

Endovascular Treatment of Abdominal Aortic Aneurysms

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Abstract

Minimally invasive endovascular techniques for the treatment of abdominal aortic aneurysm have significantly reduced its morbidity compared to that following standard surgical repair. Moreover, patients with extensive comorbid medical illnesses, for whom standard operative repair is contraindicated may be successfully treated using endovascular means. The full limitations and indications for use of endovascular grafts have not yet been fully defined. The effectiveness of commercially fabricated devices is currently being evaluated. This article describes the general principles of use for endovascular devices for the repair of abdominal aortic aneurysms and details the features of the devices currently in use, as well as the typical results.

Key Words: Abdominal aortic aneurysm, endovascular, minimally invasive, stent-graft.

Introduction

RUPTURE OF abdominal aortic aneurysms (AAA) results in considerable morbidity and mortality. Significant cost to society is also associated with the rupture and treatment of AAA (1). Estimates of the rate of occurrence of AAA are 60 per 1000 in the general population as documented by epidemiological studies (2), and between 1.8% and 6.6% according to autopsy studies (1). The incidence of AAA increases with age and appears to be increasing in industrialized countries, independent of increased longevity (2–4).

The natural history of AAA has been studied for patients who were unable to undergo surgical repair as well as for patients with AAA prior to the development of surgical treatment.

In these studies the rate of aneurysm rupture and death could exceed 60% within 3 years of the initial diagnosis (5). Surgical repair (first report in 1952 [6]) is the first and (so far) the only effective treatment for AAA. Morbidity and mortality rates ranging from 3–5% have been reported for elective standard operative repair in major vascular centers (7). However, these rates increase significantly for patients with significant comorbid medical conditions, particularly coronary artery disease, renal failure and chronic obstructive pulmonary disease. Aneurysm repair surgery is currently performed on approximately 50,000 patients per year.

In the United States, more than 15,000 deaths due to aneurysm rupture occur each year (8). It is estimated that at least 62% of patients who experience rupture of an AAA die prior to reaching the hospital (9). The overall mortality rate for ruptured AAA, including in-hospital deaths, is thought to approach 90% (9–11). In addition to the significant loss of life associated with AAA rupture, there are significant health care costs. Cost reimbursement studies document an average loss to the hospital of approximately \$25,000 per patient presenting with a ruptured AAA (12). 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 (13).

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Origins of Endovascular Abdominal Aortic Aneurysm Repair

The development of endovascular techniques for endovascular treatment of AAA was initiated by Juan C. Parodi, M.D. and his colleagues (14). These techniques use the transfemoral route of delivery of the endovascular device. Parodi's device was created from prosthetic vascular grafts or conduits combined with balloon-expandable stents. Since Parodi's initial report, numerous other endovascular devices have been developed and tested for the treatment of AAA.

Current Indications for Endovascular Repair

Since the selection criteria and indications for the endovascular repair of AAA are constantly evolving, there is no precise agreement on what these criteria should be. During the initial experience with endovascular AAA repair, patients were offered endovascular treatment on a compassionate-need basis. Endovascular grafts were used to treat patients who had aneurysms that were at significant risk for rupture but who could not tolerate standard surgical repair. 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 increased significantly. The decision to use endovascular techniques to treat AAA is greatly affected by the anatomical constraints of the device.

Anatomical Selection Criteria

A number of anatomical and technical criteria must be fulfilled if endovascular repair of AAA is to be performed successfully. These criteria include:

- The presence of an undilated segment of aorta distal to the renal ostia that is of sufficient length to allow implantation of the proximal aspect of the endovascular device; this is the proximal neck. The length of normal proximal aorta necessary for device implantation varies according to the specifications of the individual device and ranges from 1.0–1.5 cm.
- 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.

- 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.
- 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.
- The iliac vessels must demonstrate limited tortuosity.
- 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 to be a relative contraindication.

Preoperative Assessment

Adequate assessment of the AAA, using radiological evaluation, must be performed to determine the diameter and length of the endovascular device to be used. In general, a screening computed tomographic (CT) scan with intravenous contrast is performed. Ideally, a high-speed, helical scanner is used to obtain images at 3 mm intervals. 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 can be calculated. In addition, the length of the endovascular graft necessary for treatment of the aneurysm may be estimated using three-dimensional reconstruction of the CT.

Angiography with a marker catheter may be used in the assessment of arterial length as well as the adjacent arterial structures. Assessment of the renal and inferior mesenteric arteries, in particular, may be performed. A calibrating catheter with radiopaque markers at 1 cm intervals is used. This catheter allows for the com-

compensation of parallax and magnification, permitting greater accuracy in determining the length of graft necessary for endovascular treatment (15). 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 (16). 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.

Deployment of Endovascular Devices

Endovascular AAA repair is most commonly performed in the operating room. This environment is the safest and the best suited for handling potential complications that might be encountered, including iliac artery perforation, damage to the femoral access site, aortic thrombosis 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 (15).

Prior to surgery the patient is fully prepared and draped in a sterile manner. The endovascular procedure is performed under fluoroscopic guidance, so 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 or magnetic resonance imaging. 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 in side branches.

Commercially Fabricated Endovascular Devices

After the initial success of endovascular stent grafts fabricated by vascular surgeons, commercially fabricated endovascular devices began to be developed. These devices have received considerable clinical exposure, and seven of them are currently either in use or undergoing trials. One device, the Guidant Ancure, has been withdrawn from use after initial approval by the FDA.

1. AneuRx (Medtronic, Inc., Minneapolis, MN);
2. Talent (World Medical, Sunrise, FL);
3. Zenith (Cook Inc., Bloomington, IN);
4. Anaconda (Sulzer Vascutek, Austin, TX);
5. Endologix (Endologix, Irvine, CA);
6. Excluder (W.L. Gore and Associates, Flagstaff, AZ);
7. Quantum (Cordis, Inc./Cordis, Somerville, NJ).

The Guidant/EVT Ancure Device

The Guidant Ancure stent graft deserves special mention. Originally designed and produced by Endovascular Technologies, the Ancure endograft system was the first stent graft to be produced commercially. Phase I and II clinical trials were completed and the device received FDA approval in 1999 (16). Initial reports found the device to be generally safe and efficacious. (17). However, subsequent review of the data relating to the use of the Ancure graft revealed significant difficulties associated with delivery and deployment of the device. These difficulties resulted in considerable morbidity and in mortality in a significant number of cases. In addition, the Guidant Corporation misrepresented the results on the use of this stent graft to the FDA. As a result, the device has now been withdrawn from use.

The AneuRx Device

A modular, bifurcated, self-expanding stent-graft system was developed by AneuRx (Fig.

1). The modular components consist of a thin-walled, noncrimped, 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 comparing endovascular AAA treatment with the AneuRx device to conventional open repair have been reported (18) (Table). 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% with a 12% major morbid event rate, which included myocardial infarction, stroke, renal failure and arrhythmia. Minor morbidities (5%) included wound infection, minor toe embolization, mild femoral neuropathy and an increase in creatinine that did not require treatment. The use of the AneuRx device, when compared with surgical treatment, was found to offer advantages in reducing the rate of major morbidity and length of hospital stay.

The device has received approval from the U.S. FDA, having completed phase I and II trials (18). In the long-term follow-up of those patients, the AneuRx device was found to have an implant success rate of 98% with a periopera-

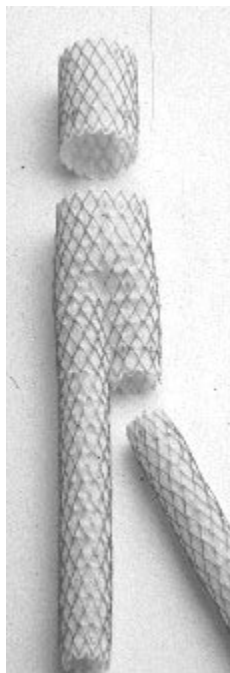


Fig. 1. AneuRx device. The modular design of this graft includes the main bifurcated segment, the contralateral limb, and the proximal and distal extender cuffs.

TABLE
Results of Medtronic AneuRx

	%
Implant success	98
30-day mortality	1.9
Perioperative conversion to standard open repair	1.3
Conversion to conventional repair (at 4 years)	2.8
Secondary procedures	8
1-year survival	94
3-year survival	84
Endoleak at 1 year	21
Endoleak at 3 years	18

tive mortality rate of 1.9%. One-year survival was 94% and 3-year survival was 84%. Conversion to conventional repair was required in 2.8% during 4-year follow-up, with AAA rupture occurring in 0.8% and being largely attributable to persistent endoleaks. The incidence of endoleak was 21% at 1 year and 18% at 3 years. Follow-up of these patients continues.

The Talent Device

The endovascular device developed by Talent has been implanted in more than 13,000 patients worldwide. The Talent graft is used in three configurations: tube/aortic, tapered/Ardeniliac, and bifurcated/aortic-iliac (Fig. 2). 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 AneuRx device. First, the aortic component, with one iliac limb, is deployed 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.

A recent report summarizes the results of an FDA-sponsored investigational device exemption trial for high-risk patients (19). In this trial all patients either had significant comorbid medical conditions or possessed a hostile abdomen. Technical success was achieved in 93% of patients treated with the Talent device. Secondary procedures were required in 8.7%. Conversion to open surgical repair was required in 1% of the cases. The overall 30-day mortality rate was 1.9%. 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 pos-



Fig. 2. Bifurcated Talent endovascular graft. The modular Talent graft utilizes a bare stent segment proximally that allows for transrenal fixation.

sesses 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 (19).

The Zenith AAA Endovascular Graft

The Zenith system from Cook is a modular bifurcated device, but is also available in an Arden-iliac configuration. It consists of woven polyester graft material supported throughout its length by self-expanding Z-stents. The introducer tip is tapered to minimize trauma at the arterial insertion site, and there are side holes at the tip to allow angiography when the system is 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 U.S..

The Anaconda System

The Anaconda stent-graft system for aneurysm treatment 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 be anchored 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 theoretically an increased risk of an endoleak developing at the graft junction sites because of the increased number of articulations between pieces. This device is also currently undergoing clinical trials.

Endologix PowerLink System

The Endologix PowerLink system is a one-piece bifurcated graft composed 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. This system is currently available for investigational use only.

The Gore Excluder Endoprosthesis

The Excluder stent-graft system is composed of thin-walled PTFE externally supported throughout its length with nitinol stents. It is a modular bifurcated system. The main body is delivered through an 18F sheath, while the contralateral limb is delivered through a 12F sheath (Fig. 3). 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.

The Quantum Endovascular Device

Transrenal fixation of the proximal aspect of the endovascular graft appears to offer significant advantages for patients with short or angulated proximal necks. 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 Quantum endovascular aortic graft is constructed from seamless nitinol hypo-tube stents, which provide the thermal memory properties of the nitinol metal material. The attachment system is equipped with a trans-



Fig. 3. Bifurcated Gore Excluder. The main body and ipsilateral limb with delivery system (left). Although the modular design is similar to other endografts, the use of PTFE graft material allows for deployment through a smaller delivery system.

renal segment, which optimizes renal artery blood flow while enhancing suprarenal fixation (Fig. 4). 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. 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 treatment of AAA has been undergoing evaluation in the clinical setting since 1991. The techniques have been carried out with considerable success at various centers in the United States and abroad. 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 AAA as

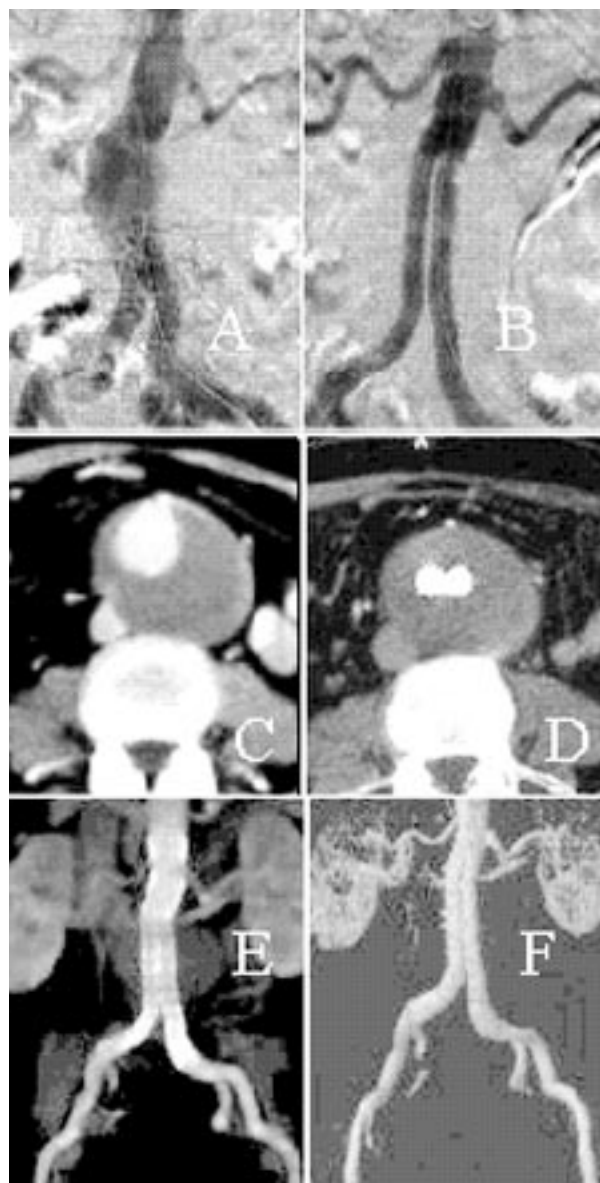


Fig. 4. Teramed Cordis endovascular aneurysm repair. Panels **A** and **C** are preoperative images of a 72-year-old man with an abdominal aortic aneurysm. Panels **B**, **D**, **E** and **F** are images following the insertion of an endovascular aortic stent graft. The aneurysm is completely excluded in the postoperative angiograms. Panel **E** is a maximum intensity projection done one year after endovascular aortic repair. Panel **F** is a 3-dimensional reconstruction which demonstrates that the aneurysm is excluded.

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 be reported 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.

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