The Concept of Knee Salvage: Why Does a Failed Femorocrural/pedal Arterial Bypass Not Affect the Amputation Level?

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Objectives: There is continued controversy over whether a failed distal bypass influences the level of amputation. This issue is important as the number of arterial bypass grafts undertaken for critical ischaemia is increasing, followed by an increasing number of failed grafts.

Setting: Teaching hospital.

Study design and materials: A prospective analysis of 109 consecutive femorocrural/pedal bypass grafts performed between June 1991 and January 1995 on patients presenting with severe critical lower limb ischaemia (CLI) to a single vascular unit. A further 43 amputations for non-reconstructible distal disease were also analysed.

Chief outcome measures: Mortality, amputation, rehabilitation, survival and knee salvage rates. The Kaplan-Meier method was used for comparison of factors associated with knee preservation.

Results: Primary amputees had a higher in-hospital mortality (18% vs. 10%) but similar 3 year survival rates (30%) compared with secondary amputees (36.6%). Patients with successful grafts showed a trend towards better survival (61.9% at 3 years) compared to amputees (38.6% at 42 months, p = 0.061). Below- to above-knee amputation ratio was similar in the two groups (0.85 in secondary vs. 0.95 in primary amputees). Factors significantly associated with knee salvage at 3 years were shown to be the condition of the inflow (81.9% for good vs. 43.1% for impaired, p = 0.000) the state of the profunda femoris artery (good 93%, impaired 71%, occluded 37% p = 0.0001) and the graft material (vein 81.8% vs. PTFE 59.8%, p = 0.033). The presence of tissue loss (p = 0.0523) and secondary procedures (p = 0.0879) showed a trend to become significant. Multivariate and Cox regression analysis showed that the most important factors were the inflow (p = 0.0001), the state of the profunda (p = 0.0001), the graft material (p = 0.034) and previous revascularisation attempts (p = 0.019).

Conclusions: The factors which determine knee loss are a compromised inflow state, the presence of an inadequate profunda femoris, previous revascularisation attempts and the use of synthetic graft material. Most of these factors (with the exception of infection related to revascularisation) are present before reconstructive arterial surgery is performed and this study shows that failure of a distal graft does not affect the final amputation level.

Key Words: Critical limb ischaemia; Femorodistal bypass; Knee salvage; Amputation; Infrapopliteal bypass; Limb salvage; PTFE bypass; Secondary arterial bypass graft.

Introduction

There has been a dramatic increase in the number of distal arterial bypass grafts and other invasive techniques (e.g. angioplasty, stenting and thrombolysis) performed to restore patency in patients with severe critical lower limb ischaemia (CLI). Some authors suggest that this has improved limb salvage and quality of life. However, the effect of these techniques on limb salvage is difficult to assess in a large population.

The relevance of a failed arterial reconstruction in determining the level of amputation is unclear. In some reports previous ipsilateral reconstruction was associated with more above-knee than below-knee amputations, while others do not show such a relation. Theoretically, any failed reconstruction could alter the amputation level by causing thrombosis of previously patent native vessels or by introducing infection. Amputation level was not adversely affected by attempted distal reconstruction in some studies; however, comparison between different series is difficult, as most authors analyse all infrapopliteal bypass grafts without defining the site of the distal anastomosis.

We have studied the issue of whether knee salvage is affected by attempted distal arterial bypass by analysing a consecutive series of 109 grafts to a single calf or foot vessel.
Patients and Methods

Revascularised patients

A consecutive series of 109 femorodistal bypass grafts were performed between June 1991 and December 1994 on 101 patients presenting with severe CLI, identified by clinical and objective findings (rest pain and/or tissue loss with ankle pressures less than 50 mmHg unless the arteries were calcified). As “distal” we considered only grafts to a single calf, ankle or foot vessel. The ratio of male to female patients was 2.15:1 (69 men, 68.3%; 32 women, 31.7%). The age distribution ranged from 46 to 94 years (median 74 years).

All patients had rest pain, while 71 limbs had evident tissue loss (65.1%) and five (4.6%) had sepsis. The extent of the tissue loss was severe in 43 (39.5%), necessitating some form of concomitant foot or toe amputation. A previous revascularisation attempt on the same leg (either angioplasty or more proximal bypass) had been undertaken in 71 patients (65.1%).

Thirty-eight (34.9%) of the grafts were undertaken in diabetic patients.

Complete data (inflow and runoff condition, admission days, type of procedure, theatre time, ITU stay, complications, etc.) were collected prospectively for all patients who were entering a prospective computerised audit. Doppler flow measurements (Quick scan, QS) were performed just before discharge. They were then entered into a graft surveillance program, with a QS performed at 3, 6 and 12 months and every 6 months thereafter. If QS detected a stenosis with a frequency ratio greater than 1:4 the patients were referred for intra-arterial digital subtraction angiogram (IADSA); angioplasty was performed at the same time if any lesion was considered suitable.

Amputation group

The 43 patients with non-reconstructible infrapopliteal disease that were subjected to a major amputation were considered as primary amputees. Eleven of them had had a previous revascularisation procedure to a more proximal level.

The indications for amputation were: intractable rest pain (all patients), established tissue loss (all) or sepsis (eight patients, 18.6%). No vessels for distal reconstruction were found on intra-arterial digital subtraction angiography, intraoperative angiography or surgical exploration. The age distribution ranged from 41 to 91 years (median 74 years). Twenty-two (51.2%) patients were men and 21 (48.8%) women. Twenty (46.5%) patients were diabetic (all of them without any previous intervention) and 23 (53.5%) non-diabetic.

Assessment of preoperative angiograms

The preoperative angiograms were reviewed by a surgeon and a radiologist and the state of the inflow, the profunda and the runoff were assessed. The profunda was characterised on preoperative angiograms as good, impaired or occluded. The profunda was classified as impaired if it was stenotic (>30%), its diameter was less than 2 mm on IADSA and the knee collaterals were thready and sparse. In 15 limbs (13.8%) the profunda was occluded, in 63 (57.8%) it was impaired and in 31 (28.4%) it was good.

Inflow was considered good if the diameter of the vessels was adequate with no significant stenosis, i.e. less than 30% reduction in diameter. It was considered impaired if there was a stenosis which reduced the diameter by 30–50% or if there was diffuse aortoiliac disease or ectasia. In cases where there was a stenosis >50% or an occlusion, an inflow procedure was undertaken before or at the same time as the bypass (i.e. iliac angioplasty, iliofemoral cross over bypass, etc.); inflow was then graded according to the result of the inflow procedure. Thirty-three limbs (30.3%) had impaired inflow and in 76 (69.7%) it was considered good.

Statistical analysis

Life-tables were constructed using the traditional and Kaplan–Meier methods. Graft patency and salvage rates were reported according to the recommendations of the ad hoc Committee of the Society of Vascular Surgery and the International Society of Cardiovascular Surgery [SVS/ISCVS]. Comparison of the actuarial curves was performed by the log-rank test.

Results

Mortality and survival

Revascularised patients. Thirty days mortality was 7.3% (eight patients), while in-hospital mortality during the first admission was 13.7% (15 patients); four of the latter died after a major amputation following a failed bypass. The in-hospital mortality rate for amputation after a failed bypass was 10.3%.

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Table 1. Mortality and amputation rates.

<table>
<thead>
<tr>
<th></th>
<th>Amputation after failed grafts (n=41)</th>
<th>Primary amputations</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>39</td>
<td>43</td>
</tr>
<tr>
<td>Mortality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 days</td>
<td>3 (7.7%)</td>
<td>4 (9%)</td>
</tr>
<tr>
<td>In-hospital</td>
<td>4 (10.3%)</td>
<td>8 (18.6%)</td>
</tr>
<tr>
<td>No. of procedures</td>
<td>58 (1.48 per limb)</td>
<td>59 (1.37 per limb)</td>
</tr>
<tr>
<td>Revision or debridement</td>
<td>14 (35.9%)</td>
<td>11 (25.6%)</td>
</tr>
<tr>
<td>BK:AK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td>2.0</td>
<td>1.26</td>
</tr>
<tr>
<td>Final</td>
<td>0.85</td>
<td>0.95</td>
</tr>
</tbody>
</table>

Survival for all patients was 84.3%, 74.8%, 63.6% and 57.9% at 6, 12, 24 and 36 months, respectively (cumulative standard error (s.e.) = 6.31). By dividing them into two cohorts, amputated and non-amputated, the respective values in the non-amputated were 61.9% at 42 months (s.e. = 9.0), compared with 38.6% at 42 months (s.e. = 9.0) in the amputated patients following failed revascularisation. There was no significant difference in survival rate between them (p = 0.61). After amputation, survival was 84.1% at 6 months, 62.6% at 1 year, 54.9% at 2 and 3 years, and 36.6% at 39 months (s.e. = 8.92).

Amputation group. Thirty day mortality was 9.3% (four patients), while in-hospital mortality was 18.6% (eight patients). Actuarial survival curve showed 70% survival at 6 months, 60% at 1 year, 37% at 2 years and 33.3% at 3 years. There was no significant difference in survival between primary and secondary amputees. There was a trend for the successfully revascularised patients with a functioning limb to survive better than primary amputees (61.9% at 3 years vs. 33.3% for primary amputees, p = 0.061). However, as the sample sizes were not equal, the failure to attain significance may be a type II error.

Amputation rates

Of the 41 grafts that occluded, 39 (95.1%) had a major amputation, usually within the first 6 months of graft implantation. A below-knee (BK) amputation was attempted whenever feasible. Twenty-six legs (66.7%) were initially amputated BK and 13 (33.3%) above-knee (AK), a BK:AK ratio of 2:1. However, 14 stumps (35.9%) had to be debrided or revised, four (30.8%) of the AK group and 10 (38.5%) of the BK group. Eight of the latter were amputated at an above-knee level (higher revision rate 30%). The final BK:AK ratio was 0.85 (21 AK amputees, 53.8% and 18 BK, 46.2%). For these 39 amputees, the total number of amputation procedures was 58 (ratio 1.5:1 per limb).

Regarding primary amputations, the initial BK:AK ratio was 1.26:1 (24 vs. 19). Eleven (25.6%) were debrided or revised resulting in a final amputation level ratio of 0.95:1. The rehabilitation rates were similar. Twelve of the 39 secondary amputees showed good independent mobility at 6 months (46.2%). This increased to 51.4% if the in-hospital deaths were excluded. Sixteen of the 43 primary amputees (37.2%) showed good independent mobility at 6 months; 45.7% of in-hospital deaths were excluded.

Knee salvage

Knee salvage was 90% at 3 months, 80% at 9 and 73% at 2, 3 and 4 years (s.e. = 5.32). Knee loss usually occurred within the first 6 months and was related to early graft failure in patients with poor distal run-off.

Factors that affect knee salvage

Univariate analysis was initially used to assess the factors associated with knee loss. Those proven to be significant in knee salvage were: the state of the profunda, the state of the inflow, the lack of vein and the presence of tissue loss. There was also a trend for patients with secondary procedures to perform less well.

Profunda femoris (Fig. 1). Knee salvage at 12 months was 37% in cases of occlusion, 71% when it was impaired and 93% when it was good (p = 0.001, s.e. = 14.00, 7.36, and 4.71, respectively).

Inflow state (Fig. 2). Knee salvage was 60.2% at 6 months and 43.1% at 1 and 3 years in patients with
Table 2. Factors that affect knee salvage (uni-, multivariate and Cox regression analysis, comparison by log-rank test).

<table>
<thead>
<tr>
<th>Factor</th>
<th>Knee salvage</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervals (months)</td>
<td></td>
</tr>
<tr>
<td>Profunda</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good</td>
<td>93.1</td>
<td>93.1</td>
</tr>
<tr>
<td>Impaired</td>
<td>88.8</td>
<td>86.4</td>
</tr>
<tr>
<td>Occluded</td>
<td>86.2</td>
<td>63.7</td>
</tr>
<tr>
<td>Inflow</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good</td>
<td>94.1</td>
<td>90.7</td>
</tr>
<tr>
<td>Impaired</td>
<td>79.3</td>
<td>70.3</td>
</tr>
<tr>
<td>Previous revascularisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>93.8</td>
<td>90.9</td>
</tr>
<tr>
<td>Yes</td>
<td>85.7</td>
<td>79.1</td>
</tr>
<tr>
<td>Graft material</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vein</td>
<td>94.4</td>
<td>92.3</td>
</tr>
<tr>
<td>PTFE</td>
<td>83.7</td>
<td>74.9</td>
</tr>
<tr>
<td>Tissue loss</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>100.0</td>
<td>97.0</td>
</tr>
<tr>
<td>Yes</td>
<td>83.5</td>
<td>77.3</td>
</tr>
</tbody>
</table>

Fig. 1. Effect of profunda femoris on knee salvage. The numbers of patients entering each interval are given on each curve. The labels show the cumulative salvage rate and the cumulative standard error corresponding to the end of the curve.

Impaired inflow, compared with 90.6%, 86.4% and 81.9%, respectively for those with good inflow (p = 0.000, s.e. = 11.0 and 5.5 in the two groups). The necessity to undertake an inflow procedure did not affect the outcome (p = 0.846).

Previous revascularisation attempts (Fig. 3). Knee salvage in patients with secondary procedures was 76.7% at 6 months, 68.9% at 1 year and 65.1% at 3 years, compared with 90.9% at 6 months and 80.7% at 2 and 3 years in patients with primary procedures. There was a trend for patients having secondary procedures to do less well compared with patients in whom the distal bypass was the first intervention; however, this difference did not attain significance (p = 0.0879, s.e. = 7.58 and 6.82, respectively).

Graft material (Fig. 4). The type of graft conduit proved to be important (p = 0.031, s.e. = 8.90 and 5.93, respectively). The 60 vein grafts (55.1%) showed a knee salvage rate of 81.8% at 3 years compared with 59.8%...
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Fig. 2. Effect of inflow on knee salvage. The numbers of patients entering each interval are given on each curve. The labels show the cumulative salvage rate and the cumulative standard error corresponding to the end of the curve.

Fig. 3. Effect of previous revascularisation attempts on knee salvage. The numbers of patients entering each interval are given on each curve. The labels show the cumulative salvage rate and the cumulative standard error corresponding to the end of the curve.

for the 49 PTFE grafts (44.9%). All PTFE grafts were performed with a vein collar.

Tissue loss (Fig. 5). The group of patients presenting with tissue loss (severe CLI) showed 72.1% knee salvage at 3 years compared with 83.9% in patients presenting with rest pain. The difference was almost significant ($p = 0.0523$, s.e. = 6.14 and 7.87, respectively). 

Multivariate analysis. As statistical analysis of the previous factors is dependable, multivariate and Cox regression analysis was performed to assess the relative significance of each factor. The most important factors were thus shown to be the inflow ($p = 0.001$), the state of the profunda ($p = 0.001$), the graft material ($p = 0.034$) and previous revascularisation attempts ($p = 0.019$). Tissue loss failed to attain significance ($p = 0.43$).

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Knee salvage (\(p = 0.0308\))

- Vein 82\%, s.e. = 7.19
- PTFE 60\%, s.e. = 10.24

**Fig. 4.** Effect of graft material on knee salvage. The numbers of patients entering each interval are given on each curve. The labels show the cumulative salvage rate and the cumulative standard error corresponding to the end of the curve.

With or without tissue loss (\(p = 0.0523\))

- No tissue loss 84\%, s.e. = 10.24
- With tissue loss, 72\%, s.e. = 7.19

**Fig. 5.** Knee salvage in patients presenting with tissue loss or rest pain. The numbers of patients entering each interval are given on each curve. The labels show the cumulative salvage rate and the cumulative standard error corresponding to the end of the curve.

**Discussion**

The choice of amputation level in patients with terminal, non-reconstructible occlusive arterial disease is influenced by the twin objectives of ensuring both primary healing and mobility with the use of an artificial limb.\(^{31-34}\) Below-knee amputation is preferred to AK amputation\(^{32-36}\) because of the better prospects of rehabilitation (50\% vs. 25\%)\(^{32,33}\) and the lower mortality rates (8\% vs. 18\%),\(^{10}\) even if secondary procedures may be required to achieve healing.\(^{7,8}\) Approximately 10–20\% of BK amputations fail to heal and require revision to a higher level.\(^{10,31}\) Above-knee amputations usually heal primarily but walking with a prosthetic limb is difficult, and if bilateral is practically impossible.\(^{32,33}\) The other limb is often affected by occlusive arterial disease\(^{10,19,34,35}\) which results in amputation in about 30\% of cases.\(^{10,21,30}\) In patients with
bilateral amputation the rehabilitation rate is only
10%\(^{32,33}\) and these low figures justify an aggressive
approach to knee salvage.

In attempting to maximise the number of BK am-
putations, some operations may be performed in-
appropriately. This is evident from the high number
of revisions reported in the literature which are of
the order of 30%, \(^{10,12,33}\) The BK:AK ratio in two series falls
from an initial 2:1 to 1:4\(^{14}\) and from 1:4 to 0.9\(^{48}\)
following revision surgery. The recognised re-
habilitation advantage of BK amputation may in-
fluence the inclusion of more marginal cases. However,
some authors report no functional benefit in favour
of BK amputation.\(^{35,37}\)

If a failed distal graft adversely affects the am-
putation level, then primary amputation should be
considered in some patients in whom the chances of
achieving acceptable patency rates are poor. Schweiger
et al.\(^{29}\) showed a secondary patency rate of 14% at 3
years in secondary femorotibial grafts undertaken for
limb salvage. Johnson et al.\(^{7}\) report that 22% of patients
would have had a more expeditious rehabilitation and
minimal impairment of their lifestyle if treated by
primary amputation rather than revascularisation.

The evidence that a distal bypass graft does not
affect the amputation level is usually based on two
observations: firstly the similarity of the BK:AK ratio
in primary compared with secondary ampu-

tations\(^{2,11-13,19,120}\) and secondly the relatively constant
number of amputations performed despite the increase
in reconstructive procedures.\(^{9,20}\) This is probably in-
correct as a direct comparison between primary and
secondary amputees cannot be made. Some primary
amputations may have been undertaken for proximal
sepsis or gangrene exceeding the midtarsal level. Fur-
thermore, some studies include patients without peri-
pheral arterial disease, while others have evaluated
the number of patients supplied with a prosthesis and
the number of amputees in a given population.\(^{35,36}\)

In this series primary amputees survived less well
(33.3% at 3 years) compared with successful grafts
(61.9%) and this confirms previous reports.\(^{33,12,35,36}\)
Inhospital mortality rate was 18% in the primary am-
putation group vs. 10% in the secondary amputees,
which probably reflects the presence of other under-
lying causes in the first group. These results are similar
to those from Bath\(^{20}\) and Birmingham.\(^{8}\)

This series is unique in that it was performed on
infrapopliteal grafts undertaken for CLI. In Cook et
al.'s\(^{20}\) and Tsang et al.'s\(^{59}\) series all infraplaugal by-
passes were included in the analysis, without regard
to the outflow site. In Sayer et al.'s report\(^{22}\) 27% of the
grafts were to the popliteal artery and some may not
have been performed for CLI. In order to be certain
that the indication for intervention was critical isch-
aemia, the secondary patency rate should be strongly
associated with limb salvage, i.e. failure to the graft
should result in a major amputation.

Regarding previous revascularisation, our results
confirm reports\(^{6.15-18,34}\) showing a higher ultimate AK
amputation rate. Although it failed to attain sig-
nificance in univariate analysis, in multivariate Cox
regression analysis it was shown to be an important
factor. The significant difference in knee salvage be-
tween vein and PTFE grafts may be related to previous
revascularisation attempts that utilised the vein and
the fact that most of the prosthetic grafts were sec-
ondary procedures. In a series of 211 bypasses to the
tibial vessels using only PTFE, primary procedures
showed a 46% patency at 3 years vs. 14% for secondary
procedures.\(^{23}\) A failed previous revascularisation at-
tempt seems to affect the patency and consequently
limb salvage rates.\(^{25,26}\) Prosthetic materials may cause
thrombosis of the native vessels and one theoretical
advantage of veins is that this may be prevented. The
use of a vein collar at the distal end of a PTFE graft
may also confer this advantage. However, in this series
PTFE grafts fared significantly worse than vein grafts
as regards knee salvage, despite all being fashioned
with a vein collar. The lack of vein may indicate that
the atherosclerosis is more aggressive and multifocal
with the vein used for cardiac bypass, upper limb or
opposite limb reconstructive surgery.

Historically profundoplasty was undertaken as a
salvage procedure but its importance seems to have
faded.\(^{39,40}\) Our results confirm the importance of a good
profunda femoris in preserving the knee in cases of
failed distal bypass grafts.

Good inflow is equally important for knee salvage,
and is probably the most significant factor. Limbs
with diseased inflow, even if not haemodynamically
significant, showed 43% knee salvage at 3 years com-
pared with 82% for limbs with intact inflow. Correction
of the inflow did not affect the outcome \(p=0.8\). Further-
more, apart from disease progression, inflow may also
be affected by intimal hyperplasia at the proximal
anastomosis of the graft, which may affect
the native vessels, resulting in late knee loss after graft
failure.

Patients presenting with tissue loss showed worse
knee salvage than those presenting with rest pain.
These patients comprise a distinct group in CLI who
seem to have a different natural history from those
who present with rest pain only.

Our results show that although limb loss is strongly
associated with graft failure \(39\) major amputations
out of 41 graft occlusions) the factors associated with knee salvage were present before the bypass was undertaken and were only partially affected by the failed infrapopliteal graft. The vasculature around the knee, particularly the popliteal and geniculate arteries, are the vessels responsible for knee preservation and loss of inflow to these vessels determines knee loss. Failure of a distal bypass graft to the crural or ankle vessels is unlikely to affect these vessels, and should not affect knee perfusion. In contrast, failure of a graft to the popliteal artery may well cause thrombosis of the geniculate vessels and be associated with a higher rate of knee loss.

In summary, knee salvage is related to perfusion of the vessels surrounding the knee, which in turn depends upon the state of the profunda, the quality of inflow vessels, the history of previous revascularisation attempts, the use of vein as a conduit and the severity of CLI. These factors which significantly affect knee salvage exist before re-construction and are not affected by occlusion of an infrapopliteal distal bypass.

References


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