PTFE Bypass to Below-knee Arteries: Distal Vein Collar or Not? A Prospective Randomised Multicentre Study

SCAMICOS1,2

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KEYWORDS
PTFE bypass; Femoro-popliteal; Femoro-crural; Popliteal arteries; Tibial arteries; Vein collar; Critical limb ischaemia

Abstract
Background: Patency and limb salvage after synthetic bypass to the arteries below-knee are inferior to that which can be achieved with autologous vein. Use of a vein collar at the distal anastomosis has been suggested to improve patency and limb salvage, a problem that is analysed in this randomised clinical study.

Methods: Patients with critical limb ischaemia undergoing polytetrafluoroethylene (PTFE) bypass to below-knee arteries were randomly either assigned a vein collar or not in two groups – bypass to the popliteal artery below-knee (femoro-popliteal below-knee (FemPopBK)) and more distal bypass (femoro-distal bypass (FemDist)). Follow-up was scheduled until amputation, death or at most 5 years, whichever event occurred first.

Results: In the FemPopBK and in the FemDist groups, 115/202 and 72/150 were randomised to have a vein collar, respectively. Information was available for 345 of 352 randomised patients (98%). At 3 years, primary patency was 26% (95% confidence interval (CI) 18–38) with a vein collar and 43 (33–58) without a vein collar for femoro-popliteal bypass and 20 (11–38), and 17 (9–33) for femoro-distal bypass, respectively. The corresponding figures for limb salvage were 64 (54–75) and 61 (50–74) for femoro-popliteal bypass, and 59 (46–76) and 44 (32–61) for femoro-distal bypass with and without a vein collar, respectively. Log-rank-test for the whole Kaplan–Meier life table curve showed no statistically significant differences with or without vein collar primary patency: \( p = 0.0853, p = 0.228 \); secondary patency: \( p = 0.317, p = 0.280 \); limb salvage: \( p = 0.757, p = 0.187 \) for FemPopBK and FemDist, respectively. The use of a vein collar did not influence patency or limb salvage.

* Randomised clinical trial.
1 Scandinavian Miller Collar Study, refer to the Acknowledgements section in this paper for further details.
2 Correspondence to: F. Lundgren, Consultant Vascular Surgeon, Department of Cardiovascular Surgery, Heart Centre, University Hospital, S-581 85 Linköping, Sweden, E-mail address: fredrik.lundgren@lio.se

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Synthetic bypass grafts to the arteries below the knee have inferior patency compared with autologous vein grafts and most vascular surgeons agree that vein is the preferred conduit for reconstruction at this level. However, for various reasons, some patients do not have a suitable vein. The question is how such patients should be handled when they suffer from critical limb ischaemia and need a femoro-popliteal below-knee or a femorodistal reconstruction. Primary amputation might be considered but it has been suggested that the interposition of a vein collar at the distal anastomosis can improve the patency to motivate a reconstruction with a synthetic graft.2,3

The present prospective randomised clinical study was designed to evaluate if such an interposed vein collar actually improves patency and limb salvage in patients undergoing reconstruction with synthetic polytetrafluoroethylene (PTFE) grafts.

Material and Methods

A total of 352 patients with critical limb ischaemia (rest pain, ulcer or gangrene) scheduled for either femoropopliteal below-knee (FemPopBK; n = 202) or femorodistal bypass (FemDist; n = 150) bypass with a PTFE graft have been randomly allocated for application of a vein collar interposed at the distal anastomosis between the PTFE graft and the recipient artery or a direct anastomosis without vein interposition. The recruitment took place from 12 January 1995 to 15 June 1998. Three centres from Denmark and 29 from Sweden participated. Randomisation was made by means of sealed envelopes. Packages of envelopes with allocated study arm and protocols for follow-up were prepared by the study office. Randomisation packages were made for each participating centre. It was done separately for patients undergoing FemPopBK and infra-popliteal reconstruction (FemDist) (to the anterior or posterior tibial artery, the peroneal artery or the tibiofibular trunk). Reconstructions to the foot arteries were not included. For each participating centre, two packages of randomisation envelopes, one for FemPopBK (16 envelopes) and the other for FemDist (16 envelopes), were prepared. In each package there was the same number of allocations to vein collar as to no-collar patients. When the surgeon had confirmed the presence of an acceptable recipient artery, an envelope was picked at random from the appropriate package. For centres that randomised more than 16 patients in any group, new packages of the same type were prepared. Participating vascular units were required to master the vein collar technique and have the experience of five such reconstructions before entering the trial. Only patients with critical ischaemia (rest pain, arterial ulcers or gangrene) were eligible for the study. Ankle blood pressure was not included in the criteria for critical ischaemia as they often are falsely high and neither was blood pressure of the first toe as this method was not available at all centres.

The type of vein collar used was left to the discretion of the operating surgeon, and some surgeons used the collar originally suggested by Miller,2 while others preferred the 'St. Mary’s boot'4 (reports of vein collar type were available for 182 of 197 operations (92%) and of these 182 operations, 91 (50%) used the original method). The use of adjuvant medication to prevent thrombosis of the grafts was also left to the discretion of the operating surgeon. At 30-day-follow-up, information concerning the use of anti-platelet or anticoagulant drugs was available for 235 patients and was: acetylsalicylic acid: 63.7%, 54.1%; anticoagulant: 16.1%, 22.5%; acetylsalicylic acid combined with anticoagulant: 1.6%, 4.5%; and other anti-platelet or anticoagulant drug: 4.8%, 8.1% for patients with and without vein collar, respectively. Thus, 86.3% and 89.2% of the patients with and without vein collar, respectively, availed of anti-platelet or anticoagulant medication. A PTFE graft from either Gore or Impra was used but there was no intention to compare the two brands. Any diameter of graft was allowed, the diameter being 6 mm in the vast majority of operations (6 mm: n = 303, 5 mm: n = 13, 8 mm: n = 2 and unknown: n = 25).

Follow-up was scheduled at 1, 3, 6 and 12 months and thereafter annually for at most 5 years, until amputation of the limb or death of the patient, whichever event occurred first.

The Swedish centres (n = 29) participating in this trial also performed an independent randomisation of the same patients to either use an external support of the PTFE graft or not. The Danish centres (n = 3) used externally supported PTFE grafts in all patients. Thus, the randomisation envelopes for Swedish centres included additional information as to whether an externally supported graft should be used or not. This was set up as a factorial design with equal probability of having external support or not in addition to a vein collar or not; consequently, 50% of the patients allocated to a vein collar had external support and 50% of the patients allocated to no-collar did not have external support. The result of this independent study is to be published separately.

Hypotheses, power calculation, statistics and ethics

Prior to the study, two primary and four secondary hypotheses were specified and it was agreed that these hypotheses should be tested by means of log-rank analysis.6

Primary hypotheses. A ‘vein collar’ at the distal anastomosis in bypass surgery ‘with PTFE’ to the below-knee popliteal artery (FemPopBK) or infra-popliteal arteries (FemDist) ‘improves primary patency’.

Secondary hypotheses. A ‘vein collar’ at the distal anastomosis in bypass surgery ‘with PTFE’ to the below-knee popliteal artery (FemPopBK) or infra-popliteal arteries (FemDist) ‘improves secondary patency’ and/or ‘limb salvage’.

Conclusion: This study failed to show any benefit for vein collar with PTFE bypass to a below-knee artery.

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End points in the study were specified as 'amputation' (above-knee, below-knee or foot) and 'death'. However, 'primary occlusion' (failed primary patency) was the primary outcome and 'secondary occlusion' (failed secondary patency) and 'amputation' (failed limb salvage) were the secondary outcomes. Graft patency was verified by the methods used by the various departments recruiting patients. The methods were angiography, duplex ultrasonography, control that an improved ankle–brachial index (ABI) after operation was maintained during follow-up, plethysmographic blood flow in the graft, a palpable pulse over the graft or a bi- or triphasic Doppler signal detected at two points over the graft. However, report of the method used to verify an occlusion in an individual patient was not demanded in the study. 'Primary patency' was defined as a patent graft without any intervention to open up or prevent a graft occlusion. 'Secondary patency' was defined as a patent graft after one or several interventions to open up or prevent a graft occlusion. When definitive information was available of patency at one point in time and non-patency at another point in time but there was no information as to when the occlusion actually did take place, the midpoint between the two dates was used as the time point of occlusion.

At the time the study was planned, the 1-year patencies after PTFE bypass in the SwedVasc Registry were 50% and 40% at 1 year of follow-up for FemPopBK and FemDist, respectively. In the literature, 75% 1-year primary patency for FemPopBK with vein collar has been claimed. We, therefore, chose to test for a 50% relative improvement of primary patency in both the FemPopBK and FemDist groups.

If patency at 1 year after FemPopBK bypass is 50%, an improvement of 50% (patency 75%) with the help of a vein collar would require \( 2 \times 55 = 110 \) patients available for evaluation at 1 year \((a = 0.05\) and \(\beta = 0.80\)). However, one-fifth of the patients are likely to die during the first year, which needs to be compensated for with nearly 20 more patients. Thus, 130 patients were required in the FemPopBK group. If patency at 1 year after FemDist bypass is 40%, an improvement of 50% (patency 60%) with a vein collar would require \( 2 \times 95 = 190 \) patients available for evaluation at 1 year \((a = 0.05\) and \(\beta = 0.80\)). Again, death during the first year will need compensation with nearly 40 extra patients. Thus, 230 patients were required in the FemDist group. Two-sided power calculations were used.

Continuous data were summarised as median (1st–3rd quartile), categorical data as \(n/N\) (percent) and life table data as percent (95% CI). Differences between categorical data were tested with the chi\(^2\) test\(^9\) and differences between data summarised using Kaplan–Meier life table technique\(^10\) were tested with the log-rank test\(^6\) for the whole life table curve. All log-rank analyses were stratified for the presence or not of external support to eliminate any possible effect of the variable ‘external support’. Patency differences between patients with and without a vein collar at a specific time point were calculated with use of effective sampling size.\(^{11}\) Interaction between factors was tested by means of Cox regression.\(^{12}\) All analyses were made on the basis of intention to treat. Calculations and analyses were performed with Microsoft\(^{13}\) Excel (Microsoft Corporation, Redmond, Washington, USA) and the R-language.\(^{13}\)

The study was approved by the Ethics Committee at the University of Linköping, Sweden and the Scientific Ethics Committee in the municipalities of Copenhagen and Frederiksberg, Denmark. Informed consent was obtained before the operation and patients were not to be randomised unless an acceptable recipient artery was available at the operation. The companies supporting the study did neither have access to the data nor any influence in preparation of the manuscript. The reporting standards of ‘The Revised CONSORT Statement for Reporting Randomised Trials: Explanation and Elaboration’ have been used for the manuscript.\(^{14}\)

**Results**

**Randomisation, missing information and protocol violations**

One female patient was reported to have been randomised but her further whereabouts, including the group she belonged to, are not known and she has been excluded in all subsequent analyses. In the FemPopBK group and in the FemDist group, 115/202 and 72/150 were randomised to have a vein collar, respectively. The distribution of the randomisation was somewhat skewed but not more than what can be expected by chance (chi\(^2\) = 2.57, df = 1, \(p = 0.11\)).

![Flow chart for 353 patients with critical ischaemia randomised to vein collar or no vein collar at the distal anastomosis in two groups: FemPopBK (femoro-politeal bypass below-knee) and FemDist (femoro-distal bypass).](image)
Information was missing for three patients in the FemPopBK group, leaving 199 for analysis (114 with collar) and for four patients in the FemDist group, leaving 146 patients for analysis (69 with collar). In total, information from 345 of 352 randomised patients was used in the analysis (98%) (Fig. 1).

Three protocol violations occurred in the FemPopBK group, including one patient having a suitable vein to be used for reconstruction, one patient having a distal reconstruction and one patient receiving a collar despite randomisation to the ‘non-collar’ group. However, all patients were analysed by intention to treat. The results were not influenced by whether an intention to treat or a per-protocol analysis was performed.

Patient population: baseline, operative data and 30-day complications

Table 1 shows the baseline data for the two randomised groups (FemPopBK and FemDist) separately for patients with and without vein collar together with overall data for the 345 analysable patients. Table 2 shows the complications and primary patency, limb salvage and survival at 30 days for the two randomised groups (FemPopBK and FemDist) separately for patients with and without vein collar together with data for all patients. There were no clinically important differences between patients with and without collar, except for primary patency in the FemDist group, which was 15% higher in patients with a collar, though not significant. More than one-fourth of the patients had at least some local complication within 30 days after surgery (Table 2). There were 8% wound complications and a mortality rate of 4% at 30 days after surgery for the whole group of patients.

Primary patency, secondary patency, limb salvage and survival

In Figs. 2–5, the probability of primary patency, secondary patency, limb salvage and survival are shown with Kaplan–Meier life table technique and the results of the log-rank test are also given for the two randomised groups (FemPopBK and FemDist) separately for patients with and without vein collar. More than 50% of the patients were deceased after 5 years (Fig. 5). Table 3 shows primary patency, secondary patency, limb salvage and survival at 3 years together with the 95% CI. From the estimated primary patency rates and with use of effective sample size,11 at 3

![Table 1](image)

Baseline data of randomised and finally analysed patients in the FemPopBK and FemDist bypass groups.a

<table>
<thead>
<tr>
<th></th>
<th>FemPopBK</th>
<th>FemDist</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No collar</td>
<td>Collar</td>
<td>No collar</td>
</tr>
<tr>
<td>N</td>
<td>85</td>
<td>114</td>
<td>77</td>
</tr>
<tr>
<td>Male sex</td>
<td>30/85 (35%)</td>
<td>47/114 (41%)</td>
<td>32/77 (42%)</td>
</tr>
<tr>
<td>Age years</td>
<td>79 (71 82)</td>
<td>76 (70 83)</td>
<td>79 (71 82)</td>
</tr>
<tr>
<td>Rest pain/ulcer/gangrene</td>
<td>80/85 (94%)</td>
<td>106/114 (93%)</td>
<td>74/77 (96%)</td>
</tr>
<tr>
<td>Acute ischaemia or severe intermittent claudication</td>
<td>5/85 (6%)</td>
<td>8/114 (7%)</td>
<td>3/77 (4%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>28/80 (35%)</td>
<td>40/109 (37%)</td>
<td>28/76 (37%)</td>
</tr>
<tr>
<td>Cardiac disease</td>
<td>50/82 (61%)</td>
<td>62/110 (55%)</td>
<td>54/75 (72%)</td>
</tr>
<tr>
<td>Previous vascular surgeryb</td>
<td>43/81 (53%)</td>
<td>60/91 (66%)</td>
<td>45/76 (59%)</td>
</tr>
<tr>
<td>Pulmonary disease</td>
<td>9/81 (11%)</td>
<td>8/109 (7%)</td>
<td>9/74 (12%)</td>
</tr>
<tr>
<td>Renal disease</td>
<td>8/81 (10%)</td>
<td>9/109 (8%)</td>
<td>8/72 (11%)</td>
</tr>
<tr>
<td>Smokersc</td>
<td>27/77 (35%)</td>
<td>35/100 (35%)</td>
<td>21/66 (47%)</td>
</tr>
</tbody>
</table>

a Median (1st and 3rd quartile) is used for age. Numbers do not necessarily add up as full information was not available for all patients.

b Any previous vascular surgery or major amputation.

c Any regular smoking during the last five years.

![Table 2](image)

Complications and some life table data within 30 days after femoro-popliteal below-knee and femoro-distal bypass and for all operated patients.a

<table>
<thead>
<tr>
<th></th>
<th>FemPopBK</th>
<th>Collar</th>
<th>FemDist</th>
<th>Collar</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound complication or infection</td>
<td>4/85 (5%)</td>
<td>12/114 (11%)</td>
<td>8/77 (10%)</td>
<td>4/69 (6%)</td>
<td>28/345 (8%)</td>
</tr>
<tr>
<td>Bleeding</td>
<td>5/85 (6%)</td>
<td>5/114 (4%)</td>
<td>10/77 (13%)</td>
<td>6/69 (9%)</td>
<td>26/345 (8%)</td>
</tr>
<tr>
<td>Cardiac complication</td>
<td>5/85 (6%)</td>
<td>5/114 (4%)</td>
<td>10/77 (13%)</td>
<td>3/69 (4%)</td>
<td>23/345 (7%)</td>
</tr>
<tr>
<td>No complication</td>
<td>70/85 (82%)</td>
<td>82/114 (72%)</td>
<td>47/77 (61%)</td>
<td>54/69 (78%)</td>
<td>253/345 (73%)</td>
</tr>
<tr>
<td>Primary patency</td>
<td>90 (84–97)</td>
<td>87 (81–93)</td>
<td>72 (63–83)</td>
<td>87 (79–95)</td>
<td>84 (80–88)</td>
</tr>
<tr>
<td>Limb salvage</td>
<td>95 (91–100)</td>
<td>95 (91–99)</td>
<td>89 (83–97)</td>
<td>96 (91–100)</td>
<td>94 (91–96)</td>
</tr>
<tr>
<td>Survival</td>
<td>98 (94–100)</td>
<td>98 (96–100)</td>
<td>90 (84–98)</td>
<td>95 (91–100)</td>
<td>96 (94–98)</td>
</tr>
</tbody>
</table>

a Categorical data is given as n/N (percent) and life table data as percent (95% confidence interval).
years CI for differences between patients without and with vein collar was calculated as +2.8% to +35% and −18% to +12% for the FemPopBK and FemDist groups, respectively. However, when all time points in the Kaplan–Meier life table were evaluated, there were no statistically significant differences between patients with and without vein collar (primary patency: $\chi^2 = 3, 1 \text{ df, } p = 0.0853$ and $\chi^2 = 1.5, 1 \text{ df, } p = 0.228$; secondary patency: $\chi^2 = 1.1 \text{ df, } p = 0.317$ and $\chi^2 = 1.2, 1 \text{ df, } p = 0.280$; limb salvage: $\chi^2 = 0.1, 1 \text{ df, } p = 0.757$ and $\chi^2 = 1.7, 1 \text{ df, } p = 0.187$ for FemPopBK and FemDist, respectively; Figs. 2–4). Only 82 patients had a secondary patency longer than their primary patency and the difference between secondary and primary patency was median (1st and 3rd quartiles) 67.6 (20 and 186) days. However, for 11 patients the difference was more than 365 days. The median (1st and 3rd quartile) observation times were 626 (183.5 and 1111) and 363.5 (91.25 and 904.25) days for FemPopBK and FemDist, respectively. Interaction between the factor ‘vein collar’ on the one hand and ‘small study centre (<10 patients randomised)’, ‘external support’ and ‘the 6% patients with acute ischaemia/severe claudication’ on the other were tested by means of Cox regression\textsuperscript{12} and no statistically significant interactions were found (results not shown).

Discussion

The present study has failed to show any beneficial effect of an interposed vein collar at the distal anastomosis in patients with critical limb ischaemia operated upon with a synthetic PTFE graft to the popliteal artery below the knee joint (FemPopBK) or to the crural arteries (FemDist). This is true with respect to primary patency, secondary patency as well as limb salvage in both groups of reconstruction.

Patients with and without vein collar compare well at baseline with respect to co-morbidities as well as sex and age distribution. This is true also with respect to the localisation of the distal anastomosis (Table 1). Unfortunately, the distal runoff was not registered in the different groups of the study and such data could have further confirmed the comparability between groups. However, the

![Figure 2](image1.png)  
**Figure 2** Primary patency for the FemPopBK (a) and FemDist (b) bypass groups. In the log-rank-test stratification was used for "external support" as explained in "Hypotheses, power calculation, statistics, and ethics". The standard error of the KM-curves did not exceed 10% anywhere in the curves.

![Figure 3](image2.png)  
**Figure 3** Secondary patency for the FemPopBK (a) and FemDist (b) bypass groups. In the log-rank-test stratification was used for "external support" as explained in "Hypotheses, power calculation, statistics, and ethics". The standard error of the KM-curves did not exceed 10% anywhere in the curves.
randomisation technique ought to cancel out such possible differences. Missing information and protocol violations were rare. Taking the old age of the patients into consideration, an acceptable follow-up rate was achieved. Patients were recruited to the FemPopBK group in excess of that which was required according to the power analysis, but the study failed to recruit the stipulated number of patients to the FemDist group. Our data are not compatible with any advantage for the collar in the FemPopBK group at the 3-year point in time (the whole CI is above 0%, +2.8% and +35%). However, in the FemDist part of the study (where CI is between −18% and +12%), our data are still compatible with clinically important better (as well as worse) patency for the interposed cuff and this may of course be an effect of the lower power in this part of the study. The lack of a positive effect of the vein collar decreases with time (Figs. 2–4). Using the results of this study to recalculate sample size indicates the need of a substantial number of patients to study the effect of a vein collar in the infra-popliteal position, which would hardly make such a study of practical interest. Making our results public seems reasonable and also ethical should anyone want to perform a meta-analysis.

The main finding of the study is the lack of any improved patency associated with the use of vein collar. In the FemPopBK group, there was, in fact, a numerically detrimental, but statistically not significant, effect of the vein collar with respect to both primary and secondary patencies. This is also supported by the estimated CI of the difference in primary patency rate at 3 years for patients with and without vein collar which did not include any higher patency for the vein collar group. The differences between primary and secondary patency were small.

Table 3  Primary patency, secondary patency, limb salvage, and survival at three years after the reconstruction with expanded PTFE graft.

<table>
<thead>
<tr>
<th></th>
<th>FemPopBK</th>
<th>FemDist</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Percent</td>
<td>95% CI</td>
</tr>
<tr>
<td><strong>Primary patency</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collar</td>
<td>26</td>
<td>18–38</td>
</tr>
<tr>
<td>No collar</td>
<td>43</td>
<td>33–58</td>
</tr>
<tr>
<td><strong>Secondary patency</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collar</td>
<td>32</td>
<td>23–44</td>
</tr>
<tr>
<td>No collar</td>
<td>42</td>
<td>31–56</td>
</tr>
<tr>
<td><strong>Limb salvage</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collar</td>
<td>64</td>
<td>54–75</td>
</tr>
<tr>
<td>No collar</td>
<td>61</td>
<td>50–74</td>
</tr>
<tr>
<td><strong>Survival</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collar</td>
<td>60</td>
<td>51–73</td>
</tr>
<tr>
<td>No collar</td>
<td>67</td>
<td>56–81</td>
</tr>
</tbody>
</table>
therefore appears that redo surgery after an occlusion has little advantage to offer to the patient. However, alternatively, this could also be accounted for by reluctance for re-intervention and 11 patients gained more than a year of further patency with a re-intervention. In the FemDist group, there was again, not statistically significant, a numerically improved patency with a vein collar during the second and part of the third year of follow-up (Fig. 2(b) and 3(b)). Although speculative in this study, this may be an effect of the suggested decreased formation of pseudo-intima with use of the vein collar\textsuperscript{15} or possibly an effect of more space being available in the vein collar to accommodate the bulk of pseudo-intima. Another suggested beneficial effect is a change in the haemodynamic forces, which has stimulated to the design of PTFE grafts with a prefabricated widened anastomotic part.\textsuperscript{16} However, the effect (true or false) diminishes with time and, overall, no statistically significant effect has been established for patency. Further, the primary patencies with use of grafts with a prefabricated widened anastomotic part\textsuperscript{16} are very similar to those found in the present study and, to the best of our knowledge, the advantage of such grafts have not been proved or tested in any randomised study.

A further suggested advantage with the vein collar is that the recipient artery may be spared from propagation of the thrombotic process after an occlusion.\textsuperscript{17} Such mechanism may have some support, although speculative, by the fact that the limb salvage rate is numerically better in patients with vein collars independent of the site of the distal anastomosis despite the fact that patency is numerically worse for those with vein collars in the FemPopBK group. However, again, no statistically significant overall effects were found with respect to limb salvage.

The Joint Vascular Research Group (JVRG) of UK has published two reports\textsuperscript{17,18} of their study of the vein collar and its effect with respect to patency and limb salvage in the above-knee and below-knee position. The first publication reported an improved patency and a tendency towards better limb salvage in the below-knee position. In the second publication (with a median follow-up time of 622 days), the improved patency was confirmed in the below-knee position but no effect was established with respect to limb salvage, albeit it appears as if the more distal reconstructions were excluded from the analysis in that report. It is not immediately evident how the discrepancies between the JVRG study and the present one should be explained. However, the patient population showed some differences. The patients in the present study were a decade older, probably explaining the higher proportion of females in this study (60\% compared with 40\% in the JVRG study). Another important difference was, however, the much higher proportion of distal bypasses in the present study. The present patient population is rather typical for Swedish patients with critical limb ischaemia — 36\% had diabetes, 61\% cardiac disease, 60\% had undergone previous vascular surgery or amputation and 32\% were smokers (Table 1). These differences between the populations may explain at least part of the different results. However, is it likely that the vein collar differs in effect between younger males and older females with thinner arteries and failing hearts?

Finally, the femoro-popliteal below-knee or more distal reconstruction to the crural arteries with synthetic graft is not a simple task in this frail group of patients with an abundance of co-morbidities and considerable age as illustrated by the high complication rates and mortality. This is especially so in light of the rather modest chances of long-term success with respect to the patency of the reconstructions with only one-fifth of the reconstructions patent at 5 years. An individual patient might well be better off with primary amputation, if necessary, and prompt rehabilitation.\textsuperscript{1} Alternatively, in individual patients, it may be wise to resort to more lenient endovascular methods if this is technically feasible. At least this may not burden the patient with complications to the same degree as open surgery does.\textsuperscript{19} Whether or not these methods give results comparable to bypass surgery in the group of patients included in this study, however, has yet to be shown in a randomised trial. In the Basil study,\textsuperscript{20} patients with critical ischaemia scheduled for an infrainguinal procedure were randomised between bypass and endovascular technique. The main conclusion was that fit patients did better on long-term basis with a bypass, whereas endovascular technique appeared to suit not-so-fit patients better. However, there are large differences between the patient population in the Basil study and in the design of that study when compared to the present one: predominately male patients, only one-third of the patients had had previous vascular surgery, one-third of the patients had an above-knee lesion, of the patients with bypass three-fourths were reconstructed with a saphenous vein. Further, the Basil study did not report on patency or limb salvage, but only on the combined end-point amputation-free survival and on general survival. Therefore, it is rather questionable if the findings of the Basil study are applicable to the population of the present study. However, the mortality of 60\% at 3 years in both studies may indicate that the general burden of disease is approximately similar in the two studies.

In conclusion, in an elderly, predominately female population with critical limb ischaemia and with a substantial share of cardiovascular disease, the use of an anastomotic vein collar did not influence patency or limb salvage when a PTFE graft was used for below-knee reconstructive bypass.

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Principal investigator and main author: Fredrik Lundgren, Consultant Vascular Surgeon, MD, PhD, Department of Cardio-Vascular Surgery, Heart Centre, University Hospital, S-581 85 Linköping, Sweden.

Monitoring committee: Professor David Bergquist, Uppsala, Sweden; Professor Lars Norgren, Örebro, Sweden; Professor Torben Schroeder, Rigshospitalet, Copenhagen, Denmark.

Statistical consultant: John Carstensen, Tema Hälsa, University of Linköping, Sweden.
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Sweden

Boden (Christian Almström, 5); Borås (Christer Drott, 18); Eskilstuna (Ingvar Jansson, 18); Falun (Stig Hallstensson, 2); Göteborg-Sahlgrenska (Lennart Jivegård, 12); Göteborg-Östra (Pelle Örtzenwall, 10); Gävle (Torbjörn Turesson, 8); Helsingborg (Gunnar Plate, 17); Kalmar (Antony Potemkowski, 17); Karlstad (Becke Lundqvist, 10); Kristianstad (Göran Emtersjö, 52); Linköping (Björn Jonsson, 11); Lund (Torbjörn Jonung, 2); Malmö (Bengt Lindblad, 5); Molala (Christian Almström, 13); Mölndal (Urban Wingren, 3); Norrköping (Monica Svensson, 11); Nyköping (Björn Formander, 10); Skellefteå (Martin Björck, 11); Skövde (Lars Brunes, 9); Stockholm-St Göran (Gunnar Johansson, 13); Stockholm-Södersjukhuset (Lars Karlstrom, 6); Trollhättan-NAL (Per Eland Tornell, 10); Uppsala (Christer Ljungman, 7); Västervik (Åke Aldman, 10); Västerås (Ota Forsberg, 30); Växjö (Hilding Björkman, 14); Örebro (Berndt Arfwidsson, 4); Östersund (Thomas Bohlin, 4).

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References