Femoropopliteal disease and critical limb ischaemia.

The clinical definition of chronic critical limb ischaemia (CLI) is two weeks or more of rest pain, ulceration or gangrene attributable to objectively proven arterial occlusive disease. The diagnosis should be confirmed by ankle brachial pressure index (ABPI) or toe pressure. Ischaemic rest pain most commonly occurs with an ankle pressure of 50mmHg or less or a toe pressure less than 30mmHg. For patients with ulcers or gangrene, CLI is suggested by an ankle pressure less than 70mmHg or toe pressure less than 50mmHg.

In patients with CLI who are not candidates for revascularisation, at one year, 25% will have died and 25% will have had a major amputation. The mortality is 40 – 70% after 5 years and 95% and 80% after 10 years for those with gangrene and rest pain. 50 – 70% of patients with critical limb ischaemia have ECG evidence of IHD. In a post mortum study of those undergoing an amputation, 92% had severe coronary atherosclerosis.

The incidence of critical ischaemia is 500 – 1000 new cases every year in a European or North American population of 1 million. In addition to reduced mortality, limb salvage has been shown to lower overall health care costs and to improve patient quality of life.

Classification systems for peripheral vascular disease.

TASC (Management of PVD JVS 2000)

	Lesion	**Recommended treatment**
A	Single stenosis, <3cm	Endovascular
B	Single stenosis 3 – 10cm, not involving popliteal. Multiple stenoses each <3cm. Single stenoses with no continuous run off	No firm recommendation. PTA alone may be inadequate
C	Single stenoses or occlusion >5cm	No firm recommendation
D	Complete CFA or SFA occlusion Popliteal or trifurcation occlusion	Surgery

Fontaine

Stage 1 = asymptomatic
Stage 2 = mild claudication
Stage 3 = moderate to sever claudication
Stage 4 = rest pain
Stage 5 = tissue loss or gangrene

Rutherford classification

0 = asymptomatic
1 = Mild claudication
2 = moderate claudication
3 = severe claudication
4 = ischaemic rest pain
5 = minor tissue loss – resting ankle pressure of less than 60mmHg, toe pressure less than 40mmHg
6 = ulceration or gangrene

Rutherford 5 and 6 have a 95% one year amputation rate if untreated.

Clinical presentation and evaluation.

Most patients would not have suffered intermittent claudication. CLI usually results from multi level disease. In some cases the haemodynamic consequences of arterial lesions may be compounded by low cardiac output.

Pain.
In most cases of CLI, pedal pain is intolerably severe and walking is severely impaired. Ischaemic rest pain typically occurs at night. Pain is localised to the foot or the vicinity of an ulcer or gangrenous toe. Partial relief of the pain is obtained by dependency of the foot. Elevation of the foot and cold increase the pain severity. Often patients sleep with the foot dangling out of the bed or they sleep in a chair leading to ankle and foot oedema. In sever cases, sleep becomes impossible. The pain usually requires opiates – see later.

Ulcers and gangrene.
Gangrene usually affects the digits or heel and if often initiated by minor trauma e.g. ill fitting shoes. Dry gangrene may autoamputate. See separate section on diabetic foot ulcers.

Differential diagnosis of rest pain.
Diabetic neuropathy – Burning or shooting sensation, worse at night, symmetrical distribution in both legs, associated with cutaneous hypersensitivity, failure to relieve symptoms on foot dependency. There may be other signs of neuropathy e.g. loss of vibratory sense and reflexes. Gabapentin is useful for this.
Complex regional pain syndrome – formally called causalgia or reflex sympathetic dystrophy.
Nerve root compression – typically associated with backache and distributed in a nerve dermatome.
Peripheral sensory neuropathy – Vit B12 deficiency, syringomylia, leprosy, alcohol excess.
Night cramps – usually involve the calf but may involve the foot. They are bloody painful – trust me! May be associated with chronic venous insufficiency.
Buergers disease – occurs in young male smokers. See arteritis chapter.
Gout -
Rhematoid arthritis
Digital neuroma
Tarsal tunnel nerve compression
Planatar fascitis

Examination.
Document presence of palpable lower limb pulses. Other non specific findings – hair loss, muscle wasting, atrophy of subcutaneous tissues and skin, dry fissured skin and dependant hyperaemia.

Objective of treatment.
The primary goals of the treatment of CLI are to relieve ischaemic pain, heal ulcers, prevent limb loss, improve patient functioning and quality of life and prolong survival. The primary outcome is amputation free survival. In order to achieve these aims, most patients will require revascularisation.

Pain control.
Initial attempts at pain relief should be with paracetamol or non steroidal anti-inflammatory drugs. If these are ineffective, which they often are, opiate analgesia is required e.g. Fentanyl lozengers (Actiq) for rapid onset pain relief or oral slow release morphine. Analgesia is more effective if taken regularly rather than as and when required. Patients with CLI are often depressed and so an antidepressant may be useful.

Medical management.
Given the association of cardiac and carotid disease with peripheral arterial disease, institution of secondary prevention is vitally important i.e. antiplatelet agent, statin, ACE inhibitor, blood pressure and diabetes control. See medical management of athererosclerosis chapter.

Management of ulcers.

Cochrane review 2009 – Dressings and topical agents for arterial leg ulcers – there was insufficient evidence to determine whether the choice of topical agent or dressing affected healing.

Revascularisation.

The treatment choices will be influenced by the patients pre morbid condition and the condition of the limb. There must be a considered balance between the risks and benefits of the various types of intervention and the expected patency and durability of the procedure. Surgeon preference is often the final determining factor. Following revascularisation for critical ischaemia, the overall one year amputation free survival is approximately 75%. This is reduced in patients on dialysis, with tissue loss, age over 75 years, haematocrit less than 30 and a history of coronary artery disease (Schazer SVS San Diego 2008).

Amputation.

Major amputation is necessary and indicated when there is overwhelming infection that threatens the patients life, when rest pain cannot be controlled or when excessive necrosis has destroyed the foot. Using these criteria, the number of major amputations should be limited. Revascularisation remains the treatment of choice for most patients, however, it is important to identify that subgroup of patients best served by a primary amputation. See amputation chapter.

Angioplasty.

The first angioplasty was by Andreas Gruentzig in February 1974.

Technical considerations.

Balloon angioplasty of arterial stenosis involves crossing the lesion with a guidewire, passing a balloon over the guidewire and inflating the balloon. When the vessel is occluded, subintimal angioplasty (SIA) can be used where a guidewire is again used to cross then lesion, usually through the wall of the occluded artery and usually the wire will re enter the patent distal lumen. This is confirmed by passing a catheter over the wire and injecting contrast into the distal lumen. Tolazoline 12.5mg can be used to act as a vasodilator following SIA. You can also use GTN, intraarterially or topically. Technical success is about 80% in most series. The Pionner catheter has been found to be useful for SIA and a crosspoint pioneer catheter can be useful to help with re-entry.

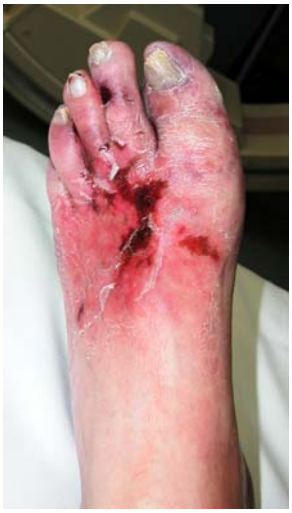
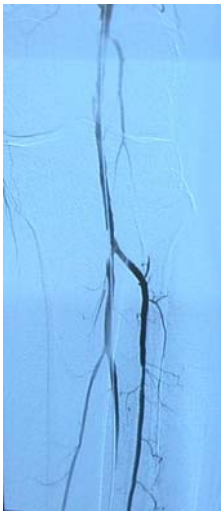
a.  b.  c. 

Figure 1. a. Diabetic patient presents with painful left foot. B. Angio shows distal popliteal occlusion. C. Recannalisation angioplasty reconstitutes three vessel run off.

Results.

For infrainguinal procedures, angioplasty and bypass have been reported to have the same patency rates up to 3 years. Angioplasty results are thought to be worse with increasing severity of ischaemia, longer lesions, poor run off and in diabetics.

	Primary and secondary patency of lower limb angioplasty:		
1 year	81%	86%	
5 years	65	73	
10 years	12	17	(JVEVT 2004)

SIA 1 year patency is 71% and 3 year patency is 58% (London 1994). Reocclusion is increased in smokers, those with poor run off and with longer occlusions, although technical success is unrelated to length of occlusion. The 6 and 12 months patency in CLI has been reported to be as low as 31% (Smith Annals of RCSE 2005). Tibial vessel angioplasty 1 year patency 53%.

In a randomised study of pacitaxel coated balloons vs. non coated balloons (Werk Circulation 2008), on follow up angiography, there was less lumen loss in those who had the coated balloon at 6 months, there were fewer revascularisations in the coated balloon group (3/45 vs. 14/42 p = 0.002).

Stents and stent grafts in the femoropopliteal segment.

Currently there is conflicting evidence on the use of stents in the femoropopliteal segment. In the presence of reocclusion, the presence of a stent makes any further attempts at endovascular recannalisation very difficult. 25 – 50% of stents placed within the SFA suffer from stent fracture. Stent fracture has been shown to be a significant risk factor for stent occlusion.

SMART stents (Cordis) vs. Wallstent (Boston Scientific) in SFA – 60% one year patency vs. 30%. SMART stent one year patency 76% in a non randomised study and 84% in another (Vogel JVS 2003).
SIROCCO 1 study – 18.2% stent fractures.
SIROCCO II – A multicentre randomised study comparing bare SMART to sirolimus coated SMART showed no difference in the patency of drug eluting vs. non drug eluting stents when placed in the femoral artery.
RESILIENT trial – a prospective multicentre trial of angioplasty vs. angioplasty and stenting in the SFA and proximal popliteal artery using a self expanding nitinol stent (Lifestent (Edwards)) which has a unique helical design. There were 206 patients of which 134 were stented. Included claudicants, lesion length not exceeding 15cm. 40% of those randomised to PTA alone went on to have stenting as bail out, mainly for flow limiting dissections. 6 month primary patency was 50% with PTA and 95% with stenting and at 12 months, 38% vs. 80%. At 12 months, follow up intervention was required in 13% following stenting and 54% following PTA.
FAST (Femoral artery stenting trial (Krankenberg Circulation 2007)) – Randomised trial of SFA lesions less than 10cm (mean 4.5cm) in length in 244 patients. 11% of PTA patients crossed over to stenting. At 1yr there was no angiographic or clinical difference in patients with short SFA lesions treated by PTA alone or stenting (Luminexx (Bard)).
FESTO – stenting used for persistent diameter reduction of more than 50% after PTA or for flow limiting dissection using SMART, SelfX or Luminex stents. 24.5% of stents suffered fracture, incidence increased with longer treated segments. Fracture was associated with reduced patency. Lowest fracture rate found with SMART stent (15.1%). Superior patency rate with SMART stent – 82% primary patency at 12 months. Stent fracture is associated with restenosis or reocclusion in at least 2/3 cases.

Schillinger NEJM 2006. Randomised trial of routine stent vs. routine angioplasty plus selective stent in 104 patients using the Dynalink or Absolute self expanding stent (Guidant). 88% were claudicants. 32% in the angioplasty arm had stents inserted. 2% early thrombotic occlusions for

stented group, nil in non stented group. On CTA or DSA, 6 month restenosis rate was 24% in stented group vs. 43% in non stented group according to intention to treat or 25% vs. 50% according to stent use. At one year, restenosis on duplex was 37% in stented group and 63% in angioplasty group. The benefit of stenting did not vary according to length of lesion. At 12 months the incidence of thrombosis or reocclusion was then same in each group (12%), reintervention were then same in each group, there were no amputations. More patients had bypass in the stented group than non stented group (3 vs. 0). The ABPI and walking distances were better in the stented group.

The Zilver stent by Cook is another stent that has been used in the SFA with a 95% and 88% one and two year patency.

In a clinical trial of the Zilver PTX, a nitinol stent covered with paclitaxel, (svs 2008), suggests improved results when compared to a non drug coated stent. With this stent the paclitaxel simply covers the stent, unlike coronary stents where it is bound by a polymer. The study protocol included 6 weeks of post insertion clopidogrel. The 1 year fracture rate was 2%.

There is some non randomised evidence that using sirolimus covered stents in the tibial vessels may improve tibial vessel patency (Siablis J Endovasc Therapy 2007 – 6 month patency 92% vs. 68%, one year patency 86% vs. 41%).

Meta-analysis of femoropopliteal stenting vs. angioplasty (Mwipatayi JVS 2008).
7 randomised trials of primary angioplasty or stenting for femoropopliteal disease.

	Angioplasty	**Stenting**
N	452	482
Mean age	66.1	67.5
Poor run off	47 patients	67 patients
Major amputations	3	4
Minor amputations	6	2
Maximum lesion length	30.2cm	32cm
Mean lesion length	4.3cm	4.6
Occlusions	19%	22%
Diabetes	31%	
30 day mortality	3%	4%
Failure rate	6.4%	2%
Overall complications	6%	11%
1 year primary patency	45 - 84.2%	63 – 90%
2 year primary patency	25 – 77.2%	46 – 87%

Pooled odds ratio for 1 year patency was 0.989, p = 0.962, showing no difference between the two groups. Pooled odds for post operative ABPI was 0.869, p = 0.5612 with a slight favour for angioplasty. This meta-analyis concluded that primary stenting did not increase patency rates when compared to angioplasty alone.

Cochrane review 2009 – angioplasty vs. stenting for superficial femoral artery lesions – stenting cannot be recommended routinely.

Blaster (Bilateral lower arterial stenting employing reopro) trial.
Prospective randomised double blind placebo controlled trial which showed that Reopro (Abciximab, a iib/iiia inbibitor) did not prevent restenosis. All patients had SMART stent. 9 month assisted primary patency 97.6% overall.

Stent grafts in the SFA.

The Gore Viabahn or newer Hemobahn is a stent graft of nitinol lined by PTFE. This was initially FDA approved for tracheobronchial use only. Arterial use remains an off label technique. Claims of better patency than uncovered stents and comparable patency to above knee prosthetic bypass have been made.
VIBRANT – a randomised prospective trial of 150 patients at 15 centres to compare Viabahn endoprosthesis versus bare nitinol stent for treatment of SFA occlusions of 8cm or more.

The Aspire (Vascular Architects) stent graft is a spiral, open architecture stent graft of nitinol covered with PTFE. It apparently reduces branch vessel coverage. Primary patency of 85% at 9 months has been reported. Aspire stent registry results (Lenti JVS 2007) showed primary patency at one year of 64% and at three years 59%. Critical ischaemia was the only predictor of late failure.

Fluency (Bard) is another commercially available stent graft for the femoral vessels.

In a randomised trial of the Gore stent graft (n = 40) with surgery using a prosthetic graft (PTFE or Dacron) (n = 46) to the above knee fem pop segment, (McQuade JVS 2008);

Table . Results of McQuades randomised study of stent graft vs. open surgery.

	Stent graft	Bypass
Primary patency 6 months	81	84
1 year	72	77
2 years	63	64
Mean hospital length of stay	0.9 days	3.1 days

Mean of 2.3 stent grafts per limb over a mean total length of 25cm. All patients randomised to stent grafting had aspirin and clopidogrel for three months.

In a randomised trial of angioplasty vs. Gore Viabahn (Richard Saxon JVIR 2008), stent grafting had improved technical success rate (95% vs. 66%) and primary one year patency (65% vs 40%).

Complications of angioplasty and stenting.
Access site complications, embolisation.

Figure 2. Embolic material retrieved following angioplasty.

Laser therapy.
Excimer laser delivers intense ultraviolet energy in short pulses. Plaque is removed by photoacoustic ablation. Said to fascilitate recannalisation of chronic occlusions.
LACI (Laser for critical limb ischaemia) trial. 145 patients, 155 limbs. Procedural success was 86% with 93% 6 month limb salvage. 96% required adjunctive angioplasty and 45% required stenting.

Excisional atherectomy.
Silverhawk , 87% success rate but one year patency only 36% and 1 yr limb salvage 86%.
Restenosis may be a concern.

Cryoplasty.

PolarCath (Boston Scientific). Delivers nitric oxide as a pressurised liquid into an angioplasty balloon. It delivers cold thermal energy to the vessel (-10 °C). Lead to apoptosis of smooth muscle cells.

Crosser (FlowCardia) catheters.
Utilize high frequency vibration to cross occlusive lesions allowing subsequent angioplasty or stenting.

Remote endarterectomy.
Involves removal of the diseased arterial core using a ring stripper and ring cutter. A stent is then placed over the distal cut plaque to secure the distal flap. In a review by Antonius (EJVES 2008), there have been no randomised trials, technical success was 94%, complication rate was 14.5% (including vessel perforation) and the one year primary patency was 60%.

Bypass surgery.
Kunlin performed the first femoro popliteal bypass (fem pop) on a man with rest pain and gangrene using a venous conduit in 1948. Should not bypass to an isolated popliteal segment of less than 7cm in length.

Anatomy, exposure and techniques.
Scarpa's fascia fuses with the deep fascia of the leg (fascia lata) 2cm below the inguinal ligament. The fascia lata arises from the inguinal ligament. Femoral artery exposure can be via a longitudinal or transverse incision. The transverse incision is cosmetically better but exposure of the femoral bifurcation can be limited. In addition, as more lymphatics are divided with a transverse incision, there is a higher risk of lymphoedema, lymphocele or lymph fistula. These can be reduced by dissecting in a vertical plan once the transverse incision is made. The femoral artery lies just lateral to a trough formed by the iliopsoas and pectineus muscles. Distal to the CFA bifurcation is a sensory branch from the femoral nerve which crosses the SFA from lateral to medial. It should be preserved to avoid medial thigh discomfort post operatively. Beware of anomalous profunda branches arising directly from the CFA. The first branch of the profunda artery is the lateral circumflex iliac branch. The lateral circumflex iliac vein runs with this artery having run from the femoral vein, under the SFA and over the top of the profunda artery. It should be ligated for profunda exposure. The more distal profunda artery can also be used for origin or termination of bypass grafts. Access is by an incision is along the lateral or medial border of the sartorius muscle. Then dissect between vastus medialis (laterally) and adductor longus (medially), through the raphe formed by the fascia of these two muscles, passing lateral to the superficial femoral vessels. The vein is usually on top of the artery. The profunda can also be approached from an upper medial thigh incision, passing posterior to adductor longus. Only the distal third of profunda can be exposed with this approach.

The above knee (AK) popliteal artery is exposed via a medial lower thigh incision, posterior to vastus medialis and anterior to sartorius. The saphenous nerve may be found and injured here. Genicular artery branches should be preserved. The popliteal vein lies behind the artery. Partial division of the medial head of gastrocnemius may aid more distal exposure of the AK popliteal artery. The AK popliteal artery can also be approached through a lateral incision, which is useful for anterior tibial (AT) or peroneal bypass. Incision and dissection is between vastus lateralis and biceps femoris. The sciatic nerve and popliteal vein will be encountered before the artery. The fascia lata needs to be "T-ed" in order to accept a graft.

The below knee (BK) popliteal artery is exposed via a medial upper calf incision. The gastrocnemius muscle is retracted posteriorly. The semimembranous and semitendonosus tendons may be divided to obtain more proximal exposure. The neurovascular bundle passes behind soleus.

Cutting its origin from the back of the tibia can expose the AT origin and the peroneal artery but beware of the soleal vein tributary that can be injured. Access to the AT artery at this level may require division of the AT vein. Opening the interosseous membrane may help expose the proximal part of the AT artery. For exposure of the tibioperoneal (TP) trunk, beware of the tibial nerve which lies anteriorly. The BK popliteal artery can also be approached from the lateral aspect. This involves removal of a segment of the proximal fibula. Beware of the superficial peroneal nerve at the level of the head of the fibula.

The AT artery in the middle third of the leg requires an incision midway between the tibia and fibula. Fibres of the anterior tibial muscle and toe extensors (extensor hallucis longus) are separated to expose neurovascular bundle lying on the interossous membrane. The vein lies over the artery. The graft can pass through the interosseous membrane or pass lateral to the knee. The AT artery can also be exposed just above the ankle where it is surrounded by tendons. The best route passes between extensor hallucis longus and extensor digitorum longus laterally and extensor hallusis brevis and tibialis anterior medially. The artery is accompanied by the deep peroneal nerve. This lower anterior leg wound can be difficult to close over a graft. Lateral release incisions may be required. Problem can be reduced by not extending the vein harvest incision below the ankle.

The distal posterior tibial (PT) artery is exposed via an incision behind medial malleolus or the posterior edge of the tibia and in front of the Achilles tendon. The nerve lies posterior to the artery. The mid PT artery can be exposed in the middle of the lower leg from the medial side. The solues muscle is divided.

The peroneal artery is best approached laterally with excision of the fibula. The vessels lie just behind the periosteum. The medial approach to the peroneal artery involves division of the soleus and the fibres of flexor hallucis longus must be separated. The PT vessels and the tibial nerve will be encountered first. The peroneal vessels lie just posterior to the tibialis posterior muscle.

Tourniquet occlusion is useful for the distal anastomosis. Below knee grafts are tunnelled below sartorius. It is easier to pass the tunneler from below towards the groin.

Conduits:

- Lower limb vein – must be more than 3mm in diameter, reversed or in situ.
- Upper limb veins – cephalic or basilic veins. Thinner walled and more difficult to work with than lower limb veins. Composite grafts have poorer patency rates.
- Human umbilical vein – glutaraldehyde tanned. High incidence of aneurysmal degeneration. Can be reinforced with Dacron mesh or by placing it within a PTFE tunnel.
- PTFE and Dacron – Dacron and PTFE have the same patency rates above the knee. Below the knee, prosthetic results are much worse than vein. 6 or 8mm diameter. The WL Gore Propaten vascular graft has heparin bonded to the luminal surface and is said to retain its activity for more than 6 months. Encouraging early patency results have been reported. No difference in patency rates with carbon coated vs. non carbon coated PTFE grafts (Kapfer EJVES 2006).
- Bovine ureter – SynerGraft (Cryolife). Denuded of cells to leave a collagen matrix. Can dilate and cause aneurysms.

VASCAN trial showed that an end to end anastomosis did not improve patency over an end to side anastomosis and if a bypass occluded with an end to end anastomosis there was a higher risk of amputation when compared to an end to side anastomosis (EJVES 2005).

PRODIGY – a randomised study of the Gore Propaten PTFE graft and autologous vein for below knee arterial bypass. Propaten has heparin bonded to its luminal surface.

Complications.
Post-operative mortality 2.2%, wound infection rate 5%, higher with venous bypass probably due to longer wounds. The incidence of wound infection in lower extremity bypass surgery was reported as 10 – 20% by Hassan (Vascular 2004 abstract). Vein harvest wound complications can be reduced by using interrupted incisions or an endoscopic technique. 38% of patients undergoing revascularisation surgery for critical limb ischaemia have evidence of peri operative myocardial injury, with a rise in serum cardiac troponin (Hobbs EJVES 2005).
Graft infections - see below.

Cochrane review 2007 – prophylactic systemic antibiotics reduce the risk of wound infection but these are not required for longer than 24 hours post operatively. There was no evidence to support rifampicin bonding, suction drains, pre operative bathing or shower regimes with antiseptic.

In a presentation at the SVS 2008 meeting, it was reported that the 30 day mortality was 2.7% and this correlated with age, weight, copd, renal failure, cerebro vascular disease. Major morbidity occurred in 18.7% including graft thrombosis (7.4%), wound infection (11.7%, with an increased risk with longer operations). There was also an increased risk of major systemic complications with ga. Mean surgical time was 4 hours. The combination of dialysis and age over 80 years resulted in a 30% mortality.

Results.
A Cochrane review in 2000 concluded that there was no clear evidence for the preference of saphenous vein or PTFE as conduit for above knee (AK) bypass but a recent meta-analysis of AK fem pop (EJVES 2004) showed:

	Venous	PTFE
2 year primary patency	81%	67%
2 year secondary patency	77%	75%
5 year primary patency	69%	49%
5 year seconday patency	65%	60%

Thus secondary patency rates are similar but primary patency rates favour vein grafts. In the Swedvasc registry (EJVES 2005), 56% of patients having AK fem pop had critical ischaemia and 44% had claudication. 28% had vein grafts, the remainder PTFE. Poor run off was more common in patients with critical ischaemia. Patency rates were worse for critical ischaemia and PTFE grafts. In 41% of those patients with claudication who's graft occluded, symptoms were worse than pre operatively. All, except one patient, with symptom aggravation had PTFE grafts. The amputation rate between vein and PTFE was no different.
In BK bypass with PTFE, patency is improved with a vein cuff (45% patency at 3 years vs. 19% with no cuff (Griffiths BJS 2004)). The Miller cuff is where vein is sutured to the vessel to form a collar. St Mary's boot is a modification.
Femoro tibial bypass primary patency at one year is 50%.
Popliteal to tibial bypass primary patency rate is 81.5% at one year and 63.1% at 5 years.

Low molecular weight heparin for three months following bypass does not aid patency (EJVES 2005).

If a BK bypass occludes there is a higher amputation rate when compared to AK bypasses.

Mofidi (VSSGBI abstract book 2007) showed that vein of less than 3.5mm on pre operative duplex resulted in grafts that required more re-interventions to maintain patency. Re-intervention was also associated with smoking, diabetes, renal failure. However, there was no difference in overall graft

patency or amputation rates when small veins were compared to larger veins. He concluded that veins less than 3.5mm should still be used in preference to synthetic grafts.

BASIL study (Lancet 2005) – bypass versus angioplasty in severe leg ischaemia. 452 patients. 6 month amputation free survival was not significantly different between bypass and angioplasty, HRQL was similar, but surgery was 30% more expensive. 30 day mortality was 5% following surgery and 3% following angioplasty. Clinical success at one year was 56% for surgery and 50% for angioplasty. However later results did show a survival advantage for bypass ($p = 0.009$) and that angioplasty was better than prosthetic bypass. They also showed that those who had a failed angioplasty had worse outcomes following bypass.

Randomised comparison of percutaneous Viabahn stent graft vs prosthetic above knee fem pop bypass (Kedora JVS 2007).
40 randomised the stent grafting and 46 to open surgery.

		3 months	6 months	12 months
Primary patent	Stent graft	84%	82%	73.5%
	Surgery	90	81.8	74.2
Secondary patency	Stent graft			83.7%
	Surgery			83.9%
Limb salvage	Stent graft			98%
	Surgery			89.6%

No significant difference in primary or secondary patency. Mean of two stent grafts per patients. Length of hospital stay was 0.9 days following stent graft and 3.1 days following surgery.

Duplex surveillance
Commonly performed but randomised trials show no difference in limb salvage. Lesions can be corrected by PTA or operation.

Intimal hyperplasia (see chapter on restenosis)
There is a compliance mismatch between the bypass graft and the native recipient artery. At the anastomosis, there is a hypercompliant zone 1 – 4mm proximal and distal to the suture line, called the para anastomotic hypercompliant zone. This may be due to the suture material or suture technique.

Graft infections.
Incidence = 1.5%. Early graft reintervention increases the risk of graft infection (Kolakowski JVS 2007). Traditional management of infected prosthetic grafts is to remove the infected graft. There are some who report success with wound debridement, antibiotics and VAC wound management.

Vascularised muscle flaps and arterial graft infection in the groin.
Rectus femoris – blood supply from profunda. Mobilisation is from distal to proximal to preserve proximal arterial inflow. The distal vascular pedicel can be ligated.
Sartorius – arises from ASIS and terminates in an aponeurosis at the medial tibia. Myoplasty involves dividing the enveloping fascia longitudinally and mobilising the herniated muscle fibres medially. Alternatively the muscle is detached from its origin and transposed medially. Sartorius has a segmental arterial supply by superficial femoral, lateral circumflex and geniculate branches from the popliteal artery. These branches enter the muscle on the posteromedial aspect, thus twisting the muscle on its medial aspect may preserve the blood supply but extensive dissection should be avoided.
Rectus abdominus muscle – arterial supply from inferior epigastric.
Gracilis
Tensor fascsia lata flap -

Limb salvage by fem distal bypass and free muscle flap transfer.
Can use gracilis muscle (minimum donor morbidity), rectus abdominus and latissimus dorsi (for more extensive defects).
One month graft patency and viable muscle flap – 85%. 60% regain full functional capacity of limb. 5yr patency – 77%. 4 year patient survival – 80%. Combination of diabetes and renal failure strongest predictor of limb loss (Czerny, EJVES 2004)

Profundaplasty.
The profunda artery arises from the posterolateral aspect of common femoral artery. The first branches are the medial and lateral circumflex branches. In 18%, these can arise directly from the CFA. Access to the profunda artery usually requires ligation of circumflex iliac vein.
Atherosclerosis of the profunda artery usually involves the proximal portion.
Patch angioplasty can use a segment of the SFA, vein or prosthetic. Profundaplasty is more successful in those with higher ABPI's. With extensive foot gangrene, profundaplasty rarely works. 60 – 70% one year patency. Good tibial outflow correlated with success.

Venous arterialisation.
Secondary graft patentcy at 12 months 46%. 12 month foot preservation rate of 71%. . Nearly all patients get leg and foot oedema. Usually resolves after 5 – 30 days. Involves distal venous arterialisation with destruction of the diatl venous valves. The valves can be destroyed by passage of Fogarty balloon or guidewire.

Drug therapy.
PGI_2 may result in resolution of rest pain and may help ulcer healing. Better results with intra-arterial infusion. There is one stable oral preparation (Beraprost) available in Japan. Intravenous iloprost is also useful at reducing rest pain in those not reconstructable. It may also lead to improved ulcer healing, reduced amputation rate and reduced death rate.
The protacyclin analog remodulin (UT-15) has recently been introduced for treatment of primary pulmonary hypertension.

Spinal cord stimulation.
There is no long term benefit for this. (Klomp EJVES 2006).

Cochrane reviews:
Antiplatelet agents for preventing thrombosis after peripheral arterial bypass surgery – aspirin has a slight benefit on the patency of peripheral bypasses, more so with prosthetic grafts than venous grafts. The effect on cardiovascular outcomes and survival was mild and not statistically significant.
Antithrombotic agents for preventing thrombosis after infrainguinal arterial bypass surgery – warfarin improves venous by not prosthetic graft patency.
Spinal cord stimulation for non reconstructable chronic critical leg ischaemia – limb salvage after 12 months is higher in the SCS group and there is better pain control. But there is no difference in ulcer healing. It is more expensive than conservative treatment.
Naftidrofuryl for critical limb ischaemia – reduced pain and analgesic requirements but not statistically significant. Withdrawn from IV treatment for limb ischaemia due to side effects.
Antiplatlet and anticoagulation drugs for prevention of restenosis/reocclusion following peripheral endovascular treatment – 60% reduction of recurrent obstruction when aspirin plus dipyridamol is compared to placebo. Periinterventional treatment with LMWH resulted in lower restenosis/reocclusion rates than with UH.

Stem cell therapy.
Stem and progenitor cells harvested from bone marrow.