GUIDELINE
AMPUTATION AND PROSTHETICS
OF THE LOWER EXTREMITIES

October 2012

Initiative:
Netherlands Society of Physical and Rehabilitation Medicine

Organisation:
CBO

Mandating Associations / Bodies:
International Society for Prosthetics and Orthotics, Netherlands branch
Royal Dutch Society for Physical Therapy
Netherlands Institute of Psychologists
Dutch Orthopaedic Association
Dutch Society for Anaesthesiology
Netherlands Association for Occupational and Industrial Medicine
Dutch Society for Surgery
Verenso, Dutch Society for Elderly Care Physicians

Funding:
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The Netherlands Society of Physical and Rehabilitation Medicine (VRA) is the national society for medical specialists in rehabilitation medicine. The core activities of a rehabilitation specialist are: diagnosis, treatment, advice and consultations for patients with loss of function due to illness, accident or a congenital condition. The aim of rehabilitation treatment is to optimise performance on both the social and societal level.

The Utrecht-based Dutch Institute for Healthcare Improvement (CBO) works to support individual healthcare practitioners, their professional associations and healthcare institutions in improving patient care. The CBO runs programmes and projects to support and assist with the systematic and structured assessment, improvement and maintenance of the quality of patient care.
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COMPOSITION OF THE WORKING GROUP

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- Dhr. J. Deckers, Royal Dutch Society for Physical Therapy
- Prof. dr. J.H.B. Geertzen, Netherlands Society of Physical and Rehabilitation Medicine, ISPO
- Dhr. L. Klein, prosthetist (on a personal basis to March 2010)
- Dr. J. Koning, Dutch Society for Surgery
- Dr. T. Kuijpers, CBO
- Dhr. R. van der Ploeg, Royal Dutch Society for Physical Therapy
- Dr. P.N. Post, CBO (to September 2010)
- Prof. dr. J.S. Rietman, Netherlands Society of Physical and Rehabilitation Medicine
- Drs. C.J.G.M. Rosenbrand, CBO
- Drs. D.B. van der Schaaf, Dutch Orthopaedic Association
- Drs. J.W.L.C. Schapendonk, Dutch Society of Anaesthesiology
- Drs. E. Schrier, Netherlands Institute of Psychologists
- Drs. R. Smit Duijzentkunst, Netherlands Association for Occupational and Industrial Medicine
- Drs. M. Spruit-van Eijk, Verenso, Society for Elderly Care Physicians
- Dr. G.J. Versteegen, Netherlands Institute of Psychologists
- Drs. H.G.J. Voesten, Dutch Society for Surgery
Chapter 2: Indication criteria

<table>
<thead>
<tr>
<th>The working group recommends that all diabetic patients with an ulcer be assessed for peripheral vascular disease using objective tests, such as duplex in combination with ankle-brachial index.</th>
</tr>
</thead>
<tbody>
<tr>
<td>To avoid possible amputation, it is recommended that patients with critical ischemia and those who develop foot ulcers receive multidisciplinary treatment (including a surgeon, interventional radiologist, vascular internist and rehabilitation physician).</td>
</tr>
<tr>
<td>When the condition of the patient is too poor to undergo a planned revascularisation procedure or when it is unlikely that restoration of circulation will lead to a functional limb, primary amputation should be considered.</td>
</tr>
<tr>
<td>Multidisciplinary treatment (surgeon, anaesthesiologist, pain specialist, rehabilitation specialist, possibly an internist) is also necessary for treatment of pain, cardiovascular risks, comorbidity and the co-determination of the level of amputation.</td>
</tr>
<tr>
<td>A secondary amputation should be performed when a subsequent vascular reconstruction is no longer possible or if, despite successful vascular reconstruction, a progressive distal deterioration has occurred.</td>
</tr>
</tbody>
</table>
| An amputation is necessary and/or indicated when there is:  
- a severe (life-threatening) infection;  
- loss of a foot to extensive necrosis;  
- intractable pain due to vascular disease.  
Critical ischemia may be an indication for amputation in patients with arterial obstructive vascular disease.  
Immediate amputation should be considered in cases of acute ischemia and sepsis. |
| Clinical criteria are used to assess the amputation level. It may be helpful to take transcutaneous oxygen or toe pressure measurements. Arterial disease can be demonstrated with non-invasive or with invasive vascular examination.  
The vascular laboratory plays an important role in non-invasive studies.  
It is advisable to assign a vascular surgeon as the chief clinician for a patient with critical ischemia.  
Prior to deciding for amputation, the vascularisation of an limb should be assessed by physical examination and the level and quality of arterial pulsations, the degree of ischemia and comorbidity should be noted. |
In addition to the clinical assessment, additional tests such as transcutaneous oxygen measurements or toe pressure measurements can be carried out. Initial localisation of vascular abnormalities can be assisted by haemodynamic measurements such as segmental blood pressure measurement or pulse volume recording.

In the case of a discrepancy between clinical and pressure measurements, vascular imaging can be definitive.

Where imaging of arterial abnormalities is necessary for treatment decisions, the following techniques are recommended: duplex examination, DSA, MRA and CTA. If the vascular status of the limb is not yet established or if demarcation of the region for amputation has not yet taken place, it is advisable to postpone amputation.

Deferred amputation should not take place within the first 3 weeks after revascularisation, because blood flow to the leg can still improve within the three weeks following revascularisation.

The decision to amputate should be taken by an experienced surgeon, familiar with the multiple treatment methods at the various amputation levels, muscle balance and wound closure. Experience with amputation techniques is of importance. The amputation should preferably be performed by an experienced surgeon or supervised by an experienced surgeon.

It is recommended that treatment takes place within a multidisciplinary amputation team (consisting of a surgeon, rehabilitation physician, anaesthesiologist-pain specialist, physiotherapist and possibly an orthopaedic technician or prosthetist).

When determining the level of amputation, the preoperative mobility and prospects for postoperative patient mobility should be considered.

In patients with an indication for amputation and limited mobility, aged over 70 years, with dementia, end-stage renal disease and/or severe coronary artery disease, a transfemoral amputation or knee disarticulation should be considered.

If the above considerations rule out a transtibial amputation, a knee disarticulation may be considered due to its relative advantages over a transfemoral amputation.
Chapter 3: Surgical techniques

In a transtibial amputation an osseous length of 10-15 centimetres below the medial knee joint gap is optimal.

The purpose of a transfemoral amputation is to obtain, by means of a myodesis, a dynamic stump with good motor control and sensitivity.

Skin incision during transfemoral amputation should preferably use the fish mouth incision.

A transfemoral amputation should strive to maintain as much length as possible. However, in order to include a knee prosthesis and to maintain an equal thigh length to the contralateral side, amputation must occur at least 10 cm proximal to the medial knee joint space.

If possible, a knee disarticulation is preferable to a transfemoral amputation. The patella should not be fixed and should not be removed. There is a strong preference for a myodesis as a means of securing the patellar tendon.

The preferred incision during a knee disarticulation extends from the attachment of the ligamentum patellae on both sides and provides two symmetrical skin flaps.

In transtibial amputations, the use of a tourniquet is recommended as this lowers blood loss and may also lead to fewer stump revisions.

Chapter 4: Patient information

The working group is of the opinion that:
- Information for patients (electronic, oral or written) and for those directly involved in patient care is an essential component in the treatment of patients undergoing amputation of a lower limb.
- Treatment should be consistent and consistently implemented, ideally in the form of a care plan.
- As treatment involves multiple disciplines, it is advisable that any items discussed are recorded and defined in a manner that is clear to all disciplines.
- Information resources should be developed at the local level.

Chapter 5: Postoperative management

The working group considers that, in patients with transtibial amputation or knee disarticulation, a rigid dressing is the treatment of choice during the early postoperative phase.
Before switching to treatment with a rigid dressing, all logistical obstacles should have been overcome.

The removable rigid dressing may be considered when one wishes to apply a rigid dressing in patients with transtibial amputation and regular wound monitoring is indicated.

The working group is of the opinion that current postoperative management regarding stump dressing in transfemoral amputation patients can be maintained. Rigid stump dressings are not recommended.

Chapter 6: Pain management

The working group considers that:
- Acute postoperative pain should be treated in accordance with the insights detailed in the Dutch guideline for the post-operative treatment of pain.
- Epidural treatment has a place in perioperative pain management.
- Continuing pain treatment by epidural or perineural catheters, despite having no significant effect on phantom pain over the (medium)long-term, has a place in the treatment of acute postoperative pain following amputation.
- Due to neurotoxicity, epidural infusion of ketamine cannot be recommended.
- The use of gabapentin can be considered for patients with phantom pain.
- The use of amitriptyline can be considered for patients with phantom pain.

Chapter 7: Complications

- To prevent wound infection following amputation, perioperative prophylactic antibiotic treatment is recommended in the form of a preoperative bolus or for 5 days starting immediately preoperatively.
- Because good surgical technique increases the chances of good postoperative mobility, amputations should only be performed by experienced surgeons carrying out a minimum of 5 to 10 amputations each year. The absolute number per year is of less importance than permanent membership of a multidisciplinary team with sufficient incentives to jointly deliver high quality work.
- The working group recommends forming a team around the amputee during the hospital phase and should at least include a surgeon, a rehabilitation physician, an anaesthesiologist and a physiotherapist, and preferably supplemented with a dietician, social worker, BIG-registered psychologist or pastoral worker.
Chapter 8: Rehabilitation process

The discharge destination of a patient with a lower limb amputation is determined in the hospital on the basis of the level of function, the social situation (opportunities for informal care) and current general health.

The working group believes that the estimation of learning, coping styles and skills should receive attention in the diagnosis phase. In addition, the impact of this life event should be assessed. In the course of rehabilitation, the adaptation process and the psychological aspects that are associated with it will need to be considered.

During treatment, a number of issues require attention, including support, adaptation, adjusting to a new situation, including body image and treatment of mental health problems.

General pain research has shown that cognitive behavioural therapy is effective. Third generation behaviour therapies also appear to be promising (Acceptance and Commitment Therapy (ACT) and Mindfulness), indicating that further research into these two treatment methods is necessary.

The working group considers that a BIG-registered psychologist and/or social worker should be part of the rehabilitation team for both the diagnosis and the treatment of patients undergoing amputation.

Chapter 9: Lower limb amputation and work

- It is important that the company doctor is involved from as early a moment as possible and is included in consultations with the patient, the (future) rehabilitation team and the employer. The attending rehabilitation physician must at least ask the patient about this and contact the company doctor if necessary.
- When patients are still actively employed, this should be taken into account by the rehabilitation team at as early a stage as possible when planning support and prescription of a prosthesis.

Chapter 10: Prosthetic provision

- The working group is of the opinion that the Dutch protocol for prosthetic prescription should be followed when prescribing a lower limb prosthesis.
- The working group is also of the opinion that the prescription protocol should be regularly reviewed.
- The working group favours a multidisciplinary approach to the first prescription of a prosthesis (although this may not be necessary for subsequent prostheses).
- The working group believes that the wishes of the patient should be the starting point when determining prescription of a prosthesis.
- The working group is of the opinion that an amputee should not only be under the ongoing supervision of a prosthetist, but that a rehabilitation physician should also be involved; changes in the patient’s circumstances should lead to review of the prosthetic prescription.
- The prevention of oedema in the immediate postoperative phase following lower limb amputation is of fundamental importance to achieving rapid prosthetic fitting.
- The working group considers the rigid stump dressing to be the preferred treatment during the early postoperative phase in patients with a transtibial amputation.
- The use of liners in oedema control is an effective method, provided that they are used according to protocol.
- Oedema control should be accompanied, for as far as possible, by the activation of the muscle pump (active exercise).
- In addition to circumference, the length of the residual limb should also be included in oedema measurements.
- A prosthesis should be ready for delivery within ten working days.
- Universal interim prostheses are less suitable for first use.
- A custom-made prosthesis (not necessarily the final product), available as early as possible in the postoperative phase, is preferable to a pre-fab prosthesis.

Chapter 11: Guideline implementation and indicators

The working group is confident that the implementation of the initiatives and proposals mentioned in above paragraphs will contribute to implementation of this guideline and therefore to an improvement in the quality of care.
KEY QUESTIONS

INDICATION and SURGICAL INTERVENTION

- Which indication criteria are available to determine the level of a lower limb amputation?
- What is the minimum required information when deciding on amputation?
- How can the most favourable moment for amputation of a lower limb be determined?
- What preoperative evaluation is required in patients undergoing amputation of a lower limb?
- Which surgical techniques are available for amputation of a lower limb? When is each technique indicated?
- What are the advantages and disadvantages of different surgical techniques for amputation of a lower limb?
- To what extent do aspects of diversity (sex, age, comorbidity) influence indication and surgical intervention?

PATIENT INFORMATION AND INFORMATION RESOURCES

- What information/advice should be provided by caregivers to the patient regarding treatment and rehabilitation, both before and after amputation?
- To what extent do aspects of diversity (gender, ethnicity, age, comorbidity) and personal situation play a role in the provision of information and advice?

IMMEDIATE POSTOPERATIVE MANAGEMENT

- What is the approach of choice to postoperative management immediately following amputation of a lower limb (immediate/delayed fitting, rigid dressing versus soft dressing)?
- What is the preferred approach to pain management (perioperative and postoperative) in lower limb amputation?
- Which complications (local/at stump level) occur following an amputation of a lower limb and how can they be prevented?
- To what extent do aspects of diversity (sex, age, comorbidity) influence management in the immediate postoperative period?
REHABILITATION

- How should an optimal rehabilitation process for patients be organised following amputation of a lower limb (organisation, care plan, psychosocial components, incorporating other disciplines)?

- To what extent do aspects of diversity (gender, age, comorbidity) and personal situation play a role in an optimal rehabilitation process?

- What are the barriers to and facilitators of a return to work in patients following amputation of a lower limb, taking into consideration the nature of the work?

PROSTHETIC PROVISION

- How can the prescription of prosthesis parts be improved? Which factors influence prosthetic prescription?

- At what moment following amputation should prosthesis fitting commence?

- To what extent do aspects of diversity (gender, age, comorbidity) and personal situation play a role in prosthetic provision?

IMPLEMENTATION

- How can the implementation of the guideline be ensured?
CHAPTER 1: GENERAL INTRODUCTION

Background
An amputation of a lower limb is a major event for the patient and his or her family. The incidence of amputation of a lower limb is about 20 per 100,000, 60% of whom are male and 80% are older than 65 years. Every year about 3300 cases of lower limb amputation occur in the Netherlands (excluding toe amputations). In around 90% of the cases, amputation is the result of vascular complications (Geertzen and Rietman 2008). Surgeons (both general and vascular) still use a range of criteria to determine whether amputation is indicated. In addition, there is considerable debate regarding immediate postoperative management, especially concerning the use of ‘immediate/delayed fitting’ versus conservative elastic bandaging. There is also considerable variation in prosthetic prescription concerning the moment of initial prosthetic fitting and the use of new components (van der Linde 2004). There is considerable ambiguity with regard to the surgical techniques, the moment of amputation and the subsequent rehabilitation program. The existing variety of approaches in these areas can lead to over- or under-treatment. The number of limb amputations will remain the same or decline slightly in the future. With increases in vascular disease and diabetes mellitus and an aging population, but also with better vascular surgery techniques, improving the quality of care for patients undergoing limb amputation is of major importance.

A structured, multidisciplinary approach is needed that includes a greater focus on the involvement of physiotherapists, psychologists and prosthetists. The information available to patients can also be significantly improved.

These considerations prompted the Netherlands Society of Physical and Rehabilitation Medicine (VRA) to take the lead in the development of a multidisciplinary, evidence-based guideline for the amputation and prosthetics of the lower extremities. The CBO provided methodological expertise.

This guideline could be realised thanks to a grant from the Quality Foundation of Dutch Medical Specialists (Stichting Kwaliteitsgelden Medisch Specialisten [SKMS]).

Objective
This guideline provides recommendations in support of daily practice. The guideline is based on the results of scientific research and further discussions focussed on establishing good medical practice. The best care (in general) for patients undergoing amputation of a lower limb is presented and discussed. The guideline provides recommendations for diagnosis, referral, assessment, treatment and reintegration of patients undergoing amputation of a lower limb and can be used to provide patient information. It also provides a starting point for local transmural agreements or protocols to promote implementation.

The specific objectives of this guideline are preventing injury to patient health by providing concrete recommendations regarding improved diagnostic and therapeutic possibilities, and the provision of clear statements on diagnosis and treatment and on the reintegration process to be followed by the patient. The goal is to achieve uniformity regarding the diagnosis, treatment and support in the various centres and to define the framework within which the multidisciplinary care of patients who undergo amputation of a lower limb should take place. This guideline will also contribute to improved communication between clinicians and patients.
and between practitioners themselves, with special emphasis on the somatic, psychological, technical and care aspects.

**Scope**
This guideline provides recommendations for the process of assessment of amputation up to and including the first definitive delivery of the prosthesis. The guideline limits itself to adult patients and makes no recommendations regarding amputation and prosthetics in children. Because 90-95% of amputations occur in patients with vascular disease, this guideline focuses primarily on this patient group. Oncological amputations and amputations due to trauma are only briefly discussed in this guideline.

**Target audience**
The guideline is intended for all healthcare professionals involved in the treatment and guidance of patients undergoing amputation of a lower limb: rehabilitation specialists, general surgeons, vascular surgeons, orthopaedic surgeons, anaesthesiologists, elderly care physicians, occupational medicine, psychologists, social workers, physiotherapists, occupational therapists, dieticians, orthopaedic technicians, nurses, prosthetists and orthopaedic technologists.

**Composition of the working group**
For the development of this guideline a multidisciplinary working group was formed in 2009, including representatives of all medical disciplines involved in the diagnosis, treatment and guidance of amputees and advisors from the CBO (see ‘Composition of the working group’). The composition of the working group reflects a number of factors, including the geographical distribution of the group members, equal representation of the various associations and bodies, as well as diversity in academic and non-academic backgrounds. The working group members acted independently and were mandated by their respective associations. An overview of the declarations of interests of group members regarding potential financial conflicts of interest can be found as an addendum to the guideline on the website.

**Approach taken by the working group**
Given the scale of the task, a number of sub-groups with representatives from relevant disciplines were formed. In addition, together with advisors from the CBO, the chairman ensured coordination and harmonisation between the subgroups.
The working group spent a period of about eighteen months answering the key questions (appendix 1) and drafting the text of the draft guideline. The subgroups appraised the scientific arguments written by CBO consultants and then formulated additional considerations and recommendations. The subgroups also prepared consensus texts when scientific evidence on a key question was lacking. These texts were discussed in plenary meetings and approved following revision based on these comments. The entire working group met eight times to discuss subgroup results as they related to each other. The various subgroup texts were reworked by an editorial team to a single coherent document, the draft guideline. This was sent to the relevant organisations for comment in May 2011. Following a re-working based on these comments, the guideline was adopted by the entire working group in November 2011 and then sent to the relevant professional bodies for approval.

Scientific evidence
The recommendations in this guideline are, for as far as possible, based on evidence from published scientific research. Relevant articles were identified by performing systematic searches in the Cochrane Library, Medline, Embase, PsycINFO and CINAHL. Languages were limited to Dutch, English, German, and French. Manual searches were also conducted. Search dates were between 1966 (Medline) or 1980 (Embase) and early 2009 and no later than January 2011. Appendix 7 shows the search period and the search terms used, by initial key question. The main keywords used to identify the patient population in Medline were: MESH (Medical Subject Heading) terms: Amputation/ or Disarticulation/ or Amputation Stumps/ or Amputation, Traumatic.

Searches were also conducted using free text (by importance): ((trans?tibial or (trans adj1 tibial)) adj2 amputat$).ti,ab. or ((trans?femoral or (trans adj1 femoral)) adj2 amputat$).ti,ab. or (knee$ adj2 (disarticulat$ or exarticulat$)).ti,ab. or (knee$ adj2 amputat$).ti,ab. or ((tibial or femoral) adj2 amputat$).ti,ab. or ((leg$ or limb$ or crural or lower extremit$) adj2 amputat$).ti,ab. or ((trans?ankle or syme) adj3 (amputat$ or disarticulat$)).ti,ab.

Important selection criteria were: comparative studies with robust evidence, such as meta-analyses, systematic reviews, randomised controlled trials (RCT) and controlled trials (CT). Where these were unavailable, further comparative cohort studies, comparative case-control studies or non-comparative studies were sought. Case reports were also used to aid opinion-forming regarding certain key questions.

The quality of these articles was assessed by epidemiologists from the CBO on the basis of evidence-based guideline development (EBRO) assessment forms. Articles of mediocre or poor quality were excluded. After this selection, the remaining articles formed the basis for the various conclusions set out in the guideline. The selected articles were then graded according to the degree of proof, using the following format (Table 1). The degree and level of evidence are described in the conclusion section of the various chapters. The main literature supporting the conclusions is also listed.
Classification of the level of supporting evidence

[Table 1: Table describing levels of evidence for articles and for the conclusions]

The description and evaluation of the various items can be found in the various sections under the heading ‘Scientific Evidence’. The scientific evidence is summarised in a ‘Conclusion’, which shows the level of the most relevant evidence.

Development of the recommendations

In order to arrive at a recommendation, in addition to the scientific evidence, other aspects are often of importance, including patient preferences, availability of special techniques or expertise, organisational aspects, social consequences and costs. These aspects are discussed below the ‘Conclusion’ in ‘Other considerations’, and the literature-based conclusion is considered in the context of daily practice, and the advantages and disadvantages of the various management options are weighed. The definitive recommendation is based on the available evidence in conjunction with these considerations. The ultimate goal behind the use of this procedure and the drafting of the guideline in this ‘format’ was to increase the transparency of the guideline. This approach allows for a more efficient discussion of the guideline during the working group meetings and also increases transparency for the user of the guideline.

Patient perspectives

The patients' perspective was taken into account during the drafting of the guideline. In the analysis of potential challenges, patients from the rehabilitation department of the St. Maartenskliniek in Nijmegen and the Centre for Rehabilitation Hoensbroeck were asked to suggest challenges of their own during a focus group meeting. Remaining problems were discussed in in a round of telephone interviews with individual patients. The draft guideline was also presented to the patient organisations in the Netherlands. Finally, in the future more educational material should be developed in collaboration with the patient organisations.

Implementation and evaluation

During the various stages of development of the concept guideline, the implementation and the actual feasibility of the recommendations was taken into account as much as possible. The guideline will be distributed to all relevant professional groups and hospitals. A summary of the guideline will also be offered for publication in the Nederlands Tijdschrift voor Geneeskunde (Dutch Journal of Medicine) and Prosthetics & Orthotics International and the guideline will receive attention in various specific journals. In addition, the full text of the guideline will be posted on the websites of the CBO, the professional associations and the patient organisations.
To encourage the implementation and evaluation of this guideline, the working group will develop a plan of implementation and a list of indicators against which implementation can be measured. Indicators generally provide caregivers with a means of assessing whether they are providing the required level of care, and can also be used to identify areas in which healthcare provision could be improved.

End users from the various regions and the scientific associations will review the guideline, with the review process including the organisation of clinical audits.

**Legal status of the guideline**

Guidelines have no formal legal status, but represent scientifically justified and widely accepted views and recommendations that healthcare providers should follow during the provision of high quality care. As guidelines are based on ‘average patients’, caregivers may deviate from the recommendations of the guideline in individual cases as necessary. Deviation from established guidelines is sometimes even essential when the condition of the patient requires it. However, any deviation from the guideline should be justified and documented and, where necessary, take place in full consultation with the patient.

**Revision**

After consultation with or on the advice of the participating associations, the Netherlands Society of Physical and Rehabilitation Medicine (VRA) will determine whether this guideline is in need of revision no later than 2016. If necessary, a new working group will be established to revise (sections of) the guideline. The guideline will cease to be valid at an earlier date should new developments necessitate an earlier revision.

**Literature**

- Amputatie en prothesiologie van de onderste extremiteit, onder redactie van Geertzen JHB en Rietman JS, Lemma 2008.
Table 1: Classification of methodological quality of individual studies

<table>
<thead>
<tr>
<th>Interventio n</th>
<th>Diagnostic accuracy of research</th>
<th>Lesion or side effects, etiology, prognosis*</th>
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<tbody>
<tr>
<td>A1</td>
<td>Systematic review of at least two independent studies of A2-level</td>
<td></td>
</tr>
<tr>
<td>A2</td>
<td>Randomised double-blind comparative clinical studies of good quality and sufficient scope</td>
<td>A study in comparison with a reference test (‘gold standard’) with predefined cut-off points and independent assessment of the results of test and gold standard values, on a sufficiently large series of consecutive patients, with all having undergone both the index and reference test</td>
</tr>
<tr>
<td>B</td>
<td>Comparative study, but not including all the features listed under A2 (this also includes case-control studies, cohort studies)</td>
<td>Study compared with a reference test, but not with all features described under A2</td>
</tr>
<tr>
<td>C</td>
<td>Non-comparative study</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>Expert opinion</td>
<td></td>
</tr>
</tbody>
</table>

* This classification applies only in situations where controlled trials are not possible for ethical or other reasons. When controlled trials are possible, the classification for interventions is valid.

Level of conclusions

<table>
<thead>
<tr>
<th>Conclusion based on</th>
<th></th>
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<tbody>
<tr>
<td>1</td>
<td>Study of level A1 or at least two independently conducted studies of A2 level, with consistent results</td>
</tr>
<tr>
<td>2</td>
<td>1 study of level A2 or at least two independently conducted studies of level B</td>
</tr>
<tr>
<td>3</td>
<td>1 study of level B or C</td>
</tr>
<tr>
<td>4</td>
<td>Expert opinion</td>
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CHAPTER 2: INDICATION CRITERIA

Key questions 1
- Which indication criteria are available to determine the level of a lower limb amputation?
- What is the minimum required information when deciding on amputation?
- How can the most favourable moment for amputation of a lower limb be determined?
- What preoperative evaluation is required in patients undergoing amputation of a lower limb?

Introduction
The text of this chapter is largely based on the international TransAtlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASCII 2007), the VA/DoD Clinical Practice Guideline For Rehabilitation of Lower Limb Amputation (2007) and the Guideline diagnostics and treatment of vascular disease of the lower limb by the Dutch Society for Surgery and the Radiological Society of the Netherlands (2005).

Amputation of lower extremities can be regarded as a delicate reconstructive procedure with the aim of producing a remnant limb with an as optimal as possible function. This applies to both the motor functions when walking with a prosthesis, as well as to sensory feedback and cosmetic aspects. The most common cause of amputation in the Netherlands is vascular disease with critical ischemia, often in combination with diabetes mellitus (90-95%). Other causes include trauma, malignancy, infection and congenital disorders.

The most common reason for amputation in Europe is vascular insufficiency with critical ischemia. In Finland, recent decades have seen a fall in the number of amputations from 29 to 15 per 100,000 inhabitants (Eskelinen 2001). In Germany, the number of major amputations (above the ankle) per year is calculated to be 8.4 per 100,000, in combination with 23 bypass operations per 100,000 and 64.4 PTA (Percutaneous Transluminal Angioplasty) per 100,000 inhabitants (Wohlgemut 2006). This decrease is attributed to improvements in vascular surgery and to improvements in the care of the diabetic foot.

Because amputations of a lower limb in the Netherlands are especially frequent in vascular disease, they receive particular attention in this chapter. Where necessary, additional comments are made with regard to other causes.

Early detection
To prevent amputation it is critical that patients with peripheral vascular disease at risk of foot complications be detected at an early stage. This includes the identification and treatment of circulatory disorders and the treatment of wounds with or without infection.
The TASC recommends that all diabetic patients with an ulcer should be investigated for peripheral vascular disease using objective tests (TASCII 2007). Bypass surgery and endovascular techniques are effective in preventing amputation (Dutch guideline diagnostics and treatment of vascular disease of the lower limb 2005). Up to 85% of diabetic ulcer-related amputations can be prevented by early diagnosis and appropriate treatment (TASCII 2007). Following successful revascularisation the risk of amputation is low: 1% per year (Van Hattum 2010, Flu 2010).

**Multidisciplinary treatment**

In order to prevent amputation it is recommended that patients with critical ischemia and those developing foot ulcers be treated using a multidisciplinary approach (surgeon, rehabilitation physician, anaesthesiologist, pain specialist and physiotherapist, with the possible additional involvement of an orthopaedic technician or prosthetist) (Dutch Guideline Diabetic Foot 2006).

Multidisciplinary treatment is also recommended for the treatment of pain, cardiovascular risks, comorbidity and the co-determination of the amputation level (TASCII 2007).

**A. Which indication criteria are available to determine the level of a lower limb amputation?**

The purpose of an amputation is to achieve (primary) wound healing as distal as possible and with the highest possible post-amputation functionality of the patient and suitability for prosthesis use. It is therefore necessary to obtain information that permits the assessment of the chances of recovery, the potential for rehabilitation and the recovery of quality of life (TASCII 2007).

When deciding on amputation, the level of amputation is determined by the clinical situation, such as the degree of expansion of gangrene or infection and the likelihood of a successful, preferably primary, wound healing. The clinical assessment of the amputation level indicates a potential for undisturbed wound healing of 80% for transtibial amputations, 90% in transfemoral amputations and 60% for knee disarticulation. The measurement of the transcutaneous partial pressure of oxygen (tcPO$_2$) may be useful when determining the chance of healing at various levels (TASCII 2007).

A primary high amputation (that is to say without prior vascular intervention) will be performed in rare cases in non-ambulatory patients. This is indicated when:

- the physical condition of the patient;
- the surgical options;
- the possibilities for rehabilitation;
- the psychological condition of the patient.

When the condition of the patient has deteriorated to the extent that a revascularisation procedure is no longer possible or when it is unlikely that the restoration of the circulation will lead to a functional limb, amputation (including removal of all necrotic tissue and the elimination of sources of rest pain) should be considered.

A secondary high amputation is performed when vascular reconstruction is no longer possible or following a progressive distal deterioration despite successful vascular
reconstruction (TASCII 2007). The probability of wound healing following a successful revascularisation and a more distal amputation (transtibial or lower) is 85%. Revascularisation fails in around 5-10% of the patients and results in an amputation at a higher level (Albrektsen 1997). An unsuccessful revascularisation often leads to an amputation level that is higher than when revascularisation was not attempted. Following a failed revascularisation, transtibial amputations are twice as often followed by transfemoral amputations than in cases where primary transtibial amputation was the initial choice (without attempted revascularisation), respectively 24% and 12.4% (Ebskov 1999).

The preservation of the knee with an adequate stump following transtibial amputation allows the use of a light-weight prosthesis, minimises energy consumption during walking and therefore also allows weaker patients to walk independently. Patients with a transtibial amputation wound that has healed well have a greater chance of independent mobility than those with a transfemoral amputation (Taylor 2005).

**B. What is the minimum required information when deciding on amputation?**

A number of factors should be taken into account when deciding on whether to amputate, including the potential for eventual recovery - for example in cases of a serious (life-threatening) infection, the possibilities for rehabilitation and quality of life.

The decision to amputate should be made by an experienced surgeon. The surgeon must be familiar with the different approaches at the various levels of amputation, muscular balance and wound closure (Smith 2004). Experience with amputation techniques is also important. A recent meta-analysis (46,311 patients) reported that the chance of amputation is lower in high-volume vascular surgery clinics than in low-volume clinics.

In patients with arterial obstructive vascular disease critical ischemia may be an indication for amputation. Critical ischemia is defined as a circulatory disturbance of sufficient gravity that there is a high probability of amputation should the limb remain untreated. Calf ischemia is characterised by rest pain (Fontaine stage III, Rutherford grade II, category 4) or tissue loss with necrosis or gangrene (Fontaine stage IV, Rutherford Grade III cat 5.6) (Schmieder 2001).

Arterial disease can be demonstrated by either non-invasive or invasive vascular tests. The vascular laboratory plays an important role in non-invasive studies. According to TASC II (2007) the following pressures indicate critical ischemia:

- Ankle pressure < 50-70 mmHg;
- Toe pressure < 30-50 mmHg;
- Transcutaneous oxygen pressure < 30-50 mmHg.

It should be established that the circulation can be improved. Revascularisation (surgical or endovascular) techniques are effective in the prevention of amputation (Dutch guideline vascular disease 2005).
Successful continuous primary healing occurs in approximately 80% of transtibial amputations and 90% of transfemoral amputations (Lim 1967). Clinical testing in conjunction with the measurement of tcPO2 can be used to predict healing at the different levels of amputation (Poredos 2005).

Assessment by a multidisciplinary team in the preoperative phase (surgeon, rehabilitation physician, anaesthetist and physiotherapist) forms the basis for the policy to be followed after surgery and during the rehabilitation process. The involvement of multiple disciplines reduces the risk of complications during surgery and during the postoperative phase (VA/DOD 2007: Interdisciplinair overleg-en beoordelingsprocedure). It is important that an interdisciplinary baseline patient status be established and that this medical status is optimised in order to obtain the best surgical and rehabilitation results.

C. How can the most favourable moment for amputation be determined?
Determining the degree of urgency is of importance when deciding for amputation with the aim of ensuring the best outcome for the patient.
Immediate surgery is indicated in cases of sepsis due to infection of the affected leg and where there is an acute risk of ischemia. An immediate vascular reconstruction can prevent amputation (also relevant in trauma patients). If necessary, a border zone amputation (at the border between viable and non-viable tissue) may be considered in cases of successful revascularisation.
Because evidence indicates that blood flow to the lower limb improves in the first three weeks after revascularisation, deferred amputation following revascularisation is preferred (Caselli 2005).

In the case of trauma in which the immediate threat to life is not serious, collateral circulation may develop during a period of conservative treatment. This can contribute to the prevention of amputation, or to amputation at a lower level than that first deemed necessary. An immediate repair of damage to blood vessels by a vascular surgeon may improve circulation and even prevent an amputation. In the total care of a patient it is important to take into account the possibility that extensive reconstructive limb surgery may result in a painful, non-functional leg.

D. What preoperative evaluation is required in patients undergoing amputation of a lower limb?

Vascular evaluation/vessel analysis
The vascular surgeon should play the coordinating role in a patient with critical ischemia and a clear risk of losing a leg (TASCII 2007).
Prior to amputation, research to assess the vascularisation of the limb should be carried out. The first step involves physical examination, including assessment of the level and quality of arterial pulsations, the degree of ischemia and comorbidity.
Ankle-brachial index, toe pressure, tcPO\textsubscript{2}
In addition to the clinical assessment, additional tests such as transcutaneous oxygen measurements or toe pressure measurement can be considered. Localisation of vascular anomalies can be achieved through haemodynamic measurements such as segmental blood pressure or pulse volume recording. A group at particular risk is the diabetes patient with peripheral arterial disease; not only is claudication with PAV seen in only 30% due to masking neuropathy, media calcification may also result in a false positive finding in the ABI index measurement.

It should be remembered that distal calcified vessels in diabetics are relatively rigid as a result of ‘medical artery calcification’ (MAC), resulting in a higher ankle pressure and consequently in a higher ankle-brachial index (ABI). The resulting normal values represent a false-positive elevated ABI, meaning that greater importance should be attached to duplex, toe pressure and tcPO\textsubscript{2} measurements. In a diagnostic RCT, the influence of ischemia treatment decisions in relation to revascularisation on the basis of the clinical picture and ankle-brachial index was compared with the decision to treat on the basis of transcutaneous oxygen tension (TcPO\textsubscript{2}) and toe pressure measurement. TcPO\textsubscript{2} and toe pressure measurement did not improve the clinical outcome, but determination can be helpful in case of doubt regarding the need for revascularisation (De Graaf 2003).

When a discrepancy between clinical and pressure measurements arises, vascular imaging should be considered (TASCII 2007).

Vascular imaging: duplex, digital subtraction angiography (DSA), computed tomography angiography (CTA), magnetic resonance angiography (MRA)

When imaging of arterial abnormalities is necessary for management decisions, the following techniques are recommended: duplex examination, DSA, MRA en CTA (TASCII 2007).

Other considerations
No clear criteria are given in literature for the clinical assessment of the amputation level (Davis 2004). The assessment of the amputation level takes place on clinical grounds, in which it is important to evaluate aspects of mobility and possible patient comorbidity.

In addition to the clinical assessment, transcutaneous oxygen measurement or toe pressure measurement can be helpful.

Mobility
When determining the level of amputation, preoperative mobility and the prospects for postoperative mobility should be taken into account. Preoperative mobility is an independent determinant of the possibility of rehabilitation. Patients with unrestricted preoperative mobility, without other comorbidities, have a 67% chance of successful rehabilitation (Taylor 2008). Patients with reduced mobility at the time of presentation for transtibial amputation with coronary artery disease or cerebrovascular pathology have a 10-20% chance of mobility with a prosthesis. One year after amputation of the lower limb about 60% of patients are mobile, while 29% are mobile following transfemoral amputation (Taylor 2008).
Patients who were only moderately mobile prior to amputation will become successfully mobile less often. When a flexion contracture of the knee occurs in a patient in need of an amputation, the lower limb forms an obstacle. A disarticulation of the knee provides a superior solution in a patient at vascular risk. Conversely, a disarticulation is an option worth exploring when a transfemoral amputation is being considered. Amputation, rather than revascularisation, may offer patients a more rapid return to an acceptable quality of life, especially when a prolonged duration of the revascularisation treatment is expected, and with a limited chance of success. The most important problem is to determine which subgroups of patients with critical ischemia would ultimately benefit more from an amputation than from revascularisation.

For example, in ambulatory older patients, extensive vascular reconstruction may result in an unstable condition in the limb with a reduced chance of mobility. Instead, a primary amputation could be considered a viable treatment option with improved mobility and quality of life (Nehler 2003). Technical factors, aspects of wound healing, deconditioning and existing comorbidity are all factors that determine whether a patient is suitable for amputation.

Comorbidity
Survival of patients undergoing transfemoral amputation is significantly worse (one and five year survival 50.6% and 22.5%, respectively) than after a transtibial amputation (one and five year survival 74.5% and 37.8%, respectively) (Aulivola 2004). Survival is linked to comorbidity, with cardiovascular condition being of particular importance (congestive heart failure, myocardial infarction), together with dementia and (especially terminal) renal impairment (O’Hare 2004). ASA 4 patients have an increased chance of mortality (Campbell 2001).

It is therefore important to weigh the chances of success of a vascular reconstruction - and subsequent mobility – against the chance of healing and mobility following a primary amputation. Patients with limited mobility, aged over 70 years, dementia, end-stage renal disease and/or severe coronary artery disease show poor mobility following transtibial amputation; a knee disarticulation or transfemoral amputation should instead be considered (Taylor 2005). In this case, the knee disarticulation is preferable to a transfemoral amputation (Faber 2001).

The treatment of comorbidity requires a multidisciplinary approach. This also applies to the treatment of pain, cardiovascular risk and the determination of the amputation level.

Primary amputation in an early phase of ischemia
In addition, it is also possible that primary amputation may be indicated at an early stage, with the aim of achieving a better long-term prospect of functionality for the patient and a lower risk of comorbidity (Tennant, 2004, Parvin 2003) This has been described as "positive amputation" by Parvin.
Immediate surgery

Acute ischemia
During rapid worsening of tissue ischemia, 25% of patients lose a portion of a limb due to the extent of ischemia, 15% Category 2 Rutherford (threatened, but vital), 10% Category 3 Rutherford (irreversible ischemia).
The chance of transfemoral amputation following acute vascular occlusion is four times greater than in chronic ischemia (acute vessel closure: transtibial ratio: transfemoral =4:1, 1:1 chronic ischemia) because the calf is often involved in acute irreversible ischemia. If immediate surgery is needed, a high amputation will therefore more often be necessary. The risk of bleeding is increased by the use of anticoagulants. The category of patients with a high amputation has a high level of cardiac and pulmonary comorbidity (TASC II 2007).

Sepsis
In wet gangrene (both in local and also in generalised) immediate surgery is indicated in order to remove the infection. In this situation the guillotine technique can be used, wherein the wound is left open. In a stable phase following recovery from sepsis syndrome, there will be an option for a subsequent definitive amputation. This leads to better results compared with a single intervention (Tisi 2004). A short period between diagnosis and amputation prevents further deterioration of the clinical condition of the patient, resulting in an increased chance of recovery.

Preparation for amputation

It is important to ensure that the contralateral leg (heel) is well-protected against pressure ulcers, both in the preoperative phase, during surgery and in the postoperative immobilisation phase.

Taking the conclusions and recommendations in the cited guidelines and the above mentioned arguments into consideration, the guideline development group has arrived at the following recommendations:

Recommendations

The working group recommends that all diabetic patients with ulcers be assessed for peripheral vascular disease using objective tests such as duplex in combination with ankle-brachial index.

To avoid possible amputation it is recommended that patients with critical ischemia and patients who develop foot ulcers be treated using a multidisciplinary approach (including a surgeon, interventional radiologist, vascular internist and rehabilitation physician).

When the condition of the patient is too poor to allow a planned revascularisation procedure or when it is unlikely that restoration of circulation will lead to a functional limb, primary amputation must be considered.
Multidisciplinary treatment (surgeon, anaesthesiologist, pain specialist, rehabilitation physician, possibly internist) is also necessary for the treatment of pain, cardiovascular risks, comorbidity and the co-determination of the amputation level.

A secondary amputation should be performed when a subsequent vascular reconstruction is no longer possible or if, despite successful vascular reconstruction, a progressive distal deterioration has occurred.

An amputation is necessary and/or indicated when there is:
- a severe (life-threatening) infection;
- a foot lost to extensive necrosis;
- intractable pain due to vascular disease.

Critical ischemia may be an indication for amputation in patients with arterial obstructive vascular disease.
Immediate amputation should be considered in cases of acute ischemia and sepsis.

Clinical criteria are used to assess the amputation level. It may be helpful to take transcutaneous oxygen or toe pressure measurements. Arterial disease can be demonstrated with non-invasive or with invasive vascular examination.
The vascular laboratory plays an important role in non-invasive studies.

It is advisable to assign a vascular surgeon as the chief clinician for a patient with critical ischemia.

Before deciding to proceed with amputation, the vascularisation of the limb should be assessed by means of physical examination and assessment of the level and quality of arterial pulsations, the degree of ischemia and co-morbidity.

In addition to the clinical assessment, additional tests such as transcutaneous oxygen measurements or toe pressure measurements can be carried out. Initial localisation of vascular anomalies can take place with the help of haemodynamic measurements such as segmental blood pressure measurement or pulse volume recording.

In the case of a discrepancy between clinical and pressure measurements, vascular imaging can be definitive.

Where imaging of arterial abnormalities is necessary for treatment decisions, the following techniques are recommended: duplex examination, DSA, MRA and CTA. If the vascular status of the limb is not yet established or if demarcation of the region for amputation has not yet taken place, it is advisable to postpone amputation.
Deferred amputation should not take place within the first 3 weeks after revascularisation, because blood flow to the leg can still improve within the three weeks following revascularisation.

The decision to amputate should be taken by an experienced surgeon, familiar with the multiple treatment methods at the various amputation levels, muscle balance and wound closure. Experience with amputation techniques is of importance. The amputation should preferably be performed by an experienced surgeon or supervised by an experienced surgeon.

It is recommended that treatment takes place within a multidisciplinary amputation team (consisting of a surgeon, rehabilitation physician, anaesthesiologist-pain specialist, physiotherapist and possibly an orthopaedic technician or prosthetist).

When determining the level of amputation, the preoperative mobility and prospects for postoperative patient mobility should be considered.

In patients with an indication for amputation and limited mobility, aged over 70 years, with dementia, end-stage renal disease and/or severe coronary artery disease, a transfemoral amputation or knee disarticulation should be considered.

If the above considerations rule out a transtibial amputation, a knee disarticulation may be considered due to its relative advantages over a transfemoral amputation.

Literature
- Ebskov L.B, Hindso K, Holstein P. Level of amputation following failed arterial reconstruction compared to primary amputation—a meta-analysis. Eur J Vasc Endovasc Surg 17(1), 35-40.
- Faber DC et al. Gritty stokes (through knee) amputation: should it be reintroduced? Southern Medical Journal 2001;94(10) 997-1001.
- Tisi PV, Callam MJ. Type of incision for below knee amputation. Cochrane Database of Systematic Reviews 2004, issue 1.
CHAPTER 3: SURGICAL TECHNIQUES

Key questions 2
- Which surgical techniques are available for amputation of a lower limb? When is each technique indicated?
- What are the advantages and disadvantages of different surgical techniques for amputation of a lower limb?
- To what extent do aspects of diversity (sex, age, comorbidity) influence the indication and surgical intervention?

Introduction
When a leg is partly or irretrievably lost amputation becomes necessary. The major amputations of the lower extremities are at the following levels: transfemoral (above the knee/AKA), knee disarticulation (through the knee) and transtibial (below the knee/BKA). Around 3300 amputations (including toes: 5000), from the sacroiliac joint level to the forefoot, are performed annually in the Netherlands. The number of amputations from the transfemoral to transtibial level is about 2000 per year, most of which are transtibial.

Scientific evidence
A systematic search of Medline and Embase (from 1990 to May 2009) was conducted, and included searching for systematic reviews, RCTs and cohort studies. The search yielded 276 abstracts. A ‘full text’ assessment was eventually performed in 48 articles, after screening for content and study design (RCT). Following evaluation, the remaining six articles all related to transtibial amputations. No items of sufficient academic quality were found on transfemoral amputation or knee disarticulation. This finding has been described earlier in the ‘ISPO consensus conference (1990) report on amputation surgery’, published in 1992. No new items have appeared since.

In a Cochrane review by Tisi and Callam of the scientific literature up to July 2008, the authors searched for RCTs that evaluated the effect of different surgical techniques in patients with ischemia of a lower limb. They only found three RCTs. Although the review was of high quality (Table 1), the included trials were of limited size with the exception of that of Ruckley et al. There was also no possibility of blinding in these studies. Therefore, the evidence from this review can be classified as level A2, once (Ruckley, 1991) and level B, twice.

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1 Because no additional studies are found after 2004, the reference is maintained by Cochrane at 2004.
Surgical techniques

‘Two stage versus one stage below knee amputation’
A comparison of ‘two-stage below knee amputations (BKA)’ (guillotine amputation at the ankle followed by a long posterior flap BKA with delayed primary skin closure) with ‘one-stage BKA’ in a small RCT of 30 patients showed a better stump healing after six months in the ‘two-stage’ group (OR 0.08; CI 0.01-0.89). However, there was no difference in the postoperative infection rate or the reamputation rate (Fischer, 1988). The mobility rate did not differ significantly (47% in the ‘two-stage’ group and 54% in the ‘one-stage’ group).

Conclusion

<table>
<thead>
<tr>
<th>Level 3</th>
<th>There are indications that ‘two-stage’ transtibial amputation stump results in better healing than the ‘one-stage’ technique with ‘long posterior flap’, but it does not lead to improved long term outcomes.</th>
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‘Skew flap’ procedure versus ‘long posterior flap’
In a trial by the Joint Vascular Research Group (n=191), ‘skew flap’ below knee amputation (BKA) was compared with ‘long posterior flap’ BKA (Ruckley, 1991). After almost 12 months, no difference in stump healing, infection or reamputation rate was found. Mobility (60% for ‘skew flaps’ and 49% for ‘long posterior flap’) was also not significantly different (RR 1.22; 95% confidence interval (CI) 0.94-1.58). The reviewers note, however, that the surgeons participating in the RCT probably had little experience with the ‘skew flap’ procedure. This may have played a role in the absence of an effect.

Conclusion

<table>
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<tr>
<th>Level 2</th>
<th>There is no evidence that the ‘skew flap’ procedure gives better results than ‘long posterior flap’ procedure.</th>
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Finally, a small RCT with 41 patients showed that stump healing in patients treated with ‘sagittal flap’ (58%) did not differ from that of patients treated with ‘long posterior flap’ (55%) (OR 1:04; CI 0:45 to 2:43). There was no difference in the reamputation rate, the percentage with a suitable prosthesis or mortality between the two groups. Mobility was also equivalent (Termansen 1977).

Conclusion

<table>
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<tr>
<th>Level 3</th>
<th>Evidence suggests that a transtibial amputation with a ‘sagittal flap’ does not give superior results compared with ‘long posterior flap’.</th>
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Stump length
A rule of thumb is that an osseous length of 10-15 centimetres below the medial knee joint gap is optimal in a transtibial amputation. An alternative is: the length of the amputated tibia is equal to the width of the tibial plateau. However contraindications are: when an infection is present at less than 3 centimetres from the tibial tuberosity. This is because knee extension cannot be performed with a very short stump. The fibula should be cut at least 1 centimetre more proximally than the tibia. The distal bone structures are sawn through at an angle of 40-60 degrees and filed to prevent damage to the myocutaneous flap. If the bone is cut with the aid of a mechanically driven saw, cooling with physiological saline can prevent thermal injury to the bone; an ischemic leg has no heat regulatory mechanisms. Irrigating the wound also prevents contamination with bone meal.

Recommendations (expert opinion of working group)
In a transtibial amputation an osseous length of 10-15 centimetres below the medial knee joint gap is optimal.

Other considerations
The evidence on surgical techniques in transfemoral amputations and knee disarticulation lacks a truly firm foundation. When a knee disarticulation is possible, it is preferable to a transfemoral amputation. There is no favoured site for the height of a transfemoral amputation. The assessment should be based on whether or not the knee joint can be saved. The skin is cut using the fish mouth approach. A priority should be to preserve as much length as possible. However, in the case of a very short thigh stump, a hip disarticulation may offer a better solution for the subsequent provision of a prosthesis. Fixation of the amputated muscles through a myodesis results in an improved and more stable stump, through the preservation of muscle volume and opportunities for improved revalidation. It is also important to avoid flexion contracture of the hip. The hip adductor muscles, in particular the adductor magnus, are important in countering lateral movements of the femur. The bonding of the adductors to the stump will therefore be a priority. If a stump is too short an abduction contracture may occur and a stump that is too long may pose a problem when installing a prosthetic knee. The contralateral side should be taken as a benchmark, with a length of at least 10 cm above the medial knee joint gap. The patellar tendon should be fixed to the cruciate ligaments in a knee disarticulation, but the patella should not to be fixed by K wires and should not be removed. Nerves should be cut under traction. The members of the working group have therefore formulated their own recommendations (based on expert opinion).

Recommendations (expert opinion of working group)
The goal of a transfemoral amputation is to obtain, by means of a myodesis, a dynamic stump with good motor control and sensitivity.

The fish mouth incision should preferably be used during transfemoral amputation.
In a transfemoral amputation the aim should be to maintain the maximum length possible. However, in order to install a knee prosthesis and to maintain a thigh of equal length to the contralateral side, amputation should occur at least 10 cm proximal to the medial knee joint space.

If possible, a knee disarticulation is preferable to a transfemoral amputation. The patella should not be fixed and should not be removed. A strong preference was expressed for a myodesis, in this case the securing of the patellar tendon.

The preferred incision in the case of a knee disarticulation extends from the attachment of the patellae ligament to both sides and produces two symmetrical skin flaps.

Use of a tourniquet

Choksy et al. published the results of a well-conducted RCT (n=64) on the effect of a tourniquet in transtibial amputation (Table 2 and 3). Use of a tourniquet resulted in less blood loss and lower transfusion requirements (Choksy 2006). In an observational pilot study in 89 patients who underwent a transtibial amputation, Wolthuis et al. looked at the effect of a tourniquet on the same and several additional outcome parameters. Similar reductions in blood loss and transfusion requirements were seen, but they also reported a significant reduction in the number of stump revisions (Wolthuis 2006).

Conclusions

<table>
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<th>Level 2</th>
<th>It is likely that the use of a tourniquet in transtibial amputation results in less blood loss and a reduced need for transfusion.</th>
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<td>A2</td>
<td>Choksy 2006</td>
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<th>Level 3</th>
<th>There are indications that the use of a tourniquet in transtibial amputation leads to fewer stump revisions.</th>
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<td>B</td>
<td>Wolthuis 2006</td>
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Recommendation

The use of a tourniquet in transtibial amputation is recommended because tourniquet use results in less blood loss and may also result in fewer stump revisions.

Literature

- Tisi PV, Callam MJ. Type of incision for below knee amputation. Cochrane Database of Systematic Reviews 2004, issue 1.
CHAPTER 4: PATIENT INFORMATION

Key question 3
- What information/advice should be provided by the caregivers to the patient before and after amputation regarding treatment and rehabilitation?

Introduction
No literature was found on the subject of information for patients with an amputation of a lower limb. Instead, information came from interviews with 32 patients.

Information is a vital part of any medical treatment and this is also confirmed in the WGBO (1995). Any information must be tailored to the specific needs of the individual patient and included in patient records.

Verbal information should be repeated by practitioners and should be supported by another form of information, because patients and their family/caregivers often do not hear and/or remember all information. The form (oral, digital, leaflets) in which the information is provided will need to be tailored to the patient.

It is useful to prepare a checklist detailing the minimum information that should be provided to the patient. This can be completed and supplemented by every practitioner involved in the treatment. As in the specific case of an amputation the patient comes into contact with a relatively large number of disciplines, the development of a single information dossier should be considered so that each discipline can see which items have already been discussed and what may still need attention.

Treatment should be consistent and consistently implemented, and should ideally follow a set framework or care plan. Therefore, when the treatment plan has changed in the course of the treatment for any reason, this must be explained and discussed with the patient. In the case of transfer to another healthcare institution, a satisfactory transfer of information must take place and the treatment should ideally be seamlessly continued.

It should be made clear that treatment is carried out by a team, with an emphasis on the influence of the patient on the treatment plan as a whole and with objectives suited to the future needs of the patient. It makes sense to ensure that recurring discussions take place not only in the presence of the patient, but also with the involvement of family members and other involved parties. A patient should in the best possible condition when deciding for amputation (in particular, pain-free).

The treating disciplines, depending on local circumstances:

- Rehabilitation physician
- Elderly care physicians
- Anaesthesiologist (pain specialist)
- Physiotherapist
- Nurse
- Prosthetist
- Orthopaedic shoemaker
- Occupational therapist
- BIG-registered psychologist
- Activity coordinator
- Social worker
- Dietician
- Pastoral carers
- Movement therapist

**Points to consider when providing information to patients undergoing limb amputation, including an aspect of self-management (the order is not intended to suggest any particular sequence in time):**

- Causes of amputation and complicating factors: DM, vascular problems in general, tumours, trauma, smoking, nutritional status
- Time schedule of the entire treatment
- Amputation level: practical consequences and future (im)possibilities
- Functional prognosis, dependent on amputation level, age and health status (comorbidity) and also the psychological condition of the patient
- Complications: wound problems (infection, wound dehiscence, poor stump shape), chances of reamputation, phantom pain(sensations), stump pain
- Importance of wound healing, stump healing and stump dressing, aspects related to oedema
- Practising with the stump in terms of agility, coordination, muscle strength and contracture prevention
- Stump and skin care
- Physical consequences for the rest of the body (for example, increased energy consumption when walking)
- Coming to terms with the amputation (anxiety, depression but also teaching of coping strategies), reaction of the social environment
- Consequences for the social environment and social contacts
- Practise by the patient with and without a prosthesis in various everyday situations (gait training, balance training, transfers, fall training, sports and games, etc.) but also in terms of ADL such as dressing, washing and household tasks
- Types of prostheses and their components
- Measuring and fitting of the prosthesis, including the maintenance and care of the prosthesis
- Sexuality
- Adjustments in the home and in assistive devices
- Social adjustments, help with dealing with government bodies, reintegration into society and the workplace
- Dismissal and any follow-up arrangements
- Patient information and peer support

Recommendations

The working group is of the opinion that:
- Information for patients (electronic, oral or written) and for those directly involved in patient care is an essential component in the treatment of patients undergoing amputation of a lower limb.
- Treatment should be consistent and consistently implemented, ideally in the form of a care plan.
- As treatment involves multiple disciplines, it is advisable that any items discussed are recorded and defined in a manner that is clear to all disciplines.
- Information resources should be developed at the local level.
CHAPTER 5: POSTOPERATIVE MANAGEMENT

Key question 4
- What is the approach of choice to postoperative management immediately following amputation of a lower limb (immediate/delayed fitting, rigid dressing versus soft dressing)?

Introduction
The main objectives in the immediate postoperative phase relate to wound healing, pain control, forming of the amputation stump and early mobilisation (Geertzen and Rietman 2008). A specific focus is the treatment of oedema, which is intrinsic to transtibial amputation and negatively affects wound healing. Oedema causes increased pressure in the stump and thereby increased tension on the suture, which may result in skin necrosis due to insufficient microcirculation (Baumgartner 1995). Both in clinical practice as well as in the scientific literature, the discussion surrounding the choice of postoperative dressing focuses on the transtibial amputation patient group. In general, light elastic bandages or stump stockings are recommended for transfemoral amputation stumps (Geertzen and Rietman 2008).

In principle, a good stump dressing should have the following characteristics:
- provide protection against bacterial infections;
- result in a reduction in oedema;
- protect against physical trauma;
- provide opportunities for early mobilisation.

Despite the fact that the objectives of postoperative management are widely endorsed, there is still no consensus on the most effective stump dressing for patients with transtibial amputations.

To date, the most frequently applied approach is still the traditional wound bandage method in which the amputation is covered with sterile gauze followed by an elastic compression bandage. The stitches are then removed in stages between the tenth postoperative day and the third week and in the case of good wound healing, bandaging can commence. The main objective of this bandaging is to reduce the occurrence of oedema and to achieve a blunt conical shape. Elastic stockings may also be used to the same effect.

In addition to the classic bandaging method, so-called rigid stump dressings have also found use in the postoperative treatment of amputation stumps. The effect of a rigid stub dressing was first described by Pieter Verdun Adriaansz in 1696: "Nouvelle method amputer pour les membres" (Geertzen and Rietman 2008). This technique would later be applied during the first world war and improved versions were described in the 1960s and 1970s by Berlemont (1961), Weiss (1966) and Burgess (1978). The principle is that of a plaster bandage that is applied to the stump immediately postoperatively (direct or immediate fitting) or after a few days (delayed postoperative fitting), and remains in place for between 14 days and 21 days. Later, the removable rigid dressing (Wu 1987) was introduced to facilitate inspection of the stump during treatment.
Advantages of these plaster techniques include the prevention of contracture.

**Scientific evidence**
A systematic search was conducted in Medline and Embase (from 1990 to May 2009) for systematic reviews, RCTs and cohort studies. The search yielded 218 abstracts. After screening for content and study design (RCT), 28 articles were reviewed in full text. Following this evaluation, six articles remained; three studies in which a ‘rigid dressing’ (RD) was compared with a soft dressing (SD) (Deutsch 2005, Woodburn 2004, Wong 2000), a study in which a ‘plaster cast socket’ was compared with an elastic bandage (Vigier 1999), a study comparing the effect of a vacuum fabricated removable rigid dressing (RRD) and that of a conventionally manufactured RD (Johannesson, 2008) and a study (Janchai 2008) in which the effect of a RRD on reduction of the stump volume was examined in comparison with an elastic bandage.

**Rigid dressing (RD) versus elastic dressing (SD)**
The methodological quality of three studies (Deutsch 2005, Woodburn 2004, Wong 2000) was poor to moderate, and included an inadequate description of co-interventions, compliance, drop-out rates and blinding. Blinding of the patient and practitioner in this type of research is difficult, but blinding of the assessor is possible in some cases. The moderate methodological quality leads to a substantial risk of bias. In most of the studies there was no or only a summary description of inclusion criteria, and some studies also lacked clear initial criteria regarding primary or secondary outcome measures, thus resulting in a possibility of selective reporting. The only outcome measure in these studies (Deutsch 2005, Woodburn 2004, Wong 2000) was ‘time (days) to fitting of a prosthesis’. The studies by Deutsch and Woodburn found no significant difference in number of days to fitting of a prosthesis, while the study by Wong did report a significant difference. Given the different approaches to data presentation, it is difficult to compare these studies (see Appendix 6).

The study by Vigier (n=56) (1999) compared the effect of a rigid stump dressing (plaster cast socket), which had to be worn for 5 hours a day, with that of an elastic dressing. The study was of poor methodological quality (e.g. poorly described randomisation, lack of blinding). Large and significant effects were found in favour of the plaster cast socket with respect to wound healing (days 71.2 ± 31.7 versus 96.8 ± 54.9 days; p =0.04) and hospital stay (99.8 days ± 22.4 versus 129.9 ± 48.3 days; p =0.04).

In a study by Johannesson (n=27) (2008), a ‘vacuum manufactured RRD’ was compared with a conventional RRD. The study was of sufficient methodological quality, and similar results were found for the vacuum manufactured RRD compared with the conventional RRD with respect to time to prosthetic fitting, wound healing and function at three months.
### Conclusions

<table>
<thead>
<tr>
<th>Level 2</th>
<th>There is a small difference in favour of the (semi-) rigid dressing in comparison with the elastic dressing in terms of a reduction in the number of days to prosthesis fitting.</th>
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<tr>
<th>Level 3</th>
<th>There is a difference in favour of the rigid dressing (RD) in comparison with the elastic dressing (SD) in the time required for wound healing.</th>
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<td></td>
<td>B Vigier 1999</td>
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<tr>
<th>Level 3</th>
<th>There appears to be no difference between the manufactured vacuum RRD and conventional RRD with respect to time to prosthesis fitting, wound healing and function at three months.</th>
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<td>B Johannesson 2008</td>
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<th>Level 4</th>
<th>In comparison with the elastic dressing (SD), the rigid dressing (RD) seems to result in fewer contractures.</th>
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<td>D Expert opinion</td>
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### Other considerations

In relation to the objectives of postoperative management and the evidence in the literature, a number of additional factors may need consideration.

**Knee flexion contracture**

The conservation of knee mobility is of great importance in the postoperative phase. There is a tendency to keep the knee bent, particularly in the presence of postoperative pain, and a rigid dressing to above the knee can prevent the early development of a flexion contracture (expert opinion).

**Wound healing of the amputation stump**

In relation to the time to wound healing, a review by Nawijn (2005) reported a trend in favour of rigid dressings. Nawijn also cited the study by Vigier (1999), to which the study by Deutsch (2005) can also be added. Although this study just fell short in terms of significance (P =0.07) in respect to the difference in time to wound healing between the RRD and the elastic bandage, a clear trend was evident. In the other studies, time to wound healing was excluded from the evaluation. Another aspect of the study by Vigier (1999) that should be noted is that this author examined wound healing in amputation stumps with an initial incision wound that was not yet closed. This amputation technique is not a routine procedure in general amputation surgery, so question marks remain as to the clinical relevance of these findings.
**Volume of the amputation stump**

The respective effect of a RRD and an elastic bandage on the reduction of stump volume was only investigated in the study by Janchai (2008). A clear but non-significant trend (p = 0.064) was observed in favour of the RRD, but only in the first 2 weeks of the therapy and this difference disappeared completely in the following two weeks. This may mean that the volume reduction effect of RRD treatment is somewhat faster, but that the later effects of both treatments are equivalent. These findings are also supported by the systematic review by Nawijn (2005), which further notes that most studies were particularly weak in terms of patient numbers.

**Stump pain management**

Although it is generally assumed (and reported in some descriptive and case studies) that rigid dressings achieve better pain reduction than elastic bandages, no significant evidence for this was found within the selected controlled trials. This may be due to the lack of power in these studies or the lack of suitably sensitive instruments to quantify postoperative pain (Smith 2003). Thus far, this pain-reducing effect has not been demonstrated.

**Stump protection**

It is generally assumed that rigid dressings provide better protection against stump trauma in the postoperative phase. Again, larger trials appear to be necessary in order to demonstrate this statistically (Woodburn 2004). An indication for a protective effect on the stump can be found in the results of the study by Deutsch (2005). Of the four patients in the RRD group who fell during the postoperative period none received stump injuries, while three of the six patients in the SD group who fell at this stage were eligible for surgical stump revision (Deutsch 2005). In a retrospective study on this issue, a 22% reduction in lesions to the transtibial stump was seen following introduction of rigid dressings (Hughes 1998).

**Time to prosthetic fitting**

As previously mentioned in the summary of the literature, the only study to show a significant difference between patient groups with a semi-rigid dressing and those with an elastic dressing in terms of time to prosthesis fitting was that by Wong (2000) (Table 2). Furthermore, this study also included transfemoral amputation patients (5 of 21). The study population was limited in number (22 amputations), so the results should be interpreted cautiously.

The lack of significance in the study by Deutsch (2005) can be explained by the fact that the centre in question has a policy of very early prosthetic fitting (even before wound healing is complete). As this short time to prosthetic fitting (22 days) cannot be practically reduced by the choice of dressing, a lower limit effect occurs (Deutsch, 2005). Furthermore, we refer to question 10 regarding the choice of time of fitting of a prosthesis (see page 73).
Woodburn (2004) conducted a multicentre RCT involving 154 patients (n=78 RD and n=76 elastic bandages) in which a median reduction of 6 days to prosthetic fitting was seen in the RD group compared with the EB group. However, this reduction did not reach statistical significance. An initial power calculation indicated that inclusion of 300 patients would be necessary to achieve significance, so larger studies appear to be necessary.

**Performance with a prosthesis**
With respect to performance with a prosthesis, there also appear to be no obvious differences between groups of patients with the elastic and rigid dressing techniques. This lack of demonstrable differences is due to several factors. Performance with a prosthesis is not well defined, meaning that studies cannot be compared. In addition, the frequent presence of confounders that must be corrected for results in the required number of patients per group needed to demonstrate a real difference becoming greater than that included in the studies (Nawijn 2005). A good example of this are the results of Wong (2000) who claimed that 67% (n=8) of the patients treated with a rigid dressing were ambulatory with a prosthesis at discharge, while in the group of patients with an elastic dressing this was only 20% (n=2). Here too, the number of patients is very small.

Vigier (1999) defined function with a prosthesis as the ability to walk with a total contact socket and found no significant differences between the group with the rigid dressing and the control group. It is unlikely that differences in performance with a prosthesis can be demonstrated on long term follow-up between the groups with different stump dressings (Nawijn 2005).

**Clinical practice and organisational considerations**
The advantages of the classic elastic stump dressing as described in the literature (bandage method) are based on the simplicity of the method, the minimal time required, the use of widely available materials and possibility for frequent wound inspection (Smith 2003, Geertzen and Rietman 2008).

Known disadvantages are the experience required by the person carrying out the bandaging in application of the dressing, the high local or proximally generated pressures that may negatively affect healing, the frequency (5x to 6x daily) of application, the tendency to loosening and sagging and the only moderate protection of the amputation stump (Smith 2003, Geertzen and Rietman 2008). A number of these disadvantages can be overcome by the use of elastic stump stockings (stump shrinkers), silicone stump stockings or the use of zinc adhesive bandages. No comparative studies were found on this subject.

As discussed above, alternative treatment methods have been developed in the form of rigid dressings which, in comparison with the elastic dressing, facilitate faster wound healing, improved stump protection and a better mobilisation (Smith 2003, Geertzen and Rietman 2008).

Some practical disadvantages are also attributed to rigid dressings in the literature. For example, their use may be limited because the surgeon requires assistance during construction, anaesthesia may have to be applied for a longer period and the wound cannot be inspected at will (Baumgartner 1995).
In this case, a solution may be available in the form of removable dressings: the removable rigid dressing and vacuum rigid dressing.

The discussion regarding the choice of postoperative stump dressing focuses on the group of patients with a transtibial amputation. In the selected studies, only Wong (2000) and Vigier (1999) included some patients with transfemoral amputations. Light elastic bandages or stump stockings are generally recommended for transfemoral amputation stumps (Geertzen and Rietman 2008).

Finally, a number of additional aspects are discussed in the literature in relation to the organisation of care and the costs associated with the postoperative management related to the amputee. Deutsch (2005) reported a positive side effect in the form of a greatly enhanced collaboration within the multidisciplinary team dealing with the immediate postoperative treatment and further rehabilitation. The treatment team's experience with a particular method is of obvious importance (Geertzen and Rietman 2008) and when switching to a different postoperative stump treatment method, experience must again be gained in the logistical consequences entailed by the new approach. The organisation of care will also need to be revised.

With respect to any additional costs associated with rigid stump treatment, it should be noted that these will be recouped through the shorter hospital stay (Smith 2003).

**Recommendations**

<table>
<thead>
<tr>
<th>Recommendation</th>
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<tbody>
<tr>
<td>The working group considers that, in patients with transtibial amputation or knee disarticulation, a rigid dressing is the treatment of choice during the early postoperative phase.</td>
</tr>
<tr>
<td>Before switching to treatment with a rigid dressing, all logistical obstacles should have been overcome.</td>
</tr>
<tr>
<td>The removable rigid dressing may be considered when one wishes to apply a rigid dressing in patients with transtibial amputation and regular wound monitoring is indicated.</td>
</tr>
<tr>
<td>The working group is of the opinion that current postoperative management regarding stump dressing in transfemoral amputation patients can be maintained. Rigid stump dressings are not recommended.</td>
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</table>

**Literature**


CHAPTER 6: PAIN MANAGEMENT

Key question 5
- What is the preferred approach to pain management (peri- and postoperative) in lower limb amputation and which interventions are useful in the prevention of chronic stump pain and phantom pain?

Introduction
Amputation of a (part of) a lower limb is a major mutilating procedure, with matching high postoperative pain scores. It is therefore important that appropriate postoperative pain management be applied in order to treat acute amputation stump pain. In addition to acute pain following amputation, a considerable number of patients develop chronic pain syndromes following treatment. Phantom pain, experienced as painful sensations in the amputated limb, is a neuropathic pain syndrome probably caused by central and peripheral neural mechanisms. There are also indications that neuroplastic changes play a role. Following the acute phase, some patients continue to experience pain in the stump, which is then described as chronic stump pain (Halbert 2002). The source of pain in chronic stump pain is in the stump itself. Many patients experience pain even before amputation. During this phase an anaesthesiologist-pain specialist and a rehabilitation physician should be involved in the consultation. The literature was searched for evidence for a reduction in the incidence and severity of stump and phantom pain due to the use of certain anaesthetic techniques or the use of adjuvant pain medication, in addition to ‘standard’ postoperative pain management.

Scientific evidence
A systematic search of Medline, Embase and PsychINFO (from 1990 to May 2009) was conducted. The search yielded 204 abstracts. After screening for content and study design (RCT), seven relevant studies remained to address this question.

Methodological quality
In general, the studies were of reasonable to good methodological quality, and almost all studies showed well-executed randomisation and blinding of patients, clinicians and assessors. The reporting of co-interventions and compliance (therapy adherence) were points on which some studies were inadequate. Most of the studies included a limited number of participants and four of the seven studies showed a high dropout rate (Nikolajsen 1998, Hayes 2004, Bone 2002, Lambert 2001).

The presentation of results is divided into the following comparisons:

Epidural or perineural administration of bupivacaine versus placebo
Two RCTs reported a comparison between administration of bupivacaine and placebo. The RCT by Nikolajsen (1997, n=56) compared epidural administration of bupivacaine to a placebo. The RCT by Pinzur (1996, n=21) compared perineural administration of bupivacaine with a placebo. Both studies found no (significant) differences between the
groups on the outcome measures stump pain and phantom pain at 6 months (measured by VAS, 0-100mm and the McGill Pain Questionnaire). A measurement at 12 months was also included in the Nikolajsen study (1997), but no significant differences in stump pain and phantom pain were found. However, the acute pain scores in the Nicolajsen study were lower preoperatively with epidural administration. In the Pinzur study, immediate postoperative pain scores were better in the intervention group.

**Ketamine versus placebo**
In two RCTs (total n=92) (Wilson 2008, Hayes 2004), a comparison was made between ketamine and placebo (saline). In the study by Wilson (2008), both groups were given epidural analgesia; one group received epidural administration of a mixture of ketamine and bupivacaine, the other bupivacaine and a placebo (physiological saline). In the study by Hayes, a sub-anesthesiological loading dose followed by continuous intravenous administration of ketamine was compared with placebo (saline). Both studies found no (significant) differences between the groups for the incidence and intensity of stump and phantom pain (VAS, 0-100mm/NRS 0-10) up to 6 months after amputation. In the study by Wilson (2008), a measurement carried out at 12 months also showed no significant differences in stump and phantom pain.

**Gabapentine versus placebo**
In two RCTs (Nikolajsen 2006, Bone 2002), gabapentin and a placebo were compared. The RCT by Nikolajsen (2006) (n=41) on perioperative administration of gabapentin, with a follow-up period of 6 months, found no significant differences between groups in the incidence of phantom pain and intensity of stump pain and phantom pain (NRS, 0 - 10). In the cross-over trial by Bone (n=19), with a follow-up period of 6 weeks, a significant difference in phantom pain (VAS, 0-100mm) was found in favour of gabapentin: 3.2 mm (SD 2.1) vs. 1.6 mm (SD 0.7), p =0.03 (after 6 weeks). These results were only based on 14 individuals who had existing phantom pain of more than 6 months duration, and were not confirmed in the RCT by Nikolajsen (2006).

**Epidural administration versus perineural administration**
Epidural and perineural analgesia (bupivacaine) were compared in an RCT (Lambert 2001, n=30), with a follow-up duration of 12 months. No differences were found between the groups in the incidence of stump or phantom pain. This study had several limitations, including large differences in baseline characteristics and a limited number of participants, which complicates the interpretation of the results.

**Side effects and complications**
In the studies which reported information on side effects (Wilson 2008 Hayes, 2004, Nikolajsen, 2006, Bone 2002), no significant differences between the groups were found.
Conclusions

<table>
<thead>
<tr>
<th>Level 2</th>
<th>Epidural or perineural administration of bupivacaine, compared with placebo, has no significant effect on the intensity of stump and phantom pain in the short/medium-long (≤ 6 months) and long-term (12 months).</th>
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<td>Nikolajsen 1997, Pinzur 1996</td>
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<th>Level 2</th>
<th>Ketamine (epidural or intravenous), compared with placebo, has no significant effect on the incidence and intensity of stump and phantom pain in the short/medium-long (≤ 6 months) and long-term (12 months).</th>
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<td>B</td>
<td>Wilson 2008, Hayes 2004</td>
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<tr>
<th>Level 2</th>
<th>Compared with placebo, gabapentin has no effect on the incidence and intensity of stump and phantom pain in the short/medium-long term (≤ 6 months).</th>
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<td>B</td>
<td>Nikolajsen 2006, Bone 2002</td>
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<tr>
<th>Level 3</th>
<th>There is no difference between epidural and perineural analgesia (bupivacaine) in the incidence of stump pain and phantom pain over the long term (12 months).</th>
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<td>B</td>
<td>Lambert 2001</td>
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Other considerations

Pharmacological interventions
Patients who undergo an amputation will, as with any major surgery of the extremities, experience moderate to severe acute postoperative pain. Pain management according to the Dutch guideline post-operative pain treatment (CBO, 2003) will therefore typically follow. In addition to oral and intravenous medications in the treatment of acute postoperative pain, epidural or perineural catheter techniques may also be used. Both in the study by Nikolajsen (1997) and in that by Pinzur (1996), acute pain scores were lower following use of epidural or perineural catheters. However, the application of these techniques does not lead to any reduction of phantom pain or chronic pain following an amputation.

Ketamine is a NMDA receptor antagonist. The NMDA receptor appears to play a role in the development of changes following central nerve injury, for example due to an amputation. Both intravenous and epidural administration of ketamine in amputation patients results in no significant reduction in chronic stump pain and phantom pain. Moreover, there is evidence that ketamine is neurotoxic (Vranken 2005), and ketamine is not registered for epidural administration.
Anticonvulsants are often used in the treatment of neuropathic pain. Of the anticonvulsants gabapentin and pregabalin, only gabapentin was studied in amputation and phantom pain patients in two RCTs. Perioperative administration of gabapentin appeared to have no effect on the incidence of phantom pain and chronic stump pain (Nikolasjen 2006). In a small study by Bone (2002), gabapentin may have shown an effect on longstanding phantom pain. Pregabalin is an anticonvulsant with a mechanism of action similar to gabapentin. No studies were found on the effect of pregabalin on phantom pain and chronic stump pain. Of tricyclic antidepressants, amitriptyline and nortriptyline have been shown to be effective against neuropathic pain. However, their role in the treatment of phantom pain has been poorly investigated. A study by Wilder-Smith (2005) suggested that, in addition to tramadol, amitriptyline may be effective in patients with phantom pain. The effects of other drugs such as dextromethorphan, botulinum toxin and capsaicin are known have only been described in small studies (Ben 2002, Kollewe 2009, Cannon 1998).

Non-pharmacological interventions
Non-pharmacological therapies such as Transcutaneous Electrical Neurostimulation (TENS), Farabloc and psychological interventions such as mirror therapy, EMDR, hypnosis, etc. are often used later in the rehabilitation process and therefore fall outside the scope of this guideline. For the effect of rehabilitation and prosthetics on chronic pain, please refer to the relevant chapters. Specialised techniques in the field of chronic pain management also fall outside the scope of this guideline.

Recommendations

<table>
<thead>
<tr>
<th>The working group believes that:</th>
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<tr>
<td>- Acute postoperative pain should be treated in accordance with the insights detailed in the guideline ‘Postoperatieve pijnbehandeling’.</td>
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<td>- Epidural treatment has a place in the perioperative management of pain.</td>
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<tr>
<td>- Continuing pain treatment by epidural or perineural catheters, despite having no significant effect on phantom pain over the medium-long term, has a place in the treatment of acute postoperative pain following amputation.</td>
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<tr>
<td>- Due to neurotoxicity, epidural infusion of ketamine cannot be recommended.</td>
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<tr>
<td>- The use of gabapentin can be considered for patients with phantom pain.</td>
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<tr>
<td>- The use of amitriptyline can be considered for patients with phantom pain.</td>
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Literature
CHAPTER 7: COMPLICATIONS

Key question 6
- Which complications (local/on stump level) occur following an amputation of a lower limb? And how can they be prevented?

Introduction
Many complications can occur following an amputation of a lower limb. They may be of a psychological nature (self-esteem, stress, etc., see also chapter 8), the effects of pre-existing comorbidities (heart failure), but may also be at the local level. Local complications may include (more at the transtibial level than the transfemoral level): wound healing disorders, skin problems, allergies (prosthetic materials), oedema, pain (phantom pain and stump pain) but also contractures of adjacent joints. These complications can occur at any level of amputation.

Amputations in the knee area result in common complications, the most important being wound healing disorders. These can be divided into disorders that lead to secondary wound healing after treatment (such as wound edge necrosis, dehiscence and infection) and disorders that are so severe that reamputation is necessary (usually progressive ischemia with extensive necrosis or wound infection with sepsis). In addition, factors related to the surgical technique can lead to amputation stumps that do not allow loading (and thus mobility). Finally, contractures may occur during the postoperative period, leading to the loss of a chance of mobility.

Scientific Evidence
A systematic search was conducted in Medline and Embase (from 1990 to February 2010) for articles (systematic reviews, RCTs and observational studies) that reported on the complications that occur in an amputation of a lower limb and/or how these complications can be prevented. The search yielded 207 abstracts. After screening for content and study design (RCT), 16 titles underwent a full text assessment. After exclusion of items that did not relate to the initial question (n=4), case reports (n=2), and a study that was already described in our selected systematic review (n=1), 10 articles remained and are discussed below.

Methodological quality
The 10 selected articles are diverse in their design (6 retrospective cohorts, three prospective cohorts and one systematic review). Besides the design, the differences in the structure of the cohorts are also large. The cohorts vary greatly in size (range 50-545 patients), in the mean age (range 28 to 81 years), in the reasons for amputation (only traumatic, only non-traumatic or a combination of both), in the level of amputation (hip, knee or ankle), and the number of inclusion and exclusion criteria vary from none to many. The most common amputation was around the knee, however, again a distinction was made (above, between or below the knee). In addition, the description of comorbidity was very different between studies.
And finally, the studies generally used different outcome measures. Together, these differences prevent the drawing of an overall conclusion. In addition, in the majority of cases the results were not categorised by amputation level, which is also not beneficial to the reliability of the results. This has resulted in a brief explanation of all 10 studies and, where possible, a combination of the scientific evidence.

The question of how the complications that occur in an amputation can be avoided was answered in a systematic review by McIntosh (2009). The review included four studies that looked at the effect of prophylactic antibiotics on the occurrence of infections due to the amputation of (part of) the leg. The methodological quality of the review was moderate, and the conclusion of the review was that the use of prophylactic antibiotics resulted in significantly fewer stump infections in comparison with placebo or no antibiotics.

A cohort study by Stone (2006) retrospectively considered 380 patients (median age 67 years) following recovery from a transtibial or transfemoral amputation. The exclusion criterion was amputation due to trauma.

The results showed a perioperative mortality of 15.5% (n=59) in this population, with a prevalence of wound complications after 90 days of 13.4% (n=51). A reamputation was performed significantly more often in patients who had undergone a transtibial amputation, while patients with a transfemoral amputation often underwent a local revision (p =0.0006). The same result was seen in a study by Cruz (2003); in a general population of 229 patients (average age 68.8 years) who had undergone a limb amputation (transtibial (n=119), transfemoral (n=177)), a significant difference in correction of the original amputation was seen in the group with a transtibial amputation (P> 0.0001).

Morse (2008, n=50) and Kock (2004, n=66) both studied retrospective cohorts of patients who had undergone knee disarticulation due to peripheral vascular disease. The patients in the study by Morse (2008) had undergone an amputation using a modified Mazet technique, while patients in the study by Kock (2004) had undergone an amputation in which a dorsal muscle flap of the gastrocnemius was used to close the wound. The results were comparable. In the Morse cohort 3 patients died (6%) as a result of surgery, 9 patients (19%) underwent a transfemoral amputation due to poor healing of wounds and 41 patients (81%) showed good wound healing. In the cohort studied by Kock (2004) 6 patients died perioperatively (9%), 9 patients (13%) required a second amputation up to the hip, and 6 patients (9%) needed an additional operation on soft tissue. Wound healing proceeded undisturbed in 48 patients (80%).

Nehler (2003) studied a cohort of 154 patients (median age 62 years) who had undergone one or more amputation(s) (transfemoral amputation (n=78), transtibial amputation (n=94)). Inclusion criteria were not formulated. Reasons for exclusion were being non-ambulatory, having dementia or having neurological disabilities. The results showed a perioperative mortality of 10%. In total, 57 revision surgeries were carried out and included transtibial amputation (n=23), transfemoral amputation (n=16) and a transfemoral reamputation in 18 patients (19%).
Campbell (2001) retrospectively studied a cohort of 312 patients with one or more amputation(s) of a lower limb (transtibial, n=192; transfemoral, n=122; Gritti-Stokes, n=34; hip disarticulation, n=1). There were no inclusion or exclusion criteria associated with recruitment to the cohort. The study looked at the overall revision rate (12%) and perioperative mortality within 30 days (18%). Although no statistical analysis comparing the different levels of amputation was reported, individual percentages were stated. The results showed that the transtibial group had the highest revision percentage (19%), and perioperative mortality was highest in the groups that had undergone a transfemoral amputation or a Gritti-Stokes (both 24%).

Johannesson (2004) prospectively followed 190 patients undergoing amputation of a lower limb over a period of 4 years. Patient recruitment was not subject to inclusion and/or exclusion criteria. The results showed that 27 patients died within one month of surgery, 24 patients had to undergo a reamputation (16 transfemoral, 8 transtibial) and, in 5 patients with a transfemoral amputation, a re-amputation had to be performed twice.

Wound complications occur more frequently in transtibial amputations than in transfemoral amputations (Nehler 2003), and explain two-thirds of reamputations. In addition, the type of anaesthesia, the location of patients (living at home) and the preoperative haematocrit (> 30) play an associative role (Stone 2006). Wound infections occur in 11-18% of amputation patients (McIntosh 2009).

Conclusions

<table>
<thead>
<tr>
<th>Level 2</th>
<th>It is likely that the use of prophylactic antibiotics leads to fewer stump infections in comparison with placebo or no antibiotic use.</th>
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<td></td>
<td>A2 McIntosh 2009</td>
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<table>
<thead>
<tr>
<th>Level 3</th>
<th>In a general population, re-amputation is significantly more common following a transtibial amputation as compared with a transfemoral amputation.</th>
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<td></td>
<td>C Stone 2006, Cruz 2003, Campbell 2001</td>
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<tr>
<th>Level 3</th>
<th>The complications following a knee disarticulation amputation include perioperative mortality (&lt;10%) and poor wound healing that often requires reamputation (20%).</th>
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</table>
In general, complications due to an amputation of the lower extremities include perioperative mortality (<18%) and re-amputation (<14%).


Factors associated with wound complications (within 90 days after amputation) are transtibial amputation, the type of anaesthesia (general and epidural), home living and a preoperative haematocrit >30.

C Stone 2006

Other considerations
The preservation of the patient’s knee has great advantages in terms of the chances of becoming mobile. Every effort must be made to achieve primary wound healing and maintain the level of a transtibial amputation.

Good surgical technique, which ensures an optimal osseous tibia stump length (10-15 cm), no excess soft tissue, no neuromas and ultimately a good blunt conical shape, mobile scars and the prevention of contractures, helps to ensure that the patient has a 10-20% greater chance of postoperative mobility. An experienced surgeon achieves better results, both in terms of the possibility of mobility as in a lower probability of reamputation (Awopetu 2010).

The annual minimum number of procedures required of a surgeon has been a matter of much debate in medical circles in the Netherlands, a debate that is equally relevant in amputation surgery.

In the learning phase, it seems appropriate that a surgeon should perform 20 major amputations with particular attention given to the composition of indicators and the complete perioperative supervision of patients. An additional important factor is not the number per year but involvement in a multidisciplinary amputation team in a hospital (see previous definition in the guideline). A figure of 5 to 10 amputations per surgeon per year may then be adequate to sufficiently stimulate the entire amputation team to together deliver good quality work.

The working group believes that patients facing amputation require subsequent supervision and treatment by a (limited) multidisciplinary team in the hospital, with continuation of outpatient rehabilitation treatment in a hospital, rehabilitation centre, nursing home or at home.
Recommendations

- To prevent wound infection following amputation, perioperative prophylactic antibiotic treatment is recommended in the form of a preoperative bolus or for 5 days starting immediately preoperatively.
- Because a good surgical technique increases the chance of postoperative mobility, amputations should be carried out by experienced surgeons who conduct a minimum number of 5 to 10 amputations each year. The absolute number per year is less important than permanent membership of a multidisciplinary team with sufficient incentives to jointly deliver good quality work.
- The working group recommends that a team be formed around the amputee in the hospital phase, and should at least include a surgeon, a rehabilitation physician, an anaesthesiologist and physiotherapist, and preferably supplemented with a dietician, a social worker, a BIG-registered psychologist or pastoral worker.

Literature

CHAPTER 8: REHABILITATION PROCESS

Key question 7
- How should an optimal rehabilitation process for patients following amputation of a lower limb be organised (organisation, care plan, psycho-social components, incorporating other involved disciplines)?
- To what extent do aspects of diversity (gender, age, comorbidity) and personal situation play a role in an optimal rehabilitation process?

Introduction
Rehabilitation in the amputation patient includes: the combined and coordinated complex of medical, paramedical, technical and psychosocial measures, with the goal of allowing the patient to function as well as possible after amputation. This presupposes that patient consultation with a rehabilitation physician takes place preoperatively. Apart from measures to prepare for the surgery itself, there are measures specific to rehabilitation that should be addressed by the rehabilitation physician before the relevant amputation is performed. Prominent among these is careful consultation between the rehabilitation physician, other members of the rehabilitation team, including the physiotherapist, BIG-registered psychologist or social worker, the surgeon and, of course, the patient and the family.

In elective surgery there is usually an opportunity for extensive preoperative consultation and advice can be given to achieve the best possible general health in the patient. For the preparation and implementation of the rehabilitation treatment plan, the following information must be derived from the patient history and physical examination:
1. the preoperative level of function of the patient;
2. the nutritional status of the patient (possible involvement of the dietician to achieve an optimal nutritional status in the patient);
3. the quality of the musculoskeletal system. Where necessary, the physiotherapist should start treatment in order to reach an optimal physical condition;
4. the psychological state of the patient;
5. the social situation of the patient;
6. the extent to which the patient has been informed about the rehabilitation process (including where rehabilitation will take place).

After the operation a consultation with the rehabilitation physician, the physiotherapist and BIG-registered psychologist or social worker should again take place. During both consultations (pre- and postoperative), plans for discharge of the patient should be discussed. The possibilities for referral include a nursing home (admittance/day treatment), rehabilitation centre (admittance/outpatient rehabilitation), outpatient rehabilitation hospital, home with optional primary care physiotherapy or referral to another hospital or other institution. The preoperative level of performance of the patient, comorbidity, the possibility for informal care and the cognitive level of the patient should be weighed in this decision. In addition, local conditions should always play an important role in this decision.
In general, it can be stated that specialized rehabilitation treatment in a rehabilitation centre or hospital is preferable to treatment in a nursing home, assuming that the patient has an adequate capacity for learning and training.

**Scientific evidence**

**Part 1: based on articles selected from the reference lists 'Organisation of care, 'care plan', ‘psychosocial component', ‘other disciplines' and ‘CINAHL/PsychINFO’.**

**Literature search and selection**

The literature search (see report in appendix) yielded 11 bibliographies:

- Organisation of Care SR (25 after selection, four assessed in full text)
- Organisation of Care RCT (173 after selection, 39 assessed in full text)
- Care plan (10 after selection, 3 assessed in full text)
- Other disciplines (48 after selection, 8 assessed in full text, one article not available)
- Psychosocial component SR (4, no articles selected)
- Psychosocial component RCT (52 after selection, 14 assessed in full text)
- Psychosoc. component + outcome (23 after selection, 138 assessed in full text)
- CINAHL + PsychINFO (56 selected, 25 full text assessed, one article not available)
- Outcome SR (2 after selection, 2 assessed in full text)
- Outcome RCT (19 after selection, 5 assessed in full text)
- Outcome CINAHL (92 after selection, 30 assessed in full text)

Of the 153 published articles assessed in full-text after selection, only 11 articles in total were included to substantiate the text. For the psychosocial component, 25 articles were included in the selection at a later stage. During assessment of the full text articles little research was found comparing the effectiveness of two or more forms of care. Of the 11 selected articles, one was a systematic review of RCTs and two other articles mentioned the results of (other) RCTs.

In a Cochrane review by Cumming et al., RCTs up to October 2008 were summarised in which the effectiveness of rehabilitation interventions was investigated in patients who underwent transfemoral amputation or knee disarticulation. Only one RCT (Meikle 2003) was included in which the effect of the weight of the prosthesis on wearer comfort was investigated. No clear preference was found for a prosthesis weight and there were no differences in the 2 minute-walk test between the three amputation level groups (Cumming 2009).

In an RCT of 58 patients who underwent a limb amputation, Rau et al. investigated the effect of an intense physical therapy program. In this RCT, unblinded for caregivers and
patients but otherwise well-designed, improvements were found in the 2-minute walk test and the maximum tolerated weight on the prosthesis (Rau 2007). In another RCT, which could not be assessed for quality, the effect of Proprioceptive Neuromuscular Facilitation on the weight bearing capacity and walking skills of 50 transfemoral amputees was investigated. Positive effects, including those on weight-bearing capacity and step length, could not be properly assessed due to the poor quality of this RCT (Ygiter 2002). In a retrospective study of the Medicare claims database in the U.S., the discharge destination that yielded the best results after amputation was examined for 2468 elderly patients who underwent an amputation of a lower limb. The 1-year survival was highest in patients discharged to a rehabilitation centre (75%), followed by a nursing home (“skilled nursing facility”) (63%) and to home (51%). The percentages for successful prosthetic prescription were 73%, 58% and 49%, respectively. Although nursing home patients were older, they did not show greater comorbidity (Dillingham 2008). In a retrospective study by the U.S. Veterans Administration in 1339 veterans, specialised rehabilitation was compared with rehabilitation on general surgical wards. After adjustment for prognostic differences, 1-year survival (91% vs. 76%), the percentage with a home discharge (84% vs. 73%) and the percentage fitted with a prosthesis (40% vs. 19%) was better in a specialised rehabilitation setting (p <0.0001 for all comparisons) (Kurichi 2009). The final retrospective study from the U.S. involved 2673 patients from the Veterans Administration who underwent transfemoral amputation. After adjustment for prognostic differences, the 1-year survival of those in acute inpatient rehabilitation (in an integrated care system) (OR 1.9, CI 1.7-2.3) was again higher. More patients went home (OR 3.4; CI 2.9-4.0) and more patients received a prosthesis (OR 1.5, CI 1.2-1.8) compared with patients who received no rehabilitation in any form (Stineman 2008). A certain degree of bias is present in these studies because groups of patients were selected on the basis of the level of function.

In a Dutch study, the effect of the ‘Rehabilitation Activity Profile (RAP) on outcome was studied in various rehabilitation patients, including amputation patients. Following the introduction of RAP into four teams over a period of 2 years, the Barthel index was actually slightly lower compared with patients treated by teams without RAP. The authors suspected that it was still too early to see possible improvements (Beckerman 2004). In a small observational study of 60 patients who underwent a transtibial amputation, the effect of inpatient rehabilitation was compared with outpatient (home-based) rehabilitation. After 12-29 weeks, no difference was observed in the use of the prosthesis. Patients in the group with outpatient rehabilitation were more satisfied and experienced more social support than patients in inpatient rehabilitation (Klein 2001). In a retrospective study of 146 patients with trauma-related amputations, the effect of rehabilitation was compared with other forms of care. After multivariate analysis, patients with inpatient rehabilitation were found to be in better health, for example with regard to the physical role functioning (Pezzin 2000).

In a historical cohort study, patients with a transtibial or transfemoral amputation who received rehabilitation via a clinical programme with a focus on rehabilitation were compared with patients who were treated prior to introduction of the clinical rehabilitation programme with only routine care or a rehabilitation consultation. Despite more comorbidity in the group...
in the clinical programme, a larger percentage returned home (17% vs. 12%) and fewer patients entered a long stay nursing home (Schaldach 1997).

**Conclusions**

<table>
<thead>
<tr>
<th>Level 3</th>
<th>An intensive physical therapy program for patients with a limb amputation seems to result in a better load-bearing capacity and an improved 2-minute walk test, in comparison with a conventional, less intensive treatment program.</th>
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<td>B Rau 2007</td>
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<tr>
<th>Level 2</th>
<th>Patients who received inpatient rehabilitation after amputation of a (lower) limb appear to have a better 1-year survival rate, greater success with prosthesis fitting, and more often return home compared with patients not receiving inpatient rehabilitation.</th>
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<tr>
<th>Level 3</th>
<th>There is evidence that patients in a clinical rehabilitation programme more often return home than patients who receive routine care.</th>
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<td>B Schaldach 1997</td>
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**Part 2: based on the articles selected from the bibliographies ‘Outcome SR, Outcome RCT, Outcome CINAHL’**.

**Scientific evidence**

Four articles were reviews (Burger 2007, Esquenazi 2001, Jelic 2003, Velzen 2006). Of these reviews, three were non-systematic and were not further considered in review of the literature, because the methods were not described and thus the validity and reliability of the findings could not be assessed (Burger 2007, Esquenazi 2001, Jelic 2003). The review by van Velzen et al. (2006) on physical capacity and walking ability after amputation of a lower limb was the only systematic review. However, this review was of moderate quality and did not address the issues in question here. Van Velzen et al. do not comment on the organisation of the rehabilitation process.

The full-text items were further selected on the basis of the subject matter of the study. This led to all articles being rejected from the selection.
**Conclusion**

| n.a. | After assessing the articles selected from the bibliographies 'Outcome SR, Outcome RCT, Outcome CINAHL', none of the studies appeared suitable as a scientific basis for how optimal rehabilitation process can be organised for patients following an amputation of a lower limb. |

**Other considerations**

There are two important stages in the rehabilitation process of an amputation patient: the hospital phase and the rehabilitation phase.

**Hospital phase**

During hospitalisation there are two important moments in the organisation of an adequate rehabilitation process for the amputee. A preoperative consultation allows the premorbid state of the amputee to be described. Besides the patient’s functional capabilities, the situation at home and the informal care network are of great importance. The rehabilitation consultant (usually the rehabilitation physician) will attempt to predict the achievable level of function of the patient. Among other things, this depends on both the amputation level and on the pre-existing level of performance at home (Taylor 2005). The rehabilitation process after surgery should be explained and, if possible, a prediction made regarding the discharge destination after surgery. The progress of the rehabilitation process is further coordinated in a postoperative consultation. In particular, advice is given regarding contracture prevention, balance training, stump treatment and, if possible, early prosthetic fitting. A final discharge destination is determined, usually in a multidisciplinary consultation. A large population-based study in the U.S. (Dillingham 2003) showed that 41% of the vascular amputation patients are immediately discharged to their homes, 37% to a nursing home and 10% to a rehabilitation centre. An analysis of changes over time showed that in the course of a 12-year study the use of inpatient rehabilitation saw substantial growth (nursing homes, 31% in 1986 to 55% in 1997; rehabilitation centres, 2% in 1986 to 13% in 1997). Other research shows roughly the same numbers regarding discharge to rehabilitation centres (16%) and nursing homes (32%) (Dillingham 2005). Patients who were discharged to a nursing home were often older than 75 years, female, and had a higher level of amputation. The comorbidity score was not significantly different between patients discharged to a rehabilitation centre compared with patients discharged to a nursing home for further rehabilitation. However, patients referred to rehabilitation centres were more likely to have diabetes mellitus (Dillingham 2008). Research in the Netherlands shows that 86% of patients referred to a rehabilitation centre returned home after completion of the rehabilitation programme (Rommers 1997).

**Rehabilitation phase**

The location of the rehabilitation process depends largely on the home situation. If the patient is able to function with or without (professional or informal) care at home, further rehabilitation in an outpatient program is preferable. Inpatient rehabilitation takes place in
a rehabilitation centre or nursing home. Outcomes described in the literature are difficult to
generalise due to the different outcome measures used. Patients successfully receive a
prosthesis in 68% of cases (Munin 2001). The main factors associated with mobility are age,
length of stay in a rehabilitation clinic, and the mobility level prior to surgery (Munin 2001,
Schoppen 2003). Wound complications (Munin 2001), a higher amputation level (Taylor
and a low level of mobility before surgery often result in unsuccessful prosthetic fitting (Taylor
2005, Schoppen 2003). Factors associated with functional status include age (Schoppen
2003, Traballesi 1998), presence of diabetes mellitus (Traballesi 1998), standing balance
and cognition (Schoppen 2003).

In a recent multicentre study of determinants of rehabilitation after amputation of a lower limb
in nursing homes in the Netherlands, 65% of the patients were discharged to a situation of
independent living (home or care home), and 50% of patients were successfully fitted with a
prosthesis. Determinants for successful fitting of a prosthesis were good walking ability at
admission to the nursing home, absence of phantom pain and transtibial amputation
(compared with a transfemoral amputation) (Spruit- van Eijk 2011).

The details of the inpatient rehabilitation of amputation patients are beyond the scope of this
guideline. For further information, the working group refers the reader to the treatment
frameworks of the Netherlands Society of Physical and Rehabilitation Medicine (VRA) and
the Society for Elderly Care Physicians (Verenso).

**Recommendation**

| The discharge destination of a patient with a limb amputation is determined in the hospital
| on the basis of the level of function, the social situation (opportunities for informal care) and
current general health. |

**Psychosocial aspects**

Patients who have undergone amputation will have to adapt to a altered body, possibly to a
prosthesis and to altered future perspectives. Many psychological and social factors play a
role in this process.

Although this section does not address the cause of amputation, in practice the cause cannot
be ignored as there may be an underlying traumatic experience that needs to be adequately
treated or the distress (disruption) resulting from an underlying disease.

The most frequently described psychological adjustment problems are mood disorders and
anxiety. In addition, problems may arise due to altered self-esteem and body image. The
impact on quality of life has been described in several studies, including the problems that can
arise in a social setting such as (lack of) social support. Furthermore, these studies described
the influence of coping on the process of adjustment and, in a few cases, the role the
prosthesis plays in the whole process. In most studies the focus is on: (active) problem
solving, seeking social support and avoidance behaviour. Avoidance particularly affects
psychological distress. When (excessive) concerns play a major role in social support, there is
a chance that feelings of helplessness become amplified, with a negative influence on the
adaptation process.
In addition to physical limitations, pain plays a major role (both stump pain and phantom pain) in determining the quality of life. Cognitive decline reduces the chance of successful rehabilitation (Larner 2003).

**Scientific evidence**
A total of 25 studies were used to support the recommendations, including one review (Horgan 2004) and 24 observational studies. Most studies were retrospective. The study population consisted of trauma patients and patients with diabetes mellitus, and it is striking that patient groups with amputations of the lower and upper extremities were usually taken together. The number of patients enrolled varied between 25 and 796. One study used the "common sense self-regulation model" (Callaghan 2008), in which a link is made between emotions, coping and cognition.

Eight studies discussed mood disorders and a further eight discussed anxiety problems (including post-traumatic stress disorder symptoms and fear of falling). The importance of social support is mentioned five times, body image four times, and other factors such as pain, phantom pain, coping, sense of self-esteem only rarely (Bak 2003, Casale 2009, Demet 2003, Hanley 2004, McCartney 1999, Miller 2001).

<table>
<thead>
<tr>
<th>Level 3</th>
<th>In addition to mood and anxiety problems in patients who have undergone an amputation, frequent problems due to self-esteem and body image occur not only immediately following the amputation but also persist for a long period afterwards.</th>
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<tr>
<th>Level 3</th>
<th>Social support seems to positively influence the adjustment process.</th>
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</table>

**Other considerations.**
Research in the field of the psychosocial impact on patients who have undergone an amputation of a lower limb is still in its infancy. Intervention studies are lacking and it is also noticeable that new developments in psychology are hardly included. Within observational studies the diagnosis of mood or anxiety problems or other adjustment problems is still far removed from the question of whether interventions are meaningful. In addition, the question of what needs to be done and by which discipline is as (yet) unanswered.
Recommendations

The working group believes that the estimation of learning, coping styles and skills should receive attention in the diagnosis phase. In addition, the impact of this life event should be assessed. In the course of rehabilitation, the adaptation process and the psychological aspects that are associated with it will need to be considered.

During treatment, a number of issues require attention, including support, adaptation, adjusting to a new situation, including body image and treatment of mental health problems.

General pain research has shown that cognitive behavioural therapy is effective. Third generation behaviour therapies also appear to be promising (Acceptance and Commitment Therapy (ACT) and Mindfulness), indicating that further research into these two treatment methods is necessary.

Other considerations.

A BIG-registered psychologist is not so much concerned with whether the symptoms are caused by psychological factors, but focuses on the consequences of the symptom. In short, a number of questions can be addressed to the psychologist:

1. Are there psychological factors that maintain and/or worsen symptoms and if so, which?
2. Is psychological treatment indicated? If so, where should this be carried out? Is the patient motivated, i.e. are the psychological factors deemed to be pliable?

Recommendation

The working group considers that a BIG-registered psychologist and/or social worker should be part of the rehabilitation team for both the diagnosis and the treatment of patients undergoing amputation.

Rehabilitation factors and training goals

Despite the lack of a scientific basis, the following are general aspects and training goals relevant to the various rehabilitation phases: the preoperative, postoperative and prosthetic phases. In the Dutch situation, there seems to be consensus on the various principles of training. However, there are differences in the implementation of rehabilitation programs in rehabilitation institutions and hospitals, where individual and group training components are varyingly applied.

Rehabilitation factors and training goals:

Preoperative

1. Joint Mobility: prevention and treatment of contractures; measuring mobility in upper joints and on the contralateral side; information on maintaining mobility.
2. Muscle strength training: measuring force to upper and lower limb,
3. **Cardiovascular**: measuring cardiovascular fitness with respect to energy consumption during future use of a prosthesis, information on increased energy consumption when walking with a prosthesis.

4. **Balance**: measuring preoperative balance; assessment of central and peripheral neurological condition.

5. **Mobility**: measurement of existing mobility.

6. **Home/self-exercise**: determining home exercises for mobility, muscle strength and overall fitness.

7. **Functional activities and ADL**: determining the preoperative activity level and independent functioning to set goals and expectations.

8. **Integration in home situation**: determining preoperative employment status, leisure activities and ambulatory patterns; information for partner and informal carers.

**Postoperative**

1. **Joint mobility**: mobility exercises in flexion/extension and abduction/adduction direction; basic positions to prevent contractures or improve mobility in hip and knee when sitting and lying down.

2. **Muscle strength training**: muscle strength training for upper and lower limb muscle groups, including torso and general stability.

3. **Cardiovascular**: training for cardiovascular fitness, prevention of cardiovascular overload and risk prevention.

4. **Balance**: aimed at improving balance, especially sitting balance, moving body weight while sitting, sitting to standing, standing with support, balance while standing on one leg.

5. **Mobility**: training independent mobility; turning while lying and transfers; wheelchair mobility training; training walking without prosthesis on a walkway and then with walking aid; independent wheelchair mobility.

6. **Home exercise**: equipment and instructions for exercising at home.

7. **Functional activities and ADL**: basic ADL exercises and any adjustments required for dressing, washing and toilet use; attention for safe operation.

8. **Integration in home situation**: if possible, assessment of home situation and home training advice; initiate leaving home without prosthesis, use of public transport, addressing situation in workplace; attention for recreational activities without prosthesis information for partner and informal carers.

**Prosthesis phase**

1. **Joint mobility**: maintaining contracture prevention with stretching exercises; maximise joint mobility with respect to prosthetic use.

2. **Muscle strength training**: continue exercise program aimed at all extremities.

3. **Cardiovascular**: improving fitness to improve outdoors walking; maintain prevention regarding cardiac condition; encourage risk prevention.

4. **Balance**: balance training in various circumstances and bilateral balance training.

5. **Mobility**: improvement of symmetric weight on legs; improved weight transfer, facilitate trunk rotations and reciprocal gait; walking with walking aid.
6. **Home exercises**: continuation home exercises focusing on joint mobility, muscle strength and endurance.
7. **Functional activities and ADL**: instruction in prosthesis care and fitting; transfer and ADL activities with prosthesis; training from lying to standing with prosthesis.
8. **Integration in home situation**: initiate prosthesis use in work situation and recreational activities; skills such as climbing stairs, steps and walking on uneven ground; improving walking distance focused on social situation; training in use of public transport or driving with prosthesis when appropriate; information for partner and informal carers.
9. **Advice relating to general movement and sport.**

**Literature**

- Beckerman HR. The value of the Rehabilitation Activities Profile (RAP) as a quality subsystem in rehabilitation medicine. Disability and Rehabilitation 26(7), 387-400.
- Cumming JC, Barr S, Howe TE, Cumming JCO, Barr S, Howe TE. Prosthetic rehabilitation for older dysvascular people following a unilateral transfemoral amputation. Cochrane Database of Systematic Reviews 2006.
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- Kurichi JES. Possible incremental benefits of specialized rehabilitation bed units among veterans after lower limb amputation. Medical Care 47(4), 457-465.
- Stineman MGK. The Effectiveness of Inpatient Rehabilitation in the Acute Postoperative Phase of Care After Transtibial or Transfemoral Amputation: Study of an Integrated Health Care Delivery System. Archives of Physical Medicine and Rehabilitation 89(10), 1863-1872.
CHAPTER 9: LOWER LIMB AMPUTATION AND WORK

Key question 8
- What are the barriers to and facilitators of a return to work in patients after amputation of a lower limb, taking the difficulty of the work into consideration?

Introduction
Although the majority of patients with an amputation has reached retirement age, there is still a considerable number of ‘youth’ who are of working age or younger at the time of amputation. The cause in young people is rarely due to vascular problems of the elderly, but rather to a trauma or malignancy. The literature on which this chapter is based relates largely to trauma and oncology patients. This means that, in principle, these patients will still have a healthy body and the thereby related expectations. The most important factor is that these patients expect a return to independence and a normal social life, in which having or keeping work occupies a prominent place. Not every patient will return to work following amputation. The working group examined the factors that play a role in whether or not an amputee returns to work and have formulated a number of recommendations that may aid in promoting a return to work.

Scientific evidence
A search was conducted for articles that reported percentages of amputees returning to work and the factors responsible. Sixty-one articles were found in Medline, 47 in Embase, 13 in CINAHL and 3 in PsycINFO. Removal of duplicates and screening of title and abstract led to further study of 22 articles. After exclusion of items that did not relate to the initial question (n=7), articles on a different population (n=2), case reports (n=1) and narrative reviews (n=1), 11 articles remained and are discussed below.

Return to work
The scientific literature indicates that a large proportion of the patients who undergo an amputation of a lower limb return to work. One year after the amputation 42% of the patients have resumed work (MacKenzie 2006) and after more than one year 58-79% of patients have returned to work or have again stopped working for reasons unrelated to the amputation (e.g. pension) (MacKenzie 2006, 2001 Schoppen, Schoppen 2001a, Fisher 2003, Hebert 2006). A subset of patients (approximately 30%) requires some adjustment in the work situation (Van der Sluis 2009).
Conclusion

**Level 2**

Of working patients, around 60-80% resumes work after amputation of a lower limb. Some of these patients do not or stop after a short time for reasons unrelated to the amputation, such as retirement.


**Barriers to and facilitators of a return to work**

In a cross-sectional study of 322 patients in the Netherlands who, on average, had undergone a limb amputation 17 years previously, multivariate analysis showed the following factors to be predictive of a return to work: comorbidity, age at the time of amputation (>40 years less favourable), comfort when wearing the prosthesis and the educational level of the amputee patient. The physical difficulty of the work (especially for the less well-educated) and the ability to change their job in cases of heavy physical work had a major influence on successful reintegration (Schoppen 2001a).

Another cross-sectional study of 652 amputees in the Netherlands showed that the possibility of changes to work and the use of aids were important factors for successful reintegration. A major negative factor was identified in the form of a long period between amputation and a return to work (Schoppen 2001).

In a retrospective study of amputee patients with phantom pain, the percentage that returned to work was lower (44%; 33% for women, 47% for men) and those without work had more serious phantom pain than those working. There were also indications for an underlying mechanism, as patients who wore their prosthesis for less than 8 hours a day were found to have more phantom pain than patients who used their prosthesis for 9-16 hours a day (*p* = 0.001) (Whyte 2002).

A retrospective study of 88 Canadian amputee patients showed that only the level of amputation was predictive (higher level: less resumption). However, other factors were predictive of the number of days with total disability: older age (longer with older age), number of surgical procedures (the more, the longer) (Hebert 2006).

In a non-systematic review the level of amputation, multiple amputations, comorbidity, reason for amputation, stump problems and phantom pain were identified as prognostic factors for resumption of work (Burger 2007).

Stump problems and/or wound healing were the main reasons for a delay in returning to work in a Dutch retrospective study of 32 patients. Half of the patients received other tasks at work or a different role. Poor support by the reintegration agency or the employer obstructed resumption of work in 34% (Bruins 2003).
Conclusions

<table>
<thead>
<tr>
<th>Level 3</th>
<th>There are indications that a higher amputation level leads to a poorer prognosis for a return to work.</th>
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<tr>
<td></td>
<td>B  Hebert 2006</td>
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<td>C  Burger 2007</td>
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<tr>
<th>Level 3</th>
<th>There are indications that comorbidity, a vascular cause of amputation, age at the moment of amputation of over 40 years, poor prosthesis comfort and a low education level all affect negatively the return to work.</th>
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<tbody>
<tr>
<td></td>
<td>B  Schoppen 2001a</td>
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<td></td>
<td>C  Burger 2007</td>
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<tr>
<th>Level 3</th>
<th>There are indications that phantom pain negatively affects the return to work because prosthesis use is lower with more severe phantom pain.</th>
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<td></td>
<td>B  Whyte 2002</td>
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<tr>
<th>Level 3</th>
<th>There are indications that, in physically demanding work, the ability to change jobs or to arrange changes in the type of work positively influences the chances of successful reintegration.</th>
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<td></td>
<td>B  Schoppen 2001, Schoppen 2001a</td>
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Other considerations

If the rehabilitation team does not promote a return to work, in whatever form, from the very beginning, an inhibitory effect on the ambitions of the patient may be seen. The demands of the workplace regarding a patient’s mobility and/or ability to stand may lead to special demands on the prosthesis. In order to realize (Schoppen 2001) as rapid a return to work as possible, it is important that this be taken into account during the first prosthetic prescription. Advice regarding choice of vocational or professional training may be necessary and possibly also career advice, if the patient is a jobseeker.

Recommendations

- It is important that the company doctor is involved from as early a moment as possible and is included in consultations with the patient, the (future) rehabilitation team and the employer. The attending rehabilitation physician must at least ask the patient about this and contact the company doctor if necessary.

- When patients are still actively employed, this should be taken into account by the rehabilitation team at as early a stage as possible when planning support and prescription of a prosthesis.
Literature
- Hebert JS, Ashworth NL. Predictors of return to work following traumatic work-related lower limb amputation. Disability & Rehabilitation 2006;28(10): 613-618.
CHAPTER 10: PROSTHETIC PRESCRIPTION

Key question 9
- How can the prescription of prosthesis parts be improved? Which factors influence prosthetic prescription?

Introduction
It is normal practice in the Netherlands that a prosthesis be prescribed by a rehabilitation physician in collaboration with a prosthetist (occasionally supplemented by advice from a physiotherapist). Empirical knowledge is essential and an increasing emphasis is now being placed on the ability to justify a particular indication and the choice of a particular prosthesis. Clinical experience plays an important role in the preparation of an appropriate prescription, which means that a clear evidence-based motivation cannot always be given for the choices made. This may also lead to local variations in prosthetic prescription, as well as to over- or under treatment with regard to the care provided. Furthermore, this creates a lack of transparency for both the patient/consumer and health insurers.

The process of provision involves the entire process of assessment, production, delivery and evaluation of a prosthetic leg. This process is also determined by laws and regulations pertaining to medical devices. These laws and regulations are subject to change, however, which in recent years has led to a shift of the responsibilities of the different actors in this process.

The provision process describes in chronological order the entire chain of (sub)processes and decisions that take place to meet the requirements of a consumer regarding a medical (technical) device. This chain includes the request for help, the medical and functional diagnosis, the intended human activities and the intended product use, the determination of the adequate performance of the device, the delivery and, finally, evaluation of the device provided. Analogously, a model was developed in which these successive steps in the prescription of a prosthetic leg are described (see diagram ‘process of provision’), which was modelled on the process description medical aids (‘procesbeschrijving hulpmiddelenzorg’ in Dutch) from the CVZ.

In 2010, a protocol was developed in which the process of provision of a prosthesis is described (‘Protocol verstrekkingproces beenprothesen’ in Dutch, 2010, see appendix’). The protocol was prepared by a nationally operating steering committee, PPP (Prostheses Logging and Price System), consisting of representatives of rehabilitation specialists, suppliers of leg prostheses and health insurers. In addition, the CG board (council for chronically ill and disabled) was involved in the progress of protocol development. In the protocol, the entire distribution process is described from the patient’s needs to the final delivery of the prosthesis and the evaluation of the results (see diagram). Central to this process is the formulation of the intended human activity based on the inventory of functions and anatomical characteristics, and the activity and participation level: the various domains within the International Classification of Functioning, Disability and Health (ICF).
The key point is that the level of mobility with a prosthesis plays an important role in activity- and participation rates, and in most cases this is the guiding factor in the choice of prosthetic components.

A uniform terminology is used within the protocol for personal characteristics and prosthetic components and the unbranded linking of these two aspects. The protocol provides a guideline for the minimum required data to provide a clear justification of prosthetic prescription and component selection, with transparency for all parties, including the health insurer and the patient.

**Method**

Articles that described how specific aspects of prostheses associated with the (functional) outcome of amputations were searched for. Medline yielded 318 items, Embase 267 and CINAHL 105. Removal of duplicates and screening of title and abstract led to further study of 16 articles. After exclusion of seven articles, the nine articles remained (3 systematic reviews and six primary studies) that are discussed below.
Summary of the literature
The primary studies discussed in the systematic reviews and found elsewhere included mainly observational studies, randomised or unrandomised cross-over trials and a few classic randomised controlled trials (RCT). These primary studies were usually very small in size (5-36 patients). The two randomised trials were of poor quality, for example, and include no description of the randomisation procedure (see Appendix 6, supporting tables: table 10.2 for details). Due to the limitations in the design and size of these studies, the evidential value of any conclusions is limited.

Prosthetic knee components
In their systematic review, Van der Linde et al. found that prosthetic knees with a pneumatic swing phase control mechanism appear to provide greater comfort and a better walking speed in active patients (Van der Linde 2004). In a non-randomised, cross-over trial that included 21 transfemoral amputees using an auto adaptive knee (AAK, formerly known as a microprocessor-controlled knee joint (MPK)), there seemed to be a greater improvement in walking down a slope than when using a mechanical knee joint in the prosthesis. Patients were also more satisfied with the AAK (Hafner 2007).

Conclusions

<table>
<thead>
<tr>
<th>Level 2</th>
<th>A prosthesis with an ‘advanced mode or swing phase control’ of a pneumatically controlled knee joint leads to increased comfort and improved walking speed in active patients.</th>
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<tr>
<td>A2</td>
<td>Van der Linde 2004</td>
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<table>
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<tr>
<th>Level 3</th>
<th>Prosthesis users with an AAK (auto adaptive knee) joint and a transfemoral amputation are better able to walk down a slope.</th>
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<td>B</td>
<td>Hafner 2007</td>
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</table>

Prosthetic foot components
In their review, Van der Linde et al. concluded that an energy-storing prosthetic foot appears to result in a faster walking speed in trauma-related transtibial amputees. However, no study was found in which a difference in patient satisfaction was reported with regard to a specific type of prosthetic foot (Van der Linde 2004).
In a Cochrane review on the effectiveness of ankle-foot mechanisms, Hofstad et al. concluded that in transtibial amputations there appears to be a greater stride length with an ‘energy-storing foot’ in comparison with a conventional fixed prosthesis foot. At high activity levels there also seems to be a better gait efficiency (Hofstad 2004).
Conclusions

<table>
<thead>
<tr>
<th>Level 2</th>
<th>In trauma-related transtibial amputees, an ‘energy-storing’ prosthetic foot seems to result in a higher walking speed.</th>
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<td></td>
<td>A2 Van der Linde 2004</td>
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<table>
<thead>
<tr>
<th>Level 2</th>
<th>A longer step length was achieved with an ‘energy-storing’ foot in comparison with a conventional fixed prosthetic foot in transtibial amputee patients. There also seems to be a better gait efficiency at high activity levels.</th>
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<td></td>
<td>A2 Hofstad 2004</td>
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Liners and type socket

In their review on the effect of silicone liners, Baars et al. concluded that silicone liners seem to lead to better suspension and better walking performance compared with a conventional supracondylar fitting (Baars 2005).

In a randomised crossover trial that involved 13 patients with a prosthesis following traumatic amputation, Coleman et al. found that more steps were taken at a higher intensity with a liner with a penn lock than with the ‘Pre-Lite’ liner. However, there was no difference in comfort or satisfaction with the prosthesis (Coleman 2004). In a Dutch RCT involving 36 patients with transtibial amputation, no differences were found in the outcomes ‘prosthetic function’ and ‘satisfaction’ in a comparison between a ‘total bearing socket’ (TBS) or a conventional ‘patellar tendon-bearing’ (PTB) socket. Although TBS production is more expensive, PTBs require more hours when fitting the prosthesis, meaning that costs (from a Dutch perspective) are broadly similar for both sockets (Selles 2005).

Conclusions

<table>
<thead>
<tr>
<th>Level 2</th>
<th>A silicone liner leads to a better suspension and better walking performance compared with a conventional supracondylar fitting.</th>
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<td></td>
<td>A2 Baars 2005</td>
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<table>
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<tr>
<th>Level 3</th>
<th>Although patients take more steps and at a higher intensity with the liner with penn lock, patients are not more satisfied with this prosthesis than with the Pre-Lite liner</th>
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<td></td>
<td>B Coleman 2004</td>
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<tr>
<th>Level 3</th>
<th>The total bearing socket (TBS) and the conventional patellar tendon-bearing (PTB) socket seem to result in no differences in outcome. There also appears to be no difference in costs.</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>B Selles 2005</td>
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</table>
Other considerations
Despite the extensive knowledge available in the scientific literature, there are significant shortcomings in objective clinical knowledge on the impacts of different prosthetic components and associated mechanical characteristics on performance with a prosthetic leg. Therefore, empirical knowledge should still primarily determine prosthetic prescription. The use of a protocol allows a better justification of a prescription and better transparency for the users.

The Dutch protocol prosthetic prescription (PPP Steering Committee, 2010) uses an unambiguous terminology for personal characteristics and prosthetic components, and their unbranded linking. It provides a guideline for the minimum required data to substantiate prosthetic prescription and component selection, with transparency for all parties, including the health insurer and the patient.

When determining patient characteristics for prosthetic prescription, a hierarchical order is maintained and the terminology used is derived from the ‘International Classification of Functioning, Disability and Health’ (ICF). In summary, the priority is to review the treatment need, function and anatomical characteristics of the patient, with an emphasis on the amputation level and stump characteristics. In addition, the functional level of the patient plays a major role, with the level of activities and participation, and especially the expected mobility level with a prosthesis, being of particular importance.

Following determination of the required performance with a prosthesis, the process of provision should establish a link with the various prosthesis components. These components should be described in a function-oriented manner, which is also a requirement of the relevant laws and regulations.

The Dutch protocol prosthetic prescription (Appendix 4b) has now been approved by the Netherlands Society of Physical and Rehabilitation Medicine (VRA) and NVOS-Orthobanda, with the recommendation that it be used in standard clinical practice when prescribing a prosthetic leg, regardless of where this takes place. The protocol, a description of mobility classifications and a prescription form, can be viewed on the website of the VRA ‘Working Group Amputation and Prosthetics’ (http://sites.google.com/site/vrawap/Home). In the future it will be great important to continue to update the guideline, and it is also advisable to further investigate the utility of the guideline through clinical trials.

Choosing between various prosthesis components in a prosthetic prescription should be based on reliable information on the characteristics of these components. Using the product information provided by the manufacturer alone is insufficient. The determination of the specific characteristics of a prosthesis should be primarily based on clinical research. It is therefore recommended that prosthetic components are tested in clinical trials before they come to market. This requires good collaboration between clinicians, research centres and the manufacturers and suppliers.

The large number of available components and technical developments means that knowledge of the properties and the possibilities for patient performance cannot rest with a
single discipline. The first prosthetic prescription should therefore take place in a multidisciplinary setting. Cooperation and dialogue between different disciplines such as the rehabilitation physician, prosthetist and paramedic is of great importance. However, the patient is central to the whole process and should therefore also be included in this consultation. The wishes of the patient should remain the starting point when determining prosthetic prescription.

**Recommendations**

- The working group is of the opinion that the Dutch protocol prosthetic prescription should be followed when prescribing a prosthetic leg.
- The working group is also of the opinion that the Dutch protocol prosthetic prescription should be regularly reviewed.
- The working group favours a multidisciplinary approach to the first prescription of a prosthesis (although this may not be necessary for subsequent prostheses).
- The working group believes that the wishes of the patient should be the starting point when determining prescription of a prosthesis.
- The working group considers that an amputee patient should not only be under the ongoing supervision of a prosthetist, but that a rehabilitation physician should also be involved; changes in the patient’s circumstances should lead to review of prosthetic prescription.

**Literature**

Key question 10
- At what moment following amputation should prosthesis fitting commence?

Introduction
It is generally accepted that fitting of a prosthesis at all levels starts when the residual limb is matured. This primarily means that the wounds are closed, the stump is oedema free and the local load capability is sufficient. Aspects such as muscle strength, presence/absence of contractures and psychological tolerance are often taken into consideration. However, little evidence can be found on this subject in the scientific literature.

Scientific evidence
A search was conducted for articles on comparative studies evaluating the effect of the timing of prosthetic fitting on outcome. Of the 103 articles found in Medline and the 39 in Embase, elimination of duplicates and screening of title and abstract led to further study of 39 articles. After exclusion of 35 articles for the reasons set out in Appendix 6, the four articles remained that are discussed below.

Three of the four remaining articles indicate that the early mobilisation of the amputation patient with the aid of (interim) prostheses leads to better outcomes.
Schon (2002) compared two groups of patients; one group was treated with a soft dressing and the other with an immediate postoperative prosthesis (IPOP). Final prosthetic fitting was achieved faster in the latter group.
Ivanic (2002) and Ross (2009) mobilised amputation patients at an early stage using a prosthesis with air chambers, Pneumatic Post-Amputation Mobility (PPAM-aid), according to protocol. It appears that activating amputation patients as early as possible yields benefits. Early mobilisation with IPOP or PPAM-Aid activates the cardiovascular system and thus results in less oedema in the stump.

A study which followed the stumps of four patients after amputation using MRI showed that stump volume decreases rapidly after surgery. This also applied to the medial but not to the lateral muscle groups (Lilja 1998). A study of a historical cohort compared 19 patients (amputated in 1998 to 2000) who used IPOP (immediate postoperative prosthesis) to 23 transtibial amputees (1989-1998) who received the standard soft dressings. The number of complications and revisions were lower in the IPOP group and the time to fitting of a prosthesis was shorter (Schon 2002). Ivanic et al. succeeded in mobilising 23 of 25 transtibial amputees with a prosthesis with air chambers within five days after surgery (Ivanic 2002). In another study, the PPAM Aid was tested and of the 62 patients with an unhealed stump, 56 (90%) were mobilised according to protocol and 46 (74%) achieved complete stump healing after an average of 141 days (van Ross 2009).
## Conclusions

<table>
<thead>
<tr>
<th>Level 3</th>
<th>Postoperative use of a prosthesis as soon as possible after transtibial amputation appears to result in fewer complications and revisions and a shorter time to fitting of a prosthesis.</th>
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<tr>
<td></td>
<td><em>B Schon 2002</em></td>
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<table>
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<tr>
<th>Level 4</th>
<th>The size of the stump decreases immediately after the operation. However, the lateral muscles (lateral head of the gastrocnemius and tibialis anterior) appear to increase in size (n=4).</th>
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<tr>
<td></td>
<td><em>D Lilja 1998</em></td>
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<tr>
<th>Level 3</th>
<th>Mobilisation shortly after transtibial amputation (5 days) seems feasible using a prosthesis with air chambers.</th>
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<td></td>
<td><em>B Ivanic 2002</em></td>
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<table>
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<tr>
<th>Level 3</th>
<th>Patients with a still unhealed stump following transtibial amputation can be mobilised using a prosthesis with air chambers (PPAM).</th>
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<tr>
<td></td>
<td><em>B Van Ross 2009</em></td>
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</table>

## Other considerations

The following parameters are used in the decision-making process leading up to prosthetic prescription, in addition to certain subjective assessment factors that are not or are insufficiently supported by evidence.

### Amputation wound

Safety is the first priority (it is better to wait than risk deterioration of the wound). Thus, wound healing is an important subjective assessment factor. With the exception of ‘immediate fitting’, one must wait until the sutures are removed. The inclusion and exclusion criteria for ‘immediate fitting’ are still unclear and depend on the assessment of the relevant surgeon.

Furthermore, the subjective assessment of wound, wound edge and scar are criteria that determine whether or not to proceed to the fitting of a prosthesis, with complete wound healing as the determining factor for the waiting period. Thus, in some cases prosthetic fitting only begins when the last scabs have disappeared and the smallest defect is completely closed.

### Oedema

If control of oedema is not started in an early phase, prosthesis fitting will be delayed. ‘Size measurements’ of the stump are taken regularly and the prosthesis is only fitted if the stump shape does not change over a period of three weeks. Circumference measurements are a relatively naive approach to volume measurement because these
measurements provide no impression of the oedema in the distal portion of the stump. Control of oedema is usually via bandaging. Bandaging techniques are not uniform and often seek a circular effect, while the oedema can freely accumulate distally. This then results in a rapidly increasing problem with prosthesis fit in the distal area.

A method that has been applied more frequently in recent years in the context of oedema control is the use of liners tailored to the stump size. They may provide a better distal pressure and their application can be better objectified.

Recently, two studies have been published that provide more information on oedema measurements (Bolt 2010, de Boer 2011). Bolt et al. showed that a 3D tracer system was the best system to determine changes in oedema (although it was only tested on models). However, de Boer et al. later showed similar results in amputation patients (n=5).

**Atrophy**

The musculature of the stump shows very slow atrophy over a long period. If the right measures are applied, oedema can decrease very rapidly. These two different aspects of the decrease in stump volume are not always well differentiated, and atrophy of the musculature of the stump is often confused with a reduction in oedema (see above).

**Logistical processes in the workshop**

Some workshops require more than four weeks from the moment of ordering to delivery of the first prosthesis. Meanwhile, changes in the stump take place (atrophy) and the fit is inevitably no longer optimal. This postponement of prosthesis fitting may increase the risk of contracture formation and does not positively contribute to the load capabilities of the stump or the development of load capacity.

**Interim prosthesis**

Interim prostheses are often used within physiotherapy as a bridging measure for the waiting period caused by the long period required for production.

The universal interim prosthesis, as the name implies, is universally applicable and therefore not optimally adapted to the specific situation of the patient's stump. Prosthesis fitting during the initial stages of rehabilitation is undesirable for the reason that no definitive prosthesis can be designed while the stump is still subject to changes in volume. Thus the use of a universal prostheses is rather controversial, except when used with the aim of preventing oedema and activation of the muscle pump.

**Recommendations**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Note</th>
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<tr>
<td>- The prevention of oedema in the immediate postoperative phase following</td>
<td>amputation of a lower limb is of fundamental importance to achieving</td>
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<tr>
<td>amputation of a lower limb is of fundamental importance to achieving rapid</td>
<td>provision of a prosthesis.</td>
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<tr>
<td>provision of a prosthesis.</td>
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<tr>
<td>- The working group considers the rigid dressing to be the preferred treatment</td>
<td>during the early postoperative phase in patients with transtibial</td>
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<td>phase in patients with transtibial amputation stump.</td>
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<tr>
<td>- The use of liners, when applied according to protocol, can be an effective</td>
<td>method in the control of oedema.</td>
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</table>
- The control of oedema should be mediated as much as possible through activation of the muscle pump (active exercise).
- Oedema measurements should not only include the circumference, but should also take the length of the stump into account.
- It should be possible to achieve delivery of the prosthesis within ten days.
- Universal interim prostheses are less suitable for first provision.
- A custom-made prosthesis (not necessarily the final version), as early as possible in the postoperative phase, is preferable to a pre-fab prosthesis.

**Literature**

CHAPTER 11: GUIDELINE IMPLEMENTATION AND INDICATORS

Key question 11
- How can the implementation of this guideline be ensured?

Introduction
The implementation of multidisciplinary guidelines has yet to be intensively investigated in the Netherlands. There is slightly more research available on the implementation of standards (for general practitioners), and the conclusions of these studies are probably also relevant to the implementation of multidisciplinary guidelines. In a research report, 'Effective implementation: theories and strategies', barriers and facilitators for the implementation of standards and guidelines were defined (Hulscher 2000). Review articles on various implementation strategies were discussed in this and in an earlier report (Hulscher 2000, Grol 2003).

This research shows that guidelines that are developed by recognized specialists in the field, which reflect current practice and that are 'interactively' distributed, appear to be relatively successful. Clearly, the form and content of a guideline also has a significant impact on the acceptance of the guideline and, after acceptance, the implementation (Grol 1998).

Ideal guidelines are valid, reliable, reproducible, multidisciplinary, applicable and flexible, clear, unambiguous and well documented. It is also conducive to the quality of a guideline that a test project for implementation is defined, that implementation can be evaluated and that the guideline can be adapted on this basis. In addition to the perspective of the care provider, it is also important that the guideline take account of the patient's perspective and the social perspective (e.g. costs and organisation of care, workplace) where relevant. Finally, it is important that implementation of the guideline is actually evaluated and, if necessary, adapted to new insights. An instrument for evaluation of these items is available (AGREE instrument).

Development of the guideline ‘Amputation and Prosthetics of the Lower Extremities’ followed the AGREE criteria as closely as possible. The guideline is transparent in its arguments with regard to the balance between scientific and other considerations, such as practice organisation, patient wishes, and preferences and social importance.

In addition to an intrinsically optimal guideline, a variety of measures can promote implementation of the guideline. The main conclusions (NHS 1999; Bero 1998; Wensing 1994; Wensing 1998) regarding the effectiveness of implementation strategies for guidelines are:
- For an optimal implementation of the guideline, factors that may promote or hinder compliance with the guideline (per target group and/or setting) require attention, and a thorough analysis of these barriers and facilitators is necessary prior to implementation.
- There is not a one-to-one relationship between the theories concerning implementation and concrete implementation strategies.
- It is not possible to recommend a single optimal intervention (simple or complex) that
promotes the implementation of innovation or change (guideline); multiple strategies will need to be combined.

Guideline implementation ‘Amputation and Prosthetics of the Lower Extremities’

The working group does not consider it their task to exactly specify how this guideline should be implemented. However, a number of proposals that may promote implementation are described in the brief contribution below.

The following activities have been undertaken or initiated to promote the implementation of the guideline ‘Amputation and Prosthetics of the Lower Extremities’:
- The use of the guideline will be facilitated by including flowcharts for diagnosis and treatment and by preparing a guideline summary.
- The guideline can be used to describe the fundamental processes underlying the clinical care plan, with an emphasis on the coordination of care and collaboration between disciplines.
- Development of a version for patients and information material for patient in support of the guideline.
- The guideline will be distributed as actively as possible among the members of the various professional associations.
- Information on the guideline will be provided in publications in the Nederlands Tijdschrift voor Geneeskunde (Dutch Journal of Medicine) and possibly in other journals.
- The Netherlands Society of Physical and Rehabilitation Medicine (VRA) will review the content of the guideline annually and decide whether total or partial revision is necessary.
- The complete guideline will be posted on the Internet on the website of the CBO (www.cbo.nl).

Where possible, the guideline will be published on the websites of the relevant scientific associations.

The working group proposes the following activities to promote the implementation of the guideline ‘Amputation and Prosthetics of the Lower Extremities’:
- Presentation of guideline recommendations at scientific meetings of the relevant professional organisations.
- To identify ‘teething problems' with the guideline and allow adjustments, the guideline should be discussed during the next annual meeting of the participating associations.
- Evaluation of progress in implementation and compliance with the guideline; this could be achieved using the internal indicators formulated by a sub-working group (see next section).
- Formulation of the remaining research topics and questions that are necessary as further support for the guideline and communication of these to the various funding bodies and policy makers.
- Development of an E-learning module so that care providers can be tested online for knowledge of the guideline.
- Development and use of tools for the implementation of the guideline in daily practice, such as a PDA version of the guideline.
- The working group recommends - where relevant – that parts of the guideline be developed as protocols, taking local circumstances into account.
- The local implementation of the guideline in local protocols will be evaluated during clinical audits of the quality of care and training.
- Targeted presentation of the guideline in the media, so that patients are made aware of changes in policy via simple and frequently consulted sources (magazines, newspapers).

**Recommendation**

The working group is confident that the implementation of the initiatives and proposals mentioned in above paragraphs will contribute to implementation of this guideline and therefore to an improvement in the quality of care.

**Literature**

Indicators ‘Amputation and Prosthetics of the Lower Extremities’

Indicators are measurable aspects of care that provide a picture of the quality of care delivered. An indicator has a signalling function: it is not a direct measure of quality, but points to a particular aspect of performance and may result in further investigation. This is an issue at the core of high quality care: the actual measurement of the quality of care and the use of these measurements to determine the possible adoption of improvements that aim to achieve a focused improvement in the quality of care.

Indicators allow healthcare providers to understand the results of their own care processes and assist in internal control and improvement. Indicators with this purpose are referred to as internal indicators. Indicators can also be used to compare institutions (benchmarks). Through constant feedback of the results of medical practice and the introduction of benchmarking, an ongoing process of improvement can be introduced. Indicators can also serve another purpose. The government, the health care inspectorate (IGZ) and patients/consumers also wish to assess whether care providers deliver sufficient quality and therefore suitable indicators are needed. Indicators for this purpose are called external indicators, and these indicators can also be used in DBC negotiations.

When preparing indicators, those parts of the care process that are expected to yield the greatest benefits are preferably chosen.

Commissioned by the Society of Medical Specialists, a methodological instrument has been developed to serve as an evaluation and assessment framework for indicators. Future indicators of care will have to comply with the methodological requirements of this instrument, known as AIRE (Appraisal of Indicators, Research and Evaluation). Relevant elements of the AIRE instrument were used in the preparation of the indicators.

The actual implementation and measurement of indicators is beyond the responsibility of the guideline development group.

**Internal indicators**

Internal indicators are intended to provide insight into the care process related to the diagnosis and treatment of amputation patients. The indicators can be used for adjustment and support of daily practice within one’s own rehabilitation centre. On the basis of measurement of the indicators, targeted improvement measures can be put in place. In addition, the indicators serve as a basis for establishing a quality framework for amputation and prosthetics care (for example, by incorporation of the indicators in a clinical audit). Ultimately, this should result in an improvement in the quality of care for amputation patients in the Netherlands and a reduction in the variation between hospitals.
The following internal indicators were selected:
1. Before an amputation, a consultation should be requested with a rehabilitation specialist, BIG-registered psychologist or social worker or pastoral assistant, and a physiotherapist, followed by a report to the primary treating physician.
2. Presence of a rehabilitation protocol describing the perioperative management regarding a limb amputation.
3. Presence of written information for the amputation patient describing the rehabilitation process.

External indicators
The intention over the coming years is that identical information on the quality of care will be supplied by all hospitals in the Netherlands, on the basis of the formulated external indicators. In the future this information will be freely available and accessible to the general public through the websites of hospitals and via the government (KiesBeter.nl). These external indicators will be adopted by Zorgverzekeraars Nederland (Dutch health insurance companies) (ZN) in their procurement guide and used for the procurement of care.

The selected external indicators are:
1. Percentage EA index that is measured in the preoperative amputation patient
2. Percentage registrations for employment reintegration (patients <65 years)
3. Percentage SIGAM/WAP registration mobility classification
4. The ratio transfemoral amputations versus knee disarticulation versus transtibial
5. Sports and games

The working group indicators consisted of the following members:
Dr. H. vd Linde
Prof. Dr. J.H.B Geertzen
CHAPTER 12: RECOMMENDATIONS FOR RESEARCH

During the development of the guideline ‘Amputation and Prosthetics of the Lower Extremities’, the working group has established that there are certain gaps in knowledge and therefore makes a number of recommendations for future research regarding amputation and prosthetics of the lower extremities.

Based on the scientific literature found and the resulting degree of evidence for basic, epidemiological and therapeutic knowledge in the field of amputation and prosthetics of the lower extremities, it can be concluded that further research is needed on each of the (sub)sections of this guideline.

There is a gap in knowledge both for the indication criteria for amputation and for surgical techniques. This is less true for postoperative pain management policy, although there are still gaps in knowledge regarding the prevention of phantom pain. Postoperative complications are numerous and also lack the necessary supporting evidence. The rehabilitation process may be transparent to those directly involved, but evidence is lacking for this aspect of care. While the return to work is quite frequently described in the literature, this often relates to amputation following trauma and not that due to vascular and/or diabetes-related amputation for which this guideline was written. There is also a significant lack of knowledge in the field of prosthetic prescription.

The working group is of the opinion that the evidence underlying this guideline is meagre and that many unknowns remain.

Clinimetrics will have to be a specific focus of future research, particularly with regard to prognosis. Prior to amputation: “is rehabilitation achievable for this patient?” Issues related to the perioperative phase: “what are the expectations regarding the level of mobility?”.

‘The rehabilitation process’ and the added value of multidisciplinary treatment are aspects that need to be further elaborated. Also issues such as: “what is prosthetic ready/fitting ready?” and “which prosthesis for which patient?” are essential research topics for the near future.

The working group also recommends that the utility of a protocol for the prescription of a leg prosthesis (prosthetic components) be tested in a clinical trial.

Based on current research, more attention can be devoted in the near future to the patient group ‘fragile elderly’, in which comorbidity and polypharmacy play an important role that also influences rehabilitation options. In addition, a supplement could be written for patients with a traumatic or oncological cause of amputation (currently 3% and 1% of the total population of amputation patients, respectively).
APPENDIX 1: KEY QUESTIONS

INDICATION and SURGICAL INTERVENTION

- Which indication criteria are available to determine the level of a lower limb amputation?
- What is the minimum required information when deciding on amputation?
- How can the most favourable moment for amputation of a lower limb be determined?
- What preoperative evaluation is required in patients undergoing amputation of a lower limb?
- Which surgical techniques are available for amputation of a lower limb? When is each technique indicated?
- What are the advantages and disadvantages of different surgical techniques for amputation of a lower limb?
- To what extent do aspects of diversity (sex, age, comorbidity) influence indication and surgical intervention?

PATIENT INFORMATION AND INFORMATION RESOURCES

- What information/advice should be provided by caregivers to the patient regarding treatment and rehabilitation, both before and after amputation?
- To what extent do aspects of diversity (gender, ethnicity, age, comorbidity) and personal situation play a role in the provision of information and advice?

IMMEDIATE POSTOPERATIVE MANAGEMENT

- What is the approach of choice to postoperative management immediately following amputation of a lower limb (immediate/delayed fitting, rigid dressing versus soft dressing)?
- What is the preferred approach to pain management (perioperative and postoperative) in lower limb amputation?
- Which complications (local/at stump level) occur following an amputation of a lower limb and how can they be prevented?
- To what extent do aspects of diversity (sex, age, comorbidity) influence management in the immediate postoperative period?
REHABILITATION

- How should an optimal rehabilitation process for patients be organised following amputation of a lower limb? (organisation, care plan, psychosocial components, incorporating other disciplines).

- To what extent do aspects of diversity (gender, age, comorbidity) and personal situation play a role in an optimal rehabilitation process?

- What are the barriers to and facilitators of a return to work in patients following amputation of a lower limb, taking into consideration the nature of the work?

PROSTHETIC PRESCRIPTION

- How can the prescription of prosthesis parts be improved? Which factors influence prosthetic prescription?

- At what moment following amputation should prosthesis fitting commence?

- To what extent do aspects of diversity (gender, age, comorbidity) and personal situation play a role in prosthetic prescription?

IMPLEMENTATION

- How can the implementation of the guideline be ensured?
APPENDIX 2: AMPUTATION AND PROSTHETICS OF THE LOWER EXTREMITIES - INVENTORY OF CHALLENGES.

Introduction
The CBO is developing a multidisciplinary evidence-based guideline ‘Amputation and Prosthetics of the Lower Extremities’. The guideline will indicate how the diagnosis, treatment and follow-up in patients with amputation and prosthetics of a lower limb should be conducted and will provide the impetus for cooperative agreements between the disciplines involved. Guideline development is by a committee consisting of representatives from all associations/organisations involved in the care of patients with amputation and prosthetics of the lower limb. The perspective of the patient plays an important role in the development of the guideline. At present the project is in the preparatory phase of development of the multidisciplinary evidence-based guideline. A crucial step in the process of guideline development is to identify relevant questions that will eventually be addressed by the guideline. It is hereby important to use existing challenges in the field as the starting point.

Method
To support the development of the guideline ‘Amputation and Prosthetics of the Lower Extremities’, a survey questionnaire on existing challenges was prepared. This questionnaire was then sent to the members of the working group, in which the various disciplines are represented. A total of eight individuals (partially) completed and returned this survey. Seven questionnaires were completed based on mono-disciplin ary consultation of the specialisms rehabilitation medicine (three times), prosthetics, orthopaedics, psychology and occupational health, one survey was completed in a multidisciplinary consultation of unknown composition and one survey was completed by a discipline of unknown origin.

A complete overview of the answers given by the members of the working group can be found in the file ‘resultaten enquête richtlijnontwikkeling amputatie en prothesiologie onderste extremiteit’. This report will provide an inventory of the results.

Following the analysis of challenges, up to ten key questions (based on evidence) will be drawn up, supplemented by possible consensus questions.

Inventory of surveys
The surveys mainly reveal the need for more clarity, protocol use and understanding and use of the knowledge and skills of the various disciplines. It is important to provide greater clarity regarding the most optimal (follow-up)treatment, when a treatment and/or technique is indicated, the advantages and disadvantages of the various treatments and the available evidence. In addition, there is currently a lack of clear direction and coordination of care.
The points that have emerged from the survey will be discussed by topic below.

**Substantive challenges**

The members of the working group have been able to define challenges in the area of assessment, diagnosis, surgical treatment, postoperative management, prosthesis fitting, complications, rehabilitation and patient information that occur in daily practice of care for patients with an amputation and a lower limb prosthesis. These challenges represent an important resource for the formulation of key questions.

**Assessment**

A challenge in relation to indications for amputation and prosthetics of the lower limb is the uncertainty regarding the moment of amputation and when clinical or outpatient rehabilitation is possible. Moreover, there is a lack of knowledge regarding the (im)possibilities relating to the amputation. As regards psychological support, a clear definition of the focus of this support is needed in the sense of either offering support or seeking alterations in behaviour.

**Diagnostics**

There is a case for additional diagnostics of comorbidity, cognitive and/or learning ability.

**Surgical treatment**

There is a need to understand technical factors as they relate to amputation level and the stump shape, with consideration for the way bone and soft tissue are cut during and after amputation and the preparation of seams, but also to be aware of the (im)possibilities regarding prostheses, so that unfounded expectations are not created.

**Postoperative management**

There is a need for a clear policy regarding wound care, stump formation, bandaging, interim prosthetics and clinical guidance. In addition, it has been pointed out that geriatric patients represent a subgroup in need of extra attention due to comorbidity.

**Prosthesis fitting**

There is a need for clear communication with the instrument makers to arrive at a patient-centred prosthesis selection. Moreover, there is need for guidelines with respect to making that choice.

**Complications**

Complications associated with amputation of a lower limb such as phantom pain and wound healing can be controlled, taking comorbidity into account, provided that adequate treatment is available. In addition, the relevant disciplines should be mobilised and have sufficient knowledge and understanding of the influence of this knowledge on the uncertainty facing patients. Psychological help that is involved at a too late a stage can lead to complications, such as mood disorders, that may be difficult to resolve.
Rehabilitation process
There is a need for clear and evidence-based training methods and time planning, so that the process and the time required is clear to patients. In addition, it was remarked that the prosthesis is only part of the treatment process and there should be due consideration for psychological aspects and coping with a sense of bereavement.
It was also indicated that in the context of a return to work, the selection of the prosthesis in relation to changes in the workplace deserves attention, with the caveat that this process takes time and may be accompanied by uncertainty.

Patient information
The extent and manner of information provision depend on the referring party. There is a need for a structured process with particular attention for the form, amount, expectations and motivation of the patient relative to the available options.

Challenges in the organisation and process of care
A multidisciplinary working group provides the opportunity for different specialties to develop agreements on the organisation of care, collaboration and communication. Therefore, an inventory of the problems experienced in practice in these areas has been prepared.

Organisation of care
There is a need for early (preoperative) involvement of the rehabilitation/nursing home physician, in order to optimize the (follow-up)care, to prepare an appropriate prosthesis and to begin the application procedure for Social Support Act (WMO) payments in a timely manner.
Both patients and partners seem to experience a feeling of helplessness when exposed to a series of different practitioners, each with their own viewpoint.

Cooperation and communication
The guideline ‘Amputation and Prosthetics of the Lower Extremities’ may stimulate positive initiatives for greater clarity regarding the treatment, policy coordination and improved communication between the disciplines involved pre- and postoperatively. This may have a positive influence on the treatment of patients with an amputation of the lower extremities. In addition, structured consultation and the use of electronic patient records would help clarify the involvement of the various specialities in this patient group, encouraging equal and shared knowledge and improved collaboration.
There is a need for uniform leaflets (and support via websites).
Early consultation with the company doctor with regard to possibilities for necessary workplace adjustments and role changes could lead to an acceleration of this process and reduce the associated uncertainty.

Prioritisation
In the survey there was an opportunity to indicate which eight of the sixteen key questions established by the preparatory group were the most important.
This prioritisation produced the following sequence of key questions, ordered from most important to least important:

1. What is the preferred postoperative approach immediately following amputation of a lower limb (immediate/delayed fitting, conservative elastic bandaging)?
2. How should an optimal rehabilitation process for patients be organised following amputation of a lower limb?
3. How can the prescription of prosthesis parts be improved?
4. What information/guidance should be provided by care providers to the patient before and after amputation regarding treatment and rehabilitation?
5. What is the preferred approach to pain management in lower limb amputation?
6. How can the implementation of the guideline be ensured?
7. Which complications occur in an amputation of a lower limb and how can they be prevented?
8. What diagnostic tools can be applied in patients in whom an amputation of a lower limb is being considered and how reliable are they?
9. What indication criteria are there for amputation of a lower limb?
10. Which surgical techniques are available for amputation of a lower limb? When is each technique indicated?
11. What are the pros and cons of the different surgical techniques for amputation of a lower limb?
12. What are the barriers and facilitators to a return to work in patients following amputation of a lower limb, in light of the demands of the work?
13. What preoperative tests are required in patients undergoing amputation of a lower limb?
14. How can the most favourable moment for amputation of a lower limb be determined?
15. At what moment following amputation should prosthesis fitting commence?
16. What is known about the cost of an amputation of a lower limb?

In addition, challenges could be indicated during the prioritisation process that could be subsequently addressed in the guideline ‘Amputation and Prosthetics of the Lower Extremities’. One person made use of the possible key questions proposed by the preparatory group and submitted the following questions as potential challenges to be addressed:

- What is the preferred postoperative management immediately after amputation of a lower limb (immediate/delayed fitting, conservative elastic bandaging)?
- How can the prescription of replacement components be improved?

The prioritisation of the remaining challenges that could be addressed in the guideline ‘Amputation and Prosthetics of the Lower Extremities’ led to the emergence of a number of themes.
- Clarity regarding indicators and treatment (both pre- and postoperative)
- Prosthesis fitting
- Coordination of care/integrated care
- Improve interdisciplinary, transmural and patient-focussed communication
- Patient/rehabilitant central
- Shorter period of hospitalisation
- Establish physical limitations, especially of transfemoral amputees
- Evidence-based rehabilitation and follow-up care
- Focus on complications, including psychological

**Indicators**

Several members of the working group have specified indicators - both medical, process-related and in communication – that may be eligible for a baseline measurement that would aid implementation of the guideline. These include:

- Prosthetic Profile of the Amputee (PPA); Ankle Brachial Index: degree of flow
- X-ray after amputation for review of bone structures
- Current prescription, in terms of fitting, rate of loading, and in terms of the prescription itself
- Current (existence/non-existence) of a consultation structure between (orth.) surgeon and rehabilitation specialist
- SIGAM/WAP score (amputation patient mobility score)
- Pre-operative consultation
- Leaflets/websites
- Successful cooperative projects related to (attempted) return to work
- Numbers of contacts between rehabilitation department and company doctor for each patient in work rehabilitation
- Number of patients with successful work-related rehabilitation: in original job or in another function
APPENDIX 3: FOCUSGROUP/TELEPHONE INTERVIEWS WITH PATIENTS

Report on patient experiences of lower limb amputation
In the context of the development of this guideline, challenges in care were catalogued as experienced by patients following an amputation of a lower limb. This ‘care’ may relate to diagnosis, treatment, counselling, organisation of care or provision of information. The challenges catalogued, especially the most important, have been used in the development of the guideline ‘Amputation and Prosthetics of the Lower Extremities’.

The expertise of individuals who will actually experience care is important for the content of the guideline. Another advantage is the opportunity to determine whether use of the guideline is feasible in practice. This does not imply that the guideline offers a ‘solution’ for every major obstacle, but it does strive to gather the information that may contribute to resolving them.

The experiences of patients were collected by means of telephone interviews (n=9), a focus group (n=10) and an additional focus group with older patients (n=3). Remarkably, comparison of the results from these three groups showed no ‘significant’ differences.

The operation
Providing information related to surgery depends on whether or not immediate surgery is needed. In cases where time was available to provide information, this varied from very clear and complete, to brief and vague indications independent of the subject (procedure, complications, pain).

Prosthesis
Most people indicate that they were not involved in the choice of the prosthesis.

Rehabilitation
Following a hospital stay of several weeks (range 6 weeks to 3.5 months), most patients go to a rehabilitation centre, followed in some cases by outpatient treatment in the rehabilitation centre. The elderly patients who were interviewed all went to a nursing home following their hospital stay. None of the patients received any prior information with regard to the rehabilitation process.

A number of people indicated that they experienced the rehabilitation process as positive and were able to come to terms with themselves and share experiences with others.

Some patients indicated that rehabilitation contributed to their being able to once again function independently, but there were also patients who indicated that returning home was their first experience of their true limitations.
It was commented that rehabilitation often focuses on avoiding falls and avoiding use of the knee, while there are many other possibilities, including learning to walk or even to run.

**Support**
Some patients did not regard their contact with a psychologist as positive. In these cases, the sessions were experienced as “coercive” and did not correspond to their psychological needs and wishes. Others had positive experiences of counselling. It was also noted that the timing was not always optimal.

**Work**
Most people needed adjustments in order to (continue to) work, but there were few obstacles to achieving this. On a few occasions the patient’s wish to resume work was not understood, while some others were hampered by (phantom) pain.

**Communication**
There was a less positive view of the quality of communication between the various institutions. In general, a new patient record was created on each new occasion. In general, communication within institutions was experienced as good.
Questionnaire for focus group/telephone interviews amputation:

- Name and age
- When was the amputation performed?
- What was the reason for amputation?
- What is the level of amputation?
- Operation
  1. Did you receive clear information about the operation, e.g. technique, level of amputation?
  2. Did you receive enough information about the possible complications of surgery, e.g. slow wound healing, phantom pain?
  3. Prior to surgery, did you receive clear information about your level of function after surgery?
  4. Did you receive this information (questions 1, 2, 3) in a timely manner?
  5. Was the pain management immediately after the operation sufficient?
- Prosthesis
  6. Did the prosthetist involve you in the selection of the prosthesis? Did the prosthetist help you understand the various prosthesis choices? (an ongoing process)
- Rehabilitation
  7. What did the rehabilitation process entail: a hospital or nursing home, training or a specialised physiotherapist?
  8. Did you receive sufficient information on the rehabilitation process beforehand, e.g. method of rehabilitation, duration, planning?
  9. What was your experience of the rehabilitation process?
 10. Has rehabilitation helped you to resume daily activities?
 11. What would be the ideal rehabilitation process for you?
- Support/ psychological counselling/ social work
  12. In what manner, before or after the amputation, did you receive psychological counselling? What was your experience of psychological counselling?
  13. Has the possibility of an altered self-image following amputation received sufficient attention?
  14. Were the effects of amputation on work, income, social functioning (roles) etc. discussed?
  15. Was timely payment of, for example, grants for facilities (alterations to house, car, etc.) arranged?
- Work
  16. What obstacles did you experience when you returned to work or wished to return to work?
  17. What obstacles were presented your employer?
  18. What obstacles arose due to the work itself?
  19. Did rehabilitation help in the return to work?
- General
  20. Was there, for you or for the practitioner, any doubt as to whether amputation was/was not necessary or desirable?
  21. How did you experience the sharing of information/communication and coordination between the various care providers (surgeon, prosthetist, rehabilitation physician, physical therapist, etc.)?
  22. Are you experiencing residual limitations? What are they?
  23. Is there anything else you wish to add?
APPENDIX 4: TREATMENT PLAN LEG AMPUTATION

Attached separately as a PDF file.
## APPENDIX 5: ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAK</td>
<td>Auto Adaptive Knee</td>
</tr>
<tr>
<td>ABI</td>
<td>Ankle Brachial Index</td>
</tr>
<tr>
<td>ACT</td>
<td>Acceptance and Commitment Therapy</td>
</tr>
<tr>
<td>ADL</td>
<td>Activities of Daily Living</td>
</tr>
<tr>
<td>AGREE-instrument</td>
<td>Appraisal of Guidelines for Research and Evaluation</td>
</tr>
<tr>
<td>AIRE instrument</td>
<td>Appraisal of Indicators Research and Evaluation</td>
</tr>
<tr>
<td>AKA</td>
<td>Above Knee Amputation</td>
</tr>
<tr>
<td>ARBO</td>
<td>Working conditions (Arbeidsomstandigheden)</td>
</tr>
<tr>
<td>BIG</td>
<td>Individual Medical Professions Act (Beroepen Individuele Gezondheidszorg)</td>
</tr>
<tr>
<td>BKA</td>
<td>Below Knee Amputations</td>
</tr>
<tr>
<td>CG raad</td>
<td>Council for the Chronically Ill and Disabled (Chronisch Zieken en Gehandicapten Raad)</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence Interval</td>
</tr>
<tr>
<td>CTA</td>
<td>Computer Tomography Angiography</td>
</tr>
<tr>
<td>CVZ</td>
<td>Board for Healthcare Insurance (College voor Zorgverzekeringen)</td>
</tr>
<tr>
<td>DBC</td>
<td>Diagnosis Treatment Combination (Diagnose Behandel Combinaties)</td>
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<tr>
<td>DM</td>
<td>Diabetes mellitus</td>
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<tr>
<td>DSA</td>
<td>Digital Subtraction Angiography (Digitale Subtraction Angiografie)</td>
</tr>
<tr>
<td>EA index</td>
<td>Ankle-Brachial Index (Enkel Arm Index)</td>
</tr>
<tr>
<td>EBRO</td>
<td>Evidence Based Guideline Development (Evidence Based Richtlijn Ontwikkeling)</td>
</tr>
<tr>
<td>ICF</td>
<td>International Classification of Functioning, Disability and Health</td>
</tr>
<tr>
<td>IGZ</td>
<td>Health Care Inspectorate (Inspectie voor de Gezondheidszorg)</td>
</tr>
<tr>
<td>IPOP</td>
<td>Immediate Post Operative Prosthesis</td>
</tr>
<tr>
<td>ISPO</td>
<td>International Society for Prosthetics and Orthotics</td>
</tr>
<tr>
<td>MRA</td>
<td>Magnetic Resonance Angiography (Magnetische Resonantie Angiografie)</td>
</tr>
<tr>
<td>MPK</td>
<td>Microprocessor Knee technology</td>
</tr>
<tr>
<td>NMDA receptor</td>
<td>N-methyl D-aspartate receptor</td>
</tr>
<tr>
<td>NRS</td>
<td>Numeric Scale (Numerieke Schaal)</td>
</tr>
<tr>
<td>OR</td>
<td>Odds Ratio</td>
</tr>
<tr>
<td>PAV</td>
<td>Peripheral Arterial Disease (Perifeer Arterieel Vaatlijden)</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
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<tr>
<td>PPA</td>
<td>Prosthetic Profile of the Amputee</td>
</tr>
<tr>
<td>PPAM</td>
<td>Pneumatic Post-Amputation Mobility</td>
</tr>
<tr>
<td>PPP</td>
<td>Prostheses Logging and Price System (Protocollering en Prijssystematiek Prothesen)</td>
</tr>
<tr>
<td>PTA</td>
<td>Percutaneous Transluminal Angioplasty (Percutane Transluminale Angioplastiek)</td>
</tr>
<tr>
<td>PTB</td>
<td>Patellar Tendon-Bearing</td>
</tr>
<tr>
<td>RAP</td>
<td>Rehabilitation Activities Profile (Revalidatie Activiteiten Profiel)</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
</tr>
<tr>
<td>RD</td>
<td>Rigid Dressing</td>
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<tr>
<td>RR</td>
<td>Relative Risk</td>
</tr>
<tr>
<td>RRD</td>
<td>Removable Rigid Dressing</td>
</tr>
<tr>
<td>SIGAM</td>
<td>Special Interest Group Amputation Medicine</td>
</tr>
<tr>
<td>SIGAM/WAP</td>
<td>SIGAM/WAP Scoreform</td>
</tr>
<tr>
<td>SD</td>
<td>Soft Dressing</td>
</tr>
<tr>
<td>SKMS</td>
<td>Quality Foundation of Dutch Medical Specialists (Stichting Kwaliteitsgelden Medisch Specialisten)</td>
</tr>
<tr>
<td>SR</td>
<td>Systematic Review (Systematische Review)</td>
</tr>
<tr>
<td>TASC</td>
<td>TransAtlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease</td>
</tr>
<tr>
<td>TBS</td>
<td>Total Bearing Socket</td>
</tr>
<tr>
<td>TENS</td>
<td>Transcutaneous Electrical Neurostimulation (Transcutane Electro Neurostimulatie)</td>
</tr>
<tr>
<td>TcPO2</td>
<td>Transcutaneous Partial Oxygen Pressure (Transcutane Partiële zuurstofspanning)</td>
</tr>
<tr>
<td>VA/DoD</td>
<td>Department of Veterans Affairs/Department of Defense</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual Analogue Scale (Visueel Analoge Schaal)</td>
</tr>
<tr>
<td>VRA</td>
<td>Netherlands Society of Physical and Rehabilitation Medicine</td>
</tr>
<tr>
<td>WAP</td>
<td>Working Group Amputation and Prosthetics (Werkgroep Amputatie en Prothesiologie)</td>
</tr>
<tr>
<td>WGBO</td>
<td>Medical Treatment Act (Wet op de Geneeskundige Behandelingsovereenkomst)</td>
</tr>
<tr>
<td>WMO gelden</td>
<td>Social Support Act (Wet Maatschappelijke Ondersteuning)</td>
</tr>
<tr>
<td>ZN</td>
<td>Netherlands Health Insurers (Zorgverzekeraars Nederland)</td>
</tr>
</tbody>
</table>
Chapter 3: Surgical techniques

Table 3.1: Systematic reviews

<table>
<thead>
<tr>
<th>Author, year</th>
<th>P</th>
<th>Long posterior flap 'burgess' below knee amputation vs. skew flap or other amputations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tisi, 2004</td>
<td></td>
<td>Patients with lower limb ischemia</td>
</tr>
<tr>
<td></td>
<td>I</td>
<td>Objective clinical measures such as primary stump healing, infection rate, no. of patients fitted with prosthesis, time to full mobility, etc and subjective measures such as symptoms and quality of life</td>
</tr>
<tr>
<td></td>
<td>S</td>
<td>Rcts comparing different surgical techniques</td>
</tr>
<tr>
<td></td>
<td>Search</td>
<td>Medline, Embase, CINAHL, central up to July 2008</td>
</tr>
<tr>
<td></td>
<td>Selection</td>
<td>Selection with listed selection criteria by one author</td>
</tr>
<tr>
<td></td>
<td>Quality assessment</td>
<td>Quality assessment (risk of bias) by 2 authors</td>
</tr>
<tr>
<td></td>
<td>Technique meta-analysis</td>
<td>Peto odds ratio’s + sensitivity analyses</td>
</tr>
</tbody>
</table>

Table 3.2: Study characteristics of included primary studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Chosky, 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>RCT</td>
</tr>
<tr>
<td>Participants</td>
<td>64 patients with PAD (rest pain, ulceration, gangrene) without success or potential for revascularisation.</td>
</tr>
<tr>
<td>Interventions</td>
<td>Transtibial amputation with (intervention) or without tourniquet</td>
</tr>
<tr>
<td>Follow-up</td>
<td>6 weeks</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Less blood loss: 255 ml (CI 150-573) vs. 550 ml (95% CI 255-1050) (p=0.014)</td>
</tr>
<tr>
<td></td>
<td>Hb decrease 1.0 (CI 0, 6-2.4) vs. 1.8 (CI 0-1.2)</td>
</tr>
<tr>
<td></td>
<td>Blood transfusion needs 33% vs. 50% and the amount of blood needed was lower (p=0.047)</td>
</tr>
<tr>
<td>Comments</td>
<td>No long-term results reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Wolthuis, 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Observational study</td>
</tr>
<tr>
<td>Participants</td>
<td>89 patients underwent a transtibial amputation</td>
</tr>
<tr>
<td>Interventions</td>
<td>A tourniquet was used in 42 patients, not used in 47.</td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Results</td>
<td>Hb decrease 5.6% vs. 14.8% (p&lt;0.0001)</td>
</tr>
<tr>
<td></td>
<td>Need for transfusion lower with tourniquet (p&lt;0.001)</td>
</tr>
<tr>
<td></td>
<td>14% vs. 38% required a postoperative stump revision (p&lt;0.025)</td>
</tr>
<tr>
<td></td>
<td>Postoperative mortality did not differ (7.1% vs. 6.4%)</td>
</tr>
<tr>
<td>Comments</td>
<td>Unclear on what grounds tourniquet application was decided.</td>
</tr>
</tbody>
</table>
Study: Jaeha 2008

Methods: RCT

Participants: n = 26, below-knee amputations
M = 11 (42.3%), F = 15 (57.7%) Av. age = 68.2 jaar (SD 10.8) Setting: hospital

Inclusion criteria: postoperative duration < 3 months
Exclusion criteria: serious wound infection

Intervention: RDD (removable rigid dressing) (n=12) vs. elastic bandage (EB) (n=14)

Results: Stump volume at 0, 2, and 4 weeks
Stump volume reduction RRD after 2 and 4 weeks: 42.7 ± 62.7; 79.9 ± 103.3
Stump volume reduction EB after 2 and 4 weeks: 21.9 ± 118.5; 83.0 ± 113.1

No significant difference between the groups

Comments:

Chapter 5: Postoperative management

Table 5.1: Study characteristics of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Deutsch 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>RCT</td>
</tr>
<tr>
<td>Participants</td>
<td>n=41, below-knee amputations (transtibial)</td>
</tr>
<tr>
<td></td>
<td>M=15, F=26</td>
</tr>
<tr>
<td></td>
<td>Av. age = 73.3 years</td>
</tr>
<tr>
<td></td>
<td>Setting: hospital</td>
</tr>
<tr>
<td>Inclusion criteria: not described</td>
<td></td>
</tr>
<tr>
<td>Exclusion criteria: not described (except reasons for loss to study)</td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>RDD (removable rigid dressing) (n=22) vs. standard soft dressing (SDD) (n=19)</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Wound healing outcomes; time to prosthetic fitting, length of hospital stay</td>
</tr>
</tbody>
</table>
## Wound healing (RRD vs. SSD): 51.2 days ± 19.4; 64.7 days ± 29.5 (p=0.07)

Time to prosthetic fitting (RRD vs. SSD): 23.3 days ± 19.5; 22.6 days ± 15.7 (p=0.45)

Length of hospital stay (RRD vs. SSD): 15.5 days ± 9.2; 17.4 days ± 14.3 (p=0.61)

### Study

#### Woodburn 2004

**Methods** RCT

**Participants**
- n=154, below-knee amputations (transtibial)
- M=114, F=96
- Av. age =73.3 years
- Setting: hospital

**Inclusion criteria:** not described

**Exclusion criteria:** not described

**Interventions**
- Rigid dressing (RD) (n=78) vs. non-rigid dressing (NRD) (n=76)

**Outcomes**
- Postoperative stump infection; time to prosthetic fitting
- Postoperative stump infection (RD vs. NRG): 21%; 18% (p=0.47)
- Time to prosthetic fitting (RD vs. NRG): median: 42 days (95% CI 36-45); 36 days (95% CI 30-47) (p=0.23)

### Study

#### Wong 2000

**Methods** RCT

**Participants**
- n=26, 17 below-knee amputations; 5 transfemoral (groups combined for analysis)
- M=10, F=11
- Av. age =ED 64.1 ± 9.3; SRD 70.8 ± 10.1
- Setting: hospital

**Inclusion criteria:** postoperative duration < 30 days after operation

**Exclusion criteria:** serious wound infection, fever

**Interventions**
- SRD (semi-rigid dressing) (n=12) vs. elastic bandage soft dressing (ED) (n=9)

**Outcomes**
- Time from admittance to rehabilitation centre to prosthetic fitting (SRD vs. ED); 20.8 days ± 12.4; 28.7 days ± 11.0
- Time from surgery to fitting (where 30% of the group are fitted with a prosthesis): SRD vs ED: 34 days vs. 64 days (p=0.025)

### Study

#### Vigier 1999

**Methods** RCT

**Participants**
- n=56, 17 below-knee amputations; 5 transfemoral (groups combined for analysis)
- M=45, F=11
- Av. age =Plaster cast 65.2 ± 12.4; SRD 66.8 ± 10.8
- Setting: rehabilitation centre

**Inclusion criteria:** <3 months below-knee amputation; amputation due to arterial (occlusive??) disease; wound surface between 8 and 24 cm²; transcutaneous oxygen tension (TcPo₂) ≥ 35 mmHg.

**Exclusion criteria:** general health problems (CVZ, arrythmi, neurological abnormalities), stump problems other than wound healing hindered socket contact (e.g. infections), ischemia of the non-amputated limb.
Intervention  | Plaster cast socket (PCS) (supracondylar type) (n=28) vs. elastic bandage (EB) (n=28)
---|---
Outcomes  | Time to stump healing; time between amputation and ability to walk with contact stocking (socket?, sock? stocking?); time in hospital
  | Time to stump healing (PCS vs. EB): 71.2 days ± 31.7; 96.8 days ± 54.9 (p=0.04)
  | Time between amputation and ability to walk with contact stocking (PCS vs. EB): 63.5 days ± 20.8; 73.3 days ± 31.2 (p=0.31)
  | Time in hospital (PCS vs. EB): 99.8 days ± 22.4; 129.9 days ± 48.3 (p=0.04)

Comments

Study  | Graf 2003
Methods  | RCT
Participants  | n=16 below-knee amputations
  | M=9, F=7
  | Age =range 41-89 years
  | Setting: hospital
  | Inclusion criteria: RRD fitted <3 days after amputation; length of acute hospital stay <21 days; no complications wound healing (infections, haematoma) Exclusion criteria: not described
Intervention  | Polymer gel sock (PGS) + RRD (n=15) vs. RRD (n=12)
Outcomes  | Stump volume
  | Baseline to shrinker (PGS vs. RRD): 2.27% (SD 1.17); 1.20 (SD 0.56) (p<0.05)
  | Baseline to cast measurement (PGS vs. RRD): 1.88% (SD 0.92); 1.31% (SD 0.62) (not significant)
Comments  | Unclear whether groups were of equal size.

Study  | Johanesson 2008
Methods  | RCT
Participants  | n=27, below-knee amputations
  | ORD M:F 9:4; RRD M:F 5:5
  | Av. age =ORD 76 (range 45-91); RRD 76 (range 43-89)
  | Setting: hospital
  | Inclusion criteria: amputation with vascular cause
  | Exclusion criteria: inability to walk, severe dementia, fractures, severe cerebrovascular, peripheral vascular or neurological problems
Interventions  | Vacuum manufactured removable rigid dressing (ORD) (n=15) vs. RRD (n=12)
Outcomes  | Primary outcome: time to prosthetic provision
  | Secondary outcomes: wound healing, performance with prosthesis after 3 months (measured with Locomotor Capability Index (LCI) and ‘timed up and go test’ (TUG).)
  | Time to prosthetic provision (ORD vs. RRD): 37 (26-54) days; 34 (21-47) days (p=0.4) performance with prosthesis after 3 months
  | Wound healing (ORD vs. RRD): n=6/13 vs. n=4/10 (p=0.6)
  | Performance with prosthesis after 3 months: no significant differences with either measure
Comments
Table 5.2: Risk of bias (RoB)

<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>Janchai 2008</td>
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<td>-</td>
<td>?</td>
<td>?</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>6</td>
</tr>
<tr>
<td>Johanessson, 2008</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>6</td>
</tr>
</tbody>
</table>

Chapter 6: Pain management

Table 6.1: Study characteristics of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Nikolajsen 1997</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>RCT</td>
</tr>
<tr>
<td>Participants</td>
<td>n=56, below-knee amputations, M=33 (59%), F=11 (41%) Av. age =68.3 (SD 13.0) Setting: hospital</td>
</tr>
<tr>
<td>Inclusion criteria:</td>
<td>patients are able to answer detailed pain questionnaire, no contraindication for epidural catheter or general anaesthesia.</td>
</tr>
<tr>
<td>Exclusion criteria:</td>
<td>acute amputation, ipsilateral reamputation, amputation foot or toes.</td>
</tr>
<tr>
<td>Interventions</td>
<td>Intervention group (i) (n=27): epidural bupivacaine and morphine</td>
</tr>
<tr>
<td>Control group (c)</td>
<td>(n=29): epidural saline</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Outcome measures (presented separately for stump pain and phantom pain)</td>
</tr>
<tr>
<td></td>
<td>- Stump pain and phantom pain (VAS 0-100mm) at the time of measurement of average</td>
</tr>
<tr>
<td></td>
<td>- Stump pain en phantom pain (VAS 0-100mm) in de week preceding amputation</td>
</tr>
<tr>
<td></td>
<td>- Consumption of analgesics</td>
</tr>
<tr>
<td></td>
<td>- Number of patients with stump or phantom pain</td>
</tr>
<tr>
<td></td>
<td>Follow-up times: 1 week, 3, 6, and 12 months</td>
</tr>
<tr>
<td></td>
<td>No significant differences between groups for all measured outcomes at all four follow-up times.</td>
</tr>
<tr>
<td></td>
<td>No information on side effects reported.</td>
</tr>
<tr>
<td>Comments</td>
<td>The statistical power was acceptable at follow-up time after 1 week (according to researchers' own power calculation), after which the number of patients showed a serious decline; time of measurement 1 year: (i) n=12 en (c) n=16.</td>
</tr>
<tr>
<td></td>
<td>In a separately published study (Nikolajsen 1998) on a subset of patients from this study, effects were again not seen for the outcomes hyperalgesia, allodynia, or wind-up-like pain.</td>
</tr>
</tbody>
</table>
Methods
RCT

Participants
n=21, amputations lower limb (including transfemoral amputations)
M=10 (59%), F=23 (41%)
Av.
age =71.8 (SD 12.3)
Setting: hospital

Inclusion criteria: Patients with an amputation of a lower limb due to ischemic necrosis related to a peripheral vascular disorder not explicitly described.
Exclusion criteria: unable to use patient-controlled analgesia use or to complete the McGill Pain Questionnaire.

Interventions
Intervention group (i) (n=9): continuous postoperative infusion of bupivacaine hydrochloride
Control group (c) (n=7): placebo (normal saline)

Outcomes
Outcome measures (residual pain: mix of stump pain and phantom pain)
- Use of morphine on day 1, 2 and 3 postoperatively (morphine pump)
- McGill Pain Questionnaire at 3 and 6 months postoperatively (no baseline measurement)

Patients in the intervention group used significantly (p<0.05) less morphine on days 1 and 2: 6.7 mg (SD 1.2), vs. 8.9 mg (SD 1.2), and 5.8 mg (SD 1.0) Vs. 6.0 (SD 0.9), respectively. No significant differences on day 3.

No significant differences found between groups on the McGill Pain Questionnaire.

No information on side effects reported.

Comments
Inadequate presentation of the results. Very small numbers.

Study Pinzur 1996

Study Wilson 2008

Methods
RCT

Participants
n=47, amputations of a lower limb (transfemoral and transtibial)
M=35 (75%), F=12 (25%)
Av. age = +/- 73 years (SD +/- 5.0)
Setting: hospital

Inclusion criteria: patients able to answer detailed pain questionnaire and undergo physical examination, no contraindication for general anaesthesia or epidural catheter.
Exclusion criteria: contraindication for ketamine or bupivacaine or general anaesthesia, acute amputation, previous amputation, further amputation during follow-up period.

Interventions
Intervention group (i) (n=24): ketamine and bupivacaine
Control group (c) (n=29): saline and bupivacaine

Outcomes
Follow-up times: 8 days, 6 weeks, 3, 6 and 12 months
Primary outcome measures:
- Incidence of stump pain and phantom pain: no significant differences at the different times (data presented at 12 months)

<table>
<thead>
<tr>
<th></th>
<th>12 months</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stump pain (%)</td>
<td>3/14 (21%)</td>
<td>5/15 (33%)</td>
</tr>
<tr>
<td>Phantom pain (%)</td>
<td>7/14 (50%)</td>
<td>6/15 (40%)</td>
</tr>
</tbody>
</table>

- Intensity of stump pain and phantom pain (VAS, 0-100mm): no differences at the different follow-up times
Secondary outcomes:
- Phantom pain questionnaire t
- McGill Pain Questionnaire (MOQ)
- Neuropathic pain scale (NPS)
- Hospital anxiety and depression scale (HADS)

No reported differences in side effects between the groups.

<table>
<thead>
<tr>
<th>Study</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hayes, 2004</td>
<td></td>
</tr>
</tbody>
</table>

**Methods**

RCT

**Participants**

n=45, transfemoral and below-knee amputations

M=26 (58%), F=19 (42%) Av. age =68.8 (SD 11.6) Setting: hospital

Inclusion criteria: patients with amputation due to peripheral vascular disease, cancer or chronic infections.

Exclusion criteria: severe ischemic heart disease, not suitable for general anaesthesia.

**Interventions**

Intervention group (i) (n=22): ketamine

Control group (c) (n=23): placebo (normal saline)

**Outcomes**

Follow-up times: 3 and 6 days, and 6 months

Outcome measures:
- Incidence of stump pain and phantom pain

<table>
<thead>
<tr>
<th></th>
<th>Stump pain</th>
<th>Phantom pain</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ketamine</td>
<td>Placebo</td>
</tr>
<tr>
<td>3 days</td>
<td>95%</td>
<td>65%</td>
</tr>
<tr>
<td>6 days</td>
<td>80%</td>
<td>65%</td>
</tr>
<tr>
<td>6 months</td>
<td>47%</td>
<td>35%</td>
</tr>
</tbody>
</table>

* Unexplained significant increase in stump pain in ketamine group

- Intensity (NRS, 0-10) of stump pain, and phantom limb pain: no significant differences between groups
- Use of medication (no significant differences between groups)
- Patient satisfaction (no significant differences between groups)
- Central sensitisation (no significant differences between the groups)

No reported differences in side effects between the groups.

<table>
<thead>
<tr>
<th>Study</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nikolajsen 2006</td>
<td></td>
</tr>
</tbody>
</table>

**Methods**

RCT

**Participants**

n=41, amputations of a lower limb

M=23 (56%), F=18 (44%) Av. age =70.3 (SD 10.2) Setting: hospital

Inclusion criteria: patients older than 18 years, amputation due to peripheral vascular disease.

Exclusion criteria: ipsilateral reamputation, foot or toe amputation, severe systemic disease, recent alcohol or drug abuse.

**Interventions**

Intervention group (i) (n=21): gabapentin

Control group (c) (n=20): placebo
<table>
<thead>
<tr>
<th>Study</th>
<th>Nikolajsen 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcomes</td>
<td>Follow-up times: 1 month (post-treatment) and 6 months</td>
</tr>
<tr>
<td></td>
<td><strong>Primary outcome measures:</strong></td>
</tr>
<tr>
<td></td>
<td>- Incidence phantom pain: no significant differences between groups:</td>
</tr>
<tr>
<td></td>
<td>1 month: risk difference 2.4% (95% BI -28.9 to 33.7%, p=0.88)</td>
</tr>
<tr>
<td></td>
<td>6 months: risk difference 8.8% (95% BI -23.3 to 40.9%, p=0.59)</td>
</tr>
<tr>
<td></td>
<td>- Intensity of stump pain and phantom pain (NRS, 0-10): no significant differences between groups:</td>
</tr>
<tr>
<td></td>
<td>1 month: median (i vs c) 2.4% (95% BI -28.9 to 33.7%, p=0.88)</td>
</tr>
<tr>
<td></td>
<td>6 months: median (i vs c) 8.8% (95% BI -23.3 to 40.9%, p=0.59)</td>
</tr>
<tr>
<td></td>
<td><strong>Secondary outcomes:</strong></td>
</tr>
<tr>
<td></td>
<td>- Frequency, duration and intensity of phantom pain; pain (McGill Pain Questionnaire); consumption of opioids (no significant differences).</td>
</tr>
<tr>
<td>Comments</td>
<td>No reported differences in side effects between the groups.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Bone 2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>RCT, cross-over studie</td>
</tr>
<tr>
<td>Participants</td>
<td>n=19</td>
</tr>
<tr>
<td></td>
<td>M=15 (79%), F=4 (21%) Av. age =56.3 (SD 17.5) Setting: hospital</td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria: patients with amputation pain (&gt; 6 months), aged between 18 and 75 years, VAS (0-100mm) pain score of at least 40 mm.</td>
</tr>
<tr>
<td></td>
<td>Exclusion criteria: severe systemic diseases, psychiatric disorders, recent alcohol or drug abuse.</td>
</tr>
<tr>
<td>Interventions</td>
<td>Intervention group (i) (n=9): placebo as first treatment</td>
</tr>
<tr>
<td></td>
<td>Control group (c) (n=10): gabapentin as first treatment</td>
</tr>
<tr>
<td></td>
<td>Each intervention given for 6 weeks</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Follow-up times: week 1, 2, 3, 4, 5, 6</td>
</tr>
<tr>
<td></td>
<td><strong>Primary outcome measures:</strong></td>
</tr>
<tr>
<td></td>
<td>- Phantom pain (PID =Pain intensity difference (PID), pain at the end of each treatment compared with baseline, based on VAS (0-100mm): PID gabapentin vs. placebo =3.2 mm (SD 2.1) vs 1.6 mm (SD 0.7), p=0.03 (at 6 weeks)*</td>
</tr>
<tr>
<td></td>
<td>- Phantom pain intensity (measured in the categories: 0 = no pain, 1 = mild pain, 2 = moderate pain; 3 = severe pain): no significant differences.</td>
</tr>
<tr>
<td></td>
<td><strong>Secondary outcomes:</strong></td>
</tr>
<tr>
<td></td>
<td>- Sleep disturbance, moods (HAD) and activities of daily life, prescribed rescue medication (no significant differences)</td>
</tr>
<tr>
<td>Comments</td>
<td>No reported differences in side effects between the groups.</td>
</tr>
</tbody>
</table>

* Effect recorded at 6 weeks due to baseline score, at weeks 1 to 5 m no significant effects. At this time there were still 14 subjects in the study.
Study Lambert 2001

Methods RCT

Participants
n=30, patients with above-the-knee and below-the-knee amputations
M=15 (79%), F=4 (21%)
Av. age =75 years (range 47- 93)
Setting: hospital

Inclusion criteria: patients with amputation of a lower limb.
Exclusion criteria: use of anticoagulants, revision surgery, bilateral amputation, time to surgery <24 hours, contraindications for epidural catheter.

Interventions
Intervention group (i) (n=16: epidural (bupivacaine)
Control group (c) (n=14): perineural (bupivacaine)

Outcomes
Follow-up times: 6 hrs, 1, 2, and 3 days, 6 and 12 months.

Primary outcomes:

- Incidence of stump pain and phantom pain

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Stump pain (n%)</th>
<th>Phantom pain (n%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Epidural</td>
<td>Perineural</td>
</tr>
<tr>
<td>3 days</td>
<td>14/16</td>
<td>1 (13%)</td>
<td>4 (25%)</td>
</tr>
<tr>
<td>6 days</td>
<td>8/8</td>
<td>4 (50%)</td>
<td>3 (38%)</td>
</tr>
<tr>
<td>6 months</td>
<td>8/8</td>
<td>1 (13%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

* Numbers too small for statistical analysis

- Use of opioids (no significant differences)

No information on side effects reported.

Comments
Large differences in baseline characteristics

Table 6.2: Risk of bias (RoB)

<table>
<thead>
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</thead>
<tbody>
<tr>
<td>Nikolajsen, 1997</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Pinzur, 1996</td>
<td>+</td>
<td>-</td>
<td>?</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>?</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Wilson, 2008</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Hayes, 2004</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Nikolajsen, 2006</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>+</td>
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<td>+</td>
<td>?</td>
<td>+</td>
<td>+</td>
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</tr>
<tr>
<td>Bone, 2002</td>
<td>+</td>
<td>+</td>
<td>?</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>?</td>
<td>?</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Lambert, 2001</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>?</td>
<td>?</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>
Chapter 7: Complications

Table 7.1: Study characteristics of included primary studies

<table>
<thead>
<tr>
<th>Study</th>
<th>McIntosh, 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>systematic review</td>
</tr>
<tr>
<td>Participants</td>
<td>Databases: Medline, Pubmed, Google Scholar, Cochrane Library</td>
</tr>
<tr>
<td></td>
<td>Search terms: major limb amputation, wound infection, antibiotic prophylaxis.</td>
</tr>
<tr>
<td></td>
<td>- No restrictions in study design, language, etc.</td>
</tr>
<tr>
<td></td>
<td>- Outcome measure: % of primary wound healing, the percentage of infected and non-infected wound necrosis, re-amputation, mortality (regardless of cause).</td>
</tr>
<tr>
<td>Interventions</td>
<td>A total of four studies were selected based on the above criteria (2 prospective controlled unblinded studies, 2 RCTs).</td>
</tr>
<tr>
<td></td>
<td>- Number of patients per study ranged from 38-152.</td>
</tr>
<tr>
<td></td>
<td>- Amputation level: below the knee, through knee amputation, above the knee amputation.</td>
</tr>
<tr>
<td></td>
<td>- The use of prophylactic antibiotics resulted in significantly fewer stump infections in comparison with placebo/no antibiotics.</td>
</tr>
<tr>
<td></td>
<td>- Type of antibiotic (amoxicillin, amoxicillin and flucloxacillin, amoxicillin and clavulanic acid) did not affect the percentage of wound infections.</td>
</tr>
<tr>
<td></td>
<td>- Wound infection was, in most cases, caused by <em>S. aureus</em> (between 21% and 75%).</td>
</tr>
<tr>
<td></td>
<td><em>Clostridium perfringens</em> was found in two studies (2% and 13% of patients, respectively)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Harris, 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Prospective observational study</td>
</tr>
<tr>
<td>Participants</td>
<td>n=545</td>
</tr>
<tr>
<td></td>
<td>Average age: not specified</td>
</tr>
<tr>
<td>Inclusion criteria:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- High-energy traumatic injury below the distal femur</td>
</tr>
<tr>
<td></td>
<td>- age between 18-69 years</td>
</tr>
<tr>
<td></td>
<td>- One or more injuries to a lower limb</td>
</tr>
<tr>
<td></td>
<td>- Gustilo type IIIb en IIIC fracture</td>
</tr>
<tr>
<td></td>
<td>- Selected type IIIa fracture</td>
</tr>
<tr>
<td></td>
<td>- Dysvascular limb</td>
</tr>
<tr>
<td></td>
<td>- Soft tissue injury on the tibia</td>
</tr>
<tr>
<td></td>
<td>- Serious foot injury</td>
</tr>
<tr>
<td>Exclusion criteria:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Brain damage (Glasgow Coma Scale score &lt;15 to 21 days of discharge)</td>
</tr>
<tr>
<td></td>
<td>- Spinal problems</td>
</tr>
<tr>
<td></td>
<td>- Previous leg or foot amputation</td>
</tr>
<tr>
<td></td>
<td>- Third-degree burn to the injured leg</td>
</tr>
<tr>
<td></td>
<td>- Arrival in hospital &gt; 24 hours after accident</td>
</tr>
<tr>
<td></td>
<td>- Unable to express themselves in English or Spanish languages</td>
</tr>
<tr>
<td></td>
<td>- Psychiatric illness or cognitive decline</td>
</tr>
<tr>
<td></td>
<td>- In army service</td>
</tr>
<tr>
<td></td>
<td>- Home too far from hospital</td>
</tr>
<tr>
<td>Interventions</td>
<td>Amputation or reconstruction</td>
</tr>
<tr>
<td>Follow-up</td>
<td>24 months</td>
</tr>
</tbody>
</table>
### Study: Harris, 2009

**Outcomes**
- Amputation: 149 patients
- Reconstruction: 371 patients

Highest incidence of complications in the first 3 months: 24.8% (n=37)

Complication after amputation occurred within 24 months:
- wound infection: 34.2%
- necrosis: 13.4%
- phantom pain: 13.4%
- stump problems: 10.7%
- stump revision: 14.5%

Patients with an initially postponed amputation (n=25).

Incidence of complications: 85%, including:
- wound infection: 68%
- pseudoarthrosis: 48%
- osteomyelitis: 40%
- stump problems: 24%

Most complications in the first 6 months

**Comments**
- Conducted in the U.S.

### Study: Morse, 2008

**Methods**
Retrospective cohort study (1998 – 2006)

**Participants**
N=50 (f:25; m:25)
- Av. age 63 years (range 37-87 years)

Inclusion criteria:
- peripheral vascular disease

Exclusion criteria:
- amputation due to trauma and malignant tumour
- indication for amputation below the knee

**Interventions**
Through-knee amputation with a modified Mazet technique.

**Follow-up**
Average of 33 months retrospectively (range 38 days to 99 months)

**Outcomes**
- Perioperative mortality: 6% (n=3)
- Reamputation above the knee due to wound not healing: 19% (n=9)
- Wound healing: 81%

**Comments**
- Conducted in the U.S.
- Main comorbidity in study population: 74% hypertension, 66% smoking, 66% cardiovascular disease, 50% diabetes, 50% end-stage renal disease.

### Study: Stone, 2006

**Methods**
Retrospective cohort study (January 1999 – December 2003)

**Participants**
N=380 (f: 148; m:232)
- Age median 67 years ± 13 years

Inclusion criteria:
- Non-traumatic amputation of a lower limb

**Interventions**
Amputation of a lower limb
- above the knee amputation (n=149)
- below the knee amputation (n=230)
- up to hip (n=1)
### Study: Stone, 2006

| Outcomes            | - After 90 days the prevalence of wound complications was 13.4% (n=51)  
|                     | - Of these complications 62.7% led to a more proximal amputation. This group included significantly more patients who had undergone a below the knee amputation (p =0.0006).  
|                     | - Below knee amputation, type of anaesthesia (general and epidural), community living and preoperative haematocrit > 30% were independently associated with wound complications in the first 90 days.  
|                     | - Perioperative mortality was 15.5% (n=59)  
|                     | - Age, albumin level, above knee amputation and history of coronary bypass surgery were independently associated with mortality.  
| Comments            | - Conducted in U.S.  
|                     |  
|                     | - Cause of amputation:  
|                     | - 78 due to acute circulation problems;  
|                     | - 173 patients due to chronic venous insufficiency;  
|                     | - 129 patients due to primary infection.  
|                     | - Comorbidity:  
|                     | - Increased blood pressure (76%)  
|                     | - diabetes (71%)  
|                     | - history of coronary bypass surgery (32%)  

### Study: Johannesson, 2004

| Methods            | Prospective cohort (1995 – 1999)  
| Participants       | n=190 (f: 95; m:79)  
|                     | Average age 81 years (range 30-101 years)  
|                     | n=174 had primary amputation of a lower limb  
|                     | n=16 had secondary amputation of a lower limb  
| Interventions      | Amputation of a lower limb  
|                     | Transfemoral amputation (TFA): n=33  
|                     | Knee amputation (KA): n=10  
|                     | Transtibial amputation (TTA): n=130  
|                     | Ankle amputation (EA): n=1  
| Outcomes           | Reamputation  
|                     | - Percentage single reamputation was 14% (n=24, TFA(16), TTA (8)).  
|                     | - Percentage double reamputation was 3% (n=5)  
|                     | Perioperative mortality ( 1 month after amputation): 16% (n=27)  
|                     | Perioperative mortality ( 3 months after amputation): 31% (n=41)  
|                     | Perioperative mortality ( 12 months after amputation): 47% (n=82)  
|                     | Perioperative mortality ( 24 months after amputation): 60% (n=104)  
| Comments           | Conducted in Sweden.  

---

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<table>
<thead>
<tr>
<th>Study</th>
<th>Kock, 2004</th>
<th>Cruz, 2003</th>
<th>Nehier, 2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>n=66 (f:33; m:33)</td>
<td>n=229 (f:8; m:221)</td>
<td>n=154 (f:24; m:130)</td>
</tr>
<tr>
<td></td>
<td>Average age 66.7 ± 11.3 years (range 42-93 years)</td>
<td>Average age 68.8 years ± 0.6 years</td>
<td>Median age 62 years</td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria:</td>
<td>Exclusion criteria:</td>
<td>Exclusion criteria:</td>
</tr>
<tr>
<td></td>
<td>- end-stage arterial occlusive disease</td>
<td>- amputation distal to ankle</td>
<td>- nonambulatory</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- dementia</td>
</tr>
<tr>
<td>Interventions</td>
<td>Through-knee amputation with dorsal gastrocnemius muscle flap.</td>
<td>Amputation of a lower limb</td>
<td>Amputation of a lower limb</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Group 1: below the knee amputation (OKA) (n=119)</td>
<td>- Above the knee amputation: n=78</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Group 2: above the knee amputation (BKA) (n=177)</td>
<td>- Below the knee amputation: n=94</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Group 3: first an OKA, followed by a BKA (n=27)</td>
<td></td>
</tr>
<tr>
<td>Outcomes</td>
<td>First 'early' results (average 24 hours with a range of 10-48 days)</td>
<td>Correction of original amputation:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Perioperative mortality: 9% (n=6)</td>
<td>- Group 1 (OKA): 30% (wound revision)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Re-amputation up to and including the hip: 13% (n=9)</td>
<td>- Group 2 (BKA): 16%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Re-operation of soft tissue: 9% (n=6)</td>
<td>This difference was statistically significant (p &gt;0.0001)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Primary wound healing: 80% (n=48)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>After an average of 26 months postoperatively (range 3 – 71 months)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- stump sensitivity: n=3</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- (occasional) phantom pain: n=5</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>After an average of 105 months postoperatively (range 96-120 months)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- (occasional) phantom pain: n=5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments</td>
<td>Conducted in Germany</td>
<td>Most common comorbidity: cardiovascular disease (65%), previous vascular surgery (64%), diabetes (59%) and hypertension (52%)</td>
<td>Conducted in U.S.</td>
</tr>
</tbody>
</table>
Outcomes

Median duration hospital stay: 14 days

Postoperative mortality (30 days): 10%

Perioperative complications:
- Pressure ulcers (sacral or the whole of other leg): 6.5% (n=10)
- Sepsis: 2.6% (n=4)
- Bleeding: 1.9% (n=3)
- Pulmonary (n=8), cardiac (n=12) and kidneys (n=1)

Surgical revision: below the knee amputation (n=23), above the knee amputation (n=16), re-amputation to the upper knee: n=18

Comments

- Conducted in U.S.
- Most common comorbidities: smoking (86%), diabetes (65%) and heart disease (39)

Study

Campbell, 2001

Methods

Participants
n=312 (f:134; m:178)
Median age: 76 years (range 39-96 years)

Interventions
Transtibial amputation: n=192
Transfemoral amputation: n=122
Gritti-Stokes : n=34
Hip disarticulation: n=1

Outcomes
Revision: overall 12%
- Transtibial amputation: 19%
- Transfemoral amputation: 3%
- Gritti-Stokes : 6%
- Hip disarticulation: 0%

Perioperative mortality (30 days): overall 18%
- Transtibial amputation: 15%
- Transfemoral amputation: 24%
- Gritti-Stokes : 24%
- Hip disarticulation: 0%

Comments

- Conducted in the United Kingdom
- Comorbidity: diabetes (41%), heart problems (31%), overall vulnerability (36%)

Study

Mohamed, 1997

Methods
Prospective cohort (January 1992 – January 1993)

Participants
n=170 (v:29;m:141)
Average age 37 years (range 5-72 years)

Interventions
- amputation below the knee: n=111
- amputation above the knee: n=52
- Syme amputation: n=7

Outcomes
- revision surgery (bone resection and reform): n=22 (16 patients were diabetic)
- wound adhesion to bone: (n=50) (developed ulcers and hardening)
- phantom pain: n=61 (of whom 26 patients had undergone an above the knee amputation and 25 patients below the knee)
- Non-specific stump pain: n=48

Comments

- Conducted in Sudan
- Main reason for amputation was diabetic foot, followed by traffic accident and Madura foot.
Methods
Retrospective cohort (1989)

Participants
n=111 (f:0; m:111)
Average age 28 years (range 10-60 years)
Inclusion criteria:
- acute below the knee amputation

Interventions
Acute below the knee amputation without wound closure during the primary operation. After 3-5 days, decision on whether the wound could be closed.

Outcomes
Complications:
- Pseudomonas infection: n=1
- single debridement before wound closure possible: n=36
- double debridement before wound closure possible: n=24
- stump revision: n=14 (13%)

- When the stump was closed within 1 week after surgery, the stump was closed without problems in 94% of the operations.
- When closing the wound took place later than 1 week after surgery, the success rate was reduced to 72%. This difference was significant (p <0.05)

Comments
- Conducted in Afghanistan, operated in Peshawar in accordance with ICRC guidelines

Chapter 8: Rehabilitation process

Table 8.1: Study characteristics systematic review

<table>
<thead>
<tr>
<th>Author, years</th>
<th>Cumming, 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Systematic Review</td>
</tr>
<tr>
<td>Participants</td>
<td>‘Dysvascular’ patients who underwent unilateral transfemoral or knee disarticulation amputation</td>
</tr>
<tr>
<td>Interventions</td>
<td>Rehabilitation interventions</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Prim. outcomes: patient satisfaction, sec: quality of life, morbidity, mortality, etc.</td>
</tr>
<tr>
<td>Studies</td>
<td>RCT or quasi-RCT</td>
</tr>
<tr>
<td>Search</td>
<td>Multiple databases to Oct 2008</td>
</tr>
<tr>
<td>Quality assessment</td>
<td>Detailed quality scoring list</td>
</tr>
<tr>
<td>Technique meta-analysis</td>
<td>n.a.</td>
</tr>
<tr>
<td>Outcomes</td>
<td>There is a lack of evidence for the optimal rehabilitation after amputation. The only RCT included did not provide clear results on the ideal prosthesis weight (150, 770 or 1625 grams)</td>
</tr>
</tbody>
</table>

Table 8.2: Study characteristics of included primary studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Marzen-Groller, 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Pre-post study design</td>
</tr>
<tr>
<td>Participants</td>
<td>44 (30 pre, 14 post) adult patients who underwent above knee (AKA), below knee (BKA) or transmetatarsal (TMA) amputation</td>
</tr>
<tr>
<td>Interventions</td>
<td>Amputee Mobility Protocol (AMP), see below. Control is usual care according to the AMP protocol</td>
</tr>
<tr>
<td>Follow-up</td>
<td>Circa 5 months</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Length of stay increased slightly with BKA and AKA. Greater functional improvement??</td>
</tr>
<tr>
<td>Comments</td>
<td>Pre and post TMA groups not matched. Baseline comparability unknown</td>
</tr>
</tbody>
</table>
Amputee Mobility Protocol (AMP)

Pre-operatively: Nursing to place PT consult if Physical Activity is “abnormal” on the Admission assessment, or if patient is pending surgical amputation.

Post-operative amputation: Nursing to place PT consult on the day of surgery.

Transtibial (BKA)/Transfemoral (AKA) Amputation
Post-op Day 1: Bedrest, Encourage use of trapeze, Physical Therapy will instruct patient in General bed exercise for the Amputee (Quad sets, Glut sets, Internal/External Rotation of the hip)
Post-op Day 2: Out of Bed (OOB) to chair, initiated by Physical Therapy. OOB no more than 2 hours BID by Nursing or Physical Therapy. Patients with transtibial amputations shall have BKA board placed in chair with cushion.
Post-op Day 3: Ambulate as tolerated with Physical Therapy or Nursing, OOB to chair no more than 2 hours BID.
Post-op Day 4 until Discharge: Continue ambulation BID, and OOB to chair BID. Progress distance of ambulation to patient’s tolerance. Encourage General bed exercises when in bed.

Post-operative edema management:
• Recommendations: Tubigrip, Ace wrap or Semi-rigid (Unna Boot) or rigid dressing

Transmetatarsal (TMA) Amputation
Post-op Day 1: Heel Wedge Shoe (Heel WB Only) OOB to chair (first time with Physical Therapy then with Nursing) no more than 2 hours BID, elevate involved extremity, WBAT operative limb
Post-op Day 2: Ambulate as tolerated TID (Nursing or Physical Therapy) heel WB on involved extremity
Post-op Day 3 until Discharge: Continue ambulation TID, and OOB to chair to tolerance. Progress distance of ambulation to patient’s tolerance.

Post-operative edema management:
• Recommendations: Tubigrip with measured minimal compression or Ace wrap

Figure 2. Amputee Mobility Protocol.
### Study: Beckerman, 2004

<table>
<thead>
<tr>
<th>Methods</th>
<th>Prospective cohort study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Patients with CVA, lower limb amputation, spinal cord lesion, MS, and other neuromuscular disorders</td>
</tr>
<tr>
<td>Interventions</td>
<td>Rehabilitation Activities Profile (RAP) as a team tool. Four teams using RAP (n=214) and five teams partially using it were compared with 9 teams that had not yet used RAP (n=437) and thus served as controls.</td>
</tr>
<tr>
<td>Follow-up</td>
<td>2.5 years</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Treatment by a RAP team was related to lower scores on the Barthel index (-3.7%, CI -7.0, -0.3) and non-significant improvement in the Nottingham Health Profile.</td>
</tr>
<tr>
<td>Comments</td>
<td>The authors suspected that the implementation of RAP was still insufficient.</td>
</tr>
</tbody>
</table>

### Study: Dillingham, 2008

<table>
<thead>
<tr>
<th>Methods</th>
<th>Retrospective study based on a sample of Medicare claims database; multivariate analysis with adjustment for confounding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>2468 elderly patients who underwent an amputation of a lower limb</td>
</tr>
<tr>
<td>Interventions</td>
<td>Discharge destination: clinical rehabilitation, nursing home <em>(skilled nursing facility: SNF)</em> or home.</td>
</tr>
<tr>
<td>Follow-up</td>
<td>12 months</td>
</tr>
<tr>
<td>Outcomes</td>
<td>One-year survival of 75%, 63% and 51% in rehabilitation centre, nursing home and home, respectively. Reamputations 18%, 23% en 25%. Successfully obtained prosthesis, 73%, 58% en 49%</td>
</tr>
<tr>
<td>Comments</td>
<td>Patients in SNF were older and more often had a transfemoral amputation. Not significantly more comorbidity in patients in a nursing home or at home (but less diabetes in nursing home patients). Attributing better outcomes to clinical rehabilitation is difficult. However, the better outcomes compared with patients going home is encouraging.</td>
</tr>
</tbody>
</table>

### Study: Klein, 2001

<table>
<thead>
<tr>
<th>Methods</th>
<th>Observational study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Patients who underwent BKA</td>
</tr>
<tr>
<td>Interventions</td>
<td>30 received clinical rehabilitation and 30 (home-based) ambulatory rehabilitation</td>
</tr>
<tr>
<td>Follow-up</td>
<td>12-29 weeks</td>
</tr>
<tr>
<td>Outcomes</td>
<td>No difference in use of the prosthesis, or the degree of ADL function. Perceived social support (3.96 vs. 3.4 with unknown instrument, p =0.012) and patient satisfaction (80% vs. 54%, p =0.028) was better in the outpatient rehabilitation group</td>
</tr>
<tr>
<td>Comments</td>
<td>Groups similar at baseline in terms of age, gender and general health immediately after amputation. Outpatient rehabilitation took longer (206 vs. 87 days)</td>
</tr>
</tbody>
</table>

### Study: Kurichi, 2009

<table>
<thead>
<tr>
<th>Methods</th>
<th>Retrospective observational study, risk adjustment using propensity risk score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>1339 veterans who underwent a leg amputation</td>
</tr>
<tr>
<td>Interventions</td>
<td>Specialised rehabilitation interventions vs. rehabilitation on general surgical wards</td>
</tr>
<tr>
<td>Follow-up</td>
<td>1 year</td>
</tr>
<tr>
<td>Outcomes</td>
<td>One-year survival 91 vs 76% <em>(p &lt;0.0001)</em>, length of stay 17 vs 11 days <em>(p &lt;0.0001)</em>; discharged home 84 vs. 73% <em>(p &lt;0.0001)</em>; prescription of prosthesis 40 vs. 19% <em>(p &lt;0.0001)</em>; increase in physical function <em>(functional independence Motor (FIM) score)</em> 19 vs 10</td>
</tr>
<tr>
<td>Study</td>
<td>Pezzin, 2000</td>
</tr>
<tr>
<td>-------</td>
<td>-------------</td>
</tr>
<tr>
<td>Methods</td>
<td>Retrospective study</td>
</tr>
<tr>
<td>Participants</td>
<td>146 patients with trauma-related amputations</td>
</tr>
<tr>
<td>Interventions</td>
<td>Clinical rehabilitation</td>
</tr>
<tr>
<td>Follow-up</td>
<td>? (long term)</td>
</tr>
<tr>
<td>Outcomes</td>
<td>After multivariate analysis, clinical rehabilitation was related to better health (SF-36), e.g. in physical role functioning (p&lt;0.01)</td>
</tr>
<tr>
<td>Comments</td>
<td>Patients in clinical rehabilitation were older, more often had comorbidity and spent more days in the ICU</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Rau, 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>RCT</td>
</tr>
<tr>
<td>Participants</td>
<td>58 patients who underwent leg amputation</td>
</tr>
<tr>
<td>Interventions</td>
<td>Intensive physiotherapy program vs. usual care</td>
</tr>
<tr>
<td>Follow-up</td>
<td>3 months?</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Better 2 min walking test (20.2 vs. 8.9, p =0.024, and walking speed (10 vs 3.9 m/min. No difference in Timed up and go (TUG) test</td>
</tr>
<tr>
<td>Comments</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Stineman, 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Retrospective cohort study</td>
</tr>
<tr>
<td>Participants</td>
<td>2673 veterans who underwent transtibial or transfemoral amputation</td>
</tr>
<tr>
<td>Interventions</td>
<td>1418 patients who received acute inpatient rehabilitation (in an integrated care system) and 1255 patients without any form of rehabilitation</td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Outcomes</td>
<td>One-year survival (OR 1.9, CI 1.7-2.3), more patients went home (OR 3.4, CI 2.9-4.0) and with prosthesis (OR 1.5, CI 1.2-1.8)</td>
</tr>
<tr>
<td>Comments</td>
<td>At baseline, more patients who received acute inpatient rehabilitation lived at home (91 vs. 80%). and more patients without rehabilitation had paralysis (7.1 vs. 4.5%) and also more often had severe additional comorbidities. Correction for confounding in analysis with propensity risk score</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Yigit, 2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>RCT</td>
</tr>
<tr>
<td>Participants</td>
<td>50 transfemoral amputees, 20-40 years old, average 7 months after amputation</td>
</tr>
<tr>
<td>Interventions</td>
<td>Proprioceptive neuromuscular facilitation (PNF) vs. traditional training</td>
</tr>
<tr>
<td>Follow-up</td>
<td>?</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Weight-bearing capacity and gait characteristics improved more (P &lt;0.05) in the PNF group, including increased stride length on amputated side 3.9 vs. 5.4 cm, walking speed improvement 17.7 vs. 936 cm/s</td>
</tr>
<tr>
<td>Comments</td>
<td>The quality of this RCT cannot be assessed due to poor reporting</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Schaldach 1997</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Retrospective observational study (historical cohort study)</td>
</tr>
<tr>
<td>Participants</td>
<td>Patients undergoing below knee or above knee amputation.</td>
</tr>
<tr>
<td>Interventions</td>
<td>Treatment took place following a clinical rehabilitation plan (n=46)</td>
</tr>
</tbody>
</table>

Richtlijn Amputatie en prothesiologie lower limb, 2012  113
between 1994 and 1995, or any of the situations before the clinical rehabilitation was instituted (between 1989 and 1992), a rehabilitation consultation (n-34) or routine care (n=104)

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>Outcomes</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Despite increased comorbidity, a higher proportion of patients returned home in the group following clinical rehabilitation (17% vs. 12%. p&gt; 0.05) and fewer people entered a nursing home (35% vs. 41%; p&gt;0.05).</td>
<td>There were more patients without comorbidity (36 vs. 15%) and more high amputations (67 vs. 46%) in the routine care group than in the clinical rehabilitation group</td>
</tr>
</tbody>
</table>

Table 8.3: Risk of bias (RoB) randomised trials

| RAU, 2007 | + | + | + | - | - | - | ? | + | ? | + |

Chapter 9: Amputation and the workplace

Table 9.1: Study characteristics

<table>
<thead>
<tr>
<th>Study</th>
<th>McKenzie 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Prospective cohort study</td>
</tr>
<tr>
<td>Participants</td>
<td>423 patients with amputation after life-threatening trauma &amp; working before injury</td>
</tr>
<tr>
<td>Interventions</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td>7 years</td>
</tr>
<tr>
<td>Outcomes</td>
<td>42% returned to work after 1 and 58% after 7 years. More likely to return to work at age &lt;55 years, higher education, non-smoker and having a medium to high self-efficacy</td>
</tr>
<tr>
<td>Comments</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Schoppen, 2001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Cross-sectional study</td>
</tr>
<tr>
<td>Participants</td>
<td>Participants 652 patients with leg amputation ≥ 2 years (average 19 years)</td>
</tr>
<tr>
<td>Interventions</td>
<td>questionnaire</td>
</tr>
<tr>
<td>Follow-up</td>
<td>-</td>
</tr>
<tr>
<td>Outcomes</td>
<td>64% working, 31% had work experience and 5% had never worked. Not different when compared with the general population, but lower employment rate in men ≥ 40 years (p&lt;0.02)</td>
</tr>
<tr>
<td>Comments</td>
<td></td>
</tr>
</tbody>
</table>
## Study 1: Schoppen 2001a

**Methods**

Cross-sectional study

**Participants**

322 patients with leg amputation ≥ 2 years ago

**Interventions**

- 79% successfully integrated (working or stopped for other reasons). Factors related to resumption: comorbidity, reason for amputation (vascular - unfavourable), phantom and stump pain, prosthetic use and limitations in mobility

**Follow-up**

- 79% successfully integrated (working or stopped for other reasons). Factors related to resumption: comorbidity, reason for amputation (vascular - unfavourable), phantom and stump pain, prosthetic use and limitations in mobility

**Outcomes**

- 79% successfully integrated (working or stopped for other reasons). Factors related to resumption: comorbidity, reason for amputation (vascular - unfavourable), phantom and stump pain, prosthetic use and limitations in mobility

**Comments**

- 79% successfully integrated (working or stopped for other reasons). Factors related to resumption: comorbidity, reason for amputation (vascular - unfavourable), phantom and stump pain, prosthetic use and limitations in mobility

## Study 2: Schoppen, 2001b

**Methods**

Cross-sectional study

**Participants**

144 amputees and 144 controls (colleague from work)

**Interventions**

- 70% of amputees satisfied with work. 30% dissatisfied, while 46% of the controls were dissatisfied (p=0.03)

**Follow-up**

- 70% of amputees satisfied with work. 30% dissatisfied, while 46% of the controls were dissatisfied (p=0.03)

**Outcome**

- 70% of amputees satisfied with work. 30% dissatisfied, while 46% of the controls were dissatisfied (p=0.03)

**Comments**

- 70% of amputees satisfied with work. 30% dissatisfied, while 46% of the controls were dissatisfied (p=0.03)

## Study 3: Van der Sluis 2009

**Methods**

Cross-sectional study

**Participants**

28 upper limb amputees, 144 lower limb amputees en 144 controls

**Interventions**

- 21 (75%) of upper limb and 100% of lower limb amputees and controls were in work. Work alterations (especially assistance from colleagues, seat adjustment, adjusting working hours) were required by 8 of the 21 (38%) upper limb and 28% of the lower limb amputees. The general health of amputees was not depend on age, level amputation or comorbidity

**Follow-up**

- 21 (75%) of upper limb and 100% of lower limb amputees and controls were in work. Work alterations (especially assistance from colleagues, seat adjustment, adjusting working hours) were required by 8 of the 21 (38%) upper limb and 28% of the lower limb amputees. The general health of amputees was not depend on age, level amputation or comorbidity

**Outcomes**

- 21 (75%) of upper limb and 100% of lower limb amputees and controls were in work. Work alterations (especially assistance from colleagues, seat adjustment, adjusting working hours) were required by 8 of the 21 (38%) upper limb and 28% of the lower limb amputees. The general health of amputees was not depend on age, level amputation or comorbidity

**Comments**

- 21 (75%) of upper limb and 100% of lower limb amputees and controls were in work. Work alterations (especially assistance from colleagues, seat adjustment, adjusting working hours) were required by 8 of the 21 (38%) upper limb and 28% of the lower limb amputees. The general health of amputees was not depend on age, level amputation or comorbidity

## Study 4: Burger 2007

**Methods**

Non-systematic review of studies of reintegration after limb amputation

**Participants**

Interventions

- Factors related to limits: level of amputation, multiple amputations, comorbidity, the reason for amputation, stump problems and phantom pain.

**Follow-up**

- Factors related to limits: level of amputation, multiple amputations, comorbidity, the reason for amputation, stump problems and phantom pain.

**Outcomes**

- Factors related to limits: level of amputation, multiple amputations, comorbidity, the reason for amputation, stump problems and phantom pain.

**Comments**

- Factors related to limits: level of amputation, multiple amputations, comorbidity, the reason for amputation, stump problems and phantom pain.

## Study 5: Pezzin, 2000

**Methods**

Retrospective study

**Participants**

146 patients with trauma-related amputations

**Interventions**

- Clinical rehabilitation

**Follow-up**

- Clinical rehabilitation

**Outcomes**

- Clinical rehabilitation

**Comments**

- Clinical rehabilitation

---

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### Study 1: Fisher 2003

**Methods**
Cross-sectional study

**Participants**
100 patients who visited a prosthetic clinic after a leg amputation ≥ 1 year ago, 17-65 years and prosthetic wearing.

**Interventions**

**Follow-up**

**Outcomes**
34% did not work after the amputation, of which 21 (62%) due to amputation or prosthesis-related factors

**Comments**

### Study 2: Hebert 2006

**Methods**
Retrospective study of a claims database using multivariate analysis of prognostic factors for return to work.

**Participants**
88 patients who underwent a leg amputation

**Interventions**

**Follow-up**
2 years

**Outcomes**
51 patients (58%) were back at work. Only amputation level (higher level, fewer working) and higher income (>$25,000/year) predictive of return to work. For the secondary outcome 'days of total disability' (TD), older age (per year TD lasted 7 days longer), number of surgical procedures (TD lasted 54 days longer per procedure), number of days in acute care (each day represents 10 days shorter TD) and the level of amputation (transfibial 564 days less TD) associated with longer duration TD

**Comments**

### Study 3: Mezghani-Masmoudi 2004

**Methods**
Retrospective study with questionnaire in 1999

**Participants**
85 patients with leg amputation in 1982-1998

**Interventions**

**Follow-up**

**Outcomes**
34 of 60 of those working before amputation (58%) worked 1-17 year after amputation

**Comments**
No prognostic factors reported

### Study 4: Whyte, 2002

**Methods**
Retrospective study with questionnaire

**Participants**
315 patients ≥ 2 years after amputation, 20-60 years of age and suffering from phantom pain

**Interventions**

**Follow-up**
≥ 2 years after leg amputation

**Outcomes**
44% resumed work (33% of women and 47% of men). Severity of phantom pain predictive of return to work (p =0.001). The more serious the phantom pain, the less the prosthesis was used per day.

**Comments**

### Study 5: Pedersen 1994

**Methods**
Cross-sectional study

**Participants**
22 patients with leg amputation after fracture, of whom 15 worked before amputation

**Interventions**

**Follow-up**

**Outcomes**
10 of 15 (67%) resumed work. The age of the working was younger (median 26) than that of the unemployed (median 55) (p <0.05)

**Comments**

---

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*Richtlijn Amputatie en prothesiologie lower limb, 2012*
Study | Bruins 2003
--- | ---
Methods | Qualitative retrospective study
Participants | 32 patients aged 18-60 years who had undergone a leg amputation ≥ 2 years ago and had paid work before amputation
Interventions | Follow-up
Outcomes | The period between amputation and return to work was approximately one year. Delay in resumption was mainly caused by problems with the stump or wound healing. Half of the patients received other tasks or another job. Motives for work resumption were mainly daily activities and social contacts in the workplace. Poor support by reintegration bodies and by the employer (34) was the main obstacle to a return to work.

Chapter 10: Prosthetic provision

Prosthetic prescription

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Van der linde 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>P</td>
<td>Patients with (lower) leg prosthesis</td>
</tr>
<tr>
<td>I</td>
<td>Several prosthetic components</td>
</tr>
<tr>
<td>C</td>
<td>Performance with prosthesis</td>
</tr>
<tr>
<td>O</td>
<td>RCT, cohort or case-control studies</td>
</tr>
<tr>
<td>S</td>
<td>Multiple databases up to 2001</td>
</tr>
<tr>
<td>Search</td>
<td>1 reviewer?</td>
</tr>
<tr>
<td>Selection</td>
<td>With scoring instrument</td>
</tr>
<tr>
<td>Quality assessment</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Results</td>
<td>40 studies of sufficient methodological quality were included. Various prosthetic techniques were compared, but few articles were based on good quality RCTs.</td>
</tr>
</tbody>
</table>

**Prosthetic foot**

Three studies of intermediate quality reported a higher walking speed with an ‘energy-storing’ prosthetic foot in traumatic transtibial amputees. No study found a difference in patient satisfaction with regard to specific types of prosthetic feet.

**Prosthetic knee**

Prostheses with ‘advanced mode or swing phase control’ such as the pneumatic Tehlin knee seem to provide greater comfort and improved walking speed, making this type of prosthesis particularly suitable for active patients. Less active, geriatric, patients are more likely to benefit from a conventional knee prosthesis with a longer stance phase.
Table 10.2: Study characteristics RCTs and other primary studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Selles 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>RCT</td>
</tr>
<tr>
<td>Participants</td>
<td>36 adult patients with a prosthesis &gt; 1 year after transtibial amputation, without stump problems.</td>
</tr>
<tr>
<td>Interventions</td>
<td>ICEX total surface bearing (TSB) socket or a conventional patellar tendon-bearing (PTB) socket</td>
</tr>
<tr>
<td>Follow-up</td>
<td>3 months</td>
</tr>
<tr>
<td>Outcomes</td>
<td>The increase in the % time spent upright was greater in the TMP group, but this may be related to the higher score at baseline in this group. There were no detectable differences in other outcomes such as graft function and patient satisfaction. While the TSB appeared more expensive in terms of production costs (1590 vs 954 euro. P =0.001), the TSB required less time to be spent on fitting the prosthesis by the prosthetist (9.2 vs 14.7 hours;. p =0.02). As a result, the cost of both sockets is similar.</td>
</tr>
<tr>
<td>Study</td>
<td>Methods</td>
</tr>
<tr>
<td>-------</td>
<td>---------</td>
</tr>
<tr>
<td><strong>Datta 2005</strong></td>
<td>Crossover trial</td>
</tr>
<tr>
<td><strong>Coleman 2004</strong></td>
<td>Randomised crossover trial</td>
</tr>
<tr>
<td><strong>Johansson 2005</strong></td>
<td>Observational study</td>
</tr>
<tr>
<td><strong>Hafner 2007</strong></td>
<td>Non-randomised cross-over trial</td>
</tr>
</tbody>
</table>
Methods: Observational study in which participants tested both types

Participants: 5 healthy and active transfemoral amputees

Interventions: The 3R80 and the Total Knee 2000 knee prosthesis

Follow-up

Outcomes: The Total Knee 2000 was less stable in the early stance phase and more stable in the middle and late stance phase. Subjective questionnaires showed a preference for the Total Knee 2000 as the users had greater confidence and felt more stable.

Table 10.2: Risk of bias (RoB) randomised trials

|----------------|-------------------------|------------------------|-----------------------------|------------------|------------------------|---------------------------|----------------------------------------|-------------------------|------------------------------------------|---------------------------------|-----------------------------|

**Moment of prosthesis fitting**

Table 10.3: Study characteristics RCTs and primary studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Schon 2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Historical cohort study</td>
</tr>
<tr>
<td>Participants</td>
<td>19 patients with intervention vs. 23 historical controls</td>
</tr>
<tr>
<td>Interventions</td>
<td>Immediate postoperative prosthesis vs. standard soft dressings</td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Results</td>
<td>3/19 in the intervention group and 11/23 in the control group had one or more complications (p &lt;0.05), while 0/19 and 12/23 had one or more falls. However, no significant difference was seen when post-acute phase falls in the intervention group were included. 0/19 in the intervention group and 8/23 in the control group required a surgical revision prior to fitting the prosthesis. The adjustment period to the prosthesis was significantly shorter in the intervention group (3.4 months, range 1.6-5.9 months) than in the control group (5.1 months, range 1-21 months)</td>
</tr>
<tr>
<td>Comments</td>
<td>Groups similar at baseline</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Lilja 1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td></td>
</tr>
<tr>
<td>Participants</td>
<td>4 transtibial amputees</td>
</tr>
<tr>
<td>Interventions</td>
<td>MRI study of the stump</td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Outcomes</td>
<td>The stump area decreased shortly after the operation, and the same applies to the medial muscle groups. However, the lateral muscles (lateral head of the gastrocnemius and tibialis anterior) increased in size.</td>
</tr>
<tr>
<td>Comments</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Ivanic 2002</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>Methods</td>
<td>Feasibility study</td>
</tr>
<tr>
<td>Participants</td>
<td>25 below knee amputees</td>
</tr>
<tr>
<td>Interventions</td>
<td>Immediate prosthesis with air bladders</td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Outcomes</td>
<td>23 of the 25 patients were mobilised in the first 5 days postoperatively. Of these, 11 were mobile. The remaining patients were not mobile, for various reasons.</td>
</tr>
<tr>
<td>Comments</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Van Ross 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Controlled trial/observational study</td>
</tr>
<tr>
<td>Participants</td>
<td>62 of 66 transtibial amputees with an unhealed stump (wound &gt; 1*1 cm &gt; 3 weeks) after amputation</td>
</tr>
<tr>
<td>Interventions</td>
<td>Mobilisation with a PPAM (pneumatic post-amputation mobility aid)</td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Outcomes</td>
<td>51 patients (82%) mobilised according to protocol and 46 (74%) achieved complete stump healing after an average of 141 days.</td>
</tr>
<tr>
<td>Comments</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX 7: SEARCH STRATEGIES

Report literature search key question 1a:
*Which indication criteria are available to determine the level of a lower limb amputation?*
*What is the minimum required information when deciding on amputation?*

On 5th May 2009 a search was carried out in Medline via the OVID interface following an explanation by Jan Koning (Medline was updated to 27-04-2009). The search in Embase (updated to week 20, 2009), using the same global search strategy, was performed by the information specialist on the same date.

In the search the following PICO(S) was formulated:

- **P** search strategy for patient population as already present; consisting of three parts. For this question, the parts 1, 2 and 3 were all combined via "or" (see rule 8 below).

- **I** indication criteria for the level of amputation, based on measurements of the blood flow in the body part requiring amputation as derived from pO2 blood, or blood pressure, or information on possible vascular insufficiency obtained through imaging techniques.

- **C**

- **O** level of amputation, technique applied for amputation, prognosis

- **S** study types
**Part P**

The following parts of 'P lower limb amputation' (combined with OR) of the search strategy stored in Ovid med090428 *P amputation en prothesiologie lower limb* was used (line 8 indicates the combination used).

The search strategy was as follows:

<table>
<thead>
<tr>
<th>P</th>
<th>keywords</th>
<th>operator</th>
<th>words with field designations such as multipurpose (mp) in title (ti), abstract (ab) or title or abstract (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amputation/</td>
<td>OR</td>
<td>(knee$ or leg$ or limb$ or crural or lower extremit$).ti,ab.</td>
</tr>
<tr>
<td></td>
<td>Disarticulation/</td>
<td></td>
<td>(trans?tibial or (trans adj1 tibial) or tibial or trans?femoral or (trans adj1 femoral) or femoral).ti,ab.</td>
</tr>
<tr>
<td></td>
<td>Amputation Stumps/</td>
<td></td>
<td>((through or above or below) adj1 knee$).ti,ab.</td>
</tr>
<tr>
<td></td>
<td>Amputation, Traumatic/</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>OR</td>
<td>(knee$ or leg$ or limb$ or crural or lower extremit$).ti,ab.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(trans?tibial or (trans adj1 tibial) or tibial or trans?femoral or (trans adj1 femoral) or femoral).ti,ab.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>((through or above or below) adj1 knee$).ti,ab.</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>1 AND 2=</td>
<td>P-part 1</td>
</tr>
<tr>
<td>4</td>
<td>Leg/su [Surgery]</td>
<td>OR</td>
<td>amput$.tw.</td>
</tr>
<tr>
<td></td>
<td>Tibia/su [Surgery]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>exp Femur/su [Surgery]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Knee/su [Surgery]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>4 AND 5=</td>
<td>P-deel 2</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
<td>OR</td>
<td>(knee$ adj4 (disarticulat$ or exarticulat$)).ti,ab.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>((through or above or below) adj1 knee$ adj4 amputat$).ti,ab.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>((trans?tibial or (trans adj1 tibial)) adj4 amputat$).ti,ab.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>((trans?femoral or (trans adj1 femoral)) adj4 amputat$).ti,ab.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(knee$ adj4 (disarticulat$ or exarticulat$)).ti,ab.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>((through or above or below) adj1 knee$ adj4 amputat$).ti,ab.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>((tibial or femoral) adj4 amputat$).ti,ab.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(leg$ or limb$ or crural or lower extremit$) adj4 amputat$).ti,ab.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>((trans?ankle or syme) adj3 (amputat$ or disarticulat$)).ti,ab.</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td>3 OR 7=</td>
<td>6 P-part3</td>
</tr>
</tbody>
</table>
### Part I

Search terms for I = indication criteria, indications for level, see combinations in line 4, variant for indications for level in line 5, imaging in line 6:

<table>
<thead>
<tr>
<th>I</th>
<th>keywords</th>
<th>operator</th>
<th>words with field designations such as multipurpose (mp) in title (ti), abstract (ab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>exp Blood Gas Monitoring, Transcutaneous/</td>
<td>OR</td>
<td>blood gas monitoring.mp. or preoperative transcutaneous oxygen tension.mp. or</td>
</tr>
<tr>
<td>2</td>
<td>exp Platinum/ or exp Oxides/</td>
<td>OR</td>
<td>platinum oxide.mp.</td>
</tr>
<tr>
<td>3</td>
<td>oxygen/bl or oxiwithry/mt,is,st or ischemia/su or exp extremities/bs</td>
<td>OR</td>
<td>(RM200 or MCPD).tw. or oxygen saturation.mp. or tcPO2.mp.</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>1 OR 2 OR 3</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>exp Gangrene/ or exp Femoral Artery/ or exp Ischemia/ or exp Arterial Occlusive Diseases/ or exp Vascular Patency/ or exp Wound Healing/ or exp Blood Pressure/</td>
<td>OR</td>
<td>gangrene.mp. or rest pain.mp. or patency.mp. or wound healing.mp. or brachial pressure index.mp.</td>
</tr>
<tr>
<td>6</td>
<td>exp Positron-Emission Tomography/ or exp Angiography/ or exp Tomography, X-Ray Computed/ or exp leg/ra or exp Leg Bones/ra, ri</td>
<td>OR</td>
<td>positron emission tomography.mp. or angiography.mp. or computer tomography.mp. or</td>
</tr>
</tbody>
</table>

**Extra search for TASC**

<table>
<thead>
<tr>
<th>B</th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti) or abstract (ab) or title or abstract (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>OR</td>
<td>(TASC or TransAtlantic Inter-Society Consensus).tw.</td>
</tr>
</tbody>
</table>

### Part O

Search terms for O=outcome, methodology in line 1, prognosis in line 2:

<table>
<thead>
<tr>
<th>O</th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti) or abstract (ab) or title or abstract (tw) of subheading (fs) or multipurpose (mp)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amputation/mt [Methods]</td>
<td>OR</td>
<td>(amput* adj3 level?.ti. or level?.tw. or ((Selection or indicat* or criteri*) adj5 amputation?).tw. or ((Selection or indicat* or criteri*) adj5 amputation?.). or ((Major or minor) adj5 amputat*).tw. or (distal adj5 shift*).tw. or mt.fs.</td>
</tr>
<tr>
<td>2</td>
<td>exp Prognosis/ or exp Treatment Outcome/ or exp Treatment Failure/ or exp Morbidity/ or exp Mobility Limitation/ or exp Survival/ or exp Survival Rate/ or exp Mortality/</td>
<td>OR</td>
<td>prognosis.mp. or treatment outcome.mp. or treatment failure.mp. or morbidity.mp. or mobility limitation.mp.or perioperative mortality.mp. or survival.mp.or mortality.mp.</td>
</tr>
</tbody>
</table>
For S, study types

For S, the following filters for study type, 1=systematic review, 2=observational studies

<table>
<thead>
<tr>
<th>S</th>
<th>keywords</th>
<th>operator</th>
<th>Free text words resp. words in specific indexes of all fields (af)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>OR</td>
<td>meta analysis.pt. or meta-anal*.af. metaanal*.af. or (quantitativ* adj10 review*).tw. or (quantitativ* adj10 overview*).tw. or (systematic* adj10 review*).tw. or (systematic* adj10 overview*).tw. or (methodologic* adj10 review*).tw. or (methodologic* adj10 overview*).tw. or medline.tw. and review-.pt. or (pooled adj3 analy*).tw.</td>
</tr>
</tbody>
</table>

Results of the search (all items are stored in Reference Manager file ‘Amputatie - vraag 1a’ with the filename as keyword):

The search strategy is indicated in brief in the table under filename. (+ means AND)
The explanation of the items named is listed in the tables I, O and S, resp.

med = the medline database
emb = the embase database

<table>
<thead>
<tr>
<th>Filename</th>
<th>number</th>
</tr>
</thead>
<tbody>
<tr>
<td>med090505 vr1a indicatiecriteria level systrev</td>
<td>4</td>
</tr>
<tr>
<td>med090505 vr1a indicatiecriteria level prognose observat</td>
<td>77</td>
</tr>
<tr>
<td>med090505 vr1a imaging observat</td>
<td>12</td>
</tr>
<tr>
<td>med 090504 vr1a level O2 meting observat</td>
<td>23</td>
</tr>
<tr>
<td>med090526 vr1a aanvulling TASC</td>
<td>28</td>
</tr>
<tr>
<td>emb090505 vr1a indicatiecriteria level systrev</td>
<td>7</td>
</tr>
<tr>
<td>emb090505 vr1a indicatiecriteria level prognose observat</td>
<td>12</td>
</tr>
<tr>
<td>emb090505 vr1a limb ischemia disease management</td>
<td>11</td>
</tr>
<tr>
<td>emb090505 vr1a imaging</td>
<td>7</td>
</tr>
<tr>
<td>emb090526 vr1a aanvulling TASC</td>
<td>16</td>
</tr>
</tbody>
</table>
Limitations: No articles exclusively about animals, only articles in the Dutch, English, German or French languages and only articles from 1990 to 2009.

General comments:
1. The number of references in Reference Manager and therefore in the literature lists differs from the number of hits because, during import into Reference Manager, an effort was made to avoid importing items that were already in the file.
2. The keywords mentioned in this report are MeSH keywords. Keywords that were as close as possible to the keywords listed, in terms of meaning, were used for other databases.
3. The search strategies used are stored in the files.

Report literature search key question 1b:
How can the most favourable moment for amputation of a lower limb be determined? What preoperative evaluation is needed in patients undergoing amputation of a lower limb?

On 5th May 2009 a search was carried out in Medline via the OVID interface following an explanation by Jan Koning (Medline was updated to 27-04-2009). The search in Embase (updated to week 20, 2009), using the same global search strategy, was performed by the information specialist on the same date.

In the search, the following PICO(S) was formulated:

PICO for: How can the most favourable moment for amputation of a lower limb be determined?

P  search strategy for patient population as already present; consisting of three parts. For this question, the parts 1, 2 and 3 were all combined via "or" (see rule 8 below).

I  timing, most favourable moment

C

O  level of amputation, technique applied for amputation, prognosis

S  study types
PICO for: What preoperative evaluation is needed in patients undergoing amputation of a lower limb?

**P**
search strategy for patient population as already present; consisting of three parts. For this question, parts 1, 2 and 3 were all combined via "or" (see rule 8 below).

**I**
preoperative evaluation

**C**

**O**
level of amputation, technique applied for amputation, prognosis

**S**
study types

**Part P**
The following parts of 'P lower limb amputation' (combined with OR) of the search strategy stored in Ovid was used (line 8 indicates the combination used). This search strategy was as follows:
### Part I

Search terms for I - most favourable moment, timing in line 1, preoperative evaluation in line 2, the following search terms were used:

<table>
<thead>
<tr>
<th>I</th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti) or abstract (ab), multipurpose(mp)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&quot;Time Factors&quot;/ or exp &quot;Age of Onset&quot;/</td>
<td>OR</td>
<td>tim*.ti. or age of onset.mp.</td>
</tr>
<tr>
<td>2</td>
<td>exp Preoperative Care/</td>
<td>OR</td>
<td>pre-operative.mp. or preoperative.mp.</td>
</tr>
</tbody>
</table>
For O = outcome, the methodology selected, the following search terms were used:

<table>
<thead>
<tr>
<th>O</th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti) or abstract (ab) title or abstract (tw) or subheading (fs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amputation/mt [Methods]</td>
<td>OR</td>
<td>(amput* adj3 level?).ti. or level?.tw. or ((Selection or indicat* or criteri*) adj5 amputation?).tw. or ((Selection or indicat* or criteri*) adj5 amputation?).tw. or ((Major or minor) adj5 amputat*).tw. or (distal adj5 shift*).tw. or mt.fs.</td>
</tr>
</tbody>
</table>

For S, the following study type filters, 1 = systematic review, 2 = observational studies

<table>
<thead>
<tr>
<th>S</th>
<th>keywords</th>
<th>operator</th>
<th>Free text words resp. words in specific index of all fields (af)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>epidemiologic-studies/ or exp case-control-studies/ or exp cohort-studies/ or cross-sectional-studies/</td>
<td>OR</td>
<td>case with control.af. or (cohort adj5 study).af. (cohort adj5 studies).af. or (cohort adj5 analy$).af. or (follow-up adj5 (study or studies)).af. or (longitudinal or retrospective or (cross adj5 sectional)).af. or (observational adj5 (study or studies)).af. or prospective.af.</td>
</tr>
</tbody>
</table>

Results of the search (all items are stored in Reference Manager file ‘Amputatie - vraag 1b’ with the filename as keyword):

The search strategy is indicated in brief in the table under filename. (+ means AND)

The explanation of the items named is listed in the tables I, O and S, resp.

med = the medline database
emb = the embase database

<table>
<thead>
<tr>
<th>Naam file</th>
<th>number</th>
</tr>
</thead>
<tbody>
<tr>
<td>med090505 vr1b preoperative evaluation.</td>
<td>33</td>
</tr>
<tr>
<td>P + I (preoperatief onderzoek regel 2) + O (methodiekkeuze regel 1) + studietype (regel 1systematic review or nr2 observational studies)</td>
<td>56</td>
</tr>
<tr>
<td>emb090505 vr1b preoperative evaluation focus</td>
<td>11</td>
</tr>
<tr>
<td>emb090505 vr1b preoperative evaluation</td>
<td>25</td>
</tr>
<tr>
<td>emb090505 vr1b timing amputation</td>
<td>18</td>
</tr>
</tbody>
</table>
Limitations: No articles exclusively about animals, only articles in the Dutch, English, German or French languages and only articles from 1990 to 2009.

General comments:
1. The number of references in Reference Manager and therefore in the literature lists differs from the number of hits because, during import into Reference Manager, an effort was made to avoid importing items that were already in the file.
2. The keywords mentioned in this report are MeSH keywords. Keywords that were as close as possible to the keywords listed, in terms of meaning, were used for other databases.
3. The search strategies used are stored in the files.

Report literature search key question 2: Which surgical techniques are available for amputation of a lower limb? When is each technique indicated? What are the advantages and disadvantages of the different surgical techniques for amputation of a lower limb?

On 3rd August 2009 a search was carried out in Medline via the OVID interface following oral and written explanations by Harry Voesten. He also provided key references that were mainly used in the selection of additional terms for the description of the procedure. Medline was updated to week 4 of July 2009 at the time of the search. The search in Embase (updated to week 31 of 2009), using the same global search strategy, was performed by the information specialist on the same date.

In the search the following PICO(S) was formulated:

P  search strategy for patient population as already present; consisting of three parts. For this question, parts 1, 2 and 3 were all combined via "or" (see rule 8 below).
I  Description surgery + adding the focus "amputation"
C   
O  outcome in 3 variants
S  study types

Part P
The following parts of 'P lower limb amputation' version 3 090428 (combined with OR) of the search strategy stored in Ovid was used (line 8 indicates the combination used). This search strategy was as follows:
<table>
<thead>
<tr>
<th>P</th>
<th>keywords</th>
<th>operator</th>
<th>words with field designations such as multi-purpose (mp) in title (ti), abstract (ab) or title or abstract (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amputation/ Disarticulation/ Amputation Stumps/ Amputation, Traumatic/</td>
<td>OR</td>
<td>(knee$ or leg$ or limb$ or crural or lower extremit$).ti,ab. (trans?tibial or (trans adj1 tibial) or tibial or trans?femoral or (trans adj1 femoral) or femoral).ti,ab. ((through or above or below) adj1 knee$).ti,ab.</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>OR</td>
<td>1 AND 2= P-part 1</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td>4 AND 5= P-part 2</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td>OR</td>
<td>(((through?tibial or (trans adj1 tibial)) adj4 amputat$).ti,ab. (((trans?femoral or (trans adj1 femoral)) adj4 amputat$).ti,ab. (knee$ adj4 (disarticulat$ or exarticulat$)).ti,ab. ((through or above or below) adj1 knee$ adj4 amputat$).ti,ab. (((tibial or femoral) adj4 amputat$).ti,ab. (((leg$ or limb$ or crural or lower extremit$) adj4 amputat$).ti,ab. (((trans?ankle or syme) adj3 (amputat$ or disarticulat$)).ti,ab.</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td>3 OR 6 OR 7= P-part3</td>
</tr>
</tbody>
</table>

### Part 1

**Intervention:** Keywords for the procedure in line 1, used focus for amputation in line 2:

<table>
<thead>
<tr>
<th>I</th>
<th>keywords</th>
<th>operator</th>
<th>words with field designations such as multi-purpose (mp) in title (ti), abstract (ab) or title or abstract (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>**Arterial Occlusive Diseases”/su or exp Gangrene/su or exp Ischemia/su</td>
<td>OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>or exp leg/su or</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>*Amputation/ or exp *Amputation Stumps/</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Part O
For O = outcome, the methodology selected, 3 groups of search terms were used

<table>
<thead>
<tr>
<th>O</th>
<th>keywords</th>
<th>operator</th>
<th>words with field designations such as multipurpose (mp) in title (ti), abstract (ab) or title or abstract (tw), subheading (fs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>exp Evidence-Based Medicine/</td>
<td>OR</td>
<td>mt.fs. or st.fs. or evidence based medicine.mp.</td>
</tr>
<tr>
<td>2</td>
<td>exp Treatment Outcome/</td>
<td>OR</td>
<td>treatment outcome.mp.</td>
</tr>
<tr>
<td>3</td>
<td>exp Patient Selection/ or exp Wound Healing/ or exp Reoperation/</td>
<td>OR</td>
<td>patient selection.mp. or wound healing.mp. or reoperation.mp.</td>
</tr>
</tbody>
</table>

### Part S
For S, the following study type filters, 1 = systematic review, 2 = observational studies, 3 = RCTs

<table>
<thead>
<tr>
<th>S</th>
<th>keywords</th>
<th>operator</th>
<th>words in all fields (af), publication type (pt) or title and abstract (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>OR (quantitativ* adj10 review*).tw. or (quantitativ* adj10 overview*).tw. or (systematic* adj10 review*).tw. or (systematic* adj10 overview*).tw. or (methodologic* adj10 review*).tw. or (methodologic* adj10 overview*).tw. or medline.tw. and review-.pt. or (pooled adj3 analy*).tw.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>OR case with control.af. or (cohort adj5 study).af. or (cohort adj5 studies).af. or (cohort adj5 analy$).af. or (follow-up adj5 (study or studies)).af. or (longitudinal or retrospective or (cross adj5 sectional)).af. or (observational adj5 (study or studies)).af. or prospective.af.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Results of the search** (all items are stored in Reference Manager file ‘Amputatie - vraag 1b’ with the filename as keyword):

The search strategy is indicated in brief in the table under filename. (+ means AND)
The explanation of the items named is listed in the tables I, O and S, resp.
med = the medline database  
emb = the embase database

<table>
<thead>
<tr>
<th>Filename</th>
<th>number</th>
</tr>
</thead>
<tbody>
<tr>
<td>med 090803 vr2 chirurgische technieken systrev</td>
<td>7</td>
</tr>
<tr>
<td>P + I(nr 1 and nr 2 naam ingreep en focus) + studietype (nr1 systematic review)</td>
<td></td>
</tr>
<tr>
<td>med 090803 vr2 chirurgische technieken rct</td>
<td>34</td>
</tr>
<tr>
<td>P + I(nr 1 and nr 2 naam ingreep en focus) + studietype (nr3 rct)</td>
<td></td>
</tr>
<tr>
<td>med 090803 vr2 chirurgische technieken extra outcome rct.</td>
<td>2</td>
</tr>
<tr>
<td>P + I(nr 1 and nr 2 naam ingreep en focus) +O (outcome nr 2 or nr 3 )+ studietype (nr3 rct)</td>
<td></td>
</tr>
<tr>
<td>med 090803 vr2 chirurgische technieken observat</td>
<td>64</td>
</tr>
<tr>
<td>P + I (nr 1 and nr 2 naam ingreep en focus) + studietype (nr2 observational studies) +O (outcome nr 1)</td>
<td></td>
</tr>
<tr>
<td>med 090803 vr2 chirurgische technieken observat.outcome</td>
<td>42</td>
</tr>
<tr>
<td>P + I (nr 1 and nr 2 naam ingreep en focus) + studietype (nr2 observational studies) +O (outcome nr 2)</td>
<td></td>
</tr>
<tr>
<td>med 090803 vr2 chirurgische technieken extra outcome observat</td>
<td>2</td>
</tr>
<tr>
<td>P + I (nr 1 and nr 2 naam ingreep en focus) + studietype (nr2 observational studies) +O (outcome nr 3)</td>
<td></td>
</tr>
<tr>
<td>emb 090803 vr2 chirurgische technieken systrev</td>
<td>5</td>
</tr>
<tr>
<td>emb 090803 vr2 chirurgische technieken dm vaten (dm=disease management)</td>
<td>10</td>
</tr>
<tr>
<td>emb 090803 vr2 chirurgische technieken rct</td>
<td>64</td>
</tr>
<tr>
<td>emb 090803 vr2 chirurgische technieken observat outcome</td>
<td>17</td>
</tr>
<tr>
<td>emb 090803 vr2 chirurgische technieken outcome articles</td>
<td>29</td>
</tr>
</tbody>
</table>

**Limitations:** No articles exclusively about animals, only articles in the Dutch, English, German or French languages and only articles from 1990 to 2009.

**General comments:**
1. The number of references in Reference Manager and therefore in the literature lists differs from the number of hits because, during import into Reference Manager, an effort was made to avoid importing items that were already in the file.
2. The keywords mentioned in this report are MeSH keywords. Keywords that were as close as possible to the keywords listed, in terms of meaning, were used for other databases.
3. The search strategies used are stored in the files.

**Report literature search key question 4:**
*What postoperative management is preferable immediately after amputation of a lower limb (immediate / delayed fitting, rigid dressing vs. soft dressing)?*

On 27th May 2009 a search was carried out in Medline via the OVID interface following an explanation. Medline was updated to week 3 of May 2009 at the time of the search.
The search in Embase (updated to week 21 of 2009), using the same global search strategy, was performed by the information specialist on the same date.

In the search the following PICO(S) was formulated:

**P**  search strategy for patient population as already present; consisting of three parts. For this question, parts 1, 2 and 3 were all combined via "or" (see rule 8 below).

**I**  postoperative phase

**C**  outcome factors relevant to a good prosthesis fit and with the focus on amputation or prosthesis

**S**  study types

---

**P**  search strategy for patient population as already present; consisting of three parts. For this question, parts 1, 2 and 3 were all combined via "or" (see rule 8 below).

**I**  indication for time of fitting or method of dressing

**C**  

**O**  

**S**  study types

---

**Part P**

The following parts of 'P lower limb amputation' version 3090428 (combined with OR) of the search strategy stored in Ovid was used (line 8 indicates the combination used). This search strategy was as follows:
<table>
<thead>
<tr>
<th>P</th>
<th>keywords</th>
<th>operator</th>
<th>words with field designations such as multi-purpose (mp) in title (ti), abstract (ab) or title or abstract (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amputation/Disarticulation/Amputation Stumps/Amputation, Traumatic/</td>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>OR</td>
<td>(knee$ or leg$ or limb$ or crural or lower extremit$).ti,ab. (trans?tibial or (trans adj1 tibial) or tibial or trans?femoral or (trans adj1 femoral) or femoral).ti,ab. ((through or above or below) adj1 knee$).ti,ab.</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>1 AND 2 = P-part 1</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>4 AND 5 = P-part 2</td>
<td>amput$.tw.</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
<td>OR</td>
<td>((trans?tibial or (trans adj1 tibial)) adj4 amputat$).ti,ab. ((trans?femoral or (trans adj1 femoral)) adj4 amputat$).ti,ab. (knee$ adj4 (disarticulat$ or exarticulat$)).ti,ab. ((through or above or below) adj1 knee$ adj4 amputat$).ti,ab. ((tibial or femoral) adj4 amputat$).ti,ab. ((leg$ or limb$ or crural or lower extremit$) adj4 amputat$).ti,ab. ((trans?ankle or syme) adj3 (amputat$ or disarticulat$)).ti,ab.</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td>3 OR 7 = P-part3</td>
<td></td>
</tr>
</tbody>
</table>
Part I
Search terms for the postoperative phase in line 1, for the methodology or bandages used in line 2:

<table>
<thead>
<tr>
<th>I</th>
<th>keywords</th>
<th>operator</th>
<th>words with field designations such as multi-purpose (mp) in title (ti), abstract (ab) or title or abstract (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>exp Postoperative Care/ or exp Postoperative Period/ or exp Time Factors/</td>
<td>OR</td>
<td>(postoperative or post-operative).tw. or time factors.mp. or (fitting adj5 (method or early or immediate or delayed)).tw. or ((reduc* adj5 time) or (short* adj3 periode)).tw. or mt.fs.</td>
</tr>
<tr>
<td>2</td>
<td>bandages/ or occlusive dressings/</td>
<td>OR</td>
<td>(dressing or bandag*).ti. or ((rigid or elastic) adj5 (bandag* or dressi*)).tw. or (prepar* adj5 (limb or prost*)).tw.</td>
</tr>
</tbody>
</table>

Part O
For O=outcome, generally specific for the prosthesis in line 1, focus on literature covering amputation or prosthesis in line 2

<table>
<thead>
<tr>
<th>O</th>
<th>keywords</th>
<th>operator</th>
<th>words with field designations such as multi-purpose (mp) in title (ti), abstract (ab) or title or abstract (tw) words in subheading (fs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>exp Prosthesis Design/ or exp Prosthesis Fitting/ or exp Artificial Limbs/ or exp Amputation Stumps/ or</td>
<td>OR</td>
<td>fitting.ti. or prosthese*.ti.</td>
</tr>
<tr>
<td>2</td>
<td>Amputation/ or exp *Amputation Stumps/ or *amputees/ or *artificial limbs/ or *prosthesis design/ or *prosthesis fitting/ or</td>
<td>OR</td>
<td>amput*.ti. or prosth*.ti.</td>
</tr>
</tbody>
</table>

Part S
For S, the following study types

<table>
<thead>
<tr>
<th>S</th>
<th>keywords</th>
<th>operator</th>
<th>words in all fields (af), publication type (pt) or title and abstract (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>exp Clinical Trial/</td>
<td>OR</td>
<td>clinical trials.mp.</td>
</tr>
<tr>
<td>2</td>
<td>exp Multicenter Study/ or Comparative Study/</td>
<td>OR</td>
<td>multicenter study.mp.</td>
</tr>
</tbody>
</table>

Results of the search
(all items are stored in Reference Manager file ‘Amputatie - vraag 1b’ with the filename as keyword):

The search strategy is indicated in brief in the table under filename. (+ means AND)
The explanation of the items named is listed in the tables I, O and S, resp.
med = the medline database
emb = the embase database

<table>
<thead>
<tr>
<th>Filename</th>
<th>number</th>
</tr>
</thead>
<tbody>
<tr>
<td>med090527 vr4 postoperative and early fitting.trials</td>
<td>38</td>
</tr>
<tr>
<td>P + I(nr 1) + O (nr 1 and nr 2 focus) + studiotype (nr1 trials)</td>
<td></td>
</tr>
<tr>
<td>med090527 vr4 postoperative and early fitting.comparative multicenter</td>
<td>62</td>
</tr>
<tr>
<td>P + I(nr 1) + O (nr 1 and nr 2 focus) + studiotype (nr2 multicenter of comparative)</td>
<td></td>
</tr>
<tr>
<td>med090527 vr4 bandages.trials comp multicenter</td>
<td>6</td>
</tr>
<tr>
<td>P + I(nr 2) + studiotype (nr1 trials or nr2 multicenter of comparative)</td>
<td></td>
</tr>
<tr>
<td>med090527 vr4 bandages rest.</td>
<td>42</td>
</tr>
<tr>
<td>P + I(nr 2) + overige studietypes (niet nr1 trials or nr2 multicenter of comparative)</td>
<td></td>
</tr>
<tr>
<td>emb090527 vr4 postoperative and early fitting.systrev</td>
<td>3</td>
</tr>
<tr>
<td>emb090527 vr4 postoperative and early fitting.trials</td>
<td>53</td>
</tr>
<tr>
<td>emb090527 vr4 bandages trials cohort</td>
<td>11</td>
</tr>
</tbody>
</table>

**Limitations:** No articles exclusively about animals, only articles in the Dutch, English, German or French languages and only articles from 1990 to 2009.

**General comments:**
1. The number of references in Reference Manager and therefore in the literature lists differs from the number of hits because, during import into Reference Manager, an effort was made to avoid importing items that were already in the file.
2. The keywords mentioned in this report are MeSH keywords. Keywords that were as close as possible to the keywords listed, in terms of meaning, were used for other databases.
3. The search strategies used are stored in the files.

**Report literature search output Question 5:**
*What is the preferred approach to pain management (perioperative and postoperative) in lower limb amputation and which interventions are worthwhile for the prevention of chronic stump pain and phantom pain?*

On 28th April 2009 a search in Medline (updated 27-04-2009), via the OVID interface, was carried out at the CBO in the presence of working group member Ronald Schapendonk. The search in Embase (updated to week 20 in 2009) and PsycINFO (both via OVID, PsycINFO updated to 18-05-2009) was carried out by the information specialist, using the same search strategy, in the presence of working group members on 20th May 2009.
Before conducting the search, this PICO was formulated:

**P** search strategy for patient population as already present, use what part?

**I** all types of known interventions: painkillers, etc.

**C**

**O** keywords for pain management

During the search all components were adjusted.

The parts 'P lower limb amputation' and 'P prosthetic provision lower limb' (combined with OR) of the search strategy stored in Ovid for the P med090428 P amputation en prothesiologie onderste extremiteit versie 3 was used. This search strategy was as follows:

<table>
<thead>
<tr>
<th></th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti), abstract (ab) or text (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amputation/Disarticulation/Amputation Stumps/Amputation, Traumatic/</td>
<td>OR</td>
<td>(knee$ or leg$ or limb$ or crural or lower extremit$).ti,ab. (trans?tibial or (trans adj1 tibial) or tibial or trans?femoral or (trans adj1 femoral) or femoral).ti,ab. ((through or above or below) adj1 knee$).ti,ab.</td>
</tr>
<tr>
<td>2</td>
<td>OR</td>
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<tr>
<td>3</td>
<td>1 AND 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>4 AND 5</td>
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<td></td>
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<tr>
<td>6</td>
<td>OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>((trans?tibial or (trans adj1 tibial)) adj4 amputat$).ti,ab.</td>
<td>OR</td>
<td>(((trans?femoral or (trans adj1 femoral)) adj4 amputat$).ti,ab. (knee$ adj4 (disarticulat$ or exarticulat$)).ti,ab. (through or above or below) adj1 knee$ adj4 amputat$).ti,ab. (tibial or femoral) adj4 amputat$).ti,ab. (leg$ or limb$ or crural or lower extremit$) adj4 amputat$).ti,ab. (trans?ankle or syme) adj3 (amputat$ or</td>
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<td>OR</td>
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<td>9 AND 8</td>
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<td>OR</td>
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<tr>
<td>13</td>
<td>12 AND 2</td>
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<tr>
<td>14</td>
<td>OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>10 OR 11 OR 13 OR 14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>8 OR 15</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For **A**, pain after amputation and phantom pain, this search strategy was devised:

<table>
<thead>
<tr>
<th>A keywords</th>
<th>operator</th>
<th>words in title (ti) or abstract (ab)</th>
</tr>
</thead>
</table>
| 1 Phantom Limb/ | OR | ((phantom or residual) adj3 limb pain).ti,ab.  
((postamputation or amput$) adj5 pain).ti,ab.  
((pre?operat$ or post?operat$) adj5 pain).ti,ab.  
((peri?operat$ or per?operat$) adj5 pain).ti,ab. |

For **S**, drugs used for pain management, this search strategy was devised:

<table>
<thead>
<tr>
<th>S keywords</th>
<th>operator</th>
<th>words in title (ti) or abstract (ab)</th>
</tr>
</thead>
</table>
| 1 exp Analgesics/  
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For T, **routes of administration, therapies and techniques used for pain management**, this search strategy was devised:

<table>
<thead>
<tr>
<th>T</th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti), abstract (ab) or text (tw)</th>
</tr>
</thead>
</table>

The search strategy for O, **outcome** is as follows:

<table>
<thead>
<tr>
<th>O</th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti) or abstract (ab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td>(((relief or reliev$ or effect$ or reduc$ or improv$ or prevent$ or control$ or manag$) adj8 pain).ti,ab.</td>
</tr>
</tbody>
</table>

**Results of the search** (all items are stored in Reference Manager file ‘Amputatie - vraag 5’ with the filename as keyword):

<table>
<thead>
<tr>
<th>database</th>
<th>number of hits</th>
<th>filename</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medline</td>
<td>114</td>
<td>med090428 vraag5</td>
</tr>
<tr>
<td>Embase</td>
<td>85</td>
<td>emb090520 vraag5</td>
</tr>
<tr>
<td>PsycINFO</td>
<td>5</td>
<td>psy090520 vraag5</td>
</tr>
</tbody>
</table>

**Limitations**: No articles exclusively about animals, only articles in the Dutch, English, German or French languages and only articles from 1990 to 2009.

**General comments**:

1. The number of references in Reference Manager and therefore in the literature lists differs from the number of hits because, during import into Reference Manager, an effort was made to avoid importing items that were already in the file.
2. The keywords mentioned in this report are MeSH keywords. Keywords that were as close as possible to the keywords listed, in terms of meaning, were used for other databases.
3. The search strategies used are stored in the files.
Report literature search key question 6:
What complications (local/at stump level) occur in an amputation of a lower limb? And how can they be prevented?

Additional information received from sub-working group (Jan Rietman) on 2nd February 2010, after which RD conducted the search in early February 2010. Surgical technical measures are of decisive influence for optimal use of an amputation stump.

Suggestions for search terms:
wound healing disturbances, secondary wound healing, infection, necrosis, reamputation, proximal joint contracture, redundant tissue, neuroma, residual limb quality.
Example article:

The overall design of the search strategy was:

\[ P + I = \text{quality of the amputation stump due to technical surgical measures, resp. decline in quality due to complications affecting the stump.} \]
\[ + S = \text{study type (systrev, RCT, observat).} \]

Additional terms were added to increase the precision of the search for articles on amputation stump. In addition, search terms were added for the study types RCTs and observational studies in order to filter out studies that simply discuss the outcomes of measures (O) from the result.

Part P
The part indicated below of 'P lower limb amputation' version 3 090428, combined via OR with the part (prosthetic provision lower limb) of the search strategy stored in Ovid was used (set number 63 was the combination used).

2 "med090428 P amputation en prothesiologie lower limb versie 3 START".ti. (0)
3 Amputation/ (13463)
4 Disarticulation/ (240)
5 Amputation Stumps/ (2217)
6 Amputation, Traumatic/ (3500)
7 or/3-6 (18299)
8 (knee$ or leg$ or limb$ or crural or lower extremi$).ti,ab. (347154)
9 (trans?tibial or (trans adj1 tibial) or tibial or trans?femoral or (trans adj1 femoral) or femoral).ti,ab. (95017)
10 (through or above or below) adj1 knee$.ti,ab. (2754)
11 or/8-10 (416794)
12 7 and 11 (7630)
13 Leg/su [Surgery] (4331)
14 Tibia/su [Surgery] (5602)
15 exp Femur/su [Surgery] (7503)
17 or/13-16 (17926)
18 amput$.tw. (24539)
19 17 and 18 (2255)
20 ((trans?tibial or (trans adj1 tibial)) adj4 amputat$).ti,ab. (267)
21 ((trans?femoral or (trans adj1 femoral)) adj4 amputat$).ti,ab. (146)
22 (knee$ adj4 (disarticulat$ or exarticulat$)).ti,ab. (175)
23 ((through or above or below) adj1 knee$ adj4 amputat$).ti,ab. (1354)
24 ((tibial or femoral) adj4 amputat$).ti,ab. (234)
25 ((leg$ or limb$ or crural or lower extremit$) adj4 amputat$).ti,ab. (5255)
26 ((trans?ankle or syme) adj3 (amputat$ or disarticulat$)).ti,ab. (85)
27 or/20-26 (6716)
28 12 or 19 or 27 (11134)
29 "P amputation lower limb".ti. (0)
30 Amputees/rh [Rehabilitation] (462)
31 exp Rehabilitation/ (114917)
32 30 or 31 (115299)
33 32 and 28 (647)
34 artificial limbs/ or knee prosthesis/ (10984)
35 implants, experimental/ or internal fixators/ or exp prosthesis design/ (30108)
36 Amputation Stumps/ (2217)
37 Prosthesis Fitting/ (2045)
38 Prosthesis Failure/ (15923)
39 (skelet$ adj3 fixat$).ti,ab. (574)
40 ((bionic$ or bone$) adj3 (implant$ or prosthesis$)).ti,ab. (8981)
41 ((trans?cut$ or trans?derm$ or (trans adj1 (cut$ or derm$))) adj3 implant$).ti,ab. (132)
42 Osseointegration/ (5353)
43 (osseo?integrat$ or (osseo adj1 integrat$)).ti,ab. (4030)
44 (intra?osse$ or (intra adj1 osse$)).ti,ab. (3905)
45 (intra?osse$ trans?cutan$ amputat$ prosthesis$ or ITAP).tw. (11)
46 (stump adj3 socket$).ti,ab. (54)
47 silicon liner socket$.tw. (1)
48 Silicones/ (9415)
49 or/35-48 (69064)
50 49 and 11 (13464)
51 ((knee$ or leg$ or limb$ or crural or lower extremit$) adj4 prosthesis$).ti,ab. (2555)
52 ((trans?tibial or tibial or (trans adj1 tibial)) adj4 prosthesis$).ti,ab. (229)
53 ((trans?femoral or femoral or (trans adj1 femoral)) adj4 prosthesis$).ti,ab. (1145)
54 ((trans?tibial or tibial or (trans adj1 tibial)) adj3 amputee$).ti,ab. (216)
55 ((trans?femoral or femoral or (trans adj1 femoral)) adj3 amputee$).ti,ab. (127)
56 ((limb$ or leg$ or knee$ or crural or syme or trans?ankle) adj3 amputee$).ti,ab. (908)
57 or/51-56 (4738)
58 33 or 34 or 50 or 57 (22235)
59 "P prothesiologie lower limb".ti. (0)
limit 62 to yr="1990 -Current" (19982) =P

I = intervention = search terms used for surgical technical measures, resp. decline in quality due to complications affecting the stump.: set 65 to 80, collected in set 83, was used and combined via "OR" with set 139.

65 (residual-limb adj3 quality).tw. (2)
66 (limb adj5 quality).tw. (141)
67 (stump adj5 quality).tw. (25)
68 (quality adj5 amputat*).tw. (79)
69 surgical technique?.tw. (28742)
70 (suitable adj5 prosth*).tw. (239)
71 (revision? or conversion?).tw. (130579)
72 reamputation?.tw. (122)
73 Amputation Stumps/co (7)
74 Amputation Stumps/pp (190)
75 **"Neuroma"/ (1369)
76 Reoperation/ (52289)
77 redundant tissue.tw. (53)
78 Necrosis/ (43309)
79 exp Surgical Wound Infection/ (23698)
80 Wound Healing/ (55433)
83 or/65-80 (318331)

The following search terms were also added on 2010-03-10
134 (acute adj5 amput*).tw. (126)
135 (delay* adj5 amput*).tw. (173)
136 (tibia adj5 length).tw. (353)
137 (femur adj5 length).tw. (1142)
138 (stump adj5 length).tw. (155)
139 or/134-138 (1871)

Search terms to increase search precision for articles discussing the amputation stump:
81 Amputation Stumps/ or stump?.tw. (12277)

Search terms that discuss the result of amputation are in set 128 (=rehabilitation as floating subheading) or 129 (explore treatment outcome (MeSH) or prospective studies.
85 prospective study.mp. or exp Prospective Studys/ (285791)
128 rh.fs. (130359)
129 exp Treatment Outcome/ (417287)
Embase was searched using a similar approach.

The table below shows the search results.

<table>
<thead>
<tr>
<th>Filename</th>
<th>number</th>
</tr>
</thead>
<tbody>
<tr>
<td>med 20100203 vr6 complications systrev</td>
<td>4</td>
</tr>
<tr>
<td>med 20100203 vr6 complications rct</td>
<td>20</td>
</tr>
<tr>
<td>med 20100203 vr6 complications observat</td>
<td>68</td>
</tr>
<tr>
<td>med 20100310 vr6 aanvulling rct</td>
<td>4</td>
</tr>
<tr>
<td>med 20100310 vr6 aanvulling observat</td>
<td>3</td>
</tr>
<tr>
<td>emb 20100203 vr6 complications systrev</td>
<td>8</td>
</tr>
<tr>
<td>emb 20100203 vr6 complications rct</td>
<td>26</td>
</tr>
<tr>
<td>emb 20100203 vr6 complications observat</td>
<td>6</td>
</tr>
<tr>
<td>emb 20100310 vr6 aanvullinng systrev</td>
<td>8</td>
</tr>
<tr>
<td>emb 20100310 vr6 aanvulling rct</td>
<td>61</td>
</tr>
</tbody>
</table>

Report literature search key question 7:

How should an optimal rehabilitation process for patients be organised following amputation of a lower limb (organisation, care plan, psychosocial component, incorporating other involved disciplines)?

To what extent do aspects of diversity (gender, age, comorbidity) and personal situation play a role in an optimal rehabilitation process?

To answer this question the information specialist conducted an independent search, from 15th to 22nd December 2009, having received key articles on the psychosocial component from Jan Geertzen and after determining search terms based on the VRA treatment policy for leg amputation as supplied by Harmen van der Linde.

Using the interface OvidSP, a search was conducted in Medline, Embase and PsycINFO, and a search was conducted in CINAHL using the EBSCOhost interface.

Before conducting the search, this PICO was formulated:

P  search strategy for patient population as already present, combined with REHABILITATION en rh.fs. (rehabilitation); LIFE CHANGE EVENTS

I  organisation of the (nl-)care:
patient care management/ or comprehensive health care/ or nursing process/ or patient care planning/ or case management/ or critical pathways/ or patient-centered care/ or progressive patient care/ or exp "delivery of health care"/ or disease management/ or patient care team/ or nursing, team/
exp Professional Practice/
exp Community Health Services/
(role adj8 (practitioner? or primary care or disciplin$ or multidisciplin$ or specialist?)!).tw.
(optimal adj5 care adj5 manag*).tw.
(appropriate adj5 care).tw.
((comprehensive or enhance*) adj5 care).tw.
OR:
exp "Delivery of Health Care"/ (ev alleen mt (methods) e/o og (organisatie en administratie)
(role adj8 (practitioner? or primary care or disciplin$ or multidisciplin$ or specialist?)).tw.
(optimal adj5 care adj5 manag*).tw.
((appropriate or advance?) adj5 care).tw.
health care quality.mp. or exp "Quality of Health Care"/
Community Health Services.mp. or exp Community Health Services/
((comprehensive or enhance*) adj5 (care or program$)).tw.

treatment:
clinic, polyclinic, outpatient, health care cent$
rehabilitation criteria exclusion inclusion/discharge
treatment/therapy objective/intention/aim/goal
phases of treatment: registration, research, treatment/therapy/rehabilitation,
discharge, after?care
orthop(a)edic, orthopaedic technician/mechanic, orthopaedist, trauma, vascular
surgeon
care plan:
CRITICAL PATHWAYS

incorporating other involved disciplines:
multidisciplin$

C

O
description of 'optimal':
"Patient Satisfaction"/
"Treatment Outcome"/
program evaluation.mp. or exp Program Evaluation/
**"Outcome and Process Assessment (Health Care)"/
ADL, self care, QoL, independence, gait, mobility, ambulation, 'goed lopen',
reintegration, independent life style?, function$
Questionnaire? or scale?, predict$/indicat$ adj8 prosth$function$
ARCHITECTURAL ACCESSIBILITY architectural/environmental barrier?
DISABILITY EVALUATION; SOCIOECONOMIC FACTORS; POSTURAL BALANCE;
SELF EFFICACY; HEALTH STATUS (INDICATOR); SICKNESS IMPACT PROFILE
socioeconomic/sociodemographic

psychosocial component:
ADAPTATION, PSYCHOLOGICAL (psychological$ or psychosocial$ or social$) adj6
(adjust$ or factor$ or component$ or aspect$ or adapt$ or predict$), body image (see
article by Horgan 2004), depress$ or coping or distress or affect$ or anxiety or
anxious$ or pain or avoid$ or emotion$ or body image
SOCIAL ADJUSTMENT; SOCIAL SUPPORT; BODY IMAGE; PROBLEM SOLVING; DENIAL (PSYCHOLOGICAL);

The parts 'P amputation lower limb' and 'P prosthetic provision lower limb' (combined with OR) of the search strategy stored in Ovid for the P patient population med090825 P amputation en prothesiologie lower limb versie 5 was used. This P was then restricted to rehabilitation-related factors. The search strategy is therefore as follows:

<table>
<thead>
<tr>
<th>P</th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti), abstract (ab) or text (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amputation/Disarticulation/Amputation Stumps/Amputation, Traumatic/</td>
<td>OR</td>
<td></td>
</tr>
</tbody>
</table>
| 2 | OR (knee$ or leg$ or lower limb$ or lower-limb$ or crural or lower extremit$ or lower-extremit$).ti,ab.  
(trans?tibial or (trans adj1 tibial) or tibial or trans?femoral or (trans adj1 femoral) or femoral).ti,ab.  
(((through or above or below) adj1 knee$).ti,ab.  
((through-the-knee or through-knee or above-knee or above-the-knee or below-knee or below-the-knee) adj4 amput$).ti,ab. | OR       |                                                                                                                                 |
| 3 | 1 AND 2                                                                   |          |                                                                                                                                 |
| 5 | amput$.tw.                                                                |          |                                                                                                                                 |
| 6 | 4 AND 5                                                                   |          |                                                                                                                                 |
| 7 | OR ((trans?tibial or (trans adj1 tibial)) adj2 amput$).ti,ab.  
((trans?femoral or (trans adj1 femoral)) adj2 amput$).ti,ab.  
(knee$ adj2 (disarticulat$ or exarticulat$)).ti,ab.  
(knee$ adj2 amput$).ti,ab.  
((tibial or femoral) adj2 amput$).ti,ab.  
((leg$ or lower limb$ or lower-limb$ or crural or lower extremit$ or lower-extremit$) adj2 amput$).ti,ab.  
((trans?ankle or syme) adj3 (amput$ or disarticulat$)).ti,ab. | OR       |                                                                                                                                 |
| 8 | 3 OR 6 OR 7                                                              |          |                                                                                                                                 |
| 9 | Amputees/rh [Rehabilitation]exp Rehabilitation/                          | OR       |                                                                                                                                 |
| 10| 9 AND 8                                                                  |          |                                                                                                                                 |
| 11| artificial limbs/exp prosthesis design/Amputation Stumps/                | OR       | (skelet$ adj3 fixat$).ti,ab.  
((bionic$ or bone$) adj3 (implant$ or prosthes$)).ti,ab. |
Prosthesis Fitting/ Prosthesis Failure/ Osseointegration/ Silicones/

<table>
<thead>
<tr>
<th>12</th>
<th>11 AND 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>OR</td>
</tr>
<tr>
<td>14</td>
<td>10 OR 12 OR 13</td>
</tr>
<tr>
<td>15</td>
<td>8 OR 14</td>
</tr>
</tbody>
</table>

**restriction to rehabilitation-related factors:**

<table>
<thead>
<tr>
<th>16</th>
<th>exp Rehabilitation/ rehabilitation centers/ or sheltered workshops/ orthopedic nursing/ or rehabilitation nursing/ exp physical medicine/ or orthopedics/ Life Change Events/</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
<td>15 AND 16 (74)</td>
</tr>
</tbody>
</table>

For **Z, organisation of care**, this search strategy was devised:

<table>
<thead>
<tr>
<th>Z</th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti) or abstract (ab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>patient care management/ or comprehensive health care/ or nursing process/ or patient care planning/ or case management/ or critical pathways/ or patient-centered care/ or progressive patient care/ or exp &quot;delivery of health care&quot;/ or disease management/ or patient care team/ or nursing, team/ exp Professional Practice/ exp Community Health Services/ exp &quot;Quality of Health Care&quot;/</td>
<td>OR</td>
<td>(role adj8 (practitioner? or primary care or disciplin$ or multidisciplin$ or specialist? or orthop$edi$ or surgeon or surgery)).tw.</td>
</tr>
</tbody>
</table>
For **G, the care plan**, this search strategy was devised:

<table>
<thead>
<tr>
<th></th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti) or abstract (ab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Critical Pathways/</td>
<td>OR</td>
<td>((clinical or critical) adj3 path$).ti,ab.</td>
</tr>
</tbody>
</table>

For **Y, the psychosocial component**, this search strategy was devised:

<table>
<thead>
<tr>
<th></th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti) or abstract (ab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Adaptation, Psychological/ Social Adjustment/ social support/ Body Image/ Problem Solving/ &quot;denial (psychology)=&quot;/</td>
<td>OR</td>
<td>((psychological$ or psychosocial$ or social$) adj6 (adjust$ or factor$ or component$ or aspect$ or adapt$ or predict$)).ti,ab. (body$ adj3 imag$).ti,ab. (depress$ or coping or distress$ or affect$ or anxiety or anxious$ or pain or avoid$ or emotion$).ti,ab.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(84)</td>
<td></td>
</tr>
</tbody>
</table>

For **A, all involved disciplines**, this search strategy was devised:

<table>
<thead>
<tr>
<th></th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti) or abstract (ab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Orthopedics/ Traumatology/ &quot;Physical Therapy (Specialty)=&quot;/ exp Psychotherapy/</td>
<td>OR</td>
<td>(orthop?edi$ or vascular sur$ or (orthop?edic adj2 (technician? or mechanic?)) or trauma$ or physiotherap$ or psychotherap$ or therap$).ti,ab.</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td>(multidisciplin$ or interdisciplin$ or disciplin$ or cooperat$ or collaborat$).ti,ab.</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>1 AND 2</td>
<td></td>
</tr>
</tbody>
</table>

In order to make the results more specific, they were combined with these words in the title:

<table>
<thead>
<tr>
<th></th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td>(lower extremit$ or limb$ or amput$ or rehabilit$).ti.</td>
</tr>
</tbody>
</table>
For O, the outcome measures, in this case terms for 'optimal' in the sense of an optimal rehabilitation process, the following search strategy was devised:

<table>
<thead>
<tr>
<th>O</th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti), abstract (ab) or text (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Patient Satisfaction/ exp treatment outcome/ Program Evaluation/ exp &quot;Outcome and Process Assessment (Health Care)/&quot; &quot;Activities of Daily Living&quot;/ &quot;Quality of Life&quot;/ Social Adjustment/ Architectural Accessibility/ exp Disability Evaluation/ exp Socioeconomic Factors/ Postural Balance/ Self Care/ self efficacy/ health status indicators/ or sickness impact profile/</td>
<td>OR (144)</td>
<td>((architectural$ or environmental$) adj4 barrier?).ti,ab. ((predict$ or indicat$) adj6 function$).ti,ab. (independen$ adj6 (life or living)).ti,ab. (social$ adj4 participat$).ti,ab.</td>
</tr>
</tbody>
</table>

The search strategy for the search filter for systematic reviews and meta-analyses med091027 CBO filter sysrev & meta Medline was as follows:

<table>
<thead>
<tr>
<th>Fsyst</th>
<th>keywords</th>
<th>operator</th>
<th>words in all fields (af), publication type (pt) or title and abstract (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>meta analysis.pt. (meta-anal$ or metaanal$).af. (quantitativ$ adj10 (review$ or overview$)).tw. (systematic$ adj10 (review$ or overview$)).tw. (methodologic$ adj10 (review$ or overview$)).tw. medline.tw. and review.pt. (pooled adj3 analy$).tw.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The search strategy for the search filter for randomised controlled trials med091027 CBO filter rct Medline was as follows:

<table>
<thead>
<tr>
<th>Frct</th>
<th>keywords</th>
<th>operator</th>
<th>words in all fields (af), publication type (pt) or title and abstract (tw))</th>
</tr>
</thead>
</table>
Results of the search (all items are stored in Reference Manager file ‘Amputatie - vraag 7’ with the filename as keyword):

<table>
<thead>
<tr>
<th>database</th>
<th>updated to</th>
<th>number of hits</th>
<th>filename</th>
</tr>
</thead>
<tbody>
<tr>
<td>combination: P AND Z AND Fsysrev</td>
<td>Medline 10 dec. 2009</td>
<td>15</td>
<td>med091215 organisatie zorg sysrev</td>
</tr>
<tr>
<td>combination: P AND Z AND Frct (without all downloaded articles)</td>
<td>Medline 10 dec. 2009</td>
<td>65</td>
<td>med091215 organisatie zorg rct</td>
</tr>
<tr>
<td>combination: P AND Z AND O AND S AND Frct (without all downloaded articles)</td>
<td>Medline 10 dec. 2009</td>
<td>156</td>
<td>emb091218 organisatie zorg en outcome en amput in ti rct</td>
</tr>
<tr>
<td>combination: P AND G</td>
<td>Medline 10 dec. 2009</td>
<td>8</td>
<td>med091215 zorgpad alles</td>
</tr>
<tr>
<td>combination: P AND Y AND Fsysrev</td>
<td>Medline 10 dec. 2009</td>
<td>5</td>
<td>med091218 psychosociale comp sysrev</td>
</tr>
<tr>
<td>combination: P AND Y AND Frct (without all downloaded articles)</td>
<td>Medline 10 dec. 2009</td>
<td>22</td>
<td>med091218 psychosociale comp rct</td>
</tr>
<tr>
<td>combination: P AND Y AND S AND Frct (without all downloaded articles)</td>
<td>Medline 10 dec. 2009</td>
<td>90</td>
<td>emb091218 psychosociale comp en amput in ti rct</td>
</tr>
<tr>
<td>combination: P AND A</td>
<td>Medline 18 dec. 2009</td>
<td>26</td>
<td>med091221 andere disciplines alles</td>
</tr>
<tr>
<td>combination: P AND O AND Fsysrev</td>
<td>Medline 10 dec. 2009</td>
<td>12</td>
<td>med091218 outcome sysrev</td>
</tr>
<tr>
<td>combination: P AND O AND Frct (without all downloaded articles)</td>
<td>Medline 10 dec. 2009</td>
<td>41</td>
<td>med091218 outcome rct</td>
</tr>
<tr>
<td>combination: P AND O AND S AND Frct (without all downloaded articles)</td>
<td>Medline 10 dec. 2009</td>
<td>173</td>
<td>med091218 psychosociale comp and outcome</td>
</tr>
<tr>
<td>combination: P AND Y AND O AND O (without all downloaded articles)</td>
<td>Medline 10 dec. 2009</td>
<td>80</td>
<td>emb091218 psychosociale comp and outcome en amput in ti</td>
</tr>
<tr>
<td>combination: P AND Fsrsysrev</td>
<td>CINAHL 11 dec. 2009</td>
<td>8</td>
<td>cin091218 P rehab sysrev S103</td>
</tr>
<tr>
<td>combination: P AND Frct</td>
<td>CINAHL 11 dec. 2009</td>
<td>21</td>
<td>cin091218 P rehab rct</td>
</tr>
<tr>
<td>combination: P AND O (without all downloaded articles)</td>
<td>CINAHL 11 dec. 2009</td>
<td>111</td>
<td>cin091218 outcome alles</td>
</tr>
<tr>
<td>combination: P</td>
<td>PsyclINFO 14 dec. 2009</td>
<td>51</td>
<td>psy091218 P and rehab alles</td>
</tr>
</tbody>
</table>

Limitations: No articles exclusively about animals, only articles in the Dutch, English, German or French languages and only articles from 1990 to date.
General comments:
1. The number of references in Reference Manager and therefore in the literature lists differs from the number of hits because, during import into Reference Manager, an effort was made to avoid importing items that were already in the file.
2. The keywords mentioned in this report are MeSH keywords. Keywords that were as close as possible to the keywords listed, in terms of meaning, were used for other databases.
3. The search strategies used are stored in the files.

Report literature search key question 8:
*What are the barriers to and facilitators of a return to work in patients following amputation of a lower limb, taking into consideration the nature of the work?*

On 17th September 2009 searches in Medline, Embase, PsycINFO via the OVID interface and in CINAHL (via the EBSCOhost interface) were performed at the CBO in the presence of the working group member Rob Smit Duijzentkunst.

Before conducting the search, this PICO was formulated:

**P**  
search strategy for patient population as already present

**I**  
Amputees/rh (rehabilitation)  
Work Capacity Evaluation/  
(work adj3 capacit$).ti,ab.  
(work adj3 disabilit$).ti,ab.  
Rehabilitation, Vocational/  
(vocational adj3 rehabilitat$).ti,ab.  
Occupational Health/  
Sick Leave/  
sick leave.ti,ab.  
(occupational$ adj3 health$).ti,ab.  
Absenceism/  
absentee$.ti,ab.  
(return to work or return-to-work).ti,ab.  
Retirement/  
retir$.ti,ab.  
extp Employment/  
((work or employment) adj3 status).ti,ab.

**C**  

**O**  
improve$, stimulate, promote, prevent, obstruct, interfere with, successful, outcome, predict$  
(factor? or relat$ or reintegrate$ or indicat$ or predict$) adj10 (outcome or depend$ or success$ or rate$)
During the search all components were adjusted.

The parts 'P amputation lower limb' and 'P prosthetic provision lower limb' (combined with OR) of the search strategy stored in Ovid for the med090825 P amputation en prothesiologie lower limb versie 5 was used. The search strategy is as follows:

<table>
<thead>
<tr>
<th>P</th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti), abstract (ab) or text (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amputation/ Disarticulation/ Amputation Stumps/ Amputation, Traumatic/</td>
<td>OR</td>
<td>(knee$ or leg$ or lower limb$ or lower-limb$ or crural or lower extremit$ or lower-extremit$).ti,ab. (trans?tibial or (trans adj1 tibial) or tibial or trans?femoral or (trans adj1 femoral) or femoral).ti,ab. ((through or above or below) adj1 knee$).ti,ab. (through-the-knee or through-knee or above-knee or above-the-knee or below-knee or below-the-knee) adj4 amput$.ti,ab.</td>
</tr>
<tr>
<td>2</td>
<td>(knee$ or leg$ or lower limb$ or lower-limb$ or crural or lower extremit$ or lower-extremit$).ti,ab. (trans?tibial or (trans adj1 tibial) or tibial or trans?femoral or (trans adj1 femoral) or femoral).ti,ab. ((through or above or below) adj1 knee$).ti,ab. (through-the-knee or through-knee or above-knee or above-the-knee or below-knee or below-the-knee) adj4 amput$.ti,ab.</td>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>1 AND 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>4 AND 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>4 AND 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>(knee$ adj2 (disarticulat$ or exarticulat$)).ti,ab. (knee$ adj2 amput$).ti,ab. (tibial or femoral) adj2 amputat$.ti,ab. (leg$ or lower limb$ or lower-limb$ or crural or lower extremit$ or lower-extremit$) adj2 amput$.ti,ab. (trans?ankle or syme) adj3 (amputat$ or disarticulat$)).ti,ab.</td>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>3 OR 6 OR 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Amputees/rh [Rehabilitation] exp Rehabilitation/</td>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>9 AND 8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>artificial limbs/ exp prosthesis</td>
<td>OR</td>
<td>(skelet$ adj3 fixat$).ti,ab. (bionic$ or bone$) adj3 (implant$ or protheses$).ti,ab.</td>
</tr>
</tbody>
</table>
For I, factors affecting return to work, this search strategy was devised:

<table>
<thead>
<tr>
<th>I</th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti) or abstract (ab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Work Capacity Evaluation/ Rehabilitation, Vocational/ Occupational Health/ sick leave/ absenteeism/ retirement/ exp Employment/</td>
<td>OR</td>
<td>(work adj3 capacit$).ti,ab. (work adj3 disabilit$).ti,ab. (vocational adj3 (rehabilitat$ or reintegrat$)).ti,ab. sick leave.ti,ab. (occupational$ adj3 health$).ti,ab. absentee$ti,ab. (return to work or return-to-work).ti,ab. retir$.ti,ab. ((work or employment) adj3 status).ti,ab.</td>
</tr>
</tbody>
</table>

Results of the search (all items are stored in Reference Manager file ‘Amputatie - vraag 8’ with the filename as keyword):

<table>
<thead>
<tr>
<th>combination: P AND I</th>
<th>database</th>
<th>updated to:</th>
<th>number of hits</th>
<th>filename</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medline</td>
<td>16 september 2009</td>
<td>61</td>
<td>med090917 werk</td>
<td></td>
</tr>
<tr>
<td>Embase</td>
<td>week 37 2009</td>
<td>47</td>
<td>emb090917 werk</td>
<td></td>
</tr>
<tr>
<td>PsycINFO</td>
<td>14 september 2009</td>
<td>3</td>
<td>psy090917 werk</td>
<td></td>
</tr>
<tr>
<td>CINAHL</td>
<td>11 september 2009</td>
<td>13</td>
<td>cin090917 werk</td>
<td></td>
</tr>
</tbody>
</table>

Limitations: No articles exclusively about animals, only articles in the Dutch, English, German or French languages and only articles from 1990 to 2009.
General comments:
1. The number of references in Reference Manager and therefore in the literature lists differs from the number of hits because, during import into Reference Manager, an effort was made to avoid importing items that were already in the file.
2. The keywords mentioned in this report are MeSH keywords. Keywords that were as close as possible to the keywords listed, in terms of meaning, were used for other databases.
3. The search strategies used are stored in the files.

Report literature search key question 9:
How can the prescription of prosthesis (components) be improved? Which factors influence prosthetic prescription?

On 21st August 2009 a search of Medline via the OvidSP interface was carried at the CBO in the presence of working group member Harmen van der Linde. However, the results contained a large number of articles on another subject. An agreement was made with Harmen that the information specialist would first adapt the search strategy for P (so that the correct subject was found as much as possible), and then combine the new P with the search strategy formulated by Harmen for I, O and V. The new P was prepared in Medline on 25th August, after which the search on this question (in the presence of the working group member) was completed in Medline (Medline via OvidSP interface). The search in Embase (also via OvidSP interface) was performed on 27th August 2009 after having prepared a new P for Embase. The search in CINAHL (via interface EBSCOhost) was performed on 28th August 2009. In this case the P was prepared first.

Before conducting the search, this PICO was formulated::

P search strategy for patient population as already present
I prescription adj4 prosthes$, prescription criteria, prosthesis design, prosthesis components
C
O ‘improvement’:
correct/accurate$/precise$ prescription, patient satisfaction, improv$/better function$/abilit$, improv$/better ambulation/mobility, functional need/benefit, daily functioning, functional outcome, QoL, independence, self care , ADL, walking distance, gait

The parts 'P amputation lower limb ' and 'P prosthetic provision lower limb ' (combined with OR) of the search strategy stored in Ovid for the P med090825 P amputation en prothesiologie lower limb versie 5 was used. The search strategy was as follows:

: 
<table>
<thead>
<tr>
<th>P</th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti), abstract (ab) or text (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Amputation/ Disarticulation/ Amputation Stumps/ Amputation, Traumatic/</strong></td>
<td>OR</td>
<td>(knee$ or leg$ or lower limb$ or lower-limb$ or crural or lower extremi$ or lower-extremi$).ti,ab. (trans?tibial or (trans adj1 tibial) or tibial or trans?femoral or (trans adj1 femoral) or femoral).ti,ab. ((through or above or below) adj1 knee$).ti,ab. ((through-the-knee or through-knee or above-knee or above-the-knee or below-knee or below-the-knee) adj4 amput$).ti,ab.</td>
</tr>
<tr>
<td>2</td>
<td>OR</td>
<td></td>
<td>(knee$ or leg$ or lower limb$ or lower-limb$ or crural or lower extremi$ or lower-extremi$).ti,ab. (trans?tibial or (trans adj1 tibial) or tibial or trans?femoral or (trans adj1 femoral) or femoral).ti,ab. ((through or above or below) adj1 knee$).ti,ab. ((through-the-knee or through-knee or above-knee or above-the-knee or below-knee or below-the-knee) adj4 amput$).ti,ab.</td>
</tr>
<tr>
<td>3</td>
<td>1 AND 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td><strong>Leg/su [Surgery]</strong> <strong>Tibia/su [Surgery]</strong> exp Femur/su [Surgery] Knee/su [Surgery]**</td>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>OR</td>
<td></td>
<td>amput$.tw.</td>
</tr>
<tr>
<td>6</td>
<td>4 AND 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>OR</td>
<td></td>
<td>((trans?tibial or (trans adj1 tibial)) adj2 amput$).ti,ab. ((trans?femoral or (trans adj1 femoral)) adj2 amput$).ti,ab. (knee$ adj2 (disarticulat$ or exarticulat$)).ti,ab. (knee$ adj2 amput$).ti,ab. ((tibial or femoral) adj2 amput$).ti,ab. ((leg$ or lower limb$ or lower-limb$ or crural or lower extremi$ or lower-extremi$) adj2 amput$).ti,ab. ((trans?ankle or syme) adj3 (amput$ or disarticulat$)).ti,ab.</td>
</tr>
<tr>
<td>8</td>
<td>OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>3 OR 6 OR 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td><strong>Artificial limbs/ exp prosthesis design/ Amputation Stumps/ Prosthesis Fitting/ Prosthesis Failure/ Osseointegration/ Silicones/</strong></td>
<td>OR</td>
<td>(skelet$ adj3 fixat$).ti,ab. ((bionic$ or bone$) adj3 (implant$ or prosthes$)).ti,ab. (trans?cut$ or trans?derm$ or (trans adj1 (cut$ or derm$))).adj3 implant$.ti,ab. (osseo?integrat$ or (osseo adj1 integrat$)).ti,ab. (intra?osse$ or (intra adj1 osse$)).ti,ab. (intra?osse$ trans?cutan$ amputat$ prosthes$ or ITAP).tw. (stump adj3 socket$).ti,ab. silicon liner socket$.tw.</td>
</tr>
<tr>
<td>12</td>
<td>9 AND 8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>OR</td>
<td></td>
<td>(((leg$ or lower limb$ or lower-limb$ or crural or</td>
</tr>
</tbody>
</table>
For the intervention **I**, in this case **prosthesis components**, this search strategy was devised:

<table>
<thead>
<tr>
<th>I</th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti) or abstract (ab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Prosthesis Design/ Prosthesis Fitting/ Prosthesis Failure/</td>
<td>OR</td>
<td>(((prosthesis or prosthetic) adj3 component$).ti,ab. (prosthetic adj3 (knee or foot or socket$ or suspension)).ti,ab.</td>
</tr>
</tbody>
</table>

For **V**, the prescription of the prosthesis, this search strategy was devised:

<table>
<thead>
<tr>
<th>V</th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti), abstract (ab) or text (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>OR</td>
<td>(((prosthetic or prosthes?s) adj4 (prescription$ or prescrib$ or outcome$ or optimiz$ or improv$ or better or correct or accurate or precis$ or manag$ or perform$ or evaluat$)).tw. ((prescription$ or prescrib$) adj4 (optimiz$ or improv$ or better or correct or accurate or precis$ or evaluat$ or enhanc$)).tw.</td>
</tr>
</tbody>
</table>

For the outcome **O**, improving the prosthesis/the prescription of the prosthesis, this search strategy was devised:

<table>
<thead>
<tr>
<th>O</th>
<th>keywords</th>
<th>operator</th>
<th>words in title (ti) or abstract (ab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Patient Satisfaction/ &quot;Quality of Life&quot;/ &quot;Activities of Daily Living&quot;/</td>
<td></td>
<td>(satisfact$ adj4 (patient$ or amputee$)).ti,ab. quality of life.ti,ab. (improv$ or better or enhanc$) adj3 (ambulation or mobility or gait or function$)).ti,ab. (gait or walking) adj3 (parameter$ or speed or cadence or distance or pattern$ or velocity or characteristic$)).ti,ab. (stride adj3 (characteristic$ or time or length)).ti,ab. (comfortable adj3 speed) or (step adj3 length) or (stance adj3 phase) or (swing adj3 phase)).ti,ab. (subjective finding$ or preference$ or comfort).ti,ab. indepence.ti,ab. joint motion.ti,ab. (energy adj3 (expenditure or cost$ or demand$ or consumption$)).ti,ab. (oxygen adj3 (uptake or cost$)).ti,ab. (metabolic cost$ or physiological measurement$).ti,ab.</td>
</tr>
</tbody>
</table>

**Results of the search** (all items are stored in Reference Manager file ‘Amputatie - vraag 9’ with the filename as keyword):
<table>
<thead>
<tr>
<th>database</th>
<th>updated to:</th>
<th>number of hits</th>
<th>filename</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medline</td>
<td>24 augustus 2009</td>
<td>68</td>
<td>med090825 prescription</td>
</tr>
<tr>
<td>Embase</td>
<td>week 34 2009</td>
<td>62</td>
<td>emb090827 prescription</td>
</tr>
<tr>
<td>CINAHL</td>
<td>21 augustus 2009</td>
<td>25</td>
<td>cin090828 prescription</td>
</tr>
</tbody>
</table>

**combination: P AND I AND V AND O**

<table>
<thead>
<tr>
<th>database</th>
<th>updated to:</th>
<th>number of hits</th>
<th>filename</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medline</td>
<td>24 augustus 2009</td>
<td>250</td>
<td>med090825 rest</td>
</tr>
<tr>
<td>Embase</td>
<td>week 34 2009</td>
<td>205</td>
<td>emb090827 rest</td>
</tr>
<tr>
<td>CINAHL</td>
<td>21 augustus 2009</td>
<td>80</td>
<td>cin090828 rest</td>
</tr>
</tbody>
</table>

**combination: P AND I AND O (without all downloaded articles)**

**Limitations:** No articles exclusively about animals, only articles in the Dutch, English, German or French languages and only articles from 1990 to date.

**General comments:**
1. The number of references in Reference Manager and therefore in the literature lists differs from the number of hits because, during import into Reference Manager, an effort was made to avoid importing items that were already in the file.
2. The keywords mentioned in this report are MeSH keywords. Keywords that were as close as possible to the keywords listed, in terms of meaning, were used for other databases.
3. The search strategies used are stored in the files.

**Report literature search output question 10:**

*At what moment following amputation should prosthesis fitting commence?*

On 20th January 2010 a search was carried out in Medline via the OVID interface following an oral explanation by Jos Deckers. Medline was updated to week 1st January 2010 at the time of the search. The search in Embase (updated to week 2, 2010), using the same global search strategy, was performed by the information specialist on the same date.

In the search the following PICO(S) was formulated:

- **P** search strategy for patient population as already present; consisting of three parts. For this question, the parts 1, 2 and 3 were all combined via "or" (see rule 8 below).
- **I** description amputation ‘timing’
- **C**
- **O** description revalidatie or rehabilitation
- **S** study types
**Part P**
The parts indicated below of 'P amputation lower limb ' version 3 090428 (combined with OR) of the search strategy stored in Ovid are used (line 8 indicates the combination used). The search strategy is follows:

<table>
<thead>
<tr>
<th>P</th>
<th>keywords</th>
<th>operator</th>
<th>words with field designations such as multipurpose (mp) in title (ti), abstract (ab) or title or abstract (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amputation/ Disarticulation/ Amputation Stumps/ Amputation, Traumatic/</td>
<td>OR</td>
<td>(knee$ or leg$ or limb$ or crural or lower extremit$).ti,ab. (trans?tibial or (trans adj1 tibial) or tibial or trans?femoral or (trans adj1 femoral) or femoral).ti,ab. ((through or above or below) adj1 knee$).ti,ab.</td>
</tr>
<tr>
<td>2</td>
<td>OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>1 AND 2=</td>
<td></td>
<td>1 AND 2= P-part 1</td>
</tr>
<tr>
<td>5</td>
<td>OR</td>
<td></td>
<td>4 AND 5= P-part 2</td>
</tr>
<tr>
<td>7</td>
<td>OR</td>
<td></td>
<td>(((trans?tibial or (trans adj1 tibial)) adj4 amputat$).ti,ab. (((trans?femoral or (trans adj1 femoral)) adj4 amputat$).ti,ab. (knee$ adj4 (disarticulat$ or exarticulat$)).ti,ab. ((through or above or below) adj1 knee$ adj4 amputat$).ti,ab. (((tibial or femoral) adj4 amputat$).ti,ab. (((leg$ or limb$ or crural or lower extremit$) adj4 amputat$).ti,ab. (((trans?ankle or syme) adj3 (amputat$ or disarticulat$)).ti,ab.</td>
</tr>
<tr>
<td>8</td>
<td>3 OR 6 OR 7=</td>
<td></td>
<td>3 OR 6 OR 7= P-part3</td>
</tr>
</tbody>
</table>
### Part I
Amputation timing

<table>
<thead>
<tr>
<th>I</th>
<th>keywords</th>
<th>operator</th>
<th>words with field designations such as multi-purpose (mp) in title (ti), abstract (ab) or title or abstract (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>early ambulation/</td>
<td>OR</td>
<td>((early adj5 fitti*) or (rapid adj5 fitting)).tw. or (tim* or day? or month? or week?).tw. OR (time or timing).ti.</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td>(begin* adj5 (rehabil* or fitting or design*)).tw.</td>
</tr>
</tbody>
</table>

### Part O
For O = outcome, the focus on the result of rehabilitation, the following search terms were used

<table>
<thead>
<tr>
<th>O</th>
<th>keywords</th>
<th>operator</th>
<th>words with field designations such as multi-purpose (mp) in title (ti), abstract (ab) or title or abstract (tw), subheading (fs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amputees/rh or exp Rehabilitation/</td>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>*artificial limbs/mt, st or artificial limbs/st, mt or muscle strength/ or postural balance/ or walking/ activities of daily living/</td>
<td>OR</td>
<td>(manag* adj5 prosthe*).tw. OR (therap* adj5 succe*).tw. OR (rehab* adj5 quality).tw. OR (mt or st).fs.</td>
</tr>
</tbody>
</table>

### Part S
For S, the following study type filters, 1=systematic review, 2=observational studies, 3=RCTs

<table>
<thead>
<tr>
<th>S</th>
<th>keywords</th>
<th>operator</th>
<th>words in all fields (af), publication type (pt) or title and abstract (tw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>OR</td>
<td>meta analysis.pt. or meta-anal*.af. metaanal*.af. or (quantitativ* adj10 review*).tw. or (quantitativ* adj10 overview*).tw. or (systematic* adj10 review*).tw. or (systematic* adj10 overview*).tw. or (methodologic* adj10 review*).tw. or (methodologic* adj10 overview*).tw. or medline.tw. and review-.pt. or (pooled adj3 analy*).tw.</td>
</tr>
<tr>
<td>2</td>
<td>epidemiologic-studies/ or exp case-control-studies/ or exp cohort-studies/ or cross-sectional-studies/</td>
<td>OR</td>
<td>case with control.af. or (cohort adj5 study).af. (cohort adj5 studies).af. or (cohort adj5 analy$).af. or (follow-up adj5 (study or studies)).af. or (longitudinal or retrospective or (cross adj5 sectional)).af. or (observational adj5 (study or studies)).af. or prospective.af.</td>
</tr>
</tbody>
</table>

---

*Richtlijn Amputatie en prothesiologie onderste extremiteit, 2012*
Results of the search (all items are stored in Reference Manager file ‘Amputatie - vraag 10’ with the filename as keyword):

The search strategy is indicated in brief in the table under filename. (+ means AND)
The explanation of the items named is listed in the tables I, O and S, resp.

med = the medline database
emb = the embase database

Summary results of question 10 moment of prosthetic fitting

Medline and Embase were searched
The file names briefly indicate the structure of the search
Systrev means systematic reviews, obsservat are observational studies.
The lists are alphabetical by author

<table>
<thead>
<tr>
<th>Filename</th>
<th>number</th>
</tr>
</thead>
<tbody>
<tr>
<td>med 20100120 start prosthesis systrev</td>
<td>16</td>
</tr>
<tr>
<td>med 20100120 start prosthesis trials observat</td>
<td>21</td>
</tr>
<tr>
<td>med 20100120 start prosthesis rest</td>
<td>66</td>
</tr>
<tr>
<td>emb 20100120 start prosthesis trials of disease mangement</td>
<td>25</td>
</tr>
<tr>
<td>emb 20100120 start prosthesis timing</td>
<td>14</td>
</tr>
</tbody>
</table>

Limitations: No articles exclusively about animals, only articles in the Dutch, English, German or French languages and only articles from 1990 to 2009.

General comments:
1. The number of references in Reference Manager and therefore in the literature lists differs from the number of hits because, during import into Reference Manager, an effort was made to avoid importing items that were already in the file.
2. The keywords mentioned in this report are MeSH keywords. Keywords that were as close as possible to the keywords listed, in terms of meaning, were used for other databases.
3. The search strategies used are stored in the files.