

# Improving Your Practice by Operating Within the IFU

Safely achieving desired results with EVAR.

BY TIMOTHY RESCH, MD, PhD



The development of endovascular aneurysm repair (EVAR) has fundamentally changed the way aortic aneurysm surgery is perceived and performed. Early on, even before any mid- or

long-term data were available, the minimally invasive nature of EVAR was seen as a dramatic development allowing aneurysm repair to be offered to the elderly and those who are physically unfit for surgery.<sup>1</sup>

The early endografts were often somewhat crude in design, simply using interrupted metal stents sewn onto graft fabric. Delivery systems were often bulky and rigid, causing difficulties when passing the EVAR devices to their target positions. However, quite rapidly, major design improvements were made to increase and expand the applicability of this exciting new technology.<sup>2</sup> Dedicated stent grafts with improved fixation systems, radiopaque markers, and flexibility were combined with delivery systems with lower profiles, better trackability, and enhanced deployment features. This resulted in an increasing number of second- and third-generation devices, expanding the scope of EVAR and, perhaps also, the perception of what EVAR could offer.

In parallel to the evolution of infrarenal stent grafts, more complex stent graft designs were developed to allow treatment of aneurysm pathology that precluded infrarenal EVAR. In the late 1990s,<sup>3</sup> fenestrated stent grafts for the treatment of juxta- and suprarenal aneurysms were introduced, as well as branched stent grafts to treat even more complex thoracoabdominal aneurysms.<sup>4</sup> Branched iliac grafts for preservation of the internal iliac circulation in the setting of common iliac aneurysm were also introduced.<sup>5</sup>

## SEALING IN A HEALTHY AORTA

After technical development had overcome the initial difficulties of device delivery and early technical failures, focus shifted to the durability of stent grafts. Early on,



Figure 1. Failed infrarenal EVAR due to neck dilatation (A). Also note the aneurysm in the distal descending aorta. The aneurysm was repaired using a t-Branch device (Cook Medical, Bloomington, IN) (B).

several factors were identified that directly affected the mid- and long-term outcomes of infrarenal endovascular repair. The presence of “suboptimal” sealing zones was clearly the main determinant of EVAR failures (Figure 1).<sup>6-8</sup> In the proximal infrarenal neck, the presence of non-parallel aortic walls, thrombus, and severe angulation predicted poor outcomes, and the same was true in the distal sealing zone in the common iliac arteries. Short and ectatic common iliac arteries during initial implantation predicted late failures with resulting endoleaks and aneurysm nonexclusion.<sup>9</sup>

The same phenomenon has also been observed when using more complex stent grafts. Even though the stent graft was now placed more proximally in the aorta, the presence of adverse features of the sealing zone, indicating a nonhealthy aorta, clearly predicted device failure.

A situation that affects EVAR, and the entire field of endovascular treatment, is that as causes of failures are identified, technical innovation moves forward at a rapid pace with renewed promise to overcome these failures. However, as the applicability of EVAR expands with improved devices, the tendency for off-label use seems to expand even more. The basic premise of suc-

cessful EVAR—safe sealing and anchoring in a healthy aortic segment—often continues to be ignored. Devices are designed and manufactured to deliver durable aortic repair for a given set of anatomical constraints. Abundant literature exists to show that these basic rules are often violated.

The recent report by Schanzer et al,<sup>10</sup> reviewing more than 10,000 patients undergoing EVAR and included in the M2S database (M2S, West Lebanon, NH), again highlighted these circumstances. Apart from the fact that almost 50% of patients treated had aneurysms < 50 mm, the authors clearly demonstrated that adverse anatomical features of the infrarenal sealing zone correlated to late aneurysm growth, thus indicating treatment failure.

Reports on long-term outcomes of fenestrated aortic repair show that moving the sealing zone more proximal in the aorta provides a durable outcome without significantly affecting the perioperative results compared to infrarenal repair.<sup>11,12</sup> In fact, increasing experience suggests that even if the fenestrated repair is made technically more complex (ie, adding more fenestrations), this can be achieved with less exposure to both contrast and radiation.<sup>11</sup>

The same holds true for the distal sealing zone. Landing a stent graft in an ectatic landing vessel greatly increases the risk of late problems. Simply embolizing the internal iliac artery and creating a landing zone in the external iliac artery causes claudication and other complications in a large number of patients. Using iliac branched grafts provides a standardized procedure to provide both seal and flow preservation without interfering with the abdominal aortic aneurysm repair. Data suggest that this is feasible in many patients and that long-term outcomes are very good, with patency rates of approximately 90% at 5 years.<sup>13</sup>

## BUILDING FOR THE FUTURE

Designing the device of the future requires examining the failures of the past. Aortic disease is a chronic process

and demands that vascular surgeons not only treat the segment that is failing right now but also analyze where it might fail next. This knowledge must then be incorporated into the repair so that doors are open for future therapy.

By utilizing knowledge of aortic disease, as well as applying modern EVAR with available devices, we can provide both a durable, stable repair for our patients and a bridge to future surgery. By moving within the instructions for use of current endovascular devices, as opposed to going off label once too often, these goals can be achieved. ■

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1. Hynes N, Sultan S. A prospective clinical, economic, and quality-of-life analysis comparing endovascular aneurysm repair (EVAR), open repair, and best medical treatment in high-risk patients with abdominal aortic aneurysms suitable for EVAR: the Irish patient trial. *J Endovasc Ther.* 2007;14:763-776.
2. Greenberg RK, Chuter TA, Sternbergh WC 3rd, Fearnot NE; Zenith Investigators. Zenith AAA endovascular graft: intermediate-term results of the US multicenter trial. *J Vasc Surg.* 2004;39:1209-1218.
3. Anderson JL, Adam DJ, Berce M, Hartley DE. Repair of thoracoabdominal aortic aneurysms with fenestrated and branched endovascular stent grafts. *J Vasc Surg.* 2005;42:600-607.
4. Chuter TA, Gordon RL, Reilly LM, et al. An endovascular system for thoracoabdominal aortic aneurysm repair. *J Endovasc Ther.* 2001;8:25-33.
5. Oderich GS, Greenberg RK. Endovascular iliac branch devices for iliac aneurysms. *Perspect Vasc Surg Endovasc Ther.* 2011;23:166-172.
6. Fulton JJ, Farber MA, Sanchez LA, et al. Effect of challenging neck anatomy on mid-term migration rates in AneuRx endografts. *J Vasc Surg.* 2006;44:932-937; discussion 937.
7. Abbruzzese TA, Kwoltek CJ, Brewster DC, et al. Outcomes following endovascular abdominal aortic aneurysm repair (EVAR): an anatomic and device-specific analysis. *J Vasc Surg.* 2008;48:19-28.
8. Falkensammer J, Hakaim AG, Andrew Oldenburg W, et al. Natural history of the iliac arteries after endovascular abdominal aortic aneurysm repair and suitability of ectatic iliac arteries as a distal sealing zone. *J Endovasc Ther.* 2007;14:619-624.
9. McDonnell CO, Semmens JB, Allen YB, et al. Large iliac arteries: a high-risk group for endovascular aortic aneurysm repair. *J Endovasc Ther.* 2007;14:625-629.
10. Schanzer A, Greenberg RK, Hevelone N, et al. Predictors of abdominal aortic aneurysm sac enlargement after endovascular repair. *Circulation.* 2011;123:2848-2855.
11. Kristmundsson T, Sonesson B, Dias N, et al. Outcomes of fenestrated endovascular repair of juxtarenal aortic aneurysm. *J Vasc Surg.* 2014;59:115-120.
12. Mastracci TM, Greenberg RK, Eagleton MJ, Hernandez AV. Durability of branches in branched and fenestrated endografts. *J Vasc Surg.* 2013;57:926-933; discussion 933.
13. Parlani G, Verzini F, De Rango P, et al. Long-term results of iliac aneurysm repair with iliac branched endograft: a 5-year experience on 100 consecutive cases. *Eur J Vasc Endovasc Surg.* 2012;43:287-292.