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[Intervention Review]

Prescription of prosthetic ankle-foot mechanisms after lower limb amputation

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ABSTRACT

Background

A prosthesis can be divided into several components: the prosthetic socket; the prosthetic ankle-foot mechanism; and for higher levels of amputation, the prosthetic knee. This review focuses on the prosthetic ankle-foot mechanism, which forms an important part of the prosthesis in terms of mobility. A correct prosthetic prescription can be derived by matching the functional abilities of the individual with a lower limb amputation with the technical and functional aspects of the various prosthetic ankle-foot mechanisms. However, there seems to be no clear clinical consensus on the precise prescription criteria for the various prosthetic ankle-foot mechanisms in relation to the functional abilities of individuals with a lower limb amputation.

Objectives

To obtain information about aspects of prosthetic ankle-foot mechanisms and daily functioning of individuals with a lower limb prosthesis, for appropriate prosthetic prescription criteria.

Search methods

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (April 2006), the Cochrane Central Register of Controlled Trials (*The Cochrane Library* 2006, Issue 2), MEDLINE (1966 to April 2006), EMBASE (1983 to April 2006), CINAHL (1982 to April 2006), AMED (Allied and Complimentary Medicine) (1985 to April 2006), and reference lists of articles. No language restrictions were applied.

Selection criteria

All randomised controlled trials and quasi-randomised controlled trials comparing different ankle foot mechanisms for lower limb amputation in adults. No language restrictions were applied.

Data collection and analysis

Two review authors independently identified potential articles from the literature search. Methodological quality was assessed using a checklist comprising 13 criteria. The reviewers extracted data using pre-defined extraction forms.

Main results

Twenty-six trials were included, with a total of 245 participants. The numbers of participants in the included trials ranged from three to sixteen. The methodological quality was moderate. Only one study was of high quality. All included studies used cross-over designs allowing sufficient control for confounding.

In individuals with a transtibial amputation, there seems to be a small tendency towards a greater stride length when walking with the Flex-foot in comparison to the SACH (solid-ankle cushioned heel) foot. When walking speed was increased, the energy cost was lower. In high activity individuals with a transfemoral amputation, there is limited evidence for the superiority of the Flex foot during level walking compared with the SACH foot in respect of energy cost and gait efficiency.

Authors' conclusions

There is insufficient evidence from high quality comparative studies for the overall superiority of any individual type of prosthetic ankle-foot mechanism, although there is a small trend towards the Flex-foot in comparison with the SACH foot for greater stride length and lower energy cost in individuals with a transtibial amputation, and improved gait efficiency and lower energy cost in high activity individuals with a transfemoral amputation. In prescribing prosthetic-ankle foot mechanisms for individuals with a lower limb amputation, practitioners should take into account availability, patient functional needs, the type of knee mechanism to be prescribed and the inter-relationship with ankle-foot mechanisms, and cost.

PLAIN LANGUAGE SUMMARY

There is not enough evidence to establish precise criteria for the prescription of prosthetic ankle-foot mechanisms in individuals with a lower limb amputation.

There are many different prosthetic ankle-foot mechanisms available. When prescribing a prosthesis, the goal is to help individuals with a lower limb amputation return to their place in society, participating in activities that are important to them. This means finding a prosthesis that is appropriate for their level of activity, ability and weight.

In high activity individuals with a transfemoral amputation, there is limited evidence for the superiority of the Flex foot during level walking compared with the solid-ankle cushioned heel (SACH) foot in respect of energy cost and, gait efficiency. This benefit has only been confirmed in individuals with a transtibial amputation during decline and incline walking and increased walking speeds. In prescribing prosthetic-ankle foot mechanisms for individuals with a lower limb amputation, practitioners should take into account availability, patient functional needs, the type of knee mechanism to be prescribed and the inter-relationship with ankle-foot mechanisms, and cost.

BACKGROUND

Prosthetic prescription for individuals with a lower limb amputation is primarily based on empirical knowledge. Many options are available for different prosthetic components; however, prescription criteria are based mainly on subjective experiences of physicians, therapists, and prosthetists (Goh 1984; Menard 1992). On the other hand, third-party payers frequently require justification for purchasing costly prostheses (Menard 1992). Also, clarity for the customer is required since quality of care is becoming more important.

In the ideal situation, prosthetic prescription is based on adjusting the mechanical characteristics of a prosthesis to the functional needs of the prosthesis user (Cortes 1997), yet no clinical guidelines seem to be available for this use. The development of scientifically based clinical guidelines is a way of making health care more consistent and efficient and diminishes the gap between what clinicians do and what scientific evidence supports. A systematic literature review is the first step in clinical guideline development. It may also highlight knowledge gaps in the existing evidence (Woolf 1999).

To our knowledge, no scientifically based guidelines for lower-limb prosthetic prescription exist. Also, no consensus seems to

exist among different professionals with regard to the criteria for selecting prosthetic components related to the functional abilities and needs of patients. In this perspective, we have decided to develop clinical guidelines for lower limb prosthetic prescription in order to obtain transparency and consensus among clinicians, manufacturers and insurance companies. The first step is to obtain explicit knowledge from the literature. For this purpose, the types of studies we are interested in are studies addressing motor performance and/or daily functioning of individuals with a lower limb amputation. These studies focus on subjective findings, energy expenditure, or gait parameters. In view of clinical guideline development these studies are considered most relevant for prosthetic prescription. Hence, this review will be restricted to these clinically oriented studies.

OBJECTIVES

The aim of this review was to obtain information about aspects of prosthetic ankle-foot mechanisms and daily functioning of adult individuals with a lower limb amputation. This information should provide an objective starting point for further development of consensus-based criteria for prosthetic prescription.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials and quasi-randomised controlled trials comparing different prosthetic devices for lower limb amputation in adults.

Types of participants

All adult (18-80 years of age) transfemoral, through-knee, and transtibial individuals with dysvascular, traumatic, congenital, or oncologic amputations. Because amputation levels other than these require individual prescription, these amputation levels (e.g. hip disarticulation or toe amputations) are not included in this review. There were no race or gender restrictions, or restrictions on setting.

Types of interventions

Any trials which compare the ankle-foot mechanisms currently in use such as SACH-feet, Flex-feet, Seattle-feet, Single-Axis feet. Trials investigating amputation techniques or early prosthetic fitting (i.e. use of a temporary prosthesis prior to the permanent prosthesis) were excluded.

Types of outcome measures

Motor performance and activities of daily living (ADL) functioning are important for prosthetic prescription, therefore data were sought for the following outcome measures:
1. Subjective findings: preference, satisfaction, Borg-scale, ease of walking, outcome of questionnaires (Prosthesis Evaluation Questionnaire, Prosthetic Profile of the Amputee, Locomotor Capabilities Index, Sickness Impact Profile, Nottingham Health Profile, Reintegration to Normal Living)
2. Energy expenditure: oxygen consumption, heart rate
3. Stride characteristics: walking speed, walking distance, stride length, step length, stride time, cadence, stance phase duration, swing phase duration
4. Kinetic parameters: ground reaction force
5. Kinematic parameters: joint motion (ankle dorsiflexion, ankle plantar flexion, knee flexion and extension, hip flexion and extension)

Search methods for identification of studies

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register of trials (April 2006), the Cochrane Central Register of Controlled Trials (*The Cochrane Library* 2006, Issue 2), MEDLINE (1966 to April 2006), EMBASE (1983 to April 2006), CINAHL (1982 to April 2006), AMED (Allied and Complimentary Medicine) (1985 to April 2006), and reference lists of articles. No language restrictions were applied.
The current search strategy for MEDLINE (OVID Web 2003 to April 2006) and the previous MEDLINE search strategy (Silverplatter 1966 to April 2003) are shown in Appendix 1. The subject specific part of these strategies were combined with a modification of the optimal trial search strategy (McDonald 2002). The MEDLINE strategy was modified for use in EMBASE (OVID Web; Appendix 2), *The Cochrane Library* (Wiley InterScience; Appendix 3), CINAHL (OVID Web; Appendix 4) and AMED (OVID Web; Appendix 5).

Data collection and analysis

Selection of studies
Two review authors independently assessed the abstracts of all studies identified by the initial search and excluded non-relevant studies. Full text articles were obtained for any studies with unclear methodology or when abstracts were not available. Disagreement on inclusion was resolved by consulting a third reviewer. Full text articles were obtained for any studies which passed the inclusion criteria as described above.
Study quality
Methodological quality was assessed using a checklist comprising 13 criteria. This checklist was based on two existing criteria lists for quality assessment (Tulder 1997; Verhagen 1998), which were

originally developed to evaluate randomised controlled trials. Each criterion was scored according to three levels: no = '0', yes = '1' or not applicable = 'NA'. The selected studies were analysed by two review authors and differences resolved by discussion.

Selection of patients

A1: Adequacy of description of inclusion and exclusion criteria. This criterion tested whether the patient sample was sufficiently defined using selection criteria. At least three of the following descriptives were required: age, level of amputation, reason for amputation, activity level of the participant, time since onset, stump condition, comorbidity, and sex.

A2: Homogeneity. The homogeneity of the study sample was assessed, in relation to activity level, age and reason for amputation. For the purpose of this review, the activity level of the investigated participants should be similar. In case the activity level of the individuals with a lower limb amputation was not described, at least an indication of the level of amputation, the reason for amputation, and the age of the participants was required to assess the activity level of the individuals with a lower limb amputation. If the study sample was a heterogeneous population, an adequate stratification of the outcome parameters was required.

A3: Prognostic comparability. In the case of a within-subject design, groups are comparable at baseline by definition. The participants studied should be comparable for possible confounding factors such as time since amputation, time since first walking with the prosthesis, unilateral amputation, prosthesis experience, stump condition (completely healed stump, residual limb stump volume, good shaped stump free from skin problems, suture defects or hypertrophic scars, no residual limb pain, swelling or pressure sores), sound limb condition, physical condition (not suffering from any concurrent illness, no history of lower extremity joint dysfunction of the non-amputated leg, no concurrent painful conditions that might affect the gait pattern, no major gait deviations, an associated handicap that might restrict walking ability, the need to use technical aids (walking sticks), intercurrent medical problems liable to modify respiratory gaseous exchanges, addiction to tobacco, presence or absence of diabetes mellitus, peripheral or central neurological disease affecting walking, lower-limb articular or pre-articular damage liable to cause walking-restricting pains, no coexisting neurologic or musculoskeletal disorders that interfere with walking).

A4: Randomisation. In randomised controlled studies, an adequate randomisation procedure should have been followed. If the randomisation procedure was described and the procedure would exclude bias, this criterion was scored as '2'. In within-subject designs, the internal validity does not depend on the randomisation as in randomised controlled trials (Piantadosi 1997).

Intervention

B5: Experimental intervention. The measurements of the experimental intervention should be given explicitly in such detail that it is possible to perform a duplicate study as described.

B6: Co-interventions. This criterion tested whether co-interventions were avoided or that co-interventions were comparable in the study groups.

B7: Blinding. The outcome assessor had to be blinded to the intervention. In most studies investigating prosthetic components, it is impossible to blind the patients.

B8: Timing of the measurement. This criterion pertained to the moment that the study was performed in relation to the time participants were able to adapt to the intervention. An adequate adaptation period was required.

B9: Outcome measures. The outcome variables should be adequate in relation to the purpose of the study and they should have been applied with a standardised protocol.

Statistical validity

C10: Drop-outs. The number of drop-outs and the reason for drop-outs had to be sufficiently reported. A drop-out rate of more than 20 per cent was considered unacceptable.

C11: Sample size. The sample size (n) in relation to the number of independent variables (K) was adequate if the ratio n:K exceeded 10:1.

C12: Intention-to-treat. Intention-to-treat analysis should be assessed in the case of drop-outs.

C13: Data presentation. This criterion required that point estimates and measures of variability were presented for the primary outcome measures.

Best-evidence synthesis

In relation to the purpose of our review, it was required that the included studies should control for selection bias and measurement bias. Therefore, only the studies in which the total score of the A criteria and B criteria was six points or more (out of a possible nine points) were used in the best-evidence synthesis. Studies were classified as A if the total score of all criteria was 11 points or more, and included a positive score for blinded outcome assessment (criterion B7) and timing of the measurement (criterion B8). Studies were classified as B if the total score was between six and 10 points, including a positive score for timing of the measurement (criterion B8). Studies were classified C studies if the total score of the A criteria and B criteria was at least than six points, but with an invalid score on the criteria B7 and B8.

In summary

A grade: 11 points or more, including six points out of the A and B criteria, which must include B7 and B8;

B grade: between six and 10 points, including six points out of the A and B criteria, which must include B8;

C grade: Studies with a total score of at least 6 points out of the A and B criteria with an invalid score on the criteria B7 and B8.

Data extraction

Data were extracted from all relevant studies independently by two reviewers (HL, CH) and entered into RevMan (RevMan 2003). Disagreements were resolved by discussion. Where possible and necessary, attempts were made to secure missing data from the authors.

Data analysis

Due to the study design of the included studies it was impossible to attempt to pool the results of the included studies in this review, due to:

- The study populations of all the different trials were heterogeneous, because of the difference in the level of amputation, the cause of amputation, and activity level of the individuals with a lower limb amputation
- There were a lot of different interventions; in 26 trials 19 prosthetic ankle-foot mechanisms were investigated
- There were a lot of different outcome parameters, measured in different ways.

Therefore, the data were not pooled but the results of the individual studies were reported in their groups of outcome parameters.

RESULTS

Description of studies

Results of the search

The searches resulted in the identification of 348 references. After further review of the abstract and keywords, both review authors considered 37 studies to be potentially eligible for review.

Included studies

All of the included studies were fully reported in English language journals. Details of the methods, participants, interventions and outcome measures of individual trials are provided in the 'Characteristics of included studies'.

Design

No classical RCTs were identified but all included studies used cross-over designs allowing sufficient control for confounding. All the included studies used a single-arm cross-over within-subject design, so that no randomisation of participants across different groups took place.

Participants

The numbers of participants in the included trials ranged from 3 to 16. In most studies, participants wore prostheses that allowed interchange of the foot component. The numbers of participants in the included trials ranged from three to sixteen. The participants' lower extremity was amputated for vascular, traumatic or oncological reason. Exclusion of participants with stump problems was reported in 12 studies.

Interventions

Several different prosthetic ankle-foot mechanisms used in the included studies: SACH-foot; Flex-foot; SAFE II; Seattle Lightfoot; Quantum foot; Carbon Copy II; Multiflex foot; Energy-storing Proteor foot; Single-axis foot; Greissinger Dynamic; Re-Flex VSP; Multiple Axis; Otto Bock Multi Axial; Otto Bock Lager; Otto Bock Dynamic Pro; Hanger Quantum; Sten foot; C-Walk.

Outcomes

Only four studies reported subjective findings as outcome measures. Casillas 1995 developed a satisfaction index; Underwood 2004 asked their subjects to rate on a scale of 1-10; MacFarlane 1991 used the Borg-scale was used; and in Postema 1994, a questionnaire was composed to obtain the preference of the participants. Furthermore, all the studies reported one of the other outcome measures of interest (energy expenditure, stride characteristics, kinetic parameters, or kinematic parameters).

Excluded studies

Eleven studies did not meet the inclusion criteria (Alaranta 1991; Arya 1995; Hayden 2000; James 1986; Mizuno 1992; Nyska 2002; Torburn 1994; Wagner 1987; vd Water 1998; Wirta 1991; Yack 1999) and were excluded (*see* the 'Characteristics of excluded studies'). An important reason for excluding these studies was that the selection of the study sample was poorly described.

In addition, several identified references reported on studies already included in the review (Culham 1984; Hsu 1999; MacFarlane 1991; MacFarlane 1997; Postema 1994).

Risk of bias in included studies

On the whole, the methodological quality of the included studies was moderate with the majority of the studies attaining an overall grade of B. Of a total possible quality score of 14, the range of the overall scores was 7 to 13, with a mean score of 9. The methodological quality scores are listed in Table 1 and Table 2.

In three studies it was unclear if the participants had a similar activity level. In two studies the reason for amputation was diverse (Boonstra 1993; Culham 1984) and in Doane 1983, the reason for amputation was not reported. In sixteen studies, the sequence of prosthetic ankle-foot mechanisms was randomised; of these, only Postema 1994 described which randomisation procedure was applied. In most studies, participants wore prostheses that allowed interchange of the foot component, therefore these studies scored '1' for the B6-criterion co-interventions. However, four studies did not report any detail of the prosthetic components of the participants, followed by a '0' score on this criterion (Hsu 1999; Nielsen 1988; Schmalz 2002; Underwood 2004). Only one study reported blinding of the participants (Postema 1994). Treatment masking or blinding is an effective way to increase the objectivity of the person(s) observing experimental outcomes. When the treatments are masked, the bias of the participants and observer are not likely to influence the measurements taken.

It is assumed that individuals with a lower limb amputation would need a period of at least one week to acclimatise to prosthetic feet (English 1995). This was not the case or not reported in five studies (Goh 1984; Lehmann 1993a; Lehmann 1993b; Nielsen 1988; Schmalz 2002; Underwood 2004). If a participant did not acclimatise to a new prosthetic foot, one could not be sure that pertinent gait parameters would have been stabilised. Nine studies failed to mention the number of drop-outs and in the tables or figures it was not clear whether all the participants were able to perform all the tests (Boonstra 1993; Cortes 1997; Doane 1983; Goh 1984; Lehmann 1993a; Lehmann 1993b; Marinakis 2004; Powers 1994; Schmalz 2002; Torburn 1990; Underwood 2004). The number of participants was very low in two studies (Barth 1992; Nielsen 1988). In Barth 1992, two subgroups were investigated; each subgroup consisted of only three participants. The population of Nielsen 1988 also consisted of only three participants. The criteria 'intention-to-treat' was not applicable for any of the included studies, since there were no drop-outs, or the number and reason for drop-outs was not mentioned.

Data were not presented sufficiently in five studies (Cortes 1997; Goh 1984; Menard 1992; Nielsen 1988; Perry 1997). Cortes 1997 investigated which factors influence the individual's gait and in which order of importance. The results did not show the effect of different prosthetic feet on the assessed outcome parameters in terms of mean and standard deviation. Therefore the results of this study cannot be included in the comparison. Perry 1997 presented the data as a percentage of healthy non-amputated controls. However, the normative values were based on unpublished laboratory data.

Effects of interventions

With the exception of the Borg-scale, the outcome parameters included in this section were measured while the participants were walking at their comfortable velocity, otherwise the data would not be comparable. All included trials concern transtibial amputations, except for two studies (Boonstra 1993; MacFarlane 1997). For all parameters in this section, the results will firstly be described for the transtibial amputations and subsequently for the transfemoral (MacFarlane 1997) or the transgenual amputations (Boonstra 1993), if applicable.

1. Comfortable walking velocity (meters per minute)

Seventeen studies used comfortable walking velocity as an outcome parameter. Only two studies reported significant differences between some prosthetic feet (Nielsen 1988; Snyder 1995). The individuals with a traumatic transtibial amputation in Nielsen's study walked faster with the Flex-foot than the SACH-foot (77.8±16.9m/min versus 71.4±15.8m/min) and individuals with diabetic transtibial amputation in Snyder's study reached a higher self-selected walking velocity with the Flex-foot than the SACH-foot (71.6±12.6m/min versus 63.6 ±10.0m/min).

2. Stride length (meters)

Ten studies used stride length as an outcome parameter. Only two studies found significant differences between the Flex foot and other prosthetic feet. The individuals with traumatic transtibial amputation in Powers 1994 had a greater stride length when walking with the Flex-foot than with the SACH and the Quantum foot (1.50±0.13m, vs. 1.44±0.15m and 1.44±0.15m). The individuals with diabetic transtibial amputation in Snyder's study also had a greater stride length when walking with the Flex-foot, compared to the SACH, the Carbon Copy II and the Seattle foot (1.35±0.19m vs. 1.25±0.16m, 1.27±0.17m, and 1.25±0.13m) (Snyder 1995).

3. Cadence (steps per minute)

Nine studies used cadence as an outcome parameter. None of the studies showed differences in cadence between the several prosthetic feet, while walking at comfortable walking velocity.

4. Energy cost (ml oxygen per kg per minute)

Ten studies used energy cost as an outcome parameter. No significant differences were found in energy cost among the prosthetic feet tested in the traumatic as well as the vascular group in Barth 1992. Both the vascular and traumatic group in Huang's study also showed no differences in energy cost when walking with the SACH-foot, single axis, or the multiple axis (Huang 2000). For the five individuals with transtibial amputation of Torburn's study there were no differences between foot-types in energy cost during free walk (Torburn 1990). This was also the case for the nine traumatic and the seven vascular individuals with a transtibial amputation in Torburn 1995.

Energy cost was identical for the two prosthetic feet as well as for the traumatic and the vascular transtibial amputation group of Casillas' study when walking on level ground at self selected walking speed (Casillas 1995). While walking on a level treadmill at a progressive speed, the energy cost was lower with the prototype foot compared to the SACH foot in the traumatic group and the difference became more significant as speed increased (22.11±3.29 ml oxygen/kg/min vs. 24.71±2.18 at 6 km/h). Energy cost was also lower when walking with the Proteor foot compared with the SACH foot with inclined and declined treadmill walking (16.79±2.32 vs. 19.31±2.80 ml oxygen/kg/min with a 5% decline on the treadmill). When the individuals with a nonvascular transtibial amputation in Hsu's study walked on the treadmill, energy cost was significantly decreased while walking with the Re-Flex VSP compared with the SACH and the Flex foot at progressive speed (36.83±5.07 ml oxygen/kg/min vs. 40.73±5.29 and 39.44±5 .37 when running at 147.51m/min), while the Flex-foot and the SACH were not statistically significant (Hsu 1999). For the eight individuals with a transtibial traumatic amputation in Schmalz' study, the values of the energy cost showed no significant differences between the various foot designs when walking at 4km/h. However, energy consumption increased when walking with the 1S71 SACH-foot at a speed of 4.8km/h compared to the other feet (16.1± 1.4 vs. 15.6±1.2 ml oxygen/kg/min) (Schmalz

2002). At walking speeds of 2.5 miles per hour, the energy cost of walking with the SACH-foot was higher than with the Flex-foot in the three individuals with a traumatic transtibial amputation in Nielsen 1988. However, no means and standard deviations of this outcome parameter were presented.

For the eight individuals with a transtibial traumatic amputation in Hsu's study it appeared that the energy expenditure of the Flex-foot was slightly less than that of the SACH-foot, and the differences between the Flex-foot and the SACH-foot appeared to progressively increase with increases in walking speed (Hsu 2006). The C-walk appeared to have lower oxygen consumption values at 67.05 and 80.46m/min when compared with the Flex-foot. However, the differences between the foot-types in this study were not significant.

In MacFarlane's study, five individuals with a traumatic transfemoral amputation walked with a lower energy cost when walking with the Flex-foot than with the SACH-foot (16.70±0.24 vs. 17.69±0.24 ml oxygen/kg/min) (MacFarlane 1997).

5. Gait efficiency (ml oxygen per kg per meter)

Nine studies used gait efficiency as an outcome parameter. Gait efficiency was lower with the Proteor foot compared with the SACH-foot for the twelve individuals with a traumatic amputation in Casillas 1995 (0.22±0.04 vs. 0.24±0.04 ml oxygen/kg/meter). Between foot-type comparisons showed progressive separation of the energy cost values (SACH>Flex-foot>Re-Flex VSP) with increasing walking speed. The differences appeared negligible for the lower two walking speeds. Hsu 1999 found that foot-type comparisons for the subjects showed progressive separation of the gait efficiency values (SACH>Flex-foot>Re-Flex VSP) with increasing walking speed (between 53.64 m/min and 147.51 m/min). The gait-efficiency of the Re-Flex VSP was significantly different compared with the SACH and the Flex-foot (0.28±0.04 vs. 0.25±0.03 ml oxygen/kg/m at a running speed of 147.51 m/min); the differences between the SACH-foot and the Flex-foot were not significantly different (Hsu 1999).

For each walking and running speed in Lehmann 1993a, there were no significant differences among the three foot designs for the nine individuals with a transtibial amputation. The same results were found in another study of Lehmann (Lehmann 1993b), while walking with the Seattle and the Flex-foot.

For the three individuals with a traumatic transtibial amputation of Nielsen's study there were no significant differences in gait efficiency between the two types of prosthetic feet at all walking speeds (Nielsen 1988). For the eight individuals with a traumatic transtibial amputation of Hsu's study the C-walk and the Flex-foot appeared to be more efficient compared with the SACH across all tested walking speeds, and with greater differences between the C-walk and the SACH-foot at mid-range speeds (67.05 and 80.46m/min), with greater differences between the Flex-foot and the SACH-foot at higher walking speeds (93.87 and 107.28m/min) (Hsu 2006). However, these results were not significant.

For the five individuals with a transtibial amputation of Torburn's study there were no differences between foot-types in gait efficiency during free walk (Torburn 1990). This was also the case for the nine individuals with traumatic and seven individuals with vascular transtibial amputation in Torburn 1995.

MacFarlane 1997 found that the mean walking efficiency was better (lower value) at each walking speed with the Flex-foot than with the SACH-foot (0.253±0.003 ml oxygen/kg/meter vs 0.270±0.003) in five individuals with a traumatic transfemoral amputation.

6. Borg-Scale

One study used the Borg-scale as an outcome parameter. In MacFarlane's study, walking with the SACH-foot was perceived to be more difficult with each grade and speed condition than walking with the Flex-foot (10.4±1.6 vs. 8.6±1.1 at level walking at medium speed) (MacFarlane 1991). The greatest difference occurred on the level and incline grades.

As for patient satisfaction, the only A study (Postema 1994) concluded that no specific prosthetic foot was consistently favoured over another type of foot by individuals with a traumatic transtibial amputation. Yet, in one B study, the prototype energy-storing foot (Proteor foot) scored a higher satisfaction rate than the SACH foot in individuals with a traumatic transtibial amputation (Casillas 1995). In one C-study the Flex foot was preferred over the SAFE foot for perceived stability and mobility, although no statistical analysis was performed (Underwood 2004). However, since the prosthetic users were not blinded in MacFarlane's, Casillas' and Underwood's studies, these results should be interpreted with caution.

Joint motion

Ten studies used joint motion as an outcome parameter. In Postema 1994, the range of motion (ROM) at the ankle during the stance phase of a single-axis conventional foot was greater than the same ROM of two energy-storing feet. This result could readily be related to the mechanical characteristics of the different feet i.e. the presence or absence of an ankle axis in the frontal plane. Furthermore, the energy storing Flex foot showed a greater late stance dorsiflexion compared with the conventional SACH foot in three B studies (Powers 1994; Snyder 1995; Torburn 1990) and two C studies (Lehmann 1993b; Schmalz 2002) on individuals with traumatic and vascular transtibial amputation. The fact that the Flex foot resulted in a greater stride-length is indicative of a greater tibial advancement as a result of increased dorsiflexion (Snyder 1995).

In addition, Marinakis 2004 studied the ROM of the hip, knee and ankle joints of nine individuals with a traumatic transtibial amputation. With the SACH-foot, the ankle joint was continuously at a low-angle dorsiflexion, reaching a maximum of 3.0 degrees. With the Greissinger plus foot, the maximum dorsiflexion was 6.5 degrees, and the maximum plantar flexion 11 degrees, resulting in an ROM within the lower limits of the range of values observed during measurements with the non-disabled subjects.

DISCUSSION

None of the included studies showed significant differences between any of the investigated prosthetic ankle-foot mechanisms for the comfortable walking speed or cadence. However, In individuals with a transtibial amputation, there seems to be a slight trend towards a greater stride length when walking with the Flex-foot in comparison to the SACH foot (Powers 1994; Snyder 1995).

During level treadmill walking there were no differences in energy cost in either the individuals with a traumatic or vascular transtibial amputations. However, when walking speed was increased or when subjects walked on a decline or incline treadmill, the energy cost was lower when walking with an energy-storing foot than with the SACH foot (Casillas 1995; Hsu 1999; Schmalz 2002). These studies indicate that the individual with a transtibial amputation who is active and is able to walk on inclines and declines could benefit from an energy-storing prosthetic foot, such as the Flex-foot, the Re-Flex foot or the Proteor foot.

In contrast, the energy cost is lower during level walking when walking with the Flex-foot compared with the SACH-foot in individuals with a transfemoral amputation (MacFarlane 1997). This raises the hypothesis that in high activity individuals with a transfemoral amputation, the design of the ankle foot mechanism may be more important than for transtibial amputees and that more studies are needed. High activity transfemoral users are likely to be prescribed more sophisticated knee mechanisms and this will impact on the decision on which foot is appropriate to complement the knee action.

When individuals with a lower limb amputation were asked which prosthetic foot they preferred, only the A-study concluded that no specific foot was favoured although there were differences in the mechanical characteristics of the prosthetic feet (Postema 1994). This implies that besides the functional benefits of a prosthesis and the functional needs of the individual, the participants' own interpretation of walking difficulty is also of value for the prosthetic prescription.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence from high quality comparative studies for the overall superiority of any individual type of prosthetic ankle-foot mechanism, although there is a small trend towards the Flex-foot in comparison with the SACH foot for greater stride length and lower energy cost in individuals with a transtibial amputation, and improved gait efficiency and lower energy cost in high activity individuals with transfemoral amputation. In prescribing prosthetic-ankle foot mechanisms for individuals with a lower limb amputation, practitioners should take into account availability, patient functional needs, patient mobility level, type of knee mechanism to be prescribed and the inter-relationship with ankle-foot mechanisms, and cost.

Implications for research

For future research, functional comparisons between different prosthetic components could be more usefully categorised according to the level of activity and intended use in specific subgroups of (for example) traumatic or vascular patients. Such an approach would better acknowledge the importance of individual needs and abilities that guide clinical decision-making in daily practice.

Functional outcomes should be assessed for various aspects of mobility such as making transfers, maintaining balance, level walking, stair climbing, negotiating ramps and obstacles, and changing walking speed. Most of the studies included in this review assessed walking on a treadmill (at self-selected walking speeds), probably for reasons of technical and practical convenience. Indeed, Mulder 1998 has already pointed out that the vast majority of clinical studies on human walking have used rather standardised gait assessment protocols with limited 'ecological validity'. Although perhaps less analytic, modern systems for ambulatory monitoring of human activity (Bussmann 2001) are able to provide objective and valid data about (changes in) human motor behaviour during prolonged periods of hours or days in a much more ecologically valid way. Also, subjective assessments of comfort, stability and efficiency should certainly be used more when blinding of the prosthetic users can be assured.

The effects of different prosthetic feet should also be evaluated in patients with a through-knee or transfemoral amputation. Generalising results from transtibial to these higher levels of amputation may be invalid.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Barth 1992

Methods	Quasi-randomised controlled trial. Within-subject, cross-over design.
Participants	Group 1: 3 men with unilateral transtibial traumatic amputation, mean age 39 years (SD 10), mean time since amputation 22 years (SD 14). Group 2: 3 men with unilateral transtibial vascular amputation, mean age 64 years (SD 5), mean time since amputation 5 years (SD 3). A test prosthesis was fabricated for each subject. Exclusion: residual limb pain, swelling or pressure sores, major gait deviations Country: USA
Interventions	1. SACH-foot 2. SAFE II 3. Seattle Lightfoot 4. Quantum 5. Carbon Copy II 6. Flex-Walk Retroreflective markers were placed at anatomical landmarks. Surface electrodes were placed at rectus femoris, vastus lateralis, medial and lateral hamstring, bilaterally. Subjects walked at self-selected speed using a treadmill
Outcomes	1. walking velocity 2. cadence 3. stride length 4. single-limb stance times 5. energy cost (ml oxygen/kg/meter) 6. joint motion
Notes	Each foot was worn on the test prosthesis for three weeks.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Boonstra 1993

Methods	Within-subject, cross-over design
Participants	6 men and 3 women with unilateral transgenual amputation. In 4 people cause of amputation was trauma, in 3 vascular disease, in 1 bone-cancer, and in 1 osteomyelitis, mean age 41 years (range 20-70), mean time since amputation 9 years (range 2-25), fitted with an end bearing socket Exclusion: painful stump with skin abrasions

Boonstra 1993 (*Continued*)

	Country: The Netherlands
Interventions	1. Multiflex 2. Quantum foot Gait analysis was performed on a 10m walkway at comfortable, fast, and slow speed and on a treadmill (2 and 2.5 km/h and comfortable speed minus 0.5km/h)
Outcomes	1. walking speed 2. duration of swing and stance phase 3. goniometry of the hip, knee and ankles 4. range of motion of the ankle, knee, and hip
Notes	At least three weeks were allowed to elapse between the changing of the foot and the evaluation

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	D - Not used

Casillas 1995

Methods	Within-subject, cross-over design
Participants	Group 1: 12 men with unilateral transtibial traumatic amputation, mean age 50 years (SD 14), amputation performed more than 2 years previously, with socket contact and a SACH-foot. Group 2: 10 men and 2 women with unilateral transtibial vascular amputation, mean age 73 years (SD 7), amputation performed more than 4 months previously, with a socket contact and a SACH-foot. Exclusion: an associated handicap that might restrict walking ability, stump problems, intercurrent medical problems, addiction to tobacco. Country: USA
Interventions	1. SACH-foot 2. Energy-storing Proteor foot Group 1: oxygen consumption was measured during rest in seated position, during walking at self-selected velocity, walking on level treadmill at different velocities (2.4, 4 and 6km/h), and walking on treadmill with an incline of 5% and decline of 5% at 4km/h. Group 2: only the self-selected speed test was performed.
Outcomes	1. oxygen consumption (ml oxygen/kg/min and ml oxygen/kg/meter) 2. heart rate 3. blood pressure For group 1 a satisfaction index was established by the subject after evaluation of each foot: the rating was determined on a visual scale ranging from 0 to 100, 0 corresponding "entirely unsatisfactory" and 100 to "entirely satisfactory"
Notes	Subjects were requested to only use the foot to be tested in the week preceding evaluation and to not change their routine

Casillas 1995 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	D - Not used

Cortes 1997

Methods	Quasi-randomised controlled trial. Within-subject, cross-over design.
Participants	8 men with unilateral traumatic transtibial amputations, mean age 35 years (range 19-49), amputation at least 2 years before the investigation, mean Day's Activity Score 24 (range 14-39), fitted with PTB prostheses, good shaped stump. Exclusion: skin problems, suffering from any concurrent illness. Country: Spain
Interventions	1. SACH-foot 2. Single-Axis 3. Greissinger 4. Dynamic Participants walked at free cadence, fast, and slower (cadence from 60-140 steps per minute), on a 12m walkway with 2 force plates, equipped with a system of polycentric electrogoniometry for the measurement of both limbs-hip, knee and ankle angles on the sagittal plane
Outcomes	A total of 18 variables was selected: 7 were kinetic (vertical, horizontal and lateral force) 10 kinematic (ankle, knee and hip angles) 1 time-related (Single-Support Stance Time (SST))
Notes	Amputees had a two-week adaptation period before a measurement

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	D - Not used

Culham 1984

Methods	Quasi-randomised controlled trial. Within-subject, cross-over design.
Participants	Group 1: 3 men with unilateral transtibial traumatic amputation, mean age 39 years (SD 10), mean time since amputation 22 years (SD 14). Group 2: 3 men with unilateral transtibial vascular amputation, mean age 64 years (SD 5), mean time since amputation 5 years (SD 3). A test prosthesis was fabricated for each subject.

Culham 1984 (*Continued*)

	Exclusion: residual limb pain, swelling or pressure sores, major gait deviations
Interventions	1. SACH-foot 2. SAFE II 3. Seattle Lightfoot 4. Quantum 5. Carbon Copy II 6. Flex-Walk Retroreflective markers were placed at anatomical landmarks. Surface electrodes were placed at rectus femoris, vastus lateralis, medial and lateral hamstring, bilaterally. Subjects walked at self-selected speed using a treadmill
Outcomes	1. walking velocity 2. cadence 3. stride length 4. single-limb stance times 5. energy cost (ml oxygen/kg/meter) 6. joint motion
Notes	Each foot was worn on the test prosthesis for three weeks.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	D - Not used

Doane 1983

Methods	Within-subject, cross-over design.
Participants	8 men with unilateral transtibial amputation, age 55-67 years, in good general health wearing a PTB prosthesis with cuff suspension, each amputee was fitted with a temporary prosthesis. Exclusion: skin problems with their stump Country: USA
Interventions	1. SACH-foot 2. Single-Axis Participants walked on a 6m walkway and were filmed simultaneously from lateral and frontal perspectives
Outcomes	1. vertical displacement and velocity of the centre of mass 2. lower limb joint angles 3. percentage of time of gait cycle of stance phase, swing phase and double support phase
Notes	A time lapse of one week was allowed if the prosthetic foot was not the same design as the one worn on their permanent prosthesis

Risk of bias

Doane 1983 (*Continued*)

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Goh 1984

Methods	Within-subject, cross-over design.
Participants	Group 1: 6 men with transtibial unilateral amputation, mean age 53 years (SD 9), mean Day's Activity Score 33. Group 2: 5 men transfemoral unilateral amputation, mean age 48 years (SD 11), mean Day's Activity Score 37. Each amputee was provided with an experimental prosthesis, which was adaptable to accommodate either the SACH or uniaxial foot. Country: United Kingdom
Interventions	1. SACH-foot 2. uniaxial foot Participants walked on a 20m walkway with 2 force plates and 3 cine cameras. Body markers were positioned at anatomical landmarks
Outcomes	Temporal components of stance phase: heel-strike to foot-flat, foot-flat to heel-rise, heel rise to toe-off (as percentage of total stance phase)
Notes	Participants were not able to adapt to the intervention.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Hsu 1999

Methods	Quasi-randomised controlled trial. Within-subject, cross-over design.
Participants	5 men with nonvascular unilateral transtibial amputation, mean age 32 years (range 27-36), mean time since amputation 13.1 years (1.5-20), mean Day Activity Scale was 32 (range 12-45). Exclusion: cardiovascular, neuromuscular or other significant abnormalities except amputation. Country: USA
Interventions	1. SACH-foot 2. Flex-foot 3. Re-Flex VSP Participants walked at 5 different walking speeds (53.64, 67.05, 80.46, 93.87 and 107.28m/min) and 3 different running speeds (120.69, 134.1 and 147.51m/min)

Hsu 1999 (*Continued*)

Outcomes	1. energy cost (ml oxygen/kg/min) 2. gait efficiency (ml oxygen/kg/meter) 3. Relative Exercise Intensity (expressed using the formula (exercise heart rate/age-predicted maximum heart rate))
Notes	Each subject had been walking on the prosthetic feet for at least 9 weeks per foot

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	D - Not used

Hsu 2006

Methods	Within-subject, cross-over design.
Participants	8 men with unilateral transtibial amputation, mean age 36 years (range 20-64, SD 15 years), mean prosthesis experience 16.6 years (1-55, SD 17.9 years), mean Day Activity Scale was 33.3 (range 21-43, SD 6.8 U)
Interventions	1. C-walk 2. Flex-foot 3. SACH foot
Outcomes	1. Walking speed treadmill test 2. Oxygen consumption (ml oxygen / kg/ min) 3. Heart rate 4. Gait efficiency (ml oxygen / kg / meter) 5. %APMHR 6. Physical activity (steps per day)
Notes	Each subject had been walking on the prosthetic feet for at least 4 weeks per foot

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	D - Not used

Huang 2000

Methods	Quasi-randomised controlled trial. Within-subject, cross-over design.

Huang 2000 (*Continued*)

Participants	Group 1: 8 men with unilateral vascular transtibial amputation, mean age 62.8 years (SD 5.5) mean time since amputation 8.9 years (SD 5.1). Group 2: 8 men with unilateral traumatic transtibial amputation, mean age 29.8 years (SD 5.9), mean time since amputation 7.4 years (SD 4.6). Each participant had been wearing a variant of a PTB definitive prosthesis with a soft removable liner for at least 1 year. Exclusion: residual limb pain, major gait deviations. Country: Taiwan
Interventions	1. SACH-foot 2. Single Axis 3. Multiple Axis Retroflective markers were attached at anatomical landmarks. Participants walked at self-selected comfortable walking speed on a treadmill (0.8 - 10.0 m/h)
Outcomes	1. energy consumption (ml oxygen/kg/min) 2. walking velocity 3. cadence 4. stride length 5. single-limb stance times 6. joint motion
Notes	Each foot was worn for 3 weeks.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	D - Not used

Lehmann 1993a

Methods	Within-subject, cross-over design.
Participants	9 unilateral transtibial amputees, age 21-53 years, at least 1 year post-amputation, independent functional ambulators able to achieve walking speeds up to 120m/min and running speeds up to 200m/min. Exclusion: history or physical signs of musculoskeletal, cardiac, or other significant abnormalities, other than the amputation. Country: USA
Interventions	1. SACH-foot 2. Seattle Foot 3. Flex Foot Biomechanical comparison was performed on both prosthetic and sound sides, during walking (73,90, 107, and 120m/min) and running (140,160,180, and 200m/min) on a treadmill

Lehmann 1993a (*Continued*)

Outcomes	1. metabolic efficiency (ml oxygen/kg/meter) 2. comfortable self-selected walking speed 3. biomechanical parameters relating to gait events, ground reaction forces, joint angles, and moment
Notes	Participants were not able to adapt to the intervention.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Lehmann 1993b

Methods	Quasi-randomised controlled trial. Within-subject, cross-over design.
Participants	10 unilateral transtibial amputees, age 21-36 years, at least 1 year post-amputation, independent functional ambulators able to achieve a walking speed up to 120m/min and running speeds up to 200m/min, each amputee was fitted with a PTB socket Exclusion: history or physical signs of musculoskeletal, cardiac, or other abnormalities, other than the amputation. Country: USA
Interventions	1. SACH-foot 2. Seattle Lite foot Reflective markers were placed on anatomical landmarks. A force platform was situated on the walkway. For the measurements of metabolic rate and efficiency, a range of walking speeds was selected (73,90,107, and 120m/min) on the treadmill
Outcomes	1. metabolic rate (cal/kg/min) 2. metabolic efficiency (cal/kg/meter) 3. self-selected walking speed 4. measurements of lower extremity kinematics, gait events, ground reaction forces
Notes	Participants were not able to adapt to the intervention.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

MacFarlane 1991

Methods	Quasi-randomised controlled trial. Within-subject, cross-over design.
Participants	7 men with unilateral traumatic transtibial amputation, mean age 35 years (range 19-49), mean time since amputation 13 years (range 3-25), mean Day's Activity Score 31 (range 17-43) proficient treadmill walkers. Country: USA
Interventions	1. SACH-foot 2. Flex-foot A 15m walkway was used to determine the self-selected walking speed. Gait measurements took place while participants walked on a treadmill. Each session consisted of a level, decline (-8.5%) and then an incline (+8.5%) walking test. Each test consisted of 3 minute bouts at slow (53.6m/min), medium (67m/min), and fast (80.5m/min) speeds. Under each grade and speed condition, participants were filmed for three gait cycles
Outcomes	1. self-selected walking speed 2. step-length 3. duration of early stance, late stance, early swing, late swing, double support, single support 4. symmetry ratios for step length 5. vertical trunk displacement 6. Borg-scale; an increasing scale from 0 to 20, where 0 equals very, very easy and 20 equals very, very difficult
Notes	Each participant had been walking on the prosthetic feet for at least 6 months per foot

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	D - Not used

MacFarlane 1997

Methods	Quasi-randomised controlled trial. Within-subject, cross-over design.
Participants	5 active men with unilateral traumatic transfemoral amputation, mean age 37 years (SD 5.1), mean time since amputation 10 years (SD 3.5), participants could walk continuously for at least 5 minutes across a functional range of speeds. Country: USA
Interventions	1. SACH-foot 2. Flex-foot Participants walked continually around a 50 meter walkway at five walking speeds (40.2, 56.6, 67.1, 80.5, 93.9m/min). A video camera recorded four strides of each participant's walking

MacFarlane 1997 (*Continued*)

Outcomes	1. relative exercise intensity (percent of age-predicted maximum heart rate) 2. energy cost (ml oxygen/kg/min) 3. gait efficiency (ml oxygen/kg/meter) 4. swing-, stance-, double-, and single-support phase variables 5. step length 6. symmetry ratios
Notes	Participants wore the testing prosthesis continuously for the week prior to testing

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	D - Not used

Marinakis 2004

Methods	Quasi-randomised controlled trial. Within-subject, cross-over design.
Participants	9 male participants with a unilateral (right) transtibial traumatic amputation. Mean age 54.3 years (SD 2.1), mean time from amputation 38.9 weeks (SD 3.1), mean time from limb fitting was 16.3 weeks (SD 5.8). Country: United Kingdom
Interventions	1. SACH foot 2. Greissinger Plus Foot
Outcomes	1. Range of motion of hip, knee and ankle 2. walking speed 3. cadence 4. stance phase period 5. symmetry indexes of temporal gait parameters
Notes	Participants were able to adapt to the new prosthetic foot for 1 week

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	D - Not used

Menard 1992

Methods	Within-subject, cross-over design.
Participants	8 physically active men with unilateral traumatic transtibial amputation, mean age 37 years (range 31-51), mean time since amputation was 8.1 years (range 4-15). Country: Canada
Interventions	1. Flex-foot 2. Seattle Foot Participants walked on a 20m indoor runway with a force platform, they walked at their natural cadence
Outcomes	Ground reaction forces (in units of newtons per kilogram body mass (N/kg))
Notes	The participants had used the two prostheses for equal amounts of time for at least two weeks before testing

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	D - Not used

Nielsen 1988

Methods	Quasi-randomised controlled trial. Within-subject, cross-over design.
Participants	7 men with unilateral traumatic transtibial amputation, mean age 27 years (SD 7). All were proficient walkers with both the Flex-foot and the SACH-foot. Country: USA
Interventions	1. SACH-foot 2. Flex-foot A 15m walkway was used for measuring the self-selected walking speed. The actual walking tests were performed on a treadmill, walking at each of seven velocities (1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5 m/h)
Outcomes	1. heart rate 2. %MHR (percent of age-predicted maximum heart rate) 3. oxygen uptake 4. gait efficiency (ml oxygen/kg/meter) 5. self-selected walking speed
Notes	Participants were not able to adapt to the intervention.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Nielsen 1988 (*Continued*)

Allocation concealment?	Unclear risk	D - Not used

Perry 1997

Methods	Quasi-randomised controlled trial. Within-subject, cross-over design.
Participants	10 men with vascular transtibial amputation, mean age 62.4 years (range 49-72), with completely healed amputation and residual stump volume stability. All participants were fitted with a prosthesis that allowed interchange of the foot components. Country: USA
Interventions	1. Single Axis 2. Seattle Lite 3. Flex-foot Gait analyses were done at a self-selected velocity over a level 10m walkway with a force plate. Foot switches were taped to the soles of the shoes to calculate stride characteristics and foot-floor contact patterns. Reflective markers were placed at anatomical landmarks
Outcomes	1. gait velocity 2. cadence 3. stride length 4. foot floor contact patterns 5. joint motion in the sagittal plane
Notes	Each foot was worn for approximately 1 month prior to testing

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	High risk	C - Inadequate

Postema 1994

Methods	Quasi randomised controlled trial. Double-blind randomised trial, within-subject, cross-over design
Participants	9 men and 1 woman with transtibial amputation. Mean age 49 years (range 34-66), mean time since amputation 24 years (range 2-46). All were active walkers able to walk at least 1 kilometre without any problem. Exclusion: stump problems. Country: The Netherlands
Interventions	1. Otto Bock Multi Axial (conventional foot) 2. Otto Bock Lager (conventional foot) 3. Otto Bock Dynamic Pro (energy-storing foot)

Postema 1994 (*Continued*)

	4. Hanger Quantum (energy-storing foot).
Outcomes	1. walking velocity 2. cadence 3. range of motion of the hips, the knees and the ankles during early stance plantar flexion and late stance dorsiflexion 4. a questionnaire was composed to obtain information about the preference of the participants. It consisted of 27 questions that were grouped into 4 categories: stability while standing, stability while walking, functional factors and special activities. The questions were answered in the form of a score in an increasing scale from 0 to 10, the mean score of all questions was the general score for a foot
Notes	Every time a foot was supplied, there was a habituation period of 2 weeks

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Low risk	A - Adequate

Powers 1994

Methods	Quasi randomised controlled trial. Within-subject, cross-over design.
Participants	10 men with transtibial traumatic amputations, mean age 50 years (range 22-72), mean time since amputation 18 years (range 3-48), independent community ambulators, displayed volume stability of the residual stump for at least 30 months. Exclusions: assistive devices Country: USA
Interventions	1. Flex-foot 2. Carbon Copy II 3. Seattle 4. Quantum 5. SACH-foot Foot switches were taped to the soles of the shoes to calculate stride characteristics and foot-floor contact patterns. Reflective markers were placed at anatomical landmarks. Participants walked at a self-selected speed along a 10m walkway with force plate and motion data being collected simultaneously
Outcomes	1. walking velocity 2. cadence 3. stride length 4. ground reaction forces for the prosthetic and the sound limb 5. ankle motion (degrees)
Notes	Each participant was given an accommodation period of 1 month

Powers 1994 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	D - Not used

Rao 1998

Methods	Within-subject, cross-over design.
Participants	9 men with unilateral transtibial vascular amputation, mean age 62 years (SD 7), with well healed amputations and residual stump volume for at least one year, all subjects were community ambulators. Country: USA
Interventions	1. Single-Axis 2. Seattle 3. Flex-foot Foot switches were used to measure stride characteristics. Retroreflective markers at anatomic landmarks were used for motion data. Gait testing was performed over a level 10m walkway
Outcomes	1. foot, shank and thigh angular velocities 2. walking velocity 3. cadence 4. stride length
Notes	Each participant accommodated to a particular foot for approximately one month

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	D - Not used

Schmalz 2002

Methods	Quasi-randomised controlled trial. Within-subject, cross-over design.
Participants	8 participants with transtibial traumatic amputation, mean age 44 years (range 17-70), mean time since amputation 18 years (3-53) Exclusion: cardiovascular disorders Country: Germany
Interventions	1. Otto Bock 1S71 2. Otto Bock 1D10 3. Otto Bock 1D25 4. Otto Bock 1C40

Schmalz 2002 (*Continued*)

	5. Flex Walk II Gait testing was performed during level walking and on the treadmill. Participants walked at 4km/h and 4.8km/h on the treadmill
Outcomes	1. Oxygen consumption 2. Walking speed 3. Stride length
Notes	Participants were not able to adapt to the intervention.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Snyder 1995

Methods	Quasi-randomised controlled trial. Within-subject, cross-over design.
Participants	7 men with diabetic transtibial amputation resulting from vascular insuffiencey, mean age 62 years (range 45-70), all were community ambulators and demonstrated residual limb volume stability of at least 6 months. Exclusion: assistive devices, complications associated with residual limb breakdown or resting limb pain. Country: USA
Interventions	1. Flex-foot 2. Carbon Copy II 3. Seattle Elite foot 4. Quantum 5. SACH Foot switches were used to calculate stride characteristics and foot-floor contact patterns. Reflective markers were placed at specific anatomic positions. Participants walked during a self-selected free walking speed while walking along a 10m walkway with force plate
Outcomes	1. walking velocity 2. stride length 3. cadence 4. ankle, knee and hip motion 5. vertical ground reaction forces
Notes	Participants were given an accommodation period of 1 month.

Risk of bias

Bias	Authors' judgement	Support for judgement

Snyder 1995 (*Continued*)

Allocation concealment?	Unclear risk	D - Not used

Torburn 1990

Methods	Quasi-randomised controlled trial. Within-subject, cross-over design
Participants	5 men with transtibial amputation (3 traumatic and 2 dysvascular), mean age 48 years (range 43-58) , mean time since amputation 11.3 years (range 2.5-20), all were independent community ambulators, each subject displayed volume stability of the residual limb for at least 30 months, each subject was fitted with a new prosthetic socket. Exclusion: assistive devices Country: USA
Interventions	1. Flex-foot 2. Carbon Copy II 3. Seattle 4. Sten 5. SACH-foot Gait analysis was done during self-selected free and fast-paced walking over a 10m level walkway with a force plate. Foot switches were used to calculate stride characteristics and foot-floor contact pattern. Reflective markers were placed at anatomical landmarks
Outcomes	1. walking velocity 2. cadence 3. stride length 4. electromyographic activity of the vastus lateralis, long head of the biceps femoris, and the gluteus maximus 5. sagittal plane motion of the pelvis, thigh, knee, and ankle 6. energy cost (ml oxygen/kg/min and ml oxygen/kg/meter)
Notes	Each participant was given an accomodation period of approximately one month

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	D - Not used

Torburn 1995

Methods	Quasi-randomised controlled trial. Within-subject, cross-over design.
Participants	Group 1: 9 men with unilateral transtibial traumatic amputations, mean age 51 years (SD 16). Group 2: 7 men with unilateral transtibial vascular amputations, mean age 62 years (SD 8). Participants were independent community ambulators Exclusion: assistive device and history of compliance

Torburn 1995 (*Continued*)

	Country: USA
Interventions	1. SACH-foot 2. Carbon Copy II 3. Seattle Lite 4. Quantum 5. Flex-foot A level 60.5m outdoor track was used for the walking trials.
Outcomes	1. respiration rate 2. heart rate 3. stride frequency 4. self-selected free walking speed 5. energy expenditure (ml oxygen/kg/meter)
Notes	Participants were given a accommodation period of 1 month to adjust to each prosthetic foot

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	D - Not used

Underwood 2004

Methods	Quasi-randomised controlled trial. Within-subject, cross-over design.
Participants	11 individuals with a unilateral traumatic transtibial amputation (8 males, 3 females), mean age 42.5 y (SD 13.1, range 22-59), mean time since amputation 11.1 y (SD 13.3, range 1-31), participants were able to ambulate independently, did not require assistive devices for ambulation ,did not experience stump pain or tenderness or other cardiovascular, neurological or musculoskeletal conditions
Interventions	1. SAFE II 2. Flex-Walk
Outcomes	1. walking speed 2. cadence 3. step length 4. stance time 5. swing time 6. peak moments of ankle, knee and hip 7. peak powers of ankle, knee and hip in sagittal and frontal plane 8. questionnaire on stability and mobility of the prosthetic foot (on a scale of 1-10)
Notes	Subjects could become familiar and comfortable with the properties of each prosthetic foot for a minimum of 30 minutes

Underwood 2004 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	High risk	C - Inadequate

Cadence: steps per minute
kg: kilograms
km/h: kilometres per hour
m: metres
m/h: miles per hour
m/min: metres per minute
N/kg: Newton per kilograms
PTB: Patellar Tendon Bearing
SD: standard deviation
transgenual amputation: through-knee amputation
y: years

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

Study	Reason for exclusion
Alaranta 1991	No description of the study population, no randomisation, no time to adapt to the new prosthetic foot
Arya 1995	A heterogeneous study population, no randomisation, no time to adapt to the new prosthetic foot, inadequate data presentation
Hayden 2000	A heterogeneous study population, no time to adapt to the new prosthetic foot
James 1986	A heterogeneous study population, no randomisation, no time to adapt to the new prosthetic foot, inadequate data presentation
Mizuno 1992	Unclear study-design. Information about study population is unclear
Nyska 2002	No description of the study population, a heterogeneous study population, no randomisation, inadequate description of the experimental intervention, no time to adapt to the new prosthetic foot, too small sample size, inadequate data presentation
Torburn 1994	No description of the study population, no randomisation
vd Water 1998	No description of the study population, no randomisation, inadequate description of the experimental intervention, comparison between The Camp Normal Activity Foot and the subject's own prosthesis

(*Continued*)

Wagner 1987	No description of the study population, no randomisation, inadequate description of the experimental intervention, no time to adapt to the new prosthetic foot
Wirta 1991	A heterogeneous study population, no randomisation, no time to adapt to the new prosthetic foot, inadequate data presentation
Yack 1999	No description of the study population, inadequate description of the experimental intervention, no time to adapt to the new prosthetic foot, too small sample size

ADDITIONAL TABLES

Table 1. Methodological quality assessment: A and B criteria

Study id	A1	A2	A3	A4	B5	B6	B7	B8	B9
Barth 1992	1	1	1	1	1	1	0	1	1
Boonstra 1993	1	0	1	0	1	1	0	1	1
Casillas 1995	1	1	1	0	1	1	0	1	1
Cortes 1997	1	1	1	1	1	1	0	1	1
Culham 1984	1	0	1	1	1	1	0	1	1
Doane 1983	1	0	1	0	1	1	0	1	1
Goh 1984	1	1	1	0	1	1	0	0	1
Hsu 1999	1	1	1	1	1	0	0	1	1
Hsu 2006	1	1	1	0	1	1	0	1	1
Huang 2000	1	1	1	1	1	1	0	1	1
Lehmann 1993a	1	1	1	0	1	1	0	0	1
Lehmann 1993b	1	1	1	1	1	1	0	0	1

Table 1. Methodological quality assessment: A and B criteria (*Continued*)

MacFarlane 1991	1	1	1	1	1	1	0	1	1
MacFarlane 1997	1	1	1	1	1	1	0	1	1
Marinakis 2004	1	1	1	0	1	1	0	1	1
Menard 1992	1	1	1	0	1	1	0	1	1
Nielsen 1988	1	1	1	1	1	0	0	0	1
Perry 1997	1	1	1	1	1	1	0	1	1
Postema 1994	1	1	1	2	1	1	1	1	1
Powers 1994	1	1	1	1	1	1	0	1	1
Rao 1998	1	1	1	0	1	1	0	1	1
Schmalz 2002	1	1	1	1	1	0	0	0	1
Snyder 1995	1	1	1	1	1	1	0	1	1
Torburn 1990	1	0	1	1	1	1	0	1	1
Torburn 1995	1	1	1	1	1	1	0	1	1
Underwood 2004	1	1	1	1	1	0	0	0	1

Table 2. Methodological quality assessment: C criteria and total scores

Study id	C10	C11	C12	C13	Total: A+B criteria	Total: C criteria	Total:A+B+C criteria	Overall Grade
Barth 1992	1	0	na	1	8	2	10	B

Table 2. Methodological quality assessment: C criteria and total scores (*Continued*)

Boonstra 1993	0	1	na	1	6	2	8	B
Casillas 1995	1	1	na	1	7	4	11	B
Cortes 1997	0	1	na	0	8	1	9	B
Culham 1984	1	1	na	1	7	3	10	B
Doane 1983	0	1	na	1	6	2	8	B
Goh 1984	0	1	na	0	6	1	7	C
Hayden 2000	0	1	na	1	6	2	8	C
Hsu 1999	1	1	na	1	7	3	10	B
Hsu 2006	1	0	1	1	7	3	10	B
Huang 2000	1	1	na	1	8	3	11	B
Lehmann 1993a	0	1	na	1	6	2	8	C
Lehmann 1993b	0	1	na	1	7	2	9	C
MacFarlane 1991	1	1	na	1	8	3	11	B
MacFarlane 1997	1	1	na	1	8	3	11	B
Marinakis 2004	0	0	na	1	7	1	8	B
Menard 1992	1	1	na	0	7	2	9	B
Nielsen 1988	1	0	na	0	6	1	7	C
Perry 1997	1	1	na	0	8	2	10	B
Postema 1994	1	1	na	1	10	3	13	A

Table 2. Methodological quality assessment: C criteria and total scores (*Continued*)

Powers 1994	0	1	na	1	8	2	10	B
Rao 1998	1	1	na	1	7	3	10	B
Schmalz 2002	0	1	na	1	6	2	8	C
Snyder 1995	1	1	na	1	8	3	11	B
Torburn 1990	0	1	na	1	7	2	9	B
Torburn 1995	1	1	na	1	8	3	11	B
Underwood 2004	0	1	na	1	6	2	8	C

APPENDICES

Appendix 1. MEDLINE search strategies

OVID Web	Silverplatter
1. amputee$.tw. 2. Amputees/ 3. or/1-2 4. (knee adj3 (disarticulat$ or exarticulat$)).tw. 5. (amputat$ adj3 (transfemoral or transtibial or lower limb or lower extremity or above knee or below knee or through knee)).tw. 6. Disarticulation/ 7. Amputation, Traumatic/ 8. Amputation/ 9. Amputation Stumps/ 10. or/6-9 11. (transfemoral or transtibial or lower limb or lower extremity or knee).tw. 12. exp Leg/ 13. or/11-12 14. and/10-13	#01 amputee* in ti,ab #02 AMPUTEES/ all subheadings #03 #1 or #2 #04 (knee near (disarticulat* or exarticulat*)) in ti,ab #05 (amputat* near (transfemoral or transtibial or lower-limb or lower-extremity or above-knee or below-knee or through-knee)) in ti,ab #06 DISARTICULATION/ all subheadings #07 AMPUTATION/ all subheadings #08 AMPUTATION, TRAUMATIC/ all subheadings #09 AMPUTATION STUMP/ all subheadings #10 #6 or #7 or #8 or #9 #11 (transfemoral or transtibial or lower-limb or lower-extremity or knee) in ti,ab #12 explode LEG/ all subheadings #13 #11 or #12 #14 #10 and #13

(*Continued*)

15. or/3-5,14
16. ((SACH adj5 feet) or (Sach adj5 foot) or (Flex adj5 feet) or (Flex adj5 foot) or (Seattle adj5 feet) or (Seattle adj5 foot) or (Single-Axis adj5 feet) or (Single-Axis adj5 foot) or (Golden-Ankle adj5 feet) or (Golden-ankle adj5 foot)).tw.
17. ((foot or feet) adj3 (energy-storing or ankle-mechanism or conventional)).tw.
18. ((prosthetic or prosthes?s) adj3 (foot or feet or ankle$ or lower-extremity)).tw.
19. Artificial limbs/
20. (artificial adj3 (leg or foot or feet or limb)).tw.
21. ((prosthetic$ or prosthes?s) adj3 (prescription$ or outcome$ or profile or assessment or casting)).tw.
22. or/16-21
23. (subjective-findings or preference? or satisfaction or comfort or Borg-scale? or rating-scale? or ease).tw.
24. (oxygen-uptake or physiological-measurement or metabolic-cost or oxygen-cost or energy-cost or energy-demands or energy-expenditure or energy-consumption or heart-rate or pulse).tw.
25. (gait-pattern or gait-characteristics or walking-speed or walking-velocity or comfortable-speed or walking-distance or cadence or stride-characteristics or stride-length or step-length or stride-time or stance-phase or swing-phase).tw.
26. (kinetic-parameters or ground-reaction-force?).tw.
27. (joint-motion or ankle-dorsiflexion or ankle-plantarflexion or knee-flexion or knee-extension or hip-flexion or hip-extensions or power-output or tibial-advancement).tw.
28. or/23-27
29. or/22,28
30. and/15,29
31. randomized controlled trial.pt.
32. controlled clinical trial.pt.
33. Random Allocation/
34. Double Blind Method/
35. Single Blind Method/
36. exp Cross-Over Studies/
37. or/31-36
38. ((clinical or controlled or comparative or placebo or prospective$ or randomi#ed) adj3 (trial or study)).tw.
39. (random$ adj7 (allocat$ or allot$ or assign$ or basis$ or divid$ or order$)).tw.
40. ((singl$ or doubl$ or trebl$ or tripl$) adj7 (blind$ or mask$)).tw.
41. (cross?over$ or (cross adj1 over$)).tw.
42. ((allocat$ or allot$ or assign$ or divid$) adj3 (condition$ or experiment$ or intervention$ or treatment$ or therap$ or control$ or group$)).tw.
43. or/38-42
44. or/37,43

#15 #3 or #4 or #5 or #14
#16 ((SACH near feet) or (SACH near foot) or (Flex near feet) or (Flex near foot) or (Seattle near feet) or (Seattle near foot) or (Single-Axis near feet) or (Single-Axis near foot) or (Golden-Ankle near feet) or (Golden-ankle near foot)) in ti,ab
#17 ((foot or feet) near (energy-storing or ankle-mechanism or conventional)) in ti,ab
#18 ((prosthetic? or prosthes?s) near (foot or feet or ankle* or lower-extremity)) in ti,ab
#19 ARTIFICIAL LIMBS/ all subheadings
#20 (artificial near (leg or foot or limb)) in ti,ab
#21 ((prosthetic? or prosthes?s) near (prescription? or outcome? or profile? or assessment? or casting)) in ti,ab 1351
#22 #16 or #17 or 18 or #19 or #20 or #21
#23 (subjective-findings or preference? or satisfaction or comfort or Borg-scale? or rating-scale? or ease or questionnaire? or Prosthesis-Evaluation-Questionnaire or Prosthetic-Profile-of-the-Amputee or Locomotor-Capabilities-Index or Sickness-Impact-Profile or Nottingham-Health-Profile or Reintegration-to-Normal-Living) in ti,ab
#24 (oxygen-uptake or physiological-measurement or metabolic-cost or oxygen-cost or energy-cost or energy-demands or energy-expenditure or energy-consumption or heart-rate or pulse) in ti, ab
#25 (gait-pattern or gait-characteristics or walking-speed or walking-velocity or comfortable-speed or walking-distance or cadence or stride-characteristics or stride-length or step-length or stride-time or stance-phase or swing-phase) in ti,ab
#26 (kinetic-parameters or ground-reaction-force?) in ti,ab 3
#27 (joint-motion or ankle-dorsiflexion or ankle-plantarflexion or knee-flexion or knee-extension or hip-flexion or hipextensions or power-output or tibial advancement) in ti,ab
#28 #23 or #24 or #25 or #26 or #27
#29 #22 or #28
#30 #15 and #29
#31 RANDOMIZED-CONTROLLED-TRIAL in PT
#32 CONTROLLED-CLINICAL-TRIAL in PT
#33 RANDOM-ALLOCATION
#34 DOUBLE-BLIND-METHOD
#35 SINGLE-BLIND-METHOD
#36 explode CROSS-OVER-STUDIES/ all subheadings
#37 #31 or #32 or #33 or #34 or #35 or #36
#38 ((clinical or controlled or comparative or placebo or prospective* or random*) near (trial or study)) in ti,ab
#39 (random* near (allocat* or allot* or assign* or basis* or divid* or order*)) in ti,ab
#40 ((singl* or double* or trebl* or tripl*) near (blind* or mask*)) in ti,ab

(*Continued*)

45. and/30,44	#41 (crossover or (cross-over*)) in ti,ab #42 ((allocat* or allot* or assign* or divid*) near (condition* or experiment* or intervention* or treatment* or therap* or control* or group*)) in ti,ab #43 #38 or #39 or #40 or #41 or #42 #44 #37 or #43 #45 #30 and #44

Appendix 2. EMBASE search strategy

OVID Web

1. amputee$.tw.
2. (knee adj3 (disarticulat$ or exarticulat$)).tw.
3. (amputat$ adj3 (transfemoral or transtibial or lower limb or lower extremity or above knee or below knee or through knee)).tw.
4. Amputation/
5. Traumatic Amputation/
6. Amputation Stump/
7. Limb Amputation/
8. or/4-7
9. (transfemoral or transtibial or lower limb or lower extremity or knee).tw.
10. exp Leg/
11. or/9-10
12. and/8,11
13. exp Leg Amputation/
14. Foot Amputation/
15. or/1-3,12-14
16. ((SACH adj5 feet) or (SACH adj5 foot) or (Flex adj5 feet) or (Flex adj5 foot) or (Seattle adj5 feet) or (Seattle adj5 foot) or (Single-Axis adj5 feet) or (Single-Axis adj5 foot) or (Golden-Ankle adj5 feet) or (Golden-ankle adj5 foot)).tw.
17. ((foot or feet) adj3 (energy-storing or ankle-mechanism or conventional)).tw.
18. ((prosthetic or prosthes?s) adj3 (foot or feet or ankle$ or lower-extremity)).tw.
19. Limb Prosthesis/
20. (artificial adj3 (leg or foot or feet or limb)).tw.
21. ((prosthetic$ or prosthes?s) adj3 (prescription$ or outcome$ or profile or assessment or casting)).tw.
22. or/16-21
23. (subjective-findings or preference? or satisfaction or comfort or Borg-scale? or rating-scale? or ease).tw.
24. (oxygen-uptake or physiological-measurement or metabolic-cost or oxygen-cost or energy-cost or energy-demands or energy-expenditure or energy-consumption or heart-rate or pulse).tw.
25. (gait-pattern or gait-characteristics or walking-speed or walking-velocity or comfortable-speed or walking-distance or cadence or stride-characteristics or stride-length or step-length or stride-time or stance-phase or swing-phase).tw.
26. (kinetic-parameters or ground-reaction-force?).tw.
27. (joint-motion or ankle-dorsiflexion or ankle-plantarflexion or knee-flexion or knee-extension or hip-flexion or hip-extensions or power-output or tibial-advancement).tw.
28. or/23-27
29. or/22,28
30. and/15,29

(*Continued*)

31. exp Randomized Controlled trial/
32. exp Double Blind Procedure/
33. exp Single Blind Procedure/
34. exp Crossover Procedure/
35. Controlled Study/
36. or/31-35
37. ((clinical or controlled or comparative or placebo or prospective$ or randomi#ed) adj3 (trial or study)).tw.
38. (random$ adj7 (allocat$ or allot$ or assign$ or basis$ or divid$ or order$)).tw.
39. ((singl$ or doubl$ or trebl$ or tripl$) adj7 (blind$ or mask$)).tw.
40. (cross?over$ or (cross adj1 over$)).tw.
41. ((allocat$ or allot$ or assign$ or divid$) adj3 (condition$ or experiment$ or intervention$ or treatment$ or therap$ or control$ or group$)).tw.
42. or/37-41
43. or/36,42
44. limit 43 to human
45. and/30,44

Appendix 3. Cochrane search strategy

Wiley InterScience

#1 amputee* in Title, Abstract or Keywords in all products
#2 MeSH descriptor Amputees explode all trees in MeSH products
#3 (knee near (disarticulat* or exarticulat*)) in Title, Abstract or Keywords in all products
#4 (amputat* near (transfemoral or transtibial or lower limb or lower extremity or above knee or below knee or through knee)) in Title, Abstract or Keywords in all products
#5 MeSH descriptor Disarticulation explode all trees in MeSH products
#6 MeSH descriptor Amputation, Traumatic explode all trees in MeSH products #7 MeSH descriptor Amputation, this term only in MeSH products
#8 MeSH descriptor Amputation Stumps explode all trees in MeSH products
#9 (#5 OR #6 OR #7 OR #8)
#10 (transfemoral or transtibial or lower limb or lower extremity or knee) in Title, Abstract or Keywords in all products
#11 MeSH descriptor Leg explode all trees in MeSH products
#12 (#10 OR #11)
#13 (#9 AND #12)
#14 (#1 OR #2 OR #3 OR #4 OR #13)
#15 ((SACH near feet) or (SACH near foot) or (Flex near feet) or (Flex near foot) or (Seattle near feet) or (Seattle near foot) or (Single-Axis near feet) or (Single-Axis near foot) or (Golden-Ankle near feet) or (Golden-ankle near foot)) in Title, Abstract or Keywords in all products
#16 (foot near (energy-storing or ankle-mechanism or conventional)) in Title, Abstract or Keywords or (feet near (energy-storing or ankle-mechanism or conventional)) in Title, Abstract or Keywords in all products
#17 (prosthetic near (foot or feet or ankle* or lower-extremity)) in Title, Abstract or Keywords or (prosthes* near (foot or feet or ankle* or lower-extremity)) in Title, Abstract or Keywords in all products
#18 MeSH descriptor Artificial Limbs, this term only in MeSH products
#19 (artificial near (leg or foot or feet or limb)) in Title, Abstract or Keywords in all products
#20 (prosthetic* near (prescription* or outcome* or profile or assessment or casting)) in Title, Abstract or Keywords or (prosthes*

(*Continued*)

near (prescription* or outcome* or profile or assessment or casting)) in Title, Abstract or Keywords in all products
#21 (#15 OR #16 OR #17 OR #18 OR #19 OR #20)
#22 (subjective-findings or (subjective findings) or preference* or satisfaction or comfort or Borg-scale* or (Borg scale*) or rating-scale* or (rating scale*) or ease) in Title, Abstract or Keywords in all products
#23 (oxygen-uptake or (oxygen uptake) or physiological-measurement or (physiological measurement) or metabolic-cost or (metabolic cost) or oxygen-cost or (oxygen cost) or energy-cost or (energy cost) or energy-demands or (energy demands) or energy-expenditure or (energy expenditure) or energy-consumption or heart-rate or (heart rate) or pulse) in Title, Abstract or Keywords in all products
#24 (gait-pattern or (gait pattern) or gait-characteristics or (gait characteristics) or walking-speed or (walking speed) or walking-velocity or (walking velocity) or comfortable-speed or (comfortable speed) or walking-distance or (walking distance) or cadence or stride-characteristics or (stride characteristics) or stride-length or (stride length) or step-length or (step length) or stride-time or (stride time) or stance-phase or (stance phase) or swing-phase or (swing phase)) in Title, Abstract or Keywords in all products
#25 (kinetic-parameters or (kinetic parameters) or ground-reaction-force* or (ground reaction force*)) in Title, Abstract or Keywords in all products
#26 (joint-motion or ankle-dorsiflexion or ankle-plantarflexion or knee-flexion or knee-extension or hip-flexion or hip-extensions or power-output or tibial-advancement or joint motion or ankle dorsiflexion or ankle plantarflexion or knee flexion or knee extension or hip flexion or hip extensions or power output or tibial advancement) in Title, Abstract or Keywords in all products
#27 (#22 OR #23 OR #24 OR #25 OR #26)
#28 (#21 OR #27)
#29 (#14 AND #28)

Appendix 4. CINAHL search strategy

OVID Web

1. amputee$.tw.
2. Amputees/
3. or/1-2
4. (knee adj3 (disarticulat$ or exarticulat$)).tw.
5. (amputat$ adj3 (transfemoral or transtibial or lower limb or lower extremity or above knee or below knee or through knee)).tw.
6. Above-Knee Amputation/ or Below-Knee Amputation/
7. Disarticulation/
8. Amputation, Traumatic/
9. Amputation/
10. Amputation Stumps/
11. or/7-10
12. (transfemoral or transtibial or lower limb or lower extremity or knee).tw.
13. exp Leg/
14. or/12-13
15. and/11-14
16. or/3-6,15
17. ((SACH adj5 feet) or (Sach adj5 foot) or (Flex adj5 feet) or (Flex adj5 foot) or (Seattle adj5 feet) or (Seattle adj5 foot) or (Single-Axis adj5 feet) or (Single-Axis adj5 foot) or (Golden-Ankle adj5 feet) or (Golden-ankle adj5 foot)).tw.
18. ((foot or feet) adj3 (energy-storing or ankle-mechanism or conventional)).tw.
19. ((prosthetic or prosthes?s) adj3 (foot or feet or ankle$ or lower-extremity)).tw.
20. Limb Prosthesis/
21. (artificial adj3 (leg or foot or feet or limb)).tw.

(*Continued*)

22. ((prosthetic$ or prosthes?s) adj3 (prescription$ or outcome$ or profile or assessment or casting)).tw.
23. or/17-22
24. (subjective-findings or preference? or satisfaction or comfort or Borg-scale? or rating-scale? or ease).tw.
25. (oxygen-uptake or physiological-measurement or metabolic-cost or oxygen-cost or energy-cost or energy-demands or energy-expenditure or energy-consumption or heart-rate or pulse).tw.
26. (gait-pattern or gait-characteristics or walking-speed or walking-velocity or comfortable-speed or walking-distance or cadence or stride-characteristics or stride-length or step-length or stride-time or stance-phase or swing-phase).tw.
27. (kinetic-parameters or ground-reaction-force?).tw.
28. (joint-motion or ankle-dorsiflexion or ankle-plantarflexion or knee-flexion or knee-extension or hip-flexion or hip-extensions or power-output or tibial-advancement).tw.
29. or/24-28
30. or/23,29
31. and/16,30
32. exp Clinical Trials/
33. exp Evaluation Research/
34. exp Comparative Studies/
35. exp Crossover Design/
36. clinical trial.pt.
37. or/32-36
38. ((clinical or controlled or comparative or placebo or prospective or randomi#ed) adj3 (trial or study)).tw.
39. (random$ adj7 (allocat$ or allot$ or assign$ or basis$ or divid$ or order$)).tw.
40. ((singl$ or doubl$ or trebl$ or tripl$) adj7 (blind$ or mask$)).tw.
41. (cross?over$ or (cross adj1 over$)).tw.
42. ((allocat$ or allot$ or assign$ or divid$) adj3 (condition$ or experiment$ or intervention$ or treatment$ or therap$ or control$ or group$)).tw.
43. or/38-42
44. or/37,43
45. and/31,44

Appendix 5. AMED search strategy

OVID Web

1. amputee$.tw.
2. (knee adj3 (disarticulat$ or exarticulat$)).tw.
3. (amputat$ adj3 (transfemoral or transtibial or lower limb or lower extremity or above knee or below knee or through knee)).tw.
4. Amputation/
5. Amputation Stumps/
6. or/4-5
7. (transfemoral or transtibial or lower limb or lower extremity or knee).tw.
8. exp Leg/
9. or/7-8
10. and/6,9
11. or/1-3,10
12. ((SACH adj5 feet) or (Sach adj5 foot) or (Flex adj5 feet) or (Flex adj5 foot) or (Seattle adj5 feet) or (Seattle adj5 foot) or (Single-Axis adj5 feet) or (Single-Axis adj5 foot) or (Golden-Ankle adj5 feet) or (Golden-ankle adj5 foot)).tw.

(*Continued*)

13. ((foot or feet) adj3 (energy-storing or ankle-mechanism or conventional)).tw.
14. ((prosthetic or prosthes?s) adj3 (foot or feet or ankle$ or lower-extremity)).tw.
15. Artificial limbs/ or Prosthesis Design/
16. (artificial adj3 (leg or foot or feet or limb)).tw.
17. ((prosthetic$ or prosthes?s) adj3 (prescription$ or outcome$ or profile or assessment or casting)).tw.
18. or/12-17
19. (subjective-findings or preference? or satisfaction or comfort or Borg-scale? or rating-scale? or ease).tw.
20. (oxygen-uptake or physiological-measurement or metabolic-cost or oxygen-cost or energy-cost or energy-demands or energy-expenditure or energy-consumption or heart-rate or pulse).tw.
21. (gait-pattern or gait-characteristics or walking-speed or walking-velocity or comfortable-speed or walking-distance or cadence or stride-characteristics or stride-length or step-length or stride-time or stance-phase or swing-phase).tw.
22. (kinetic-parameters or ground-reaction-force?).tw.
23. (joint-motion or ankle-dorsiflexion or ankle-plantarflexion or knee-flexion or knee-extension or hip-flexion or hip-extensions or power-output or tibial-advancement).tw.
24. or/19-23
25. or/18,24
26. and/11,25
27. randomized controlled trial.pt.
28. controlled clinical trial.pt.
29. Random Allocation/
30. Double Blind Method/
31. ((clinical or controlled or comparative or placebo or prospective$ or randomi#ed) adj3 (trial or study)).tw.
32. (random$ adj7 (allocat$ or allot$ or assign$ or basis$ or divid$ or order$)).tw.
33. ((singl$ or doubl$ or trebl$ or tripl$) adj7 (blind$ or mask$)).tw.
34. (cross?over$ or (cross adj1 over$)).tw.
35. ((allocat$ or allot$ or assign$ or divid$) adj3 (condition$ or experiment$ or intervention$ or treatment$ or therap$ or control$ or group$)).tw.
36. or/27-35
37. and/26,36

WHAT'S NEW

Last assessed as up-to-date: 30 June 2006.

Date	Event	Description
9 May 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 1, 2003

Review first published: Issue 1, 2004

Date	Event	Description
16 April 2008	New search has been performed	In this update of the review (Issue 2, 2008), the search strategy was updated to April 2006 and a total of three new trials included

CONTRIBUTIONS OF AUTHORS

Cheriel Hofstad, corresponding author:

- protocol production

- literature search

- screening search results against inclusion criteria

- screening retrieved papers against inclusion criteria

- appraising quality of papers

- designing and co-ordinating the review

- data management

- data extraction

- interpretation of data

- writing the review

- updating the review.

Harmen van der Linde:

- protocol production

- screening search results against inclusion criteria

- screening retrieved papers against inclusion criteria

- appraising quality of papers

- designing the review

- data extraction

- interpretation of data

- writing the review.

Jacques van Limbeek:

- protocol production

- designing the review

- providing a methodological perspective

- interpretation of data

- providing general advice on the review.

Klaas Postema:

- providing a clinical perspective

- interpretation of data.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- Sint Maartenskliniek, Nijmegen, Netherlands.

External sources

- Board of Health Insurance (CVZ), Netherlands.

INDEX TERMS

Medical Subject Headings (MeSH)

*Artificial Limbs; Amputation [*rehabilitation]; Cross-Over Studies; Foot [*surgery]; Prosthesis Design

MeSH check words

Humans