Late-Breaking Trials: Embargoed Until 10:10 AM PST

HIGHLIGHTS FROM TODAY'S TRIAL PRESENTATIONS.

ESPRIT I TRIAL: 3-YEAR RESULTS OF THE EVALUATION OF THE ESPRIT BIORESORBABLE VASCULAR SCAFFOLD IN THE TREATMENT OF PATIENTS WITH OCCLUSIVE VASCULAR DISEASE OF THE SFA OR COMMON OR EXTERNAL ILIAC ARTERIES

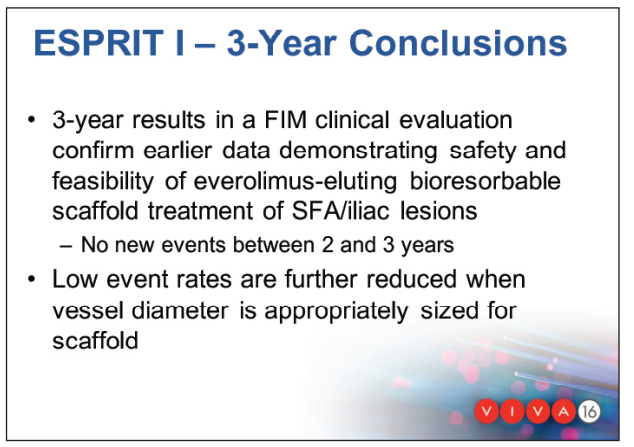
Presenter: Michael R. Jaff, DO

The purpose of the ESPRIT I clinical investigation was to evaluate the safety and performance of the Esprit everolimus-eluting bioresorbable vascular scaffold (Abbott Vascular) in subjects with symptomatic claudication from occlusive vascular disease of the superficial femoral (SFA) or common or external iliac arteries. The trial was a prospective, single-arm, open-labeled, multicenter clinical investigation in which 35 subjects were enrolled at seven clinical sites in Europe. The study subjects have completed follow-up through 3 years.

Clinical assessment and peak systolic velocity ratio assessed by duplex ultrasound was performed at 1, 6, and 12 months and at 2 and 3 years. Angiographic follow-up was performed at 12 months.

Thirty-five study scaffolds (6- X 58-mm size) and one non-study stent were placed in 35 patients who had Rutherford Becker (RB) category 1 to 3 with lesion length of 35.5 mm and reference vessel diameter of 4.9 mm. Acute device success was 100%. Angiographic restenosis at 1 year was lower in smaller vessels, where scaffold size was matched appropriately to vessel diameter. The 3-year results confirm earlier data demonstrating the safety and feasibility of treatment with the Esprit bioresorbable vascular scaffold for SFA and iliac lesions, with no new events occurring between 2 and 3 years.

Duplex ultrasound showed sustained patency through 3 years, with peak systolic velocity ratio of 1.67, 1.56, and 1.66 at 1, 2, and 3 years, respectively. There was one death which was unrelated to the study procedure or device. There were no amputations, and scaffold occlusion rate was 2.9%. The Kaplan-Meier freedom from target lesion revascularization was 91.2%, 88.1%, and 88.1% at 1, 2, and 3 years, respectively. The improvement in RB category observed after procedure was sustained through 3 years, where the claudication-free RB category 0 comprised 73.5%, 71%, and 76% of subjects at 1, 2, and 3 years, respectively.



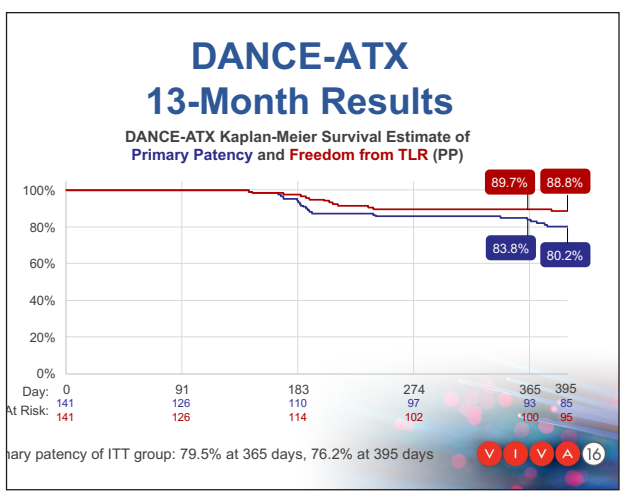
12-MONTH RESULTS FROM THE DANCE TRIAL ATHERECTOMY COHORT

Presenter: Chris Owens, MD, MSc

The DANCE trial is a 281-patient, multicenter, single-arm trial examining the local micro-infusion delivery of dexamethasone into the adventitial and perivascular tissues via the Bullfrog device (Mercator MedSystems) to safely reduce restenosis rates in patients with atherosclerotic obstructive lesions of the superficial femoral and/or popliteal arteries. Two revascularization treatment options were evaluated with dexamethasone use: atherectomy and percutaneous transluminal angioplasty. The primary efficacy endpoint is primary patency (lack of target lesion revascularization and duplex ultrasound peak systolic velocity ratio ≤ 2.4) at 12 months.

The adventitia is an ideal drug reservoir for treating cardiovascular diseases that are subject to barotrauma and thus, inflammation. Local delivery of the generic anti-inflammatory steroid dexamethasone at a dose of 1.6 mg per centimeter along the target lesion length is intended to block the injury-related vessel inflammation associated with revascularization and thereby reduce restenosis. By placing drug through the media and outside the external elastic lamina, the onset of the restenosis cascade can be treated without the uncertainty of whether sufficient drug has migrated from the intima outwardly through calcification or heavy plaque burden.

The DANCE trial enrolled 157 patients who received primary atherectomy revascularization and 124 patients who received PTA without atherectomy. Enrollment demographics showed a higher proportion of critical limb ischemia (Rutherford 4), complex lesions (TASC II B), and severe calcification than published drug-coated balloon studies. After revascularization, at 4 weeks, 6, 12, and 18 months, hemodynamic, clinical, and duplex ultrasound assessments were performed. The atherectomy group has completed 1-year follow-up, and the intent-to-treat population had a 1-year primary patency rate of 79.5% by Kaplan-Meier. The per-protocol population (for the purpose of matching eligibility to published drug-coated balloon trials) had a Kaplan-Meier primary patency rate of 83.8% at 365 days and 80.2% at 395 days.



USE OF AN ePTFE BALLOON-EXPANDABLE COVERED STENT FOR OBSTRUCTIVE LESIONS IN THE ILIAC ARTERY: 9-MONTH RESULTS FROM THE PROSPECTIVE, MULTICENTER BOLSTER TRIAL

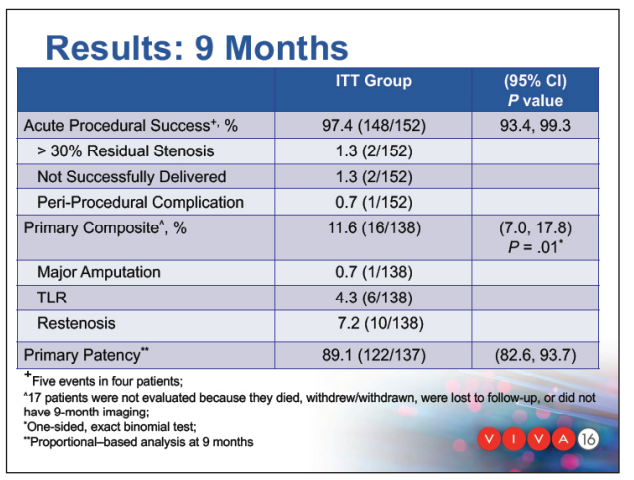
Presenter: John Laird, MD

BOLSTER is a prospective multicenter study with 17 enrollment sites in the United States, Europe, and New Zealand. Independent core labs analyzed the imaging studies, and a clinical events committee adjudicated major adverse events.

The LifeStream balloon-expandable covered stent (Bard Peripheral Vascular) comprises an electropolished, 316-L stainless steel balloon-expandable stent encapsulated between two layers of expanded polytetrafluoroethylene. It is premounted on a noncompliant balloon on an 0.035-inch guidewire–compatible delivery catheter. Radiopaque markers on the balloon shaft indicate the ends of the covered stent.

In BOLSTER, the LifeStream covered stent was successfully deployed in 98.3% of cases, with an acute procedural success rate of 97.4%. At 9 months, 11.6% of evaluated patients met the primary composite endpoint (device- and/or procedure-related death or myocardial infarction through 30 days or any target lesion revascularization, major limb amputation, or restenosis), which was significantly less than the historical performance goal (19.5%; $P = .01$). The primary patency rate (proportional-based analysis) was 89.1%, and the rate of freedom from target lesion revascularization was 96.7% at 270 days. There was one major amputation.

The BOLSTER trial is ongoing, with duplex ultrasound imaging follow-up to continue through 3 years.



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HIGHLIGHTS FROM TODAY'S TRIAL PRESENTATIONS.

CAROTID STENT FRACTURES ARE NOT ASSOCIATED WITH DEATH, STROKE, MYOCARDIAL INFARCTION AND STENT RESTENOSIS: RESULTS FROM THE ACT 1 MULTICENTER RANDOMIZED TRIAL

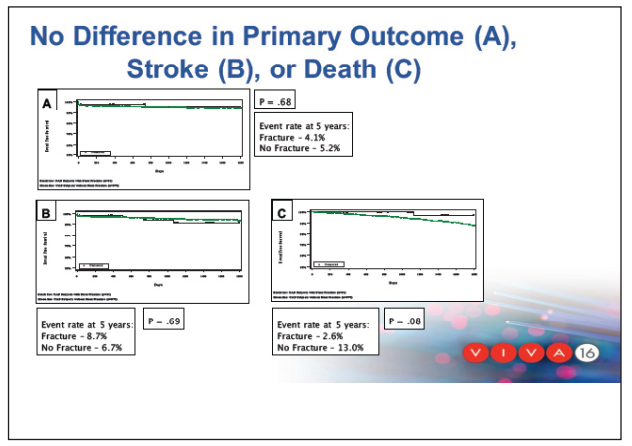
Presenter: Ido Weinberg, MD

The rate of carotid artery stent fractures and its association with neurologic or cardiac events, death, or in-stent restenosis has only been studied in small series. The objective of this study was to report the stent fracture rate as well as its association with carotid in-stent restenosis and clinically meaningful adverse outcomes in ACT-1.

ACT-1 is the largest prospective, multicenter randomized trial of standard-risk asymptomatic patients with severe carotid artery stenosis randomized to carotid artery stenting (CAS) or carotid endarterectomy (CEA) (Abbott Vascular). All patients were required to undergo duplex ultrasound (DUS) surveillance at 30 days and annually thereafter. After 771 patients had been randomized, all subsequent randomized patients were required to also undergo annual radiographic (XR) analysis for stent fracture. All DUS and XR images were independently adjudicated by a vascular core laboratory (VasCore, Massachusetts General Hospital). The primary endpoint was the composite of death, stroke (ipsilateral or contralateral, major or minor), or myocardial infarction during the 30 days after the procedure and ipsilateral stroke during the 365 days after the procedure.

Of 1,021 patients who were randomized to CAS, 822 had at least one XR and one DUS during a follow-up period of 5 years. Stent fracture was reported in 51 (5.4%) patients. Adverse clinical outcomes up to 5 years occurred in 47 CAS patients enrolled in ACT 1 (5.2%). There was no association between stent fracture and restenosis ($P = .53$). Neither stent fracture ($P = .73$) nor restenosis ($P = .56$) was associated with the primary endpoint to 5 years.

ACT-1 demonstrates that carotid stent fracture rate was low and was not associated with major adverse clinical events or in-stent restenosis.



NOVEL NITINOL STENT FOR LONG LESIONS IN THE SUPERFICIAL FEMORAL ARTERY AND PROXIMAL POPLITEAL ARTERY: 24-MONTH RESULTS FROM THE TIGRIS RANDOMIZED TRIAL

Presenter: John Laird, MD

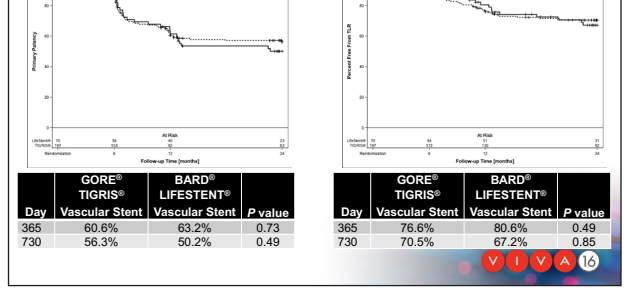
The Tigris stent (Gore & Associates) has a dual-component design that aims to allow natural movement and conforming to the vessel, maximizing flexibility while minimizing risk of fracture, and allow axial compression while resisting stent elongation.

The TIGRIS trial is a prospective, multicenter, randomized controlled noninferiority clinical study. Patients were randomized 3:1 to treatment with either the Tigris stent or LifeStent (Bard Peripheral Vascular). There were 33 enrollment sites in the United States and three in Europe; 274 patients were enrolled on an intention-to-treat basis, and 267 patients were per protocol.

The mean pretreatment lesion lengths were 107.6 ± 68.6 mm and 117.9 ± 75.4 mm in the Tigris and LifeStent arms, respectively ($P = .292$). The total stented length was 129 ± 73.3 mm for Tigris (LifeStent, 148.7 ± 75.4 mm; $P = .057$). In the Tigris arm, 51.1% of lesions required implantation of one stent for coverage, 28.1% required two, 18.4% required three, and 2% required four (LifeStent arm, 62.9%, 31.4%, 5.7%, and 0%, respectively). Occlusive disease accounted for 42.1% of lesions treated with Tigris arm and 37.1% with LifeStent.

The Kaplan-Meier estimates for 24-month primary patency and freedom from target lesion revascularization are 63% and 76.6% for the Tigris stent, respectively, versus 67.4% and 80.6% for LifeStent. There were no stent fractures observed at 24-month follow-up with the Tigris stent, whereas the LifeStent stent fracture rate was 28.8%, with the majority being grades 3 to 5.

The challenging, head-to-head, real-world, long-lesion trial met its endpoints and demonstrated Tigris' safety and efficacy. The high LifeStent fracture rate was notable. The novel design of the Tigris stent matches the demands of high-flexion areas.



PRISM: ASSESSING THE SAFETY AND TECHNICAL EFFECTIVENESS OF THE PENUMBRA INDIGO ASPIRATION SYSTEM WHEN USED AS A FRONT-LINE TOOL AND AS SALVAGE THERAPY FOR THE TREATMENT OF THROMBOEMBOLISM IN THE PERIPHERAL VASCULATURE

Presenter: Richard R. Saxon, MD, FSIR

A total of 85 patients were enrolled in PRISM. In 43 patients (50.6%), aspiration thromboembolectomy with the Indigo aspiration system (Penumbra, Inc.) was used as the initial therapy. In an additional 42 patients (49.4%), thrombolysis or other mechanical intervention was attempted before the study device was used. Vessel patency was determined via angiogram before and after the various treatments and at completion of all therapies using the thrombolysis in myocardial infarction (TIMI) scale to evaluate efficacy. Study device-related adverse events and periprocedural serious adverse events were documented.

The location of occlusions were 54.1% (n = 46) below the knee (BTK), 34.1% (n = 29) in the femoral or superficial femoral arteries, and the remainder in the superior mesenteric (n = 3), renal (n = 2), common iliac (n = 1), external iliac (n = 1), sciatic (n = 1), brachial (n = 1), and pulmonary arteries (n = 1). TIMI 2-3 flow (ie, flow past the lesion to the distal vascular bed or normal flow) was achieved using the study device alone as an initial therapy in 81.4% of patients (n = 43). After additional endovascular interventions, TIMI 2-3 was recorded in 95.3% of these patients. TIMI 2-3 flow was achieved in 92.9% (39/42) of patients who had the study device used as salvage therapy after other endovascular techniques had failed. Overall, complete restoration of flow (TIMI 3) was achieved in 77.6% of patients (n = 66). No device-related adverse events occurred (0%).

Mechanical aspiration thromboembolectomy using the Indigo system is effective for revascularization of peripheral arterial occlusions. The study device was equally effective as a front-line, primary therapy and as a salvage therapy after other endovascular techniques had failed.