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Research Review
EDUCATIONAL SERIES

Vascular Stents in the Treatment of Coronary Artery Disease

About the Reviewer

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Dr Kwok has actively participated in virtually all major live case conferences held in the United States, Paris and the Asia-Pacific region as an international faculty member, case operator and speaker for over ten years. He has also won numerous challenging case awards in international and local live case conferences. Dr Kwok serves on the Asian Pacific Society of Interventional Cardiology as an advisory board member. He has pioneered the use of a number of novel devices in Hong Kong and China and been principal investigator in a number of first-in-human studies. Prof. Jeffrey Popma (Harvard Medical School) and Dr Kwok implanted the first drug-eluting stent in Hong Kong in May 2002.

This review is intended as an educational resource for healthcare professionals. It overviews the evolution of stent technology in the treatment of coronary artery disease, and in particular the place in therapy of the everolimus-eluting bioresorbable vascular scaffold (Absorb) relative to conventional drug-eluting stents. Summaries of peer-reviewed clinical studies are presented with accompanying expert commentary from Dr Vincent Kwok to provide a local clinical practice context.

Introduction

Heart disease is the most common cause of death in the world, and in a developed country such as the US the most common type of heart disease is coronary artery disease.[1,2] In addition to lifestyle modification and the use of lipid-lowering drugs, coronary angioplasty using vascular stent technology is sometimes required to open an occluded coronary vessel in the clinical management of patients with coronary artery disease.[3]

Evolution of Stent Technology

The genesis of stent technology was the invention in 1977 of balloon angioplasty, for the treatment of obstructive coronary artery disease (**Table 1**). There is no doubt that balloon angioplasty was revolutionary, achieving stenotic dilation without the need for coronary bypass surgery. Unfortunately, the technique was associated with two major drawbacks: acute vessel closure and restenosis. The acute vessel occlusion was secondary to extensive coronary dissection, often requiring emergency bypass surgery. The restenosis resulted from constrictive vascular remodelling, often offsetting the late luminal enlargement and positive vascular remodelling that could occur.[4,5]

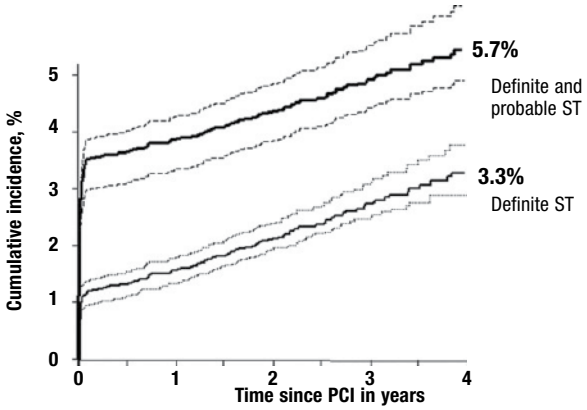
To overcome these drawbacks, bare-metal stents were developed (**Table 1**). First used in 1986, coronary artery stents provided a stainless steel scaffold that prevented acute and sub-acute vessel occlusion by sealing the dissection flaps and preventing recoil, drastically reducing the need for emergency bypass surgery. However, restenosis rates, although halved, were not eliminated, and neo-intimal hyperplasia still occurred. Moreover, the benefits of late luminal enlargement and vascular remodelling were lost due to the vessel being caged in metal.[4,6]

Drug-eluting metallic stents, the third technological advance, were developed to solve the problem of in-stent restenosis (**Table 1**). First appearing in 2002, they featured a non-erodible permanent polymer coating on the steel scaffold and the release of an anti-proliferative drug. Drug-eluting stents were effective in minimizing the need for repeat revascularisation, almost matching the performance of coronary bypass graft surgery. Despite this initial success, an increased risk of late stent thrombosis was revealed (**Figure 1**). In addition, evidence of abnormal structure and function of the endothelium remained.[4,5,7] The increased risk of late stent thrombosis stents is thought to be at least partially due to the stent's permanent polymer coatings causing delayed healing, impaired endothelialisation, and hypersensitivity reactions.[8]

	First Advance Balloon Angioplasty (circa 1977)	**Second Advance** Bare-metal Stent (circa 1986)	**Third Advance** Drug-eluting Stent (circa 2002)	**Fourth Advance** Biodegradable stents (circa 2012)
Advantages				
Late luminal enlargement	Yes	No	No	Yes
Vascular remodelling	Yes	No	No	Yes
Disadvantages				
Acute occlusions due to dissection	Yes	No	No	No
Acute stent thrombosis	N/A	Yes	Yes	Yes
Sub-acute stent thrombosis	N/A	No	Yes	Yes
Acute recoil	Yes	No	No	No
Constrictive remodelling	Yes	No	No	No
Neo-intimal hyperplasia	N/A	Yes	Reduced	Reduced
Late stent thrombosis	N/A	Yes	Yes	No

Table 1. Comparison of the four most important advances in stent technology for use in interventional cardiology[4,5]
Abbreviations: N/A not applicable due to absence of stent.

Concerns regarding the safety of drug-eluting stents, especially late stent thrombosis, prompted research into improving the properties of the permanent polymer. The outcome of this research has been the development of drug-eluting stents with biocompatible or biodegradable polymer coatings, polymer-free drug-eluting stents, and completely biodegradable scaffold stents.[9]



Months	1	12	24	36	48
Cumulative incidence definite ST, %	1.2	1.6	2.1	2.7	3.3
Cumulative incidence probable and definite ST, %	3.7	4.1	4.6	5.2	5.7
Patients at risk	7537	7209	5157	2747	1051

Figure 1. Kaplan-Meier curve showing the increasing incidence of stent thrombosis during long-term follow-up after the insertion of a drug-eluting metallic stent.[7]

Abbreviations:
PCI = percutaneous coronary intervention; ST = stent thrombosis.

Fully biodegradable stents are generally considered the fourth most important advance in stent technology, offering the promise of reduced late stent thrombosis and endothelial dysfunction (**Table 1**). The stent remains in situ, eluting an anti-proliferative drug, long enough to oppose constrictive remodelling and excessive neo-intimal hyperplasia. Within several years the device is completely integrated into the vessel wall, accompanied by infiltration of smooth muscle cells. The overall result is lumen enlargement and beneficial vascular remodelling. Normal vasodilatory response and endothelial structure and function are also restored.[4,5]

Benefits of Biodegradable Stents

To be effective in the treatment of coronary artery disease, an 'ideal' stent must be deliverable and flexible, cause minimal vessel wall trauma at deployment, produce minimal inflammation, not inhibit endothelialisation, provide sufficient support for the vessel, and promote vessel healing and remodelling. A comparison of how the different types of drug-eluting stents meet these requirements is presented in **Table 2**. In short, the comparison of performance characteristics suggests that fully biodegradable stents come closest to fulfilling the requirements of the 'ideal' stent.[6]

	Traditional DES	New DES	Biodegradable polymer DES	Fully biodegradable DES
Deliverability	+	++	++	+
Scaffolding/recoil prevention	+++	+++	++	++
Minimal vessel trauma	+	++	++	++
Low level of inflammation	–	+	+++	+++
Anti-restenosis properties	++	++	++	++
Endothelialisation	–	+	++	++
Long-term anti-platelet therapy avoided	–	–	+	++
Positive vessel remodelling	–	–	N/A	+++

Table 2. Comparison of the relative performance features of drug-eluting stents.[6]
Abbreviations: DES = drug-eluting stent; N/A = insufficient data. Symbols: – = poor; + = acceptable; ++ = good; +++ = excellent.

Biodegradable stents offer potential advantages versus drug-eluting metallic stents, which include the following:

- Avoidance of 'late' and 'very late' stent thrombosis because no foreign materials remain after two years.
- Restoration of vessel vasomotion, adaptive shear stress, and late expansile remodelling, which are facilitated by absorption of the rigid scaffolding.
- Reduced risk of bleeding complications because long-term anti-platelet therapy is not necessary once absorption of the scaffold is complete.
- Future percutaneous or surgical revascularisation is not restricted as is potentially the case with permanent metallic stent implants.
- Use of non-invasive imaging techniques such as computed tomography or magnetic resonance imaging is not restricted, as is the case with metallic stents.
- Concerns some patients might have about a permanent implant residing inside their bodies may be reduced.[4]

After development of the first metallic biodegradable stent and then the first non-metallic biodegradable stent to be implanted in humans, the Igaki-Tamai stent, the next fully biodegradable device to enter clinical trials, and the first to be marketed, was the everolimus-eluting bioresorbable vascular scaffold.

Bioresorbable Vascular Scaffold

The bioresorbable vascular scaffold (Absorb) is a stent system composed of four key components:

1. balloon-expandable polymer stent backbone
2. polymer drug reservoir coating
3. everolimus
4. drug-delivery mechanism.[9]

The balloon-expandable polymer backbone is composed of a semi-crystalline high molecular-weight poly-L-lactic acid (PLLA), which provides stent integrity. The PLLA backbone is similar in structure and metabolism to that used in the Igaki-Tamai stent. Through a different method of processing, however, the PLLA backbone of the bioresorbable vascular scaffold has greater radial strength and its surface is coated with a matrix of the immunosuppressive and anti-proliferative drug, everolimus, and poly-D,L-lactic acid (PDLLA) in a 1:1 ratio. The PDLLA coating allows controlled release of everolimus at an elution rate that is optimised to provide neo-intimal hyperplasia suppression.[9,10] The combination of a biosorbable polymer and everolimus has been shown to be an effective and safe stent coating.[11]

Biodegradation process and lifecycle

The PLLA backbone and the PDLLA coating of the bioresorbable vascular scaffold are both fully degradable. Over a period of approximately 12 to 18 months, PLLA and PDLLA degrade to lactic acid. The lactic acid is subsequently completely metabolised via the Krebs cycle into H_2O and CO_2, which are absorbed by the body.[9] Scaffold degradation results in the loss of radial support one year after implantation, with the entire resorption process being completed within three years.[12]

The bioresorbable vascular scaffold has a three-stage lifecycle. In the first stage, revascularisation, which takes place during the first three months after implantation, the biodegradable scaffold provides good deliverability, high radial strength, and prevention of recoil and neo-intimal thickening that is comparable to that of metallic drug-eluting stents. The second stage, restoration, involves the gradual erosion of radial strength and a loss of structural continuity, which allows the return of normal vasomotor function to facilitate improved long-term outcomes. Finally, in the resorption stage, luminal support progressively declines as the scaffold is resorbed and processed by the body.[12]

Clinical experience

The first clinical studies evaluating the bioresorbable vascular scaffold, even if in small numbers of patients, the ABSORB Cohort A and Cohort B studies, have shown the feasibility of its use for the treatment of coronary artery disease and promising results with positive clinical and angiographic outcomes, and low rates of major adverse cardiac events, up to 5 years' follow-up. The results have highlighted the importance of late lumen enlargement and restoration of a normal vascular function.[4,13,14]

The first version of the bioresorbable vascular scaffold (BVS 1.0) showed considerable late shrinkage in the ABSORB Cohort A study, which contributed to late luminal loss, albeit less than that observed with bare metal stents.[15] The shrinkage was shown to have resulted from the polymeric scaffold losing structural integrity, in association with fatigue and constrictive remodelling of the vessel in the initial months following vessel injury. This prompted modification of the polymer and the

development of the second version of the bioresorbable vascular scaffold (BVS 1.1). BVS 1.1 has been shown in the ABSORB Cohort B study to have less late shrinkage and less neointimal growth than BVS 1.0, by virtue of a more uniform strut distribution and increased radial strength.[16,17]

In addition to the ongoing ABSORB Cohort B study, two more large studies, ABSORB-EXTEND and ABSORB II, have recently commenced. ABSORB-EXTEND is a registry that hopes to recruit 1000 patients and report the safety and efficacy of the device. ABSORB II is a prospective, randomized trial that will compare the safety, efficacy and performance of the bioresorbable vascular scaffold with that of the everolimus-eluting metallic stent in 501 patients with stable angina and single- or two-vessel disease. The ABSORB II study is expected to be completed by 2015.[18,19]

Benefits and limitations

The advantages of the bioresorbable vascular scaffold versus a metallic drug-eluting stent include the following:

- vessel is able to respond normally to pulsatile flow and factors released by the endothelium
- vessel is able to positively remodel
- compatibility with imaging by computed tomography and magnetic resonance
- stented segment is more likely to be suitable for future surgical revascularisation
- restenosis risk is reduced by release of everolimus
- reduction in bleeding complications – degradation and resorption of the scaffold potentially allows a shortened duration of anti-platelet therapy
- reduction in adverse events, such as scaffold-related thrombosis, because scaffolding and drug elution are temporary.[10]

Despite these many potential benefits, fully biodegradable stents, such as the bioresorbable vascular scaffold, have not completely replaced drug-eluting stents. Clinical data on biodegradable stents published to date is restricted to their use in simple lesions. In addition, compared with metallic drug-eluting stents, they are bulkier and not as easy to deploy and manoeuver in complex lesions. They also have size and length limitations, including restricted side-branch access. Therefore, biodegradable stents are not recommend for exceedingly tortuous vessels, heavily calcified vessels, complex bifurcation lesions, or left main disease. There are also concerns about their limited extensibility and risk of scaffold fracture.[17]

Future of the Bioresorbable Vascular Scaffold

The application and deployment limitations of the bioresorbable vascular scaffold in clinical practice are likely to be overcome with ongoing improvements in specific properties of the polymer scaffold, including reduced strut thickness, increased radial strength and extensibility, improved deliverability and versatility (i.e. range of sizes and lengths), and increased rate of resportion.

In terms of clinical outcome and utility, the use of the bioresorbable vascular scaffold has largely been restricted to small numbers of select patients recruited into clinical trials and a relatively small number of real-world patients treated. Further studies are needed to confirm the long-term efficacy and safety of the bioresorbable vascular scaffold in a wider range of patients, explore more extensively its use in real-world settings, and identify the subset of patients that will benefit the most from its use.[10,17,20]

EXPERT COMMENTARY ON KEY CLINICAL STUDIES

Circumferential evaluation of the neointima by optical coherence tomography after ABSORB bioresorbable vascular scaffold implantation: can the scaffold cap the plaque?

Brugaletta S et al.[21]

Summary: This study quantified the circumferential healing process using optical coherence tomography at six (28 patients; 28 lesions) or 12 (30 patients; 31 lesions) months follow-up in a total of 58 patients (59 lesions) who received an ABSORB BVS 1.1 implantation. The neointima area was not different between six and 12 months follow-up (1.57±0.42mm^2 vs 1.64±0.77mm^2; p=0.691). In addition, no difference was found in the mean thickness of the neointima (median [IQR]) between the two follow-up time points (210µm [180-260]) vs 220µm [150-260]; p=0.904). However, the symmetry of the neointima thickness was higher at 12 than at six months follow-up (ratio: 0.23 [0.13-0.28] vs 0.16 [0.08-0.21]; p=0.019).

Expert Commentary: This preliminary study sheds light on the potential future application of the bioresorbable vascular scaffold in treating vulnerable plaque by forming a stable neointima. It serves as a background evidence for future clinical research.

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?

Brugaletta S et al.[13]

Summary: This study assessed the vasoreactivity of a coronary segment, previously scaffolded using the bioresorbable vascular scaffold device, in relationship to its intravascular ultrasound-virtual histology (IVUS-VH) composition and reduction in greyscale echogenicity of the struts. Patients from the ABSORB Cohort A and B trials, who underwent a vasomotion test and IVUS-VH investigation at 12 and 24 months, were included. Overall, 26 patients underwent the vasomotion test (18 at 12 and 8 at 24 months). Vasodilatory response to Ach was quantitatively associated with larger reductions over time in polymeric strut echogenicity (y=–6.85–0.159x; r=–0.781, p<0.001). Scaffolded segments with vasoconstriction to acetylcholine had larger vessel areas (14.37±2.50 vs 11.85±2.54mm^2, p=0.030), larger plaque burden (57.31±5.96 vs 49.09±9.10%, p=0.018), and larger necrotic core areas [1.39 (+1.14, +1.74) vs 0.78mm^2 (+0.20, +0.98), p=0.006] compared with those with vasodilation.

Expert Commentary: Bioresorption of the scaffold restores the endothelial function over time. Larger vessels and lesions with a greater plaque burden or necrotic core may need more time to restore endothelial function.

Clinical and intravascular imaging 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

Diletti R et al.[22]

Summary: In this study, the impact of vessel size on long-term outcomes after bioresorbable vascular scaffold implantation was measured. In ABSORB Cohort B trial, 45 out of the total study population of 101 patients were assigned to undergo 6-month and 2-year angiographic follow-up (Cohort B1) and 56 patients to have angiographic follow-up at 1-year (Cohort B2). The pre-reference vessel diameter (RVD) was <2.5mm (small-vessel group) in 41 patients (41 lesions) and ≥2.5mm (large-vessel group) in 60 patients (61 lesions). At 2-year angiographic follow-up, no differences in late lumen loss (0.29±0.16mm vs 0.25±0.22mm, p=0.4391), and in-segment binary restenosis (5.3% vs 5.3% p=1.0000) were demonstrated between groups. In the small-vessel group, intravascular ultrasound analysis showed a significant increase in vessel area (12.25±3.47mm^2 vs 13.09±3.38mm^2, p=0.0015), scaffold area (5.76±0.96mm^2 vs 6.41±1.30mm^2, p=0.0008) and lumen area (5.71±0.98mm^2 vs 6.20±1.27mm^2, p=0.0155) between the 6-month and 2-year follow-up. No differences in plaque composition were reported between groups. At the 2-year clinical follow-up, no differences in ischaemia-driven major adverse cardiac events (7.3% vs 10.2%, p=0.7335), myocardial infarction (4.9% vs 1.7%, p=0.5662), or ischaemia-driven target lesion revascularisation (2.4% vs 8.5%, p=0.3962) were reported between small and large vessels. No deaths or scaffold thrombosis were observed.

Expert Commentary: This study suggests that the bioresorbable vascular scaffold works well in small vessels despite its thicker strut. Positive remodelling and bioresorption might counter balance the effect of neointimal hyperplasia. Further studies are necessary to determine the true benefit of the bioresorbable vascular scaffold in small vessels.

6-month clinical outcomes following implantation of the bioresorbable everolimus-eluting vascular scaffold in vessels smaller or larger than 2.5 mm

Diletti R et al.[23]

Summary: These researchers investigated 6-month clinical outcomes after implantation of second-generation 3.0mm bioresorbable everolimus-eluting vascular scaffolds (BVS) in small coronary vessels (<2.5mm). The ABSORB Cohort B trial is a multicentre, single-arm, prospective, open-label trial assessing the performance of the second-generation BVS, in which 101 patients were enrolled. The pre-procedural reference vessel diameter (RVD) was assessed by quantitative coronary angiography during post hoc analysis. The vessel size was overestimated, by visual assessment, in 41 patients before implantation of 3.0mm BVS in vessels with a pre-procedural RVD <2.5mm. The study population was divided into two groups, group I (n=41) with RVD <2.5 mm and group II (n=60) with RVD ≥2.5mm. The composite endpoint of ischemia-driven major adverse cardiac events, defined as ischemia-driven target lesion revascularization, myocardial infarction, or cardiac death, was assessed. Of the 45 patients scheduled for 6-month coronary angiography, 42 patients had the procedure performed, with intravascular ultrasound undertaken in 40 of these patients. At 6 months, there were no significant differences in ischaemia-driven major adverse cardiac events (3 of 41 [7.3%] cases vs 2 of 60 [3.3%] cases; p=0.3933) observed in the small- and large-vessel groups, respectively. No cardiac deaths or episodes of in-scaffold thromboses occurred. Angiographic and intravascular ultrasound follow-up demonstrated no differences in late lumen loss (0.16±0.18mm vs 0.21±0.17mm; p=0.3525) or percentage lumen area stenosis (17.6±6.0% vs 19.8±8.5%; p=0.3643).

Expert Commentary: This small study also suggests that the bioresorbable vascular scaffold works well in small vessels. However, further studies are needed to better define its role in small vessels.

Serial analysis of the malapposed and uncovered struts of the new generation of everolimus-eluting bioresorbable scaffold with optical coherence tomography

Gomez-Lara J et al.[24]

Summary: This study assessed the serial changes in strut apposition and coverage of the bioresorbable vascular scaffolds in 25 patients at baseline and six months, and related this with the presence of intraluminal masses at six months using optical coherence tomography. Struts were classified according to apposition, coverage, and presence of intraluminal masses. Persistent incomplete strut/scaffold apposition (ISA) was defined as malapposed struts present at baseline and follow-up, and late acquired ISA as ISA developing at follow-up, and scaffold pattern irregularities when the strut distribution suggested scaffold fracture. Of the 3,686 struts analysed at baseline, 128 (4%) were ISA and 53 (1%) were located over side-branches (SB). Of the 3,905 struts analysed at six months, 32 (1%) were ISA, and 35 (1%) were at the SB. Persistent ISA occurred more frequently than late acquired-ISA (81% vs 16%; 3% were unmatchable). Late acquired ISA was associated with scaffold pattern irregularities, which were related to overstretching of the scaffold. Uncovered struts (63 struts, 2%) occurred more frequently in ISA and SB struts compared with apposed struts (29% vs 1%; p<0.01). Intraluminal masses (14 cross-sections, 3%; in six patients, 24%) were more frequently located at the site of ISA and/or uncovered struts (39% vs 2% and 13% vs 2%, respectively; p<0.01).

Expert Commentary: This study showed that strut apposition during deployment was crucial to scaffold integrity and uniform resorption over time. Further study is needed to see whether strut malapposition will dictate future clinical outcome.

EXPERT'S CONCLUDING COMMENTS

The bioresorbable vascular scaffold is certainly a breakthrough in stent technology, a decade after drug-eluting stents. A biodegradable platform is the way to go!

In the meantime, there is still room for improvement in the current bioresorbable vascular scaffold platform. The bioresorbable vascular scaffold has a bigger profile than contemporary drug-eluting stents. Therefore, deliverability is not as good as its metallic counterpart. It has to be handled with extreme care to avoid dislodgement and damage to the scaffold. If the bioresorbable vascular scaffold is over-dilated it may fracture and collapse. If the scaffold is under-dilated there may be malapposition, which may predispose to scaffold thrombosis. The bioresorbable vascular scaffold strut is by far the thickest among the current drug-eluting stents. Side branch access and re-cross ability is thus limited as compared with the thinner strut of the drug-eluting stents.

If the side branch is over-dilated, the connector might fracture. In general, kissing balloon angioplasty is not recommended. However, several techniques have emerged to optimise bioresorbable vascular scaffold integrity in bifurcated lesions, such as mini-kissing balloon angioplasty and 'snuggle' kissing balloon angioplasty. In principle, the technique involves 'gentle' bifurcation dilation to avoid scaffold fracture. The 'TAP' technique ('T" with protrusion) may be applied in bail-out stenting in case of side-branch closure or dissection.

Prolonged inflation time during bioresorbable vascular scaffold deployment will increase the ischaemic time and patient intolerance. The lesion should be well expanded before deploying the stent. The 'dog-bone' effect in the bioresorbable vascular scaffold delivery system might increase the risk of edge tear. Optical coherence tomography is the best imaging technique to check the integrity, expansion, and apposition of the bioresorbable vascular scaffold.

With the improvements that have been made to the bioresorbable vascular scaffold platform and growing clinical experience with its use, this technology will be increasingly employed for more complex lesions. In addition, with increasing use, the bioresorbable vascular scaffold will hopefully become more affordable.

The benefits of the bioresorbable vascular scaffold compared with metallic implants include the absence of a metallic fixture, restoration of natural vessel function and elasticity, minimum risk of late-stent thrombosis, and capacity for future interventional procedures or bypass surgery at the same segment. Largely for these reasons, the bioresorbable vascular scaffold is very well accepted by patients, particularly younger patients.

Research is underway to look into the role of the bioresorbable vascular scaffold in vulnerable plaques. It would be very exciting to know whether the biosresorbable vascular scaffold could 'cap off' vulnerable plaques to prevent future plaque rupture.

Take-home Messages

The implantation of a coronary stent is one of the most common medical interventions used to re-open an occluded vessel. A bare metal stent is effective initially, but restenosis frequently occurs. The introduction of drug-eluting metallic stents has reduced restenosis rates, but they predispose recipients to late stent thrombosis, disrupted vascular function, and may preclude future revascularisation. Fullybiodegradable stents, including the everolimus-eluting bioresorbable vascular scaffold were developed to overcome these disadvantages. The main learning points from this review are as follows:

1. Biodegradable stents provide transient vessel support and anti-proliferative drug delivery without the limitations of – late stent thrombosis and impaired vascular function.
2. Biodegradable stents permit use of non-invasive techniques to check the performance of treated arteries and do not restrict future treatment options because the arteries are left free of a permanent implant.
3. The ABSORB series of clinical trials has demonstrated that the bioresorbable vascular scaffold is a safe and effective alternative to drug-eluting metallic stents in the treatment of patients with coronary artery lesions.
4. Additional studies are needed to confirm the long-term efficacy and safety of the bioresorbable vascular scaffold and to identify the type of patient who will benefit most from its use.

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