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Dutch evidence-based guidelines for amputation and prosthetics of the lower extremity: Rehabilitation process and prosthetics. Part 2

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Abstract

Background: A structured, multidisciplinary approach in the rehabilitation process after amputation is needed that includes a greater focus on the involvement of both (para)medics and prosthetists. There is considerable variation in prosthetic prescription concerning the moment of initial prosthesis fitting and the use of replacement parts.
Objectives: To produce an evidence-based guideline for the amputation and prosthetics of the lower extremities. This guideline provides recommendations in support of daily practice and is based on the results of scientific research and further discussions focussed on establishing good medical practice. Part 2 focuses on rehabilitation process and prosthetics.
Study design: Systematic literature design.
Methods: Literature search in five databases and quality assessment on the basis of evidence-based guideline development.
Results: An evidence-based multidisciplinary guideline on amputation and prosthetics of the lower extremity.
Conclusion: The best care (in general) for patients undergoing amputation of a lower extremity is presented and discussed. This part of the guideline provides recommendations for treatment and reintegration of patients undergoing amputation of a lower extremity and can be used to provide patient information.

Clinical relevance

This guideline provides recommendations in support of daily practice and is based on the results of scientific research and further discussions focussed on establishing good medical practice.

Keywords

Rehabilitation, prosthesis

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Background

In this Part 2 of the Dutch evidence-based guidelines for amputation and prosthetics of the lower extremity, the focus will be on the rehabilitation process including psychosocial aspects, rehabilitation factors and training goals, return to work, prosthetic provision and components and other considerations.

Rehabilitation process

Rehabilitation in the amputation patient includes the following: 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, healthcare 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:

- Preoperative level of function of the patient;
- Nutritional status of the patient;
- Quality of the musculoskeletal system;
- Psychological state of the patient;
- Social situation of the patient;
- Extent to which the patient has been informed about the rehabilitation process.

After the operation, a consultation with the rehabilitation physician, the physiotherapist and healthcare 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 skilled nursing facility (SNF; 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, co-morbidity, 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 specialist rehabilitation treatment in a rehabilitation centre or hospital is preferable to treatment in an SNF, assuming that the patient has an adequate capacity for learning and training. Of the 153 published articles assessed in full-text after selection, only 11 articles in total were included to substantiate the text.[1–11]

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 randomised controlled trials (RCTs) and two other articles mentioned the results of (other) RCTs.

In a Cochrane Review by Cumming et al.,[1] RCTs up to October 2008 were summarised in which the effectiveness of rehabilitation interventions was investigated in patients who underwent transfemoral amputation (TFA) or knee-disarticulation (KD). Only one RCT[2] 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-min-walk test between the three amputation level groups.[1]

In an RCT of 58 patients who underwent a leg amputation, Rau et al. investigated the effect of an intense physical therapy programme. In this RCT, unblinded for caregivers and patients but otherwise well-designed, improvements were found in the 2-min walk test and the maximum tolerated weight on the prosthesis.[3] 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.[4] In a retrospective study of the Medicare Claims Database in the United States, the discharge destination that yielded the best results after amputation was examined for 2468 elderly patients who underwent an amputation of a lower extremity. The 1-year survival was highest in patients discharged to a rehabilitation centre (75%), followed by a SNF (63%) and to home (51%). The percentages for successful prosthetic prescription were 73%, 58% and 49%, respectively. Although SNF patients were older, they did not show greater co-morbidity.[5] In a retrospective study by the US 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%) were better in a specialised rehabilitation setting ($p < 0.0001$ for all comparisons).[6] The final retrospective study from the United States involved 2673 patients from the Veterans Administration who underwent TFA. After adjustment for

prognostic differences, the 1-year survival of those in acute inpatient rehabilitation (in an integrated care system) (odds ratio (OR) 1.9, confidence interval (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.[7] 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 Activities 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.[8] In a small observational study of 60 patients who underwent a transtibial amputation (TTA), 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.[9] 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.[10]

In a historical cohort study, patients with a TTA or TFA 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 co-morbidity in the group in the clinical programme, a larger percentage returned home (17% vs 12%) and fewer patients entered a long-stay SNF.[11] There is no scientific basis for how optimal rehabilitation process can be organised for patients following an amputation of a lower extremity.

An intensive physical therapy programme for patients with a leg amputation seems to result in a better load-bearing capacity and an improved 2-min walk test, in comparison with a conventional, less intensive treatment programme (Level 3).

Patients who received inpatient rehabilitation after amputation of a (lower)leg 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 (Level 2).

There is evidence that patients in a clinical rehabilitation programme more often return home than patients who receive routine care (Level 3).

The discharge destination of a patient with a leg 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 (Level 4).

Psychosocial aspects

Patients who have undergone amputation will have to adapt to an 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.[12] A total of 24 studies were used to support the recommendations, including one review[13] and 23 observational studies.[14–36] 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’,[30] 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 and sense of self-esteem only rarely.[31–36]

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 (Level 3).

Social support seems to positively influence the adjustment process (Level 3).

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 (Level 4).

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 and Mindfulness), indicating that further research into these two treatment methods is necessary (Level 4).

The working group considers that a healthcare psychologist and/or social worker should be part of the rehabilitation team for both the diagnosis and the treatment of patients undergoing amputation (Level 4).

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 programmes 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; and information on maintaining mobility.
2. *Muscle strength training*: measuring force to upper and lower extremities.
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 activities of daily living (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 extremity 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 programme 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 focussing 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 focussed 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*.

Lower extremity amputation and work

Although the majority of patients with an amputation have 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 part is based relates largely to trauma and oncology patients. This means that, in principle, these patients will still have a healthy body and 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. A search was conducted for articles that reported percentages of amputees returning to work and the factors responsible. In total, 61 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.[9,37–45] The scientific literature indicates that a large proportion of the patients who undergo an amputation of a lower extremity return to work. One year after the amputation, 42% of the patients have resumed work,[37] and after more than 1 year, 58%–79% of patients have returned to work or have again stopped working for reasons unrelated to the amputation (e.g. pension).[37–41] A subset of patients (approximately 30%) requires some adjustment in the work situation.[42]

Of working patients, around 60%–80% resumes work after amputation of a lower extremity. Some of these patients do not or stop after a short time for reasons unrelated to the amputation, such as retirement (Level 2).

In a cross-sectional study of 322 patients in the Netherlands who, on average, had undergone a leg amputation 17 years previously, multivariate analysis showed the following factors to be predictive of a return to work: co-morbidity, age at the time of amputation (>40 years less favourable), comfort when wearing the prosthesis and the educational level of the amputee. 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.[39]

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.[38]

In a retrospective study of amputees 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 h a day were found to have more phantom pain than patients who used their prosthesis for 9–16 h a day ($p = 0.001$).[43]

A retrospective study of 88 Canadian amputees 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) and number of surgical procedures (the more, the longer).[41]

In a non-systematic review, the level of amputation, multiple amputations, co-morbidity, reason for amputation, stump problems and phantom pain were identified as prognostic factors for resumption of work.[44]

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%.[45]

There are indications that a higher amputation level leads to a poorer prognosis for a return to work (Level 3).

There are indications that co-morbidity, 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 the return to work (Level 3).

There are indications that phantom pain negatively affects the return to work because prosthesis use is lower with more severe phantom pain (Level 3).

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 (Level 3).

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 realise as rapid a return to work as possible, it is important that this be taken into account during the first prosthetic prescription.[38] Advice regarding choice of vocational or professional training may be necessary and possibly also career advice, if the patient is a jobseeker.

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 (all Level 4).

Prosthetic provision

It is normal practice in the Netherlands that a prosthetic leg 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.

In 2010, a protocol was developed in which the process of provision of a prosthesis is described.[46] The protocol was prepared by a nationally operating steering committee, Protocol and Price System Prostheses (PPP), consisting of representatives of rehabilitation specialists, suppliers of leg prostheses and health insurers. In addition, the patient organisation 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. 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).[47] 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 provision and component selection, with transparency for all parties, including the health insurer and the patient.

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 (three systematic reviews and six primary studies) that are discussed below.[48–56]

The primary studies discussed in the systematic reviews and found elsewhere included mainly observational studies, randomised or un-randomised crossover trials and a few classic RCTs. 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. 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.[56] found that prosthetic knees with a pneumatic swing phase control mechanism appear to provide greater comfort and a better walking speed in active patients. In a non-randomised, crossover trial that included 21 transfemoral amputees using an auto adaptive knee (AAK), 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.[51]

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 (Level 2).

Prosthesis users with an AAK joint and a TFA are better able to walk down a slope (Level 3).

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.[56]

In a Cochrane review on the effectiveness of ankle–foot mechanisms, Hofstad et al. concluded that in TTAs 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.[52]

In trauma-related transtibial amputees, an 'energy-storing' prosthetic foot seems to result in a higher walking speed (Level 2).

A longer step length was achieved with an 'energy-storing' foot in comparison with a conventional fixed prosthetic foot in transtibial amputees. There also seems to be a better gait efficiency at high activity levels (Level 2).

Liners and type socket

In their review on the effect of silicone liners, Baars and Geertzen[48] concluded that silicone liners seem to lead to better suspension and better walking performance compared with a conventional supracondylar fitting.

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 pin lock than with the 'Pre-Lite' liner. However, there was no difference in comfort or satisfaction with the prosthesis.[49] In a Dutch RCT involving 36 patients with TTA, no differences were found in the outcomes 'prosthetic function' and 'satisfaction' in a comparison between a 'total bearing socket' (TBS) and 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.[54]

A silicone liner leads to a better suspension and better walking performance compared with a conventional supracondylar fitting (Level 2).

Although patients take more steps and at a higher intensity with the liner with pin lock, patients are not more satisfied with this prosthesis than with the Pre-Lite liner (Level 3).

The TBS and the conventional PTB socket seem to result in no differences in outcome. There also appears to be no difference in costs (Level 3).

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 PPP Steering Committee uses an unambiguous terminology for personal characteristics and prosthetic components and their unbranded linking.[46] It provides a guideline for the minimum required data to substantiate prosthetic provision 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 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.

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.

The working group is of the opinion that the PPP protocol should be followed when prescribing a prosthetic leg and that the protocol should be regularly reviewed.

A multidisciplinary approach to the first prescription of a prosthesis (although this may not be necessary for subsequent prostheses) is favoured.

The wishes of the patient should be the starting point when determining prescription of a prosthesis.

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 prosthetic prescription (all Level 4).

It is generally accepted that fitting of a prosthesis at all levels starts when the stump is 'prosthesis ripe'. 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.

A search was conducted for articles on comparative studies evaluating the effect of the timing of prosthetic fitting on outcome. Of the 103 items 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 items, four articles remained that are discussed below.[57–60]

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 et al.[58] 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 and Ross mobilised amputation patients at an early stage using a prosthesis with air chambers (Pneumatic Post-Amputation Mobility Aid (PPAM-Aid)), according to protocol. It appears that activating amputation patients as early as possible yields benefits.[59,60] 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 magnetic resonance imaging (MRI) showed that stump volume decreases rapidly after surgery. This is also applied to the medial but not to the lateral muscle groups.[57] A study of a historical cohort compared 19 patients (amputated in 1998–2000) who used IPOP 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.[58] Ivanic et al.[59] succeeded in mobilising 23 of 25 transtibial amputees with a prosthesis with air chambers within 5 days after surgery. 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.[60]

Postoperative use of a prosthesis as soon as possible after TTA appears to result in fewer complications and revisions and a shorter time to fitting of a prosthesis (Level 3).

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) (Level 4).

Mobilisation shortly after TTA (5 days) seems feasible using a prosthesis with air chambers (Level 3).

Patients with a still unhealed stump following TTA can be mobilised using a PPAM (Level 3).

Other considerations

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

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.

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 3 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.[61,62] Bolt et al.[61] 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-Wilzing et al.[62] later showed similar results in amputation patients ($n = 5$). 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.

Some workshops require more than 4 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 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.

The prevention of oedema in the immediate postoperative phase following amputation of a lower extremity is of fundamental importance to achieving rapid provision of a prosthesis.

The working group considers the rigid dressing (RD) to be the preferred treatment during the early postoperative phase in patients with TTA stump.

The use of liners, when applied according to protocol, can be an effective method in the control of oedema.

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 (all Level 4).

Conclusion

The 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. 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 provision.

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.

Based on current research, more attention can be devoted in the near future to the patient group 'fragile elderly', in which co-morbidity and polypharmacy play an important role that also influences rehabilitation options.

We hope that the Dutch guidelines will form the base for the ISPO international guidelines.

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This article is an abstract of the Dutch evidence-based guidelines for amputation and prosthetics of the lower extremity.

Author contribution

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