Treating a Type Ia Endoleak Using EndoAnchors

Successful endoleak resolution after endovascular abdominal aortic aneurysm repair.

BY RIPAL T. GANDHI, MD, AND BARRY T. KATZEN, MD, FACC, FACR, FSIR

Two decades after the first abdominal aortic aneurysm (AAA) was treated with an endovascular stent graft by Dr. Juan Parodi, this technology has revolutionized the treatment of AAAs. Endovascular aortic repair (EVAR) offers a minimally invasive treatment approach with excellent clinical outcomes and decreased perioperative morbidity and mortality, and it has become the treatment of choice in many medical institutions.[1,2] Drawbacks of EVAR include procedure-related complications such as endoleaks, graft fatigue, and device migration that result in continued sac pressurization and aneurysm rupture. We report a case that was presented live at the 2012 International Symposium on Endovascular Therapy demonstrating the successful utilization of EndoAnchors (Aptus Endosystems, Inc., Sunnyvale, CA) to secure a type Ia endoleak and discuss the potential benefits of this technology.

CASE REPORT

An 80-year-old man presented with progressive lifestyle-limiting left lower extremity calf claudication. During his clinical evaluation and workup, the patient was found to have an occluded left external iliac artery, but a 5.6-cm infrarenal AAA was also incidentally discovered (Figure 1A and 1B). The patient had significant cardiovascular and pulmonary comorbidities, including chronic obstructive pulmonary disease, hypertension,

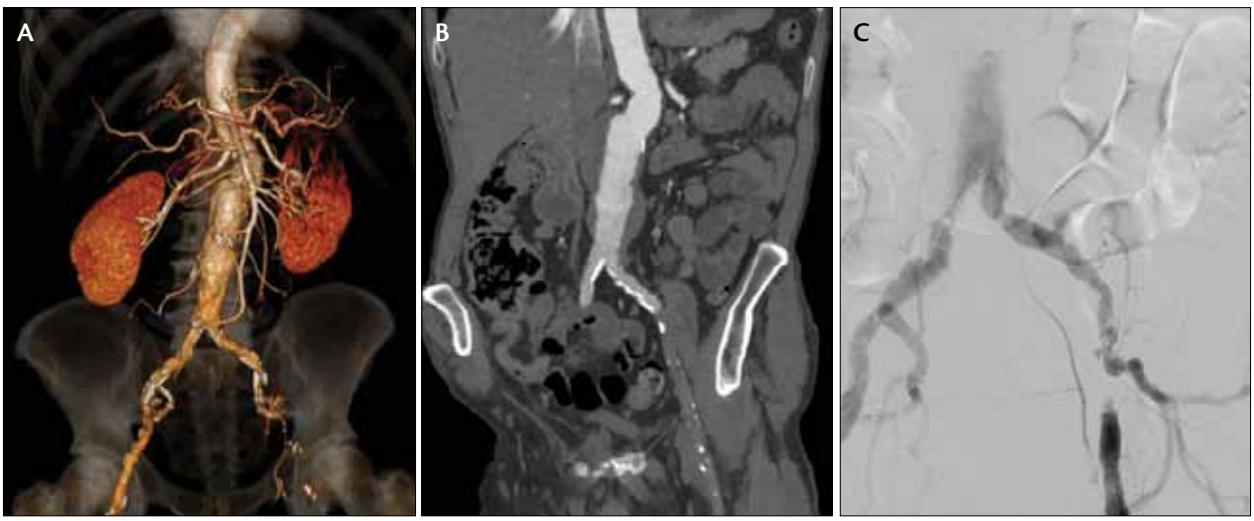

Figure 1. Three-dimensional computed tomography angiographic reconstruction shows a 5.6-cm AAA with an occluded left external iliac artery (A). Maximum-intensity projection computed tomographic angiogram shows occlusion of the left external iliac artery. The proximal aortic neck measures approximately 1 cm and is reverse tapered in shape (B). Angiogram via a combined right and left femoral approach demonstrates occlusion of the left external iliac artery just beyond the hypogastric artery (C).

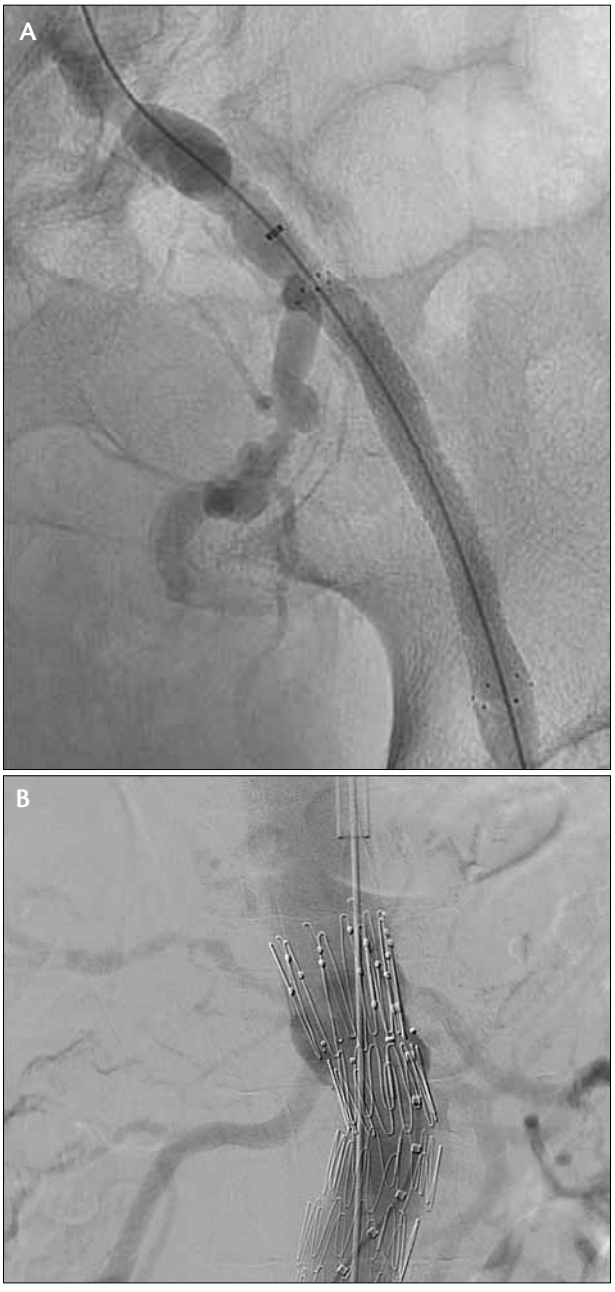

Figure 2. Angiogram showing successful placement of an 8- X 60-mm Smart Control iliac stent in the recanalized left external iliac artery with an excellent result (A). After placement of a Zenith Flex aortic stent graft and balloon dilatation, the aortogram showed a small type Ia endoleak, most prominent on the left side of the stent graft (B).

and coronary artery disease with a history of two-vessel coronary stenting. The occluded external iliac artery and a short (1 cm) reverse tapered proximal aortic aneurysm neck presented additional technical challenges to the procedure.

Angiography via a combined right and left femoral approach demonstrated occlusion of the left external iliac artery just beyond the hypogastric artery (Figure 1C). The left external iliac artery was successfully crossed with a Newton LLT guidewire (Cook Medical, Bloomington, IN) and stented with an 8- X 60-mm Smart Control iliac stent (Cordis Corporation, Bridgewater, NJ), with an excellent angiographic result (Figure 2A).

A Zenith Flex AAA stent graft (Cook Medical) was advanced via the right femoral approach. A stenosis in the right external iliac artery was easily navigated by the 16-F low-profile stent graft with hydrophilic coating. The main body was accurately deployed just inferior to the lower right renal artery. An EndoSure s2 Wireless AAA Pressure Measurement Sensor (CardioMEMS, Inc., Atlanta, GA) was implanted in the aneurysm sac, followed by deployment of the right and left limbs. After balloon dilatation of the stent graft, the pressure sensor showed systemic aortic pressures inside the aneurysm sac, indicating an endoleak. Subsequent aortography confirmed a small type Ia endoleak, most prominent on the left side of the stent graft (Figure 2B).

Repeat balloon dilatation was performed, but it failed to resolve the endoleak. Given that the stent graft was placed immediately adjacent to the right renal artery, there was not sufficient space for placement of an aortic cuff. A decision was made to deploy HeliFX EndoAnchors (Aptus Endosystems, Inc.) in the stent graft just below the renal arteries to secure the graft to the aortic wall and resolve the endoleak (Figure 3A and 3B). The 16-F (outer diameter) steerable HeliFX guide easily tracked through the stent graft via the right femoral artery and was used to position the HeliFX Applier (an electromechanical implantation tool) to the targeted EndoAnchor implantation site. A total of six EndoAnchors were placed circumferentially around the stent graft, with particular attention to the area where the endoleak was thought to originate. Final angiography demonstrated resolution of the type Ia endoleak after fixation with the EndoAnchors (Figure 3C).

DISCUSSION

Type I endoleaks generally must be treated because they result in systemic pressurization of the aneurysm sac and pose a risk of aneurysm rupture. According to the clinical practice guidelines of the Society for Vascular Surgery and the European Society for Vascular Surgery, all type I endoleaks should be treated.[3-5] Bernhard and colleagues reviewed the literature and reported 47 ruptures secondary to endoleak, the majority being type I.[6] Overall mortality was 50%, with an

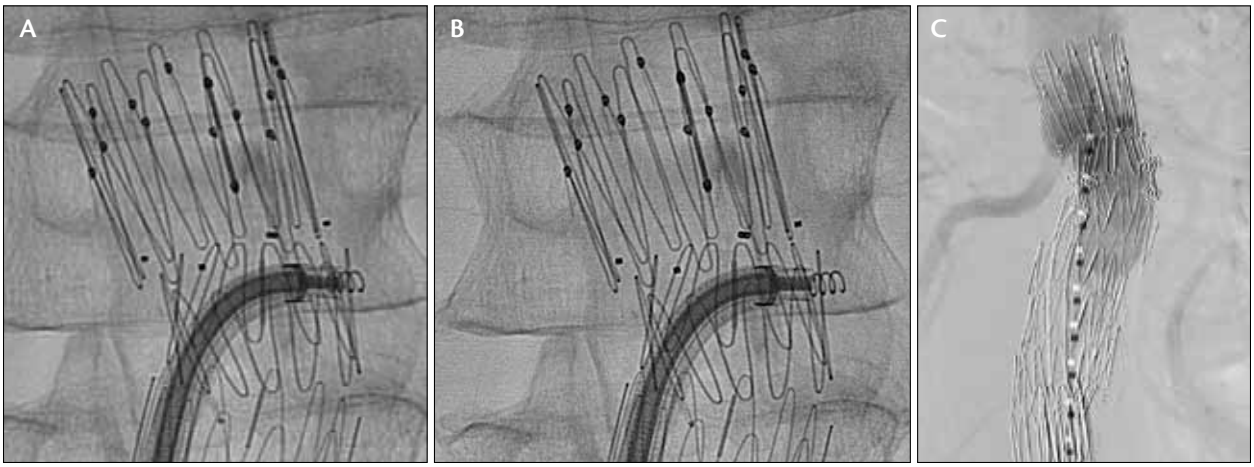

Figure 3. Fluoroscopic images demonstrating the EndoAnchor being implanted into the stent graft just below the renal arteries to secure the graft to the aortic wall. Partial deployment of the EndoAnchor (A). If the EndoAnchor is not in the desired location, it may be removed and repositioned at this point. Final implantation of the anchor into the aortic wall (B). After fixation with six EndoAnchors around the circumference of the stent graft, final angiography demonstrated resolution of the type Ia endoleak (C).

operative mortality rate of 41%. This study underscores the critical need to repair type I endoleaks without delay.

A type I endoleak may be secondary to incomplete dilatation of the stent graft, inaccurate sizing of the stent graft, diseased aortic neck with thrombus, aortic tortuosity, and significant angulation of the proximal neck. In our case, the type I endoleak was likely secondary to a short aortic neck with a reverse tapered shape.

The initial approach to the treatment of type I endoleaks is balloon dilatation to push the device against the vessel wall. If this is unsuccessful, an aortic extension cuff may be placed if there is adequate distance between the renal artery and the stent graft. If there is insufficient space to place an aortic cuff, a Palmaz stent (Cordis Corporation) may provide an effective seal. If these techniques fail to resolve the endoleak, conversion to open surgical repair must be considered.

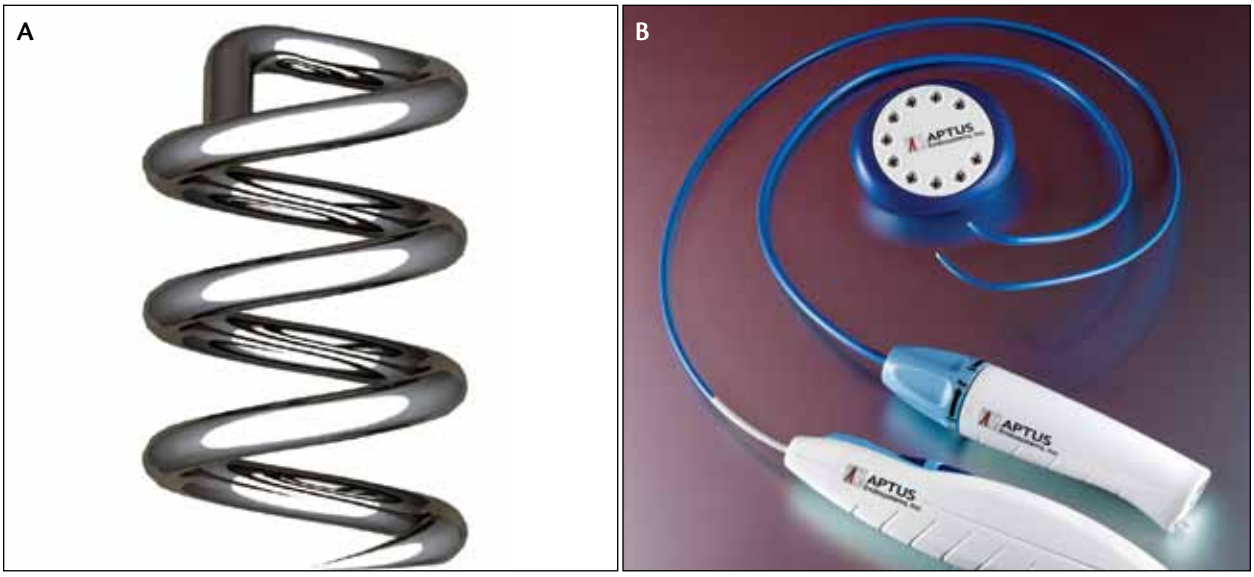

Figure 4. The HeliFX EndoAnchor is manufactured from 0.5-mm-diameter medical-grade wire (A). It is approximately 4.5 mm in length and 3 mm in diameter. The HeliFX Guide is a 16-F outer diameter deflectable guide catheter that is used to deploy the EndoAnchors (B). Images courtesy of Aptus Endosystems, Inc. (published with permission).

This case shows that aortic EndoAnchors can provide a therapeutic approach to managing type I endoleaks after EVAR. The EndoAnchors provided effective fixation and augmented sealing between the stent graft and the aorta, resulting in endoleak resolution. HeliFX EndoAnchors (Figure 4A) are helical anchors 3 mm in diameter and 4.5 mm in length that are delivered by a deflectable guide sheath (Figure 4B). They are intended to engage the adventitia, and each EndoAnchor is designed to withstand a force of 20 N in a silastic model.[7] A minimum of four EndoAnchors is recommended for aortic necks up to 29 mm in diameter and at least six EndoAnchors for larger necks. The Aptus EndoAnchors have been evaluated and determined to be compatible with the Zenith, Excluder (Gore & Associates, Flagstaff, AZ), and AneuRx, Talent, and Endurant stent grafts (Medtronic, Inc., Minneapolis, MN).

Despite significant advances in stent graft design, a hostile proximal aortic neck is problematic and may result in a type Ia endoleak or device migration. Specifically, aortic necks that are short, reverse tapered in shape, markedly angulated, and/or contain thrombus or calcification, present challenges to existing technology. Current stent grafts have used suprarenal fixation, hooks, and barbs to address these issues; however, they are not always successful. EndoAnchors provide an alternative approach to achieving fixation, which may be particularly attractive in patients with difficult aortic necks. Another potential advantage of endoanchoring is the prevention of aortic dilatation at the attachment site over time, which in turn, could decrease long-term complications and secondary interventions.

There are several additional possible applications of EndoAnchors, including to secure migrated stent grafts, aortic cuffs, or extension limbs after failed EVAR.[8] If the main body of the stent graft has migrated into the aneurysm sac, it may sit freely in the sac and not be in apposition to the aortic wall. This complication could potentially be treated by endoanchoring an aortic cuff to the main body and subsequently placing EndoAnchors in the cuff to secure it to the aortic wall. Type III endoleaks related to device separation may be prevented by anchoring the two graft components, although no data currently exist to support this potential application. EndoAnchors may be deployed to treat stent graft infolding secondary to oversizing. Finally, once a longer-shaft guide sheath is designed, it is possible that the "bird-beaking" associated with thoracic endovascular aortic repair may be resolved by securely attaching the inferior portion of the thoracic graft to the aortic wall.

The Aptus Endovascular Stapling System (now known as the HeliFX Aortic Securement System) received CE Mark in Europe in September 2009 and 510(k) clearance from the US Food and Drug Administration in November 2011.

CONCLUSION

EndoAnchors expand the therapeutic armamentarium available to physicians involved in the endovascular treatment of AAAs. They may increase the long-term durability of EVAR by decreasing type Ia endoleaks and device migration, although long-term studies are needed. As depicted in our case, patients with difficult anatomy including hostile aortic necks that are difficult to treat with conventional stent grafts alone may be particularly well suited to this technology. ■

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