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# Improving Anatomic Conformability in EVAR

How years of stent graft design innovation guided by real-world research and formal feedback have resulted in a device with better anatomic conformability.

BY JEFFREY INDES, MD, AND MANSI SANGHVI, MD

The development of stent grafts for endovascular aneurysm repair (EVAR) has been driven by the pursuit of two distinct but complementary goals: improved performance and increased patient applicability. Safer and more effective stent grafts are associated with fewer complications, such as endoleaks and graft occlusions, which can require secondary surgical or endovascular interventions and shorten patient survival. Stent grafts with greater patient applicability permit the choice of EVAR for more patients, while devices and delivery systems with more adaptive flexibility support procedural success and improved safety and efficacy outcomes by conforming to the anatomical characteristics of individual patients.

It is readily apparent that contemporary stent grafts for EVAR have made significant progress toward these complementary goals. In the United States, this success has been confirmed by the rapid and widespread adoption of EVAR. In a retrospective analysis of the epidemiology of aortic aneurysm repair, querying the US Nationwide Inpatient Sample database of the US Agency for Healthcare Research and Quality, Dua et al<sup>1</sup> found that from 2000 to 2010, the percentage of all intact abdominal aortic aneurysms (AAAs) repaired by EVAR increased 14-fold, from 5.9% to 77.8%.

The increased use of EVAR has reduced the rate of short-term all-cause mortality and aneurysm-related mortality relative to outcomes with open surgical repair.<sup>2</sup> Over the 11-year period covered by the retrospective analysis of Dua et al,<sup>1</sup> the rate of in-hospital mortality was significantly less for patients treated with EVAR than for patients undergoing open repair (1% vs 4% for intact AAAs and 27% vs 41% for ruptured AAAs;  $P < .001$ ). As a sign of steady improvement in stent graft technology and physician technique, between 2000 and 2010, the rate of in-hospital mortality associated with EVAR declined by more than 50%, from approximately 2% to < 1% ( $P = .001$ ), while the rate of in-hospital mortality associated with open repair showed a nonsignificant increase (from 3.8% to 4.8%;  $P > .05$ ).

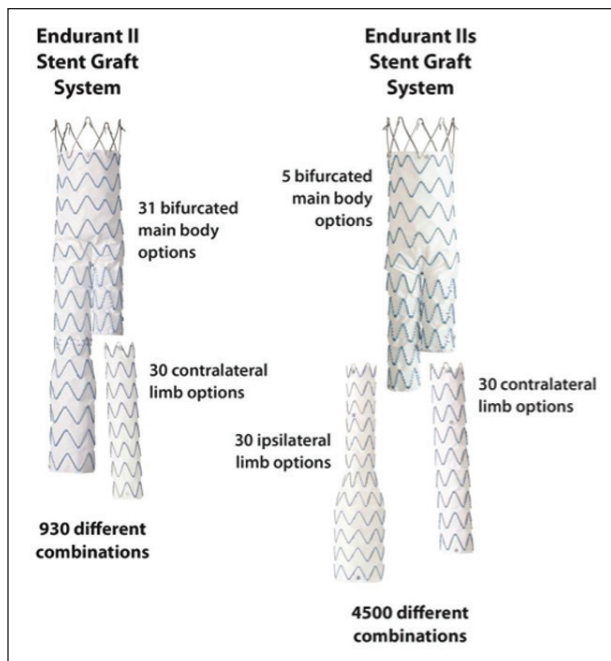
## THE ENDURANT STENT GRAFT DESIGN PROJECT

The creation of the Endurant® stent graft (Medtronic Endovascular) by a team of engineers and vascular surgeons has been recounted by Arko et al.<sup>3</sup> Specifically, the team had four key objectives for the Endurant stent graft system: (1) treating short and highly angulated necks; (2) accommodating tortuous anatomies; (3) ensuring long-term device integrity; and (4) expanding treatment accessibility with improvements in profile and deliverability. To accomplish these objectives, the design team focused on optimizing key performance attributes, such as sealing, durability, conformability in tortuous anatomies, fixation, and delivery system performance. They used a novel multidisciplinary approach that incorporated feedback from more than 150 physicians as well as clinical imaging, computational modeling, and in vitro bench testing.

The Endurant stent graft was thus engineered specifically for performance in patients with AAAs who had either straightforward or challenging anatomies. To provide optimal sealing in short and angulated proximal aneurysm necks, the stent graft has a sinusoidal M-shaped architecture with a small amplitude. The M-shaped proximal stent at the upper end of the stent graft body facilitates wall apposition, minimizing the risk of graft material infolding. To reduce the risk of graft migration, the Endurant stent graft relies on a suprarenal bare stent ring with anchoring pins for proximal active fixation. The radiopaque markers at the proximal and distal edges of the stent graft as well as the flow divider and contralateral gate markers ensure accurate positioning of the device. The spacing between stent rings in the limbs reduces kinking. The Endurant delivery system, with an 18-F or 20-F outer diameter for the main body, relies on a tip-capture mechanism for accurate positioning, and the hydrophilic coating of the delivery system allows access even in small and tortuous iliac arteries.

## REAL-WORLD RESEARCH KEY TO FURTHER ENGINEERING IMPROVEMENTS

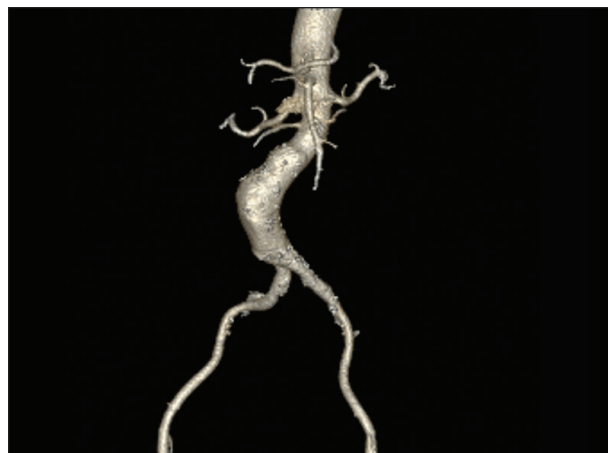
Among EVAR stent grafts, the Endurant stent graft has been the focus of intense postmarket clinical



**Figure 1.** The design of the Endurant IIS stent graft system simplifies the number of bifurcated main body options compared to the predecessor Endurant II stent graft but allows for a 4.5-fold increase in the number of possible component combinations.

research scrutiny, which in turn has provided feedback for device improvements that further the objectives of the Endurant design project. Notably, the device performance has been studied in a postmarket registry of unprecedented scale for aneurysm repair, the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE). With an enrollment of 1,263 patients with AAAs, ENGAGE is a prospective, observational study conducted at 79 centers in 30 countries across six different continents. Inclusion criteria for the ENGAGE registry were minimal, allowing investigator discretion for the determination of eligibility for stent grafting, and follow-up protocols were as close as possible to the standard regimens at the individual sites.<sup>4</sup> Thus, in addition to the enrollment of real-world patients, the treatment applied in ENGAGE represented real-world practice.

In ENGAGE, overall technical success was 99%, and the 30-day reintervention rate was 1.5%.<sup>5</sup> At 1-year follow-up for the first 500 ENGAGE patients, the Kaplan-Meier survival estimates for all-cause mortality and aneurysm-related mortality were  $91.6\% \pm 1.4\%$  and  $98.8\% \pm 0.5\%$ , respectively. As Stokmans et al<sup>5</sup> observed in their trial report, the rates of all-cause mortality and aneurysm-related mortality seen in ENGAGE were comparable



**Figure 2.** CT imaging demonstrating rapid growth of an infrarenal AAA in a 56-year-old woman. She had bilateral accessory renal arteries originating well below her main renal arteries, at a distance of just 112 mm from her hypogastric (internal iliac) artery, and her common iliac arteries were relatively narrow.

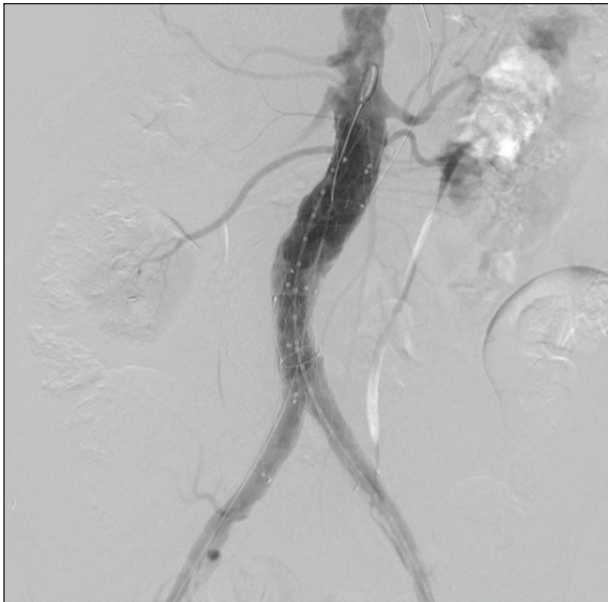
to those seen in the EVAR-1 (Endovascular Repair versus Open Repair)<sup>6</sup> and DREAM (Dutch Randomised Endovascular Management)<sup>7</sup> randomized controlled trials of EVAR versus open repair for intact AAAs. But while American Society of Anesthesiologists class IV patients, defined as having incapacitating disease that is a constant threat to life, were excluded entirely by protocol from the EVAR-1 and DREAM trials, they made up 10.6% of the ENGAGE cohort.<sup>5</sup> At 2 years in ENGAGE, for 1,143 patients, the Kaplan-Meier rate of freedom from stent graft limb occlusion was 97.9%.<sup>8</sup>

In addition, subgroup analyses of the ENGAGE registry have found no differences in 30-day outcomes for patients with symptomatic AAAs versus patients with asymptomatic AAAs<sup>9</sup> or for female patients versus male patients, despite the fact that female gender is an established independent risk factor for worse outcomes after AAA repair.<sup>10</sup> When ENGAGE patients were categorized by whether or not they had challenging neck anatomy, there were no differences between treatment groups at 30 days or 1 year in terms of mortality or secondary procedures.<sup>11</sup> The ENGAGE registry data have also demonstrated that octogenarians can be safely treated with the Endurant stent graft, with high technical success and low 30-day mortality,<sup>12</sup> and that 1-year outcomes for the Endurant aorto-uni-iliac (AUI) device configuration are similar to those for the bifurcated device configuration.<sup>13</sup>

## ANATOMIC CONFORMABILITY

The original Endurant stent graft system received approval by the US Food and Drug Administration

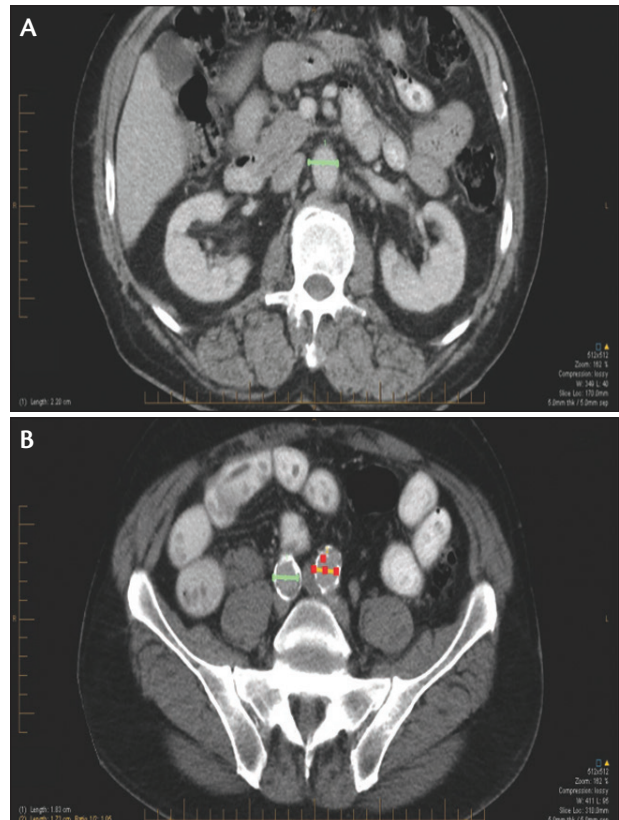
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**Figure 3.** The standard shorter ipsilateral limb length (103 mm) of the bifurcated main body of the Endurant IIs stent graft system allowed deployment below the accessory renal arteries and preservation of the ipsilateral hypogastric artery. The ipsilateral and contralateral limb options available with the Endurant IIs stent graft system enabled customization of the distal limb components to achieve a taper down to the 13-mm diameter in the common iliacs.

(FDA) in December 2010. But since the introduction of the device, the Endurant design project has steadily progressed, with upgrades and new features almost every year—with the Endurant II stent graft receiving FDA approval in June 2012, the Endurant II AUI stent graft configuration receiving FDA approval in May 2013, and (most recently) the Endurant IIs stent graft receiving FDA approval in November 2014.

The latest version of the Endurant stent graft, the Endurant IIs, has exactly the same features as its predecessor Endurant stent graft, the Endurant II, which reduced the profile of the original Endurant stent graft and improved radiopacity. But with a now standardized length of the main bifurcated graft body, the Endurant IIs has a simplified three-piece design—different from the two-piece design of the original Endurant stent graft and the Endurant II stent graft. The shortened ipsilateral leg of the bifurcated main body of the Endurant IIs stent graft is now a standard 20 mm longer than the contralateral limb. Completion of the implantation of the device requires limb placement on both the ipsilateral and contralateral sides, with appropriate combination of the optional limb components, including bilateral flared or tapered components. Both leg diameters are 14 mm. Since the limb



**Figure 4.** In a 74-year-old man with a rapidly expanding symptomatic AAA, CT imaging showed that the infrarenal aorta was 22 mm in diameter (A), while the bilateral common iliac arteries were ectatic, up to 18 mm in diameter (B).

components can be used on either side, precase planning is simplified significantly.

In moving from the Endurant II to the Endurant IIs stent graft, the number of bifurcated main body configurations has thus been reduced from 31 to five. But at the same time, with the ipsilateral and contralateral limb options, the number of possible different combinations of the Endurant IIs stent graft components is 4,500 (5 × 30 × 30), representing a 4.5-fold increase over the total of 930 combinations that were possible with the Endurant II (Figure 1).

In placement of the limbs, the Endurant IIs stent graft design offers the ability to perform in situ sizing on the ipsilateral side, as the component overlap can be adapted between 3 mm and 5 mm during the procedure, ensuring the maximum landing zone apposition without the need for multiple stent pieces. Moreover, with the Endurant IIs stent graft system (bifurcated main body plus limbs), the distal diameter is reduced by as much as 20% when compared with the Endurant II stent graft system. That reduction allows the device to be placed more readily in smaller, calcified distal aortic segments.





**Figure 5.** Combining the appropriate optional components of the Endurant IIS stent graft in this situation allowed for a more precise customization through the entire length of treated aorta (with the 25-mm bifurcated main body) and common iliac arteries, and the optional 20-mm ipsilateral limb component permitted a successful adaptation to the diameter of the patient's limbs.

### CASES ILLUSTRATING INCREASED PATIENT CUSTOMIZATION WITH ENDURANT IIS

A 56-year-old woman presented for follow-up for an infrarenal AAA. Surveillance ultrasound showed that the aneurysm had grown 1.1 cm during the previous year, from 3 to 4 cm, > 1.5 times the diameter of her more proximal juxtarenal aorta, warranting endovascular intervention. Case-planning imaging revealed that she had bilateral accessory renal arteries originating well below her main renal arteries, at a distance of just 112 mm from her hypogastric (internal iliac) artery (Figure 2). In addition, her common iliac arteries were relatively narrow. Using the Endurant IIS stent graft system in this case allowed deployment of the bifurcated main body below the accessory renal arteries and preservation of the ipsilateral hypogastric artery due to the device's standard shorter ipsilateral limb length (103 mm) (Figure 3). Then working from the reduced diameter of the legs of the bifurcated main body, the ipsilateral and contralateral limb options available with the Endurant IIS stent graft enabled customization of the distal limb components to achieve a taper down to the 13-mm diameter in the common iliacs (Figure 3). The patient's postoperative recovery was uneventful, and at the 6-month follow-up ultrasound examination, there were no AAA- or device-related complications.

Another case demonstrating the crucial usefulness of the expanded customization options with the Endurant IIS stent

graft involved a rapidly expanding symptomatic AAA in a 74-year-old man. CT imaging showed that the infrarenal aorta was 22 mm in diameter, while the bilateral common iliac arteries were ectatic, up to 18 mm in diameter (Figure 4A and 4B). Combining the appropriate optional components of the Endurant IIS stent graft in this situation allowed for a more precise customization through the entire length of treated aorta (with the 25-mm bifurcated main body) and common iliac arteries, and the optional 20-mm ipsilateral limb component permitted a successful adaptation to the diameter of the patient's limbs (Figure 5). This patient's postoperative recovery was also uneventful, with no AAA- or device-related complications at the 6-month follow-up ultrasound examination.

### SUMMARY

Since its introduction, the Endurant stent graft system has demonstrated excellent safety and performance results. As the latest update of the Endurant design project, the Endurant IIS stent graft system continues with the performance-tested device features while providing more options for anatomic conformability and broader patient applicability. ■

*Jeffrey Indes, MD, is an associate professor of surgery (vascular) at the Yale University School of Medicine in New Haven, Connecticut. He has disclosed that he is a paid consultant to Medtronic Endovascular. Dr. Indes may be reached at [jeffrey.indes@yale.edu](mailto:jeffrey.indes@yale.edu).*

*Mansi Sanghvi, MD, is a postdoctoral research fellow in the department of vascular surgery at the Yale University School of Medicine in New Haven, Connecticut. He has stated that he has no financial interests related to this article.*

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