk of target-vessel MI (OR 1.5; 95% CI 1.04-2.17; P = 0.03) and thrombotic events (OR 2.85; 95% CI 1.33-6.11; P = 0.007) at 1-year.	Large and recent studies included.
De Rosa R, Silverio A, Varricchio A et al. (2018) Meta-analysis comparing outcomes after everolimus-eluting bioresorbable vascular scaffolds versus everolimus-eluting metallic stents in patients with acute coronary syndromes. The American Journal of Cardiology. 122: 61-68.	Meta-analysis 6 studies n= 2,318 patients Median follow-up was 9.5 (6 to 19.5) months.	Recent meta-analysis on 2,318 patients aimed to assess the safety and efficacy of BVS versus EES in ACS patients having PCI. There was a higher risk of definite stent thrombosis in patients treated with BVS compared to EES (2.3% versus 1.08%, P = 0.03) and an increased risk of TLR at mid-term (9.5 months) follow-up.	More recent studies included.
Diletti R, Farroq V, Girasis C et al. (2013) Clinical and intravascular outcomes at 1 and 2 years after implantation of absorb everolimus eluting bioresorbable vascular scaffolds in small vessels. Late lumen enlargement: does bioresorption matter with small vessel size? Insight from the ABSORB cohort B trial. Heart 99: 98-105.	Case series N = 101 Follow-up: 2 years	Angiographic and clinical outcomes in small vessels similar to those in large vessels.	Post-hoc analysis – no new clinical outcomes reported.

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Diletti R, Onuma Y, Farooq V et al. (2011) 6-month clinical outcomes following implantation of the bioresorbable everolimus-eluting vascular scaffold in vessels smaller or larger than 2.5mm. Journal of the American College of Cardiology 58 (3): 258-264.	Case series N=101 Follow-up: 6 months	Angiographic and clinical outcomes in small vessels similar to those in large vessel.	Post-hoc analysis – no new clinical outcomes reported.
Diletti R, Karanasos A, Muramatsu T et al (2014) Everolimus-eluting bioresorbable vascular scaffolds for treatment of patients presenting with ST-segment elevation myocardial infarction: BVS STEMI first study. Eur Heart J. 35(12):777-86.	Case series n=49 Patients with STEMI. everolimus-eluting BVS Follow-up: 30 days	Procedural success was 97.9%. A TIMI-flow III was achieved in 91.7% of patients, diameter stenosis was 14.7% and no visible residual thrombus. OCT in 31 patients showed that the mean lumen area was 8.02 mm, mean incomplete scaffold apposition area 0.118 mm, mean intraluminal defect area 0.013 mm, and mean percentage malapposed struts per patient 2.80%. Scaffolds with >5% malapposed struts were 7. At 30-days follow-up, target-LFR was 0%. Non-TVR and target-vessel MI were reported. A non-target-vessel non-Q-wave MI occurred. No cases of cardiac death or ScT were seen.	Studies with longer follow included in table 2.
Dudek D, Onuma Y, Ormiston JA et al. (2012) Four-year clinical follow-up of the ABSORB everolimus-eluting bioresorbable vascular scaffold in patients with de novo coronary artery disease: the ABSORB trial. EuroIntervention 7: 1060-1061.	Case series (ABSORB cohort A) 30 patients with a single de novo native coronary artery lesion.	At 4 years, the hierarchical ID-MACE of 3.4% remained unchanged without any late complications such as stent thrombosis. Clopidogrel therapy had been stopped in all patients.	Large and more recent studies included.

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Elias J, van Dongen IM, Kraak RP et al. (2017) Mid-term and long-term safety and efficacy of bioresorbable vascular scaffolds versus metallic everolimus eluting stents in coronary artery disease: a weighted meta-analysis of seven randomised controlled trials including 5577 patients. Netherlands Heart Journal. 25: 429-438.	Meta-analysis n=3258 patients treated with BVS and 2319 with EES.	The BVS group had higher rates of TLF (OR 1.34; P = 0.003), definite/probable DT (OR 2.86; P < 0.001) extending beyond 1 year of follow-up (OR 4.13; P < 0.001), clinically indicated or ischemia driven TLR, and all-cause MI. There was no significant difference with respect to cardiac death.	More recent studies included.
Elias J, van Dongen IM, Kraak RP et al. (2017) Mid-term clinical outcomes with everolimus eluting bioresorbable scaffolds versus everolimus-eluting metallic stents for percutaneous coronary interventions: a meta-analysis of randomized trials. EuroIntervention. 25: 429-438.	Meta analysis in 5583 patients. 7 trials were included (BVS n = 3258, Xience n = 2319) with follow-up between 1-3 years.	BVS displayed a higher risk of TLF (OR= 1.35; P = 0.0028) and stent thrombosis (OR 3.24; P < 0.0001) compared to EES particularly after 1 year from implantation. At mid-term follow-up, BVS had a higher risk of TLR and stent thrombosis than the second-generation DES in patients with ACS. Stent thrombosis was the key factor indicating the decreased safety and effectiveness of BVS relative to DES.	Large and recent studies included.
Ellis SG, Kereiakes DJ, Metzger DC, et al. (2015) Everolimus-Eluting Bioresorbable Scaffolds for Coronary Artery Disease. N Engl J Med; 373: 1905-15.	RCT Absorb III N=2008 patients with stable or unstable angina (Absorb scaffold 1322 versus DES Xience 686 patients)	In this large-scale, randomised trial, treatment of noncomplex obstructive CAD with an everolimus-eluting bioresorbable vascular scaffold, as compared with an everolimus-eluting cobalt-chromium stent, was within the prespecified margin for noninferiority with respect to target-lesion failure at 1 year.	Large and recent studies included.
Erbel R, Di Mario C, Bartunek J et al. (2007) Temporary scaffolding of	Case series N=63 (71 stents) Follow-up 12 months.	Diameter stenosis was reduced from 61·5% to 12·6% with an acute gain of 1·41 mm and in-stent late loss of 1·08 mm. The	Large and more recent studies included.

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coronary arteries with bioabsorbable magnesium stents: a prospective, non-randomised multicentre trial. Lancet 369 (9576): 1869-1875		ischaemia-driven TLR rate was 23·8% after 4 months, and the overall TLR rate was 45% after 1 year. No MI, subacute or late thrombosis, or death occurred.	
Fam JM, Ojeda S, Garbo R et al. (2017) Everolimus-eluting bioresorbable vascular scaffolds for treatment of complex chronic total occlusions. EuroIntervention; 13:355-363.	Registry N=105 patients with complex chronic total occlusions who had Absorb BVS 6 months follow-up.	Device success and procedural success rates were 98.1% and 97.1%, respectively. At 6-month follow-up, a total of 3 events were reported: 1 periprocedural MI, 1 late ScT and 1 additional TLR.	Larger studies included.
Farag M, Spinthakis N, Gorog DA, et al. (2016) Use of bioresorbable vascular scaffold: a meta-analysis of patients with coronary artery disease. Open Heart; 3: e000462.	Meta-analysis comparing outcomes between BVS and DES in patients with CAD 6 randomised trials (3818 patients) and 6 registry studies (1845 patients)	In 6 randomised trials (3818 patients), BVS increased the risk of subacute stent thrombosis (ST) over and above DES (OR 2.14; CI 1.01 to 4.53; p=0.05), with a trend towards an increase in the risk of MI (125 events in those assigned to BVS and 50 to DES; OR 1.36; CI 0.97 to 1.91; p=0.07). The risk of in-device late lumen loss (LLL) was higher with BVS than DES (mean difference 0.08 mm; CI 0.03 to 0.13; p=0.004). There was no difference in the risk of death or TVR between the 2 devices. In 6 registry studies (1845 patients), there was no difference in the risk of death, MI, TVR or subacute ST between the 2 stents. Final BVS dilation pressures were higher in registry than in randomised studies (18.7±4.6 vs 15.2±3.3 atm; p<0.001).	More recent studies included.
Felix CM, Vlachojannis GJ, Ij AJJ et al. (2017) Potentially increased incidence of scaffold thrombosis in patients treated with Absorb BVS who terminated	Registries of 3 centres were pooled (808 patients) 18 months.	Data pooled from 3 registries suggested that in patients event-free at 6 months, the incidence of ScT was low while on DAPT but higher when DAPT was terminated before 18 months.	Large and recent studies included.

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DAPT before 18 months. EuroIntervention;13: e177–e184.			
Felix CM, Fam JM, Diletti R, et al. (2016) Mid- to long-term clinical outcomes of patients treated with the everolimus-eluting bioresorbable vascular scaffold: the BVS Expand Registry. JACC: Cardiovasc Intervent; 9(16):1652–63.	Prospective case series N=249 patients with 335 lesions Absorb BVS Median follow-up period was 622 (interquartile range: 376 to 734) days.	The MACE rate at 18 months was 6.8%. Rates of cardiac mortality, MI, and TLR at 18 months were 1.8%, 5.2%, and 4.0%, respectively. Definite ScT rate was 1.9%. In our study, BVS implantation in a complex patient and lesion subset was associated with an acceptable rate of adverse events in the longer term, whereas no cases of early thrombosis were seen.	Larger studies included.
Gomez-Lara J, Ortega-Paz L, Brugaletta S et al. (2020) Bioresorbable scaffolds versus permanent sirolimus-eluting stents in patients with ST-segment elevation myocardial infarction: vascular healing outcomes from the MAGSTEMI trial. EuroIntervention. 16(11):e913-e921.	N=95 patients from the randomised MAGSTEMI trial MgBRS =48, and sirolimus-eluting stents (SES=47) had OCT imaging at 1 year.	Both MgBRS and SES exhibited a low degree of neointima healing, but lumen dimensions were smaller with MgBRS at 1 year. Although the advanced bioresorption state of MgBRS hampers the assessment of scaffold collapse, this seems to be the main mechanism of restenosis. Future generations of MgBRS should increase and prolong the radial force.	Related publications included.
Gao R, Yang Y, Han Y, et al. (2015) Bioresorbable vascular scaffolds versus metallic stents in patients with coronary artery disease: ABSORB China trial. J Am Coll Cardiol; 66(21):2298–309.	RCT (NCT01923740) N=480 patients 241 BVS versus 239 DES CoCr EES Follow-up 1 year	Acute clinical device success (98.0% versus 99.6%; p = 0.22) and procedural success (97.0% and 98.3%; p = 0.37) were comparable in BVS- and CoCr-EES-treated patients, respectively. The primary endpoint of in-segment LL at 1 year was 0.19 ± 0.38 mm for BVS versus 0.13 ± 0.38 mm for CoCr-EES; the 1-sided 97.5% upper confidence limit of the difference was 0.14 mm, achieving noninferiority of BVS compared with CoCr-EES (noninferiority = 0.01). BVS and CoCr-EES also had similar 1-year rates of TLF (cardiac death, target vessel MI,	Study included in systematic reviews and HTA

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		or ischemia-driven TLR; 3.4% versus 4.2%, respectively; p = 0.62) and definite/probable scaffold/stent thrombosis (0.4% versus 0.0%, respectively; p = 1.00).	
García-García HM, Gonzalo N, Pawar R et al. (2008) Assessment of the absorption process following bioabsorbable everolimus-eluting stent implantation: temporal changes in strain values and tissue composition using intravascular ultrasound radiofrequency data analysis. A substudy of the ABSORB clinical trial. EuroIntervention 4: 443-448	Case series N = 27 IVUS radiofrequency data analysis, RF (13 IVUS virtual histology and 12 palpography) Follow-up: 6 months	Authors conclude that there were changes in the BVS with a reduction of radiofrequency backscattering by polymeric struts. An increase in endoluminal deformability of the vessel was also suggested at 6 months.	Sub-study. Focus on imaging outcomes.
Gheorghe L, Millan X, Jimenez- Kockar M et al. (2019) Bioresorbable vascular scaffolds in coronary chronic total occlusions: clinical, vasomotor and optical coherence tomography findings at three year follow-up (ABSORB -CTO study). EuroIntervention 15, 99-107.	Case series ABSORB CTON=33 patients (35 CTO lesions) Follow-up 3 years	Late acquired incomplete scaffold apposition (LAISA) seen at 12 months in 3 patients was completely undetectable at 3 years. Successful recanalisation of coronary CTO with BVS implantation is associated with favourable clinical and imaging outcomes. Despite vessel motility restoration, successfully treated CTOs remain with signs of endothelial dysfunction.	Larger studies included.
Goel S, Pasam RT, Chava S et al. (2020) Three to four years outcomes of the absorb bioresorbable vascular scaffold versus second-generation drug-	Meta-analysis N=4 RCTs (n = 3,245, BVS = 2075, DES = 1,170) Follow-up 4 years	Pooled analysis revealed that there was no difference between absorb BVS and second-generation DES with respect to TLF (OR = 1.23, 95% CI = 0.73–2.07, p = 0.44), TV-MI (OR = 1.03, 95%	Larger studies included.

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eluting stent: A meta-analysis. Catheter Cardiovasc Interv; 95:216–223.		CI = 0.42–2.53, p = 0.95), TLR (OR = 1.61, 95% CI = 0.77–3.33, p = 0.20) and definite/probable DT (OR = 0.71, 95% CI = 0.10–5.07, p = 0.74). Also, there was no difference in cardiac mortality (OR = 0.66, 95% CI = 0.22–1.94, p = 0.45).	
Gogas BD, Serruys PW, Diletti R et al. (2012) Vascular response of the segments adjacent to the proximal and distal edges of the ABSORB everolimus-eluting bioresorbable vascular scaffold: 6-month and 1-year follow-up assessment. JACC: Cardiovascular Interventions 5 (6): 656-665.	Case series N= 101 Follow-up: 1 year	Authors conclude that similar to metallic DES, there was some proximal edge constrictive remodelling and distal edge increase in fibrofatty tissue.	Sub-study. Focus on imaging outcomes.
Gogas BD, Bourantas CV, Garcia-Garcia HM et al (2013). The edge vascular response following implantation of the Absorb everolimus-eluting bioresorbable vascular scaffold and the XIENCE V metallic everolimus-eluting stent. First serial follow-up assessment at six months and two years: Insights from the first-in-man ABSORB Cohort B and SPIRIT II trials. EuroIntervention.9 (6) (pp 709-720).	Comparative study ABSORB (BVS) Cohort B1 (n=45) and the SPIRIT II (EES) (n=113)	22 proximal and 24 distal edge segments were available for analysis in the ABSORB Cohort B1 trial. In the SPIRIT II trial, 33 proximal and 46 distal edge segments were analysed. At the 5-mm proximal edge, the vessels treated with an Absorb BVS from post procedure to 2 years demonstrated a lumen loss (LL) of 6.68% (-17.33; 2.08) (p=0.027) with a trend toward plaque area increase of 7.55% (- 4.68; 27.11) (p=0.06). At the 5-mm distal edge no major changes were evident at either time point. At the 5-mm proximal edge the vessels treated with a XIENCE V EES from post procedure to 2 years did not show any signs of LL, only plaque area decrease of 6.90% (-17.86; 4.23) (p=0.035). At the distal edge no major changes were evident with regard to either lumen area or vessel remodelling at the same time point.	Study reports mainly, IVUS outcomes.

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Gori T, Weissner M, Gonner S et al. (2017) Characteristics, Predictors, and Mechanisms of Thrombosis in Coronary Bioresorbable Scaffolds: Differences Between Early and Late Events. JACC Cardiovasc Interv; 10:2363−71	Registry analysis N=657 patients who had 925 coronary bioresorbable scaffolds (BRS) 3-year follow-up.	28 stent thrombosis recorded: 14 early (2.2%), 5 late (0.9%), and 9 very late (1.7%).The incidence of both early and late or very late stent thrombosis were lower (~80% reduction) when an optimal implantation technique was used. The most important factor appeared to be vessel and BRS sizing.	Large and recent studies included.
Ghimire G, Spiro J, Kharbanda R et al. (2008) Initial evidence for the return of coronary vasoreactivity following the absorption of bioabsorbable magnesium alloy coronary stents. EuroIntervention 4: 481-484.	N = 5 absorbable metallic stents versus 10 permanent metal stents Follow-up: 4 months	Authors conclude that vasomotor function in reference segments is similar for absorbable metallic stents and permanent metal stents although there is also vasodilatation in those with absorbable metallic stents.	Sub-study. Focus on imaging outcomes.
Gomez-Lara J, Brugaletta S, Farooq V et al. (2011) Angiographic geometric changes of the lumen arterial wall after bioresorbable vascular scaffolds and metallic platform stents. JACC: Cardiovascular interventions 4 (7): 789-799.	N: 86 (BVS) versus 75 (metallic platform stent) Follow-up: 12 months.	Authors conclude that coronary geometry findings of BVS were similar to that of the metallic platform stent.	Comparative sub-study. Focus on imaging outcomes,
Gomez-Lara J, Brugaletta S, Farooq V et al. (2011). Head-to head comparison of the neointimal response between metallic and bioresorbable everolimus-eluting scaffolds using optical	N: 30 (BVS) versus 14 (DES) Follow-up: 1 year	Authors conclude that similar neointimal responses were seen in the tw2o types of stent although intraluminal masses in a small proportion of patients with a BVS were also seen.	Comparative sub-study. Focus on imaging outcomes.

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coherence tomography. JACC: Cardiovascular Interventions 4 (12): 1271-1280.			
Gomez-Lara J, Diletti R, Brugaletta S, Onuma Y et al. (2011) Angiographic maximal luminal diameter and appropriate deployment of the everolimus-eluting bioresorbable vascular scaffold as assessed by optical coherence tomography: an ABSORB cohort B trial sub-study. Eurointervention 8: 214-224.	N = 53 Follow-up: post-procedure.	Authors conclude that lesions of diameter 2.5-3.3mm achieved better deployment than those of other sizes	Sub-study. Focus on imaging outcomes.
Guitérrez-Chico JL, Radu MD, Diletti R et al. (2012) Spatial distribution and temporal evolution of scattering centers by optical coherence tomography in the poly (L-lactide) backbone of a bioabsorbable vascular scaffold. Circulation Journal 76: 342-350.	N=3 Follow-up: 6 months.	Scattering centres seen on OCT imaging of the BVS were only located at inflection points and did not increase between baseline and 6 months follow-up.	Sub-study. Focus on imaging outcomes.
Guitiérrez-Chico JL, Serruys PW, Girasis C et al. (2012) Quantitative multi-modality imaging analysis of a fully bioresorbable stent: a head-to-head comparison between QCA, IVUS and OCT. International Journal of Cardiovascular Imaging 28: 467-478.	N = 45 (quantitative coronary angiography), 40 (IVUS), 29 OCT, 26 (all imaging) Follow-up: 6 months	Authors conclude that OCT was the most accurate method to measure BVS length and there was poor agreement between difference imaging modalities with respect to minimal lumen diameter measurements.	Sub-study. Focus on imaging outcomes.

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Grundeken MJ, White RM, Hernandez JB, et al. The incidence and relevance of site-reported versus patient-reported angina: insights from the ABSORB II randomized trial comparing Absorb everolimus-eluting bioresorbable scaffold with XIENCE everolimus-eluting metallic stent. Eur Heart J Qual Care Clin Outcomes 2016;2(2):108–16.	RCT Absorb BVS II 501 (335 versus 166) Everolimus-eluting BRS/Absorb® versus everolimus-eluting permanent metallic stent/Xience® Follow-up 4 years.	We showed that the site-reported angina through AE reporting may be clinically relevant because of their relation with cardiovascular events (mostly repeat revascularisations), cardiovascular resource utilisation, ETT, and SAQ.	Large and longer follow-up studies included.
Haude M, Erbel R, Erne P et al. (2013) Safety and performance of the drug-eluting absorbable metal scaffold (DREAMS) in patients with de novo coronary lesions: 12 month results of the prospective, multi-centre, first-in-man BIOSOLVE-I trial. Lancet 381: 836-844.	Case series n=46 (47 lesions) DREAMS scaffold Magmaris symptomatic patients with de-novo coronary lesions. 12 months follow-up.	Device and procedural success was 100%. 2/46 (4%) patients had TLF at 6 months, and 3/43 (7%) at 12 months.1 periprocedural target vessel MI occurred during angiography at 12 month, no cardiac death or ScT. Mean late lumen loss with the Magmaris DES was somewhat higher than is seen with metallic DES and remained stable between 6 and 12 months: in-segment late lumen loss 0.20 mm and 0.25, p = 0.117, delta late loss 0.05 mm (95% CI: 20.01; 0.12); in-scaffold late lumen loss 0.37 mm versus 0.39 mm, p = 0.446, delta late loss 0.03 (95% CI: 20.04–0.10), respectively.	Larger and more recent studies included.
Haude M, Ince H, Abizaid A, et al. (2016) Sustained safety and performance of the second-generation drug-eluting absorbable metal scaffold in patients with de novo coronary lesions: 12-month	Case series n= 123 patients with Magmaris drug-eluting stents (BIOSOLVE-II study) 12 months.	Overall rates of clinical events at 12 months were low: TLF was seen in 3.4%, 95% CI: 0.9–8.4. mean late lumen loss at follow-up with the DES Magmaris was somewhat higher than is seen with conventional metallic DES and remained stable between 6 and 12 months: in-segment late lumen loss 0.20 mm and 0.25 mm, P =	Larger and more recent studies included.

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clinical results and angiographic findings of the BIOSOLVE-II first-in-man trial. Eur Heart J; 37:2701–2709.		0.117, delta late loss 0.05 mm (95% CI: 20.01; 0.12); in-scaffold late lumen loss 0.37 mm vs 0.39 mm, p = 0.446, delta late loss 0.03 (95% CI: 20.04 to 0.10), respectively.	
Haude M, Ince H, Abizaid A et al. (2016) Safety and performance of the second-generation drug-eluting absorbable metal scaffold in patients with de-novo coronary artery lesions (BIOSOLVE-II): 6 month results of a prospective, multicentre, non-randomised, first-in-man trial. Lancet; 387:31–39.	Case series n= 123 patients coronary target lesions. Magmaris drug-eluting results from the BIOSOLVE-II study 6 months follow-up.	At 6 months, mean in-segment late lumen loss was 0·27 mm, and vasomotion was documented in 80% 20/25 patients. IVUS assessments showed a preservation of the scaffold area (mean 6·24 mm^2 post-procedure *vs* 6·21 mm^2 at 6 months) with a low mean neointimal area (0·08 mm^2 [0·09]), and OCT did not detect any intraluminal mass. TLF occurred in 4 (3%) patients: 1(<1%) patient died from cardiac death, 1 (<1%) patient had periprocedural MI, and 2 (2%) patients needed clinically driven TLR. No definite or probable ScT was seen.	Larger studies included.
Hellenkamp K, Becker A, Gabriel YD et al. (2017) Mid- to long-term outcome of patients treated with everolimus-eluting bioresorbable vascular scaffolds: data of the BVS registry Göttingen predominantly from ACS patients. International Journal of Cardiology. 234: 58-63.	BVS registry Göttingen N=195 patients 44 BVS were implanted.	Although, the rates of (potentially) device-related complications following BVS implantation are acceptable, they are nonetheless not negligible. Interestingly, they did not decline over time. Bifurcation stenting could be found as relevant procedure-related predictor of DOCE, especially in ACS patients.	Large and recent studies included.
Hommels TM, Hermanides RS, Berta B et al. (2020) Everolimus-eluting bioresorbable scaffolds and metallic stents in diabetic patients: a patient-	N=499 diabetic patients who were treated with EE-BRS or EES in 3 prospective clinical trials:	The adverse events rates were similar in both treatment groups for TLF (7.2 versus 5.2 events per 100 PY, p=0.39; adjusted HR=1.48 (95% CI: 0.77–2.87, p=0.24), MACE (9.1 versus 8.3 per 100 PY, p=0.83; adjusted HR=1.23 (95% CI: 0.70–2.17,	Larger studies included.

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level pooled analysis of the prospective ABSORB DM Benelux Study, TWENTE and DUTCH PEERS Cardiovasc Diabetol 19:165.	150 had EE-BRS and 249 had EES Follow-up was 222.6 patient years (PY) in the EE-BRS and 464.9 PY in the EES group.	p=0.47), and ST (0.9 versus 0.6 per 100 PY, p>0.99). In this patient-level pooled analysis of patients with diabetes mellitus from 3 clinical trials, EE-BRS showed clinical outcomes that were quite similar to EES.	
Hoppmann P, Kufner S, Cassese S et al. (2016) Angiographic and clinical outcomes of patients treated with everolimus-eluting bioresorbable stents in routine clinical practice: results of the ISAR-ABSORB registry. Catheter Cardiovasc Interv; 87:822–829.	Case series N=419 patients implanted everolimus-eluting BRS. 12 months follow-up.	At angiographic follow-up in-stent late loss was 0.26 ± 0.51 mm, in-segment diameter stenosis was 27.5 ± 16.1, and binary angiographic restenosis was 7.5%. At 12 months, the rate of death, MI, or TLR was 13.1%. Definite stent thrombosis occurred in 2.6%.	Large and recent studies included.
Ishibashi Y, Muramatsu T, Nakatani S, et al. Incidence and potential mechanism(s) of post-procedural rise of cardiac biomarker in patients with coronary artery narrowing after implantation of an everolimus-eluting bioresorbable vascular scaffold or everolimus-eluting metallic stent. JACC: Cardiovasc Intervent 2015;8(8):1053–63.	RCT Absorb BVS II 501 (335 versus 166) Everolimus-eluting BRS/Absorb® versus everolimus-eluting permanent metallic stent/Xience® Follow-up 4 years.	Incidence of side branch occlusion and any anatomic complications assessed by angiography was similar between the 2 treatment arms (side branch occlusion: Absorb: 5.3% versus Xience: 7.6%, p = 0.07; any anatomic complication: Absorb: 16.4% versus EES: 19.9%, p = 0.39).There were no differences in the incidence of CB rise and PMI between Absorb and EES. Device overlap might be a precipitating factor of myocardial injury.	Large and recent studies included.
Ishibashi Y, Nakatani S, Sotomi Y et al. (2015) Relation between bioresorbable scaffold sizing using QCA-Dmax and clinical outcomes at 1 year in	1,248 patients had Absorb scaffolds in the ABSORB Cohort B study (N = 101), ABSORB EXTEND study (N = 812), and	The rates of MACE and MI at 1 year were significantly higher in the scaffold oversize group than in the scaffold non-oversize group (MACE 6.6% versus 3.3%; log-rank p < 0.01, all MI: 4.6% versus 2.4%; log-rank p = 0.04), mainly driven by a higher MI rate within 1	Large and recent studies included.

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1,232 patients from 3 study cohorts (ABSORB Cohort B, ABSORB EXTEND, and ABSORB II). JACC Cardiovasc Interv; 8:1715−26.	ABSORB II trial (N = 335).	month post-procedure (3.5% versus 1.9%; p = 0.08). Implantation of an oversized Absorb scaffold in a relatively small vessel appears to be associated with a higher 1-year MACE rate driven by more frequent early MI.	
Ishibashi Y, Onuma Y, Muramatsu T, et al on behalf of the ABSORB EXTEND Investigators (2014). Lessons learned from acute and late scaffold failures in the ABSORB EXTEND trial. EuroIntervention 9-online publish-ahead-of-print January 2014.	Case series (Absorb extend) N=450 Follow-up 12 months	low rates of ischaemia-driven MACE (4.2%) and TVF (4.7%) at 12 months. 7 cases of device failure: 3 scaffold dislodgement (0.67%) and 4 subacute or late ScT (0.89%). In 2 dislodgement was seen after reinsertion. 2 subacute ScT and 2 late scaffold thromboses were seen and related to either premature stopping of dual antiplatelet therapy (DAPT) or resistance to clopidogrel.	Large studies included.
Ielasi A, Cortese B, Moscarella E et al. (2018) One-year clinical outcomes after unrestricted implantation of the Absorb bioresorbable scaffold (RAI registry). EuroIntervention. 14: e546-e553.	RAI registry N=1505 Patients with pre-dilatation and post-dilatation. 1 year follow-up	At 1-year follow-up, TLR and ScT rates were 3.3% and 1.3%, respectively. TLR was significantly higher in the off-label group (4.0% versus 2.2%; P = 0.05) while a trend towards a higher ScT rate was seen in the off-label group (1.7% versus 0.6%; P = 0.06). At multivariate analysis, treatment of in-stent restenosis, chronic total occlusion and BVS diameter were independent predictors of TLR.	Large and recent studies included.
Ielasi A, Cortese B, Varricchio A, et al. Immediate and midterm outcomes following primary PCI with bioresorbable vascular scaffold implantation in patients with ST-segment myocardial infarction: insights from the multicentre “Registro ABSORB	Prospective cohort analysis N= 72 STEMI patients who had primary PCI with BVS implantation. 6 month follow-up.	BVS implantation in STEMI patients can be successfully performed with a high procedural success rate and encouraging midterm outcomes. Larger randomised trials and longer follow-up are needed to assess the potential clinical benefit of BVS versus new-generation DES in this setting.	Large studies included.

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Italiano" (RAI registry). Eurointervention 2015;11(2):157–62.			
Ielasi A, Varricchio A, Campo G, et al. (2017) A prospective evaluation of a standardized strategy for the use of a polymeric everolimus-eluting bioresorbable scaffold in ST-segment elevation myocardial infarction: Rationale and design of the BVS STEMI STRATEGY-IT study. Catheter Cardiovasc Interv. 2017; 89(7):1129-1138.	Prospective registry n= 500 STEMI patients having primary PCI with BVS (1.1 or GT1)	The first study investigating the feasibility and the early- and long-term clinical impact of a prespecified BVS implantation protocol in thrombotic lesions causing STEMI. Here, we describe the rationale and the design of the study.	Only design of the study.
Ielasi A, Campo G, Cortese B et al. (2019) One-Year Results Following a Pre-Specified ABSORB Implantation Strategy in ST-Elevation Myocardial Infarction (BVS STEMI STRATEGY-IT Study). Cardiovasc Revasc Med. 2019 Aug;20(8):700-704.	N=505 STEMI patients having PCI with Absorb. Follow-up 1 year.	A pre-specified Absorb implantation strategy in STEMI patients was associated with persistent low DOCE and ScT rates at 1-year. Longer term follow-up is needed to assess the role of this strategy on preventing very-late events (NCT02601781)	Large studies included.
Jabbour RJ, Tanaka A, Capranzano P et al. (2017) Bioresorbable vascular scaffolds as a treatment option for left main lesions. JACC: CARDIOVASCULAR INTERVENTIONS VOL. 10 (7)	Retrospective analysis International registry N=60 patients (2,765 PCI) Absorb BVS median follow-up time was 593 days (interquartile range: 230 to 817 days)	The primary endpoint of TLF occurred in 14.9% (n =7) and 25.0% (n=10) of patients at 1 and 2 years, respectively. This was primarily caused by ischemia-driven TLR because the overall TLR rate was 13.4% (n= 6) and 23.6% (n = 9) at 1 and 2 years. The cardiac death rate was 1.8% (n =1) at 2 years and there were no target vessel MI or definite/probable ST segment events at 2 years.	Larger studies included.

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Jaguszewski M, Ghadri JR, Zipponi M et al. (2015) Feasibility of second-generation bioresorbable vascular scaffold implantation in complex anatomical and clinical scenarios. Clin Res Cardiol; 104:124–135	N=106 patients had in total 193 BVS implantations. Mean follow-up of 147 ± 119 days	Rate of device-related events was 2.0 %, whereas patient-related composite events occurred in 6.1 %. Our results strongly suggest that BVS implantation is feasible in a wide spectrum of patients and complex anatomy of coronary lesions.	Large and recent studies included.
Katagiri Y, Onuma Y, Asano T et al. (2018) Three year follow-up of the randomised comparison between an everolimus-eluting bioresorbable scaffold and a durable polymer everolimus-eluting metallic stent in patients with ST-segment elevation myocardial infarction (TROFI II trial). EuroIntervention;14: e1224-e1226.	N=191 patients withSTEMI had either the Absorb BRS (n=95) or the XIENCE metallic everolimus-eluting stent (n=96). Follow-up 3 years	At 3 years, the rates of DOCE were 5.3% (5/95) in the BRS arm and 3.1% (3/96) in the EES arm without a statistically significant difference (p=0.465). There were 2 cardiac deaths (2.1%) in the BRS arm: 1 was a cardiac death on day 280, the second patient died on day 999 revealed no evidence of ScT. There were no cardiac deaths in the EES arm.	Larger studies included.
Kajiya T, Liang M, Sharma RK et al. (2013) Everolimus-eluting bioresorbable vascular scaffold (BVS) implantation in patients with ST-segment elevation myocardial infarction (STEMI). EuroIntervention 9-online publish-ahead-of-print May 2013.	Case series N=11 Median 53 days	One patient presented to the hospital with cardiogenic shock and subsequently died. The other 10 patients did not have any MACE. There were no acute or subacute stent thromboses at short-term follow-up.	Large and more recent studies included.
Keh YS, Yap J, Yeo KK et al (2016) Clinical Outcomes of Bioresorbable Scaffold in Coronary Artery Disease: A Systematic Literature Review.	Systematic Review 31 studies included.	The studies were categorised into: STEMI, stable CAD, and “all-comers” group. 31 studies were included; 8 in STEMI patients (all ABSORB), 15 stable CAD patients. In the STEMI group (n=606), acute procedural success ranged from 96% to	More recent reviews included.

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Journal of Interventional Cardiology, 29 (1), 57-69.		100%, cardiac mortality 0–9.1%, recurrent MI and stent thrombosis rates were 0–4.3%. In the stable CAD group, the 13 ABSORB studies (n=3259) demonstrated cardiac mortality rate of 0–0.6%, recurrent MI rate 0–4.5%, and stent thrombosis rate 0–4.3%	
Kereiakes DJ, Ellis SG, Metzger C et al. (2017) ABSORB III Investigators. 3-Year Clinical Outcomes With Everolimus-Eluting Bioresorbable Coronary Scaffolds: The ABSORB III Trial. J Am Coll Cardiol. 12; 70 (23): 2852-2862.	RCT ABSORB III N=2,008 patients with CAD randomised to BVS versus cobalt-chromium everolimus-eluting stents (EES).	The target LFR at 3 years was 13.4% for BVS compared with 10.4% in the everolimus-eluting stent group (p = 0.06). Target vessel MI (8.6 versus 5.9% respectively, p = 0.03) and ScT (2.3 versus 0.7% respectively, p = 0.01) were also significantly higher in the BVS arm. 3-year adverse event rates were higher with BVS than EES, particularly TVMI and device thrombosis.	Larger and more recent studies added.
Kereiakes DJ, Ellis SG, Metzger C, et al. (2019) Clinical outcomes before and after complete everolimus-eluting bioresorbable scaffold resorption. Five-year follow-up from the ABSORB III Trial. Circulation;140:1895–1903.	ABSORB III RCT 1322 BVS compared with 686 cobalt chromium everolimus-eluting stents. Follow-up 5 years	In the ABSORB III trial, cumulative 5-year adverse event rates were increased after BVS compared with everolimus-eluting stents. However, the period of excess risk for BVS ended at 3 years, coincident with complete scaffold resorption. Between the 3- and 5-year follow-up, substantial reductions in BVS-relative hazards for TLF and ScT were seen, coincident with complete BVS resorption.	Large and more recent studies added.
Kocka V, Maly M, Tousek P et al. (2014) Bioresorbable vascular scaffolds in acute ST-segment elevation myocardial infarction: a prospective multicentre study 'Prague 19'. European Heart Journal. 35, 787–794.	Prospective study N=41 BVS implantation during PCI in STEMI	The BVS device success was 98%, thrombolysis in MI 3 flow was restored in 95% of patients, and acute scaffold recoil was 9.7%. Event-free survival was the same in both groups; 95% for BVS and 93% for control group, P =0.674.	Large and more recent studies added.
Kočka V, Toušek P, Kozel M et al. Bioresorbable scaffold implantation in STEMI	Case series N=83 STEMI patients with BRS	Invasive imaging results 5 years after BRS implantation in STEMI showed complete resorption of scaffold struts and stable lumen	Large studies included.

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patients: 5 years imaging sub-analysis of PRAGUE-19 study. J Transl Med; 18(1):33	5 year follow-up was done in 25 patients.	vessel diameter. 3 patients developed small coronary artery aneurysm in the treated segment.	
Kozuma K, Tanabe K, Hamazaki Y et al. (2020) Long-term outcomes of absorb bioresorbable vascular scaffold versus everolimus-eluting metallic stent— A randomized comparison through 5 years in Japan. Circulation Journal Circ J; 84: 733–741	ABSORB Japan RCT randomised 400 patients into either Absorb (n=266) or XIENCE (n=134) follow-up 5 years	There were no significant differences in the composite or individual endpoint outcomes between the Absorb and XIENCE arms through 5 years or between 3 and 5 years. Numerically lower TVF, MACE, and all MI rates were seen for the Absorb versus XIENCE arm after 3 years. No scaffold/stent thrombosis was reported beyond 3 years. Post-procedure imaging subgroups showed comparable event rates.	Included in systematic reviews.
Liang M, Kajiya T, Lee CH et al (2013). Initial experience in the clinical use of everolimus-eluting bioresorbable vascular scaffold (BVS) in a single institution. International Journal of Cardiology.168 (2) (pp 1536-1537).	Case series n=35 [41 lesions] Patients with an ACS including stable angina, unstable angina, non-STEMI, STEMI had ABSORB BVS implanted. 60 days follow-up.	45 BVS were successfully implanted in 93.3% (33/35) patients. In 41 implantations, the success rate was 100% for LAD (22/22), 100% for RCA (11/11) AND 75% (6/8) FOR LCX. 2 patients with circumflex stenosis (unsuccessful implantations) were treated with DES. There were no procedure related acute or subacute stent thrombosis, in hospital or adverse events.	Larger studies with longer follow included in table 2.
La, Manna A, Ohno Y, Attizzani, GF et al (2013). Successful retrograde recanalization of chronic total coronary occlusion with multiple bioresorbable vascular scaffolds ('full polymer jacket'): Initial experience and rationale. European Heart Journal.34 (37) (pp 2925).	Case report	Multiple (4) BRS used in a patient with very long chronic total occlusion. Excellent angiographic and OCT results obtained.	Study reports mainly angiographic, IVUS and OCT outcomes.
Lesiak M, Lanocha M, Araszkiewicz A et al. (2016) Percutaneous coronary intervention for chronic total	Case series (registry)	Procedural success was achieved in all patients with no device-related complications. There were no deaths, 1 patient experienced subacute and late ScT, and	Larger studies included.

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occlusion of the coronary artery with the implantation of bioresorbable everolimus-eluting scaffolds. Poznan CTO-Absorb Pilot Registry. EuroIntervention;12: e144- e151.	N= 40 patients with CTO treated with BVS. Follow up (median 556 days)	another 1 developed symptomatic in-scaffold focal restenosis treated with repeat PCI. No more restenosis or vessel reocclusion was found.	
Lipinski MJ, Escarcega RO, Baker NC, et al. (2016) Scaffold Thrombosis After Percutaneous Coronary Intervention With ABSORB Bioresorbable Vascular Scaffold: A Systematic Review and Meta-Analysis. JACC Cardiovasc Interv; 9:12-24.	Systematic Review and Meta-Analysis. N=10510 patients treated with BVS where post-dilatation was performed in 52% of lesions.	Compared to DES, there were higher rates of MI (OR 2.06, p =0.002) and definite or probable ScT (OR 2.06, P = 0.03) in the BVS group [24]. No significant difference was found for all-cause and cardiovascular mortality.	More recent studies included.
Mahmoud AN, Barakat AF, Elgendy AY et al. (2017) Long-term efficacy and safety of everolimus-eluting bioresorbable vascular scaffolds versus everolimus-eluting metallic stents A meta-analysis of randomized trials. Circ Cardiovasc Interv 10:e005286	meta-analysis of RCTs n= 6 trials with 5392 patients were included (mean follow-up, 25 months).	Compared with everolimus-eluting stents, BVS is associated with increased risk of TLF driven by the increased rates of target vessel MI and ischemia-driven TLR in these studies (mean follow-up, 25 months). The risk of definite or probable stent/ScT and very late stent/ScT seems to be higher with BVS.	More comprehensive studies included.
Moriyama N, Shishido K, Tobita K et al. (2017) Persistent bioresorbable vascular scaffold by optical coherence tomography imaging at 5 years. JACC: CARDIOVASCULAR INTERVENTIONS; 10 (2), e11-13.	Case report N=1 with Absorb BVS	the first case of incomplete absorption for BVS at 5 years. OCT confirmed nearly complete scaffold resorption in the proximal segments, but “black box” objectives remained visible at the distal end of BVS.	Larger studies included.

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Muramatsu T, Onuma Y, García-García HM et al. (2013) Incidence and short-term clinical outcomes of small side branch occlusion after implantation of an everolimus-eluting bioresorbable vascular scaffold. An interim report of 435 patients in the ABSORB-EXTEND single-arm trial in comparison with an everolimus-eluting metallic stent in the SPIRIT First and II trials. JACC: Cardiovascular Interventions 6 (3): 247-257.	Post-hoc analysis of 3 case series: ABSORB EXTEND (with SPIRIT First and II trial as historical controls) n=719 (469 ABSORB BVS vs 250 XIENCE V DES) follow-up 30 days.	Post-procedural side branch occlusion (SBO) was seen in 73 side branches (6.0%) in BVS group and 28 side branches (4.1%) in EES group (p = 0.09). Patients with post-procedural SBO were significantly associated with an increased incidence of in-hospital MI (6.5% in SBO group versus 0.5% in non-SBO group, p < 0.01). Multivariable analysis revealed that BVS was an independent predictor of post-procedural SBO (OR: 2.09; 95% CI: 1.18 to 3.68).	Large and more recent studies included.
Mukete BN, Van der Heijden LC, Tandjung K et al. (2016) Safety and efficacy of everolimus-eluting bioresorbable vascular scaffolds versus durable polymer everolimus-eluting metallic stents assessed at 1-year follow-up: A systematic review and meta-analysis of studies. International Journal of Cardiology. 221, 1087-1094.	Systematic review Of RCTs and propensity scored matched studies (6 trials with 5588 patients were analysed) compared BVS and cobalt-chromium durable polymer everolimus-eluting stents (EES). 1 year follow-up.	Device oriented end point was reached by 308 BVS or EES patients (195/3253 versus 113/2315). Meta-analysis showed that patients treated with BVS had a higher incidence of MI and ScT. The risk of DOCE was not significantly different. As BVS may pay off later, future robust data on long-term clinical outcome will be of paramount importance.	Larger and more recent reviews included.
Nairooz R, Saad M, Sardar P et al. (2017) Two-year outcomes of bioresorbable vascular scaffold versus drug-eluting stents in coronary artery disease: a	Meta-analysis comparing BVS with DES for CAD N=10 studies (with 2360 patients) 2 years of follow-up	BVS was associated with higher rates of DOCE (6.9% vs 4.5%, OR=1.53; 95% CI 1.06 to 2.23; p=0.02), absolute risk increase (ARI) 2.4%, relative risk increase (RRI) 53%, TV-MI (4% vs 1.8%, OR=1.94; 95% CI 1.02 to 3.67; p=0.04), ARI 2.2%, RRI 122% and definite stent thrombosis	Large and recent studies included.

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meta-analysis. Heart;103:1096–1103.		(2.1% vs 0.6%, OR=3.39; 95% CI 1.46 to 7.88; p=0.005), ARI 1.5%, RRI 250% compared with DES. No differences in all-cause mortality (OR=0.86; 95% CI 0.26 to 2.81; p=0.80) and TLR (OR=1.44; 95% CI 0.81 to 2.54; p=0.21) were seen between both groups.	
Nieman K, Serruys PW, Onuma Y et al (2013). Multislice computed tomography angiography for non-invasive assessment of the 18-month performance of a novel radiolucent bioresorbable vascular scaffolding device: the ABSORB trial (a clinical evaluation of the bioabsorbable everolimus eluting coronary stent system in the treatment of patients with de novo native coronary artery lesions). Journal of the American College of Cardiology 62 (19) 1813-1814.	ABSORB Cohort B n=101 18 months follow-up	At 18 months there were no cardiac deaths and 3 non-Q-wave MIs: 2 during the index procedure, 1 during an intercurrent invasive investigation, and 5 ischemia driven TLRs. The hierarchical major adverse clinical cardiac event rate was 7.9% (n=8).	Study reports mainly angiographic, IVUS and OCT outcomes. Clinical outcomes from long term follow-up studies included in table 2.
Nooryani AA, Elabbassi WN, AlBaba B et al. (2019) Long-term outcome of first 300 implanted Absorb bioresorbable vascular scaffolds in an all-comers Middle East population. Journal of International Medical Research. 47(1) 173–187.	Prospective registry n=217 patients with 300 treated lesions treated with Absorb BVS. median follow-up, 36 months	TVF rate was 32/201 (15.9%), including cardiac death in 10 (5%), target vessel MI in 13 (6.5%), and TLR in 22 patients (10.9%). Definite or probable device thrombosis occurred in 11/201 patients (5.5%). TVF was associated with heart failure, worse ejection fraction, multi-vessel BVS, multi BVS in lesion, and total BVS length >50 mm.	Larger studies included.

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Nishio S, Kosuga K, Igaki K et al. (2012) Long-term (>10 years) clinical outcomes of first in-human biodegradable poly-l-lactic acid coronary stents: Igaki-Tamai stents. Circulation 125: 2343-2352.	Case series n=50 patients (63 lesions; 84 stents; 57 procedures) mean 121 months	There were 1 cardiac death, 6 noncardiac deaths, and 4 Mis. Survival rates free of all-cause death, cardiac death, and MACE at 10 years were 87%, 98%, and 50%, respectively. The cumulative rates of TLR (TVR) were 16% (16%) at 1 year, 18% (22%) at 5 years, and 28% (38%) at 10 years. Two definite scaffold thromboses (1 subacute, 1 very late) were recorded.	Larger and more recent studies included.
Ormiston JA, Serruys PW, Regar E et al.(2008) A bioabsorbable everolimus-eluting coronary stent system for patients with single de novo coronary artery lesions (ABSORB): a prospective open-label trial. Lancet 371: 899-907.	Case series N=30 Follow-up: 1 year		Reported in Table 2; shorter follow-up presented in this paper.
Ormiston JA, Serruys PW, Onuma Y et al (2012). First serial assessment at 6 months and 2 years of the second generation of Absorb everolimus-eluting bioresorbable vascular scaffold: a multi-imaging modality study. Circulation. Cardiovascular Interventions 5: 620-632.	Case series (ABSORB cohort B) N=45 Follow-up 24 months.	From 6 to 24 months, late luminal loss increased from 0.16±0.18 to 0.27±0.20 mm on QCA, with an increase in neointima of 0.68±0.43 mm(2) on OCT and 0.17±0.26 mm(2) on IVUS. Struts still recognisable on OCT at 2 years showed 99% of neointimal coverage with optical and ultrasonic signs of bioresorption accompanied by increase in mean scaffold area compared with baseline (0.54±1.09 mm(2) on IVUS, p=0.003 and 0.77±1.33 m(2) on OCT, p=0.016). 2 year MACE rate was 6.8% without any ScT.	Large and more recent studies included.
Ormiston JA, Webber B, Ubod B et al (2015) An independent bench comparison of two bioresorbable drug-eluting coronary	Absorb and DESolve bioresorbable scaffolds compared with metallic drug-	The metallic stent has thinner struts, lower profile, and greater radial strength than the polymeric scaffolds. Different safe pressure thresholds exist for different scaffolds/stents. Unlike the	Mechanical and physical properties assessed.

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scaffolds (Absorb and DESolve) with a durable metallic drug-eluting stent (ML8/Xpedition). EuroIntervention;11(1) :60-7	eluting XIENCE Xpedition stent. Bench testing	others, the DESolve showed "self-correction" or enlargement after initial recoil.	
Okamura T, Garg S, Gutiérrez-Chico JL et al. (2010) In vivo evaluation of stent strut distribution patterns in the bioabsorbable everolimus-eluting device: an OCT ad hoc analysis of the revision 1.0 and 1.1 stent design in the ABSORB clinical trial. EuroIntervention 5: 932 – 938.	N = 4 (BVS 1.0) versus 4 (BVS 1.1) Follow-up: Post-procedure only	Authors conclude that imaging confirms the differing strut distribution of the BVS 1.1 from the BVS 1.0.	Comparative sub-study. Focus on imaging outcomes.
Onuma Y, Serruys PW, Gomez J et al. (2011). Comparison of In Vivo Acute Stent Recoil Between the Bioresorbable Everolimus-Eluting coronary Scaffolds (Revision 1.0 and 1.1) and the Metallic Everolimus-Eluting Stent. Catheterization and Cardiovascular Interventions 78: 3-12.	N = 27 (BVS 1.0) versus 88 (BVS 1.1) versus 27 metallic DES Follow-up: post-procedure.	Authors conclude that acute recoil was slightly higher in the BVS 1.1 and similar to the BVS 1.0 but this was not statistically significant.	Comparative sub-study. Focus on imaging outcomes.
Okamura T, Onuma Y, García-García HM et al. (2010) 3-dimensional optical coherence tomography assessment of jailed side branches by bioresorbable vascular scaffolds. A Proposal for classification. JACC: Cardiovascular	N = 25 (3D assessment) Follow-up: post-procedure	Authors conclude that reconstruction with 3-dimensional OCT in the evaluation of orifices of side branches jailed with BVS was feasible.	Sub-study. Focus on imaging outcomes.

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Interventions 3 (8): 836-844.			
Otsuka M, Tanimoto S, Sianos G et al. (2009) 'Radio-lucent' and 'radio-opaque' coronary stents characterized by multislice computed tomography. International Journal of Cardiology 132: e8-e10.	Case report N = 1 Follow-up: 4 days	Authors conclude that there are potential advantages (clear depiction of in-stent lumen) of radio-lucent polymer stents compared with metallic stents with respect to non-invasive multi-slice computed tomography coronary angiography.	Case report of patient included in ABSORB A cohort. Focus on imaging outcomes.
Onuma Y, Dudek D, Thuesen L et al (2013). Five-year clinical and functional multislice computed tomography angiographic results after coronary implantation of the fully resorbable polymeric everolimus-eluting scaffold in patients with de novo coronary artery disease. The ABSORB Cohort A Trial. JACC Cardiovascular Interventions 6 (10): 999-1009.	Case series (ABSORB cohort A) 30 patients with a single de novo coronary artery lesion were treated with Absorb scaffold. 5 years follow-up.	At 46 days, 1 patient had chest pain and had a TLR. At 5 years, the ischemia-driven MACE rate of 3.4% remained unchanged. 4ScT was not seen. 2 noncardiac deaths were reported, 1 caused by duodenal perforation and the other from Hodgkin's disease. At 5 years, 18 patients had MSCT angiography. All scaffolds were patent, with a median minimal lumen area of 3.25 mm2. Non-invasive FFR analysis was feasible in 13 of 18 scans, which yielded a median distal FFR of 0.86.	Large and more recent studies included.
Onuma Y, Collet C, Geuns RJV et al. (2017) Long-term serial non-invasive multislice computed tomography angiography with functional evaluation after coronary implantation of a bioresorbable everolimus-eluting scaffold: the ABSORB cohort B MSCT substudy.	ABSORB cohort B (101 patients with non-complex de novo lesions) Follow up 72 months	53 patients hent MSCT imaging at 72 months. The MACE rate was 1.9% (1/53). At 72 months, the median minimal lumen area (MLA) was 4.05 mm2 and the mean percentage area stenosis was 18%, 1 scaffold was totally occluded. n 39 patients with paired MSCT analysis, the MLA significantly increased from the first to the second follow-up. In 39 patients with paired MSCT analysis, the MLA significantly increased from	Imaging outcomes.

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European Heart Journal - Cardiovascular Imaging, 18, 870–879.		the first to the second follow-up (p=0.002).	
Onuma Y, Serruys PW, Ormiston JA et al. (2010) Three-year results of clinical follow-up after a bioresorbable everolimus-eluting scaffold in patients with de novo coronary artery disease; the ABSORB trial. EuroIntervention 6: 447 – 453.	Case series (ABSORB cohort A) 30 patients with a single de novo native coronary artery lesion	3-year clinical results have demonstrated a sustained low MACE rate (3.4%) without any late complication such as stent thrombosis. 2 non-cardiac deaths were reported; 1 from duodenal perforation, the other from Hodgkin disease. 2 patients had non-ischaemia driven TVR.	Large and more recent studies included.
Onuma Y, Chevalier B, Ono M et al. (2020) Bioresorbable scaffolds versus everolimus-eluting metallic stents: five-year clinical outcomes of the randomised ABSORB II trial. EuroIntervention;16: e938- e941.	RCT ABSORB II trial N=501 patients randomised to Absorb scaffold or XIENCE stent. Follow-up 5 years in 256 patients (76.4%) and 125 patients (75.3%) in the Absorb arm and the XIENCE arm.	Extended follow up of the randomised ABSORB II trial demonstrates the absence of scaffold/stent thrombosis from 4 to 5 years, and very low additional events beyond 3 years, the time point of full scaffold resorption. The advantage of a bioresorbable scaffold over a metallic stent was not demonstrated.	Large and more recent studies included.
Ortega-Paz L, Capodanno D, Gori T et al. (2017) Predilation, sizing and post-dilation scoring in patients undergoing everolimus-eluting bioresorbable scaffold implantation for prediction of cardiac adverse events: development and internal validation of the PSP score. EuroIntervention; 12:2110–2117.	GHOST-EU registry N=1,736 lesions treated with BVS were analysed.	Predilation, correct scaffold sizing, and post-dilation with a non-compliant balloon were performed in 95.7%, 50.2%, and 26.2% of the cases and scored 0.63, 1.96 and 1.93 points, respectively, in the PSP-1 model. PSP-1 was an independent predictor of 1-year device oriented composite endpoint (HR 0.75, 95% CI: 0.61-0.93; p=0.007). No patient with a maximum PSP-1 score had ScT, compared to those with a non-maximum PSP-1 score (0% versus 2.3%; p=0.095). Modification of implantation	Large and recent studies included.

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		technique might lead to improved clinical outcomes.	
Ozaki Y, Garcia-Garcia HM, Shlofmitz E et al. (2020) Second-generation drug-eluting resorbable magnesium scaffold: review of the clinical evidence. Cardiovascular Revascularization Medicine; 21: 127-136.	Review BIOSOLVE-II and BIOSOLVE-III with 184 patients who had DREAMS 2G scaffold (i.e. 2nd generation; Magmaris®, Biotronik AG)	At 24 months, the TLF, TVMI, and TLR rates were 5.9%, 0.9%, and 3.4% respectively with no definite or probable stent thrombosis. The BIOSOLVE-IV was a single-arm, multicentre registry that included data of 400 patients with a 12-month follow up. RMS showed similar performance to second-generation DES.	Review
Pellicano M, Di Gioia, Ciccarelli G et al. (2020) Procedural microvascular activation in long lesions treated with bioresorbable vascular scaffolds or everolimus-eluting stents: the PROACTIVE trial. EuroIntervention; 16: e147- e154.	RCT N=66 having elective PCI in long lesions were randomised 1:1 to either 33 BVS or 33 EES	In long lesions, BVS implantation is associated with a significant reduction in pressure-derived corrected index of microvascular resistance as compared with EES. The limited acute impact of BVS on the microcirculation effect is associated with an optimal periprocedural and short-term platelet inhibition, without significant difference in periprocedural myonecrosis as compared with patients treated with EES.	Larger studies included.
Polimeni A, Anadol R, Münzel T et al (2017) Long-term outcome of bioresorbable vascular scaffolds for the treatment of coronary artery disease: a meta-analysis of RCTs. BMC Cardiovascular Disorders. 17: 147.	Meta-analysis N=5219 patients (BVS versus DES EES).	For BVS with higher rates of TLF (9.4% vs 7.2%; OR = 1.33; P = 0.008) and DT (2.3% vs 0.7%; OR = 3.22; P <0.0001) compared with EES. BVS were associated with worse clinical outcomes at 2-years and higher incidence of both early (within 30 days after implantation) and very-late (> 1 year) DT.	More recent studies included.
Puricel S, Cuculi F, Weissner M et al. (2016) Bioresorbable Coronary Scaffold Thrombosis: Multicenter Comprehensive Analysis of Clinical	Registry analysis N=1,305 consecutive patients (mean age 64 years, 78% male) who had 1,870 BVS	Stent thrombosis occurred in 42 patients. The incidence of probable and definite stent thrombosis was 1.8% at 30 days and 3.0% at 12 months this could be significantly. The rate of ScT declined significantly in patients when a strategy optimised for	Large and recent studies included.

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Presentation, Mechanisms, and Predictors. J Am Coll Cardiol; 67:921−31.	Follow-up 485 days.	BVS was applied rather than a DES-oriented implantation strategy.	
Reichart C, Wohrle J, Markovic S et al. (2019) Clinical results of bioresorbable drug-eluting scaffolds in short and long coronary artery lesions using the PSP technique. BMC Cardiovascular Disorders, 19:22	Prospective study N=326 patients with 421 lesions PCI with the Absorb BVS patients with short (< 20 mm) and long (≥20 mm) coronary artery lesions after implantation of bioresorbable vascular scaffolds (BVS) via PSP-technique. Follow-up 36 months	Device oriented composite endpoint (DOCE) after 12 months were 2.63% for short lesions and 8.09% for long lesions (p =0.0131), 5.51% versus 11.35% (p = 0.0503) after 24 months and 8.00% versus 18.00% (p = 0.0264) after 36 months of clinical follow-up. Kaplan-Meier estimates for TLR after 12 months were 1.46% for short and 7.69% for long lesions (p = 0.0012),2.06% versus 8.75% after 24 months (p = 0.0027) and 4.96% versus 9.59% after 36 months of follow-up (p = 0.0109). ScT rates were low.	Large and more recent studies included.
Rzeszutko Ł, Siudak Z, Włodarczak A, et al. (2014) Contemporary use of bioresorbable vascular scaffolds (BVS) in patients with stable angina and acute coronary syndromes. Polish National Registry. Kardiologia Polska; 72: 1394-1399.	Polish registry N=591	In patients with ACS and those with complex lesions, early in-hospital results showed no significant differences between BVS and EES in the primary composite MACE end-point.	Large and recent studies included.
Sarno G, Onuma Y, Garcia-Garcia HM et al. (2010) IVUS radiofrequency analysis in the evaluation of the polymeric struts of the bioabsorbable everolimus-eluting device during the bioabsorption process. Catheterization and	Case series N= 20 Follow-up: 2 years	Authors conclude that a 24% seen decrease in necrotic core area between 6 months and 2 years could be due to bioabsorption and everolimus anti-inflammatory action,	Sub-study. Focus on imaging outcomes.

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Cardiovascular Interventions 75: 914-918.			
Sarno G, Bruining N, Onuma Y et al. (2012) Morphological and functional evaluation of the bioresorption of the bioresorbable everolimus-eluting vascular scaffold using IVUS, echogenicity and vasomotion testing at two year follow-up: a patient level insight into the ABSORB A clinical trial. International Journal of Cardiovascular Imaging 28: 51-58.	Case series N =9 Follow-up: 2 years	Authors conclude that the return of endothelial and non-endothelial dependent vasomotion is associated with the bioresorption process.	Sub-study. Focus on imaging outcomes.
Serruys PW, Ormiston J, Onuma Y et al. (2009) A bioabsorbable everolimus-eluting coronary stent system (ABSORB): 2- year outcomes and results from multiple imaging methods. Lancet 373: 897-910.	Case series N=29 patients with a single de-novo coronary artery lesion who had BVS. Follow-up: 2 years.	At 2 years, there were no cardiac deaths, ischaemia-driven TLR, or stent thromboses and only 1 MI (non-Q wave). CT (in 25 patients) showed a mean diameter stenosis of 19%. At 2-year angiography, the in-stent late loss of 0·48 mm and the diameter stenosis of 27% did not differ from the findings at 6 months. The luminal area enlargement on OCT and IVUS between 6 months and 2 years was due to a decrease in plaque size without change in vessel size. At 2 years, 34·5% of strut locations presented no discernible features by OCT.	Reported in Table 2; shorter follow-up presented in this paper.
Shin E-S, Garcia-Garcia HM, Garg S et al. (2010) Assessment of the serial changes of vessel wall contents in atherosclerotic coronary lesion with bioresorbable everolimus-eluting vascular scaffolds	Case series N = 29 Follow-up: 2 years	Authors conclude that virtual histology IVUS analysed using Shin's method can be used to assess bioresorption in those having a BVS.	Sub-study. Focus on imaging outcomes.

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using Shin's method: an IVUS study. International Journal of Cardiovascular Imaging 27: 931-937.			
Shin E, Garcia-Garcia HM, Sarno G et al. (2010) Reproducibility of Shin's method for necrotic core and calcium content in atherosclerotic coronary lesions treated with bioresorbable everolimus-eluting vascular scaffolds using volumetric intravascular ultrasound radiofrequency-based analysis. International Journal of Cardiovascular Imaging 28: 43-49	Case series N = 8 Follow-up: 2 years	Authors conclude that Shin's method showed good reproducibility.	Sub-study. Focus on imaging.
Sheehy A, Guitérrez-Chico JL, Diletti R et al. (2012) In vivo characterisation of bioresorbable vascular scaffold strut interfaces using optical coherence tomography with Gaussian line spread function analysis. EuroIntervention 7: 1227 – 1235.	N = 12 Follow-up: 6 months	Authors conclude that more precise assessment of strut thickness and coverage is possible with OCT with Gaussian line spread function analysis.	Sub-study. Focus on imaging outcomes.
Serruys P, Onuma Y Garcia-Garcia HM, et al. (2013) Dynamics of vessel wall changes following the implantation of the Absorb everolimus-eluting bioresorbable vascular scaffold: a multi-imaging modality study at 6, 12, 24 and	Case series (ABSORB cohort B) N=101 (45 cohort B1) and 56 cohort B2) Follow-up 2 years	Between 1 and 3 years, late luminal loss remained unchanged (6 months: 0.19 mm, 1 year: 0.27 mm, 2 years: 0.27 mm, 3 years: 0.29 mm) and the in-segment angiographic restenosis rate for the entire cohort B (n=101) at 3 years was 6%. On IVUS, mean lumen, scaffold, plaque and vessel area showed enlargement up to 2 years. Mean lumen and	Large and more recent studies included.

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36 months. EuroIntervention 9 (11):1271-1284.		scaffold area remained stable between 2 and 3 years. The 3-year MACE rate was 10% without any ScT.	
Serruys PW, Onuma Y, Dudek D et al. (2011) Evaluation of the second generation of a bioresorbable everolimus-eluting vascular scaffold for the treatment of de novo coronary artery stenosis: 12-month clinical and imaging outcomes. Journal of the American College of Cardiology 58 (15): 1578-1588	Case series (ABSORB cohort B) N=56 patients (57 scaffolds) 12-month follow-up	Overall the scaffold area remained unchanged, whereas the radiofrequency backscattering and the echogenicity of the struts decreased by 16.8% ($p < 0.001$) and 20% ($p < 0.001$), respectively. The angiographic late lumen loss amounted to 0.27 mm with an IVUS relative decrease in minimal lumen area of 1.94% ($p = 0.12$). The OCT at follow-up showed that 96.69% of the struts were covered and that malapposition, was only detected in 4 scaffolds. 2 patients experienced peri-procedural and iatrogenic MI, 2 had repeat intervention, resulting in the MACE rate of 7.1% (4/56).	Large and more recent studies included.
Serruys PW, Chevalier B, Sotomi Y, et al. Comparison of an everolimus-eluting bioresorbable scaffold with an everolimus-eluting metallic stent for the treatment of coronary artery stenosis (ABSORB II): a 3 year, randomised, controlled, single-blind, multicentre clinical trial [Erratum appears in Lancet 2017;389(10071):804; PMID: 28248178]. Lancet 2016;388(10059):2479–91	RCT Absorb BVS II 501 (335 versus 166) Everolimus-eluting BRS/Absorb® versus everolimus-eluting permanent metallic stent/Xience® Follow-up 4 years.	The trial did not meet its co-primary endpoints of superior vasomotor reactivity and non-inferior late luminal loss for the Absorb bioresorbable scaffold with respect to the metallic stent, which was found to have significantly lower late luminal loss than the Absorb scaffold. A higher rate of DOCE due to target vessel MI, including peri-procedural MI, was seen in the Absorb group. The POCE, anginal status, and exercise testing, were not statistically different between both devices at 3 years.	Included in systematic reviews
Serruys PW, Ormiston J, Geuns RJV et al. (2016) A polylactide bioresorbable scaffold	ABSORB B N=101	At 5 years, bioresorbable scaffold implantation in a simple stenotic lesion resulted in stable lumen dimensions and low restenosis	Larger studies included.

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eluting everolimus for treatment of coronary stenosis 5-year follow-up. JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY. 67 (7), 766-776.	5 years follow-up (n=50)	and major adverse cardiac event rates.	
Serruys PW, Chevalier B, Dudek D, et al. A bioresorbable everolimus-eluting scaffold versus a metallic everolimus-eluting stent for ischaemic heart disease caused by de-novo native coronary artery lesions (ABSORB II): an interim 1-year analysis of clinical and procedural secondary outcomes from a randomised controlled trial. Lancet 2015;385(9962):43–54	RCT Absorb BVS II 501 (335 versus 166) Everolimus-eluting BRS/Absorb® versus everolimus-eluting permanent metallic stent/Xience® Follow-up 4 years.	The 1-year composite device orientated endpoint was similar between the BRS and metallic stent groups (16 patients [5%] vs 5 patients [3%], p=0.35). Three patients in the BRS group had definite or probable scaffold thromboses, compared with no patients in the metallic stent group. There were 17 (5%) major cardiac adverse events in the BRS group compared with 5 (3%) events in the metallic stent group, with the most common adverse events being MI (15 cases [4%] versus 2 cases [1%], respectively) and clinically indicated TLR (4 cases [1%] vs 3 cases [2%], respectively).	Larger studies included.
Shreenivas S, Kereiakes DJ, Ellis SJ et al. (2017) Efficacy and Safety of the Absorb Bioresorbable Vascular Scaffold in Females and Males Results of an Individual Patient-Level Pooled Meta-Analysis of Randomized Controlled Trials. JACC: CARDIOVASCULAR INTERVENTIONS, 10 (18), 1881-1890	Meta-analysis of RCTs 4 studies (n= 3,384 patients)	The 2-year rates of TLF with BVS versus everolimus-eluting stent in females were 8.9% versus 6.2% (HR 1.47; 95% CI: 0.88 to 2.46) and 8.9% versus 6.4% in males (HR: 1.40; 95% CI: 1.02 to 1.92; p interaction = 0.85). There were no significant interactions between sex and device type for any of the components of TLF.	Larger and more recent studies included.

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Simsek C, Karanosos A, Magro M et al. (2016) Long-term invasive follow-up of the everolimus-eluting bioresorbable vascular scaffold: five-year results of multiple invasive imaging modalities. EuroIntervention;11:996-1003.	Patients included in the ABSORB cohort A 8 of 16 patients had imaging assessment.	At 5 years, the Absorb BVS is no longer discernible by any invasive imaging method and endothelial function is restored. Late luminal enlargement persists up to 5 years of follow-up without adaptive vessel remodelling.	Sub-study. Focus on imaging outcomes.
Simsek C, Magro M Onuma Y et al. (2013) Procedural and clinical outcomes of the Absorb everolimus-eluting bioresorbable vascular scaffold: one-month results of the Bioresorbable vascular Scaffold Evaluated At Rotterdam Cardiology Hospitals (B-SEARCH) EuroIntervention 2013; 9-online publish-ahead-of-print September 2013	Case series, n=88 (92 lesions), Patients included in 3 study cohorts (ABSORB Cohort A, Cohort B and EXTEND) at 2 centres in Rotterdam 1month follow-up	Lesion length was significantly longer in the ABSORB EXTEND cohort 11.34mm (9.20mm; p<0.01) and RVD was smaller 2.53mm (2.87mm; p<0.001) compared to previous cohorts. The scaffold was successfully implanted in 90/92 lesions (97.8%). Post-dilatation was performed in 55% of the patients (53% EXTEND versus 56% Cohort A and B; p=0.7). The acute gain was 1.21mm. Absolute recoil was 0.16mm with percentage acute recoil of 5.60%. At 1 month, none of the patients had a MACE.	Study includes patients from Absorb A, B and extend study from 2 centres with 1 month follow-up. Longer follow-up studies already included in table 2.
Sorrentino S, Giustino G, Mehran R et al. (2017) Everolimus-eluting bioresorbable scaffolds versus everolimus-eluting metallic stents. Journal of the American College of Cardiology. 69: 3055-3066.	7 trials, n=5,583 patients were randomised to have either BVS (n = 3,261) or the EES (n = 2,322). Median time of follow-up was 2 years (range 2 to 3 years).	There was a higher incidence of TLF (9.6% versus 7.2% with number needed to harm: 41; P < 0.003) and stent thrombosis (2.4% vs 0.7% with number needed to harm: 60; p <0.0001) in the BVS group. The increased risk for stent thrombosis was consistent across early (< 30 days), late (30 days to 1 year), and very late (> 1 year) periods.	More recent reviews included.
Stone GW, Gao R, Kimura T et al. (2016) 1-year outcomes with the Absorb bioresorbable scaffold in patients with	Meta-analysis 4 RCTs BVS Absorb	Pooled analysis of individual patient data from the 4industry-sponsored studies showed broadly concordant findings. Most of this increased risk occurred inside the first 30 days suggesting	Meta-analysis

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coronary artery disease: a patient-level, pooled meta-analysis. Lancet. 26; 387 (10025):1277-89.		an association with the procedural outcomes. In this meta-analysis, BVS did not lead to different rates of POCE and DOCE adverse events at 1-year follow-up compared with CoCr-EES.	
Stone GW, Abizaid A, Onuma Y, Seth A, Gao R, Ormiston J, et al. Effect of Technique on Outcomes Following Bioresorbable Vascular Scaffold Implantation: Analysis From the ABSORB Trials. J Am Coll Cardiol 2017;70:2863−74	Retrospective analysis N=2,973 patients with 3,149 BVS-treated coronary artery lesions from 5 prospective studies (ABSORB II, ABSORB China, ABSORB Japan, ABSORB III, and ABSORB Extend). Outcomes through 3 years	In the present large-scale analysis from the major ABSORB studies, after multivariable adjustment for baseline patient and lesion characteristics, vessel sizing and operator technique were strongly associated with BVS-related outcomes during 3-year follow-up.	Large and recent studies included.
Sotomi Y, Suwannasom P, Serruys PW et al. (2017) Possible mechanical causes of scaffold thrombosis: insights from case reports with intracoronary imaging. EuroIntervention; 12: 1747- 1756.	Review	Insights into the possible mechanical causes of ScT in early and late phases with data stemming from intracoronary imaging (IVUS and OCT) of the currently published ScT cases following the implantation of BVS and reviewed practical recommendation for implantation of the BVS made by a group of experts.	Large and recent studies included.
Tanimoto S, Bruining N, van Domburg RT et al. (2008). Late stent recoil of the bioabsorbable everolimus-eluting coronary stent and its relationship with plaque morphology. Journal of the American College of Cardiology 52 (20): 1616 – 1620.	Case series N = 16 Follow-up: 6 months	Authors report late BVS recoil of 23% although the type of lesion morphology may have affected the degree to which this occurred.	Sub-study. Focus on imaging outcomes.

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Toušek P, Kočka V, Malý M et al. (2016) Long-term follow-up after bioresorbable vascular scaffold implantation in STEMI patients: PRAGUE-19 study update. EuroIntervention;12(1) :23-9.	N=117 STEMI patients with BVS. mean follow-up 730±275 days	Overall mortality of 4.4%. Definite ScT occurred in 2 patients in the early phase after BVS implantation; there was no late thrombosis. VS struts were still visible at 3 years and 99.4% of them were well apposed and covered.	Large studies included.
Tousek P, Kocka V, Maly M et al. (2016) Two-year follow-up after bioresorbable vascular scaffold implantation in STEMI patients — Results from PRAGUE-19 study. International Journal of Cardiology 209; 20–21.	Prospective study BVS group (n = 40), versus control DES group (n=57) 2 year follow-up	No differences in primary composite endpoint during the 2 year follow-up have been found between the BVS and control group (7,5% versus 18.9%; P = 0.141). Regarding functional clinical status, no differences were seen in NYHA and CCS class at 2 year follow-up. There was 1 acute definitive stent thrombosis in the BVS group already presented in the short-term clinical follow-up of the study. No other definitive/probable stent thrombosis occurred in both groups up to the 2 year follow-up.	Large and recent studies included.
Tarantini G, Masiero G, Fovino LN, et al. (2018) "Full-plastic jacket" with everolimus-eluting Absorb bioresorbable vascular scaffolds: clinical outcomes in the multicenter prospective RAI registry (NCT02298413). Int J Cardiol; 266:67–74.	RAI Registry N=1384 patients compared those related with 'full-plastic jacket' (FPJ) everolimus-eluting Absorb BRS (>56 mm of overlapping BRS in at least 1 vessel) versus non FPJ 21.6 months follow-up	At a median follow-up of 649 days, no differences were seen between full-plastic jacket' [FPJ] and non-FPJ groups in terms of the D0CE (5.6% versus 4.4%, p = 0.675) or PoCE (20.9% versus 15.9%, p = 0.149). Patients having FPJ had higher rates of target vessel repeat revascularisation (TVR) (11.2% versus 6.3%, p = 0.042). In the FPJ group, there was no cardiac death and only 1 (very late) stent thrombosis (ST) (0.7%).	Larger and more recent studies included.
Tamai H, Igaki K, Kyo E et al. (2000) Initial and 6-month results of biodegradable poly-/-lactic acid coronary stents in humans.	Case series N=15 PLLA Igaki-Tamai stent implantation Follow-up: 6 months	Our preliminary experience suggests that coronary PLLA biodegradable stents are feasible, safe, and effective in humans. Long-term follow-up with more patients will be required to	Patients included within larger study with longer follow-up.

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Circulation 102: 399-404.		validate the long-term efficacy of PLLA stents.	
Tanimoto S, Serruys PW, Thuesen L, et al. (2007) Comparison of in vivo acute stent recoil between the bioabsorbable everolimus-eluting coronary stent and the everolimus-eluting cobalt chromium coronary stent: Insights from the ABSORB and SPIRIT trials. Catheterization and Cardiovascular interventions 70: 515 – 523.	Case series N =27 (BVS) versus 27(DES)	Authors conclude that in some patients, BVS acute stent recoil of the BVS was slightly larger but not significantly different from that of a DES.	Sub-study. Focus on imaging outcomes.
Tijssen RYG, Kraak RP, Elias J et al. (2018) Implantation techniques (predilatation, sizing, and post-dilatation) and the incidence of scaffold thrombosis and revascularisation in lesions treated with an everolimus-eluting bioresorbable vascular scaffold: insights from the AIDA trial. EuroIntervention; 14:e434−e42.	Retrospective analysis of Absorb BVS Absorb-treated AIDA patients implantation in 1,074 lesions 158 (14.7%) lesions met PSP criteria.	Definite stent thrombosis occurred in 4/158 PSP-treated lesions compared with 27/916 non PSP-treated lesions, with 2-year KM estimates of 3.0% versus 4.1% and an HR of 1.14 (p=0.811). TLR occurred in 8/158 PSP-treated lesions compared with 61/916 non PSP-treated lesions, with KM estimates of 5.6% versus 7.1% and an HR of 1.29 (p=0.492). Scaffold implantation according to an optimised PSP protocol did not result in lower stent thrombosis or TLR rates.	Large and recent studies included.
Toyota T, Morimoto T, Shiomi H et al. (2017) Very late scaffold thrombosis of bioresorbable vascular scaffold systematic review and a meta-analysis. JACC: CARDIOVASCULAR INTERVENTIONS, 10 (1), 27-37.	Meta-analysis of 24 studies (BVS: n =2,567 and EES: n =19,806) reporting the 2-year outcomes of BVS and/or EES to compare the risk of BVS versus EES for stent/ScT (ST) and target lesion	In the 7 comparative studies, the risk for VLST between 1 and 2 years was numerically higher in BVS than in EES (OR: 2.03 [95% CI: 0.62 to 6.71]). The excess risk of BVS relative to EES for ST through 2 years was significant (OR: 2.08 [95% CI: 1.02 to 4.26]). The risk for TLF was neutral between BVS and EES. In the 24 studies, the pooled estimated incidence rates of VLST, and ST	Large and recent studies included.

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	failure (TLF) in 7 comparative studies (3 randomised and 4 observational), and to estimate the pooled incidence rates of ST and TLF including additional 17 single-arm studies.	through 2 years were higher in BVS than in EES (0.240 [95% CI: 0.022 to 0.608]% versus 0.003 [95% CI: 0.000 to 0.028]%, and 1.43 [95% CI: 0.67 to 2.41]% versus 0.56 [95% CI: 0.43 to 0.70]%, respectively). The corresponding rates for TLF were comparable between BVS and EES (1.88 [95% CI: 1.30 to 2.55]% and 1.78 [95% CI: 1.17 to 2.49]% and 7.90 [95% CI: 6.26 to 9.69]% and 7.49 [95% CI: 5.86 to 9.29]%, respectively).	
Xu B, Yang Y, Han Y et al. (2017) Comparison of everolimus eluting bioresorbable vascular scaffolds and metallic stents: three-year clinical outcomes from the ABSORB China randomised trial. EuroIntervention. 22. Pii: EIJ-D-17-00796.	RCT absorb China N=480 patients with 1 or 2 native coronary artery lesions were randomised 1:1 to BVS (N=241) versus CoCr-EES (N=239).	In the ABSORB China trial, BVS and CoCr-EES had similar results up to 3-year follow-up, the time at which the scaffold has completely resorbed. BVS outcomes may be further optimised by appropriate lesion selection and implantation technique.	Large and more recent studies included.
Verheye S, Woldarczak A, Montorsi P et al. (2021) BIOSOLVE-IV-registry: Safety and performance of the Magmaris scaffold: 12-month outcomes of the first cohort of 1,075 patients. Catheter Cardiovasc Interv; 98:E1–E8.	BIOSOLVE-IV international registry N= 1,075 patients with 1,121 lesions who had Magmaris BVS Follow-up 12 months.	BIOSOLVE-IV confirms the safety and performance of the Magmaris scaffold in a large population with excellent device and procedure success and a very good safety profile up to 12 months in a low-risk population.	Longer follow-up studies included.
Verheye S, Costa RA, Schofer J et al. (2019) Five-year safety and performance data of a novel third-generation novolimus-eluting bioresorbable scaffold in single de novo lesions.	DESolve nonrandomised study n= 126 patients with a de novo lesions treated with BVS 2 years follow-up	After the 2-year follow-up, 2 patients were lost to follow-up. Two patients had a major adverse cardiac event (MACE) - a cardiac death at 3 years and a target vessel-related non-Q-wave MI due to a proximal target segment stenosis treated with a stent at 4 years. The cumulative MACE rate	Larger studies included.

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EuroIntervention 2019;15:685-687		at f5ive years was 9.0%. There were no reported definite scaffold thromboses.	
Vijayvergiya R, Reviah PC, Kasinadhuni G et al. (2020) In-scaffold neovascularization of a bioresorbable vascular scaffold after 6 years of implantation. European Heart Journal - Case Reports, 4, 1–2	Case report n=1 patient with chronic stable angina stented with a bioresorbable vascular scaffold (BVS)	Patient remained asymptomatic for the next 6 years. OCT findings at 6 years were consistent with the formation of neovascular channels within the neo plaque after BVS implantation.	Larger studies included.
Vandeeper M (2016) Bioresorbable vascular scaffolds for coronary artery disease. Technology brief update. Health Policy Advisory Committee on Technology (HealthPACT). Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S)		The currently available evidence raises some doubts as to whether patient outcomes with the BVS technology are equivalent in effectiveness and safety compared to those achieved in patients treated with conventional DES. In addition, HealthPACT noted that the Absorb Bioresorbable Vascular Scaffold System is listed on the Prostheses List (AY045) at an equivalent price to drug eluting coronary artery stents, with a list price of $3,450, which is significantly higher than the negotiated price in the public sector.	
Vanhaverbeke M, McCutcheon K, Dubois C et al. (2018) Long-term intravascular follow-up of coronary bifurcation treatment with Absorb bioresorbable vascular scaffold. ACTA CARDIOLOGICA, 73,4, 413–414	Case report N=1 patient treated with modified-T stenting of a true bifurcation lesion	the bifurcation lesion was successfully treated with implantation of BVS. The patient remained angina free at 30 months. Angiography and OCT revealed complete restoration of the bifurcation anatomy and excellent vessel-wall healing characteristics at 30 months.	Larger studies included.
Verdoia M, Kedhi E, Suryapranata H et al. (2020) Poly (L-lactic	Meta-analysis	Mortality occurred in 2.71% of the patients, with no difference according to the type of implanted	More recent reviews included.

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acid) bioresorbable scaffolds versus metallic drugeluting stents for the treatment of coronary artery disease: A meta-analysis of 11 randomized trials. Catheter Cardiovasc Interv; 96:813–824.	11 randomised trials, for a total population of 10,707 patients, 54.5% treated with BVS mean follow-up of 2.64 years (1–5 years)	stent (OR[95%CI] = 0.94 [0.74, 1.20], p = .62). No interaction was seen according to patients' risk profile or the rate of diabetes and ACS. However, a significant increase in MI, stent thrombosis, TLR and TLF was seen with BVS as compared to DE.	
Waksman R, Erbel R, Di Mario C et al. (2009). Early- and long-term intravascular ultrasound and angiographic findings after bioabsorbable magnesium stent implantation in human coronary arteries. JACC: Cardiovascular Interventions 2 (4): 312-320.	N = 63 Follow-up: 20.3 months	Authors report that degradation occurred at 4 months with durability of results without early or late adverse findings.	Sub-study. Focus on imaging outcomes.
Waksman R, Prati F, Bruining N et al (2013). Serial observation of drug-eluting absorbable metal scaffold: multi-imaging modality assessment. Circulation: Cardiovascular Interventions 6 (6) 644-653.	N=46 BIOSOLVE-I Case series 12 months follow-up	Arterial curvature and angulation significantly increased by the degradation. Vasoconstriction was seen at 6 months. The percent hyper echogenicity of the scaffolded segments decreased in the first 6 months (from 22.1 to 15.8%; p<0.001). Struts on OCT at 6 and 12 months showed full neointimal coverage, with stabilisation of the mean scaffold area from 6 to 12 months. The mean neointimal area (1.55 versus 1.58mm(2); p=0.794) remained unchanged from 6 to 12 months.	Study reports mainly angiographic, IVUS and OCT outcomes. Clinical outcomes from related paper reported in table 2
Wiebe J, Hoppmann P, Colleran R et al. (2017) Long-term clinical outcomes of patients treated with everolimus-eluting bioresorbable stents in routine practice: 2-	ISAR-ABSORB registry. 419 patients	In the ISAR-ABSORB registry, at 2 years, the primary endpoint had occurred in 21.6% of patients: death in 6.3%, MI in 3.9%, TLR in 16.0%, and definite stent thrombosis in 3.8%. Long-term follow-up of patients treated with	Large and recent studies included.

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year results of the ISAR-ABSORB registry. JACC Cardiovasc Interv. 26;10(12):1222-1229.		BRS in routine practice showed higher event rates than expected.	
Wykrzykowska JJ, Kraak RP, Hofma SH, et al. (2017) Bioresorbable Scaffolds versus Metallic Stents in Routine PCI. N Engl J Med; 376:2319-28.	ADIA trial 1845 patients (with either a BVS 924 patients or a DES 921 patients) median follow-up was 707 days.	There was no significant difference in the rate of target-vessel failure between the patients who had a bioresorbable scaffold and the patients who had a metallic stent. The bioresorbable scaffold was associated with a higher incidence of device thrombosis than the metallic stent through 2 years of follow-up.	Large and recent studies included.
Woldarczak A, Gracia LAI, Karjalailen PP et al. (2019) Magnesium 2000 postmarket evaluation: Guideline adherence and intraprocedural performance of a sirolimus-eluting resorbable magnesium scaffold. Cardiovascular Revascularization Medicine, 20, 12, 1140-1145	Review of 2000 procedures Magmaris postmarket program (survey)	The Magmaris 2000 program includes the first commercial cases at each hospital. Overall, data on 2018 implantations were collected. The high rate of pre- and post-dilatation as well as other parameters confirm that generally the implantation guidelines are adhered to and the good intraprocedural performance (rated as good or very good in 96%) confirm the theoretical advantages of a metallic scaffold in practice.	More relevant studies included.
Woudstra P, Grundeken MJ, Kraak RP et al (2014). Amsterdam Investigator-initiated Absorb strategy all-comers trial (AIDA trial): A clinical evaluation comparing the efficacy and performance of ABSORB everolimus-eluting bioresorbable vascular scaffold strategy vs the XIENCE family (XIENCE PRIME or	RCT Absorb BVS vs XIENCE DES	The AIDA trial is a prospective, randomised (1:1), active-control, single-blinded, all-comer, non-inferiority trial. A total of 2,690 subjects will be enrolled with broad inclusion and limited exclusion criteria according to the “Instructions for Use” of the Absorb BVS strategy. The study population includes both simple and complex lesions, in patients with stable and ACS. The follow-up continues for 5years. The primary end point of the trial is TVF, defined as the composite of cardiac death, MI, and target	Study protocol only. Results not reported yet.

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XIENCE Xpedition) everolimus-eluting coronary stent strategy in the treatment of coronary lesions in consecutive all-comers: Rationale and study design. American Heart Journal 167 (2) 133-140.		vessel revascularization, at 2 years.	
Wiebe J (1), Möllmann H, Most A et al (2013). Short-term outcome of patients with ST-segment elevation myocardial infarction (STEMI) treated with an everolimus-eluting bioresorbable vascular scaffold. Clin Res Cardiol. 2014 Feb; 103 (2):141-8. Doi: 10.1007/s00392-013-0630-x. Epub 2013 Oct 18.	Patients with ST-segment elevation myocardial infarction (STEMI). N=25 (31 lesions) Case series ABSORB BVS 132 days follow-up.	Procedural success was achieved in 97 %. 2 MACE occurred during hospitalisation and follow-up: 1 patient with cardiogenic shock at the index procedure subsequently died. 1 patient suffered from instable angina with need for interventional revascularisation of a previously untreated vessel. 1 TVF as a consequence of an intra-procedural dissection was seen. However, no TLF was noted and no patients died.	Similar study included in table 2
Wiebe J, Dorr O, Ilstad H et al. (2017) Everolimus-versus novolimus-eluting bioresorbable scaffolds for the treatment of coronary artery disease: a matched comparison. JACC Cardiovasc Interv; 10:477–485.	Comparative analysis between the DESolve BRS and the Absorb BRS using a propensity-score matching model.	The main finding was that outcomes at 1 year were similar between the 2 devices: the 1-year rates of TLF (4.7 versus 4.5%; p = 0.851), TLR (2.6 versus 3.5%; p = 0.768), cardiac death (1.5 versus 2.0%; p = 0.752), and definite stent/ScT (2.0 versus 1.0%; p= 0.529) did not differ significantly between Absorb BRS and DESolve BRS. 6-month angiographic follow-up, the novolimus-eluting bioresorbable DESolve scaffold showed in-stent late lumen loss of 0.20 mm.	Large and more recent studies included.
Wohrle J, Naber C, Schmitz T et al.	Assure registry	procedural success was achieved in all patients. Acute gain was	Larger studies included.

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(2015) Beyond the early stages: insights from the ASSURE registry on bioresorbable vascular scaffolds.	N=183 patients with de novo CAD	1.54±0.51 mm, resulting in a final minimal lumen diameter (MLD), which met the baseline RVD, although visual estimates overrated the RVD by 0.5±0.5 mm. Up to 12 months, 1 patient (0.5%) had died from gastrointestinal bleeding, 3 (1.7%) non-target vessel MIs occurred, and 5 (2.8%) TLR had become necessary because of restenosis.	
Ke J, Zhang H, Huang J et al. (2020) Three-year outcomes of bioresorbable vascular scaffolds versus second-generation drug-eluting stents. Medicine. 99: e21554.	Meta-analyses of 6 RCTs with 3 years follow-up - 5,412 patients (BVS n = 3,177; DES n = 2,235),	At 3 years, BVS was associated with higher rates of TLF (OR = 1.33, 95%CI: 1.10-1.60, P = 0.003) and definite/probable stent/ScT (OR = 3.75, 95% CI: 2.22-6.35, P < .00001)compared with DES. The incidence of target vessel MI (OR = 1.68, 95% CI: 1.30-2.17, P < .0001), ischemia-driven TLR (OR = 1.46, 95% CI: 1.14-1.86, P = .003), and the POCE (OR = 1.20, 95% CI: 1.04-1.39, P = .01) were higher for those treated with BVS compared with DES. However, there was no significant difference in risk of cardiac death (OR = 0.94, 95%CI: 0.61-1.45, P = .79) between treatment groups.	Large and recent studies included.
Zhang XL, Zhu L, Wei ZH et al. (2016) Comparative efficacy and safety of everolimus eluting bioresorbable scaffold versus everolimus-eluting metallic stents: A systematic review and meta-analysis. Ann Intern Med; 164(11):752-6	Meta-analysis 6 randomised, controlled trials and 38 observational studies, each involving at least 40 patients with BVS implantation	The pooled incidence of definite or probable stent thrombosis after BVS implantation was 1.5 events per 100 patient-years (PYs) (95% CI, 1.2 to 2.0 events per 100 PYs) (126 events during 8508 PYs). Six randomised trials that directly compared BVSs with EESs showed a non-statistically significant increased risk for stent thrombosis (OR, 2.05 [CI, 0.95 to 4.43]; P = 0.067) and MI (OR, 1.38 [CI, 0.98 to 1.95]; P = 0.064) with BVSs. The 6 observational studies that compared BVSs with EESs showed increased risk for stent thrombosis (OR, 2.32 [CI, 1.06 to 5.07]; P = 0.035) and MI	More recent reviews included.

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		(OR, 2.09 [CI, 1.23 to 3.55]; P = 0.007) with BVSs. The relative rates of all-cause and cardiac death, revascularisation, and TLF were similar for BVSs and EESs.	
Zhang H, Zhao J, Xu Y et al. (2019) Three-year outcome of everolimus-eluting bioresorbable vascular scaffold versus everolimus-eluting metallic stents: a comprehensive updated meta-analysis of randomized controlled trials. EXPERT REVIEW OF MEDICAL DEVICES, 16, 5, 421–427	Meta-analysis N=6 studies [5,474 patients] Most studies were randomised multicentre trials with over 2-years follow-up. The experimental group was ABSORB EE-BRS and the control group was EES.	There was no difference regarding DOCEs, POCEs and ID-TLRs for 1 or 2 years, whereas there were significant differences regarding thrombosis between EE-BRS and EES interventions in the 1-year (pooled HR, 2.15, 95%CI: 1.11, 4.18) and 2-year follow-ups (pooled HR, 2.02, 95%CI: 1.08, 3.78), but not in the 3-year follow-up (pooled HR, 1.57, 95%CI: 0.66, 3.75) anymore. The results of this study showed no inferiority of EE-BRS regarding TVF, DOCE, POCE and ID-TLR 1-year and 2-years after interventions, but enhanced risk of thrombosis in the EE-BRS patients, which disappeared in 3-year follow-ups	More recent reviews included.
Zasada W, Rzeszutko L, Dziewierz A, and Dudek D. (2013) Patient with non-ST-segment elevation myocardial infarction treated by Absorb bioresorbable scaffold implantation. Kardiologia Polska. 71 (10), 1091-1092.	Case report n=1 Patient with non-ST segment elevation MI	We present the case of a 57-year-old male patient with a diagnosis of non-STE MI. Taking into consideration the clinical presentation and angiographic findings, the patient was qualified for emergent PCI with aspiration thrombectomy and bioresorbable vascular scaffold implantation (BVS; Absorb, Abbott), with good angiographic result.	Case study Larger studies with longer follow-up included in table 2.
Zechmeister-Koss I, Rothschedl E. (2015) Fully bioresorbable scaffolds for coronary artery disease. Decision Support Document Nr. 81; Vienna: Ludwig Boltzmann	Systematic review	The current evidence is not sufficient to prove that the BVS is more or at least equally effective and safer than current revascularisation technologies. Hence, the inclusion in the catalogue of benefits is currently not recommended.	More recent studies included.

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