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Prosthetic rehabilitation for older dysvascular people following a unilateral transfemoral amputation (Review)

Barr S, Howe TE

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Prosthetic rehabilitation for older dysvascular people following a unilateral transfemoral amputation.
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[Intervention Review]

Prosthetic rehabilitation for older dysvascular people following a unilateral transfemoral amputation

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ABSTRACT

Background

Dysvascularity accounts for 75% of all lower limb amputations in the UK. Around 37% of these procedures are done at the transfemoral level (mid-thigh), with most patients over the age of 60 and having existing comorbidities. A significant number of these amputees are prescribed a lower limb prosthesis for walking. However, many amputees do not achieve a high level of function following prosthetic rehabilitation. This is the third update of the review first published in 2005.

Objectives

To identify and summarise the evidence evaluating prosthetic rehabilitation interventions for prosthetic ambulation following unilateral transfemoral or transgenicular amputation in older dysvascular people, whether community dwelling or institutionalised.

Search methods

The Cochrane Vascular Information Specialist searched the Cochrane Vascular Specialised Register and CENTRAL, MEDLINE, Embase, and CINAHL databases; the World Health Organization International Clinical Trials Registry Platform; and the ClinicalTrials.gov trials registry to 14 June 2018. We performed additional searches by handsearching citations of studies identified by the electronic search. We applied no restrictions on language or publication status.

Selection criteria

Randomised and quasi-randomised controlled trials testing prosthetic rehabilitation interventions following a unilateral transfemoral or transgenicular amputation in older (aged 60 years or older) dysvascular people.

Data collection and analysis

Two review authors independently scanned the search results for potentially eligible studies and, on obtaining full reports of these, selected studies for inclusion and exclusion. Two review authors independently assessed the methodological quality of studies and extracted data. We used GRADE to assess the overall quality of evidence supporting the outcomes assessed in this review.

Main results

We identified no new studies for inclusion in this update. In total we included one trial, excluded 18 trials, classed one trial as ongoing, and classed another as awaiting classification. The total number of participants in the included trial was 10, and the methodological quality of this trial was moderate because of high risk of bias in relation to two domains (random sequence generation and allocation

concealment) but low risk of bias for the four remaining domains (blinding, incomplete outcome data, selective reporting, and any other bias). The included trial was a short-term cross-over randomised trial undertaken in Canada, which tested the effects of adding three seemingly identical prosthetic weights (150 g vs 770 g vs 1625 g) to the prostheses of a total of 10 participants with unilateral dysvascular transfemoral amputation. Eight participants were over 60 years of age. Trial authors found that four participants preferred the addition of the lightest weight (150 g), five preferred the middle weight (770 g), and one preferred the heaviest weight (1625 g). Researchers interpreted this as equating to user satisfaction (success) and reported no adverse effects.

Authors' conclusions

The limited evidence presented in this review is of very low quality and is insufficient to inform the choice of prosthetic rehabilitation, including the optimum weight of the prosthesis, after unilateral transfemoral amputation in older dysvascular people. A programme of research that includes randomised controlled trials to examine key interventions is urgently required in this area.

PLAIN LANGUAGE SUMMARY

Artificial limb rehabilitation for older people with a leg amputated at or above the knee because of blood circulation problems

Background

Problems with inadequate circulation in the legs (dysvascularity), particularly in people over the age of 60 years, can be so severe that they need a leg amputated. This may occur as high as at or above the knee. Accompanying medical conditions (comorbidities) such as diabetes and cardiovascular or heart disease can affect a person's rehabilitation. When an above- or through-knee artificial limb (prosthesis) is fitted, it is hard for the person to regain mobility and function, and some people choose to use a wheelchair. Motivation, comfort, cosmetic appearance, functionality, reliability, ease of use, previous mobility, and the extra exertion needed to use an artificial leg are all important factors that can affect a person's independence and use of the prosthesis. Fear of falling, number of falls, social circumstances, and help and support from other people are also important influences. The review authors searched for trials comparing different types of rehabilitation that may benefit mobility or function in older people using an artificial limb.

Study characteristics and key results

Reviewers found only one controlled trial of moderate methodological quality (most recent search, 14 June 2018). This trial had a cross-over design, and each of the 10 participants had three seemingly identical prosthetic weights added to the prosthesis below the knee in random order. All artificial limbs were modular-style prostheses. The participants - nine men and one woman - were over 50 years of age, and eight were over 60 years old. Over the few hours of the trial, four participants preferred the lightest weight (150 g), five preferred the medium weight (770 g), and one preferred the heaviest weight (1625 g). Seven of the 10 people successfully ranked the weights from lightest to heaviest. The weights did not alter participants' walking speed in a two-minute walk test. Study authors reported no adverse effects.

Quality of the evidence and conclusions

The inclusion of only one trial with a small number of participants, short exposure to different weights in a laboratory setting, and the fact that there were differences in weight between people and their prostheses limit the usefulness of these findings. The limited evidence included in this review is of very low quality and is insufficient to inform the choice of prosthetic rehabilitation, including optimum weight of the prosthesis, after unilateral transfemoral amputation in older dysvascular people.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Prosthetic rehabilitation for older dysvascular people after a unilateral transfemoral amputation

Patient or population: adults over the age of 50 with a unilateral transfemoral amputation
Settings: community
Intervention: prosthetic rehabilitation[a]
Comparison: different rehabilitation

Outcomes	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
Success of prosthetic rehabilitation (preference) (1 day)	10 (1 RCT)	⊕◯◯◯ **Very low**[b]	Inclusion of only 1 trial with a small number of participants and short exposure to different weights in a laboratory setting limit the usefulness of these findings, and evidence is insufficient to inform the choice of prosthetic rehabilitation after unilateral transfemoral amputation in older dysvascular people
Adverse effects (1 day)	See comment.		The study reported no adverse effects.

GRADE Working Group grades of evidence
High quality: further research is very unlikely to change our confidence in the estimate of effect
Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low quality: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low quality: we are very uncertain about the estimate

[a]For the one included study (Meikle 2003), the intervention involved adding different weights below the knee joint to each participant's prothesis in a single session. Trialists compared three weights in total and the study's primary outcome measure was preference. For this review, prosthetic rehabilitation included the provision of a prescribed prosthesis post amputation that was suitable for the individual's needs with the aim of achieving an optimum level of function and mobility following therapy intervention. Interventions that may form part of the prosthetic rehabilitation package are described under Types of interventions.

[b]Evidence was downgraded by three steps owing to risk of bias, imprecision in the results due to the small sample size, and indirectness.

BACKGROUND

Description of the condition

More than 6000 leg amputations are performed in the United Kingdom (UK) each year (ISD 2004), and more than two million people with limb loss are reported to be living in the United States (LLS 2000; Ziegler-Graham 2008). In 2009, amputation was associated with hospital costs of USD8.3 billion in the United States (HCUP Nationwide Inpatient Sample (NIS) 2009). No organisation currently tracks the number of amputees worldwide. However in the developing world, the leading cause of amputation is trauma (Esquenazi 2004). A retrospective study undertaken in Kolkata, India, identified the prevalence of traumatic lower limb amputation to be 70.3% (Das Pooja 2013). The incidence of dysvascularity (poor circulation) increases with age, as does the presence of comorbidities (other medical conditions) such as diabetes. In England, more than 90% of amputations performed in people over the age of 50 are the result of peripheral arterial disease (Moxley 2010). Approximately 55% of all lower limb amputations performed in the United States are the result of dysvascularity (Ziegler-Graham 2008).

Description of the intervention

After the lower limb is amputated, a prosthesis (artificial leg) is frequently prescribed, followed by a period of prosthetic rehabilitation. The primary aim of prosthetic rehabilitation for lower limb amputees is to achieve maximum patient independence safely, with minimal extra energy expenditure and consideration of the patient's pre-amputation lifestyle, expectations, and medical limitations (Broomhead 2012). It is reported that older dysvascular unilateral transfemoral amputees do not achieve a high level of prosthetic mobility or function, particularly in comparison with transtibial (through the calf) amputees. However, success rates for prosthetic rehabilitation in this population differ markedly. Davies 2003 found that only 25% of transfemoral amputees over 50 years of age achieved community mobility, and that this figure was reduced with advancing age. In contrast, an earlier study found that only 4% of this population were community ambulators (Houghton 1992).

Some studies have attempted to identify factors that contribute to functional outcomes for amputees. These factors include psychological and social aspects, the presence of comorbidities, and age. Investigators have attempted to use such factors to predict successful rehabilitation (Munin 2001). Clinical guidelines in the UK recommend that patients should be made aware that concurrent pathologies and previous mobility affect realistic goal setting and the outcomes of prosthetic rehabilitation (Broomhead 2012). Success of prosthetic provision and rehabilitation is frequently judged in terms of clinical measures of impairment or function, for example, walking 45 m with the prosthesis (Munin 2001). However, the relationship between the amputee and his or her prosthesis is potentially more complex, involving motivation, comfort, cosmetic appearance, functionality, reliability, ease of use, and degree of energy expenditure during use. Traditionally, self-reported measures have been used to measure mobilisation with a prosthesis. However advances in technology and the use of wearable devices have made it possible for patients to measure more accurately time spent using a prosthesis.

Transfemoral amputees have a greater level of disability and use 65% more energy than individuals with bipedal (normal) walking (Waters 1976). The prevalence of coexisting cardiovascular disease in patients with dysvascular amputation may be as high as 75%, and comorbid heart disease may prevent patients from achieving maximum functional independence (Roth 1998). Therefore, older dysvascular transfemoral amputees with cardiac abnormalities may be at increased risk of an adverse event, such as heart failure, when they are exercised during prosthetic rehabilitation.

Why it is important to do this review

Older people undergoing a unilateral transfemoral amputation make up an increasingly important subgroup of amputees that has been identified as having a low success rate with a prosthesis in terms of functional mobility and usage. Healthcare professionals involved in amputee rehabilitation need more evidence to support clinical decisions regarding the suitability of a patient in this age group for prosthetic rehabilitation, especially when patient expectations do not match clinical decisions. Furthermore, patients and carers have a right to good, evidence-based information on which they can base their decisions regarding living either independently or with care in the community. This includes assessing whether mobility or function will be achievable with a prosthesis, a wheelchair, or a combination of both. It is a professional's duty to discuss the advantages and disadvantages of each path and to inform the patient of any associated clinical risk. It is important to review available interventions that can improve rehabilitation prospects. Therefore, we conducted this systematic review of evidence related to prosthetic rehabilitation in older dysvascular unilateral transfemoral amputees to inform clinical practice.

OBJECTIVES

To identify and summarise the evidence evaluating prosthetic rehabilitation interventions with prosthetic ambulation following unilateral transfemoral or transgenicular amputation in older dysvascular people, whether community dwelling or institutionalised.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) and quasi-randomised trials (e.g. randomised by date of birth or hospital record number) that evaluated the success of prosthetic rehabilitation following a unilateral transfemoral or transgenicular amputation in older dysvascular people.

Types of participants

Male or female participants described as:

- older adults, elderly, veteran, geriatric, aged, seniors, or all over the age of 60 years;
- living in the community or in institutional care;

and

- dysvascular; and
- having a unilateral transfemoral amputation, including transgenicular (through the knee), and provided with a transfemoral prosthesis for walking and functional rehabilitation.

Participant characteristics of interest included age, gender, previous level of mobility, and comorbidities.

Types of interventions

Prosthetic rehabilitation included provision of a prescribed prosthesis post amputation that was suitable for the individual's needs, with the aim of achieving an optimum level of function and mobility following therapy intervention.
Interventions that may form part of the prosthetic rehabilitation package included, but were not limited to:

- education on how to safely put on and take off the prosthesis, dressing practice, and footwear provision;
- education on skin and residual skin care, hygiene of the prosthesis and socks, and fit of the prosthesis;
- therapeutic interventions to increase muscle power and range of movement, to improve core stability, and to optimise gait and control of the prosthesis;
- balance and mobility training whilst wearing the prosthesis, including in different environments, negotiating hazards, and getting up from a fall;
- training in functional activities of daily living, including domestic activities; and
- general advice (e.g. where to seek help, aids, adaptations, driving, support groups, return to work).

We considered trials in which participants were randomised to receive any combination of the following: usual care, a single-therapy intervention, or a multiple-therapy intervention. We also planned to include trials comparing two or more interventions. We considered trials that focused on prosthetic rehabilitation and included the provision of a prescribed prosthesis post amputation that was suitable for the individual's needs, with the aim of achieving an optimum level of function and mobility following therapy intervention. Interventions could include education on safe donning and doffing of the prosthesis, dressing practice, and footwear provision. We also considered interventions that focused on skin care for the residual limb, including hygiene of the prosthesis and socks, and prosthetic fit. In addition, we considered for inclusion therapeutic interventions that focused on increasing muscle power and range of movement, as well as providing re-education for gait and activities of daily living; and studies that focused on providing advice and support in relation to driving or returning to employment and leisure activities. Therapy interventions could take place in the home, an institutional dwelling, the community, a gymnasium, or a clinic setting, and they could be self-supervised (e.g. using exercise sheets or a video), individually supervised, or given in the setting of a supervised group.

Types of outcome measures

The primary outcome of interest was 'success' as defined below. We classified outcome measures according to the dimensions of the International Classification of Functioning, Disability, and Health (ICF) (WHO 2001): impairment, activity limitation, and participation restriction.

Primary outcomes

- Success: based on comfort, cosmetic appearance, frequency of prosthetic use, satisfaction for purpose, levels of function, and independence. Measures or scales included Prosthetic Socket Fit Comfort Score, Harold-Wood Stanmore Mobility Grades, Locomotor Capabilities Index, Rivermead Mobility Index, Prosthesis Evaluation Questionnaire, Satisfaction With Prosthesis Questionnaire, Functional Measure for Amputees, and Russek's Scale
- Adverse effects

Secondary outcomes

- Quality of life (QoL): measured by Sickness Impact Profile, Nottingham Health Profile, and Medical Outcomes Study (MOS) Short Form (SF)-36 (or others)
- Morbidity and comorbidities
- Mortality
- Compliance with rehabilitation
- Psychological distress (anxiety or depression, or both)
- Discharge setting and level of wheelchair use
- Indicators of previous level of mobility
- Number of falls experienced
- Problems associated with dysvascularity of the remaining limb
- Sensory impairment

- Risk of falls and fear of falling
- Social circumstances and level of support available or required

Search methods for identification of studies

We applied no restrictions on language or publication status during the search.

Electronic searches

For this update, the Cochrane Vascular Information Specialist first searched the following databases for relevant trials.

- Cochrane Vascular Specialised Register (16 January 2017).
- Cochrane Central Register of Controlled Trials (CENTRAL; 2016, Issue 11), in the Cochrane Library, via the Cochrane Register of Studies Online.

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

The Information Specialist searched the following trial registries for details of ongoing and unpublished studies.

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

See Appendix 2 for details of the search strategy used to search trial registries.

The Cochrane Vascular Information Specialist subsequently conducted a top-up search of the following databases in June 2018.

- Cochrane Vascular Specialised Register via the Cochrane Register of Studies (CRS-Web, searched to 15 June 2018).
- Cochrane Central Register of Controlled Trials (CENTRAL), in the Cochrane Library, via the Cochrane Register of Studies Online (CRSO) (2018, Issue 5).
- MEDLINE (Ovid MEDLINE® Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE® Daily, and Ovid MEDLINE®) (searched from 1 January 2017 to 14 June 2018).
- Embase Ovid (searched from 1 January 2017 to 15 June 2018).
- Cumulative Index to Nursing and Allied Health Literature (CINAHL) Ebsco (searched from 1 January 2017 to 15 June 2018).
- Allied and Complementary Medicine Database (AMED) Ovid (searched from 1 January 2017 to 15 June 2018).

The Information Specialist modelled search strategies for the listed databases on the search strategy designed for CENTRAL. When appropriate, we combined these strategies with adaptations of the highly sensitive search strategy designed by Cochrane for identifying RCTs and controlled clinical trials (as described in Chapter 6 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011)). We have provided in Appendix 3 our search strategies for the major databases.

The Information Specialist also performed top-up searches of the following trials registries on 15 June 2018.

- World Health Organization International Clinical Trials Registry Platform (who.int/trialsearch).
- ClinicalTrials.gov (clinicaltrials.gov).

Searching other resources

We performed additional searches by handsearching citations of studies identified by the search.

Data collection and analysis

Selection of studies

From the title, abstract, and descriptors, two review authors (SB and TH) independently reviewed results of the literature searches to identify potentially relevant trials for full review. Upon review of full texts, the same two review authors independently selected for inclusion trials that met the selection criteria. We planned to resolve disagreements by consensus.

Data extraction and management

If necessary, two review authors (SB and TH) would have independently extracted data using a customised data extraction tool that was tested before use. We extracted no new data for this update. Contacting authors of studies was not necessary. We planned to resolve disagreements by consensus.

Assessment of risk of bias in included studies

One review author (SB) assessed the included trial using Cochrane's 'Risk of bias' tool as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). This tool measures risk of study bias with attention to randomisation, allocation, blinding of participants and personnel, blinding of outcome assessment, completeness of data, subsequent reporting of data, and any other potential risk of bias. Review author TH checked judgements. We planned to resolve disagreements by consensus.

Measures of treatment effect

We planned to present quantitative data for the outcomes listed in the inclusion criteria, when available and appropriate. For outcomes with dichotomous data, we planned to present risk ratios

(RRs) and 95% confidence intervals (CIs). For outcomes with continuous data, we planned to present mean differences (MDs) and 95% CIs.

Unit of analysis issues

We focused on the individual patient as the unit of analysis and identified no unit of analysis issues in the included study.

Dealing with missing data

We planned to contact the study authors first via email if contact information was available or by post to request any data that were missing. When these data were not available, we planned to conduct an intention-to-treat analysis. This was not required, as the included study provided a complete data set.

Assessment of heterogeneity

We planned to test heterogeneity between comparable trials using a standard Chi² test, and we considered results to be statistically significant at $P < 0.1$ after due consideration of the I^2 value. We did not need to do this as only one study was included in the review.

Assessment of reporting biases

We will test for publication bias using funnel plots if we identify sufficient trials in future updates.

Data synthesis

We planned to undertake meta-analysis of the results of comparable groups of trials using the fixed-effect model and 95% CIs. As pooling of data was not possible because we included only one study, we presented a narrative synthesis of study findings.

Subgroup analysis and investigation of heterogeneity

We planned to carry out separate outcome analyses to test the following hypotheses when data were available.

- Prosthetic rehabilitation is equally successful in males and females.
- Success does not depend on the duration and (or) intensity of prosthetic rehabilitation.
- Success does not depend on the setting in which prosthetic rehabilitation is delivered.
- Success does not depend on the level or type of supervision provided for prosthetic rehabilitation.

Sensitivity analysis

We planned to perform sensitivity analyses, when indicated and appropriate, to investigate the effects of allocation concealment, methodological quality, and intention-to-treat analysis. This was not possible as we included only one study.

'Summary of findings' table

As we included only one study, we created a narrative summary of findings table and included it in this review (Summary of findings for the main comparison). This comprised the primary outcomes of success and adverse effects (as described in Types of outcome measures) related to the effectiveness of prosthetic rehabilitation in older dysvascular unilateral transfemoral amputees. We presented the number of total participants for each outcome. We assessed the evidence for each outcome using the GRADE approach, which grades the quality of the evidence as high, moderate, low, or very low based on within-study risk of bias, directness of evidence, heterogeneity, precision of effect estimates, and risk of publication bias (Guyatt 2008).

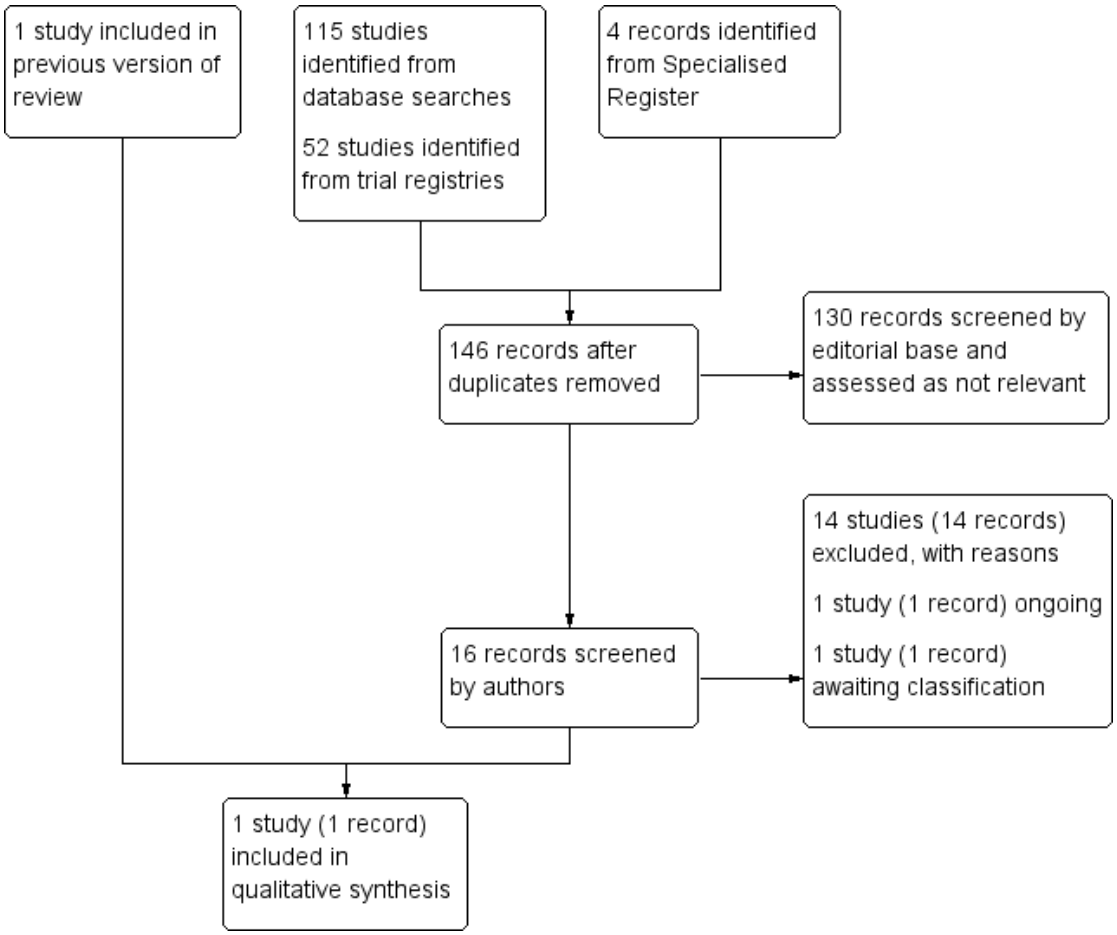
RESULTS

Description of studies

Results of the search

See Figure 1.

Figure 1. Study flow diagram.



For this update, we identified no new studies for inclusion. We excluded 14 new studies (Agrawal 2015; Chin 2016; Christiansen 2018; Hafner 2015; Imam 2015; Madsen 2017; Mandel 2016; Miller 2017; Morgan 2016; NCT03296904; NCT03376919; NCT03433300; Samitier 2016; Simanic 2015), identified one ongoing study (NCT01942798), and classed one study as awaiting classification (NCT03094208).

Included studies

One study met the inclusion criteria, and we included it in this review (Meikle 2003). This study was a cross-over randomised trial that tested the effects of adding three seemingly identical prosthetic weights (150 g vs 770 g vs 1625 g) in a randomised order to the prostheses of 10 amputees (Meikle 2003). All participants had undergone transfemoral amputation for vascular reasons. The mean age of participants was 65 years, although two participants were between 50 and 60 years of age. One participant was female.

All participants were community ambulators who were at least three months past their amputation and had similar activity levels. This study compared the effects of adding three different weights below the knee joint to each participant's prosthesis during a single session. The primary outcome measure was participant preference, which was based on the rank order of preference of the participant for the three different weights. Researchers interpreted this as equating to user satisfaction. The other main outcome measure of the trial was participant gait speed as measured by the Two-Minute Walk Test (2MWT).

Researchers also investigated participants' ability to identify the weight that had been added.

See the Characteristics of included studies table for summary details.

Excluded studies

We excluded a total of 18 studies (Agrawal 2015; Alexander 1978; Chin 2016; Christiansen 2018; Godfrey 1977; Hafner 2015; Imam 2015; Madsen 2017; Mandel 2016; Miller 2017; Morgan 2016; NCT03296904; NCT03376919; NCT03433300; Presern-Strukel 2000; Samitier 2016; Simanic 2015; Wong 2002). See the Characteristics of excluded studies table for summary details.

Ongoing studies

We identified one ongoing study (NCT01942798). See Characteristics of ongoing studies for further details.

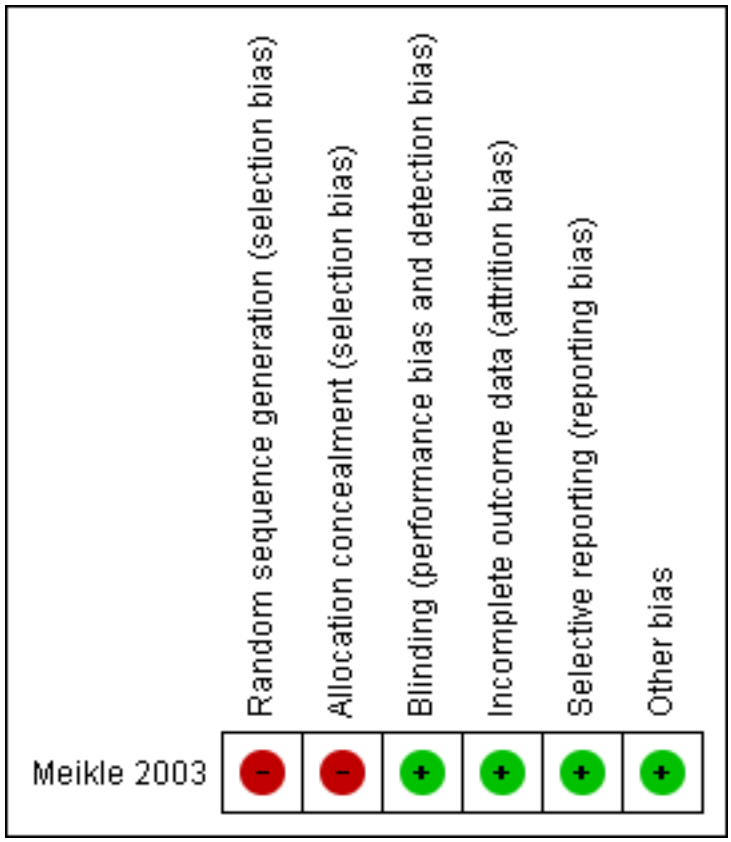
Studies awaiting classification

We classed one ongoing study as awaiting classification (NCT03094208). We could consider this study in the future if we were able to extract the data specifically for older adults. See Characteristics of studies awaiting classification for further details.

Risk of bias in included studies

See Figure 2.

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



We judged Meikle 2003 as being at high risk of bias for two domains (random sequence generation and allocation concealment) but at low risk of bias for the remaining four domains (blinding, incomplete outcome data, selective reporting, and any other bias). We have detailed this under Characteristics of included studies.

Allocation

Meikle 2003 used a randomised prospective cross-over design, with all participants receiving all of the interventions (i.e. differing weights added during their procedure). Study authors made no

mention of the method used for sequence allocation or allocation concealment of the interventions but stated that the interventions were applied to each participant in randomised order.

Blinding

Both participants and the assessor were blinded to the interventions (i.e. the weights added to the intervention), so we judged Meikle 2003 to be at low risk of performance and detection bias.

Incomplete outcome data

Meikle 2003 was a laboratory-based study with no follow-up. All participants completed the study.

Selective reporting

We found no evidence of selective reporting. Researchers included and reported on all outcome data.

Other potential sources of bias

We identified no other sources of bias.

Effects of interventions

See: **Summary of findings for the main comparison** Prosthetic rehabilitation for older dysvascular people after a unilateral transfemoral amputation

We included only one study (Meikle 2003).

Meikle 2003 reported the primary outcome 'success' in the form of weight preference. Of 10 participants in the trial, four preferred the placebo weight (150 g), five preferred 770 g, and one preferred 1625 g. Seven participants successfully ranked the weights from lightest to heaviest. Meikle 2003 reported that results showed no significant differences in participant gait speed when three different weights were added to the prosthesis.

The authors of this study used the term 'weight' rather than the more correct term 'mass' to describe additions to the prosthesis. We have retained the study authors' terminology in this review as it is more commonly used outside the scientific community.

Meikle 2003 reported no adverse effects.

Meikle 2003 did not report on the secondary outcomes listed under Types of outcome measures.

DISCUSSION

Summary of main results

The included trial was a short-term cross-over randomised trial that tested the effects of adding three seemingly identical prosthetic weights (150 g vs 770 g vs 1625 g) to the prostheses of 10 participants with unilateral dysvascular transfemoral amputation. Eight participants were over 60 years of age. Trial authors found that four participants preferred addition of the lightest weight (150 g), five preferred the middle weight (770 g), and one preferred the heaviest weight (1625 g). As acknowledged by trialists in Meikle 2003, the most notable feature of the study results is that they challenge any assumption that patients will always prefer the lightest prosthesis. Even this assertion must be seen in the context of the very short-term nature of the intervention (a few hours). Other issues also merit consideration. All interventions in this study were identical (weight added to a prosthesis) and were assessed as absolute values that were identical between participants. However, the body weight of the individual participants varied from 52 kg to 112 kg, thus the relative mass (weight) was different among participants. The pre-intervention weight of the prosthesis used by each participant also differed, from 2.8 to 4.2 kg. Therefore, in both cases, the perceived weight that was added to the prosthesis may have been different. Participants were permitted only five to 10 minutes to familiarise themselves with the new prosthetic weight before taking the walk test. It may have been that in this population, participants would have benefited from a longer period to acclimatise to the increased weight of the prosthetic limb. Participants used their own prosthetic limbs; all were endoskeletal prostheses with modified quadrilateral sockets and the same types of suspension. However, knee and foot prosthetic components were not standardised among participants. These factors - individually or in combination - could potentially confound the results of this study. Meikle 2003 trialists also acknowledge the difficulties of performing trials in a rehabilitation setting, where the question under study and interpretation of findings may not be quite as straightforward as they initially appear.

Certainly, research on the optimum weight of a prosthetic limb in this population would be useful. Such research should include assessment of the high energy expenditure costs that older unilateral dysvascular transfemoral amputees are known to experience in the presence of comorbidities. A much larger sample size, standardisation of prosthetic components, randomisation into separate treatment groups, longer trial duration, and appropriate follow-up may provide the necessary clinically relevant data on the optimum weight of a prosthetic limb for this population.

Overall completeness and applicability of evidence

We aimed to identify and summarise the evidence from randomised controlled trials evaluating prosthetic rehabilitation interventions for prosthetic ambulation following unilateral transfemoral or transgenicular amputation in older dysvascular people. The limited evidence identified and summarised has not suffi-

ciently addressed the expressed objectives of this review. Although the weight of an amputee's prosthetic limb is clinically important, particularly from the point of view of amputee satisfaction, the included study provided only minimal evidence of effect. Indeed, the small number of participants, limitations of the cross-over design, the short duration of the intervention, the laboratory nature of the trial, the absence of follow-up, and the limited nature of outcome assessment prevent such a trial from providing adequate evidence to inform the prescription of prosthetic limbs. We did not identify studies that evaluated the effectiveness of prosthetic rehabilitation interventions to improve prosthetic ambulation in this important subgroup of lower limb amputees.

Quality of the evidence

Only one randomised trial with 10 participants satisfied the eligibility criteria for this review (Meikle 2003). The overall quality of the evidence was very low. We downgraded the quality of the evidence owing to high risk of bias in relation to two domains (random sequence generation and allocation concealment), imprecision due to the small sample size, and indirectness, as the study fails to address the review question.

Older people with a unilateral transfemoral amputation are an increasingly important subgroup of amputees identified as having a low success rate with a prosthesis, in terms of functional mobility and usage. It is disappointing, therefore, that there is a paucity of good quality and reliable research evidence that can be used to inform clinical practice.

Potential biases in the review process

We used a systematic approach to our search for evidence. Study selection and data extraction methods followed those recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). The search was sufficiently broad to include both published and unpublished evidence and included relevant databases, handsearching, and contact with experts in the field. We placed no language restrictions on the searches nor on inclusion of studies. We are confident that we have included all available evidence in this field. The main limitation of this review is that we identified and summarised only one study of moderate quality.

Agreements and disagreements with other studies or reviews

We have found no other similar reviews dealing with this population for comparison with the findings of this review. Deficiency of evidence may also apply to other transfemoral amputee groups. We did identify a randomised controlled trial evaluating the feasibility of a Wii Fit intervention for improving walking in older adults with a lower limb amputation (Imam 2015). However this study included a mixed population of transtibial and transfemoral amputees with mixed causes of amputation. Investigators noted a medium effect favouring the Wii.n.Walk intervention group for the Two-Minute Walk Test. Results of this trial suggest that older lower limb amputees would benefit from larger randomised controlled trials conducted to determine the efficacy of the Wii as an intervention provided during prosthetic rehabilitation to improve walking in this group. We also identified one randomised controlled study investigating the effects of a therapeutic intervention during the prosthetic rehabilitation of young traumatic transfemoral amputees (Yigiter 2002). This trial found that proprioceptive neuromuscular facilitation was more effective than traditional training for gait and weight bearing in younger traumatic unilateral transfemoral amputees. Few high-quality studies have investigated the effectiveness of prosthetic rehabilitation in lower limb amputees of all ages and levels, with variable causation.

AUTHORS' CONCLUSIONS

Implications for practice

The limited evidence included in this review is insufficient to inform the choice of prosthetic rehabilitation, including the optimum weight of a prosthesis, after unilateral transfemoral amputation in older dysvascular people.

Implications for research

Most research in this area of clinical practice has been reported by cohort studies and has been based upon prognostic indicators of success. These have included psychological and cognitive aspects, comorbidities, functional abilities, compliance, and use of assessment tools. This is not enough to inform practice. Reliable evidence is urgently needed from high-quality and sufficiently powered randomised controlled trials exploring the success (e.g. user satisfaction based on comfort, cosmetic appearance, frequency of prosthetic use, satisfaction for purpose, levels of function, and independence) of key prosthetic rehabilitation interventions following transfemoral amputation in older dysvascular people. Research topic priorities informed by clinicians and amputees must be ascertained before a research programme can be set up to address important questions in this clinical area.

ACKNOWLEDGEMENTS

We would like to acknowledge the contributions of Jane Cumming, who was the lead author on the original review and subsequent updates. She conceived the review and designed the protocol alongside the co-review authors. She led the development and

running of search strategies, study selection, review of the included study, and production of drafts of the review.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Meikle 2003

Methods	Study design: single-centre, randomised, double-blind cross-over trial Exclusions post randomisation: none Losses to follow-up: none
Participants	Country: Canada Setting: community No. of participants: 10 Inclusion criteria: loss of limb due to PVD; over the age of 50; ambulant in the community for a minimum of 3 months since amputation; independent community ambulator with prosthesis with or without aids; ability to walk for 2 minutes consecutively Exclusion criteria: cognitive impairment sufficient to limit ability to participate. Of 12 participants who were eligible for the study, 2 refused to participate
Interventions	Single session assessment. Added weight to prosthetic limb below the knee: 150 g (placebo) vs 770 g vs 1625 g Duration: 1 day Follow-up: none - single assessment only
Outcomes	Primary: Two-Minute Walk Test Secondary: participant preference in terms of weight applied
Notes	No follow-up following the trial period

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "weights were applied in random order by a secondary investigator who was not involved in any of the data collection" Study authors made no mention of the method used to randomise the sequence of interventions
Allocation concealment (selection bias)	High risk	Quote: "weights were applied in random order by a secondary investigator who was not involved in any of the data collection" Study authors made no mention of the method used to conceal the allocation of interventions
Blinding (performance bias and detection bias) All outcomes	Low risk	Both participants and assessors were blinded to the interventions

Meikle 2003 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	All outcome data were reported and analysed.
Selective reporting (reporting bias)	Low risk	Review authors found no evidence of selective reporting of study data
Other bias	Low risk	Review authors noted no other sources of bias.

PVD: peripheral vascular disease

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

Study	Reason for exclusion
Agrawal 2015	Population did not include unilateral transfemoral amputees.
Alexander 1978	Participants did not meet the inclusion criteria. Experimental group included only 1 transfemoral amputee below the age of 60. Outcome measure selected was not used in prosthetic rehabilitation
Chin 2016	Wrong patient population: transtibial amputees
Christiansen 2018	Wrong intervention: study authors did not look at prosthetic rehabilitation
Godfrey 1977	Not a randomised or a quasi-randomised controlled trial
Hafner 2015	Wrong intervention: focused on the type of prosthetic component - not on rehabilitation
Imam 2015	Transfemoral and transtibial data were not supplied separately
Madsen 2017	Wrong study design: systematic review
Mandel 2016	Wrong patient population: transtibial amputees
Miller 2017	Wrong study design
Morgan 2016	Wrong intervention: study authors did not look at prosthetic rehabilitation
NCT03296904	Wrong intervention: focused on type of prosthetic component - not on rehabilitation
NCT03376919	Wrong intervention: focused on type of prosthetic component - not on rehabilitation
NCT03433300	Wrong intervention: focused on type of prosthetic component - not on rehabilitation

(*Continued*)

Presern-Strukel 2000	Study authors did not look at prosthetic rehabilitation
Samitier 2016	Wrong study design: quasi-experimental before-and-after study
Simanic 2015	Participants did not meet the inclusion criteria. Study population included individuals with diabetic gangrene, vascular disease, and trauma; transfemoral and transtibial data were not supplied separately
Wong 2002	Investigators provided a pre-prosthetic rehabilitation intervention that falls outside the scope of this review

Characteristics of studies awaiting assessment *[ordered by study ID]*

NCT03094208

Methods	Study name: The Effects of Dual Task Balance Training in Individuals With Above Knee Amputation Randomised controlled trial
Participants	Transfemoral amputees between 18 and 80 years of age
Interventions	Dual task balance training (muscle strengthening, weight transfer, dual task balance exercises, dual task gait exercises) vs traditional balance training (muscle strengthening, weight transfer, balance exercises, gait exercises) Training takes 4 weeks and is provided 3 days a week.
Outcomes	Gait speed (10-meter walk test) Gait analysis (footprint method) Cognition (Montreal Cognitive Assessment) Depression (Beck Depression inventory) Balance (1-leg stance test) Balance (4-square step test) Functional mobility (timed up and go test)
Notes	Study is ongoing. Study could be considered for inclusion in the future if we were able to extract data specifically for older adults

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

NCT01942798

Trial name or title	Study of Wii Fit to Enhance Walking in Older Adult Amputees
Methods	Randomised controlled trial
Participants	Unilateral transfemoral or transtibial amputees over the age of 50

NCT01942798 (*Continued*)

Interventions	Active comparator: cognitive games Wii Big Brain Academy Degree programme Participants will receive the intervention for 40-minute sessions, 3×/week for 4 weeks. Interventions will be administered as combination of onsite group training and individualised home-based training Experimental: Wii.N.Walk intervention Nintendo Wii Participants will receive the intervention for 40-minute sessions, 3×/week for 4 weeks. Interventions will be administered as combination of onsite group training and individualised home-based training
Outcomes	Mini Mental State Examination (MMSE) Two-Minute Walk Test (2MWT) Short Physical Performance Battery (SPPB) Walking While Talking Test (WWT) Activities-specific Balance Confidence (ABC) Scale Physical Activity Scale for the Elderly (PASE) Four-Square Step Test (FSST)
Starting date	April 2014
Contact information	Bita Imam; bita.imam@alumni.ubc.ca
Notes	

APPENDICES

Appendix 1. CENTRAL search strategy

Search run on Mon Jan 16 2017		
#1	MESH DESCRIPTOR Arteriosclerosis	868
#2	MESH DESCRIPTOR Arteriolosclerosis EXPLODE ALL TREES	0
#3	MESH DESCRIPTOR Arteriosclerosis Obliterans	71
#4	MESH DESCRIPTOR Atherosclerosis	619

(*Continued*)

#5	MESH DESCRIPTOR Arterial Occlusive Diseases	724
#6	MESH DESCRIPTOR Intermittent Claudication	712
#7	MESH DESCRIPTOR Ischemia	789
#8	MESH DESCRIPTOR Peripheral Vascular Diseases EXPLODE ALL TREES	2201
#9	(atherosclero* or arteriosclero* or PVD or PAOD or PAD):TI,AB,KY	9119
#10	((arter* or vascular or vein* or veno* or peripher*) near3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)):TI,AB,KY	7966
#11	(peripheral near3 dis*):TI,AB,KY	3371
#12	(claudic* or IC):TI,AB,KY	3063
#13	(isch* or CLI):TI,AB,KY	23713
#14	arteriopathic:TI,AB,KY	7
#15	dysvascular*:TI,AB,KY	10
#16	(leg near3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)):TI,AB,KY	95
#17	(limb near3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)):TI,AB,KY	145
#18	((lower near3 extrem*) near3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)):TI,AB,KY	77
#19	MESH DESCRIPTOR Leg EXPLODE ALL TREES WITH QUALIFIERS BS	1107
#20	MESH DESCRIPTOR Iliac Artery	144

(*Continued*)

#21	MESH DESCRIPTOR Popliteal Artery	278
#22	MESH DESCRIPTOR Femoral Artery	810
#23	MESH DESCRIPTOR Tibial Arteries	33
#24	(((femor* or iliac or popliteal or fempop* or crural or poplite* or infrapopliteal or inguinal or femdist* or inguinal or infrainquinal or tibial) near3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*))):TI,AB,KY	1157
#25	MESH DESCRIPTOR Gangrene EXPLODE ALL TREES	62
#26	MESH DESCRIPTOR Diabetic Angiopathies EXPLODE ALL TREES	2129
#27	gangren*:TI,AB,KY	307
#28	(diabet* near3 angio*):TI,AB,KY	1149
#29	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28	45998
#30	MESH DESCRIPTOR Amputation EXPLODE ALL TREES	313
#31	MESH DESCRIPTOR Amputees EXPLODE ALL TREES	81
#32	(leg near3 amput*):TI,AB,KY	115
#33	(extrem* near3 amput*):TI,AB,KY	75
#34	(limb near3 amput*):TI,AB,KY	199
#35	exarticulat*:TI,AB,KY	0
#36	disarticulat*:TI,AB,KY	17
#37	transgeni*:TI,AB,KY	171

(*Continued*)

#38	#30 OR #31 OR #32 OR #33 OR #34 OR # 35 OR #36 OR #37	792
#39	MESH DESCRIPTOR Artificial Limbs	108
#40	MESH DESCRIPTOR Joint Prosthesis EXPLODE ALL TREES	1612
#41	prosthe*:TI,AB,KY	9428
#42	(artificial near3 (leg or limb or low or extremity)):TI,AB,KY	25
#43	MESH DESCRIPTOR Rehabilitation EXPLODE ALL TREES	16901
#44	rehabilit*:TI,AB,KY	26625
#45	#39 OR #40 OR #41 OR #42 OR #43 OR # 44	45906
#46	#29 AND #38 AND #45	73
#47	* NOT SR-PVD:CC AND 28/02/2015 TO 28/02/2017:DL	157820
#48	#46 AND #47	8

Appendix 2. Trial registries searches

ClinicalTrials.gov
33 studies found for: transfemoral amputation
World Health Organization International Clinical Trials Registry Platform
8 records for 8 trials found for: transfemoral amputation
ISRCTN Register
No results found for "transfemoral amputation"

Appendix 3. Database searches June 2018

Source	Search strategy	Hits retrieved
CENTRAL via CRSO	#1 MESH DESCRIPTOR Arteriosclerosis 946 #2 MESH DESCRIPTOR Arteriolosclerosis EXPLODE ALL TREES 0 #3 MESH DESCRIPTOR Arteriosclerosis Obliter-	11

(*Continued*)

	ans 78 #4 MESH DESCRIPTOR Atherosclerosis 1055 #5 MESH DESCRIPTOR Arterial Occlusive Diseases 817 #6 MESH DESCRIPTOR Intermittent Claudication 821 #7 MESH DESCRIPTOR Ischemia 1526 #8 MESH DESCRIPTOR Peripheral Vascular Diseases 711 #9 (atherosclero* or arteriosclero* or PVD or PAOD or PAD):TI,AB,KY 11989 #10 ((arter* or vascular or vein* or veno* or peripher*) near3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)):TI,AB,KY 10474 #11 (peripheral near3 dis*):TI,AB,KY 4773 #12 (claudic* or IC):TI,AB,KY 4031 #13 (isch* or CLI):TI,AB,KY 31615 #14 arteriopathic:TI,AB,KY 7 #15 dysvascular*:TI,AB,KY 20 #16 (leg near3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)):TI,AB,KY 128 #17 (limb near3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)):TI,AB,KY 213 #18 (lower near3 extrem*) near3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*) 107 #19 MESH DESCRIPTOR Leg 2788 #20 MESH DESCRIPTOR Iliac Artery 158 #21 MESH DESCRIPTOR Popliteal Artery 300 #22 MESH DESCRIPTOR Femoral Artery 896 #23 MESH DESCRIPTOR Tibial Arteries 37 #24 ((femor* or iliac or popliteal or fempop* or crural or poplite* or infrapopliteal or inguinal or femdist* or inguinal or infrainquinal or tibial) near3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)):TI,AB,KY 1694 #25 MESH DESCRIPTOR Gangrene EXPLODE ALL TREES 67 #26 MESH DESCRIPTOR Diabetic Angiopathies EXPLODE ALL TREES 2802 #27 gangren*:TI,AB,KY 391 #28 (diabet* near3 angio*):TI,AB,KY 1249 #29 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #	

(*Continued*)

	7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR # 19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 60581 #30 MESH DESCRIPTOR Amputation EXPLODE ALL TREES 360 #31 MESH DESCRIPTOR Amputees EXPLODE ALL TREES 97 #32 (leg near3 amput*):TI,AB,KY 154 #33 (extrem* near3 amput*):TI,AB,KY 116 #34 exarticulat*:TI,AB,KY 0 #35 disarticulat*:TI,AB,KY 24 #36 transgeni*:TI,AB,KY 213 #37 (limb near3 amput*):TI,AB,KY 343 #38 #30 OR #31 OR #32 OR #33 OR #34 OR # 35 OR #36 OR #37 1075 #39 MESH DESCRIPTOR Artificial Limbs 127 #40 MESH DESCRIPTOR Joint Prosthesis EXPLODE ALL TREES 1740 #41 prosthe*:TI,AB,KY 11543 #42 (artificial near3 (leg or limb or low or extremity)):TI,AB,KY 28 #43 MESH DESCRIPTOR Rehabilitation EXPLODE ALL TREES 29098 #44 rehabilit*:TI,AB,KY 34988 #45 #39 OR #40 OR #41 OR #42 OR #43 OR # 44 64511 #46 #29 AND #38 AND #45 125 #47 01/01/2017 TO 14/06/2018:CD 285491 #48 #46 AND #47 11	
Clinicaltrials.gov	transfemoral amputation | Start date on or after 01/01/2017 | Last update posted on or before 06/15/2018	9
ICTRP Search Portal	transfemoral amputation | Start date on or after 01/01/2017 | Last update posted on or before 06/15/2018	2
MEDLINE	1 ARTERIOSCLEROSIS/ 56445 2 exp ARTERIOLOSCLEROSIS/ 150 3 Arteriosclerosis Obliterans/ 3973 4 ATHEROSCLEROSIS/ 31164 5 Arterial Occlusive Diseases/ 26484 6 Intermittent Claudication/ 7594 7 ISCHEMIA/ 47531 8 exp Peripheral Vascular Diseases/ 50035 9 (atherosclero* or arteriosclero* or PVD or PAOD or PAD).ti,ab. 171401 10 ((arter* or vascular or vein* or veno* or peripher*)	31

(*Continued*)

	adj3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)).ti,ab. 142921 11 (peripheral adj3 dis*).ti,ab. 37792 12 (claudic* or IC).ti,ab. 62023 13 (isch* or CLI).ti,ab. 345828 14 arteriopathic.ti,ab. 162 15 dysvascular*.ti,ab. 216 16 (leg adj3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)).ti,ab. 707 17 (limb adj3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)).ti,ab. 1805 18 (lower adj3 extrem* adj3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)).ti,ab. 1480 19 exp LEG/su [Surgery] 5038 20 Iliac Artery/ 13352 21 Popliteal Artery/ 8964 22 Femoral Artery/ 27058 23 Tibial Arteries/ 1484 24 ((femor* or iliac or popliteal or fempop* or crural or poplite* or infrapopliteal or inguinal or femdist* or inguinal or infrainquinal or tibial) adj3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)).ti,ab. 9685 25 exp GANGRENE/ 7947 26 exp Diabetic Angiopathies/ 45387 27 gangren*.ti,ab. 15698 28 (diabet* adj3 angio*).ti,ab. 2405 29 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 838651 30 exp AMPUTATION/ 19780 31 exp AMPUTEES/ 3073 32 (leg adj3 amput*).ti,ab. 1202 33 (extrem* adj3 amput*).ti,ab. 2761 34 (limb adj3 amput*).ti,ab. 5211 35 exarticulat*.ti,ab. 218 36 disarticulat*.ti,ab. 1467 37 transgeni*.ti,ab. 115853 38 or/30-37 143335 39 Artificial Limbs/ 6234 40 exp Joint Prosthesis/ 40671	

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	41 prosthe*.ti,ab. 111922 42 (artificial adj3 (leg or limb or low or extremity)).ti,ab. 616 43 exp REHABILITATION/ 274914 44 rehabilit*.ti,ab. 144455 45 or/39-44 504799 46 29 and 38 and 45 1738 47 randomized controlled trial.pt. 464667 48 controlled clinical trial.pt. 92510 49 randomized.ab. 415972 50 placebo.ab. 190292 51 drug therapy.fs. 2030526 52 randomly.ab. 292859 53 trial.ab. 433053 54 groups.ab. 1809780 55 or/47-54 4235260 56 exp animals/ not humans.sh. 4474870 57 55 not 56 3661363 58 46 and 57 257 59 (2017* or 2018*).ed. 1446470 60 58 and 59 31	
Embase	1 arteriosclerosis/ 33957 2 exp arteriolosclerosis/ 595 3 peripheral occlusive artery disease/ 33159 4 atherosclerosis/ 136005 5 peripheral occlusive artery disease/ 33159 6 intermittent claudication/ 9753 7 ischemia/ 76563 8 exp peripheral vascular disease/ 1657628 9 (atherosclero* or arteriosclero* or PVD or PAOD or PAD).ti,ab. 235882 10 ((arter* or vascular or vein* or veno* or peripher*) adj3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)).ti,ab. 196809 11 (peripheral adj3 dis*).ti,ab. 54205 12 (claudic* or IC).ti,ab. 62544 13 (isch* or CLI).ti,ab. 500348 14 arteriopathic.ti,ab. 205 15 dysvascular*.ti,ab. 239 16 (leg adj3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)).ti,ab. 987 17 (limb adj3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)).ti,ab. 2660 18 (lower near3 extrem* adj3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or	51

(*Continued*)

	lesio* or block* or harden* or stiffen* or obliter*)).ti,ab. 0 19 exp leg/su [Surgery] 8660 20 iliac artery/ 14573 21 popliteal artery/ 8505 22 femoral artery/ 30203 23 tibial artery/ 2623 24 ((femor* or iliac or popliteal or fempop* or crural or poplite* or infrapopliteal or inguinal or femdist* or inguinal or infrainquinal or tibial) adj3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)).ti,ab. 14004 25 exp gangrene/ 10875 26 exp diabetic angiopathy/ 12013 27 gangren*.ti,ab. 18519 28 (diabet* adj3 angio*).ti,ab. 3407 29 or/1-28 2052432 30 exp amputation/ 43014 31 exp amputee/ 523 32 (leg adj3 amput*).ti,ab. 1452 33 (leg adj3 amput*).ti,ab. 1452 34 (limb adj3 amput*).ti,ab. 6843 35 exarticulat*.ti,ab. 247 36 disarticulat*.ti,ab. 1733 37 transgeni*.ti,ab. 147153 38 or/30-37 193556 39 limb prosthesis/ 3285 40 exp joint prosthesis/ 62957 41 prosthe*.ti,ab. 132403 42 (artificial adj3 (leg or limb or low or extremity)).ti,ab. 726 43 exp rehabilitation/ 346472 44 rehabilit*.ti,ab. 203634 45 or/39-44 621858 46 29 and 38 and 45 2196 47 randomized controlled trial/ 506330 48 controlled clinical trial/ 460965 49 random$.ti,ab. 1311150 50 randomization/ 78484 51 intermethod comparison/ 235763 52 placebo.ti,ab. 273660 53 (compare or compared or comparison).ti. 470243 54 ((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab. 1755056 55 (open adj label).ti,ab. 64646 56 ((double or single or doubly or singly) adj (blind	

(*Continued*)

	or blinded or blindly)).ti,ab. 209275 57 double blind procedure/ 150748 58 parallel group$1.ti,ab. 21840 59 (crossover or cross over).ti,ab. 93056 60 ((assign$ or match or matched or allocation) adj5 (alternate or group$1 or intervention$1 or patient$1 or subject$1 or participant$1)).ti,ab. 283339 61 (assigned or allocated).ti,ab. 332397 62 (controlled adj7 (study or design or trial)).ti,ab. 295531 63 (volunteer or volunteers).ti,ab. 224702 64 trial.ti. 251606 65 or/47-64 4042810 66 46 and 65 300 67 (2017* or 2018*).em. 3577308 68 66 and 67 51 69 from 68 keep 1-51 51	
CINAHL	S60 S58 AND S59 14 S59 EM 2017 OR EM 2018 363,970 S58 S44 AND S57 163 S57 S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 341,446 S56 MH "Placebos" 8,351 S55 MH "Random Assignment" 38,557 S54 MH "Single-Blind Studies" or MH "Double-Blind Studies" or MH "Triple-Blind Studies" 32,692 S53 MH "Crossover Design" 11,188 S52 MH "Factorial Design" 919 S51 MH "Clinical Trials" 93,051 S50 TX "multi-centre study" OR "multi-center study" OR "multicentre study" OR "multicenter study" OR "multi-site study" 4,468 S49 TX crossover OR "cross-over" 14,532 S48 AB placebo* 28,242 S47 TX random* 218,592 S46 TX trial* 249,926 S45 TX "latin square" 142 S44 S28 AND S36 AND S43 540 S43 (TX rehabilit*:) AND (S37 OR S38 OR S39 OR S40 OR S41 OR S42) 187,865 S42 TX rehabilit*: 187,865 S41 (MH "Rehabilitation+") 186,200 S40 TX artificial n3 (leg or limb or low or extremity) 253 S39 TX prosthe* 34,777 S38 (MH "Joint Prosthesis+") 4,078 S37 (MH "Limb Prosthesis") 1,376	14

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	S36 S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 9,167 S35 TX transgeni* 1,964 S34 TX disarticulat* 338 S33 TX exarticulat* 7 S32 TX extrem* n3 amput* 1,069 S31 TX leg n3 amput* 317 S30 (MH "Amputees") 1,940 S29 (MH "Amputation+") 5,215 S28 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 95,405 S27 TX diabet* n3 angio* 1,748 S26 TX gangren* 1,314 S25 (MH "Diabetic Angiopathies+") 9,730 S24 (MH "Gangrene") 365 S23 TX (femor* or iliac or popliteal or fempop* or crural or poplite* or infrapopliteal or inguinal or femdist* or inguinal or infrainquinal or tibial) n3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*) 1,102 S22 (MH "Tibial Arteries") 146 S21 (MH "Femoral Artery") 1,208 S20 (MH "Popliteal Artery") 363 S19 (MH "Iliac Artery") 460 S18 (MH "Leg/SU") 258 S17 TX (lower n3 extrem*) n3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*) 122 S16 TX limb n3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter* 274 S15 TX leg n3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*) 123 S14 TX dysvascular* 172 S13 TX arteriopathic 10 S12 TX isch* or CLI 39,373 S11 TX claudic* or IC 5,850 S10 TX peripheral n3 dis* 9,241 S9 TX (arter* or vascular or vein* or veno* or peripher*) n3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*) 12,648	

(*Continued*)

	S8 TX atherosclero* or arteriosclero* or PVD or PAOD or PAD 26,344 S7 (MH "Peripheral Vascular Diseases+") 10,398 S6 (MH "Ischemia") 3,367 S5 (MH "Intermittent Claudication") 852 S4 (MH "Arterial Occlusive Diseases") 1,607 S3 (MH "Arteriosclerosis") 4,829 S2 (MH "Arteriosclerosis+") 17,789 S1 (MH "Arteriosclerosis") 4,829	
AMED	1 arteriosclerosis/ 78 2 atherosclerosis/ 221 3 intermittent claudication/ 73 4 ischemia/ 263 5 exp peripheral vascular disease/ 118 6 ((arter* or vascular or vein* or veno* or peripher*) adj3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)).ti,ab. 458 7 (peripheral adj3 dis*).ti,ab. 435 8 (claudic* or IC).ti,ab. 1024 9 (isch* or CLI).ti,ab. 1666 10 arteriopathic.ti,ab. 1 11 dysvascular*.ti,ab. 57 12 (leg adj3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)).ti,ab. 21 13 (limb adj3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)).ti,ab. 32 14 (lower near3 extrem* adj3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)).ti,ab. 0 15 [exp leg/su [Surgery]] 0 16 ((femor* or iliac or popliteal or fempop* or crural or poplite* or infrapopliteal or inguinal or femdist* or inguinal or infrainquinal or tibial) adj3 (occlus* or reocclus* or re-occlus* or steno* or restenos* or obstruct* or lesio* or block* or harden* or stiffen* or obliter*)).ti,ab. 109 17 gangren*.ti,ab. 86 18 (diabet* adj3 angio*).ti,ab. 14 19 or/1-18 3850 20 exp Amputation/ 2066 21 (leg adj3 amput*).ti,ab. 81 22 (extrem* adj3 amput*).ti,ab. 205 23 (limb adj3 amput*).ti,ab. 684 24 exarticulat*.ti,ab. 0	0

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	25 disarticulat*.ti,ab. 131 26 transgeni*.ti,ab. 48 27 or/20-26 2323 28 Artificial limbs/ 338 29 exp Joint prosthesis/ 639 30 prosthe*.ti,ab. 2628 31 (artificial adj3 (leg or limb or low or extremity)).ti,ab. 31 32 exp Rehabilitation/ 54176 33 rehabilit*.ti,ab. 25009 34 or/28-33 62822 35 19 and 27 and 34 118 36 exp CLINICAL TRIALS/ 3749 37 RANDOM ALLOCATION/ 314 38 DOUBLE BLIND METHOD/ 657 39 Clinical trial.pt. 1211 40 (clinic* adj trial*).tw. 5381 41 ((singl* or doubl* or trebl* or tripl*) adj (blind* or mask*)).tw. 2833 42 PLACEBOS/ 586 43 placebo*.tw. 3102 44 random*.tw. 17520 45 PROSPECTIVE STUDIES/ 1097 46 or/37-45 22515 47 35 and 46 7 48 ("2017" or "2018").yr. 2075 49 47 and 48 0	

WHAT'S NEW

Date	Event	Description
16 August 2018	New citation required but conclusions have not changed	New searches run. No new studies included, 14 new studies excluded, one study ongoing, and one study awaiting classification. No changes to conclusions
16 August 2018	New search has been performed	New searches run. No new studies included, 14 new studies excluded, one study ongoing, and one study awaiting classification. Review amended to reflect current Cochrane standards. 'Summary of findings' table added

HISTORY

Protocol first published: Issue 2, 2005

Review first published: Issue 4, 2006

Date	Event	Description
11 December 2014	New search has been performed	New searches run. No new included studies. Minor text changes made
11 December 2014	New citation required but conclusions have not changed	New searches run. No new included studies. No changes to conclusions
4 October 2010	New search has been performed	CENTRAL search amended and re-run. No new trials found
28 October 2008	New search has been performed	Searches re-run. No new trials found
23 May 2008	Amended	Review converted to new review format
30 April 2007	Amended	Minor copyedits made to correct incomplete last sentence in Authors' conclusions and to correct Acknowledgements. Search dates updated. No changes to conclusions

CONTRIBUTIONS OF AUTHORS

SB performed previous work fundamental to the update, assessed articles for inclusion, assessed risk of bias, wrote the update, and served as guarantor of the review update.

TH performed previous work fundamental to the update, assessed articles for inclusion, and provided general advice during preparation of the update.

DECLARATIONS OF INTEREST

SB has declared that his Institution received a small grant from the Physiotherapy Research Fund for some expenses associated with undertaking this review.

TH was employed by Glasgow Caledonian University until March 2018, is an Honorary Professor at University of Manchester, a Visiting Professor at Hong Kong Polytechnic University, is a member of the Governing Board of Cochrane and City of Glasgow College and former Trustee of the Picker Institute Europe and has undertaken consultancy for Brunel University, Cardiff University, Kingston University, University of Central Lancashire, University of Plymouth and Edward Healthcare.

SOURCES OF SUPPORT

Internal sources

- University of Teesside, UK.
- Glasgow Caledonian University, Glasgow, UK.

External sources

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

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

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

For this update, we have assessed the included study for bias by using Cochrane's 'Risk of bias' tool as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We have updated additional methods sections to reflect current Cochrane standards and have added a 'Summary of findings' table.

INDEX TERMS

Medical Subject Headings (MeSH)

Amputation [methods; *rehabilitation]; Artificial Limbs [*psychology]; Femur [*surgery]; Leg [blood supply; surgery]; Patient Satisfaction; Randomized Controlled Trials as Topic

MeSH check words

Aged; Humans; Middle Aged