Endoluminal Versus Open Repair for Abdominal Aortic Aneurysms

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This presentation explores current knowledge about the epidemiology of abdominal aortic aneurysms (AAAs) and their treatment by observation, open surgical repair or endoluminal grafting (ELG). It is illustrated by experience with 187 patients treated by ELG in our unit in Melbourne, Australia.

1. THE NATURAL HISTORY AND RISK OF RUPTURE FOR AAAs.

Active treatment is justified only if the risk from intervention is substantially less than for observation. Risks for aneurysm rupture must outweigh the risks from surgical repair. Single-centre studies provide information about the aetiology, natural history and management options, but much more has now been learned from the multi-centre UK Small Aneurysm Trial. These have defined factors that influence outcome, time relations between expansion and risk of rupture for AAAs, and risk of death from other causes.

Maximum AAA diameter has long been considered the best predictor for outcome. However, small aneurysms can rupture with lethal results. A study for patients with ruptured AAAs measured diameter by ultrasound or computed tomography en route to theatre and found that 10% were 5.0cm or less in diameter (1). Another study showed that 5-year risks for rupture for small AAAs treated conservatively were 4% for patients with AAA < 4cm diameter and 21% for patients with AAA 4-5cm diameter (2). A further study found that the risk for rupture within 3 years for large AAAs in patients considered unfit for open surgery was 28% for AAAs 5.0-5.9cm diameter and 41% for AAAs > 6cm diameter, but that the larger proportion died from other causes (3).

The UK Small Aneurysm Trial commenced in 1991 and results have been reported since 1998 (4-9). The trial randomly assigned 1090 patients aged 60-76 years with asymptomatic AAAs 4.0-5.5 cm in diameter to undergo early elective open surgery or ultrasound surveillance. The 30-day operative mortality in the early-surgery group was 5.8%. Late mortality did not differ significantly between groups at 2-6 years. Health service costs were higher for surgery than surveillance.

The annual rupture rate was 2.2% and most occurred with AAAs 5-5.5 cm diameter. Risk was independently associated with female sex, larger initial AAA diameter, current smoking, lower FEV1, and higher mean blood pressure, but not with age, body mass index, serum cholesterol, or the ankle/brachial pressure index. Women were three times more likely to rupture than men. Risk was diminished if hypertension was well controlled or the patient stopped smoking. It was concluded that ultrasound surveillance is safe for small abdominal aortic aneurysms, that early surgery does not provide a long-term advantage, and that patients should have regular ultrasound surveillance followed by surgery for AAAs that grow by more than 1 cm per year or that reach 5.5 cm diameter.

An independent statistical analysis of the trial from the United States considered that early surgery could be cost-effective for younger patients with larger AAAs, but that decision-making should be guided by patient preference since gains in life expectancy would be small (10).

Local features within an AAA identify increased risk for rupture. Saccular AAAs have a more ominous
natural history than typical fusiform aneurysms (11). Weakened areas within the wall increase the risk and these can be detected by CT scans (12). Spiral CT can show pathological dissection into the mural thrombus that predicts rupture (13). Direct pressure measurements near the aneurysm wall during open surgery show that thrombus within an aneurysm does not reduce the pressure near the wall so that it does not protect an AAA from rupture (14). Studies of AAA models show that pulsatile vortex flow and turbulence are responsible for expansion and eventual rupture (15). Operation and post-mortem studies find that most ruptures occur in the middle third where the aneurysm diameter is greatest (16).

Systemic factors also have an effect. There is a stronger relation to smoking, male gender, diastolic hypertension and family history for AAA than for atherosclerotic occlusive arterial disease, with no significant relation to serum lipid levels and an inverse relation to diabetes (17). Concomitant lower limb occlusive arterial disease does not adversely affect long-term survival for patients who undergo open surgical repair for AAA (18).

2. DETECTING AAAs

The most common way to diagnose an AAA is by opportunistic detection without prior clinical suspicion during routine clinical examination, investigation for other diseases or laparotomy. However, opportunistic detection is not as effective as a formal screening program (1). Physical examination can miss more than one-third of AAAs detected radiologically (2).

Much has been learned from community ultrasound screening programs for AAAs, particularly in Europe and Western Australia. Attendance rates for those invited are 70-80% (3-5). A study of 13,000 men aged 60-75 years in Birmingham (UK) found the prevalence to be 6.9% for AAAs > 29mm diameter, and 1.8% for those > 40mm diameter (6). Screening is worthwhile if it reduces the risk of rupture. A study from the UK found that rupture was twice as likely in subjects invited to participate in screening compared to those not invited (7). Ultrasound screening for AAAs for more than 11,000 subjects in the UK and Netherlands showed that the risk of rupture over 5 years was < 20% for AAAs with initial diameter 4.5cm, and < 4% for AAA with initial diameter 3.0cm. (8, 9). However, there are conflicting views on whether surveillance is cost-effective and it would require a prospective trial comparing screened and non-screened populations to resolve this question (10).

Resources for surveillance are limited so that it should be more effective to target high-risk groups, such as relatives of patients with AAA, patients with symptomatic occlusive peripheral or cerebral artery disease, and patients with hypertension or those who smoke (11,12). These can be selected by a simple medical questionnaire (13). Even this is justified only if they are good candidates for surgery. In a British study, both the prevalence of existing and incidence of new AAAs rose steadily by age to reach a peak at age 65 after which both fell (14). However, an Australian study found that the prevalence increased from 4.8% in men aged 65-69 years to 10.8% for men aged 80-83 years (5). The prevalence for AAA was 11.9% in those with isolated systolic hypertension and 6.5% for normotensives (15). A recent study showed that current smokers were 7.6 times more likely and ex-smokers 3.0 times more likely to have an AAA than non-smokers (16). Each year of smoking increased the risk of AAA by 4%, and there was a slow decline in the incidence after stopping smoking. Serum cotinine levels were higher in men with a small aneurysm than in those with a large aneurysm suggesting that smoking is an initiating event, and cotinine levels were similar for stable and expanding aneurysms. The Australian study of over 12000 men found a significantly increased prevalence for Mediterranean-born compared to Australian-born men, for smokers, and for patients with associated peripheral or coronary artery disease, and a significantly lower prevalence for those who exercised regularly (5).

Screening might lead to unnecessary harmful psychological effects. However, a study that used a standard questionnaire for anxiety or depression found no significant difference between subjects screened and found not to have AAA, patients with known small aneurysms attending for follow-up scans, those with known AAA on waiting lists for surgery, or controls (17).
3. THE RATE OF AAA EXPANSION

An important finding from screening programs has been the rate at which AAAs enlarge, and this determines how often ultrasonography should be repeated. In the Birmingham report, one-quarter of AAAs did not enlarge at all over a mean 32 month follow-up, one-half enlarged by less than 2.5mm per year and the remaining one-quarter by 2.5-5mm per year, while sudden rapid enlargement was not observed (1). In another study, the mean expansion was 2.2mm/year in non-smokers and 3.0mm/year in smokers (2).

If the first ultrasound screen is negative for AAA, then it is necessary to ask whether it should be limited to once in a lifetime or repeated at intervals. The Birmingham study recommended that it was sufficient to perform ultrasonography at two-yearly intervals for AAAs < 40mm diameter, and at yearly intervals for larger AAAs (1). A study of more than 5000 men aged 50-79 years in the USA assessed the rate at which new AAAs develop (3). Of those with infrarenal aortic diameter <3.0cm on the initial ultrasound, follow-up at 4 years showed that only 2.2% had developed a new AAA and only 5% of these were > 4.0cm diameter. It was concluded that repeat screening at 4 years was of little value but that screening after 8 years would provide yields similar to those for the initial screening.

True growth can be diagnosed only if the measured increase in AAA diameter exceeds inherent variability for accuracy for the ultrasound scanning measurement. The Birmingham study noted that interobserver variability for ultrasound was similar to the upper limits for annual expansion (1). A Dutch study showed that the mean difference between two observers for ultrasound was 0.32mm for the proximal aorta, but that maximum differences between observers were 4.0mm (4). Interobserver variability increased with increasing waist circumference and increasing AAA diameter. A Canadian study showed that there was good interobserver agreement, but that only changes in measured diameter > 8mm indicate AAA growth at the 95% confidence level (5). Accuracy is greater for small aortas than for larger AAAs (6).

Studies in males for expansion rates for iliac artery aneurysms (IAAs) show that IAAs expand at a considerably slower rate than AAAs (7). The only patients to develop symptoms all had IAAs > 4 cm diameter. Mean expansion rates were 11mm/year for IAAs < 3cm diameter, and 26mm/year for IAAs 3-5cm diameter. The study concluded that IAAs < 3.5 cm diameter should be followed with 6-monthly ultrasound, and that surgery should be considered for asymptomatic IAAs > 3.5cm in good-risk patients, and for IAAs > 4 cm in all patients. Co-existent femoral or popliteal aneurysms are present in approximately 15% of males though rarely in females (8).

4. THE EVOLUTION OF TREATMENT FOR AAA

Most surgeons consider that surgical repair in fit patients is justified for AAAs > 50-55mm diameter (1) as shown in Figure 4.1 (2). The higher the operative risk, the larger the AAA needs to be before intervention should be considered (3).
For the past 50 years, standard surgery for AAA has been by open replacement with a Dacron graft, as introduced by Dubost in 1952 (4). This has proven to be durable but the operation is substantial with a potential for significant blood loss, serious metabolic changes, cardiac, respiratory and renal stress, and a more prolonged stay in the intensive care and general wards. A recent American study for open repair showed that the median stay in the intensive care unit was 2 days, and median in-hospital stay was 9 days with in-hospital mean cost of approximately US$26,000 (5).

The alternative now is endoluminal grafting (ELG) introduced by Parodi, Palmaz and Barone (6). ELG with straight, uni-iliac or bifurcated stent-grafts passed up through the femoral arteries and deployed under radiological control is effective. Non-randomized studies show that ELG for AAA is feasible in one-half to two-thirds of patients, with a low mortality and acceptable success rate during the short to intermediate term (7-15). Most surgeons find there is a steep learning curve for the first 50 patients or so (16). However, May and colleagues from Sydney found a similar incidence of adverse events in patients treated early or later in their experience suggesting that there are inherent risks for ELG rather than iatrogenic complications from the learning curve (17). There is far less blood loss, surgical stress and length of hospital stay after ELG than after open repair, although duration of surgery is about the same (18).

However, the respective merits for the two operations remain uncertain. One study calculated quality-adjusted life expectancy rates after open repair and ELG and found no benefit for ELG for men in average health with gradually enlarging AAAs and only minimal benefit for older men in poor health (19). Skeptics contend that although stent-grafts appear to be generally safe, their long-term efficacy is unknown, endovascular AAA repair has neither fewer complications nor lower mortality rates than open repair, and there are new complications particularly “endoleak” and device failure (20). Although it is uncommon, delayed AAA rupture after seemingly successful endovascular repair for AAA has been reported. They warn that these unique faults for ELG require a cautious approach to its clinical application.

Some follow-up studies report considerable anatomical changes in the aneurysms that place severe strains on the stent-grafts (21-23). The Sydney group point out that the ability of ELG to cause AAA shrinkage has the paradoxical risk of distorting the supporting metallic framework to predispose to late failures (24). It appears that reoperation is much more likely after ELG than for open repair (9,25) and this must be included in any analysis of long-term results.
Every vascular team that enters this field should audit their results. Responsible surgeons in several countries have taken auditing a step further by developing voluntary multi-centre registries. An outstanding example is EUROSTAR (European Collaborators on Stent-graft Techniques for Abdominal Aortic Aneurysm Repair) led by Harris and Buth who have collected more than 1500 patients (26-30). Their follow-up has identified that as many as two-thirds of patients develop appreciable anatomical changes in AAAs that predispose to structural breakdown of the prostheses and this has led to major manufacturing modifications. Another important registry is RETA (Registry of Endovascular Treatment of Aneurysms) led by surgeons and radiologists for the Vascular Surgical Society of Great Britain and Ireland which includes over 600 patients from 31 centers (31,32).

Harris and Buth (33) responded to criticism from Rutherford (34) that EUROSTAR had failed to promptly warn surgeons of structural defects in a commercial prosthesis, although manufacturers have been highly responsible in communicating device problems. Noncommercial regulatory bodies have not rushed forward to support the considerable costs of such audits, nor are all surgeons prepared to engage in the onerous task of completing audit forms. A result is that regulatory bodies in some countries are threatening to introduce compulsory auditing to receive payment for treatment.

These major exercises to seek information will unearth many problems with surgical technique and graft design but cannot answer the hypothesis that ELG is as effective as open repair in reducing the risk of death from AAAs (35). Audit alone will not validate the operation. Massive numbers will be required to develop matched patients in the many subgroups that can be defined. By the time such information is collected, major changes in surgical techniques and prosthesis design will make the early results obsolete.

Retrospective studies of ELG compared to historical controls for open surgical repair cannot prove the hypothesis that ELG is as effective as open repair for preventing death either from rupture of the AAA or from the treatment. The potential benefit is diminished trauma to the patient (36), although this becomes irrelevant if the new operation does not work sufficiently well. The potential cost is added expense to already depleted health resources which will likely be accepted if the new operation is effective.

Independent advisors argue that proving the hypothesis requires level I evidence with statistical evaluation from rigorous prospective randomized trials. A prospective randomized trial for ELG versus open repair has commenced in the United Kingdom, led by vascular surgeons who are well aware of the potential pitfalls (RM Greenhalgh, oral communication, December 1999). Their patient net is wide, all vascular surgeons who wish to participate are welcome, and realistic guidelines for patient selection have been based on current accepted indications for open repair. However, many patients will need to be recruited and followed over several years before statistical analysis is able to answer the null hypothesis that ELG is at least as good as open repair. Many vascular surgeons argue that by the time results are known, the new procedure will have changed to such a degree that the early operations in the trial will be archaic and irrelevant. Prospective randomized trials may be far more appropriate for long-established operations such as carotid endarterectomy than for evolving techniques. There has been a tendency for such trials to be restricted to a small group of elite surgeons treating a select fraction of the patient population to provide artificial results that do not apply to the "real world."

5. TECHNIQUES FOR OPEN SURGICAL REPAIR FOR AAA

Techniques for open repair are now very standardized with most surgeons performing an inlay operation suturing a tube or bifurcated graft within the aneurysm sac. There are a few disputed aspects. One relates to the best surgical exposure, particularly by the transperitoneal or retroperitoneal approach. In one American study, there was no difference between the frequency of pulmonary complications or incisional hernias, but significant reduction in cardiac and gastrointestinal complications, longer operative time and blood loss, less requirement for intravenous narcotics or epidural analgesia, and shorter hospital length of stay and hospital charges for the retroperitoneal approach (1).

Another American study found that there was no significant differences in mortality rates, and that
retroperitoneal repair was associated with less frequent respiratory failure but more frequent wound complications, and lower hospital costs (2).

Another factor to consider is the presence of an infrarenal neck allowing clamping below the renal arteries. There have been studies of repair for AAAs involving the suprarenal, visceral, and lower thoracic aortic segments. These juxtrarenal, pararenal or suprarenal aneurysms present a particular challenge. They require suprarenal clamping with the risk of ischemic renal damage and they may require re-implantation or bypass grafting to renal or visceral arteries. An American study showed a 30-day mortality rate of 7% for elective repair and a survival rate of 71% at 3 years and 50% at 5 years (3). An Italian study found similar results with a 7% mortality rate for elective cases, and showed that age > 70 years, and coronary artery disease were the only independent predictors of early mortality (4).

The outcome for AAAs that have ruptured remains poor. A Swiss study found that a haemoglobin < 90g/l, systolic blood pressure < 80 mmHg and ECG signs of ischemia at admission were highly significant risk factors for a fatal outcome and that most deaths were due to multi-organ failure (5). An Italian study recorded a mortality rate of 24% with death due to irreversible haemorrhagic shock, intestinal infarction, acute renal failure, myocardial infarction, respiratory insufficiency or multiorgan failure (6).

6. TECHNIQUES FOR ENDOLUMINAL GRAFTING FOR AAA

Stent-grafts are of two types (1). The first is based on the concept that they should mimic standard surgical grafts with a unibody system as a tube or with two limbs. The second uses stent-grafts constructed within the AAA from modular components. Most surgeons now favour a prosthesis that is self-expanding with good radial force and longitudinal rigidity. This is most often placed as a bifurcation graft. The optimal design for the metal stent framework and its relation to the graft fabric is not known. It will be several years before it is clear as to how much metal corrosion or fatigue with late fracture occurs although this is already being seen in the early grafts. Nor is it known whether the relatively thin graft material used for the stents is strong enough to withstand deformation from prolonged beating with the pulse. Many grafts used have a metal framework of nitinol and we have reviewed the characteristics of this material (2).

The first generation stent-grafts included Parodi’s original graft (3), many home made devices and the pioneering Mintec Stentor graft introduced by Miahle (4). Several companies have developed second generation grafts listed in Table 6.1 and their websites provide varying information about the individual stent-grafts. May and colleagues from Sydney have compared results for early and more recent stent-grafts and have shown better patient survival and probability of graft success with second-generation prostheses (5). Third generation improvements are eagerly awaited as there are still many design faults recognised with growing experience. The challenge is to progressively improve both their design and surgical techniques to cope with the many difficult anatomical deviations that occur from patient to patient. Preliminary results have been identified for the Vanguard (6-9), Talent (10-14), EVT/Ancure (14-17), AneuRx (18-20), Zenith (21) and Endologix (22) grafts.
The following discussion will describe some of the manoeuvres that we have used to allow ELG in these patients in the past and present practice with third generation stent-grafts (23). Our early experience was with the MinTec Stentor graft (29 patients), Boston Scientific Vanguard graft (22 patients), World Medical Talent graft (23 patients), and then with the Medtronic AneuRx graft (36 patients), but our preference now is to exclusively use the Cook Zenith graft (77 patients).

There were 18 straight grafts, 9 aorto-uni-iliac grafts with a femoro-femoral bypass, and 5 extension grafts, a modular bifurcated graft being used in the remaining 155 patients.

Table 6.1. Some commercial endoluminal grafts and their manufacturers.

<table>
<thead>
<tr>
<th>Graft</th>
<th>Manufacturer</th>
<th>Address</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vanguard</td>
<td>Boston Scientific</td>
<td>Natick, MA, USA</td>
<td><a href="http://www.bsci.com">www.bsci.com</a></td>
</tr>
<tr>
<td>Talent</td>
<td>World Medical (Medtronic)</td>
<td>Sunrise, Fl, USA</td>
<td><a href="http://www.medtronic.com">www.medtronic.com</a></td>
</tr>
<tr>
<td>AneuRx</td>
<td>Medtronic</td>
<td>Sunnyvale, Calif, USA</td>
<td><a href="http://www.medtronic.com">www.medtronic.com</a></td>
</tr>
<tr>
<td>EVT/Ancure</td>
<td>Endovascular Technologies/Guidant</td>
<td>Menlo Park, Calif, USA</td>
<td><a href="http://www.guidant.com">www.guidant.com</a></td>
</tr>
<tr>
<td>Zenith</td>
<td>Cook Vascular Inc</td>
<td>Leechburg, PA, USA</td>
<td><a href="http://www.cookgroup.com">www.cookgroup.com</a></td>
</tr>
<tr>
<td>Lifepath</td>
<td>Edwards Lifesciences</td>
<td>Irvine, Calif, USA</td>
<td><a href="http://www.edwards.com">www.edwards.com</a></td>
</tr>
<tr>
<td>Endologix</td>
<td>CR Bard Inc</td>
<td>Murray Hill, NJ, USA</td>
<td><a href="http://www.bard.com">www.bard.com</a></td>
</tr>
<tr>
<td>Excluder</td>
<td>WL Gore</td>
<td>Newark, Delaware, USA</td>
<td><a href="http://www.gore.com">www.gore.com</a></td>
</tr>
<tr>
<td>Anaconda</td>
<td>Sulzer Vasutek</td>
<td>Renfrewshire, Scotland, UK</td>
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Acces for the sheaths for Stent-Grafts

An attempt has been made to insert all grafts through the common femoral arteries. Occasionally, it was predicted that the device would not pass up the external iliac artery because it was too small or tortuous, and it was then necessary to anastomose a short length of a wide-diameter Dacron graft to the common iliac artery through an extraperitoneal exposure to allow access. At the end of the procedures, the graft can be brought down as an iliofemoral bypass. It is current practice to expose both common femoral arteries to place a bifurcation graft but others are starting to achieve a bilateral percutaneous approach for both sides with preliminary placement of percutaneous closure devices. A long outer sheath directed over a super-stiff Lunderqvist (Cook) guide wire is now used to facilitate exchange for the graft. Several techniques were used in the past to gain access through a graft sutured to the artery or by arteriotomy, but current grafts are now introduced by arterial puncture (Figure 6.1).
It is necessary to place a wire into the open limb of the main stem to lock in the contralateral limb. This can usually be quickly achieved by passing the wire up with a guiding catheter from the contralateral side. Occasionally, it was necessary to either pass the wire over the bifurcation from the ipsilateral side into the sheath or to thread the wire down from the arm. The various companies manufacture the main stem in different lengths. The longer the main stem, the easier it is to pass the wire if the iliac arteries are straight but the more difficult it can be if the iliac arteries are angulated (Figure 6.2).
Tracking through the iliac arteries

Early devices were prone to cause trauma to the femoral and external iliac arteries, particularly from repeated exchange of the device. Both access and tracking was sometimes difficult or impossible if the external iliac arteries were too small or tortuous and this lead to danger of external iliac artery rupture or occlusion. The challenge to all companies has been to provide a sheath that is sufficiently narrow to allow easy passage thorough the iliac system yet strong enough to prevent kinking at points of angulation and flexible enough to track around curves. Newer sheaths with a long tapered tip to the dilator allow progressive dilatation and straightening making passage relatively safe and easy. Iliac tortuosity is not a contraindication to endoluminal grafting, for most iliac arteries can be straightened out, but the patient should be rejected if the tortuous artery is also heavily calcified indicating inability to straighten.

There are several techniques to improve access (Figure 6.3). The super-stiff guide wire by itself will partly straighten out a tortuous iliac artery. In difficult cases in the past, the iliac artery was further straightened by pulling on a wire passed from a left brachial sheath through the length of the descending aorta and iliac artery and out through the femoral sheath, but this is now rarely required.
Achieving a proximal seal

Several grafts have bare wire extending beyond the upper extent of the synthetic cover and it is now known that this bare wire can be placed across renal arteries without restricting renal blood flow. Accordingly, it is possible to place the Dacron right up to the renal arteries so as to require a very short length of neck. In practice, at least 1cm of neck is required between the lowest renal artery and the aneurysm for current grafts.

If there is angulation of the neck, then there is a risk that the graft will be poorly applied to the aortic wall on the convex side of the curve resulting in an endoleak (Figure 6.4). However, proximal angulation should not be a contraindication to endoluminal grafting. A marker board with a rotation screw to vary the marker position placed behind the patient helps to ensure that the graft is deployed immediately below the renal arteries. The screen is coned down to show the precise centre and the marker is placed in this position so as to avoid any parallax error. A straight multi-sidehole catheter is passed from the contralateral side to show the renal arteries by angiography. The image intensifier is moved until angiography shows that the renal arteries are in the centre of the screen at the level of the marker. Angiography is repeated immediately prior to deployment to ensure that the graft is at exactly the correct level. If a preoperative lateral DSA has shown that there is anterior angulation then this manoeuvre is performed with the image intensifier tilted at an appropriate angle so as to avoid positioning the graft too low (Figure 6.5). The ideal system provides extensions that can be placed at the time of operation if deployment is inadvertently too low so as to ensure that the upper end is well seated in the neck immediately distal to the renal arteries.
Achieving a distal seal

The length of the main limb is calculated before operation to extend down to a segment of iliac artery that allows a distal seal, preferably above the internal iliac artery, at least on one side. It may be necessary to deliberately extend to below an internal iliac artery but this can cause severe buttock claudication. An aorto-uni-iliac graft can be placed with a femoro-iliac crossover graft to preserve the contralateral internal iliac artery, but this technique is rarely required now.

Extension of a common iliac aneurysm to the internal iliac artery on one or even both sides is not a contraindication to ELG. If the internal iliac is to be covered, then it is necessary to occlude it by coil embolization to prevent reflux into the AAA. Newer grafts are flared at the distal ends to seal wide common iliac arteries above the internal iliacs.

New techniques to allow for a short or absent proximal neck

Techniques are evolving that allow the graft to be placed well above the renal and visceral arteries if
required, to achieve a firm seal to avoid an endoleak. Two groups from Australia have developed grafts with fenestration at the upper end at sites of renal or visceral arteries to allow stent-grafts to be placed above these vessels to secure an aortic seal if there is a very short neck (24-26). Fenestrations were cut into custom-made or commercially manufactured Zenith stent-grafts to preserve side-branch perfusion and guiding catheters were used to place Palmaz stents to overlap each fenestration and vessel orifice to secure the junction (Figure 6.6).

Recently, branched stent-grafts have been developed in Japan and the USA for AAAs that extend above the renal and visceral arteries, greatly extending the potential scope for the technique (27,28). Inoue and colleagues have developed multiple-branched stent grafts that can be delivered through a 22-24F sheath.
Chuter and colleagues have described clinical application of a stent-graft system that preserves side branch perfusion (28). A modular endograft system includes three components that are delivered sequentially through surgically exposed femoral and right brachial arteries. The primary stent-graft is custom-made from conventional graft fabric and Gianturco Z-stents and the distal extensions are made from modified Zenith grafts (Figure 6.7).

![Figure 6.7. A technique using graft extensions to place an ELG above renal and visceral arteries.

a) Steps in the deployment of the visceral extensions. A-catheterization of the coeliac stump, B-catheterization of the coeliac artery, C-insertion of a long, angle-tipped guiding catheter, D-insertion of an extension delivery system, E-deployment of the coeliac extension, F-deployment of the superior mesenteric extension.

b) Steps in the deployment of the distal extension. A-a view of the infrarenal aorta and common iliac arteries, B-deployment of the main body of the distal extension, C-deployment of the iliac components of the distal extension.

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7. PREOPERATIVE MEASUREMENT OF AAAs FOR ELG

We favour the following protocol to measure an AAA to assess whether it is suitable for ELG and to order a graft with suitable proportions if it is decided to proceed. Duplex ultrasound scanning will frequently have been performed to detect the AAA and a high-quality ultrasound scan is also arranged to measure the diameter of the iliac arteries and detect any stenotic or occlusive disease. A standard contrast-enhanced computed tomographic scan (CTA) with very fine slices at each end (2-3mm) is performed. Electronic calipers measure the dimensions of the neck (suprarenal diameter, length of the neck, diameter of the infrarenal neck just below the lowest renal artery and just above the AAA), diameter of the AAA, and diameters of the common iliac arteries. The CT scan also displays whether there is thrombus, calcification or atheroma in the neck. Three-dimensional reconstruction is very useful to measure angulation in the lateral and anteroposterior planes of the neck at the junction of the suprarenal and infrarenal segments and junction of the infrarenal segment with the AAA, as well as tortuosity of the iliac arteries.

If the CTA shows that the anatomy is suitable, then digital subtraction angiography (DSA) is arranged with a marker pigtail catheter. After a preliminary run to determine the level of the visceral arteries, the infusion holes of the catheter are drawn down to be level with the renal arteries to give best definition of the neck. Films of the neck and AAA are obtained in the anteroposterior projection and with 200 oblique projections to best show each renal artery and a lateral projection to show the visceral arteries. The marker catheter is then used to show the length of the neck and length from the lowest renal artery to AAA bifurcation. The catheter is drawn down to cover the low AAA and iliac arteries and anteroposterior
and 300 obliques are used for further runs. The length from the AAA bifurcation to the ipsilateral internal iliac artery is measured and an extrapolation is made for the length of the contralateral common iliac artery. Calculations are made for each diameter as for the CT scan as well as for iliac artery diameters. Angles at the neck and angles and tortuosity for each iliac artery system are determined. If renal function permits, further films are obtained to demonstrate each femoropopliteal runoff segment.

Beebe and colleagues have promoted spiral CTA with 3-dimensional reconstruction without preoperative DSA to evaluate the aortoiliac segment for ELG (1). A French study considered that helical CTA is highly accurate for measurements of AAAs (2). Hopkinson and colleagues from Nottingham found a good agreement between CTA and DSA for measuring aortoiliac length, with 69% of aortic and 76% of iliac measurements within 1 cm and > 90% within 2 cm of each other (3). However, DSA overestimated renal artery to aortic bifurcation length in patients with large-diameter aneurysms and wide aneurysm lumens. They consider that CTA is sufficiently accurate in most cases to be used as the sole basis for constructing ELGs. A Swedish study found that AAA neck diameter was consistently smaller on DSA than on CTA (mean 20.7 mm versus 23.0 mm), and that the length from the most distal renal artery to the aortic bifurcation was greater from DSA than from CTA (mean difference 10.0 mm) (4). A Belgian study found that observer variability for CT measurements of the aorta and iliac arteries for patients with AAAs regularly exceeded 2 mm in spite of using a workstation and electronic calipers (5). Additional functional information about renal perfusion can be obtained from the initial timing scan of a CT study (6). An American group found that DSA cost over 3 times more than CTA for preoperative imaging for AAA (7).

Gadolinium-enhanced magnetic resonance angiography (MRA) is accurate when compared to DSA or CTA (8). The Nottingham group consider that contrast-enhanced MRA can be effective as the sole imaging modality to assess patients prior to ELG (9). Gadolinium-enhanced MRI readily demonstrates features of inflammatory AAAs, and it may be preferable to CTA in view of potential renal impairment in these patients (10). Intravascular ultrasound provides accurate and reproducible measurements of AAAs (11).

8. SELECTION FOR TREATMENT FOR AAAs

There is uncertainty as to the indications for operation for AAAs by any method. There is even less agreement as to the relative indications for open repair and ELG. In addition, laparoscopic repair for AAAs is being explored (1,2). Because ELG for AAAs is less invasive, some surgeons have suggested that this should broaden the indications for elective intervention. However, the prognosis for healthy patients who undergo elective AAA repair by open surgery is good (3). Mohan and Harris suggest that contraindications to open repair are few but include small aneurysms (< 5.5 cm), a co-morbidity that increases surgical risk by > 10% and a life expectancy of < one year (4). Much the same could be said about ELG.

Factors that influence the decision to consider ELG are AAA diameter, physician and patient preference, general health of the patient, and anatomical criteria that allow for ELG to be considered. The influence of AAA diameter and other aneurysm characteristics have been discussed.

Physician and patient preference

There are important unanswered philosophical questions. Should ELG be reserved for poor-risk patients who might not tolerate open surgery? Would liberal expansion of the indications to all suitable candidates bring about more effective and cheaper treatment? Is the best time to treat an AAA when it is small and thus simple and safe to control? ELG may be seen to be an easy option to arrest expansion long before an AAA poses a threat. This in turn would intensify a push for early detection by ultrasound screening. It remains to be seen whether this would be cost-effective.

General health of the patient

The most usual criteria for assessing fitness is the American Society for Anesthesiology (ASA) classification. The Nottingham group defined "high-risk patients" as having at least one of the following features - serum creatinine > 150 micromol/l, ischemic heart disease or poor left ventricular function, respiratory function < 50% of predicted normal, ruptured or symptomatic AAA, contraindication to or
failed open repair, and age > 80 years (5). Health systems in some countries restrict ELG to poor-risk patients to restrain costs. Initially, we restricted ELG to poor-risk patients with aneurysms > 50mm diameter, but we now consider fit patients who prefer this procedure. Endovascular repair for ruptured AAAs is feasible (6).

**Anatomical requirements for ELG**

Not all aneurysms are suitable for ELG as the graft must be able to form a good seal against relatively normal artery at each end. Several anatomic constraints are common for each graft (7). Ideally, the AAA should commence well below the level of the renal arteries providing a long, straight and relatively narrow aortic neck to allow a good proximal seal. There should be minimal dilatation of the common iliac arteries, tapering down to a relatively small diameter to allow a good distal seal above the internal iliac arteries. Finally, there should be good access through a wide and relatively straight external iliac artery on each side. These may be found in patients with relatively small aneurysms, but it is uncommon to have all or indeed any of these favorable anatomical configurations for patients with larger aneurysms.

The first generation grafts had a rather narrow application due to anatomical constraints. American surgeons found that the first-generation EVT system was unsuitable for a tube graft in 90% and for a bifurcated device in 85% due to an unsuitable proximal neck in 48%, and unsuitable iliac arteries in 41% (8). Another American report for the early EVT graft found that many patients were rejected due to insufficient proximal neck (21%), proximal neck too large (17%), calcification, kink, or extensive thrombus in the proximal neck preventing safe graft attachment (5%), distal common iliac aneurysm or insufficient distal iliac neck (21%), iliac stenosis (28%), and patient preference (8%) (9).

Subsequent second generation grafts could be more widely applied. The Nottingham group found that commercially available devices could be used in about one-half of potential candidates (10). An American group also found that about one-half were potentially eligible for ELG with the AneuRx device, the most common cause for rejection being an inadequate proximal neck (11). Over 3 years, the eligibility rate increased from 45% during the first 18 months to 63% during the second 18 months. Potential candidates were younger, and their aneurysm diameter tended to be smaller. A study of the Ancure and Talent systems examined gender-related anatomic variables and found that 63% of women were rejected versus only 33% of men (12). Maximum AAA diameter and iliac artery tortuosity were similar in both but proximal neck length was shorter, proximal neck width was wider, proximal neck angulation was greater, and the external iliac artery was smaller in women than in men.

We studied 158 potential candidates for ELG with the earlier Vanguard and Talent grafts and the numbers suitable for ELG and the anatomical reasons for rejection are shown in Table 8.1-8.2-8.3. The numbers suitable for ELG would now be higher with the introduction of third generation grafts, and ELG may become suitable for all patients if recent developments for stent-grafts with branches that allow extension above and below critical arteries are shown to be effective.

<table>
<thead>
<tr>
<th>AAA Diameter</th>
<th>&lt; 50mm</th>
<th>50-60mm</th>
<th>&gt; 60mm</th>
<th>All AAAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck too wide</td>
<td>8%</td>
<td>11%</td>
<td>28%</td>
<td>13%</td>
</tr>
<tr>
<td>Neck too short</td>
<td>12%</td>
<td>11%</td>
<td>28%</td>
<td>14%</td>
</tr>
<tr>
<td>Iliacs too wide</td>
<td>22%</td>
<td>31%</td>
<td>44%</td>
<td>26%</td>
</tr>
<tr>
<td>Iliac stenoses</td>
<td>4%</td>
<td>7%</td>
<td>0%</td>
<td>6%</td>
</tr>
<tr>
<td>Any reason</td>
<td>22%</td>
<td>42%</td>
<td>60%</td>
<td>38%</td>
</tr>
</tbody>
</table>
ELG can be safely performed for patients with anomalous renal vessels when the main renal vascular anatomy can be preserved and when the loss of only small branches (< 3 mm) occurs in patients with otherwise normal renal function (13). ELG is the technique of choice for many patients with a horseshoe kidney (14). The inflammatory aneurysm is well suited to endoluminal repair (15).

9. COMPLICATIONS AND RESULTS AFTER OPEN SURGICAL REPAIR FOR AAA

The postoperative mortality rate for elective open repair in most series is approximately 5% (1), and although this is far lower in selected fit young patients, it can be disturbingly high in older poor-risk patients. A recent Dutch study found that in-hospital mortality after elective surgery for infrarenal AAA was 4.1%, more than half resulting from cardiac failure (2). They found that 26% experienced some systemic complication, the most frequent being cardiac and pulmonary (10% each). Another analysis for mortality after elective open repair showed that age, AAA diameter, postoperative myocardial infarction, operation time and volume of intraoperative blood loss, and respiratory complications or gastrointestinal bleeding were determining factors (3). A German study presented 10 year follow up for 521 patients operated on elective open repair for AAA between 1978 and 1987 (4). The in-hospital mortality rate was 6.4%, and the cumulative survival rate was 65% at 5 years and 41% at 10 years, the mean survival time being 95 months. Age, coronary artery disease and hypertension were adverse factors for survival.

Inhibition of systemic fibrinolysis and intense thrombin generation contribute to microvascular and macrovascular thrombosis and these predispose to myocardial infarction, multiple organ failure, and thromboembolism and account for much of the morbidity and mortality for open repair (5). Thrombogenicity and platelet deposition may be most active in the aneurysm sac (6,7).

<table>
<thead>
<tr>
<th>AAA Diameter</th>
<th>&lt;50 mm</th>
<th>50-60 mm</th>
<th>&gt;60 mm</th>
<th>All AAAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not suitable</td>
<td>16%</td>
<td>18%</td>
<td>44%</td>
<td>22%</td>
</tr>
<tr>
<td>Femoral approach</td>
<td>72%</td>
<td>75%</td>
<td>56%</td>
<td>71%</td>
</tr>
<tr>
<td>Iliac approach</td>
<td>12%</td>
<td>7%</td>
<td>0%</td>
<td>8%</td>
</tr>
<tr>
<td>Not known</td>
<td>22%</td>
<td>8%</td>
<td>0%</td>
<td>8%</td>
</tr>
<tr>
<td>All suitable</td>
<td>64%</td>
<td>82%</td>
<td>56%</td>
<td>79%</td>
</tr>
</tbody>
</table>

Table 8.2. Suitability according to the approach to place the sheath for 158 patients assessed in our unit for Vanguard or Talent ELGs.

<table>
<thead>
<tr>
<th>AAA Diameter</th>
<th>&lt;50 mm</th>
<th>50-60 mm</th>
<th>&gt;60 mm</th>
<th>All AAAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bifurcated</td>
<td>64%</td>
<td>60%</td>
<td>40%</td>
<td>58%</td>
</tr>
<tr>
<td>Straight</td>
<td>14%</td>
<td>11%</td>
<td>0%</td>
<td>10%</td>
</tr>
<tr>
<td>Uni-iliac</td>
<td>6%</td>
<td>11%</td>
<td>16%</td>
<td>10%</td>
</tr>
<tr>
<td>Any graft</td>
<td>64%</td>
<td>82%</td>
<td>56%</td>
<td>78%</td>
</tr>
</tbody>
</table>

Table 8.3. Suitability according to the type of graft used for 158 patients assessed in our unit for Vanguard or Talent ELGs.
Open surgery for juxta- or pararenal aortic aneurysms provide particular technical problems and risk to the patient compared to those for infrarenal aneurysms. In one study there was a higher risk of early mortality (12% v 3.5%) and reduced long-term survival (40% at 5 years) (8). The reported mortality for ruptured abdominal aortic aneurysms (RAAA) remains very high varying from 15% to 50%, commonly due to irreversible haemorrhagic shock, intestinal infarction, acute renal failure, myocardial infarction, respiratory insufficiency or multiorgan failure (9).

Preoperative cardiac screening, for example with thallium scanning and/or coronary angiography, can reduce perioperative risk and improve long-term outcome. In a recent study, 33% of patients with no cardiac history and a normal ECG were found to have significant coronary artery disease and 20% required initial cardiac intervention followed by expedient aneurysm repair with zero mortality (10).

10. COMPLICATIONS AFTER ELG FOR AAA

**Endoleaks**

These are classified in Table 10.1 (1-3). The Nottingham group studied the risk of proximal type I endoleak or graft migration in relation to aortic neck morphology (4). Neck diameter and angulation were greater for both complications, but conical shape, thrombus, atheroma lining or calcification in the neck not influence the risk for either. For the early EVT grafts, endoleaks were frequent (38%) but most closed spontaneously (5). In vitro studies with IVUS and CT show that the stent at the upper end follows aortic wall movement through the cardiac cycle to differing degrees, and that oversizing the stent in relation to neck diameter can lead to graft folding with a potential for poor apposition during systole predisposing to endoleaks (6).

<table>
<thead>
<tr>
<th>Endoleak Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type I</td>
<td>Endoleak related to the graft device itself.</td>
</tr>
<tr>
<td>Type II</td>
<td>Endoleak due to retrograde flow from collateral branches</td>
</tr>
<tr>
<td>Type III</td>
<td>Endoleak due to fabric tears, graft disconnection, or disintegration.</td>
</tr>
<tr>
<td>Type IV</td>
<td>Flow through the graft presumed to be associated with graft wall &quot;porosity&quot;</td>
</tr>
<tr>
<td>Endotension</td>
<td>Persistent or recurrent pressurisation of the sac with no evidence of endoleak.</td>
</tr>
</tbody>
</table>

Table 10.1 Definitions of endoleak and endotension (1-3)

Many endoleaks close spontaneously. Endovascular treatment for primary or secondary endoleaks is usually possible by placing graft extensions or bare stents, and this is usually safer than conversion to an open procedure (7). Coiling to produce a radiographic seal can be achieved in all persistent cases, but whether this method is effective in the long term remains to be seen (8).

The Nottingham group described a method to prevent lumbar artery type II endoleaks (9). An aneurysmogram performed prior to deploying the iliac occluder detects patent aortic side branches. If
these are found, an absorbable gelatin sponge is inserted into the aneurysm sac via the sheath. No side branch endoleaks were detected over a median 4 month follow-up. Type II endoleaks shown to be due to retrograde flow in the inferior mesenteric artery by selective arteriography with a catheter in the superior mesenteric artery can be controlled by coil embolization after advancing the catheter through to the left colic artery (10). Similar techniques have been described to occlude the inferior mesenteric by advancing a catheter from the internal iliac to the left colic artery (11).

**Aneurysm shrinkage causing graft distortion**

Several studies have shown that AAAs shrink after complete endovascular exclusion. Measured changes in the aortic neck diameter, AAA diameter and aortic length show patterns that may affect the durability of endovascular repair and potential strategies for future graft design (12). The Stanford group measured maximum AAA diameter after ELG by CTA and found that the mean absolute decrease in diameter was > 3mm at 6 months and > 5.5mm at 12 months for patients without endoleaks (13). The Sydney group measured endograft length after implantation and found graft shortening > 15mm in approximately one-half using Vanguard or AneuRx ELGs (14). A Dutch study came to a different conclusion using the EVT graft, which is a vertically non-rigid prosthesis that should potentially accommodate longitudinal changes (15). At 6 months follow-up, there was a decrease in AAA volume in two-thirds of patients, but changes in length were within the measurement error range of 4 mm in most, and they concluded that aortic shortening is not a clinically significant problem. However, a German group reported surveillance after ELG by DSA and CTA in 291 patients and documented distortions considered to be mild (31%), significant (angulations reaching 60-90º - 22%), or severe (angulations ≥ 90º - 3%) (16). They concluded that the durability of stent-grafts cannot be evaluated with less than 3 years follow-up.

**Aneurysm dilatation and graft migration**

Long-term changes in the infrarenal neck diameter after open surgery show that the annual growth rate is approximately 0.5 mm, and this raises concern regarding long-term success after endovascular repair (17). For straight EVT grafts, neck diameters at both graft attachment sites measured by CT scans showed dilatation by 0.7-0.9mm/year for the proximal aortic neck and 1.7-1.9mm/yr for the distal end (18). Expansion rates did not relate to initial neck size, stent-graft dimensions, AAA size change, endoleak, or attachment system fracture. The Sydney group confirmed the poor mid-term outcome for tube prostheses due to distal aortic dilatation (19). A Dutch study for the EVT stent-graft found a median increase in proximal neck diameter by 10% at 6 months and 15% at 12 months (20). There was no correlation between the amount of dilatation and pre- or postoperative neck-size, graft diameter or amount of graft-oversizing. A Swedish study using CT found a mean 1.65mm increase in the infrarenal AAA neck diameter, but only 0.52mm increase in diameter at the level of the superior mesenteric artery after 2 years (21). There was no correlation between diameter change and preimplantation infrarenal neck diameter.

A study of distal migration after ELG showed migration (distal movement > 5 mm) in 45% during a mean 13 month follow-up due to proximal AAA neck dilatation or poor patient selection (22). These were treated by additional stent-grafts as proximal extensions or late conversion to open repair.

**Conversion to open surgery**

Conversion from endovascular to open repair may be required and reasons that have been reported are shown in Table 10.2 (23-25). The EUROSTAR collaborators studied factors that increased the risk for conversion (23). Patients who were converted were significantly older, and had a lower body weight, and higher prevalence of chronic obstructive pulmonary disease. Conversion was more likely with shorter, wider infrarenal necks and larger aneurysms. Conversion was less likely for teams that had performed more than 30 procedures, and in procedures performed during the last two years of the study period. Patients who required primary conversion had an 18% mortality rate compared to 2.5% mortality for patients without conversion.
Haematological and biochemical changes

Barras studied patients in our unit for several parameters and showed that most biochemical and hematological parameters were far less disturbed by ELG compared to open repair. (26). A Norwegian group measured leukocytes, platelets, myeloperoxidase, lactoferrin, beta-thromboglobulin, C-reactive protein, interleukin-6, tumor necrosis factor alpha and complement activation products before, during and after ELG or open surgery (27). Leukocyte and platelet activation occurred with both, perhaps due to radiographic contrast media for ELG and declamping after open repair, while the other products showed little change. A Japanese study measured the white blood cell count, granulocyte elastase, interleukin-6 and -8, and serum C-reactive protein as markers for biological responses, and found that all were higher after ELG than after open repair, levels peaking on the third postoperative day (28). The Nottingham group found that plasma endotoxin, tumor necrosis factor alpha (TNF-alpha), and interleukin 6 (IL-6) levels were lower after ELG compared to open repair, and they provided some evidence to suggest that this may be due to sigmoid colon ischaemia (29). There are similar responses in circulating monocytes and HLA-DR expression on lymphocytes after endovascular and open repair of AAA, and there is pronounced downregulation of monocyte HLA-DR expression in patients with severe postoperative complications after either treatment (30).

Local complications

For most devices, proximal stent-graft fixation is improved by placing an uncovered part of the proximal stent above one or both renal artery orifices, and experimental and clinical data suggest that this does not lead to impaired renal function (31). Femoral artery access complications, risk of distal femoral artery occlusion and immediate graft limb occlusion are all highly dependent on the graft used and are becoming far less common with new systems that do not require arteriotomy. Rectum and sigmoid colon necrosis with fatal outcome due to cholesterol embolization after implantation of a stent-graft for an infrarenal AAA has been reported (32).

Systemic complications

Impaired renal function can be a problem with ELG. In one study, approximately 6% of patients with normal preoperative renal function developed renal dysfunction after ELG, independent of the median dose of intravascular contrast used (33). The perioperative mortality rate was 27% for patients with preoperative renal impairment. ELG under local anesthesia can be performed safely in patients with significant comorbidities, potential advantages including decreased cardiopulmonary morbidity, shorter stay in hospital, and lower hospital costs (34).

11. RESULTS AFTER ELG FOR AAA
Good initial results can be achieved with stent-grafts and the less invasive nature of the technique makes it most attractive. However, there are various perioperative and late complications.

May and colleagues from Australia probably have the largest reported single unit experience (1). For 243 patients with AAA who underwent primary ELG, grafts were successfully deployed in over 90% and the perioperative mortality rate was 3.3%. In a separate publication, they compared elective open repair in 195 patients and endoluminal repair in 108 patients with no significant difference for perioperative mortality or late survival (2). Success for ELG was defined as continuing graft function without endoleak or conversion to open repair and there was a 3-year graft success probability of 70%. The same group reported life-table analysis for 266 patients treated by ELG for AAA between May 1992 and December 1998 (3). Primary success was defined as exclusion of the aneurysm from the circulation from the original operation. Assisted success occurred when aneurysms with endoleaks became excluded from the circulation as a result of supplementary endovascular intervention.

Hopkinson and colleagues from Nottingham found from their extensive experience with ELG in over 200 patients that the overall perioperative mortality for ELG was 3.7% in "acceptable-risk patients" and 11.3% in "high-risk patients" (4,5).

The most common causes of perioperative death were multisystem organ failure and myocardial infarction. They encountered intraoperative technical problems in 40% including endoleaks, graft stenosis, failure of graft deployment, graft thromboses, aortoiliac ruptures, renal artery occlusions, and internal iliac occlusions, so that conversion to open repair was required in 19%

The early success rate and risk factors for adverse events were reported for the EUROSTAR audit of 1554 patients with AAAs treated between 1994 and 1999 (6). Thirty-day mortality was 2.6% and mortality was related to the ASA classification, year of operation and need for adjuvant procedures. There were systemic complications in the first 30 days in 18% and this was higher for age > 75 years, impaired cardiac status, and for patients considered unfit for an open procedure. Intraoperative complications were failure to complete the procedure (2.5% of which two-thirds underwent conversion to an open repair), device-related or procedure-related complications (10%), and arterial complications (3%). Important risk factors for failure to complete the procedure were AAA diameter > 60mm and a need for adjuvant procedures. Factors that predicted device-related and arterial complications were the team experience and need for adjuvant procedures. An endoleak was detected at completion in 16% and was still present after one month in 9%, and risk factors for primary endoleaks were female gender and age >75 years.

For the AneuRx graft, a prospective nonrandomized multicentre trial that compared ELG with open repair showed no significant difference in operative mortality rates between the groups (7). Patients treated by ELG had significantly less blood loss, time to extubation, and days in the intensive care unit and in hospital, with an earlier return to function.

Primary technical success at discharge for patients with ELG was 77%, largely due to a 21% endoleak rate that had decreased to 9% by one month. A European study for 104 patients treated with the AneuRx graft reported two conversions, a mean operating time of 148 min and mean blood loss of 605 ml, and few complications except for four endoleaks persisting at 12 months (8).

The more recent Ancure endografting system has now been used in over 870 patients to late 1999 (9). The device was deployed successfully in over 90%, mortality rates were similar to those for open surgery but serious morbidity was reduced. Long-term follow-up of the bifurcated group showed only one migration and no ruptures, and aneurysm size was reduced in over 50% at one year and 68% at two years. Type I endoleaks were noted in only 2.7% at 1 year and 1.3% at 2 years.

The most recent multi-centre review of the Zenith graft used in 528 patients with a 2-year follow-up found successful graft implantation in all but four, an overall endoleak rate of 15% of which 4% were
treated urgently for attachment site faults, 8 endograft migrations with an early version of the system, three late conversions and two ruptures (10).

We have performed endoluminal repair for AAAs in 187 patients over a six-year period from December 1994 to March 2001. Throughout this time, our policy has been to consider a patient for intervention only if the aneurysm was 5cm or more in diameter. An exception was made in three patients with smaller saccular aneurysms, two atherosclerotic and one post-traumatic where it was considered that the risk of rupture was high. Initially, it was our policy to limit endoluminal grafting to patients with serious co-morbidity, most often from severe coronary artery disease, chronic obstructive airways disease or chronic renal failure. We now accept any patient for ELG who elects to prefer the procedure after full discussion of the known benefits, late complications and unknown outcome. Endoluminal grafting is also preferred to open surgery if there is a "hostile abdomen". It is necessary to have an anatomical configuration suitable for endoluminal grafting. The initial results are shown in Table 11.1 and the long-term life-table analysis for success (continuing patency without endoleak or occlusion) for first operations on an intention-to-treat basis in 172 patients are shown in Figure 11.1. There is a highly significant improvement in outcome for the first half of the patients treated compared to the more recent second group.

<table>
<thead>
<tr>
<th>Graft type (number)</th>
<th>Stentor (29)</th>
<th>Vanguard (19)</th>
<th>Talent (23)</th>
<th>AneuFix (36)</th>
<th>Zenith (77)</th>
<th>All (187)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-day mortality</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Failure to deploy</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Arterial rupture</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Arterial occlusion</td>
<td>1</td>
<td>6</td>
<td>4</td>
<td>11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endoleak</td>
<td>8</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td>Graft separation</td>
<td>2</td>
<td>2</td>
<td></td>
<td></td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Graft stenosis</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Conversion</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>8</td>
<td></td>
</tr>
</tbody>
</table>

Table 11.1. Perioperative complications in our unit with various commercial stent-grafts used for ELG for AAA.
12. SURVEILLANCE AFTER ELG FOR AAA

An American group has described an algorithm to diagnose persistent primary endoleaks (1). A spiral CT scan is performed in all patients prior to discharge. If the initial CT shows no endoleak, colour-flow duplex scanning is performed at 1 month, with repeat CT scans at 6 months and 1 year. If the initial CT reveals an endoleak, a repeat CT scan is performed at 2 weeks, 1 month, and 3 months, or until the endoleak resolves. If an endoleak persists beyond 3 months, angiography is performed to localize the source.

A blinded study showed that the sensitivities and specificities for detecting a type I endoleak were 63% and 77% for conventional DSA and 92% and 90% for CTA, showing that the latter is more accurate (2). Another study compared the accuracy of ultrasound scanning compared to CT scans to diagnose endoleaks (3). Ultrasound showed satisfactory B-mode images in 93%, satisfactory colour-Doppler scan images in 76%, colour-Doppler scan assessment of the entire AAA sac in 55%, spectral Doppler scan waveform confirmation of suspected endoleaks in 27%, and all four criteria in 19%.

However, the sensitivity, specificity, positive and negative predictive values and accuracy for ultrasound compared to CT using any criteria were 97%, 74%, 66%, 98% and 82% respectively, and the excellent sensitivity and negative predictive value were considered to make ultrasound assessment reliable for surveillance. An Australian study concluded that CT did not provide any additional information than that obtained from the duplex scan for endoleaks (4). A French study found that duplex ultrasound scanning had a sensitivity of 96% and specificity of 94% when compared to CT but that it was a poor method for determining changes in AAA diameter (5).

13. COMPARISON OF COSTING FOR OPEN REPAIR AND ELG

Financial implications have been studied. It is calculated that the rise in the number of elderly people over the next two decades will increase the workload by over 40% for AAAs (1). At this time, tangible benefits for ELG are reduced costs for inpatient stay and less or no need for intensive care facilities during recovery. As yet, there is no less time spent in the operating theatre but this may come down as surgeons become more proficient and devices become more user-friendly.

Initially, many surgeons and radiologists wanted to be involved, but manpower requirements are already retreating to the conventional anaesthetist, surgeon and single assistant. There has been a far greater
requirement for expensive investigations by imaging during preoperative evaluation and postoperative surveillance for ELG, but as techniques improve and confidence grows these will progressively decrease in number.

An early study by our group that concentrated on the impact that this new technology would have on financial support in a public hospital concluded that development of ELG is economically incompatible with current funding methods (2). This work was continued by Barras who showed that there were savings for ELG for both direct and indirect hospital costs but that the average cost of prostheses for ELG was more than 10 times that for open repair, amounting to well over 50% of the average overall cost (3). The results for in-hospital expenses are summarized in Figure 13.1. A further Australian study took the process a step further (4). They showed that combined costs for primary in-hospital treatment, readmissions and lifelong follow up were more than 50% higher for ELG than that for open repair. There was less time spent in hospital and intensive care so that hospital costs were some 50% lower for ELG, and this was only partly offset by higher preoperative and postoperative costs for imaging and surveillance for ELG. The reason for the overall discrepancy was the cost of the stent-graft which amounted to some 50% of the total immediate expense for ELG.

Several American studies have analyzed where cost savings could be effected. Quinones-Baldrich and colleagues (5,6) concluded that endovascular grafting is "unlikely to save money for the health care system (and) its use is likely to be driven by patient and physician preference in view of a significant decrease in the morbidity rate and length of hospital stay." Another study showed that total inpatient hospital costs for ELG were significantly higher than for open repair (mean $19,985 versus $12,546), and
that stent-graft cost ($10,400) accounted for 52% of the total cost for ELG (7).

They anticipated that reductions in cost for ELG may result if use of diagnostic studies, operating time, and length of stay decrease, but that device cost has the single greatest impact on the expense, and that Medicare reimbursement does not cover the cost. Another analysis agreed that operating room time, length of stay, costs for the hospital stay, laboratory, pharmacy, nursing, and anesthesia requirements were all higher for open repair than for ELG, but that despite these marked differences, the total cost was much higher for ELG due to the expense of the stent-grafts (8). A further study found that ELG is a cost-effective alternative on the basis of average costs for immediate hospitalization ($16,016 for open repair, $20,083 for ELG), complications from each procedure, and subsequent interventions, provided that ELG produced a large reduction in combined morbidity and mortality (9).

The expense for a prosthesis does not rest in the wire, fabric and plastic accessories of the device itself. Recompense is due to companies for the intellectual effort, prolonged research, inevitable setbacks, and risk taken by the manufacturers. Many presumably also realize that their days in the field are few and that profits must be taken quickly. Nevertheless, the trade in general is at risk of outpricing itself. As the number of operations performed increases, exponentially it seems, the burden will undoubtedly result in protest from those who supply the money.

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