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[Intervention Review]

Type of incision for below knee amputation

Paul V Tisi[1], Mary M Than[2]

[1]Department of Vascular Surgery, Bedford Hospital, Bedford, UK. [2]General Surgery, Bedford Hospital NHS Trust, Bedford, UK

Contact: Paul V Tisi, Department of Vascular Surgery, Bedford Hospital, Kempston Road, Bedford, Bedfordshire, MK42 9DJ, UK. pvtisi@rcsed.ac.uk.

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ABSTRACT

Background

Below knee amputation (BKA) may be necessary in patients with advanced critical limb ischaemia or diabetic foot sepsis in whom no other treatment option is available. There is no consensus as to which surgical technique achieves the maximum rehabilitation potential. This is the third update of the review first published in 2004.

Objectives

To assess the effects of different types of incision on the outcome of BKA in people with lower limb ischaemia or diabetic foot sepsis, or both. The main focus of the review was to assess the relative merits of skew flap amputation versus the long posterior flap technique.

Search methods

For this update the Cochrane Peripheral Vascular Diseases Group Trials Search Co-ordinator (TSC) searched the Specialised Register (last searched 28 March 2013) and CENTRAL (2013, Issue 2).

Selection criteria

Randomised controlled trials comparing two or more types of skin incision for BKA were identified. People with lower limb ischaemia (acute or chronic) or diabetic foot sepsis, or both, were considered for inclusion. People undergoing below knee amputation for other conditions were excluded.

Data collection and analysis

One review author identified potential trials. Two review authors independently assessed trial quality and extracted the data. Additional information, if required, was sought from study authors.

Main results

Three studies with a combined total of 309 participants were included in the review. One study compared two-stage versus one-stage BKA; one study compared skew flaps BKA versus long posterior flap BKA; and one study compared sagittal flaps BKA versus long posterior flap BKA. Overall the quality of the evidence from these studies was moderate. BKA using skew flaps or sagittal flaps conferred no advantage over the well established long posterior flap technique (primary stump healing was 60% for both skew flaps and long posterior flap (risk ratio (RR) 1.00, 95% confidence interval (CI) 0.71 to 1.42) and primary stump healing was 58% for sagittal flaps and 55% for long posterior flap (Peto odds ratio (OR) 1.04, 95% CI 0.45 to 2.43). For participants with wet gangrene, a two-stage procedure with a guillotine amputation at the ankle followed by a definitive long posterior flap amputation led to better primary stump healing than a one-stage procedure (Peto OR 0.08, 95% CI 0.01 to 0.89). Post-operative infection rate or wound necrosis, reamputation, and mobility with a prosthetic limb were similar in the different comparisons.

Authors' conclusions

There is no evidence to show a benefit of one type of incision over another. However, in the presence of wet gangrene a two-stage procedure leads to better primary stump healing compared to a one-stage procedure. The choice of amputation technique can, therefore, be a matter of surgeon preference taking into account factors such as previous experience of a particular technique, the extent of non-viable tissue, and the location of pre-existing surgical scars.

PLAIN LANGUAGE SUMMARY

Type of incision used for below knee amputation to create a skin flap that maximises healing

Below knee amputation may be necessary for people with critical limb ischaemia caused by advanced vascular disease or diabetic foot infection (sepsis) where no other treatment option is possible. Keeping the knee joint gives a better chance of walking using an artificial leg or prosthesis and social independence after the amputation. The surgical technique is important. Bone and deep tissues are generally treated in a similar way but the type of skin incision varies between techniques. A skin flap is designed to go over the stump, where the main consideration is to maximise blood supply and healing. A long posterior skin flap and unequal (skewed) anterior and posterior muscle and skin (myocutaneous) flaps are most often used, although other techniques have been described.

Three randomised controlled studies were identified. Overall the quality of the evidence from these studies was moderate. They were reported on between 1977 and 1991 and involved a total of 309 participants. Each reported on different comparisons. Below knee amputation using skew flaps or sagittal flaps provided no advantage over the long posterior flap technique on primary stump healing, which approached 60% for all groups. In the third study, involving 30 participants with wet gangrene, a two-stage procedure with a guillotine amputation at the ankle followed by long posterior flap amputation led to better primary stump healing than a one-stage procedure with delayed skin closure. Post-operative infection rate or wound necrosis, reamputation and mobility with a prosthetic limb were similar in the different comparisons.

Nearly all the surgeons in the study that looked at skew flap amputation versus the long posterior flap technique were new to the skew flap operation and so were on a learning curve. Factors which might have influenced the findings include previous experience of a technique, the extent of non-viable tissue, and location of pre-existing surgical scars.

BACKGROUND

Description of the condition

Below knee amputation (BKA) has been increasingly used as a therapeutic option since the 1950s. This is in preference to above knee amputation, which has a more limited chance of achieving successful rehabilitation (Silbert 1950). BKA is necessary for patients with advanced critical limb ischaemia who cannot be treated with reconstructive vascular surgery (to restore blood flow to the leg) or in whom vascular surgery has failed. It may also be necessary for patients with aggressive diabetic foot infections or gangrene, or both; for those with extensive venous ulceration; or following major trauma. Guidelines from the Vascular Surgical Society of Great Britain and Ireland recommend that all patients undergo a vascular surgical assessment prior to amputation (VSSGBI 1996). The current quality improvement framework for major amputation surgery (VSGBI 2010) aims to reduce the mortality rate post major amputation surgery to less than 5% by 2015 and states that "amputation for vascular disease and diabetes should only be undertaken after formal investigation to the arterial system by angiography (diagnostic conventional angiography (DSA), computed tomographic angiography (CTA) or magnetic resonance angiography (MRA)) or specialist ultrasound imaging, except when the leg is clearly beyond salvage".

Description of the intervention

The results of BKA are influenced by the surgical technique used. Most of the described operative techniques treat the bone and deep tissues in a similar way, although there may be some variation in the level of bone section and formation of the muscle flaps used to cover the bone ends. However, the type of skin incision varies between techniques. The main consideration in designing a skin flap is to maximise its blood supply in order that healing may occur. The 'gold standard' BKA is the long posterior flap as popularised by Burgess (Burgess 1968a; Burgess 1968b), see Figure 1. The rationale behind this technique is that the poorly vascularised anterior skin flap is compensated by the relatively well vascularised posterior skin flap (Chavatzas 1975). Robinson showed in an uncontrolled study that 69% of patients treated by a long posterior flap walked with a prosthetic limb (Robinson 1976). Numerous alternative techniques have been described. These include unequal anterior and posterior myocutaneous (muscle and skin) flaps (Haimovici 1996; Kaufman 1995); equal anterior and posterior myocutaneous flaps (McCullough 1981); equal medial (inner side of leg) and lateral (outer side of leg) flaps (that is sagittal) (Alter 1978; Persson 1974); a 'laterally based' skin flap (Catre 1997); and creation of a broad posterior flap with burying of the ends of the flap (after removal of the outer skin layer) to provide extra padding for the stump (Galvao 1975). The 'skew' flap technique reported by Robinson (see Figure 2) is widely considered to be superior to the long posterior flap in terms of wound healing and time to full mobility (Harrison 1987; Robinson 1982; Robinson 1991). The aim of this review was to assess the evidence supporting the use of these techniques.

Figure 1. Long posterior (Burgess) flap.

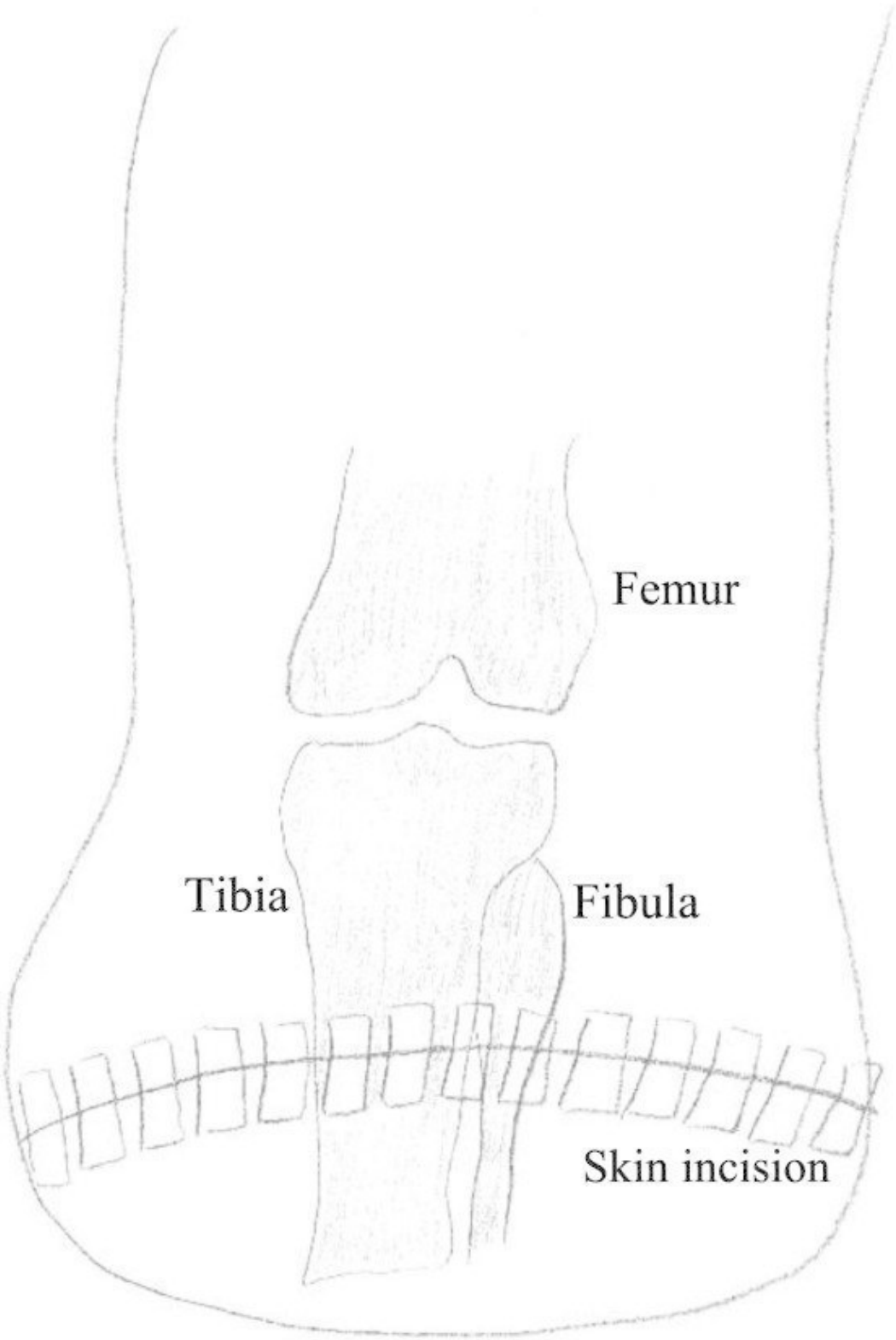
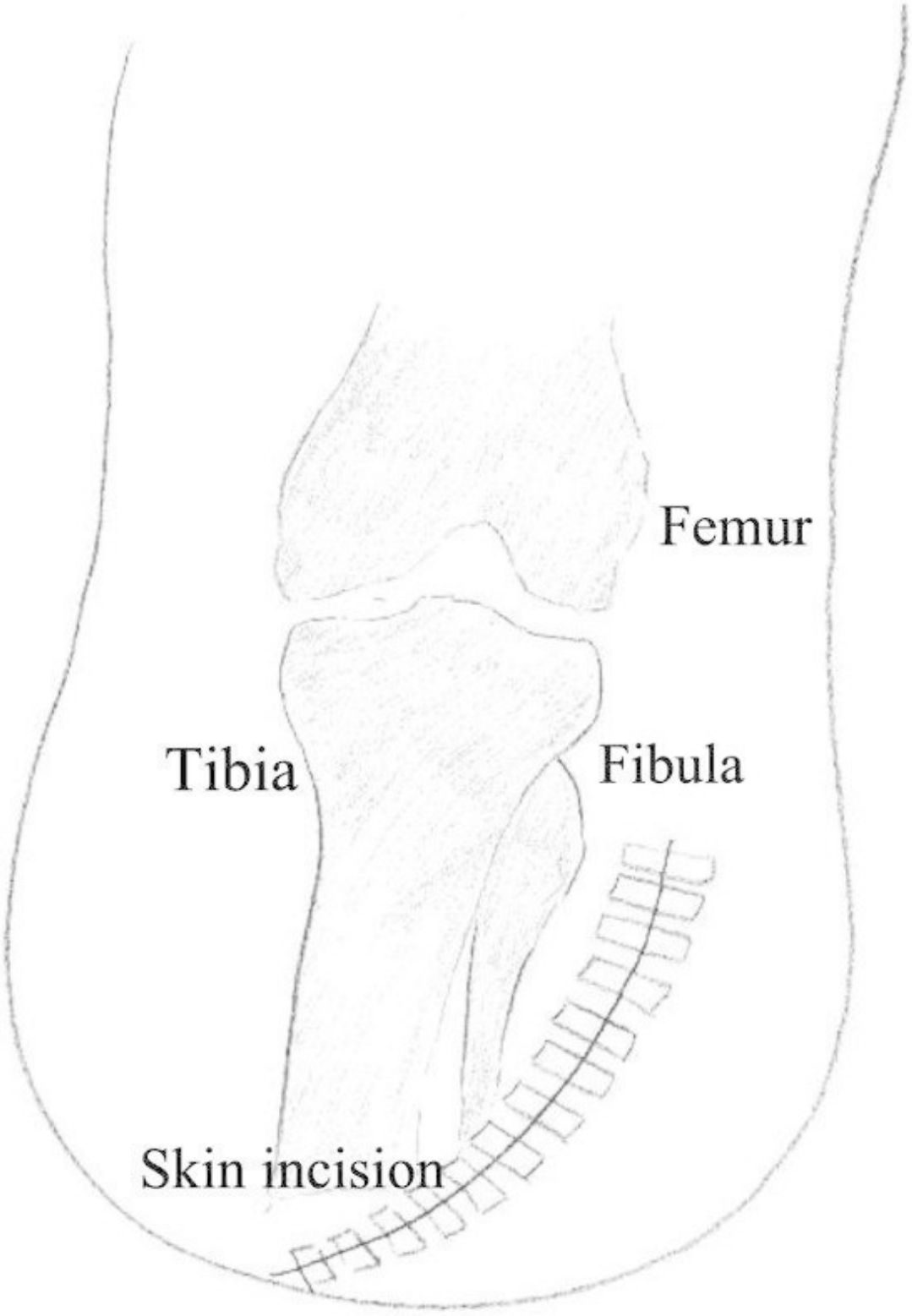


Figure 2. Skew flap.



How the intervention might work

Careful judgement is required in patient selection and decision making about the amputation level in order to maximise the rehabilitation potential. There is no doubt that preservation of the knee joint leads to improved function and social independence, with one report suggesting that 87% of previously mobile patients with peripheral arterial disease could maintain independent ambulation after BKA (Pinzur 1993).

Why it is important to do this review

This is the third update of a Cochrane review first published in 2004. The main findings from previous versions of the review were that the choice of amputation technique has no effect on outcome and can, therefore, be a simple matter of surgeon preference. Factors which might influence this finding include previous experience of a particular technique, the extent of non-viable tissue, and the location of pre-existing surgical scars. An update of the review was conducted to identify any new evidence since the publication of the last version of this review.

OBJECTIVES

To assess the effects of different types of incision on the outcome of below knee amputation (BKA) in people with lower limb ischaemia or diabetic foot sepsis, or both.

The main focus of the review was to assess the relative merits of skew flap amputation versus the long posterior flap technique.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised trials comparing two or more different skin incisions or surgical techniques for BKA were considered for inclusion in this review.

Types of participants

People with lower limb ischaemia (acute or chronic) or diabetic foot sepsis, or both, were considered for inclusion without age restriction. This included patients who had venous disease as well as peripheral arterial disease (PAD). People undergoing BKA for lower limb trauma and those requiring amputation for miscellaneous conditions such as bone or soft tissue tumours were excluded.

Types of interventions

Long posterior flap (Burgess) BKA versus skew flap amputations, or versus other less commonly used surgical techniques.

Types of outcome measures

Primary outcomes

(1) Primary stump healing, defined as a painless, healed suture line enabling fitting of a prosthetic limb (if appropriate) and regaining of mobility

(2) Post-operative infection rate, including the specific incidence of methicillin-resistant *Staphylococcus aureus* (MRSA) infection

(3) Rate of reamputation at (a) same level; (b) higher level

(4) Number of participants mobilising with a prosthetic limb

Secondary outcomes

(1) Number of participants fitted with a prosthetic limb

(2) Thirty-day mortality rate

(3) Length of hospital stay

(4) Symptoms relating to the stump, such as pain and swelling

(5) Phantom limb pain

(6) Quality of life measures, using formal quality of life questionnaires administered either in person or by post

Search methods for identification of studies

Electronic searches

For this update, the Cochrane Peripheral Vascular Diseases (PVD) Group Trials Search Co-ordinator (TSC) searched the Specialised Register (last searched 28 March 2013) and the Cochrane Central Register of Controlled Trials (CENTRAL) (2013, Issue 2) in *The Cochrane Library* (www.thecochranelibrary.com). See Appendix 1 for details of the search strategy used to search CENTRAL. The PVD Specialised Register is maintained by the TSC and is constructed from weekly electronic searches of MEDLINE, EMBASE, 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 PVD Group module in *The Cochrane Library* (www.thecochranelibrary.com).

Data collection and analysis

Selection of studies

One review author collated all randomised trials identified from the search strategy for potential inclusion in the review. Additional information, if required, was sought from the relevant authors to enable the quality of the trials to be assessed.

Potentially eligible trials were assessed independently by two review authors to determine the relevance of each study. Ideally, studies should have had sufficient statistical power to detect a difference between treatment groups. Trials were only accepted if both review authors agreed on the inclusion criteria being met. Disagreements were resolved through discussion.

Data extraction and management

Data from the trials were extracted independently by two review authors. The figures were then cross-checked for agreement. Disagreements were resolved through discussion.

Assessment of risk of bias in included studies

Two review authors independently assessed the risk of bias in each included study according to the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We assessed the following domains of trial quality: random sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting and other bias. We gave trials a quality rating

of 'low risk', 'unclear risk' or 'high risk' of bias for each of these domains according to the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Disagreements were resolved through discussion.

Measures of treatment effect

Results were expressed as Peto odds ratios (OR) with 95% confidence intervals (CI) for dichotomous variables, although for comparisons with a high frequency of events the outcomes were given as risk ratio (RR) with 95% CI. Results for continuous variables were expressed as standardised mean differences (SMD) with 95% CIs. For studies where the standard deviation was not given, further analysis was impossible and the studies were therefore not pooled.

Unit of analysis issues

The unit of analysis was the individual patient.

Dealing with missing data

Missing follow-up data were sought from the original investigators, where possible. If this information was unavailable, the data were re-analysed using a reasonable range of values for the missing data to determine if this affected the overall results.

Assessment of heterogeneity

Finer points of the analysis were determined by the type and quality of the data extracted. Heterogeneity of the combined results from the different studies for each comparison was to be assessed using a Chi^2 test as well as by clinical judgement. However, this did not apply in this review as each comparison related to a single study only.

Assessment of reporting biases

Both the original and re-analysed results were reported, if appropriate. A funnel plot was considered to identify any publication bias, although it was not appropriate to conduct such an analysis due to the limited number of studies included.

Data synthesis

We used a fixed-effect model meta-analysis for the data analyses of the treatment effect.

Subgroup analysis and investigation of heterogeneity

Subgroup analysis (for example diabetic participants who could be stratified into the presence or absence of peripheral arterial disease) proved impossible in the trials identified.

Sensitivity analysis

This was not applicable to this review due to the limited number of studies included.

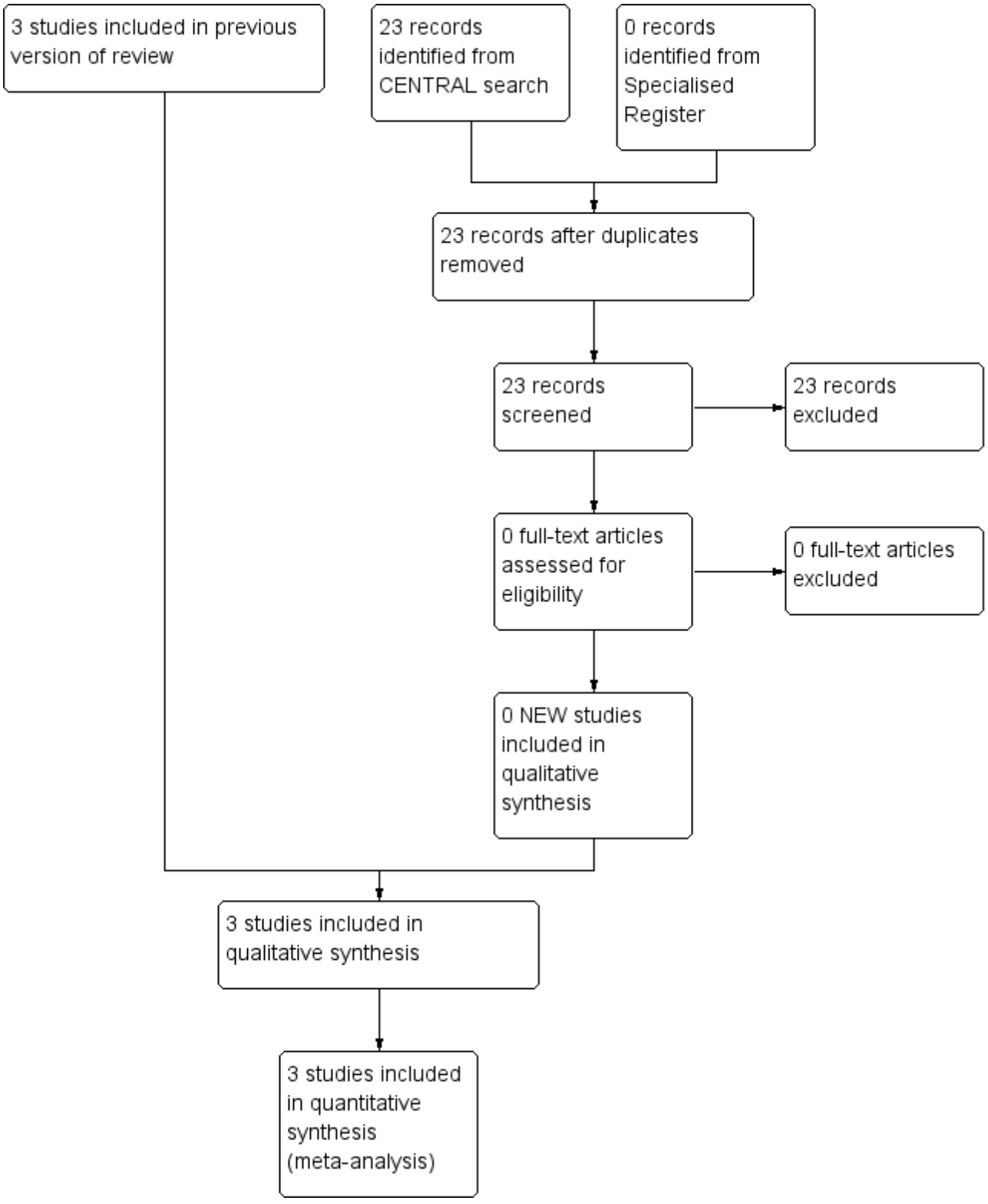
RESULTS

Description of studies

Results of the search

See Figure 3.

Figure 3. Study flow diagram.



No new relevant studies were identified for this update.

Included studies

Three studies were included in the review. Duration of recruitment ranged from 28 to 30 months and the study follow-up was two months in one study (Fisher 1988), six months in a second study

(Ruckley 1991) and a mean (range) of 11.7 months (3.5 to 22 months) in the third study (Termansen 1977). All were parallel trials. Participants, inclusion and exclusion criteria, interventions, and outcomes are described in the table 'Characteristics of included studies'. The studies examined three comparisons: two-stage versus one-stage long posterior flap BKA (Fisher 1988); skew flaps BKA versus long posterior flap BKA (Ruckley 1991); and sagittal flaps BKA versus long posterior flaps BKA (Termansen 1977). Fisher 1988 also included participants undergoing above knee amputation (AKA) but these data were excluded from the analyses of this review.

Excluded studies

No studies were excluded.

Risk of bias in included studies

See Figure 4; Figure 5.

Figure 4. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

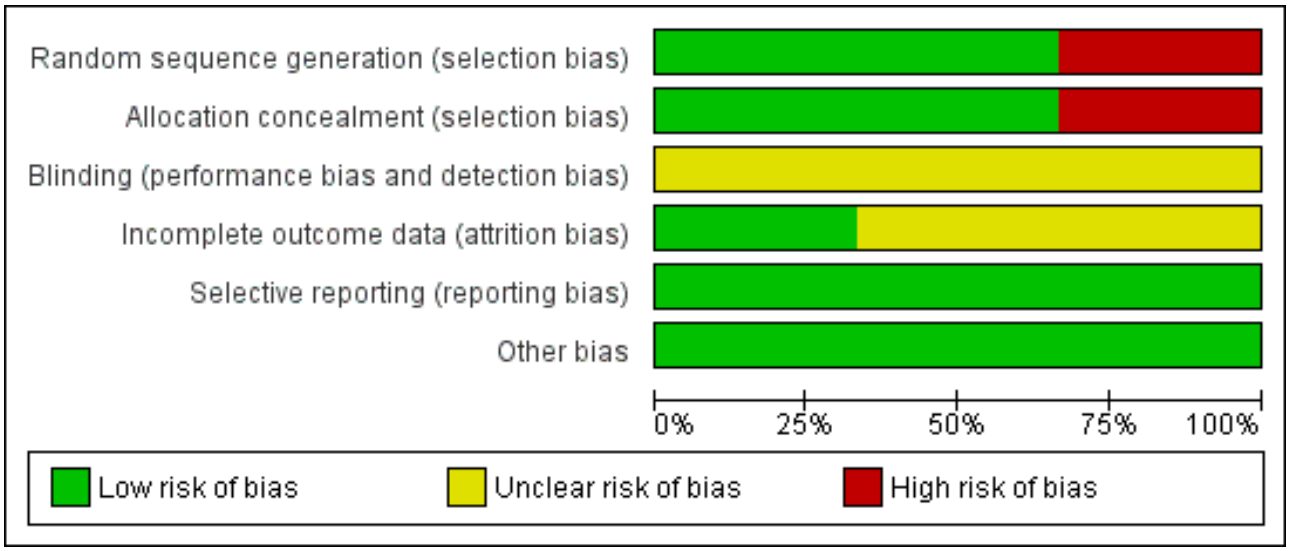
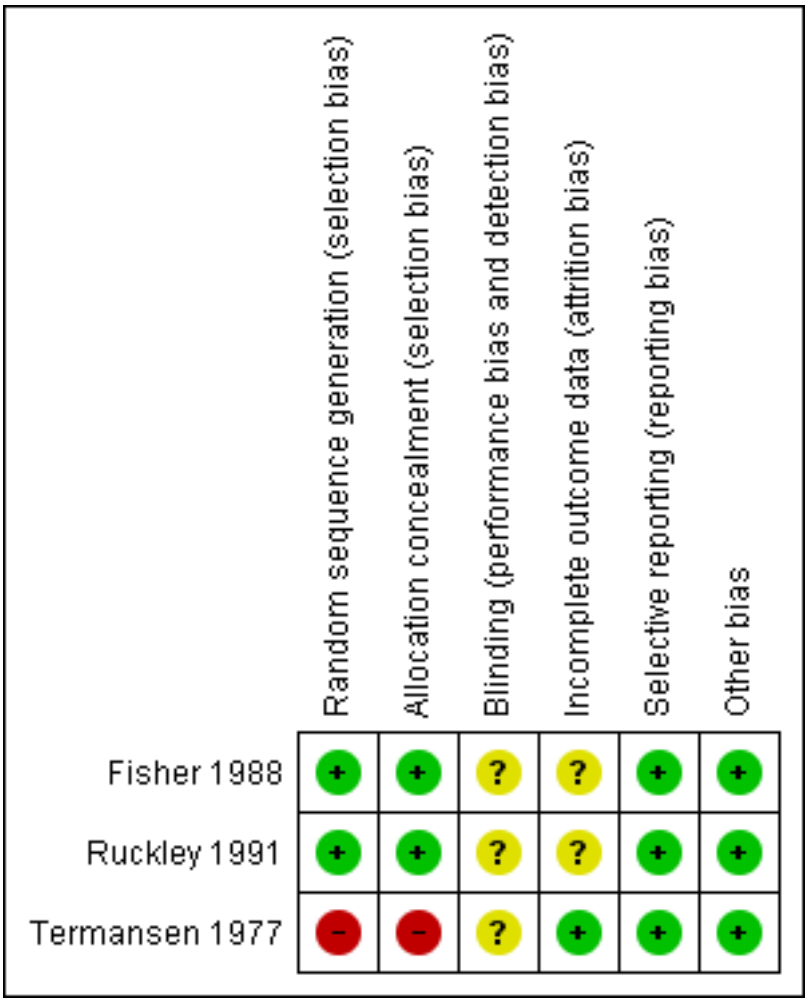


Figure 5. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Allocation

The randomisation method was different in each of the three included studies: sealed envelopes (stratified by centre) (Ruckley 1991); random numbers table (Fisher 1988); and year of birth (even or odd) (Termansen 1977). Allocation concealment was considered adequate in two studies (Fisher 1988; Ruckley 1991) because of the randomisation methods used and was inadequate in one study (Termansen 1977) because the allocation could be deduced from the date of birth.

Blinding

Blinding was impossible in all studies looking at objective outcomes such as primary stump healing as the surgical technique used would be obvious to the observer.

Incomplete outcome data

As detailed below, statistical analysis of 'length of hospital stay' could not be undertaken due to failure to report standard deviations in two included studies (Fisher 1988; Ruckley 1991).

Selective reporting

No concerns over the selective reporting of data were identified from the three included studies.

Other potential sources of bias

No concerns over other potential sources of bias were identified from the three included studies.

Effects of interventions

Tests for heterogeneity and sensitivity analyses were not possible in this review as each comparison related to a single study only.

One study compared two-stage BKA (a guillotine amputation at the ankle as the primary procedure followed by a long posterior flap BKA with primary skin closure as a secondary procedure) with one-stage BKA (long posterior flap BKA with delayed skin closure) in 30 participants with wet gangrene of the foot (Fisher 1988). There was significantly better (100%) primary stump healing in the two-stage group than in the one-stage group (Peto OR 0.08, 95% CI 0.01 to 0.89). There was no difference between the two groups in post-operative infection rate, reamputation at the same level, or reamputation at a higher level. Mobility with a prosthetic limb was 47% in the two-stage group and 54% in the one-stage group. This was not statistically different (Peto OR 0.87, 95% CI 0.43 to 1.78). Mean length of hospital stay was 44 days in the two-stage group and 67 days in the one-stage group. Statistical analysis could not be applied to this length of stay as the standard deviation of hospital

stay was not given in the paper. See Data and analyses Comparison 1.

The Joint Vascular Research Group (JVRG) study randomised 191 participants in 11 vascular centres to skew flaps BKA (n = 98) or long posterior flap BKA (n = 93) (Ruckley 1991). There was no difference in primary stump healing between the two groups (60% for both the skew flaps and long posterior flap) (RR 1.00, 95% CI 0.71 to 1.42). The rates of post-operative wound necrosis, reamputation at the same level, and reamputation at a higher level were again no different between the groups. Thirty-day mortality and number of participants fitted with a prosthetic limb were not different between the groups. Mobility with a prosthetic limb was 60% in the skew flaps group and 49% in the long posterior flap group, although this was not statistically different (RR 1.22, 95% CI 0.94 to 1.58). Mean length of hospital stay was 36 days in the skew flaps group and 42 days in the long posterior flap group. Statistical analysis could not be applied as the standard deviation of hospital stay was not given in the paper. See Data and analyses Comparison 2.

The last study compared 41 participants treated with sagittal flaps BKA to 47 participants with a long posterior flap (Termansen 1977). There was no difference in primary stump healing between the two groups (58% for sagittal flaps, 55% for long posterior flap) (Peto OR 1.04, 95% CI 0.45 to 2.43). The rates of reamputation at the same level, reamputation at a higher level, and mortality after three months were no different between the two groups. Overall percentages of participants fitted with a prosthetic limb were 78% in the sagittal flaps group and 72% in the long posterior flap group, although this difference was not statistically significant (RR 1.08, 95% CI 0.85 to 1.37). Numbers of participants mobilising with a prosthetic limb were not stated. However, the study quoted numbers of participants fitted with a patellar tendon-bearing prosthesis, which one would normally associate with good mobility: 44% in the sagittal flaps group compared to 55% in the long posterior flap group (RR 0.79, 95% CI 0.52 to 1.22). See Data and analyses Comparison 3.

The predefined secondary outcomes symptoms relating to the stump, such as pain and swelling, phantom limb pain and quality of life measures, were not reported in the three included studies.

DISCUSSION

Summary of main results

Only a limited number of trials were identified which addressed these important issues. The most important question to be answered was whether the skew flap technique conferred any advantage over the long posterior flap amputation in terms of primary stump healing, reamputation rate and return to full mobility with a prosthetic limb. The single multicentre Joint Vascular Research Group (JVRG) study addressed this issue and found no significant difference between the two techniques in all outcome measures (Ruckley 1991). It could be concluded from this study that the choice of technique is a matter of surgeon preference.

There was no difference in primary stump healing, rates of reamputation at the same level, reamputation at a higher level, and mobility after three months between sagittal flaps and the long posterior flap (Termansen 1977). A higher percentage of participants were fitted with prosthetic limb in the sagittal flaps group than in the long posterior flap group (78% versus 72%), however more patellar tendon-bearing prostheses were fitted in the latter group (44% versus 55%) (Termansen 1977).

In the presence of wet gangrene, there was significantly better (100%) primary stump healing in the two-stage group than in the one-stage group, although there was no difference between the two groups in post-operative infection rate, reamputation at the same level, or reamputation at a higher level (Fisher 1988). Mobility with a prosthetic limb was higher in the one-stage group (54% versus 47%) however this was not statistically significant (Fisher 1988).

Mobility with a prosthetic limb following below knee amputation (BKA) appears relatively consistent between studies, at 47% to 60% (Pinzur 1993).

Overall completeness and applicability of evidence

The three included studies were published more than 20 years ago. As indicated in the Implications for practice section below, in modern vascular surgery both skew flaps and long posterior flap below knee amputations continue to be used. Length of stay data quoted in the included studies look to be outside what would now be deemed acceptable in modern clinical practice as the limiting factor for discharge is often social care rather than a requirement for inpatient medical care.

One could conclude from Ruckley 1991 that the choice of technique is a matter of surgeon preference. However, nearly all the members of the JVRG group were new to the skew flap operation and were therefore on a learning curve, which may have influenced the results.

Quality of the evidence

The overall body of evidence to support one surgical technique over another for BKA is limited to three studies which are different in their scope. Overall, there is a low risk of selection bias in two out of the three studies; unclear risk of bias for blinding and incomplete outcome data; and low risk for selective reporting and any other sources of bias. Therefore, the overall strength of the evidence could be considered as 'moderate'.

Potential biases in the review process

No obvious bias was identified in the review process.

Agreements and disagreements with other studies or reviews

To the review authors' knowledge no other evidence has addressed this issue.

The type of prosthesis used was not mentioned by Ruckley 1991. Trial participants would have accessed different limb fitting centres that would have decided which prosthesis was appropriate for an individual patient. Mobility with a prosthetic limb following BKA appears relatively consistent between studies, at 47% to 60%, and this appears to reflect current clinical practice. This contrasts with the report from Pinzur which suggests that 87% of participants could maintain independent ambulation following BKA (Pinzur 1993).

AUTHORS' CONCLUSIONS

Implications for practice

Sagittal flaps below knee amputation is seldom used in clinical practice. There is no evidence that this confers any advantage to the long posterior flap technique. The main question in clinical practice is whether the skew flaps technique improves the outcome compared with the long posterior flap. The single multicentre randomised controlled trial (RCT) that was identified demonstrated no obvious benefit of one technique over the other. We conclude that there is no evidence to show a benefit of one technique over the other except in the presence of wet gangrene, where a two-stage procedure has a benefit of better primary stump healing over a one-stage procedure. Factors which might influence the choice of one technique versus the other include previous experience of a technique, the extent of non-viable tissue, and the location of pre-existing surgical scars, for example from a previous vascular reconstruction.

Implications for research

A further RCT comparing skew flaps to the long posterior flap, involving surgeons with experience of both techniques, should be considered. This would negate the possible effects of a learning curve, which might have influenced the JVRG study.

ACKNOWLEDGEMENTS

We would like to thank Mr Michael J Callam for his work on previous versions of this review.

We would like to thank the Cochrane Consumer Network for providing a plain language summary.

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CHARACTERISTICS OF STUDIES

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

Fisher 1988

Methods	Duration of recruitment to study: 28 months Duration of follow-up: 2 months after discharge from hospital Parallel trial Randomisation method: random numbers table
Participants	30 participants Age: not stated Sex: not stated Inclusion criteria: necrotising wet gangrene of the foot; participants were stratified for presence or absence of diabetes Exclusion criteria: suitable for lesser (minor) amputation Dropouts: none
Interventions	Two-stage amputation (guillotine amputation at ankle followed by long posterior flap BKA with primary skin closure, n = 17) versus one-stage amputation (long posterior flap BKA with delayed skin closure, n = 13)
Outcomes	1. Primary stump healing 2. Post-operative infection rate 3. Rate of reamputation at same level 4. Rate of reamputation at higher level 5. Length of hospital stay 6. Number of participants mobilising with a prosthetic limb
Notes	Above knee amputation cases were excluded from data analyses

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation by random numbers table (Fisher 1988)
Allocation concealment (selection bias)	Low risk	Adequate measures were undertaken for allocation concealment (random numbers table)
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding was impossible due to the nature of the procedure undertaken
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Statistical analysis of outcome 'length of stay' could not be undertaken due to failure to report standard deviations
Selective reporting (reporting bias)	Low risk	No concerns over the selective reporting of data
Other bias	Low risk	No concerns over other bias

Ruckley 1991

Methods	Duration of recruitment to study: not stated Duration of follow-up: 6 months Parallel trial Randomisation method: sealed envelopes, stratified by centre
Participants	191 participants in 11 centres (Joint Vascular Research Group) Age (mean (range)): 70 years (35 to 93) skew flaps; 72 years (39 to 92) long posterior flap Sex (M:F): 65:33 skew flaps; 60:33 long posterior flap Inclusion criteria: critical limb ischaemia where no other treatment option available Exclusion criteria: none stated
Interventions	Skew flaps BKA (n = 98) versus long posterior flap BKA (n = 93)
Outcomes	1. Primary stump healing (1 week) 2. Post-operative wound necrosis 3. Rate of reamputation at same level 4. Rate of reamputation at higher level 5. 30-day mortality 6. Length of hospital stay 7. Number of participants fitted with a prosthetic limb 8. Number of participants mobilising with a prosthetic limb
Notes	Length of stay (mean (range)): skew flap 36 days (7 to 409); posterior flap 42 days (6 to 385)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation by sealed envelopes (stratified by centre)
Allocation concealment (selection bias)	Low risk	Adequate measures were undertaken for allocation concealment (sealed envelopes)
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding was impossible due to the nature of the procedure undertaken
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Statistical analysis of outcome 'length of stay' could not be undertaken due to failure to report standard deviations
Selective reporting (reporting bias)	Low risk	No concerns over the selective reporting of data
Other bias	Low risk	No concerns over other bias

Termansen 1977

Methods	Duration of recruitment to study: 30 months Duration of follow-up (mean (range)): 11.7 months (3.5 to 22) Parallel trial Randomisation method: year of birth (even/odd)

Termansen 1977 *(Continued)*

Participants	88 participants Age (mean in years): 70.0 sagittal flap; 70.5 long posterior flap Sex (M:F): 24:17 sagittal flap; 22:25 long posterior flap Inclusion criteria: acute limb ischaemia, critical limb ischaemia, diabetes, mixed arterio-venous ulceration Exclusion criteria: none stated
Interventions	Sagittal flaps BKA (n = 41) versus long posterior flap BKA (n = 47)
Outcomes	1. Primary stump healing 2. Rate of reamputation at same level 3. Rate of reamputation at higher level 4. Mortality at 3 months 5. Number of participants fitted with a prosthetic limb - overall - below knee prosthesis - patellar tendon-bearing (PTB) prosthesis
Notes	No exclusion criteria stated, e.g. those participants not suitable for a long posterior flap (previous vascular surgery) or refusal to enter study

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Randomisation by year of birth (even or odd)
Allocation concealment (selection bias)	High risk	Inadequate as this was based on the year of birth
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding was impossible due to the nature of the procedure undertaken
Incomplete outcome data (attrition bias) All outcomes	Low risk	No concerns over incomplete outcome data
Selective reporting (reporting bias)	Low risk	No concerns over the selective reporting of data
Other bias	Low risk	No concerns over other bias

BKA: below knee amputation
PTB: patellar tendon bearing

DATA AND ANALYSES

Comparison 1. Two-stage amputation versus one-stage amputation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Failed primary stump healing	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
2 Post-operative infection rate	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
3 Reamputation at same level	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
4 Reamputation at higher level	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
5 Mobility with prosthetic limb	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

Analysis 1.1. Comparison 1 Two-stage amputation versus one-stage amputation, Outcome 1 Failed primary stump healing.

Study or subgroup	Two-stage amputation n/N	One-stage amputation n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Peto Odds Ratio Peto, Fixed, 95% CI
Fisher 1988	0/17	3/13		0.08[0.01,0.89]
		Favours two-stage	0.005 0.1 1 10 200	Favours one-stage

Analysis 1.2. Comparison 1 Two-stage amputation versus one-stage amputation, Outcome 2 Post-operative infection rate.

Study or subgroup	Two-stage amputation n/N	One-stage amputation n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Peto Odds Ratio Peto, Fixed, 95% CI
Fisher 1988	0/17	2/13		0.09[0.01,1.58]
		Favours two-stage	0.001 0.1 1 10 1000	Favours one-stage

Analysis 1.3. Comparison 1 Two-stage amputation versus one-stage amputation, Outcome 3 Reamputation at same level.

Study or subgroup	Two-stage amputation n/N	One-stage amputation n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Peto Odds Ratio Peto, Fixed, 95% CI
Fisher 1988	0/17	0/13		Not estimable
		Favours two-stage	0.02 0.1 1 10 50	Favours one-stage

Analysis 1.4. Comparison 1 Two-stage amputation versus one-stage amputation, Outcome 4 Reamputation at higher level.

Study or subgroup	Two-stage amputation n/N	One-stage amputation n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Peto Odds Ratio Peto, Fixed, 95% CI
Fisher 1988	0/17	1/13		0.1[0,5.19]

Favours two-stage 0.001 0.1 1 10 1000 Favours one-stage

Analysis 1.5. Comparison 1 Two-stage amputation versus one-stage amputation, Outcome 5 Mobility with prosthetic limb.

Study or subgroup	Two-stage amputation n/N	One-stage amputation n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Fisher 1988	8/17	7/13		0.87[0.43,1.78]

Favours one-stage 0.1 0.2 0.5 1 2 5 10 Favours two-stage

Comparison 2. Skew flaps amputation versus long posterior flap amputation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Failed primary stump healing	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2 Post-operative wound necrosis	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
3 Reamputation at same level	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
4 Reamputation at higher level	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
5 Fitted with prosthetic limb	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
6 Mobility with prosthetic limb	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
7 30-day mortality	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected

Analysis 2.1. Comparison 2 Skew flaps amputation versus long posterior flap amputation, Outcome 1 Failed primary stump healing.

Study or subgroup	Skew flaps n/N	Long posterior flap n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Ruckley 1991	39/98	37/93		1[0.71,1.42]

Favours skew flaps 0.1 0.2 0.5 1 2 5 10 Favours long post flap

Analysis 2.2. Comparison 2 Skew flaps amputation versus long posterior flap amputation, Outcome 2 Post-operative wound necrosis.

Study or subgroup	Skew flaps n/N	Long posterior flap n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Peto Odds Ratio Peto, Fixed, 95% CI
Ruckley 1991	21/98	23/93		0.83[0.42,1.63]

Favours skew flaps 0.1 0.2 0.5 1 2 5 10 Favours long post flap

Analysis 2.3. Comparison 2 Skew flaps amputation versus long posterior flap amputation, Outcome 3 Reamputation at same level.

Study or subgroup	Skew flaps n/N	Long posterior flap n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Peto Odds Ratio Peto, Fixed, 95% CI
Ruckley 1991	7/98	7/93		0.95[0.32,2.8]

Favours skew flaps 0.1 0.2 0.5 1 2 5 10 Favours long post flap

Analysis 2.4. Comparison 2 Skew flaps amputation versus long posterior flap amputation, Outcome 4 Reamputation at higher level.

Study or subgroup	Skew flaps n/N	Long posterior flap n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Peto Odds Ratio Peto, Fixed, 95% CI
Ruckley 1991	10/98	7/93		1.39[0.51,3.75]

Favours skew flaps 0.1 0.2 0.5 1 2 5 10 Favours long post flap

Analysis 2.5. Comparison 2 Skew flaps amputation versus long posterior flap amputation, Outcome 5 Fitted with prosthetic limb.

Study or subgroup	Skew flaps n/N	Long posterior flap n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Ruckley 1991	64/98	50/93		1.21[0.96,1.54]

Favours long post flap 0.1 0.2 0.5 1 2 5 10 Favours skew flaps

Analysis 2.6. Comparison 2 Skew flaps amputation versus long posterior flap amputation, Outcome 6 Mobility with prosthetic limb.

Study or subgroup	Skew flaps n/N	Long posterior flap n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Ruckley 1991	59/98	46/93		1.22[0.94,1.58]

Favours long post flap 0.1 0.2 0.5 1 2 5 10 Favours skew flaps

Analysis 2.7. Comparison 2 Skew flaps amputation versus long posterior flap amputation, Outcome 7 30-day mortality.

Study or subgroup	Skew flaps n/N	Long posterior flap n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Peto Odds Ratio Peto, Fixed, 95% CI
Ruckley 1991	11/98	16/93		0.61[0.27,1.38]

Favours skew flaps 0.1 0.2 0.5 1 2 5 10 Favours long post flap

Comparison 3. Sagittal flaps amputation versus long posterior flap amputation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Failed primary stump healing	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
2 Reamputation at same level	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
3 Reamputation at higher level	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected
4 Fitted with prosthetic limb - overall	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
5 Fitted with prosthetic limb - below knee prosthesis	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
6 Fitted with prosthetic limb - PTB prosthesis	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
7 Mortality at 3 months	1		Peto Odds Ratio (Peto, Fixed, 95% CI)	Totals not selected

Analysis 3.1. Comparison 3 Sagittal flaps amputation versus long posterior flap amputation, Outcome 1 Failed primary stump healing.

Study or subgroup	Sagittal flaps n/N	Long posterior flap n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Peto Odds Ratio Peto, Fixed, 95% CI
Termansen 1977	17/41	19/47		1.04[0.45,2.43]

Favours sagittal flaps 0.1 0.2 0.5 1 2 5 10 Favours long post flap

Analysis 3.2. Comparison 3 Sagittal flaps amputation versus long posterior flap amputation, Outcome 2 Reamputation at same level.

Study or subgroup	Sagittal flaps n/N	Long posterior flap n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Peto Odds Ratio Peto, Fixed, 95% CI
Termansen 1977	1/41	4/47		0.33[0.05,1.97]

Favours sagittal flaps 0.01 0.1 1 10 100 Favours long post flap

Analysis 3.3. Comparison 3 Sagittal flaps amputation versus long posterior flap amputation, Outcome 3 Reamputation at higher level.

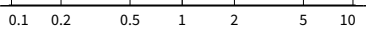
Study or subgroup	Sagittal flaps n/N	Long posterior flap n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Peto Odds Ratio Peto, Fixed, 95% CI
Termansen 1977	14/41	10/47		1.9[0.75,4.84]

Analysis 3.4. Comparison 3 Sagittal flaps amputation versus long posterior flap amputation, Outcome 4 Fitted with prosthetic limb - overall.

Study or subgroup	Favours sagittal flaps n/N	Long posterior flap n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Termansen 1977	32/41	34/47		1.08[0.85,1.37]

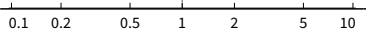
Analysis 3.5. Comparison 3 Sagittal flaps amputation versus long posterior flap amputation, Outcome 5 Fitted with prosthetic limb - below knee prosthesis.

Study or subgroup	Sagittal flaps n/N	Long posterior flap n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Termansen 1977	25/41	29/47		0.99[0.71,1.38]



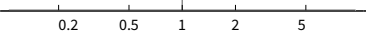
Analysis 3.6. Comparison 3 Sagittal flaps amputation versus long posterior flap amputation, Outcome 6 Fitted with prosthetic limb - PTB prosthesis.

Study or subgroup	Sagittal flaps n/N	Long posterior flap n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Termansen 1977	18/41	26/47		0.79[0.52,1.22]



Analysis 3.7. Comparison 3 Sagittal flaps amputation versus long posterior flap amputation, Outcome 7 Mortality at 3 months.

Study or subgroup	Sagittal flaps n/N	Long posterior flap n/N	Peto Odds Ratio Peto, Fixed, 95% CI	Peto Odds Ratio Peto, Fixed, 95% CI
Termansen 1977	4/41	8/47		0.54[0.16,1.83]



APPENDICES

Appendix 1. CENTRAL search strategy

#1	MeSH descriptor: [Amputation] explode all trees	304
#2	MeSH descriptor: [Knee] explode all trees and with qualifiers: [Surgery - SU]	156
#3	amput*:ti,ab,kw (Word variations have been searched)	915
#4	below near/3 knee:ti,ab,kw (Word variations have been searched)	250
#5	#1 or #2 or #3 or #4	1227
#6	MeSH descriptor: [Surgical Flaps] explode all trees	849
#7	transverse near/3 technique:ti,ab,kw (Word variations have been searched)	7
#8	*flap:ti,ab,kw (Word variations have been searched)	1418
#9	incision	4167
#10	#6 or #7 or #8 or #9	5723
#11	#5 and #10 in Trials	23

WHAT'S NEW

Date	Event	Description
5 August 2013	New search has been performed	Searches re-run; no new studies were identified.
5 August 2013	New citation required but conclusions have not changed	Searches were re-run and no new studies were identified. New author joined review team, methods updated to reflect current Cochrane standards, risk of bias tables completed. Conclusions not changed.

HISTORY

Protocol first published: Issue 3, 2002
Review first published: Issue 1, 2004

Date	Event	Description
23 July 2008	New search has been performed	Searches re-run and no new trials found. The review was assessed as up to date.
23 July 2008	Amended	Converted to new review format.
14 December 2007	Amended	New plain language summary added.

Date	Event	Description
3 April 2006	New search has been performed	Searches re-run and no new trials found. The review was updated with no changes other than dates of last search.

CONTRIBUTIONS OF AUTHORS

Paul Tisi: identified trials for inclusion; contacted authors for additional information; assessed eligibility and quality of trials; extracted data; and wrote the review.

Mary Than: assessed quality of the trials and updated the review.

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

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

  The PVD Group editorial base is supported by the Chief Scientist Office.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In line with current Cochrane Collaboration guidelines the assessment of the methodological quality of the studies was conducted according to Higgins 2011.

NOTES

The title of the protocol for this review was: 'Type of skin incision for below knee amputation'.

INDEX TERMS

Medical Subject Headings (MeSH)

Amputation, Surgical [*methods]; Diabetic Foot [*surgery]; Gangrene [complications] [surgery]; Ischemia [*surgery]; Leg [*blood supply]; Randomized Controlled Trials as Topic; Reoperation; Surgical Flaps; Treatment Outcome; Wound Healing

MeSH check words

Humans