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Endurant IIs Advances the Legacy of the Endurant Project

A promising off-the-shelf option for endovascular aneurysm repair for abdominal aortic aneurysms.

BY ALAN M. DIETZEK, MD, RPVI, FACS

Since its introduction in 2011, the Endurant® design project has evolved significantly in the form of Endurant II, Endurant II aorto-uni-iliac (AUI), and now the Endurant IIs stent graft system. The initial goal of the Endurant program was to broaden the use and applicability of endovascular aneurysm repair (EVAR) for abdominal aortic aneurysms (AAAs). Key areas of advancement targeted by the Endurant design improvement program have aimed for better conformability to short and angulated necks, better accommodation of tortuous anatomies, long-term device integrity, and improvements in profile and deliverability with expansion of treatment accessibility.[1]

With the latest Endurant iteration (the Endurant IIs and its new three-piece design) these objectives appear to have been accomplished, particularly with further expansion of treatment accessibility. In 2012, the approval of Endurant II presented improvements in its reduced profile for most common sizes (28 mm/18 F) and improved radiopaque markers and extended coating. This enabled patients to be treated with smaller profile access, longer limbs and fewer pieces per case, and shorter procedure times. In April 2013, the Endurant II AUI stent graft became the first and only device with an US Food and Drug Administration (FDA)–approved AUI indication for anatomy unsuitable for bifurcated repair, opening the door to treat even more challenging anatomies, including calcified, narrow distal aortas. In November 2014, the new three-piece Endurant IIs received FDA approval, representing a significant expansion of customization options while simultaneously simplifying case planning.

ENDURANT IIs PROVIDES A STREAMLINED THREE-PIECE DESIGN, LEVERAGING ADVANCEMENTS OF ENDURANT/ENDURANT II

The Endurant IIs stent graft system shares the same delivery system and proven stent graft design and performance of Endurant II; in fact, it is identical to the Endurant II above the bifurcated divider. The key differences between the two devices lie below the flow divider. The distal configuration of the Endurant IIs is notably shorter, resulting in 103-mm covered length compared to even the shortest (124 mm) Endurant II length or that of other endografts, allowing for more flexible limb placement. At 100 mm in length, the ipsilateral leg is notably shorter than that of its predecessors. The contralateral leg is 20 mm shorter still, at 80 mm, and the new design features fixed distal leg diameters of 14 mm, which enables any limb to be used on either side. As all proximal limb diameters are 16 mm, when placed in 14-mm diameter ipsilateral and contralateral legs, the result is consistent oversizing with any of the Endurant IIs legs.

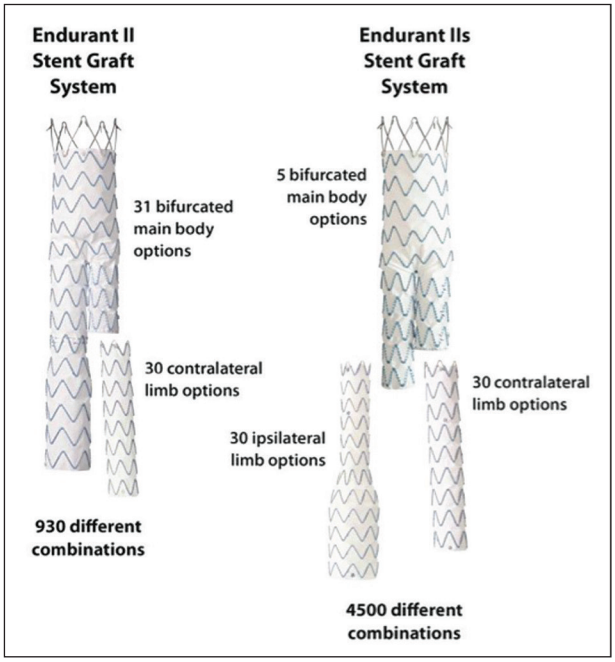

Figure 1. Endurant IIs features 5 main body sizes, compared to 31 with Endurant II, but this simplification also allows the Endurant IIs to achieve a 4.5-fold increase in potential combinations with appropriate ipsilateral and contralateral limbs.

Figure 2. Preoperative anterior-posterior CT three-dimensional reconstruction shows short common iliac arteries, specifically the LCIA.

Figure 3. Preoperative CT (coronal view) shows a 5.1-cm fusiform aneurysm and a conical aortic neck.

Maximum landing zone apposition can be achieved by adjusting component overlap in situ between 3 and 5 cm with select ipsilateral limbs. Bilateral flared or tapered components are available, with a broad sizing range compared to other grafts (8-mm, 10-mm, 13-mm, 16-mm, 20-mm, 22-mm, 24-mm, and 28-mm diameters are available). Compared to the Endurant II, the Endurant IIs (with limbs) provides up to a 20% reduction in distal diameter compared to select Endurant II bifurs. Pre-case planning and inventory management is significantly simplified from 31 sizes of the Endurant II down to 5 sizes of the Endurant IIs. When paired with appropriate ipsilateral and contralateral docking limbs, the Endurant IIs can treat up to 4,500 combinations (5 bifur options X 30 contralateral side limb options X 30 ipsilateral side limb options) compared to the 930 combinations served by the 31 Endurant II stent grafts, dramatically multiplying the number of possible combinations by 4.5-fold (Figure 1).

AAA: 75-YEAR-OLD WOMAN WITH SHORT ILIAC ARTERIES

A 75-year-old Caucasian woman presented with a fusiform AAA that was first discovered in 2010 and observed with annual ultrasounds. The patient had no prior history of aneurysms, but she did have a significant history of hypertension and hypercholesterolemia and, in the distant past, total abdominal hysterectomy-bilateral salpingo-oophorectomy. In 2014, the AAA sac enlarged from 4.1 to 4.9 cm in diameter, growing to 5.1 cm in 2015, as confirmed by a CT angiogram (Figures 2 and 3 show preoperative imaging, Figures 4 and 5 show intraoperative imaging). The patient then insisted on the repair of her aneurysm. Significant anatomical features of her aneurysm included a 3-cm-long conical neck with a diameter of 19 mm immediately below the lowest renal artery and, 2 cm distal to this, a diameter of 24.5 mm. Most notably, the common iliac arteries were unexpectedly short at 3.5 cm on the right and 2.5 cm on the left. The length from the renal arteries to the common iliac artery bifurcation was 160 mm on the left and 170 mm on the right. Diameters of the external iliac artery diameters were 8.85 mm on the left and 8.75 mm on the right. Because the patient had a conical infrarenal

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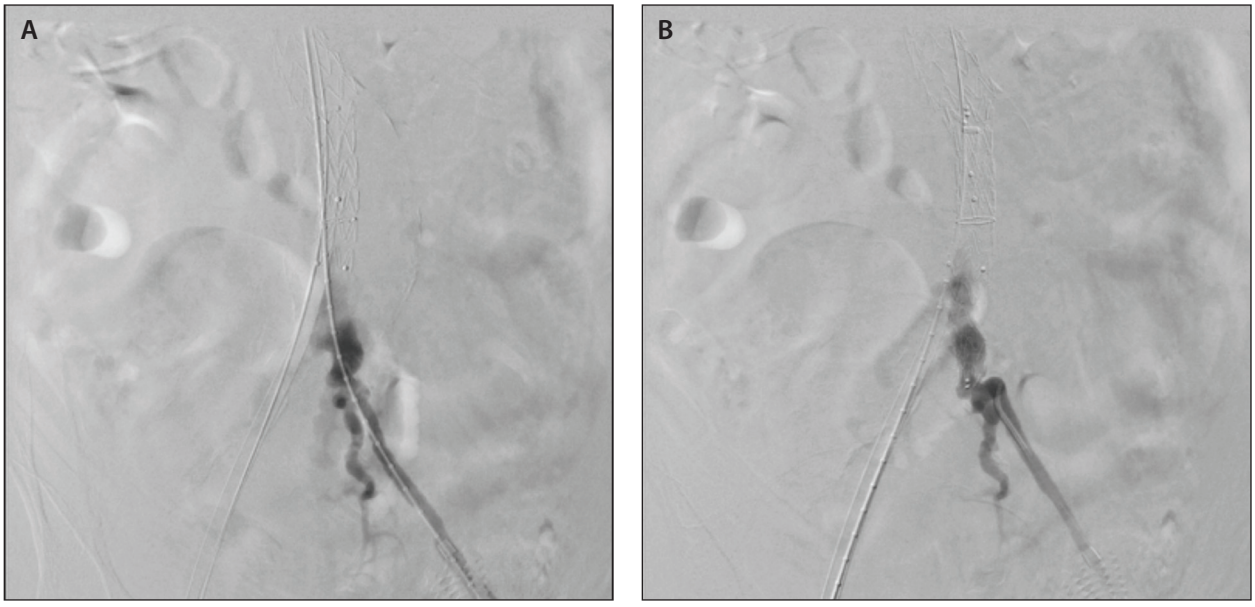

Figure 4. Intraoperative angiogram illustrates the short length LCIA (A), and the following Endurant IIs limb placement in the LCIA (B).

Figure 5. Intraoperative anterior-posterior view completion angiogram shows the Endurant IIs deployed at the origin of renal arteries, maximizing proximal seal zone.

neck with very short common iliac arteries, particularly the left common iliac artery (LCIA), there was some apprehension that stent graft length might be problematic. Given the short body design of the Endurant IIs and multiple options in limb size, access could be obtained on either side without concern about excessive stent graft length in the LCIA.

Elective EVAR was undertaken and percutaneous access was obtained via the right femoral artery. Although the external iliac artery was tortuous and heavily calcified, the delivery system tracked very well and an Endurant IIs main body stent graft was successfully placed with suprarenal fixation (28 mm X 14 mm X 103 mm; 18 F). Limbs were then introduced and successfully deployed on the left and right (16 mm X 13 mm X 124 mm and 16 mm X 16 mm X 124).

If the tortuosity of the right iliac had proved prohibitive, attempting access on the left with an even more acutely tortuous left iliac (total length of 150 mm) was likely still feasible with the short-bodied Endurant IIs (103 mm). By contrast, longer stent grafts might have been unfeasible, particularly if pre-case measurements (which can be inexact vs actual) overestimated lengths, potentially resulting in coverage of the hypogastric artery. Thus, the Endurant IIs allowed us to preserve options that otherwise would not have been available with other longer devices, and proved to be an ideal selection given this patient's anatomy. Furthermore, delivery of this three-piece system was expeditious at 65 minutes, a duration comparable to two-piece delivery procedure times. Estimated blood loss was approximately 100 mL, and the patient recovered well. At 1- and 6-month follow-up, there was no evidence of migration or endoleak, and aneurysm sac size was observed to shrink slightly to 4.8 cm.

AAA AND ANEURYSM OF THE LCIA: 71-YEAR-OLD MAN WITH HORSESHOE KIDNEY (HSK)

In the summer of 2015, a 71-year-old Caucasian man was hospitalized for diverticulitis. The patient reported a past history of hypertension and a myocardial infarction several years ago, but he did not have a primary

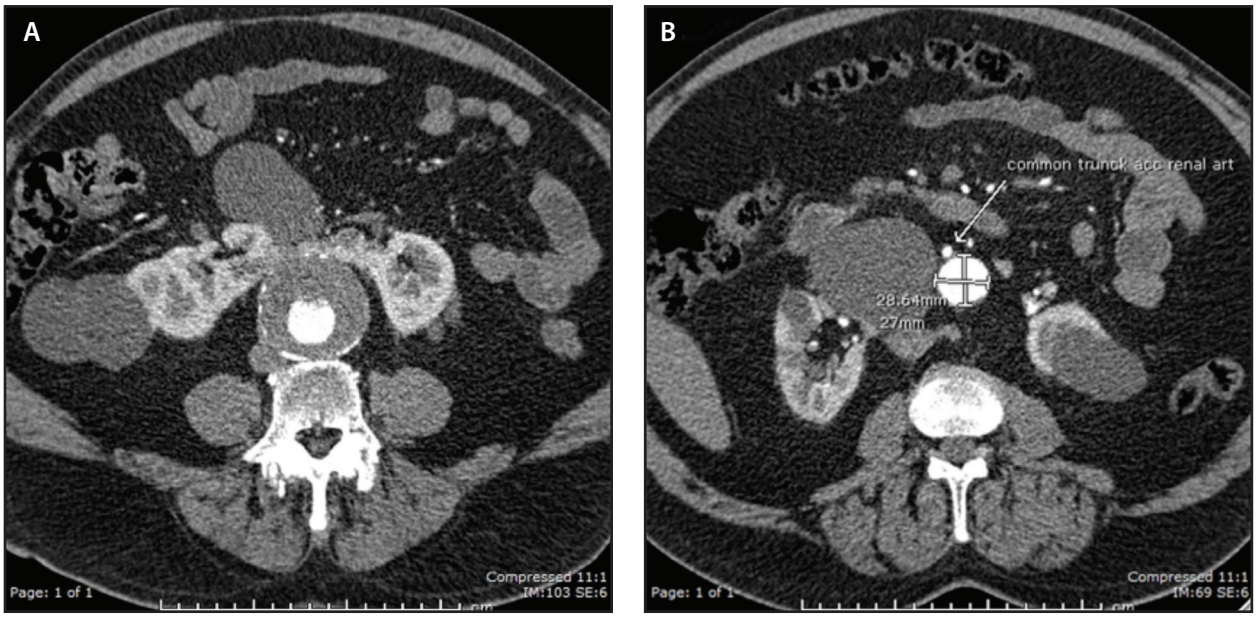

Figure 6. Preoperative CT (axial view) revealed a 6.1-cm AAA and HSK (A). The accessory renal artery is shown in (B).

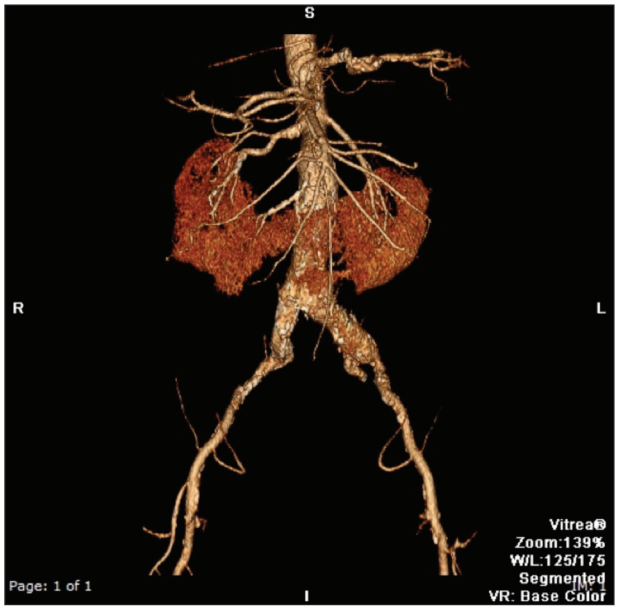

Figure 7. Preoperative CT three-dimensional reconstruction shows a 6.1-cm AAA, a 25-mm LCIA aneurysm, and HSK morphology.

care physician, nor had he seen any physician for several years. During hospitalization, abdominal computed tomography angiography revealed a 6.1-cm AAA, a 25-mm LCIA aneurysm (Figure 6), and HSK with accessory renal arteries supplying less than 25% of total renal perfusion (Figures 7 and 8). These vessels arose at 3.6 cm distal to the lowest right renal artery and at the aortic bifurcation. Imaging revealed a fairly long conical neck 18 mm in length, with a diameter of 19.9 mm proximally and 27.1 mm distally. Maximal diameters of the left and right common iliac arteries were 26.5 mm and 17.6 cm, respectively, and the common femoral and external iliac arteries were noted to be significantly calcified. Luminal diameter of the left and right potential access arteries were 7.2 mm and 5.6 mm, respectively. The patient received intravenous sedation and spinal anesthesia.

We opted to place the Endurant IIs main body device (28 mm X 14 mm X 103 mm; 18 F) via the right common femoral artery to minimize manipulation of the LCIA aneurysm (Figure 9). Angioplasty of the right external and common iliac arteries was performed up to 8 mm prior to placement of the limbs, which were then placed on the left and right (16 mm X 28 mm X 156 mm and 16 mm X 20 mm X 124 mm). No difficulties were encountered in percutaneous placement of the sheaths or the device. Both accessory renal arteries were covered by the device. Despite evidence of some predominantly posterior wall calcifications, both percutaneous groin punctures were successfully closed with the Perclose ProGlide Suture-Mediated Closure System (Abbott Vascular). Complications of the Perclose ProGlide system are reported to be infrequent. A 2015 study of the Perclose ProGlide system, used in association with the Endurant stent graft system for asymptomatic infrarenal AAA by van Dorp and colleagues, reported conversion to femoral cutdown was necessary in only 2.4% of access sites (2 of 85).[2]

Follow-up duplex ultrasound surveillance at 1-month postprocedure (August 22, 2015) revealed the patient's aneurysm to be slightly smaller and without endoleaks. There were no significant changes in renal function with preservation of a normal serum creatinine and glomerular

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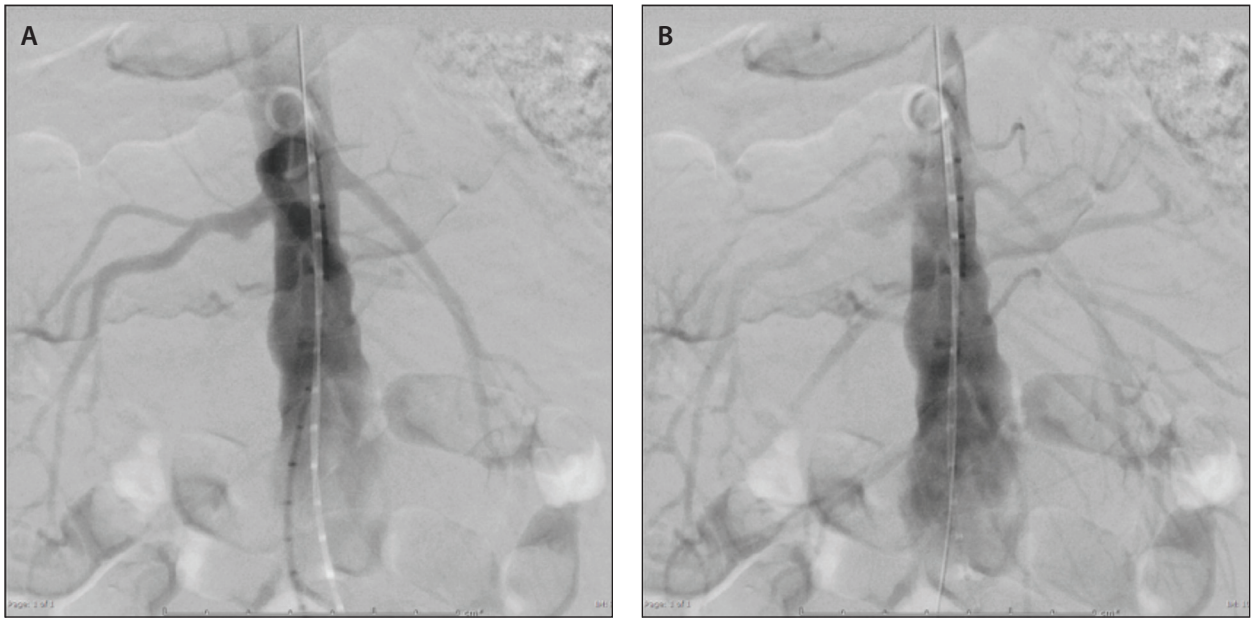

Figure 8. Intraoperative angiogram shows primary blood supply to the HSK (A). Accessory renals can be viewed in (B).

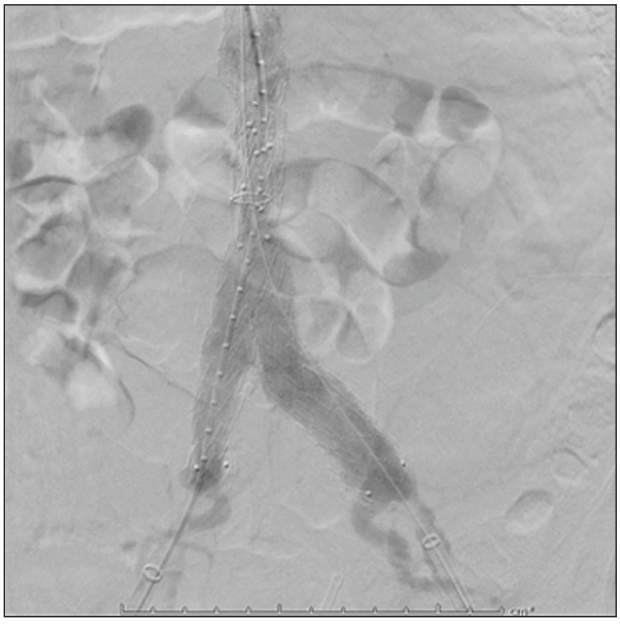

Figure 9. Intraoperative angiogram shows final placement of the Endurant IIs bilateral limb sealing bilaterally, including in the aneurysmal LCIA.

filtration rate. Although this patient's anatomy could have been treated by a number of device options with respect to limb diameters and lengths, the Endurant IIs was highly desirable because pre-case planning was simplified and the device and delivery offered a straightforward off-the-shelf solution option to treat this patient's LCIA aneurysm.

Although HSK is rare in the general population, it is the most common congenital anomaly of the urologic system coincident to AAAs and AAA procedures,[3] estimated to form in approximately 1 out of every 400 to 600 individuals, and is known to occur more frequently in males than females at a ratio of 2:1.[4] HSK has been reported in the AAA literature as far back as the 1950s and 60s and more frequently in past two decades.[5,6] An aberrant arterial supply of the HSK has been known to be a challenging problem that can complicate surgical or endovascular intervention,[7] but several cases dating back to 1997 demonstrate EVAR is an acceptable solution, provided renal vascularization is preserved or minimally compromised, with a number of cases treated by off-the-shelf endografts.[7-9] In 2003, an emergent patient who presented with a large AAA coincident with HSK was successfully treated with an AUI stent graft modified from a Talent acute endovascular aneurysm repair kit with quick recovery.[10] Some renal circulation issues may even be avoided altogether with innovative EVAR devices and techniques.[11-13]

THE ENDURANT IIs: FEASIBLE FOR RUPTURE

Preparedness for endovascular treatment of ruptured AAA (rAAA) cases will likely benefit from the simplicity of inventory management and the expanded range of possible customizations offered by the Endurant IIs. This makes the fourth-generation Endurant IIs an attractive option for both the surgeon and cost-cutting administration in the management of emergent rAAAs, providing a literal off-the-shelf availability and grab-and-go appeal, reducing the need for large amounts of product and alternative inventory. Furthermore, the Endurant and Endurant II line has demonstrated worldwide applicability for treating complex hostile neck anatomies

(including short proximal aortic necks, large-diameter aortic necks, angulated necks), and small external iliac arteries,[14] also supported by data from the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE).[15] Endurant and Endurant II have also been reported to have low rates of reinterventions[16] and endoleaks in elective and emergent EVAR,[17] as well as comparable success in challenging scenarios beyond standard EVAR.[18-20] Not only have individual rAAA case reports shown clinical success of Endurant II applicability,[21,22] but both midterm[20,23] and long-term[24] rAAA results in patient samples using Endurant and Endurant II have been reported with excellent technical success and lower rates of mortality compared to open repair. For all these reasons, this variation of Endurant II renders it a promising off-the-shelf option for elective cases as well as for more emergent rAAA. ■

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