Cochrane Library

Cochrane Database of Systematic Reviews

Graft type for femoro-popliteal bypass surgery (Review)

Ambler GK, Twine CP

Ambler GK, Twine CP.
Graft type for femoro-popliteal bypass surgery.
Cochrane Database of Systematic Reviews 2018, Issue 2. Art. No.: CD001487.
DOI: 10.1002/14651858.CD001487.pub3.

www.cochranelibrary.com

WILEY

TABLE OF CONTENTS

HEADER . . . 1
ABSTRACT . . . 1
PLAIN LANGUAGE SUMMARY . . . 2
SUMMARY OF FINDINGS FOR THE MAIN COMPARISON . . . 4
BACKGROUND . . . 6
OBJECTIVES . . . 6
METHODS . . . 6
RESULTS . . . 8
Figure 1. . . . 9
Figure 2. . . . 11
Figure 3. . . . 12
ADDITIONAL SUMMARY OF FINDINGS . . . 16
DISCUSSION . . . 23
AUTHORS' CONCLUSIONS . . . 25
ACKNOWLEDGEMENTS . . . 25
REFERENCES . . . 25
CHARACTERISTICS OF STUDIES . . . 30
DATA AND ANALYSES . . . 56
WHAT'S NEW . . . 60
HISTORY . . . 61
CONTRIBUTIONS OF AUTHORS . . . 61
DECLARATIONS OF INTEREST . . . 61
SOURCES OF SUPPORT . . . 61
DIFFERENCES BETWEEN PROTOCOL AND REVIEW . . . 62
INDEX TERMS . . . 62

[Intervention Review]

Graft type for femoro-popliteal bypass surgery

Graeme K Ambler[1,2], Christopher P Twine[1,2]

[1]South East Wales Vascular Network, Aneurin Bevan University Health Board, Newport, UK. [2]Division of Population Medicine, Cardiff University School of Medicine, Cardiff, UK

Contact address: Christopher P Twine, South East Wales Vascular Network, Aneurin Bevan University Health Board, Royal Gwent Hospital, Cardiff Road, Newport, NP20 2UB, UK. Chris_twine@hotmail.com.

Editorial group: Cochrane Vascular Group.
Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 2, 2018.

Citation: Ambler GK, Twine CP. Graft type for femoro-popliteal bypass surgery. *Cochrane Database of Systematic Reviews* 2018, Issue 2. Art. No.: CD001487. DOI: 10.1002/14651858.CD001487.pub3.

ABSTRACT

Background

Femoro-popliteal bypass is implemented to save limbs that might otherwise require amputation, in patients with ischaemic rest pain or tissue loss; and to improve walking distance in patients with severe life-limiting claudication. Contemporary practice involves grafts using autologous vein, polytetrafluoroethylene (PTFE) or Dacron as a bypass conduit. This is the second update of a Cochrane review first published in 1999 and last updated in 2010.

Objectives

To assess the effects of bypass graft type in the treatment of stenosis or occlusion of the femoro-popliteal arterial segment, for above- and below-knee femoro-popliteal bypass grafts.

Search methods

For this update, the Cochrane Vascular Information Specialist searched the Vascular Specialised Register (13 March 2017) and CENTRAL (2017, Issue 2). Trial registries were also searched.

Selection criteria

We included randomised trials comparing at least two different types of femoro-popliteal grafts for arterial reconstruction in patients with femoro-popliteal ischaemia. Randomised controlled trials comparing bypass grafting to angioplasty or to other interventions were not included.

Data collection and analysis

Both review authors (GKA and CPT) independently screened studies, extracted data, assessed trials for risk of bias and graded the quality of the evidence using GRADE criteria.

Main results

We included nineteen randomised controlled trials, with a total of 3123 patients (2547 above-knee, 576 below-knee bypass surgery). In total, nine graft types were compared (autologous vein, polytetrafluoroethylene (PTFE) with and without vein cuff, human umbilical vein (HUV), polyurethane (PUR), Dacron and heparin bonded Dacron (HBD); FUSION BIOLINE and Dacron with external support). Studies differed in which graft types they compared and follow-up ranged from six months to 10 years.

Above-knee bypass

For above-knee bypass, there was moderate-quality evidence that autologous vein grafts improve primary patency compared to prosthetic grafts by 60 months (Peto odds ratio (OR) 0.47, 95% confidence interval (CI) 0.28 to 0.80; 3 studies, 269 limbs; P = 0.005). We found low-quality evidence to suggest that this benefit translated to improved secondary patency by 60 months (Peto OR 0.41, 95% CI 0.22 to 0.74; 2 studies, 176 limbs; P = 0.003).

We found no clear difference between Dacron and PTFE graft types for primary patency by 60 months (Peto OR 1.67, 95% CI 0.96 to 2.90; 2 studies, 247 limbs; low-quality evidence). We found low-quality evidence that Dacron grafts improved secondary patency over PTFE by 24 months (Peto OR 1.54, 95% CI 1.04 to 2.28; 2 studies, 528 limbs; P = 0.03), an effect which continued to 60 months in the single trial reporting this timepoint (Peto OR 2.43, 95% CI 1.31 to 4.53; 167 limbs; P = 0.005).

Externally supported prosthetic grafts had inferior primary patency at 24 months when compared to unsupported prosthetic grafts (Peto OR 2.08, 95% CI 1.29 to 3.35; 2 studies, 270 limbs; P = 0.003). Secondary patency was similarly affected in the single trial reporting this outcome (Peto OR 2.25, 95% CI 1.24 to 4.07; 236 limbs; P = 0.008). No data were available for 60 months follow-up.

HUV showed benefits in primary patency over PTFE at 24 months (Peto OR 4.80, 95% CI 1.76 to 13.06; 82 limbs; P = 0.002). This benefit was still seen at 60 months (Peto OR 3.75, 95% CI 1.46 to 9.62; 69 limbs; P = 0.006), but this was only compared in one trial. Results were similar for secondary patency at 24 months (Peto OR 4.01, 95% CI 1.44 to 11.17; 93 limbs) and at 60 months (Peto OR 3.87, 95% CI 1.65 to 9.05; 93 limbs).

We found HBD to be superior to PTFE for primary patency at 60 months for above-knee bypass, but these results were based on a single trial (Peto OR 0.38, 95% CI 0.20 to 0.72; 146 limbs; very low-quality evidence). There was no difference in primary patency between HBD and HUV for above-knee bypass in the one small study which reported this outcome.

We found only one small trial studying PUR and it showed very poor primary and secondary patency rates which were inferior to Dacron at all time points.

Below-knee bypass

For bypass below the knee, we found no graft type to be superior to any other in terms of primary patency, though one trial showed improved secondary patency of HUV over PTFE at all time points to 24 months (Peto OR 3.40, 95% CI 1.45 to 7.97; 88 limbs; P = 0.005).

One study compared PTFE alone to PTFE with vein cuff; very low-quality evidence indicates no effect to either primary or secondary patency at 24 months (Peto OR 1.08, 95% CI 0.58 to 2.01; 182 limbs; 2 studies; P = 0.80 and Peto OR 1.22, 95% CI 0.67 to 2.23; 181 limbs; 2 studies; P = 0.51 respectively)

Limited data were available for limb survival, and those studies reporting on this outcome showed no clear difference between graft types for this outcome. Antiplatelet and anticoagulant protocols varied extensively between trials, and in some cases within trials.

The overall quality of the evidence ranged from very low to moderate. Issues which affected the quality of the evidence included differences in the design of the trials, and differences in the types of grafts they compared. These differences meant we were often only able to combine and analyse small numbers of participants and this resulted in uncertainty over the true effects of the graft type used.

Authors' conclusions

There was moderate-quality evidence of improved long-term (60 months) primary patency for autologous vein grafts when compared to prosthetic materials for above-knee bypasses. In the long term (two to five years) there was low-quality evidence that Dacron confers a small secondary patency benefit over PTFE for above-knee bypass. Only very low-quality data exist on below-knee bypasses, so we are uncertain which graft type is best. Further randomised data are needed to ascertain whether this information translates into an improvement in limb survival.

PLAIN LANGUAGE SUMMARY

Choice of bypass graft material for lower-limb arterial bypasses

Background

A person with severely diseased arteries in one or both legs can experience pain on walking (intermittent claudication), pain at rest, or death of tissues in the leg. When the main thigh artery has a long blockage, the best option is to insert a bypass to carry the blood

from an artery with good blood flow to the affected artery below the blockage. Bypass is intended to improve walking, or to save limbs that might otherwise require amputation. The different types of material available to create the bypass include the person's own vein (autologous vein), human umbilical vein, and the prosthetic materials polytetrafluoroethylene (PTFE) or Dacron, alone or with the blood thinning agent heparin bonded to the inside of the graft. Bypass grafts extending to below the knee are not as effective at remaining patent (open) with good blood flow as those above the knee. The aim of this review was to determine the most effective type of material to use for above-knee and below-knee bypass grafts.

Study characteristics and key results

We identified 19 randomised controlled trials that included a total of 3123 people. Of these people, 2547 were given above-knee bypass grafts and 576 were given bypass grafts below the knee. The evidence in our review is current until 13 March 2017. From our analysis, we found that grafts made from a person's own vein had a better primary patency (blood flow) rate than the prosthetic materials PTFE or Dacron for above-knee bypass grafts. Meanwhile, Dacron (and possibly also human umbilical vein) achieved better blood flow (patency) than PTFE. We also found that Dacron with supporting rings around it (designed to prevent external compression) showed worse patency than non-supported Dacron when used in grafts above the knee.

Adding a 'cuff' of vein did not improve the patency of PTFE for grafts extending to below the knee. The included trials provided few results on how long people's limbs survived following the bypass procedure. There was not much consistency between the trials (and sometimes within the trials) with regards to people taking additional medications such as antiplatelets or anticoagulants, and this might have affected the results.

Quality of the evidence

The overall quality of the evidence ranged from very low to moderate. Issues which affected the quality of the evidence included differences in the design of the trials, and differences in the types of grafts they compared. These differences meant we were often only able to combine and analyse small numbers of participants and this resulted in uncertainty over the true effects of the graft type used.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Autologous vein compared to other graft types for above-knee femoro-popliteal bypass surgery

Patient or population: people with peripheral vascular disease requiring above-knee femoro-popliteal bypass surgery
Setting: hospital
Intervention: autologous vein
Comparison: other graft types

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of limbs (studies)	Quality of the evidence (GRADE)	Comments
	Risk with other graft types	Risk with autologous vein				
Primary patency (24 months)	Study population		OR 0.59 (0.37 to 0.94)	422 (4 RCTs)	⊕⊕◯◯ LOW [1,2]	92 fewer autologous vein grafts per 1000 (10 to 152 grafts per 1000) lose primary patency by 24 months compared to other grafts studied
	275 per 1000	183 per 1000 (123 to 263)				
Primary patency (60 months)	Study population		OR 0.47 (0.28 to 0.80)	269 (3 RCTs)	⊕⊕⊕◯ MODERATE [3]	172 fewer autologous vein grafts per 1000 (54 to 264 grafts per 1000) lose primary patency by 60 months compared to other grafts studied
	451 per 1000	279 per 1000 (187 to 397)				
Secondary patency (60 months)	Study population		OR 0.41 (0.22 to 0.74)	176 (2 RCTs)	⊕⊕◯◯ LOW [1,2]	213 fewer autologous vein grafts per 1000 (75 to 330 grafts per 1000) lose secondary patency by 60 months compared to other grafts studied
	526 per 1000	313 per 1000 (196 to 451)				

Limb salvage	-	-	-	-	-	No studies of these graft types reported on this outcome

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: Confidence interval; **OR:** Odds ratio

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1] Downgraded due to serious risk of bias resulting from lack of blinding and poor randomisation techniques
[2] Downgraded due to imprecision because results based on small trials with few participants and events
[3] Downgraded due to risk of bias resulting from lack of blinding and poor randomisation techniques. We did not downgrade further for imprecision because the effect was large and highly consistent between studies

BACKGROUND

Description of the condition

Femoro-popliteal bypass grafting for lower limb ischaemia is one of the most common procedures undertaken by vascular surgeons. Since its inception in the 1940s the procedure has evolved significantly in terms of technical intricacy, graft type, anticoagulant medication use and patient selection. Various graft types have been used, including: autologous vein (in situ or reversed), human umbilical vein (HUV), synthetic polymers, polytetrafluoroethylene (PTFE) and Dacron; and more recently heparin-bonded synthetic polymers.

During femoro-popliteal bypass grafting, the proximal anastomosis is taken from the common, superficial or profunda femoris artery and the distal anastomosis may be to the popliteal artery either above or below the knee (referred to as above- and below-knee grafts).

Description of the intervention

Controversy still exists over the most appropriate type of graft to use in bypass surgery. It is generally accepted that autologous vein should be used wherever possible, but there are surgeons who believe that using vein is a more demanding and time-consuming operation that involves a longer duration of anaesthesia in relatively frail patients. When vein is unavailable there are widespread differences in the material used. This is due, in part, to a lack of relevant randomised evidence. Early trials did not separate above- and below-knee grafts, were underpowered, had inadequate randomisation and the patient populations were less relevant to modern practice. As new materials became available they were implemented as standard practice for many surgeons, but with a lack of high-quality supporting evidence. Even fairly recent meta-analyses have relied heavily on non-randomised, retrospective data (Pereira 2006).

How the intervention might work

Arterial bypass grafting works by routing arterial blood around blocked or narrow sections of artery using an alternative conduit. This conduit may either be a section of the patient's own vein (reversed or with the valves cut and disrupted); or an alternative biological conduit such as human umbilical vein; or an artificial material.

Why it is important to do this review

Outcomes from infrainguinal bypass grafting continue to be poor; at a median follow-up of five years, the landmark randomised trial comparing bypass surgery to angioplasty in severe limb ischaemia reported overall survival of less than 50% (Bradbury 2010). There are economic and patient advantages to successful bypass grafting (Luther 1997; Perler 1995). When this is considered in the context of the controversy surrounding choice of graft material and differences in surgical practice, it is vital to make decisions based on the best evidence currently available.

OBJECTIVES

To assess the effects of bypass graft type in the treatment of stenosis or occlusion of the femoro-popliteal arterial segment, for above- and below-knee femoro-popliteal bypass grafts.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (RCTs) comparing at least two different graft types. All graft types were eligible for inclusion.

Types of participants

We included patients with femoro-popliteal ischaemia requiring arterial reconstruction. These were mainly patients with critical claudication, rest pain or tissue loss (Rutherford category 3 to 6 Consensus Document), but could also include some stable claudicants (Rutherford grade 1 to 2) in earlier trials. Trials in which a clear distinction was not made between patients receiving grafts to the popliteal artery and to the tibial arteries were excluded. For trials analysing above- and below-knee procedures together, trialists were contacted for data and excluded if the results were inseparable.

Types of interventions

We included studies comparing two or more graft materials. Randomised controlled trials comparing bypass grafting to angioplasty or to other interventions were not included.

Types of outcome measures

Primary outcomes

- Primary patency, defined as continuous patency of the graft without need for further intervention (including primary assisted patency if performed during the primary procedure)

Secondary outcomes

- Secondary patency, defined as continuous patency of the graft, with or without further procedures such as angioplasty or surgical patching to prevent occlusion
- Limb survival or limb salvage

We assessed these outcomes at three months, six months, one year, two years, three years and five years after surgery.

Search methods for identification of studies

We placed no restrictions on language.

Electronic searches

For this update, the Cochrane Vascular Information Specialist (CIS) searched the following databases for relevant trials:

- the Cochrane Vascular Specialised Register (13 March 2017);
- the Cochrane Central Register of Controlled Trials (CENTRAL (2017, Issue 2)) via the Cochrane Register of Studies Online.

See Appendix 1 for details of the search strategy used to search CENTRAL.

The Cochrane Vascular Specialised Register is maintained by the CIS and is constructed from weekly electronic searches of MEDLINE Ovid, EMBASE Ovid, CINAHL, AMED, and through handsearching relevant journals. The full list of the databases, journals and conference proceedings which have been searched, as well as the search strategies used are described in the Specialised Register section of the Cochrane Vascular module in the Cochrane Library (www.cochranelibrary.com).

The CIS also searched the following trial registries for details of ongoing and unpublished studies (13 March 2017); See Appendix 2 for details.

- ClinicalTrials.gov (www.clinicaltrials.gov)
- World Health Organization International Clinical Trials Registry Platform (www.who.int/trialsearch)
- ISRCTN Register (www.isrctn.com/)

Searching other resources

We searched the reference lists of relevant articles identified through the electronic searches to identify further trials.

Data collection and analysis

Selection of studies

For this update, both review authors (GKA and CPT) independently selected trials for inclusion in the review. The section 'Criteria for considering studies for this review' details the inclusion criteria used for the selection process.

Data extraction and management

Data were independently extracted by GKA then cross checked by CPT. The following information was extracted on each trial.

- Trial methods: method of randomisation, method of allocation.
- Participants: country of origin, age, sex distribution, severity of disease as measured by the ankle brachial index (ABI) and the European Consensus definition of critical ischaemia (Consensus Document), presence of diabetes, inclusion and exclusion criteria.
- Interventions: type of graft, level of anastomosis, use of aspirin or anticoagulants, smoking habit after surgery, attendance at a graft surveillance programme.
- Outcomes: primary and secondary patency, limb survival.

Assessment of risk of bias in included studies

For this update, both review authors independently assessed the risk of bias in the included studies according to the guidelines given in the *Cochrane Handbook for Systematic Reviews of Interventions*, (Higgins 2011). We assessed the new studies included in the updated review and we re-assessed the studies already included from the previous versions of the review.

We assessed the following domains as low risk of bias, unclear risk of bias, or high risk of bias:

- sequence generation;
- allocation concealment;
- blinding of participants and personnel;
- blinding of outcome assessment;
- incomplete outcome data;
- selective outcome reporting;
- other bias.

These assessments are reported for each individual study in the Characteristics of included studies tables.

Measures of treatment effect

We presented the results from the dichotomous outcomes (primary or secondary patency; limb salvage) as odds ratios (ORs) with 95% confidence intervals (CIs).

Unit of analysis issues

The unit of analysis was the limb. Some participants in some trials were enrolled more than once, as each lower limb was allowed to be entered into some of the trials independently. This created a unit of analysis issue when considering survival with intact limb, but it was felt that effects on both primary patency (our primary outcome) and secondary patency would be small, so these trials were not excluded. None of the included studies allowed previous bypass in the affected limb. Survival data were only considered where it was clear that participants could not be enrolled in the same trial more than once.

Dealing with missing data

Where data were missing we attempted to determine the reasons for this. If data were missing due to participants being lost to follow up or because participants were not followed up to a certain time point prior to publication (censoring) and reasons were clearly described, we assumed the data were missing at random.

Assessment of heterogeneity

Heterogeneity was assessed visually (for methodological or clinical heterogeneity) by inspecting the forest plots and statistically by using Review Manager 5 software (Higgins 2003). We obtained P values comparing the test statistic with a Chi^2 distribution. The Chi^2 statistic describes the percentage of total variation across studies due to heterogeneity rather than by chance. A value of 0% indicates no observed heterogeneity and larger values show increasing heterogeneity.

Assessment of reporting biases

We planned to assess reporting bias by presenting funnel plots if more than 10 studies were included in the analysis. We also searched trial registries to look for unreported studies.

Data synthesis

We analysed and presented data into groups according to whether the distal anastomosis was above or below the knee.

We only undertook meta-analysis when we felt there was no significant methodological heterogeneity, and statistical heterogeneity was not revealed by either calculation of I^2 or performing Chi^2 tests. The effect estimate was calculated using Peto ORs with 95% CIs. Peto ORs were used as it was anticipated that intervention effects would mainly be small, and that most trials would have similar numbers in experimental and control groups. We used fixed-effect methods as there was no significant heterogeneity detected. All analyses were based on endpoint data from the individual clinical trials, which all quoted intention-to-treat results. The data were synthesised by comparing group results. Individual patient data from different trials were not amalgamated.

Subgroup analysis and investigation of heterogeneity

We performed subgroup analysis according to graft type.

Sensitivity analysis

We performed sensitivity analysis to consider whether excluding studies with higher risk of bias led to significant changes in the results.

Summary of findings

We created 'Summary of findings' tables using GRADEpro software (GRADEpro GDT 2015). The study population consisted of patients with femoro-popliteal ischaemia requiring arterial reconstruction, and we created tables for the comparisons of 'Autologous vein compared to other graft types for above-knee femoro-popliteal bypass surgery' (Summary of findings for the main comparison); 'PTFE compared to Dacron for above-knee femoro-popliteal bypass surgery' (Summary of findings 2); 'Externally supported Dacron compared to unsupported Dacron for above-knee femoro-popliteal bypass surgery' (Summary of findings 3) and 'PTFE compared to PTFE with vein cuff for below-knee femoro-popliteal bypass surgery' (Summary of findings 4). The most important and clinically relevant outcomes (both desirable and undesirable) that were thought to be essential for decision-making were the outcomes primary patency (at 24 and 60 months follow-up), secondary patency (at 60 months follow-up) and limb salvage (at 24 months follow-up). Assumed control intervention risks were calculated by the mean number of events in the control groups of the selected studies for each outcome. We used the system developed by the Grades of Recommendation, Assessment, Development and Evaluation working group (GRADE working group) for grading the quality of evidence as high, moderate, low or very low, based on within-study risk of bias, inconsistency, directness of evidence, imprecision, and publication bias (GRADE 2004; GRADEpro GDT 2015).

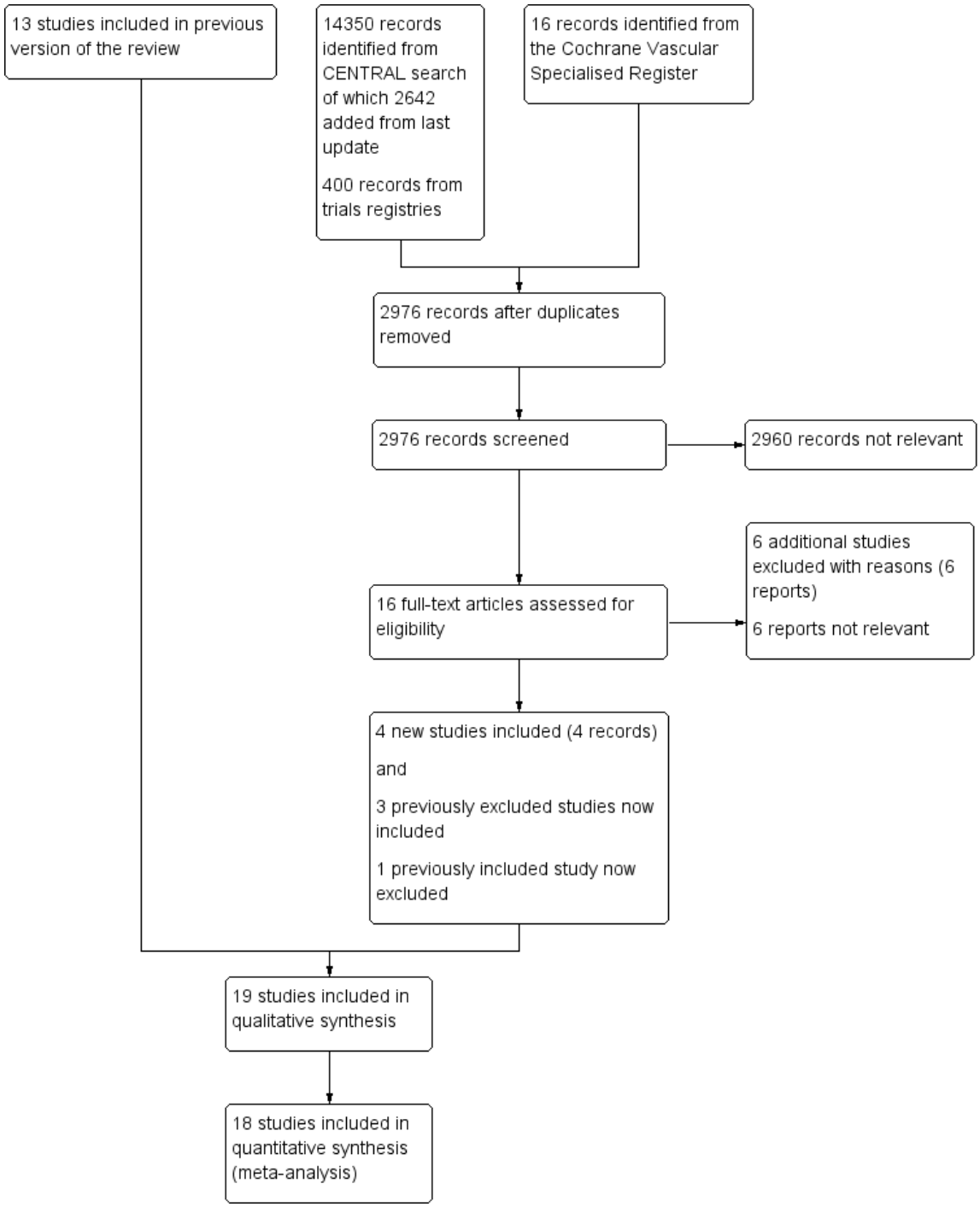
RESULTS

Description of studies

Results of the search

See Figure 1.

Figure 1. Study flow diagram.



Included studies

For summarised details of the included studies, see Characteristics of included studies.

We included seven additional studies in this review update (Davidovic 2010; Gloor 1996; Gupta 1991; Lumsden 2015; SCAMICOS 2010; Solakovic 2008; Vriens 2013), making a total of 19 randomised controlled trials which met the criteria for inclusion (Aalders 1992; Abbot 1997; Ballotta 2003; Davidovic 2010; Devine 2004; Eickhoff 1987; Gloor 1996; Gupta 1991; Jensen 2007; Klinkert 2003; Lumsden 2015; Post 2001; SCAMICOS 2010; Scharn 2008; Solakovic 2008; Stonebridge 1997; Tofigh 2007; van Det 2009; Vriens 2013). We had excluded three of the studies from the previous version of this review due to unclear randomisation methods (Gloor 1996; Gupta 1991; Solakovic 2008), but we were able to include them in this version due to the use of Cochrane's 'Risk of bias' tool. Follow-up was reported to six months (Lumsden 2015), one year (Davidovic 2010; Gloor 1996), two years (Jensen 2007; Post 2001; Scharn 2008; Tofigh 2007; Vriens 2013), three years (Gupta 1991; SCAMICOS 2010), four years (Eickhoff 1987), five years (Aalders 1992; Abbot 1997; Ballotta 2003; Devine 2004; Klinkert 2003; Solakovic 2008; Stonebridge 1997) and 10 years (van Det 2009). There were a total of 3123 patients (2547 above-knee, 576 below-knee), with bypasses being performed on 3238 limbs (2662 above-knee, 576 below-knee). Nine types of graft were compared: autologous vein; polytetrafluoroethylene (PTFE) with and without vein cuff and with or without external support; human umbilical vein (HUV); Dacron and heparin bonded Dacron (HBD); FUSION BIOLINE and Dacron with external support).

Above-knee bypass

Two trials compared autologous vein and PTFE grafts above the knee (Ballotta 2003; Klinkert 2003). In Ballotta 2003, 102 limbs (51 patients) with bilateral disabling claudication were randomised to receive reversed saphenous vein or PTFE. Klinkert 2003 also compared reversed saphenous vein with PTFE, in 151 limbs. Anticoagulation protocols and medication checks varied between these trials; see Characteristics of included studies for details.

In Tofigh 2007 autologous vein was compared with a polyester graft, while Solakovic 2008 compared autologous vein with a prosthetic graft, which was allowed to be either PTFE of Dacron. These have been considered separately for analysis from those trials where the prosthetic material was more clearly specified.

One trial compared PTFE with HUV in 93 limbs (Aalders 1992). Five trials compared PTFE with Dacron (Abbot 1997; Davidovic 2010; Jensen 2007; Post 2001; van Det 2009). We did not use Davidovic 2010 the quantitative analysis due to concerns over risk of bias in outcome data (see Characteristics of included studies). The trial with the largest number of limbs was Jensen 2007, in which 205 PTFE grafts were compared with 208 Dacron grafts. Unfortunately, anticoagulant and follow-up protocols varied between departments in this study. In van Det 2009, 114 limbs were randomised to PTFE and 114 limbs to Dacron; the trialists used warfarin with a consistent protocol for anticoagulation, and they continued follow-up for 10 years. One trial compared PTFE with the FUSION BIOLINE graft (Lumsden 2015), which is a two-layer graft, the inner layer being heparin-bonded expanded PTFE (ePTFE) which is glued to an outer knitted polyester textile. Above the knee, 88 limbs were randomised to FUSION BIOLINE graft, whilst 86 received standard ePTFE. Gupta 1991 considered PTFE with or without ringed support; 29 limbs received ringed grafts and 30 limbs received unringed grafts above the knee.

One trial looked at fluoropolymer-coated Dacron graft with or without external support (Vriens 2013), with 134 limbs assigned to externally supported graft and 119 treated with unsupported graft.

One trial compared PTFE with PTFE and vein cuff in above-knee bypass (Stonebridge 1997). The study included 74 limbs with PTFE and 76 with PTFE and vein cuff. The numbers of continuing smokers and of participants on antiplatelet and anticoagulant therapy were not given. Peri-operative complications were not stated.

One study compared HBD with HUV (Scharn 2008) and one trial compared HBD with PTFE (Devine 2004). The anticoagulant protocol was not stated in the latter (Devine 2004).

One study compared polyurethane (PUR) with Dacron (Gloor 1996). Both primary and secondary patency rates were poor for the PUR grafts and the trial was stopped early due to safety concerns after only 20 limbs had been randomised.

Below-knee bypass

There were far less data available for below-knee bypass, with 651 procedures analysed. No studies compared autologous vein with PTFE, HUV or other graft types. One trial compared PTFE with Dacron (Post 2001), however there were low numbers of participants in each group (26 in the PTFE group, 27 in the Dacron group). Two trials (Stonebridge 1997; SCAMICOS 2010) compared PTFE with PTFE and vein cuff. One study (Lumsden 2015) compared standard ePTFE with the FUSION BIOLINE graft, though numbers of below-knee popliteal procedures were low in each group (14 in the FUSION BIOLINE group, 14 in the PTFE group). Gupta 1991 included 63 below-knee bypasses, and compared PTFE with or without ringed support in 29 and 34 limbs respectively.

One study (Eickhoff 1987) compared PTFE with HUV. This trial

also separately analysed patency rates in claudicants and those with good distal runoff, and found those patients to have a patency advantage. The study authors did not state the anticoagulants used. Devine 2004 gave separate below-knee data.

There were no statistically significant differences in the major co-founders of sex, age, smoking, dyslipidaemia (abnormal concentrations of lipids or lipoproteins in the blood), diabetes or hypertension reported between groups in any of the above- or below-knee trials.

Excluded studies

For this update, we excluded six additional studies (Lindholt 2011; Linni 2015; Lundgren 2013; Midy 2016; NCT00617279; NCT00845585); we also excluded a study which had been included in previous versions of the review (Watelet 1997). We excluded three studies because above- and below-the-knee data could not be separated for analyses (Lindholt 2011, Linni 2015; Watelet 1997) . We excluded Lundgren 2013 because it included a mixture of femoro-popliteal and femoro-tibial bypass patients, and results for the subset of patients treated with femoro-popliteal bypass were not presented separately. We excluded one study (Midy 2016) as it failed to recruit even 30% of the planned number of patients, and more than 25% of those recruited had no follow-up. We excluded NCT00617279 and NCT00845585 for similar reasons; the former trial was terminated by the sponsor due to slow recruitment and no results were ever presented, whereas the latter trial was terminated before a single patient was recruited. Full reasons for trials being excluded can be found in the Characteristics of excluded studies table.

Ongoing studies

We identified two ongoing studies as being relevant to this review and these may be included in future updates (NCT00205790; NCT00147979). See Characteristics of ongoing studies.

Risk of bias in included studies

See Figure 2 and Figure 3.

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

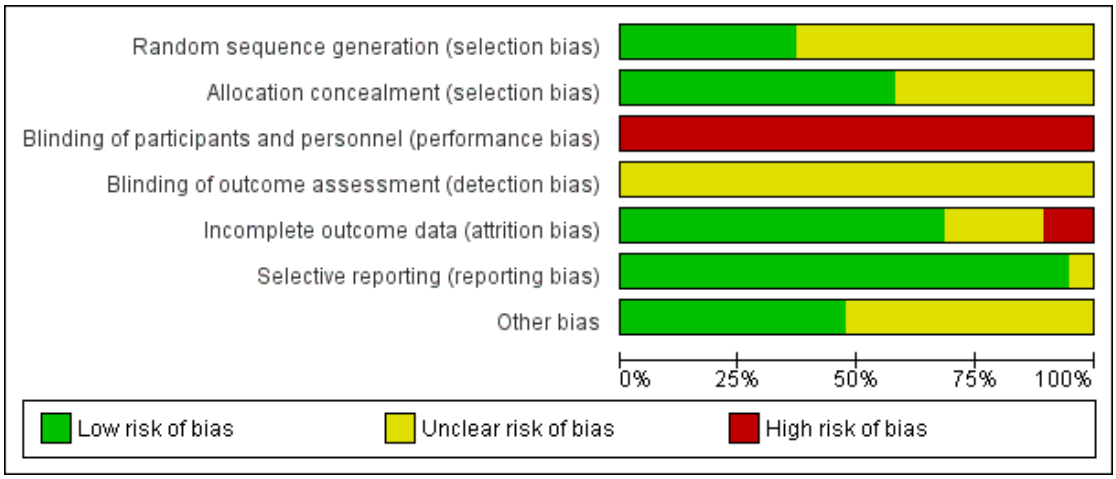
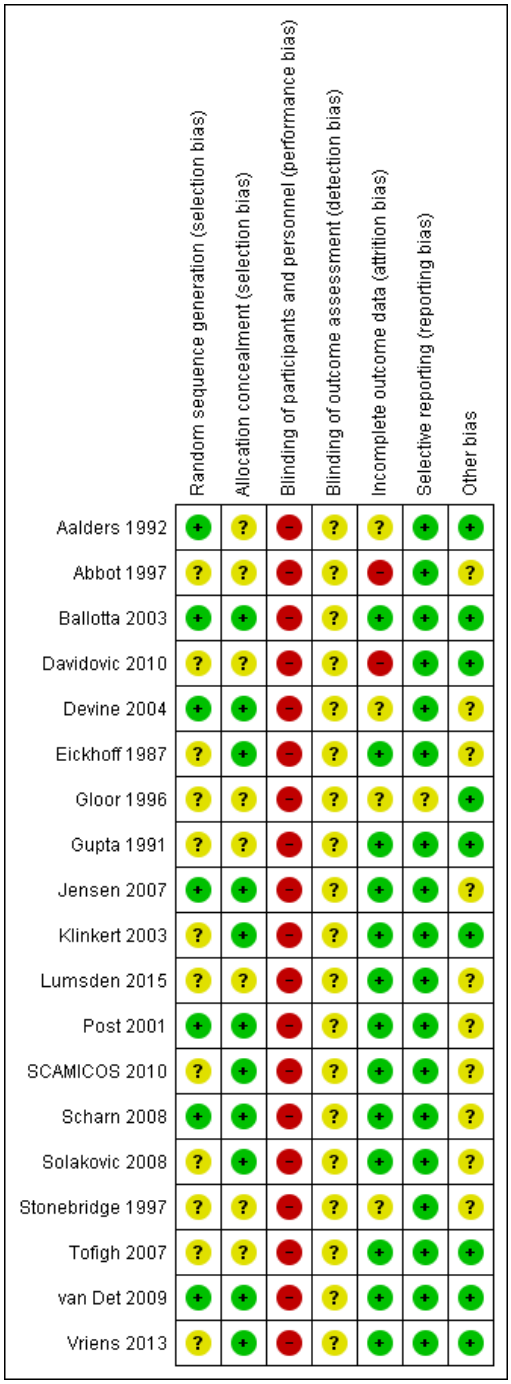


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Overall, the risk of bias was significant, principally due to a lack of blinding. There were issues to do with attrition and it was unclear whether there might have been issues of selection bias in some studies.

Allocation

Random sequence generation

Seven studies were at low risk of bias as their sequence generation was adequate (Aalders 1992; Ballotta 2003; Devine 2004; Jensen 2007; Post 2001; Scharn 2008; van Det 2009). We judged the remaining 12 studies to have unclear risk of bias as they failed to describe the method of randomisation, or used a non-standard technique (Abbot 1997; Davidovic 2010; Eickhoff 1987; Gloor 1996; Gupta 1991; Klinkert 2003; Lumsden 2015; SCAMICOS 2010; Scharn 2008; Solakovic 2008; Stonebridge 1997; Tofigh 2007; Vriens 2013).

Allocation concealment

Eleven studies had adequate allocation concealment (Ballotta 2003; Devine 2004; Eickhoff 1987; Jensen 2007; Klinkert 2003; Post 2001; SCAMICOS 2010; Scharn 2008; Solakovic 2008; van Det 2009; Vriens 2013). The remaining eight were at unclear risk of bias as allocation concealment was not clearly discussed (Aalders 1992; Abbot 1997; Davidovic 2010; Gloor 1996; Gupta 1991; Lumsden 2015; Stonebridge 1997; Tofigh 2007).

Blinding

Blinding for graft insertion is impossible in surgical trials of this nature. Outcome assessment may be blinded, however this was not the case in any of the included studies and we are unsure what effect this may have had on the outcomes in question. For this reason all included studies were judged to be at high risk of performance bias and at unclear risk of detection bias.

Incomplete outcome data

We judged one study (Abbot 1997) to be at high risk of attrition bias as 13 participants were lost following randomisation and results were reported without specifically stating what happened to these participants. Davidovic 2010 failed to present numbers at risk at different time points and secondary patency was presented as worse than primary patency, which is impossible. Due to these issues we judged this study to be at high risk of bias and did not include it in meta-analysis. We assessed Gloor 1996 as having unclear risk of bias as they failed to include a CONSORT flow diagram and there was no mention of patients excluded prior to randomisation or after randomisation. All the remaining studies were at low risk of bias, since any losses were minimal or described clearly.

Selective reporting

One study (Gloor 1996) failed to present details of complications occurring within the first 30 days which did not lead to reintervention, though this was a stated secondary outcome. As this is a patient population with significant comorbidity, it is likely that there were some undisclosed complications, so we judged the study to be at unclear risk of reporting bias. There were no concerns over selective reporting in any of the other included studies.

Other potential sources of bias

Three trials had antiplatelet and anticoagulant protocols which obviously varied within the trial: Post 2001 used heparin, warfarin or antiplatelet agents (specific agent not stated); Scharn 2008 used aspirin or coumarin derivatives; and Jensen 2007 used different anticoagulation protocols in each centre. One study (Lumsden 2015) left decisions about heparin, protamine and topical haemostatics to the operating surgeon, but specified that postoperative aspirin therapy was compulsory in all participants. Five trials did not state their anticoagulation protocol (Abbot 1997; Devine 2004; Eickhoff 1987; SCAMICOS 2010; Stonebridge 1997). One study (Solakovic 2008) gave a clear protocol of anticoagulants in the perioperative period and antiplatelet agents following discharge, but gave no details of compliance checks. We considered all these studies to have unclear risk of other sources of bias.

Effects of interventions

See: **Summary of findings for the main comparison** Autologous vein compared to other graft types for above-knee femoro-popliteal bypass surgery; **Summary of findings 2** PTFE compared to Dacron for above-knee femoro-popliteal bypass surgery; **Summary of findings 3** Externally supported graft compared to unsupported graft for above-knee femoro-popliteal bypass surgery; **Summary of findings 4** PTFE compared to PTFE with vein cuff for below-knee femoro-popliteal bypass surgery

Above-knee bypass

Autologous vein compared to other graft types

Four studies compared autologous veins to other grafts prosthetic materials (Ballotta 2003; Klinkert 2003; Solakovic 2008; Tofigh 2007).

Primary patency

We were able to include four trials comparing autologous vein to prosthetic materials in a meta-analysis (Ballotta 2003; Klinkert 2003; Solakovic 2008; Tofigh 2007). We found no clear difference between the groups in primary patency at 3, 6 or 12 months. See Analysis 1.1; Analysis 1.2; Analysis 1.3 respectively. Although individual trials failed to show clear benefit, once results of the four trials were combined a long-term benefit for autologous vein was observed at 24 months (Peto odds ratio (OR) 0.59, 95% confidence interval (CI) 0.37 to 0.94; 422 limbs; 4 studies; P = 0.03; low-quality evidence; Analysis 1.4). This was reflected in the continued benefit in primary patency for autologous vein over prosthetic grafts by five years (Peto OR 0.47, 95% CI 0.28 to 0.80; 269 limbs; 3 studies; P = 0.005; moderate-quality evidence; Analysis 1.5). The comparison with polytetrafluoroethylen (PTFE) contributed the majority of weight to this result (weight 63.6%, OR 0.48, 95% CI 0.25 to 0.95).

Secondary patency

Three studies comparing autologous vein to prosthetic materials reported on this outcome and were pooled in a meta-analysis (Klinkert 2003; Solakovic 2008; Tofigh 2007). No improvement in secondary patency was found at 3, 6, 12 or 24 months. See Analysis 1.6; Analysis 1.7; Analysis 1.8; Analysis 1.9 respectively. A benefit was seen at five years (Peto OR 0.41, 95% CI 0.22 to 0.74; 176 limbs; 2 studies; P = 0.003; low-quality evidence; Analysis 1.10). However Ballotta 2003 and Tofigh 2007 were not included in analysis at this timepoint, reducing the power of the comparison. There was no evidence of significant statistical heterogeneity between these trials.

Limb survival or limb salvage

No data available

Polytetrafluoroethylen (PTFE) compared to other graft types

Eight studies compared PTFE to other grafts (Aalders 1992; Abbot 1997; Davidovic 2010; Jensen 2007; Lumsden 2015; Post 2001; Stonebridge 1997; van Det 2009).

Primary patency

Of the five studies comparing PTFE with Dacron (Abbot 1997; Davidovic 2010; Jensen 2007; Post 2001; van Det 2009), four were considered suitable for meta-analysis (Abbot 1997; Jensen 2007; Post 2001; van Det 2009). We did not include Davidovic 2010 because of concerns about risk of bias (see Incomplete outcome data (attrition bias)). All four studies reported at 12 and 24 months; the remaining timepoints had data available from one or two studies.

Three studies (Jensen 2007; van Det 2009; Post 2001) showed a non-significant trend towards a greater benefit with Dacron and Abbot 1997 showed a non-significant trend in favour of PTFE. Abbot 1997 was the weakest trial in terms of potential bias; see Figure 3 and the table Characteristics of included studies.

Once combined, we found no significant difference in primary patency between PTFE and Dacron at any time point. Removing the one trial with significant bias issues (Abbot 1997) did not change this result, except at 60 months, where data from one study (van Det 2009) suggested that Dacron grafts may potentially have a small benefit in primary patency at this time point (OR 1.87; 95% CI 1.01 to 3.43; Analysis 2.5).

One study (Aalders 1992) compared PTFE with human umbilical vein (HUV). No difference in primary patency was seen at three or six months (Analysis 2.1 and Analysis 2.2 respectively). Our analysis suggests a benefit in primary patency for HUV by 12 months (Peto OR 3.17, 95% CI 1.04 to 9.64; P = 0.04; 83 limbs; 1 study), which continued to 24 months (Peto OR 4.80, 95% CI 1.76 to 13.06; 82 limbs; 1 study; P = 0.002 (Analysis 2.4)). This benefit was still evident at five years (Peto OR 3.75, 95% CI 1.46 to 9.62; 69 limbs; 1 study; P = 0.006), Analysis 2.5), but the results are limited because of small numbers of participants.

In Stonebridge 1997, there was no significant difference between PTFE and PTFE with vein cuff used above the knee for the outcome primary patency at any time point (Analysis 2.3; Analysis 2.4).

One study (Lumsden 2015) compared a new graft material, FUSION BIOLINE, which is composed of an inner heparin bonded PTFE layer glued to an outer knitted polyester layer. This study found a significant improvement in primary patency at six months for above-knee bypass done with FUSION BIOLINE, when compared with a standard PTFE graft (Peto OR 2.99, 95% CI 1.43 to 6.26; 174 limbs; 1 study; P = 0.004; Analysis 2.2) . Results reported at other time points were only presented for both above- and below-knee grafts combined, and failed to show a significant difference at either 90 days or 12 months, though the results at six months were also significant in the combined analysis.

Secondary patency

There was no clear difference in secondary patency between PTFE and Dacron at 6 months (Peto OR 1.01, 95% CI 0.25 to 4.13; 225 limbs; 1 study) or 12 months (Peto OR 1.19, 95% CI 0.76 to 1.86; 581 limbs; 2 studies). See Analysis 2.7 and Analysis 2.8. A benefit from the use of Dacron grafts was seen at 24 months (Peto OR 1.54, 95% CI 1.04 to 2.28; 528 limbs; 2 studies; P = 0.03) and 60 months (Peto OR 2.43, 95% CI 1.31 to 4.53; 167 limbs; 1 study; P = 0.005). See Analysis 2.9 and Analysis 2.10.

In Stonebridge 1997, there was no significant difference between PTFE and PTFE with vein cuff used above the knee for the outcome secondary patency at any time point (Analysis 2.8; Analysis 2.9).

One study (Aalders 1992) compared PTFE with human umbilical vein (HUV). No clear difference in secondary patency was seen at three, six and 12 months (Analysis 2.6; Analysis 2.7 and Analysis 2.8 respectively). Our analysis suggests a benefit in secondary patency for HUV by 24 months (Peto OR 4.01, 95% CI 1.44 to 11.17; 93 limbs; 1 study; P = 0.008), which continued to 60 months (Peto OR 3.87, 95% CI 1.65 to 9.05; 93 limbs; 1 study; P = 0.002) (Analysis 2.10).

Limb survival or limb salvage

Only two studies reported detailed limb salvage rates for above-knee femoro-popliteal bypass (Jensen 2007; Stonebridge 1997). Jensen 2007 compared PTFE with Dacron and Stonebridge 1997 compared PTFE with PTFE and vein cuff. Neither found differences in limb salvage rates between graft types at one month or 24 months (Analysis 2.11; Analysis 2.12).

Heparin bonded Dacron (HBD) versus other grafts

Two studies compared heparin bonded Dacron grafts with other grafts (Devine 2004; Scharn 2008). Devine 2004 compared heparin bonded Dacron to PTFE and Scharn 2008 compared HBD to HUV.

Primary patency

In Devine 2004, no difference in patency was detected at 12 or 24 months, though by 60 months, HBD showed improved patency compared to PTFE (Peto OR 0.38, 95% CI 0.20 to 0.72; 146 limbs; 1 study; P = 0.003). In Scharn 2008 there was no improvement in primary patency at any time interval when HBD was compared to HUV.
The combined overall primary patency for HBD compared to HUV/PTFE was improved at 12 months (Peto OR 0.58, 95% CI 0.34 to 0.98; 294 limbs; 2 studies); 24 months (Peto OR 0.62, 95% CI 0.38 to 1.02; 282 limbs; 2 studies); and 60 months (Peto OR 0.55, 95% CI 0.33 to 0.93; 232 limbs; 2 studies). See Analysis 3.1 to Analysis 3.3.

Secondary patency

No data available

Limb survival or limb salvage

No data available

Externally-supported Dacron or PTFE grafts compared to other grafts

One trial examined whether adding external support to Dacron might improve outcomes in above-knee femoro-popliteal bypass (Vriens 2013), while another considered the same question for PTFE grafts (Gupta 1991).

Primary patency

Although short-term primary patency rates were comparable (Analysis 4.1; Analysis 4.2), by 24 months the externally supported Dacron grafts showed worse primary patency when compared to their unsupported counterparts (Peto OR 2.09, 95% CI 1.26 to 3.46; 240 limbs; 1 study; P = 0.004; Analysis 4.3).
Results from Gupta 1991 showed similar primary patency for PTFE grafts with and without ringed support at 6, 12 and 24 months (Analysis 4.1; Analysis 4.2; Analysis 4.3).

Secondary patency

Although short-term secondary patency rates were comparable, by 24 months the externally supported Dacron grafts showed worse secondary patency when compared to their unsupported counterparts (Peto OR 2.25, 95% CI 1.24 to 4.07; 236 limbs; 1 study; P = 0.008; Analysis 4.6).

Limb survival or limb salvage

No data available

Polyurethane (PUR) graft compared to other grafts

One trial examined a new PUR graft type (Gloor 1996).

Primary patency

Primary patency was worse for the PUR grafts at all time points and the trial was stopped due to safety concerns after only 20 limbs had been randomised. See Analysis 5.1; Analysis 5.2; Analysis 5.3.

Secondary patency

Secondary patency was worse for the PUR grafts at all time points and the trial was stopped due to safety concerns after only 20 limbs had been randomised. See Analysis 5.4; Analysis 5.5; Analysis 5.6.

Limb survival or limb salvage

No data available

Below-knee bypass

PTFE compared to other graft types

Six studies reported on primary or secondary patency, or both, but analysis was limited by different graft comparisons and reporting

at different timepoints (Eickhoff 1987; Gupta 1991; Lumsden 2015; Post 2001; SCAMICOS 2010; Stonebridge 1997).

Primary patency

There was no clear difference in primary patency for PTFE compared to Dacron at 12 months (Peto OR 0.47, 95% CI 0.12 to 1.79; P = 0.27; 45 limbs; 1 study; Analysis 6.2) and 24 months (Peto OR 0.41, 95% CI 0.12 to 1.42; 40 limbs; 1 study; P = 0.16; Analysis 6.3), however the analysis only included one trial (Post 2001).

The two trials comparing PTFE with a vein cuff to PTFE alone in below-knee femoro-popliteal bypass were heterogeneous: Stonebridge 1997 suggested a benefit with the addition of a vein cuff, whilst SCAMICOS 2010 favoured no cuff. Pooling the data showed no difference in primary patency at six, 12 and 24 months (24 months: Peto OR 1.08, 95% CI 0.58 to 2.01; 182 limbs; 2 studies; Analysis 6.3). Allocation concealment and random sequence generation were not clearly described in Stonebridge 1997, so results may be attributable to selection bias in that trial.

One study (Gupta 1991) considered whether ringed support was of benefit in PTFE grafts below the knee. We found no difference of effect at any time point (Analysis 6.2).

A small number of patients in the FUSION BIOLINE trial had below-knee bypass (Lumsden 2015). We found no significant difference in primary patency between FUSION BIOLINE and PTFE in this case (Analysis 6.1).

Secondary patency

One trial provided results on below-the-knee secondary patency for PTFE versus HUV (Eickhoff 1987).This trial showed improved patency rates for HUV grafts at all time intervals from three months to 24 months. See Analysis 6.5 to Analysis 6.8 (24 months: Peto OR 3.40; 95% CI 1.45 to 7.97, P = 0.005; 88 limbs; 1 study).

The two trials comparing PTFE with a vein cuff to PTFE alone in below-knee femoro-popliteal bypass were heterogeneous (SCAMICOS 2010; Stonebridge 1997). Pooling the data showed no difference in secondary patency at 12 and 24 months (24 months: (Peto OR 1.22, 95% CI 0.67 to 2.23; 181 limbs; 2 studies; Analysis 6.8). Allocation concealment and random sequence generation were not clearly described in Stonebridge 1997, so results may be attributable to selection bias in that trial.

Limb survival or limb salvage

Limited information was available on limb survival for below-knee femoro-popliteal bypass. Only Stonebridge 1997 and SCAMICOS 2010 reported this outcome, for PTFE versus PTFE with vein cuff. They found no clear difference at 12 months (Peto OR 1.35, 95% CI 0.72 to 2.55; 225 limbs; 2 studies) or 24 months (Peto OR 1.34, 95% CI 0.72 to 2.49; 196 limbs; 2 studies; Analysis 6.10 and Analysis 6.11).

Heparin bonded Dacron versus all other graft materials

Primary patency

Only Devine 2004 compared HBD grafts with other grafts. No clear differences in primary patency were observed between HBD and PTFE below the knee at any time interval in this study (Devine 2004; Analysis 7.1; Analysis 7.2; Analysis 7.3; Analysis 7.4; Analysis 7.5).

Secondary patency

No data available

Limb survival or limb salvage

No data available

ADDITIONAL SUMMARY OF FINDINGS [Explanation]

PTFE compared to Dacron for above-knee femoro-popliteal bypass surgery

Patient or population: people with peripheral vascular disease requiring above-knee femoro-popliteal bypass surgery
Setting: hospital
Intervention: PTFE
Comparison: Dacron

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of limbs (studies)	Quality of the evidence (GRADE)	Comments
	Risk with Dacron	Risk with PTFE				
Primary patency (24 months)	Study population		OR 1.23 (0.92 to 1.65)	764 (4 RCTs)	⊕⊕◯◯ LOW [12]	Our confidence in the effect is limited and this may differ substantially from the estimate of the effect
	404 per 1000	454 per 1000 (384 to 528)				
Primary patency (60 months)	Study population		OR 1.67 (0.96 to 2.90)	247 (2 RCTs)	⊕⊕◯◯ LOW [12]	Our confidence in the effect is limited and this may differ substantially from the estimate of the effect
	606 per 1000	720 per 1000 (597 to 817)				
Secondary patency (24 months)	Study population		OR 1.54 (1.04 to 2.28)	528 (2 RCTs)	⊕⊕◯◯ LOW [12]	81 more PTFE grafts per 1000 (7 to 168 per 1000) suffer from failed secondary patency by 24 months compared to Dacron
	212 per 1000	293 per 1000 (219 to 380)				
Limb salvage (24 months)	Study population		OR 0.82 (0.27 to 2.48)	322 (1 RCT)	⊕⊕◯◯ LOW [12]	Our confidence in the effect is limited and this may differ substantially from the estimate of the effect

	44 per 1000	37 per 1000 (12 to 103)		

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: Confidence interval; **OR:** Odds ratio;**PTFE**: polytetrafluoroethylene

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1] Downgraded because of serious risk of bias due to lack of blinding and poor randomisation techniques
[2] Downgraded due to imprecision because of the low number of participants and events

Externally supported graft compared to unsupported graft for above-knee femoro-popliteal bypass surgery

Patient or population: people with peripheral vascular disease requiring above-knee femoro-popliteal bypass surgery
Setting: hospital
Intervention: externally supported graft
Comparison: unsupported graft

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of limbs (studies)	Quality of the evidence (GRADE)	Comments
	Risk with unsupported graft	Risk with externally supported graft				
Primary patency (24 months)	Study population		OR 2.08 (1.29 to 3.35)	270 (2 RCTs)	⊕⊕◯◯ LOW [12]	180 fewer unsupported prosthetic grafts per 1000 (61 to 293 grafts per 1000) lose primary patency by 24 months compared to externally supported prosthetic grafts
	376 per 1000	556 per 1000 (437 to 669)				
Primary patency (60 months)	-	-	-	-	-	No studies comparing supported and unsupported Dacron reported on primary patency at 60 months
Secondary patency (24 months)	Study population		OR 2.25 (1.24 to 4.07)	236 (1 RCT)	⊕⊕◯◯ LOW [12]	143 fewer unsupported Dacron grafts per 1000 (32 to 281 grafts per 1, 000) lose secondary patency by 24 months compared to externally supported Dacron grafts

	165 per 1000	308 per 1000 (197 to 446)				
Limb salvage	-	-	-	-	-	No studies of these graft types reported on this outcome

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

__CI:__ Confidence interval; __OR:__ Odds ratio;

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1] Downgraded because of serious risk of bias due to lack of blinding and poor randomisation techniques
[2] Downgraded due to imprecision because of the low number of participants and events

PTFE compared to PTFE with vein cuff for below-knee femoro-popliteal bypass surgery

Patient or population: people with peripheral vascular disease requiring below-knee femoro-popliteal bypass surgery
Setting: hospital
Intervention: PTFE
Comparison: PTFE with vein cuff

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of limbs (studies)	Quality of the evidence (GRADE)	Comments
	Risk with PTFE with vein cuff	Risk with PTFE				
Primary patency (24 months)	Study population		OR 1.08 (0.58 to 2.01)	182 (2 RCTs)	⊕◯◯◯ VERY LOW [123]	Findings from two small trials were inconsistent so our confidence in the effect is limited and this may differ substantially from the estimate of the effect
	626 per 1000	644 per 1000 (493 to 771)				
Primary patency (60 months)	-	-	-	-	-	No studies comparing PTFE with and without a vein cuff for below-knee bypass reported on primary patency at 60 months
Secondary patency (24 months)	Study population		OR 1.22 (0.67 to 2.23)	181 (2 RCTs)	⊕◯◯◯ VERY LOW [123]	Findings from two small trials were inconsistent so our confidence in the effect is limited and this may differ substantially from the estimate of the effect

	557 per 1000	605 per 1000 (457 to 737)				
Limb salvage (24 months)	Study population		OR 1.34 (0.72 to 2.49)	196 (2 RCTs)	⊕⊕◯◯ LOW [13]	Our confidence in the effect is limited and this may differ substantially from the estimate of the effect
	266 per 1000	327 per 1000 (207 to 474)				

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: Confidence interval; **OR:** Odds ratio;

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1] Downgraded due to serious risk of bias resulting from lack of blinding and poor randomisation techniques
[2] Downgraded due to significant heterogeneity in studies
[3] Downgraded due to imprecision because of the low number of participants and events

DISCUSSION

Summary of main results

Our major findings were that autologous vein grafts have long-term patency benefits over prosthetic grafts in above-knee femoro-popliteal bypass (moderate-quality evidence). In the long term (greater than two years), we found that Dacron may confer a slight benefit in secondary patency over polytetrafluoroethylene (PTFE) for above-knee bypasses (low-quality evidence). There was no significant improvement in primary and secondary patency for below-knee PTFE bypasses when a vein cuff was included. Limited evidence was available on below-knee procedures for all graft types. There was also limited evidence on limb survival for both above- and below-knee bypass surgery.

Overall completeness and applicability of evidence

While there have been many randomised controlled trials conducted for lower limb bypass surgery, the overall quality of these was poor and meant that we had to exclude 24 trials (see Characteristics of excluded studies). Some of the main reasons we excluded trials were because they failed to randomise patients, they did not report the data for above- and below-knee procedures separately, or because they had severe methodological flaws which led to significant bias within the trial.

We only found low numbers of trials for some analyses, especially for below-knee bypass, which is partly indicative of the numbers of new graft types being introduced and partly indicative of the reduced numbers of lower-limb bypass procedures now performed. Inclusion criteria for randomised controlled trials produce the potential problem of reducing the applicability of the results to the overall patient population. This was especially a problem in older trials, which included stable or long-distance claudicants, who are generally not offered surgery in contemporary practice. A subcomponent of any trial including such patients will therefore not be applicable to the overall patient population, but should have a minimal effect on the overall results as these trials have smaller numbers than the more recent included trials. The included trials are largely reflective of modern surgical practice in the UK and are therefore relevant.

Data on limb salvage and survival with limb intact were generally not included for analysis in trials. In the future this should be included as it is an important outcome, both for the patient and from a health economics point of view (Luther 1997; Perler 1995), and may therefore influence practice significantly. Quality-of-life data would also be useful in influencing treatment strategy (Nolan 2007). This information might augment the applicability of bypass surgery in general, as evidence is still lacking when comparing infrainguinal bypass with other treatments for lower limb ischaemia (Fowkes 2008).

Human umbilical vein (HUV) has primary patency results comparable with other non-vein graft types, and may show an improvement in primary and secondary patency compared to polytetrafluoroethylene (PTFE) below the knee. However, in one trial up to 30% of HUV grafts showed graft dilation and aneurysm formation (Aalders 1992). This, in combination with other data at the time, has led to the diminished popularity of HUV in recent years. More recent reviews did not find these factors to be a significant issue (Dardik 2002) and the patency data from this meta-analysis infer that HUV may be a suitable alternative to synthetic materials when no autologous vein is available.

Heparin bonded Dacron is showing promising early results in randomised trials (Devine 2004). Heparin bonded PTFE is also being widely utilised in contemporary practice. While there are case series data implying that this is an effective material, we could not include data from randomised trials in this review because the results are either awaited (see table Characteristics of ongoing studies), unavailable due to the trial being terminated early (NCT00617279), or reported in a way that does not separate above- and below-knee results (Lindholt 2011).

A single small trial examined the use of polyurethane (PUR) grafts (Gloor 1996). The trial was stopped early due to astonishingly poor primary and secondary patency rates in the limbs treated with the new graft material, so this material cannot be recommended.

Several specific problems could not be assessed in this analysis. Firstly, infection of synthetic bypasses has disastrous consequences for the patient (Siracuse 2013), whereas infection of venous bypasses tends not to, and is easier to treat (Reifsnyder 1992). Occlusion of synthetic bypasses appears to lead to limb loss more frequently than venous (Jackson 2000), which is why it is so important that future trials measure limb survival. A second limitation of this review is the lack of information on antiplatelet and anticoagulant protocols in the included studies; this may have produced bias in the results and their interpretation. Finally, the majority of included studies were not stratified according to graft length, inflow site quality or inflow procedures, or patency of runoff vessels. While the randomisation of participants should have achieved balance with respect to these factors, the small numbers of participants could potentially have led to imbalance between treatment arms, in turn leading to biased results.

Quality of the evidence

While there were low numbers of trials for some comparisons, these trials are mainly of reasonable methodological quality with acceptable allocation concealment techniques, though often simple sealed envelopes were used and little-if any-effort appeared to have been made to blind participants, practitioners or outcome assessors (Figure 2; Figure 3). As a result, we assessed the majority of the evidence contributing to above-knee bypass comparisons as low quality, which rose to moderate quality for one outcome. We assessed the quality of the evidence on below-knee by-

pass comparisons as very low-quality. Further details are included in Summary of findings for the main comparison, Summary of findings 2, Summary of findings 3 and Summary of findings 4.

All trials included a Kaplan-Meier analysis, and most supplemented this with numbers-at-risk and life table analyses. The numbers of participants at each stage of the trial were usually clear. However, antiplatelet protocols were generally lacking. There is clear evidence for antiplatelet therapy in cardiovascular stenting (NICE 2003), which may be applicable to lower-limb arterial stents (Twine 2009). While the evidence is less clear for lower-limb bypass grafts (Brown 2008; Dorffler-Melly 2003); clear protocols should be set in future trials to avoid the potential bias caused by individual preferences by surgeons or centres for particular antiplatelets or anticoagulants. Choice of anticoagulant for lower-limb bypass grafts requires good-quality randomised controlled trials to determine efficacy.

Potential biases in the review process

Although we are confident that a thorough search was carried out for all relevant studies, we were unable to separate data from trials from patients of below- and above-the-knee bypasses in all cases. It has been clear for some time that below-knee bypass grafts have significantly inferior patency rates to above-knee grafts (Cranley 1982; McCollum 1991). Most trials since the early 1990s have therefore separated the two types of bypass for reporting results, to avoid bias. This led to the division of above- and below-knee procedures in this review. Three trials which were included in previous editions of the review have been excluded in this update or previous updates (or both) as the above- and below-knee data were inseparable (McCollum 1991; Moody 1992; Watelet 1997). More recent trials with combined above- and below-knee procedures had other severe methodological flaws which, in combination, led us to exclude them (Robinson 1999; Robinson 2003). In addition, we excluded two more recent trials either because of combined above- and below-knee numbers (Lindholt 2011), or combined below-knee and distal bypass numbers (Lundgren 2013). See the table Characteristics of excluded studies.

Agreements and disagreements with other studies or reviews

There are several recent meta-analyses of graft type for femoro-popliteal bypass grafts (Albers 2005; Pereira 2006; Roll 2008; Rychlik 2014a). In Albers 2005, alternative autologous vein (defined as any autologous venous conduit other than a single section of great saphenous vein) was compared with PTFE, HUV and cryopreserved vein. Randomised controlled trials and cohort controlled trials were considered for inclusion. The authors included retrospective data and combined above- and below-knee bypasses. Thirty-two articles with 2618 patients from studies conducted between 1982 and 2004 were included. Pooled estimate analysis was performed in which the authors found no difference in primary patency between autologous vein and PTFE, but reported a significant improvement in secondary patency and foot preservation for alternative autologous veins. While not directly comparable with our analysis, these data provide more evidence for autologous vein over prosthetic grafts.

In Pereira 2006, above-knee autologous vein, PTFE and below-knee autologous vein were compared. Randomised controlled trials and cohort trials were considered for inclusion. Forty-nine retrospective articles and 24 prospective articles from 1986 to 2004 were included. As well as including retrospective data, the authors included several studies which we excluded from our analysis because of inadequate randomisation. Pooled estimate analysis was performed, in which the authors found a significant improvement in primary patency for above-knee autologous vein when compared with PTFE. Secondary patency was lower for all graft types and showed no significant difference. Therefore, Pereira 2006 also broadly agrees with the findings of this analysis that autologous vein performs better than PTFE above the knee. The authors' findings should, however, be interpreted with caution due to the nature of the data included.

One meta-analysis (Roll 2008), compared Dacron with PTFE and found no difference between the graft types. The authors included bypasses other than femoro-popliteal (axillo-bifemoral, aorto-bifemoral, etc.) but had strict inclusion criteria and therefore included good-quality trials. Our analysis is in broad agreement with the findings of Roll 2008 in terms of primary patency, though we did find an improvement in secondary patency at 24 months and five years, the latter as a result of data from the van Det study (van Det 2009), published after Roll (Roll 2008). Therefore, the findings of our analysis are broadly in agreement with Roll 2008. For this reason, the long-term secondary patency benefit towards Dacon is tentative, as discussed throughout the text.

One meta-analysis (Rychlik 2014a) compared Dacron with PTFE above the knee.It had similar exclusion criteria to our review and found results from five studies which are included in our analysis, in addition to one study which we excluded from our meta-analysis due to its methodological flaws (Davidovic 2010). They chose to include the results of Devine 2004, which compared heparin bonded Dacron with PTFE, alongside the four studies comparing standard Dacron with PTFE (Abbot 1997; Jensen 2007; Post 2001; van Det 2009). Their conclusions were similar to our results in this context: that Dacron has superior patency to PTFE at 2 and 5 years follow-up.

A previous meta-analysis (Twine 2012) has shown benefit for PTFE with vein cuff for below-knee bypass. This analysis included non-randomised studies, and based on the results seen in our analysis, the benefit shown in Twine 2012 may be because of selection bias in the non-randomised data. It is unlikely that another RCT of cuffed bypass will be performed, and most surgeons will perform a cuffed anastomosis for synthetic bypass distal to the

knee. Registry data is becoming increasingly prevalent in vascular surgery and may help to answer this question more definitively in the future.

AUTHORS' CONCLUSIONS

Implications for practice

We found moderate-quality evidence that autologous vein grafts improve long-term (60 months) primary patency over prosthetic graft materials for femoro-popliteal bypass above the knee. There was low-quality evidence that Dacron grafts had improved long-term (two to five years) secondary patency compared to polytetrafluoroethylene (PTFE) above the knee. External reinforcement of Dacron grafts had inferior primary patency above the knee. Human umbilical cord (HUV) and heparin bonded Dacron (HBD) may also have superior patency to PTFE, but the results are from only one trial in each case. There was no evidence to support any one synthetic material for bypasses below the knee. Further randomised data are needed to ascertain whether this information translates into an improvement in limb survival.

Implications for research

Randomised trials of synthetic materials versus autologous vein and other prosthetic materials are ongoing (NCT00205790; NCT00147979). While data on new graft types are invaluable, further randomised data are needed on 'established' materials used for femoro-popliteal bypasses. This especially includes the use of vein cuffs with different prosthetic materials below the knee. Randomised trials of HBD versus Dacron would also be useful, as would randomised data comparing 'alternative' autologous vein (for example profunda femoris, arm vein and 'inadequate' saphenous vein) with prosthetic materials.

Future trials need to include data on limb survival, quality of life and costs, as well as patency rates, to ascertain whether the improvements in patency found in this analysis translate into improvements in these important outcomes. It would also be helpful if infection rates could be reported in future trials, though the low event rates seen in observational studies of graft infection would suggest that studies looking at this issue might need to be very large.

While vein cuffs or pre-cuffed grafts are widely utilised below the knee, this practice is based on case-series data. This would be a useful topic to study in future trials, since vein is not always available and the results of randomised studies of this technique are conflicting.

The effects of antiplatelets or anticoagulants on graft patency also need to be investigated further in the context of randomised controlled trials. This would facilitate graft-type trial medication protocols and remove a major potential source of bias from future studies.

ACKNOWLEDGEMENTS

We are grateful to Drs Cathryn Broderick, Marlene Stewart and Karen Welch for their invaluable help and assistance in the preparation of this review.

REFERENCES

References to studies included in this review

Aalders 1992 ***{published and unpublished data}***
Aalders GJ, van Vroonhoven TJMV. Polytetrafluoroethylene versus human umbilical vein in above-knee femoro-popliteal bypass: Six-year results of a randomized clinical trial. *Journal of Vascular Surgery* 1992;**16**:816–24.

Abbot 1997 ***{published data only}***
Abbot WM, Green RM, Matsumoto T, Wheeler JR, Miller N, Veith FJ, et al. Prosthetic above-knee femoro-popliteal bypass grafting: results of a multicenter randomized prospective trial. *Journal of Vascular Surgery* 1997;**25**:19–28.
Green RM, Abbott WM, Matsumoto T, Wheeler JR, Millem N, Veith FJ, et al. Prosthetic above-knee femoro-popliteal bypass grafting: Five-year results of a randomized trial. *Journal of Vascular Surgery* 2000;**31**(3):417–25.

Ballotta 2003 ***{published data only}***
Ballotta E, Renon L, Toffano M, Da Giau G. Prospective randomized study on bilateral above-knee femoro-popliteal revascularization: Polytetrafluoroethylene graft versus reversed saphenous vein. *Journal of Vascular Surgery* 2003; **38**(5):1051–5. PUBMED: 14603216]

Davidovic 2010 ***{published data only}***
Davidovic L, Jakovljevic N, Radak D, Dragas M, Ilic N, Koncar I, et al. Dacron or ePTFE graft for above-knee femoropopliteal bypass reconstruction. A bi-centre randomised study. *Vasa* 2010;**39**:77–84.

Devine 2004 ***{published data only}***
Devine C, McCollum C. Heparin-bonded Dacron or polytetrafluorethylene for femoro-popliteal bypass: Five-year results of a prospective randomized multicenter clinical trial. *Journal of Vascular Surgery* 2004;**40**(5):924–31.
Devine CM, McCollum CN. Heparin-bonded Dacron or polytetrafluoroethylene for femoro-popliteal bypass grafting: a multicenter trial. *Journal of Vascular Surgery* 2001;**33**(3):533–9.

Eickhoff 1987 *{published data only}*

* Eickhoff JH, Broome A, Ericsson BF, Hansen HJB, Kordt K F, Mouritzen C, et al. Four years' results of a prospective, randomized clinical trial comparing polytetrafluoroethylene and modified human umbilical vein for below-knee femoro-popliteal bypass. *Journal of Vascular Surgery* 1987;**6**:506–11.
Eickhoff JH, Hansen HJB, Bromme A, Ericsson BF, Kordt KF, Mouritzen C, et al. A randomized clinical trial of PTFE versus human umbilical vein for femoro-popliteal bypass surgery. Preliminary results. *British Journal of Surgery* 1983; **70**:85–8.

Gloor 1996 *{published data only}*

Gloor B, Wehrli E, Rotzer A, Brunner D, Wilms C, Largiader J. Polyurethane small artery substitutes for femoro-popliteal above knee bypass. *Swiss Surgery* 1996;**1 Suppl**:13–8.

Gupta 1991 *{published data only}*

Gupta SK, Veith FJ, Kram HB, Wengerter KR. Prospective randomized comparison of ringed and nonringed polytetrafluoroethylene femoro-popliteal bypass grafts: A preliminary report. *Journal of Vascular Surgery* 1991;**13**: 162–72.

Jensen 2007 *{published data only}*

Jensen LP, Lepantalo M, Fossdal JE, Roder OC, Jensen BS, Madsen MS, et al. Dacron or PTFE for above-knee femoro-popliteal bypass. a multicenter randomised study. *European Journal of Vascular and Endovascular Surgery* 2007;**34**(1): 44–9. PUBMED: 17400486]

Klinkert 2003 *{published data only}*

Burger DH, Kappetein AP, Van Bockel JH, Breslau PJ. A prospective randomized trial comparing vein with polytetrafluoroethylene in above-knee femoro-popliteal bypass grafting. *Journal of Vascular Surgery* 2000;**32**(2): 278–83. PUBMED: 10917987]
Klinkert P, Schepers A, Burger DH, van Bockel JH, Breslau PJ. Vein versus polytetrafluoroethylene in above-knee femoro-popliteal bypass grafting: five-year results of a randomized controlled trial. *Journal of Vascular Surgery* 2003;**37**(1):149–55. PUBMED: 12514593]

Lumsden 2015 *{published data only}*

Lumsden AB, Morrissey NJ, Comparison of safety and primary patency between the FUSION BIOLINE heparin-coated vascular graft and EXXCEL Soft ePTFE (FINEST) trial Co-investigators. Randomized controlled trial comparing the safety and efficacy between the FUSION BIOLINE heparin-coated vascular graft and the standard expanded polytetrafluoroethylene graft for femoropopliteal bypass. *Journal of Vascular Surgery* 2015;**61**:703–12.

Post 2001 *{published data only}*

Post S, Kraus T, Muller-Reinartz U, Weiss C, Kortmann H, Quentmeier A, et al. Dacron vs polytetrafluoroethylene grafts for femoro-popliteal bypass: a prospective randomised multicentre trial. *European Journal of Endovascular Surgery* 2001;**22**:226–31.

SCAMICOS 2010 *{published data only}*

SCAMICOS. PTFE bypass to below-knee arteries: distal vein collar or not? A prospective randomised multicentre study. *European Journal of Vascular and Endovascular Surgery* 2010;**39**:747–54.

Scharn 2008 *{published data only}*

Scharn DM, Dirven M, Barendregt WB, Boll AP, Roelofs D, van der Vliet JA. Human umbilical vein versus heparin-bonded polyester for femoro-popliteal bypass: 5-year results of a prospective randomized multicentre trial. *European Journal of Vascular and Endovascular Surgery* 2008;**35**(1): 61–7.

Solakovic 2008 *{published data only}*

Solakovic E, Totic D, Solakovic S. Femoro-popliteal bypass above knee with saphenous vein vs synthetic graft. *Bosnian Journal of Basic Medical Sciences* 2008;**8**:367–72.

Stonebridge 1997 *{published data only}*

Griffiths GD, Nagy J, Black D, Stonebridge PA. Randomized clinical trial of distal anastomotic interposition vein cuff in infrainguinal polytetrafluoroethylene bypass grafting. *British Journal of Surgery* 2004;**91**(5):560–2. PUBMED: 15122605]
Stonebridge PA, Prescott RJ, Ruckley CV. Randomized trial comparing infrainguinal polytetrafluoroethylene bypass grafting with and without vein interposition cuff at the distal anastamosis. *Journal of Vascular Surgery* 1997;**26**: 543–50.

Tofigh 2007 *{published data only}*

Tofigh AM, Warnier De Wailly G, Rhissassi B. Comparing vein with collagen impregnated woven polyester prosthesis in above-knee femoro-popliteal bypass grafting. *International Journal of Surgery* 2007;**5**(2):109–13. PUBMED: 17448975]

van Det 2009 *{published data only}*

van Det RJ, Vriens BHR, van der Palen J, Geelkerken RH. Dacron or ePTFE for Femoro-popliteal above knee bypass grafting: Short- and Long-term results of a multicentre randomised trial. *European Journal of Vascular and Endovascular Surgery* 2009;**37**:457–63.

Vriens 2013 *{published data only}*

Vriens BHR, van Det RJ, Meerwaldt R, van der PJ, Gerrits DG, Zeebregts CJ, Geelkerken RH. Superior two-year results of externally unsupported polyester compared to supported grafts in above-knee bypass grafting: A multicenter randomised trial. *European Journal of Vascular and Endovascular Surgery* 2013;**45**(3):275–81.

References to studies excluded from this review

Bennion 1985 *{published data only}*

Bennion RS, Williams RA, Stabile BE, Fox MA, Owens ML, Wilson SE. Patency of autogenous saphenous vein versus polytetrafluoroethylene grafts in femoro-popliteal bypass for advanced ischaemia of the extremity. *Surgery, Gynecology & Obstetrics* 1985;**160**:239–42.

Chikiar 2003 *{published data only}*
Chikiar DS, Grandjean M, Abelleyra A. Femoropoliteal bypass grafting for arterial occlusive disease. Patency and complications. Randomised retrospective study. *Prensa Medica Argentina* 2003;**90**(4):338–44.

Erasmi 1996 *{published data only}*
Erasmi H, Walter M, Schmitz-Rixen T, Kristen F. Preliminary results of a prospective randomised study regarding femoro-popliteal bypass material. *Zentralblatt für Chirurgie* 1996;**121**:228–33.

Hamann 1998 *{published data only}*
Hamann H, Krawczynski H, Mayer W, Wack HO. Above knee femoropopliteal vein bypasses versus vascular prostheses. *Gefasschirurgie* 1998;**3**:14–9.

Hobson 1980 *{published data only}*
Hobson RW, O'Donnell JA, Jamil Z, Mehta K. Below knee bypass for limb salvage. *Archives of Surgery* 1980;**115**: 833–7.

Johnson 2000 *{published data only}*
Johnson WC, Lee KK. A comparative evaluation of polytetrafluoroethylene, umbilical vein, and saphenous vein bypass grafts for femoral-popliteal above-knee revascularization:a prospective randomized Department of Veterans Affairs cooperative study. *Journal of Vascular Surgery* 2000;**32**(2):268–77.
Johnson WC, Lee KK, VA Cooperative Study Group 141. Comparative evaluation of PTFE, HUV and saphenous vein bypasses in fem-pop AK vascular reconstructions. *Journal of Vascular Surgery* 1992;**15**:1070.

Kreienberg 2002 *{published data only}*
Kreienberg PB, Darling RC 3rd, Chang BB, Champagne BJ, Paty PS, Roddy SP, et al. Early results of a prospective randomized trial of spliced vein versus polytetrafluoroethylene graft with a distal vein cuff for limb-threatening ischemia. *Journal of Vascular Surgery* 2002;**35** (2):299–306. PUBMED: 11854728]

Kumar 1995 *{published data only}*
Kumar KP, Crinnion JN, Ashley S, Case WG, Gough MJ. Vein, PTFE or Dacron for above-knee femoro-popliteal bypass?. *International Angiology* 1995;**14**:200.
Kumar KP, Homer-Vanniasinkam SM, Gough MJ. Femoro-popliteal bypass grafting: fact or fiction?. Cardiovascular Surgery 22nd World Congress. 1995:116.

Lindholt 2011 *{published data only (unpublished sought but not used)}*
Lindholt JS, Gottschalksen B, Johannesen N, Dueholm D, Ravn H, Christensen ED, Viddal B, Florenes T, Pedersen G, Rasmussen M, Carstensen M, Grondal N, Fasting H. The Scandinavian propaten trial - 1-year patency of PTFE vascular prostheses with heparin-bonded luminal surfaces compared to ordinary pure PTFE vascular prostheses - a randomised clinical controlled multi-centre trial. *European Journal of Vascular and Endovascular Surgery* 2011;**41**: 668–73.

Linni 2015 *{published data only}*
Linni K, Aspalter M, Butturini E, Dabernig W, Guggenbichler S, Hitzl W, Hölzenbein T. Arm veins versus contralateral greater saphenous veins for lower extremity bypass reconstruction: preliminary data of a randomised study. *Annals of Vascular Surgery* 2015;**29**(3):551–9.

Lundgren 2013 *{published data only}*
Lundgren F, Swedish External Support Study. External support of a polytetrafluoroethylene graft improves patency for bypass to below-knee arteries. *Annals of Vascular Surgery* 2013;**27**(8):1124–33.

McCollum 1991 *{published data only}*
McCollum C, Kenchington G, Alexander C, Franks PJ, Greenhalgh RM. PTFE or HUV for femoro-popliteal bypass: A multicentre trial. *European Journal of Vascular Surgery* 1991;**5**:435–43.
McCollum CN, Alexander CE, Kenchington G, Franks PJ, Greenhalgh RM. PTFE or HUV for femoro-popliteal bypass: a multi-centre trial. Proceedings of the European Society for Vascular Surgery 4th Annual Meeting. Rome, Italy, 1990:44.

Midy 2016 *{published data only}*
Midy D, Papon X, Patra P, Hassen Kodja R, Feugier P, Plissonnier D, et al. Randomized study of noninferiority comparing prosthetic and autologous vein above-knee femoropopliteal bypasses. *Annals of Vascular Surgery* 2016; **31**:99–104.

Moody 1992 *{published data only}*
Harris PL, How TV, Jones DR. Prospectively randomized clinical trial to compare in situ and reversed saphenous vein grafts for femoro-popliteal bypass. *The British Journal of Surgery* 1987;**74**:252–5.
Moody AP, Edwards PR, Harris PL. In situ versus reversed femoro-popliteal vein grafts: long-term follow up of a prospective randomized trial. *The British Journal of Surgery* 1992;**79**(8):750–2.

Motta 1989 *{published data only}*
Motta G, Ratto GB, Sacco A. Long term evaluation of human umbilical vein as small caliber arterial substitute. *Vascular Surgery* 1988;**22**(5):328–34.

NCT00617279 *{published data only}*
NCT00617279. GORE PROPATEN vascular graft vs. disadvantaged autologous vein graft (PRODIGY). clinicaltrials.gov/ct2/show/NCT00617279?term= NCT00617279&rank=1 (first received 18 December 2007).

NCT00845585 *{unpublished data only}*
NCT00845585. Ovine graft (Omniflow II) versus PTFE in below knee arterial reconstruction. clinicaltrials.gov/ct2/ show/NCT00845585?term=NCT00845585&rank=1 (first received 16 February 2009).

Robinson 1999 *{published data only}*
Fletcher JP, Robinson BI. A prospective randomised comparison of PTFE and Dacron for femoro-popliteal bypass. *ANZ Journal of Surgery* 1995;**67 Suppl 1**:A85.
Robinson BI, Fletcher JP, Tomlinson P, Allen RD, Hazelton SJ, Richardson AJ, et al. A prospective randomized multicentre comparison of expanded polytetrafluoroethylene and gelatin-sealed knitted Dacron grafts for femoro-popliteal bypass. *Cardiovascular Surgery (London, England)* 1999;**7**(2):214–8. PUBMED: 10353674]

Robinson 2003 *{published data only}*
Robinson BI, Fletcher JP. Fluoropolymer coated Dacron or polytetrafluoroethylene for femoro-popliteal bypass grafting: a multicentre trial. *ANZ Journal of Surgery* 2003; **73**(3):95–9. PUBMED: 12608965]

Schulman 1987 *{published data only}*
* Schulman ML, Badhey MR, Yatco R. Superficial femoro-popliteal veins and reversed saphenous veins as primary femoro-popliteal bypass grafts: A randomized comparative study. *Journal of Vascular Surgery* 1987;**6**:1–10.
Schulman ML, Badhey MR, Yatco R, Pillari G. An 11-year experience with deep leg veins as femoro-popliteal bypass grafts. *Archives of Surgery* 1986;**121**:1010–5.

Tilanus 1985 *{published data only}*
Tilanus HW, Obertrop H, van Urk H. Saphenous vein or PTFE for femoro-popliteal bypass. A prospective randomized trial. *Annals of Surgery* 1985;**202**:780–2.

Veith 1986 *{published and unpublished data}*
Bergan JJ, Veith FJ, Bernhard VM, Yao JST, Flinn WR, Gupta SK, et al. Randomization of autogenous vein and polytetrafluoroethylene grafts in femoro-distal construction. *Surgery* 1982;**92**:921–30.
* Veith FJ, Gupta SK, Ascer E, White-Flores S, Samson RH, Scher LA, et al. Six-year prospective multicenter randomized comparison of autologous saphenous vein and expanded polytetrafluoroethylene grafts in infrainguinal arterial constructions. *Journal of Vascular Surgery* 1986;**3**: 104–14.

Watelet 1997 *{published and unpublished data}*
* Watelet J, Cheysson E, Poels D, Menard J-F, Papion H, Saour N, et al. In situ versus reversed saphenous vein for femoro-popliteal bypass: a prospective randomized study of 100 cases. *Annals of Vascular Surgery* 1986;**1**:441–52.
Watelet J, Soury P, Menard J-F, Plissonnier D, Peillon C, Lestrat J-P, et al. Femoropopliteal bypass: in situ or reversed vein grafts? Ten-year results of a randomized prospective study. *Annals of Vascular Surgery* 1997;**11**:510–9.

Zilla 1994 *{published data only}*
Zilla P, Deutsch M, Meinhart J, Puschmann R, Eberl T, Minar E, et al. Clinical in vitro endothelialization of femoro-popliteal bypass grafts: an actuarial follow-up over three years. *Journal of Vascular Surgery* 1994;**19**:540–8.

References to ongoing studies

NCT00147979 *{published data only}*
NCT00147979. Multicentric, Prospective, Randomized, Comparing Trial Between Bypass of the Femoropoplitea by PTFE and Heparin Bounded PTFE. clinicaltrials.gov/ct2/show/NCT00147979?term=NCT00147979&rank=1 (first received 6 September 2005).

NCT00205790 *{published data only}*
NCT00205790. GORE-TEX PROPATEN Vascular Graft Study. clinicaltrials.gov/ct2/show/NCT00205790?term=NCT00205790&rank=1 (first received 12 September 2005).

Additional references

Albers 2005
Albers A, Romiti M, Brochado-Neto FC, Pereira CAB. Meta-analysis of alternative autologous vein bypass grafts to infra popliteal arteries. *Journal of Vascular Surgery* 2005;**42**: 449–55.

Bradbury 2010
Bradbury AW, Adam DJ, Bell J, Forbes JF, Fowkes FG, Gillespie I, et al. Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial: An intention-to-treat analysis of amputation-free and overall survival in patients randomized to a bypass surgery-first or a balloon angioplasty-first revascularization strategy. *Journal of Vascular Surgery* 2010;**51**:5S–17S.

Brown 2008
Brown J, Lethaby A, Maxwell H, Wawrzyniak AJ, Prins MH. Antiplatelet agents for preventing thrombosis after peripheral arterial bypass surgery. *Cochrane Database of Systematic Reviews* 2008, Issue 4. [DOI: 10.1002/14651858.CD000535.pub2

Consensus Document
Anonymous. Second European Consensus Document on chronic critical leg ischemia. *Circulation* 1991;**84 Suppl**(4): 1–26.

Cranley 1982
Cranley JJ, Hafner CD. Revascularisation of the femoro-popliteal arteries using saphenous vein, polytetrafluoroethylene and umbilical vein grafts. *Archives of Surgery* 1982;**117**:1543–50.

Dardik 2002
Dardik H, Wengerter K, Qin F, Pangilinan A, Silvestri F, Wolodiger F, et al. Comparative decades of experience with glutaraldehyde-tanned human umbilical cord vein graft for lower limb revascularization: an analysis of 1275 cases. *Journal of Vascular Surgery* 2002;**35**(1):64–71. [PUBMED: 11802134]

Dorffler-Melly 2003
Dorffler-Melly J, Buller HR, Koopman MM, Prins MH. Antithrombotic agents for preventing thrombosis after infrainguinal arterial bypass surgery. *Cochrane Database of Systematic Reviews* 2003, Issue 4. [DOI: 10.1002/14651858.CD000536

Eiberg 2006
Eiberg JP, Roder O, Stahl-Madsen M, Eldrup N, Qvarfordt P, Laursen A, et al. Fluoropolymer-coated dacron versus PTFE grafts for femorofemoral crossover bypass: randomised trial. *European Journal of Vascular and Endovascular Surgery* 2006;**32**(4):431–8. [PUBMED: 16807001]

Fowkes 2008
Fowkes F, Leng GC. Bypass surgery for chronic lower limb ischaemia. *Cochrane Database of Systematic Reviews* 2008, Issue 2. [DOI: 10.1002/14651858.CD002000.pub2

GRADEpro GDT 2015 [Computer program]
McMaster University (developed by Evidence Prime). GRADEpro GDT. Version accessed 30 March 2017. Hamilton (ON): McMaster University (developed by Evidence Prime), 2015.

Higgins 2003
Higgins JPT, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ* 2003;**327**: 557–60.

Higgins 2011
Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.handbook.cochrane.org.

Jackson 2000
Jackson MR, Belott TP, Dickason T, Kaiser WJ, Modrall JG, Valentine RJ, et al. The consequences of a failed femoropopliteal bypass grafting: comparison of saphenous vein and PTFE grafts. *Journal of Vascular Surgery* 2000;**32**: 498–504.

Luther 1997
Luther M. Surgical treatment for chronic critical leg ischaemia: a 5 year follow-up of socioeconomic outcome. *European Journal of Vascular and Endovascular Surgery* 1997; **13**(5):452–9. [PUBMED: 9166267]

NICE 2003
The National Institute for Clinical Excellence. *Coronary artery stents: rapid systematic review and economic evaluation*. Liverpool: Liverpool reviews and implementation group, 2003. https://www.nice.org.uk/guidance/ta71/documents/assessment–report–coronary–artery–stents–rapid–systematic–review–and–economic–evaluation–4.

Nolan 2007
Nolan B, Finlayson S, Tosteson A, Powell R, Cronenwett J. The treatment of disabling intermittent claudication in patients with superficial femoral artery occlusive disease--decision analysis. *Journal of Vascular Surgery* 2007;**45**(6): 1179–84. [PUBMED: 17543682]

Pereira 2006
Pereira CE, Albers M, Romiti M, Brochado-Neto FC, Pereira CA. Meta-analysis of femoro-popliteal bypass grafts for lower extremity arterial insufficiency. *Journal of Vascular Surgery* 2006;**44**(3):510–7. [PUBMED: 16950427]

Perler 1995
Perler BA. Cost-efficacy issues in the treatment of peripheral vascular disease: primary amputation or revascularization for limb-threatening ischemia. *Journal of Vascular and Interventional Radiology: JVIR* 1995;**6 Suppl**(6 Pt 2):111–5. [PUBMED: 8770853]

Reifsnyder 1992
Reifsnyder T, Bandyk D, Seabrook G, Kinney E, Towne JB. Wound complications of the in situ saphenous vein bypass technique. *Journal of Vascular Surgery* 1992;**15**:843–8.

Roll 2008
Roll S, Muller-Nordhorn J, Keil T, Scholz H, Eidt D, Greiner W, et al. Dacron vs. PTFE as bypass materials in peripheral vascular surgery--systematic review and meta-analysis. *BMC Surgery* 2008;**8**:22. [PUBMED: 19099583]

Rychlik 2014a
Rychlik IJ, Davey P, Murphy J, O'Donnell ME. A meta-analysis to compare Dacron versus polytetrafluroethylene grafts for above-knee femoropopliteal artery bypass. *Journal of Vascular Surgery* 2014;**60**:506–15.

Siracuse 2013
Siracuse JJ, Nandivada P, Giles KA, Hamdan AD, Wyers AC, Chaikov EL, et al. Prosthetic graft infections involving the femoral artery. *Journal of Vascular Surgery* 2013;**57**: 700–5.

Twine 2009
Twine CP, Coulston J, Shandall A, McLain AD. Angioplasty versus stenting for superficial femoral artery lesions. *Cochrane Database of Systematic Reviews* 2009, Issue 2. [DOI: 10.1002/14651858.CD006767.pub2

Twine 2012
Twine CP, Williams IM, Fligelstone LJ. Systematic review and meta-analysis of vein cuffs for below-knee synthetic bypass. *British Journal of Surgery* 2012;**99**:1195–202.

Vogt 2007
Vogt KC, Uhlyarik M, Schroeder TV. Moist wound healing compared with standard care of treatment of primary closed vascular surgical wounds: a prospective randomized controlled study. *Wound Repair and Regeneration* 2007;**15** (5):624–7. [PUBMED: 17971007]

References to other published versions of this review

Mamode 1999
Mamode N, Scott RN. Graft type for femoro-popliteal bypass surgery. *Cochrane Database of Systematic Reviews* 1999, Issue 2. [DOI: 10.1002/14651858.CD001487

Twine 2010
Twine CP, McLain AD. Graft type for femoro-popliteal bypass surgery. *Cochrane Database of Systematic Reviews* 2010, Issue 5. [DOI: 10.1002/14651858.CD001487.pub2

* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Aalders 1992

Methods	Site: Femoral to AK popliteal Study design: Single-centre RCT Method of randomisation: sealed envelopes Blinding: unblinded, intention to treat Exclusions post randomisation: none Losses to follow up: none
Participants	Country: Holland No. of participants: 85 patients(93 limbs; 46 PTFE, 47 HUV) Age: 64 yrs Sex: 67 male, 18 female DM 16, critical 17 Inclusion criteria: AK femoro-popliteal graft for IC (or limb salvage if vein unavailable) Exclusion criteria: those with previous femoro-popliteal graft
Interventions	6 mm PTFE versus 6 mm HUV
Outcomes	Primary patency, secondary patency, complications
Notes	All had post-op anticoagulants

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Random permuted blocks"
Allocation concealment (selection bias)	Unclear risk	Not specifically stated. Probably not done
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Some patients lost to follow-up early on, but clear life table data
Selective reporting (reporting bias)	Low risk	All stated outcomes reported

Aalders 1992 (*Continued*)

Other bias	Low risk	No other obvious bias

Abbot 1997

Methods	Site: Femoral to AK popliteal Study design: Multicentre RCT Method of randomisation: central randomisation, but exact method unclear Blinding: unblinded, intention to treat Exclusions post randomisation: not discussed Losses to follow up: high rate of losses to follow-up (37 within first 12 months of follow-up)
Participants	Country: USA Setting: multicentre No. of participants: 231 patients (240 limbs; 122 PTFE, 118 Dacron) Age: mean 67.1 yrs Sex: 145 male, 95 female Inclusion criteria: angiographically demonstrated superficial femoral artery occlusion with reconstitution of a popliteal segment above the knee Exclusion criteria: earlier infrainguinal vascular procedures Unclear whether patients had IC or critical ischaemia
Interventions	PTFE versus Dacron (diameter at discretion of operating surgeon)
Outcomes	Primary patency, secondary patency, peri-operative complications
Notes	13 patients randomised but not described. Unclear how many patients had post-op aspirin

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients were randomised centrally after eligibility was determined by the operating surgeon and informed consent obtained."
Allocation concealment (selection bias)	Unclear risk	Not specifically stated. Probably not done
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded

Abbot 1997 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	High risk	37 patients randomised lost by 12 months
Selective reporting (reporting bias)	Low risk	All stated outcomes reported
Other bias	Unclear risk	Anticoagulation protocol not stated

Ballotta 2003

Methods	Site: Femoral to AK popliteal Study design: RCT Method of randomisation: concealed randomisation using computer generated randomisation envelopes Blinding: unblinded, intention to treat Exclusions post randomisation: none Losses to follow up: none
Participants	Country: Italy Setting: hospital No. of participants: 51 (102 limbs; 51 PTFE, 51 reversed vein) Age (mean): 62 yrs Sex: 33 males, 18 females Inclusion criteria: severe claudication, SFA occlusion with one to three runoff vessels Exclusion criteria: untreated inflow disease of ipsilateral pelvic arteries (more than 50% stenosis or occlusion); previous bypass procedure or stent in target SFA; multiple lesions exceeding 10 cm; acute critical limb ischaemia; an untreated ipsilateral iliac artery stenosis; known intolerance to study medications or contrast agents
Interventions	8 mm PTFE and reversed vein graft Oral warfarin from one day pre-op and continued for 6 months; 325 mg aspirin afterwards
Outcomes	Primary assisted patency as remedial surgery for late bypass stenosis was not considered a primary failure 5-year data
Notes	Compliance with medication not checked

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "Concealed randomisation using computer generated randomisation envelopes."
Allocation concealment (selection bias)	Low risk	Envelopes sealed as above

Ballotta 2003 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No patients lost to long term follow up (mean 59 months)
Selective reporting (reporting bias)	Low risk	All stated outcomes reported
Other bias	Low risk	No other obvious bias

Davidovic 2010

Methods	Site: Femoral to AK popliteal Study design: RCT Method of randomisation: not described Blinding: unblinded, intention to treat Exclusions post randomisation: none Losses to follow up: not specified
Participants	Country: Serbia Setting: hospital No. of participants: 85 (43 ePTFE, 42 Dacron) Age (mean): 65.5 yrs Sex: 71 males, 14 females Inclusion criteria: severe claudication or critical ischaemia, "considered suitable for surgical revascularization using above-knee prosthetic bypass graft" Exclusion criteria: previous procedures on aorto-iliac or ipsilateral femoro-politeal arterial segments
Interventions	8 mm FlowNit Biosel (Dacron) or 8mm FlowLine BioPore (ePTFE) bypass graft from femoral to above-knee popliteal artery. All patients given 4 days' antibiotic prophylaxis with a second generation cephalosporine and started on acetylsalicylic acid immediately after surgery
Outcomes	Primary: primary patency, early complications (mortality, bleeding and infection), early limb salvage Secondary: secondary patency, mid-term complications (mortality, false anastomotic aneurysms and infection), mid-term limb salvage
Notes	Clear antibiotic and antiplatelet protocols
Risk of bias	

Davidovic 2010 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not specified
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not discussed
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	Numbers at risk not presented with survival curves, secondary patency presented as worse than primary patency, which is impossible
Selective reporting (reporting bias)	Low risk	All outcomes presented, but numbers at risk at different time points not given so impossible to discern significance of different rates
Other bias	Low risk	Clear antiplatelet and antibiotic protocols

Devine 2004

Methods	Site: Femoral to AK and BK popliteal Study design: RCT Method of randomisation: concealed randomisation using computer generated randomisation envelopes Blinding: unblinded, intention to treat Exclusions post randomisation: none Losses to follow up: none
Participants	Country: UK Setting: hospital No. of participants: 209 (AK: 88 PTFE, 91 HBD; BK: 15 PTFE, 15 HBD) Age (mean): 63 yrs Sex: 142 males, 67 females Inclusion criteria: severe claudication, SFA occlusion with one to three runoff vessels Exclusion criteria: emergency surgery for trauma, acute thrombosis, embolism, or popliteal artery thrombosis Symptoms not sufficiently severe to disrupt lifestyle or ABI > 0.8 at rest (unless aneurysm) , the diagnosis or treatment for malignancy within 12 months including all cases with residual malignancy being followed up or observed, hospital inpatient treatment for

Devine 2004 (*Continued*)

	cardiac failure in the previous 6 months, where adequate follow-up would be impossible to arrange because the patient lived or was moving to an area where independent follow up could not be arranged	
Interventions	HBD or PTFE (diameter at discretion of operating surgeon) Anticoagulation not stated	
Outcomes	Primary patency	
Notes	Anticoagulation not stated	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "Randomization, stratified for AK or BK and by surgeon, was performed for eligible patients, using a dedicated computer program."
Allocation concealment (selection bias)	Low risk	Quote: "Sealed randomization envelopes (1 for AK, 1 for BK) were delivered to the vascular surgeon before surgery."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No losses, but numbers at risk not given for below knee outcomes so attrition not clear for this outcome
Selective reporting (reporting bias)	Low risk	All stated outcomes reported
Other bias	Unclear risk	Anticoagulation protocol not stated

Eickhoff 1987

Methods	Site: Femoral to BK popliteal Study design: multicentre RCT Method of randomisation: sealed envelopes Blinding: unblinded, intention to treat Exclusions post randomisation: none Losses to follow up: none
Participants	Country: Scandinavia Setting: hospital No. of participants: 105 (55 PTFE, 50 HUV) Age: 68 yrs Sex: 60 male, 45 female Inclusion criteria: DM 12, critical ischaemia 80. BK fem-pop for short distance IC or critical ischaemia, if no vein or CABG intended Exclusion criteria: short life expectancy, previous graft, Buerger's, coagulopathy
Interventions	PTFE versus HUV (diameter at discretion of operating surgeon)
Outcomes	Secondary patency
Notes	Post-op anti-thrombotic/coagulant therapy unknown

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Unclear as to how the randomisation sequence was generated
Allocation concealment (selection bias)	Low risk	Sealed envelopes used
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses, clear life table data
Selective reporting (reporting bias)	Low risk	All stated outcomes reported
Other bias	Unclear risk	Anticoagulation protocol not stated

Gloor 1996

Methods	Site: Ilio or femoral to AK popliteal Study design: single-centre RCT Method of randomisation: not explicitly stated Blinding: stated to be single-blind Exclusions post randomisation: not stated Losses to follow up: none Protocol violations: none stated
Participants	Country: France Setting: hospital No. of participants: 18 (20 limbs; 10 PUR graft, 10 Dacron) Age (mean): PUR group: 70.7 years; Dacron: 70.5 years Sex: Overall 13 men, 7 women; PUR group: 6 men, 4 women; Dacron group: 7 men, 3 women Inclusion criteria: peripheral arterial occlusion of lower limb graded Fontaine stage IIb-IV requiring AK synthetic ilio- or femoro-popliteal bypass Exclusion criteria: obesity, emergency surgery, critical threat to limb
Interventions	Iliac or Femoral to AK popliteal bypass graft with either 6 mm PUR or 6 mm Dacron
Outcomes	Primary and secondary patency, complications in first 30 days, reintervention rate
Notes	Clear anticoagulation/antiplatelet protocol

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not stated
Allocation concealment (selection bias)	Unclear risk	Timing of randomisation not declared
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial, though participants were blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No PRISMA flow chart, no mention of patients excluded prior to randomisation or after randomisation
Selective reporting (reporting bias)	Unclear risk	Primary and secondary patency as well as reinterventions reported, but no complications in first 30 days which did not lead to reintervention mentioned

Gloor 1996 (*Continued*)

Other bias	Low risk	Clear anticoagulation and antiplatelet protocol

Gupta 1991

Methods	Site: Femoral to AK or BK popliteal Study design: single-centre RCT Method of randomisation: selecting a random card from an unsorted deck of cards marked with the choice of graft material Blinding: unblinded, no documented crossover so as treated/intention to treat analysis not discussed Exclusions post randomisation: none Losses to follow up: none Protocol violations: none
Participants	Country: USA Setting: hospital No. of participants: 122 (59 AK of whom 29 ringed, 63 BK of whom 29 ringed) Age (mean): 71 yrs Sex: split not specified Inclusion criteria: patients without an available ipsilateral ASV long enough to serve as femoro-popliteal bypass on the basis of a history of prior removal, duplex ultrasonography, saphenous venography or operative findings requiring an AK or BK femoro-popliteal bypass. Patients whose life expectancy was judged to be less than 3 years were also included whether or not an ipsilateral ASV was available Patients with Rutherford category 1 to 5 ischaemia were eligible, though all but 4 patients had rest pain or tissue loss Exclusion criteria: patients with extensive necrosis requiring sequential grafts to distal arteries, patients requiring bypass for reasons other than arteriosclerotic occlusive disease
Interventions	6 mm ringed or unringed PTFE
Outcomes	Primary patency, secondary patency, limb salvage (secondary patency and limb salvage not presented separately for above and below-knee grafts so not included)
Notes	Clear anticoagulation and antiplatelet protocol

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomisation by selection of "a random card from an unsorted deck of cards marked with the choice of graft material"
Allocation concealment (selection bias)	Unclear risk	Timing of randomisation not declared

Gupta 1991 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses, clear life table data
Selective reporting (reporting bias)	Low risk	All stated outcomes reported
Other bias	Low risk	Clear anticoagulation and antiplatelet protocol

Jensen 2007

Methods	Site: Femoral to AK popliteal (POPUP study) Study design: RCT Method of randomisation: randomisation envelopes Blinding: unblinded, intention to treat Exclusions post randomisation: 13 (8 Dacron, 5 PTFE) Losses to follow up: 51 (12%)
Participants	Country: Scandinavia Setting: hospital (13 departments) No. of participants: 426 (413 for analysis due to exclusions; 205 PTFE, 208 Dacron) Age (mean): 66 yrs Sex: 152 males, 261 females Inclusion criteria: "chronic lower limb ischaemia" Exclusion criteria: less than 18, pregnant, could not obtain informed consent
Interventions	6 mm PTFE and 6 mm Dacron graft Anticoagulation as per individual centre protocol
Outcomes	Primary patency, secondary patency and limb survival
Notes	No common anticoagulation pathway. Multiple, different surgeons

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Grafts were contained in envelopes, however the randomisation procedure is unclear. Probably done as other papers from this unit clearly use random sequences

Jensen 2007 (*Continued*)

		(Eiberg 2006; Vogt 2007)
Allocation concealment (selection bias)	Low risk	Quote: "Immediately before surgery, the graft material was selected by a pre-processed sealed envelope. Randomisation was stratified for each centre."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses, clear life table data
Selective reporting (reporting bias)	Low risk	All stated outcomes reported
Other bias	Unclear risk	Anticoagulation as per individual centre protocol and therefore inconsistent

Klinkert 2003

Methods	Site: Femoral to AK popliteal Study design: RCT Method of randomisation: concealed randomisation using computer generated randomisation envelopes Blinding: unblinded, intention to treat Exclusions post randomisation: none Losses to follow up: 11 (7%)
Participants	Country: the Netherlands Setting: hospital No. of participants: 136 (151 limbs; 75 Saphenous vein, 76 PTFE) Age (median): 69 yrs Gender: 88 males, 48 females Inclusion criteria: severe claudication, rest pain, tissue loss Exclusion criteria: patients with earlier bypass or previously removed long saphenous vein
Interventions	6 mm PTFE and reversed vein graft Oral warfarin from one day pre-op continued for 6 months. 38 mg aspirin afterwards
Outcomes	Primary and secondary patency 5-year follow up

Klinkert 2003 (*Continued*)

Notes	No compliance checks	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Unclear. No specific description
Allocation concealment (selection bias)	Low risk	Quote: "randomization took place with closed envelope allocation."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	13 patients lost to long term follow up, clearly described
Selective reporting (reporting bias)	Low risk	All stated outcomes reported
Other bias	Low risk	Oral warfarin from one day pre-op continued for 6 months. 38mg aspirin afterwards

Lumsden 2015

Methods	Site: Femoral to AK or BK popliteal Study design: multicentre RCT Method of randomisation: not stated Blinding: unblinded, as treated analysis Exclusions post randomisation: 3 (1.4%) Losses to follow up: 4 (1.9%) Protocol violations: 1 (treatment with a non test graft)
Participants	Country: 18 centres in the USA and 7 in Europe Setting: hospital No. of participants: 209 (105 FUSION BIOLINE, 101 standard ePTFE, 2 no graft implanted, 1 non test graft implanted so latter 3 excluded) Age (median): 62 yrs in standard ePTFE group, 67 in FUSION BIOLINE group Sex: 145 males, 58 females; 2 excluded Inclusion criteria: patients requiring an AK or BK femoro-popliteal bypass with the proximal anastomosis at the level of the distal external iliac, common femoral, profunda femoral, or proximal superficial femoral artery. The study protocol specified that a prosthetic femoro-popliteal bypass must be medically necessary, but did not, per se, exclude

	those without an adequate autogenous conduit. Patients with Rutherford category 1 to 5 ischaemia were eligible, with symptoms of claudication, rest pain, or with superficial ulceration in the target lower extremity Exclusion criteria: acute arterial occlusion requiring urgent intervention; prior open surgical bypass in the target extremity; angioplasty or stenting at the site of a planned anastomosis within the previous 30 days; serum creatinine > 2.5 mg/dL; recent (< 6 weeks) MI or stroke; coagulation or bleeding disorders; receiving warfarin therapy where oral anticoagulation could not be withheld
Interventions	FUSION BIOLINE heparin coated vascular graft or standard ePTFE graft (diameter at discretion of operating surgeon)
Outcomes	Primary endpoints: efficacy: primary graft patency at 6 months as assessed by duplex ultrasound imaging and ABI. Safety: the composite of MALE and POD. MALE included major amputation, major graft reintervention with placement of a new graft or an interposition graft, open or percutaneous graft thrombectomy, pharmacologic thrombolysis, or graft excision. POD was defined as those that occurred within 30 days of the index procedure or any remedial procedure performed at the same anatomic site. Secondary endpoints: efficacy: primary assisted patency, secondary patency, and bleeding at the suture hole as judged subjectively by the operating surgeon and objectively by recording the time between restoration of flow into the graft and the absence of detectable bleeding from the suture holes
Notes	No consistent anticoagulation protocol

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No description of randomisation sequence generation technique
Allocation concealment (selection bias)	Unclear risk	Timing and method of randomisation allocation not stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only 4 patients had missing data at 6-month follow-up
Selective reporting (reporting bias)	Low risk	All stated outcomes reported

Lumsden 2015 (*Continued*)

Other bias	Unclear risk	No consistent anticoagulation protocol

Post 2001

Methods	Site: Femoral to AK and BK popliteal Study design: RCT Method of randomisation: concealed randomisation using computer generated randomisation envelopes Blinding: unblinded, intention to treat Exclusions post randomisation: 3 (1%) Losses to follow up: 6 (2%)
Participants	Country: Germany Setting: hospital No. of participants: 203 (194 limbs analysed. AK: 65 PTFE, 76 Dacron, BK: 26 PTFE, 27 Dacron) Age (median): 66 yrs Sex: 155 males, 48 females Inclusion criteria: severe claudication, rest pain, tissue loss Exclusion criteria: infection, emergency surgery for acute ischaemia, distal anastomosis below anterior tibial origin, concomitant disease not expected to live past 3 years, contraindication to anticoagulants
Interventions	PTFE and Dacron (diameter at discretion of operating surgeon) Post-op warfarin, heparin or antiplatelet agents
Outcomes	Primary patency 3-year follow up
Notes	No consistent anticoagulation protocol. No compliance checks

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "The order of Secondary endpoints assignment had been generated by random digits from a statistical software package (SAS)."
Allocation concealment (selection bias)	Low risk	Quote: "Patients were randomised to either treatment arm intraoperatively by sealed envelopes."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial

Post 2001 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses, clear life table data
Selective reporting (reporting bias)	Low risk	All stated outcomes reported
Other bias	Unclear risk	No consistent anticoagulation protocol

SCAMICOS 2010

Methods	Site: BK popliteal and distal (the latter not included in this review) Study design: multicentre RCT Method of randomisation: concealed randomisation using sealed envelopes in blocks of 16 per centre Blinding: unblinded, intention to treat Exclusions post randomisation: 3 (1%) Losses to follow up: 0 (0%) Protocol violations: 3 (1 - suitable vein available, 1 - distal reconstruction below popliteal artery, 1 - crossover from non-collar to collar group)
Participants	Country: 29 centres in Sweden and 3 in Denmark Setting: hospital No. of participants: 202 (87 PTFE, 115 PTFE with vein collar) Age (median): 79 yrs in PTFE group, 76 yrs in PTFE with collar group Gender: 77 males, 122 females; 3 excluded Inclusion criteria: rest pain, tissue loss Exclusion criteria: no suitable distal anastomotic target, distal anastomosis AK or below anterior tibial origin for BK popliteal group, or below-ankle for distal group
Interventions	Gore or Impra PTFE graft with or without distal vein cuff, diameter not specified (diameter at discretion of operating surgeon)
Outcomes	Primary patency; secondary patency; amputation; death
Notes	No consistent anticoagulation protocol

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No description of randomisation sequence generation technique

SCAMICOS 2010 (*Continued*)

Allocation concealment (selection bias)	Low risk	Envelope selected at random after confirmation of suitable target vessel
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only 3 patients had missing follow-up data
Selective reporting (reporting bias)	Low risk	All stated outcomes reported
Other bias	Unclear risk	No consistent anticoagulation protocol

Scharn 2008

Methods	Site: AK Study design: RCT Method of randomisation: controlled by the BOA-trial agency using a dedicated computer program Blinding: unblinded, intention to treat Exclusions post randomisation: 8 (6%) Losses to follow up: 13 (9%)
Participants	Country: the Netherlands Setting: hospital No. of participants: 137 (137 limbs with 8 excluded; 59 HBD, 70 HUV) Age (median): 65 yrs Sex: 87 males, 50 females Inclusion criteria: severe claudication, rest pain, tissue loss Exclusion criteria: patients younger than 30 or older than 90 yrs of age; patients with an ABI higher than 0.8 at rest, emergency surgery for trauma, acute thrombosis or embolism of the popliteal artery, the diagnosis or treatment for malignancy within 12 months, hospital in-patient treatment for cardiac failure in the previous 6 months, the absence of the possibility for adequate follow up or contraindications for anticoagulant drug therapy
Interventions	Heparin bonded Dacron and HUV (diameter at discretion of operating surgeon) Aspirin 80 mg daily or coumarin derivates (Sintrom)
Outcomes	Primary patency. 5-year follow-up
Notes	No consistent anticoagulation protocol. No compliance checks

Scharn 2008 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was controlled by the BOA-trial agency using a dedicated computer program."
Allocation concealment (selection bias)	Low risk	Not specifically stated but assumed done as BOA-trial agency involved
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses, clear life table data
Selective reporting (reporting bias)	Low risk	All stated outcomes reported
Other bias	Unclear risk	No consistent anticoagulation protocol

Solakovic 2008

Methods	Site: AK popliteal Study design: single-centre RCT Method of randomisation: concealed randomisation using sealed envelopes following intraoperative assessment of artery and vein Blinding: unblinded, intention to treat Exclusions post randomisation: none Losses to follow up: 9 (7%) Protocol violations: none
Participants	Country: 1 centre in Bosnia Setting: hospital No. of participants: 109 patients, 121 limbs (12 patients had a second bypass in the contralateral limb during the study period). There were 60 reversed LSV bypasses and 61 prosthetic bypasses (PTFE or Dacron, material not further specified) Age (median): 70 yrs in reversed LSV group, 68 in prosthetic group Sex: 70 males, 51 females Inclusion criteria: rest pain, tissue loss, 'disabling claudication' Exclusion criteria: previous revascularisation in treated leg, LSV not available or suitable, CFA or AK popliteal not suitable site for anastomosis

Solakovic 2008 (*Continued*)

Interventions	Reversed LSV or 6 mm prosthetic bypass from CFA to above-knee popliteal artery
Outcomes	Primary patency, secondary patency
Notes	All patients received prophylactic clexane at a dose of 0.5 ml/kg while in hospital and then 150 mg/day aspirin after discharge. Compliance with this protocol was not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No description of randomisation sequence generation technique
Allocation concealment (selection bias)	Low risk	Envelope selected at random after confirmation of suitable target vessel and suitable vein
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only 7% of patients lost to follow-up over 5 years
Selective reporting (reporting bias)	Low risk	Stated outcomes reported
Other bias	Unclear risk	Consistent anticoagulation protocol but no compliance checks reported

Stonebridge 1997

Methods	Site: Femoral to AK or BK popliteal Study design: multicentre RCT Method of randomisation: central randomisation centre assessment of artery and vein Blinding: unblinded, intention to treat Exclusions post randomisation: not specified Losses to follow up: not stated Protocol violations: none declared
Participants	Country: UK Setting: multicentre No. of participants: 246 Inclusion criteria: femoro-popliteal graft to AK (76 cuff, 74 no cuff) or BK (48 cuff, 47

Stonebridge 1997 (*Continued*)

	no cuff) popliteal Exclusion criteria: trauma	
Interventions	6 mm PTFE with and without a vein cuff	
Outcomes	Primary patency, secondary patency, limb salvage	
Notes	No consistent anticoagulation protocol	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No description of randomisation technique
Allocation concealment (selection bias)	Unclear risk	No clear description
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition rates not clearly presented
Selective reporting (reporting bias)	Low risk	All stated outcomes reported
Other bias	Unclear risk	No consistent anticoagulation protocol

Tofigh 2007

Methods	Site: AK Study design: RCT Method of randomisation: unclear Blinding: unblinded, intention to treat Exclusions post randomisation: none Losses to follow up: 6 (6%)
Participants	Country: France Setting: hospital No. of participants: 85 (103 limbs; 51 reversed vein, 52 polyester) Age (median): 69 yrs Sex: 49 males, 36 females Inclusion criteria: severe claudication, rest pain, tissue loss

Tofigh 2007 (*Continued*)

	Exclusion criteria: patients with earlier bypass or un-useable LSV
Interventions	6 mm collagen-impregnated woven polyester prosthesis and reversed vein graft Oral warfarin from one day pre-op continued for 6 months. 38 mg aspirin afterwards
Outcomes	Primary and secondary patency 5-year follow-up
Notes	No medication compliance checks. Unclear randomisation

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No description of randomisation technique
Allocation concealment (selection bias)	Unclear risk	No clear description
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses, clear data
Selective reporting (reporting bias)	Low risk	All stated outcomes reported
Other bias	Low risk	No obvious other source of bias

van Det 2009

Methods	Site: AK Study design: RCT Method of randomisation: sealed envelopes Blinding: unblinded, intention to treat Exclusions post randomisation: none Losses to follow up: 4 (%)
Participants	Country: France Setting: hospital No. of participants: 228 (228 limbs; 114 Dacron, 114 PTFE) Age (median): 66 yrs Sex: 147 males, 81 females

van Det 2009 (*Continued*)

	Inclusion criteria: severe claudication, rest pain, tissue loss Exclusion criteria: patients with earlier bypass contraindication to long term anticoagulant therapy, life expectancy less than 1 year	
Interventions	6 mm PTFE or 6 mm Dacron. Warfarin post-op (all patients)	
Outcomes	Primary, primary assisted and secondary patency 10-year follow-up	
Notes	Good anticoagulation protocol. Clear numbers of patients throughout (flow chart)	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer program used for sequence generation
Allocation concealment (selection bias)	Low risk	Sealed envelopes used
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses, clear life table data
Selective reporting (reporting bias)	Low risk	All stated outcomes reported
Other bias	Low risk	Good anticoagulation protocol. Clear numbers of patients throughout (flow chart)

Vriens 2013

Methods	Site: Femoral to AK popliteal Study design: multicentre RCT Method of randomisation: concealed randomisation using sealed envelopes in blocks of 4 per centre Blinding: unblinded, as treated analysis Exclusions post randomisation: 1 (0.4%) Losses to follow up: 4 (1.5%) Protocol violations: 1 (1 - crossover from allocated group)
Participants	Country: 6 centres in the Netherlands Setting: hospital No. of participants: 266 (136 externally supported polyester, 129 non-externally supported polyester, 1 not treated according to protocol so excluded) Age (median): 65 yrs in externally supported group, 67 in non externally supported group Sex: 199 males, 66 females; 1 excluded Inclusion criteria: all patients requiring AK femoro-popliteal bypass for disabling claudication, rest pain, tissue loss in the absence of a suitable venous conduit Exclusion criteria: no suitable distal anastomotic target, distal anastomosis not above knee, previous ipsilateral femoro-popliteal procedures, contra-indication for the use of acetyl salicylic acid or anticoagulants, patients receiving chemo- or radiotherapy, malignancy diagnosed or treated within 12 months, known allergy to iodine or contrast medium, and impaired renal function
Interventions	Fluoropassiv 6 mm knitted polyester, either externally supported thin-wall fluoropolymer coated or 6 mm externally unsupported thin wall
Outcomes	Primary endpoints: primary patency at 1 and 2 years post-op. Secondary endpoints: mortality, primary assisted and secondary patency
Notes	Clear anticoagulation protocol. Clear numbers of patients throughout (flow chart)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No description of randomisation sequence generation technique
Allocation concealment (selection bias)	Low risk	Envelope selected at random after confirmation of suitable target vessel
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operative blinding impossible in this type of trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors and patients not obviously blinded

Vriens 2013 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Only 4 patients (1.5%) were lost to follow-up
Selective reporting (reporting bias)	Low risk	All stated outcomes reported
Other bias	Low risk	Good anticoagulation protocol. Clear numbers of patients throughout (flow chart)

ABI: ankle brachial index
AK: above knee
ASV: autologous saphenous vein
BK: below knee
CABG: coronary bypass graft
CFA: common femoral artery
DM: diabetes mellitus
HBD: heparin bonded Dacron
HUV: human umbilical vein
IC: intermittent claudication
LSV: long saphenous vein
MALE: major adverse limb events
MI: myocardial infarction
POD: peri-procedural death
post-op: post-operative/operatively
pt: patient
PTFE: polytetrafluoroethylene
PUR: polyurethane
RCT: randomised controlled trial
SFA: superficial femoral artery
yrs: years

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Bennion 1985	Results presented include non-randomised patients. Randomisation technique unclear. Distal grafts included, not intention to treat
Chikiar 2003	Retrospective, non-randomised study (not an RCT or CCT): retrospective study where data were collected from patient records
Erasmi 1996	The trial was performed in patients having femoro-popliteal bypass both above and below the knee. Outcomes for the above- and below-knee subgroups were not reported so it was not possible to include the trial

(*Continued*)

Hamann 1998	Randomisation technique unclear, above-knee, below-knee and distal bypasses inseparable (English title states above-knee but methods talk about below-knee bypass)
Hobson 1980	Case series, not randomised trial data
Johnson 2000	Inadequate randomisation process. Quote: "the choice between a PTFE and HUV bypass graft was randomized in the operating room, initially to favour saphenous vein." The data were presented as vein versus HUV versus PTFE and was inseparable for analysis
Kreienberg 2002	Bypass to any below-knee artery, not just popliteal. Randomisation technique unclear
Kumar 1995	Unclear randomisation process. Results never fully published in paper form, only as two abstracts. Data presented as vein versus PTFE versus Dacron and were inseparable for analysis
Lindholt 2011	The trial was performed in patients having femoro-popliteal bypass both above and below the knee. Outcomes for the above- and below-knee subgroups were not reported so it was not possible to include the trial
Linni 2015	The trial was performed in patients having femoro-popliteal and more distal bypass. Outcomes for the subgroups of patients with distal anastomosis the above-knee popliteal or below-knee popliteal artery were not reported so the study could not be included
Lundgren 2013	The trial was performed in both patients having femoro-popliteal bypass below the knee and patients having femoro-distal bypass. Outcomes for the subgroup having femoro-popliteal bypass alone were not reported
McCollum 1991	Unable to separate above- and below-knee data
Midy 2016	Trial failed to recruit 30% of planned patients, and lost 26% of these to follow up. Results only presented at 5 years follow-up using an unusual system to impute missing data
Moody 1992	Unable to separate above- and below-knee data
Motta 1989	Above-knee, below-knee and distal bypasses inseparable; unclear randomisation
NCT00617279	Trial terminated by sponsor due to slow recruitment. No results available
NCT00845585	Trial withdrawn prior to enrolment of any patients
Robinson 1999	Unable to separate above- and below-knee data. A proportion of both above- and below-knee anastomoses included endarterectomies and or vein cuffs which the study authors concede produced a significant difference in patency without giving detailed subgroup analysis. Unclear randomisation
Robinson 2003	Unable to separate above- and below-knee data. Below-knee anastomotic site described as 'distal' in some cases without detailed anatomical description. A proportion of both above- and below-knee anastomoses included endarterectomies and or vein cuffs which the study authors concede produced a significant difference in patency without giving detailed subgroup analysis. Unclear randomisation

(*Continued*)

Schulman 1987	Patients received both above- and below-knee bypass grafts but results presented together. Poor randomisation (month of birth)
Tilanus 1985	Unable to separate above- and below-knee data. Unclear randomisation technique
Veith 1986	Unable to separate above- and below-knee data. Inadequate randomisation (hospital number, card pulling, random number generator)
Watelet 1997	The trial was performed in patients having femoro-popliteal bypass both above and below the knee. Outcomes for the above- and below-knee subgroups were not reported so it was not possible to include the trial
Zilla 1994	Unable to separate above- and below-knee data, not intention to treat. Inadequate randomisation (random number generator, concealment not stated)

CCT: clinically controlled trial
HUV: human umbilical vein
PTFE: polytetrafluoroethylene
RCT: randomised controlled trial

Characteristics of ongoing studies *[ordered by study ID]*

NCT00147979

Trial name or title	Multicentric, Prospective, Randomized, Comparing Trial Between Bypass of the Femoropoplitea by PTFE and Heparin Bounded PTFE
Methods	Randomised controlled trial
Participants	18 years and older, peripheral vascular disease requiring above- or below-knee femoro-popliteal bypass
Interventions	PTFE versus PTFE with bonded heparin
Outcomes	Primary outcome measures: primary patency after 2 years Secondary outcome measures: secondary patency; limb salvage; mortality; re-intervention
Starting date	April 2004
Contact information	Frank Vermassen, MD, PhD, University Hospital, Ghent
Notes	A preliminary survival curve was presented at the Charing Cross Symposium in 2009. No useable data could be gleaned from this and no official abstract was published. The lead author was contacted for results but did not reply. The study is reported as completed on ClinicalTrials.gov but has not been published ClinicalTrials.gov identifier: NCT00147979

NCT00205790

Trial name or title	GORE-TEX PROPATEN Vascular Graft Study
Methods	Single-blind randomised controlled trial
Participants	21 years and older, peripheral vascular disease requiring above-knee femoro-popliteal bypass
Interventions	GORE-TEX PROPATEN vascular grafts versus thin walled GORE-TEX Stretch vascular grafts
Outcomes	Primary outcome measures: primary patency at 12 months; major device complication rates at 12 months Secondary outcome measures: technical failures; secondary patency
Starting date	February 2003. Trial completed recruitment in 2007 but still has not published results
Contact information	Enrico Ascher, MD Maimonides Hospital, Brooklyn NY
Notes	Sponsored by WL Gore & Associates ClinicalTrials.gov identifier: NCT00205790

PTFE: polytetrafluoroethylene

DATA AND ANALYSES

Comparison 1. Above-knee autologous vein versus all other graft materials

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Primary patency at 3 months	4	466	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.20 [0.58, 2.48]
1.1 Autologous vein v PTFE	2	249	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.27 [0.41, 3.97]
1.2 Autologous vein v other graft types	2	217	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.16 [0.45, 2.96]
2 Primary patency at 6 months	4	452	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.01 [0.56, 1.83]
2.1 Autologous vein v PTFE	2	245	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.12 [0.45, 2.78]
2.2 Autologous vein v other graft types	2	207	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.94 [0.43, 2.05]
3 Primary patency at 12 months	4	440	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.73 [0.44, 1.22]
3.1 Autologous vein v PTFE	2	238	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.81 [0.37, 1.76]
3.2 Autologous vein v other graft types	2	202	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.67 [0.34, 1.33]
4 Primary patency at 24 months	4	422	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.59 [0.37, 0.94]
4.1 Autologous vein vs PTFE	2	232	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.67 [0.34, 1.33]
4.2 Autologous vein vs other graft types	2	190	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.52 [0.28, 0.99]
5 Primary patency at 60 months	3	269	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.47 [0.28, 0.80]
5.1 Autologous vein v PTFE	2	191	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.48 [0.25, 0.95]
5.2 Autologous vein vs other graft type	1	78	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.44 [0.18, 1.07]
6 Secondary patency at 3 months	3	364	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.05 [0.47, 2.32]
6.1 Autologous vein v PTFE	1	147	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.08 [0.30, 3.87]
6.2 Autologous vein v other graft types	2	217	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.03 [0.37, 2.83]
7 Secondary patency at 6 months	3	351	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.95 [0.49, 1.82]
7.1 Autologous vein v PTFE	1	143	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.98 [0.36, 2.69]
7.2 Autologous vein v other graft types	2	208	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.92 [0.39, 2.19]
8 Secondary patency at 12 months	3	338	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.81 [0.45, 1.45]
8.1 Autologous vein v PTFE	1	136	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.99 [0.39, 2.51]
8.2 Autologous vein v other graft types	2	202	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.71 [0.34, 1.50]
9 Secondary patency at 24 months	3	320	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.70 [0.41, 1.19]
9.1 Autologous vein v PTFE	1	130	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.83 [0.37, 1.87]
9.2 Autologous vein v other graft type	2	190	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.62 [0.31, 1.24]
10 Secondary patency at 60 months	2	176	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.41 [0.22, 0.74]
10.1 Autologous vein v PTFE	1	98	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.44 [0.20, 0.99]
10.2 Autologous vein v other graft types	1	78	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.37 [0.15, 0.90]

Comparison 2. Above-knee PTFE versus all other graft materials

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Primary patency at 3 months	2	312	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.36 [0.81, 6.87]
1.1 PTFE v HUV	1	93	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.55 [0.26, 9.33]
1.2 PTFE v Dacron	1	219	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.97 [0.78, 11.25]
2 Primary patency at 6 months	5	824	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.11 [1.37, 3.25]
2.1 PTFE v HUV	1	90	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.56 [0.69, 9.47]
2.2 PTFE v Dacron	2	421	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.57 [0.79, 3.11]
2.3 PTFE v PTFE with vein cuff	1	139	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.80 [0.57, 5.60]
2.4 PTFE v FUSION BIOLINE	1	174	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.99 [1.43, 6.26]
3 Primary patency at 12 months	6	1088	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.23 [0.93, 1.64]
3.1 PTFE v HUV	1	83	Peto Odds Ratio (Peto, Fixed, 95% CI)	3.17 [1.04, 9.64]
3.2 PTFE v Dacron	4	875	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.24 [0.91, 1.70]
3.3 PTFE v PTFE with vein cuff	1	130	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.64 [0.26, 1.56]
4 Primary patency at 24 months	6	945	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.31 [1.00, 1.71]
4.1 PTFE V HUV	1	82	Peto Odds Ratio (Peto, Fixed, 95% CI)	4.80 [1.76, 13.06]
4.2 PTFE V Dacron	4	764	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.23 [0.92, 1.65]
4.3 PTFE v PTFE with vein cuff	1	99	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.86 [0.37, 2.02]
5 Primary patency at 60 months	3	316	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.06 [1.28, 3.31]
5.1 PTFE v HUV	1	69	Peto Odds Ratio (Peto, Fixed, 95% CI)	3.75 [1.46, 9.62]
5.2 PTFE v Dacron	2	247	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.67 [0.96, 2.90]
6 Secondary patency at 3 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
6.1 PTFE v HUV	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Secondary patency at 6 months	2	318	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.32 [0.48, 3.62]
7.1 PTFE v HUV	1	93	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.76 [0.42, 7.44]
7.2 PTFE v Dacron	1	225	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.01 [0.25, 4.13]
8 Secondary patency at 12 months	4	806	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.18 [0.80, 1.74]
8.1 PTFE v HUV	1	93	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.60 [0.43, 5.89]
8.2 PTFE v Dacron	2	581	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.19 [0.76, 1.86]
8.3 PTFE v PTFE with vein cuff	1	132	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.99 [0.39, 2.52]
9 Secondary patency at 24 months	4	700	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.66 [1.18, 2.33]
9.1 PTFE V HUV	1	93	Peto Odds Ratio (Peto, Fixed, 95% CI)	4.01 [1.44, 11.17]
9.2 PTFE v Dacron	2	528	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.54 [1.04, 2.28]
9.3 PTFE v PTFE with vein cuff	1	79	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.22 [0.48, 3.06]
10 Secondary patency at 60 months	2	260	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.86 [1.73, 4.72]
10.1 PTFE v HUV	1	93	Peto Odds Ratio (Peto, Fixed, 95% CI)	3.87 [1.65, 9.05]
10.2 PTFE v Dacron	1	167	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.43 [1.31, 4.53]
11 Limb salvage at 1 month	2	560	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.68 [0.12, 3.98]
11.1 PTFE v Dacron	1	410	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.14 [0.01, 2.20]
11.2 PTFE v PTFE with vein cuff	1	150	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.02 [0.21, 19.72]

12 Limb salvage at 24 months	2	389	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.73 [0.33, 1.62]
12.1 PTFE v Dacron	1	322	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.82 [0.27, 2.48]
12.2 PTFE v PTFE with vein cuff	1	67	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.64 [0.20, 2.04]

Comparison 3. Above-knee heparin bonded Dacron versus all other graft materials

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Primary patency at 12 months	2	294	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.58 [0.34, 0.98]
1.1 HBD v HUV	1	123	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.47 [0.20, 1.12]
1.2 HBD v PTFE	1	171	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.65 [0.34, 1.25]
2 Primary patency at 24 months	2	282	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.62 [0.38, 1.02]
2.1 HBD v HUV	1	117	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.59 [0.26, 1.33]
2.2 HBD v PTFE	1	165	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.64 [0.34, 1.19]
3 Primary patency at 60 months	2	232	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.55 [0.33, 0.93]
3.1 HBD v HUV	1	86	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.07 [0.45, 2.51]
3.2 HBD v PTFE	1	146	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.38 [0.20, 0.72]

Comparison 4. Above-knee externally supported graft versus unsupported graft materials

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Primary patency at 6 months	2	299	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.28 [0.71, 2.31]
1.1 Externally supported dacron versus unsupported dacron	1	253	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.29 [0.69, 2.39]
1.2 Externally supported PTFE versus unsupported PTFE	1	46	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.21 [0.16, 9.25]
2 Primary patency at 12 months	2	286	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.78 [1.06, 2.98]
2.1 Externally supported dacron versus unsupported dacron	1	246	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.71 [0.99, 2.93]
2.2 Externally supported PTFE versus unsupported PTFE	1	40	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.73 [0.49, 15.28]
3 Primary patency at 24 months	2	270	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.08 [1.29, 3.35]
3.1 Externally supported dacron versus unsupported dacron	1	240	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.09 [1.26, 3.46]
3.2 Externally supported PTFE versus unsupported PTFE	1	30	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.01 [0.46, 8.76]
4 Secondary patency at 6 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected

5 Secondary patency at 12 months	1	Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
6 Secondary patency at 24 months	1	Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected

Comparison 5. Above-knee polyurethane (PUR) versus all other graft materials

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Primary patency at 3 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
2 Primary patency at 6 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
3 Primary patency at 12 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
4 Secondary patency at 3 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
5 Secondary patency at 6 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
6 Secondary patency at 12 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected

Comparison 6. Below-knee PTFE versus all other graft materials

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Primary patency at 6 months	4	319	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.12 [0.67, 1.87]
1.1 PTFE v ringed PTFE	1	44	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.47 [0.32, 6.71]
1.2 PTFE v PTFE with vein cuff	2	247	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.00 [0.56, 1.78]
1.3 PTFE v FUSION BIOLINE	1	28	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.96 [0.39, 9.83]
2 Primary patency at 12 months	4	305	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.96 [0.60, 1.55]
2.1 PTFE v Dacron	1	45	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.47 [0.12, 1.79]
2.2 PTFE v PTFE with vein cuff	2	224	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.02 [0.59, 1.76]
2.3 PTFE v ringed PTFE	1	36	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.48 [0.35, 6.24]
3 Primary patency at 24 months	4	250	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.94 [0.56, 1.57]
3.1 PTFE v Dacron	1	40	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.41 [0.12, 1.42]
3.2 PTFE v PTFE with vein cuff	2	182	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.08 [0.58, 2.01]
3.3 PTFE v ringed PTFE	1	28	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.32 [0.31, 5.67]
4 Primary patency at 36 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
4.1 PTFE v PTFE with vein cuff	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Secondary patency at 3 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
5.1 PTFE v HUV	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Secondary patency at 6 months	2	242	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.21 [0.69, 2.13]
6.1 PTFE v HUV	1	71	Peto Odds Ratio (Peto, Fixed, 95% CI)	3.01 [1.12, 8.07]
6.2 PTFE v PTFE with vein cuff	1	171	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.79 [0.40, 1.56]
7 Secondary patency at 12 months	3	325	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.48 [0.94, 2.34]
7.1 PTFE v HUV	1	101	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.46 [1.10, 5.49]

7.2 PTFE v PTFE with vein cuff	2	224	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.16 [0.66, 2.03]
8 Secondary patency at 24 months	3	269	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.72 [1.05, 2.80]
8.1 PTFE v HUV	1	88	Peto Odds Ratio (Peto, Fixed, 95% CI)	3.40 [1.45, 7.97]
8.2 PTFE v PTFE with vein cuff	2	181	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.22 [0.67, 2.23]
9 Secondary patency at 36 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
9.1 PTFE v PTFE with vein cuff	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Limb salvage at 12 months	2	225	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.35 [0.72, 2.55]
10.1 PTFE v PTFE with vein cuff	2	225	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.35 [0.72, 2.55]
11 Limb salvage at 24 months	2	196	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.34 [0.72, 2.49]
11.1 PTFE v PTFE with vein cuff	2	196	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.34 [0.72, 2.49]

Comparison 7. Below-knee heparin bonded Dacron versus all other graft materials

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Primary patency at 3 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
1.1 HBD v PTFE	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Primary patency at 6 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
2.1 HBD v PTFE	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Primary patency at 12 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
3.1 HBD v PTFE	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Primary patency at 24 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
4.1 HBD v PTFE	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Primary patency at 60 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
5.1 HBD v PTFE	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	0.0 [0.0, 0.0]

WHAT'S NEW

Last assessed as up-to-date: 13 March 2017.

Date	Event	Description
13 March 2017	New citation required but conclusions have not changed	Search updated. Seven new studies included, six new studies excluded and two new ongoing studies identified. Text updated to reflect recent Cochrane standards. All included studies assessed for risk of bias using Cochrane's 'Risk of bias' tool. 'Summary of findings' table added. No change to conclusions

(*Continued*)

13 March 2017	New search has been performed	Search updated and seven new studies included, six new studies excluded and two new ongoing studies identified

HISTORY

Review first published: Issue 2, 1999

Date	Event	Description
10 March 2010	New citation required and conclusions have changed	Review updated by new authors. Eight additional trials included and four trials which were included in the previous version of the review excluded
1 September 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

GA: identified relevant trials, assessed quality for all included trials, extracted data and updated the text of review.

CT: identified relevant trials, assessed quality, extracted data, wrote text of previous version of review, and reviewed updated text.

DECLARATIONS OF INTEREST

GA: has declared that he previously held a National Institute for Health Research Academic clinical fellowship (2011-2014) and that he received funds for a grant from Heath and Care Research Wales regarding research for patient and public benefit (grant number 1198); there are no known conflicts of interest with this review.

CT: has declared that he received money from Cook Medical for travel/accommodation/meeting expenses unrelated to this review and that he received funds for a grant from Heath and Care Research Wales regarding research for patient and public benefit (grant number 1198); there are no known conflicts of interest with this review.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- Chief Scientist Office, Scottish Government Health Directorates, The Scottish Government, UK.

The editorial base of Cochrane Vascular is supported by the Chief Scientist Office.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

For this update, the risk of bias in all included studies was assessed using Cochrane's 'Risk of bias' tool and a 'Summary of findings' table has been added.

We reworded the objective so to adhere better to the Cochane guidelines.

We amended the 'types of studies' to include all possible graft types.

We provided definitions of the outcomes primary and secondary patency.

We analysed and presented data into groups according to whether the distal anastomosis was above or below the knee.

INDEX TERMS

Medical Subject Headings (MeSH)

Arterial Occlusive Diseases [*surgery]; Blood Vessel Prosthesis Implantation; Femoral Artery [*surgery]; Intermittent Claudication [surgery]; Leg [*blood supply]; Polyethylene Terephthalates; Polytetrafluoroethylene; Popliteal Artery [*surgery]; Randomized Controlled Trials as Topic; Saphenous Vein [*transplantation]; Transplantation, Autologous; Umbilical Veins [*transplantation]; Vascular Surgical Procedures

MeSH check words

Humans