Table 1. Inclusion and Exclusion Criteria

"Real World" Patients
No lesion length limit
Multiple stents allowed
Common stent fractures (Grades 1 - 3)
Popliteal stents included
Key Inclusion Criteria
ISR lesion ≥ 4 cm
Rutherford classification 1 - 4
RVD ≥ 5.0 mm and ≤ 7.0 mm
≥ 1 patent tibial artery
Key Exclusion Criteria
Target lesion extends > 3 cm beyond stent margin
Untreated inflow lesion
Grade 4 or 5 stent fracture
Follow-up
Discharge, 30 days, 6 months, and 1 year post procedure

ISR, in-stent restenosis; RVD, reference vessel diameter.
Reproduced with permission from EJ Dippel, MD.

Procedural success was significantly greater for and residual stenosis was significantly less in the ELA + PTA group (94% vs 83%; $P = .03$ and 5% vs 14%; $P = .02$). The need for TLR in the year following surgery was significantly less for those receiving ELA + PTA ($P < .003$). One-year survival and freedom from major adverse events was significantly higher in those receiving ELA + PTA ($P < .005$ and $P < .001$, respectively).

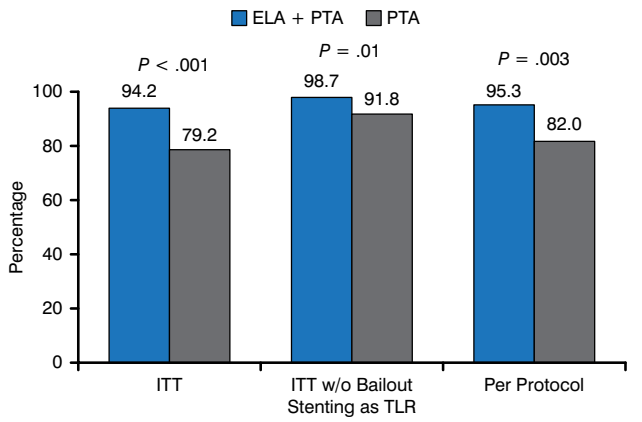
ELA + PTA compared with PTA alone was associated with less TLR (5% vs 16%; $P = .008$), dissection (8% vs 17%; $P = .03$), > Grade C (2% vs 7%; $P = .08$), bailout stenting (4% vs 11%; $P = .02$), thrombosis (1% vs 3%; $P = .25$), and abrupt closure (0% vs 1%; $P = .23$). PTA alone was associated with decreased embolization (8% vs 5%; $P = .47$).

The primary safety and efficacy end points significantly favored ELA + PTA (Figures 1 and 2).

The advantage of ELA + PTA over PTA held following a battery of subgroups included those based on age, diabetes, prior ISR, artery occlusion, artery diameter, lesion length, and other parameters.

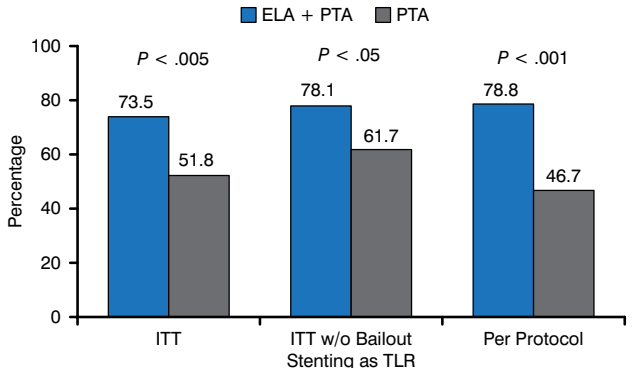
Thus, ELA + PTA treatment of ISR was found to be superior to PTA for the treatment of femoropopliteal ISR involving complicated lesions. Large scale trials are needed to determine if this should be considered standard of care in patients with femoropopliteal ISR.

Figure 1. Primary Safety End Point



ELA, excimer laser atherectomy; ITT, intention-to-treat; PTA, percutaneous transluminal angioplasty; TLR, target lesion revascularization.
Reproduced with permission from EJ Dippel, MD.

Figure 2. Primary Efficacy End Point



ELA, excimer laser atherectomy; ITT, intention-to-treat; PTA, percutaneous transluminal angioplasty; TLR, target lesion revascularization.
Reproduced with permission from EJ Dippel, MD.

Satisfactory Angiographic and Clinical Outcomes With the Everolimus-Eluting BVS

Written by Toni Rizzo

New generation drug-eluting stents (DESs) are increasingly efficient and safe. The ABSORB everolimus-eluting bioresorbable vascular scaffold (BVS) is thought to reduce long-term complications, including neoatherosclerosis and very late stent thrombosis. The effectiveness of the BVS has been demonstrated in patients with noncomplex lesions but it is increasingly being

used in patients with complex lesions. The objective of the Comparison of Everolimus- and Biolimus-Eluting Stents With Everolimus-Eluting Bioresorbable Vascular Scaffold Stent trial [EVERBIO II; NCT01711931], presented by Stéphane Cook, MD, University of Fribourg, Fribourg, Switzerland, was to compare the efficacy of the BVS with the best-in-class new generation DESs—the everolimus-eluting stent (EES PROMUS ELEMENT) and biolimus-eluting stent (BES BIOMATRIX FLEX).

Patients with stable coronary artery disease (CAD) or acute coronary syndrome (ACS) undergoing percutaneous intervention (PCI) were randomized to the EES (n = 80), BES (n = 80), or BVS (n = 78). Clinical follow-up took place at 1, 6, 9, and 12 months and 2 and 5 years, with angiography at 9 months. The primary end point was in-stent late lumen loss (LLL) at 9 months. Secondary end points were in-segment LLL, patient-oriented major acute cardiac events (MACE; death, myocardial infarction [MI], and target vessel revascularization [TVR]), device-oriented MACE (cardiac death, MI, and target lesion revascularization), and stent thrombosis.

There were no significant differences in baseline characteristics between the 3 groups. No significant difference was observed in the cumulative frequency of in-stent LLL between the EES and BES groups combined (EES/BVS; 0.25 ± 0.36 mm) and the BVS group (0.28 ± 0.39 mm; $P = .30$). At nine months, there was no significant difference in the cumulative frequency of in-stent LLL between the EES (0.24 ± 0.32 mm), BES (0.25 ± 0.41 mm), and BVS (0.28 ± 0.39 mm) groups.

Stratified analysis found no significant differences in in-stent LLL between the EES/BES and BVS groups in patients with or without diabetes, ACS, or complex lesions.

In-segment LLL was significantly more frequent with the BVS (0.30 ± 0.44 mm) vs the EES/BES (0.19 ± 0.42 mm; $P = .03$). Stratified analysis found no significant differences in in-segment LLL between the EES/BES and BVS groups in patients with or without diabetes, ACS, or complex lesions.

There were no significant differences in dual antiplatelet therapy (DAPT) use in the EES/BES vs BVS, EES vs BVS, and BES vs BVS groups. No significant differences were observed in clinical outcomes at 9 months, including device-oriented MACE, patient-oriented MACE, TVR, and stent thrombosis, in the EES/BES vs BVS, EES vs BVS, and BES vs BVS groups.

This study had several limitations. It was not powered for noninferiority or to detect differences in clinical event rates. The study was performed in a single center with uniform procedural strategies that limit generalizations to other centers. Additionally, the investigators did not address the effect of the BVS on thrombotic risk.

In a patient population with minimal exclusion criteria and using LLL as an early and robust marker for restenosis, the BVS demonstrated satisfactory angiographic and clinical outcomes compared with the EES/BES. In-segment LLL was slightly but significantly higher with the BVS compared with the EES/BES. A possible explanation for this difference may be the modest and transient constrictive effect at the scaffold edges [Gogas B et al. *JACC Cardiovasc Interv.* 2012]. These results reinforce the authors' primary hypothesis of DES superiority within 6 to 12 months. The optimal DAPT duration after BVS implantation is not known.

Similar 12-Month BP Reductions With Renal Denervation and Sham Procedure

Written by Toni Rizzo

The Renal Denervation in Patients With Uncontrolled Hypertension trial [SYMPLICITY HTN-3; NCT01418261] was the first randomized, blinded, sham-controlled clinical trial of renal denervation for treatment-resistant hypertension. The 6-month results confirmed the safety of renal denervation but the primary efficacy end point was not met [Bhatt DL et al. *N Engl J Med.* 2014]. In addition to the blinding and sham control, post hoc analyses have identified potential factors that may account for the negative results, including the patient population and procedural variability. Deepak L. Bhatt, MD, MPH, Brigham and Women's Hospital, Boston, Massachusetts, USA, presented the 12-month post hoc analysis of the SYMPLICITY HTN-3 trial.

After 2 screening visits, potential subjects with refractory hypertension underwent renal angiogram and eligible patients were randomized to renal denervation (n = 364) or a sham procedure (n = 171) [Bhatt DL et al. *N Engl J Med.* 2014]. Medication changes were not permitted for 6 months. The primary efficacy end point of office systolic BP (SBP) at 6 months was significantly reduced from baseline in the denervation (n = 353; $P < .001$) and sham (n = 171; $P < .001$) groups but was not significantly different between the 2 groups ($P = .26$).

All clinicians and patients were unblinded to randomization after the 6-month evaluation. Sham control patients were permitted to crossover to renal denervation following the 6-month primary assessment if they continued to meet the study inclusion criteria. Study follow-up will continue for up to 5 years.

A total of 322 patients (91%) in the denervation group completed the 12-month postdenervation follow-up.