Stent-graft design: the good, the bad and the ugly

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10 years of experience with endovascular AAA repair has yielded important information regarding the relationship between stent-graft design and stent-graft performance. Commercially available systems differ in important ways. General conclusions regarding endovascular AAA repair need to be qualified by reference to a specific system, or systems. Nevertheless, one can draw conclusions regarding the observed effects of certain design features, some of which are common to several devices. For example: tapered, trackable delivery systems (=20 French in diameter) rarely fail to traverse tortuous iliac arteries; transmural barbs provide the most secure means of proximal attachment; column strength is of little value; proximal stent migration is becoming the primary late failure mode; modular stent-grafts are more versatile than unibody stent-grafts; fully-stented graft limbs are less prone to thrombosis than unstented graft limbs; iliac implantation and low porosity are associated with lower rates of aneurysm dilatation in the absence of endoleak (endotension); any movement between the angle of a stent and the overlying fabric will lead to graft erosion; unpolished (black) Nitinol is prone to fracture; and a long trunk/short limb combination is more stable than a short trunk/long limb combination.

Introduction

Parodi’s first description of endovascular aneurysm repair has to be one of the most important papers in vascular surgery [1]. Although the six cases in this series were hardly a great success, they opened the door to a whole new way of treating aneurysms. Now, ten years and more than 10,000 cases later, some leaders in the vascular surgery community remain in the first stages of grief, while others have embraced all things endovascular with uncritical zeal. Meanwhile, millions of dollars have been spent in the rush to capture a huge potential market. Each of these competing interests spins the data in a different way. They are able to find evidence to support virtually any view of endovascular aneurysm repair, because long-term results are scarce, industry controls most of the pooled data, and devices change more rapidly that investigators can accumulate and publish significant volumes of clinical experience.

Nevertheless, some conclusions are inescapable. The first thing to remember is that everything in this field is device specific and that every feature of device design has consequences for device performance. Many devices share common features, which allow their behavior to be predicted and explained by reference to earlier clinical experience. The goal of this paper is to describe some of the lessons of clinical experience and draw connections between stent-graft design and performance.

The distal end of the stent-graft needs to be implanted securely in non-dilated arteries

Parodi’s first stent-grafts [1] were attached proximally, but not distally, which proved to be a mistake. Retrograde leakage into the aneurysm left the patients at risk of rupture. In addition, the unattached distal end of the graft migrated back into the aneurysm. This is not surprising, because pulsatile
flow through a curved graft generates traction on both its ends. Nevertheless, this lesson has had to be learned and re-learned several times.

The distal aorta rarely provides a secure attachment site. The ‘distal neck’ is usually short, wide, calcified, and thrombus-lined, leading to high rates of failure, both early and late. Even when the procedure appeared to be successful, aorto-aortic stent-grafts are particularly prone to distal stent-graft migration and secondary endoleak. Early studies, which relied heavily upon aorto-aortic grafts, were notable for a steady decline in the number of patients in whom the grafts continued to function as intended [2, 3]. The reliance on a thrombus lining as the site of distal implantation also lead to a high incidence of endotension, in which the aneurysm continued to dilate, or even rupture, despite the absence of demonstrable endoleak [3]. One of the few remaining indications for aorto-aortic repair is juxtarenal anastomotic pseudoaneurysm where the distal implantation site is provided by a previously placed graft [4].

Even bifurcated stent-grafts need secure distal attachment. The original Stentor system relied for distal attachment entirely on the friction generated by its relatively compliant Nitinol stents. In addition, the graft limbs were long, flexible, and often slightly undersized. As a result, the ends slowly pulled out of the common iliac arteries and as the limbs bent more and more the forces became higher until the limb either thrombosed or popped back into the aneurysm, causing a endoleak [5].

A lack of secure distal attachment is also proving to be a weakness of many thoracic stent-graft designs. Other factors that influence the stability of distal stent-graft implantation include the stiffness of the stent-graft, the curve of the aorta, the diameter of the lumen, and the length between implantation sites. It is not possible to stiffen the entire stent-graft, which often needs to traverse the distal aortic arch. When a flexible stent-graft bridges a long, empty, curved segment, there is a real risk that the forces generated by flowing blood will pull its distal end into the aneurysm. There are only two practical ways to address this potential source of late failure. One is to stiffen the central segment of the stent-graft, the other is to add some form of anchor to the distal end. The simplest solution would be cranially-directed barbs, but these impose constraints on delivery system design because they tend to penetrate the sheath during deployment. Alternatively, the distal end of the stent-graft can have an uncovered segment, to encourage incorporation.

The proximal end of the stent-graft needs to be implanted securely in non-dilated arteries

Multivariate analysis of Eurostar data reveals only three independent predictors of aneurysm rupture after endovascular aneurysm repair: a history of continuing aneurysm dilatation, proximal stent migration, and type III endoleak [6]. Most of the instances of late rupture in the Eurostar database are Vanguard cases, but other devices, such as the AncureRx device, are becoming more prominent worldwide as a source of late ruptures [7]. Interestingly, the Ancure device, another entirely infrarenal stent-graft, has not been plagued by proximal stent-migration or late rupture [8]. While the largely unstented Ancure device hangs from stout transmural barbs, the AncureRx device relies on a combination of friction, stent incorporation, and ‘column strength’. Unfortunately, column strength works poorly in a tortuous aorta (column strength and flexibility are mutually exclusive), the friction generated by a self-expanding stent is relatively low, and stent incorporation is unpredictable.

The most secure proximal stent fixation is obtained using a pararenal, barbed stent (Figure 1). This is effective [9, 10], but is associated with two potential problems. First, the attachment between the suprarenal stent and the proximal end of the graft rarely allows more than 30–45 degrees of angulation between the two. Transrenal fixation functions poorly in those rare cases where the angle between the suprarenal aorta and the neck exceeds this limit. Although stent-graft fixation is unaffected, distortion of the stent-graft may result in a type I endoleak. Second, the pararenal stent could theoretically obstruct flow through the renal orifices, induce thrombus deposition with renal embolism, or induce hyperplasia with delayed renal stenosis. However, none of these problems have been seen in multiple studies using radioisotopic, CT, angiographic, and biochemical indicators of renal perfusion [11–13]. At present it appears that pararenal fixation is a relatively safe and reliable way to prevent proximal stent migration.

Type III endoleak leads to rupture

There are three causes of type III endoleak to worry about: disconnection of modular stent-graft components, erosion of graft fabric, and diffuse suture-mediated leakage. The Stentor and Vanguard devices have provided examples of all three failure modes [5]. These devices were the source of most of the Eurostar data regarding the dire consequences of type III endoleak, but other devices are beginning to show a disturbing tendency to develop late type III endoleak [7, 14].

Disconnection

The long, flexible limbs and short docking site of the Stentor/Vanguard stent-graft predisposed to bowing, kinking and disconnection [5]. All current modular stent-grafts have a longer overlap between the main
body and the contralateral limb, but none have any active mechanisms to secure the connection between the two; they all rely on friction. The most stable of these is probably the Zenith device, because its short, stiff limbs allow little potential for bowing within the aneurysm [9].

Stent-breakage and graft erosion

The Nitinol endoskeleton of the Stentor (or Vanguard) device was held together with polypropylene sutures. When these sutures broke, or became untied, the stent framework buckled, bringing its tips into contact with the overlying graft [5]. The result was graft erosion, type III endoleak, and aneurysm rupture. Causative factors were an unstable stent, movement between the tip of the stent and the overlying fabric, and a flimsy fabric. Unfortunately, these features are not unique to Boston Scientific.

Breakage of the Nitinol stent framework has been reported with both of the Medtronic devices. The Talent stent-graft is prone to breakage of the longitudinal support bar, and the AneuRx device is prone to breakage of the stent. Nitinol is a very versatile material with some unusual thermal properties that make it an appealing substrate for stent manufacture. However, it is also rather fragile in the long-term unless strain is kept within narrow limits, and surface irregularities are polished away. Any stent that looks black or gray is a cause for concern. Properly polished stents have a shiny silver surface.

Diffuse leakage through a porous stent-graft

The term ‘type IV endoleak’ was coined to distinguish diffuse seepage of contrast-enhanced blood through many holes in a porous stent-graft from the leakage that occurs through a frank hole or break in the stent-graft. The former appears to be a self-limited phenomenon as little holes become plugged with thrombus, while the latter leads to aneurysm dilatation and rupture. However, type IV endoleak may not be as benign as was once supposed. Although the plugs of thrombus serve as a barrier to leakage, they may still allow the aneurysm to remain pressurized; hence, the different in rates of aneurysm shrinkage seen after repair with porous versus non-porous stent-grafts. Repair with the non-porous Ancure stent-graft [8] produces a more rapid decline in aneurysm size than repair with the porous AneuRx stent-graft [15]. Moreover, the structure of a porous stent-graft is more likely to deteriorate, leading to enlargement of the holes and frank type III endoleak [14] with the concomitant risk of rupture [7].

Type I endoleak leads to rupture

A primary type I endoleak indicates failure to exclude the aneurysm from the central circulation. In the presence of a type I endoleak the aneurysm still pulsates [16], dilates [17] and ruptures [7].

There is no reason to observe a patient with a type I endoleak in the hope of spontaneous resolution. Thrombus may eliminate CT signs of endoleak, but
the risk of recurrent endoleak and rupture persist [17]. Type I endoleak should be treated. Distal endoleaks are easy enough to eliminate. If one is willing to sacrifice the internal iliac artery, the conduit can be extended into the external iliac artery. If not, one can create a surgical bypass from the external iliac artery to the internal iliac artery [18] or use a branched stent-graft to provide dedicated outflow to the internal and external iliac arteries (Figure 2).

A proximal type I endoleak is a more difficult problem. The list of helpful endovascular maneuvers includes balloon dilatation, additional stents, and additional stent-grafts [19]. In the absence of gross technical error, a type I endoleak represents a failure of patient selection. Risk factors include short neck, angulated neck, wide neck, irregular neck and conical neck [20]. Any of the above may cause a leak, but combinations of two or more factors are particularly dangerous. In such cases, pararenal stent fixation may improve stability, but does little to improve the seal. The only reliable way to avoid a type I endoleak is to move the implantation site to a more proximal level, while preserving flow to vital branches, such as the renal arteries, through fenestrations [21] and branches [22]. It will be a long time before we have the data to conclude that these demanding procedures are safe and effective. Until then, 20–30% of patients with AAA must remain beyond the reach of endovascular technique.

Type II endoleak is of uncertain significance

According to the Eurostar data, type II endoleak does not confer any increased risk of rupture [6]. However, trans-catheter measurements in cases of type II endoleak often show systemic arterial pressures within the aneurysm [23] and type II endoleak is sometimes associated with continuing aneurysm dilatation [24]. Our impression has been that type II endoleak through the inferior mesenteric artery is more dangerous, but easier to treat, than type II endoleak through the lumbar arteries alone, because the collateral connections between the superior mesenteric artery and inferior mesenteric artery are larger.

Endovascular methods of aneurysm packing are being developed to prevent and treat type II endoleak [25]. These techniques will have a role if type II endoleak, or a subset of type II endoleak, prove to be more malignant than they currently appear.

Figure 2  (a) Preoperative angiogram, showing tortuosity, calcification, and bilateral iliac aneurysm. (b) Intraoperative angiograms with and without contrast, showing a stent-graft that bifurcates in the distal common iliac artery into internal and external iliac branches
Modular designs are more versatile and more flexible than unibody designs

The typical bifurcated stent-graft has three implantation sites, each of which has a wide range of diameters. The distance between implantation sites also varies widely, resulting in a 5-dimensional matrix of possible stent-graft shapes and sizes. If each parameter were to have five possible sizes, the number of combinations would be more than 1500 (right and left are interchangeable). Therefore, no manufacturer could manage the inventory necessary to have every possible combination immediately available in unibody form. Nor would they want to custom-make every stent-graft to order. The answer is to separate the components, as in a modular design, and vary each parameter independently. Then, each of three components can be available in five diameters and five lengths from a stock of only 50 components. This degree of versatility also confers greater flexibility. Given a small stock of spares, one can change, or augment, the combination during the operation.

As the designer of the first bifurcated stent-graft [26], I have a fondness for the unibody approach, which my original system employed. Nevertheless, I have to conclude that modular stent-grafts have overwhelming advantages, whereas the only advantage of unibody design is a reduced potential for type III endoleak. There are no components to separate. However, a properly designed modular stent-graft, with relatively short limbs and a locking mechanism between components, virtually eliminates this risk.

Self-expanding stent-grafts should be oversized by 10–20%

According to Eurostar data, the rate of type I endoleak falls as the degree of oversizing increases from 0% to 20%, whereupon it plateaus. Further increases in the degree of oversizing are not associated with any change in the risk of endoleak. Based on these findings, the lower limit of oversizing is 20%. An analysis of EVT and Ancure results yields the same findings.

In our experience, a policy of 20% oversizing results in a proximal stent-graft diameter of 28 mm, or more, in over than half of AAA cases. Similarly, a policy of 10% oversizing at the iliac end of the stent-graft, results in most being 14 mm, or more. Both FDA approved stent-grafts have a rather limited range of sizes. The usual result is a lower degree of oversizing. This may be satisfactory in the short-term, but leaves very little margin for subsequent increases in the diameter of the neck [27]. Similar concerns apply to the use of large diameter stent-grafts in ectatic iliac implantation sites, although these arteries appear to be relatively stable [28]. We feel comfortable implanting stent-graft up to 24 mm in diameter in iliac arteries up to 20 mm in diameter.

Unstented limbs are prone to thrombosis

The early experience (1993) with a bifurcated unibody stent-graft made it abundantly clear that unstented graft limbs were prone to kinking, longitudinal folding and thrombosis, while fully-stented limbs (Wallstents) almost never suffered this fate [26]. This observation applies equally well to the current bifurcated Ancure device. Some operators routinely line the Ancure graft limbs with Wallstents, others do so selectively, based on the intraoperative appearance on angiography or intravascular ultrasound. Neither policy is encouraged by the manufacturer, Guidant, which raises two arguments against stenting the graft limb. The first is that an unstented limb is less able to accommodate postoperative changes in ‘aneurysm morphology’, by which they mean aneurysm shortening. The concept of postoperative aneurysm remodeling was initially promoted by Boston Scientific as an explanation for kinking of the Vanguard device, and is now maintained as a marketing tool. However, most studies demonstrate that significant aneurysm shortening does not occur [29]. Besides, the rate of graft limb thrombosis is far higher for unstented Ancure graft limbs than for those that contain Wallstents. The second argument, based largely on Vanguard experience, is that stents can erode through graft limbs. However, many Ancure grafts have been lined with Wallstents over several years, yet there has never been a reported case of graft limb erosion. This concern for the consequences of a stent-fabric interaction may be more valid in the case of some other fully-stented grafts, depending on the specific profile of the stent, the nature of the graft fabric, and the potential for movement between the two. The risk of erosion is minimized by designs that have rounded stent surfaces and durable fabrics, and achieve intimate attachment between the stent and graft.

In addition to kink resistance, fully-stented limbs have several other advantages. The stents, or connections between the stents, render the graft stable longitudinally, so that it can be re-instrumented without fear of collapse. This feature is particularly important for modular devices, which have to be catheterized from below while still unattached distally.

Iliac tortuosity, calcification, and isolated stenosis rarely preclude device insertion

Inability to traverse the iliac arteries used to be the commonest source of procedural failure [2, 3]. It is now a rare event, even when the iliac arteries are very tortuous. A stiff guidewire (Lunderquist) alone will
often straighten the iliac arteries completely. The external iliac arteries, which are usually the site of the greatest tortuosity, are usually the most easily straightened. Acutely angled common iliac arteries are another matter, especially if they are heavily calcified. But even these arteries yield to the combination of a stiff guidewire and a trackable delivery system. A trackable system need not necessarily be very flexible, but it must have a smooth gradient of stiffness from its tip to its shaft, and a smooth, tapered external profile (Figure 3). Unfavorable features include a blunt metal tip, and a thin-walled kink prone sheath.

Stent-graft orientation must be easy to control

Bifurcated stent-grafts have an optimal orientation within the aorta. Any other orientation causes twisting. One cannot assume that the orientation will remain constant during insertion. The distal iliac arteries sometimes impose a small degree of bending on the delivery system. As the delivery system moves proximally the direction of iliac curvature changes. Instead of bending again, the delivery system rotates and the stent-graft ends up 180° out of its intended orientation. It is therefore important to have some means of determining and controlling the orientation of the stent-graft. The best devices have prominent markers and a 1:1 response to externally applied torque. The worst have confusing markers and a partial response with a difference between the ends of the prosthesis. This leads to twisting of the stent-graft, which can cause far more problems that malorientation of the entire stent-graft.

A maloriented modular stent-graft can be difficult to catheterize, but the consequences are not usually serious. In contrast, a maloriented or twisted uni-body stent-graft can be a real problem. Experienced users of the Ancure system have learned how to jiggle the system around while moving it back and forth through the iliac artery, but this aspect of stent-graft insertion is often a source of frustration for new users.

Perception dictates the market and the market dictates research and development

Developments in surgical technique usually follow developments in technology. This is especially true of minimally invasive surgery, in which the operative field that cannot be seen or touched directly. While we rely on industry for new tools, they rely on us for guidance. Industry will make what they think physicians will buy. In most companies, the marketing department has a huge influence over both the funding and direction of the research and development department. For example, the late failures of the Vanguard and AneuRx devices are starting to focus attention on the issue of durability. Any device perceived as flimsy will find itself without a market. This includes all devices whose primary design principle is low profile. Hence, a waning interest in developing a percutaneous device. In fact, low profile and durability are not mutually exclusive, but when it comes to new device development, perception is the most important factor.

Conclusion

Some authors have a tendency to base broad generalizations regarding the costs, complications, and limitations of endovascular aneurysm repair on a narrow experience of one or two devices. Some general conclusions are valid, but they need to be qualified by reference to the specific characteristics of the stent-graft and the specific circumstances of the study. One of the more important aspects of any paper on endovascular aneurysm repair is the information it yields on the relationship between device design and device performance.

Given the corporate influence over data, opinions, and programs, physicians need to pay very close attention to the design and performance characteristics of the devices they use.
attention to reported adverse events, not just in the United States, but in Europe too. Then they need to decide which data and whose opinions can be trusted. Pity the people at the FDA who have to sort all this out in a highly political environment.

References