The choice of intervention, between open surgery and an endovascular procedure, can be difficult, often weighing risks to life and limb against each other in an attempt to save both. There are risks to limb and life involved in any attempted revascularisation procedure, particularly in some difficult surgical bypasses, but patients with CLI have complex lesions not suitable for endovascular treatment, and amputation has the same risk. Accurately predicting the result of a particular revascularisation in an individual is difficult based on available literature. The assessment of chances of success in an individual case would be better based on the audited results obtained in the relevant institution rather than published results from other centres (see p S220). It is important to develop guidelines regarding the likelihood of success below which a reconstruction should not be attempted.

References

D 4.11
General Issues Relating to Surgical Treatment

D 4.11.1
Anaesthesia

Either general or regional anaesthesia may be used for lower-extremity bypass grafts. Some centers advocate the use of a combination of both techniques for aortic surgery for optimal patient comfort and minimal respiratory depression. There have been reports of increased distal graft patency when epidural/spinal anaesthesia are used. However, the results of a recent randomised control trial failed to show any effect of the type of anaesthesia on the 30-day patency rate of infrainguinal bypass grafts.1

The choice and conduct of the anaesthetic technique is more important in the transabdominal aortoiliac reconstructions. All inhalation anaesthetics are myocardial depressants; intravenous narcotic analgesics such as fentanyl are often used as an alternative to inhalation anaesthetics because they produce minimal myocardial depression. However, large doses of narcotics may be necessary to avoid hypertension during intraabdominal procedures, and as a consequence may produce ventilatory depression. Spinal or epidural anaesthesia has no direct effect on the myocardium but may increase myocardial oxygen consumption because they may be associated with hypertension and bradycardia resulting from sympathetic blockade. Prospective studies that have compared general and epidural anaesthesia have found no advantage to either technique in reducing perioperative cardiac complications in patients undergoing aortic surgery or infrainguinal procedures.2,3 Systemic anticoagulation is not a contraindication for epidural anaesthesia if begun after catheter placement, although it is uncertain how long a delay is necessary after catheter placement before anticoagulation can be instituted.4

D 4.11.2
Antibiotic Prophylaxis for Vascular Procedures

It is generally believed that graft contamination occurs most commonly at the time of the original operation. This emphasises the importance of a meticulous sterile technique with avoidance of skin contact by the use of adherent plastic drapes. Several randomised studies have now demonstrated the efficacy of antibiotic prophylaxis in reducing the incidence of vascular graft infection, and its perioperative use is now well accepted.5,6 There is evidence that antibiotic prophylaxis should continue until drains and invasive monitoring lines are removed.6,7 The same principles of sterile techniques must apply to endovascular procedures with stent implantation, evidence that the same principles should apply to stents. Covered stents should be treated as prosthetic grafts in terms of use of prophylactic antibiotics. However, the need for and effectiveness of antibiotic prophylaxis with other endovascular techniques is unknown.8,9,10,11

Recommendation 94: Use of prophylactic antibiotics with prosthetic grafts
Patients undergoing prosthetic grafts should have prophylactic antibiotic therapy perioperatively.

Critical Issue 36: Duration of prophylactic antibiotics with prosthetic grafts
There is a need for more data to determine how long antibiotic prophylaxis is required when prosthetic grafts are implanted.
D 4.11.3
Perioperative Care of the Diabetic Patient

Ideally, blood sugar should be normalised in the diabetic patient before surgical intervention. This may involve the switch from oral agents to insulin in some patients. The control of sepsis in the diabetic foot may help control hyperglycaemia and ketoacidosis. Particular attention to the renal function is needed in patients with diabetes, because investigations such as angiography may lead to deterioration. The rationale for striving to achieve near-normal glucose has been established, but other factors must be considered in patients with diabetes who must undergo surgery with less than optimal control of metabolism in an acute situation. Such patients can be haemodynamically unstable during anaesthesia because of dehydration and osmotic shifts. Furthermore, such patients are more prone to infection, have decreased wound healing, and may have increased free fatty acids, the metabolism of which increases myocardial oxygen consumption.

D 4.11.4
Treatment of the Failing Graft

The concept of the “failing graft” has been emphasised by several series documenting improved results when intervention is directed at the time when the graft is still patent, that is, failing rather than failed. Graft surveillance is necessary to detect a failing graft at this preocclusive stage. The details are dealt with in D 4.14, Surveillance After Revascularisation (p 5214). Grafts may fail on the basis of intrinsic graft pathology or pathology in the inflow or outflow segments. Inflow and outflow lesions should be managed according to the principles outlined elsewhere in this document. Graft stenoses can be managed by either interposition or jump graft segmental bypass or patch angioplasty, depending on the length of the lesion. Debate continues, but current opinion favours segmental bypass or patch angioplasty rather than percutaneous balloon angioplasty for most lesions.

D 4.11.5
Treatment of Graft Thrombosis: The Failed Graft

The choice between thrombolysis and thrombectomy for graft occlusion is complicated by the fact that these tend to be linked with PTA and surgical revascularisation, respectively, in trials. As a result of this and also of a significant technical failure rate, four major trials have failed to show an overall advantage for thrombolysis on an intent-to-treat basis. However, its obvious potential advantages (stated previously) and the relative ease of the procedure probably can be achieved only by selective application. Although urgent thrombectomy may be required for immediate limb threat, and surgical reconstruction is preferred in delayed occlusions (>14 days’ duration), thrombolysis holds the advantages in terms of mortality and amputation for less than 14 days’ occlusion. This complex subject is dealt with in more detail in C 4.2.2, Contraindications to Thrombolysis, p 5130. Open surgical procedures have been the traditional approach for bypass graft occlusion, directing procedures at thrombectomy, and revision or replacement of the existing graft, with the latter giving best results. Thrombolysis has been advocated as a less invasive, alternative means of restoring graft function that also provides the opportunity to unmask stenotic lesions responsible for the occlusive event and to clear the run-off vessels. The unmasked lesion is then addressed with an endovascular or operative approach after successful thrombolysis, the choice depending on the characteristics of the lesion (eg, neointimal hyperplasia or diffuse or local atherosclerotic involvement). The most appropriate treatment for a valve cusp stenosis is operative patching or resection and reconstruction. The results for open repair are believed to be superior to dilatation and yield excellent secondary patency rates. If the distal anastomosis is involved or should there be progression of disease, there may be a need to extend the bypass graft. Whatever method is used, good success rates have been achieved with the use of alternative vein sources. If an established bypass graft fails less than 6 months after construction, then graft replacement of this disadvantaged conduit is indicated.

Recommendation 95: Treatment of chronic critical leg ischaemia due to bypass graft occlusion
In patients with chronic critical leg ischaemia, surgical revision or graft replacement is the preferred treatment for bypass graft occlusion. Thrombolysis may be considered as a treatment option in patients who present early after their bypass graft occlusion where the limb is not immediately threatened.

The treatment strategy for bypass graft occlusion must be tailored to the clinical setting and the risks and benefits associated with the therapeutic options. In addition to the characteristics of the underlying lesion, the parameters that are important in determin-
ing appropriate therapy include the severity of the patients’ symptoms, the duration of the occlusion, and the nature of occluded conduit (autogenous or prosthetic). For instance, in patients with occluded lower-limb grafts who present with sudden-onset claudication, the clinician will need to consider the original indications for the graft and possible future surgical options if no attempt is made to rescue the graft.

The most common source of morbidity and mortality after revascularisation for PAD is myocardial ischaemia. Although operative mortality is decreasing steadily, long-term survival of these patients continues to be compromised. The cumulative long-term survival is 40% to 50% at 10 years. Patients with CLI, extensive arterial disease, or diabetes have a less favourable long-term prognosis than patients with localised disease and claudication. Most late deaths are also attributed to atherosclerotic heart disease.\(^{25}\) (see A 2.7, Fate of Patients With CLI, p S21). Other specific complications are outlined in the following paragraphs.

**Deep vein thrombosis**

A randomised prospective trial of deep venous thrombosis (DVT) prophylaxis in aortic surgery failed to show any increased incidence after aortic surgery in the control group compared with the prophylaxis group.\(^{26}\) A second study reported a DVT incidence of 9.8% in patients undergoing either aortic or distal revascularisation (with the highest incidence following amputation).\(^{27}\) All patients in this study had received DVT prophylaxis. Therefore, although pharmacotherapy to avoid arterial thrombosis after revascularisation also frequently reduces the risk of DVT, this risk cannot be neglected entirely.

**Cardiac mortality and morbidity**

Currently, excellent early and late results of direct aortoiliac reconstructions for occlusive disease can be anticipated. Perioperative mortality rates are well under 3% in many centres, and patency rates of close to 85% at 5 years and 75% at 10 years are expected.\(^{28,29}\) Though somewhat dated, a list of complications of aortoiliac reconstruction other than graft failure are summarised in Table 52.

**Acute complications; limb ischaemia**

Acute limb ischaemia occurring shortly after aortic operation for occlusive disease is generally attributable to acute thrombosis of the graft or one of its limbs and occurs in 1% to 3% of patients. The main causes are twisting, kinking of the graft limb, or technical problems at the distal femoral anastomosis site. Acute limb ischaemia also can occur as a result of intraoperative thromboembolic events, all related to technique and all preventable.

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**Table 52. Complication of aorto-iliac bypass grafts**

<table>
<thead>
<tr>
<th>Complication</th>
<th>Incidence (%)</th>
<th>Aetiology/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial Infarction(^{30,31})</td>
<td>0.8–5.2</td>
<td>Concurrent cardiac disease</td>
</tr>
<tr>
<td>Death(^{32,33,34,35,36,37,38})</td>
<td>0–3.3</td>
<td>Usually myocardial</td>
</tr>
<tr>
<td>Intestinal ischaemia(^{39})</td>
<td>1.1</td>
<td>Ligation IMA—colonic</td>
</tr>
<tr>
<td>Renal failure(^{40,41,42,43})</td>
<td>0–4.6</td>
<td>Preexisting SMA disease</td>
</tr>
<tr>
<td>Ureteral injury(^{44})</td>
<td>1.6</td>
<td>Prevention renal dysfunction increases risk</td>
</tr>
<tr>
<td>Spinal cord ischaemia,(^{45,46})</td>
<td>0.25</td>
<td>Frequent association with graft complication</td>
</tr>
<tr>
<td>Graft infection(^{47,48})</td>
<td>0.1–1.3</td>
<td>Atheroemboli, occlusion vascular supply</td>
</tr>
<tr>
<td>Aortoenteric fistula(^{47,48})</td>
<td>0.1–0.5</td>
<td>Higher incidence involving groin anastomosis</td>
</tr>
<tr>
<td>Lymph fistula(^{49})</td>
<td>1.5–3.5</td>
<td>Erosion, lack of reperitonealisation, aortic false aneurysms</td>
</tr>
<tr>
<td>False aneurysm(^{50,51,52})</td>
<td>3–5</td>
<td>Division of lymphatics</td>
</tr>
<tr>
<td>Altered sexual function(^{53})</td>
<td>20</td>
<td>Infection, native artery degeneration</td>
</tr>
</tbody>
</table>
Intestinal ischaemia

Intestinal ischaemia is more likely after aortic surgery for aneurysmal disease than after that for PAD but may occur after the latter. A large or meandering inferior mesenteric artery (IMA) with upward flow warns of concomitant coeliac or superior mesenteric artery (SMA) disease deserving attention and mandates IMA preservation. Otherwise, preservation of hypogastric internal iliac artery outflow is the key to avoiding intestinal ischaemia, impotence, or paraplegia (see next paragraph). As discussed earlier, this may dictate the choice between proximal end-to-side and end-to-end anastomosis.

Erectile impotence

The incidence of iatrogenic erectile impotence after aortic reconstruction may approach 25%. Most often, impotence implies inadequate preservation of the hypogastric artery and pelvic circulation. Retrograde ejaculation is also a frequent occurrence and is attributable to disturbance of autonomic nerve fibres that course along the left wall of the aorta and cross the common iliac arteries. As described by De Palma et al, a nerve-sparing approach to the infrarenal aorta is helpful, and preservation of the hypogastric artery flow by a variety of techniques is also essential.

Anastomotic false aneurysms

The incidence of anastomotic false aneurysm formation after aortoiliac reconstruction varies from 1% to 5% and is by far most common at the femoral anastomosis. Previously these were related to the use of silk sutures and, rarely, prosthetic suture material may fracture. Degenerative changes within the host arterial wall leading to weakness and dehiscence of the intact suture line appear to be the most common cause. Infection may be a contributing cause and always needs to be considered as a possible causative factor.

The true incidence of proximal aortic anastomotic aneurysm may be higher than previously thought after aortic surgery for PAD; a study by Edwards et al reported a 10% incidence, of mostly asymptomatic anastomotic aneurysms, at a mean interval of 12 years after initial revascularisation. These anastomotic aortic aneurysms are more common after lateral anastomosis than after end-to-end anastomosis. This suggests that CT scans should be a routine part of the late follow-up of patients with an aortic graft, that is, beginning at 3 years postintervention.

Aortoiliac, aortofemoral graft infection

The incidence of graft infection is between 1% and 5% after aortic surgery. It may be difficult to prove unequivocally that a graft is infected. Despite this, all efforts should be made to determine whether a peri-graft collection is present, whether graft infection is likely, and which infecting organisms are involved. Once this has been determined, the likelihood of infection must be balanced against the general condition of the patient, the extent of revision surgery, and the necessity for immediate intervention.

The organisms most commonly isolated from blood or from wounds are Pseudomonas, Staphylococcus, and streptococcus species. Computed tomography scanning and magnetic resonance imaging are very helpful in demonstrating fluid collections around a suspect aortic graft. Labelled white cell scans also can be useful if performed more than 4 weeks after surgery. Treatment of aortic graft infection is challenging. Graft conservation with local debridement of infected tissue followed by local irrigation with antibiotics has been advocated by some authors.

However, many authors believe that most graft infections involve the whole length of the prosthesis, even though presentation or imaging may suggest a local sepsis. Graft excision has been recommended by most authors. This decision should be made carefully, and, whenever possible, the patient's condition needs to be optimised before surgery. After excision, extensive retroperitoneal debridement must be done. A number of recent reports have advocated direct in situ replacement with a rifampin-soaked Dacron or PTFE graft. However, these selected exceptions to the generally accepted policy of complete graft excision and extraanatomic bypass primarily involve late indolent infections with Staphylococcus epidermidis with little associated systemic sepsis. Placement of a graft in a site that is potentially infected might result in higher risk of future reinfection.

Autogenous vein grafts provide an alternative to prosthetic material for in situ reconstruction, but sufficient vein is difficult to obtain, and this technique is not practised widely. However, recently good experiences have been reported with the use of the superficial femoral vein for this purpose, because size mismatch is less of a problem. The consequences of harvesting this vein have been surprisingly mild. Cryopreserved homografts to reconstruct the aortoiliac anatomy have recently been advocated for replace-
ment of infected aortic prosthetic grafts. Concern regarding long-term dilatation remain, although they seem resistant to reinfection.\textsuperscript{65} When complete graft excision with extraanatomic reconstruction using bilateral axillounifemoral bypasses is not feasible because of extensive groin/thigh sepsis or previous extraanatomic bypass failure, in situ reconstruction using (superficial femoral or popliteal) veins may be the only remaining option. However, because of its significant mortality and morbidity, it is reserved for situations in which life or limb loss would probably result without revascularisation.\textsuperscript{63,64,65,66} Some experience has been achieved using in situ allograft replacement.\textsuperscript{67}

**D 4.11.8**

Complications of Infrainguinal Vein Bypass Grafting

(Table 53)

**Wound complications**

The in situ technique has a recorded wound complication rate of 10\% to 30\%, with most problems occurring in the distal wound or the mid thigh.\textsuperscript{74,75} Meticulous dissection without creation of flaps and tension-free closure are emphasised to reduce this complication. A retrospective comparative study showed that the in situ technique was associated with a higher rate of wound complications than nonreversed or reversed subcutaneously placed long saphenous vein grafts (23\% vs. 9.3\%). A continuous incision was also associated with higher rates of wound complications.\textsuperscript{70} A prospective randomised trial, however, failed to confirm this difference in wound complications seen in situ (15\%) and reversed vein (17\%) graft reconstructions.\textsuperscript{69}

**Arteriovenous fistula**

These are avoided by on table graft assessment (angiogram, Doppler assessment) but occasionally become apparent after the operation. Arteriovenous fistulae may be treated by ligation or embolisation under local anaesthetic.

**Leg swelling**

Leg swelling after revascularisation is an accepted complication of any infrainguinal bypass. The origin of the swelling has been investigated and found to be related to the lymphatic disruption and interruption in the groin along the path of vein harvest and increased lymph production during postoperative reactive hyperaemia.\textsuperscript{76,77}

**Early graft occlusion**

Early failure rates have been reported to be as high as 17\% for grafts to the popliteal artery and 24\% for grafts to more distal arteries and is related to technical failure (eg, missed valve cusp, twist, anastomotic error).\textsuperscript{78,79,80,81} In 63\% of the graft failures in one study, the cause was intrinsic to the graft or anastomosis.\textsuperscript{78} Early graft thrombosis is usually attributed to technical error, hypercoagulable state, or periods of hypotension or hypoperfusion. A randomised trial reported the benefit of Dextran 40 in preventing early graft thrombosis of “difficult” distal bypasses.\textsuperscript{82} The 1-week occlusion rate was 20.5\% in the control group and 6.9\% (0\% in vein grafts) in the Dextran 40 group. The overall early graft occlusion rate can be reduced by good technique, intraoperative monitoring of the

<table>
<thead>
<tr>
<th>Complication</th>
<th>Incidence (%)</th>
<th>Aetiology/comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death\textsuperscript{69}</td>
<td>1.3–6</td>
<td>Usually cardiac</td>
</tr>
<tr>
<td>Myocardial infarction\textsuperscript{68,84}</td>
<td>1.9–3.4</td>
<td></td>
</tr>
<tr>
<td>Wound:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vein\textsuperscript{74,75}</td>
<td>10–30</td>
<td></td>
</tr>
<tr>
<td>Prosthetic\textsuperscript{71}</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Exposure/blowout\textsuperscript{64}</td>
<td>9.5/1.6</td>
<td></td>
</tr>
<tr>
<td>Infection:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vein\textsuperscript{71}</td>
<td>1.36</td>
<td></td>
</tr>
<tr>
<td>PTFE/Dacron\textsuperscript{71}</td>
<td>3.56</td>
<td></td>
</tr>
<tr>
<td>HUV\textsuperscript{71}</td>
<td>1.48</td>
<td></td>
</tr>
<tr>
<td>Leg oedema\textsuperscript{72}</td>
<td>50–100</td>
<td>Resolution usually by 4 months</td>
</tr>
<tr>
<td>Lymph leak\textsuperscript{4,73}</td>
<td>0.5–1.8</td>
<td>Lower with femoral distal than with</td>
</tr>
<tr>
<td>Acute limb ischaemia</td>
<td>1–2</td>
<td>aortofemoral</td>
</tr>
</tbody>
</table>

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completed bypass, and adjuvant therapy (see D 4.13, Adjuvant Therapy After Revascularisation p S209; D 4.14, Surveillance After Revascularisation, p S214).

Haemodynamic failure

This may be said to occur when limb viability is threatened or not reversed even in the face of a patent bypass graft. Occasionally, limb loss may occur despite a patent graft. The current objective criteria for haemodynamic failure is failure to increase the ABI or toe-brachial index more than 0.10.83

References

Treatment of Critical Limb Ischaemia


D 4.12
General Issues Relating to Endovascular Treatment

D 4.12.1
Need for Surveillance

As with surgical bypass grafts, it is likely that surveillance and repeat intervention would improve the assisted primary patency of PTA. In infrainguinal PTA, primary and assisted primary patency rates approximate each other because re-intervention is attempted in a relatively small proportion of PTA patients. For example, Gallino et al repeated PTA on only 14% of failed or failing femoropoliteal PTA, whereas Capek et al reported a re-intervention rate of only 8%. However, when repeat PTA is performed in a higher percentage of patients, patency can be improved. For example, Harris et al, in a series of PTA performed by surgeons, used surveillance and re-intervention as needed with 57% primary 6-month patency and 82% assisted primary 6-month patency.

Although the ability of periprocedural duplex to predict ultimate PTA durability is controversial, duplex ultrasound may be useful in an appropriate longitudinal postprocedure surveillance program. Vroegindewij et al found that duplex ultrasound is sensitive in detecting restenosis and, along with clinical and other noninvasive follow-up, it could be very useful in augmenting the durability of femoropopliteal PTA.

Table 5-1: Ideal characteristics of stents and delivery systems

<table>
<thead>
<tr>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allow for efficiency in and ease of deployment</td>
</tr>
<tr>
<td>- Use percutaneous technique</td>
</tr>
<tr>
<td>- Have a low-profile delivery system</td>
</tr>
<tr>
<td>- Have a high expansion ratio</td>
</tr>
<tr>
<td>- Be available in a wide range of diameters and lengths</td>
</tr>
<tr>
<td>- Have longitudinal flexibility</td>
</tr>
<tr>
<td>- Ability to be optimally and precisely positioned</td>
</tr>
<tr>
<td>- Have high radio-opacity</td>
</tr>
<tr>
<td>- Have minimal foreshortening</td>
</tr>
<tr>
<td>- Ability to be retrieved or repositioned</td>
</tr>
<tr>
<td>- No slippage of stent on balloons; rupture-resistant balloon (for stent/balloon delivery system)</td>
</tr>
<tr>
<td>Yield durable clinical results</td>
</tr>
<tr>
<td>- Reliably oppose elastic recoil, stenosis, or dissection flap</td>
</tr>
<tr>
<td>- Be thromboreistant</td>
</tr>
<tr>
<td>- Resist restenosis</td>
</tr>
<tr>
<td>- Resist compression, deformation, or fracture</td>
</tr>
<tr>
<td>- Be biologically compatible, to resist infection and minimise inflammatory reaction</td>
</tr>
<tr>
<td>- Be incorporated into vessel wall with thin neointima/functional endothelium</td>
</tr>
<tr>
<td>- Do not embolise or migrate</td>
</tr>
<tr>
<td>- Be inexpensive</td>
</tr>
<tr>
<td>- Allow for noninvasive imaging and follow-up with CT, MRA, and ultrasound.</td>
</tr>
</tbody>
</table>

D 4.12.2
Comparison of Available Stents

Currently all intravascular stents in clinical use are permanent and metallic. Stent designs and technologies used for managing peripheral vascular disease are continually evolving. The availability of and approved indications for specific stents vary by country. The ideal stent and delivery system should have the following characteristics:

Stents are generally stratified into balloon-expandable (e.g., Palmaz, Streeker) and self-expandable. The self-expandable stents are generally based on one of two designs: (1) spring-open expansion after removal of restraint (e.g., Wallstent) or (2) thermal memory expansion at body temperature (e.g., Memotherm, Nitinol stents). Currently thermal stents are constructed of Nitinol (nickel-titanium alloy), and self-expand-