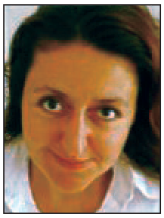
Iliac Branch Devices

An overview of these devices from bifurcated to helical configurations.

BY TARA M. MASTRACCI, MD, FRCSC



Although, on the surface, the development and introduction of iliac branch devices (IBDs) to treat pathologies in the iliac territory may seem like an incremental step in the evolution of treatment for aortic diseases, this advance actually heralded a major change in the approach and conceptualization of endovascular devices. At that point in history, the major strength of open surgery was the ability of the surgeon to create bespoke repairs that responded to any pathology that might be present in an individual patient. Unfortunately, this ability did not transfer to endovascular repair. Until branch devices became available, endovascular surgeons had a prosaic approach to aneurysm repair, relying heavily on the stars aligning for perfect landing zone anatomy, meaning that there were many anatomic exclusions or "off-label" implantations.

Fenestrated devices allowed for expansion of the proximal seal zone above the renal arteries, but there was a need to incorporate branches in more tortuous areas of the aorta, namely large thoracoabdominal aneurysms, supra-aortic trunks, and iliac arteries. It quickly became apparent to thought leaders like Roy Greenberg, MD, among others, that a branch solution was required if surgeons wanted to expand the indications of repair. In addition to this, early use of complex devices was restricted to high-volume centers, implying that a superspecialized skill set was required to use this new technology and that endovascular surgeons had limited opportunity to learn the platform without a dedicated training period. The introduction of IBDs for pathologies in the iliac arteries both proved the concept that a branch could be used and provided a platform by which any endovascular surgeon could begin incorporating more complex technology in his or her own practice.

INCIDENCE

Solitary iliac artery aneurysms likely comprise 0.5% to 1.9% of all intra-abdominal aneurysms,[1,2] but concurrent iliac artery aneurysms can complicate infrarenal aneurysms in 40% of patients.[3] Most agree that the indication for repair is iliac artery aneurysms > 3.5 cm when found in isolation,[4] but iliac aneurysms are commonly repaired when the aortic aneurysm reaches an operative threshold, even if this is before they mature. In modern practice and parlance, iliac arteries are considered ectatic when they become too large for the largest endovascular device—which on some platforms can be as large as 24 mm.

Early experience with endovascular aortic repair began to reveal that larger iliac landing zones compromised the durability of the repair.[5-7] The high incidence of type Ib endoleaks with early devices both demonstrated the need for a technology to deal with ectatic iliac arteries and created a market for a device that could rescue earlier devices that had failed. In addition, the higher incidence of short common iliac arteries in very specific populations[3] made routine endovascular repair challenging, often requiring internal iliac artery coil embolization or transposition as a matter of course, which was less than ideal. In all of these scenarios, the IBD was the next logical step.

EARLY TECHNIQUES

Prior to the use of custom devices in the iliac territory, there were different approaches to dealing with ectatic iliac arteries that can be classified in two categories: occlusive and inclusive. Perhaps the most commonly used approach was occlusive. For these techniques, some form of occlusion was placed in the internal iliac, after which the device limb was then extended down into the external iliac. The use of both coils and plugs were described, with the general consensus now being that a patent internal iliac must have some form of occlusive device placed because failure to do so would lead to a type II endoleak.[8] Occlusion of the iliac territory was very commonly associated with buttock claudication in patients who were ambulatory[9] and could be associated with more nefarious complications such as rectal or bowel ischemia and lumbar plexopathy.[10,11]

In one study of 71 patients who had undergone internal iliac artery occlusion, the incidence of fatal pelvic ischemia was 2.8%, and buttock claudication occurred in 25%.[11] In addition, it is thought that occlusion of the internal iliac may have some bearing on erectile function, although this has not been proven in patients with aneurysmal diseases.

The category of inclusive techniques for dealing with iliac arteries included "bell-bottom" devices and chimney grafts. Fashioning larger iliac devices from aortic cuffs or other larger-diameter devices allowed the surgeon to keep the internal iliac artery in circulation, while still achieving seal. However, this approach ultimately failed, as it was later found that landing in an unhealthy iliac artery was associated with early device failure.[12,13] The use of chimney devices was described in early experiences, but no long-term experience has been published to determine the durability of this approach.[14]

THE MOVEMENT TO "GENTRIFY" THE ILIAC TERRITORY

The presence of ectatic iliac arteries, and their risk of rupture, is only one consideration in the development of IBDs. As the endovascular movement gained a greater foothold and more complex aneurysms were being treated with endovascular devices, the importance of preserving the iliac territory to prevent spinal cord injury became imperative. In the early endovascular era, many surgeons opted to embolize internal iliac arteries on one or both sides in order to achieve seal in "healthier-looking" external iliac arteries. Although this improved the ease of implantation, longer-term follow-up began to reveal that the occlusion of territories during a previous surgery had immediate and long-term functional consequences, including decreased mobility due to buttock claudication and an increased proclivity to spinal cord ischemia if further aortic surgery was needed.[15,16]

Interest in the iliac territory also coincided with a need to find a more robust solution for thoracoabdominal aneurysms. At the time, fenestrations had proven the concept that endovascular repair could be used for complex aneurysms, but the effectiveness of a fenestration with a mating branch stent was questioned in thoracoabdominal aortic aneurysm cases. Developing a branch for the iliac territory provided a testing ground for branch-based systems for the thoracoabdominal aorta. Specifically, development of the helical branch for the internal iliac allowed the engineers an in vivo platform for testing these branches. Between 2002 and 2005, the biomedical engineering lab run by Dr. Greenberg produced an iterative succession of helical limbs, with the aim of finding solutions to both the iliac and thoracoabdominal challenges. Certainly, loss of the iliac bed, although not ideal, would be far more tolerable than loss of the mesenteric bed in early device experience.

CURRENT DEVICES

Iterations of various IBDs have resulted in three main configurations that are available for clinical use today. Broadly, these include the straight branch, helical branch, and bifurcated-bifurcated devices.

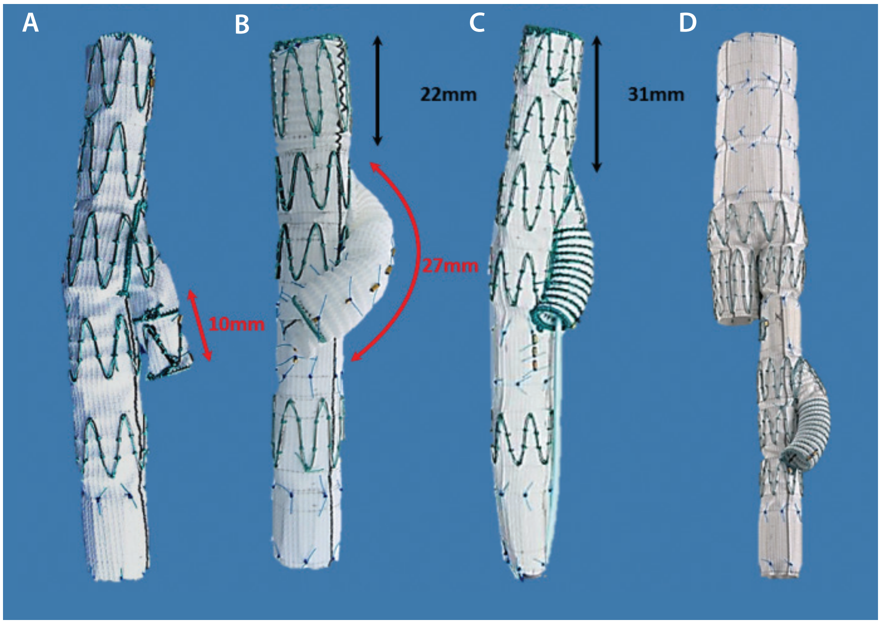


Figure 1. Iliac branch device configurations: straight IBD (A), helical IBD (B), helical limb from the contralateral side (C), and bifurcated-bifurcated device (D).

Straight IBD

The straight IBD (Figure 1A) is available from multiple manufacturers. The general concept of this device is that a straight branch comes off the main body of the limb and is mated to a stent that bridges to the internal iliac artery. The length of the branch is constricted by the diameter and length of the common iliac artery. For the Zenith Branch Iliac Graft* (Cook Medical), this length is 14 mm. For the Excluder iliac branch endoprosthesis (Gore & Associates), the length of overlap is 25 mm, and the diameter of the internal iliac branch is up to 14.5 mm. Experience with this device configuration is growing, and recent publications show promising results, with some limb-related complications.[17] For the Cook device, a two-center experience with up to 5 years of follow-up showed a freedom from reintervention rate of 81.4%, a branch patency rate of 91.4%, and a technical success rate of 95%.[18]

Helical IBD

The helical IBD (Figure 1B) was developed by Dr. Greenberg to address concerns that there was insufficient overlap in the straight branch configuration to accommodate a self-expanding stent, with the theoretical assumption that a self-expanding stent would be better suited to the tortuous angles that exist within the pelvis. The length of overlap between the mating stent and branch is 2.7 cm.

Bifurcated-Bifurcated Device

After early experience with IBDs, the indications were refined, and it became clear that the pitfalls of the devices were related to use in severely calcified internal iliac arteries, as well as in short common iliac arteries. The need for a long common iliac artery can be difficult to meet in certain populations in which short common iliac arteries are more typically seen. The bifurcated-bifurcated device grew out of this perceived challenge, and as it gained use in some centers, it became apparent that it was also quite useful in long common iliac aneurysms to provide a more stable platform for repair and to decrease the use of multiple additional pieces.[19]

As its name suggests, this device is a bifurcated infrarenal device that has a helical branch on the ipsilateral limb. Cannulation of the helical branch is made possible through the introduction of a self-sealing fenestration, developed by Dr. Greenberg, that permits access to the helical limb from the contralateral side (Figure 1C). This element overcame the need for brachial access and standardized the implantation procedure to be similar to that of existing IBDs. Thus, device delivery involves introduction of the device into the infrarenal position, cannulation of the helical branch, stenting of the internal iliac artery, and then cannulation of the gate and placement of the contralateral limb. By removing the joint between the iliac device and the main body, the bifurcated-bifurcated device creates a far more stable repair (Figure 1D).

Dr. Greenberg's team reported their 5-year experience with the helical IBD and bifurcated-bifurcated device, which revealed a technical success rate of 94% and 5-year branch patency rate of 81.8%.[19] The population of patients reported in this series included 35% who had internal iliac aneurysms. Also, 45% of treated patients had narrow common iliac arteries (< 16 mm), an exclusion criterion with the use of the straight IBD in earlier studies. Lessons learned from this experience include that technical success was lower if an internal iliac stenosis existed, but that, overall, these devices fared well in difficult anatomy.

CONCLUSION

Although not commonly acknowledged, IBDs have been a major advance in the treatment of aortic disease because they proved the concept that branched devices could be durable, provided an "entry level" platform for incorporating branches into aortic repair and removed a common criterion for anatomic exclusion. Dr. Greenberg's contribution to the devices used to treat this territory is present at every stage. Currently, IBDs are available either commercially or through investigative trials in most jurisdictions and should be considered when iliac arteries are short or ectatic. Treating iliac arteries with branch grafts when pathology exists serves the patients well, as they preserve important territory for future repair and restore functional capacity to ambulatory patients despite the presence of complex pelvic pathologies. ■

**The Zenith Branch Iliac Graft is an investigational device in the United States. Limited by United States law to investigational use. It is CE Mark approved with indications for use in the endovascular treatment of patients with an aortoiliac or iliac aneurysm, an insufficient distal sealing site within the common iliac artery, and having morphology suitable for endovascular repair.*

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