

11th Annual Complex Cardiovascular Catheter Therapeutics: Advanced Endovascular and Coronary Intervention Global Summit (C3)

June 2015, Orlando, Florida

The C3 conference has been specifically designed for physicians who specialize in interventional cardiology, vascular surgery, and interventional radiology, as well as fellows, residents, and other healthcare professionals interested in atherosclerotic cardiovascular disease. C3 offers presentations and debates with expert global faculty, live and pre-recorded cases, industry-sponsored and supported symposia, exhibit booths, poster sessions, case presentations, hands-on workshops, and a simulator alley.

Effect of Transcatheter Aortic Valve Replacement on Right Ventricular Function: Systematic Review and Meta-Analyses Manvah Zahaf; Roberto M. Lang; John W. Bokowski; Igor Palacios; Sanjib Basu

Background. Transcatheter aortic valve replacement (TAVR) is an alternative to surgical aortic valve replacement (SAVR) in high-risk patients with severe aortic stenosis (AS). Improvement of left ventricle (LV) function after both procedures is evident; however, no systematic review has studied the impact of TAVR on right ventricle systolic function (RVSF).

Objective. We undertook systematic review to study primarily early and mid-term change in RVSF after: (1) TAVR and SAVR; (2) transfemoral (TF) and transapical (TA) TAVR delivery approaches; and (3) Medtronic CoreValve (MC) and Edwards Sapien valve (ES) TAVR devices. The secondary endpoints were RVSF echo parameters validation post aortic intervention for AS (standardized endpoint definitions), and composite biventricular systolic function.

Methodology. *Data source:* PubMed, EMBASE, Cochrane library, and references of selected articles. *Study eligibility criteria and participants:* Comparative studies concerning RVSF post TAVR and/or post SAVR were assessed quantitatively and included in meta analyses. Those were in English and involved only adult human, and has been published before July 2014. Abstracts were excluded. *Endpoint measurement:* Transthoracic echocardiography was utilized to assess the change in RVSF post TAVR vs SAVR using tricuspid annular plane systolic excursion (TAPSE), and fractional area change (RVFAC). LV systolic function was measured using LV ejection fraction (LVEF). *Statistical analyses:* Random effect model on standardized mean difference (Hedges; g) of the continuous variables used to assess the study endpoints. Heterogeneity assessment (I-squared and Q) was done. Analyses were performed using Comprehensive meta-analysis software version 2 (CMA).

Results. A total of 485 subjects from five single-center observational studies met our inclusion criteria and were analyzed quantitatively, including 355 subjects in TAVR group and 130 subjects in SAVR group. When TAVR was compared with SAVR, TAVR resulted in better improvement in RVSF [TASPE ($g=2.88$, $SE=0.63$, $P<.001$, $Q=73.18$, $I^2=94.53$, $r=0.65$), RVFAC ($g=0.91$, $SE=0.16$, $P<.001$, $Q=2.39$, $I^2=16.61$, $r=0.65$), preferably assessed by RVFAC. Though TAVR improved LVEF, when compared with SAVR, the effect was similar ($g=0.31$, $SE=0.19$, $P=.005$, $Q=7.96$, $I^2=62.29$, $r=0.7$).

Conclusion. Compared with SAVR, TAVR resulted in improved RV performance and therefore might be the preferred aortic intervention in patients with severe AS and RV systolic dysfunction. When both aortic interventions were compared, their effects on LVEF were similar, with a slight improvement in favor of TAVR.

Disclosure and acknowledgement. The study has no funding or affiliated industry, and no conflict of interest to disclose. Special thanks and gratitude to Salma Gasil, Neeraj Jolly, Rami Doukky, Clifford Kavinsky, Luis Fogg, Jerome Loew, Arlen Brickman, Gabriella Szabo, Zhiyu Dai, John Somberg, and Graduate College at Rush University, Chicago, Illinois.

Outpatient Percutaneous Endovascular Abdominal Aneurysm Repair

Po-Jen Ko

Introduction. The treatment for abdominal aortic aneurysm (AAA) has evolved a lot in recent 2 decades toward a less invasive direction from traditional open repair to endovascular treatment. Endovascular aneurysm repair (EVAR) has been adopted increasingly as the treatment modality of infrarenal aortic aneurysm in recent years worldwide. EVAR has proven to be less invasive in terms of preoperative mortality, morbidity, and postoperative length of stay. With the improvement of endograft design, imaging facility, operative technique, anesthesia method, and postoperative care, EVAR was furthermore modified to be more effective and less invasive. According to the literatures and clinical experience, we had decided to further improve the hospital stay of our EVAR patients.

Operative technique. Outpatient clinic patients with asymptomatic infrarenal AAA indicated for treatment were included as our candidates. All cases were treated as day procedures under intravenous sedation with local anesthesia after meticulous preoperative

planning by our vascular intervention team, comprised of surgeons and radiologists. Vascular access was gained using the “Preclose technique” with suture-mediated devices (Proglide, Abbott Vascular). Half-strength contrast medium was used during the procedure to minimize the risk of contrast-induced nephropathy. Ambulation and oral intake was allowed after 2 hours of postoperative bedrest. The patient was then discharged from hospital and followed up in outpatient clinic 4–8 days postoperatively.

Results. We successfully performed 68 outpatient EVARs (male:female=63:50; average age, 73 ± 9.6 years) from February 2012 through December 2014, with 100% technical successful rate and 0% operative mortality. No transfusion was needed for all patients and the average hemoglobin level dropped from 13.4 ± 1.9 mg/dL to 11.9 ± 1.9 mg/dL postoperatively. The 14-day readmission rate was 2.9% (both because of acute iliac limb occlusion). The patients were followed for 17 ± 9.9 months with survival rate of 93% and 89% at 12 months and 24 months, respectively. During the follow-up period, 93% of patients' aneurysm sizes remained the same or smaller. Only 10.3% of secondary intervention rate was observed in our OPD EVAR patients. These outcomes are comparative with other EVAR series.

Conclusion. With careful patient selection, preoperative planning and proper operative technique, EVAR for infrarenal AAA can be performed as a day surgery procedure safely and effectively.

Comparison of Iodixanol and Ioxaglate for Coronary Optical Coherence Tomography Imaging

Georgios E. Christakopoulos, MD; Anna Kotsia, MD; Georgios Christopoulos, MD; Shuaib Abdullah, MD; Bavana V. Rangan, BDS, MPH; Michele Roesle, RN, BSN; Subhash Banerjee, MD; Emmanouil S. Brilakis, MD, PhD
From the VA North Texas Health Care System, Dallas, Texas and University of Texas, Southwestern Medical School, Dallas, Texas

Key words. coronary artery disease, imaging, radiographic contrast, iodixanol, ioxaglate

Background. The impact of contrast type on coronary imaging using optical coherence tomography (OCT) has received limited study. We compared OCT imaging obtained using the non-ionic, iso-osmolar iodixanol with the ionic, low-osmolar ioxaglate.

Methods. Twenty-two vessels in 20 patients were imaged twice using manual injection of iodixanol and ioxaglate in random order. OCT images were analyzed at 1 mm intervals to determine lumen area, diameter and the area of artifact, as well as stent strut coverage and malapposition in OCT pullbacks that included stents.

Results. There were no complications related to OCT imaging or to contrast administration. A total of 2184 cross-sections (1092 with iodixanol and 1092 with ioxaglate) were analyzed. Compared with iodixanol, imaging using ioxaglate provided similar mean lumen area (6.21 ± 2.83 mm² vs 6.27 ± 2.83 mm²; Spearman's rho, 0.982), mean minimum lumen diameter (2.47 ± 0.59 mm vs 2.50 ± 0.58 mm; Spearman's rho, 0.939), and mean maximum lumen diameter (2.99 ± 0.71 mm vs 3.01 ± 0.70 mm; Spearman's rho, 0.964), but lower mean artifact area per cross-section (0.099 ± 0.325 mm² vs 0.068 ± 0.329 mm²; $P < .001$). Analysis of 3303 stent struts in 388 cross-sections (194 with iodixanol and 194 with ioxaglate) demonstrated similar rates of strut malapposition (11.82% vs 13.90%; $P = .10$) and strut coverage (41.92% vs 40.33%; $P = .35$).

Conclusions. Compared with iodixanol, OCT imaging using ioxaglate provided similar lumen and diameter measurements and stent strut characterization, but smaller area of artifact.

Conflict of interest disclosures. Dr Banerjee: research grants from Gilead and the Medicines Company; consultant/speaker honoraria from Covidien and Medtronic; ownership in MDCare Global (spouse); intellectual property in HygeiaTel. Dr Brilakis: consulting/speaker honoraria from Abbott Vascular, Asahi, Boston Scientific, Elsevier, Somahlution, St. Jude Medical, and Terumo; research support from Guerbet and InfraRedx; spouse is employee of Medtronic.

Funding. This study was funded through a grant from Guerbet LLC.

Publication history. *J Invasive Cardiol.* 2015 Dec;27(12):E287–E290. Epub 2015 Sep 15.

Two-Year Safety Outcomes in Diabetic Patients Treated with Orbital Atherectomy for De Novo, Severely Calcified Coronary Lesions: A Sub-Analysis of the ORBIT II Trial

Jeffrey W. Chambers, MD

Background. Severely calcified lesions make successful balloon angioplasty and stent delivery more difficult during percutaneous coronary intervention (PCI) and treatment may lead to serious procedural complications. Patients with diabetes mellitus (DM) are at increased risk for severe coronary artery calcification. Compared with non-diabetics, diabetics have increased incidence of major adverse cardiac events (MACE) after PCI. In this analysis, we evaluated the 2-year safety outcomes in ORBIT II patients with or without DM treated with the Diamondback 360 Coronary Orbital Atherectomy System (OAS; Cardiovascular Systems, Inc).

Methods. ORBIT II, a prospective trial conducted in the United States (443 subjects, 49 sites) was designed to evaluate the safety and efficacy of the OAS to prepare *de novo*, severely calcified coronary lesions for stent deployment. Two-year MACE (defined as cardiac death, myocardial infarction [MI, CK-MB $>3 \times$ ULN], and target-vessel revascularization [TVR]) was compared in patients with history of DM (DM group, $n = 160$) vs patients without history of DM (no-DM group, $n = 283$).

Results. Patients in the DM group were younger (70.3 ± 0.7 years vs 72.0 ± 0.6 years; $P = .02$), had higher body mass index (31.0 ± 0.5 vs 28.5 ± 0.3 ; $P < .001$), higher prevalence of hypertension (96.3% vs 89.0%; $P = .01$), and higher rate of previous coronary artery bypass graft (20.0% vs 11.7%; $P = .02$). As estimated by Kaplan-Meier, at 2 years both DM and non-DM patients had similar low rates of MACE (20.6% vs 18.7%; $P = .71$), cardiac death (5.3% vs 3.7%; $P = .45$), MI (8.1% vs 10.6%; $P = .40$), and TVR (8.7% vs 7.8%; $P = .75$).

Conclusion. Using the OAS as a lesion preparation tool prior to stent deployment resulted in low rates of MACE at 2 years post procedure in both diabetic and non-diabetic patients with severely calcified coronary lesions. Treatment with the OAS demonstrated a safe and efficacious treatment option in this high-risk population; however, further studies are needed to better understand the impact of diabetes on the treatment of calcific coronary artery disease.

Short-Term Outcome of Everolimus-Eluting Bioabsorbable Vascular Scaffold (BVS) in the Management of ST-Segment Elevation Myocardial Infarction (STEMI) — A Real-World Experience

Rabin Chakraborty; Soumya Patra; Aftab Khan; Suvro Banerjee; Prakash Chandra Mandol; Debashish Ghosh; Sankha Subhro Das; Raja Nag; Swapan Kumar De; Arindam Pande

From the Department of Cardiology, Apollo Gleneagles Hospitals, Kolkata, India

Key words. bioabsorbable vascular scaffold, everolimus-eluting, ST-segment elevation myocardial infarction

Background. Although recent studies have demonstrated the safety and efficacy of everolimus-eluting bioabsorbable vascular scaffold (BVS) in the management of stable coronary artery disease (CAD), there is lack of data regarding use of BVS for primary percutaneous coronary intervention (PCI) in the management of ST-segment elevation myocardial infarction (STEMI).

Aims. To evaluate immediate procedural success and safety and efficacy of the everolimus-eluting BVS in patients with STEMI.

Methods. From January 2013 to December 2014, patients with STEMI who received BVS implantation during primary PCI were included in this study. Among 220 patients of primary PCI, those 35 patients who received BVS stent were included in this study.

Results. Mean age was 59.2 ± 9 years. Mean duration of follow-up was 11.5 ± 5 months. Eighty percent of patients had single-vessel CAD. Femoral access was used in 51% of cases. Mean door-to-balloon time was 93 ± 30 minutes. Anterior-wall STEMI was more frequent than inferior-wall STEMI involving right coronary artery territory. Mean BVS length and BVS diameter per patient were 24.6 ± 4.7 mm and 3.2 ± 0.3 mm, respectively. About 66% of patients received thromboaspiration during PCI and thrombolysis in myocardial infarction (TIMI) III flow was achieved in 94% of patients. Procedural success was achieved in 94% of the cases. Only 1 case had non-cardiac death within 1 month.

Conclusion. The use of BVS in this cohort reflecting day-to-day real-world clinical practice is feasible and associated with good procedural safety and angiographic success rate.

Corresponding address. Dr Soumya Patra, Associate Consultant, Department of Cardiology, Apollo Gleneagles Hospitals, Kolkata, India. Email: dr_soumyapatra@rediffmail.com

A Comparison of Outcomes Between Conventional and Percutaneous Aortic Valve Replacement in Very Elderly (>85 Years) Patients

Hailan A; Obaid D; Ashraf S; Bhatti F; Dorman S; Ionescu A; Kumar P; Youhana A; Zaidi A; Smith D; Chase A

Background. Due to the elderly demographics of our patient population, our institution has a high incidence of very elderly (>85 years) patients with severe symptomatic aortic stenosis who are treated with conventional aortic valve replacement with excellent risk adjusted outcomes. We examined the impact of our percutaneous transcatheter aortic valve implantation (TAVI) program on outcomes of aortic valve intervention in very elderly patients.

Methods. A total of 139 consecutive patients >85 years who had aortic valve intervention between 2009 and 2015 were included. Forty-eight patients underwent TAVI (81.3% transfemoral, 10.4% transapical, 8.3% direct aortic). Valve implantation success rate was 100%, but vascular complications occurred in 4.2% of patients. Ninety-one patients underwent conventional aortic valve replacement, 14.5% were isolated aortic valve replacement with no coronary bypass grafts, 33.9% had 1 graft, 27.4% had 2 grafts, 21.0% had 3 grafts, 3.2% had 4 grafts. There was 1 perioperative death in the conventional surgery group (1.1%).

Results. Comparing the patients who underwent TAVI with conventional aortic valve replacement, there was no significant difference in age (mean age, 89 ± 2.8 years vs 87 ± 1.7 years; $P>.99$), logistic EuroSCORE (22% vs 22%), sex (male 50% vs 48%; $P=.80$), baseline creatinine (111 ± 34.7 $\mu\text{mol/L}$ vs 108 ± 60.0 $\mu\text{mol/L}$; $P=.70$), chronic lung disease (25% vs 30%; $P=.46$), previous MI (29% vs 15%; $P=.06$), left ventricular impairment (48% vs 71%; $P=.09$), or preoperative coronary disease (57% vs 69%; $P=.47$). There were significantly more diabetics in the TAVI group (21% vs 6%; $P=.01$), previous stroke (17% vs 6%; $P=.04$), and previous cardiac surgery (27% vs 2%; $P<.001$). There was no significant difference in mortality between TAVI and conventional aortic valve replacement at 30 days (4% vs 6%; $P=.72$), or 1 year (23% vs 18%; $P=.47$). There were no postoperative strokes or myocardial infarctions in either group. There was less incidence of acute kidney injury following TAVI (6% vs 22%; $P=.02$) and lung complications (2% vs 22%; $P<.001$). The total length of stay was significantly shorter following TAVI compared with conventional surgery (mean stay, 10.5 ± 5.9 days vs 20.5 ± 20.2 days; $P=.001$). Similarly, bearing in mind important resource implications, length of ITU stay was also significantly shorter following TAVI (mean 2.7 ± 1.4 days vs 6.0 ± 4.4 days; $P<.001$).

Conclusions. Aortic valve intervention can be performed in patients >85 years of age with acceptable 1-year mortality. TAVI can be performed in this group with similar mortality to the gold standard of conventional surgery, but with significant reductions in ITU and overall hospital stay as well as postoperative complications.

Primary Aortic Coarctation: Endovascular Treatment with Thoracic Covered Stents

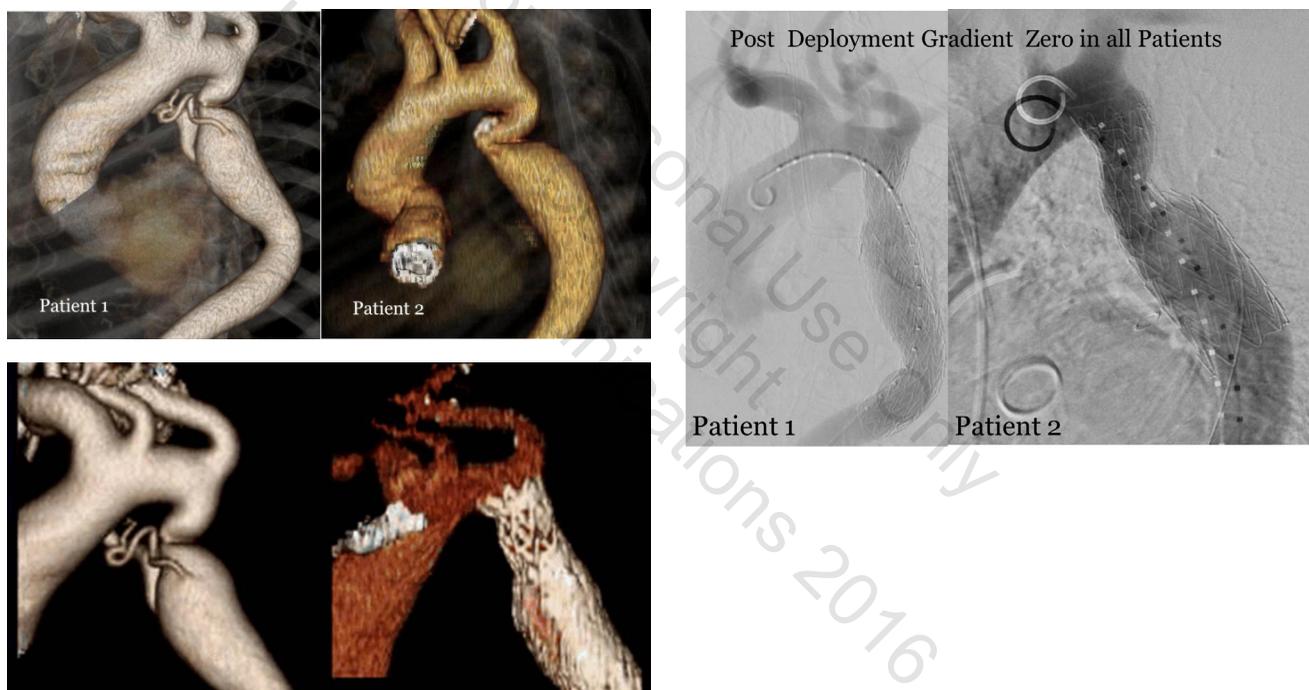
Keith B. Allen, MD; Alessandra Puggioni, MD; Steve Laster, MD; A. Michael Borkon, MD; Sangeev Aggarwal, MD; J. Russell Davis, MD

Background. Primary aortic coarctation has been successfully managed in younger patients with uncovered stents; however, this treatment in older adults is associated with an increased incidence of complications, particularly aortic dissection or rupture. We describe the use of covered thoracic stents to successfully manage previously undiagnosed primary aortic coarctation in 2 older adults.

Methods. Primary aortic coarctation was identified in 2 adult patients at two centers. Endovascular management included the use of covered thoracic stents (CTAG; W.L. Gore & Associates) by themselves or in combination with abdominal aortic extension cuffs (Excluder extension cuffs; W.L. Gore & Associates). In addition to demographics, endpoints in this retrospective review included operative details, procedural complications, and follow-up.

Results. Covered stents were successfully used in both patients (1 female/1 male). Average age was 66 years (range, 56–76 years). Both patients were symptomatic and presented with ischemia (cerebral and colonic). Covered thoracic stents were delivered through femoral cut downs in both patients. Graft deployment was facilitated using 30 mg adenosine to obtain transient asystole in both patients. Predeployment dilatation was not performed; however, grafts were dilated post deployment. There were no complications including death, spinal cord ischemia, or vascular access morbidity. Average pretreatment gradient across the coarctation was 66 mm Hg; following stenting, the pressure gradient across the coarctation was reduced to zero in both patients. Average length of stay was 4 days (range, 2–5 days). With follow-up of 1–25 months, all patients are alive and well with stable endografts by computed tomography.

Conclusions. The treatment of primary aortic coarctation in adults using covered stents is feasible and may reduce the risk of aortic disruption, particularly in older patients, compared with uncovered stents.



Utilizing Zilver PTX Drug-Eluting Stent in Combination With Viabahn Stent-Graft to Promote SFA Patency in Long-Segment TASC-D Lesions

Kevin Herman, MD; Joshua Kornblum, RN; John H. Rundback, MD

Objectives. To assess the clinical outcomes utilizing the Zilver PTX (Cook Medical) drug-eluting stent as a proximal bridge in combination with Viabahn (W. L. Gore and Associates) stent-graft for the treatment of long-segment femoropopliteal lesions.

Background. Historically, primary patency rates of long-segment femoropopliteal lesions have been poor when utilizing endovascular techniques. More recently, the use of the Viabahn stent-graft for the treatment of TASC C and D lesions has conferred better overall primary patency (Saxon et al, 2013). Of note, edge stent stenosis has been found to be a leading cause of Viabahn stent-graft failure in the treatment of long-segment femoropopliteal lesions (Saxon et al, 2007). The use of paclitaxel-eluting stents has been shown to result in higher patency rates in moderate-length femoropopliteal lesions (Dake et al, 2011). We hypothesized that the use of a proximal drug-eluting stent in combination with long-segment stent-graft would decrease edge stent stenosis and confer better patency in TASC D lesions. To our knowledge, there have been no data published describing the

use of Zilver PTX DES placement in combination with Viabahn stent-graft placement for treatment of long-segment TASC-D lesions of the femoropopliteal segment.

Methods. A preliminary retrospective evaluation was conducted on 12 limbs in 11 patients from March 2014 to April 2015 at Holy Name Medical Center in Teaneck, New Jersey. Inclusion was based on treatment of a TASC D lesion with at least one Viabahn stent-graft and at least one proximal bridging Zilver PTX DES. Study endpoints were loss of primary, assisted, and secondary patency at 6 months. Patency was determined via arterial doppler studies and clinical assessment. Primary patency was defined as the interval between initial procedure and subsequent intervention to restore flow through the target lesion. Assisted patency was defined as the interval until restenosis or occlusion, including any additional interventions to restore flow, with the exception of thrombolytic treatment. Secondary patency was defined as the interval until unresolvable restenosis or occlusion.

Results. Six-month primary, assisted, and secondary patency rates in TASC D lesions treated with a Viabahn stent-graft with proximal bridging Zilver PTX DES were 91.7%, 100%, and 100%, respectively. The mean age of patients treated was 70.9 ± 8.8 . Male to female ratio was equal with each group representing 50%. Patient history included hypertension (83.3%), hyperlipidemia (75%), coronary artery disease (41.7%), and diabetes mellitus (33.3%). A total of 16.7% of patients were active smokers at the time of intervention. Mean estimated lesion length was 318.75 ± 76.34 mm. Average Viabahn stent-graft length was 304.2 ± 81.1 mm per lesion. 1.8 ± 0.6 Viabahn stent-grafts were used per case. 60% of the stent-grafts used had a 5 mm diameter, while 40% had a 6 mm diameter. Average Zilver PTX DES length was 96.7 ± 30.6 mm per lesion. Only 6 mm diameter Zilver PTX DESs were used, with 1.2 ± 0.4 stents used per case. Revascularization using subintimal technique was successful in all cases. In 2 cases (16.7%) the Outback LTD Reentry catheter (Cordis) was required for successful revascularization. In 4 cases (33.3%), atherectomy of the index lesion was performed. 75% of patients included in this study had multilevel vascular disease indicative of the complexity in this patient population. In 41.7% of patients, adjunctive treatment of inflow vessels was performed in the same setting. In 33.3% of patients, there was adjunctive treatment of tibial outflow or distal popliteal vessels.

Conclusions. This study demonstrates high patency rates of Viabahn stent-grafts when utilized in conjunction with a proximal bridging Zilver PTX DES for the treatment of long-segment TASC-D lesions of the superficial femoral artery.