Endograft Treatment of Complex Aortoiliac Disease

Six case studies detailing the use of balloon-expandable PTFE-covered stent endografts in the iliac anatomy.

BY LEONARDO C. CLAVIJO, MD, PhD, AND JOHN R. LAIRD, Jr, MD

Compared to surgery, current endovascular strategies for the treatment of aortoiliac arterial disease are associated with similar initial clinical success, faster recovery, and lower morbidity and mortality risk. In contrast to balloon angioplasty, stenting of the iliac arteries is associated with higher technical success and overall 39% risk reduction of long-term failure.[1] One-year primary patency rates of new-generation self-expanding stents exceed 90% and are associated with low complications and high clinical success.[2] Hence, stenting is considered the strategy of choice for treating aortoiliac occlusive disease. The type of stent (balloon-expandable vs self-expanding) to be used depends on the characteristics and location of the lesion, with preference given to balloon-expandable stents for lesions requiring very precise placement or high radial strength, such as those involving aortoiliac bifurcation, proximal common iliac artery, heavily calcified lesions, and longer chronic total occlusions.

Recently, the FDA approved the iCast (Atrium Medical Corporation, Hudson, NH) polytetrafluoroethylene (PTFE)-covered balloon-expandable stent for treating tracheobronchial strictures.[3] Tracheobronchial and biliary stents have been used extensively to treat vascular abnormalities in the peripheral circulation.[4] Currently, there are two balloon-expandable covered stents available in the US: the Graft Master Jostent (Abbott Vascular, Santa Clara, CA) and the iCast covered stent. Multiple reports in the literature document the successful use of covered stents in the peripheral circulation with a wide array of clinical applications—mostly for treating arterial aneurysms or pseudoaneurysms, vascular perforations, and fistulas.[5-9] More recently, the use of self-expanding covered stents to treat recurrent in-stent restenosis is gaining interest.

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The Jostent is composed of two metal stents with a PTFE layer in the middle. It is only available for coronary perforations as a humanitarian device, and its use for any other indication requires an investigational device exemption. The iCast covered stent is a balloon-premounted, ultrathin, stainless steel stent encapsulated in PTFE. It is available in diameters from 5 mm to 12 mm and lengths of 16 mm, 22 mm, 38 mm, and 59 mm. In comparison to self-expanding stent grafts of similar diameter, the Jostent has a lower profile, and stents up

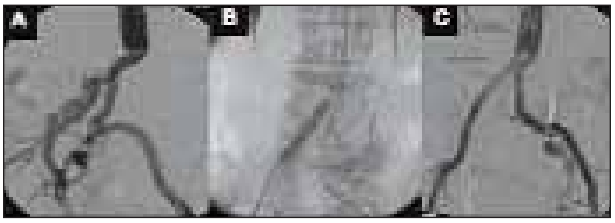

Figure 1. Distal aortoiliac angiography at baseline demonstrates stenosis of the distal anastomosis, kinking of the left aortobi-iliac graft limb, and an aneurysm of the right common-external iliac arteries (A). The right common-external iliac aneurysm was treated with a 9-mm X 59-mm iCast covered stent and postdilated with 8-mm X 40-mm and 9-mm X 40-mm balloons (B). The stenosis of the left limb of the graft was treated with an 8-mm X 39-mm bare metal stent and postdilated with an 8-mm X 40-mm balloon. Final angiogram (C).

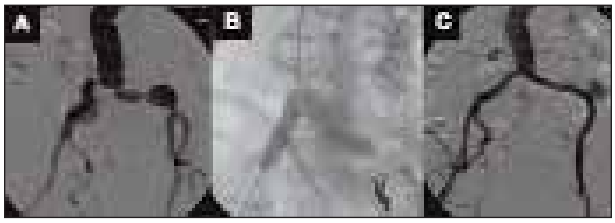

Figure 2. Baseline angiography demonstrates severe bilateral common iliac ostial disease and poststenotic aneurysmal dilatation (A). Endovascular treatment included coil embolization of the left internal iliac artery, kissing stenting of the common iliac arteries with two 9-mm X 590-mm iCast stents, and kissing postdilatation with two 10-mm X 40-mm balloons (B). Final angiogram (C).

Figure 3. Right groin angiography revealed laceration of the inferior epigastric artery with bleeding into the retroperitoneal space (A). After contralateral access via the left common femoral artery, a 7-F crossover sheath was advanced over a stiff .035-inch wire into the right common iliac artery and a 6-mm X 16-mm iCast covered stent deployed and postdilated with an 8-mm X 20-mm balloon (B). The final angiogram showed no evidence of further bleeding (C).

to 10 mm in diameter are compatible with a 7-F sheath. The iCast covered stent has a higher radial strength and because of the double lumen balloon inflation system, it expands from the edges toward the center (dog bone effect), and offers the theoretical advantage of capturing material and preventing embolization. The aim of this article is to describe our experience with the iCast covered stent for treating complex aortoiliac disease. After approval by the Institutional Review Board, we retrospectively analyzed data from six patients who underwent peripheral stenting of the aortoiliac arterial system with an iCast covered stent and performed clinical follow-up. Results are presented as case reports.

CASE 1

A 79-year-old man with a history of peripheral arterial disease, surgical abdominal aortic aneurysm (AAA) repair 15 years prior, dyslipidemia, hypertension, and coronary artery disease, had severe, lifestyle-limiting, lower-extremity intermittent claudication. Diagnostic angiography revealed right common-external iliac aneurysmal dilatation and occlusive disease of the left aortobi-iliac graft limb (Figure 1A). The patient was pretreated with clopidogrel (300 mg) and aspirin (325 mg). The right common-external iliac artery aneurysm was successfully treated with two 9-mm X 59-mm iCast stents (Figure 1B, C). The patient was discharged 24 hours later in stable condition. At 14-month follow-up, the patient remained free of symptoms of claudication, and ankle-brachial indexes were 0.98 bilaterally.

CASE 2

A 65-year-old man with a history of hypertension, tobacco use, dyslipidemia, chronic renal insufficiency, previous coronary artery bypass grafting, mitral valve repair, AAA surgical repair 2 years prior, and carotid artery stenting, had lifestyle-limiting claudication of the lower extremities. Diagnostic angiography revealed a patent distal aortic graft, bilateral severe stenoses at the origin of the common iliac arteries, and distal aneurysmal dilatation (Figure 2A). The patient was successfully treated with coil embolization of the left internal iliac artery and bilateral common iliac kissing stenting using two 9-mm X-59 mm iCast stents (Figure 2B, C). The patient was discharged home the following day in stable condition. At 13-month follow-up, the patient was free of symptoms of claudication, the ankle-brachial indexes were >1.0 bilaterally, and an arterial duplex ultrasound demonstrated patent iliac artery stents without evidence of restenosis.

CASE 3

A 52-year-old man with a history of hypertension and dyslipidemia was admitted to the hospital with a diagnosis of non-ST–elevation myocardial infarction after presenting with chest pain to the emergency department. A left heart catheterization was performed, which revealed

Figure 4. Baseline angiogram reveals a 3.5-cm aneurysm of the right common iliac artery (arrow) (A). Deployment of a 9-mm X 38 -mm iCast covered stent, followed by balloon postdilatation with a 9-mm X 20-mm balloon (B). Final angiogram demonstrates complete exclusion of the aneurysm (C).

severe left anterior descending and circumflex coronary artery disease and moderate aortic insufficiency. A right groin angiography was performed before coronary intervention and revealed an iatrogenic laceration of the right inferior epigastric artery with evidence of retroperitoneal bleeding (Figure 3A). The coronary intervention was deferred, and contralateral access via the left common femoral artery and retrograde access to the right common iliac artery were obtained with a 7-F crossover sheath. A 6-mm X 16-mm iCast stent was then deployed and postdilated with an 8-mm X 20-mm balloon in the distal segment of the right external iliac artery at the level of the inferior epigastric artery, and the bleeding effectively stopped (Figure 3B, C). The hemoglobin level remained stable, and CT angiography revealed no further bleeding. The patient returned to the catheterization laboratory 24 hours later, at which time successful coronary intervention of the left anterior descending and circumflex arteries was performed. The patient was discharged from the hospital 48 hours later in stable condition. At 1-year follow-up, the patient remained stable without further coronary events, no lower-extremity symptoms, and normal peripheral pulses on clinical exam.

CASE 4

An 82-year-old man with a history of dyslipidemia and peripheral arterial disease was referred for management of a right common iliac artery aneurysm. Initially, the patient was seen at a different institution with lower abdominal pain, and a CT scan revealed a 3.5-cm right common iliac artery aneurysm with changes suggestive of perivascular inflammation. An attempt for open surgical repair was unsuccessful, and the patient was referred for endovascular treatment. The aneurysm was successfully treated with a 9-mm X 38-mm iCast covered stent and postdilated with a 9-mm X 20-mm balloon with excellent angiographic result (Figure 4). The patient was discharged 24 hours later in stable condition. A 3-month follow-up scan demonstrated complete exclusion of the aneurysm without evidence of endoleak and patency of all iliac vessels. Nine months later, the patient was not available for clinical follow-up; however, during a phone interview, he reported no additional symptoms and denied any adverse events.

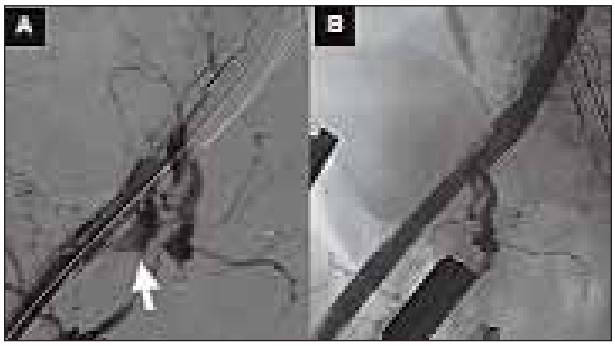

Figure 5. Iliac artery angiography, after endovascular aortic repair with an endograft, reveals a right external iliac artery perforation with substantial contrast extravasation into the retroperitoneal space (arrow) (A). Final angiogram after implantation of a 9-mm X 59-mm iCast covered stent demonstrates complete seal of the perforation and patency of the internal iliac artery (B).

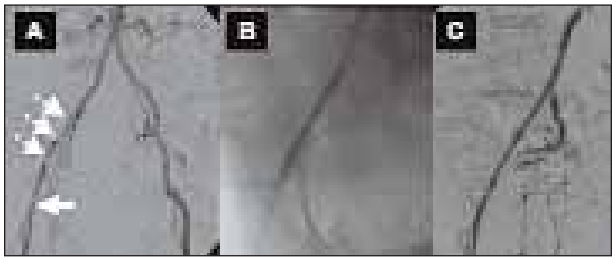

Figure 6. Baseline angiography reveals severe diffuse in-stent restenosis of the right external iliac artery (dotted arrows) and a severe focal lesion of the right common femoral artery (solid arrow) (A). The right external iliac artery restenotic segment was treated with a 6-mm X 59-mm iCast covered stent (B). The common femoral artery was treated with a 6-mm X 20-mm cutting balloon (not shown). Final angiogram demonstrated excellent results in both lesions (C).

CASE 5

An 80-year-old woman with a history of hypertension, coronary artery disease, previous coronary artery bypass grafting, carotid artery disease, and past right carotid endarterectomy, was recently diagnosed with a large infrarenal AAA. The patient was electively admitted for endovascular AAA repair with an endograft. Because of diffuse iliac and femoral artery disease, surgical iliac conduits to provide access were necessary. The surgical con-

duit was sewn to the external iliac artery because of severe aortic and common iliac artery calcification. The AAA was repaired with a Zenith aortic endograft (Cook Medical, Bloomington, IN). After successful deployment of all aortic endograft components, an iliac arteriogram revealed a perforation of the right external iliac artery proximal to the conduit with retroperitoneal contrast extravasation (Figure 5A). The perforation was effectively treated with a 9-mm X 59-mm iCast covered stent (Figure 5B). The postoperative course was uncomplicated, and the patient was discharged home 3 days later in stable condition. At 8-month follow-up, the patient was stable without lower-extremity symptoms, and duplex ultrasound revealed patent stents and no evidence of endoleak.

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CASE 6

An 84-year-old woman with a history of diabetes mellitus, hyperlipidemia, chronic renal insufficiency, coronary artery disease, hypertension, and peripheral arterial disease, was admitted to the hospital with symptoms of right lower-extremity, lifestyle-limiting claudication. The patient had undergone right external iliac artery stenting with one episode of restenosis treated with angioplasty 1 year before and left external iliac to popliteal bypass 4 years earlier. The patient underwent diagnostic angiography of the lower extremities, which demonstrated severe diffuse in-stent restenosis of the right external iliac artery and severe stenosis of the right common femoral artery (Figure 6A). The restenotic lesion in the right external iliac artery was treated initially with a 6-mm X 60-mm balloon dilatation and subsequently with implantation of a 6-mm X 59-mm iCast covered stent (Figure 6B). The lesion in the right common femoral artery was treated with a 6-mm X 20-mm cutting balloon. The final angiographic result was excellent (Figure 6C). The patient was discharged home 24 hours later in stable condition. At 10-month follow-up, the patient was clinically stable without symptoms of claudication.

CONCLUSION

The collective experience using PTFE-covered stents in the peripheral circulation is extensive. Initially, covered stents were introduced to treat vascular perforations and aneurysms with excellent results. We report our initial experience with the iCast balloon-expandable PTFE-covered-stent in patients with complex aortoiliac disease, including iliac perforations, aneurysmal disease, and lesions with "high embolic potential," complex plaque composition, and recurrent in-stent restenosis. Our results are favorable and may be related to the design of the stent—its high radial strength and the ability to capture and create a physical barrier between the lumen and embolic and/or neointimal material. In all cases, the stent was delivered without difficulty via a 6-F or 7-F sheath with good stent expansion and apposition to the vessel wall. We had no events of device failure, and, in all instances, the stent was effective in treating the intended lesion. The mid- and long-term follow-up demonstrated sustained clinical benefit and no evidence of accelerated in-stent restenosis. These results are encouraging, but longer follow-up and randomized controlled trials of the iCast stent in the aortoiliac arteries are necessary. ■

Leonardo C. Clavijo, MD, PhD, is Director of Vascular Medicine and Peripheral Vascular Interventions at Keck School of Medicine, University of Southern California, in Los Angeles, California. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Clavijo may be reached at (323) 442-6130; lclavijo@usc.edu.

John R. Laird, Jr, MD, is Professor of Medicine and Director of the Clinical Vascular Program at 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. Dr. Laird may be reached at (916) 734-5105; john.laird@ucdmc.ucdavis.edu.

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