ISPO Report
Lower Limb Amputations Due to Vascular Disease: A Multidisciplinary Approach to Surgery and Rehabilitation

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INTRODUCTION

Vascular disease is the most common cause of amputation, accounting for 82% of all amputations. Although the incidence of amputations due to trauma and cancer has decreased, amputation due to vascular disease continues to increase. In this report, we discuss the evaluation and management of peripheral arterial disease (PAD); limb salvage; amputation and amputation surgery; early management and prosthetic rehabilitation following amputation due to vascular disease. Assessment by a multidisciplinary team in the preoperative phase forms the basis for the policies to be followed after surgery and during the rehabilitation process. The involvement of multiple disciplines reduces the risk of complications during surgery and the postoperative phase.

This ISPO consensus report is realized thanks to ISPO International, Otto Bock, Protheor, Ossur, and Blatchford with the engagement and cooperation of the members of the ISPO consensus meeting February 2015, Basingstoke, UK. A Dutch guideline on amputations and prosthetic rehabilitation due to vascular disease was published in 2012. Over the past five years, additional relevant papers regarding management of lower limb amputation due to vascular disease have been published. The ISPO International Consensus Group comprised of academicians, clinicians, and researchers was chosen to update the 2012 guidelines. The composition of the Consensus Group was based on profession, region of the world, and expertise. Members included orthopaedic surgeons, rehabilitation physicians, prosthetists, therapists, and engineers all with expertise in amputation surgery and prosthetic rehabilitation. The goal of this report is to provide an updated version of the previous guidelines. This report is created for care providers throughout the world who are involved in the care of people with lower limb amputation due to vascular disease. Resources and expertise differ widely in many parts of the world. We hope that updating the Dutch guidelines to create an international report will help nations establish their own guidelines.

METHODS
DATA SOURCES AND SEARCHES

In 2012, the Netherlands Society of Physical and Rehabilitation Medicine (VRA), a national society for medical specialists in rehabilitation medicine, and the Utrecht-Based Dutch
Institute for Healthcare Improvement (CBO) developed the Dutch Guidelines for amputation and prosthetics of the lower extremities.

The recommendations in the 2012 Dutch guidelines were 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.

The current report was developed by a consensus process and is based on additional relevant references found through a consensus meeting February 2015, in Basingstoke, UK. We sought to capture the highest quality of literature available regarding lower limb amputation due to vascular disease. The text was reviewed and revised by the consensus group. We formulated updated recommendations of key points for daily practice based both on available evidence and expert opinion.

The report underwent a Delphi Consensus among the panel members. The first draft of this guideline was presented in 2017 at the ISPO World Congress for public comment. Subsequent drafts were revised based on those comments.

EVALUATION OF THE PERSON WITH VASCULAR DISEASE PRIOR TO LOWER LIMB AMPUTATION

Guideline #1.1: To prevent amputation, it is critical that patients with peripheral arterial disease (PAD) at risk of amputation are detected at an early stage. This includes the identification and treatment of circulatory disorders and wounds.

Updated Evidence: In order to prevent amputation it is recommended that patients with critical limb ischemia (chronic ischemic rest pain, ulcers, or gangrene) receive a multidisciplinary evaluation and treatment (including surgeon, interventional radiologist, vascular internist, rehabilitation physician, anaesthesiologist, pain specialist and physiotherapist, with the possible additional involvement of an orthopaedic technician or prosthetist). (Dutch Guideline Diabetic Foot 2006)

Prior to amputation, the medical comorbidities and vascular status (perfusion of the limb) should be assessed. The first step to evaluate the vascular status involves physical examination including pulse exam and assessing the degree of ischemia.

The working group recommends that all diabetic patients with ulcers be assessed for PAD using objective tests, such as duplex ultrasound and ankle-brachial indices. In patients with peripheral arterial disease and diabetes, claudication may be masked due to neuropathy. The use of transcutaneous oxygen pressure (TcPO₂) may provide an important tool to make clinical decisions regarding an appropriate level of amputation.¹

Guideline #1.2: Where arterial imaging is necessary for treatment decisions, the following imaging techniques are recommended: duplex examination, DSA, MRA and CTA. If the vascular status is not yet established or if demarcation of the region for amputation has not yet taken place, it is advisable to postpone amputation.
Updated Evidence: Arterial disease can be demonstrated by either non-invasive or invasive vascular tests. The vascular laboratory plays an important role in non-invasive studies.

In addition to the clinical assessment, anatomic localization of vascular disease can be obtained with segmental blood pressure or pulse volume recordings. Arterial calcification may result in non-compressible vessels with the inability to obtain ankle brachial indices (ABIs). The ABI is not accurate when the systolic blood pressure cannot be abolished using a blood pressure cuff. The incidence of non-compressible (artifactually high), calcified conduit arteries is highest in diabetic, elderly, and chronic renal failure patients. The resulting ABI values can be falsely elevated. Despite high recorded systolic pressure, these individuals may have severe disease. In this population, a greater importance should be attached to toe pressures and TcPO$_2$ measurements.$^5$

In a randomized controlled trial (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 TcPO$_2$ and toe pressure measurements. TcPO$_2$ and toe pressure measurement did not improve the clinical outcome, but determination can be helpful in case of doubt regarding the need for revascularisation.$^5$

When a discrepancy between clinical findings and non-invasive vascular studies arises, vascular imaging should be considered.$^6$

Guideline #1.3: When a patient has multiple medical comorbidities and is unable to undergo a planned revascularization procedure or when it is unlikely that restoration of circulation will lead to a functional limb, initial amputation should be considered.

Updated Evidence: Revascularisation (surgical or endovascular) are effective in the prevention of amputation. (Dutch guideline vascular disease 2005). Because evidence indicates that blood flow to the lower limb improves in the first three weeks after revascularisation, deferred amputation following revascularisation is preferred.$^7$ An amputation should be performed when a subsequent vascular reconstruction is no longer possible or if, despite successful revascularization, progressive ischemia is noted.

When revascularization is not an option or revascularization will not result in a functional limb, amputation should be considered. Amputation, rather than revascularisation, may offer patients a more rapid return to an acceptable quality of life.

The European Consensus document defines CLI as persistently recurring ischemic rest pain or ulceration, or gangrene of a foot or toes lasting greater than two weeks.$^8$

According to TASC II$^6$ the following indicate critical limb ischemia:

- Ankle pressure < 50 mm Hg
- Toe pressure < 30 mm Hg
- TcPO$_2$ < 30 mmHg

It is estimated that 5%-10% of patients with peripheral arterial disease older than 50 years develop CLI within five years.$^9$
In a study looking at the costs of management of CLI looking at wound healing, functional outcomes, quality adjusted life years (QALY), and cost, surgical revascularization was the most cost effective alternative to local wound care alone for patients with critical limb ischemia with tissue loss.\textsuperscript{10}

Critical limb ischemia (CLI) may be an indication for amputation in patients with PAD. Early amputation may be indicated in critical limb ischemia, with the aim of achieving a better long-term function and a lower risk of comorbidity.\textsuperscript{11, 12}

Decision-making regarding limb salvage versus amputation remains complex and is best made by the consensus of surgical and rehabilitation subspecialities. Evidence suggests that there is no significant difference in outcomes at two years when comparing revascularization versus amputation, although limb salvage is associated with higher risk of complications, additional surgeries, and re-hospitalizations.\textsuperscript{13}

An important question is to determine which subgroups of patients with critical limb ischemia would ultimately benefit more from an amputation than from revascularisation. For example, in ambulatory older individuals, extensive revascularization surgery may result in reduced mobility. Instead, an initial amputation could be considered a viable treatment option with improved mobility and quality of life.\textsuperscript{14} Technical factors, aspects of wound healing, deconditioning and existing comorbidities are all factors that determine whether a patient is suitable for amputation.

Critical limb ischemia is associated with high morbidity and mortality. Evaluating 13 studies enrolling 1,527 patients with a median follow up of 12 months, all-cause mortality was 22% and major amputation rate was 22%.\textsuperscript{15}

30% of patients with CLI require amputation within the first year after diagnosis. The five-year mortality rate for CLI patients is 70% and most of those deaths are cardiovascular related.\textsuperscript{9}

Revascularization is more expensive and less beneficial in the end stage renal disease (ESRD) patient population than in the general CLI population.\textsuperscript{16} Two characteristics of the end stage renal disease patient population make attempts at limb preservation through revascularization and subsequent wound healing very challenging (1) limb salvage attempts fail more frequently in the ESRD population than in non-ESRD critical limb ischemia; (2) the perioperative survival rate and the long-term survival rate of patients with ESRD are both significantly lower than those of the non-ESRD CLI population.\textsuperscript{17, 18}

These challenges have led to some uncertainty about whether efforts to achieve limb preservation are cost effective in the end-stage renal disease patient population. The current analysis suggests that local wound care and endovascular intervention would be options that are more cost effective than primary amputation.\textsuperscript{16, 19}

An amputation is indicated if there is: a severe (life threatening) infection, tissue loss due to extensive necrosis, intractable pain. Immediate amputation should be considered in cases of acute ischemia and sepsis.\textsuperscript{6}

In wet gangrene (whether local or generalised) immediate surgery is indicated to remove the infection. A guillotine amputation can be used in this situation. A short period between
diagnosis and amputation prevents further deterioration of the patient’s clinical condition, resulting in an increased chance of recovery. In the stable phase following recovery from sepsis syndrome, there will be an option for a subsequent definitive amputation. This leads to better results than does a single intervention.\textsuperscript{20}

**Guideline #1.4:** The purpose of an amputation is to achieve (initial) wound healing as distal as possible with the highest possible post-amputation function.\textsuperscript{6} No clear criteria are given in the literature for the clinical assessment of the amputation level.\textsuperscript{21}

**Updated Evidence:** The level of amputation is determined by the clinical situation (degree of ischemia, gangrene, pain, or infection) and the likelihood of successful initial wound healing. It is important to evaluate patients’ comorbidities and mobility. In general more distal surgery provides a better functional outcome, but has increased risk of non-healing, re-ulceration, and re-amputation. Noninvasive arterial studies including TcPO\textsubscript{2}S or toe pressure measurements may be useful to determine the optimal amputation level.\textsuperscript{9}

Multidisciplinary evaluation and treatment (surgeon, anaesthesiologist, pain specialist, rehabilitation physician, and vascular medicine specialist) is important for treatment of pain, cardiovascular risks, comorbidities, and determine the level of amputation. The patient should be seen in consultation with a rehabilitation physician preoperatively.

When an important decision like amputation needs to be made, the patient’s opinion should be incorporated into the decision. Some patients may weigh the risks of a reduced rate of healing of a distal amputation as acceptable if they have a higher likelihood of mobility. Others may prefer a transtibial amputation where the probability of primary healing is better and mobility may be adequate.\textsuperscript{22}

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 initial wound healing and maintain the level of a transtibial amputation. A transfemoral level amputation is not a preferred level from a functional point of view due to the loss of the knee joint and the increased metabolic cost of ambulation. It is considered when more distal levels are not an option due to inadequate tissue or poor perfusion. An initial transfemoral level amputation (without prior vascular intervention) is performed in rare cases (non-ambulatory patients). The indication for this will be determined by:

- the risk of surgery due to medical comorbidities
- surgical options
- the patient’s function and possible rehabilitation
- the patient’s cognitive status and ability to show carryover in therapies

**Guideline #1.5:** When determining the level of amputation, preoperative mobility and the prospects for postoperative mobility should be taken into account.

**Updated Evidence:** Predicting whether a patient will use a prosthesis is a clinical judgement taking many factors (physical, medical, psychological, and social) into account. It is important to weigh the chances of successful vascular reconstruction - and subsequent mobility – against the chance of healing and mobility following initial amputation.
Functional outcomes after amputation are highly variable and are often related to age, premorbid function and medical comorbidities. At 1 year post-amputation, functional prosthetic use is reported in 47%-70% of persons with limb loss. Persons with transtibial level amputation were more likely to be prosthetic ambulators (60-70%) than those with transfemoral level amputation (40-50%). In one study, 5 years post-amputation, the number of prosthetic ambulators decreased to 17%. Increased age is associated with poor functional outcomes after amputation. Schoppen reported a very low functional level in amputees over 60 years old. Those over 75 years old rarely used a prosthesis or were ambulatory. The perioperative consultation should address the likelihood of successful prosthetic fitting and use. This can assist the team to determine the optimal level of amputation. If a patient is not a prosthetic candidate, they may be better served with a transfemoral level amputation. Premorbid level of function is also predictive of post-amputation level of function. Patients who are non-ambulatory prior to amputation are unlikely to resume ambulation after amputation. Post-amputation function is also influenced by the patient’s medical and social condition. Increased medical comorbidities are associated with poorer function. In particular, chronic obstructive pulmonary disease, end-stage renal disease requiring hemodialysis, diabetes, hypertension, alcohol use disorder and history of treatment for anxiety or depression are all associated with worse functional outcomes. On the contrary, white race, being married and having at least a high school education are associated with better outcomes. Outcomes in the rehabilitation phase are difficult to generalize due to the different outcome measures used. Patients successfully receive prostheses in 68% of cases. The main factors associated with mobility are age, length of stay in a rehabilitation facility, and the mobility level prior to surgery. Wound complications, a higher amputation level, older age and a low level of mobility before surgery often result in unsuccessful prosthetic fitting. Factors associated with functional status include age, presence of diabetes mellitus, standing balance and cognition. A subset of patients experienced improvements in their functional mobility after amputation. Norvell reported that 37% of individuals with amputation returned to or exceeded their premorbid level of function at 1 year post-amputation. Johnson also reported that many persons with unilateral transtibial amputation are able to maintain or improve their function after amputation. Because patients undergoing lower extremity amputation due to vascular disease have often been functionally limited by peripheral arterial disease, foot ulcers, infections, and weight-bearing restrictions (sometimes for years prior to amputation) definitive management with amputation surgery can sometimes improve their function.

Patients who were only moderately mobile prior to amputation will be less likely to become successfully mobile after amputation. In patients with limited mobility, dementia, end-stage
renal disease and/or severe coronary artery disease; a knee disarticulation or transfemoral amputation should be considered.\textsuperscript{26}

With a flexion contracture of the knee, a knee disarticulation or long transfemoral amputation may provide a superior option. Conversely, a knee disarticulation is an option worth exploring when a transfemoral amputation is being considered.

It has been suggested that persons with amputations comprise 2 distinct groups: the fit (often traumatic amputation); and the older, medically unfit patient who has vascular disease and a poor prognosis.\textsuperscript{33} Among this latter group, there is a great variation in functional outcome dependent on age, medical status and other factors. The ability to predict which among these patients are prosthetic candidates may reduce the costs and burden of care resulting from unsuccessful prosthetic fitting and allow earlier focus on interventions that will increase the patient’s independence and quality of life.

Interestingly, when prosthetic fitting patterns were examined over 40 years, no marked changes in the rate of fitting or wear patterns occurred, despite technologic developments, advances in revascularization procedures, and provision of rehabilitation services. This suggests that a physiologic limit to successful prosthetic fitting may exist in the geriatric patient due to advanced age and comorbidity. This will have implications on health care allocation in the future, as the number of major lower-extremity amputations due to dysvascular disease increases.\textsuperscript{34}

SURGICAL TECHNIQUE IN LOWER EXTREMITY AMPUTATION DUE TO VASCULAR DISEASE

\textbf{Guidelines #2.1:} Good surgical technique, which ensures no excess soft tissue, no neuromas, a good residual limb shape, mobile scars and no joint contracture, 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 possible mobility and lower risk of re-amputation.\textsuperscript{35}

\textbf{Updated Evidence:} Amputation surgery should be viewed as a reconstructive procedure. The working group recommends that amputations be carried out by experienced, prosthetically aware, surgeons who conduct a minimum of 5 to 10 amputations each year. The absolute number per year is less important than involvement with a multidisciplinary team with good outcomes.

The basic principle of all amputations is preservation of maximal length consistent with optimal function, control of disease, and satisfactory surgical wound management. Adherent scarred distal tissues or redundant soft tissue should be avoided.

At all levels of lower extremity and hindquarter amputations, nerves are encountered which require transection. For larger nerves such as the sciatic and femoral nerves, the nerves should be suture ligated prior to transection since they are accompanied by a large vasa nervorum. All nerves should be transected sharply under tension. Prior to allowing the nerve to retract, they can be infiltrated with local anesthetic to provide postoperative pain control. The transected nerve is then allowed to retract into the adjacent soft tissues, away from the areas where it could become adherent or a source of pressure irritation from the
socket.

An attempt should be made to minimize possible complications following lower extremity amputation. The working group believes that patients facing amputation require subsequent supervision and treatment by a multidisciplinary team in the hospital, with continuation of outpatient rehabilitation treatment in a rehabilitation center, nursing home or at home. (Expert opinion of working group)

**Guidelines #2.2:** A comparison of ‘two-stage transtibial amputation (guillotine amputation at the ankle followed by a long posterior flap transtibial amputation with delayed initial skin closure)’ with ‘one-stage transtibial amputation’ 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 re-amputation rate. Mobility did not differ significantly (47% in the ‘two-stage’ group and 54% in the ‘one-stage’ group).

**Updated Evidence:** 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.

Intraoperatively meticulous handling of the skin and soft-tissues is critical as traumatic handling can lead to postoperative wound necrosis and further complications. Skin incisions should be made in a layered fashion first only going through skin, then through the subcutaneous tissues, fascia and deeper layers. This allows for a layered closure and obtaining full thickness soft-tissue flaps. An incision straight through skin, subcutaneous tissue and fascia is not advised as this makes it difficult to obtain a robust layered closure. The wound is typically closed from the periphery moving central in order to avoid “dog-ears”. If “dog-ears” are present, they should not be trimmed as this could lead to flap failure. The wound should be closed without tension.

**Guideline #2.3:** In a trial by the Joint Vascular Research Group (n=191), ‘skew flap' transtibial amputation was compared with 'long posterior flap' transtibial amputation. After almost 12 months, no difference in stump healing, infection or re-amputation 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).

**Updated Evidence:** There is no evidence that the ‘skew flap’ procedure gives better results than ‘long posterior flap’ procedure. A well-fashioned ‘skew flap’ will facilitate mobilization with less initial volume reduction.

A small RCT with 41 patients showed that residual limb healing in patients treated with a 'sagittal flap' (58%) did not differ from that of patients treated with a 'long posterior flap' (55%) (OR 1:04; CI 0.45 to 2:43). There was no difference in the re-amputation rate, the percentage with a suitable prosthesis or mortality between the two groups. Mobility was also equivalent.

The outcome of a standard surgical (sagittal incision) procedure in 217 consecutive patients that underwent initial unilateral transtibial amputation due to peripheral arterial disease was followed for 10 years. 119 (55%) were fit with a definitive prosthesis at a median time of 41 (range, 12–147) days after amputation.
Evidence suggests that a transtibial amputation with a ‘sagittal flap’ does not give superior results compared with a ‘long posterior flap’.20

Guideline #2.4: A rule of thumb is that an osseous length of 10-15 cm below the medial knee joint gap is optimal in a transtibial amputation.

Updated Evidence: In a transtibial amputation, an osseous length of 10-15 cm below the medial knee joint has been thought to be optimal. Alternatively, the length of the amputated tibia can be equal to the width of the tibial plateau. There is literature that supports that longer residual limbs result in reduced metabolic energy expenditure. A longer residual limb up to 19 centimeters, as long as it is compatible with soft tissue coverage and healing, may be optimal. The fibula is typically cut 1.5 cm proximal to the planned tibial cut and then a further 2-3 cm more proximal, to assist with exposure of the deeper posterior compartment and assist with wound closure. The distal bones are cut 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.

Guideline #2.5: Evidence for surgical techniques in transfemoral amputations and knee disarticulation is limited.

Updated Evidence: Flap design for a knee disarticulation amputation is different from other distal leg amputations since the main flap relies on the anterior skin and soft tissue. A fish mouth incision with a flap that is twice as long anteriorly as it is posteriorly is used. This is to allow adequate mobilization of the patella tendon. For individuals with vascular disease, knee disarticulation is a relatively rare level of amputation compared to transtibial and transfemoral levels. The benefits of this level include no disruption of the bony cortex, greater proprioception, greater end weight-bearing ability and the long lever arm of the residual limb. The drawbacks are poor cosmesis due to the bulbous shape of the distal limb and less room for knee components. The leg lengths of the prosthetic and sound thigh can appear uneven at this level, especially in sitting. With amputation due to vascular disease, a transfemoral amputation is more common than a knee disarticulation.

In a transfemoral amputation the goal is to maintain the maximum length possible. The ideal length of a transfemoral residual limb is 5-7 cm proximal to the knee joint. The contralateral side should be taken as a benchmark. Flap design is based on the medial and lateral soft-tissues. Similar to other amputations, a fish-mouth designed flap is used, with a medial flap that is longer than the lateral flap. This is to allow mobilization of the adductor muscle group and perform a myodesis. The femur is typically transected 12 cm proximal to the knee joint. This allows the adductor magnus to be used as a dynamic stabilizer of the residual limb. The hip adductor muscles, in particular the adductor magnus are important in countering lateral movements of the femur. As the amputation is taken more proximal, there is a reduction in the strength of the adductor and less stabilization. If the residual limb is too short, an abduction contracture may occur. It is also important to avoid a flexion contracture of the hip. (Expert opinion of working group)
**Guideline #2.6:** Choksy, et al., found the use of a tourniquet resulted in less blood loss and lower transfusion requirements. In an observational, feasibility study of 89 patients who underwent a transtibial amputation, Wolthuis, et al. found similar reductions in blood loss and transfusion requirements and a significant reduction in the number of stump revisions.

**Updated Evidence:** 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. (Expert opinion of working group)

Skin incisions should be made under tourniquet control. Meticulous hemostasis is mandatory to avoid postoperative hematoma. It is essential that all larger blood vessels are suture ligated, and when indicated oversewn. All wounds are drained for at least 48 hours postoperatively. It is not uncommon to have drains in place longer for more proximal level amputations. Incisional negative pressure wound dressings can also be used for hip disarticulations and hindquarter amputations to reduce wound drainage.

**Guideline #2.7:** There are some reports regarding bone bridging in transtibial amputation (Ertl procedure).

**Updated Evidence:** Because of the longer surgical and tourniquet times associated with the bone bridge synostosis technique, it is best reserved for young, healthy individuals.

**Guideline #2.8:** Complications can be divided into disorders that lead to delayed wound healing (wound edge necrosis, dehiscence and infection) and those that are more severe (progressive ischemia with extensive necrosis, infection, revision, venous thromboembolism, sepsis and death).

Wound healing is of primary importance after amputation due to the morbidity associated with delayed wound healing and re-amputation. Wound care, edema management, diabetic control, smoking cessation and adequate nutrition are all important factors. Optimally, wound healing takes 6-8 weeks after amputation. Amputations due to vascular disease may have a more prolonged course. Healing for a transmetatarsal amputation due to vascular disease ranged from 3-20 months with a mean of 7 months. Healing at 100 and 200 days was 55% and 83% for transtibial and 76% and 85% for transfemoral amputations.

A systematic review by McIntosh looking at the effect of prophylactic antibiotics on infection following amputation suggested the use of prophylactic antibiotics resulted in significantly fewer residual limb infections in comparison with placebo or no antibiotics. The working group recommends perioperative antibiotic treatment in the form a perioperative bolus or five days starting immediately postoperatively.

Robertson reviewed the literature regarding the effectiveness of thromboprophylaxis in preventing venous thromboembolism in people undergoing major lower extremity amputation. Only two studies were included in this review, each comparing different interventions. There is inadequate evidence to make any conclusions regarding the most effective thromboprophylaxis regimen in patients undergoing lower limb amputation.
Mortality after amputation is very high in the dysvascular population. 30 day mortality after amputation is 8-10%.\textsuperscript{14, 46, 47} 1 year survival is 60-70% and 5 year survival is 35% following amputation due to vascular disease.\textsuperscript{46, 48}

A cohort study by Stone\textsuperscript{49} retrospectively evaluated 380 patients (median age 67 years) following recovery from 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). 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;\textsuperscript{50} in 229 patients (average age 68.8 years) who required amputation (transtibial (n=119), transfemoral (n=177)), a significant difference in revision of the original amputation was seen in the group with a transtibial amputation (P> 0.0001).

Morse\textsuperscript{51} (n=50) and Kock\textsuperscript{52} (n=66) both studied retrospective cohorts of patients who had undergone knee disarticulation due to PAD. The patients in the study by Morse\textsuperscript{51} had a modified Mazet technique, while patients in the study by Kock\textsuperscript{52} had a dorsal gastrocnemius muscle flap to close the wound. The results were comparable. In the Morse cohort 3 patients died (6%) as a result of surgery, 9 patients (19%) required revision to a transfemoral amputation due to delayed healing and 41 patients (81%) showed good wound healing. In the cohort studied by Kock\textsuperscript{52} 6 patients died perioperatively (9%), 9 patients (13%) required revision amputation surgery up to the hip, and 6 patients (9%) needed an additional operation on soft tissue. Wound healing was successful in 48 patients (80%).

Nehler\textsuperscript{14} studied a cohort of 154 patients (median age 62 years) who had one or more amputation(s) (transfemoral amputation (n=78), transtibial amputation (n=94)). Reasons for exclusion were non-ambulatory, dementia, or neurologic disorders. The results showed a perioperative mortality of 10%. 57 revision surgeries were required (transtibial amputation (n=23); transfemoral amputation (n=16); transfemoral reamputation in 18 patients (19%)).

Campbell\textsuperscript{53} retrospectively studied a cohort of 312 patients with one or more lower extremity amputation(s) (transfemoral amputation (n=192); transfemoral, n=122; Gritti-Stokes, n=34; hip disarticulation, n=1). 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 showed that the transfemoral group had the highest revision percentage (19%), and perioperative mortality was highest in the groups that required transfemoral or Gritti-Stokes amputation (both 24%).

Johannesson\textsuperscript{54} prospectively followed 190 patients undergoing lower extremity amputation over a period of 4 years. The results showed that 27 patients died within one month of surgery, 24 patients required reamputation (16 transfemoral, 8 transtibial), and 5 patients with transfemoral amputation, required reamputation twice.

Certain comorbid conditions increase risk. Perioperative sepsis, congestive heart failure, renal failure and liver disease were associated with higher mortality in hospital, at 30 days and at 1 year.\textsuperscript{46, 55} 1 year and 5 year survival was found to be comparable in patients with diabetes (69.4% and 30.9% survival at 1 and 5 years), but much worse in patients with either end-stage renal disease (51.9% and 14.4% survival at 1 and 5 years) or renal insufficiency.
(55.9% and 19.4% at 1 and 5 years).\textsuperscript{46} Patients with renal insufficiency were also more likely to undergo repeat amputation within 30 days.\textsuperscript{56}

Higher level of amputation is also associated with increased mortality. Mortality from in hospital to 5 years is higher for those with transfemoral compared to transtibial amputation.\textsuperscript{46, 55} 1 year survival was 75\% in persons with transtibial compared to 50\% with transfemoral amputation. 5 year survival was 38\% with transtibial level amputation compared to 23\% with transfemoral amputation.\textsuperscript{46}

Given the high mortality after amputation due to vascular disease, it is important to identify appropriate interventions and rehabilitation goals to improve mobility, independence and quality of life early following amputation. Delayed wound healing will mean more time spent in the hospital, more medical appointments, and greater burden of care over many months. It is important to discuss prognosis and realistic goals with the patient and their family to avoid a prolonged period trying to heal a distal amputation or attempting prosthetic rehabilitation, if they are unlikely to be a functional prosthetic user. Some may be better served by a more proximal amputation, successful healing, and wheelchair mobility.

**Postoperative Management in the Immediate Postoperative Period (Up to Three Days) and Early Rehabilitation**

**Guideline #3.1:** The benefits of soft dressings are ease of application, low cost and easy access to the wound. The drawbacks include: they become loose and fall off; they do not prevent joint contracture; they cause risk of a “choke” of the distal residual limb if too much compression is applied proximally and they do not protect the limb in the event of a fall.

**Updated Evidence:** 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.\textsuperscript{57, 58}

Different kinds of soft or compressive dressings include self-adherent compressive bandage, figure of 8 compressive wrap, and a postoperative prosthetic sock with a garter belt suspension.

Known disadvantages are the experience required (in application of the dressing) by the persons applying the dressing, the high local or proximally generated pressures that may negatively affect healing, the required frequency (4 to 6 times daily) of application, the tendency of the dressings to loosen and sag and the limited protection of the amputation stump.\textsuperscript{57, 58} A number of these disadvantages can be overcome by the use of elastic compression socks (stump shrinkers), or silicone liners when tolerated. No comparative studies were found on this subject. The treatment team’s experience with a particular method is of obvious importance.\textsuperscript{58}

**Guideline #3.2:** Rigid dressings can be applied to the residual limb in the postoperative period to help optimize wound healing, control edema, shape the residual limb, prevent contracture, protect the limb and control pain.

**Updated Evidence:** There are different types of dressings that can be applied to the...
residual limb in the postoperative period to help protect the limb and control edema. For
transfemoral amputations, typically soft dressings are used.

The effect of a rigid stump dressing was first described by Pieter Verduyn Adriaansz in 1696:
"Nouvelle method amputer pour les membres." 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 5 days and 3
weeks.

There is a considerable body of evidence in the literature in favor of rigid dressings applied
directly after the amputation. Advantages of rigid dressings include edema management
prevention of contracture, and protection in case of a fall. The use of a rigid removable dressing
is thought to facilitate early mobilization. A randomized controlled study by Traballesi showed that the use of a vacuum-assisted socket system allowed early fitting. The benefits of a
non-removable rigid dressing are that they help to control edema, protect the limb from
trauma, prevent knee flexion contracture, reduce pain, and increase tolerance to weight-bearing. The drawbacks of a non-removable plaster cast are that it requires weekly
application by a skilled professional, prevents monitoring of the wound and is heavier and
more costly than a soft dressing.

A nonremovable rigid dressing allows the attachment of an immediate (or early)
postoperative prosthesis, which includes a connector, pylon and foot. The pylon cast has
been purported to allow patients with transfemoral amputations the opportunity for early
ambulation without increased complications compared with other postoperative
dressings. At the transfemoral level, a locking knee is used in the early postoperative
provisional prosthesis to avoid excess motion and shearing along the surgical incision.

The impact of early weight-bearing on wound healing is unclear. Potential complications
include tissue necrosis if incorrectly applied and mechanical tissue trauma inside the cast.
Despite a pylon cast, patients were mostly sedentary and had a low quality of life in the first
six weeks after transtibial amputation.

A rigid removable dressing can be taken off to monitor the incision and is less heavy and
costly than a non-removable rigid dressing. Studies of rigid dressings show that they
decrease time to prosthetic fitting compared to other management. The comparison
between a rigid removable dressing (RRD) and an elastic bandage on the reduction of stump
volume was investigated by Janchai. A clear but non-significant trend (p =0.064) was
observed in favour of the RRD, but only in the first 2 weeks of use. This difference disappeared
completely in the following two weeks. These findings are also supported by the systematic
review by Nawijn which further notes that most studies were particularly weak in terms of
patient numbers.

Before initiating any type of dressing, the team should be well prepared and trained. Before
switching to using rigid dressings for postoperative management, all logistical obstacles should
be overcome. If there is a lack of experience, choose the easiest method with least risk of
complication. With transfemoral level amputation, rigid stump dressings can be challenging (incontinence, suspension). Postoperative management with light elastic bandages or stump socks may be preferable.

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 in 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. Thus far, this pain-reducing effect has not been demonstrated.

The working group recommends a rigid dressing as the treatment of choice during the early postoperative phase for persons with transtibial or knee disarticulation level amputations. After using a rigid dressing, compression is used to shape the limb prior to prosthetic fitting. Different methods are used around the world (elastic bandage, socks within RRD, compression garments or liners) with very little or no scientific evidence.

**Guideline #3.3:** Patients should be educated about stretching and positioning to avoid joint contracture.

**Updated Evidence:** Education is provided to optimize positioning; to avoid contracture or dependent edema; review mobility, balance training, and safety. Maintaining 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. A rigid nonremovable dressing (extending above the knee) can prevent knee flexion contracture. (Expert opinion of working group)

To prevent hip flexion contracture, patients are educated to spend time prone with a pillow or towel under the anterior thigh (if tolerated). Knee flexion contractures can be prevented by using an elevated leg rest on the wheelchair, a residual limb support, and by educating the patient in proper positioning (avoid lying supine with a pillow under the knee). Although the focus is usually on the amputated side, attention should also be paid to the contralateral side. 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 immobilization phase.

**The Rehabilitation Process from Amputation to Initial Prosthetic Management**

**Guideline#4.1:** Treatment should be consistent, consistently implemented, and follow a set framework or care plan. Information is a vital part of any medical treatment. Any information must be tailored to the specific needs of the individual and included in their medical record.

**Updated Evidence:** The main objective in the period from amputation to initial prosthetic fitting is to focus on recovery from the surgery, achieve medical stability, prevent complications and optimize mobility. This includes pain management, surgical site management, residual limb management (edema control, strengthening, and range of motion), psychological support, therapy, and care of the contralateral limb.

Objectives should be suited to the future needs of the patient. Discussions should take place not
only in the presence of the patient, but also with the involvement of family members and other caregivers.

Information for patients (electronic, oral, or written) and those directly involved in the patient’s care is an essential component in the treatment of patients undergoing lower extremity amputation. As treatment involves multiple disciplines, it is advisable that items discussed are recorded in a manner that is clear to all disciplines. Information resources should be developed at the local level. (Expert opinion of working group)

The relationship between shared decision-making and evidence-based practice is becoming increasingly recognized. Shared decision-making provides a process for bringing evidence into the consultation and incorporating it into discussions with the patient, along with discussions about the patient’s values and preferences. Shared decision-making may also help reduce the unwarranted variation in care.

To optimize the rehabilitation process, the team will determine the patients’ perioperative function, sock management, the importance of monitoring their skin, the impact of weight change on prosthetic fit, nutritional status (ideally a dietician will help optimize nutrition status), strength, range of motion (quality of the musculoskeletal system), daily living activities, adjustment to their impairment, and social situation.

Verbal education and printed materials are provided by various members of the rehabilitation team throughout the hospital stay. Education includes adjusting/adaptation to limb loss, optimizing functional mobility (bed mobility, wheelchair mobility, ambulation, and transfers), optimizing daily living skills, obtaining appropriate adaptive and durable medical equipment, caregiver support, communication with other care providers, decision-making on health risks, optimizing care options (including prosthetic fitting, prosthetic adjustments, prosthetic training, cardiovascular conditioning, risk factor prevention, and accessing emergency care if necessary).

The person with limb loss and their family are instructed in measures to avoid further limb loss, risk factors with the use of a prosthesis, fall prevention and management, home modifications, home safety, energy conservation, and expenditure. Also addressed is the importance of follow up to prevent complications, information about consumer groups, and peer support including how to access them. Assistance in locating and accessing appropriate resources in local communities for self-advocacy, financial assistance, emotional support, and support groups are provided with phone numbers and numbers of contact persons, and documented in the medical record.

In the perioperative period, the team works with social services to develop and implement the discharge plan including follow-up clinical care services and interventions that address the use of financial resources, equipment, and community support as indicated by individual patient’s needs.

Verbal information should be supported in other formats, as patients and their relatives (and other parties involved) often do not hear and/or remember everything. The format (oral, digital, leaflets) in which the information is provided will need to be tailored to the patient.

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.

The discharge summary includes an acute medical history, rehabilitation medical history, description of the rehabilitation course, and ongoing care needs. The discharge summary also outlines the plan for community-based services (pedorthotic services, foot care, health or behavioral issues that require follow up). The discharge summary is reviewed by the patient and their family/support system. In addition, a copy of the discharge summary is sent to the primary physician as designated by the patient or the healthcare facility to which the patient transitions. The discharge plan is updated throughout the course of the patient’s stay and is reassessed frequently to ensure that the patient’s continuing care needs are identified. The following factors are assessed: the patient’s ability to return to their previous level of functioning; identification of resources previously used or those necessary to facilitate continuity of care; social/family support; medical needs. The discharge plan is documented in the medical record including patient assessment data and a plan for continuing care.

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. Developing 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.

**Guideline #4.2:** Intensive therapy following lower extremity amputation improves function.

**Updated Evidence:** An intensive physical therapy program for patients with a lower extremity amputation results in better load-bearing capacity and an improved 2-minute walk test, in comparison with a less intensive treatment program. Patients who receive inpatient rehabilitation after lower extremity amputation have a better 1-year survival rate, greater success with prosthesis fitting, and are more likely to return home than patients not receiving inpatient rehabilitation. There is evidence that patients in a clinical rehabilitation program are more likely to return home than patients who receive routine care.

An analysis of changes over time showed that in the course of a 12-year study, the use of inpatient rehabilitation showed substantial growth (skilled nursing facilities, 31% in 1986 to 55% in 1997; rehabilitation facilities, 2% in 1986 to 13% in 1997). Other research shows roughly the same numbers regarding discharge to rehabilitation facilities (16%) and skilled nursing facilities (32%). Patients who were discharged to a skilled nursing facility 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 facility compared with patients discharged to a skilled nursing facility for further rehabilitation. Patients referred to rehabilitation facilities were more likely to have diabetes. Research from the Netherlands shows that 86% of patients referred to a rehabilitation facility returned home after completion of the rehabilitation program. (Dutch Guideline 2012).

In a multicentre study of rehabilitation after amputation of a lower limb in nursing homes in the Netherlands, 65% of the patients were discharged to independent living, and 50% of patients were successfully fit 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 (as opposed to transfemoral) level amputation.
Following lower limb amputation, discharge planning should be based on the degree of function, social situation, and the patient’s health.

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 lower extremity amputation. 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 prescriptions were 73%, 58% and 49%, respectively. Although nursing home patients were older, they did not show greater comorbidity. A retrospective study by the U.S. Veterans Administration compared specialized rehabilitation with rehabilitation on general surgical wards for 1339 veterans. 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). Another 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) than did those who received no rehabilitation. An additional study showed that persons with amputation who received specialized rehabilitation had motor FIM gains that were on average 8.0 points greater than those who received consultative rehabilitation. It was suggested that those receiving specialized rehabilitation can be expected to make comparatively greater gains, regardless of timing and clinical complexity. A certain degree of bias is present in these studies because groups of patients were selected on the basis of their degree of functioning.

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 too early to see possible improvements.

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. 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.

Specific attention should be paid to hip strengthening training. In a twice weekly hip strengthening program, the training group increased hip strength and decreased oxygen consumption compared to a control group, who continued their usual activities. Hip strength was reduced in the group not following the training program. Another study showed improvement of functional performance and balance confidence following intense hip abductor strength training during an 8-week program of twice weekly hip abductor strength training or arm ergometry.
**Guideline #4.3:** While in the hospital, the multidisciplinary rehabilitation team determines the discharge destination for a patient with lower limb amputation based on the expected degree of functioning, social situation, and medical comorbidities.

**Updated Evidence:** Another important perioperative goal is to ensure that the patient can adequately function in their home with or without a prosthesis on discharge. This should include evaluation for adaptive and durable medical equipment needs. If the patient cannot safely function in their home environment after amputation, discharge to a rehabilitation setting is necessary.

In addition to the patient’s functional ability, the home setup, caregivers, and support network are of great importance. The rehabilitation consultant will attempt to optimize the patient’s achievable level of function. This depends on both the amputation level and premorbid function.26

A final discharge destination is determined, usually in a multidisciplinary consultation. A large population-based study in the U.S.88 showed that 41% of patients with vascular disease requiring amputation are discharged to their homes, 37% to a skilled nursing facility, and 10% to a rehabilitation facility.

**Guideline #4.4:** Following amputation, a patient needs to adapt to an altered body, postoperative management (possibly a prosthesis), and an altered future.

**Updated Evidence:** The most frequently described psychological adjustment issues are mood disorders and anxiety. In the course of rehabilitation, the adaptation process and the psychological aspects that are associated with it need to be considered. The working group recommends a psychologist and/or social worker be part of the rehabilitation team for both the diagnosis and treatment of patients undergoing amputation.

Concern may arise due to altered self-esteem and body image. The impact on quality of life has been described in several studies, including treatment of mental health problems, lack of social support, adjusting to a new situation, and change of body image. These studies describe the influence of coping on the process of adjustment and, in a few cases, the role the prosthesis plays in the process. Social support positively influences the adjustment process.89-93

The working group believes that optimal learning methods, coping styles, and skills should be determined in the diagnosis phase and reassessed during the course of rehabilitation.

Cognitive decline reduces the chance of successful rehabilitation.94 Cognitive impairment appears to be more prevalent among persons with lower limb amputations than in the general population and is negatively associated with mobility, prosthetic use, and maintaining of independence following amputation.95 Cognitive screening prior to rehabilitation could assist in determining patients’ suitability for a prosthesis versus wheelchair use and decision making for a specific rehabilitation program.95

**Guideline #4.5:** Return to work following lower extremity amputation due to vascular disease
Updated Evidence: Although the majority of patients with an amputation due to vascular disease have reached retirement age, there are patients who are of working age at the time of amputation. The literature on return to work following amputation is based largely on patients with amputations due to trauma and tumor. The working group examined factors that play a role in return to work and formulated recommendations that may aid in promoting return to work. If the rehabilitation team does not promote return to work, in whatever form, from early in the process, it may inhibit the patients return to work. The worksite physician should be involved in the rehabilitation process as possible.

The literature indicates that a large proportion of individuals who undergo lower extremity amputation return to work. One year after the amputation, 42% of have resumed work, and after more than one year 58-79% have returned to work or have stopped working for reasons unrelated to the amputation. A subset of patients (approximately 30%) required adjustments in their work situation to return to work.

Residual limb problems and/or wound healing were the main reasons for a delay in return to work in a Dutch retrospective study of 32 patients. Poor support to adjust work responsibilities by the reintegration agency or employer prevented return to work in 34%.

Of working patients, 60-80% resumed work after lower extremity amputation. A higher amputation level results in a poorer prognosis for return to work. Comorbidities, amputation due to vascular disease, age greater than 40 at the time of amputation, poor prosthetic fit, and limited education, all negatively affect return to work. Phantom pain may negatively impact return to work. In physically demanding work, the ability to change jobs or the type of work has a positive effect on successful work reintegration.

The demands of a patient’s workplace should be taken into account when prescribing a prosthesis.

Pain Management Following Amputation

Guideline 5.1: In addition to physical limitations, pain plays a major role (both stump pain and phantom pain) in determining the quality of life. (Dutch Guideline 2012).

Updated Evidence: Careful consideration of several patient factors can improve success in medical therapy for phantom and postoperative pain. The patient’s medical comorbidities should be considered. Limiting factors such as pulmonary, cardiovascular, renal, or hepatic impairment should be identified as these may influence medication choice.

Patients who undergo an amputation will experience moderate to severe acute postoperative pain. In addition to oral and intravenous medications in the treatment of acute postoperative pain, epidural or perineural pain control may also be used.

In addition to acute pain following amputation, a considerable number of patients develop chronic pain syndromes. Phantom pain, experienced as painful sensations in the amputated limb, is a neuropathic pain syndrome probably caused by central and peripheral neural mechanisms. There is no evidence for prevention of phantom pain. Pharmacologic treatment, psychologic treatment, positioning, and postoperative dressings are important in the management of pain.
Epidural or perineural administration of bupivacaine, compared with placebo, has no significant effect on the intensity or incidence of stump and phantom pain in the early perioperative period up to six months and long-term (12 months). The methods used are effective in treating acute postoperative pain. The working group believes epidural treatment has a place in the perioperative management of pain.

Anticonvulsants are often used in the treatment of neuropathic pain. Compared with placebo, gabapentin has no effect on the incidence and intensity of stump and phantom pain in the perioperative period up to 6 months. Perioperative administration of gabapentin appeared to have no effect on the incidence of phantom pain and chronic stump pain. In a recent Cochrane Review, these agents showed no benefit in the relief of phantom limb pain. In a small study by Bone, gabapentin may have shown an effect on longstanding phantom pain. Pregabalin’s mechanism of action is similar to gabapentin. No studies were found on the effect of pregabalin on phantom pain and chronic stump pain.

Amitriptyline and nortriptyline have been shown to be effective against neuropathic pain. Their role in the treatment of phantom pain has been poorly investigated. A study by Wilder-Smith suggested that, in addition to tramadol, amitriptyline may be effective in patients with phantom pain.

A randomized double-blinded pilot study Wu showed that both Botox and Lidocaine/Depo-Medrol injected intramuscularly and subcutaneously at local tender points resulted in immediate improvement of residual limb pain (not phantom limb pain) and pain tolerance, which lasted for 6 months in persons with amputation who failed conventional treatments.

Ketamine (epidural or intravenous), compared with placebo, has no significant effect on the incidence and intensity of stump and phantom pain in the perioperative period up to 6 months and long-term (12 months). Due to neurotoxicity, epidural infusion of ketamine cannot be recommended.

While pain following amputation can prove difficult to treat, there are a variety of therapeutic options including behavioral therapies, physical modalities, topical and oral medications, and implantable devices. Medication side effects can be a barrier to treatment success. A frank conversation discussing common or serious side effects should be performed prior to starting a new treatment. Many of the treatment side effects can be improved over time due to progressive tolerance. Each medication should be maintained at the lowest effective dose. Topical medications, behavioral strategies, and physical modalities can be particularly beneficial in combination with other treatments due to their negligible side effect profiles.

Specialized modalities used in chronic pain management fall outside of the scope of this guideline.

Pain research has shown that cognitive behavioral therapy is effective in the perioperative period. Third generation behavioral therapy (Acceptance and Commitment Therapy (ACT) and Mindfulness) also appear to be prominently seen and indicate that future research into these treatment methods is necessary.

Prosthetic Prescription Following Lower Extremity Amputation due to Vascular Disease
**Guideline #6.1:** Ideally, a prescription should be generated with a multidisciplinary team including a physician familiar with rehabilitation requirements, a prosthetist, and a physical therapist.

**Updated Evidence:** Clinical experience and component availability play an important role in determining an appropriate prescription and may lead to local variations. A clear evidence-based rationale cannot always be given for the components chosen. The working group recommends that prosthetic fitting start as soon as possible after the incision has healed.

When prescribing an initial prosthesis, a multidisciplinary approach is optimal (although this may not be necessary for subsequent prostheses). New technology is constantly being introduced that promises improved function but often at a higher cost. Research focused on quantifying a cost benefit ratio could be a great aid for prescription practices aimed at cost savings. The large number of available components and technical developments mean that knowledge of the properties and the possibilities for patient performance cannot rest with a single discipline. Cooperation and dialogue between different disciplines (rehabilitation physician, prosthetist and therapist) is of great importance.

Prescribing a prosthesis is a process which involves assessment, production, delivery and evaluation of a prosthetic leg. Prescription and fitting processes vary significantly between countries. The way national public health insurances are organized also influence the processes and available choices.

When determining patient characteristics for a prosthetic prescription, a hierarchical order is maintained and the terminology used is derived from the ‘International Classification of Functioning, Disability and Health’ (ICF). The priority is to review the function and anatomical characteristics of the patient (amputation level and residual limb characteristics). Function and especially the expected mobility level with a prosthesis, being of particular importance.

The most fundamental question when developing a prosthetic prescription is the patient’s need and their ability to utilize the prosthesis. The key point is the anticipated level of mobility with a prosthesis is the guiding factor in the choice of prosthetic components.

Different healthcare systems have developed protocols and processes that attempt to increase transparency and objectivity for prosthetic management. An example of a centralized process is the Dutch Protocol (prescription process for leg prosthetics). Central to this process is the formulation of the anticipated activity based on anatomic characteristics, activity and participation; the various domains within the international classification of functioning, disability, and health (ICF). The protocol aims to provide a guideline for the minimum and to support a clear justification for the prosthetic prescription and component selection with maximum transparency for all parties, including the health insurer and the patient. Some healthcare systems provide clear indications for specific components. Others request documented and outcome-based justification of an individual fitting attempt. Choosing between various prosthetic components should be based on reliable evidence-based information on the characteristics of these components.
If the decision is made to prescribe a prosthesis, details of the prosthetic prescription including socket design, suspension, interface, pylon, knee, and foot components (with input from the prosthetist and the patient) is provided.

Prosthetic training should be arranged when the initial prosthesis is prescribed. Options include outpatient physical therapy, subacute rehabilitation, or inpatient rehabilitation. Once the prosthesis is fabricated, the physiatrist will often evaluate the fit and quality of the limb before or during prosthetic training. A well-fitting prosthesis with appropriate components, supervised training, and ongoing follow-up optimizes prosthetic use and function.

A patient must understand that successful prosthetic rehabilitation is a prerequisite for optimal performance. A state-of-the-art prosthesis will not provide optimal performance to a user who is not physically capable of taking advantage of its features. Conversely, optimal performance will not be achieved with a prosthesis that does not provide a level of technical sophistication that matches or challenges the user’s physical capabilities.

There are significant limitations of the objective clinical knowledge available on the impact of different prosthetic components on performance with a prosthetic leg. Further, it is challenging to predict an individual’s response to a specific component on clinical variables alone. Therefore, empiric knowledge and individual judgement remain indispensable to determine the appropriate prosthetic prescription. The measurement and documentation of clinical performance is recommended.

Choosing between the various components of 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 and functional quality of a prosthesis should be primarily based on clinical and biomechanical research. It is therefore recommended that prosthetic components be tested in clinical trials before they come to market. This requires good collaboration between clinicians, research centres, manufacturers and suppliers. The use of clinically evaluated systems is recommended.

**Guideline #6.2:** 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 than a conventional supracondylar socket suspension.\(^{127}\)

**Updated Evidence:** The socket is where the prosthesis and the body connect. It is the most critical element in prosthetic design.

Unlike the plantar tissues of the intact foot, residual limb soft tissues are not accustom to bearing loads.\(^{128}\) Loads imparted on the residual limb by the prosthetic socket can cause wounds and other skin conditions. This is problematic as treatment may require stopping the use of the prosthesis. To help cushion the transfer of load between the prosthetic socket and residual limb, soft prosthetic liners have been used. Historically, liners were made from open and closed cell foams.\(^{129}\) Recently, silicone and other elastomers that roll onto the residual limb have been used. Some have felt the roll-on liners offer better suspension, durability, and cushioning than foam.\(^{130}\)

Many liners exist on the market.\(^{131}\) The clinician choses a particular liner based on product
literature, colleague recommendations, and/or prior experience. There is a growing desire in the prosthetic field to include scientific evidence when making prescription decisions. A survey was obtained from a small number of individuals with lower extremity amputation to compare silicone and Pelite liners. Some preferred the silicone liner because it distributed pressures differently and had a close connection between the liner and socket. Others rejected the silicone liner for the same reasons. The difference between mineral oil gel liners with locking pin suspension and Pelite liners with neoprene sleeve suspension were evaluated in a randomized controlled trial with 13 subjects. The study found that 77% of the subjects preferred the Pelite system, took 83% more steps and wore the system six hours per day longer than the gel liner. When interviewed, subjects expressed advantages and disadvantages of both systems. Both systems performed similarly in terms of pain and comfort.

In a randomized crossover trial that involved 13 individuals with traumatic amputations, Coleman et al. found that more steps were taken at a higher intensity with a liner with a pin lock than with a Pelite liner. However, there was no difference in comfort or satisfaction with the prostheses. In a Dutch RCT involving 36 patients with transtibial amputation, no differences were found in the outcomes ‘prosthetic function’ and ‘satisfaction’ when comparing a total surface bearing socket (TSB) or a conventional patellar-tendon bearing (PTB) socket. Although TSB production is more expensive, PTB sockets require more hours to fit. As a result, the cost (from a Dutch perspective) is similar for both sockets.

Prosthetists’ expertise suggests that total contact sockets with proximal ischial or ramus containment elements have significant improvements in both biomechanical and clinical outcomes. Stabilization in the sagittal and frontal plane lead to improved gait (including reduced compensational trunk movements) and relief of the residual bony structures. The reduction of force on the medial soft tissue areas (the adductor muscles, the adductor tendon, or the anterior Scarpa triangle) prevents excess force (that can lead to wounds and soft tissue infection) and enhances blood and lymph circulation.

*Guideline #6.3:* Patients with a transfemoral amputation using a microprocessor knee, are better able to walk down a slope.

*Updated Evidence:* Microprocessor controlled knee components have been investigated over the last decade. Independent systematic reviews by Samuellson, et al., Highsmith, et al., suggest that hydraulic microprocessor knees (MPKs) are associated with improved patient satisfaction, safety, energy consumption, and are cost effective. A systematic review by Kannenberg, et al., concludes that the benefits of a MPK are also apparent with subjects of limited mobility. As MPKs vary in type, different designs maybe associated with different effects. A systematic review by Sawyers, et al., found moderate evidence of improved confidence, mobility, and decreased cognitive demands. They also concluded that no evidence could be found where non-microprocessor knees were associated with clinical advantages over MPKs. Larger observational studies suggest that the benefits of the MPK are not limited by age, mobility grade, etiology, BMI, and other clinical variables.

*Guideline #6.4:* Persons with transtibial level amputation due to trauma walk at a higher speed with an energy-storing (dynamic response) foot. No study was found in which a difference in patient satisfaction was reported with regard to a specific prosthetic foot.
**Updated Evidence:** In a Cochrane Review on the effectiveness of ankle foot mechanisms, Hofstad, et al., concluded that in transtibial amputations, there appears to be greater stride length with a dynamic response foot in comparison with a conventional fixed prosthetic foot. At high activity levels, there also seems to be a better gait efficiency.\(^{147}\)

Hydraulic and microprocessor controlled feet (MPF) have recently become available in some countries. Such devices are associated with a reduction of internal stress of the amputated limb\(^{148}\) and optimize pressure distribution at the residual limb.\(^{149}\) They are also associated with an increase in minimal toe clearance\(^{150},^{151}\) which may contribute to a reduction in the risk of falling. Patients report feeling safer during ramp descent.\(^{152}\)

**Guideline #6.5:** By using a small pump to create a vacuum a more consistent environment of negative pressure is produced by drawing the skin and soft tissues to the wall of the socket. Conceptually by maintaining a constant limb volume control throughout the day, there is no longer a need for stump socks. Board and colleagues found that positive pressures during stance phase were significantly lower and negative pressure during swing phase were significantly greater with the vacuum-assisted socket system (VASS).\(^{153}\)

**Updated Evidence:** Residual volume stability varies among amputees. Some people have little change in volume whereas others have significant fluctuations during the course of the day. Designing a socket shape and method of suspension for the potential short- and long-term changes in residual limb volume has long been a challenge for prosthetists.

Kahle, et al.,\(^{154}\) conclude in their systematic review that the strongest evidence supporting the clinical outcomes of VASS is residual limb physiology. The mechanical principles of VASS applied to prosthetic use may have physiological and functional merit. Applying the associated principles to prosthetic design may create alternative interface design configurations for both the transtibial amputees and the transfemoral amputees.

Samitier, et al.,\(^{155}\) evaluated 16 individuals with transtibial amputation due to vascular disease and assessed changes in mobility, balance, risk of falling and satisfaction. Significant improvements were found in TUG, six minute walk test, four square step tests and Berg Balance scale. The authors concluded that vacuum-assisted socket systems are useful for improving balance, gait, and transfers in those with transtibial amputation due to vascular disease over the age of 50.

**Guideline #6.6:** Psychosocial consequences of a prosthetic prescription

**Updated Evidence:** Schaffalitzky\(^{156}\) stresses the importance of psychosocial outcomes in prosthesis prescription and use. Psychosocial outcomes are as important as physical outcomes. It is concluded that only limited improvement in physical capabilities may provide important gains in independence.


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136. Samuellson. Controlled knee components (MPKs) are associated with improved patient satisfaction 2012.


33