Significant morbidity and mortality results from abdominal aortic aneurysms (AAAs). In addition, there is a significant cost to society associated with AAAs. Autopsy studies show that the incidence of AAAs is between 1.8–6.6%. Epidemiological studies estimate the rate of occurrence of AAAs to be 60 per 1,000 in the general population. The incidence of AAAs appears to be increasing in industrialized countries, independent of increased longevity.

The natural history of AAAs has been studied, particularly in the era before aneurysm repair became the standard of care. Based on these studies, the rate of aneurysm rupture and death could exceed 60% within 3 years of the initial diagnosis. The first report of a successful AAA repair was published in 1952. Surgery remains the only effective treatment for AAAs. Morbidity and mortality rates in the 3–5% range for elective standard operative repair have been reported in major vascular centers. However, these rates may be increased considerably in patients with significant comorbid medical conditions. Aneurysm repair is currently performed in approximately 40,000 patients per year.

In the United States, more than 15,000 deaths due to aneurysm rupture occur each year. It is estimated that at least 62% of patients who experience rupture of an AAA die prior to reaching the hospital. The overall mortality rate for ruptured AAAs, including in-hospital deaths, is thought to approach 90%. In addition to the significant loss of life associated with AAA rupture, there are considerable health care costs. Cost reimbursement studies document an average loss to the hospital of approximately $25,000 per patient presenting with a ruptured AAA. It is estimated that 2,000 lives and $50 million could be saved annually in the United States alone if aortic aneurysms were repaired prior to rupture.

Endovascular aneurysm repair. Juan C. Parodi and his colleagues conducted the initial studies in endovascular grafting that led to the development of effective techniques for endovascular repair of AAAs using the transfemoral route of delivery. They combined prosthetic vascular grafts with balloon-expandable stents to create an endovascular device. Since Parodi’s initial report, numerous endovascular devices have been developed and tested for the treatment of AAAs.

Indications for endovascular repair. The selection criteria and indications for the endovascular repair of AAAs are continuing to evolve. Universal agreement on what these criteria should include has not been reached. In the past, patients were offered endovascular repair on a compassionate-need basis. Patients who...
had aneurysms that were at significant risk for rupture but who could not tolerate standard surgical repair were treated with endovascular techniques. Indeed, endovascular repair remains the most appropriate treatment choice for this category of patient. However, the use of endovascular devices to treat AAAs in patients who would be candidates for open surgical repair has significantly increased. The decision to use endovascular techniques to treat AAAs is now chiefly based on the anatomical constraints of the device.

**Anatomical selection criteria.** A number of anatomical and technical criteria must be fulfilled in order to allow endovascular treatment of AAAs. These include: 1) The presence of an undilated segment of aorta of sufficient length to allow implantation of the proximal aspect of the endovascular device distal to the renal ostia (the proximal neck). The length of normal proximal aorta necessary for device implantation varies according to the specifications of the individual device, but is generally in the 0.5–1.5 cm range. 2) Severe angulation of the proximal neck may also preclude endovascular treatment. Generally, an angle less than 60° between the suprarenal aorta and the proximal neck is considered excessive, although variation according to the specific device type ultimately determines the maximum acceptable angle. 3) If a straight or tube graft is to be employed, an undilated segment of distal aorta above the bifurcation must be present (the distal neck). Again, the length of distal neck necessary varies with the specifications of the individual device. 4) If the site selected for distal implantation is the iliac artery, its morphology must be adequate for seating of the distal attachment system of the endovascular device. 5) The common and external iliac arteries must be of sufficient caliber to allow passage of the introducer sheath or must be amenable to balloon dilatation to facilitate passage. 6) Similarly, the iliac vessels must demonstrate limited tortuosity after arteriolar straightening maneuvers are completed. 7) Aberrant vessels, particularly an indispensable inferior mesenteric or accessory renal artery, must not be present in the segment of aorta to be excluded from the circulation. If these criteria are not met, it may not be possible to carry out the procedures because of technical reasons. In addition, some investigators consider a life expectancy of less than 2 years and a patient body weight in excess of 350 pounds to be relative contraindications.

**Preoperative assessment.** Radiological evaluation is required prior to endovascular treatment of AAAs. Several imaging procedures are performed with near uniformity regardless of the device used for the AAA repair. In general, a screening computed-tomographic (CT) scan with intravenous contrast is performed. Ideally, a high-speed, helical scanner is used to obtain 1–3 mm sections. Three-dimensional reconstruction images may also be obtained. The dimensions of the proximal and distal aortic necks as well as the aneurysm length and composition may be calculated. However, CT scanning has been noted to overestimate aortic diameter as a result of obliquity of the proximal and distal necks relative to the axis at which the CT images were obtained. This must be considered when determining the dimensions of the endovascular device to be used. In addition, the length of the endovascular graft necessary for treatment of the aneurysm is best confirmed with use of arteriography.

After the CT scan is performed, the work-up proceeds with aortic arteriography. Assessment of the renal and inferior mesenteric arteries is also essential. The arteriogram may be performed with a calibrated catheter that has radiopaque markers at 1 cm intervals. This catheter allows for the compensation of parallax and magnification, permitting greater accuracy in the determination of the length of graft necessary for endovascular treatment. A wire pull-back technique may also be employed so that distances can be measured from the movement of the guidewire relative to the end of the angiographic catheter as the tip of the guidewire is pulled from one anatomical structure to another. Arteriography provides invaluable information regarding the presence of aberrant vessels as well as the presence of tortuosity and kinking of the iliac vessels. The precise measurements obtained by arteriography can be used to tailor the endovascular device to the patient’s particular requirements.

**General principles for the deployment of endovascular devices.** Endovascular AAA repair is most commonly performed in the operating room. This environment is the safest and the best suited to handle potential complications that might be encountered, including iliac artery perforation, damage to the femoral access site, aortic thrombosis or aortic rupture, and the need to rapidly convert to an open repair. Also, since these procedures involve the introduction of a vascular graft, sterile technique is of the utmost importance; some investigators believe that this is best maintained in the operating room.

In preparation for surgery the patient is fully prepared and draped in a sterile manner. The endovascular procedure is performed under fluoroscopic guidance. The operating room should be equipped with advanced fluoroscopic instruments and a radiolucent operating table. A radiopaque marked backboard or ruler may be placed beneath the patient to provide fluoroscopic reference measurements. Access to the arterial system is obtained either through exposure of the common
femoral artery or, if this vessel is inadequate, through a limited retroperitoneal approach to the iliac artery. Once arterial access has been obtained, wire and catheter techniques are employed to place the device. Following deployment of the endovascular graft, a completion arteriogram is performed. Some centers advocate the use of intravascular ultrasound to assess graft deployment and determine the presence of graft stenosis or kinking. Luminal narrowing, particularly in the iliac limbs of the graft, may be treated by balloon angioplasty and stent placement. Follow-up regimens vary, but usually include serial abdominal CT scans and may include color-flow duplex scanning as well. If an abnormality or change from baseline is detected, arteriography is performed to fully evaluate the status of the graft and the implantation sites as well as any persistently patent endoleaks or patent aneurysm sidebranches.

Commercially fabricated endovascular devices. Commercially fabricated endovascular devices began to be developed after the initial experiences with devices fabricated by vascular surgeons proved successful. These devices have received considerable clinical exposure and are now entering into widespread use. A total of 11 commercial endovascular devices are currently in use: 1) EVT/Guidant (Endovascular Technologies, Menlo Park, California); 2) AneuRx (Medtronic, Inc., Minneapolis, Minnesota); 3) Vanguard (Boston Scientific Corp., Natick, Massachusetts); 4) Talent (World Medical, Sunrise, Florida); 5) Zenith (Cook Inc., Bloomington, Indiana); 6) Anaconda (Sulzer Vascutek, Austin, Texas); 7) Endologix (Endologix, Irvine, California); 8) Excluder (W.L. Gore and Associates, Flagstaff, Arizona); 9) Teramed (Teramed, St. Paul, Minnesota); 10) LifePath (Baxter Healthcare Corporation, Irvine, California); 11) Cordis (Johnson & Johnson, Sommerville, New Jersey).

The EVT/Guidant device. The Endovascular Technologies endograft system has been in worldwide use since 1993. Currently, the device is available for use in 2 configurations: tube/aortic and bifurcated/aortobi-iliac (Figure 1). Phase I and II trials have been completed in the United States and the device has received limited approval by the Food and Drug Administration for use in the treatment of AAAs. During the period from 1993–1997, a total of 669 patients underwent attempted treatment of their AAAs with the EVT device. Of these, 19 (3%) required conversion to open surgical repair. The causes of immediate conversion were inaccurate proximal or distal attachment device deployment (11), twists in the system (3), mechanism malfunction during deployment (4), and aortic tear (1). A total of 28 patients required late removal of the device because of persistent endoleaks (20), graft occlusion (3), aortic dissection (1), aneurysm rupture (3), and graft migration (1).

The overall perioperative mortality rate was 1.5% for all patients undergoing AAA treatment with the EVT device. However, the mortality rate for those requiring conversion to open surgery was 11% and for those requiring graft removal it was 7%. The incidence of initial endoleak for the EVT device was 9%. These endoleaks were followed with observation alone and subsequently 50% spontaneously sealed. However, the persistence of an endoleak was associated with continued aneurysm enlargement. Supplemental procedures including endoluminal grafting and embolization were performed. Ultimately, 20 patients required open surgical repair of their AAAs. Late explantation and AAA repair frequently required suprarenal aortic cross-clamping. Other complications associated with EVT device deployment included myocardial infarction, iliofemoral arterial injury, wound infection, transient fever, and minor embolization resulting in foot petechiae. Overall, endovascular repair using the EVT/Guidant system was generally successful, safe, and efficacious.

The AneuRx device. A modular, bifurcated, self-expanding stent-graft system has been developed by AneuRx (Figure 2). The modular components consist of a thin-walled, non-crimped, woven polyester graft supported by a nitinol (nickel-titanium alloy) frame.
Modular aortic and iliac extenders may also be added. All components are contained in a delivery sheath, which is introduced bilaterally through the femoral vessels.

The results of a nonrandomized, multicenter clinical trial were recently reported by Zarins and his colleagues. During an 18-month period, 190 patients underwent AAA repair using this device. The operative mortality rate was 2.6%. The overall morbidity rate was 17%, 12% of which were considered to be major morbidity events. These included myocardial infarction, stroke, renal failure, and arrhythmia. Minor morbidities, which occurred in 5% of the patients, included wound infection, minor toe embolization, mild femoral neuropathy, and an increase in creatinine that did not require treatment. A total of 9% of the patients required reoperation.

Primary technical success was accomplished in 77% of the cases. Failure to achieve success was largely due to the presence of an endoleak, which occurred in 21% of the patients. At 1 month, the endoleak rate had decreased to 9%. The aneurysm exclusion rate was 91% at 6 months. The primary patency rate was 97% at 6 months. Endovascular device migration occurred in three patients and in each case resulted in the development of a late endoleak that was treated by placement of an aortic modular extender. No aneurysm ruptures were reported and there were no conversions to open repair. The use of the AneuRx device was compared with surgical treatment and the device was found to offer advantages in reducing the rate of major morbidity and length of hospital stay. The device has received limited approval from the U.S. Food and Drug Administration (FDA), having completed phase I and phase II trials.

The Vanguard endoaortic graft. The Vanguard device is available in tube and bifurcated configurations. The bifurcated device is a two-piece modular graft that represents a second-generation design that was achieved through modification of the Stentor system. The graft is composed of polyester with a nitinol frame. The modular components attach to the native aorta and iliac vessels as well as to each other (Figure 3). A 21 French (Fr) introducer sheath makes up the final component of the endovascular grafting system. Placement of the introducer sheath requires femoral artery cut-down and arteriotomy.

The results of a multicenter trial using the bifurcated Vanguard endovascular device were recently reported. In this trial, 75 patients underwent implantation. The technical success rate was 100%. There were no perioperative deaths. Six local complications required reoperation (8%). The average hospital stay was 6 days. Endoleaks were diagnosed by CT scans in 30% of the patients in the immediate perioperative period. One patient died of aneurysm rupture during the mean follow-up period of 18 months. In addition, 21 subsequent endovascular procedures were required to treat graft limb occlusion (12%) or to seal endoleaks (11%). Significant aneurysm enlargement was observed in patients with persistent endoleaks. It was concluded from the study that the Vanguard endovascular device could be deployed in selected patients, with low morbidity and mortality rates. A decrease in aneurysm size was consistently observed after successful AAA exclusion, and provides evidence of the effectiveness of treatment with the Vanguard device.

Figure 3. Vanguard (right) and Stentor devices (left). The Vanguard device was developed through modification of the original Stentor device. These devices are modular, with a main body that contains the aortic and ipsilateral iliac portions and the separate modular contralateral iliac limb.
The Talent device. The endovascular device developed by Talent has been implanted in more than 2000 patients worldwide. A recent report summarizing this experience and the results of the phase I FDA trial was presented by Criado and his colleagues. The Talent graft is used in three configurations: tube/aortic, tapered/aortouni-iliac, and bifurcated/aortobi-iliac. It is self-expanding and composed of Dacron with a nitinol frame, which supports the graft. Deployment of the device is similar to that of the Vanguard and AneuRx devices. The aortic component, with one iliac limb, is deployed first through a femoral artery cut-down. The second, contralateral iliac limb module is then deployed via the contralateral femoral artery with the proximal aspect seating within the aortic component.

In the United States trial, all patients either had significant comorbid medical conditions or possessed a hostile abdomen. Worldwide data are available on 358 patients; of all the procedures performed, endoleaks were observed in 19% of the patients, 75% of which sealed within 30 days of the procedure. Significant technical difficulties during deployment were documented in 20% of the cases but exclusion of the AAA was achieved in the majority of patients. Conversion to open surgical repair was required in 7.4% of the cases. The overall 30-day mortality rate was 3.5%. From the reported experience it was concluded that the Talent endovascular device was suitable for the treatment of AAAs in a significant proportion of patients. It was noted that the proximal aortic fixation device possesses approximately 1 cm of uncovered nitinol frame proximal to the fabric portion of the device. This uncovered portion permits transrenal fixation of the device, thereby allowing the treatment of AAAs with relatively short proximal necks.

The Zenith™ AAA endovascular graft. The Zenith™ system from Cook consists of woven polyester graft material supported throughout its length by self-expanding Z-stents. The device comes as a modular bifurcated device but is also available in an aortouni-iliac configuration. The introducer tip is tapered to minimize trauma at the arterial insertion site and there are side holes at the tip to allow angiography with the system in place. The Zenith stent-graft system has a bare proximal stent that expands radially upon deployment. There are barbs at the top of this bare stent to secure the device to the suprarenal aortic wall. The suprarenal bare stent is deployed after being released by a trigger wire, which holds it in place to avoid premature deployment. This device is currently undergoing clinical trials and is not yet approved for use in the United States.

The Anaconda™ system. The Anaconda™ stent-graft system for aneurysm treatment has several unique features. It is a fully modular system made of woven material one-third thinner than conventional graft material. The stents are made of nitinol. A unique feature is the proximal ring stent, which is composed of multiple turns of nitinol wire. The hoop strength that results from the radial force of this ring stent allows the proximal end to anchor to the aortic wall. Because of the saddle configuration of the proximal ring stent, the device can be placed so that the graft is situated at and above the renal ostia while the renal ostia themselves are uncovered. A system of magnets is used to aid in cannulating the main body of the graft in order to position the contralateral limb in place. Because it is a fully modular system, there is a theoretical increased risk of type 3 endoleaks because of the increase in number of articulations between pieces. This device is also currently undergoing clinical trials.

Endologix PowerLink™ system. The Endologix PowerLink™ system is a newer device that introduces several novel innovations. The system is a one-piece bifurcated graft of polytetrafluoroethylene (PTFE). The one-piece design eliminates the risk of endoleaks seen at attachment sites in modular devices. In addition, the frame is composed of a self-expanding non-nitinol wire, which eliminates the need for sutures to hold individual stents in place. The graft is thin-walled PTFE, which may allow for downsizing of the delivery system. As with most of the newer devices, this system is currently available for investigational use only.
The Excluder™ endoprosthesis. The Excluder™ stent-graft system is a modular bifurcated system. It is composed of thin-walled PTFE externally supported throughout its length with nitinol stents (Figure 15). The main body is delivered through an 18 Fr sheath while the contralateral limb is delivered through a 12 Fr sheath (Figure 4). There are no suture holes in the graft material; thus the risk for leakage through fabric tears is reduced. There is an external sealing cuff at the proximal end to aid in fixation to the proximal attachment point. A PTFE fiber deployment line is pulled to permit rapid deployment of the device. The release occurs rapidly and without lengthening or shortening of the prosthesis. The Excluder™ is currently undergoing clinical trials in the United States.

Teramed endovascular device. The experience accumulated with the deployment of endovascular devices has indicated a need for transrenal fixation of the proximal fixation device. In addition, the ability to adjust iliac graft length once an endovascular device has been inserted into the arterial system is necessary to provide optimal aneurysm exclusion. The Teramed Ariba™ endovascular aortic graft is constructed from seamless nitinol hypotube stents, which provide the thermal memory properties of the nitinol metal material. The attachment system is equipped with a transrenal segment, which optimizes renal artery blood flow while enhancing suprarenal fixation (Figure 5). Fully integrated self-deploying barbs engage the aortic wall immediately below the lowest renal artery. This region of the aorta has proven to be least susceptible to progressive dilatation as first described by Marin et al. The aortic body and iliac extender limbs have been designed to achieve in situ sizing of the endograft. Once the aortic body of the endograft is deployed, the length of the iliac limbs can be adjusted to provide optimal exclusion of the iliac aneurysmal component, while preserving flow to the internal iliac artery. Modular extenders for aortic and iliac components are also available to further optimize durable aneurysm exclusion.

Summary. Endovascular repair has been evaluated in the clinical setting since 1991. The techniques have been carried out at various centers in the United States and abroad, with considerable success. When the AAA is successfully treated endovascularly, a reduction in diameter is frequently observed. Complications including death and technical difficulties relating to device deployment have been encountered. Nevertheless, significant reductions in major morbid events have been observed with endovascular treatment of AAAs as compared with standard open surgery. In addition, endovascular devices provide a means of treating patients whose comorbid illnesses make conventional open repair difficult or impossible. Long-term follow-up is only now beginning to
accumulate for patients treated with endovascular devices and these initial long-term data appear promising. The eventual patient criteria for the use of endovascular devices in the treatment of AAAs will need to be more completely defined as additional clinical experience is gained and the long-term results of prospective, randomized trials are evaluated.

REFERENCES