

Covered Stents for Treating Aortoiliac Occlusive Disease

The use of covered stents as a novel technique for preventing and treating restenosis in the iliac arteries.

BY ANDREW T. KWA, MD; DAVID L. DAWSON, MD; AND JOHN R. LAIRD, MD

Endovascular revascularization for aortoiliac occlusive disease has made remarkable progress over the years. Despite the excellent results achieved with percutaneous transluminal angioplasty and stenting, there remains a risk for restenosis and a need for repeat intervention when stents are used to treat complex aortoiliac bifurcation disease and TransAtlantic Inter-Society Consensus (TASC) C and D iliac lesions. The use of covered stents is an innovative

treatment option with potential for preventing and better treating restenosis in the iliac arteries.

COVERED STENTS

Covered stents are composed of fabric or graft material, such as polytetrafluoroethylene (PTFE), covering a metal stent. They have various clinical applications in peripheral arterial disease management. Applications include treatment of atherosclerotic disease, sealing

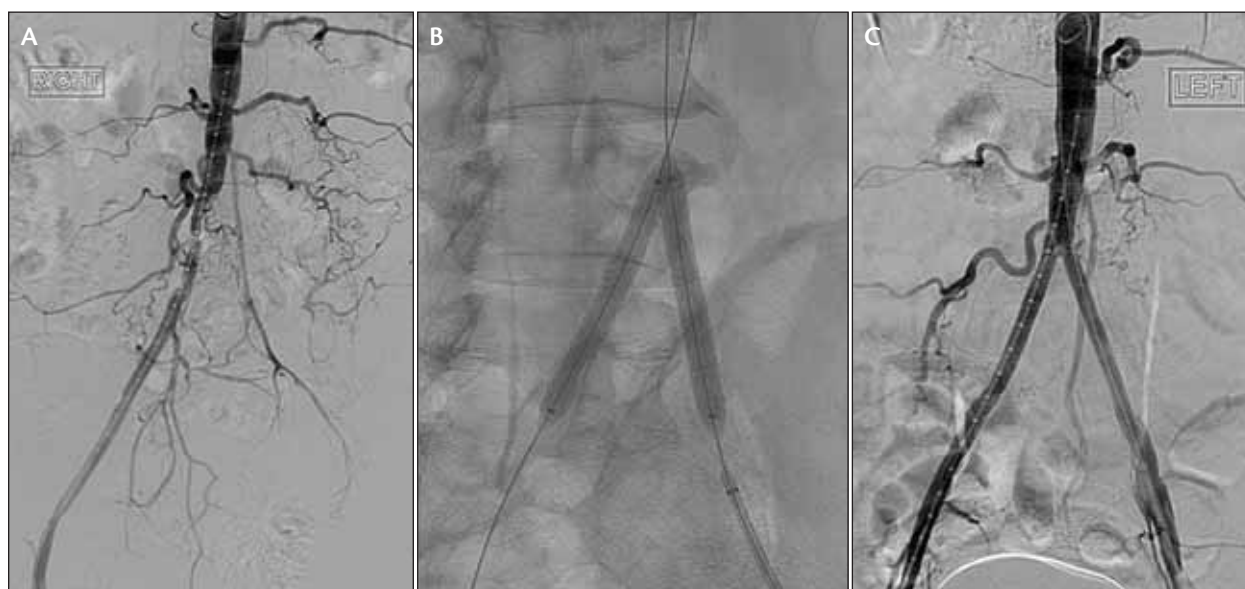


Figure 1. Occlusive atherosclerotic disease of the left common iliac artery and severe stenosis of the right common iliac artery (A). Two iCast stents (Atrium Medical Corporation, Hudson, NH) deployed in a simultaneous kissing-stent fashion (B). Final results showing revascularized right and left common iliac arteries (C).

iatrogenic vessel perforations or ruptures, exclusion of aneurysms and pseudoaneurysms, treatment of arteriovenous fistulae, and management of failing dialysis grafts. Several covered stents are commercially available, including both self-expanding and balloon-expandable varieties (Table 1). Of these, only the self-expanding Viabahn endoprosthesis (Gore & Associates, Flagstaff, AZ) is approved by the US Food and Drug Administration (FDA) for use in iliac arteries. Outside the United States, the Advanta V12 (Atrium Medical Corporation) is approved for iliac and renal artery occlusive disease. The United States version, the iCast stent (Atrium Medical Corporation), is currently being evaluated for use in the treatment of iliac artery occlusive disease. Covered stents that have been approved for other indications are used “off label” for treating peripheral arterial disease.

The principal argument for the use of covered rather than bare-metal stents is that the layer of graft material provides a direct barrier to tissue ingrowth from neointima hyperplasia. With both percutaneous transluminal angioplasty and stenting, vessel wall injury results in activation of macrophages and the release of proinflammatory mediators that promote neointimal growth, cytokines, metalloproteinases, and various growth factors. Covered stents provide a direct barrier to the ingrowth of neointimal hyperplasia, sealing off the exposed inflammatory surface, and thus have the potential to inhibit restenosis.¹ However, vessels treated with covered stents can develop restenosis at the edges where injured intima is not covered by graft material. This pattern of restenosis, in which the main body of the graft is free of restenosis and the edges restenose, appears to be the primary pattern of restenosis related to these devices.²⁻⁴

iCast, Advanta V12, and Large Diameter V12

The iCast stent (named Advanta V12 in markets outside of the United States) is a balloon-expandable stainless steel stent that is fully encapsulated in two layers of PTFE. The PTFE has a porosity of 100 to 120 μ m. The system is premounted on a noncompliant balloon catheter with gold markers embedded at the ends of the balloon. The current-generation iCast endoprosthesis is available in diameters of 5 to 12 mm. Available stent lengths are 16, 22, 38, and 59 mm, with 38- and

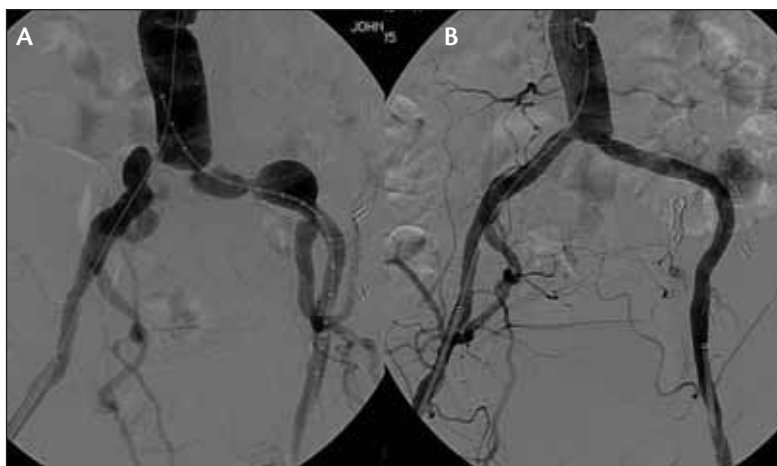


Figure 2. Bilateral common iliac artery aneurysms and stenoses (A). After coil embolization of the left internal iliac artery and simultaneous deployment of two iCast stents (B).

59-mm devices that have the ability to be postdilated to 12 mm. Due to the slotted tube design of these stents, there is some stent shortening with deployment. All iCast stents are 0.035-inch guidewire compatible and are mounted on a 5-F catheter shaft size with available lengths of 80 and 120 cm. Devices are compatible with either a 6- or 7-F introducer sheath. The iCast is currently approved for the treatment of tracheobronchial strictures.

Outside of the United States, the Large Diameter V12 covered stent (Atrium Medical Corporation) is available in diameters of 12, 14, and 16 mm with the ability to be postdilated to 20 mm. Available lengths include 29, 41, and 61 mm. The Large Diameter V12 is compatible with 9- or 11-F sheaths and comes in 80- and 120-cm shaft lengths. This particular device is approved for restoring and improving patency of iliac arteries.

Figure 1A shows a case example of a patient with an occlusive left common iliac artery and high-grade stenosis of the right common iliac artery. Simultaneous kissing stenting of the common iliac arteries with two iCast stents was performed after bilateral guidewire access was obtained (Figure 1B), resulting in restoration of inflow (Figure 1C). Covered stents have also been used to treat aneurysms of the iliac arteries (Figure 2A). After coil embolization of the left internal iliac artery, two iCast stents were simultaneously deployed in a kissing fashion with resultant exclusion of the iliac artery aneurysms and treatment of the high-grade common iliac artery stenoses (Figure 2B).

In a study that specifically evaluated patients with aortic bifurcation disease, Sabri et al performed a retrospective review of 54 consecutive patients with aortic

TABLE 1. STENT GRAFTS AVAILABLE IN THE UNITED STATES

Company Name	Product Name	FDA Indicated Use
Abbott Vascular (Santa Clara, CA)	Jostent GraftMaster	Coronary-free perforations
Atrium Medical Corporation (Hudson, NH)	iCast	Tracheobronchial strictures
Bard Peripheral Vascular, Inc. (Tempe, AZ)	Flair	Stenosis at venous anastomosis of ePTFE or other synthetic AV grafts
	Fluency Plus	Tracheobronchial strictures
Boston Scientific Corporation (Natick, MA)	Wallgraft	Complex occlusive disease or peripheral arterial aneurysms and trauma
LeMaitre Vascular, Inc. (Burlington, MA)	aSpire	Tracheobronchial strictures
Gore & Associates (Flagstaff, AZ)	Viabahn endoprosthesis and Viabahn endoprosthesis with heparin bioactive surface	5–8 mm indicated for SFA; 5–13 mm indicated for iliac artery; 9–13 mm indicated for tracheobronchial strictures
	Viabil endoprosthesis	Malignant biliary strictures
	Viatorr endoprosthesis	TIPS or tracheobronchial strictures

Abbreviations: AV, arteriovenous; SFA, superficial femoral artery; TIPS, transjugular intrahepatic portosystemic shunt.

bifurcation disease who were treated with bilateral common iliac artery kissing-balloon stenting.⁵ Patients with TASC II A, B, C, and D lesion characteristics were included. Twenty-six patients received stent grafts, and 28 patients received balloon-expandable bare-metal stents. Technical success was seen in 100% of patients in both groups. When compared to balloon-expandable bare-metal stents, covered stents were superior in regard to primary patency at a mean follow-up of 29.5 months (92% vs 62%; $P = .02$). Patients who received covered stents in this study had more TASC II C and D lesions.

COBEST (Covered Versus Balloon Expandable Stent Trial) is a multicenter, randomized clinical trial that is currently underway in Australia comparing the Advanta V12 covered stent to a balloon-expandable bare-metal stent in patients with iliac occlusive disease. This study randomized 167 limbs in 123 patients with TASC B, C, or D lesions in iliac arteries. Eighty-three limbs received the Advanta V12 covered stent, and 84 limbs received bare-metal stents. Characteristics were similar in all groups except for a higher number of TASC D lesions in the stent graft group and more patients with hyperten-

sion in the bare-metal stent group. Interim analysis at 18 months showed better primary patency (95.4% vs 82.2%; $P < .05$) and clinical improvement (94.2% vs 76.7%; $P < .008$) with the Advanta V12 compared to bare-metal stents, respectively. Additionally, the covered stent group had lower amputation rates (1.2% vs 3.6%). Most of the benefit of the Advanta V12 over bare-metal stents was seen in TASC C and D lesions.⁶

The iCARUS study is a prospective, multicenter, non-randomized, single-arm registry being executed in the United States to evaluate the balloon-expandable iCast covered stent in patients with de novo or restenotic lesions in the common and/or external iliac arteries. The primary endpoint is a composite endpoint defined as the occurrence of death within 30 days, target site revascularization, or restenosis (by ultrasound determination) within 9 months after the procedure. This study has completed enrollment, and follow-up data are being collected. Completed 1-year data should be available for presentation this fall. It is expected that Atrium Medical Corporation will file for an iliac artery indication with the FDA based on the results of the iCARUS trial.

Viabahn Endoprosthesis

Currently, the only covered stent system that has been approved for use in the iliac and superficial femoral artery in the United States is the Gore Viabahn endoprosthesis. Originally introduced in 1996 to the European market as the Gore Hemobahn endoprosthesis, its name was changed to Viabahn in 2002 when it was introduced to the United States market. The initial Hemobahn, like the Viabahn, was designed as a self-expanding endoprosthesis comprising an ultrathin expanded-PTFE (ePTFE) graft on the luminal surface of a self-expanding nitinol stent. The stent is covered internally with a 100- μ m-thick ePTFE graft. The small 30- μ m internodal distance or pore size is designed to prevent neointimal growth. The endoprosthesis is compressed and attached to a dual-lumen delivery catheter, and two radiopaque metallic bands are attached to the catheter shaft for positioning. The Viabahn endoprosthesis is deployed from tip to hub, which allows for uniform radial expansion, making crimping and folds less likely.

The latest version of the Viabahn endoprosthesis reduces the profile of the 5- to 8-mm-diameter devices. The 5- and 6-mm devices now fit through a 6-F sheath, and the 7- and 8-mm devices fit through a 7-F sheath. All of the 5- to 8-mm-diameter devices are 0.014- or 0.018-inch guidewire compatible and come in lengths of 2.5, 5, 10, and 15 cm in the United States. A 25-cm length is available in markets outside of the United States.

The larger-diameter device profiles remain unchanged: the 9-mm device may be delivered through 9-F sheaths, 10-mm devices through 11-F introducer sheaths and select 10-F sheaths (Avanti sheath introducer [Cordis Corporation, Bridgewater, NJ], Super Sheath introducer sheath [Boston Scientific Corporation, Natick, MA], and Intradyn introducer sheath [B. Braun Interventional Systems Inc., Bethlehem, PA]), 11-mm devices through 11-F introducer sheaths, and 13-mm devices through 12-F introducer sheaths. The 9- to 13-mm-diameter devices are all 0.035-inch guidewire compatible. In the United States, the 9-mm-diameter devices come in 5-, 10-, and 15-cm lengths. The 10-mm-diameter devices are available in 2.5-, 5-, 10-, and 15-cm lengths, and the 11- and 13-mm diameters in 2.5-, 5-, and 10-cm lengths. In markets outside the United States, the 2.5-cm-length devices are not available for 10- to 13-mm devices.

In 2008, the Gore Viabahn received FDA indication for use in iliac occlusive disease treatment. This indication was obtained from data that were collected as part of the Gore Viabahn Endoprosthesis Feasibility Study, which took place between 1996 and 1999 in the United States and Europe. Forty-five limbs in 42 subjects with Rutherford category 3 or less and iliac arterial occlusive disease were treated with the first-generation Viabahn endoprosthesis.

Technical success was achieved in 100% of patients, with procedural success in 93.2%. The primary outcome of 12-month patency was 86.1%.⁷

CONCLUSION

Both the balloon-expandable iCast and the self-expanding Viabahn have an important role in treating occlusive iliac artery disease. Balloon-expandable stents have classically been the therapy of choice for aortoiliac bifurcation disease, but evolving data suggest that the iCast could be a suitable alternative. The iCARUS trial will further define the role of stent grafts in aortoiliac occlusive disease. The Viabahn endoprosthesis is the only currently available FDA-approved covered stent for the iliac artery and is a viable alternative to self-expanding nitinol stents in the external iliac vessel. Future trials will provide additional data on appropriate patient selection, as well as the safety and efficacy of these devices. ■

Andrew T. Kwa, MD, is with the UC Davis Vascular Center, University of California, Davis Medical Center in Sacramento, California. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein.

David L. Dawson, MD, is Professor of Surgery at the UC Davis Vascular Center, University of California, Davis Medical Center in Sacramento, California. He has disclosed that he is a consultant to Boston Scientific Corporation, is a speaker for Abbott Vascular and Medtronic, Inc., and receives research/grant support from Abbott Vascular.

John R. Laird, MD, is Director of the UC Davis Vascular Center, University of California, Davis Medical Center in Sacramento, California. He has disclosed that he is a consultant/advisory board member for Abbott Vascular, Bard Peripheral Vascular, Boston Scientific Corporation, Cordis Corporation, ev3 Inc., and Medtronic, Inc., and receives research support from Atrium Medical Corporation. Dr. Laird may be reached at (916) 734-2028; john.laird@ucdmc.ucdavis.edu.

1. Gilbertson JJ, Pettengill OS, Cronenwett JL. Antiproliferative effect of heparin on human smooth muscle cells cultured from intimal hyperplastic lesions of vein grafts. *Ann Vasc Surg.* 1992;6:265-271.
2. Cragg AH, Dake MD. Percutaneous femoropopliteal graft placement. *Radiology.* 1993;187:643-648.
3. Gimple LW, Gertz SD, Haber HL, et al. Effect of chronic subcutaneous or intramural administration of heparin on femoral artery restenosis after balloon angioplasty in hypercholesterolemic rabbits. A quantitative angiographic and histopathological study. *Circulation.* 1992;86:1536-1546.
4. Chadda N. Heparin-bonded Viabahn stent graft for SFA lesions: incidence of stent thrombosis and heparin-induced thrombocytopenia. Abstract presented at: Transcatheter Cardiovascular Therapeutics 20th Annual Scientific Symposium; October 12–17, 2008; Washington, DC.
5. Sabri SS, Choudhri A, Orgera G, et al. Outcomes of covered kissing stent placement compared with bare metal stent placement in the treatment of atherosclerotic occlusive disease at the aortic bifurcation. *J Vasc Interv Radiol.* 2010;21:995-1003.
6. Mwipatayi P. Interim analysis of Covered Versus Balloon Expandable Stent Trial (COBEST). Paper presented at: Vascular Interventional Advances 2009; October 20–23, 2009; Las Vegas, NV.
7. Gore Viabahn Endoprosthesis [IFU]. Gore Viabahn Endoprosthesis Feasibility Study: United States and Europe. Flagstaff, AZ; Gore & Associates.