

Impact of endograft design and product line on the device cost of endovascular aneurysm repair

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Objective: Device cost is a substantial component of the overall cost of endovascular abdominal aneurysm repair (EVAR), and the four commercially available devices differ significantly in the cost of their basic configuration. This study examined the impact of three different endografts and their product lines on the overall cost of repair.

Methods: Implant records of 467 EVAR procedures performed during 2000 through 2006 were reviewed. The three devices used were the AneuRx in 178 (38.1%; Medtronic, Santa Rosa, Ca), the Excluder in 123 (26.3%; W. L. Gore & Associates, Flagstaff, Ariz), and the Zenith in 166 (35.5%; the Cook Zenith (Bloomington, Ind). The Powerlink device (Endologix, Irvine, Calif) was not studied. The specific device implanted was determined by its commercial availability at the time of repair, patient anatomy, and surgeon preference. Retail list prices were used for all calculations, and only devices used during the original repair were used for analysis.

Results: The device cost of the most basic configuration for repair (ie, 2 pieces for AneuRx and Excluder, 3 pieces for Zenith) differed by \$3022 between the most expensive (Zenith) to the least expensive (AneuRx). However, the AneuRx system required the most number of extensions (1.90 ± 1.25 per case; range, 0-7), whereas the Zenith required the fewest (0.21 ± 0.51 per case; range, 0-3). When the costs of the extensions were added, the overall mean device costs per case were similar.

Conclusion: The initial cost advantage of the AneuRx and Excluder endograft systems were offset by the more frequent need for proximal and distal extensions. The minimum device cost of a basic repair should not factor into the decision to select one specific device over another because additional devices may be required depending on the design and construction of the endograft system and the accuracy and reliability of their deployment mechanisms. (J Vasc Surg 2008;47:499-503.)

The repair of infrarenal abdominal aortic aneurysms (AAA) has undergone a dramatic change during the past two decades. The traditional open surgical approach has been largely replaced by endovascular techniques; however, certain anatomic criteria must still be met to achieve a successful and durable repair. The cost of these devices has been a subject of considerable controversy regarding the overall cost-effectiveness of the therapy and remains a fiscal obstacle to its wider adoption in certain health care systems.

The current study compared the overall costs of three of the four currently commercially available devices in the United States: the AneuRx (Medtronic, Santa Rosa, Calif), the Excluder (W. L. Gore & Associates, Flagstaff, Ariz), and the Zenith (Cook, Bloomington, Ind). Specifically, we sought to compare the costs of completing an endovascular repair under actual, real-world conditions with an unselected cohort of AAA anatomies that were deemed suitable for endovascular therapy.

METHODS

We retrospectively reviewed a prospectively maintained clinical database of all endovascular repairs of AAA (EVAR) during a 7-year period (2000-2006). All of the procedures were performed at a single tertiary-care university medical center by one of five vascular surgeons. Preoperative planning was based on thin-cut (2- to 3-mm slice thickness) computed tomography (CT) angiograms with three-dimensional (3D) reconstructions and center-path analyses performed using one of three software platforms: Medical Metrix Systems (Hanover, NH), Vitrea (Vital Images, Minnetonka, Minn), and Aquarius (TeraRecon, San Mateo, Calif).

The specific device chosen was determined by its commercial availability at the time of repair (AneuRx, September 1999; Excluder, November 2002; Zenith, May 2003), patient anatomy, and surgeon preference. The principles of endovascular repair remained relatively constant throughout the course of the study regardless of the device used and were similar amongst the different operating surgeons. More specifically:

- The main device was routinely deployed as close to the lowermost renal artery as possible using the full length of the infrarenal neck. A proximal cuff was used if the primary device was deployed >10 mm below renal arteries or if there was <10-mm fixation on completion angiography, regardless of an endoleak. We believed that this yielded the best chances for long-term outcome.

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Table I. Demographics and selected procedural measures among the three devices studied^a

Demographic	AneuRx	Excluder	Zenith
No. of patients	178	123	166
Age, mean \pm SD years	71.7 \pm 13.5	68.9 \pm 18.6	71.1 \pm 14.4
Female, No. (%)	13 (7.3)	14 (11.4)	21 (12.7)
General anesthesia, No. (%)	166 (93.3)	61 (49.6)	74 (44.6)
Fluoroscopy, mean \pm SD min	27.1 \pm 11.1	21.1 \pm 12.7	28.1 \pm 11.5
IV contrast, mean \pm SD mL	88.6 \pm 30.5	92.5 \pm 43.1	103.6 \pm 44.2
Procedure time, mean \pm SD min	194 \pm 75	135 \pm 58	133 \pm 47
EBL, mean \pm SD mL	285 \pm 369	235 \pm 291	227 \pm 125
Urgency, No. (%)			
Elective	159 (89.3)	110 (89.4)	159 (95.6)
Symptomatic	11 (6.2)	5 (4.1)	6 (3.6)
Ruptured	8 (4.5)	8 (6.5)	1 (0.6)
LOS, median (range) days	2 (1–61)	1 (1–40)	1 (0–26)

EBL, Estimated blood loss; IV, intravenous; LOS, length of stay.

- The iliac limbs were always extended as close to the hypogastric arteries as possible, regardless of common iliac length. In cases of ectasia (common iliac diameters ≤ 20 mm), flared limbs or “bell-bottom” techniques with aortic cuffs were used.¹

During the latter half of the study period, the Excluder flared contralateral limbs became available (October 2003), whereas flared limbs were available on both ipsilateral and contralateral limbs in the Zenith device since its initial commercial introduction. More recently, Medtronic had introduced the AneuRx AAAAdvantage line extension that included flared iliac limbs, but the AneuRx implants included in this study all occurred before this. In cases where the iliac artery was >20 mm in diameter without a suitable landing zone proximal or distal to the aneurysmal segment, the iliac limb was extended to the external iliac artery with either surgical revascularization or coil embolization of the hypogastric artery.

Device configurations and list prices (US \$)

Medtronic AneuRx. The minimum construction for repair using this system is two pieces consisting of a main body-ipsilateral limb with a covered length of 13.5 and 16.5 cm, and a contralateral limb with a length of 8.5 and 11.5 cm. Straight limb extensions and aortic cuffs (\$2025) were available. At the time of this study, the minimum list price of one main body (\$7250–\$7550) and one contralateral limb (\$2225–\$2425) was \$9475. The total cost of the entire product matrix (30 pieces comprising one of each diameter and length) was \$117,500.

W. L. Gore Excluder. Similar to the AneuRx, this is a two-piece construction consisting of a main body-ipsilateral limb (\$6980) and a contralateral limb (\$3223). The limb and proximal extenders cost \$2259. A simple two-piece repair would cost \$10,203. The cost of the entire inventory of 39 pieces would be \$187,539. This does not reflect the flared iliac limbs introduced after the original commercial release of the system.

Cook Zenith. This is a 3-piece system consisting of a main body (\$7400) and two iliac limbs (\$2700 each). The

minimum cost of a repair was \$12,800. Owing to the sheer number of different diameters and lengths of the main body and iliac limbs and extensions (\$1500), the entire product matrix consisted of 94 devices at a total cost of \$367,300. This does not reflect the recent introduction of the 36-mm main body.

Only the direct costs of the devices were analyzed. The cost of ancillary devices, such as balloons, bare-metal peripheral stents, and coils, were estimated to be equivalent among the three devices. Data are presented as mean \pm standard deviation where appropriate. The Student *t* test for continuous and the Fisher exact test for categorical variables were used for analysis. Statistical significance was achieved at $P < .05$.

RESULTS

During the 7-year period, 467 patients underwent EVAR using one of the three devices. These included 178 AneuRx (38.1%), 123 Excluder (26.3%), and 166 Zenith (35.5%) cases. The mean age of patients undergoing EVAR was 70.5 ± 15.9 years, and 48 (10.3%) were women. Patient age among the three groups was similar, and each group had approximately the same proportion of women (Table I).

Significantly more AneuRx patients underwent general anesthesia vs local or regional, which was simply reflective of the anesthetic technique used during that segment of the study period. The mean estimated blood loss, fluoroscopy time, and amount of contrast used were similar among the three groups. The total procedure time was significantly longer for the AneuRx cohort (194 ± 75 minutes) than for patients who received the Excluder (135 ± 58 minutes) and Zenith (133 ± 47 minutes $P < .0001$). The median length of stay was 2 days for the AneuRx group, and 1 day for the Excluder and Zenith groups (Table I).

The proportion of patients requiring elective EVAR was similar among the three devices. In the entire cohort, 450 patients (96.4%) had an intact aneurysm at the time of repair. The mean maximal aortic diameters (60.0 ± 12.5 mm for AneuRx, 57.5 ± 9.5 mm for Excluder, and $59.8 \pm$

Table II. Abdominal aortic aneurysm anatomy among the three devices

Anatomy	AneuRx	Excluder	Zenith
Intact, No (%)	170 (95.5)	115 (93.5)	165 (99.4)
AAA size, mean ± SD mm	60.0 ± 12.5	57.5 ± 9.5	59.8 ± 10.8
Neck diameter, mean ± SD mm	22.8 ± 2.1	22.2 ± 2.3	25.2 ± 3.2
Neck length, mean ± SD mm	29.3 ± 16.8	33.9 ± 13.9	31.1 ± 14.0
Iliac aneurysm, No (%)	63 (35.6)	29 (23.6) ^a	53 (31.9)

^aPatients who had an Excluder repair had fewer concomitant iliac aneurysms ($P < .05$).

Table III. Extension usage among the three devices

Extensions	AneuRx	Excluder	Zenith
Total extensions, No.	339	146	35
Proximal	105	47	0
Distal	234	99	35
Extensions per case	1.90	1.19	0.21
Cost of extension	\$2025	\$2259	\$1500
Cost of extensions per case, mean	\$3857	\$2681	\$316
2- or 3-piece repair, minimum cost	\$9,475	\$10,203	\$12,800
Total mean cost ^a	\$13,332	\$12,884	\$13,116
Cost relative to AneuRx	\$0	-\$448	\$216

^a2- or 3-piece construction + cost of extension.

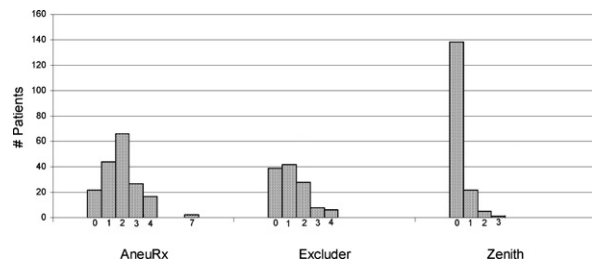


Fig 1. Histogram of extension usage for each device. Most of the AneuRx cases required two or more extensions to complete the repair, and 68.3% of Excluder cases required at least one extension to complete the repair. For the Zenith implants, 83.1% of patients required only the basic three-piece configuration, without any additional pieces.

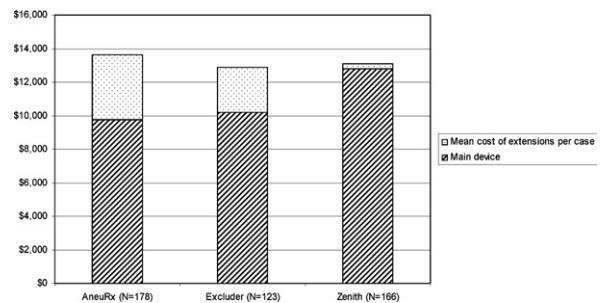


Fig 2. Mean overall cost of the endograft (cost of the basic 2- or 3-piece construction plus the mean cost of extensions) per case.

10.8 mm for Zenith) and the aortic neck diameters and lengths were comparable in all groups (Table II). Slightly fewer patients in the Excluder group had a concomitant iliac aneurysm compared with the rest of the cohort (23.5% for Excluder vs 33.7% for AneuRx and Zenith, $P < .05$).

Each AneuRx repair required an average of 1.90 extensions (range, 0-7). By comparison, the Excluder device required 1.19 extensions per case (range, 0-4), and the Zenith required 0.21 extensions per case (range, 0-3; Table III, Fig 1). When the cost of the extensions was included, the differences in the overall costs of the endografts for the three types of repairs were small and \leq \$500 of each other.

Of interest was that although the basic cost of the AneuRx two-piece repair was the least expensive, in actual practice it was the most costly, and the Zenith system, whose basic three-piece construction was the most expen-

sive, actually cost less than the AneuRx (Fig 2). The Excluder and Zenith endografts required obligatory ballooning with a compliant aortic occlusion balloon to mold the endograft attachment sites and junctions, whereas the AneuRx did not. Factoring the approximate \$350 cost of this balloon, however, did not materially alter the overall mean device cost of the repairs.

To determine if the number of extensions used was reflective of a device-specific learning curve, we compared the mean number of extensions used for each of the three devices in the first 30 patients and compared that with the last 30 patients with the same device. Surgeon experience appeared to show an inconsistent effect on extension usage (Table IV). The number of extensions used with the AneuRx device increased significantly, whereas the number of extensions required among patients repaired with a Zenith device decreased with experience. Some of this may represent the paradox of learning curve, where more complex cases are treated as experience is gained, which in turn may require a higher number of devices.

Table IV. Rate of extension usage (mean \pm SD) between the first and last 30 consecutive series of patients for each device

Group	<i>AneuRx</i>	<i>Excluder</i>	<i>Zenith</i>
First 30 cases	1.53 \pm 1.22	0.83 \pm 0.95	0.47 \pm 0.68
Last 30 cases	2.40 \pm 1.19	1.30 \pm 1.18	0.13 \pm 0.57
<i>P</i>	.007	.09	.04

At follow-up, reinterventions were required in 29 *AneuRx* (16.3%), 13 *Excluder* (10.6%), and six *Zenith* (3.6%) patients. For those late secondary procedures that required placement of extensions, more proximal extensions were used for the *AneuRx* device ($n = 13$) than *Excluder* ($n = 0$) and *Zenith* ($n = 1$) devices. Similarly, distal extensions were required more frequently with *AneuRx* ($n = 6$) than *Excluder* ($n = 3$) or *Zenith* ($n = 0$). It should be noted, however, that reintervention is a time-dependent event, and the *AneuRx* cohort had the longest mean follow-up among the three groups.

DISCUSSION

This study examined the real-life costs of different endograft systems used to treat an unselected, consecutive series of patients with AAA suitable for EVAR. Our results showed that the basic cost of repair—meaning the minimum number of devices required to achieve a bifurcated construction—does not tell the whole story. Indeed, despite an initial cost differential of $>$ \$3000 from the least expensive device to the most expensive device, in the final analysis, the mean cost of actual repair differed by $<$ \$500 among the three devices.

The reasons for this include what is considered “optimal” endovascular repair, endograft-dependent factors, and the current limitations of sizing and planning. In our practice, we strongly believed that optimal repair is achieved with maximal coverage of the proximal and distal landing zones. Although there is little controversy about deployment of the main body as close to the renal arteries as possible,² there is some controversy about the routine extension of the iliac limbs to the hypogastric arteries,^{3,4} especially when there is 2 cm or more of relatively undiseased or nonaneurysmal artery. As reported by Arko et al,⁵ for the *AneuRx* system, which relies on columnar support as an important mechanism of fixation, it has been shown that full coverage of the common iliac arteries resulted in better late outcomes in terms of migration and limb retraction. Furthermore, there is a small but definite risk of late aneurysmal degeneration of the uncovered iliac segment.

Once commercialization of a medical device occurs, application of that device in anatomic situations outside of the manufacturer’s instructions for use (IFU) is common. This is obviously in contrast to the strict constraints of clinical trials that comprise the initial experience of any new medical technology. In the idealized conditions of a clinical trial and strict guidelines of the device IFU, our results may

not hold. However, when such restrictions are lifted by operator discretion, off-label use of additional devices, such as aortic cuffs in iliac limbs, occurs frequently. It is in this context that the results of this study should be viewed.

In this study, 3D reconstructions of CT angiograms were used routinely for preoperative planning and sizing of the cases. Conventional preoperative angiography with marker catheters was rarely used. Although diameter measurements have become fairly reliable, path-length measurements remain the least reliable indicator in endograft sizing and planning, regardless of which method is used. Axial CT tends to underestimate the path length, 3D reconstructions tend to overestimate, and angiography falls somewhere in between, depending on a host of anatomic factors and techniques. In practice, “fudge-factors” are used to compensate for these variabilities in the different imaging modalities. One of the main indications for additional extensions in the *AneuRx* and *Excluder* cases in this series was to achieve limb extensions to the hypogastric arteries when a shorter main body and contralateral limb was purposely selected in borderline cases to avoid inadvertent coverage of the hypogastric artery.

Arguably, had an accurate and reliable method of length measurement been available, iliac extension usage could have been decreased. Alternatively, a method of “trombone-ing” the iliac limb within the docking gate of the main body would allow sufficient intraoperative flexibility to overcome this preplanning deficiency. This concept of intraoperative adjustability of the iliac limbs can be extended not only to just the contralateral limb but also to both limbs to provide the maximum degree of deployment flexibility.

Another method of potentially reducing extension usage would be, theoretically, to stock an unlimited inventory where intraoperative selection of any device can be made on-the-fly. Even with wider availability of consignment stock by the different manufacturers, it is generally impractical from the standpoint of space and inventory management to stock the entire product matrix. A more realistic alternative is if multiple lengths of the same diameter devices could be ordered without additional financial burden (per-case consignment) so that the operator has the option of choosing the optimal lengths of the devices at the time of the procedure and pay for only those devices used for repair. During the period of this study, such purchase agreements were not available, and ordering two main bodies of differing lengths was not a fiscally viable practice. On the other hand, the capacity to have some method of adjusting length built into the device would help in the amount of inventory one would have to stock. Along these lines, a larger variety of device configurations would further obviate the need for aortic cuff usage for “bell-bottoming” purposes. Although not applicable for this study, flared iliac limbs are now available for all the devices examined in this article.

Deployment accuracy also affects cuff and extension usage. Especially proximally, in cases of neck angulation, different mechanisms of deployment can significantly influ-

ence the need for a proximal cuff to remediate a low, suboptimal deployment. Indeed for AneuRx and Excluder cases, proximal cuffs accounted for 31% and 32%, respectively, of the entire extension usage (vs 0% for Zenith; Table III).

The study has a number of limitations. First, as mentioned, the more recent expansions to the product lines of the respective devices were not considered. Most of the experience reported here predated the additional sizes and lengths that could have materially impacted the overall results and their applicability.

Second, although only the endograft costs were considered, there may be other ancillary disposable equipment unique to a particular endograft system that could impact the overall device-related cost of the procedures. However, any variability would likely have been a small fraction of the overall cost.

In a related manner, this analysis was based on a static cost of the devices. Were those prices to change significantly, our results might be significantly altered. To our knowledge, although the AneuRx device has been discounted slightly from its original list price, no substantial price changes have occurred in any of the other endograft systems. Given the current competitive marketplace, however, creative consignment and purchasing programs individually negotiated between the hospital and the vendor are more widely available today than in the early years of this study. This could affect the ability to intraoperatively change device selections and lower the need for extensions.

Third, our bias of routine iliac extension to the hypogastric arteries is not supported by any clear scientific evidence of improved patient outcome. If such a policy had not been practiced, the results could have been significantly different than reported.

Fourth, complexity of an endograft system (2-piece vs 3-piece construction, single-stage deployment vs multi-stage deployment) may lead to prolongation of procedure time and increased operating room costs. Of interest, however, was that the mean procedure time was almost 60 minutes longer for the AneuRx procedures than for the Excluder and Zenith procedures. This may be a reflection of a learning curve effect and the additional time expended for implantation of the extensions.

Finally, we did not consider the Powerlink (Endologix, Irvine, Calif) device, a unibody device that may offer a significant competitive fiscal advantage compared with the other three devices.

In this study, we arbitrarily chose a rather narrow measure of "device cost" as a measure of repair

among many other equivalent or potentially even more valid surrogate measures. Arguably, in endovascular repair, the cost of the endograft comprises a dominant component of the immediate cost of the therapy because other factors such as use ancillary devices, routine postoperative care, and lengths of stay are all fairly similar. As far as the overall cost of EVAR is concerned, clearly, many other factors must be considered such as follow-up imaging and the cost of reinterventions, which speaks more to the long-term efficacy of a particular device.

CONCLUSION

The basic cost of repair using a particular device does not always equal the actual cost. In fact, the overall costs of the devices were fairly equivalent among the three devices considered. Therefore, the minimum cost of the two- or three-piece construction should not influence the decision to use a particular endograft system from a fiscal standpoint. A large product matrix and ability for intraoperative adjustment of lengths may reduce need for additional devices and the final endograft-related cost of repair.

AUTHOR CONTRIBUTIONS

Conception and design: RF, WL

Analysis and interpretation: RF, WL

Data collection: RF, WL

Writing the article: RF, WL

Critical revision of the article: RF, TH, SB, PN, JS, WL

Final approval of the article: RF, TH, SB, PN, JS, WL

Statistical analysis: RF, WL

Obtained funding: Not applicable

Overall responsibility: WL

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