Part VII

Surgical treatments

Patency of Infrainguinal Bypass Grafts with Distal Venous Adjuncts

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The commonest indication for infrainguinal bypass is critical limb ischemia. Far fewer of these bypasses are performed for claudication. Approximately 500-1000 people per million population per year will develop critical ischemia (1). Of these about 70% will undergo some form of reconstruction (2). This will commonly involve an infrainguinal bypass. It is generally accepted that the best conduit for these bypasses is autogenous long saphenous vein. In some patients, however, this is not available and a prosthesis has to be used. It is recognised that prosthetic bypasses generally have worse patency rates than autogenous vein bypasses. This has lead to attempts to improve the patency of prosthetic bypasses using a variety of surgical adjuncts at the distal anastomosis.

Description of Adjunctive Methods

Composite Bypass

This simply involves the creation of a conduit using a length of autogenous vein and a length of prosthesis anastomosed together in end to end fashion. The distal segment of the conduit is comprised of vein which may be either in the reversed or non-reversed configuration.

Vein Cuffs

MILLER CUFF (3)

First described in 1984, this is the most frequently used adjunct. A length of vein twice as long as the arteriotomy is opened and sutured to the arteriotomy as a cuff. The prosthesis is then sutured to the cuff (Figure 1).

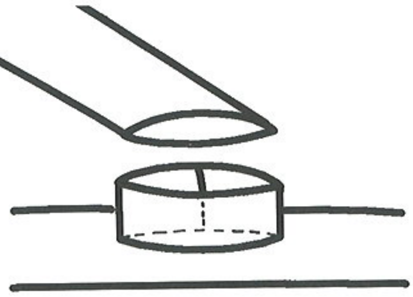

FIGURE 1
Miller Cuff

WOLFE BOOT (4)

This is a modification of the Miller cuff designed to streamline the toe of the anastomosis in an attempt to improve flow patterns (Figure 2).

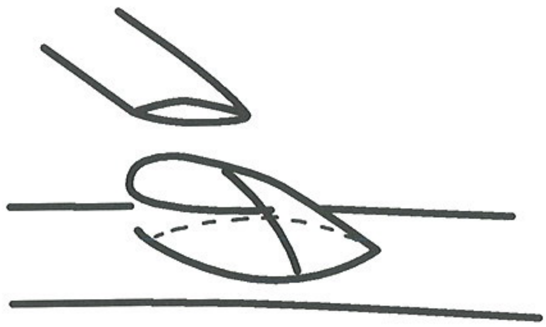

FIGURE 2
Wolf boot

Vein patch

TAYLOR (5)

This involves direct suture of the heel of the prosthesis to the artery. The prosthesis only extends halfway along the arteriotomy and the anastomosis is completed by suturing a vein patch from the prosthesis to the distal end of the arteriotomy (Figure 3).

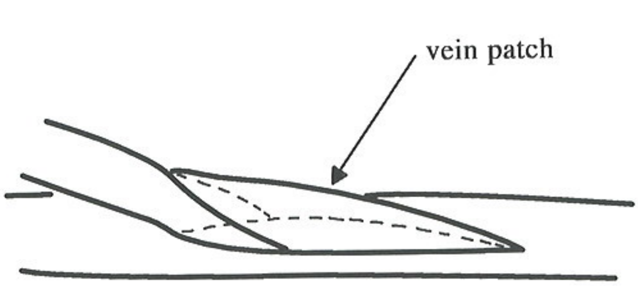

FIGURE 3
Taylor patch

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Linton

This involves initial closure of the arteriotomy using a vein patch sutured in place in the usual fashion. A longitudinal venotomy is then made in the proximal two thirds of the patch and the prosthesis sutured to this as a standard end to side anastomosis (Figure 4).

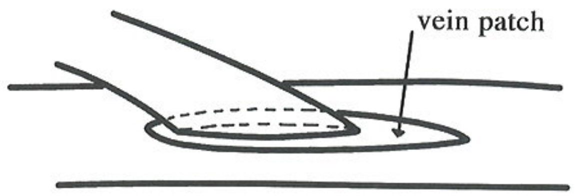

FIGURE 4
Linton patch

AV fistula

A vein adjacent to the artery is dissected out and a venotomy of the same length as the arteriotomy is made in it. The adjacent edges of the venotomy and arteriotomy are sutured together to form a common ostium to which the prosthesis is sutured end to side.

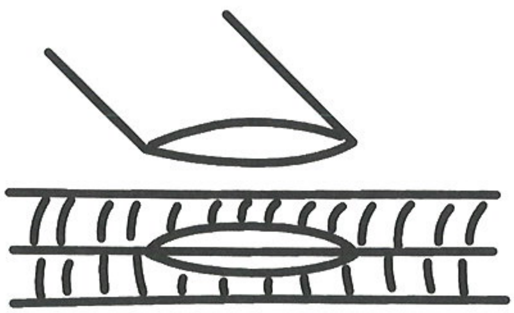

FIGURE 5
Arterio-venous fistula

Miller Cuff Patency rates

It is not surprising that most of the data available on enhanced prosthetic graft patency relates to grafts augmented with a Miller cuff since this was the first adjunct to be widely popularised.

Nevertheless, there is still a paucity of randomised, prospective data.

One multicentre, randomised, prospective, controlled trial has been performed (6). The trial compared PTFE bypasses with or without a Miller cuff onto three distal anastomotic sites:

a) above knee popliteal
b) below knee popliteal
c) tibial bypasses

Only 15 patients with tibial bypasses were randomised - an insufficient number to analyse. Patients were not entered consecutively into the trial, thus raising the risk of selection bias.

In the above knee popliteal position, 150 patients were randomised. A Miller cuff conferred no additional benefit with 1 year primary patency rates for cuffed and uncuffed bypasses being 80% and 84% respectively; two year primary patency figures were also similar at 72% and 70% respectively.

Ninety six patients undergoing below knee popliteal bypasses were randomised. A Miller cuff did significantly improve patency. One year primary patency rates for cuffed and uncuffed bypasses were 80% and 65% respectively, while 2 year primary patency rates were 52% and 29% respectively ($p=0.03$). Secondary patency rates were very similar to these results and there was no evidence to suggest that secondary procedures were facilitated by the presence of a Miller cuff.

There were no significant differences in limb salvage rates between cuffed and uncuffed bypasses at each level, although there was a trend in favour of increased limb salvage when below knee popliteal bypasses were carried out with a Miller cuff. In contrast, however, limb salvage was non-significantly better in above knee bypasses when a cuff was not used.

Interestingly, this study showed reduced bypass patency and limb salvage in the early post-operative period in the below knee popliteal group without a Miller cuff compared to those with a Miller cuff. This difference was maintained over the follow up period with no further separation of the patency or limb salvage plots. This implies that the advantage conferred by the Miller cuff in the below knee popliteal position is apparent in the immediate post-operative period and suggests that the cuff has an early but not late antithrombotic effect in the broadest sense. This may well be related to the greater technical ease with which a vein cuff compared to a prosthesis can be sutured to an artery. This supports the original reason for introducing of a vein cuff, namely that of facilitating the distal anastomosis (7).

This study is the only randomised trial assessing the value of Miller cuffs or any other vein adjunct to PTFE bypasses. Being critical, however, its value is diminished by the fact that patients were not entered consecutively and so selection bias is a real possibility. Follow up numbers were also fairly small, particularly in the below knee group where only 10 patients with a cuff and 5 without were followed for 2 years. The limb salvage data raises interesting questions. Why was it (non-significantly) better in the above knee bypass group who did not have a patch, when there was no difference in graft patency rates? Why was limb salvage reduced in the immediate post-operative period in the below knee bypass group without a patch - does this imply that this group had a worse degree of ischemia? In spite of these doubts, however, it is generally felt that these results are valid, particularly as there is support for them from elsewhere.

A large but retrospective and non-randomised review by Miller and his co-worker, Raptis, analysed 559 PTFE bypasses (8). Four hundred and thirty three patients received a Miller cuff, 56 a vein patch at the distal anastomosis which partially surrounded the PTFE and 70 had direct suture of PTFE to the distal artery.

In the above knee position, there was no improvement in primary patency with a Miller cuff, with three year primary patency rates being 69% and 68% for cuffed and uncuffed bypasses respectively.

Below the knee, a cuff did produce benefit with 3 year primary patency being 57% for cuffed and 29% for uncuffed bypasses.

In common with many retrospective series however, there are confounding factors in this study:

a) the patient numbers in the uncuffed group were much smaller than in the cuffed group;
b) a greater proportion of claudicants was included in the above knee position than in the below knee position, and overall more patients with claudication than critical ischemia were included in the series;
c) an uncuffed anastomosis was only used on healthy arteries;
d) the vein patch augmented distal anastomosis was not included separately in the analysis.

The follow up numbers in the cuffed group were good, with 51 patients with below knee bypasses being followed to 3 years. The uncuffed numbers were very small - 8 below knee bypasses being followed to 3 years.

This study did not find the immediate reduction in patency with below knee uncuffed bypasses compared to cuffed below knee bypasses. The patency plots started separating at 3 months, suggesting that some factor other than technical ease was responsible for improving the patency rates of cuffed below knee bypasses.

The authors suggested that the presence of a cuff protected the arterial run off from occlusion when the PTFE bypass thrombosed. This was based on the fact that 51% of bypasses which occluded needed only thrombectomy or the suture of a new bypass onto the old Miller cuff for salvage. No comparison is made, however, with thrombosed uncuffed bypasses and so this conclusion has to be guarded.

Less rigorous support for the use of vein cuffs is provided by Pappas et al (9). A series of vein cuff enhanced PTFE bypasses onto the popliteal artery (above and below knee) or calf vessels was compared with historical controls (uncuffed PTFE bypasses onto the same anatomical sites) from the same institution. Two year patency for popliteal bypasses was 75% and 46% for cuffed and uncuffed bypasses respectively; similarly 2 year patency for infrapopliteal bypasses was 62% and 12% respectively. The improved patency with cuffed anastomoses was translated into better limb salvage - 76% compared to 37%, although again with only historical controls. The numbers in the series were small, 20 popliteal and 23 infrapopliteal, with 2 patients being operated on for claudication and the remainder for critical ischemia.

Three non-comparative case series (10,11,12) have shown 2 year patency rates of 32% to 50% for PTFE bypasses augmented by a vein cuff onto predominantly the below knee popliteal or tibial vessels.

In these three studies the authors all advocated the use of PTFE popliteal and infrapopliteal bypasses with a vein cuff in selected patients where vein was not available.

High quality evidence supporting the use of Miller cuffs when carrying out PTFE infrainguinal bypasses is therefore scanty and is likely to remain so for the foreseeable future because of increasing fears of prosthetic graft infection leading to the use of vein whenever possible. Many centres now use duplex vein mapping and autogenous composite vein grafts (using the long and short saphenous veins as well as arm veins) in an attempt to avoid prostheses. The numbers required to reproduce the randomised controlled trial discussed above would therefore be difficult to recruit.

Decisions on the value of Miller cuffs therefore have to be made on the basis of the currently available evidence.

This evidence comprises one randomised controlled trial, one large, non-randomised and retrospective study, one small study using historical controls and a number of non-comparative case series (6-11). The evidence is consistent, however, suggesting improved patency of PTFE bypasses with Miller cuffs in the below knee position compared to bypasses without Miller cuffs. The data does not explain why Miller cuffs should give this advantage. The randomised controlled study found that the patency and limb salvage benefit was apparent in the first 30 days and that beyond this time there was no further advantage. This suggests that there is an early anti-thrombotic effect of the cuff as intimal hyperplasia or progression of disease cannot be implicated at this early stage.

The anti-thrombotic effect could relate to the greater technical ease of suturing a vein cuff compared to PTFE to the below knee popliteal artery. This would result in fewer technical errors and lower rates of early thrombosis.

Miller's retrospective study found that the patency rates of cuffed grafts only started improving compared to uncuffed grafts after 3 months. Greater technical ease could not account for this and alternatively the vein cuff may confer a beneficial effect via its endothelium or via the different flow mechanics it induces. Such effects would be expected to be long lasting and could explain the results of Miller's study.

In summary, the relatively small number of studies that have been performed have shown that Miller cuffs improve prosthetic infrainguinal graft patency in the below knee position. From the best available clinical data, the mechanism by which they improve patency may be related to a reduction in the rate of technical errors compared to direct suture of PTFE to the below knee popliteal artery.

Other Adjunctive Methods

Composite Vein and PTFE

A non randomised study (13) has found similar patency rates using PTFE with either a Miller cuff or a distal segment of reversed vein when anastomosing onto the popliteal or crural arteries. There were only small numbers with a Miller cuff compared to the distal reversed vein segment and the comparison was made on a historical basis. Patency rates were only acceptable if run off was good, but in this situation a composite segment of distal reversed vein may be an acceptable alternative to a vein cuff.

Arteriovenous fistula

An arteriovenous fistula (AVF) at the distal anastomosis has been used for both vein and prosthetic bypasses to improve flow through the bypass and thus improve patency rates. The AVF is performed as described above. There are reports of anastomoses of vein to the common ostium, PTFE to the common ostium and PTFE with a Miller cuff to the common ostium. The results are variable.

One prospective, randomised controlled trial (14) has been performed. This compared PTFE bypasses to the crural vessels with or without an AVF. All patients had a vein cuff. There were no significant differences between the groups in patency or limb salvage rates at one year.

In a non-randomised descriptive series of bypasses onto the popliteal, crural and pedal vessels, Biancari et al (15) found improved prosthetic patency and limb salvage in cases where an AVF was fashioned (most of their prosthetic bypasses also had a Miller cuff), although interestingly the mortality rate was higher in the group of patients who had an AVF.

Harris et al (16) examined bypasses onto single tibial vessels. They found that PTFE bypasses with an AVF and a vein cuff had a significantly better chance of patency than a PTFE bypass with an AVF alone. Vein graft patency was similar to patency in PTFE bypasses with a vein cuff and AVF. Limb salvage rates mirrored the patency results. Again, however, the study was non-randomised and used historical controls.

Wijesinghe et al (17) were not able to draw firm conclusions regarding the efficacy of an AVF at the distal anastomosis in their series offemoro-distal bypasses, but their results suggested that an AVF did not affect graft patency or patient survival but did reduce limb salvage.

Another non-randomised case series (18) has compared the use of either a vein cuff or an AVF at the distal anastomosis in PTFE bypasses onto crural vessels. It was found that while 3 year primary patency was better in the AVF group, 3 year secondary patency rates were no different and limb salvage was better in the vein cuff group. It was concluded that prosthetic grafts with vein cuffs offer improved limb salvage rates and a better chance of revision after occlusion compared to prosthetic grafts with an AVF.

Vein Patches

Published results studying patients with prosthetic grafts enhanced by a distal vein patch are scanty.

A non-comparative, non-randomised series (19) of such bypasses using the Linton vein patch technique onto crural vessels reported a 4 year primary patency of 63% and limb salvage of 79%. A similar study by Taylor using the Taylor patch yielded 5 year patency rates of 71% for bypasses onto the popliteal artery and 54% for those onto crural vessels.

Explanation for the patency difference with Miller cuffs

There appears to be a real improvement in patency of below knee popliteal prosthetic bypasses when a Miller cuff is used. One factor explaining this, and the reason why the procedure was first introduced, is the greater technical ease of suturing a vein cuff to the below knee popliteal. This would be expected to result in fewer technical errors and a higher early (but not later) patency rate – as shown in the randomised controlled trial of the technique. Another explanation of this improved early (but not later) patency is a subtle antithrombotic effect of the cuff which is either lost as time passes or becomes negligible in comparison to the other occlusive forces of intimal hyperplasia, disease progression and a long thrombogenic graft. Such an antithrombotic effect could be based on either more favourable flow patterns or on the anti-thrombogenic endothelium. In Miller's non-randomised series, however, the advantage of the cuff was not early but became apparent after 3 months. In order to explain this the cuff would have to have some effect on the occlusive forces acting after 3 months - these are dominated by intimal hyperplasia, suggesting that the mechanical or biological effect of the cuff may be important. Essentially, it is not clear why Miller cuffs have the effect they appear to have, but work examining the mechanical and biological effects of cuffs will be summarised.

Effects on Flow Mechanics

Using non-compliant in vitro polyester cast models of a standard end to side anastomosis, a Miller cuff, a Linton patch and a Taylor patch, Noori et al showed similar flow patterns in all the anastomotic types except the Miller cuff. A vortex forms in systole in all anastomoses. In the Miller cuff it persists through diastole and moves a little towards the toe of the anastomosis. In the other types of anastomosis the vortex moves towards the heel in diastole and breaks down before systole restarts. Another group has extended this work to examine the shape and size of the Miller cuff. It was found that the vortex was stable and persistent throughout the cardiac cycle in standard or high cuffs (13mm long and 8-11mm high). In longer or lower cuffs, the vortex became unstable and complex with large areas of flow separation and low velocities. This information is difficult to interpret clinically however, particularly as the Miller cuff flow pattern is different to that in a standard vein to artery end to side anastomosis. Nevertheless, these workers have suggested that lack of stagnation and constant washout of the anastomotic cavity may contribute to higher patency rates.

Low wall shear stress is associated with intimal hyperplasia. How et al examined the effect of a cuff on wall shear stress distribution in an in vitro model. In standard end to side anastomoses, low wall shear stress was found at the heel and along the floor of the anastomosis. In the model of a cuffed anastomosis, wall shear stress was higher at the heel, was only low along the floor of the anastomosis and the areas of low shear stress were less extensive than in the uncuffed model. It was felt that higher wall shear stress at the heel may be associated with less development of intimal hyperplasia at this site.

The presence of vein at the distal anastomosis alters compliance. This was studied by Piorko et al using PTFE anastomosed in vitro to bovine carotid artery. With a standard end to side anastomosis the area of artery just distal to the suture line showed increased compliance compared to artery well away from the anastomosis. When a Linton patch or Miller cuff was used, this area of artery just distal to the suture line showed compliance very similar to distant artery. As would be expected, however, compliance within the Linton patch or Miller cuff was higher than any other area measured. This shift in the area of maximal compliance from the artery immediately distal to the suture line to the vein patch/cuff was postulated to reduce occlusion rates, possibly by reducing the formation of intimal hyperplasia.

Increased blood flow through the graft and anastomosis would reduce the risk of thrombosis. Beard et al compared pulsatile blood flow rates through PTFE grafts anastomosed to cadaveric internal mammary arteries with and without a Miller cuff. The arteries were matched for internal diameter.

Below an artery diameter of 2.0 mm flow through grafts with a Miller cuff was significantly higher than through grafts without a cuff. It was suggested that this was due to the greater compliance of the cuff reducing the anastomotic resistance.

This was confirmed in work measuring the impedance index of various in vitro PTFE end to side anastomoses. The impedance index was lower in the presence of a Miller cuff regardless of the angle of the anastomosis. Furthermore, as the angle of the anastomosis became more acute, the impedance index fell.

The flow patterns found in Miller cuff anastomoses have been reproduced in a commercially available cuffed PTFE bypass. Using duplex ultrasound, 77% of patients having a bypass with a precuffed graft were found to have a similar vortex pattern within the distal anastomosis as was shown in anatomically accurate in vitro models.

The presence of a Miller cuff undoubtedly alters the flow dynamics at the distal anastomosis, with a reduced resistance, a constant stable vortex, a smaller area of low wall shear stress, higher wall shear stress at the heel, a constant washout of the anastomosis, normal compliance of the artery just distal to the suture line with a higher compliance within the cuff itself and a reduced resistance to flow across the anastomosis. Some or all of these factors in whole or in part may contribute to the improved patency of bypasses with a Miller cuff in the below knee position. There is no proof of this, however, and there is no explanation why above knee bypass patency is not also improved by a Miller cuff.

Biological factors

In addition to differences related to flow patterns within a Miller cuff, it is possible that the presence of venous endothelium may contribute to improved patency. This possible biological effect was compared to the mechanical effect of the cuff by Noberto et al. They performed bilateral bypasses to the carotid arteries of dogs in vivo. In one group the left sided operation included a vein cuff, while the right sided operation again had a vein cuff but this was surrounded by a PTFE jacket to prevent compliant distension of the vein cuff.

No significant difference was found in the thickness of intimal hyperplasia between the two groups after 10 weeks. In a further experiment, the left sided bypass was performed in a standard end to side fashion, while the right sided anastomosis was created by suturing a 1cm length of PTFE to the arteriotomy in the same fashion as a vein cuff and then anastomosing the bypass to this cuff. In 80% of these animals there was bilateral graft thrombosis. This work suggests that it is the presence of vein in the cuff rather than the cuffs compliance which results in less intimal hyperplasia.

This work was confirmed by Kissin et al. PTFE bypasses were placed into pigs using 3 types of distal anastomosis. The first was a standard end to side, the second used a vein cuff and the third used a PTFE cuff. It was found that there was significantly less intimal hyperplasia in the vein cuff anastomoses than in either of the other two groups. Furthermore the vein cuff altered the distribution of intimal hyperplasia from the toe area in the end to side and PTFE cuff anastomoses to the vein: PTFE suture line in the vein cuff anastomosis. Again this suggests that the protective effect of a vein cuff is related to biological rather than haemodynamic factors.

Further support for biological factors playing an role in reducing intimal hyperplasia comes from a dog model of a PTFE dialysis loop fistula. Gentile et al compared femoral artery to femoral vein PTFE loop fistulae with and without a Taylor patch at the venous anastomosis. They found a significantly greater thickness of intimal hyperplasia in the suture line of the unpatched group. The unpatched group also had significantly greater intimal thickening in the outflow vein.

The major drawback with these studies is that they were all carried out in animal models which have questionable relevance to the human situation. This concern is highlighted by the short duration of graft implantation – less than 10 weeks for all studies. This is felt to be barely long enough for intimal hyperplasia to start developing in humans, raising the possibility that a different disease process is being studied in animal models. Nevertheless, the results do all show a reduction in intimal hyperplasia with vein cuffs which appears to require the presence of vein rather than PTFE in the cuff.

Conclusions

The available evidence does suggest that Miller cuffs increase the patency rates of PTFE infrainguinal bypasses when these are placed onto the below knee popliteal artery. The cuff confers no benefit in the above knee position. It is not known why there should be this difference, but it could be postulated that the patency of below knee prosthetic bypasses is much more precarious than above knee bypasses (because of their greater length, their anatomical course and because they cross the knee joint) and that any small benefit will have a clinically observable effect. Further, more rigorous studies are required before this can be confirmed and before the case for Miller cuffs could be said to be proven.

This uncertainty extends into the possible reasons why there appears to be this advantage. The best clinical evidence suggests this may be simply due to greater technical ease. Not all the clinical evidence supports this, however, and mechanical and biological differences have been described which may explain these other clinical results. The place of preformed cuffed grafts is not clear and randomised trials are required to clarify this.

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