Empowering EVAR Clinical Performance

Consistent Durable Outcomes At 3-Year Follow-Up Across Endurant Trials*

BY SHARIF H. ELLOZY, MD

Endovascular aneurysm repair (EVAR) has gradually become the gold standard for the treatment of infrarenal abdominal aortic aneurysms (AAAs) since the FDA approved the first devices in September 1999. Multiple generations of devices have been developed, but the characteristics of the ideal stent graft are consistent. Namely, the device has to be durable, comformable to variant anatomy, and safe to deliver. It needs to be deployed in a precise and reliable fashion. With these characteristics in mind, Medtronic, Inc. (Minneapolis, MN) developed the Endurant® Stent Graft, using a novel multidisciplinary approach that incorporated feedback from > 150 physicians, clinical imaging, computational modeling, and in vitro bench testing.[1]

The Endurant® II Stent Graft, the second-generation Endurant Stent Graft, is composed of woven polyester and electropolished nitinol stents. The suprarenal component is a laser cut nitinol stent with anchoring pins, enhancing proximal fixation. The M-shaped proximal stent allows for conformability and seal in irregular and short necks. The limbs are designed for flexibility and conformability in tortuous anatomy. The delivery system is low profile and hydrophilic, allowing it to track through challenging access vessels. Ultimately, however, the most important characteristic to consider in evaluating a device is the durability of the repair—migration resistance, low endoleak rate, aneurysm sac stability or shrinkage, and low secondary intervention rate. In addition to the 2-year follow-up data available through the ENGAGE study, 3-year follow-up results are now available from the US IDE evaluation of Endurant.

US IDE CONTROLLED TRIAL

The US regulatory trial of the Endurant Stent Graft system was a prospective, two-arm, multicenter trial. The bifurcated arm enrolled 150 patients at 26 sites in the United States and the aortouniiliac (AUI) arm enrolled 44 patients at 15 sites. The sites were a combination of academic and private hospitals, and practitioners from multiple specialties participated. Of note, the study was designed for a minimal neck length of

TABLE 1. 1-YEAR OUTCOMES ACROSS TRIALS

	EU Trial (N = 80)[3]	US IDE (N = 150)[2]	ENGAGE Registry (N = 1,263)[4]
Type I endoleak	0%	0%	0.4%
Whole body migration	0%	0%	0%
Conversion to surgery	0%	0%	0.6%
Aneurysm-related mortality	95% freedom from all-cause mortality[a]	0%	1.5%
Secondary endovascular procedure	3.8%	95.3% freedom from secondary endovascular procedure	5.6%

[a]0% postoperative rupture at 1 year.

*Trials and registry evaluated the Endurant® stent graft system.

TABLE 2. 3-YEAR OUTCOMES FROM US IDE TRIAL

US IDE Trial	(N = 150) 1-Year Results[2]	(N = 138) 2-Year Results[5]	(N = 124) 3-Year Results[6]
Type I endoleak	0%	0%	0.9%[a]
Whole body migration	0%	0%	0%
Aneurysm sac diameter: decrease or stable	99.2%	96.9%	95.4%
Aneurysm-related mortality	0%	0%	0%
Conversion to surgery	0%	0%	0%
Freedom from secondary endovascular procedure	95.3%[b]	93.9%	91.5%

[a]One subject experienced a new type I endoleak at the 3-year time frame that led to an aneurysm expansion. The subject refused intervention and voluntarily entered hospice and died on day 1,212 due to an aneurysm rupture.
[b]Value is calculated from 31–365 days

10 mm, which was the shortest neck length of any US trial up to that point. Fifteen patients (10%) had a neck length between 10 and 14 mm. Other anatomic criteria included an infrarenal neck angulation of 60° or less and an iliac sealing zone of at least 15 mm. This article will discuss the midterm results from the Endurant® US IDE bifurcated arm.

Consistent Results at 1-, 2- and 3-Year Follow-Up

Acute procedural outcomes were very good. Implantation was completed successfully in 149 patients (99.3%). The single failure was due to an inability to cannulate the contralateral gate after implantation of the main bifurcated body. There were no deaths at 30 days, and major adverse events were seen in only six patients (4%). Outcomes at 1-year follow-up, initially published in the *Journal of Vascular Surgery*, were very promising. Six patients died during the first year of causes unrelated to their aneurysm. No patients were lost to follow-up. There were no type I endoleaks, no instances of migration, no ruptures, and no sac enlargements. Sac shrinkage was observed in 64 of 136 patients (47%) at 1 year.[2]

These results are comparable to the 1-year outcomes reported in the Endurant EU trial[3] and the ENGAGE Registry,[4] a global registry of Endurant® cases (Table 1).

The US IDE results at 2 years (Table 2) continued to demonstrate the durability of repair.[5] There were no late type I endoleaks and no instances of migration. The sac size had decreased in 60.3% of patients, remained stable in 36.6% of patients, and increased in only 3.1% of patients. Through 2-year follow-up, 93.9% of patients were free from secondary procedures.

From the most recent 3-year follow-up for the US IDE trial,[6] the Endurant Stent Graft continues to deliver sustained clinical performance across key endpoints. From the 3-year data, the type I endoleak rate was 0.9% (n = 1/107) with no instances of migration, post-implant rupture, or conversion to open repair. As well, aneurysm sac diameter had decreased in 62.7% of patients, remained stable in 32.7% of patients, and increased in only 4.5% of patients. Through the most recent 3-year follow-up, 91.5% of patients were free from secondary procedures.

Ultimately, the durability of the Endurant II Stent Graft is further emphasized with the consistency of outcomes between the rigorous US IDE trial and the ENGAGE global registry. In particular, a good measurement of durability is the AAA sac diameter decrease, which is similar in both trials at 2 years (Figure 1): in the ENGAGE registry, a sac size reduction was reported in 56.1% of patients, stable sacs in 40.0% of patients, and an increase in sac size in only 3.9% of patients at 2-year follow-up.

CONCLUSION

Despite its use in patients with challenging anatomy, the Endurant Stent Graft has proven to be safe and efficacious. Durable aneurysm exclusion has been achieved in the controlled setting of the US IDE and Endurant

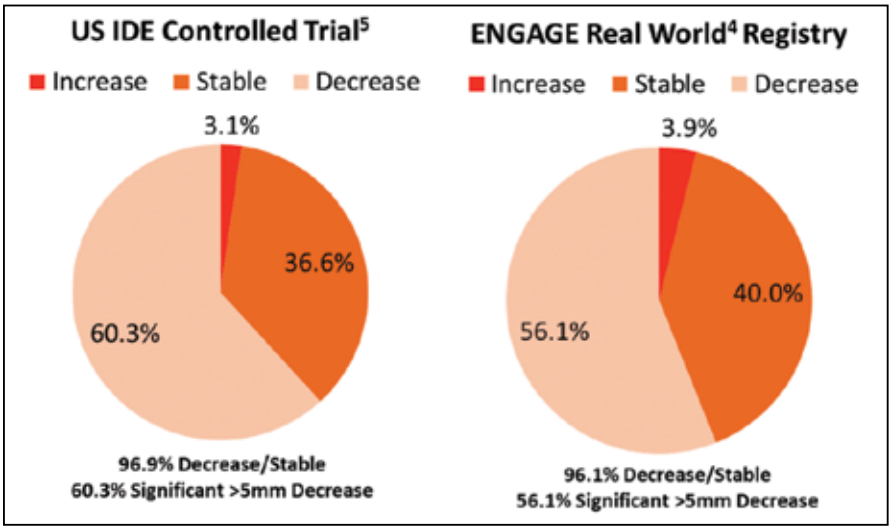

Figure 1. AAA sac diameter change through 2 years.

EU clinical trials, as well as in a real-world registry such as ENGAGE. Finally, these results continue to be consistent at 3-year follow-up, which brings further confidence in the Endurant II Stent Graft's midterm performance, treating over 100,000 patients on a worldwide basis.[7] ■

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