Device-Specific Outcomes in Endovascular Abdominal Aortic Aneurysm Repair: Does the Graft Make a Difference?

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Endovascular grafts are remarkably simplistic devices, constructed of metallic stents, fabric, and, in most cases, sutures. The objective of the repair is straightforward; the device must protect the aneurysm sac from arterial pressure and must accomplish this over the natural life of the patient, without displacement from sites of attachment or degeneration of components.

Design features attain great significance in the long-term performance of the endografts. For instance, a device with bare fabric between rigid stents (the previously available Guidant Ancure device and Cordis Fortron) has the ability to adapt to morphologic changes, specifically aneurysm shortening, without forced dislocation at the attachment sites. The use of barbs (Cordis, Excluder, and Zenith) provides an active fixation mechanism to discourage graft migration over time. The presence of a bare suprarenal stent (Cordis, Talent, and Zenith) increases the length over which friction is applied, placing the fixation segment into more normal aortic wall, potentially decreasing the risk of migration. As well, the shape of the suprarenal component may play a role in fixation; a "flowering" suprarenal stent structure (Talent and Zenith) may decrease the risk of cranial or caudal displacement of the device. The Vanguard experience emphasized the importance of minimizing interplay between the fabric and stent. When these two elements move independently with each heartbeat, the stent usually wins and the fabric loses. In the quest to achieve an approximation of a motionless true "composite structure," devices with insecure fixation between fabric and stent are prone to fabric wear that may culminate in perforation. Lastly, the number of stent "peaks and troughs" oriented around the circumference of the proximal stent may play a role in conforming to the aortic neck. Pleating of a device with a modest number of peaks and troughs may be associated with sealing failure, especially when the device is greatly oversized.

At the Cleveland Clinic, we had the opportunity to treat 703 infrarenal abdominal aortic aneurysms (AAAs) with five endovascular devices between 1996 and 2002. Patients that were part of investigational device exemption (IDE) trials were treated under protocols approved by the institutional review board of the Cleveland Clinic Foundation. Our experience included 63 Ancure (Guidant), 203 AneuRx (Medtronic), 25 Excluder (Gore), 39 Talent (Medtronic), 325 Zenith (Cook), and 48 miscellaneous devices. The Zenith group was further subdivided into those devices placed as part of the US multicenter trial (Zenith-MCT, n = 144) and those that were placed as part of a sponsor-investigator investigational device exemption study (Zenith-SIT, n = 181). The Zenith-SIT subgroup was composed of patients who, usually for reasons of challenging anatomy or medical comorbidities, did not qualify for the Zenith multicenter trial.

Aneurysm-related deaths included any death from rupture or that occurred within 30 days of a primary or secondary procedure. Aneurysm-related death was observed in 12 patients (1.7%). There were no device-specific differences in the risk of aneurysm-related death, averaging 2% or less in all electively treated patients at 12 months. There were three post-implantation aneurysm ruptures that occurred 4, 7, and 19 months following implantation, for a rupture-free probability of 98.7 ± 0.9% at 60 months. Among the ruptured aneurysms, two occurred in patients treated with Zenith devices (one implanted as part of the sponsor-investigator IDE and one as part of the multicenter pivotal trial). The third rupture occurred in a patient treated with a post-commercialization AneuRx device.

Secondary procedures were necessary in 104 patients (15%), and 8 of the patients (7.7%) died within 30 days of the intervention. The 12-month risk of secondary procedures did not differ between device groups, ranging from 8.8 ± 2.1% in the AneuRx patients to 20 ± 5.6% in the Zenith-MCT patients. Conversion to open surgical repair was required in 13 patients (1.9%), and 2 of these patients died (15%). The risk of conversion did not differ significantly between devices. Graft limb occlusions were detected in 19 patients (2.7%) and were most frequent in the Ancure group (11 ± 4.6% at 12 months) but were rarely observed beyond this time point. Migration developed in 25 patients (3.6%) overall. The 12-month risk of migration ranged from zero (Ancure, Excluder, and Talent patients) to 8.2 ± 4.3% (Zenith-MCT patients). Endoleaks were documented in 162 patients (23.0%). The risk of developing an endoleak was 22 ± 1.9% at 6 months, 30 ± 2.3% at 12 months, and 42 ± 3.4% at 24 months following implantation (Kaplan-Meier analysis). There were device-specific differences in the frequency of endoleaks of any type, with the highest 12-month rate in patients treated with the Excluder device (64 ± 11%) and the lowest in patients treated with the Talent (19 ± 7.1%), Ancure (25 ± 7.9%), and Zenith-MCT devices (27 ± 5.4%). Type I leaks were documented in 21 patients (3.0%), type II leaks in 130 patients (18%), and type III leaks in 16 patients (2.3%). When analyzed by the specific type of leak, significant differences were noted between the device groups. The frequency of type II leaks was greatest in the patients treated with the Excluder device (58 ± 11% at 12 months) and least in patients treated with the Talent (19 ± 7.1% at 12 months) device. The frequency of type I leaks did not differ significantly between groups.

Sac shrinkage of 5 mm or more occurred in 8.3 ± 1.4% of the patients at 6 months, 39 ± 2.7% at 12 months, 60 ± 3.2% at 2 years, and 68 ± 3.6% at 3 years after the aneurysm repair. Sac enlargement was observed in 1.8 ± 0.7% of patients at 6 months, 3.5 ± 1.0% at 12 months, 11 ± 2.5% at 2 years, and 21 ± 4.5% 3 years following repair. There were dramatic differences in the rate of sac shrinkage in the six device groups. The frequency of sac shrinkage was greatest in the patients with Zenith devices (54 ± 7.3% and 55 ± 7.8% of patients at 12 months in the Zenith-MCT and IST groups, respectively) and Talent devices (52 ± 9.7% of patients at 12 months) and least in patients treated with the Excluder (15 ± 7.9% of patients at 12 months). Ancure and AneuRx devices were associated with an intermediate rate of shrinkage, averaging 43 ± 9.6% and 29 ± 3.7%, respectively. There were device-specific differences in the frequency of sac enlargement as well. The frequency of sac enlargement was highest in the Zenith-SIT group (13 ± 4.5% at 12 months). The frequency of enlargement was relatively low in the other groups, averaging 5% or less at 12 months.

These results, although not generated from a prospective, randomized trial and subject to the limitations of selection bias, do hint that there may be a relationship between long-term outcome and the type of endovascular device used. Knowledge of the structure of the device and the anatomic idiosyncrasies of each patient are important when planning endovascular aneurysm repair.

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