Abdominal aortic aneurysms are the 13th leading cause of death in the US with approximately 15,000 deaths each year due to ruptured aortic aneurysms. The prevalence of aortic aneurysms is increasing as the population ages and it is estimated that one in 10 men over the age of 75 will have an aortic aneurysm. The risk of rupture increases with increasing aneurysm size and the overall mortality rate for ruptured aortic aneurysms exceeds 90%. The annual risk of rupture of medium-sized aneurysms – 4.5–5.9cm – is 1.7% with a calculated maximal potential risk of rupture of 10% per year. Aneurysms larger than 6cm have a 25% annual risk of rupture. Rupture can be prevented by elective open surgical repair of the aneurysm and this has been the standard of care for the past 50 years. However, surgical repair requires a major operative procedure under general anaesthesia with open exposure of the abdominal aorta, aortic cross-clamping and prosthetic aortic graft replacement. The operative mortality of open surgical repair is approximately 5%, although many have reported an operative mortality of 1–2% in selected, good-risk patients. Since aneurysms are a disease of the elderly, a large proportion of aneurysm patients have multiple co-morbidities that increase operative risk such as cardiac disease, chronic obstructive pulmonary disease and renal insufficiency. Patient selection for open aneurysm repair is based on an assessment of the risk of rupture compared with the risk of open surgical repair. Many patients with aneurysms are judged to be poor operative candidates and are not treated because of advanced age and compromised cardiopulmonary condition.

In 1991, Juan Parodi performed the first successful endoluminal repair of an abdominal aortic aneurysm using a modified Palmaz stent to secure the end of a woven prosthetic graft to the infrarenal aorta. This procedure did not require open exposure of the aorta and aortic cross-clamp, but only exposure and repair of the femoral arteries in the groin with fluoroscopic image guidance, to position properly the endograft to exclude the aneurysm from the circulation. This greatly reduced the magnitude of the operative procedure to repair aortic aneurysms and stimulated worldwide interest in less invasive strategies to treat aortic aneurysms. In a short period of time, a variety of endovascular grafts were developed for the treatment of AAA and this resulted in the explosive growth of the field of endovascular surgery. The first controlled clinical trials to evaluate the performance of industry-developed endovascular devices compared with open surgical repair were begun in 1995, and in 1999 the FDA approved the first two endovascular devices for use in the US – Guidant Ancure and Medtronic AneuRx. Since that time, three additional endovascular devices – Gore Excluder, Cook Zenith and Endologix Powerlink – have been FDA-approved for use in the US, with newer endovascular devices in current clinical trials. The Medtronic Talent endovascular device is most widely used in Europe. All clinical trials of these devices have shown significant early benefit with lower operative morbidity, less blood loss, lower blood transfusion requirements, shorter intensive care and hospital stays and more rapid patient recovery compared with open surgical repair. More than 120,000 patients with infrarenal aortic aneurysms have now been treated with endovascular devices.
before use along with knowledge of patient selection criteria and follow-up protocols. At the present time, four FDA-approved endovascular devices are commercially available for implantation by trained practitioners in the US. These are the Medtronic AneuRx, Gore Excluder, Cook Zenith and Endologix Powerlink devices. The Guidant Ancure device – originally known as the Endovascular Technologies device – was FDA approved in 1999 but withdrawn from the market in 2003 due to delivery system malfunctions and improper reporting to the FDA.

All endovascular devices require an infrarenal aortic neck of sufficient length – usually 15mm – and diameter for proximal fixation and seal of the device. The maximum aortic neck diameter that can be treated with currently approved FDA devices is 28mm. Approximately 50% of patients with infrarenal aortic aneurysms are not suitable candidates for endovascular repair using currently available devices primarily because of inadequacy of the infrarenal neck – too large, too short or too angulated. While the Talent device can treat aortic necks up to 32mm in diameter, it is not FDA-approved for use in the US.

**AneuRx Stent Graft**

The Medtronic AneuRx device is a modular bifurcated stent-graft with a thin-wall woven polyester fabric graft sutured to an exoskeleton of self-expanding nitinol (nickel-titanium alloy) stent rings. The fabric graft is fully supported by the exoskeleton, thus providing significant longitudinal columnar support while maintaining flexibility. Proximal and distal extender modules allow longitudinal extension of the device as needed to achieve fixation. Maximum device diameter is 28mm, thus the maximum diameter infrarenal neck which can be treated is 26mm. The AneuRx device was FDA-approved in 1999 and the multicentre clinical trial patient cohort is the largest endovascular patient group – 1,193 patients – with the longest comprehensive follow-up. Migration has been noted in 8% of patients and appears to be due to initial device placement low below the renal arteries, resulting in poor proximal fixation, or with little extension into the iliac arteries, resulting in poor distal fixation. Current recommendations are to extend the device from the renal to the level of the hypogastric arteries and this appears to prevent device migration. The device has undergone several enhancements with modification of the stent design to increase flexibility and improve the polyester fabric with a tighter weave and the introduction of the Xcelerant delivery system with a more flexible, tapered-tip delivery nose cone and delivery handle for more precise and controlled deployment. The device remains the market leader for infrarenal aortic aneurysms with more than 60,000 patients treated.

**Excluder Stent Graft**

The Gore Excluder is a modular stent graft system comprising an expanded polytetrafluoroethylene (ePTFE) graft bonded to a self-expanding nitinol exoskeleton. To aid in proximal fixation, the stent graft has seven pairs of nitinol anchors/barbs at the proximal end of the bifurcation module. The device is delivered through an 18 French flexible introducer sheath with a maximum proximal diameter of 28.5mm, allowing treatment of aneurysms with infrarenal neck diameter up to 26mm. Proximal and distal extender modules allow custom fitting of length as needed with large-diameter iliac limb modules up to 20mm. The device is deployed by pulling an ePTFE cord, which unzips a constraining ePTFE sheath that encases the graft, allowing the device to self-expand. Recent five-year results report no migrations, ruptures, limb disconnections or graft occlusions. A significant number of patients – 41% have experienced continued aneurysm enlargement after endovascular repair and this is thought to be due to transgraft transmission of serous fluid through the porous ePTFE fabric. Although this enlargement has not been associated with aneurysm rupture, continued monitoring and surveillance of patients is indicated. Recent modification of the fabric to reduce porosity of the graft material appears to reduce the likelihood of aneurysm enlargement.

**Zenith Stent Graft**

The Cook Zenith device is a modular stent graft system with a suprarenal fixation system with anchoring hooks to minimise stent graft migration. The woven polyester graft is supported by independent, stainless steel z-stent bodies to provide increased stent/vessel apposition. The low iliac graft bifurcation provides columnar strength and facilitates cannulation of the contralateral limb. The 24 French delivery system includes a haemostatic valve to minimize blood loss. Maximum graft size is 32mm allowing treatment of patients with 28mm diameter aortic necks. Iliac limbs are flared to provide good fixation and seal of large diameter iliac arteries. Suprarenal fixation is achieved with metallic stent struts with anchoring barbs which extend proximally from the fabric-covered main graft body and may partially cover the orifice of the renal arteries. This does not appear to impair renal function, but long-term observation will be needed to verify this observation. Aneurysm shrinkage is noted in three-quarters of patients at 24 months with an endoleak rate of only 5%.

**Powerlink Stent Graft**

The Endologix Powerlink stent graft has a unique design with a one-piece bifurcated ePTFE graft with
a single-piece cobalt chromium (Elgiloy) stent on the lumen side of the ePTFE fabric. The body of the device is long so that the graft bifurcation rests on the aortic bifurcation, thus reducing the risk of endograft migration. The proximal uncovered stent provides suprarenal fixation. The largest device diameter is 28mm allowing treatment of aneurysms with neck diameters of 26mm. The multicentre trial reported a 2.2% migration rate at a mean follow-up time of 22 months.

**Ancure Stent Graft**

The Ancure stent graft is an unsupported, bifurcated polyester fabric graft with stainless steel stents with penetrating hooks at the proximal and distal ends of the graft to provide fixation. The device is effective in excluding the aneurysm from the circulation and was FDA-approved in 1999. However, the delivery system required to deliver the iliac limb to the contralateral side was complex and malfunctions resulted in withdrawal of the device from the market in 2003. In addition, the unsupported iliac limbs were prone to compression and there was a high rate of iliac limb occlusions. This complication is rarely seen with current devices which have stented iliac limbs.

**Patient Selection**

Proper patient selection is important for successful endovascular repair, and not all patients with infrarenal aortic aneurysms are suitable candidates. Pre-operative imaging with a contrast computed tomography scan is essential for evaluating aneurysm, infrarenal neck and iliac artery anatomy. Three-dimensional image reconstruction with orthonormal image projection is helpful and provides more accurate measurements for procedure planning. Most patients who are excluded from endovascular aneurysm repair have unfavourable proximal aortic neck anatomy. Usually, a 15mm long non-aneurysmal attachment site below therenal arteries is required along with a neck diameter smaller than the endovascular device diameter. Angulation above 60º and an ‘inverse’ funnel shaped aortic neck are also considered unfavourable anatomical features for endovascular therapy.

Selection of patients with inadequate proximal neck anatomy may result in poor proximal fixation and endograft migration. Severe calcification and the presence of a large thrombus at the attachment site may also interfere with proper graft attachment. Common iliac aneurysms can be treated, but if the distal attachment sites are aneurysmal the hypogastric artery must either be coil-embolised with extension of the device to the external iliac artery or revascularised with a bypass.

Evaluation of the femoral and external iliac vessels for access of the device is also essential. Characteristics that may complicate transfemoral access include small vessel diameter, severe calcification, or extreme tortuosity. Stiff guidewires may help overcome some tortuous anatomy. When the external iliac vessels are too small to accept outer sheaths with diameters ranging from 12 French to 24 French, a common iliac conduit may be created using synthetic graft material. This requires retroperitoneal surgical exposure of the iliac artery, but is still considerably less invasive than a traditional open aneurysm repair since it requires only iliac artery clamping.

**Results of Endovascular Aneurysm Repair – Lifeline Registry**

Each of the endovascular devices described above received FDA approval for clinical use in the US on the basis of a controlled, multicentre clinical trial, which compared patients treated with a specific endovascular device with a control group of patients treated with standard open surgical repair. A condition of FDA approval for each device was long-term monitored follow-up of all clinical trial patients for a period of five years. This provided a unique opportunity to gain valuable information on the overall long-term results of endovascular aneurysm repair by combining the results of the individual device-specific clinical trials into one registry. This was accomplished by the establishment of the Lifeline Registry for Endovascular Aneurysm Repair by the Society for Vascular Surgery in 1998. Long-term data from four of the five clinical trials are included in this registry, which covers a total of 2,664 patients treated with endovascular repair and 334 control patients, who were treated with open surgery. The Lifeline Registry showed that the 30-day operative mortality rate for endovascular repair was 1.7%. Kaplan-Meier analysis at six years revealed that endovascular repair was successful in preventing aneurysm rupture in 99% of patients and that the aneurysm-related death-rate remained at the low level of 2% throughout the six-year period. At the end of five years, only 4% of patients had required surgical conversion to open aneurysm repair, thus demonstrating the durability of endovascular repair. Endoleaks were observed throughout the study period and secondary interventions were required in 22% of patients at five years and 27% of patients at six years (Kaplan-Meier analysis). Nonetheless, endovascular repair was highly effective in achieving the primary objective of preventing aneurysm rupture and maintaining a low aneurysm related death rate over a six-year period.

*This article is continued, with five graphics, in the Reference Section on the website supporting this briefing (www.touchbriefings.com).*