Current Status of Bioresorbable Scaffolds in the Treatment of Coronary Artery Disease

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ABSTRACT

State-of-the-art drug-eluting metal stents are the gold standard for interventional treatment of coronary artery disease. Although they overcome some disadvantages and limitations of plain balloon angioplasty and bare-metal stents, some limitations apply, most notably a chronic local inflammatory reaction due to permanent implantation of a foreign body, restriction of vascular vasomotion due to a metal cage, and the risk of late and very late stent thrombosis. The development of biodegradable scaffolds is a new approach that attempts to circumvent these drawbacks. These devices provide short-term scaffolding of the vessel and then dissolve, which should theoretically circumvent the side effects of metal drug-eluting stents. Various types of these bioresorbable scaffolds are currently under clinical evaluation. This review discusses different concepts of bioresorbable scaffolds with respect to material, design, and drug elution and presents the most recent evidence. (J Am Coll Cardiol 2014;64:2541–51) © 2014 by the American College of Cardiology Foundation.

New techniques for interventional treatment of coronary artery disease are continuously being developed. Important milestones include the launch of balloon angioplasty in 1977, the introduction of bare-metal stents in the 1980s, and the application of drug-eluting stents (DES) since 2000. DES were widely investigated in different settings, demonstrated clinical success, and entered into clinical guidelines as the treatment of choice for interventional revascularization of coronary artery stenosis (1,2). DES overcome disadvantages, such as acute vessel recoil and dissection risk after plain balloon angioplasty and decreased myocardial infarction and target lesion revascularization (TLR) rates compared with bare-metal stents due to reduced neointimal tissue growth (2). Despite these and other benefits, some concerns remain: the risk of late and very late stent thrombosis; continued neointimal tissue growth and neoatherosclerosis; malapposition; potential stent fracture; incomplete endothelialization; and vessel caging causing abnormal vasomotion.

An anticipated major cause of late and very late DES thrombosis is impaired arterial healing, possibly due to the durable coating, which results in a chronic inflammatory reaction with incomplete stent endothelialization and persistent fibrinogenesis and platelet aggregation, affecting blood flow and vessel remodeling (4–7). Next-generation metal stents with biodegradable polymer coatings are designed to overcome these shortcomings. A trial that randomly assigned patients to percutaneous coronary intervention (PCI) with DES with either a bioresorbable polymer coating or a durable coating demonstrated a significantly...
lower rate of definite very late stent thrombosis with the bioresorbable polymer coating during a 4-year follow-up (8). Additionally, improved vasomotion and endothelialization was seen (9,10), although hard endpoints (e.g., myocardial infarction, TLR, cardiac death) did not differ significantly (8,11). In another randomized, controlled trial, no significant differences were observed in outcomes between DES types during a 3-year follow-up (12). Furthermore, a recent meta-analysis revealed nonsuperiority, even inferiority, of DES coated with bioresorbable polymer compared with cobalt-chromium everolimus-eluting stents (13). In addition to the need for more long-term data, further challenges must be addressed to improve preliminary results. Nevertheless, this stent type cannot resolve long-term vessel caging and the side effects associated with permanent implants.

The next interventional cardiology advance may be the introduction of bioresorbable scaffolds (BRS). The term scaffold highlights the temporary nature of a BRS, distinct from a stent associated with a permanent implant. All resorbable scaffolds are commonly referred to as bioresorbable, even though some are not made of biomaterials.

The idea of dissolvable scaffolds is not new, dating to the description of Tamai et al. (14) of the first successful use of a fully degradable stent in the early 1990s. However, this concept was nearly forgotten due to the success of bare-metal stents and, later, DES. With long-term data and the revelation of the risks of metal stents, BRS development was reinitiated, resulting in a variety of devices.

MATERIAL COMPOSITION AND PROPERTIES

The optimal BRS should ensure adequate short- to mid-term scaffolding of the previously stenosed vessel to avoid recoil and completely dissolve afterward to prevent side effects. Thus, temporarily sufficient radial support is needed, with struts as thin as possible. The design should warrant deliverability and straightforward handling, flexibility in different anatomic circumstances, and integrity during resorption. The optimal duration until full resorption is not yet defined. To achieve these goals, a considerable variety of materials and designs are under investigation.

Furthermore, the use of drug elution is inconsistent. Several different substances have been applied, and some BRS are noneluting. The current trend is toward broader use of drug elution, with mTOR (mammalian target of rapamycin) inhibitors as the most frequently used antiproliferative drugs in DES.

The Central Illustration provides an overview of different designs and characteristics of existing BRS, with representative images in Figures 1 and 2.

POLY-L-LACTIC ACID. Different materials are used for manufacturing BRS, with poly-L-lactic acid (PLLA) being the most commonly used. For most existing PLLA-based devices, strut thickness is 150 μm. A BRS currently being developed has the thinnest struts (100 μm) of all BRS, irrespective of composition. According to the manufacturer, a PLLA-based scaffold has radial strength comparable to that of current drug-eluting metal stents. Directly after implantation, radial strength is ~1,200 mm Hg, and the observed radial force can still be as great as 800 mm Hg after 1 year. Degradation by hydrolysis of interlactic bonds of the long PLLA chains results in particles that macrophages can phagocytose. The end product is lactic acid, metabolized via pyruvate into carbon dioxide and water through the Krebs cycle (15), with complete degradation achieved in 1 to 3 years (Central Illustration). Figure 3 shows degradation over time of the BRS compared with the Xience DES (Abbott Vascular, Santa Clara, California). PLLA-based devices ensure radial support for ~6 months.

MAGNESIUM. Magnesium, complemented by rare earth metals to improve radial strength, is another currently used BRS production base. The first magnesium-based scaffolds were uncoated and lacked antiproliferative drug elution. The underlying idea is that the electronegative charge that emerges during the degradation of metal BRS is antithrombotic (16,17). A further potential benefit is its high mechanical strength, making it a stent with thinner struts, but radial strength similar to that of other bioresorbable scaffolds, possible. Depending on composition, degradation takes between 2 and 12 months. The products of stent dissolution by corrosion are inorganic salts (17). The latest generation device offers 9 to 12 months of radial support (18).

OTHER MATERIALS

A tyrosine polycarbonate-based BRS providing up to 6 months of radial support is also under investigation. Resorption takes between 24 and 36 months. Final products of degradation, which starts with hydrolysis and ends with the Krebs cycle, are ethanol, water, and carbon dioxide (19).

A BRS made of polyactic anhydride containing 2 salicylic acid molecules linked to 1 sebacic acid...
molecule was developed to provide mechanical support. Degradation into salicylate, water, and carbon dioxide is complete within ~15 months (19).

**POTENTIAL BENEFITS**

BRS achieve successful acute revascularization of coronary artery lesions and show reasonably low rates of TLR and major adverse cardiac events (MACE) during early follow-up (Central Illustration). Multiple imaging analyses reveal beneficial plaque stabilization and sealing caused by BRS-induced remodeling (20), although the clinical impact needs further assessment. Due to BRS degradation, no foreign body remains in the vessel long term. Thus, late and very late stent thrombosis risks are potentially reduced or eliminated, depending on resorption duration. Total stent length is a well-known stent thrombosis risk factor. Because BRS dissolve, this risk may be reduced, especially in long or complex lesions and diffuse disease, when several would be implanted simultaneously. Additionally, the permanent complete side-branch occlusion risk may decrease. Because struts degrade, long-term uncovered stent struts are unlikely to factor in stent thrombosis. Incomplete endothelialization was observed for DES as long as 40 months after implantation (7). There are also reduced neointimal tissue growth and neoatherosclerosis and chronic inflammation risks as actions to a permanent metal implant, all well-known late and very late stent thrombosis triggers in DES. Because the BRS coating is degradable, not durable, another stent thrombosis stimulus is absent. Intravascular ultrasound (IVUS) and optical coherence tomography (OCT) examinations display late lumen enlargement in numerous patients with the Absorb biodegradable vascular scaffold (BVS) and DESolve BRS (Elixir Medical Corporation, Sunnyvale, California) (15,21-29).

The initial mechanical flexibility of some BRS may maintain original vessel geometry better than rigid metal stents; this would reduce their influence on biomechanical properties and blood flow. Furthermore, minor malaposition can be resolved by BRS self-correction, and its degradation avoids long-term malaposition (29). Incomplete stent apposition, as observed with DES after thrombus resolution, is also unlikely. Because there is no long-term vessel caging, abnormal shear stress may be reduced, as revealed by restored vasomotion (30). In contrast, paradoxical vasoconstriction was observed after DES implantation, most likely due to impaired endothelial function (31). BRS are better suited than metal stents for noninvasive imaging, such as coronary computed tomography and magnetic resonance imaging, because they do not cause artifacts, and follow-up is possible with these modalities. Moreover, BRS implantation might allow surgeons to carry out anastomosis of coronary artery bypass grafts at distal segments, and in patients who might require multiple interventions, there will be no interference with previously implanted DES because side branches can sometimes be especially difficult to recross.

**THE FIRST BIORESORBABLE SCAFFOLD**

The Igaki-Tamai stent (Kyoto Medical Planning Co., Ltd., Kyoto, Japan) was the first BRS used in humans. This PLLA-based BRS is self-expandable when heated; consequently, contrast dye at 80°C is used for balloon inflation. Expansion continues at body temperature until dilation and vessel wall resistance reach equilibrium. In 2000, Tamai et al. (14) reported initial results from 15 patients in whom 25 stents were successfully implanted. Long-term data with >10 years of follow-up for 50 patients treated with 84 Igaki-Tamai biodegradable stents are available (32). Interestingly, during the first 6 months, minimal lumen diameter decreased and then constantly increased to 2.22 ± 0.56 mm at the 3-year follow-up. IVUS analysis showed almost constant stent cross-sectional area after 1, 2, and 3 years, whereas minimal lumen cross-sectional area decreased from 5.44 mm² immediately after the procedure to 3.64 mm² after 6 months, then increased to 5.18 mm² after 3 years. During the follow-up period, a total of 14 TLRs, 1 acute scaffold thrombosis and 1 very late scaffold thrombosis, 1 lesion-related myocardial infarction, and 1 cardiac death were noted. Accordingly, cumulative TLR rates per patient were 16% after 1 and 3 years, 18% after 5 years, and 28% after 10 years (32).

Despite these promising results, development of the Igaki-Tamai biodegradable stent was discontinued due to 2 limitations: first, implantation requires an 8-French guiding catheter, and second, the heated contrast dye may cause vessel wall injury. A new version of the device is currently undergoing pre-clinical evaluation.

**BIORESORBABLE SCAFFOLDS CURRENTLY AVAILABLE IN CLINICAL PRACTICE**

Several BRS types are currently in development, but only 2 have the Conformité Européenne (CE) mark for use in coronary artery disease: the Absorb biodegradable vascular scaffold (BVS) (Abbott Vascular) and the DESolve scaffold (Elixir Medical Corporation).
### Results for Current Existing Bioresorbable Scaffolds

<table>
<thead>
<tr>
<th>Basic material</th>
<th>POLY-LACTIC ACID</th>
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<tbody>
<tr>
<td><strong>Scaffold name</strong></td>
<td>Igaki-Tamai Stent</td>
</tr>
<tr>
<td><strong>Manufacturer</strong></td>
<td>Kyoto Medical Planning Co, Ltd, Kyoto, Japan</td>
</tr>
<tr>
<td><strong>Composition</strong></td>
<td>PLLA</td>
</tr>
<tr>
<td><strong>Design of the latest generation</strong></td>
<td>Zigzag helical coil</td>
</tr>
<tr>
<td><strong>Thickness of strut, μm</strong></td>
<td>170</td>
</tr>
<tr>
<td><strong>Visualization</strong></td>
<td>Radiopaque markers at both ends</td>
</tr>
<tr>
<td><strong>Special feature</strong></td>
<td>Self-expandable when heated</td>
</tr>
<tr>
<td><strong>Anti-proliferative drug elution</strong></td>
<td>No</td>
</tr>
<tr>
<td><strong>Resorption time</strong></td>
<td>3 yrs</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>CE mark (for peripheral use)</td>
</tr>
<tr>
<td><strong>Trials (no. in cohort and duration)</strong></td>
<td>Igaki-Tamai-FIM</td>
</tr>
<tr>
<td><strong>Imaging findings</strong></td>
<td>Acute recoil: 22 ± 7%</td>
</tr>
<tr>
<td><strong>Target lesion recanalization</strong></td>
<td>16% at 1 year</td>
</tr>
<tr>
<td><strong>Major adverse cardiac events</strong></td>
<td>50% at 10 yrs</td>
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**Continued on the next page**
The Igaki-Tamai stent (Kyoto Medical Planning Co., Ltd.) also has the CE mark, but only for peripheral use. No devices have U.S. Food and Drug Administration approval.

The most widely investigated bioresorbable scaffold to date is the BVS. It is made of PLLA, its strut thickness is 150 μm, and it elutes a 1:1 mixture of poly-D,L-lactic acid and the antiproliferative drug, everolimus. Full hydrolytic degradation takes as long as 3 years. (21)

The first-generation BVS was investigated in the ABSORB Cohort A, a first-in-humans trial. This prospective, open-label study included 30 patients with a single de novo coronary artery lesion. Device success was achieved in 94% of the patients (15). During 5 years of follow-up, the MACE rate was 3.4%, owing to

<table>
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<tr>
<th>Scaffold name</th>
<th>MAGNESIUM</th>
<th>OTHER</th>
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<tbody>
<tr>
<td><strong>Basic material</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Manufacturer</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Composition</strong></td>
<td>Magnesium and rare earth metals</td>
<td>Magnesium and rare earth metals</td>
</tr>
<tr>
<td><strong>Design of the latest generation</strong></td>
<td>4-crown design</td>
<td>6-crown design</td>
</tr>
<tr>
<td><strong>Thickness of strut, μm</strong></td>
<td>165</td>
<td>120</td>
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<tr>
<td><strong>Visualization</strong></td>
<td>Latest generation with radiopaque markers</td>
<td>Fully radiopaque</td>
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<tr>
<td><strong>Special feature</strong></td>
<td>Electronegative charge that emerges during degradation process has an antithrombotic function</td>
<td>--</td>
</tr>
<tr>
<td><strong>Anti-proliferative drug elution</strong></td>
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<td>Paclitaxel</td>
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<tr>
<td><strong>Resorption time</strong></td>
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<td>--</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>Clinical evaluation</td>
<td>Clinical evaluation</td>
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**Trials (no. in cohort and duration)**

| | PROGRESS AMS | BIOSOLVE-I | BIOSOLVE-II | FIM | RESTORE |
| | 63 patients up to 28 mos | 46 patients up to 3 yrs | -- | 15 mos | 26 patients 12 mos |

**Imaging findings**

| | In-stent lumen diameter: 2.47 ± 0.37 mm post-procedural; 1.38 ± 0.51 mm at 4 mos | Degree of stenosis: 12.65 ± 5.33% post-procedural; 48.37 ± 17.0% at 4 mos | LLL: 0.29 ± 0.33 mm at 12 mos | -- | -- |
| | MLD: 0.65 ± 0.5 at 6 mos; 0.52 ± 0.39 mm at 12 mos | Scaf- fold CSA: 7.29 ± 1.39 mm² post-procedural; 6.49 ± 2.11 mm² at 6 mos; 6.40 ± 20.4 mm² at 12 mos | -- | 3 cases after 12 mos | -- |
| | Target lesion revascularization | 39.7% at 4 mos 45.0% at 12 mos | 4.7% at 12 mos | -- | -- |
| | Major adverse cardiac events | 23.8% at 4 mos 26.7% at 12 mos | -- | -- | -- |

Various bioresorbable scaffolds (BRS) are under investigation, and an overview of the different compositions, designs, current status, and results are presented. CE = Conformité Européene; CSA = cross-sectional area; DES = drug-eluting stent; FiM = first-in-man; ID = ischemia driven; LLL = late lumen loss; MLD = minimal lumen diameter; PDLA = poly-D-lactic acid; PLLA = poly-L-lactic acid.
1 non-Q-wave myocardial infarction in a previously untreated vessel (22). Furthermore, restoration of vasomotion was demonstrated by OCT (23). A decrease in stent minimal lumen diameter during 2 years of follow-up was also noted (23). Additional evaluation showed BVS shrinkage due to acute recoil in quantitative coronary angiography and late recoil in IVUS (24,25).

Taking these findings into account, a new version, BVS 1.1, was developed. The struts were redesigned, leading to increased radial strength, longer radial support, and optimized drug transfer. BVS strut thickness was unchanged, and room-temperature BVS storage was now possible (26). The ABSORB Cohort B study evaluated the second-generation BVS. During 2 years of follow-up, the overall MACE rate was 9.0% (27). Late lumen loss in quantitative coronary angiography was substantially lower than in Cohort A. IVUS demonstrated a significant minimal lumen area decrease at the 6-month follow-up, which remained almost unchanged at the 2-year follow-up. Remarkably, the mean lumen area also decreased initially, but then increased significantly 2 years after the index procedure. OCT showed a constantly increasing scaffold area (27). In contrast, the mean scaffold area did not change significantly between the post-procedural and 12-month OCT and IVUS examinations in the Cohort B2 study (28). Nevertheless, there was no evidence of late or very late scaffold recoil. Vasomotion was tested by application of either acetylcholine or methylergonovine and subsequent lumen measurements, which revealed restoration of pharmacologically induced vasomotion 12 months after the procedure (28).

ABSORB EXTEND is another international multicenter study, including those with long lesions and small vessels (33). Preliminary results published with 24 months of clinical follow-up of 250 patients demonstrated a MACE rate of 7.3%, an ischemia-driven TLR rate of 4.0%, and a stent thrombosis rate of 0.8% (according to the Academic Research Consortium possible/definitive definition) (34). A randomized, controlled trial comparing BVS and DES is currently ongoing.

The other CE-approved, commercially available (in Europe) BRS is the DESolve scaffold (Elixir Medical Corporation), manufactured from PLLA and eluting a mixture of anti-inflammatory myolimus and PLLA. Strut thickness is 150 μm, and >95% of the device is resorbed after ~1 year. Its advantage, compared with other BRS, is a wider range of expansion, with consequently reduced strut fracture risk, and self-correction of minor malapposition. During the 12-month follow-up period of the multicenter DESolve first in humans trial, 1 TLR occurred between 30 days and 6 months; there were
2 other MACE events but no evidence of scaffold thrombosis.

The DESolve Nx study is currently investigating a DESolve scaffold refinement, including elution of antiproliferative novolimus and a larger device size spectrum. The MACE rate at 1-year follow-up was 5.7% for 126 enrolled patients. Additionally, the lumen area, assessed by OCT, IVUS, and computed tomography, was almost constant during follow-up (35). Further evaluation in the DESolve NX II pivotal trial is ongoing. A refined version, with 100-µm strut thickness, will soon be available commercially.

In addition to the devices carrying the CE mark, other BRS concepts are under clinical and pre-clinical evaluation. The Central Illustration provides an overview of different designs and characteristics of existing BRS, with representative images in Figures 1 and 2.

**OFF-LABEL USE AND SPECIAL CONSIDERATIONS**

Preliminary results from registries investigating patients with acute coronary syndrome and ST-segment elevation myocardial infarction are available and show reasonable short-term outcomes and results comparable to those of patients treated with DES (36,37). Data comparing BRS use in diabetic with nondiabetic patients and diabetic patients who underwent DES implantation found no significant differences regarding the composite endpoint of cardiac death, target vessel myocardial infarction, and TLR at 1-year follow-up (38). However,
Diabetic patients have an increased repeat revascularization risk due to diffuse diseased vessels and a higher in-stent restenosis and stent thrombosis risk (3). Hence, from a long-term perspective, diabetic patients might benefit from BRS rather than DES.

Although BRS use for left main coronary artery disease was described (39), because the left main coronary artery usually has a larger vessel diameter than other coronary arteries and BRS are only available in limited sizes and have strict expansion ranges, its application should be limited. In contrast, BRS use is more feasible in small vessels and with reasonable results (40).

BRS seem attractive for treatment of in-stent restenosis (41). Compared with drug-eluting balloons, they provide short-term scaffolding, ensure drug delivery, and do not affect vessel diameter with another metal layer, as with DES. Indeed, BRS strut thickness must be considered in deciding whether to use BRS or another option.

BRS implantation for treatment of chronic total occlusions is feasible (42) because stent length is a predictor of in-stent restenosis, and stent thrombosis can be avoided by device dissolution. If multiple BRS are required, special care should be taken to minimize overlap due to the strut thickness of currently available BRS. In addition, the feasibility of subintimal tracking is thus far unclear.

Successful BRS use in bifurcations was also described (43,44). When treating bifurcations, simultaneous post-dilation of the main and side branches (“kissing”) is often required to resolve stent distortion. Due to scaffold fracture risk, post-dilation in BRS-treated patients should be performed with a “mini-kissing” post-dilation technique with minimal balloon overlap (44).

Although challenging, BRS implantation is also feasible for ostial lesions (45). Proper lesion sizing and BRS positioning are essential to avoid malapposed scaffold struts that protrude from the ostium because subsequent post-dilation may cause scaffold fracture. BRS implantation in vein grafts was also performed (46), but vessel dimensions and a tapered shape often limit their use.

These findings are derived from registry data and case reports, all performed with the Absorb BVS. All cases were highly selected, and procedures were performed in high-volume centers experienced in PCIs with BRS. General BRS use restrictions must always be considered, including the presence of heavy calcification, severe tortuosity, and the BRS expansion ranges. Thus, BRS implantation should currently be reserved for patients with simple lesions.
and, until more evidence is available, should always be performed according to the manufacturer’s recommendation.

CURRENT LIMITATIONS

Some possible benefits of BRS are hypothetical or only demonstrated in animal testing or small human cohorts, for example, the impact of resting vaso-motion. Most data derive from small, nonrandomized studies investigating patients with stable coronary artery disease and de novo lesions. Hence, relatively few patients were treated and experience in other anatomic settings (e.g., bifurcation lesions, long lesions, small vessels) or clinical presentations (e.g., acute coronary syndrome) is limited. Thus, in complex lesions, intravascular imaging should support BRS implantation.

There are practical concerns regarding strut thickness, which is greater than in conventional stents and may lead to vessel injury, nonlaminar flow, platelet deposition, and poor deliverability. Thus, mechanical considerations seem more challenging, especially when calcification or tortuosity are present. Regardless of lesion anatomy, pre-dilation is mandatory; direct stenting is not possible. Due to pre-dilation, a longer balloon inflation time, and post-dilation, if necessary, more induced myocardial ischemia might be associated with BRS implantation than DES. Due to the lack of radial strength of some BRS and poor deliverability in complex lesions, prolonged, extensive, and time-consuming pre-dilation is required, increasing the risk of pre-dilation dissections that might require longer and/or overlapping stents. There is an apparently increased scaffold fracture risk with over-dilation; thus, significant BRS upsizing is impossible. The relatively long dilation time during deployment may also need to be reduced. Only limited scaffold sizes are currently available, and special facilities are needed for storage of some. Due to these technical particularities, the total cost and duration of PCI with a BRS may be higher than with a conventional DES.

Thus far, the optimal duration of dual-antiplatelet therapy in conjunction with BRS application is unclear. Although with some devices, resorption is achieved after a relatively short time and a reduction seems prudent, reduced shear stress from the thick struts of current BRS may cause platelet activation.

Multiple processes, including release of active drugs and polymer resorption, could adversely affect metal DES. This is illustrated by the impact of acquired malapposition, in the sense of defective healing, compared with the lack of stent strut apposition at the end of the procedure. Thus, defective healing and late adverse reactions may not be completely avoided with BRS.

Current BRS limitations will likely be resolved in the future. Although their advantages already outnumber their disadvantages, large, randomized, controlled trials are still needed.

CONCLUSIONS

Considerable progress is being made in advancing BRS for interventional treatment of coronary artery disease. This technique offers advantages beyond scaffolding a stenosed vessel and may circumvent limitations of current DES. Preliminary results demonstrate technical feasibility and variable, partly positive clinical outcomes. Increasing BRS experience is resulting in a broader spectrum of indications for their use. However, some restrictions exist, and further refinements are required. Although numerous bioresorbable stent devices are designed to achieve outcomes superior to state-of-the-art metal DES, for many, current results are inferior with respect to device success, recoil, MACE, lumen areas, and TLR. More randomized clinical data will be required to determine whether this new technology’s theoretical advantages will outweigh its limitations.

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