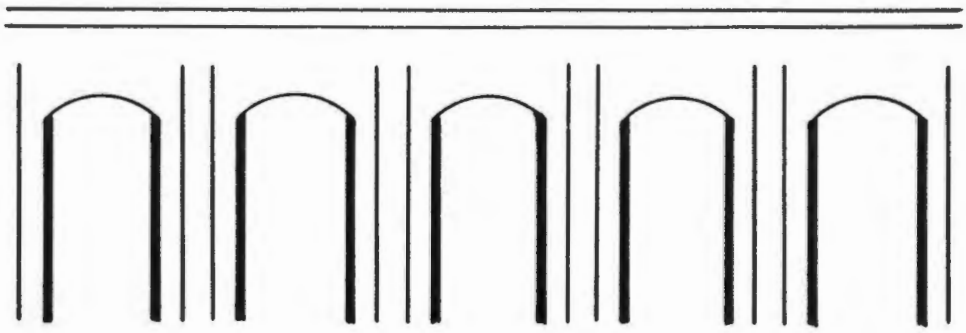

# INFRA-INGUINAL ARTERIAL BYPASS PROCEDURES AT GROOTE SCHUUR HOSPITAL 1977-1983

## Analysis and evaluation of Results

DAVID HYMAN BASS, MB ChB FCS(SA)

A Dissertation submitted to the Faculty of Medicine of the University of Cape Town in partial fulfilment of the requirement for the Degree of Master of Medicine (Surgery)

Date Submitted - July 1986

I hereby declare that this Dissertation is my own work and has not been presented for any Degree of another University.

Signed by candidate

Signature removed

David Hyman Bass

20th July, 1986.

The work reported in this Dissertation was performed in the Department of Surgery, University of Cape Town, and the Department of Computer Studies, University of Birmingham, United Kingdom.

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ABSTRACT

Infra-inguinal arterial bypass is becoming increasingly popular as a means of alleviating incapacitating symptoms of atherosclerosis and other progressive diseases affecting the arteries of the lower limb. The role of this procedure in limb salvage is controversial but an aggressive attitude is emerging from many centres. It is accepted that the majority of atherosclerotic patients have a short life expectancy but reconstructive vascular surgery has an important role to play in improving their quality of life. Progress in infra-inguinal bypass surgery has centred mainly on the development of synthetic grafts but the performance of autologous saphenous vein has not been bettered in terms of long-term results and cost-effectivity.

The initial experience of infra-inguinal bypass at Groote Schuur Hospital, Cape Town, is examined retrospectively with the objective of demonstrating the possible influence of patient factors and specific surgical practices on the outcome of results.

## INTRODUCTION

Atherosclerotic occlusive disease of the lower limb constitutes a significant cause of disability in the sixth and seventh decades, presenting as intermittent claudication, rest pain or as an area of ischaemic necrosis. In 1949 Kunlin described the first use of reversed autologous saphenous vein (RSV) to bypass an atherosclerotic occlusion of the superficial femoral artery and this technique still exists as the "gold standard" of femoro-distal bypass surgery today (Kunlin 1949; De Weese 1977). The realisation that suitable autologous saphenous vein would not always be available inspired enthusiastic research into the development of synthetic alternatives. The use of polyethylene terephthalate (Dacron™) grafts was first reported by De Bakey in 1958 and the use of this material in infra-inguinal bypass surgery has been popularised by Sauvage and others (Sauvage 1981; Mosley 1986). The need for preclotting and high thrombogenicity of knitted Dacron prostheses may in part have been responsible for the emergence of expanded polytetrafluoroethylene (PTFE) grafts as the vein substitutes of choice and these have been in widespread use for the last 10 years (Campbell 1976; Klimach 1984). At the present time, however, the cost of PTFE is substantially higher than that of Dacron.

Despite early scepticism it now appears from the results of both retrospective and prospective studies that PTFE grafts perform as well as RSV with regard to above-knee anastomoses

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Veith 1978; Bergan, Veith et al 1982). Where anastomosis to the distal popliteal artery or tibial vessels is necessary saphenous vein, either reversed or utilised by the increasingly popular "in situ" technique still remains the most "ideal conduit" (Bergan, Yao et al 1982; Ricco 1983).

It is unfortunately the patient factors in peripheral bypass surgery that defy improvement by scientific means. Vascular surgeons are faced with the sombre reality that patients requiring femoro-popliteal and especially femoro-tibial bypass are elderly and have a high incidence of associated cardio-vascular and cerebrovascular disease. It is now accepted that approximately 50% of patients undergoing femoro-distal bypass for occlusive disease will have died from associated athero-sclerotic disease within 5 years (De Weese 1977). This gloomy prognosis has fostered a critical, even pessimistic, outlook towards reconstructive surgery on the part of some authors but the call for conservative rather than surgical management becomes fainter as time progresses and improved results for limb salvage after bypass surgery appear in the literature (Veith 1981). The rising cost of arterial bypass surgery is yet another problem facing advocates of reconstructive surgery. This had led some American surgeons to question again whether primary amputation might not be a more cost-effective solution to critical ischaemia than attempts at reconstruction (Mackay 1985).

This Dissertation describes the Groote Schuur Hospital experience of 156 infra-inguinal bypass operations and the results achieved in terms of graft patency and limb salvage.

Included in this study are sufficient numbers of RSV and PTFE grafts allowing a comparative evaluation of our experience with each of these 2 conduits. Our approach to limb salvage has been surgically aggressive and it is also the purpose of this study to reveal whether such a policy is justified in terms of cumulative limb salvage as well as rising financial costs.

## PATIENTS AND METHODS

Examination of theatre records at Groote Schuur Hospital, Cape Town, revealed that between January 1977 and December 1983 148 patients had undergone a total of 172 femoro-popliteal or femoro-tibial bypass procedures. During the first 6 months of 1985 the case-sheets of these patients were examined. Patients on whom follow-up data were incomplete were recalled to the vascular laboratory at the above institution for clinical assessment and measurement of peripheral arterial pressures by Doppler ultrasound. Clinical assessment was performed by the author and ultrasonic measurement by a nursing sister experienced in non-invasive investigation. Sixteen patients were unavailable for follow-up, all having originally been referred to us from outside South Africa. Follow-up data were therefore available on 89.2% of our patients.

TABLE I - Clinical Features of the Patients Studied (n=132)

| | | |
|---|---|---|
| Age Distribution: | Mean | 59 yrs |
| | Range | 28-87 yrs |
| Sex Distribution: | Male | 109 (83%) |
| | Female | 23 (17%) |
| Race Distribution: | White | 72 (54.2%) |
| | Coloured | 59 (45%) |
| | Black | 1 (0.8%) |
| Incidence of Cigarette Smoking: | Smokers | 112 (85%) |
| | Non-smokers | 20 (15%) |
| Incidence of Diabetes Mellitus: | Diabetic | 29 (22%) |
| | Non-diabetic | 103 (78%) |
| Incidence of Ischaemic Heart Disease: | Present | 70 (53%) |
| | Absent | 62 (47%) |
| History of Previous Aorto-Iliac Surgery: | Prev surgery | 30 (23%) |
| | No prev surgery | 102 (77%) |

The clinical features of the patients are summarised in

Table I. Of note is the large number of patients who were cigarette smokers. On the basis of clinical and angiographic features, arterial pathology in 125 (95%) patients was attributed to senile atherosclerosis. Other primary diseases were thromboangiitis obliterans (5 patients), juvenile atheroma (1 patient), while one young male patient with rheumatic heart disease required femoro-popliteal bypass following an unsuccessful femoral embolectomy.

Of 156 bypass procedures only 44 (28.2%) were indicated for incapacitating intermittent claudication, whilst the remaining 112 were performed as limb salvage procedures in patients presenting with critical ischaemia. The latter description was applied to patients with (a) a convincing history of rest pain [36], (b) gangrene extending proximal to the metatarso-phalangeal joints of the foot [39], and (c) a Doppler pressure of less than 40mmHg at the posterior tibial artery [37]. Thirty bypass operations were performed on patients who had previously undergone proximal (i.e. aorto-iliac) surgery for either aneurysmal or stenosing disease. No patient in this series, however, underwent proximal surgery simultaneously with infra-inguinal bypass.

Pre-Operative Assessment

All patients selected for lower limb arterial bypass were admitted to hospital for clinical assessment and peripheral angiography. Arteriographic run-off was poor (0-1 vessel) in 71 (45.5%) legs, good (2-3 vessel) in 84 (54%) legs, and unknown in one case. From 1978 onwards Doppler measurement of all peripheral pulse pressures was routine for pre-operative assessment as well as post-operative monitoring of graft function.

Grafts and Technique

In 40 (25.6%) bypasses ipsilateral RSV was sought, found to be of good quality and used as a graft. Of these, almost equal numbers were placed distally above (22) and below (18) the knee. The technique used for harvesting and placing the vein graft was similar to that described by De Weese and Rob (De Weese 1977). PTFE (Impra™ or Gore-Tex™) were used in 95 (60.9%) operations, either because suitable RSV was not available or in order to allow a quicker operation in high-risk patients. Altogether 72/95 PTFE grafts were utilised for limb salvage procedures. Forty PTFE grafts were placed above the knee and 55 below. Other grafts used were composite (PTFE to the knee, RSV across the knee) in 7 (4.5%), and knitted Dacron in 14 (9%) operations. Of 156 grafts, 67 (43.6%) were anastomosed distally to the popliteal artery above the knee, 65 (41.7%) to the same vessel below the knee joint, and 24 (14.7%) to the tibioperoneal trunk or a single calf vessel. Sixty-eight (77.3%) of the 89 operations involving below-knee anastomoses were indicated for limb salvage. Intra-operative angiography was not used. Where a limb was considered clinically viable despite poor angiographic run-off from the popliteal artery, the latter was often explored at the knee to confirm the quality of retrograde flow before the ultimate decision was taken whether to proceed with or abandon the bypass.

All patients with synthetic grafts were given a 24-hour course of parenteral antibiotic cover, beginning with induction of anaesthesia. Post-operatively, all patients were advised to take 100 mg dipyridamole and 75 mg acetylsalicylic acid daily if prosthetic grafts had been used.

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## Follow-Up Routine

The majority of patients discharged from hospital after successful bypass were followed-up as outpatients. Patients from the metropolitan area of Cape Town attended regularly. Those from far outlying areas, however, often returned to our Unit with severe recurrent ischaemia requiring major amputation or, less frequently, another bypass for limb salvage. Patients whose state of health, ambulation or graft function was not recently documented in their case-sheets were contacted by telephone, letter, home-visit, or via their general practitioners. Appointments were then offered for return to our vascular laboratory for clinical and Doppler pressure assessment.

## Definitions

In the assessment of results after bypass operations in this series, loss of graft patency was considered to have occurred only when there was convincing evidence clinically (loss of a previously palpable pulse at the distal end of the graft), confirmed by a new fall in Doppler-measured pulse pressures. Limb salvage ended when the patient died, required major amputation of the limb, or was selected for a secondary bypass. Neither graft patency nor limb salvage was considered as interrupted where a patient required graft thrombectomy or revision of either anastomosis in the post-operative period.

## RESULTS

All patient data were fed into a Honeywell microcomputer as part of the Multics system at the University of Birmingham. Cumulative graft patency and limb salvage rates were calculated by the life-table method, using a statistical programme designed for social sciences. The significance of various factors possibly influencing patency and salvage rates was tested using log-rank analysis by the Lee Desu method (Lee 1972).

### Operative Morbidity and Mortality

Early post-operative complications directly attributable to bypass are summarised in Table II.

TABLE II POST-OPERATIVE COMPLICATIONS AFTER 156 OPERATIONS

| | No | %age |
|---|---|---|
| Death | | |
| - due to related causes | 7 | 4.5 |
| - due to unrelated causes | 1 | 0.6 |
| Sepsis | | |
| - affecting graft | 0 | |
| - superficial | 7 | 4.5 |
| Wound haematoma | 3 | 1.9 |
| Compartment syndrome | 2 | 1.3 |
| Calf vein thrombosis | 2 | 1.3 |
| Lateral popliteal nerve palsy | 1 | 0.7 |
| TOTAL | 23 | 14.8 |

Superficial sepsis refers to that which involved no more than the skin and subcutaneous tissue adjacent to either femoral or popliteal incision. Post-operative mortality is defined as death within 30 days of a bypass operation and includes patients

who died following amputation for a failed bypass. Of the 8 deaths in this period, the 7 due to related causes occurred in patients with a background of cerebrovascular or ischaemic heart disease. The remaining patient, aged 30 years, died in a motor traffic accident. Seven of the 8 deaths occurred in patients who had undergone limb salvage procedures.

Delayed Mortality

Twenty-one (15.9%) patients in this series are known to have died later than 30 days after bypass surgery. Of these, only 4 died from unrelated causes, those being malignancy (3) and necrotising fasciitis (1). Of the 15 patients dying from atheroma-related conditions, all but one had a background of ischaemic heart disease. Only 13 (9.9%) of the 21 patients dying enjoyed limb salvage up to the time of death.

Graft Patency

Life-table analysis of cumulative graft patency for all operations is shown in Table III. Of the 127 grafts occluding between 1977 and 1985, 25 (19%) occluded within the post-operative period and a further 18 (13%) within the first 6 months. Cumulative graft patency rates were therefore 71% at 6 months, falling to 32% at 2 years and 14% at 4 years. The mean value for length of graft patency in the series was 16.31 ± 19.95 months.

Limb Salvage

Life-table analysis of cumulative limb salvage achieved in this series is shown in Table IV. Limb salvage was lost immediately after 17 (10.9%) operations and within 6 months for a further 11 (8%). Cumulative limb salvage was therefore 81% at 6 months, falling to 56% at 2 years and 23% at 4 years.

TABLE III CUMULATIVE PATENCY RATES FOR ALL 156 OPERATIONS

| INTERVAL (months) | NO GRAFTS ENTERING | NO WITHDRAWN | NO GRAFTS AT RISK | NO GRAFTS OCCLUDING | PROPORTION OCCLUDING | PROPORTION PATENT | CUMULATIVE PATENCY RATE (%) |
|---|---|---|---|---|---|---|---|
| 0 - 6 | 156 | 17 | 147.5 | 43 | 0.2915 | 0.7085 | 70.85 |
| 7 - 12 | 96 | 4 | 94.0 | 18 | 0.1915 | 0.8085 | 57.28 |
| 13 - 18 | 74 | 1 | 73.5 | 13 | 0.1769 | 0.8231 | 47.15 |
| 19 - 24 | 60 | 0 | 60.0 | 12 | 0.2000 | 0.8000 | 37.72 |
| 25 - 30 | 48 | 1 | 47.5 | 7 | 0.1474 | 0.8526 | 32.16 |
| 31 - 36 | 40 | 1 | 39.5 | 9 | 0.2278 | 0.7722 | 24.83 |
| 37 - 42 | 30 | 1 | 29.5 | 7 | 0.2373 | 0.7627 | 18.94 |
| 43 - 48 | 22 | 1 | 21.5 | 5 | 0.2326 | 0.7674 | 14.54 |
| *48+ | 16 | 3 | 14.5 | 13 | 0.8966 | 0.1034 | 1.50 |

*48+ : This interval includes grafts failing up to 84 months after surgery

TABLE IV CUMULATIVE LIMB SALVAGE RATES FOR ALL 156 OPERATIONS

| INTERVAL (months) | NO LIMBS ENTERING | NO WITHDRAWN | NO LIMBS AT RISK | *LIMBS NO LONGER SALVAGED | PROPORTION FAILING | PROPORTION SALVAGED | CUMULATIVE SALVAGE RATE (%) |
|---|---|---|---|---|---|---|---|
| 0 - 6 | 156 | 15 | 148.5 | 28 | 0.1886 | 0.8114 | 81.14 |
| 7 - 12 | 113 | 3 | 111.5 | 12 | 0.1076 | 0.8924 | 72.41 |
| 13 - 18 | 98 | 2 | 97.0 | 8 | 0.0825 | 0.9175 | 66.44 |
| 19 - 24 | 88 | 0 | 88.0 | 13 | 0.1477 | 0.8523 | 56.62 |
| 25 - 30 | 75 | 1 | 74.5 | 12 | 0.1611 | 0.8389 | 47.50 |
| 31 - 36 | 62 | 1 | 61.5 | 9 | 0.1463 | 0.8537 | 40.55 |
| 37 - 42 | 52 | 1 | 51.5 | 13 | 0.2524 | 0.7476 | 30.32 |
| 42 - 48 | 38 | 2 | 37.0 | 9 | 0.2432 | 0.7568 | 22.94 |
| 48+ | 27 | 4 | 25.0 | 23 | 0.9200 | 0.0800 | 1.84 |

*Limb salvage lost due to death, amputation or timing of study

TABLE Va GRAFT PATENCY AND LIMB SALVAGE: FACTORS AFFECTING THE OUTCOME OF 156 OPERATIONS

| | | Graft Patency Mean Value (months) | Significance | Limb Salvage Mean Value (months) | Significance |
|---|---|---|---|---|---|
| RACE | | | | | |
| White | (n=83) | 21.67 | p=0.02* | 35.63 | p=0.01* |
| Coloured | (n=70) | 11.63 | | 24.74 | |
| DIABETIC STATUS | | | | | |
| Non-diabetic | (n=125) | 17.72 | p=0.12 | 29.40 | p=0.14 |
| Diabetic | (n=31) | 10.67 | | 23.60 | |
| INDICATION FOR BYPASS | | | | | |
| Claudication | (n=44) | 23.16 | p=0.32 | 31.07 | p=0.22 |
| Critical ischaemia | (n=112) | 18.74 | | 24.21 | |
| HISTORY OF CIGARETTE SMOKING | | | | | |
| Smokers | (n=129) | 14.11 | p=0.40 | 27.51 | p=0.32 |
| Non-smokers | (n=27) | 16.71 | | 37.18 | |
| PREVIOUS PROXIMAL SURGERY | | | | | |
| Previous surgery | (n=28) | 10.81 | p=0.46 | 29.39 | p=0.50 |
| No previous surgery | (n=128) | 18.93 | | 23.02 | |
| ANGIOGRAPHIC RUN-OFF | | | | | |
| Poor (0-1 vessel) | (n=71) | 12.31 | p=0.10 | 18.34 | p=0.03* |
| Good (2-3 vessels) | (n=84) | 18.62 | | 29.92 | |
| DOPPLER ANKLE PRESSURE | | | | | |
| <40 mmHg | (n=37) | 15.64 | p=0.10 | 22.32 | p=0.09 |
| ⩾40 mmHg | (n=70) | 20.01 | | 28.40 | |
| GRAFT USED | | | | | |
| RSV | (n=40) | 18.93 | p=0.14 | 28.57 | p=0.50 |
| PTFE | (n=95) | 14.21 | | 27.73 | |
| SITE OF DISTAL ANASTOMOSIS | | | | | |
| Above-knee | (n=67) | 21.05 | p=0.08 | 31.17 | p=0.07 |
| Below-knee | (n=89) | 13.89 | | 21.43 | |

*denotes a significant difference between 2 of each pair of values ($p<0.05$)

Factors Influencing Graft Patency and Limb Salvage

The effect of various patient, angiographic and operative factors on patency and salvage are summarised in Table Va.

Patient factors: The only factor significantly affecting both patency and salvage was racial difference, with White patients enjoying better results than Coloureds on both counts. The contrast between results for limb salvage is illustrated in Figure 2a. In view of these findings, the clinical, angiographic and operative features of the 2 racial groups are presented for comparison in Table Vb.

TABLE Vb COMPARISON OF CLINICAL, ANGIOGRAPHIC AND OPERATIVE FEATURES ACCORDING TO RACE

| | Whites (n=83) | Coloureds (n=70) |
|---|---|---|
| INDICATION FOR BYPASS | | |
| Intermittent claudication | 24 (28.9%) | 20 (28.6%) |
| Critical ischaemia | 59 (71.1%) | 50 (71.4%) |
| SMOKING HABITS | | |
| Smokers | 64 (77.1%) | 62 (88.6%) |
| Non-smokers | 19 (22.9%) | 8 (11.4%) |
| ANGIOGRAPHIC RUN-OFF | | |
| Poor (0-1 vessel) | 35 (42.2%) | 36 (51.4%) |
| Good (2-3 vessel) | 48 (57.8%) | 34 (48.6%) |
| GRAFT USED | | |
| RSV/Composite | 35 (42.2%) | 28 (40.0%) |
| PTFE/Dacron | 48 (57.8%) | 42 (60.0%) |
| SITE OF DISTAL ANASTOMOSIS | | |
| Above-knee | 33 (39.8%) | 34 (48.6%) |
| Below-knee | 50 (60.2%) | 36 (51.4%) |

It can be seen that the indications for surgery were similarly distributed in both groups but that cigarette smoking

was more common in Coloured patients. More White than Coloured patients had good calf-vessel run-off on pre-operative angiography but, in contrast, the proportion of grafts anastomosed distally below the knee was greater in Whites. The distribution of graft material used was similar in both racial groups.

Mean values for both patency and salvage were better for non-diabetics, non-smokers, patients presenting with claudication rather than critical ischaemia, and for those patients with ankle systolic pressures of 40mmHg or more. That these differences did not attain statistical significance may be partially attributable to the unequal numbers available for comparison.

Angiographic factors: Both graft patency and limb salvage were better in patients with 2 or 3 vessel run-off than in those with single vessel run-off or a blind popliteal segment, the difference in terms of salvage only attaining statistical significance.

Operative factors: Better results were achieved overall with RSV than with PTFE, but the differences were not significant for either graft patency or limb salvage. The difference between limb salvage values for all grafts taken distally below the knee-joint and those placed above the knee approached significance ($p=0.07$).

Patency and salvage results for RSV and PTFE anastomosed distally above and below the knee-joint respectively are compared in Table Vc. Although RSV performed consistently better than PTFE, the differences in results between the 2 grafts were generally small. Life-table analysis reveals that

TABLE Vc COMPARISON OF MEAN GRAFT PATENCY AND LIMB SALVAGE (IN MONTHS) FOR RSV AND PTFE ACCORDING TO THE SITE OF DISTAL ANASTOMOSIS

| | Graft Patency | Limb Salvage |
|---|---|---|
| ABOVE-KNEE | | |
| RSV (n=22) | 21.67 | 35.58 |
| PTFE (n=40) | 20.59 | 29.41 |
| BELOW-KNEE | | |
| RSV (n=18) | 14.29 | 26.45 |
| PTFE (n=55) | 13.04 | 18.92 |

of 55 PTFE grafts placed distally below the knee, only 4 (7.3%) were patent at 4 years, all 4 operations having been performed for claudication. None of the 38 PTFE grafts taken across the knee-joint for limb salvage remained patent for longer than 30 months. Life-table analysis also reveals that cumulative patency at 6 months was superior for PTFE than for RSV but the reversal of fortunes at 4 years (19% for RSV, 12% for PTFE) suggests that PTFE grafts on the whole tended to fail later than RSV.

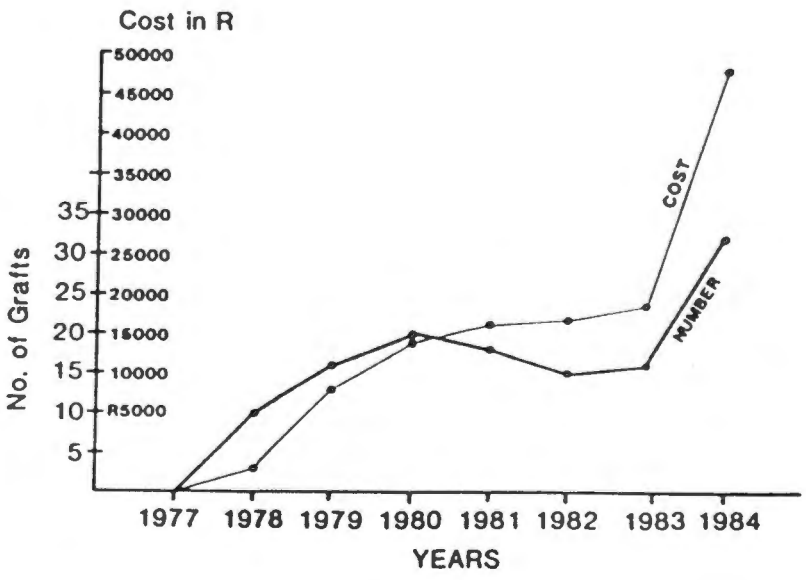


Fig. 2b Increasing costs of PTFE Grafts

The rising cost of PTFE grafts over the period of this study is illustrated in Figure 2b .

Amputation

Forty-nine patients (37%) in this series required major lower limb amputation for failed bypass or unsalvageable recurrent ischaemia at various times after reconstruction. The timing and extent of all amputations is summarised in Table VI. Only 11 (28%) amputations were successfully performed below the knee. Two required revision from below-knee to above-knee level. All but 3 limbs ultimately requiring amputation had originally been bypassed for critical ischaemia rather than claudication.

TABLE VI AMPUTATIONS (n=49)

| Time Interval After Bypass (Months) | AKA | BKA | TOTAL |
|---|---|---|---|
| 0 - 1 | 12 | 3 | 15 |
| 1 - 3 | 9 | 3 | 12 |
| 3 - 12 | 8 | 4 | 12 |
| 12 - 60 | 9 | 1 | 10 |
| TOTAL | 38 | 11 | 49 |

Reoperation

Sixteen patients required 21 operations for graft thrombectomy with or without revision of either proximal or distal anastomosis. Only 2 were performed on RSV grafts. Four of the procedures were necessary within 30 days of bypass and resulted in limb salvage lasting 2, 18, 36 and 48 months respectively. In the 17 cases where graft thrombectomy was performed more than 30 days after bypass, immediate failure required for major

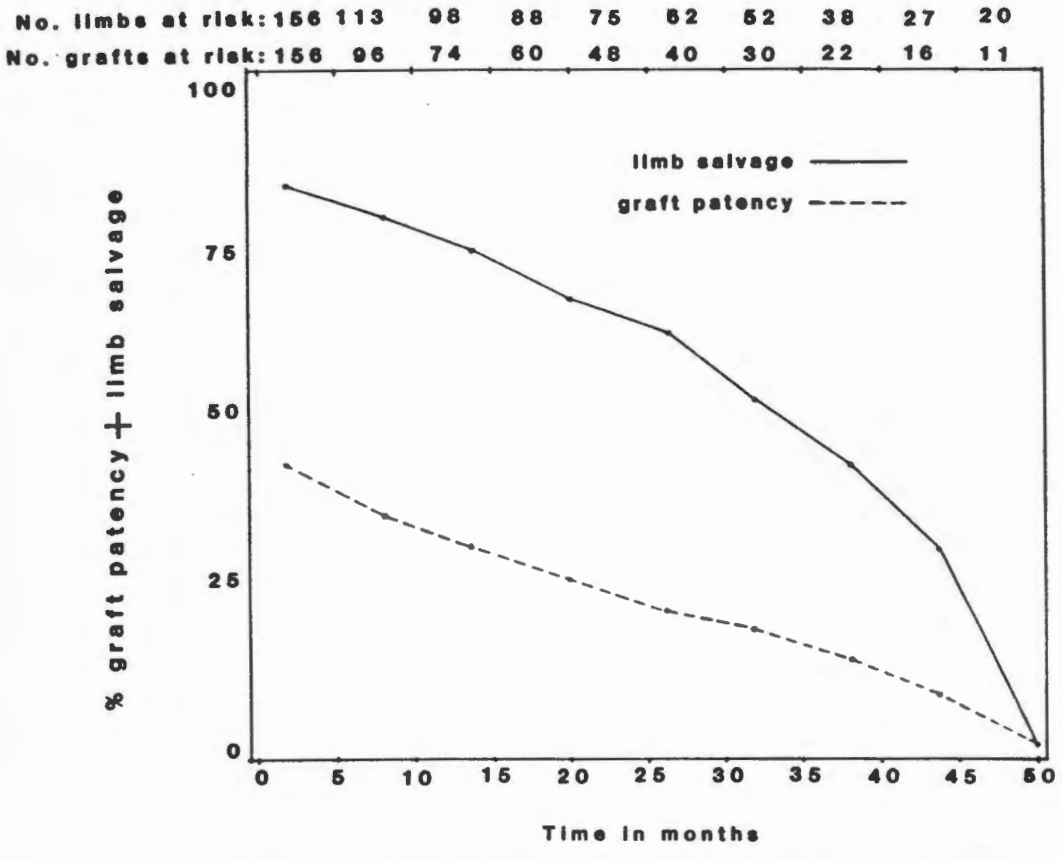


**Fig. 1 - Comparison of cumulative graft patency and limb salvage following 156 operations**

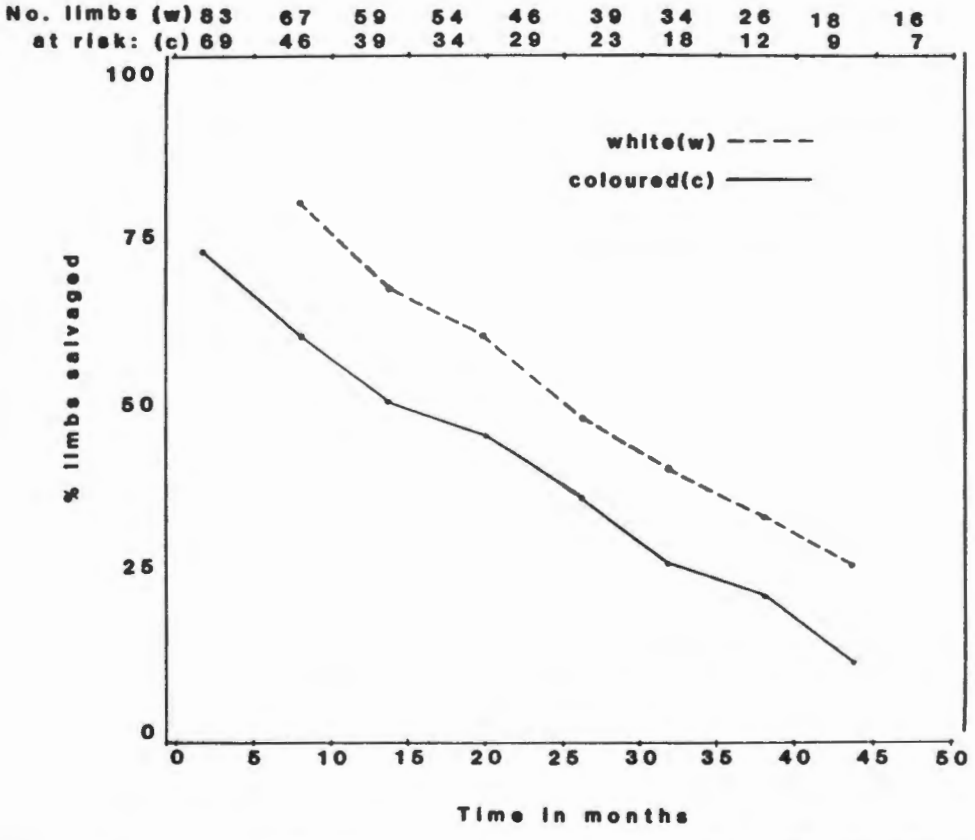


**Fig. 2 - Cumulative limb salvage compared for race**

amputation of 5 legs but the remaining 12 resulted in an average of 19.5 additional months (range 5-45 months) of limb salvage. The benefit of graft thrombectomy in each case is illustrated in Figure 3.

Fourteen grafts were replaced in 13 patients when occlusion of the original grafts precipitated recurrent critical ischaemia. All these secondary procedures were performed within 40 months of the original bypass and represent only 13.5% of the total number of grafts failing

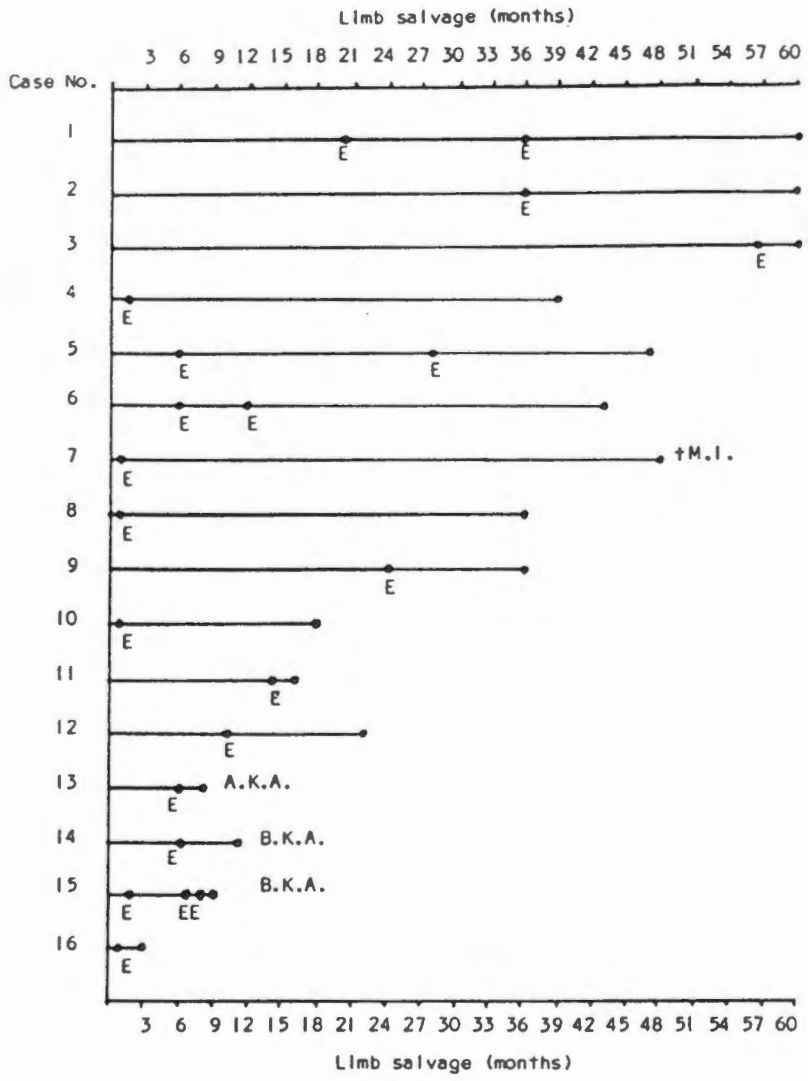


Fig. 3 Results for limb salvage in patients requiring embolectomy after bypass

E - Stage when embolectomy was performed
A.K.A. - Above knee amputation
B.K.A. - Below knee amputation
† - Died

within the same period. Five failed RSV grafts were replaced, 3 with RSV from the other leg, one with PTFE and another with Dacron. Seven PTFE grafts and one Dacron graft which occluded were all replaced with PTFE. The mean value for the additional period of limb salvage resulting from these secondary bypasses was 30.6 months. Only 3 of these operations failed immediately, thus necessitating major amputation. In contrast, 8 of the 14 regraft procedures conferred an additional 3-5 years of limb salvage. The results of these secondary procedures are shown in Figure 4.

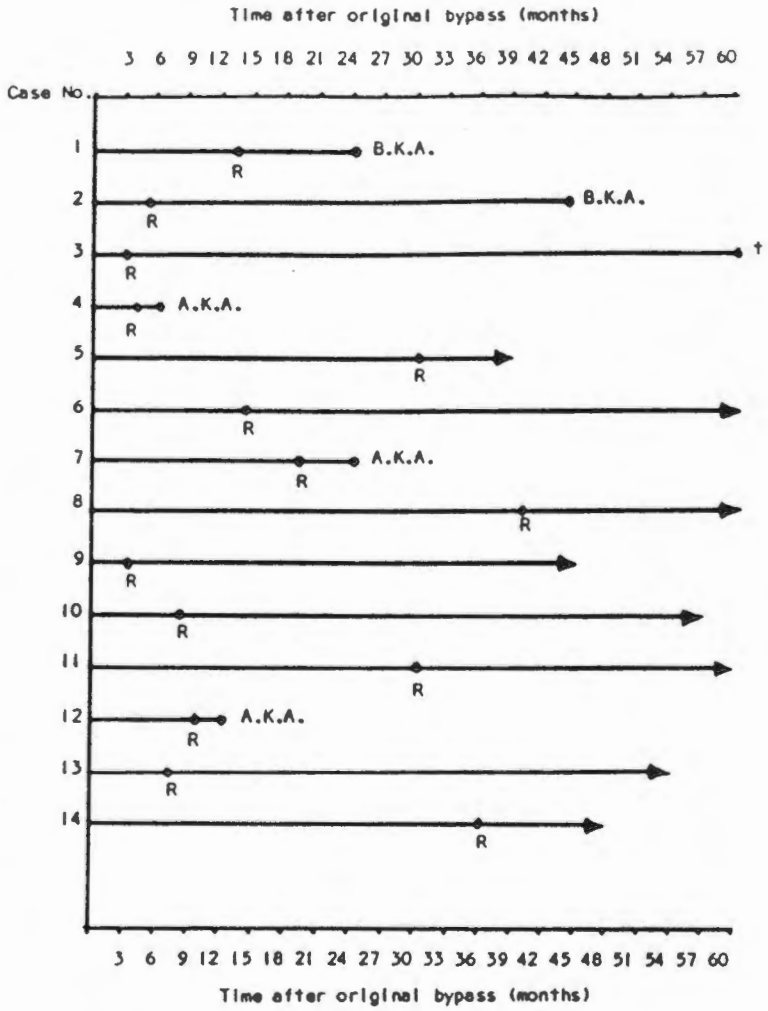


Fig. 4 Results from limb salvage in patients undergoing secondary bypass.

R - Stage when regrafting was performed
A.K.A. - Above knee amputation
B.K.A. - Below knee amputation
→ - Alive
† - Died

## DISCUSSION

The last 12 years have seen an evolution in the philosophy and, consequently, the practice of reconstructive surgery for peripheral vascular disease. On the whole, results of infra-inguinal bypass surgery quoted in recent studies are an improvement on those reported in the 1970s and this has encouraged a more optimistic and aggressive approach to reconstructive arterial surgery, particularly for limb salvage. The discrepancy between cumulative rates for graft patency and limb salvage has been reported by virtually all studies of this nature. This might possibly point to inappropriate selection of patients for bypass in many cases, i.e. a certain number of patients, had they not undergone revascularisation, need not necessarily have required amputation. It is also possible that certain patients with non-healing ulcers require only a short period of graft patency in order to heal compromised tissue and, thereafter, enjoy prolonged limb salvage.

The results achieved in this series for both graft patency and limb salvage are poor in comparison with most others reported in the literature and it is vital to seek out the factors which might have been responsible for shaping these results.

Retrospective studies are frequently criticised on the grounds that results are derived from large numbers of patients followed-up for a short period of time and small numbers followed-up for longer periods, creating an illusion of long-term follow-up for all (De Weese 1977). With this in mind a "silent

interval" of 18 months was observed in this study from the time of the last operation in December 1983 to the time of data collection in mid-1985. Our mean period of follow-up for all grafts was 24.2 months and it is likely that the high early attrition rate in terms of limb loss was largely responsible for only 46 (30%) of our grafts being followed-up for more than 3 years.

## The Patients: Risk Factors and Selection

The age and sex distribution of the patients in this study are similar to those described by other authors, despite our having included for analysis a small number of young males with thromboangiitis obliterans (De Weese 1977; Szilagyi 1979; Reichle 1979). It is generally accepted that age correlates with the extent of atherosclerosis in all areas of the cardiovascular system, specifically the medium-sized coronary, cerebral and tibial arteries. Older patients undergoing bypass surgery therefore have a shorter life expectancy and this, together with the extent of atheromatous disease below knee level, will allow them limited benefit in the form of limb salvage after reconstruction. Ricco et al (1983) have shown, however, that age alone does not significantly prejudice graft patency results up to 2 years after femoro-distal reconstruction, and this has been corroborated by others (Williams 1985). It is therefore both unfounded and unfair to withold infra-inguinal bypass surgery from patients on the grounds of advanced age in the absence of other clinical contraindicating factors. Handicapped as they often are by poor vision, osteoarthritic disease and social factors, it is the geriatric group of patients to whom the

preservation of bipedal gait is most vital.

The significantly poorer results for both graft patency and limb salvage achieved in our Coloured patients is a revelation. The Coloured population of the Western Cape area have undergone a marked degree of urbanisation during the last 50 years, leaning far more toward the lifestyle of the European community than toward that of their Black compatriots. They have therefore begun to reap the dubious benefits of a refined Western diet but, on this premise alone, one would not expect the scale of their atheromatous disease to exceed that of our White patients. It is tempting to implicate a multiplicity of socio-economic factors in trying to explain the discrepancy between patency and salvage results for these 2 race groups but, in the absence of hard data, it is virtually impossible to perform an objective comparison on such a broad basis.

One risk factor which invites scrutiny, however, is the smoking habits of the 2 population groups. The detrimental effects of cigarette smoking on both the atheromatous process and long-term graft patency are well documented (Birkenstock 1975; Myers 1978; Greenhalgh 1981). Although long-term graft patency was not significantly affected by cigarette smoking in this study, the unequal numbers of smokers (85%) and non-smokers (15%) entered for analysis might well have biased our results. What does emerge, however, is that 22% of our White patients, but only 11% of our Coloured patients, were non-smokers and this may in part explain our results. Comparison of the 2 racial groups certainly does not reveal any other difference between them that

could have explained the poorer patency and salvage results achieved in Coloureds.

The finding that only one Black patient was selected for lower limb reconstruction in the 7-year period of this study deserves brief mention. The entity of juvenile arteritis in Black South Africans has been well described but the aetiology is as yet uncertain (Grobelaar 1974). Previously thought to represent a delayed hypersensitivity reaction to tuberculous infection, the disease affects small vessels of the extremities which become occluded by progressive transmural fibrosis, and pursues a relentless course. Reconstructive surgery usually provides only brief palliation before amputation is necessary, as was the case with our one patient. Robbs (1985) has shown recently that atherosclerotic occlusive disease is becoming much more common as a primary pathology in Black patients admitted to his unit for reconstructive arterial surgery, and that the clinical features in this group are similar to those of White and Coloured patients.

The presence of diabetes mellitus in patients requiring arterial bypass to the lower limb has traditionally been thought to prognosticate poorly with regard to long-term graft patency and limb salvage. This was not found to be the case in our patients nor in those followed-up for longer periods by other authors (Szilagyi 1979; Ricco 1983). It does appear, however, that where femoro-tibial bypass is performed in diabetic patients, long-term patency and salvage results may be significantly affected by the type of graft used (Ricco 1983;

Williams 1985). This will be discussed further below.

The large number of patients in this study requiring lower limb bypass for critical ischaemia (77.8%) rather than intermittent claudication (28.2%) is a feature in common with previously published reports (McAuley 1984; Williams 1985). Although it would seem rational to attribute this to a large number of patients presenting to us at a late stage of their disease, such an approach would be simplistic. The unpredictable course of atherosclerotic disease is well documented and it is the experience of other authors that many patients presenting with ischaemic foot lesions of varying severity have had no previous history of intermittent claudication (Veith 1981; McGrath 1983). Categorisation of patients into claudicating and critically ischaemic groups has often been arbitrary in the past but Bell and co-workers (1982) have attempted to define the concept of critical ischaemia more precisely by emphasising the significance of pre-operative ankle Doppler pressures as a criterion. Although our patients undegoing surgery for disabling claudication enjoyed better results for both graft patency and limb salvage than those with critical ischaemia, the difference for neither set of results was significant.

Mortality

The concept of atherosclerosis as a malignant disease is in no way an overstatement. Vascular surgeons now accept that reconstructive arterial surgery will, at best, improve the quality of life in their patients but does nothing to retard the progress of the cardiovascular and cerebrovascular disease which

account for a 5-year mortality of up to 50%. Both the early and long-term mortality rates recorded in this study are lower than those reported by most other authors (5% and 15.9% respectively) but most likely represent an underestimate, as many of our patients were followed-up for less than 5 years. It is interesting to note however that the long-term mortality in a similar group of patients studied prospectively at our institution in the last decade was only 5% (Birkenstock 1975).

Pre-Operative Assessment

The Investigations: Incapacitating claudication, rest pain or threatened viability of a limb remain the primary indications for reconstructive surgery in patients with atherosclerosis affecting the arteries of the lower limb. All investigations specific to the vasculature of the lower limb serve to define the anatomy and extent of the disease, enabling the surgeon to decide on the feasibility and intricacies of the proposed reconstruction.

In our local experience, on which this study is based, peripheral angiography has been the mainstay of pre-operative assessment and associated morbidity in our hands has been acceptably low. Early suggestions that the quality of angiographic run-off from the popliteal artery might predict the success or failure of infra-inguinal bypass procedures have not been proven (Dean 1975; Veith 1981b; Ricco 1983). The finding in this study that pre-operative calf vessel run-off significantly influenced limb salvage results but not those for graft patency is not easily explained, other than by the discrepancy between results for graft patency and limb salvage on the whole.

Menzoain (1985) has shown recently that angiographic run-off in fact correlates poorly with measured peripheral vascular resistance and has also stressed the magnitude of observer error in the interpretation of angiographic plates. It is possibly for the latter reason that pre-operative angiography fails somewhat as a means to prognosticate degrees of success of femoro-popliteal and femoro-tibial grafting procedures.

Digital subtraction angiography (DSA) was introduced in 1981 with the advantages that a lower dose of contrast medium is required and is injected intravenously (Turnipseed 1981). We have been evaluating this technique since early 1985 but whether the accuracy of DSA in our hands is such that it may replace conventional pre-operative arteriography remains to be concluded.

Whilst angiography might only illustrate accurately the anatomy of atheromatous lesions, Doppler measurement of segmental pulse pressures has long been accepted as a means of interpreting the functional effect of arterial stenoses and occlusions. The appeal of non-invasive studies is enhanced by the finding that both absolute measurement of ankle pressures and the Doppler-derived ankle-brachial pressure index correlates well with both the degree of ischaemia distally and the likelihood of successful reconstruction for atherosclerotic disease (Bell 1982; Marston 1985). These relationships do not hold, however, for diabetic vascular disease, where calcification of medium-sized arteries may produce falsely high pressure readings; also in thromboangiitis obliterans normal ankle pressure readings are possible despite distal arterial occlusion, which may precipitate

pedal gangrene. As this study includes operations on patients with diabetic as well as senile arteriosclerotic disease, it is not surprising that we found no significant influence of pre-operative Doppler ankle pressures on long-term graft patency or limb salvage.

Despite their limitations, the complementary information offered by conventional peripheral angiography and Doppler pressure studies still ensure their existence as the investigations of choice in patients selected for infra-inguinal bypass surgery.

The Operation: Grafts and Techniques

It is undoubtedly on the subject of grafts - both biologic and synthetic - that vascular surgeons have focussed their greatest interest over the last decade. We are faced with the virtual impossibility of replacing a diseased artery with a healthy one from whatever source and the search for an ideal arterial substitute is far from being abandoned.

For infra-inguinal arterial bypass, reversed autologous saphenous vein (RSV) still exists as the standard against which the performance of all other grafts is measured. In an early study Darling and Linton (1972) reported a gratifying 5-year patency rate for RSV in femoro-popliteal bypass. Cumulative patency rates reported later were somewhat lower, varying from 49% to 56%, but faith in RSV has nevertheless been sustained (De Weese 1977; Szilagyi 1979). Both short- and long-term cumulative patency rates for RSV used at our institution have been

disappointing. At 6 months, 67% of grafts were patent, falling to 60% at 12 months and 19% at 4 years.

The advantages of RSV over synthetic alternatives are its availability, appropriate diameter, strength and the fact that it costs nothing! In a certain number of patients, however, the vein may be varicose, too narrow or thrombosed, and therefore unusable. The presence of valves requires that the vein be reversed for use, and harvesting is a time-consuming procedure. For these reasons, many surgeons now prefer synthetic grafts for femoro-popliteal bypass, where the distal anastomosis is above knee level. In the first prospective randomised trial comparing RSV with PTFE grafts in infra-inguinal bypass, Bergan and his co-workers (1982b) have shown no significant difference in graft patency up to 2½ years when one or the other graft is inserted distally to the proximal popliteal artery. Where more advanced disease demands that the graft be inserted to the infra-popliteal artery or one of the tibial vessels, however, there is no doubt that the use of RSV will result in significantly better cumulative results for both graft patency and limb salvage (Bergan 1982b; Ricco 1983). It could be suggested, therefore, that the decision to perform femoro-infrapopliteal or femoro-tibial bypass should be influenced by the availability or otherwise of a good quality ipsilateral saphenous vein.

The tendency for RSV grafts to early thrombotic occlusion can be attributed to two outstanding drawbacks to this technique. Firstly, harvesting effectively devitalises the vein causing ischaemic degeneration of the endothelial lining and, thereby,

an increased thrombogenic tendency (Stanley 1978). Secondly, reversal of the vein provides two anastomotic ends, the diameters of which are unmatched with those of the arteries to which they connect. The reversed taper also limits the length of vein that can be used and imposes flow characteristics on the bypass which are unphysiological (Lee 1983).

The concept of arterial bypass using the saphenous vein "in situ" was developed jointly in the early 1960s.by Charles Rob in London and Karl Victor Hall in Oslo (Hall 1962; May 1965). The practical advantages of this technique are clear; apart from at its proximal and distal ends, the vein is not disturbed from its nutritive bed and the endothelial lining should theoretically remain intact. The natural taper of the vein is preserved so that the diameters at either end are more compatible with the arteries to which they are anastomosed, enabling longer bypasses (and therefore more distal anastomoses) to be performed with greater technical ease. Also, veins of narrower diameter can be used, allowing a higher rate of vein utilisation than is possible with RSV. All in all, the long saphenous vein used in situ would appear to provide a far more physiological conduit than it would reversed. Venous valves remain the only problem.

The earliest attempts at in situ saphenous vein bypass described blind disruption of the venous valves using the blunt end of a vein stripper introduced through the proximal end of the vein. In situ vein treated by this method failed early, and Hall himself chose to deal with the valves by direct excision via

multiple transverse venotomies (Hall 1978). Most surgeons found the latter technique too tedious and preferred to rely on the method of blind valve fracture. Results thus obtained were universally poor and a critical report by Barner in 1969 heralded a sharp decline in the popularity of the in situ technique (Barner 1969). Ironically, it seems to have been the increasing popularity of reversed saphenous vein grafting that inspired Leather and his colleagues at The Albany Medical Center in New York to resurrect the in situ method in 1972. Initially rendering the valves incompetent by the Hall technique, Leather subsequently refined that of closed valve incision using a combination of valve scissors and a valvulotome (Leather 1984).

In situ saphenous vein has been enthusiastically adopted by many vascular surgeons, particularly for limb salvage procedures requiring distal anastomoses below the knee joint. Most series of infra-inguinal bypass by this method reported to date have involved small numbers and have been uncontrolled (Rogers 1986). The two largest consecutive series have reported patency rates at both 2 and 3 years of 85-90% for all grafts (Karmody 1984; Buchbinder 1986). By far the most impressive results are those reported by Leather himself: in a series of 539 in situ saphenous vein bypasses performed for limb salvage, cumulative patency at 5 years was 82% for femoro-popliteal grafts and 71% for infrapopliteal procedures (Leather 1986). The only prospective randomised trial to date comparing in situ vein and RSV was conducted by the Albany group as well, but was terminated when the clearly superior performance and higher rate of utilisation of in situ vein became apparent at 30 months

(Buchbinder 1981).

Several experimental studies have been conducted in attempts to explain the resistance of in situ vein to early thrombosis. In addition to the superior flow characteristics shown in in situ vein as compared with RSV, it has also been demonstrated that the endothelial lining of in situ vein remains structually and metabolically far more intact and, therefore, less thrombogenic than does that of RSV (Bush 1984). Ischaemic changes may however occur in the endothelium at the vein ends where a certain amount of mobilisation is unavoidable.

The problem of iatrogenic arteriovenous fistulae can be minimised by the use of on-table arteriography after completion of reconstruction with in situ saphenous vein. Major fistulae discovered only in the post-operative period may be ligated under local anaesthesia. There can be little doubt that, at the present stage of our knowledge, in situ saphenous vein is the conduit of choice for femoro-distal bypasses, in particular those undertaken for limb salvage. Initial experience at Groote Schuur Hospital has been extremely encouraging.

If the acclaim for in situ saphenous vein has been unanimous, then that for human umbilical vein (HUV) has been far more critical. The HUV graft was first used for femoro-popliteal bypass in 1974 by Dardik (1976) who had developed it and after whom it has been named commercially (Dardik Biograft, Meadox Medicals Inc, Oakland, New Jersey). HUV is harvested from hospital obstetric suites and tanned in glutaraldehyde to destroy

antigenicity and maintain structural integrity. The graft is now reinforced with a surrounding Dacron mesh to prevent aneurysmal dilatation. The complex tanning and stabilisation process necessary in the manufacture of HUV makes it an expensive alternative to autologous saphenous vein, one factor which has mitigated against its widespread acceptance.

As is the case with any graft tested for infra-inguinal bypass, the range of results obtained with HUV is considerable. In a consecutive series of 183 patients reconstructed for critical ischaemia, Dradik himself (1980) reported 3-year cumulative patency of 94.6% and 76.4% for HUV grafts anastomosed to the popliteal artery above and below the knee respectively. No investigator to date, however, has managed to equal Dardik's results and published studies of this graft are difficult to compare due to variations in patient selection (Clifford 1986). Boontje (1980), for example, reported an 87% 1-year cumulative patency rate for 100 patients with HUV grafts but only 10% of his patients had critical ischaemia and $\frac{2}{3}$ of his grafts were placed above the knee. At the other end of the scale, Klimach and Charlesworth (1983) reported 28% 1-year and 9% 2-year patency rates for HUV used in 112 femoro-tibial bypasses for limb salvage. This latter study reported the frequent problem of early thrombosis occurring in HUV grafts taken across the knee, a finding that has been confirmed by others (Raithel 1984; Anderson 1984; Harris 1984). Some surgeons have voiced objections regarding the handling characteristics of HUV (Weisel 1981; Harris 1984), claiming that it tends to tear easily and does not suture well.

Both retrospective and prospective comparisons between HUV and PTFE grafts attest more to the unsuitability of PTFE than to the prowess of HUV in limb salvage (Weisel 1981; Eickhoff 1983). The ultimate fate of HUV seems at present to be hanging in the balance: it is as expensive as any synthetic graft but seems to lack any specific advantage over these. It is unlikely that the popularity of HUV will increase much beyond what it is at present.

In the sphere of synthetic grafts currently available, there is none that satisfies the criteria of an "ideal conduit". The immense popularity of expanded PTFE grafts, however, is attributable to several features; handling characteristics are superior, preclotting is unnecessary, and the highly electro-negative inner surface theoretically decreases thrombogenicity. Long-term patency rates for PTFE grafts placed below the inguinal ligament vary tremendously, influenced predominantly by the proportion of limb salvage precedures included in each series. Cumulative patency rates quoted range from 60% to as low as 18% at 5 years (Veith 1981; McAuley 1984; Williams 1985). Cumulative life-table patency results for PTFE used in infra-inguinal bypass at our institution were again low, viz 74% at 6 months, 54% at 12 months, and 12% at 4 years. Of the 95 PTFE grafts described in this study, 72 had been used in patients with critically ischaemic limbs but, more importantly, 55 had been placed below the knee. Only 4 of these 55 PTFE grafts were patent at 4 years, placing serious doubt on whether there is any place at all for PTFE grafts in infra-popliteal or tibial vessel anastomoses.

The appeal of PTFE is further tarnished by the rising cost of the material. The cost of a single PTFE graft in the Republic of South Africa is now in excess of R2,000 and may rise further still due to monetary exchange rates. Costing less than one-third as much as PTFE, knitted Dacron must be seen as a prime contender for the material of choice in above-knee femoro-popliteal grafting when RSV is not available or considered too time-consuming in high-risk patients. Having been previously shunned by many vascular surgeons because of high thrombogenicity compared with PTFE, as well as the need for pre-clotting, the virtues of this less expensive material are being considered anew, with patency rates of up to 50% having recently been reported after femoro-popliteal bypass (Mosley 1985).
Non-crimped, externally supported (EXS) Dacron grafts have been developed and promoted by Sauvage and co-workers as a synthetic alternative to RSV for crossing the knee joint (Kenney 1982). An external coil of polypropylene is fused to the Dacron tube and should prevent kinking of the graft during flexion of the knee. Preliminary results with EXS Dacron have been favourable (Kremen 1986; Clifford 1986), but whether this mechanical advantage will decrease the risk of late thrombosis in long Dacron grafts is yet to be proven.

A detailed discussion of the operative techniques involved in infra-inguinal bypass is beyond the scope of this dissertation. Certain technical aspects are thought relevant to this study and deserve mention, specifically the use of intra-operative angiography, the management of proximal vascular disease and the choice of inflow sites for graft placement.

Routine intra-operative angiography has not achieved widespread popularity despite having been shown by Dardik (1978) to be of value in detecting technical faults, especially those associated with anastomoses to the calf vessels. At Groote Schuur Hospital we have not made use of on-table angiography, having been concerned about the quality of plates and, consequently, the reliability of the information yielded by this method. We have preferred to judge the feasibility of reconstruction on pre-operative angiography and the vigour of arterial backflow at exploration.

Several centres have investigated intra-operative methods of assessing the outflow of blood into the foot as a means of predicting success or failure of grafting procedures (Parvin 1984; Stirnemann 1986). Such measurements are made once the distal artery has been dissected. Even if, in theory, poor readings thus obtained would discourage reconstruction, the patient is not saved the trauma of a general anaesthetic. Similarly, peri-operative Doppler flow studies and wave-form analysis performed at the site of reconstruction have been reported to be of value in predicting the likelihood of post-operative graft failure (Inokuchi 1979; Lee 1986). In isolation the data obtained from these tests are unlikely to be of more than academic significance, relating as they do to only the immediate aspect of reconstuction. In combination with other factors such as the indication for surgery and graft availability, however, the objective information rendered by intra-operative studies may assist the vascular surgeon in making a rational choice between reconstruction, amputation or simply

abandonment of the procedure for each patient.

The importance of ensuring maximal possible inflow to the common femoral artery before embarking on infra-inguinal bypass has been stressed by other authors (Porter 1977; Veith 1981). Comparing the 30 patients in this series who had undergone proximal aorto-iliac reconstruction prior to lower limb bypass with the 102 who had not, both graft patency and limb salvage results were in fact better for the latter group, but the difference was not significant. Increasing use is being made of percutaneous transluminal angiography (PTA) for dilatation of functional iliac stenoses in patients being assessed for infra-inguinal bypass (Johansen 1981). Since acquiring the expertise to perform PTA, we have adopted this method of dealing with localised proximal lesions as a means of improving common femoral inflow and also obviating many bypasses across the inguinal ligament.

The relationship between graft length, flow velocity and patency of femoro-popliteal grafts has been well described (Reichle 1979; Hobson 1980; Bandyk 1985). In an attempt to improve graft patency rates following arterial reconstruction below knee level, Veith (1981c) and others (Buchbinder 1985) have advocated using the superficial femoral or popliteal arteries as inflow sites for distal bypass in the absence of more proximal disease. This practice allows shorter grafts to be placed but is limited by the availability of autologous saphenous vein, best utilised by the in situ method (Corson 1984). Small diameter PTFE grafts at this level produce very poor results but 2-year

limb salvage rates of 80% have been reported with saphenous vein, either reversed or in situ (Buchbinder 1985).

Graft Failure: Prevention and Management

The many possible reasons why bypass grafts fail at various times after surgery have been well documented (McCollum 1985). Whilst understanding the progressive nature of arteriosclerotic disease and thereby the strictly palliative effect of bypass surgery on this condition, it is never wise to accept graft failure as inevitable. There are factors contributing toward the failure of bypass grafts over which the surgeon may exercise a certain degree of control and these are discussed here.

Early graft occlusion is usually attributed to errors in surgical technique, to haemodynamic factors, and to the thrombogenic surface of the graft used.

The pathophysiology of delayed graft failure is more complex. The progression of atherosclerosis and detrimental effects of continued smoking after surgery are largely beyond the surgeon's control and have been discussed above. Other factors contributing toward late graft occlusion are directly related to the properties of the grafts themselves and may well be influenced by post-operative management.

Neointimal fibrous hyperplasia (NFH) is a process which occurs to differing degrees in all grafts, particularly at graft-artery anastomoses. Although the exact aetiology of NFH is uncertain, it seems to result from the migration of smooth muscle

cells to the "intimal" layer of each graft where proliferation and myofibroblast formation result (Imperato 1981). At anastomoses turbulent flow may result in adherence of platelets, thrombus formation and also NFH via the release of platelet substances. In addition to these processes, it is understood that the luminal surfaces of all currently available grafts attract platelet deposition to some degree and, lacking as they do the endogenous platelet inhibitors of arterial intima, laminated thrombus formation is initiated. This is least a problem with RSV, more significant with PTFE and most marked in Dacron grafts. Strong evidence is now emerging whereby the administration of aspirin and dipyridamole, which have a combined anti-platelet function, will decrease platelet adherence in PTFE grafts placed below the inguinal ligament resulting in significantly improved short-term patency rates (Green 1982). A similar effect is yet to be shown on infra-inguinal RSV grafts.

Graft occlusion within 3 months of surgery is of grave significance and often culminates in major amputation. In this study 27 amputations were necessary for graft failure within 3 months of bypass, representing 55% of all grafts failing within this period. Twenty-one of these amputations were necessary above knee level. All but one of these amputations were performed on patients in whom bypass had been indicated for critical ischaemia. Although it has been suggested that failed bypass increases the risk of above-knee rather than below-knee amputation (Stoney 1978; Szilagyi 1979), the possible risk of a higher ablation itself does not mitigate against bypass for limb salvage in the absence of other contraindications (Dardik 1982).

Infra-inguinal graft occlusion at any stage is by no means synonymous with limb loss. Graft failure in the early post-operative period may be due to reversible technical errors. Graft thrombectomy alone or combined with revision of either graft-artery anastomosis may confer on the patient months or even years of additional limb salvage. The consequences of late graft occlusion vary from the return of mild claudication to the threat of limb loss. In the latter instance re-operation is no less justified than the original reconstruction. This attitude has been expressed by Veith who also points out the advantage of PTFE grafts over RSV in being suitable for graft thrombectomy up to 30 days after occlusion (Veith 1980). Our results of graft thrombectomy and secondary bypass are undermined only by the small number of procedures undertaken in the course of 7 years. Only 5 out of 21 graft thrombectomies and 3 out of 15 secondary reconstructions failed immediately necessitating major amputation. We believe, however, that the additional limb salvage of between 1 and 4 years resulting from more than half of these secondary procedures justifies an aggressive approach to the management of graft failure.

Limb Salvage: Alternatives to Revascularisation

Despite growing acceptance of infra-inguinal bypass as a means to improve the quality of life in atherosclerotic patients, the value of this procedure in limb salvage has not been universally appreciated. Stoney has suggested that the rewards of femoro-distal bypass for limb salvage seldom justify the risk involved and that primary below-knee amputation constitutes an option in rehabilitation of patients with critically ischaemic

limbs (Stoney 1978). As has been alluded to above, the ambulation of elderly amputees is often limited by their overall state of health and social resources. Re-employment prospects following amputation must also be severely restricted in patients under 65 years of age. It has been shown that, where feasible, infra-inguinal bypass will restore independent gait much more quickly than primary major amputation, although graft failure may minimise this disadvantage by the third year after surgery (Robbs 1984). A recent American study has compared the overall cost of revascularisation by critical ischaemia with that of primary major amputation. The expenses accrued by each operation were almost identical although no mention was made of whether prosthetic or RSV grafts were predominantly used for bypass (Mackey 1986). The concept of cost-effectivity as applied to arterial reconstruction of the lower limb once again demands that expensive prosthetic materials such as PTFE be utilised only where dictated by the unavailability of suitable autogenous saphenous vein.

Although not universally accepted, non-operative means of palliative treatment for patients with critically ischaemic but unreconstructable limbs have their advocates. Rest pain in the absence of gangrene can be relieved for 3 months or more by chemical lumbar sympathectomy (Cotton 1985), so that amputation, although inevitable, may be postponed for an indefinite period during which the vascular patient enjoys a good quality of life. Prostaglandins E1 and I2 (prostacyclin) have been given by intra-arterial and intravenous infusion to patients with critically ischaemic limbs with varying degrees of success over

the last 8 years (Szczeklik 1979; Pardy 1980; Cronenwett 1986) but the unpredictability of response, as well as the instability and expense of those compounds, has precluded their widespread use.

## CONCLUSIONS

This study represents the initial experience of infra-inguinal bypass at one institution. The results for graft patency and limb salvage fall into the lower end of the scale of those previously reported in similar studies. An attempt has been made to identify those factors which correlate with both graft and limb survival.

The discrepancy between results for graft patency and those for limb salvage implies that certain patients may require only a short period of graft patency to salvage and maintain an intact limb. This reinforces the conviction for limb salvage procedures in suitably selected patients, not least of all the elderly who are less likely to regain independent mobility after primary amputation. Also, the results of graft thrombectomy, revision of anastomoses and secondary grafting are encouraging and suggest that aggressive management for both early and late graft failure is worthwhile in selected patients.

The poor results of reconstruction in Coloured patients and the possible relationship to smoking habits have both emerged. This, as well as the variable influence on results of other established risk factors suggest the need for a weighted scoring system which takes all factors into account and might simplify the selection of patients for reconstruction.

As far as grafts are concerned, there can be little doubt that autologous saphenous vein should be the first choice for all

infra-inguinal reconstructions. When no vein is available for above-knee femoro-popliteal bypass, knitted Dacron is a far more cost-effective synthetic substitute than PTFE. It is suggested that altogether much less reliance should be placed on PTFE grafts in view of both the high cost and its poor performance across the knee. Limb salvage procedures involving distal anastomoses below the knee should only be undertaken in selected patients if a suitable autologous saphenous vein is available. Failing this, primary below-knee amputation is more likely to be in the best interests of the patient as a whole.

## FUTURE PERSPECTIVES

Like so many forms of medical and surgical therapy, arterial bypass for atherosclerotic disease has weathered the early years of precocious enthusiasm, a rebound period of disillusionment and has settled comfortably into a "middle age" of critical reappraisal. The vast amount of biomedical and clinical research being directed at present towards increasing the rewards of infra-inguinal bypass confirms the established place of this procedure in the management of symptomatic atheroslcerotic disease. It is the purpose of this final section to outline three distinct areas of research, each of which has attained a high profile in recent years and all of which aim to achieve the same goal - to prolong the patency of infra-inguinal grafts.

As ever, it is the eternal search for improved synthetic alternatives to autologous saphenous vein that appears to dominate surgical research interest relevant to peripheral vascular disease. Much work has been directed at decreasing the thrombogenicity of synthetic grafts by seeding the luminal surfaces with autologous endothelial cells. These cells are enzymatically harvested from either autologous vein (Callow 1985) or peritoneal mesothelium (Clark 1985) and are grown in tissue culture. From whichever source, once seeded on to either PTFE or Dacron, the endothelial cells remain metabolically intact secreting anti-aggregatory prostaglandins, thus providing an actively antithrombotic graft lining. The seeding of PTFE following implantation into the peritoneal cavity of experimental animals has also been described (Castronuovo 1986). Clinical

reports of infra-inguinal bypass with seeded synthetic grafts are only beginning to appear (Herring 1984) and it remains to be seen whether the expense and effort involved in this technique will prove worthwhile in prolonging the patency of these grafts.

There is a growing body of evidence to support the value of anti-platelet therapy in decreasing thrombus formation and improving early patency of grafts used for medium and small arterial replacement. It now seems necessary to commence anti-platelet therapy pre-operatively to prevent the initial activation of platelets by the thrombogenic graft surface and the areas of endothelium disrupted by implantation. Post-operatively there appears to be little benefit in prolonging anti-platelet therapy beyond 24 months in patients with synthetic grafts (Sheehan 1986). Much more data are still required to clarify both the ideal dose and combination of anti-platelet medication necessary to reduce the incidence of early graft failure.

Refinement of local thrombolytic therapy promises to bring about change in the management of thrombosed infra-inguinal grafts. Urokinase, although unfortunately far more costly than its predecessor, streptokinase, appears to be more effective at clot dissolution and is also associated with a lesser incidence of haemorrhagic complications. Reported success rates of clot lysis in occluded grafts vary from 20-90% and the incidence of haemorrhagic complications from 3-50% (Mannick 1986). It has been suggested that anticoagulation with intravenous heparin concomitant with fibrinolytic therapy may reduce rethrombosis around the intra-arterial catheter as clot lysis proceeds more

distally (Wolfson 1984). An exciting development is that of tissue-type plasminogen activator (TTPA) by the recombinant DNA technique. This substance has the theoretical advantage of activating only the plasminogen bound to thrombus, so that the risk of haemorrhage should be reduced. To date, TTPA has been used with success in the lysis of recent coronary artery thrombi but its application to occluded femoro-popliteal grafts is yet to be explored.

It is vital that, with all advances in vascular surgery including those mentioned above, perspective is maintained regarding the ultimate cost and application to both surgeon and patient. For whatever benefit it might provide the symptomatic atherosclerotic patient, femoro-popliteal bypass is essentially a palliative procedure and every development aimed at its improvement must be seen in that light. As may well happen with, for example, PTFE and HUV grafts, it is unfortunate to witness new materials or techniques appear briefly only to price themselves into early obsolescence.

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