Aortic stent grafts

G S Soor,1 M O Chakrabarti,1 J R Abraham,1 S W Leong,1 I Vukin,1 T Lindsay,2 J Butany1,3

ABSTRACT

Abdominal aortic aneurysms (AAAs) occur when weakened areas of the abdominal aortic wall result in a ballooning of the blood vessel.1 Attributed risk factors include smoking, atherosclerosis and hypertension. Generally, AAAs are initially asymptomatic. On progression, symptomatic aneurysms may result in back, abdominal, buttock, groin or testicular pain; the mortality rate is as high as 90% when the aneurysm ruptures outside a hospital. It is estimated that 9% of individuals in the USA over 65 years old have an undetected aneurysm, leading to approximately 15 000 deaths every year.1

AAAs were traditionally treated with open surgery involving a large abdominal incision and the placement of a synthetic graft. In 1991, Parodi et al6 presented “endovascular stent placement” as a new technique for the treatment of AAAs. It was not until 1999 though, that the first aortic stent grafts for the treatment of AAAs became commercially available to physicians and patients, following which many models have been introduced onto the market (table 1). Stent grafts (SGs) can be classified based on several characteristics: whether they are self-expanding, balloon inflated, consist of one single continuous body or have attachable iliac segments. They are manufactured from stainless steel,3 cobalt chromium alloy4 or nickel alloys (Nitinol),5 and have additional unique structures that increase their longevity (table 2). In the future, they may be impregnated with collagen to help the body heal after implantation.

When compared to open repair, endovascular aneurysm repair (EVAR) has many advantages, chief among which is a lower perioperative morbidity and mortality rate.7 This is particularly important when determining treatment options for elderly and high-risk patients, such as those with several co-morbidities. However, despite a reported 97% technical success rate,8 there is an associated 20% endoleak rate with EVAR. Endoleaks are defined as leakage of blood through or around the graft and into the aneurysm, and are associated with continuous growth and consequential rupture of the aneurysm. In addition, other complications such as stent migration and post-implantation syndrome (a weakly defined condition that is postulated to include significant leucocytosis, fever and/or coagulation disturbances) may arise.9

The FDA has approved several stents for the treatment of AAAs, provided that patients meet specific, pre-set guidelines. These guidelines include morphological qualifications such as vessel and aneurysm size. Though several SGs have not yet been approved by the FDA, they are approved for use by other governments around the world or are undergoing clinical trials.

This review is a guide to the many FDA approved stent grafts, which are/were commercially available, and those likely to become available following clinical trials. This guide is not all encompassing, but is intended to help the practising pathologist identify the different SGs they may encounter at the surgical bench or at autopsy, and to help in the assessment of common modes of failure (tables 3 and 4). This review is not an endorsement of any particular device or devices. In examining a particular SG, the specimen in which it was placed should be measured, photographed, and radiographed (fig 1). Sections should then be taken for further study, where the gross and histological findings must be correlated with clinical data (fig 2). An essential but expensive and time consuming part of the study and evaluation of an explanted stent/stent-graft is the embedding of a segment of the synthetic material and surrounding tissues in “plastic” (Araldite or methyl methacrylate). This allows for detailed evaluation of reactions, if any, between host tissue and stent fabric or metal components.

DESCRIPTIONS OF STENTS

The descriptions of stents provided hereafter are divided into sub-categories according to type, size range and physical characteristics. Also included are details and references listing their complications and/or successes. The material for this paper was obtained from the medical literature as well as the manufacturers’ and FDA websites. Every attempt has been made in our review to avoid any semblance of bias. “Homemade” stents made...
by surgeons from commercially available components are not included. The authors have no bias for or against any of the stents included in this review or their manufacturers, nor do they have any commercial interest of any kind, in any of the products. One of the authors (JB) was at one time involved in the early post-implant studies of two of the stents (made by the World Medical Corporation, Florida, USA, and by Teramed, Minneapolis, USA).

Ancure

Model
Ancure system (fig 3).

Type
Self expanding multi-body stent with balloon catheter.

Technical information
Manufactured by Guidant Corporation (Menlo Park, California, USA).

Size range
- Tube diameter: 20.0–26.0 mm
- Tube length: 9.0–16.0 cm

Table 1 Stents available and included in review

<table>
<thead>
<tr>
<th>Stent</th>
<th>Manufacturer</th>
<th>FDA device approval</th>
<th>Withdrawal from market</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ancure</td>
<td>Guidant Corporation (California, USA)</td>
<td>September 1999</td>
<td>March 2001</td>
</tr>
<tr>
<td>AneuRx</td>
<td>Medtronic AVE (California, USA)</td>
<td>September 1999</td>
<td>In use</td>
</tr>
<tr>
<td>Aorfix</td>
<td>Lombard Medical (UK)</td>
<td>–</td>
<td>NA</td>
</tr>
<tr>
<td>Excluder</td>
<td>WL Gore and Associates (Delaware, USA)</td>
<td>November 2002</td>
<td>In use</td>
</tr>
<tr>
<td>Fortron</td>
<td>Cordis Corporation (Minnesota, USA)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Lifepath</td>
<td>Edwards Life Sciences (California, USA)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Powerlink</td>
<td>Endologix (California, USA)</td>
<td>October 2004</td>
<td>December 2005 (delivery system)</td>
</tr>
<tr>
<td>Talent</td>
<td>Medtronic AVE (Florida, USA)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Zenith</td>
<td>Cook (Indiana, USA)</td>
<td>May 2003</td>
<td>In use</td>
</tr>
</tbody>
</table>

Table 2 Desirable features of components of an aortic stent-graft

<table>
<thead>
<tr>
<th>Component</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivery system</td>
<td>Low profile Flexible for manoeuvrability Rigid to resist kinking Haemostatic User-friendly</td>
</tr>
<tr>
<td>Graft material</td>
<td>Low profile Strong and durable Reasonably thin</td>
</tr>
<tr>
<td>Stent frame</td>
<td>Provide high column strength and ductility Compression/kink resistant from external forces Radiopaque Corrosion resistant Long fatigue-free life</td>
</tr>
</tbody>
</table>

AneuRx

Model
AneuRx stent graft (fig 4).

Type
Self expanding multi-body Nitinol stent with catheter based delivery system.

Technical information
Manufactured by Medtronic AVE (Santa Rosa, California, USA).

Size range
- Proximal diameter: 20.0–28.0 mm
- Distal diameter: 12.0–16.0 mm
- Length: 13.5–16.5 cm

Bifurcated stent graft
- Bifurcated length: 12.0–19.0 cm
- Bifurcated diameter: 20.0–16.0 mm

Physical characteristics
The AneuRx device consists of a Nitinol frame with woven polyester graft tubes. The frame contains no joints or welds and is designed to stay in place with a friction fit.

FDA approved
The Guidant Ancure device was approved in September 1999. The company withdrew the device from the market in March 2001 when Endovascular Technologies (a division of Guidant responsible for the Ancure device) announced that it had failed to report 2628 cases in which 12 deaths and 52 emergency operations had occurred.

Aorfix

Model
Aorfix stent graft (fig 4).

Excluder

Model
Excluder stent graft (fig 4).

Fortron

Model
Fortron stent graft (fig 4).

Lifepath

Model
Lifepath stent graft (fig 4).

Powerlink

Model
Powerlink stent graft (fig 4).

Talent

Model
Talent stent graft (fig 4).

Zenith

Model
Zenith stent graft (fig 4).
Zarins et al. reported a 98.7% success rate for the insertion procedure. The endoleak rate at discharge was 36% and decreased to 18% after one month. There were no deaths related to aneurysm rupture. Krajcer et al. presented four cases where blunt physical trauma or violent physical activity had caused type I and type III endoleaks (table 4) after successful implantation of the device. The FDA, in collaboration with Medtronic AVE, found a 1.5% mortality rate at up to 30 days after implantation of the device. The mortality rate continues to increase to 1.9% after 1 year, 2.2% after 2 years, and 2.7% after 3 years.

FDA approval

The Medtronic AneuRx was approved by the FDA in September 1999. In 2001, the FDA released a public health notice on the AneuRx device recommending that patients and physicians should consider factors such as centre experience with endovascular procedures, patient life expectancy, and other surgical co-morbidities before implanting the AneuRx stent-graft.

Aorfix

Model

Aorfix endovascular stent-graft (fig 5).

Type

Self expanding Nitinol multi-body stent with a woven polyester fabric.

Table 3 Complications associated with stent-graft placement

<table>
<thead>
<tr>
<th>Complications</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early</td>
<td>Vascular (occlusive) complications</td>
</tr>
<tr>
<td></td>
<td>Renal failure</td>
</tr>
<tr>
<td></td>
<td>Bowel infarction</td>
</tr>
<tr>
<td></td>
<td>Lower extremity embolism</td>
</tr>
<tr>
<td></td>
<td>Paraplegia or paraparesis</td>
</tr>
<tr>
<td>Mechanical complications</td>
<td>False-lumen formation/rupture of aneurysm</td>
</tr>
<tr>
<td></td>
<td>&quot;Post-implantation&quot; syndrome</td>
</tr>
<tr>
<td></td>
<td>Migration</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
<tr>
<td></td>
<td>Infection</td>
</tr>
<tr>
<td>Delayed</td>
<td>Device related</td>
</tr>
<tr>
<td></td>
<td>Stent fracture</td>
</tr>
<tr>
<td></td>
<td>Stent-graft migration or prolapse into the aneurysm</td>
</tr>
<tr>
<td></td>
<td>Stent-graft erosion into oesophagus</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
<tr>
<td></td>
<td>Distal embolisation</td>
</tr>
<tr>
<td></td>
<td>Bowel ischaemia</td>
</tr>
<tr>
<td></td>
<td>Infection of stent-graft</td>
</tr>
<tr>
<td></td>
<td>Expansion and rupture of treated aneurysm</td>
</tr>
<tr>
<td></td>
<td>Endovascular leak</td>
</tr>
</tbody>
</table>

Additional comments

Zarins et al. reported a 98.7% success rate for the insertion procedure. The endoleak rate at discharge was 56% and decreased to 18% after one month. There were no deaths related to aneurysm rupture. Krajcer et al. presented four cases where blunt physical trauma or violent physical activity had caused type I and type III endoleaks (table 4) after successful implantation of the device. The FDA, in collaboration with Medtronic AVE, found a 1.5% mortality rate at up to 30 days after implantation of the device. The mortality rate continues to increase to 1.9% after 1 year, 2.2% after 2 years, and 2.7% after 3 years.

FDA approval

The Medtronic AneuRx was approved by the FDA in September 1999. In 2001, the FDA released a public health notice on the AneuRx device recommending that patients and physicians should consider factors such as centre experience with endovascular procedures, patient life expectancy, and other surgical co-morbidities before implanting the AneuRx stent-graft.

Aorfix

Model

Aorfix endovascular stent-graft (fig 5).

Type

Self expanding Nitinol multi-body stent with a woven polyester fabric.

Table 4 Types of Endoleak

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type I</td>
<td>Blood flow into aneurysm sac due to incomplete or ineffective seal at ends of grafts</td>
</tr>
<tr>
<td>Type II</td>
<td>Blood flow into aneurysm sac due to opposing blood flow from collateral vessels</td>
</tr>
<tr>
<td>Type III</td>
<td>Blood flow into aneurysm sac due to incomplete or ineffective sealing of graft joints or rupture of graft fabric</td>
</tr>
<tr>
<td>Type IV</td>
<td>Blood flow into aneurysm sac due to pores in graft fabric</td>
</tr>
</tbody>
</table>

Technical information

Manufactured by Lombard Medical (Oxon, UK).

Size range

- Proximal diameter: 24.0–31.0 mm
- Graft body length: 96.0–142.0 mm
- Ipsilateral diameter: 10.0–20.0 mm
- Ipsilateral length: 63.0–97.0 mm
- Contralateral diameter: 10.0–20.0 mm
- Contralateral length: 56.0–106.0 mm
Physical characteristics
The Aorfix endovascular stent-graft includes an electropolished Nitinol stent and a large opening to the contralateral socket.20

Additional comments
Hinchliffe et al.,21 in a study of 24 Aorfix stent-graft implants, found one stent not deploying correctly and one type II endoleak which was not graft related. The remaining 22 patients required only one day in an intensive care or high dependency unit, and on release had no graft related endoleaks. Albertini et al.22 reported a 96% successful deployment rate, with one patient dying of multi-organ failure after revision of a groin wound for haemorrhage. Follow-up found one patient with an endoleak even after extensions were deployed, and one death after four years due to wire-form fractures.25

FDA approved
In February 2006, Lombard Medical received full Investigational Device Exemption (IDE) for clinical trials in the United States. As of May 2007, Lombard Medical has received supplemental FDA approval to increase the number of trial centres from 10 to 20, and broaden patient entry criteria.47

Excluder
Model
Gore Excluder AAA Endoprosthesis.

Figure 2 (A) The synthetic fabric (Dacron) of the graft is seen here. The image shows large numbers of multinucleate giant cells (arrows), surrounding individual synthetic threads of the Dacron fabric (arrowheads). A pseudointima and perigraft fibrosis as well as tissue ingrowth into the graft are present. (B) Photomicrograph of a section of the stent graft showing the Dacron fabric (with polarised light).

Figure 3 Diagram of an Ancure (Guidant Corporation) device.49

Figure 4 Diagram of an Aneurx AAAdvantage (Medtronic AVE) stent-graft. Additional segments can be added to the iliac arms, as needed or necessary.50
Type
Self expanding Nitinol support structure, catheter based delivery.  

Technical information
Manufactured by WL Gore & Associates (Newark, Delaware, USA).  

Size range  
Trunk-ipsilateral leg endoprosthesis
- Aortic diameter: 23.0–28.5 mm
- Iliac diameter: 12.0–14.5 mm
- Prosthesis length: 14.0–18.0 cm

Contralateral leg endoprosthesis
- Prosthesis diameter: 12.0–20.0 mm
- Prosthesis length: 9.5–14.0 cm

Physical characteristics
The Gore Excluder consists of an ePTFE (expanded polytetrafluoroethylene) graft (fig 6), low permeability film, ePTFE reinforcing film, electropolished Nitinol stent, and bonding film for stent to graft attachment.  

Additional comments
The Gore Excluder device had less adverse effects compared to open endovascular repair. Fillenger determined that 34% of patients had enlarging AAAs after four years of follow-up and 39% of patients had endoleaks. Leurs et al. found a 3% higher aneurysm-related death rate in patients with larger aneurysms (3%) three years after implanting the Excluder device. The Gore Excluder has also been used for the treatment of aneurysms and ruptures of the descending thoracic aorta.  

FDA approved
The Gore Excluder device was approved by the FDA in November 2002.  

Fortron  
Model
Fortron stent-graft.  

Type
Self expanding multi-body stent. Catheter based delivery.  

Technical information
Manufactured by Cordis Corporation (Miami Lakes, Florida, USA).  

Size range
- Main body length: 8.0 cm
- Main body diameter: 30.0–34.0 mm
- Iliac leg length: 10.0–14.0 cm
- Iliac leg diameter: 16.0–22.0 mm

Physical characteristics
The Fortron device consists of a Nitinol stent and a woven polyester graft.  

Additional comments
Brener et al. reported type II endoleaks in 10 of 29 patients following implantation of a Fortron device. There were no deaths, ruptures, migrations, fractures, occlusions or conversions. There were no new type I or type III endoleaks after 4 years follow-up although four type II endoleaks persisted. Stent fractures were detected in three patients. A study conducted by the Cordis Company in Europe, involving 65 patients, reported a 100% technical success rate, although at 1 year follow-up, there were three type II endoleaks and two unrelated deaths, but no aneurysm ruptures or other graft-related complications.  

FDA approved
No record of FDA approval.  

Lifepath  
Model
Lifepath stent-graft device (fig 7).  

Type
Multi-body stent which can be self or balloon inflated.  

Technical information
Manufactured by Edwards Life Sciences (Irvine, California, USA).  

Figure 5  Diagram of an Aorfix (Lombard Medical) device.  

Figure 6  This section of a graft shows Gortex fabric (PTFE, polytetrafluoroethylene) with pseudointima (asterisk), comprised largely of macrophages and multinucleate giant cells (curved arrow). Arrows, Gortex fabric.  

The Lifepath device consists of a metal frame made of Elgiloy and stainless steel with a Dacron graft.

Additional comments
Schumacher et al.\textsuperscript{35} reported a 100% technical success rate in patients with the Lifepath device. There was one endoleak which disappeared by 3 months and no complications after 2 years follow-up. McCann\textsuperscript{34} reports an operative mortality rate of 1.3% with no late device related deaths or aneurysm ruptures. Endoleaks (type I, type II) were present in 19% of patients during deployment, but after one month this number decreased to 10%. At 6 months, the endoleak rate was 7% and after 24 months the rate was 0.5% (one type II endoleak). Wire fractures were identified in 47% of patients, but they did not cause rupture, conversion to open repair or endoleak development. Nevertheless, Edwards Life Sciences announced that as of 30 June 2004, they would not continue development of the Lifepath device.\textsuperscript{48}

FDA approved
No record of FDA approval.

Powerlink
Model
Powerlink system.

Type
Self expanding unibody stent with a catheter based delivery system.\textsuperscript{7}

Technical information
Manufactured by Endologix (Irvine, California, USA).\textsuperscript{36}

Size range\textsuperscript{36}
- Proximal neck diameter: 16.0–36.0 mm
- Length: 5.0–12.0 cm
- Bifurcated graft size: 20.0–36.0 mm

Physical characteristics
The Endologix Powerlink stent has a frame made of cobalt chromium alloy with an ePTFE graft.\textsuperscript{7}

Additional comments
Albertini et al.\textsuperscript{37} reported that 4.7% of patients at 3 year follow-up developed type I endoleaks related to stent migration, and 9.4% developed secondary endoleaks.

FDA approved
The Endologix Powerlink device was approved by the FDA in October 2004.\textsuperscript{38} The manufacturer Endologix issued a voluntary recall on the Powerlink device in December 2005 because the tip of the device often separated from the catheter during insertion. The implanted devices themselves are not being recalled.\textsuperscript{39}

Talent
Model
Talent stent-graft (fig 8).

Type
Self expanding multi-body stent with a balloon catheter.\textsuperscript{40}

Technical information
Manufactured by Medtronic AVE (Sunrise, Florida, USA).\textsuperscript{14}

Size range\textsuperscript{40}
- Proximal neck diameter: 16.0–36.0 mm
- Length: 5.0–12.0 cm
- Bifurcated graft size: 20.0–36.0 mm
Physical characteristics
The Talent device consists of a Nitinol stent in a serpentine design with Dacron fabric attached to the graft. The outside has small barbs to help it anchor in place.\(^4\)

Additional comments
Criado \textit{et al.}\(^4\) reported a 2.5\% mortality rate within 30 days of implantation with an overall technical success rate of 94\%. Endoleaks decreased from 15\% at initial CT scan to 8\% at 30 days follow-up. Torsello \textit{et al.}\(^4\) found a 94.5\% survival rate after one year of implantation, with one death being attributed to aneurysm rupture. The graft showed a durability of 5–7 years, relatively longer than first generation stent grafts. The Talent device has also been used for the treatment of thoracic aneurysms and ruptures, with patients often making a full recovery.\(^4\) \(^1\) \(^2\)

FDA approved
No record of FDA approval.

Zenith

Model
Zenith AAA Endovascular Graft (fig 9).

Type
Self expanding multi-body stent.

Technical information
Manufactured by Cook (Bloomington, Indiana, USA).\(^6\)

Size range\(^6\)

\textbf{Main body}
- Diameter: 22.0–32.0 mm
- Contralateral length: 74.0–132.0 mm
- Ipsilateral length: 104.0–162.0 mm

\textbf{Iliac leg}
- Diameter: 8.0–24.0 mm
- Length: 37.0–122.0 mm

Take-home messages
- The introduction of endovascular aneurysm repair (EVAR) has proved to have many advantages over open repair, chief among which is a lower perioperative morbidity and mortality rate.
- The stent grafts that are used in this procedure offer distinct advantages such as ease of deployment, lower cost, shorter hospitalisation times post-surgery, and better patient health. EVAR is likely to continue to evolve and the complications associated with these devices will likely continue to decrease.
- Although endovascular aneurysm repair may be more effective than open repair, postoperative problems are still fairly common.
- It is important for the practising pathologist to be aware of complications such as stent migration, endoleaks, and implantation problems that are prevalent during the EVAR procedure.

Physical characteristics
The Zenith device consists of a woven polyester fabric sewn to a stainless steel stent. There are barbs placed every 3 mm to help prevent stent movement.\(^5\)

Additional comments
A patient with the Zenith device for treatment of an AAA showed no symptoms of post-implantation syndrome. The patient was doing well at 3 months follow-up.\(^43\) The Zenith device has also been used for thoracic injuries, with the patient remaining healthy beyond 18 months.\(^44\)

FDA approval
The Cook Zenith was approved by the FDA in May 2003.\(^45\)

CONCLUSION
There are a number of stents available for the endovascular repair of AAAs. This review highlights some of the stents available on the market. EVAR has obvious positives, not the least of which is the absence of a long surgical scar and significant morbidity. Although endovascular aneurysm repair may be more effective than open repair, postoperative problems are still fairly common. Complications such as stent migration, endoleaks, and implantation problems are important considerations to keep in mind during EVAR. The practising pathologist must also be aware of these complications during surgical pathology/autopsy examination of these devices. In spite of all the potential and reported problems, EVAR represents a good alternative treatment for aortic aneurysms, especially for the elderly and even more so for those with significant co-morbidities. The stents offer distinct advantages such as ease of deployment, lower cost, shorter hospitalisation times post-surgery, and better patient health. EVAR is likely to continue to evolve and the complications associated with these devices will likely continue to decrease. The continued and detailed analysis of explanted devices is essential if the devices are to continue to evolve, and for others to become aware of complications with any new device.

Competing interests: None.
REFERENCES


34. McCann RL. Multicentre results with the Edwards Lifepath AAA graft system for EVAR. 30th Global: Vascular and Endovascular Issues, Techniques and Horizons (abstract), 2003.


