Feature

Late Failures of Devices Used for Endovascular Treatment of Abdominal Aortic Aneurysm: What Have We Learned and What is the Task for the Future?

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ABSTRACT **Since their introduction in 1991, endografts for the exclusion of abdominal aortic aneurysms have evolved by "learning from failures." As significant device failure modes are reported, manufacturers modify device design to improve effectiveness and durability based on analysis of clinical results. This article summarizes what has been learned from a variety of device failures with a view toward understanding the implications for future activity in the continuing development of endovascular technology. Secondary interventions have been used to improve late outcomes of many devices. Long-term durability remains an issue because the limited data on follow-up beyond 3 or 4 years show gradually accumulating device failures in ways that were not anticipated. The future of successful endografting requires more and longer-term follow-up data, better understanding of the interaction between aortoiliac morphology and device design, improved imaging techniques, development of physiologic methods for endograft assessment, investigation of adjunctive measures to control the abdominal aortic aneurysm (AAA) sac environment, and expansion of the dialogue between clinicians and industry.**

Keywords **Abdominal aortic aneurysm, endograft failure, stent-graft durability**

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The seminal report by Parodi[1] in 1991 establishing clinical endovascular treatment of abdominal aortic aneurysm came at a propitious time because catheter-based therapy for other vascular conditions was already being rapidly accepted and minimally invasive surgery in many specialties was well into a logarithmic phase of development. Two additional factors influenced the advent of endografting—the rapid entry of multiple device manufacturers into the field and the lack of a suitable animal model or ex vivo simulation as a substitute for human investigational trials as a proving ground for the technology.

What this background meant for the clinician and the patient was that devices to be employed were largely based on theoretical considerations. Of course, good manufacturing principles and the regulatory process required bench-testing simulation to evaluate strength of materials using mechanical means. But this did not predict device behavior and function in actual clinical use. Animal models, sometimes using normal anatomy and sometimes with crude simulations of aneurysm by prosthetic patch angioplasty, were largely used to refine concepts for delivery and fixation of devices. They were not capable of showing late outcomes as might be anticipated in humans.

This article is a brief attempt to summarize what has been learned about device failures across a general experience with endografts of many types with a view toward understanding the implications for future activity in the continuing development of endovascular exclusion of abdominal aortic aneurysm (AAA).

THE EARLIEST DAYS

Even during his training in the United States in the 1970s, Dr. Juan Parodi had planned for what he was to accomplish years later at home in Buenos Aires in offering an alternative to conventional open surgery for large, life-threatening AAA in patients whose comorbidity made them exceptionally high operative risks. In addition to being a major stimulus to the field, this earliest clinical experience, reported in 1991[1] after acute experiments with simulated aneurysms in animals, had three important lessons bearing on the subject of learning from failures. The first was that with appropriate conservatism in the application of unproven technology, the procedure was limited to patients in very poor general health. As anticipated, though not described in the initial report, late mortality from other causes was sufficiently high in such a group that meaningful long-term data were unable to be accumulated. It is still true today that follow-up beyond 3 or 4 years is available in only small numbers of cases.[2]

A second point from this first report was that a failure mode was already observed that had implications for device design change. The initial configuration for the aortoaortic, so-called straight graft used a single proximal anchoring stent and none distally. Follow-up observation showed blood flow

reflux into the aorta above the distal extent of the endograft. Although some patients appeared to be adequately treated by this first design, modification to include a second stent placed at the distal end of the fabric tube was adopted as standard for future endografting. This is a simple illustration of the basic process that continues today. Observations of physiologic responses and clinical events, largely through evaluation of vascular imaging, are analyzed and translated into design changes. Originally this was simple and direct, as Dr. Parodi applied it, but endograft development has become much more involved now because large company structures, teams of engineers, multicenter trial data, and the requirements and control of regulatory agencies have added complexity, cost, and time to the process.

Another important feature that has recently emerged as a major influence on late results of aortic endografting was contained in this original report in a single sentence that read, "The size of the excluded AAA is considered to have decreased in three patients."[1] This observation was not known at the time to be a powerful and still somewhat poorly understood factor, but today it is clear that the changing shape of the excluded aortoiliac anatomy is highly significant in many ways, including a direct cause of endograft failure. The unexpected observation that became rapidly evident from the earliest cases was that many excluded AAAs shrink, some so much that they can be truly said to have disappeared. This cannot be accounted for by simple pressure changes within the endografted AAA. It is still not known what accounts for this shrinkage in most AAAs and why some apparently excluded AAAs do not shrink. But the principle became clear through empirical data that by excluding AAAs from the circulation, a response can be induced that causes shrinking. The resultant morphology change can exert forces to alter the configuration of endografts and may cause them to fail.

MODES OF FAILURE

There is a long list of causes and modifying influences resulting in late failure of aortic endografts. Not all of these can be examined in detail in this discussion, but an inclusive outline may be helpful as an overview, as shown in Table 1. In addition to this list of causes and influences, another element needs to be considered—patient selection. The reason for this lies in the influence of anatomic features on late results. If the goal of endografting for AAAs is to protect the patient from rupture risk by excluding the AAA from the circulation, then the durability of the required sealing and attachment may be strongly influenced by accepting candidates with marginal anatomic features. Examples of this are many. Considering only the upper attachment zone, examples include choosing patients whose proximal neck is so large that the endograft has minimal contact with the arterial wall; inserting endografts into a proximal neck that contains significant thrombus that may provide only a temporary seal; a proximal neck that is very short and angled,

Table 1 Causes and Influences Resulting in Late Failure of Aortic Endografts

1. **Insertion or Deployment Problems**
   a. Delivery system torque causing endoprosthesis misalignment
   b. Endoprosthesis damage from insertion forces
   c. Misplacement of proximal attachment (too high, too low)
   d. Inadequate distal anchoring zone
   e. Inadequate length of iliac artery insertion for bifurcation endograft
   f. Failure to appose arterial wall (proximally and/or distally)
2. **Migration**
   a. Patient attachment zone enlargement
   b. Device structural failure
   c. Inadequate friction with increased displacement forces
3. **Device Structural Failure**
   a. Modular component separation
      i. Design limitations
      ii. Inadequate overlap
      iii. Morphology change induced traction
   b. Prosthesis fabric failure
      i. Sutured fabric seam disruption
      ii. Angled stent impact trauma
      iii. Stent pinching of fabric
      iv. Fabric motion induced fretting
      v. Sutured stent attachment
4. **Endograft or Vessel Thrombosis**
   a. Design promoters
   b. Morphology change induced kinking
   c. Attachment zone placement

allowing only tenuous attachment; and the possible adverse late effect of accepting a patient for endograft treatment with a very large proximal neck that may be destined to continue to enlarge in the course of developing a true juxtarenal aneurysm after treatment.

DEVICE FAILURE IN RELATION TO MORPHOLOGY CHANGE AFTER ENDOGRAFTING

Because the phenomenon of aortoiliac dimension change following stent graft exclusion has such important meaning for late endograft function and is a direct influence on late failure, it deserves understanding before looking at specific examples of device failures. In an early report, when aortic endografting had not really achieved widespread use in the United States, May and colleagues[3] at the University of Sydney described what they saw in follow-up computed tomography (CT) scans of patients 6 months or more after endoluminal AAA repair. Two groups were identified: (1) 23 patients whose AAA diameter was observed to shrink a mean of 9 mm in 1 year and

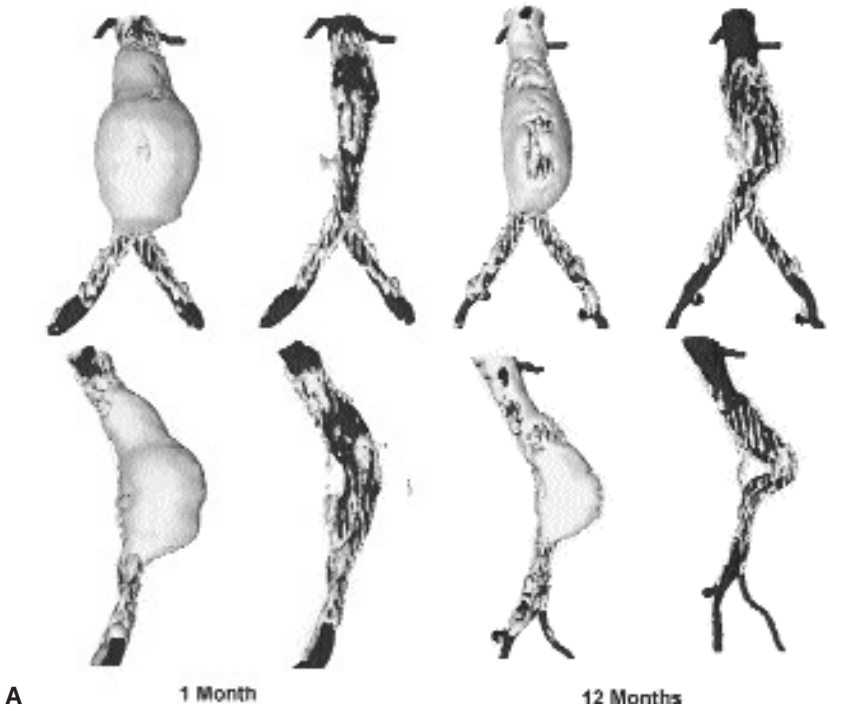
who had no evidence of "contrast extravasation" (the now commonplace term *endoleak* had not yet been coined by the Sydney group); and (2) 4 patients whose AAA sac increased significantly in diameter with evidence of contrast extravasation. Also of great continuing interest were three patients in this report whose AAA increased in size *without* evidence of contrast extravasation. Whether this observation was the result of an imaging artifact that failed to show blood flow in the sac or because of pressure transmission through thrombus was unknown. This report is important when considering late failures because it shows that the simplistic notion that clinical success can be evaluated by knowing only whether an endoleak is present is wrong. Confirmation of this line of thinking soon came from many other investigators, who also indicated that the change in AAA sac after exclusion was poorly understood.[4–6]

There are other important parameters used to describe aortoiliac morphology change that may cause or contribute to late device failure. Two of them, angulation and length changes, are interesting in their own right and all the more so because they cause us to consider the effect of the measurement process on our understanding of post-endograft changes. Angulation changes occur in the excluded vascular structures and may result in either straightening or increased tortuosity. Furthermore, changes in angulation of the endovascular prosthesis may be independent of those in its surrounding artery. The following case illustrates the problem.

Case 1

A 67-year-old woman presented with recurrent, vague abdominal pain that had been a source of concern over the preceding year because of her known 4.5-cm-diameter AAA. Repeated CT scans had shown no evidence of rupture or other disease but gradual enlargement of 6 mm in diameter during the 12-month interval. A modular, self-expanding type of aortic endograft was inserted. Over the course of the first postoperative year, gratifying shrinkage in AAA size was documented. However, it was also observed that as the AAA sac size decreased, increasing angulation of the endograft was occurring (Fig. 1A). At 12-month follow-up examination, distal migration of the uppermost part of the endograft and severe kinking of the midstent graft were observed (Fig. 1B) without any evidence of endoleak or AAA enlargement. While these findings were being evaluated, the endograft thrombosed, presumably because of the marked degree of angulation. Open operative conversion to standard surgical repair was followed by uneventful recovery.

This case illustrates several important issues that bear on device failure and the quality of data used to understand its causes. First, it shows that assessment of what constitutes a successful outcome of aortic endografting is not as simple as knowing that the AAA has decreased in size and that endoleak is not present because this patient's stent graft failed despite both of those con-



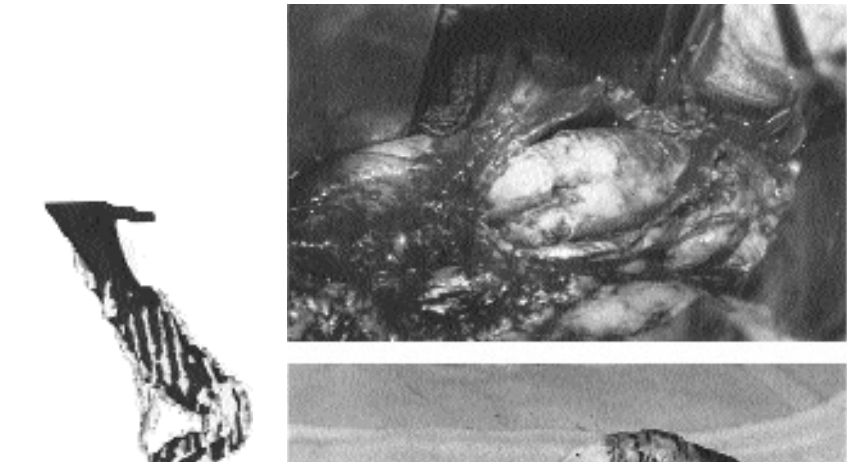


Fig. 1 **(A)** 3D models made by postprocessing of spiral CT scans (Medical Media Systems, West Lebanon, NH) are shown in frontal and lateral projections with and without the aneurysm sac. Note the obvious AAA shrinkage at 12 months compared with 1 month and the marked increase in angulation of the endograft seen in the lateral (lower) projections. **(B)** On the left is a computerized rendering of the endograft within the aorta showing both angulation and distal migration of the upper end of the endograft at 12 months. The upper photograph on the right shows the appearance of the endograft within the aorta at the time of explantation for graft thrombosis. The removed endograft specimen shows the angulation observed during follow-up imaging.

ditions having been met. Second, it raises concern over how to measure the morphology change in vessels and endografts. Using ordinary CT scan methods, duplex ultrasound, and arteriography singly or in combination, it is not possible to describe accurately changes in angle, volume, and length of the relevant structures. The basic problem is that two-dimensional imaging methods do not work when information is needed to describe three-dimensional objects.[7] A discussion of imaging problems and how they affect the understanding of endograft function is beyond the scope of this article. But the debate about whether the aorta changes length following endografting illustrates the issue. One well-recognized European center concluded that "longitudinal shrinkage of the sac following endovascular aortic aneurysm repair led to buckling or kinking of the endograft within 1 year in 69% of patients. This appears to be an important source of delayed complications."[8] At the same time another well-regarded European center also with considerable aortic endograft experience concluded that "in this group of shrinking aneurysms after AAA repair, foreshortening of the excluded aortic segment appears not to be a clinically significant problem."[9] Cause of the apparent contradiction probably lies in the application of two-dimensional tools when the aorta and the endograft lying within it exist in three dimensions. So the unfortunate reality at present is that although morphology assessment is extremely important in understanding late endograft failures, much work remains to be done to improve the process of data acquisition and the assessment of graphic data.

This case can also provide a stimulus for considering the differences between endografts that are fully stent supported throughout their entire length and those that are fixed by stents only at the proximal and distal attachment zones with unsupported fabric between them, much like conventional vascular prosthetic grafts. Many device failures are a direct result of morphology change in relationship to the characteristics of particular endograft types. Although there are important differences in the design and placement of stents in the fully supported grafts, they have in common an intent to provide resistance to deformation and kinking. But kinking can still cause fully stented endograft failure, as this case illustrates. The greater flexibility of endografts that are not fully stent supported allows easier adaptability to tortuous and changing anatomy. But this approach has its own set of problems, as illustrated by reports of the common need for adjunctive stenting to reduce external compression.[10] One report of results with the Ancure device (Guidant Corp., Menlo Park, CA), without stent support through the length of the endograft, described 46% of 88 devices inserted requiring adjunctive stenting for graft narrowing.[11]

A form of device failure that has been reported to result in late AAA rupture after endografting is separation of device components leading to the rapid development of a large pressurizing endoleak. The problem of limb separation is specific to the modular endograft type in which components of the stent graft are assembled in situ as opposed to other types that are one

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piece in construction even though bifurcated in shape. But the occurrence of this complication has been observed with various manufacturers' modular designs.[12,13] Under nominal conditions after initial deployment of a modular stent graft, the frictional forces between its elements are sufficient to maintain a stable position. But as the excluded aortoiliac anatomy changes shape in the process of shrinking, forces are applied to the endograft. Available endografts from different manufacturers are varied in their column strength and resistance to bending forces. If a stent graft is relatively flexible, it will bend in response to the changing aorta. If it is rigid, it may accumulate tension until the yielding point provides an outlet for that tension. In some cases this appears to be the junction between components of the endograft, as illustrated by the patient reported by Politz et al.,[14] whose endograft developed severe angulation 2 years postoperatively associated with limb separation, endoleak, and rupture (Fig. 2).

When Zarins et al.[15] reported on seven cases of late AAA rupture, they documented the contribution of operator error to the problem of limb separation. Early postoperative radiographs showed that the contralateral limb had been inserted into the junction between the two components for an insufficient length and was thus liable to separate more easily than if it had been nominally positioned. This illustrates that operator variability is another factor in the analysis of device failures that cannot be ignored.

MECHANICAL FAILURE

Structural failure can occur independent of stress on the prosthesis induced by morphologic change in vascular anatomy. Reports of three different types of endograft failure show how this occurs. An early endograft was a one-piece design introduced into clinical trials by Endovascular Technologies, Inc. (EVT) (Menlo Park, CA), available in both straight and bifurcation configurations. One of the unique features of this endograft was the use of penetrating hooks that were driven into the aortic wall at the proximal fixation point by balloon inflation in addition to friction from a self-expanding stent. Soon after beginning human implantation, insecurity of proximal fixation was associated with radiographic evidence of fractures of the anchoring hooks. Jacobowitz and colleagues,[16] reporting the worldwide EVT experience, found three late ruptures among a total of 669 endografted patients, two of which showed hook fractures. Although this was not uniformly associated with adverse clinical consequences, the company suspended its clinical trial while the cause was identified and manufacturing process changes instituted to correct the problem. Matsumura and Moore[17] reported 10 explants of early EVT grafts, eight of them demonstrating attachment system hook fracture. Although most of these patients had migration with resultant endoleak that led to planned conversion to open surgery, one had AAA rupture and survived. Brewster et al.[18] showed that a satisfactory course over a period of years

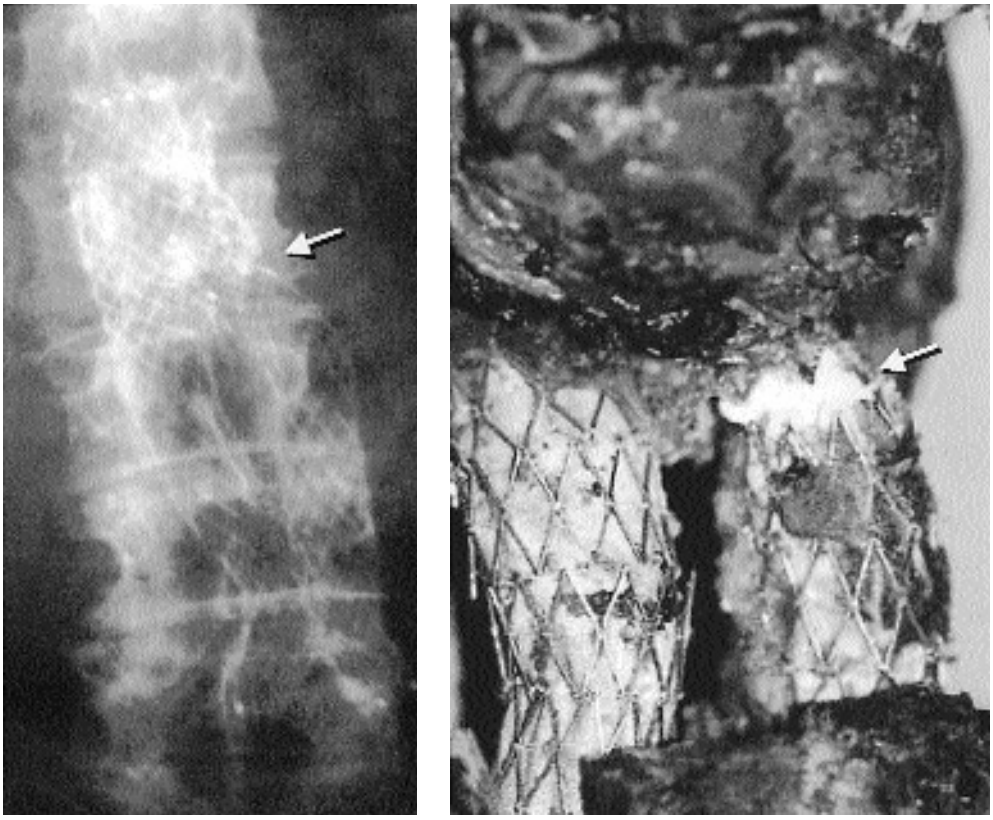

Fig. 2 On the left is a plain film showing three sets of radiopaque limb markers of which the most inferior marks are located on top of the iliac limb (arrow). There is evidence of limb dislocation shown on the plain film. This was confirmed at surgery for graft explantation shown in the specimen photograph on the right. Separation between iliac limb and endograft main body (arrow) has been highlighted by a white marker inserted in the lumen. (From Politz JK et al. J Vasc Surg 2000;31:599–606, with permission.)

with marked shrinking of the treated AAA is not sufficient to predict continued success when they reported rupture 2.5 years following apparent success after EVT endografting. During the successful emergency surgery, complete loss of distal fixation associated with hook fractures was found (Fig. 3). Subsequently, the redesigned endograft was reintroduced into trials that proved clinically successful and led to regulatory approval for commercial sale.[2]

Another example of an early endograft type that showed mechanical failure in clinical use was the Stentor prosthesis (Boston Scientific Corp., Natick, MA). This graft employed a fabric tube that was constructed with a lengthwise suture line in the polyester fabric supported by underlying Nitinol stents. Although there were other late problems induced by morphologic changes, one problem that seemed clearly to have a direct mechanical cause was rupture of the long suture line that led to failure of AAA exclusion.[19,20]

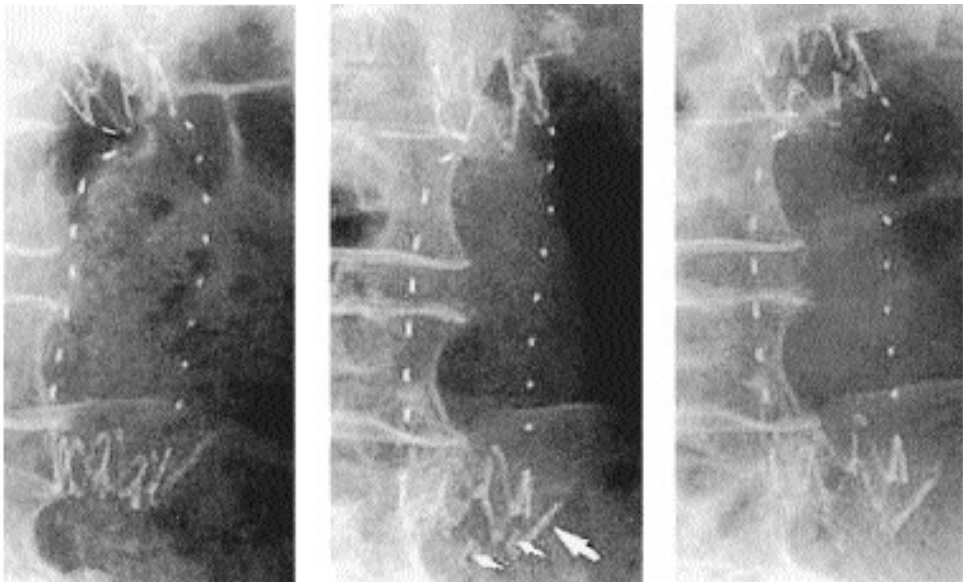

Fig. 3 This series of plain radiographs taken at 6, 24, and 30 months (left to right) following endograft insertion show hook fractures (small arrows, middle) and proximal migration of the lower end of the stent graft (right). Aortic wall calcification serves as a migration marker (middle, large arrow). (From Brewster DC et al. J Vasc Surg 1998;27:992–1003, with permission.)

Mechanical failure was invoked in the cause of AAA rupture with associated aortoenteric fistula 17 months after apparently successful functioning of an early Stentor endograft. The authors concluded that "suture disruption between the internal support stents is a recognized complication in the first-generation Stentor device."[21] Schunn and colleagues[22] assessed long-term safety and efficacy in 190 patients, most treated with early generation stent grafts. After observing changes in the endoprosthesis that they interpreted as "suggestive of endograft disintegration" in 30% of their patients treated with three different devices, they concluded, with understandable frustration, that "technical improvements in stent materials and design are necessary to guarantee long-term stability and safety of the device."

It would be fortunate if mechanical failures were limited only to the earliest designs of aortic endograft, but such is not the case. Even more recent designs have shown evidence of mechanical failing, as illustrated by the following case.

Case 2

An 89-year-old woman with an asymptomatic 9-cm-diameter aneurysm was treated with a Vanguard I aortic endograft (Boston Scientific Corpora-

tion, Natick, MA). For the first 12 months her aneurysm remained excluded and the endograft appeared satisfactory in position. There was no change in the aneurysm size, but no evidence of endoleak was found on technically adequate CT scanning and multiple duplex ultrasound examinations. At 18 months there was moderate increase in endograft tortuosity, but the maximum diameter of the aneurysm remained unchanged (Fig. 4A). Abdominal pain soon thereafter led to repeated CT examination, which now showed an endoleak. Arteriography revealed evidence of a type III direct endoleak from the aortic trunk of the endograft (Fig. 4B). Advice to permit a secondary endovascular procedure for endograft placement was refused, and the patient expired of ruptured aneurysm 2 weeks later. At autopsy, multiple perforations of the endograft fabric by underlying stents were observed (Fig. 5). That this occurred without the kind of extreme kinking and angulation caused by AAA shrinking led to assigning direct mechanical cause as the basis for the failure. The environment inside the aorta is a physically harsh one both in terms of mechanical forces and in terms of the corrosive effect of ionized blood.[23] The mechanical bench testing apparatus used by most manufacturers to meet required testing for regulatory approval does apply relevant stress to endografts under study and allows rapid accumulation of data intended to simulate the effects of millions of cardiac cycles in a compressed time interval (Fig. 6). But these tests are not really the same as the in vivo situation for many reasons, not the least of which is that they lack the variable complexity of biological systems and chaotic interactions that make empirical observations still valuable no matter how appealing the theoretical prediction of results.

Some newer and yet-to-be-introduced endograft designs are pursuing the goal of having smaller diameter endograft delivery systems. There is an intuitively obvious benefit in having smaller catheters to place stent grafts, such as avoiding groin incisions and femoral dissection and safer passage of potentially traumatic instruments through the access vessels and others. But if the decreased size of the delivery system is achieved by reducing the dimensions of materials that make up the stent graft that will be left in place, the theoretical concern over strength of the endograft and its ability to offer durable protection from a life-threatening condition grows larger. Early experience with conventional aortic prostheses during the 1960s and 1970s demonstrated some device failures directly due to problems with strength of materials.[24–27] This lesson might still be relevant in the investigation of aortic endografts today.

MAGNITUDE OF THE ENDOGRAFT FAILURE PROBLEM

Complete device failure resulting in ruptured AAA after endografting is a continuing problem at the end of the first decade of endograft experience in a small number of patients. This dramatic and disappointing outcome is the basis for the strong admonition in virtually every report of late results that

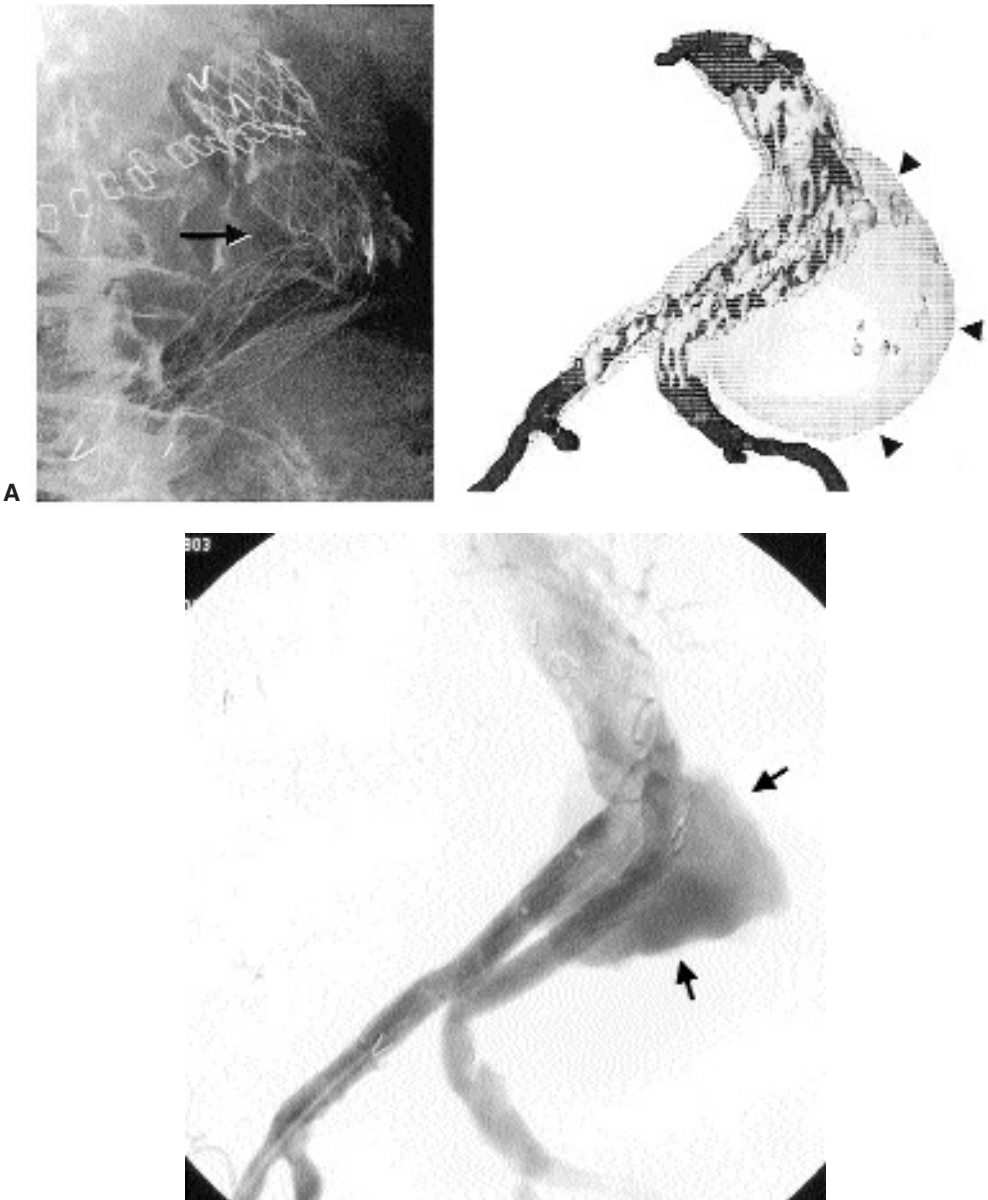

Fig. 4 **(A)** On the left, a plain radiograph taken at 18 months postoperatively shows marked angulation of the endograft prosthesis (arrow). On the right, a computerized model (Medical Media Systems, West Lebanon, NH) shows the endograft in relationship to the AAA sac (arrowheads). **(B)** A contrast aortogram shows a large endoleak (arrows). This was demonstrated by multiple views to be arising directly from the body of the prosthesis, so a Type III endoleak was proven radiographically.

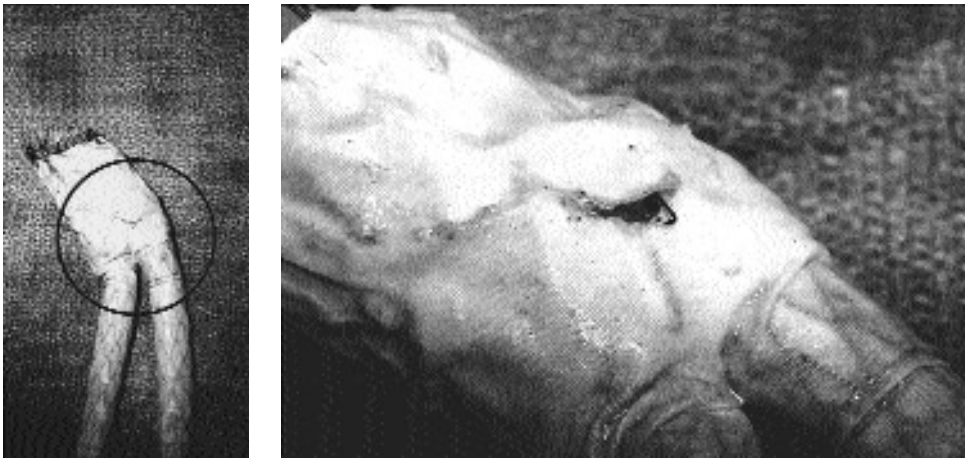

Fig. 5 A specimen photograph taken at autopsy and close-up of the anterior surface in the region identified by the circle. An underlying stent apex can be seen protruding through the fabric.

careful lifelong follow up is mandatory for all endograft recipients. Anecdotally, many centers with an endograft experience extending over 4 or 5 years seem to find that a significant number of patients either fail to meet their schedule for detailed follow-up with its accompanying CT imaging or complain about doing so. So follow-up data, outside of well-controlled clinical trials, may not be reliable. But the need for late data is more and more apparent as reports of device failures accumulate, and some experienced endovascular centers have concluded that durability of an endograft cannot be evaluated with less than 3 years of follow-up.[20]

In 1995 Lumsden and colleagues[28] described two patients who had rupture following an early attempt at endograft exclusion, one attributed to poor patient selection because the distal anchoring zone was inadequate and resulted in death. The other patient had a persistent endoleak because the device failed to seal distally and survived an emergency operation 2 weeks following the original, incomplete procedure. Thus, this early failure report shows the interplay between patient selection and device characteristics—both contributing to failure.

Reports containing significant cohort size give some indication of the prevalence of the worst-case problem of post-endograft rupture, but the duration of the observation period is still short for the majority. This was emphasized in the current report of the U.S. Vanguard trial, which describes outcomes for 268 patients receiving endografts with varying numbers of them followed from 12 to 36 months.[29] Ruptured AAA occurred in three patients, successfully managed by emergency surgery in one. A variety of

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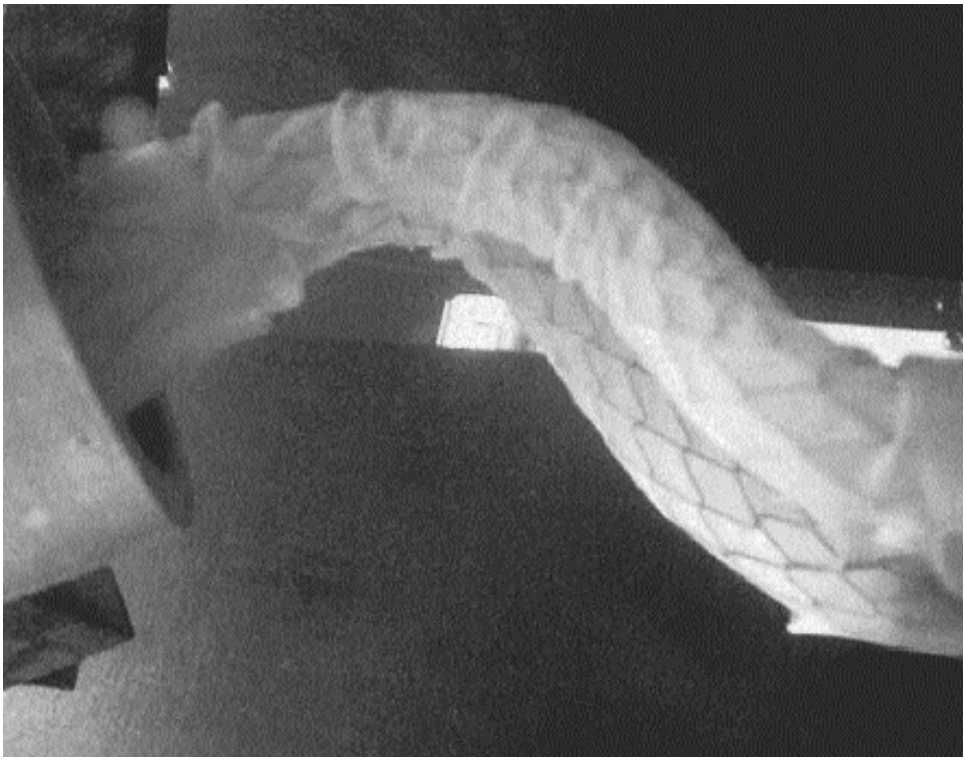

Fig. 6 This shows a Vanguard stent graft in an apparatus simulating the angulation of implanted iliac limbs. The effects of pulsatile forces can be studied by ex-vivo testing. (From: Beebe HG. Late risks of endograft for aortic aneurysm: observations from the United States Vanguard trial. In: Greenhalgh RM, ed. The Durability of Vascular and Endovascular Surgery. London: W.B. Saunders Co. Ltd; 1999, p. 415, with permission.)

other types of device failure and their management were also described in detail. But the conclusion of greatest importance from this report was that a 12-month follow-up observation period is not enough to reveal all safety issues.

Among 243 patients receiving a wide variety of endograft types at the University of Sydney between 1992 and 1998, 7 of 17 requiring late conversion to open repair had ruptured AAA as the indication.[30] Six of the seven survived. The most recent follow-up data for the Ancure device (Guidant Corporation, Menlo Park, CA), which includes only patients with the redesigned attachment system, reveal no report of late rupture among 268 patients followed for 2 years.[31]

A large database was established in Europe in 1996 to accumulate self-reported late outcomes of endografts for AAA provided by 88 centers. A report on late rupture risk among 2464 patients with a mean follow-up of approximately 12 months showed 14 with confirmed rupture.[32] These occurred from 3 to 24 months postoperatively with 57% occurring later than 12 months, suggesting again that short-term data do not adequately inform.

Not all endograft "failures" are the complete calamity represented by late rupture. There are an increasing number of reports documenting the relatively high number of lesser degrees of failure that result in the need for secondary endovascular procedures or late conversion to open surgical repair. Becquemin et al.[33] emphasized the need for secondary intervention among 73 patients in a French endograft trial by reporting that primary success rate at 12 months, defined as AAA exclusion without secondary intervention, was only 74%. Beebe et al.[29] have reported the need for secondary endovascular intervention with successful outcome for a variety of late problems that included migration, limb separation, and thrombosis. Overall, these indications for secondary treatment of milder forms of functional device failure were found in 27 (10%) of 268 patients treated with endografts in the Vanguard trial. All limb occlusion, limb migration, and three endograft migration cases were successfully treated with secondary endovascular procedures. Two additional endograft migration cases were successfully converted to open repair.

The combination of a requirement for close follow-up and more frequent secondary intervention, regardless of device type, in patients treated with endovascular AAA exclusion compared with conventional open repair is a burden of cost, patient anxiety, and utilization of resources that must be added to the risk of rupture.

TASKS FOR THE FUTURE

What the accumulating evidence of various types of endograft failure implies for the future is a complex matter, but some areas needing work can be identified that should yield clinical benefit.

1. Clearly the need for more and longer term follow-up data is still not met. The new registry under the auspices of the LifeLine Foundation in the United States has begun acquiring data from patients treated in investigational device trials sanctioned by the Food and Drug Administration (FDA). The process will include follow-up data accumulated by an independent research organization and analysis of outcomes through cooperative efforts that include manufacturers, physicians, and federal regulators.
2. The impact of morphology change as a contributor to device failure will be better understood with wide application of more sophisticated imag-

ing that takes advantage of three-dimensional tools and computerized postprocessing methods. It is imperative that good-quality imaging data before and after endografting be an integral part of all trials and clinical research on endografts. Combining three-dimensional imaging with computerized finite element analysis of the physical forces acting on the endograft, generated by blood flow and surrounding vascular structures, will provide direction for endograft design changes and construction of more functional ex vivo models.[34,35]

3. Even though improved imaging will yield better quantitation of device and anatomic dimensions, there is a need to move toward physiologic follow up of the excluded aneurysm. Duplex ultrasound with still-improving methods of providing color flow images and three-dimensional information seems to be a direction worth pursuing. But remote-sensor pressure monitoring could be an even more direct approach to early warning of impending device failure to exclude the AAA.
4. Investigation of adjunctive measures to change the contents of the excluded AAA sac and behavior of the arterial wall after endograft insertion has already begun.[36] A variety of therapeutic substances can be imagined to have potential benefit in influencing morphology change and reducing late rupture risk. This can be confidently expected to be an active area of investigation in the near term.
5. Perhaps the most important task for the future lies in expanding on what should be an active dialogue between clinicians investigating this new method of AAA repair and research and development engineers to extract maximum value from the human experiment that is ongoing. Promotion of open communication, to the extent that legitimate proprietary interests can permit it, that can use the outcome databases as a start will yield improved endograft designs.

The most certain overall conclusion that can be drawn from analysis of the first decade of experience with aortic endografts is that the process of developing this minimally invasive approach still has a long way to go before the presently identified problems are resolved.

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Expert Commentary

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The article by Dr. Beebe provides a review of the lessons learned during clinical application of endovascular prostheses to the treatment of abdominal aortic aneurysms. As Dr. Beebe suggests, a review of device failures can help identify important factors that can be used to enhance the design of newer prostheses that acutely exclude of aneurysms and have mechanical properties that adapt to the morphologic changes that occur in the aneurysms following implantation.

Although the focus of the article looks at failure, the incidence of catastrophic events has been remarkably low for a new evolving technology. It is clear that over time there will be continuing adverse events that need to be carefully addressed, with many of the analysis parameters being extensively outlined in this article. As more patients are implanted with endovascular devices, it is becoming apparent that the known mechanical wear of conventional fabrics and stents is also a long-term limitation in these new devices. In endovascular prostheses, material-related failures may be more frequent due to an attempt to reduce the profile of delivery catheters by thinning of fabrics and device components. For this reason careful monitoring and testing of new materials and long-term surveillance are particularly important.

An important component of the endoluminal prosthesis trials has been an investigation of the morphology of abdominal aortic aneurysms prior to implantation and an understanding of changes that occur over time. In general, patients with conventional aortic surgeries have been followed infrequently with imaging studies so the identification of degenerative changes in vascular prostheses or enlargement or atherosclerotic involvement of adjacent arterial segments has not been studied unless there has been a concomitant clinical event precipitating this evaluation. Because of ongoing imaging surveillance requirements for the endovascular prostheses, a new understanding of the changes that occur in aortic morphology and adjacent vessel disease is providing information that was previously unavailable.

An important component of this article is the author's emphasis on long-term surveillance. At the present time a challenging clinical scenario is to develop cost-effective, efficient means to obtain surveillance of the devices and to suggest protocols for interventions when indicated. The images must be interpreted expeditiously with results readily available for patient encounters and clinical decisions. Not only does this require a significant increase in

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time for repetitive office visits and interpretation of studies, but it also requires significant resources to store data for later reference. At present, there are unanswered questions regarding the reimbursement for these services provided by both imaging centers and physicians; there questions add a new dimension to the adaptation of this technology.

The Last Word — Hugh G. Beebe, M.D.

Dr. White expresses the opinion that "the incidence of catastrophic failures has been remarkably low for a new evolving technology." From recollection of the early use of aortic prostheses in the 1960s, one might agree that endograft failure rates could be considered low in that comparison. But, in the 21st century, we have a very effective and proven treatment in the form of conventional open surgery that didn't exist 40 years ago. So, the challenge now is for endovascular repair to meet the expectation of long-term success that the average-risk patient, having elective treatment of an aortic aneurysm, is entitled to expect. It is encouraging to note that aortic endografting is now making a transition from theoretical considerations to prostheses designed with observed performance data for guidance.