Endovascular treatment of abdominal aortic aneurysms

Jonathan B. Towne, M.D.*

Medical College of Wisconsin, 9200 W Wisconsin Avenue, Milwaukee, WI 53226, USA

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Abstract

Background: Endovascular treatment of abdominal aortic aneurysms is a rapidly evolving technique that has gained broad acceptance in the treatment of patients with abdominal aortic aneurysms.

Methods: A review of the English literature was done to determine the short- and long-term outcomes of endovascular repair of abdominal aortic aneurysms. Reports of complications such as endoleak, graft migration, graft limb occlusion, aneurysm rupture, and aneurysm enlargement were evaluated.

Results: Short-term results of endovascular repair of abdominal aortic aneurysms are excellent. The necessity for open conversions is less than 5%. The cumulative risk of aneurysm rupture is approximately 1% per year. The coverall incidence of graft limb occlusion was 2.8% in the follow-up period. The cumulative risk for a secondary procedure was 12% at 1 year, 24% at 2 years, and 35% at 3 years. Moderate and severe neck angulation was associated with an increased incidence of adverse events in the follow-up period. Endografts have the potential to become infected and develop aortoduodenal fistula. The treatment of ruptured aneurysms with endovascular grafts has been successful and a technique that is increasingly used.

Conclusion: Endovascular treatment of abdominal aortic aneurysm is an effective technique with excellent short-term results. The long-term results remain to be determined. Ongoing surveillance is necessary to avoid late complications of aneurysm rupture. © 2005 Excerpta Medica Inc. All rights reserved.

Keywords: Abdominal aortic aneurysm; Endovascular stent grafts; Aortic prosthesis; Blood vessel prosthesis; Implantation; Vascular grafts

With the publication in 1986 by Balko and associates [1] of a technique of treating abdominal aortic aneurysms with transfemoral intraluminal graft implantation, a whole new field in vascular surgery was introduced. In 1991, Parodi et al [2,3] published the initial human experience, and in 1995, the first transfemoral endovascular repair of an abdominal aortic aneurysm in the United States was performed. In the following 13 years, there has been an increase in sophistication of these devices, so currently more than half the abdominal aortic aneurysms are being treated by this newer endovascular approach in many medical centers [4]. With multiple reports of successful implantation of these devices, the focus of the investigation has shifted from showing the feasibility of this treatment to the durability of these repairs. Continued modification of these devices has occurred and currently devices in which side branches can be passed into renal and/or mesenteric arteries are now under development.

The appeal for endovascular treatment is quite obvious. The avoidance of major abdominal incisions and the attendant respiratory, renal, and cardiac complications associated with this procedure is a significant advantage. In patients who have significant comorbidities, which would make an open operation impossible or certainly high risk, the opportunity to prevent rupture of an abdominal aortic aneurysm by the insertion of a device placed transfemorally is a significant advancement.

Types of Devices

Initial devices were assembled by combining stents and cloth fabric that were designed for other purposes. In Parodi’s initial graft, the grafts were only anchored proximally by stents, but because of an unacceptable high rate of leakage (endoleak) at the distal graft attachment site, stents were included at the distal attachment site as well [2]. Currently, all types of grafts use fixation both at the proximal and distal end of the graft [2,5,6].
The first device specifically manufactured for endovascular repair of abdominal aortic aneurysm was designed by Harrison M. Lazarus and developed by the Endovascular Technologies Company [7,8]. This device was the first to begin the United States Food and Drug Administration (FDA) approval process for the phase I, II, and III trials. The first human implant of the device was performed in February 1993. In September 1999, two devices, the AneurRx and Ancure devices, were granted FDA approval for marketing. Subsequently, the Gore Excluder device and the Cook Zeinth devices have also been approved. There are three components necessary for the endovascular treatment of abdominal aortic aneurysm. First is the ability to access the aneurysm through the iliac arteries, second is to obtain graft fixation both proximally and distally to the aneurysm, and third is to decompress or depressurize the residual aneurysm sac [9].

**Fixation**

The first variable we will consider is fixation. Grafts can either have fixation as a result of the radial force exerted by a metallic stent or it can have, in addition to the stent, barbs or hooks that are embedded in the normal aorta above the aneurysm, which would assist in preventing the graft from migrating distally. The second aspect in terms of fixation is infrarenal fixation versus suprarenal fixation. Grafts have now been developed that can be attached to the suprarenal aorta. This is accomplished by having an amount of bare stent that crosses the orifice of the renal arteries but allows blood to flow through its interstices. The fabric portion of the graft begins distally in the infrarenal aortic segment. The long-term effects, if any, of having renal blood passing through a wire mesh on renal function remain to be determined.

**Delivery System**

With advancing technology, the delivery systems are becoming smaller. Initially, these were in the range of 27-French diameter and are often now 22- and even 19-French diameter. The delivery system has to be small enough to pass through the iliac arteries, which in some patients can be quite small, particularly in women (Fig. 1A and B). Because the course of the vessels tend to be tortuous and the fact that from the aortic bifurcation to the iliac bifurcation the common iliac artery generally has a posterior lateral course and from the iliac bifurcation to the common femoral it has more of an anterior lateral course makes navigation of these vessels with a rigid device difficult. Limitations on the size of the iliac arteries, either because of small size or atherosclerotic disease particularly circumferential calcification, can result in difficulty passing the device into the aorta.

**Prosthesis**

An endograft is composed of two components: the fabric graft and the metallic skeleton. Both PTFE and Dacron have been used for the fabric component. Because the fabric is in close apposition to the metal cage and realizing the heart beats 32 million times a year, the effects of wear and tear on the fabric over time become a significant factor. The fabric can be attached outside the metal stents or embedded in it. Commonly, fabric is attached to the exoskeleton by sutures. The devices can be straight, tapering grafts, or bifurcated grafts. The bifurcated graft can be a single graft or modular device.

A variety of exoskeletons grafts have been developed. Some grafts have stent fixation proximally and distally with nothing but fabric graft between the two. This is compared with others in which there is a metal exoskeleton throughout the length of the graft. The biocompatible metals used are stainless steel, Elgiloy (Elgiloy Limited Partnership, Elgin, IL), and nitinol. Elgiloy is a nickel, cobalt, and chromium super alloy (40% cobalt, 20% chromium, and 15% nickel, the remainder iron manganese, molybdenum mohybian no- lithium, carbon and beryllium) that exhibits high strength and ductility, a long fatigue life, and corrosion resistance [9]. Nitinol is a nickel titanium alloy that is 55% nickel and 45% titanium, with the ability to return to a predetermined shape (shape memory) along with fatigue and corrosion resistance [9].

The factors that determine the durability of the stent graft include the ability of the graft to remain in position, the risk of graft fabric wear or degeneration, and the effect of metal fatigue of the metallic compounds. Also sutures in which the fabric graft is attached to the stent can fracture resulting in decreased columnar strength. Because of the stringency of the FDA’s rules, most of the development in terms of initial clinical use of stent grafts for aneurysm repair has
been done in Europe and/or Australia and the longest-term follow-up has come from these countries.

Endoleak

To have common reporting standards, the Ad Hoc Committee for the Standardized Reporting Practices in Vascular Surgery of the Society for Vascular Surgery and the American Association of Vascular Surgery established standards and terminology for endovascular aortic aneurysm repair [10]. Definition of clinical success is on the intent to treat basis and require successful deployment of endovascular devices at the intended location without death as a result of treatment or presence of type I or type III endoleaks, graft infection or thrombosis, aneurysm expansion that is defined as a change in the aneurysm of greater than 5 mm or volume increase greater than 5%, aneurysm rupture, or conversion to open repair.

Type I endoleak is defined as an inadequate seal at the proximal end of the graft, an inadequate seal at the distal end of the graft, or an inadequate seal at the iliac occluder plug (Fig. 2). Type II endoleak is defined as flow from the visceral vessels, lumbar, inferior mesenteric artery, accessory renal, or hypogastric into the aneurysm sac that does not involve the site of graft attachment to the proximal or distal artery. Type III endoleak is flow from module disconnection or flow from fabric disruption (minor) when the perforation of the fabric is less than 2 mm; disruption (major) is when fabric perforation is greater than 2 mm (Fig. 3). Type IV endoleak is a flow from porous fabric at graft placement. An endoleak of undefined origin is flow visualized in the aneurysm sac in which the source is unidentified.

Evolution of Technology

There has been an evolution of design as sophisticated engineering as well as experience has been used to improve the design of these devices. One of the first problems noted in the EVT device was fracture of the attachment hooks that required additional engineering to solve the problem [11]. Furthermore, the use of aortoarto (tube type) grafts has essentially been discontinued because of the difficulty gaining attachment at the aortic bifurcation to exclude the aneurysm sac from blood flow. Some grafts have been removed from the market because of problems with holes being worn in the fabric material. Long-term follow-up will evaluate the effects of the corrosion of metals and long-term wear and tear of the fabric on device function.

The first US report of FDA phase I studies was the presentation of the North American EVT phase I trial, which was published in 1996 [11]. This multicenter trial reported on 46 patients who underwent endovascular repair of abdominal aortic aneurysms ranging from in size 3.8 to 7.1 cm. Eighty-five percent of the implants were successful. The average operating time was 194 minutes. Seven attempts were unsuccessful and converted to open repair. In four of these patients failure of graft implantation was because of iliac stenosis, subintimal deployment, proximal displacement, and a short distal neck in one patient each. No patients died within 30 days of surgery. Initially, there was
evidence of an endoleak detected in 44% of the patients of which 53% resolved spontaneously. Of the 8 persistent endoleaks, one was controlled with transluminal balloon angioplasty and one patient required surgical explantation because of aneurysm enlargement. This study noted that the metallic hook attachment system fractured in 23% of the patients that resulted in the suspension of this trial while the metallic stents were reengineered [11].

Need for Open Conversions

The important aspect of intraluminal graft repair is the need for conversion to open repair. At the time of implantation, the etiology is related to difficulty accessing the infrarenal aorta and failures of device deployment. Long term, the cause of failure is secondary to wear and fatigue of graft components.

Buth et al [12] presented data on 3,529 patients who underwent endovascular treatment for abdominal aortic aneurysm between January 1994 and July 2001. The incidence of open conversion was in 4.2%. This was necessary during the initial procedure or later in the first postoperative month in 1.9% and 2.3% during the subsequent follow-up (sometimes after 1 month). Conversion at the primary procedure was mostly caused by access problems and device migration. Secondary conversions (those performed after 1 month) were performed for rupture in 16 patients (0.5%). Elective conversion was associated with persistent endoleak with or without aneurysm growth in 35 patients (1%). The cumulative rate of conversion was 11.7% at 4 years. Primary conversion was associated with large aneurysm diameters, the use of an EVT device, operations performed in the early years of the study period, and presence of pulmonary disorders. Secondary conversion correlated with aneurysm enlargement, type I and type II endoleak, device migration, and occurrence of aneurysm rupture. Secondary conversion was associated with a perioperative mortality rate of 19% and when performed for rupture 50%. Twenty-seven (0.8%) patients had a confirmed rupture of their aneurysm. The mean interval (range 3-60 months) between the initial procedure and rupture was 25 months. The cumulative rate of rupture the first year was .3%, and thereafter 1% per year. Major risk factors for rupture were midgraft type III endoleaks, graft migration, and enlargement of the aneurysm.

Zarins et al [13] reported a 1-year risk of rupture by life-table analysis of 4% and 2 year of 2.6%. Five of the seven aneurysm ruptures were in patients with angulated infrarenal necks, four of whom had an insecure proximal fixation because of a short neck or low placement in the neck at the graft in the neck of the aneurysm.

In October 2000, Harris et al [14] reported the Eurostar Data (European Collaborators on Stent Graft Techniques for aortic aneurysm repair). This registry was established in 1996 to collect data on the treatment outcomes of patient with infrarenal aneurysms and endovascular repair. There were 88 European centers of vascular surgery that participated in this study. By March 2000, 2,464 patients had been registered with a mean duration of follow-up of 12.19 months. There were 14 patients with confirmed ruptured aneurysms in the follow-up period (Fig. 4). The cumulative risk of aneurysm rupture was approximately 1% per year. Emergency surgery was undertaken in 86% of those 14 patients, of whom 41.6% survived. Two patients who were not treated surgically also died. Significant risk factors for rupture were proximal type I endoleak, type III endoleaks, graft migration, and postoperative kinking of the endograft. Forty-one patients underwent late conversion to open repair with a perioperative mortality rate of 24%. The cumulative risk of late conversion was approximately 2.1% per year. Risk factors for late conversion were distal type I endoleaks, type III endoleaks, type II endoleak, graft migration, and graft kinking. The importance of this study was to determine the risk of late rupture of the aneurysm as the cause of morbidity and mortality. These authors showed that there is
a small but measurable continued ongoing risk of aneurysm rupture in these patients. This study involves a variety of devices, some of which have been currently removed from the market [14].

In early 2000, the effect of endoleaks was evaluated in the Eurostar study [15]. This multicenter study included 1,554 patients who were evaluated and treated in 56 European centers. Endoleak was detected during the procedure in 16% and included type I in 43%, type II in 35%, type III in 7%, and type IV in 8%. The site of the endoleak was uncertain in 5%. The risk factors for primary endoleaks were female gender and age 75 years or older. The endoleaks resolved at 1 month after the procedure in 74%. Sixteen percent (16%) of patients developed a new endoleak at 1 month postoperatively.

The effect of endoleaks on the long-term success of endograft repair is not well understood. Certainly, type I and type III endoleaks are related to aneurysm enlargement and rupture. Type II endoleaks in a stable or decreasing aneurysm diameter probably can be followed. Zarins et al [16] did not notice any effect in the AneuRx Multicenter trial between patients with and patients without endoleak at discharge in incidence of aneurysm rupture, surgical conversion, and aneurysm enlargement.

Intermediate and Long-Term Follow-up

The intermediate and long-term follow-up after placement of an aortic stent graft falls into the following categories of potential concern. The first cause of concern is patients who have failures of initial treatment, which include residual types I and type II endoleaks. The second cause of concern is the development of problems in what was initially a satisfactory treated aneurysm, including development of endoleaks, migration of the graft distally in the aorta, disconnection of segments of a modular graft system, graft limb thrombosis, and, most serious of all, abdominal aortic aneurysm rupture.

Graft limb occlusion is a major complication in the follow-up period. Sampram et al [17] reported an overall incidence of 2.8% graft limb occlusion (24 graft limb occlusions in 20 patients) in a group of 703 patients who had aortic stent grafts placed from a single institution. This risk was 2.7% at 1 year, 4.1% at 2 years, and 5.5% 3 years after the repair. They noted no new limb occlusions after 30 months. Migration was noted in 3.6% of their grafts. This incidence appeared to increase in frequency over the follow-up period. There was a 1% incidence of migration at 1 year, rising to 12% after 3 years. There were three post implantation aneurysm ruptures, which occurred at 4, 7, and 19 months, which resulted in a 0.7% annualized risk of rupture.

The Eurostar experience of 3,075 patients who underwent operations at 101 European centers was reported by Buth et al [18]. Life table results show a 3-year survival rate of 83% in patients with normal operative risk and 68% in patients with significant comorbid diseases. They noted a decrease in long-term survival with larger aneurysms of more than 6 cm in diameter. Becquemin and his group [19] reported in 1999 the midterm results of second-generation study of the Vanguard prosthesis, which evaluated 75 patients with asymptomatic abdominal aortic aneurysms that were recruited from 14 French vascular centers. All grafts were successfully implanted, resulting in 100% success rate on an intent-to-treat basis. On discharge, there were no deaths, 6 significant local complications (8%) that necessitated surgery, no vascular complications, and 6 systemic complications (8%). PredischARGE computed tomography scans showed 5 type I and 18 type II endoleaks for a total endoleak rate of 30%. The follow-up period had a mean duration of 18.4 months, during which 7 patients (9%) had died, only one from an aneurysm rupture. The 2-year cumulative survival rate was 86%. Twenty-one subsequent endovascular vascular procedures were neccessitated in 17 patients (23%) to treat graft limb occlusion or stenosis or to seal an endoleak. The 2-year cumulative survival rate free of intervention was 67%. In this study, a persistent endoleak was significantly associated with increase in aneurysm diameter. In 2000, Zarins et al [16] reported the results of the AneuRx multicenter phase II clinical trial. There was a 38% incidence of endoleaks on predischARGE computed tomography in 398 patients. The endoleak rate decreased to 13% at 1 month. One patient ruptured his aneurysm and underwent successful open repair at 14 months. This patient had a type I endoleak at discharge but no endoleak at 1 month. Patients with type I endoleaks at discharge were more likely to experience aneurysm enlargement at 1 year. The actual rate of survival of all patients undergoing endovascular aneurysm repair was 96% at 1 year. Of the 425 patients entered in this phase II trial, the device was successfully deployed in 97%. In 8 patients (2%), the iliac arteries were too small or tortuous to place a device. The in-hospital mortality rate was 1%; the open surgical conversion rate was 1%.

It is essential to know the incidence of secondary procedures to accurately evaluate the long-term results of this procedure. The Cleveland Clinic group noted secondary procedures were more common in patients with larger aneurysms and in patients who received a large aortic stent because of a proximal endoleak evident at the initial aneurysm repair [17]. The cumulative risk for a secondary procedure was 12% at 1 year, 24% at 2 years, and 35% at 3 years. Open surgical conversion was rarely necessary, and, most importantly, the aneurysm-related death after endovascular repair was 3.6% over a 3-year follow-up, which was inclusive of the initial perioperative deaths. Only 2 of their patients died of a ruptured aneurysm after treatment at a mean of 1 year. Their data suggest that larger aneurysms are more prone to secondary problems. As aneurysms increase in size, the length of the infrarenal neck
tends to decrease, increasing the difficulty of adequately securing the proximal graft to the infrarenal aorta.

**Stent Graft Migration**

The incidence of stent graft migration is a challenging complication. In the AneuRx trial, there was a 2% (7 patients) incidence of graft migration in 375 patients, of whom 4 were associated with an endoleak [16]. The importance of migration was illustrated in the Eurostar experience in which they noted a significant risk for aneurysm rupture. Of the 67 (2.9%) graft migrations in the registry of 2,315 patients, 3 (4%) lead to aneurysm rupture [13]. There are basically two possible reasons for the migration: (1) the possibility that over time the neck of the aneurysm increases in size, therefore decreasing the friction between the device and the aortic wall; and (2) the nature of the proximal fixation.

Conners and associates [20] evaluated endograft migration from 1 to 4 years after endovascular abdominal aortic aneurysm repair with the AneuRx device at a single institution. These authors described migration as a ≥5-mm change in endograft position. In a total of 91 patients with a minimum of 1-year follow-up, the authors noted endograft migration in 15 patients given a cumulative event rate of 7.2% at 1 year, 20.4% at 2 years, 42.1% at 3 years, and 66.7% at 4 years. Although the initial aortic neck diameter did not differ between the groups, significant late aortic neck enlargement was seen in patients with migrations but not in patients who did not migrate. A significant correlation existed between endograft over sizing (ratio of endograft diameter divided by aortic diameter at site of implantation at proximal aortic neck) and late neck dilation. The overall risk was 29.2% in patients whose endograft was oversized greater than 20% and 18.6% in patients oversized less than 20%. This study raises an essential concern. In devices that do not have some sort of fixation proximally and who rely on their remaining in place by lateral wall tension, over a long period of time (5 years) what is the natural history of a segment of aorta that has the capacity to develop aneurysm as noted more distally. The long-term effect of radial tension on the aorta remains to be determined. Certainly, the answers to this question will determine the future design of endografts. The development of attachment devices currently in the developmental stage may help to resolve this potential problem. Also, the initial feeling of investigators is if one oversized these devices significantly, you will compensate for any mild changes in the aorta; this may not be valid because oversizing the graft may hasten the dilatation of the aortic neck.

Malina and associates [21] showed the addition of stents and barbs enhanced the proximal fixation in grafts. In a study of 137 stent deployments in cadaveric aortas, they determined that stent barbs and hooks increased the fixation of stent grafts 10-fold as compared with radical force, which had no impact. Kalliafas et al [22] noted in a series of 176 consecutive patients that the rate of graft migration in infrarenally fixed grafts (10.9%) was higher than in suprarenal fixed grafts (2.1%). The need for fixation is emphasized by increasing data on graft explantations in which there is no incorporation of vascular fabric as is seen in open aortic aneurysm repair [22–24].

**Neck angulation**

Sternberg et al [25] looked at the role of aortic neck angulation in terms of adverse outcome with endovascular repair. Aortic neck angulation is defined as the angle between the proximal aortic neck and the longitudinal axis of the aneurysm (Fig. 5). They collected data on 148 consecutive repairs, all of whom were treated with a modular bifurcated device (AneuRx). The mean follow-up time was 20.6 months. They found that the risk of patients experiencing one or more adverse events was 70%, 54.5%, and 16.6% in those with severe (≥60° angulation), moderate (40°–59° angulation), and mild (<40° angulation). Adverse events, including deaths within 30 days, acute conversion to open repair, aneurysm expansion, device migration, and type I endoleak, occurred in significantly greater incidence in patients with moderate or severe neck angulation when compared with those with mild angulation. Aortic neck length, diameter, age, and medical comorbidities were not significantly related. These authors recommend caution for endovascular repair of aneurysms with angulation equal to or greater than 40°.

**Long-Term Durability of Grafts**

One of the important aspects of long-term endograft function is the durability of the various components of the endografts. Heintz et al [26] examined 21 explanted Stentor...
device and one Cragg stent with photography, stereomicroscopy, electron microscopy, and energy dispersive x-ray analysis to look at the evidence, if any, of corrosion of nitinol wires. The mean implantation interval for these endografts is 29 months, range of 5 to 46 months. All explants, even those retrieved after a few months, showed pit-like surface damage (10-25 mm in diameter). Larger, irregular shape surface alterations were observed in approximately 70% of the explants. Older explants, defined as age >32 months after implantation, presented regions of decay, bending of the wire, and stress cracks in some areas. Energy dispersive x-ray examination revealed decrease nickel concentration in the corroded regions. These changes weaken the wire, which can lead to stress cracks and eventual fracture of the stent wire under circulatory pulsation. Guidoin and associates [27] also noted corrosion on nitinol wires. These findings raise the issue of the long-term durability of devices whose structural integrity depend on metallic components.

The other component of all these grafts is the fabric that forms the barrier between the lumen of the graft and the aneurysm sac. Degeneration of the fabric prosthesis is a factor both in open as well as endovascular techniques. The primary difference in endovascular techniques is that there is a metal skeleton that provides an area of friction that one does not get in the open repair.

Reipe and colleagues [28] looked at 170 explanted polyester vascular grafts obtained from 29 clinics in Western Europe. They found scission of a macromolecular chain and resulting loss of strength in many of these grafts. They showed hydrolytic degradation of polyester takes place with increasing time of implantation in humans. Polyester grafts lose 31.4% of the bursting strengths in 10 years, 100% in 25 to 39 years after implantation. The fact that there is some degradation with time in the polyester fabric component, coupled with the fact there is some evidence of degradation of the metal components, raises some issues in terms of the durability of some of these grafts for periods beyond 15 to 20 years. Jacobs and associates noted evidence of mechanical failure in endografts in 60 patients from a series of 686 implants [29]. The average time to diagnosis was 19 months. There were 43 metallic stent failures, 14 suture disruptions, and 3 graft holes.

**Internal Iliac Artery Occlusion: Its Need for Endovascular Repair**

When aneurysmal disease involves the common iliac artery, it is often necessary to extend the endograft to the external iliac artery eliminating the internal iliac artery (IIA) from the circulation. To prevent a type II endoleak, the IIA is often embolized. Consequences of IIA occlusion include buttock claudication, buttock necrosis, or colon ischemia. In an attempt to minimize these complications, Wyers and associates [30] proposed covering the IIA orifice without embolization. These authors reviewed 204 consecutive cases performed from 1996 to 2001. In 33 cases, the internal iliac artery was occluded (33 times in 31 cases). In 22 cases, the internal iliac artery was covered without coil embolization. A requirement for covering the IIA orifice was the ability to oversize the graft 10% to 15% in the distal 5 mm of common iliac artery and 15 mm of the proximal external iliac artery. There were 11 patients (33%) with inadequate graft oversizing in the common iliac artery who underwent coil embolization. Buttock claudication was seen in the group without embolization in 27% of the patients, which resolved completely in 5 of the 6 patients. In the coil group, 45% had buttock claudication, additionally 1 case of buttock necrosis, and 1 case of ischemic neuropathy occurred. Covering the internal iliac artery without coiling can effectively exclude the common iliac artery aneurysm in cases that have the proper morphology for the graft, developing a seal in the very distal common iliac artery and proximal external iliac artery. By covering the origin of the IIA without coil embolization deceased, the incidence of buttock necrosis is decreased, and more severe cases of buttock necrosis and ischemic neuropathy are eliminated.

**Endotension**

The concept of endotension was developed to explain how some patients have pressurization of the aortic sac outside the endograft in the absence of any documentable endoleak. Initially, the absence of endoleak was thought to eliminate, for the patient, the risk of aneurysm dilation and eventual rupture. There are reports as well as observation by the author of some patients with type II endoleaks who did have continued shrinkage of the aneurysm, which one would think is a sine qua non for adequate treatment of the aneurysmal disease. Likewise, there have been a variety of cases reported in which the aneurysm sac has enlarged and no endoleak can be detected using a contrast-enhanced tomography or angiography [31]. Gilling-Smith et al [32] categorized endotension in three grades. Grade 1 was high pressure, high flow and is often related to type I graft-related endoleak. Grade 2 is high pressure, low flow and usually type II side branch endoleak. Grade 3 is high pressure, no flow that represents a sealed endoleak with pressure transmission through the graft. Determining the source of the endoleak is dependent on the quality of the diagnostic arteriography and/or computed tomography angiography. With low flow endoleaks, often the timing on the computed tomography scan or angiography is not sufficiently long or precise to detect small amounts of contrast entering the aneurysm sac. Particularly in view of the new radiologic techniques in which subtraction technology is used to enhance the images, small amounts of contrast could very easily be subtracted out of the resulting processed images. It is the authors’ feeling that all cases of endotension represent some communication with the systemic circulation, be it by
leaking around the proximal or distal end of the graft or through patent lumbar or inferior mesenteric artery. These probably do not have significance if the aneurysm remains stable in size or more importantly decreases in size. However, all patients who have aneurysm enlargement should be very carefully evaluated. If the source of the enlargement cannot be found, these patients should be converted to an open repair.

White et al [33] noted 4 cases of systemic sac pressurization after endovascular repair. Two of these had proximal attachment migration, one patient developed an endoleak at 6 months that ruptured at 12 months and the last case had an increase in aneurysm size over 36 months but no endoleak detected. A possible problem in accurately determining the source of a small endoleak at time of graft explantation is that depressurization of the aneurysm sac may obscure the source of an endoleak. The authors have evidence of a patient whose endoleak only occurred at the end of systole, a brief portion of the cardiac cycle. Because this was at the midportion of the graft, it was very difficult to see, even with rotation of the table, because of the contrast flowing down the barrel of the graft obscured the evidence of the endoleak. Deaton et al [34] in a study of patients with 3 years of follow-up, evaluated 80 patients for aneurysm enlargement with an Ancure Guidant EVT-type device. A change of 5 mm in transverse diameter relative to the original diameter was the value determined to indicate a significant increase or decrease in the aneurysm. Endoleak was a poor predictor of aneurysm growth but was statistically associated with enlargement. The absence of endoleak is strongly but not entirely predictive of lack of aneurysm growth. Endoleak is a risk factor for aneurysm enlargement warranting further investigation to examine its etiology.

**Infectious Complications**

The insertion of a device transfemorally has not eliminated the possibility of graft infection or the occurrence of aortoduodenal fistula [35–37]. A variety of anecdotal cases have been reported, reporting both aortoduodenal fistulae after endovascular stent graft placement as well as graft infection. These obviously represent significant challenges to patient care. There are not enough data at this point to determine whether the incidence is less than with a traditional open repair, but it certainly occurs.

**Ruptured abdominal aortic aneurysm**

The remaining challenge in treating infrarenal abdominal aortic aneurysms is to treat ruptured aneurysms by endovascular techniques. This requires a relatively hemodynamically stable patient, access to stent grafts of varying diameter, or a graft that can treat several different aortic diameters.

Two approaches have been developed. The first is the insertion of an aortomono iliac device that requires a block-

**Future**

The future of endovascular treatment of abdominal aortic aneurysm is going to take several courses. The first is the development of grafts that can be delivered through smaller catheters. This will allow devices to be placed percutaneously, which will decrease the morbidity associated with current techniques. It will probably require a device that can be inserted reliably through a 15-French sheath. The second area of advancement is the development of techniques to catheterize and place side branches into branch vessels such as the renal and mesenteric vessels. There are several investigators who have successfully inserted side grafts into renal and mesenteric vessels, but these techniques are not yet ready for wide spread distribution. Thirdly, and potentially a very exciting area, is the development of techniques to secure the graft either proximally and/or distally. Trout and Tanner [45] have developed a vascular endostaple that literally can attach the graft to the artery. This is delivered through a 13-French insertion sheath. A laser is used to create a hole in the aorta through which a staple is inserted. This technology really has several advantages. In patients who develop type I endoleaks because of difficulty with fixation proximally, this endostaple could secure the graft firmly to the aortic wall. It has the advantage with time that it most closely reproduces the advantage of an open technique, namely a suture technique that should resist dilatation at the proximal graft fixation point. This device should begin phase I trials within the next several months. The
fourth developmental area of is in the area of potential biochemical markers to detect the presence of endoleaks. Lorelli and associates [46] evaluated MMP9 levels in patients who had endovascular repairs and noted that in patients who did not develop an endoleak, the MMP level decreased in the follow-up period, whereas in those with endoleaks this remained elevated. The potential to develop a biochemical marker to aid in the detection of endoleak would be helpful. The incidence of late rupture is worrisome, and the development of a simple biochemical test that might help identify patients at risk would be a significant advancement.

The major question facing surgeons treating aneurysmal disease is the relative benefit in comparison of endovascular-treated grafts with traditional open repairs. Schermerhorn and associates [47] evaluated the life expectancy after endovascular versus open abdominal aneurysm repair based on the data from the EUROSTAR registry. They determined most patients who are candidates for abdominal aortic repair, both endograft treatment as well as open treatment, resulted in similar quality-adjusted life expectancy. Data have suggested that open repair may be for younger patients with low operative risks and endovascular procedures may be more applicable for older patients with higher operative risks. Because the outcomes of these two repair techniques are similar the patient should be involved in decision making. The choice the patient has is that in current practice the open repair has a higher cost in terms of patient pain and suffering, but the endovascular repair requires ongoing surveillance for the remaining life of the patient, certainly with the current status and art of endovascular repair. Therefore, the patient has to be fully informed regarding possible choices.

Because previous studies, which include the United Kingdom small aneurysm trial as well as the Veteran’s Administration study, showed that there was no survival benefit from early surgery compared with surveillance with small aneurysms, generally those defined up to 5.5 cm in diameter [48,49]. The one shortcoming of the Veteran’s Administration hospital study is that they did not include women, and there is some evidence that women whose aorta are generally smaller than a man’s can rupture at a lower diameter. There is general agreement that small aneurysms, particularly in patients with limited life expectancy, should be followed and should not be treated by either modality. In view of the current data, it is the authors’ feeling that consideration of repair is given for good risk patients when their aneurysms exceed 5 cm in diameter.

More complete, longer-term data will become available when the results of both the British EVAR trial, which began recruitment in September 1999 and concluded recruitment in December 2003, with the report expected out later in 2005. This very well-controlled study will assess the efficacy of endovascular repair compared with open repair, in terms of mortality, quality of life, durability, and cost-effectiveness. Similarly, in the United States, the OVER trial (a Veterans’ Administration Cooperative Study), is a randomized prospective trial comparing open with endovascular surgery for treatment of abdominal aortic aneurysms. This study is still in the early to midphases of patient recruitment and will provide excellent long-term critical data on the efficacy and relative advantages of the two types of aneurysm repair.

One additional element that needs to be considered is the cost of these devices. Although with all emerging technology, the cost of a particular device is somewhat of a moving target, generally being quite expensive on its introduction and with time decreasing. Sternbergh and Money [50] evaluated the inpatient hospital costs of endovascular repair and compared them with open repair and noted the cost of endovascular repair were significantly higher. This difference in cost is primarily related to the endograft device costs. Cost of these devices can range from $10,000 to $15,000 depending on the number of devices, the amount of catheters, balloons, and so on that are used to place these. As time evolves, it will be interesting to see what the ultimate effect of cost will have on the treatment of this disease.

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