

# Early Experience of Limb Salvage in Critical Leg Ischaemia

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## ABSTRACT

**Background:** We report the retrospective review of 82 leg bypass grafts done in 79 patients who had critical leg ischaemia between May 1993 and November 1996. The mean age of the patients was 68 years (range 50 to 82).

**Patients:** There were 49 male and 35 female patients. Fifty-nine percent of the study population presented with gangrene, 33% had ischaemic ulceration and 58% had rest pain. Seventy-five percent of them were diabetics. Thirty-eight femoro-popliteal, 28 femoro-distal, 6 popliteal-distal, 5 pedal, 1 aorto-bifemoral, 3 axillo-bifemoral and 1 cross-over bypass grafts were done.

**Results:** The peri-operative mortality rate was 11.3% and 71% of patients were discharged with salvaged feet. Ninety percent of these legs were still viable 12 months after the operation.

**Keywords:** limb salvage, critical ischaemia, bypass grafts, diabetes mellitus

## INTRODUCTION

Critical leg ischaemia (CLI) is due to chronic arterial insufficiency from atherosclerosis which has become so severe that the foot is threatened, and unless revascularisation of the ischemic limb is undertaken promptly, limb loss would result (Figs 1a, b). Early recognition of this condition is important as the ischaemic process is gradual and insidious and guidelines are provided by the Consensus Document of Chronic Critical Leg Ischaemia to facilitate diagnosis. Essential clinical features include intractable rest pain, ulceration (Fig 1c) and gangrene (Fig 2a) in the toes or parts of the foot.

It may not be widely appreciated that this is a group of patients with limited life expectancy from severe atherosclerotic disease and only 50% of them will be alive 5 years after the diagnosis of critical limb ischaemia<sup>(2)</sup>. Most patients succumb to cardiac and cerebro-vascular complications. Amputation surgery in these patients can result in a peri-operative mortality of up to 15%<sup>(1)</sup>.

It is important to draw a distinction between patients with critical limb ischaemia and those with non-critical limb ischaemia who present with claudication or pain in their calves during walking which subsides with rest. Although these patients have a lower life expectancy at 5 years (70%)<sup>(2,3)</sup> from atherosclerotic disease, their condition can be greatly

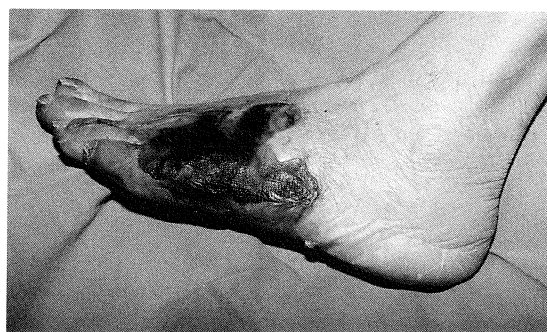


Fig 1a – Extensive foot gangrene – too late for salvage.



Fig 1b – Amputation of gangrenous third toe without revascularisation resulting in recurrent gangrene.

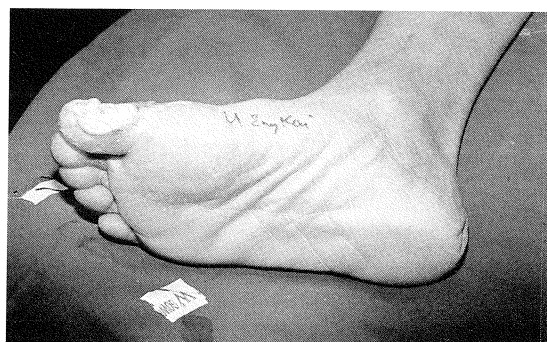


Fig 1c – Ischemic ulceration – note sloughy base with no granulation tissue.



Fig 2a – Ischemic leg with fourth toe gangrene

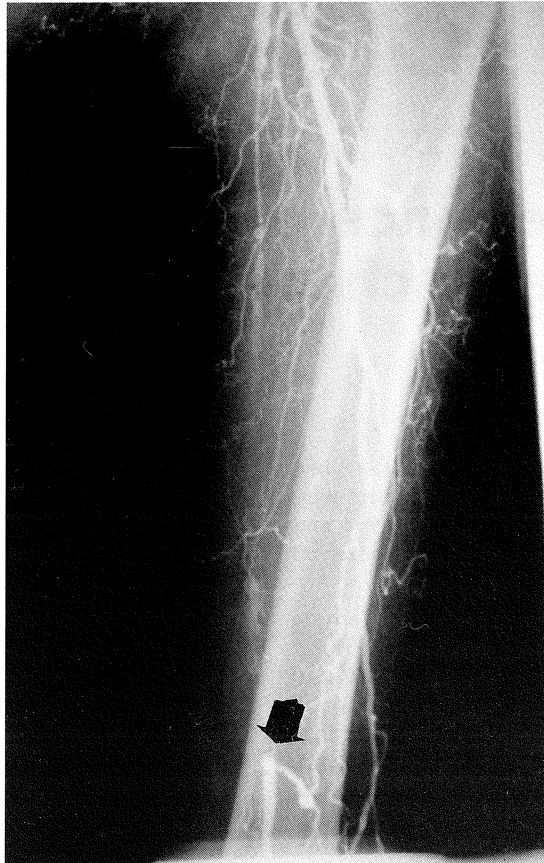
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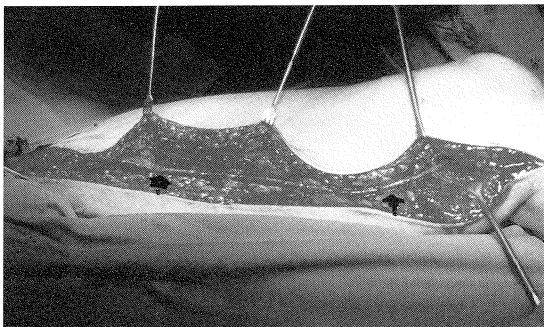
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**Fig 2b** – Arteriogram showing blocked superficial femoral artery. Popliteal artery reconstituted by profunda femoris (arrow).



**Fig 2d** – Intra-operative arteriogram showing vein bypass graft from common femoral artery proximally bringing blood to the popliteal artery bypassing the occluded superficial femoral artery.



**Fig 2c** – Above knee bypass graft using reversed vein (arrow).



**Fig 2e** – Amputation of gangrenous fourth and fifth toes with good bleeding (fifth toe became gangrenous too).

improved with exercise and cessation of cigarette smoking. Deterioration of symptoms was seen in 25% of patients over 5 years<sup>(4)</sup>. Between 9% and 21% of these patients required arterial reconstruction<sup>(4,6)</sup>.

Although the prevalence of CLI in Britain is estimated to be at 1 in 2,500 population and surgery of these patients comprise up to 50% of the workload of vascular surgeons there<sup>(7)</sup>, local figures are not yet available.

Primary major amputation is one of the ways in which patients with critical limb ischaemia can be treated. Experience in developed countries has also shown that “limb-saving” revascularisation procedures (Figs 2a-f) affect morbidity and mortality rates and is a welcoming measure which allows patients to be discharged to a better quality of life and not pose a burden to the family or support services<sup>(8)</sup>. Primary amputation has therefore been relegated as a last resort when limb salvage procedures like bypass operations have failed or are not possible<sup>(1)</sup>.



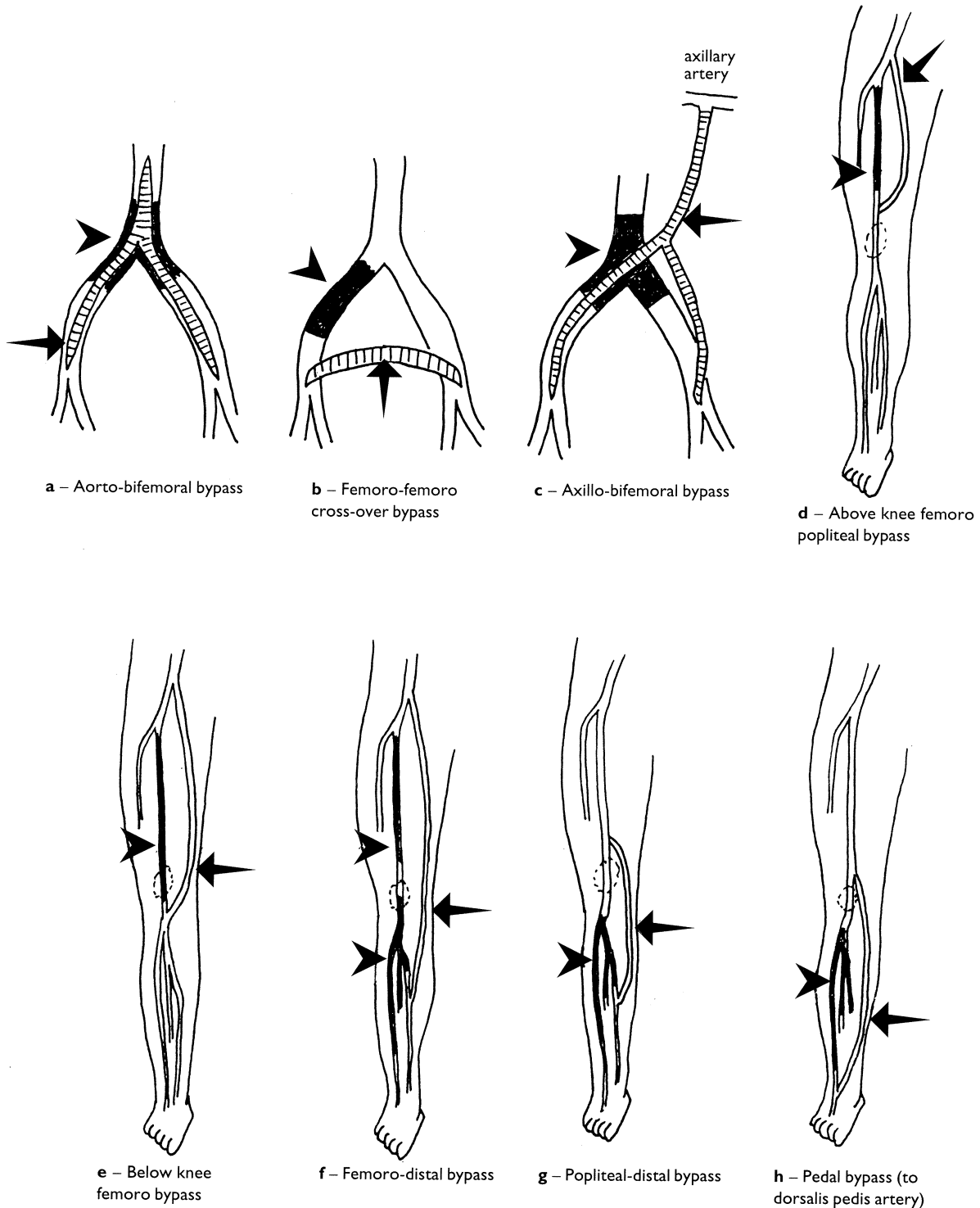
**Fig 2f** – Good healing as a result of revascularisation.

The Vascular Unit of the Department of Surgery, Singapore General Hospital has been involved in the management of these patients since its inception in 1993 and the following is a report of our early experience with these cases.

**MATERIALS AND METHODS**

The case records of 79 patients who had leg bypass procedures done for critical leg ischaemia during the period August 1993 to November 1996 were reviewed retrospectively. Patients were either recalled or interviewed over the phone. All of them had

symptoms and signs of chronic critical leg ischaemia requiring revascularisation. Bypass procedures were performed as appropriate depending on the distribution of arterial lesions as seen on the arteriograms (Figs 3a-h). Minor amputations or debridement were done for localised areas of gangrene. A successful outcome is defined as a patient who is discharged from the hospital with no rest pain and at least an intact forefoot. Patients were followed up in the outpatient clinic or visits made to them at their homes to assess the patency of their bypass grafts and the state of their healing wounds. Statistical analysis was done using the SPSS statistical package.



**Fig 3** – Types of leg bypass grafts ( → – bypass grafts    ➤ – arterial occlusion )

## RESULTS

During the 40-month period, 79 patients had 82 leg bypass operations for critical leg ischaemia. Three patients had bilateral procedures for critical limb ischaemia done within an interval period of one month, two months and two years. There were 49 men and 35 women and the mean age was 68 years (range 50 to 82). Table I shows the various modes of presentation and their proportions. Eighty-two percent of these patients had gangrene and/or ulceration resulting from critical ischaemia. Table I also shows the various associated risk factors and their proportions in the group. Seventy-five percent of them had diabetes. Their stratification according to the American Society of Anesthesiologists is shown in Table I. One third belonged to ASA category III. Table II shows the number and type of bypass done and Figs 3 a-h illustrate the configuration of the grafts. Nine patients died post-operatively from myocardial infarctions (5), sepsis (3) and pneumonia (1) giving a perioperative mortality of 11.3%. Six of the deceased belonged to ASA category III. The mortality rate stood at 30% at 6 months, the causes of which are listed in Table III. Sixteen patients encountered unsuccessful limb salvage. The types of complications are shown in Table IV. On the whole, 80% of patients had their feet spared from major amputation as a result of revascularisation. Seventy-one percent of our patients

**Table I – Presentation**

Type	No.	%
Gangrene	47	59
Ischaemic ulcers	26	33
Rest pain	46	58

### Risk factors

Type	No.	%
Hypertension	31	39
Diabetes mellitus	60	75
Ischemic heart disease	32	41
Cerebrovascular disease	10	13
Smoking	21	27

### ASA Physical classification status

Type	No.	%
I	0	0
II	54	68
III	25	32
IV	0	0

**Table II – Types of leg bypass procedure (Figs 3a-h)**

Type	No.	%
Femoro-popliteal	38	(46)
Femoro-distal	28	(34)
Aorto-bifemoral	1	(1)
Axillo-bifemoral	3	(4)
Cross-over	1	(1)
Popliteal distal	6	(7)
Pedal bypass	5	(6)
Total	82	(100)

**Table III – Causes of late mortality**

Type	No.
Gangrene	2
Pneumonia	1
End-stage renal failure	1
Cerebro-vascular accident	4
Ischemic heart disease	7
Bleeding graft	1

**Table IV – Complications**

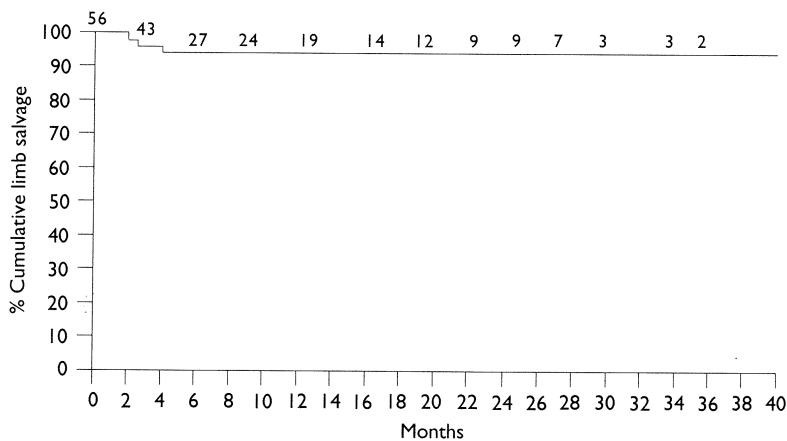
Local	No.
Wound infection	7
Wound haematoma	4
False aneurysm	1
Foot infection/poor healing	9
Bleeding graft	4
<b>General</b>	
Pneumonia	4
Myocardial infarction	7
Cerebro-vascular accident	2
Erythema multiforme major	1
Bleeding GIT	3
Congestive cardiac failure	4
COLD exacerbation	1

were discharged from hospital with salvaged feet (this number does not include in-patient mortalities), and life table analysis revealed that 90% of them were doing well 19 months after their operation (Fig 4). Only 56 patients were available for follow-up after excluding peri-operative deaths and patients with failed salvage due to foot infection or blocked grafts.

## DISCUSSION

The management of patients with critical limb ischaemia has usually been discouraging as limb loss was often necessary after minor ablative surgery for gangrene in view of the poor blood supply and retarded wound healing. Elderly patients do not rehabilitate well with their prostheses and become dependent on their families or support services. Those who are bed-ridden eventually succumb to problems associated with immobilisation such as pneumonia, bedsores, urinary tract infection, osteoporosis, deep vein thrombosis etc. Many become depressed as a result of the major amputation and a significant number (up to 30%) would also lose the other leg within 3 years from atherosclerotic disease. Operative mortality for major amputation is 10% to 15% for diabetic gangrene<sup>(1)</sup> and late mortality is 25%, consistent with the poor life expectancy of these patients as a whole (50% in 5 years)<sup>(2)</sup>.

It is advisable to attempt to "save" their feet through revascularisation wherever possible to facilitate rehabilitation and ensure a good quality of life for the limited number of their remaining years. In this sense, reconstructive surgery for leg ischemia is a "palliative" undertaking similar to palliation in cancer<sup>(8)</sup>.



**Fig 4** – Kaplan-Meier curve showing cumulative limb salvage. Numbers in italics are number of limbs at risk at beginning of each 3-month period.

Patients with chronic limb ischemia are typically afflicted with generalised atherosclerotic disease characterised predominantly by males, old age, multiple associated medical problems and a strong history of cigarette smoking as in the Western communities. Our patient cohort is slightly different with a lower median age of 68 and only 27% were smokers.

The reason may be related to the other significant finding of which 75% of them were diabetic (Table I), and this doubled the proportion reported in Western literature. This has important implications for the management of these patients as 8% of the population of Singapore is diabetic<sup>(9)</sup> and 50% will have foot problems at some stage with 60% of them being associated with ischaemia, which may be amenable to revascularisation<sup>(10)</sup>. It is well known that diabetics often have more distal atherosclerotic disease of the leg and they present at a younger age<sup>(11)</sup>.

However, it may not be obvious to many that revascularisation can still be possible and limb salvage is achievable<sup>(2)</sup>. Diabetics have exactly the same ischemic problems as non-diabetics except for the more frequent distal distribution of their atherosclerotic disease affecting mainly the calf vessels and should be treated in the same way by revascularisation if possible<sup>(13)</sup>. The proportion of distal bypasses (Table III) is a reflection of this but it is also noteworthy that half of the patients with femoro-popliteal bypass done were diabetics as well. Certainly, diabetic patients should not be denied vascular assessment for possible leg bypass procedures where necessary and recent evidence do not give credence to the pessimistic and nihilistic view attached to “diabetic microangiopathy”<sup>(2)</sup>.

A “wholistic” approach to patient care is mandatory in achieving good surgical outcomes as many of these patients have multiple medical problems (Table I) and one quarter of them are significantly debilitated (Table II). This is reflected in the peri-operative (30-day) mortality of 11%, and a late mortality of 30% (Table IV) between 4 and 14 months after surgery. Seven patients who died had functioning grafts and salvageable feet. A multidisciplinary approach involving cardiologist, endocrinologist, anaesthetist, physiotherapist, podiatrist is often necessary and post-operative monitoring in the High Dependency Unit and even Intensive Care Unit is usually required. Compromised physical status (ASA III) need not be a contraindication to reconstructive surgery provided that pre-operative optimisation is adequate with close intra- and post-operative monitoring and maintenance of hemodynamic status. Ouriel et al reported lower mortality rates and shorter hospital stays in patients with revascularisation compared to those who had amputation<sup>(14)</sup>.

**Table V** – Life table analysis of limb salvage

Interval (months)	No. of limbs at risk at start	No. of failed salvage	No. of withdrawn patients due to			Interval salvage rate	Cumulative salvage (%)	Standard error (%)
			Duration	Lost to F/U	Death			
0 – 3	56	1	9	0	3	0.98	98	2.0
3 – 6	43	2	6	2	6	0.94	93	4.2
6 – 9	27	0	2	0	1	1.00	93	4.2
9 – 12	24	0	3	0	2	1.00	93	4.2
12 – 15	9	1	3	0	1	0.94	87	6.6
15 – 18	14	0	2	0	0	1.00	87	6.6
18 – 21	12	0	3	0	0	1.00	87	6.6
21 – 24	9	0	0	0	0	1.00	87	6.6
24 – 27	9	0	2	0	0	1.00	87	6.6
27 – 30	7	0	4	0	0	1.00	87	6.6
30 – 33	3	0	0	0	0	1.00	87	6.6
33 – 36	3	0	1	0	0	1.00	87	6.6
36 – 39	2	0	2	0	0	1.00	87	6.6

F/U – follow-up

Ten of our patients had primary graft failure within 24 hours. Five were due to poor run-off vessels with high resistance to flow, 4 were technical failures and one had poor inflow. Patient selection continues to be a challenging area of clinical judgement here as there is no foolproof formula to ensure success in every case. Intra-operative resistance measurements of the run-off bed has been shown to be useful in predicting graft failures<sup>(15)</sup> but we have not done this on our patients. Five diabetic patients had functioning grafts but salvage was not possible because of persistent foot infection. Another diabetic patient had an infected functioning graft that bled and had to be ligated.

Our 71% limb salvage rate is an encouraging result. Harris also reported a 75% limb salvage rate in a National Survey conducted by the Vascular Surgical Research Society of Great Britain and Ireland<sup>(7)</sup>. The mean mortality rate was 13.5%. In his study, amputation was associated with a significantly higher mortality, longer hospital stay and a larger proportion of patients requiring long-term hospitalisation.

In conclusion, patients with critical leg ischaemia should be promptly admitted for early assessment and have revascularisation done wherever feasible to save their feet regardless of diabetic status. Patient education with regard to the early symptoms and signs of this condition will greatly assist in limb salvage before it is too late (Fig 1a). The medical community on its part should constantly be alert to ensure early diagnosis and treatment.

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