Prostetic prescription in lower limb amputation : Development of a clinical guideline in the Netherlands.

Linde, Harmen van der

Prosthetic Prescription in Lower Limb Amputation

Development of a Clinical Guideline in the Netherlands

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The publication of this thesis is financially supported by:
Stichting Prothese en Orthesemakerij POM Nijmegen, Loth Fabenim, Revalidatie Centrum St. Maartenskliniek, Basko Healthcare BV, OIM Groep Haren, Anna-fonds, ISPO Nederland, Otto Bock Benelux BV, Livit Orthopedie BV, Centrum voor Revalidatie Rijksuniversiteit Groningen, Ambroise

Printed by Quickprint, Nijmegen, the Netherlands
Cover Painting by Tilly Gerbecks
Photography by Peter Bersch
Lay-out Cheriel Hofstad

Linde, H van der. Prosthetic Prescription In Lower Limb Amputation, development of a clinical guideline in the Netherlands. Thesis University of Groningen, the Netherlands - With ref. - With summary in Dutch

ISBN 90-9018126-1

Stellingen

Behorende bij het proefschrift

Prosthetic Prescription in Lower Limb Amputation
Development of a Clinical Guideline in the Netherlands

1. Bij het opstellen van het prothesevoorschrift speelt het activiteitenniveau van de patiënt met een beenamputatie een belangrijke rol (dit proefschrift)

2. Ondanks de grote hoeveelheid beschikbare kennis in de literatuur, zijn er belangrijke tekortkomingen in de objectieve klinische kennis betreffende de effecten van verschillende prothesecomponenten en bijbehorende mechanische karakteristieken op het functioneren met een beenprothese (dit proefschrift)

3. Wanneer voor bepaalde zorgaspecten geen gerandomiseerde en gecontroleerde onderzoeken zijn uitgevoerd, vormen de 'expert' mening van klinische professional en patiënt met betrekking tot verschillende zorgopties de belangrijkste informatiebron (dit proefschrift)

4. Het voorschrijven van een beenprothese en de daarbij gebruikte methodologie is voornamelijk gebaseerd op empirische kennis (dit proefschrift)

5. De integratie van kennis afkomstig uit onderzoek, de expert mening van klinische professionals en de wensen van de patiënt, kan een solide basis vormen voor een procedure voor het ontwikkelen van een richtlijn voor het voorschrijven van een beenprothese (dit proefschrift)

6. Het gebruik van een klinische richtlijn kan leiden tot een meer consistente en efficiënte dagelijkse praktijkvoering (dit proefschrift)

7. De hulpvraag van de patiënt dient het primaire uitgangspunt te vormen bij het bepalen van een individueel prothesevoorschrift

8. Om samenwerking te verbeteren en daarmee ook de kwaliteit van de zorg rondom de patiënt met een beenamputatie dient 'eenheid van taal' nagestreefd te worden

9. In het proces van voorschrijven van een medisch hulpmiddel dient een daartoe deskundig medicus een centrale rol te spelen

10. De decentralisatie processen van de overheid in combinatie met de gecommercialiseerde samenleving maken het de ouder wordende mens steeds moeilijker om de kwaliteit van leven op een aanvaardbaar peil te houden

11. Errare humanum est. Ook ten hele gedwaald kan een mooie wandeling opleveren

12. Humor is een goede graadmeter voor sociale intelligentie en algemene ontwikkeling

13. Genieten kan men op vele manieren, maar niet genoten is altijd mis ('Loesje')

Harmen van der Linde, 2004

RIJKSUNIVERSITEIT GRONINGEN

Prosthetic Prescription In Lower Limb Amputation

Development of a Clinical Guideline in the Netherlands

Proefschrift

ter verkrijging van het doctoraat in de
Medische Wetenschappen
aan de Rijksuniversiteit Groningen
op gezag van de
Rector Magnificus, dr. F. Zwarts,
in het openbaar te verdedigen op
woensdag 16 juni 2004
om 16.15 uur

door

Harmen van der Linde

geboren op 8 december 1955
te Steenwijkerwold

Promotores	Prof. Dr. K. Postema Prof. Dr. J.H.B. Geertzen
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Voorwoord

Voorwoord

In de laatste jaren is geleidelijk aan een herziening opgetreden in het beleid van de overheid en zorgverzekeraars rondom het verstrekken van een medisch hulpmiddel. In de Regeling Hulpmiddelen, daterend van 1996, is de aanspraak van verzekerden gelimiteerd met betrekking tot aantallen en zijn er gebruikstermen voor de aanspraak geïntroduceerd. Tevens werden door de zorgverzekeraars met de leveranciers maatregelen getroffen om de inkoop en distributie van hulpmiddelen te optimaliseren. In juni 2000 werd een convenant afgesloten tussen het Ministerie van Volksgezondheid Wetenschappen en Sport (VWS) en Zorgverzekeraars Nederland (ZN) met als doel te komen tot een vergroting van de doelmatigheid bij zowel het voorschrijven als het verstrekken van hulpmiddelen alsmede bij de inkoop en distributie. Een van de overwegingen in het convenant is dat versterking van de regierol van de zorgverzekeraars kan bijdragen aan een vergroting van de doelmatigheid. In het verlengde hiervan is een proces van vergaande deregulering van de overheid naar de zorgverzekeraars ingegaan op 1 januari 2002. Dit heeft naar verwachting grote gevolgen voor het verstrekkingsproces van een medisch hulpmiddel. Hierbij werd een aantal besluiten genomen die hebben geleid tot:

- Het ontwikkelen van een hulpmiddelenkompas door het College voor Zorgverzekeringen (CvZ) om behandelaars en verwijzers te ondersteunen bij de keuze van een medisch hulpmiddel voor patiënten
- Het ontwikkelen van een Nederlandse classificatie van hulpmiddelen op basis van beoogd gebruik, de CLassificatie Implementeert Qualiteit (CLIQ classificatie), mede nodig in het kader van Europese wetgeving
- Het ontwikkelen van richtlijnen op het terrein van medische hulpmiddelen.

Op verzoek van CvZ en het ministerie van VWS werd in het kader hiervan in 2000 een project gestart voor het ontwikkelen van een klinische richtlijn ter ondersteuning van het voorschrijven van een beenprothese onder auspiciën van de werkgroep Prothesen Orthesen Richtlijnen Onderzoek (PORO) van de Vereniging van Artsen voor Revalidatie en Physische Geneeskunde (VRA). In dezelfde periode werd door deze werkgroep, eveneens op verzoek van het CvZ, de nota 'generiek model hulpmiddelen in de zorg' geschreven, waarin een visie wordt gegeven op het stellen van een indicatie voor een medisch hulpmiddel en de typering ervan in het kader van het verstrekkingsproces. Vanuit zorginhoudelijke motieven wordt met dit generieke model primair een gestructureerde basis en uitgangspunten beschreven voor beleid met betrekking tot hulpmiddelen. Met deze basisgedachte wordt in hoofdlijnen richting gegeven aan hoe de pijlers ervan, zoals hulpmiddelenkompas, CLIQ classificatie en richtlijnen voor het voorschrijven, ontwikkeld zouden moeten

worden. Tevens wordt met het generiek model het verstrekkingsproces inzichtelijk gemaakt voor patiënten, zorgverleners, zorgverzekeraars en overheid.
Het generiek model was een belangrijk uitgangspunt in het proces van richtlijnontwikkeling voor het beenprothesevoorschrift. Het onderzoek met als doel het ontwikkelen van een concept richtlijn kreeg als naam *Proguide* mee, samengesteld uit de woorden *Prosthesis*, *Guideline* en *Development*. De verschillende onderdelen van het onderzoek worden in het navolgende beschreven.

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Chapter

Introduction and Outline of the Thesis

Introduction

In the year 2000 a Prosthetics and Orthotics Guideline Development Group within the Dutch Society of Physical and Rehabilitation Medicine (VRA) was commissioned by the Dutch College of Health Care Insurances (CvZ) and the Ministry of Health Care to develop a clinical guideline on prosthetic prescription in lower limb amputation. The aim of this *Prosthesis Guideline Development* project (Proguide) is to obtain a guideline on a scientific basis.

In the Netherlands the incidence of major lower limb amputation is about 19 per 100.000 inhabitants [1]. These include amputations from the transmetatarsal to the transpelvic level. In an amputee population in the north of the Netherlands approximately 82% of the total lower limb amputations occurred as a result of vascular disease, 9% were traumatic amputations, and 9% had an oncological origin (period 1991-1992) [2]. In the Netherlands, 86% of all lower extremity amputations are trans-femoral (TF) amputations (34%), knee disarticulations (KD) (10%) or trans-tibial (TT) amputations (42%) [1]. Of all lower limb amputees, approximately 48% are fitted with a limb prosthesis [3].

The reason for Proguide

In the Netherlands a prosthesis is prescribed in clinical practice by a medical doctor in Physical and Rehabilitation Medicine (MD in P&RM) in collaboration with a Certified Prosthetist (CP) and sometimes on the advice of a Physical Therapist (PT). In the Netherlands, and probably everywhere else in the world, prosthetic prescription for lower limb amputees and the used methodology are primarily based on empirical knowledge. This knowledge is transmitted to professionals by "residents' clinical training" and is constantly developed and renewed in clinical practice and through courses and symposiums. These developments and renewals have not been established in a standardized way, i.e. there is no existing clinical guideline. Experience plays an important role in an adequate prescription. This means that a clear evidence-based motivation for the choices made cannot always be given. It can lead to local prescription variations as to the overuse or underuse of prosthetic care and a lack of transparency for consumers and health insurance companies. Hence, a clinical guideline will lead to a more consistent and efficient clinical practice and more uniform high-quality care [4,5].

Guideline development

In general the definition of clinical guidelines is as follows: systematically developed statements to assist practitioner and patient decisions about

appropriate health care for specific clinical circumstances [6,7]. This definition emphasizes the clinical guideline as a practical instrument for daily practice and, therefore, as a support in taking decisions in specific clinical situations both for professional and patient. According to Grol 2 important objectives can be identified [8]. Firstly it can be considered as the representation of a 'state of the art' guideline in a discipline. Therefore, it can be the starting-point for the collaboration of a number of disciplines, which are involved in a specific form of health care. Secondly the guideline can serve as an instrument for external control. It can provide more insight for third parties such as health insurance companies and the government. Therefore, it can serve as a guideline for aspects like efficacy, control of costs and quality of care.

Many of these rely on systematic literature reviews, which were either published previously or created de novo by guideline developers. Systematic reviews can aid in guideline development because they involve searching for, selecting, critically appraising, and summarizing the results of primary research [9]. Randomised clinical trials are the preferred evidence source for clinical guidelines [10]. However, not all questions about treatment and care are suitable to the randomized controlled trial design. It is therefore important that evidence comes from the most appropriate source for the question being asked. In addition, not all aspects of treatment and care will have been the subject of research. In cases where randomized controlled trials have not been conducted we have to rely on other sources of evidence. Accordingly, clinicians can provide "expert" opinion and patients can also take part in developing guidelines to provide an "expert patient opinion" on care options [10].

Obviously guidelines also have disadvantages and limitations. The most important limitation of guidelines is that the recommendations may be wrong, or at least wrong for individual patients [5]. Guideline developers may err for three important reasons, according to Woolf [5], in determining what is best for patients:

1. Scientific evidence about what to recommend is often lacking, misleading, or misinterpreted. The quality of research studies is insufficient or will involve subjective value judgments.
2. Recommendations are influenced by the opinions and clinical expert opinion and composition of the guideline development group. Treatment or prescription criteria that experts believe are valid may in practice be inferior to other options, even ineffective.
3. The patients' needs may not be the only priority in making recommendations. Practices that are suboptimal from the patients' perspective might be recommended to help control costs or protect special interests, those of doctors, health insurance companies etc.

According to the first rules of the Appraisal Instrument for Guidelines, Research and Evaluation in Europe (Agree-instrument) a general aim and a clinical question have to be formulated clearly [8,11]. In the Proguide project the guideline development was restricted to the adult population (over 18 years of age) with a trans-tibial, knee disarticulation or trans-femoral amputation level. As the amputation levels at ankle or foot and hip or pelvis occur less frequently and prosthetic prescription demands more individually determined aspects they were left out of this guideline development project.

Prescription criteria

The process of provision of medical aids has recently changed in the Netherlands. On request of the CvZ the prosthetics and orthotics guideline group of the VRA developed a general model for the provision of medical aids (see Addendum). In this respect the provision of a lower limb prosthesis has to match these general agreements. The aim of the guideline group was to describe the process of formulating an indication and the typification of medical aids. This provision process is presented in the addendum.

Prescription criteria of importance for a lower limb amputee deal with body structure and body functions and with specific aspects related to everyday life. Therefore, besides aspects of the amputation stump, general condition of the patient, co-morbidity and level of activity in home and employment situation are of interest in prosthetic prescription [12-14]. There is a growing awareness that the prosthetic prescription has to match the intended use of a prosthesis [15,16].

Aim of the study and outline of the thesis

The primary aim of the study is to obtain a first concept of a transparent and controllable guideline for the prescription of a lower limb prosthesis. The guideline has to be based as much as possible on valid research and on clinical and empirical knowledge of the involved professional disciplines. The aim is to use the guideline to formulate an adequate prescription for at least 80 per cent of all amputees who receive prostheses.

The study is based on the consultation of different sources of information. This is achieved by collecting and summarizing the scientific knowledge contained in the available literature. This is performed according to the protocol of the Cochrane Collaboration [17]. The next step in collecting knowledge is the consultation of a panel of clinical experts in the field of amputation and prosthetics. Subsequently

the collected information is converted in order to present it to clinical professionals in a consensus procedure. Finally, after drafting a concept guideline, the process of implementation follows. After the first implementation round adjustments can be made and subsequently there is the implementation of a definitive guideline. The implementation and adjustment rounds are not part of this thesis.

Literature review

With literature research the question can be answered if published studies indicate "the best possible treatment". For this purpose the method of systematic review is performed which has to result in an overview of a 'state of the art' prosthetic prescription. The literature review is focused on existing guidelines as well as on different aspects, which are of importance in functioning with a prosthesis. We hypothesized that there would be insufficient comparative studies to draw firm conclusions from literature and that we should rely on other sources of information. With the literature review the first part of explicit knowledge is obtained.

Goal of this systematic literature review was to obtain evidence-based information about the effects of different prosthetic components on human functioning with a lower limb prosthesis. In this respect two types of studies can be distinguished: (a) clinical studies focusing on motor performance or everyday functioning with a lower limb prosthesis and, (b) technical studies concentrating on the mechanical characteristics of prosthetic components without specifically human functions. In view of prosthetic guideline development, only studies addressing motor performance and human functioning with a lower limb prosthesis are considered relevant. Hence, this review is restricted to these clinically orientated studies. The literature review is described in chapters 2 and 3.

Clinical practice

In chapter 4 the observations of clinical practice are described. The purpose of this study was to get insight into possible similarities in prescription criteria in practice. Secondly, we were interested if prosthetic prescription was primarily based on the amputee's level of activity or the intended use of the prosthesis. The procedure according to which prosthetic prescription is effectuated was determined by means of a semi-structured observation method. The selected locations were spread throughout the Netherlands and had to fulfil certain specific criteria of expertise. The clinical practices were located in rehabilitation centres and general hospitals.

An interview with clinical experts is described in chapter 5. The aim of this study was to collect the implicit knowledge about the prescription of a lower limb prosthesis through a semi-structured interview method with clinical experts. Secondly we were interested in the measure of agreement within the options mentioned for several prosthetic components.

Consensus procedure

The ability to make effective decisions in situations where there is contradictory or insufficient information has led to an increased use of consensus methods, namely brainstorming, the nominal group technique and the Delphi survey technique (Delphi) [18]. In the Proguide project the Delphi method, originally developed by Helmer and Dalkey (RAND Corporation) [19], was used in a modified form. The Delphi survey is a group facilitation technique and is a way of identifying whether there is any consensus in an expert group and clarifying the agreements. This is accomplished through iterative rounds of questionnaires completed by a panel of experts [20]. It is essential that the questionnaires are filled in anonymously by the participants. The questionnaire contains feedback on the answers given by the same expert panel from the previous rounds. Therefore it is a flexible approach with an iterative multi-stage process, able to transform opinion into group consensus [18]. The procedure aims at determining the central topics in the process of prosthetic prescription.

The overall aim of this project is to develop a combination of evidence-based and consensus-based clinical practice guidelines for lower limb prosthetic prescription in order to obtain transparency and consensus among clinicians, manufacturers and insurance companies. In chapter 6 the Delphi method is described which evolved from the different methods of evidence collection described in the previous chapters.

The participants invited are all clinical experts in the field of amputation and prosthetics. They represent the three key disciplines in this field, namely MD in P&RM, CP and PT. Orthopaedic surgeons and vascular surgeons are not involved in the prosthetic prescription process anymore, in any case not in the Netherlands.

In this anonymous procedure statements are presented to the participants through the Internet. By means of this interactive electronic version of the postal rounds it is possible to read the comments of other participants (anonymous) and to give a reaction to them. This can be seen as a form of discussion in which participants can answer to every part of all the statements at a convenient moment.

The procedure is completed by a plenary session. In the first part of this session, presided by an independent chairman, the remaining statements (without

consensus after the postal rounds) are argued. After the arguments are given there is an anonymous vote on these statements. In the second part of this meeting a format is discussed in which the statements are categorized. This format can serve as a starting point for a convenient manual of the concept guideline.

Questionnaire

There is a growing interest in the role of the patient in determining the quality of health care. This also applies to patients who lay claim to a medical aid, such as a lower limb prosthesis. Patients are highly experienced experts and are able to judge the way in which health care is supplied and the measure in which patients' expectations are met. Health care institutions should adjust their procedures to the expectations of patients regarding the service provided. Therefore, the prosthetic user should be involved in the process of prosthetic prescription in order to formulate their wishes concerning the prosthesis and to evaluate the experiences in everyday practice.

In chapter 7 of this thesis the opinion of the patient is described regarding the service and provision of a lower limb prosthesis. The goal of this study is to obtain information about the wishes and experiences of patients with a lower limb amputation regarding prosthetic prescription and the exchange of information with the health care providers. Consistent with the Quote questionnaires a focus group technique was used in drawing up the questionnaire. The specific expectations and experiences of prosthetic users are compared with the functioning of the health care providers. Accordingly points of improvement are presented that can be of interest for the prescription process and the provided service. Based on the structure of the Quote questionnaire a list of 24 items is formulated, divided into 4 categories, all part of the prosthetic prescription process: (1) service demand, (2) formulation of the prosthetic prescription, (3) training, information and aftercare, (4) claim and insurance aspects.

This thesis describes the process of the development of a draft clinical guideline. The limitations of the different forms of collecting information and the consensus procedure are described in the general discussion (chapter 8). We also concentrate on the limitations and disadvantages of a clinical guideline for everyday practice. Finally we propose aspects of future research regarding the implementation of the draft clinical guideline. An example of a practical completion of the results of this study for clinical practice is presented.

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Addendum

A general model for the provision of medical aids

Process	Action	Aim	Classification	Information
Service demand		Dissolve problem in general functioning		
Medical diagnosis	Determination of burden of disease and the actual impairments in level of activities and problems in participation level	Level of daily functioning (without an aid)	ICD ICF	• Illness • Body functions • Body structure • Activities • Participation
Intended patient functioning	Necessity aid Determination of disability weight (difference between impairments and level of activities and problems in participation level)	Aim of use, patient related intended use	ICF	• Patient characteristics • Body functions • Body structure • Activities • Participation
Intended use Product (aid)	Product characteristics	Suitability product related intended use	ISO ISO/ICF	• Product demand
Match	Matching intended functioning patient (disability weight) with intended use product (suitable use of the product)	Adequate function of aid	ISO ISO/ICF	• Patient characteristics • Product characteristics
Supply product	Supply of aid Information Aftercare	Suitable use of aid		• Directions for use • Upkeep instructions
Evaluation	Control and adjustments	Determination effectiveness aid	ICF	• Evaluation/intervention effect in relation to goal of treatment

Chapter 2

A Systematic Literature Review of the Effect of Different Prosthetic Components on Human Functioning with a Lower Limb Prosthesis

H van der Linde, CJ Hofstad, ACH Geurts, K Postema, JHB Geertzen, J van Limbeek
Journal of Research Rehabilitation and Development 2004;Volume 41-3 (B): in press

Abstract

Objective: A systematic literature review was performed to obtain evidence based information about the effects of different prosthetic components on human functioning with a lower limb prosthesis. This should provide an objective starting point for further development of consensus-based criteria for prosthetic prescription in the Netherlands.

Methods: Clinical studies addressing the effects of different prosthetic components on human functioning with a lower limb prosthesis were identified by a systematic search using the Medline Database, Current Contents, The Cochrane Database, and Psyclit. The following keywords and their synonyms were used: lower limb prosthesis, lower limb amputation, prosthetic prescription, prosthetic foot, prosthetic knee, prosthetic suspension, stump, socket, and physiological and biomechanical parameters. The quality of the studies was assessed using predetermined methodological criteria.

Results: Out of 356 potentially relevant studies, 40 studies eventually qualified for final methodological analysis and review. Twenty-eight publications focused on the prosthetic foot, 5 on the prosthetic knee, 1 on the prosthetic socket, and 6 studies focused on the effect of prosthetic mass. Four satisfied all the criteria and were labelled as A studies. Twenty-six publications received a B label, and 10 studies were labelled as C studies.

Discussion and conclusion: There is some evidence that energy-storing feet result in a comfortable walking speed and stride length that are about 7-13% higher than with a conventional foot in both traumatic and vascular trans-tibial amputees. Possibly, such feet also facilitate the symmetry of gait. These considerations seem important particularly for the active prosthetic user. Inactive prosthetic users may benefit from an early foot-flat mechanism to facilitate weight transfer onto their prosthesis.

With regard to the prosthetic knee active prosthetic users may profit from the advanced characteristics of swing-phase controllers, whereas the geriatric vascular patient may still profit from the stance-phase stability.

Despite a huge amount of literature, there are considerable gaps in our formal clinical knowledge concerning the effects of different prosthetic components and their mechanical characteristics on human functioning with a lower limb prosthesis. Therefore, with regard to prosthetic guideline development, we must still largely rely on clinical consensus among experts. The integration of knowledge from research with the expert opinion of clinical professionals and the opinions and wishes of consumers can form a solid base for a procedure on guideline development for prosthetic prescription.

Introduction

Prosthetic prescription for patients with lower extremity amputation is primarily based on empirical knowledge. There are many options for different prosthetic components, however, prescription criteria are mainly based on subjective experiences of physicians, therapists and prosthetists [1,2]. On the other hand, third-party payers frequently require justification for purchasing costly prostheses [2]. Also clarity for the customer is required since quality of care is becoming more important. In the ideal situation prosthetic prescription is based on adjusting the mechanical characteristics of a prosthesis to the functional needs of the prosthetic user [3], yet there seem to be no clinical guidelines to serve this purpose.

The development of scientifically based clinical guidelines is a way of making health care more consistent and efficient and diminishes the gap between what clinicians do and what scientific evidence supports. A systematic literature review is a first step in clinical guideline development. It may also highlight knowledge gaps in the existing evidence [4]. To our knowledge, there are no scientifically based guidelines for lower limb prosthetic prescription. Also, there seems no consensus among different professionals with regard to the criteria for selecting prosthetic components related to the functional abilities and needs of patients. In this perspective, the Dutch Health Care Insurance Board (CvZ) has initiated a national project to develop clinical guidelines for lower limb prosthetic prescription to obtain consensus among clinicians, manufacturers and insurance companies in the Netherlands. The first step is to extract as much scientifically based knowledge from the literature as possible. In this respect, two types of studies can be distinguished: (a) clinical studies focusing on motor performance or daily functioning with a lower limb prosthesis and, (b) technical studies focusing on the mechanical characteristics of prosthetic components without specifically human functioning. In view of prosthetic guideline development, only studies addressing motor performance and human functioning with a lower limb prosthesis are considered relevant. Hence, this review will be restricted to these clinically orientated studies.

Method

Procedure

A systematic search was performed using the Medline Database (from 1966), Current Contents (from 1996), The Cochrane Database (2001 Issue), and Psyclit (from 1971) until February 2001. A combination of the following keywords and their synonyms was used: 'lower limb prosthesis', 'lower limb amputation', 'prosthetic prescription', 'prosthetic foot', 'prosthetic knee', 'prosthetic suspension', 'stump',

'socket', and 'physiological and biomechanical parameters'. Also the references from the retrieved articles and (systematic) reviews were checked to extend the search.

Based on their abstracts, studies were further considered when (a) the articles were written in the English, German or Dutch languages, (b) the study design was either a (randomised) controlled trial, a cohort-study, or a case-control study allowing at least some control of confounding factors, (c) the study investigated patients with a trans-femoral, knee disarticulation, or trans-tibial amputation, (d) the study used subjective findings, ADL-measures and/or functional characteristics of human stance or gait (spatio-temporal, physiological, kinematic, kinetic or EMG parameters) as outcome variables, (e) the study evaluated specific components of the prosthesis, (f) the goal of the study was to provide insight into the effects of different prosthetic components on human functioning with a lower limb prosthesis.

Methodological criteria

After this abstract-based selection of relevant studies, the methodological quality of each article was assessed using a checklist of 13 predetermined criteria. This checklist was based on the integration of two existing criteria lists for quality assessment [5,6], which were originally developed to evaluate randomised controlled trials (see Addendum [7,8]). Some criteria were adapted for non-randomised controlled trials. Each criterion was scored at two levels: invalid/no '0', and valid/yes '1'. In the case a criterion was not applicable, it was scored '0'. The studies were independently analysed by two reviewers (HL and CH). In the case of discrepancy, consensus was achieved in the second instance.

In relation to the purpose of this review, it was required that the included studies should sufficiently control for selection and measurement bias. Studies were labelled as A-level study when the total score of all criteria was 11 points or more, including a positive score for blinded outcome assessment (criterion B7) and timing of the measurement (criterion B8). Studies were classified as B-level study if the total score was between 6 and 10 points, including a positive score for timing of the measurement (criterion B8). Studies were classified as C-level study if the total score from the A and B criteria was at least 6 points with an invalid score on the criteria B7 and B8 (outcome blinding and timing of measurement) (Table 1). Therefore, only the studies in which the total score of the A and B criteria was at least 6 out of a possible 9 points were used in the best-evidence synthesis.

Table 1 Best-evidence synthesis

A-studies:	Studies with a total score of at least 11 points; including 6 points out of the A- and B-criteria, including at least B7 and B8
B-studies:	Studies with a total score between 6 and 10 points; including at least B8
C-studies:	Studies with a total score of at least 6 points out of the A- and B-criteria with an invalid score on the criteria B7 and B8

Results

Selection of studies:

Out of 356 potentially relevant studies on lower limb prosthetic functioning, 63 studies were selected based on their abstracts (Figure 1, selection algorithm according to the QUOROM statement [9]). References from the retrieved studies and (systematic) reviews yielded 72 more articles. The abstracts of these 72 studies were similarly assessed which resulted in 17 additional studies fulfilling the preliminary selection criteria. Most of the studies that did not meet these criteria were uncontrolled case series or case reports (criterion 1) or their primary purpose was not related to human functioning with a prosthesis (criterion 6). For instance, many articles focused only on amputation techniques or on the technical possibilities of early prosthetic fitting. Hence, the full texts of 81 selected studies [1-3,10-87] were methodologically assessed using the above-mentioned checklist of 13 criteria. Based on these assessments, 40 studies received an A-, B- or C-level classification and were included for final review (see Table 2). An important reason for excluding the 41 other studies was that the selection of the study sample was so poorly described, that the results could not be reliably interpreted from a clinical perspective.

No classical Randomised Controlled Trials (RCT's) were identified, yet, all included studies used cross-over designs allowing sufficient control for confounding. Four articles were labelled as A-level studies [17,18,67,68], 26 as B-level studies [2,3,13,16,20,22,23,27,30,36,37,42,44-46,55-58,61,66,69,71,77,81,83], whereas 10 studies were labelled as C-level studies [1,15,35,39,52-54,59,63,76]. The main difference between the A and B studies was a negative score on the 'blinded assessment' criterion (B7). Indeed, only Postema [67,68], Boonstra [17,18] and Gailey [35] (C study) reported that their subjects were blinded to the intervention. Seven studies [2,20,42,46,52,61,71] applied no randomisation of the sequence of interventions and, therefore, had a negative score on the A4 criterion. Of the other studies, only Postema *et al.* [67,68] described

which randomisation procedure was applied. The randomisation was carried out with the aid of a dice and the code was broken only after the entire trial had been completed. Seven articles [16-18,22,23,30,81] scored negatively for functional homogeneity. Based on the provided subject characteristics, it could be concluded that the study sample was considerably heterogeneous for activity level, which was not accounted for by a stratified analysis.

In some studies the prosthetic components, other than the component investigated, were not kept constant resulting in a '0' on the B6 criterion [1,15,39,44,55,56,61,63,76]. In 8 studies on prosthetic mass [35,39,52-54,59,63,76] and Board's study on prosthetic socket design [15], the subjects were not allowed sufficient time to adapt to the intervention, so that a negative B8 score was given. Eight studies did not indicate possible drop-outs [1,3,16,30,52,53,76,81]. Insufficient information was available about how many subjects were eventually subjected to the intervention. Therefore, this study received a negative score on the C10-criterion. In 6 studies, the authors failed to provide adequate measures of variability, even though such data were necessary to interpret the results [1,13,15,63,71,81].

Study results:

The selected studies on functioning with a lower limb prosthesis allowed a division in 4 categories based on their focus of attention: effects of different (a) prosthetic feet, (b) prosthetic knees, (c) prosthetic sockets, and (d) prosthetic mass. The prosthetic foot was the focus of investigation in 28 studies [1-3,13,16,20, 22,23,30,36,44,45,52,53,55-58,63,66-69,71,76,77,81,83] (Table 3) , the prosthetic knee in 5 studies [17,18,42,46,61], the prosthetic socket in 1 study [15] and prosthetic mass in 6 studies [25,35,37,39,54,59] (Table 4).

As dependent variables, time-distance parameters are probably the most easily obtainable objective data for the evaluation of changes in patient's gait performance [86]. From a clinical point of view, such parameters are also readily interpretable. Hence, many of the included studies focused primarily on these parameters as well as on kinematic variables [1-3,13,15,16,22,30,36,37,39,45, 52,53,56,57,59,61,63,66-68,71,76,77,81,83]. Fifteen studies used oxygen uptake as an outcome parameter [13,17,20,25,35,44,45,52,54,58,59,63,76,81,83] and 2 studies assessed heart rate [46,63]. One study used the Borg-scale to evaluate the difficulty of walking [55], 2 studies evaluated patient satisfaction [20,67], and 21 studies used walking speed to investigate differences between specific prosthetic components [1,2,13,16,20,22,25,39,46,52-54,61,63,66,68,69,71,76,77,81].

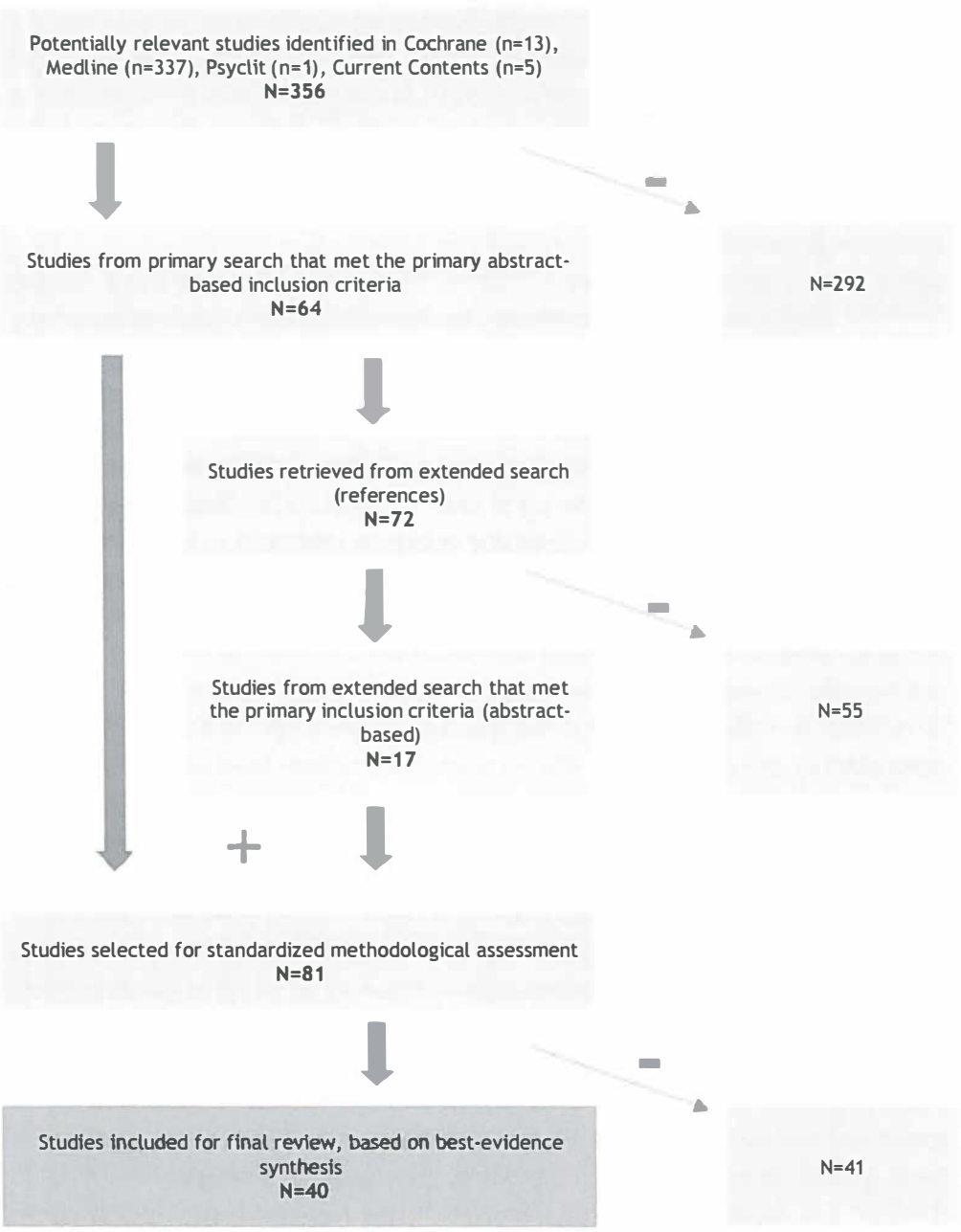

Figure 1 Selection algorithm

Many different comparisons were made. Furthermore, differences in selected and presented outcome parameters among studies investigating the same prosthetic components did not allow a true meta-analysis of the results. Hence, we decided to focus our review on the consistency of clinical findings across studies on the same topic. In the case of inconsistency, methodological quality was used for final interpretation.

Studies on prosthetic feet

One A study [67],fifteen B studies [2,3,13,16,20,22,30,56,57,66,69,71,77,81,83] and five C studies [1,52,53,63,76] used time-distance parameters to compare different types of prosthetic feet. In general, few discriminative effects were found. For instance, in most studies the self-selected (comfortable) walking speed was not influenced by the type of prosthetic foot in traumatic [2,3,13,56,67,76,81,83] or vascular [13,22,66,71,81,83] trans-tibial amputees, and traumatic trans-femoral amputees [57]. There were, however, a few exceptions. Compared to the SACH foot, three B studies found a higher self-selected walking speed with a prototype energy-storing foot in traumatic trans-tibial amputees [20] and with the Flex foot in traumatic [69] and vascular trans-tibial amputees [77]. Casillas *et al.* [20] explained their results by the higher bioenergetic efficiency level the subjects experienced while walking with the prototype energy-storing foot. Powers *et al.* [69] and Snyder *et al.* [77] both explained the observed difference in walking speed by the greater stride length with the Flex foot compared to the SACH foot, while cadence remained constant. Two studies reported a change in cadence. MacFarlane's study [56] found a lower cadence when walking with the Flex foot compared to the SACH foot in combination with a greater stride length for the Flex foot. Due to a trade-off effect, no differences were found in walking speed. The study of Torburn [81] found a greater cadence for the Carbon Copy II foot compared with Flex foot and SACH foot. A possible explanation for the slightly different study results may be found in the differences in the selection of the study groups. In two B studies, MacFarlane [56,57] reported a more symmetrical gait pattern with the Flex foot compared to a SACH foot in both trans-tibial and trans-femoral amputees related to symmetrization of the late stance and late swing phase durations in particular.

Some studies investigated *joint motion* as an outcome parameter [13,16,22,45,52,53,66,67,69,77,81]. In the A study by Postema *et al.* [67], the range of motion (ROM) at the ankle during the stance phase of a single-axis conventional foot was greater than the same ROM of two energy-storing feet. This result could readily be related to the mechanical characteristics of the different feet, i.e. the presence or absence of an ankle axis in the frontal plane. The presence of an ankle axis allowed greater early-stance plantarflexion immediately after heel contact [66, 67]. Furthermore, the

energy storing Flex foot showed a greater late stance dorsiflexion compared with the conventional SACH foot in three B studies [69,77,81] and two C studies [52,76] on traumatic and vascular trans-tibial amputees. The fact that the Flex foot resulted in a greater stride-length is indicative of a greater tibial advancement as a result of increased dorsiflexion [77].

Nine B studies [13,20,44,45,52,58,76,81,83] assessed *oxygen consumption*. In 3 studies with traumatic trans-tibial amputees, oxygen consumption per distance travelled was slightly lower with a prototype energy-storing foot [20] or with the Flex foot [58,63] than with the SACH foot. In the study of Hsu with nonvascular amputees oxygen consumption was lower with the Re-flex foot compared with SACH and Flex foot [44]. However, in the other 6 studies no such beneficial effect of energy-storing feet was found [13,45,52,76,81,83]. This discrepancy in results is, however, hardly clinically significant and may again be related to differences in the selection of the study groups.

As for *patient satisfaction*, the only A study [68] concluded that no specific prosthetic foot was consistently favoured over another type of foot by traumatic trans-tibial amputees. Yet, in one B study, the prototype energy-storing foot scored a higher satisfaction rate than the SACH foot in traumatic trans-tibial amputees [20]. Another B study concluded that walking with the SACH foot was perceived to be more difficult than walking with the Flex Foot [56]. However, since the prosthetic users were not blinded in the latter 2 studies, these results should be interpreted with caution.

Studies on prosthetic knees

Each of the five studies on prosthetic knees made different comparisons (Table 4). The A study of Boonstra *et al.* [18] concluded that a Tehlin knee with a pneumatical swing phase controller resulted in a more comfortable and faster walking performance during normal and fast walking compared to a knee with mechanical swing phase control, i.e. Otto Bock 3R20 (results from questionnaires). This result was explained by a shorter swing phase duration of the prosthetic leg caused by an impeded knee flexion. However, energy expenditure at 3 km/h was somewhat higher with the pneumatically controlled knee [17]. Apparently, the preference of the amputees in favour of the Tehlin knee was not related to lower energy costs. Similar results were found in two B studies. Heller *et al.* [42] found that a conventional knee unit resulted in greater total frontal plane excursion of the head compared to the Intelligent Prosthetic knee (a microprocessor-controlled prosthesis), whereas Murray *et al.* [61] found more symmetry in both stance and swing phase duration and a higher comfortable and fast walking speed for a prosthesis with a hydraulic knee compared to a prosthesis with a constant-friction

knee in traumatic trans-femoral amputees. Apparently, these results indicate that a more advanced mode of control of the prosthetic knee movement during the swing phase can lead to more gait symmetry and speed than simply applying constant friction or force to the knee, particular in active prosthetic users. The improvements in the smoothness of walking are most likely related to the restraining effect of the hydraulic or pneumatic component at the beginning and the end of the prosthetic swing phase, allowing more normal weight acceptance at the beginning of prosthetic stance phase and easier weight transfer at the end of prosthetic stance phase [61]. On the other hand, the B study of Isakov *et al.* [46] concluded that a Mauch S-N-S hydraulic knee prosthesis with a locked knee may enable vascular patients to adopt a higher walking speed compared to an unlocked open knee unit. This finding should be interpreted in view of the fact that their study sample was characterized by an older age (50-70 years) and a lower activity level (i.e. vascular amputees with additional health problems, such as diabetes mellitus, hypertension, heart failure and myocardial infarction) compared to the studies of Boonstra [17,18] and Heller [42].

Study on prosthetic socket

Board's C study [15] investigated the effect of prosthetic socket type on time-distance parameters in trans-tibial amputees (Table 4). More symmetrical step length and stance duration and less stump volume loss were observed with a vacuum total surface-bearing suction socket compared to a normal total surface-bearing suction socket. This result can be explained by the assumption that a vacuum socket provides a better fitting of the stump tissues and a better 'total skin' contact allowing more mechanical and sensory control over the prosthetic leg. The subjects reported that their prosthetic limb was held more firmly with the vacuum socket and that their stump pistoned less within the socket during walking. Due to the better fit, the amputees spent more time on their prosthetic limb, and felt more confident of the control over and position of their prosthesis. The methodological quality of this study was, however, poor because the other prosthetic components were not kept constant with the different sockets. Also the time to adapt to the prosthetic change was relatively short, i.e. subjects were familiarized with the intervention for only 15 minutes. Therefore, the results of this study should be interpreted with caution.

Studies on prosthetic mass

The 6 studies on prosthetic mass (Table 4) did not reveal any influence of mass on the efficiency or kinematics of gait, with one exception. Lehmann's C study showed that a more proximal center of mass location produced a more efficient gait in traumatic trans-tibial amputees. Although Selles *et al.* [89] reviewed a slightly

different selection of studies on this specific topic, their conclusion is more or less the same. More specifically, they concluded that inertial loading of the modern lightweight lower limb prosthesis has no beneficial effect on the amputee's gait pattern or energy expenditure.

Discussion

Limited unbiased information can currently be obtained from studies on the effects of different prosthetic components on human functioning with a lower limb prosthesis for evidence-based prosthetic prescription. Only four A studies were identified, 2 on prosthetic feet and 2 on prosthetic knees.

There is some evidence that energy-storing feet such as the Flex foot result in a comfortable walking speed and stride length that are about 7-13% higher than with a conventional SACH foot in both traumatic and vascular trans-tibial amputees [20,69,77]. This difference is probably related to a slightly lower oxygen consumption while walking with an energy-storing foot [20,58]. Possibly, such feet also facilitate the symmetry of gait [57]. These considerations seem important particularly for the active prosthetic user. On the other hand, prosthetic feet with an ankle axis in the frontal plane such as the single-axis Lager foot (Otto Bock) mimic the normal roll-off motion of the ankle-foot complex in the sagittal plane allowing an early foot-flat position and concomitant early-stance-phase stability. It is believed that especially the more inactive prosthetic users may benefit from an early foot-flat mechanism to facilitate weight transfer onto their prosthesis [1,66,67]. According to Perry *et al.*, the stability of timely foot flat support with limited knee flexion requires a greater arc of functionally restrained plantarflexion [66]. Also, uphill and downhill walking may be easier with a wide range of motion at the prosthetic ankle joint [58]. A single-axis foot, however, may offer relatively little late-stance stability due to an unrestrained dorsiflexion [66]. In this respect, the Flex foot and the SACH foot provide more stability during the late-stance phase [45] and may be preferable to patients that tend toward a short prosthetic stance phase. Hence, individual considerations related to intended use and activity level remain important with respect to the definitive choice of the prosthetic foot. It should be noted that in the reviewed studies *dorsiflexion* is also used for the prosthetic feet that have rigid ankles. This can be confusing because they do not truly dorsiflex, but bend. Therefore *pseudo-dorsiflexion* could be more appropriate when discussing the properties of rigid ankles.

As for the prosthetic knee in trans-femoral amputees, it can be concluded that prosthesis with an advanced mode of swing-phase control, either by a pneumatic or a hydraulic knee unit, is somewhat superior to a prosthetic knee that only provides

a constant force or friction. Especially active prosthetic users may profit from the advanced characteristics of swing-phase controllers such as the Tehlin Knee in terms of gait symmetry and comfortable walking speed [42,61]. These beneficial effects cannot readily be explained on the basis of energy expenditure. On the other hand, the typical geriatric vascular patient may still profit from the stance-phase stability that is provided by a conventional locked knee unit [46]. In how far prosthetic knees with stance-phase stabilizers such as the Intelligent Prosthetic Knee should be prescribed to these or other patients based on its functional benefits has to be further supported by clinical evidence. Hence, again, individual considerations must ultimately determine the choice and prescription of the prosthetic knee.

With regard to the prosthetic socket in trans-tibial amputees, hardly any firm conclusions can be drawn from the literature. It is, nevertheless, plausible from a clinical perspective that a vacuum (total-surface bearing) socket assures a better skin contact than a normal suction or suspension socket and, thus, a better control over the prosthetic limb [14]. Within certain limits, prosthetic mass does not seem to influence the gait pattern or efficiency in lower limb amputees. There is, however, some evidence that a proximal center of mass location results in a slightly more efficient gait than a distal distribution of prosthetic mass [54].

Functional outcomes should be assessed for various aspects of mobility such as making transfers, maintaining balance, level walking, stair climbing, negotiating ramps and obstacles, changing walking speed et cetera. Most studies reviewed in this paper assessed walking on a treadmill (at self-selected walking speeds), probably for reasons of technical and practical convenience. Indeed, Mulder *et al.* already pointed out that the vast majority of clinical studies on human walking have used rather standardized gait assessment protocols with limited "ecological validity" [90]. Although perhaps less analytic, modern systems for ambulatory monitoring of human activity [91] are able to provide objective and valid data about (changes in) human motor behaviour during prolonged periods of hours or days in a much more ecologically valid way. Also, subjective assessments of comfort, stability and efficiency should certainly be used more when blinding of the prosthetic users can be assured. Secondly, the effects of different prosthetic feet should also be evaluated in patients with e.g. a knee disarticulation or trans-femoral amputation because generalizing results from trans-tibial amputees to these higher levels of amputation may be invalid. Lastly, more research is needed into the effects of prosthetic knees with stance-phase stabilizers as well as into the

functional effects of different prosthetic sockets in knee disarticulation and trans-femoral amputees.
Therefore, with regard to prosthetic guideline development, we must still largely rely on clinical consensus among experts. In a formal consensus procedure different sources of evidence are needed.

Conclusion

The most important conclusion that can be drawn from this review is that there are considerable gaps in our formal clinical knowledge concerning the (beneficial) effects of different prosthetic components on human functioning with a lower limb prosthesis. For future research, functional comparisons between different prosthetic components should be better categorized according to the level of activity of the amputee and the intended use of the prosthesis. Such an approach would better acknowledge the importance of individual needs and abilities that guide clinical-decision making in daily practice. The integration of knowledge from research with the expert opinion of clinical professionals and the opinions and wishes of consumers can form a solid base for a procedure on guideline development for prosthetic prescription.

Table 2a: Assessment of methodological aspects of reviewed studies on prosthetic feet

Author	Parameters	Subjects (reason and level of amputation, and age (yrs), (range or mean ±SD))	Selection					Intervention						Statistical validity				Total score	Level of evidence
			A1	A2	A3	A4	A	B5	B6	B7	B8	B9	B	C10	C11	C13	C		
Barth (13)	Walking speed; step length; cadence; VO_2 (ml/kg/min, ml/kg/m); joint motion (degrees); time-related variables	3 traumatic TT, 39±10; 3 vascular TT, 64±5	1	1	1	1	4	1	1	0	1	1	3	1	0	0	1	8	B
Boonstra (16)	Walking speed; joint motion (degrees); time-related variables	9 TT, 20-70	1	0	1	0	2	1	1	0	1	1	4	0	1	1	2	8	B
Casillas (20)	VO_2 (ml/kg/min, ml/kg/m); satisfaction (0-100); walking speed	12 traumatic TT, 50±14; 12 vascular TT, 73±7	1	1	1	0	3	1	1	0	1	1	4	1	1	1	3	10	B
Cortes (3)	Kinetic, kinematic and time-related variables	8 traumatic TT, 19-49	1	1	1	1	4	1	1	0	1	1	4	0	1	1	2	10	B
Culham (22)	Walking speed; stride length; cadence; time-related variables; knee motion (degrees)	10 TT (9 vascular, 1 traumatic), 32-79	1	0	1	1	3	1	1	0	1	1	4	1	1	1	3	10	B
Culham (23)	Electromyographic activity of the vastus lateralis and the medial hamstrings, bilaterally	10 TT (9 vascular, 1 traumatic), 32-79	1	0	1	1	3	1	1	0	1	1	4	1	1	1	3	10	B
Doane (30)	Centre of mass displacement and velocity; joint motion (degrees); time-related variables;	8 TT, 55-67	1	0	1	0	2	1	1	0	1	1	4	0	1	1	2	8	B
Gitter (36)	Joint muscle power output (Watt)	5 traumatic TT, 20-50	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
Goh (1)	Walking speed; time-related variables	6 TT, 53±9; 5 TF, 48±11	1	1	1	0	3	1	0	0	1	1	3	0	1	0	1	7	C
Hsu (44)	VO_2 (ml/kg/min, ml/kg/m)	5 TT, 27-36	1	1	1	1	4	1	0	0	1	1	3	1	1	1	3	10	B
Huang (45)	VO_2 (ml/kg/min); joint motion (degrees)	8 traumatic TT, 30±6; 8 vascular TT, 63± 5	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
Lehmann (52)	VO_2 (ml/kg/m); walking speed; ground reaction forces (N/kg); joint motion (degrees)	9 TT, 21-53	1	1	1	0	3	1	1	0	0	1	3	0	1	1	2	8	C
Lehmann (53)	Metabolic rate (cal/kg/min, cal/kg/meter); walking speed; ground reaction forces (N/kg); joint motion (degrees)	10 TT, 21-36	1	1	1	1	4	1	1	0	0	1	3	0	1	1	3	10	C
MacFarlane (56)	Borg-scale (0 - 20 scale)	7 traumatic TT, 19-49	1	1	1	1	4	1	0	0	1	1	3	1	1	1	3	10	B

MacFarlane (55)	Linear and temporal and gait symmetry variables	7 traumatic TT, 19-49	1	1	1	1	4	1	0	0	1	1	3	1	1	1	3	10	B
MacFarlane (58)	Linear and temporal and gait symmetry variables	5 traumatic TF. 37±5	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
MacFarlane (57)	VO_2 (ml/kg/min, ml/kg/m)	5 traumatic TF, 37±5	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
Menard (2)	Ground reaction forces (N/kg); walking speed	8 traumatic TT, 31-51	1	1	1	0	3	1	1	0	1	1	4	1	1	1	3	10	B
Nielsen (63)	Walking speed; VO_2 (ml/kg/min, ml/kg/m), heart rate	7 traumatic TT, 27±7	1	1	1	1	4	1	0	0	0	1	2	1	0	0	1	7	C
Perry (66)	Walking speed; cadence; joint motion (degrees) and velocities (rad/s)	10 vascular TT, 49-72	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
Postema (67)	Preference (0 - 10 scale)	10 traumatic/oncologic TT, 34-66	1	1	1	1	4	1	1	1	1	1	5	1	1	1	3	12	A
Postema (68)	Walking speed; cadence; joint motion; ground reaction forces; energy absorption	10 traumatic/oncologic TT, 34-66	1	1	1	1	4	1	1	1	1	1	5	1	1	1	3	12	A
Powers (69)	Walking speed; stride length; cadence; ground reaction forces (% body weight); ankle motion (degrees)	10 traumatic TT, 22-72	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
Rao (71)	Walking speed; stride length (m); cadence; foot, shank and thigh velocities (rad/s)	9 vascular TT, 62±7	1	1	1	0	3	1	1	0	1	1	4	1	1	0	2	9	B
Schmalz (76)	Walking speed; stride length; VO_2 (ml/kg/m)	8 traumatic TT, 17-70	1	1	1	1	4	1	0	0	0	1	2	0	1	1	2	8	C
Snyder (77)	Walking speed; stride length; cadence; ground reaction forces (N/kg); ankle and knee motion (degrees)	7 vascular TT, 45-70	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
Torburn (81)	Walking speed; cadence; stride length; EMG; VO_2 (ml/kg/min, ml/kg/m); joint motion (degrees)	5 TT (3 traumatic, 2 dysvascular), 43-58	1	0	1	1	3	1	1	0	1	1	4	0	1	0	1	8	B
Torburn (83)	VO_2 (ml/kg/min, ml/kg/m); walking speed; stride length; cadence	10 traumatic TT, 51±6; 7 vascular TT, 62±8	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B

See methods for explanation of criteria and symbols. TT=trans-tibial amputees; TF=trans-femoral amputees. Criterion C12 (intention-to-treat) is not mentioned in this table, because in all finally included studies, this criterion was not applicable.

Table 2b: Assessment of methodological aspects of reviewed studies on prosthetic knee, prosthetic socket and prosthetic mass

Author	Parameters	Subjects (reason and level of amputation, and age (yrs), (range or mean ±SD))	Selection					Intervention					Statistical validity				Total score	Level of evidence
			A1	A2	A3	A4	A	B5	B6	B7	B8	B9	B	C10	C11	C13	C		
Board (15)	Stump volume (ml); pistoning (cm); step length, stance duration	11 traumatic TT, 32-64	1	1	1	1	4	1	0	0	0	1	2	1	1	0	2	8	C
Boonstra (17)	VO_2 (ml/kg/min, ml/kg/m), preference	28 TF traumatic/oncologic, 15-63	1	0	1	1	3	1	1	1	1	1	5	1	1	1	3	11	A
Boonstra (18)	Walking distance, ease of walking, temporal variables, goniometry	28 TF traumatic/oncologic, 15-63	1	0	1	1	3	1	1	1	1	1	5	1	1	1	3	11	A
Czerniecki (27)	VO_2 (ml/kg/m); walking speed	8 traumatic/oncologic TF, 30-44	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
Gailey (35)	VO_2 (ml/kg/min)	10 traumatic/oncologic TT, 24-52	1	1	1	1	4	1	1	1	0	1	4	1	1	1	3	11	C
Gitter (37)	Muscle power output (watt); Joint power output (watt)	8 traumatic/oncologic TF, 30-44	1	1	1	1	4	1	1	0	1	1	4	1	1	1	3	11	B
Hale (39)	Walking speed; Joint motion	6 traumatic/oncologic TF, 22-61	1	1	1	1	4	1	0	0	0	1	2	1	1	1	3	9	C
Heller (42)	Sway velocities (mm/s)	10 TF traumatic/oncologic, 38	1	1	1	0	3	1	1	0	1	1	4	1	1	1	3	10	B
Isakov (46)	Heart rate, walking speed	14 TF vascular, 50-75	1	1	1	0	3	1	1	0	1	1	4	1	1	1	3	10	B
Lehmann (54)	Self selected walking speed, VO_2 (ml/kg/m)	15 TT, 18-70	1	1	1	1	4	1	1	0	0	0	2	1	1	1	3	9	C
Mattes (59)	VO_2 (J/s); step length; swing time; stance time	6 traumatic/oncologic TF, 18-50	1	1	1	1	4	1	1	0	0	1	3	1	1	1	3	10	C
Murray (61)	Walking speed; stride length; cadence; temporal components of gait	7 traumatic TF, 33-46	1	1	1	0	3	1	0	0	1	1	3	1	1	1	3	9	B

See methods for explanation of criteria and symbols. TT=trans-tibial amputees; TF=trans-femoral amputees. Criterion C12 (intention-to-treat) is not mentioned in this table, because in all finally included studies, this criterion was not applicable.

Table 3: Main clinical findings of reviewed studies on prosthetic feet

Author	*Intervention*	Outcome	Level of evidence
Barth (13)	*SACH foot, SAFE II, Seattle Lightfoot, Quantum, Carbon Copy II, Flex-Walk*	For traumatic amputees: significantly shorter sound-limb when wearing the Flex-Walk and the SAFE II, however, when wearing the SACH, they a significantly longer sound-limb step length. Total group: with SACH foot less dorsiflexion , with Flex-Walk greater dorsiflexion than sound limb, when wearing the Carbon Copy II and the Quantum the sound limb acceptance forces were greater. No significant differences in energy cost among the prosthetic feet.	B
Boonstra (16)	*Multiflex, Quantum*	No differences in walking speed, plantar-dorsiflexion range of motion, knee joint range of motion, hip flexion-extension range of motion. Quantum foot: longer swing phase on prosthetic side, step time longer, inversion-eversion angle was 2.1° larger, adduction-abduction range of motion was 3.1° larger.	B
Casillas (20)	*SACH foot, energy-staring foot (prototype)*	For traumatic amputees with energy-storing foot: free walking speed was higher, the VO_2 (per meter) was lower, more significant as speed increased. Higher satisfaction rating when walking with the energy storing foot. No differences found for the vascular patients.	B
Cortes(3)	*SACH foot, Single-Axis, Greissinger, Dynamic-foot*	Similar behaviour for SACH and Dynamic feet (non-articulated mechanism) on the one hand, and for Single-Axis and Greissinger (articulated mechanism) on the other hand.	B
Culham (22)	*SACH foot, Single-Axis*	No differences in walking speed, cadence, stride length, gait cycle duration, mean peak stance phase flexion of prosthetic and contralateral limb. The angle of peak swing flexion was 46.37±9.60° with the SACH and differed significantly from the Single Axis (41.34±7.44°) in the prosthetic limb, for the contralateral limb the following angles were found: 51.35±4.12° 47.71±7.10°.	B
Culham (23)	*SACH foot, Single-Axis*	No differences of the activity patterns of the quadriceps in the sound limb. SACH foot: peak quadriceps activity occurred later (30%) in the stance phase of the prosthetic limb than the single axis foot (30%). SACH foot: the hamstrings of the prosthetic limb were active throughout the early and mid stance phase and peak activity occurred at 30% of the gait cycle, with single axis foot two peaks of hamstrings activity were observed (at 10% and 60%).	B
Doane (30)	*SACH foot, Single Axis*	No differences in velocity of center of mass. SACH foot: the ankle angle of the prosthetic leg during foot flat was less than with the single axis foot (-5.4±2.1° and -11.9±3.0° respectively)	
Gitter(36)	*SACH foot, Seattle-foot, Flex foot*	Seattle and Flex foot: increase in energy absorption and release during pushoff, but no differences in the pattern or magnitude of knee and hip power outputs compared to the SACH foot.	B
Goh (1)	*SACH foot, uniaxial foot*	No differences in walking speed. SACH foot: the period of heel-strike to foot-flat of the prosthetic leg took twice as long as that of the uniaxial foot for the trans-tibial and trans-femoral amputees (44.5% vs. 22.4% and 33.7% vs. 20.4% respectively). The trans-tibial and trans-femoral showed an average difference of 7.5° and 5° respectively in the ankle angle during early stance phase. No differences in ground reaction forces for trans-tibial amputees. The vertical ground reaction force on the prosthetic side for the trans-femoral amputees showed differences in its loading pattern; the SACH foot has two peak loading pattern, the uniaxial a three peak loading pattern.	C
Hsu (44)	*SACH foot, Flex foot, Re-Flex VSP*	Improvements of Re-Flex VSP versus Flex foot and SACH foot: energy cost: walking 5% and running 11%, gait efficiency: walking 6% and running 9%. No differences between the Flex foot and the SACH foot.	B
Huang (45)	*SACH foot, single-axis and multiple-axis*	No differences in energy consumption. SACH foot: good late-stance stability, limited dorsi-flexion. Multiple axis foot: less late-stance stability, more late-stance dorsiflexion. Degree of freedom of ankle joint is an important factor for comfort; multiple-axis most comfortable.	B
Lehmann (52)	*SACH foot, Seattle foot, Flex foot*	No differences in walking speed, and metabolic efficiency during walking and running. Flex foot: the longest midstance phase, the greatest ankle angle range, and greater forward movement of the center of pressure.	C
Lehmann (53)	*SACH foot, Seattle foot*	No differences in walking speed, and metabolic efficiency during walking and running. Seattle foot: longer midstance phase, pushoff phase was shorter, range of ankle motion during stance was greater (20.2° v. 9.8°), maximal dorsiflexion moment was greater (97.5Nm vs. 84.3Nm), range of knee motion during stance was greater (43.2° vs. 34.3°), range of knee motion during swing was greater (66.0° vs. 62.1°).	C
MacFarlane (56)	*Conventional foot, Flex foot*	Walking with the conventional foot was more difficult across all grade and speed conditions.	B
MacFarlane	*Conventional foot, Flex*	No differences in walking speed. Flex foot: stride length increased (134.3cm compared to 129.8cm) and cadence decreased, single support time increased,	B

(55)	*foot*	allowing larger, more normal steps with uninvolved leg, which means decrease of cadence, reflected by the increase in cycle time (124.3 for the Flex foot and 122.2 for the conventional foot).	
MacFarlane (58)	*SACH foot and Flex foot*	No differences in stride length. Flex foot: more symmetrical late stance phase and decrease in the physiological requirement of walking.	B
MacFarlane (57)	*SACH foot and Flex foot*	Flex foot: lower exercise intensity, lower energy cost and a more efficient gait in a range of walking speeds.	B
Menard (2)	*Seattle-foot, Flex foot*	No differences in walking speed. In terms of symmetry, the Flex foot more closely matches the intact side overall than the Seattle foot.	B
Nielsen (63)	*SACH foot, Flex foot*	SACH foot: at walking speeds of 2.5 mph and above energy cost was higher, relative exercise intensity was higher, at walking speeds of 2.5 mph and above the energy cost per meter was higher.	C
Perry (66)	*Single-axis, Seattle lite, Flex foot*	No differences in walking speed, stride length and cadence. The time of peak knee flexion was significantly later than normal for the Seattle, the Single Axis and the Flex foot. Seattle and the Flex foot: less plantar flexion than the Single-Axis foot. Single-axis foot: no intrinsic restraint to control plantar flexion or dorsal flexion.	B
Postema (67)	*two conventional (Otto Bock multi Axial and Otto Bock Lager) and two energy storing prosthetic feet (Otto Bock Dynamic Pro and Hangar Quantum)*	None of the prosthetic feet favoured by the subjects. The score of one conventional foot (Otto Bock Lager) was statistically lower than the scores for the other feet.	A
Postema (68)	*two conventional and two energy storing prosthetic feet*	No differences in walking speed or cadence. Range of motion at the ankle with Otto Bock Lager (conventional foot) was greater. Increase in late stance dorsiflexion results in increase of knee flexion moment and decrease in knee stability.	A
Powers (69)	*Flex foot, Carbon Copy II, Seattle, Quantum, SACH foot*	No differences in cadence. Flex foot: walking speed (although not significantly) and stride length was greater compared to the SACH and Quantum (1.50m vs. 1.44m and 1.44m). Flex foot: greater dorsiflexion compared to the Carbon Copy II, Seattle, Quantum and SACH foot.	B
Rao (71)	*Single-Axis, Seattle Lite, Flex foot*	No differences in walking velocities, stride characteristics, cadence, mean shank velocity curves and mean thigh velocity patterns. Single-Axis: uncontrolled foot and shank mobility. Flex foot and Seattle Lite: restricted mobility.	B
Schmalz (76)	*Otto Bock 1S71, Otto Bock 1D10, Otto Bock 1D25, Otto Bock 1C40, Flex Walk II*	No differences in walking speed, stride length, and energy consumption at 4.0km/h. 1S71 SACH foot: higher energy consumption at 4.8km/h, smaller plantar flexion moment immediately after heel contact. 1C40 and Flex Walk II produce higher maximum dorsiflexion moments during toe-off.	C
Snyder (77)	*Flex foot, Carbon Copy II, Seattle lite, Quantum, SACH foot*	Flex foot: free walking velocity was greater compared to the SACH foot, stride length was greater than SACH (1.35m vs. 1.25m), Carbon Copy II, and Seattle Lite foot. No differences in cadence. Flex foot and Quantum: greater terminal stance dorsiflexion than the Seattle, Carbon Copy II and the SACH. Flex foot: greater dorsiflexion means greater tibial advancement and results in greater stride length.	B
Torburn (81)	*Flex foot, Carbon Copy II, Seattle, Sten, SACH foot*	No differences in walking speed, stride length, phasing of activity of muscles tested, and energy cost. Carbon Copy II: greater cadence than SACH or Flex-foot (102 vs 98). Flex-foot: greater dorsiflexion (19.8±3.3° vs. 13±4.2°), maximum dorsiflexion torque occurring at the ankle joint during stance was greater (19.9±7.5° vs. 10.4±2.0°), more rapid rate of progression of center of pressure during single-limb support.	B
Torburn (83)	*SACH foot, Carbon Copy II, Seattle Lite, Quantum, Flex foot*	No differences in energy consumption. Energy rate traumatic group greater than the dysvascular group. No difference in walking speed, stride length and cadence.	B

Table 4: Main clinical findings of reviewed studies on prosthetic knee, prosthetic socket and prosthetic mass

Author	*Intervention*	Outcome	Level of evidence
KNEE			
Boonstra (17)	*Mechanical swing phase control (Otto Bock) and pneumatic swing phase control (Tehlin knee)*	6 patients preferred the Otto Bock 3R20 because bending the Tehlin knee was very easy which gave an unsafe feeling, 19 patients preferred the Tehlin knee because they walked more easily and/or faster. Walking with the Tehlin knee required more energy.	A
Boonstra (18)	*Mechanical swing phase control (Otto Bock) and pneumatic swing phase control (Tehlin knee)*	Normal speed: walk faster and more comfortably with the Tehlin knee. Fast walking easier with Tehlin knee. Tehlin knee: duration of swing phase of the prosthetic side is greater, stride time is greater, hip range of motion is not different, knee range of motion is smaller, the 10° flexion duration is shorter.	A
Heller (42)	*Conventional knee unit versus Intelligent Prosthesis knee unit*	Gait using the Intelligent Prosthesis was not less cognitively demanding then using the conventional knee mechanism. Total sway during gait was significantly less for the Intelligent Prosthesis than for the conventional prosthesis.	B
Isakov (46)	*Prosthesis with an open knee mechanism versus a locked mechanism*	The locked-knee enabled a higher walking speed with a lower heart rate increase than the open knee.	B
Murray (61)	*The hydraulic knee (HK) and the constant friction knee component (CFC)*	At slow speed: no differences in velocity, cadence, or stride length. Free-speed and fast walking: increase in cadence and walking speed with the HK. More asymmetry in stance phases and swing phases with CFC.	B
SOCKET			
Board (15)	*30 min walk under vacuum condition and normal condition*	With vacuum stump volume increased 3.7%, in normal condition volume decreased 6.5%. Both step length and stance durations were more symmetrical with the vacuum.	C
MASS			
Czerniecki (27)	*Three load conditions: 0kg, 0.68kg, 1.34kg of extra moss*	No differences in self-selected walking speeds and metabolic cost.	B
Gailey (35)	*Three load conditions: 0g, 454g, 907g of extra moss*	No differences in metabolic cost.	C
Gitter (37)	*Three load conditions: 0kg, 0.68kg, 1.34kg of extra moss*	No differences in the timing or duration of stance and swing phase, but there was a combined increase in hip flexor muscle contraction work and mechanical energy transfer across the hip joint.	B
Hale (39)	*Three load conditions: 0%, 75%, 100% of subject's sound shank mass (1.33-3.37kg)*	No differences in walking speed, stride length, stride time, and swing time. Increase in prosthetic mass: decreased knee flexion, prolonged knee extension.	C
Lehmann (54)	*Proximal center of mass location versus distal center of mass location, prosthesis weights of 42% to 70% of normal limb weight*	Proximal center of mass location produced a more efficient gait. Weight change from 42% to 70% of normal had no significant effect.	C
Mattes (59)	*Three load conditions: 0%, 50%, 100% of subject's sound shank mass (0.85-1.70kg)*	No differences in step length and symmetry in step length. Prosthetic limb swing time increased as its mass and moment of inertia were increased, whereas that for the intact limb was relatively unaffected by inertial manipulation of the prosthetic limb. The energy cost of walking increased significantly as the inertial properties of the prosthetic limb and intact limbs became more similar due to prosthetic limb loading.	C

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Addendum

Selection of patients

A1, Adequacy of description of inclusion and exclusion criteria: This criterion tested whether the patient sample was sufficiently defined using selection criteria, such as: age, gender, level of amputation, reason for amputation, activity level of the amputee, time since onset, stump condition, and comorbidity.

A2, functional homogeneity: The homogeneity of the study sample was assessed for all study designs. In view of clinical guideline development, at least the activity level of the included subjects should be reasonably equal. When the activity level of the patients was not described, sufficient indication of the level of amputation, the reason for amputation, and the age of the subjects was required to globally estimate the activity level of the patients. If the study sample was heterogeneous, a stratified analysis of the outcome was required to obtain a '1' score.

A3, prognostic comparability: As for group designs, the study groups should be comparable for possible confounding factors such as time since onset, and time since first walking with the prosthesis. In the case of a within-subjects design, this criterion was scored '1'.

A4, randomisation: In group designs, an adequate randomisation procedure should have been applied. If the randomisation procedure was described and the procedure reasonably excluded bias, this criterion was scored as '1'. In within-subjects designs, this criterion was applied to the sequence of interventions (7).

Intervention & Assessment

B5, experimental intervention: The experimental intervention had to be given explicitly in such detail to make it possible to perform a duplicate study as described.

B6, co-interventions: This criterion tested whether co-interventions were avoided or were comparable between the study groups.

B7, blinding: In any case, the outcome assessor had to be blinded to the intervention. In many studies investigating prosthetic components, it is hard to always reassure blinding of the patients. Therefore, this type of blinding was required only for studies using subjective outcome measures.

B8, timing of the measurement: This criterion pertained to the moment that the outcome was assessed in relation to the time period subjects were given to adapt to the prosthetic change. An adequate adaptation period was required. According to English *et al.*, trans-femoral amputees need at least three weeks of walking with a new knee mechanism to be sure that gait parameters are stable (8). Also according to English's results (8) and based on clinical experience, it was assumed

that amputees need a period of at least one week to adapt to a new prosthetic foot or to a change in prosthetic mass.

B9, outcome measures: The outcome parameters should be adequate in relation to the purpose of the study and they should have been collected using a standardised protocol.

Statistical validity

C10, drop-outs: The number of drop-outs and the reason for dropping out had to be sufficiently reported. A drop-out rate of more than 20% was considered as insufficient.

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

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

C13, data presentation: This criterion required that adequate point estimates and measures of variability were

Chapter

Prescription of Prosthetic Ankle-Foot Mechanisms after Lower Limb Amputation

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Prescription of prosthetic ankle-foot mechanisms after lower limb amputation (Cochrane Review). In: *The Cochrane Library*, Issue 1, 2004. Chichester, UK: John Wiley & Sons, Ltd.

ABSTRACT

Background: A correct prosthetic prescription can be derived from adapting the functional benefits of a prosthesis to the functional needs of the prosthetic user. For adequate matching, the functional abilities of the amputees are of value, as well as the technical and functional aspects of the various prosthetic ankle-foot mechanisms. There seems to be no clear clinical consensus on the precise prescription criteria for the various prosthetic ankle-foot mechanisms related to the functional abilities of amputees.

Objectives: To obtain information about aspects of prosthetic ankle-foot mechanisms and daily functioning of amputees with a prosthesis, for appropriate prosthetic prescription criteria.

Search Strategy: We searched the Cochrane Musculoskeletal Injuries Group specialised register of trials (April 2003), the Cochrane Central Register of Controlled Trials (The Cochrane Library issue 1, 2003), MEDLINE (1966 to April 2003), EMBASE (1983 to April 2003), CINAHL (1982 to April 2003) and reference lists of articles. No language restrictions were applied.

Selection Criteria: All randomised controlled trials and quasi-randomised controlled trials comparing different prosthetic devices for lower limb amputation in adults. No language restrictions were applied.

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

Main Results: Twenty-three trials were included, with a total of 217 participants. The methodological quality was moderate. Only one study was of high quality. No classical RCT's were identified, yet, all included studies used cross-over designs allowing sufficient control for confounding. In high activity trans-femoral amputees, there is limited evidence for the superiority of the Flex-foot during level walking compared with the SACH foot in respect of energy cost and, gait efficiency. This benefit has only been confirmed in trans-tibial amputees during decline and incline walking and increased walking speeds.

Reviewers' conclusions: There is insufficient evidence from high quality comparative studies for the overall superiority of any individual type of prosthetic ankle-foot mechanism. In high activity trans-femoral amputees, there is limited evidence for the superiority of the Flex foot during level walking compared with the SACH foot in respect of energy cost and, gait efficiency. This benefit has only been confirmed in trans-tibial amputees during decline and incline walking and increased walking speeds. In prescribing prosthetic-ankle foot mechanisms for lower-limb amputees, practitioners should take into account availability, patient functional needs, and cost.

Background

Prosthetic prescription for lower extremity amputees is primarily based on empirical knowledge. There are many options for various prosthetic ankle-foot mechanisms but, at present, prescription criteria can only be derived from the experiences of physicians, therapists and prosthetists [7,14]. Furthermore, third-party payers frequently require justification for purchasing costly prostheses [14] and customers also require transparency in the choice of the correct prosthetic ankle-foot mechanism for them.

A correct prosthetic prescription can be derived from adapting the functional benefits of a prosthesis to the functional needs of the prosthetic user [4]. For adequate matching, the functional abilities of the amputees are important, as well as the technical and functional aspects of the various prosthetic ankle-foot mechanisms. The development of clinical guidelines is one way of making care more consistent and efficient, and for diminishing the gap between what clinicians do and what scientific evidence supports. A systematic review of the literature as a part of clinical guideline development focuses attention on fundamental questions that must be answered to establish the efficacy of technical interventions. It may also highlight gaps in the existing literature [38].

To our knowledge, there are no useful scientifically based clinical guidelines for lower limb prosthetic prescription. Also, there seems no clear clinical consensus on the precise prescription criteria for the various prosthetic ankle-foot mechanisms related to the functional abilities of amputees. From this perspective, we have decided to develop clinical guidelines for lower limb prosthetic prescription in order to obtain transparency and consensus among clinicians, manufacturers and insurance companies. The first step is to obtain explicit knowledge from the literature. For this purpose, the types of studies we are interested in are studies addressing motor performance and/or daily functioning of amputees with a lower limb prosthesis. These studies focus on subjective findings, energy expenditure, or gait parameters. In view of clinical guideline development these studies are considered most relevant for prosthetic prescription.

Objectives

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

Criteria for considering studies for this review

Types of studies

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

Types of participants

All adult (18-80 years of age) trans-femoral, knee disarticulation, and trans-tibial amputees with dysvascular, traumatic, congenital, or oncologic amputations. There were no race or gender restrictions, or restrictions on setting.

Types of intervention

Any trials which compare the ankle-foot mechanisms currently in use such as SACH-feet, Flex-feet, Seattle-feet, Single-Axis feet. Trials investigating amputation techniques or early prosthetic fitting were excluded.

Types of outcome measures

Motor performance and activities of daily living (ADL) functioning are important for prosthetic prescription, therefore data were sought for the following outcome measures:

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

Search strategy for identification of studies

See: Cochrane Musculoskeletal Injuries Group search strategy

We searched the Cochrane Musculoskeletal Injuries Group specialised register of trials (April 2003), the Cochrane Central Register of Controlled Trials (The Cochrane Library issue 1, 2003), MEDLINE (1966 to April 2003), EMBASE (1983 to April 2003), CINAHL (1982 to April 2003) and reference lists of articles. No language restrictions were applied.

The search strategy for MEDLINE (SilverPlatter) is shown in Table 1. The subject specific search was combined with a modification of the optimal trial search strategy (McDonald 2002). This strategy was modified for use in other databases.

Table 1: MEDLINE search strategy

	search terms
#1	amputee* in ti,ab
#2	AMPUTEES/ all subheadings
#3	#1 or #2
#4	(knee near (disarticulat* or exarticulat*)) in ti,ab
#5	(amputat* near (transfemoral or transtibial or lower-limb or lower-extremity or above-knee or below-knee or through-knee)) in ti,ab
#6	DISARTICULATION/ all subheadings
#7	AMPUTATION/ all subheadings
#8	AMPUTATION, TRAUMATIC/ all subheadings
#9	AMPUTATION STUMP/ all subheadings
#10	#6 or #7 or #8 or #9
#11	(transfemoral or transtibial or lower-limb or lower-extremity or knee) in ti,ab
#12	explode LEG/ all subheadings
#13	#11 or #12
#14	#10 and #13
#15	#3 or # 4 or # 5 or #14
#16	((SACH near feet) or (SACH near foot) or (Flex near feet) or (Flex near foot) or (Seattle near feet) or (Seattle near foot) or (Single-Axis near feet) or (Single-Axis near foot) or (Golden-Ankle near feet) or (Golden-ankle near foot)) in ti,ab
#17	((foot or feet) near (energy-storing or ankle-mechanism or conventional)) in ti,ab
#18	((prosthetic? or prosthes?s) near (foot or feet or ankle* or lower-extremity)) in ti,ab
#19	ARTIFICIAL LIMBS/ all subheadings
#20	(artificial near (leg or foot or feet or limb)) in ti,ab
#21	((prosthetic? or prosthes?s) near (prescription? or outcome? or profile? or assessment? or casting)) in ti,ab
#22	#16 or #17 or #18 or #19 or #20 or #21
#23	(subjective-findings or preference? or satisfaction or comfort or Borg-scale? or rating-scale? or ease or questionnaire? or Prosthesis-Evaluation-Questionnaire or Prosthetic-Profile-of-the-Amputee or Locomotor-Capabilities-Index or Sickness-Impact-Profile or Nottingham-Health-Profile or Reintegration-to-Normal-Living) in ti,ab
#24	(oxygen-uptake or physiological-measurement or metabolic-cost or oxygen-cost or energy-cost or energy-demands or energy-expenditure or energy-consumption or heart-rate or pulse) in ti,ab
#25	(gait-pattern or gait-characteristics or walking-speed or walking-velocity or comfortable-speed or walking-distance or cadence or stride-characteristics or stride-length or step-length or stride-time or stance-phase or swing-phase) in ti,ab
#26	(kinetic-parameters or ground-reaction-force?) in ti,ab
#27	(joint-motion or ankle-dorsiflexion or ankle-plantarflexion or knee-flexion or knee-extension or hip-flexion or hip-extensions or power-output or tibial-advancement) in ti,ab
#28	#22 or #23 or #24 or #25 or #26 or #27
#29	#22 or #28
#30	#15 and #29
#31	RANDOMIZED-CONTROLLED-TRIAL in PT
#32	CONTROLLED-CLINICAL-TRIAL in PT
#33	RANDOM-ALLOCATION
#34	DOUBLE-BLIND-METHOD
#35	SINGLE-BLIND-METHOD
#36	explode CROSS-OVER-STUDIES/
#37	#31 or #32 or #33 or #34 or #35 or #36
#38	((clinical or controlled or comparative or placebo or prospective* or random*) near (trial or study)) in ti,ab
#39	(random* near (allocat* or allot* or assign* or basis* or divid* or order*)) in ti,ab
#40	((singl* or doubl* or trebl* or tripl*) near (blind* or mask*)) in ti,ab
#41	(crossover or (cross-over*) in ti,ab
#42	((allocat* or allot* or assign* or divid*) near (condition* or experiment* or intervention* or treatment* or therap* or control* or group*)) in ti,ab
#43	#38 or #39 or #40 or #41 or #42
#44	#37 or #43
#45	#30 and #44

Methods of the review

Selection of studies:

Two reviewers independently assessed the abstracts of all studies identified by the initial search and excluded non-relevant studies. Full text articles were obtained

for any studies with unclear methodology or when abstracts were not available. Disagreement on inclusion was resolved by consulting a third reviewer. Full text articles were obtained for any studies which passed the inclusion criteria as described above.

Study quality:

Methodological quality was assessed using a checklist comprising 13 criteria. This checklist was based on two existing criteria lists for quality assessment [36,37], which were originally developed to evaluate randomised controlled trials. Each criterion was scored according to three levels: no '0', yes '1' or not applicable 'na'. The selected studies were analysed by two reviewers, and differences resolved by discussion.

Selection of patients:

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

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

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

gaseous exchanges, addiction to tobacco, presence or absence of diabetes mellitus, peripheral or central neurological disease affecting walking, lower-limb articular or pre-articular damage liable to cause walking-restricting pains, no coexisting neurologic or musculoskeletal disorders that interfere with walking).

A4: Randomisation. In randomised controlled studies, an adequate randomisation procedure should have been followed. If the randomisation procedure was described and the procedure would exclude bias, this criterion was scored as '2'. In within-subject designs, the internal validity does not depend on the randomisation as in randomised controlled trials [34].

Intervention:

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

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

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

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

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

Statistical validity:

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

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

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

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

Best-evidence synthesis:

In relation to the purpose of our review, it was required that the included studies should control for selection bias and measurement bias. Therefore, only the studies in which the total score of the A criteria and B criteria was six points or more (out

of a possible nine points) were used in the best-evidence synthesis. Studies were classified as A if the total score of all criteria was 11 points or more, and included a positive score for blinded outcome assessment (criterion B7) and timing of the measurement (criterion B8). Studies were classified as B if the total score was between six and 10 points, including a positive score for timing of the measurement (criterion B8). Studies were classified C studies if the total score of the A criteria and B criteria was at least than six points, but with an invalid score on the criteria B7 and B8.

In summary:
A grade: 11 points or more, including six points out of the A and B criteria, which must include B7 and B8;
B grade: between six and 10 points, including six points out of the A and B criteria, which must include B8;
C grade: Studies with a total score of at least 6 points out of the A and B criteria with an invalid score on the criteria B7 and B8.

Data extraction:
Data were extracted from all relevant studies independently by two reviewers (HL, CH) and entered into RevMan [35]. Disagreements were resolved by discussion. Where possible and where necessary, attempts were made to secure missing data from the authors.

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

- The study populations of all the different trials were heterogeneous, because of the difference in the level of amputation, the cause of amputation, and activity level of the amputees
- There were a lot of different interventions; in 23 trials 18 prosthetic ankle-foot mechanisms were investigated
- There were a lot of different outcome parameters, measured in different ways.

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

Description of studies
Twenty-nine studies fulfilled the criteria for considering studies for this review. The total score of the A criteria and B criteria was at least six points in 23 studies

and were therefore included. No classical RCT's were identified, yet, all studies used within-subject crossover designs, i.e. one group of amputees wore different prosthetic feet.
The numbers of participants in the included trials ranged from three to sixteen. The participants' lower extremity was amputated for vascular, traumatic or oncological reason. Exclusion of participants with stump problems was reported in 12 studies.

The different prosthetic ankle-foot mechanisms used in the included studies were:

- SACH-foot
- Flex-foot
- SAFE II
- Seattle Lightfoot
- Quantum foot
- Carbon Copy II
- Multiflex foot
- Energy-storing Proteor foot
- Single-axis foot
- Greissinger
- Dynamic
- Re-Flex VSP
- Multiple Axis
- Otto Bock Multi Axial
- Otto Bock Lager
- Otto Bock Dynamic Pro
- Hanger Quantum
- Sten foot

Only three studies reported subjective findings as outcome measures. In Casillas' study a satisfaction index was developed [3], in MacFarlane's study the Borg-scale was used [12] and in Postema's study a questionnaire was composed to obtain the preference of the participants [17]. Furthermore, all the studies reported one of the other outcome measures of interest (energy expenditure, stride characteristics, kinetic parameters, or kinematic parameters).

Methodological quality

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

Table 2: **Methodological quality scores and overall grade**

Study id	A1	A2	A3	A4	B5	B6	B7	B8	B9	C10	C11	C12	C13	Total	Overall Grade
Barth 1992	1	1	1	1	1	1	0	1	1	1	0	na	1	10	B
Boonstra 1993	1	0	1	0	1	1	0	1	1	0	1	na	1	8	B
Casillas 1995	1	1	1	0	1	1	0	1	1	1	1	na	1	11	B
Cortes 1997	1	1	1	1	1	1	0	1	1	0	1	na	0	9	B
Culham 1984	1	0	1	1	1	1	0	1	1	1	1	na	1	10	B
Doane 1983	1	0	1	0	1	1	0	1	1	0	1	na	1	8	B
Goh 1984	1	1	1	0	1	1	0	0	1	0	1	na	0	7	C
Hsu 1999	1	1	1	1	1	0	0	1	1	1	1	na	1	10	B
Huang 2000	1	1	1	1	1	1	0	1	1	1	1	na	1	11	B
Lehmann 1993a	1	1	1	0	1	1	0	0	1	0	1	na	1	8	C
Lehmann 1993b	1	1	1	1	1	1	0	0	1	0	1	na	1	9	C
MacFarlane 1991	1	1	1	1	1	1	0	1	1	1	1	na	1	11	B
MacFarlane 1997	1	1	1	1	1	1	0	1	1	1	1	na	1	11	B
Menard 1992	1	1	1	0	1	1	0	1	1	1	1	na	0	9	B
Nielsen 1988	1	1	1	1	1	0	0	0	1	1	0	na	0	7	C
Perry 1997	1	1	1	1	1	1	0	1	1	1	1	na	0	10	B
Postema 1994	1	1	1	2	1	1	1	1	1	1	1	na	1	13	A
Powers 1994	1	1	1	1	1	1	0	1	1	0	1	na	1	10	B
Rao 1998	1	1	1	0	1	1	0	1	1	1	1	na	1	10	B
Schmalz 2002	1	1	1	1	1	0	0	0	1	0	1	na	1	8	C
Snyder 1995	1	1	1	1	1	1	0	1	1	1	1	na	1	11	B
Torburn 1990	1	0	1	1	1	1	0	1	1	0	1	na	1	9	B
Torburn 1995	1	1	1	1	1	1	0	1	1	1	1	na	1	11	B

na: not applicable

In four studies it was unclear if the participants had the similar activity level. In three studies the reason for amputation was diverse [2,5] and in Doane's study the reason for amputation was not reported [6]. In fifteen studies the sequence of prosthetic ankle-foot mechanisms was randomised, of these studies only Postema described which randomisation procedure was applied [17]. In most studies, participants wore prostheses that allowed interchange of the foot component, therefore these studies scored '1' for the B6-criterion co-interventions. However, three studies did not report any detail of the prosthetic components of the participants, followed by a '0' score on this criterion [8,15,20]. Only one study reported blinding of the participants [17]. Treatment masking or blinding is an effective way to increase the objectivity of the person(s) observing experimental outcomes. When

the treatments are masked, the bias of the participants and observer are not likely to influence the measurements taken.

It is assumed that amputees would need a period of at least one week to acclimatise to prosthetic feet [31]. This was not the case or not reported in five studies [7,10,11,15,20]. If a participant did not acclimatise to a new prosthetic foot, one could not be sure that pertinent gait parameters would have been stabilised. Nine studies failed to mention the number of drop-outs and in the tables or figures it was not clear whether all the participants were able to perform all the tests [2,4,6,7,10,11,18,20,22]. The number of participants was very low in two studies [1,15]. In Barth's study two subgroups were investigated; each subgroup consisted of only three participants. The population of Nielsen's study also consisted of only three participants. The criteria intention to treat was not applicable for any of the included studies, since there were no drop-outs, or the number and reason for drop-outs was not mentioned.

Data were not presented sufficiently in five studies [4,7, 14-16]. Cortes' study investigated which factors influence the amputee's gait and in which order of importance. The results did not show the effect of different prosthetic feet on the assessed outcome parameters in terms of mean and standard deviation. Therefore the results of this study cannot be included in the comparison. In Perry's study, the data were presented as a percentage of healthy nonamputated controls. However, the normative values were based on unpublished laboratory data.

Results

Study selection

The EMBASE search (1983 to April 2003) resulted in the identification of 139, the CINAHL search (1982 to April 2003) in 42, the Cochrane Central Register of Controlled Trials (The Cochrane Library issue 1, 2003) in six and the MEDLINE search (1966-April 2003) in four potentially eligible studies. This search was extended with relevant references from the retrieved studies, yielding 21 more articles.

After reviewing the information on authors, title, abstract and keywords, both reviewers considered 35 studies to be potentially eligible for review. Reviewing the full articles of these studies resulted in agreement about 29 studies meeting the eligibility criteria. Six studies did not meet the eligibility criteria [24-29]. An important reason for excluding these studies was that the selection of the study sample was poorly described.

The two articles of Culham (1984; 1986) reported on the same study (Culham 1984), this was also the case for the two articles of Hsu (1999; 2000) (Hsu 1999), the two articles of MacFarlane (1991a; 1991b) (MacFarlane 1991), two other articles of MacFarlane (1997a; 1997b) (MacFarlane 1997), and the three articles of Postema (1994; 1997a; 1997b) (Postema 1994). This resulted in an overall inclusion of 23 studies.

Study characteristics

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

Except for the Borg-scale, the outcome parameters included in this section are parameters measured while the participants were walking at their comfortable walking velocity, otherwise the data would not be comparable.

Comfortable walking velocity (meters per minute)

Fourteen studies used comfortable walking velocity as outcome parameter. Only two studies reported significant differences between some prosthetic feet [15,21]. The traumatic trans-tibial amputees in Nielsen's study [15] walked faster with the Flex-foot than the SACH-foot (77.8±16.9m/min versus 71.4±15.8m/min) and the diabetic trans-tibial amputees in Snyder's study [21] reached a higher self selected walking velocity with the Flex-foot than the SACH-foot (71.6±12.6m/min versus 63.6 ±10.0m/min).

Stride length (meters)

Stride length was an outcome parameter in eight studies. Only two studies found significant differences between the Flex foot and other prosthetic feet. The traumatic trans-tibial amputees in Powers' study had a greater stride length when walking with the Flex-foot than with the SACH and the Quantum foot (1.50±0.13m, vs. 1.44±0.15m and 1.44±0.15m) [18]. The diabetic trans-tibial amputees in Snyder's study also had a greater stride length when walking with the Flex-foot, compared to the SACH, the Carbon Copy II and the Seattle foot (1.35±0.19m vs. 1.25±0.16m, 1.27±0.17m, and 1.25±0.13m) [21].

Cadence (steps per minute)

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

Energy Cost (ml oxygen per kg per minute)

No significant differences were found in energy cost among the prosthetic feet tested in the traumatic as well as the vascular group in Barth's study [1]. The vascular and traumatic amputees in Huang's study also showed no differences in energy cost when walking with the SACH-foot, single axis, or the multiple axis 9. For the five trans-tibial amputees of Torburn's study there were no differences between foot-types in energy cost during free walk [22]. This was also the case for the nine traumatic and the seven vascular trans-tibial amputees of an other study of Torburn [23].

Energy cost was identical for the two prosthetic feet as well as for the traumatic and the vascular trans-tibial amputees of Casillas' study when walking on level ground at self selected walking speed [3]. During walking on level treadmill at progressive speed, energy cost was lower with the prototype foot compared to the SACH foot in the traumatic group and the difference became more significant as speed increased (22.11±3.29 ml oxygen/kg/min vs. 24.71±2.18 at 6 km/h). Energy cost was also lower when walking with the Proteor foot compared with the SACH foot with inclined and declined treadmill walking (16.79±2.32 vs. 19.31±2.80 ml oxygen/kg/min with decline treadmill 5%). When the nonvascular trans-tibial amputees in Hsu's study walked on the treadmill, energy cost was significantly decreased while walking with the Re-Flex VSP compared with the SACH and the Flex foot at progressive speed (36.83±5.07 ml oxygen/kg/min vs. 40.73±5.29 and 39.44±5 .37 when running at 147.51m/min), while the Flex-foot and the SACH were not statistically significant [8].

For the eight trans-tibial traumatic amputees in Schmalz' study the values of the energy cost showed no significant differences between the various foot designs when walking at 4km/h. However, energy consumption increased when walking with the 1S71 SACH-foot at a speed of 4.8km/h compared to the other feet (16.1± 1.4 vs. 15.6±1.2 ml oxygen/kg/min) [20]. At walking speeds of 2.5 miles per hour, the energy cost of walking with the SACH-foot was higher than with the Flex-foot in the three traumatic trans-tibial amputees of Nielsen's study [15]. However, no means and standard deviations of this outcome parameter were presented.

In MacFarlane's study, 5 traumatic trans-femoral amputees walked with a lower energy cost when walking with the Flex-foot than with the SACH-foot (16.70±0.24 vs. 17.69±0.24 ml oxygen/kg/min) [13].

Gait efficiency (ml oxygen per kg per meter

Gait efficiency was lower with the Proteor foot compared with the SACH-foot for the twelve traumatic amputees in Casillas study (0.22±0.04 vs. 0.24±0.04 ml oxygen/kg/meter) [3]. Between foot-type comparisons showed progressive separation of the energy cost values (SACH>Flex>Re-Flex VSP) with increasing walking speed. The differences appeared negligible for the lower two walking speeds. In Hsu's study between foot-type comparisons for the amputees showed progressive separation of the gait efficiency values (SACH>Flex-foot>Re-Flex VSP) with increasing walking speed (between 53.64 m/min and 147.51 m/min) [8]. The gait-efficiency of the Re-Flex VSP was significantly different compared with the SACH and the Flex-foot (0.28±0.04 vs. 0.25±0.03 ml oxygen/kg/m at a running speed of 147.51 m/min); the differences between the SACH-foot and the Flex-foot were not significantly different [8].

For each walking and running speed in Lehmann's study [10] there were no significant differences among the three foot designs for the nine trans-tibial amputees. The same results were found in another study of Lehmann [11], while walking with the Seattle and the Flex-foot. In MacFarlane's study, at each walking speed the mean walking efficiency was better (lower value) with the Flex-foot than with the SACH-foot (0.253±0.003 ml oxygen/kg/meter vs 0.270±0.003) in five traumatic trans-femoral amputees [13].

For the three traumatic trans-tibial amputees of Nielsen's study there were no significant differences in gait efficiency between the two types of prosthetic feet at all walking speeds [15].

For the five trans-tibial amputees of Torburn's study there were no differences between foot-types in gait efficiency during free walk [22]. This was also the case for the nine traumatic and the seven vascular trans-tibial amputees of an other study of Torburn [23].

Borg-Scale

In MacFarlane's study, with each grade and speed condition, walking with the SACH-foot was perceived to be more difficult than walking with the Flex-foot (10.4±1.6

vs. 8.6±1.1 at level walking at medium speed) [12]. The greatest difference occurs on the level and incline grades.
As for patient satisfaction, the only A study [17] concluded that no specific prosthetic foot was consistently favoured over another type of foot by traumatic trans-tibial amputees. Yet, in one B study, the prototype energy-storing foot (Proteor foot) scored a higher satisfaction rate than the SACH foot in traumatic trans-tibial amputees [3]. However, since the prosthetic users were not blinded in MacFarlane's and Casillas' studies, these results should be interpreted with caution.

Joint motion
Some studies investigated joint motion as an outcome parameter. In the A study by Postema et al. [17], the range of motion (ROM) at the ankle during the stance phase of a single-axis conventional foot was greater than the same ROM of two energy-storing feet. This result could readily be related to the mechanical characteristics of the different feet, i.e. the presence or absence of an ankle axis in the frontal plane. Furthermore, the energy storing Flex foot showed a greater late stance dorsiflexion compared with the conventional SACH foot in three B studies [18, 21, 22] and two C studies [11, 20] on traumatic and vascular trans-tibial amputees. The fact that the Flex foot resulted in a greater stride-length is indicative of a greater tibial advancement as a result of increased dorsiflexion [21].

Discussion
None of the reviewed studies showed significant differences between any of the investigated prosthetic ankle-foot mechanisms for the comfortable walking speed or cadence. However, there is a small tendency that when walking with the Flex-foot the stride length is greater compared to the SACH foot [18,21].
During level treadmill walking there were no differences in energy cost in both the traumatic and the vascular trans-tibial amputees. However, when walking speed was increased or when amputees walked on decline or incline treadmill, energy cost was lower when walking with an energy-storing foot than with the SACH foot [3,8,20]. This means that when prescribing a prosthetic ankle-foot mechanisms for the more active amputee (who is able to alter his walking speed and walk on inclines and declines), they would benefit from an energy-storing prosthetic foot, such as the Flex-foot, the Re-Flex foot or the Proteor foot.
In contrast with the trans-tibial amputees, in the trans-femoral amputees the energy cost is lower during level walking when walking with the Flex-foot compared with the SACH-foot [13]. This raises the hypothesis that in high activity trans-femoral amputees the design of the ankle foot mechanism may be more

important than in trans-tibial amputees and that more studies are needed. When amputees were asked which prosthetic foot they preferred, only the A-study concluded that no specific foot was favoured, although there were differences in the mechanical characteristics of the prosthetic feet [17]. This implies that besides the functional benefits of a prosthesis and the functional needs of the amputee, also the amputees' interpretation of walking difficulty is of value for the prosthetic prescription.

Reviewer's conclusion

Implications for practice

There is insufficient evidence from high quality comparative studies for the overall superiority of any individual type of prosthetic ankle-foot mechanism. In high activity trans-femoral amputees, there is limited evidence for the superiority of the Flex foot during level walking compared with the SACH foot in respect of energy cost and gait efficiency. This benefit has only been confirmed in trans-tibial amputees during decline and incline walking and increased walking speeds. In prescribing prosthetic-ankle foot mechanisms for lower-limb amputees, practitioners should take into account availability and patient functional needs.

Implications for research

For future research, functional comparisons between different prosthetic components should be better categorised according to the level of activity and intended use in specific subgroups of e.g. traumatic or vascular amputees. Such an approach would better acknowledge the importance of individual needs and abilities that guide clinical-decision making in daily practice. Secondly, functional outcomes should be assessed for various aspects of mobility such as making transfers, maintaining balance, level walking, stair climbing, negotiating ramps and obstacles, changing walking speed et cetera. Most studies reviewed in this paper assessed walking on a treadmill (at self-selected walking speeds), probably for reasons of technical and practical convenience. Indeed, Mulder et al. already pointed out that the vast majority of clinical studies on human walking have used rather standardised gait assessment protocols with limited "ecological validity" [33]. Although perhaps less analytic, modern systems for ambulatory monitoring of human activity [30] are able to provide objective and valid data about (changes in) human motor behaviour during prolonged periods of hours or days in a much more ecologically valid way. Also, subjective assessments of comfort, stability and efficiency should certainly be used more when blinding of the prosthetic users can be assured. Thirdly, the effects of different prosthetic feet should also be evaluated in patients with e.g. a knee disarticulation or trans-femoral amputation

because generalising results from trans-tibial amputees to these higher levels of amputation may be invalid. Lastly, more research is needed into the effects of prosthetic knees with stance-phase stabilisers as well as into the functional effects of different prosthetic sockets in knee disarticulation and trans-femoral amputees.

Acknowledgements
Thank you to the following for useful comments at editorial review: Bill Gillespie, Lesley Gillespie, Peter Herbison, Marc Swiontkowski, Janet Wale, Keith Jeffery and Jane Cumming.

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** Indicates the major publication for the study*

Chapter

Prosthetic Prescription in the Netherlands: An Observational Study

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Prosthetics and Orthotics International 2003 (27): 170-178

Abstract

Introduction: Prosthetic prescription for lower limb amputees and the used methodology are primarily based on empirical knowledge. Clinical expertise plays an important role that can lead to an adequate prescription; however, a clear evidence based motivation for the choices made cannot be given. This can lead to local prescription variations with regard to overuse or underuse of prosthetic care and a lack of transparency for consumers and health insurance companies. Hence a clinical guideline may lead to a more consistent and efficient clinical practice and thus more uniformly high quality care.

Objective: The purpose of this study was to get insight into potential similarities in prescription criteria in clinical practice in the Netherlands. Secondly, we were interested if prosthetic prescription was primarily based on the level of activity or intended use of the prosthesis.

Methods: As part of the development of a consensus-based clinical guideline a multi-centred, cross-sectional study was carried out in order to observe the prosthetic prescription of a group of lower extremity amputees. Therefore prescription data were collected from 151 amputees with a trans-femoral, knee disarticulation or trans-tibial amputation.

Results: Results of the multiple logistic regression show no relationship between the activity level and any of the variables included in the equation such as the hospital or medical doctor in Physical and Rehabilitation Medicine (MD in P&RM), prosthetic components, age of the amputee or reason of amputation. The criteria used are merely based on the clinical expertise and local experience whereas the actual prescriptions differ from location to location.

Discussion and Conclusion: In conclusion the development of a clinical guideline for prosthetic prescription in lower limb amputation is recommended. The information gained from this observational study will be used in a clinical guideline procedure for prosthetic prescription in the Netherlands.

Introduction

In the Netherlands the incidence of major lower limb amputation is about 19 per 100.000 habitants [4]. These include amputations from the transmetatarsal to the transpelvic level. For an amputee population in the north of the Netherlands in 1991 and 1992 [17] approximately 82% of the total lower limb amputations occurred as a result of vascular diseases, 9% were traumatic amputations, and 9% were the result of oncological amputations. Stewart *et al.* found similar figures in Scotland [19]. In the Netherlands, 86% of all lower extremity amputations are trans-femoral (TF) (34%), knee disarticulation (KD) (10%) or trans-tibial (TT) amputations (42%) [4]. Of these amputees, 48% were fitted with a prosthesis [15].

In the Netherlands a prosthesis is prescribed in clinical practice by a medical doctor in Physical and Rehabilitation Medicine (MD in P&RM) in collaboration with a prosthetist and sometimes with the advice of a physical therapist. This clinical practice is mostly located in rehabilitation centres or general hospitals. The role of the MD in P&RM and the prosthetist as members of a clinical team is slightly different from that in other industrialised countries. The MD in P&RM is not only responsible for information on medical aspects but also has a leading role in choosing the prosthetic components. In addition, the training level of the prosthetists has been of a lower category (ISPO level II) up to now.

In the Netherlands, and probably everywhere else in the world, prosthetic prescription for lower limb amputees and the used methodology are primarily based on empirical knowledge. This knowledge is transmitted to professionals by 'residents' clinical training' and is further developed and renewed in clinical practice and by courses and symposiums. These developments and renewals have not been established in a standardized way, i.e. there is no existing clinical guideline. Experience plays an important role that can lead to an adequate prescription; however, a clear evidence-based motivation for the choices made cannot always be given. This can lead to local prescription variations as to overuse or underuse of prosthetic care and a lack of transparency for consumers and health insurance companies. Hence a clinical guideline can lead to a more consistent and efficient clinical practice and more uniformly high quality care [21,22].

Multiple factors must be considered in the prosthetic prescription for an individual amputee. The amputee's general health (co-morbidity), mental state, living circumstances and vocational interests must be considered in addition to the level of amputation [2,17]. There is a growing awareness that the prescription has to match the intended use of a prosthesis [5,12].

Classification of amputees based on functional abilities can be of use in differentiating among the different levels of prosthetic prescription [6]. In general

terms a prosthetic prescription should be based on matching the functional needs of the amputee with the functional capacities of the prosthetic device [5]. In our view an adequate instrument in the classification of amputees for prosthetic prescription is not available. The Special Interest Group for Amputee Medicine (SIGAM) of the British Society of Rehabilitation Medicine (BSRM) uses a validated scale of 'disability mobility grades' in prosthetic prescription [20]. Several questionnaires on prosthetic use, functional aspects of a prosthesis and general activities are available too. However, none of these offer explicit information on how to translate the amputee's functional ability into an adequate prosthetic prescription [1,7,11]. A mobility scale can be a good starting point. However, Rommers *et al.* found that the existing mobility instruments for lower limb amputees differ considerably and only measure certain aspects of mobility [16]. In our opinion for this study the 5-level functional classification used by the US Health Care Financing Administration (HCFA) is most suitable [9]. Based on this classification Gailey *et al.* developed "The Amputee Mobility Predictor" as a valid instrument to measure the ability to ambulate with a prosthesis. However, prosthetic prescription needs additional research [6].

There are some difficulties in using the results from studies on biomechanical aspects and functional characteristics of several prosthetic components for prescription criteria. Outcome measures differ from study to study, therefore comparison or meta-analysis of the results is difficult. However, the explicit knowledge derived from literature is needed to develop a clinical guideline [22]. In cases where literature findings are not appropriate or subject areas have not been researched, development of a clinical guideline has to rely on other sources of evidence. Accordingly, professionals can provide expert opinion and in addition knowledge from clinical experience [18].

As part of the development of a consensus-based clinical guideline we gathered implicit information on prosthetic prescription in the Netherlands by using an observational study of prescription in clinical practice and an interview with leading experts in the field of prosthetics.

The purpose of this study was to get insight into possible similarities in prescription criteria in practice. Secondly, we were interested if prosthetic prescription was primarily based on the amputee's level of activity or the intended use of the prosthesis.

The results will be used in the guideline-developing consensus procedure carried out in the Netherlands concerning the prescription for prosthetics of the lower limb.

Methodology

Subjects

In the present study a multi-centred, cross-sectional study was carried out in order to observe the prosthetic prescription of a group of lower extremity amputees. To collect these data, 16 hospitals were selected. A hospital was included if sufficient and adequate expertise on amputation and prosthetics was present in the rehabilitation team that provided the prosthesis. The MD in P&RM within those teams were all members of a professional working-group of physicians in P&RM focused on amputation and prosthetics in the Netherlands. Secondly the amount of prosthetic prescriptions in the selected hospitals had to exceed 100 prescriptions on an annual basis. The selected hospitals were evenly distributed across The Netherlands.

Data were collected from inpatient and outpatient amputees with a TF, KD and TT amputation. Patients with primary as well as secondary amputations were included. There were no restrictions concerning age, gender or race of the amputees, on the side and date of the amputation and the reason for amputation.

Since no valid assessment instrument was available, an assessment form was developed on which data of patient, hospital and prosthesis could be recorded in a standardised way.

For classification of the amputee's level of activity the coding system of the HCFA seemed the most appropriate [9]:

- If an amputee has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence, he or she is assessed as K1. This can be typified as a limited and unlimited household ambulator.
- A K2-amputee has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. This is typical for the limited community ambulator.
- A more active amputee with the ability or potential for ambulation with variable cadence is assessed as K3. This is a community ambulator who has the ability to traverse most obstacles and may have vocational, therapeutic or exercise activities that demand prosthetic utilization beyond simple locomotion.
- Most active amputees are graded as K4 and have the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. This is typical for the prosthetic demands of a child, an active adult or an athlete.

The observations were performed by two researchers (HL and CH). The observed decisions or remarks were extended with questions to rehabilitation-team members

or amputees when items on the structured observation list were not mentioned. The activity level resulted from the appraisal of both the remarks of the team members and the amputees on this subject.

Analysis

To facilitate the analyses, level of activity was assessed as a dichotomous variable. Therefore the amputees were classified into two levels of activity. Activity level 1 included K1 and K2-amputees, whereas activity level 2 included the K3 and K4-amputees.

The Netherlands was divided into three areas: the northern and eastern part including 7 hospitals, the western part with 6 hospitals, and the southern area with 3 hospitals.

Data were processed using SPSS version 9.0 and Egret. The statistical procedures used were Spearman correlations and Multiple Logistic Regressions, to find relationships between activity level and prosthetic prescription, patient data and data of the hospitals visited.

Results

The studied population consisted of 151 amputees, including 3 bilateral ones, of whom both prostheses were separately recorded in the databases. The realisation of 154 prosthetic prescriptions for major lower limb amputations was observed during 25 visits of 16 hospitals in the Netherlands. For one amputee the assessment form was incomplete and therefore it was left out of the databases. For two amputees it was impossible to assess their activity level, because these patients were amputated for complex regional pain syndrome type I (CRPS I) and the patient as well as the MD in P&RM were uncertain about the future activities of the amputee. These three amputees were left out of the database. In all, the total database included 151 prescriptions of whom 94 cases were TT amputees (62%), 41 TF cases (27%) and only 16 cases (11%) were KD amputees.

The majority of the studied population was 70 years old or older (37%), the group of 55-70 year olds was somewhat smaller (35%) (Figure 1). Seventy per cent was male and 75% of the studied population was graded into the group with activity level 1. In 36% of the cases amputation was performed because of vascular reasons (with or without Diabetes Mellitus), in 27% and 29% amputation had been performed for vascular or traumatic/oncological/congenital reasons, respectively. Most amputations had been performed more than 2 years before this study. In 57% of the total cases it concerned primary amputations. Hundred and twenty-seven cases (84%) were free from medical limitations/restrictions, while 16 cases (11%)

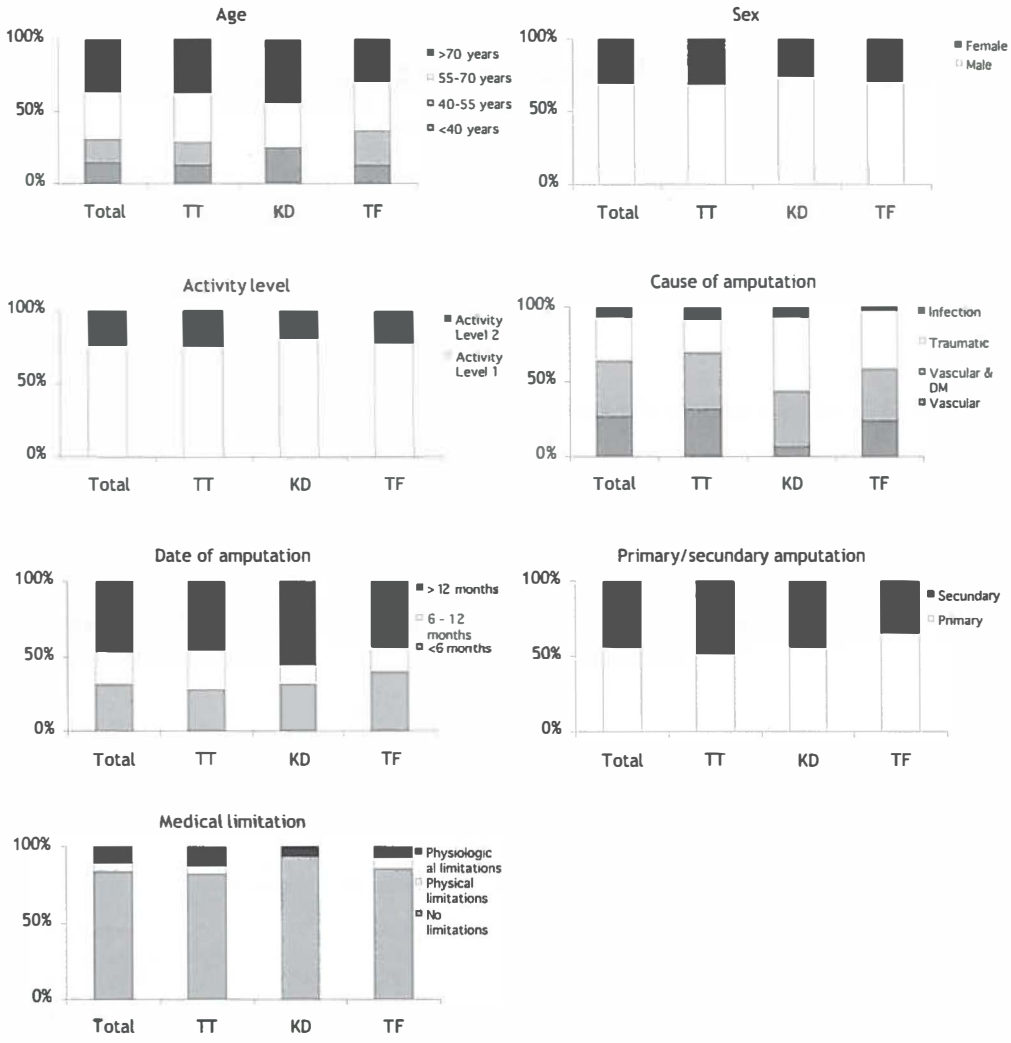

Figure 1: Amputees' demographics: 'Total' = total database (n=151), 'TT' = database trans-tibial amputees (n=94), 'KD' = database knee disarticulation amputees (n=16), 'TF' = database trans-femoral amputees (n=41).

had physical restrictions such as cardiac diseases and 8 cases (5%) suffered from limitations due to Rheumatoid Arthritis or Stroke.

Seventy-eight (51%) of the amputees received their prostheses in the western part of the Netherlands, while 31% went to hospitals in the northern and eastern part of the country. 50% of the MDs in P&RM were trained in the north and east of the Netherlands, 48% in the western part. The professional experience of the MDs in P&RM in the field of amputation and prosthetics did not seem to influence the prosthetic prescriptions.

Table1a: Prosthetic components for trans-tibial prostheses (94 prescriptions)

	Suspension			Weight bearing			Prosthetic feet	
	Act. 1	Act. 2		Act. 1	Act. 2		Act. 1	Act. 2
Supracondylar	28 (39)	6 (26)	PTB	67 (94)	21 (92)	Solid Ankle	35 (49)	4 (18)
Liner	22 (31)	12 (52)	Femur	4 (6)	1 (4)	Single Axis	9 (13)	5 (22)
Femur	2 (3)	2 (9)	Combination	0 (0)	1 (4)	Energy Storing	6 (8)	7 (30)
Combination	19 (27)	3 (13)				Multi Flexible	21 (30)	7 (30)
Total	71 (100)	23 (100)	Total	71 (100)	23 (100)	Total	71 (100)	23 (100)

Table 1b: Prosthetic components for knee disarticulation prostheses (16 prescriptions)

	Suspension			Weight bearing			Prosthetic feet	
	Act. 1	Act. 2		Act. 1	Act. 2		Act. 1	Act. 2
Supracondylar	7 (54)	0 (0)	Condylar	13 (100)	3 (100)	Solid Ankle	7 (54)	1 (33)
Liner	5 (38)	3 (100)				Single Axis	3 (23)	2 (67)
Combination	1 (8)	0 (0)				Energy Storing	1 (8)	0 (0)
						Multi Flexible	2 (15)	0 (0)
Total	13 (100)	3 (100)	Total	13 (100)	3 (100)	Total	13 (100)	3 (100)

	Socket			Prosthetic knee			Knee-lock	
	Act. 1	Act. 2		Act. 1	Act. 2		Act. 1	Act. 2
Open socket	5 (38)	1 (33)	Single axis	1 (8)	0 (0)	Without knee lock	13 (100)	3 (100)
Closed socket	8 (62)	2 (67)	4 axes	7 (54)	2 (67)	Knee lock	0 (0)	0 (0)
			>4 axes	5 (38)	1 (33)			
Total	13 (100)	3 (100)	Total	13 (100)	3 (100)	Total	13 (100)	3 (100)

Table 1c: Prosthetic components for trans-femoral prostheses (41 prescriptions)

	Suspension			Weight bearing			Prosthetic feet	
	Act. 1	Act. 2		Act. 1	Act. 2		Act. 1	Act. 2
Vacuum	15 (47)	7 (78)	Tuber	12 (38)	4 (44)	Solid Ankle	13 (41)	3 (33)
Liner	7 (22)	0 (0)	NML	9 (28)	5 (56)	Single Axis	8 (25)	1 (11)
Pelvis	7 (22)	1 (11)	Combination	11 (34)	0 (0)	Energy Storing	3 (9)	0 (0)
Combination	3 (9)	1 (11)				Multi Flexible	8 (25)	5 (56)
Total	32 (100)	9 (100)	Total	32 (100)	9 (100)	Total	32 (100)	9 (100)

	Socket			Prosthetic knee			Knee lock	
	Act. 1	Act. 2		Act. 1	Act. 2		Act. 1	Act. 2
QUAD	20 (63)	6 (67)	Single Axis	15 (47)	1 (11)	Without knee lock	22 (69)	9 (100)
Trilateral	1 (3)	0 (0)	4 Axes	13 (41)	5 (56)	Knee lock	10 (31)	0 (0)
NML	2 (6)	3 (33)	5 Axes	0 (0)	1 (11)			
Combination	9 (28)	0 (0)	7 axes	4 (12)	2 (22)			
Total	32 (100)	9 (100)	Total	32 (100)	9 (100)	Total	32 (100)	9 (100)

Table 1d: Prosthetic feet for the total population (151 prescriptions)

	Prosthetic feet	
	Act. 1	Act. 2
Solid Ankle	55 (47)	8 (23)
Single Axis	20 (17)	8 (23)
Energy Storing	10 (9)	7 (20)
Multi Flexible	31 (27)	12 (34)
Total	116 (100)	35 (100)

Act. 1: amputees with activity level (K1 or K2).
Act. 2: amputees with activity level 2 (K3 or K4).
In the tables the absolute figures (and percentages) are listed.

The results of the observations on the prosthetic prescription for all 151 cases are shown in Table 1. Prosthetic prescription is split up for the three amputation levels and the activity level. Four different ankle-foot mechanisms were distinguished (Solid Ankle, Single Axis, Energy Storing, Multi Flexible). The solid-ankle foot is prescribed primarily for TT amputees with a lower activity level (49%). The energy-storing feet are prescribed more often in the prescriptions for TT amputees with a higher activity level (30% vs. 8%). However, the 4 distinguished ankle-foot mechanisms are evenly distributed for this activity level. For KD and TF amputees the choice for the prosthetic foot is not clearly related to the level of activity either.

Two aspects of the prosthetic socket were distinguished: the suspension and weight bearing principles. We noticed a distribution over the various principles for the 3 amputation levels, without a clear relationship to the level of activity. Single-axis or four-axe knee-mechanisms were prescribed merely for lower-activity TF amputees with a 31% knee lock in this group.

Results of the multiple logistic regression showed no relationships between the activity level and any of the variables included in the equation, such as the hospital or MD in P&RM, prosthetic components, age of amputee or reason for amputation (Table 2).

Discussion

The aim of this part of the study was to get insight into the degree of agreement on prosthetic prescription criteria for lower limb amputees in the Netherlands. The statistical results of the observation of clinical practice do not reveal any consensus between clinicians on criteria for prosthetic prescription. As to the second question of this study, there was no clear relationship between the level of activity and the

Table 2a: Multiple Logistic Regression. Database: total n=151

MODEL FITS RESULTS						
Summary statistics		Value	DF	p-value		
Deviance		112.2	147			
Likelihood ratio test		97.2	4	<0.001		
PARAMETER ESTIMATES						
Terms	**Coefficients**	**Std. Error**	**p-value**	**Odds Ratio**	**95% C.I. Lower**	**95% C.I. Upper**
% GM	37.8	$1.2*10^{7}$	1.00	$2.7*10^{16}$	0	$1.7*10^{38}$
Age	-1.18	0.27	**<0.001**	0.31	0.18	0.51
Reason for amputation	0.24	0.29	0.41	1.27	0.72	2.25
Co-morbidity	-36.3	$1.2*10^{7}$	1.00	0	0	$1.7*10^{38}$

Table 2b: Multiple Logistic Regression. Database: trans-tibial n=94

MODEL FITS RESULTS						
Summary statistics		Value	DF	p-value		
Deviance		74.9	90			
Likelihood ratio test		55.4	4	<0.001		
PARAMETER ESTIMATES						
Terms	**Coefficients**	**Std. Error**	**p-value**	**Odds Ratio**	**95% C.I. Lower**	**95% C.I. Upper**
% GM	35.7	$2.4*10^{7}$	1.00	$3.2*10^{16}$	0	$1.7*10^{38}$
Age	-0.91	0.31	**0.0031**	0.40	0.22	0.74
Reason for amputation	0.40	0.34	0.24	1.49	0.77	2.88
Co-morbidity	-35.07	$2.4*10^{7}$	1.00	0	0	$1.7*10^{38}$

Table 2c: Multiple Logistic Regression. Database: trans-femoral n=41

MODEL FITS RESULTS						
Summary statistics		Value	DF	p-value		
Deviance		27.7	37			
Likelihood ratio test		29.12	4	<0.001		
PARAMETER ESTIMATES						
Terms	**Coefficients**	**Std. Error**	**p-value**	**Odds Ratio**	**95% C.I. Lower**	**95% C.I. Upper**
% GM	39.94	$2.4*10^{7}$	1.00	$2.2*10^{15}$	0	$1.7*10^{38}$
Age	-1.68	0.65	**0.0095**	0.19	0.05	0.66
Date of amputation	0.13	0.56	0.82	1.14	0.38	3.41
Co-morbidity	-37.05	$2.4*10^{7}$	1.00	0	0	$1.7*10^{38}$

prosthetic components within the prescriptions noted during the observational study. The criteria used are merely based on clinical expertise and local experience whereas the actual prescriptions differ from location to location. These prescription variations can either lead to underuse or overuse of prosthetic care in individual cases.

For none of the prosthetic components (prosthetic foot, knee mechanism and socket) a relationship was found with the level of activity, age of the amputee or time since amputation. Analysis of location in the Netherlands or years of experience of the MD in P&RM did not show any relationship with the prosthetic prescription. The total population size in this study was significant for an analysis on correlations. However, subgroups based on the level of amputation were too small to allow this analysis. Causes of amputation differed from those in the Dutch population as we only observed amputees who were thought to be able to function with a prosthesis.

During the observation of clinical practice the functional abilities of individual patients were mentioned in all individual cases (n=151); however, they were not explicitly translated into prosthetic prescription. The decisions seem to be more influenced by the local experience with prosthetic components and also based on the implementation of new products. But there was some agreement with regard to the prescriptions for the three different amputation levels. In TT amputees the total of prescriptions of a gel-liner for amputees with a lower activity level was almost equal to that of the supracondylar-polyform fitting; whereas for the higher activity level the amount of prescriptions tended towards the gel-liner (66% v. 34%). In literature we could not find any evidence for this subject. As for the prosthetic foot in TT amputees, a solid-ankle and a single-axis foot were prescribed in 62% of the lower activity amputees and a multi-flexible foot in 30% of the subjects. For the higher activity level this was 39% and 30%, respectively. Hence no explicit agreement has been found in choosing the prosthetic foot in TT amputees related to the level of activity. Gait-analysis studies on this matter offer additional information. The solid-ankle foot is described as appropriate for lower-activity-level amputees, the single-axis foot for average-activity level and the multiple-axis foot for moderate-level amputees [10]. The energy-storing feet are more appropriate for active walking amputees [3,12].

The motivation for the choice of the prosthetic foot in KD and TF amputees was widespread. Several arguments were given, for example its dependence on the choice of a specific prosthetic knee. The properties of a prosthetic knee during gait depend on the properties of the prosthetic foot used, too. Other arguments were stability aspects during gait, level of activity of the amputee and the experience

with various prosthetic feet. However, no clear agreement was found. Literature evidence on this subject is limited. A more symmetrical gait pattern was seen in TF amputees with a Flex-foot compared to those using a conventional foot [11].

For the prosthetic socket in KD amputation there is agreement on the use of a hard socket in combination with a polyform inner socket as a first choice and the use of a gel-liner in case of specific stump problems. There were, however, no prescriptions of gel-liners observed for KD amputees. In TF amputees the use of gel-liner sockets seems a new alternative. In the prescriptions 22% of the TF sockets contained a gel-liner, not for a specific reason like stump problems or improvement of suspension, however.

There was a wide range of prosthetic knee-mechanisms used in the prescriptions, without a clear overall agreement. Arguments given for making a choice are most often measure of control on knee stability and the intended walking speed.

From the observational study we can conclude that there is some agreement on several items. Level of activity is an important factor when prescribing a prosthesis in lower limb amputees. However, explicit criteria are at our disposal when matching the functional ability of the prosthetic user with the functional properties of prosthetic components or the complete prosthesis.

There was a wide range of prosthetic components used for TF, KD and TT amputees in our study. This could be expected due to a lack of guidelines for prescription criteria. Several authors state that the most import indicator for making choices in the prescription process is the functional ability of the amputee [6,8,1213]. In our opinion the use of a classification based on these functional abilities is therefore to be recommended. In addition, It seems appropriate to look at aspects of activities of daily life, such as employment-related factors, to complete the intended use.

Another cause of the lack of consensus and the wide range of prosthetic components used can be found in the level of training and the experience of the prosthetic team members. The introduction of a university course for prosthetists could offer more consistent information for the clinical team on functional aspects of prosthetic components. Therefore, the prosthetist ought to have a more important role in the prescription process than this has been the case up to now. Recently the upgrading of the prosthetist's educational level has started in the Netherlands. Secondly, the continuing education of MD in P&RM is necessary in order to assure consistency in knowledge about possible medical problems and functional abilities of amputees.

We conclude that there is no consensus in the Netherlands on prescription criteria for prosthetic components in lower limb amputation. However, the agreements

found in this study offer the opportunity for further development of a consensus-based clinical guideline on prosthetic prescription.

The development of clinical guidelines is a way of making prosthetic care more consistent and efficient and of diminishing the gap between what clinicians do and what scientific evidence supports [22]. Guidelines for prosthetic prescription can be of use now there are more and more options for prosthetic components. In the Netherlands third party payers increasingly ask for more extended motivation for costly prostheses. For the consumer more transparency is necessary too, when quality of care becomes more important.

Recommendations

The development of a clinical guideline for prosthetic prescription in the Netherlands in lower limb amputation is recommended. The use of a classification of amputees based on mobility can be a starting point when defining intended use with an additional status of activities in daily life and participation such as vocational interests. The information gained from this observational study will be combined with the implicit knowledge given by professional experts (part 2) and the scientific evidence from the available literature. This combined knowledge will be used in a clinical guideline procedure for prosthetic prescription in the Netherlands.

Last not least consumers should take part in such a process. Lower limb amputee patients can also take part in developing clinical guidelines to provide "expert patient opinions" on care options [18]. Therefore a consumer questionnaire is recommended as part of a consensus procedure on prosthetic prescription.

Acknowledgement

The authors acknowledge Lieselotte Toelle for reading the manuscript. This work was supported by a grant from the Dutch Health Care Insurance Board (CvZ).

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Chapter

Prosthetic Prescription in the Netherlands: An Interview with Clinical Experts

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Prosthetics and Orthotics International 2004; in press

Abstract

Introduction: In the process of guideline development for prosthetic prescription in the Netherlands we did a study of the daily clinical practice of lower limb prosthetics. Besides the evidence-based knowledge from literature the more implicit knowledge from clinical experts is of importance for guideline development.

Methods: In order to obtain this information we performed both an observational study of clinical practice and an interview study with 11 clinical experts from the three key disciplines in this field. The latter study will be presented here as a descriptive and qualitative study.

Results: The combination of the opinions on prescription criteria given in these semi-structured interviews appeared divided with regard to various options in the prescription of a lower limb prosthesis. However, in our opinion the implicit knowledge is of importance for the consensus procedure on guideline development.

Discussion: Prosthetic prescription criteria seem to be based on local experience and partly on assumptions. A consensus procedure can lead to improvement of the knowledge about prosthetic prescription.

Introduction

Clinical guidelines are becoming of more interest, not only for clinicians but also for Health Care Insurance Companies and for the Government. It is assumed that clinical guidelines improve quality of care for patients and that healthcare organisations and individual clinicians can use them to improve clinical effectiveness [2].

There are increasingly more options for the various prosthetic components in a lower limb prosthesis without specific knowledge from which to choose. On the other hand Health Care Insurance Companies ask for a thorough motivation of costly prostheses. The number of prosthetic components to choose from is on the increase and therefore the insight for consumers is limited. This makes it difficult for the consumer to participate in the process of prosthetic prescription. Additionally this can cause local prescription variations, which can either lead to overuse or underuse [17]. A prosthetic and orthotic guideline development group of the Dutch Society of Physical and Rehabilitation Medicine was commissioned by The Dutch College of Health Care Insurances (CvZ) and the Ministry of Health Care to develop a clinical guideline on prosthetic prescription in lower limb amputation.

A preferred evidence source for clinical guidelines is found in randomised controlled trials [13]. However, this design is very difficult to establish in the field of human functioning with a prosthesis. Literature shows that most studies focus on prosthetic components compared with each other in cross-over designs [15]. These studies offer information, which can be used in guideline development, but they do not necessarily lead to prosthetic prescription. Not all aspects of treatment and care for amputees have been the subject of research. Hence, we have to rely on other sources of knowledge about prosthetic prescription and functioning with a lower limb prosthesis. Accordingly, professionals can provide expert opinion and consumers expert patient opinions on prosthetic options [12]. Especially in the care for amputees and the area of prosthetic prescription there are individual differences and wishes, which makes the expertise of both the clinician and the consumer important in coming to a decision. Therefore the clinical expertise is an important source of information for guideline development.

As part of an ongoing national guideline development process for the prescription of a lower limb prosthesis in the Netherlands we consulted clinical practice of prosthetic prescription. To obtain the information from this practice we used two methods. Firstly, an observation of clinical practice, which is a more quantitive study [16]. Secondly we interviewed with clinical experts, active in the field of amputees and prosthetics, a qualitative descriptive study. The current study discusses the interviews with the clinical experts.

The aim of this study was to collect the implicit knowledge about the prescription of a lower limb prosthesis through a semi-structured interview method with clinical experts. Secondly we were interested in the measure of agreement within the options mentioned for several prosthetic components.

Method

Selection of participants

The participants were selected on the basis of clinical experience and questioning within the interdisciplinary groups of physical therapists, prosthetists and medical doctors in Physical and Rehabilitation Medicine (MD in P&RM) in the Netherlands. In our country vascular or orthopaedic surgeons are not involved in the prescription process of prostheses anymore. The set-up of the group was based on a good spreading of the location of the clinical practice of the participants across the Netherlands. In our opinion it was not necessary to have an equal spreading across the three represented key disciplines. Eleven clinical experts were selected, 5 prosthetists (years of experience ranging from 10 to 31 years), 4 MDs in P&RM (experience 10-23 years) and 2 physical therapists (experience 14 and 26 years). The authors were excluded. The MDs in P&RM and the physical therapists all have prosthetic care as their main clinical task.

The interview method

A semi-structured interview method was carried out, structured around the three levels of amputation, i.e. trans-tibial (TT), knee disarticulation (KD) and trans-femoral (TF). For each level of amputation the primary options, for the first prosthetic prescription, were inquired about for each prosthetic component given a certain patient situation, based on stump aspects like stump length and skin aspects. For example, in a "normal" stump situation, an average stump length was given in a TT amputation (12-15 cm), in the absence of skin problems like spread tissue scars and pressure sores. For this standard stump description the primary options were asked regarding different prosthetic components, i.e. socket, knee and prosthetic foot, i.e. in the first prescription. Subsequently the options had to be given in case of specific stump conditions like a sensitive skin, pressure sores and short or long residual limb length. Lastly the participants were asked to take into account aspects like mobility or level of activity of the amputee. Where possible they were asked to give arguments for their choices. The interviews were taken in the period 2000-2001.

The interview data did not lend themselves to statistical analysis.

Results

Description of the primary options, for the first prosthetic prescription mentioned by the 11 participants will be described for each amputation level and summarized in Tables 1,2,3 and 4.

Table 1: Suspension- and weightbearing principle for trans-tibial, knee disarticulation and trans-femoral level.

		Socket principle	PR	PT / MD	Arguments
TRANS-TIBIAL	Suspension (N=11)	KBM-supracondylar fitting (hard socket with foam liner)	3	3	• Volume fluctuation • First prescription simple • Donning and doffing important • Stump shape • Supracondylar fitting
		Gel liner (with locking mechanism or sleeve)	2	3	• Suspension improvement • Shear forces • Pressure distribution
	Weightbearing (N=11)	PTB	5	4	No specific arguments
		Total contact	-	2	No specific arguments
KD	Suspension (N=11)	Hard socket with leather and lace fastening	-	3	In case of volume fluctuation
		Hard socket	4	4	Standard in all situations
	Weightbearing (N=11)	Femur condyles	5	6	No specific arguments
		Tuber ischiadicum	-	-	No specific arguments
TRANS-FEMORAL	Suspension (N=11)	Hard socket suction	5	6	No specific arguments
		Hip joint and pelvic-belt	-	-	Short stump or lower activity (N=3)
		Gel liner	-	-	Not common yet
	Weightbearing (N=9)	NML	-	1	Depending on shape of stump/ os ischium
		QUAD	2	2	First choice in elderly amputees
		Combination NML/QUAD	2	2	No specific arguments

PR= prosthetist, PT=physical therapist, MD=Medical Doctor
KBM=Kondylen Bettung Munster principle, NML=Narrow Medial Lateral fitting, QUAD=Quadrilateral fitting, PTB=Patella Tendon Bearing, KD=knee disarticulation

Trans-tibial prostheses

Six participants mention a silicone or polyurethane liner-containing socket as the primary option for the standard TT stump condition in a first prescription. Five

participants choose the supracondylar suspension with a hard socket and foam liner as the first option (Table 1). The arguments given for a socket with a gel liner are (1) a better pressure distribution over the limb, (2) the cushioning of shear forces and (3) the creation of a total contact between socket and limb. Two clinicians mention the possibility of 'total surface bearing' with a gel liner. The choice of a specific liner is primarily based on the properties of the material, like thickness and resistance of the liner material. Suspension of the socket can primarily be supported through a locking mechanism (according to all participants). Visual impairment or extreme valgus or varus deviation in the knee are arguments to prescribe a gel liner with a prosthetic sleeve or cord fixation. Donning and doffing aspects are not thought to have a primary influence on prosthetic prescription.

According to all participants the options for prosthetic-foot mechanisms in TT amputees primarily depend on the level of activity or balance control (Table 2). In what way the level of activity of the amputee is assessed is not made explicit. For elderly amputees or amputees with a lower activity level two ankle-foot mechanisms are mentioned as the first choice, a single-axis foot (N=4) or a solid-ankle foot (N=6). Here the choice is not made explicit either. Most participants mention local experience of physician or prosthetist with a certain ankle-foot mechanism as the criterion for the definitive choice.

Table 2: Ankle-foot mechanism for trans-tibial level

Activity level	Ankle-foot mechanism	PR	PT/ MD	Arguments
Low (N=10)	Solid Ankle	3	3	Improvement of stability
	Single axis	2	2	Early foot-flat
High (N=11)	DER or Multiflexible	5	6	No specific arguments for choice between the two feet

PR= prosthetist, PT=physical therapist, MD=Medical Doctor, DER=dynamic-elastic respons

Knee disarticulation prosthesis

In general there is agreement about the choice of the prosthetic socket in a standard KD stump situation (Table 1). The hard socket with a foam liner is the first option (N=8). The main argument for this choice is the stiffness of this socket when compared with an open-frame socket. The socket suspension is the femoral supracondylar fitting and weight bearing on the condylar block. Three participants, however, mention the hard socket with leather and lace fastening in a first prosthesis because volume fluctuation can be dealt with in a better way. A gel liner

is only applied in case of specific skin problems (N=9) or to improve the suspension (N=5).

Table 3: Prosthetic knee for knee disarticulation and trans-femoral level.

Activity level	Knee-mechanism	PR	PT / MD	Arguments
Low (N=9)	Knee-lock mechanism	4	4	Improvement of safety and stability
	Constant friction	-	1	Improvement of safety and stability
High (N=11)	Multiple axes (swing-phase control)	5	6	No specific arguments
	Electronic control mechanism	5	6	Variable walking speed and distance

PR= prosthetist, PT=physical therapist, MD=Medical Doctor

The choice for a knee unit (Table 3) is primarily based on the level of activity or stability control and in the second place on cosmetic aspects (the length of components). There is agreement about the application of a swing-phase controller in the knee unit for the more active prosthetic user (N=11). The choice of a 4-axis, 5-axis or 7-axis knee unit is based on a number of arguments and is not made explicit. In low activity amputees the use of a knee-lock mechanism is mentioned as the first option (N=8).
The choice for a specific ankle-foot mechanism largely depends on the combination with the chosen knee mechanism according to all participants (Table 4). However, the level of activity of the amputee is an important factor too. The options mentioned are the same as in TT prostheses although in combination with a knee-lock mechanism the choices for the ankle-foot mechanism differ.

Trans-femoral prosthesis
In general it is mentioned that especially for the TF amputee the individual stump properties determine the prosthetic prescription. Stump properties like length and skin aspects determine which socket principle is chosen, a Narrow Medial Lateral fitting (NML), a Quadrilateral fitting (QUAD) or a combination of these principles (Table 1). However, it is also mentioned that local experience of the prosthetist is a determining factor for the choice. A hard-socket suction principle is a primary option in a standard stump situation (N=11). For the more active prosthetic user the NML socket form is generally preferred, whereas for the elderly amputee, with shorter walking distances and fewer standing and walking activities the QUAD principle is preferred. One of the arguments for the latter is better sitting comfort. Arguments mentioned for the NML socket are the more 'natural' fitting of the limb

and a better ability to control the prosthetic limb. The prosthetists in the interview group mention that the socket principle is gradually becoming a hybrid system, i.e. a combination of several principles (NML and QUAD) and depend on individual stump conditions.

The choice for a knee-mechanism and ankle-foot mechanism (Tables 3 and 4) largely depend on stability control or level of activity and are in accordance with the options mentioned for the KD prosthesis. However, there is no clear agreement and the options are not made explicit. No specific differences are given by the participants in the KD and TF prostheses regarding the choice of both knee-mechanism and ankle-foot mechanism.

Table 4: Ankle-foot mechanism for knee disarticulation and trans-femoral level.

Activity level	Knee-mechanism	Ankle-foot mechanism	PR	PT / MD	Arguments
Low (N=10)	Knee-lock mechanism	• Single axis	2	2	No specific arguments
		• Solid ankle	1	1	
		• Multiflexible	2	2	
High (N=11)	Multiple axes (swing-phase control)	Single axis, or DER, or Multiflexible	5	6	No specific arguments

PR= prosthetist, PT=physical therapist, MD=Medical Doctor, DER=dynamic-elastic respons

Discussion

The current study shows that there is little agreement among clinicians in the Netherlands on the criteria of importance for prosthetic prescription in TT, KD and TF amputees. There is apparently a lot of implicit clinical knowledge that only in certain aspects of prosthetic prescription can be made more explicit. The participants often mention that local experience or expertise plays an important role. A lack of arguments for making choices for several prosthetic components may be due to a lack of knowledge concerning properties of the various several prosthetic components. Most knowledge is probably based on assumptions rather than on existing literature. However, with the diverging opinions on prosthetic prescription, individual clinical knowledge is still of great importance in our opinion. The combination of this individual knowledge and the identification of agreement on certain aspects of prescription can lead to a broadening of this knowledge.

There were, however, prescription aspects in which there was agreement among the participants. For example this agreement was seen in the choice for the prosthetic foot in TT amputees. The level of activity of the amputee was the most

important criterion. It was not made explicit how the activity level had been assessed. The use of a mobility scale is not yet common practice among clinicians in the Netherlands.

A solid-ankle and a single-axis foot were chosen for TT amputees with a lower activity. A dynamic-elastic response (DER) foot or multi-flexible foot were mentioned as the primary options for younger amputees or those with a higher activity level. Specific arguments for the choice between those two options were not made explicit. For these the gait-analysis literature offers information that is in accordance with the opinion of the participating clinicians. From these studies there is some evidence that the use of an energy-storing foot such as the Flex foot results in a comfortable walking speed and stride length. These parameters are about 7-13% higher than with a conventional foot (SACH foot) in both traumatic and vascular TT amputees [1,11,14]. These considerations seem particularly important for the active prosthetic user and are in accordance with the opinions given in the interviews.

The literature also shows some evidence that the more inactive prosthetic users may benefit from an early foot-flat mechanism to facilitate weight transfer onto their prostheses [3,9]. Prosthetic feet with an ankle axis in the frontal plane such as the single-axis Lager foot mimic the normal roll-off motion of the ankle-foot complex in the sagittal plane, thus allowing an early foot-flat position and concomitant early-stance-phase stability [10]. The choice for these feet for amputees with a lower activity level is in accordance with our interview opinions. However, we can find more functional aspects in the literature that we can consider in prosthetic prescription. According to Perry et al. a single-axis foot may offer relatively little late-stance stability due to an unrestrained dorsiflexion [9]. And in this respect, the Flex foot and the SACH foot provide more stability during the late-stance phase [5] and may be preferable to patients that tend towards a short prosthetic stance phase. Also, uphill and downhill walking may be easier with a wide range of motions at the prosthetic ankle joint [7]. Hence, it seems that individual considerations related to intended use and activity level remain important with respect to the final choice of the prosthetic foot.

A second clear agreement among the interviewed participants was found for the use of a swing-phase controlling mechanism in the prosthetic knee in the more active TF amputees. For this prescription aspect there is some evidence in the literature, too. For TF amputees it was found that a prosthesis with an advanced mode of swing-phase control, either by a pneumatic or a hydraulic knee unit, is superior to a prosthetic knee that only provides a constant force or friction. Especially active prosthetic users may profit from the advanced characteristics of

swing-phase controllers such as the Tehlin Knee in terms of gait symmetry and comfortable walking speed [4,8]. On the other hand, the typical geriatric dysvascular patient may still profit from the stance-phase stability that is provided by a conventional locked knee unit [6]. Hence, individual considerations must ultimately determine the choice and prescription of the prosthetic knee based on level of activity and stability control. The integration of explicit knowledge from literature and the combined implicit knowledge from clinical practice can lead to improvement of criteria development for prosthetic prescription.

The interview method used in this study has its shortcomings. We chose a more open interview method in order to prevent directing the answers. On the other hand a more structured method could have produced more specific information. A round table conference with the same participants would give the opportunity to work out more details by means of a discussion. In this stage of the ongoing clinical guideline process we did not choose for this option because the interview method is part of the collection of implicit and explicit knowledge, which will be used in the consensus procedure on prosthetic prescription. Those opinions will then be integrated with the explicit knowledge from literature obtained from a systematic search [15]. A round table conference will be part of the final performed consensus procedure.

The absence of the prosthetic user in this interview round could also be seen as a shortcoming. In a separate study, however, we performed a consumer questionnaire about wishes and experiences with prosthetic prescription in the Netherlands.

Conclusion

The clinical knowledge of professionals based on their clinical experience is of importance, especially where there is little evidence-based information in literature about prosthetic prescription criteria. In our opinion there is, however, a lot of implicit knowledge, partly based on assumptions that should be made more explicit. Apparently much of this knowledge is also based on local experience and therefore it is not likely that it will develop easily. The integration of knowledge of the three key disciplines and the exchange of arguments that are given for certain choices within the prosthetic prescription can lead to a better understanding of prescription criteria. In our view the qualitative information from this interview study can serve as one of the information sources for the ongoing consensus guideline procedure for the development of a clinical guideline for prosthetic prescription.

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Chapter

The Use of the Delphi Technique to Develop a National Clinical Guideline for the Prescription of Lower Limb Prostheses

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Journal of Rehabilitation Research & Development; submitted

Abstract

Objective: The overall aim of this project was to develop a combination of evidence-based and consensus-based clinical practice guidelines for lower limb prosthetic prescription in order to obtain transparency and consensus among clinicians, manufacturers and insurance companies. This paper describes the Delphi method that evolved during the development of a national clinical guideline, based on different methods of collecting evidence.

Methods: In this guideline development project a multi-method approach was used to develop a guideline for clinical practice of prosthetic prescription for lower limb amputees. The Delphi technique was central in the process and the panel was made up of experts of the three key disciplines on a national level. Our approach required various methods: a systematic review, a survey of national clinical practice on prosthetic prescription, interviews with experts. This resulted in 45 statements about prosthetic prescription. The views of the national expert panel were then combined with a consensus development conference.

Results and Discussion: The participants of the Delphi process achieved consensus about 37 statements on the prosthetic limb for lower limb amputees, which are applicable in the prescription process. These statements were divided according to the amputation level and split up into different domains. The total process resulted in the development of a draft clinical guideline comprising guidance for the tasks of prescribing prostheses for the lower limb. The validity of this guideline will have to be measured and evaluated in the not too distant future.

Introduction

There is a broad interest in improving the quality of health care not only among clinicians but also for politics and health care insurances. An important clinical tool for improvement are clinical guidelines. These guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances [1-4]. Clinical guidelines ought to be based on the best evidence available and where possible on scientifically judged research literature. There are, however, aspects of care where there is little literature evidence available.

The Dutch College of Health Care Insurances and The Dutch Ministry of Health Care commissioned the Dutch Society of Physical and Rehabilitation Medicine to develop a National guideline for the prosthetic prescription of lower limb prostheses. Prosthetic prescription for lower extremity amputees is primarily based on empirical knowledge. There are many options for prosthetic components, however; prescription criteria can only be derived from the experiences of physicians, therapists and prosthetists [5,6]. On the other hand third-party payers frequently ask for a solid motivation of costly prostheses [6]. Therefore it is possible that patients with identical clinical problems receive different care depending on their clinician, hospital, or location. These variations in service among providers, hospitals, and geographical regions are of interest with the assumption that at least some of these variations stem from inappropriate care, i.e. overuse or underuse of services. Hence, there is an intrinsic desire of healthcare professionals to offer- and of patients to receive- the best care possible [3]. Developing guidelines has been seen as potentially being one of the most useful tools in achieving changes in behaviour and therefore more uniform, high quality care [7]. It also makes care more consistent and efficient and it may highlight knowledge gaps in the available literature [3].

According to the conclusions of Shekelle *et al.* [8] three principles remain the basis of the development of valid and usable guidelines:

- Sufficient research knowledge, preferably available from a systematic literature review
- the development of guidelines requiring sufficient resources in terms of people with a wide range of skills, including expert clinicians, health services researchers, finally group process leaders, last not least financial support
- A multidisciplinary group assembled to translate the evidence into a guideline.

The first step is to extract as much scientifically based knowledge from the literature as possible. There are, however, some difficulties in using the results from studies on biomechanical aspects and functional characteristics of several prosthetic components for prescription criteria [9]. Outcome measures differ from

study to study, therefore comparison or meta-analysis of the results are difficult. However, explicit knowledge derived from literature is needed to develop a clinical guideline [3].

Despite a huge amount of literature, there are considerable gaps in our formal clinical knowledge concerning the effects of different prosthetic components and their mechanical characteristics on human functioning with a lower limb prosthesis [9]. Therefore, with regard to prosthetic guideline development, we must still to a large extent rely on clinical consensus among experts. The integration of knowledge from research together with the expert opinions of clinical professionals and the opinions and wishes of consumers can form a solid basis for a procedure on guideline development for prosthetic prescription.

In order to create a consensus-based clinical guideline, a method to create consensus should be used. The ability to make effective decisions in situations where there is contradictory or insufficient information has led to an increased use of consensus methods, namely brainstorming, nominal group techniques and the Delphi Survey Technique [10]. The Delphi process was originally developed in the 1950s by Olaf Helmer and Norman Dalkey as an iterative, consensus building process to forecast futures. It has since been deployed as a generic strategy to develop consensus and make group-based decisions in a variety of fields [11].

The overall aim of this project was to develop a combination of evidence-based and consensus-based clinical practice guidelines for lower limb prosthetic prescription in order to obtain transparency and consensus among clinicians, manufacturers and insurance companies. This paper describes the Delphi method that evolved during the development of a national clinical guideline, based on different methods of collecting evidence.

Methods

Our pragmatic approach to develop a guideline for adults with lower limb amputations required various methods: a systematic review, a survey of national clinical practice on prosthetic prescription, interviews with experts. The views of a national expert panel using the Delphi technique were then combined with a consensus development conference. The overall process of developing the guideline is shown in Figure 1.

Sources of evidence

Systematic Review

We performed a systematic literature analysis of clinical studies to identify aspects of functioning with a lower limb prosthesis. This was performed in accordance with

the criteria of the Cochrane Collaboration. For this purpose, two types of studies can be distinguished: a) clinical studies addressing motor performance and/or ADL-functioning with a lower limb prosthesis and b) technical studies focusing on the mechanical characteristics of prosthetic components without addressing human functioning. In view of clinical guideline development, only studies of motor performance and ADL functioning were considered relevant for prosthetic prescription. All relevant studies were assessed using a checklist of 13 criteria for internal, statistical and external validity. The studies were divided into three levels of evidence according to these criteria [9].

Survey of clinical practice on prosthetic prescription

Recommendations solely based on clinical judgement and experience are likely to be more susceptible to bias and self-interest. Therefore, after deciding what role the expert opinion has to play, the next step is to decide how to collect and assess expert opinion. Currently there is no optimum method for this, but the process needs to be made as explicit as possible [8]. A multi-centred, cross-sectional study was carried out in order to observe the prosthetic prescription of a group of lower extremity amputees in the Netherlands. The purpose of this study was to get insight into possible similarities in prescription criteria in practice and to find out if prosthetic prescription was primarily based on the amputee's level of activity or the intended use of the prosthesis. Data were collected from inpatient and outpatient amputees with a trans-femoral, knee disarticulation or trans-tibial amputation.

The implicit clinical knowledge about prosthetic prescription was gathered during visits of the specialist in rehabilitation medicine and the research assistant at consultation hours in sixteen rehabilitation clinics through out the Netherlands [12].

Interview with experts

In order to collect implicit knowledge about prosthetic prescription, local consultants were contacted by the research assistant. Semi-structured interviews were conducted covering prosthetic prescription concerning trans-femoral, knee disarticulation and trans-tibial amputations [13].

Delphi-procedures

From the existing consensus methods, we chose the 'Modified Delphi Technique', which has been developed by the RAND corporation [14]. This is the most commonly used method for clinical guidelines [15]. This formal consensus method consists of two postal rounds and a final consensus meeting. The two postal rounds were conducted by the internet. An advantage of the Computer Mediated Delphi Method,

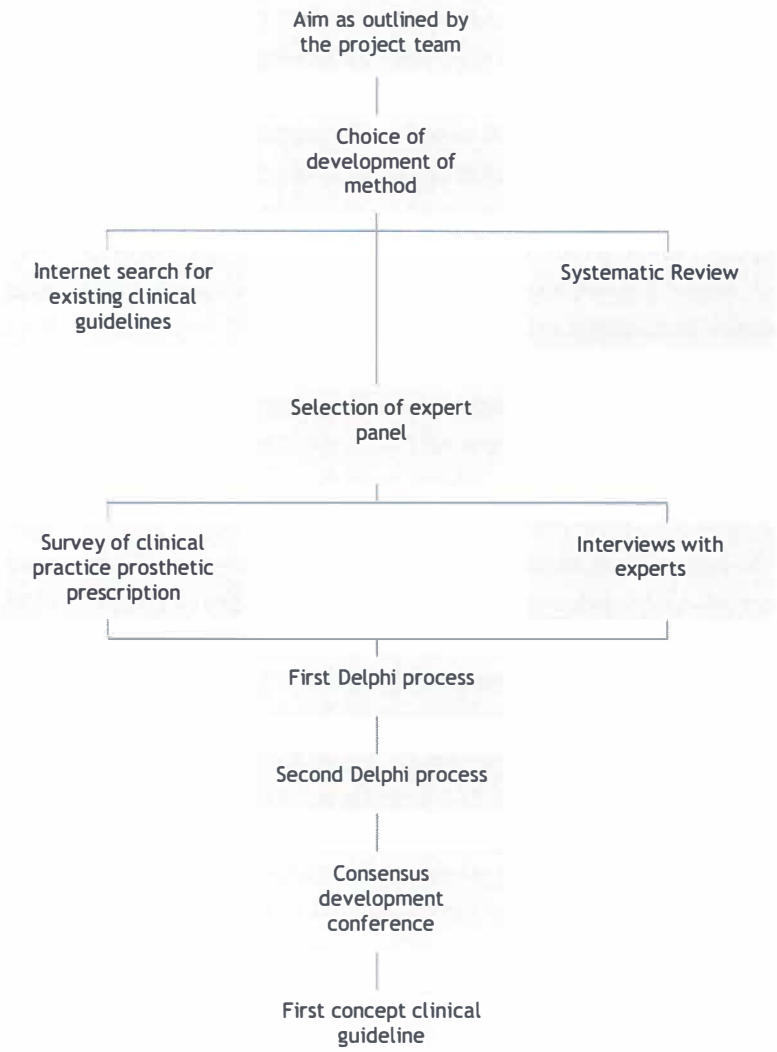

Figure 1: Prosthetic Guideline Development Process. Time span = 18 months

is 'collective intelligence'. This is the ability of a group to produce a result that is of higher quality than any single individual in the group could achieve on their own. This rarely occurs in face-to-face groups [11].

The project team

A project team was formed to initiate this research; it consisted of all the authors of this article. The project team comprised a methodologist who is also a clinician and who has a statistical background, three specialists in rehabilitation medicine, specialised in amputation and prostheses and a research assistant. The staff team

was responsible for the procedures for the selection of items for the Delphi-technique and the participants and was responsible for the development of the questionnaires and the analysis of the responses. During the internet process the project team was assisted by an ICT company, an organisation specialised in the Computerized Delphi Technique.

Selection of participants

Preferably, guidelines should be developed and disseminated by a group, team, or organisation which is perceived by the target group of clinicians [15,16]. All the groups whose activities would be covered by the guideline or who have other legitimate reasons for having an input into the process have to participate in the development of the guideline. This is important to ensure adequate discussion of the evidence (or its absence) when developing the recommendations in the guideline [8]. Therefore, the participants in this project were physicians, prosthetists or physical therapists, specialized in both amputees and prostheses. In this project we formed a participant group of 32 members, representing the above mentioned key disciplines.

Statement	**An energy-storing foot is indicated for high active trans-tibial amputees** *[grade of evidence: 1]* • Highly active trans-tibial amputees who are able to walk with variable speeds and grades prefer the energy-storing feet to the conventional ones (MacFarlane 1991, Casillas) • From information from the interviews it becomes clear that clinicians prescribe the Flex-foot more often for young active amputees than less active ones • For active people, especially people involved in jumping sports, the Flex-foot is probably more suitable for the sports activities, but in all likelyhood it will be too lively for comfortable use for other activities (Menard, 1992)
Statement	**Reaching foot flat early in stance phase is an important parameter for the choice of prosthetic foot** *[grade of evidence: 1]* • Compared to the Seattle and the Flex-foot, a single-axis foot reached foot flat earlier which promotes preserving limb stability (Postema 1998, Perry 1997, Rao 1998) • From information from the interviews it becomes clear that clinicians prescribe the SACH-foot more often because it reaches foot-flat earlier in the stance phase which means stability and a feeling of safety for the amputee

Figure 2: example of statements for the Delphi-rounds

Selection of the statements

The statements for the Delphi process were developed by the project team by combining the information of a systematic review [9], a survey of clinical practice on prosthetic prescription [12] and interviews with experts [14] (see Figure 2 for examples of statements). The statements were graded according to their evidence as follows:

1. Based on a well performed randomised controlled trial, with sufficient control for confounding factors
2. Based on a randomised controlled trial, with some control for confounding factors
3. Based on limited scientific evidence which does not meet all the criteria taken into consideration
4. Based on expert opinion of clinicians

Delphi internet postal rounds

The ICT company developed a website on which the participants could enter their personal code and password after which the pages with the statements were opened. Participants were asked whether they did or did not agree with the statements. We invited participants to give reasons for their choices [17]. The participants were given the opportunity to react to the arguments of the other (anonymous) participants [17].

Two internet Delphi rounds were considered sufficient to reach consensus, consensus being defined as a 'general agreement of a substantial majority' (>75%) [17].

The first Delphi round consisted of 45 statements. The project team analysed every consensus and the comments on the statements. When there was general agreement of >75%, the statement was entered in the clinical guideline. In case of 60-75% agreement, statements were changed with the aid of the participants' comments. Again, participants were asked whether they agreed. In this round the participants had no opportunity to give their comments. A few newly formulated statements were presented in Delphi-2, which were developed out of the participants' comments on statements of Delphi-1. Participants were invited to give reasons for their decisions, i.e. for these newly formulated statements only. Statements with no agreement (40-60% agreement) were included for the consensus developing conference (Figure 1).

After the Delphi round, a feedback report was made to inform the participants about the opinions and arguments of their colleagues.

Consensus Development Meeting

In a consensus development conference, a selected group is brought together to consider certain questions in the light of the evidence presented to attempt to reach a consensus. However, the group is also encouraged to include minority or alternative views where consensus cannot be achieved [15]. With formal methods it is ensured that all members have a chance to voice their views, all options are

discussed, feedback is provided, judgments are made confidentially [15]. A chairperson is one of the most important elements in a successful conference; he or she facilitates the exchange of relevant information [15]. Groups generate more alternatives when leaders encourage members to present different opinions rather than encouraging consensus [8,15]. They stimulate discussion and allows the group to identify genuine agreement but does not contribute his or her own opinion in the process. This meeting was facilitated by a member of the project team with both clinical and group process skills. He or she helped to ensure that the process ran smoothly and that good quality decisions were made.
The consensus developing meeting was used to discuss the remaining statements with no agreement (40-60%) and the statements which reached a minor agreement (60-75%) in Delphi-2. After the discussion of each statement, participants had the opportunity to vote anonymously. Eventually, participants had to vote in which domains statements should be placed and whether a statement should be prescriptive or additive.

Results

Participants

For the Delphi expert panel we started with 32 persons, i.e. 21 physicians, 8 prosthetists and 3 physical therapists, of whom 32 (100%) responded at Delphi-1 and 31 at Delphi-2. At the consensus developing meeting there were 12 physicians, 5 prosthetists and 2 physical therapists (60%). The reason mostly mentioned for not being present at the meeting was lack of time.

Delphi-1

All 32 participants responded and a lot of comments on the statements could be analysed. The feedback report of Delphi-1 presented all the items
with their scores of agreement in percentages. Eleven statements reached major agreement and were included in the clinical guideline. Twenty-three statements reached minor agreement and were reformulated and presented in Delphi-2. Eleven statements reached no agreement (40-60%) and were included in the consensus developing conference (Figure 3).

Delphi-2

This round consisted of twenty-three statements. Fifteen statements reached major agreement and were included in the clinical guideline. Six statements reached minor agreement and were included in the consensus developing meeting, together with the two statements which reached no agreement (40-60%) (Figure 3).

Consensus Development Meeting

After the two Delphi rounds, 19 statements reached no or minor agreement. Because of a fully scheduled consensus developing meeting, the project team decided to delete 3 statements: statements with the smallest level of evidence, which also showed some overlap with other statements. The participants had to discuss the 16 remaining statements with no or minor agreement. After each statement, participants voted anonymously whether they agreed or not. In this meeting, 11 statements reached major consensus, 5 statements did not reach any consensus and were excluded from the guideline.

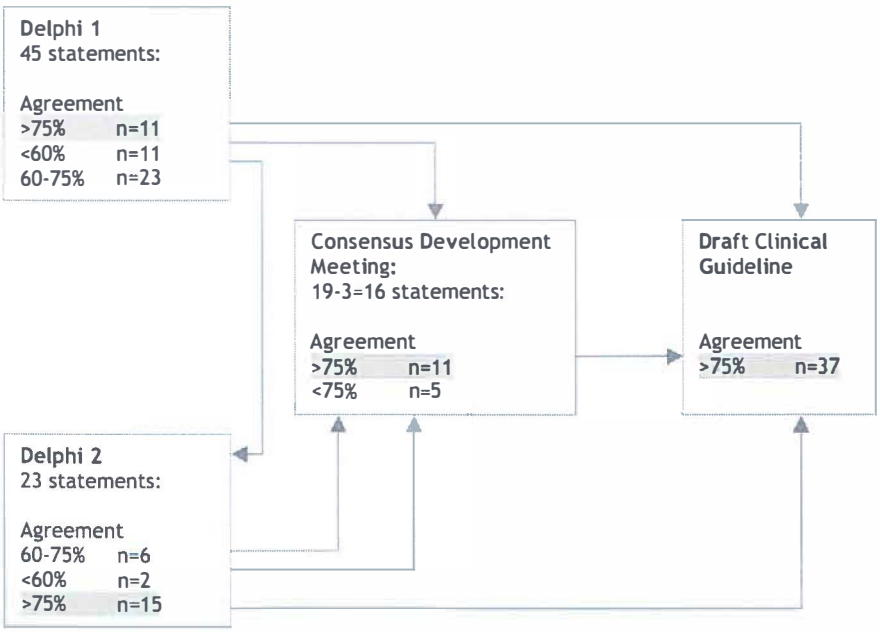

Figure 3: Agreement of statements in different stages of the process of developing the draft clinical guideline. >75% means that more than 75% of the participants agreed with the statement, <60% means that there was no agreement on the statement, 60-75% means that there was minor agreement on the statement. Only statements with major agreement were included in the Draft Clinical Guideline.

Eventually 37 statements reached major agreement (Figure 3). These statements were divided according to the amputation level and split up into different domains, see Table 1.

Table 1: Subdivision-table

Domains	Trans-tibial	Knee disarticulation	Trans-femoral
	General	General	General
	Socket	Socket	Socket
	Foot	Knee	Knee
		Foot	Foot

The statements were divided according to the subdivision-table, and the participants decided whether the statements were prescriptive or additive. The prescriptive statements were prioritized within each subdomain. Some statements fit into different amputation levels and/or domains.

Specific format

Eventually, after dividing and prioritising the statements, the format for the draft of the guideline was developed (Figure 4).

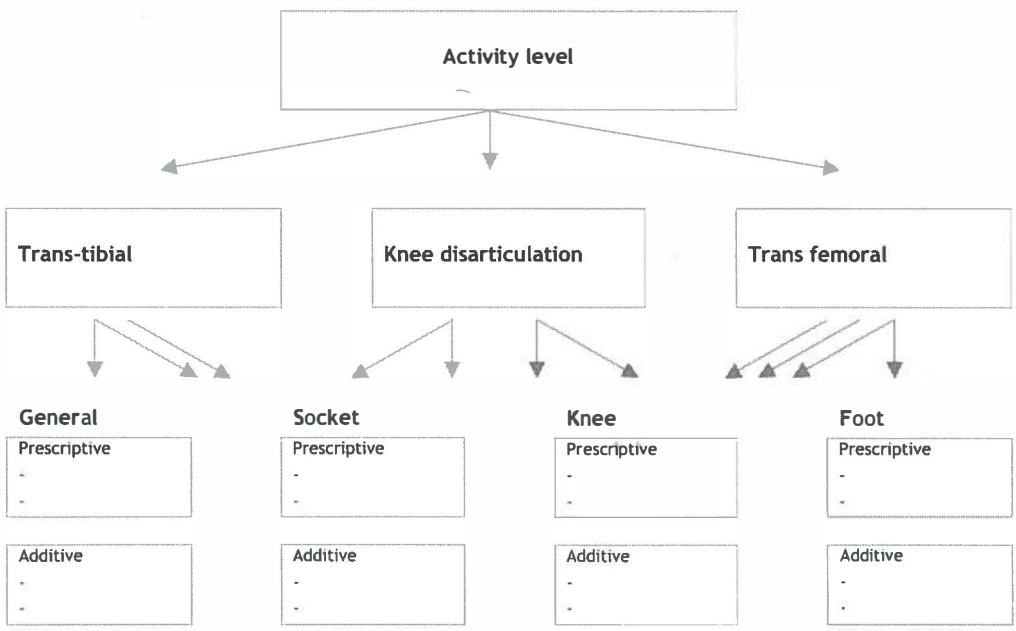

Figure 4: format of the draft guideline

The feedback report of the consensus developing meeting was sent to all participants. It presented all the statements with their scores of agreement in percentages, and the format for the draft version. Participants were given the opportunity to make comments. From this process minor comments were incorporated into the draft of the guideline.

This draft guideline includes:

- A summary of all the statements and the percentages of agreement
- Percentages of agreements divided into the subgroups, i.e. specialists in rehabilitation medicine on the one hand, and physical therapists and prosthetists on the other
- A philosophy of care which makes suggestions about the environment within which the recommendations in the guideline should be implemented
- (evidence-linked) recommendations to:
    - identify which amputees could wear certain prosthetic feet
    - identify which amputees could wear certain prosthetic knees
    - identify which amputees could wear certain prosthetic sockets.

Discussion

In this guideline development project a multi-method approach was used to develop a guideline for clinical practice of prosthetic prescription for lower limb amputees. The Delphi technique was central in the process and the panel was made up of experts of the three key disciplines on a national level. The prescription format consisting of 37 theses (Figures 5a-c) was based on the scientific evidence derived from a systematic review of critically appraised literature and integrated with the expert opinions of clinicians. The total process resulted in the development of a draft clinical guideline comprising guidance for the tasks of prescribing prostheses for the lower limb.

Advantages of the method used

Delphi, as a tool, has reached a stage of maturity as it is used fairly extensively in organisational settings in either the paper and pencil mode or in combination with face-to-face meetings and Nominal Group Techniques. The advantage of a consensus method such as the Delphi approach is that the different ideas of the concept of quality are integrated in the resulting criteria list, thus determining the content validity [17]. Compared to other consensus methods, the computerized Delphi-technique has several advantages, for example:

- participants react anonymously, which means a decrease of mutual influence
- a person may choose to participate in the group communication process when they feel they want to or are able to
- by communication through the internet geographical obstacles are avoided and takes less time
- sending information to participants by the internet is quick, which makes more participants join the Delphi-process; this has a positive effect on its validity.

Choice of participants

In a consensus procedure, the choice of the participants is crucial. In the process of selecting the participants, our aim was to achieve a broad representation of all different points of view about prescribing prostheses for the lower limb using three different groups of experts. There is, however, the chance that subjectivity interferes. Psychosocial interactions within the group process could have been present. The process design however minimises this aspect, because most parts were anonymous and the nominal group meeting was managed by skilled and objective professionals. The participation of all in clinical practice involved disciplines also creates a solid basis for the process of implementation.

Decisions of project team

In the Delphi consensus procedure, the staff team have to decide about the procedural steps. Their decisions can vary from fully autocratic to fully democratic ones. Because of the expected fundamental differences, we assumed that a too directive role would be ineffective. Therefore, we decided to allow all Delphi-1 items with minor agreement a second chance. The data of Delphi-2 showed much more agreement, and we thought that a consensus could be achieved. After the consensus development meeting, the participants seemed satisfied with the resulting format for the guideline.

At the consensus meeting 60% of the participants were present, whereas in the postal rounds all participants took part. However the three key disciplines were represented sufficiently in our opinion during the meeting and a consensus of about 70% of the theses was reached during the postal rounds.

The scientific evidence from the systematic review consisted of information on functional aspects of prosthetic feet, knee mechanisms, sockets and prosthetic weight. Specific prescription criteria could not be gained from the literature. Therefore, one of the restrictions of this process is caused by the limited explicit information available from it. A guideline based on the mixture of evidence from research literature and consensus opinion could be regarded as less scientifically valid. It would, however, when limiting the development for a guideline to those areas where there is a sufficient research basis, reduce the possibility for those areas that do not lend themselves for randomised controlled trials. Limiting recommendations to where evidence exists would reduce the scope of guidelines and limit their value to clinicians and policy makers who need to make decisions in the presence of imperfect knowledge [18].

The consensus based guideline process has created the opportunity for collaboration of the three disciplines active in the area of prosthetic prescription in the Netherlands. This is important for the clinicians who are going to use the guideline and it will improve the process of implementation. It also gives the opportunity to control the effectiveness of the guideline and to add adjustments.
The prescription format will now be evaluated nationally in clinical practice. Furthermore we need the introduction of the assessment of the mobility level of amputees supplemented by the activities in daily life (participation level) as it forms the basis of the prescription format.

Conclusion

The participants of the Delphi process achieved consensus about 37 statements on the prosthetic limb for lower limb amputees, which are applicable in the prescription process. This resulted in a draft clinical guideline for prosthetic prescription. The adoption of this core set by the participants may be the first step toward a minimum reference standard of quality measures for clinical practice. It is not our intention to replace existing individual clinical expertise, but we suggest that these statements should be used alongside the view of clinicians. The validity of this guideline will have to be measured and evaluated in the not too distant future.

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	General	Socket	Foot
Prescriptive	1. Activities including many rotational movements are an indication for the prescription of a rotator	1. Wearing a gelliner causes cushioning of shear forces between the socket and the skin of the distal stump 2. For an extremely short trans-tibial stump a gelliner should be prescribed 3. If an amputee suffers from sensibility disorders of the stump a gelliner should be prescribed 4. A limited weight bearing stump is an indication for a conventional trans-tibial prosthesis	1. Walking on even ground is an indication for the prescription of a multiflexible foot 2. Early foot flat during the stance phase of the prosthetic leg provides early stance phase stability which is an important parameter in prescribing the prosthetic foot 3. An energy-storing foot should be prescribed for highly active trans-tibial amputees
Additive		• Excessive perspiration of the stump is not a contra-indication for the prescription of a gelliner • For a trans-tibial stump without specific stump problems, the conventional trans-tibial prosthesis is not the standard prescription. • A gel-liner is not only indicated for improving total contact between socket and stump in the first instance • If donning of the gel-liner needs assistance from others it is not a contra-indication for the prescription of a gel-liner	• When walking at high speed it is preferable that the prosthetic foot should have a wide range of dorsiflexion

Figure 5a: The prescription format for prescribing prostheses for trans-tibial amputees.

	General	Socket	Knee	Foot
Prescriptive	1. Activities including many rotational movements are an indication for prescribing a rotator	1. Standard prosthetic prescription for the transgenual prosthesis includes a hard socket in combination with a polyform inner socket 2. Wearing a gelliner causes cushioning of shear forces between the socket and the skin of the distal stump 3. If an amputee suffers from sensibility disorders of the stump a gelliner should be prescribed	1. Standard prosthetic prescription for the transgenual prosthesis includes a 4-axes knee unit	1. Having to walk on uneven ground is an indication for prescribing a multiflexible foot 2. If a knee-lock mechanism is prescribed a single-axis or multiple-axes foot is indicated
Additive		• Reduced femur condyle contours can be an indication for a gel-liner to improve suspension • Excessive perspiration of the stump is not a contra-indication for prescribing a gelliner • Improving comfort during sitting can be established by prescribing an open socket instead of a closed socket • If there are problems with passing the femur condyles an open socket could be prescribed • A gel-liner is not only indicated for improving total contact between socket and stump in the first instance • If donning of the gel-liner needs assistance from others it is not a contra- indication for the prescription of a gel-liner (9).	• A 7-axes knee-unit provides more stability during the stance phase than a 4-axes knee unit	• Early foot flat during the stance phase of the prosthetic leg provides early stance phase stability which is an important parameter in prescribing the prosthetic foot • When walking at high speed the prosthetic foot should preferably have a wide range of dorsiflexion

Figure 5b: The prescription format for prescribing prostheses for amputees with an knee disarticulation.

	General	Socket	Knee	Foot
Prescriptive	1. Activities including many rotational movements are an indication for the prescription of a rotator	1. Standard prosthetic prescription for the trans-femoral socket includes a combination of the NML and quadrilateral principles for the socket 2. If an amputee suffers from sensibility disorders of the stump a gelliner should be prescribed 3. In case the trans-femoral prosthesis is only used for making transfers a non-suction/pelvic-belt suspension is to be preferred	1. Electronic knee units are indicated for patients with a high demand for stability control 2. A knee-lock mechanism is only prescribed if there is insufficient stability control during the stance phase 3. If balance training does not improve the poor balance control a knee-lock mechanism should be prescribed	1. Walking on even ground is an indication for the prescription of a multiflexible foot 2. An energy-storing foot should be prescribed for highly active trans-femoral amputees 3. If a knee-lock mechanism is prescribed combination with a single-axis or multiple-axes foot is indicated
Additive	• Improving the comfort during sitting is an indication for a lotus-adaptor • The weight of the prosthesis is not the essential criterion in the prosthetic prescription for young trans-femoral amputees • To increase stability over the hip joint of trans-femoral amputees an RPB should be prescribed	• Wearing a gelliner causes cushioning of shear forces between the socket and the skin of the distal stump • Excessive perspiration of the stump is not a contra-indication for the prescription of a gelliner • If donning of the gel-liner needs assistance from others it is not a contra-indication for the prescription of a gel-liner • A gel-liner is not only indicated for improving total contact between socket and stump in the first instance • In case a suction socket is not sufficient, an elastic pelvic bandage should be prescribed to improve the suspension • In case of insufficient vascularisation of the upper leg an non-suction/pelvic-belt suspension socket should be prescribed • Not being able to donning a suction socket is not an indication for prescribing a pelvic belt suction • In case an amputee has a lower activity level an NML socket should not be prescribed	• A 7-axes knee unit provides more stability during stance phase than a 4-axes knee unit A single-axis knee unit is not the primary prescription for trans-femoral amputees with a low activity level • The 5-axes or 7-axes knee unit is not the primary prosthetic prescription for trans-femoral amputees with a high activity level	• Early foot flat during the stance phase of the prosthetic leg provides early stance phase stability which is an important parameter in prescribing the prosthetic foot • When walking at high speed it is preferable that the prosthetic foot should have a wide range of dorsiflexion

Figure 5c: The prescription format for prescribing prostheses for trans-femoral amputees.

Chapter

From Satisfaction to Expectation: Measurement of Patients' Experience with Everyday Practice

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International Journal for Quality in Health Care; submitted

Abstract

Introduction: Traditional questionnaires compiled by providers of health care do not reflect the true experience of patients about the quality of the care provided. Due to lack of specific questions general answers and high satisfaction scores are obtained. The Quote questionnaires are a good alternative. These questionnaires contain three dimensions: (1) patient experience concerning health care aspects, (2) importance of certain aspects according to patients and (3) an impact factor based on the multiplication of these two aspects.

The goal of the present study is to obtain information about the wishes and experiences of patients with a lower limb amputation with regard to prosthetic prescription and their exchange of information with the health care providers.

Method: In analogy with the Quote questionnaires a focus group technique was used. Based on the structure of this questionnaire 24 specific items are formulated which are of importance according to the prosthetic users. The items are divided into 4 categories: (1) service demand, (2) formulation of the prosthetic prescription, (3) training, information and aftercare, (4) claim and insurance aspects. The questionnaire consists of two sets (A and B) of 24 items. Part A rates the importance of each item, part B rates the experience in daily practice with the same items.

Results: One hundred and thirteen questionnaires were mailed with a response of 73 per cent. The outcomes of the questionnaires result in 2 sets of information: one concerning the importance of several items in the process of prosthetic prescription, the other the experience of the prosthetic user. In both sets we observed high mean values, which suggests that the respondents meet with a high level of expertise among care providers. By multiplying the scores on importance by the percentage of negative experience per item (impact score) we formulated points of improvement for clinical practice.

Conclusion: In conclusion we notice a discrepancy between the needs of patients and what they experience in their contacts with clinical professionals as the most important dimension. The results of this questionnaire are useful in the process of guideline development for prosthetic prescription. A questionnaire with specific items for a homogeneous target group is a good method to formulate points of improvement for daily practice in health care.

Introduction

There is a growing interest in the role of the patient in determining the quality of the health care provided. This also applies to patients who are in need of a medical aid, such as a lower limb prosthesis. Patients are pre-eminently experienced experts and are able to judge the way health care is supplied and the measure in which patients' expectations are met.

From a governmental viewpoint there is also a growing interest in improving the quality in health care on the European as well as on the Dutch level. Clinical guidelines can play an important role in improving health care. In assessing the quality and usability of guidelines it is important that the interests and opinions of patients are taken into consideration. For example this can be realised through questionnaires, literature research and by dealing with the patients' opinions about health care delivery [1]. The role of the patient in the process of health care itself is of increasing importance. In the Netherlands this has been laid down in a law that requires participation of clients in an advisory board or otherwise in health care institutions[2]. According to this law a treatment plan must take patients' wishes and expectations into account. The patient should also play a more central role in the provision of medical aids. In the field of prosthetics and orthotics there is an increasing interest in the role of the patient, especially patient satisfaction in relation to the service and quality of care provided [3,4].

The opinion about the way in which we should assess patients' wishes and satisfaction is changing. According to Williams, traditional questionnaires have their limitations [5]. In most questionnaires patients have to give their opinion on items invented by the providers of health care. The answers do not on beforehand reflect their true experience about the quality of the provided care. Moreover, general answers and high satisfaction scores are obtained due to a lack of specific questions regarding the nature and consequences of the disorder and the health care needed. Conclusions based on such questionnaires are not valid with relation to what they intend to measure, namely patient satisfaction. Therefore, the questionnaire cannot be used as an instrument for assessing the changing aspects of health care.

As the role of the patient has changed into that of a consumer in the last decades, especially in the field of prosthetics and orthotics [4], measurement of patient satisfaction alone has become of less interest. A new paradigm regarding patient involvement is establishing itself. Patients are now seen as experienced experts who know how to formulate their wishes and demands regarding the processes and contents of health care services. More explicitly the questionnaire has to fulfill two important requirements [6]: (1) the subjects in the questionnaire have to correspond

to the experiences of the patient category for which the instrument is intended; (2) patients have to be involved in the development process of the instrument from the start.

In the development of the Quote (Quality of Care through the Eyes of the Patient) questionnaires the patient has been given a central position [7,8]. This instrument contains three dimensions: (1) patient experience concerning health care aspects, (2) importance of certain aspects according to patients and (3) an impact factor based on the multiplication of these two aspects.

To improve the quality of care for patients with a lower limb amputation in the Netherlands the development of a clinical guideline for prosthetic prescription was set up. This guideline development project was commissioned by the Dutch Health Care Insurance Board. Parts of this project are a systematic literature review and the systematic analysis of the clinical experts' opinions regarding prescription criteria and the intended use of a prosthesis [9,10]. In a study regarding prosthetic prescription and functioning with an upper limb prosthesis Postema concluded that the wishes and opinions of the patients did not match the opinions held by the clinicians[11]. Hence, the goal of the present study is to obtain information about the wishes and experiences of patients with a lower limb amputation regarding prosthetic prescription and the exchange of information with the health care providers.

Method

Consistent with the Quote questionnaires a focus group technique was used. Four experienced prosthetic users were invited to formulate the items that are thought to be of importance in both prosthetic prescription and the supply of a prosthesis An existing questionnaire for people with a physical handicap was used as a format [12,13]. Based on the structure of this questionnaire specific items were formulated which are of importance according to the prosthetic users. In a second group of amputees the items were tested with regard to clarity and usefulness. Scoring of the items and statistical analyses were performed in analogy with the Quote method. This resulted in a questionnaire with specific items for a homogeneous target group.

The questionnaire contains 24 items divided into 4 categories, all part of the prosthetic prescription process: (1) service demand, (2) formulation of the prosthetic prescription, (3) training, information and aftercare, (4) claim and insurance aspects.

The questionnaire consists of two parts. In part A the participants were asked to rate the importance of each item on a 4-point scale (not important to most

important). In part B the same 24 items were presented. However, in this part of the questionnaire if the participants had positive or negative experiences with these items in daily practice. The latter was defined as the clinical practice in which the patient contacts the Medical doctor in Physical Rehabilitation and Medicine (MD in P&RM), the Prosthetist (CP) and the Physical Therapist (PT). The 4-point scale ranged from no to yes. Finally, the participants were asked if they were satisfied with the functioning and cosmetics of the prosthesis.
The questionnaire was sent to 113 experienced prosthetic users from the age of 18 onwards. The participants were randomly selected from a list of 300 amputees who visited our outpatient department in the years 2001 and 2002 (Rehabilitation Centre St. Maartenskliniek).

To identify different dimensions within the 24 items a factor analysis in SPSS was performed for list A and B, followed by a varimax rotation. To determine the number of factors a screenplot was studied and the Kaiser rule (eigenvalue>1) was applied. As criterion for a factor at least 4 items had to be within one factor and every item had to have a loading on that factor of at least 0.40. Every item has a loading on each factor. Ultimately, the item is categorised in the factor on which it had the highest loading. To calculate the impact factors the following formula was used: impact factor= (mean score of importance on an item) x (percentage of patients that experienced this item as negative). For the latter score the first 2 points on the 4-point scale were put together as being negative.

Results

One hundred and thirteen questionnaires were sent by mail, 82 of which were filled in. This is a response of 73 per cent. From the non-respondents 5 patients had died, 2 were not able to fill in the questionnaire, 6 patients were not satisfied with the prosthesis or the service of the care providers and were therefore not interested in filling in the questionnaire. One person had moved and 17 patients did not respond at all. This implies a net response of 82 per cent. The demographics of the respondents and non-respondents are given in Table 1. There was no statistical difference between the groups regarding age, gender, level of amputation and reason for amputation.
Relevant outcomes are given in Tables 2 and 3. The principle component analysis of the 24 items of part A shows that 6 factors accounted for 64 per cent of the total variance (see Table 2). In practice the items loaded slightly differently on factors than originally thought. Seven items were added to the first factor (information), 4 items to the fourth (insurance), 2 items to the fifth factor (prosthetic prescription)

and 1 item to the sixth factor (care providers). One of the criteria constituting a factor was that a factor had to have at least 4 items. Hence, the last 2 factors were excluded (see end of Table 2).

Table 1: *Patient demographics*

		Respondents (n=82)	Respondents + Non respondents (n=113)
Age	mean ± sd	55.8 ± 15.9	58 ± 15.2
Gender	Male	51	69
	Female	31	44
Level of amputation	Trans-tibial	35	55
	Knee disarticulation	13	16
	Trans-femoral	34	42
Reason for amputation	Diabetes Mellitus	10	11
	Vascular disease	19	31
	Trauma / tumour	42	50
	Infection / other	11	21
Satisfied with the cosmetics of the prosthesis*	Yes	70	-
	No	11	-
Satisfied with functioning with the prosthesis*	Yes	56	-
	No	25	-

* One respondent gave no satisfaction rating because he had had his prosthesis for just 1 day

The principle component analysis of part B (experience) shows that 6 factors account for 72 per cent of the total variance (see Table 3). These items were also ranged differently from the original questionnaire. Seven items were added to the first presupposed factor (service demand), 5 items to the second factor (prosthetic prescription), 4 items to the third factor (information about the prosthesis), 4 items were added to the fourth factor (general information), 3 to factor 5 (insurance) and 1 item to factor six (training). The last two factors were excluded because they had less than four items (see end of Table 3).

When comparing Tables 2 and 3 one can notice a difference between part A (importance) and B (experience) of the questionnaire. There is also a difference in the way of ranging the items within the various factors in both parts. Therefore, the outcome of the questionnaire results in 2 sets of information, one concerning the importance patients attribute to the items in the process of prosthetic prescription, the other concerning the experience in daily practice with the items of importance for the prosthetic user.

***Table* 2** Factor analysis questionnaire part A rating 'importance'

item		% missing	Mean	SD	Factor
	FACTOR 1 INFORMATION, eigenvalue=7.7				
12	The PC give me information about what to do in case of prosthetic problems; for instance who to call in case something does not work	0	3.23	0.81	0.79
13	The PC inform me about the existence of patient associations	0	2.16	0.94	0.53
15	The PC inform me if I can return to my former job	6	2.45	1.11	0.43
16	The PC explain to me what kind of shoes I can wear with my prosthesis; they explain to me which combinations of shoes and prosthesis are possible	0	2.90	1.03	0.64
17	The PC explain to me how to use the prosthesis; they inform me about the functional possibilities with my prosthesis	0	3.26	0.81	0.78
18	The PC inform me about the maintenance of the prosthesis	0	3.11	0.77	0.70
20	The PC inform me about the frequency and duration of visits to the clinic when getting a new prosthesis	0	3.07	0.78	0.72
	FACTOR 2 PROSTHETIC PRESCRIPTION, eigenvalue=2.1				
5	In the prescription process my opinion is decisive	1	2.93	0.79	0.79
8	In the prescription process my level of activity is of great importance	0	3.35	0.69	0.56
14	The PC inform me about the costs of the prosthesis and relating aspects	0	2.35	0.91	0.73
22	The PC let me decide how to spend my health care budget	9	2.61	1.00	0.70
	FACTOR 3 SERVICE DEMAND, eigenvalue=1.5				
1	The PC communicate well with me	0	3.27	0.61	0.74
2	The PC have sufficient knowledge of amputation aspects and prosthetics	0	3.51	0.59	0.71
3	The PC inform me in an understandable language	0	3.43	0.63	0.58
11	The PT offers sports and dance activities besides a prosthetic training when I ask for this	0	2.54	0.91	0.43
19	The PC give me time to get used to a new prosthesis or changes to the old one and inform me about what changes have to be made in future	0	3.54	0.69	0.60
	FACTOR 4 INSURANCE, eigenvalue=1.4				
9	A new prescription (changes in the prescription) is given by an MD in P&RM and a CP and in consultation with me	1	3.47	0.59	0.50
10	A repeat prescription (no changes in the prescription) is performed by an MD in P&RM and a CP and in consultation with me	1	3.00	0.77	0.72
21	The costs of care regarding the use of a prosthetic limb will be covered by the insurance	0	3.40	0.77	0.54
23	The PC will prescribe a new prosthesis whenever necessary instead of waiting for the 3 year period laid down by the insurance company	0	3.49	0.74	0.73
24	It is the MD in P&RM and/or the CP who communicate with the health care insurer about a new prosthesis primarily	1	3.30	0.75	0.60
	PROSTHETIC PRESCRIPTION, eigenvalue=1.3				
6	In the prescription process the PC consider my needs in daily life (employment, hobby, sports)	0	3.38	0.62	0.52
7	The CP is informed about the latest developments on prosthetics	0	3.57	0.61	0.66
	MULTIDISCIPLINARY TEAM, eigenvalue=1.3				
4	The PC collaborate in a multidisciplinary team (MD in P&RM, CP, PT)	1	3.38	0.68	0.69

%missing=percentage missing values with 82 participants. *Mean*=mean score on this item, minimum score is 0, maximum score is 4. *SD*=standard deviation of the mean score. *Factor*=value after factor analysis.
PC=Providers of Care. *MD P&RM*=Medical Doctor in Physical Medicine and Rehabilitation. *PT*=Physical Therapist. *CP*=Certified Prosthetist

Table 3 Factor analysis questionnaire part B rating 'experience'

item		% missing	Impact score	Mean	SD	Factor
	FACTOR 1 SERVICE DEMAND, eigenvalue= 8.9					
1	The PC communicate well with me	0	0.319	3.52	0.80	0.62
2	The PC have sufficient knowledge of amputation aspects and prosthetics	5	0.171	3.63	0.63	0.90
3	The PC inform me in an understandable language	1	0.167	3.68	0.65	0.88
4	The PC collaborate in a multidisciplinary team (MD in P&RM, CP, PT)	5	0.545	3.37	0.88	0.72
6	In the prescription process the PC consider my needs in daily life (employment, hobby, sports)	2	0.906	3.11	1.03	0.53
7	The CP is informed about the latest developments on prosthetics	12	0.711	3.6	0.62	0.83
19	The PC give me time to get used to a new prosthesis or changes to the old one and inform me about what changes have to be made in future	2	0.216	3.66	0.64	0.75
	FACTOR 2 PROSTHETIC PRESCRIPTION, eigenvalue= 2.8					
5	In the prescription process my opinion is decisive	5	0.928	2.9	1.11	0.77
8	In the prescription process my level of activity is of great importance	4	0.131	3.28	0.99	0.77
9	A new prescription (changes in the prescription) is performed by an MD in P&RM and a CP and in consultation with me	7	0.736	3.36	0.95	0.69
10	A repeat prescription (no changes in the prescription) is performed by an MD in P&RM and a CP and in consultation with me	6	0.550	3.38	0.92	0.74
22	The PC let me decide how to spend my health care budget	22	1.052	2.42	1.31	0.66
	FACTOR 3 INFORMATION, eigenvalue= 1.8					
13	The PC inform me about the existence of patient associations	4	1.632	1.81	1.08	0.73
14	The PC inform me about the costs of the prosthesis and relating aspects	1	1.780	1.9	1.08	0.76
15	The PC inform me if I can return to my former job	18	1.257	2.24	1.22	0.82
18	The PC inform me about the maintenance of the prosthesis	1	1.138	2.95	1.07	0.50
	FACTOR 4 INFORMATION, eigenvalue= 1.5					
12	The PC give me information about what to do in case of prosthetic problems; for instance who to call in case something does not work	0	0.512	3.48	0.98	0.74
16	The PC explain to me what kind of shoes I can wear with my prosthesis; they explain to me which combinations of shoes and prosthesis are possible	2	1.310	2.78	1.27	0.50
17	The PC explain to me how to use the prosthesis; they inform me about the functional possibilities with my prosthesis	1	0.754	3.23	1.00	0.46
20	The PC inform me about the frequency and duration of visits to the clinic when getting a new prosthesis	1	0.937	3.09	1.10	0.57
	INSURANCE, eigenvalue= 1.2					
21	The costs of care regarding the use of a prosthetic limb will be covered by the insurance	2	0.913	3.20	1.22	0.71
23	The PC will prescribe a new prosthesis whenever necessary instead of waiting for the 3 year period laid down by the insurance company	12	0.936	2.96	1.24	0.51
24	It is the MD in P&RM and/or the CP who communicate with the health care insurer about a new prosthesis primarily	4	0.121	3.77	0.60	0.80
	TRAINING, eigenvalue= 1.1					
11	The PT offer sports and dance activities beside a prosthetic training when I ask for this	22	0.476	2.84	1.17	0.72

%missing=percentage missing values with 82 participants. *Mean*=mean score on this item, minimum score is 0 (bad experience), maximum score is 4 (good experience). *SD*=standard deviation of the mean score. *Factar*=value after factor analysis. *PC*=Provides of Care. *MD P&RM*=Medical Doctor in Physical Rehabilitation and Medicine. *PT*=Physical Therapist. *CP*=Certified Prosthetist

Discussion

In our view the questionnaire developed with the help of a prosthetic-user focus group is a list, both concise and precise with relevant items for patients who are potential users of a lower limb prosthesis. However, the classification of the items under the several factors was different from what was originally hypothesized (see method section). For both part A and part B the factor analysis showed a slightly different classification of items (see Tables 2 and 3).

From other studies it is known that over 80% of the problems with the quality of health care is due to faults lying in the system, processes, structure and practices of organisations. Only a minority of the problems is traceable to a person who was not conscientious enough [4,14-16]. It is also known that patients are satisfied very easily with the health care items. Eighty five percent of patients are supposed to be satisfied with the care provided (85/15 rule) [4,14-16]. In our study high mean values were observed in both item sets. These mean values are directly comparable to each other and are an indicator of the importance of the item or the experience with it in everyday practice. For example, item 11 (sports and dance combined with prosthetic training), item 13 (knowledge about patient associations) and item 14 (information about the costs of a prosthesis) have a relatively low mean score and are therefore judged as less important. The experience of patients with the care offered shows that there is also a low scoring on these items. Therefore, it seems that they get less attention from the care providers in relation to other aspects of care.

The standard deviation gives information on how unanimous the participants were in their judgment. In the item list where experience is rated there are a great number of missing values on some items (for example item 15 concerning the employment situation). Probably this is due to the mean age of the study population with 75 per cent older than 65 and their matching experiences. Therefore certain items could be of less importance for some participants. The knowledge of the care providers about aspects of prosthetic prescription (item 2), prescription of a new prosthesis on time (item 23) and the knowledge of the CP about the latest developments on prosthetics (item 7) are judged as very important items.

In general 4 large factors can be distinguished in the item set 'importance' as well as in the item set 'experience'. They both have the same headings in Tables 2 and 3; however, they contain slightly different items. In the list 'importance' we can distinguish the dimensions information, prosthetic prescription, service demand and insurance. In the list 'experience' the same dimensions, however, come up in a different order, i.e. service demand, prosthetic prescription, information and

insurance. From the results of this questionnaire it can be derived that the respondents experience the care providers as highly qualified. Based on the high mean scores we can state that the care providers are seen as professionals who communicate in understandable language with the patient (item 30), who take the time needed by a patient as a guiding principle (item 19) and protect them from unnecessary communication with the health care insurance companies (item 24).
The impact score used in this study has a specific value. It can serve as a guiding instrument for improvements in the provision of care on service demands. From these scores we made up a top-5 list of specific points which have to be improved in our own clinical practice. The care providers should give more information or attention to the patients about:

1. the existence of patient associations (item 13),
2. the aspects concerning costs of the prosthesis (item 14),
3. cosmetic aspects of the prosthesis, especially shoes (item 16),
4. the possibility to return to their old job (item 15),
5. the maintenance of the prosthesis (item 18).

The results of this study, as far as it concerns measuring items regarding the role, attitude and professional knowledge of clinicians, cannot straightforwardly be generalized to other health care situations. This emphasizes the importance of the impact factor as a local instrument for improvement. There is a clear relationship between the height of the mean score on an item, the standard deviation of the values and the height of the impact score. This gives confidence in the method of measuring these scores and its use as an indicator for improvement. Secondly, if the mean score gets higher and the standard deviation smaller, the impact score becomes lower.
The importance of patient involvement in the prosthetic prescription process is underlined by the study of Postema [11]. This study shows that the involvement of the patient was proportionate to the compliance of patients with regard to the use of an upper limb prosthesis. There was no clear agreement between wishes and opinions of patients and the ideas of professionals about the compilation of prosthetic components and their functioning with the prosthesis. Therefore patients did not use their prosthesis or there was disappointment for patients and professionals.
The next step in our research will be a nationwide study based on this questionnaire. It will be interesting to know if a larger group of prosthetic users rates the same items as important and if there are differences in 'importance' factors and experiences with clinical practice in different parts of the Netherlands.

Differences between subgroups regarding age and gender and satisfaction about the prosthetic are of interest.

Conclusion

We notice a discrepancy between the expectations of patients and their experience in the contact with clinical professionals as most important dimension. The results of this questionnaire are useful in the process of guideline development for prosthetic prescription. A questionnaire with specific items for a homogeneous target group is a good method to formulate points of improvement for daily practice in health care.

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General Discussion and Conclusion

General discussion

The aim of this study was to create a draft clinical guideline for the prosthetic prescription of a lower limb prosthesis in the Netherlands. The starting point was the gathering of evidence and opinion based knowledge to create a basis for further discussion with clinical experts. The results and limitations of these information sources for the process are discussed in this chapter. Central to the guideline development process was the Delphi procedure. Results and limitations of this consensus procedure are discussed and then followed by a practical format of the concept clinical guideline, which can be used in a first implementation round. As stated in chapter 1 guidelines generally have potential limitations and harms. These are discussed in view of the guideline on prosthetic prescription. Furthermore the different steps of the process, which are part of this thesis are compared with the list of the Appraisal Instrument for Guidelines, Research and Evaluation in Europe (Agree-instrument) [1]. The list is presented in addendum 1 of this chapter. References regarding this instrument are mentioned with the corresponding number of the Agree item in the text or in the addendum referring to a specific chapter of this thesis.

Dissemination and implementation of the guideline are not part of this thesis. However, they are essential parts of the guideline development process. Therefore, these steps in the development process will be sketched and outlined in this chapter. Finally several recommendations for the training of professionals, future research and clinical practice will be given.

Literature review

What did it reveal and what are its limitations?

As stated in chapters 2 and 3 there is limited unbiased information, which can currently be obtained from studies on the effects of different prosthetic components on patient's functioning with a lower limb prosthesis for evidence-based prosthetic prescription. Hence, there are considerable gaps in our formal clinical knowledge concerning the effects of different prosthetic components. Only 7 statements formulated for the consensus procedure were based on this explicit knowledge (Chapter 6) (AGREE 10). Therefore, evidence-based knowledge has a lesser contribution to the concept guideline than the knowledge of clinical experts. As stated in the introduction the primary limitation of a guideline can be lack of scientific evidence [2]. Therefore, to improve the long-term guideline more explicit knowledge is needed concerning prosthetic components, evaluation of prosthetic use and patient satisfaction.

For future research, functional comparisons between different prosthetic components should be better categorized more precisely according to the level of activity and use in specific subgroups of traumatic or vascular amputees for example. Such an approach may better acknowledge the importance of individual needs and abilities that guide clinical-decision making, e.g. for drawing the prosthetic prescription. Secondly, functional outcomes should be assessed for various aspects of mobility such as making transfers, maintaining balance, level walking, stair climbing, negotiating ramps and obstacles, changing walking speed etc. With these criteria the intended functioning of the amputee can be described and in addition matched with the intended use of the prosthesis. Although perhaps less analytical, modern systems for ambulatory monitoring of human activity [3] are able to provide objective and valid data about human motor behaviour and its changes during prolonged periods in a much more ecologically valid way [4].

The opinion of clinical experts

What are the limitations of this source of information?

The collected information from the literature search, the observational studies and the interviews was converted in order to use it in the Delphi procedure. To a large extent the information used in the guideline procedure stems from the clinical knowledge gathered through observations in daily practice and interviews with professionals. There is quite a lot of empirical knowledge about the functioning of amputees and prosthetic components available. However, the observational studies performed did not reveal any consensus among clinicians on criteria for prosthetic prescription. A wide range of prosthetic components was used for trans-femoral (TF), knee disarticulation (KD) and trans-tibial (TT) amputees in the observational study and also suggested in the interviews with clinical experts. This was to be expected of formal knowledge about and the lack of guidelines for prescription criteria. However, according to Woolf, a second potential limitation of a guideline is that recommendations can be influenced by the opinions, clinical experience and composition of the guideline group [2]. Recommendations made solely on clinical judgment and experience are likely to be more susceptible to bias and self-interest. Currently there is no optimum method to collect and assess expert opinion, but the process needs to be as explicit as possible [5]. In chapter 4 it is concluded that there is some agreement on several items. Therefore, we have explicit criteria at our disposal for the matching of the functional ability of the prosthetic user with the functional properties of prosthetic components or the complete prosthesis. For example, level of activity is an important factor when

prescribing a prosthesis in lower limb amputees. However, the conclusion is that there is a lack of literature evidence, a lack of consensus in everyday practice and a lack of prescription criteria when defining the instruments for evaluation of functioning with a prosthesis.

As stated in the introduction one of the important goals of guideline development is that it can serve as a starting-point for the collaboration of a number of disciplines which are involved in a specific form of health care. As we have noticed in the consensus procedure the motivation of the clinical professionals to take part in this procedure was very promising. Therefore, it can be concluded that with the knowledge available in different clinics a further development of the draft clinical guideline with the help of these professionals is certainly possible.

During the guideline development process we noticed that opinions about prosthetic prescription can change rapidly. With a lack of formal evidence or the absence of a standard among the involved disciplines for the implementation of new prosthetic components there is no clear reason for these changes. Probably they are due to classical 'technology driven' developments and the tendency of clinicians to use these rapidly in everyday practice. For example in the last two years the choice made for a prosthetic socket in transtibial amputees has changed to the use of a gel liner within a hard socket. In the observational studies and interviews approximately 50 per cent of the professionals mentioned the polyform socket as their first choice. This new information is based on feedback from participants of the consensus procedure. A second example is the growing interest in an increasing experience with electronic swing-phase and stance-phase control of prosthetic-knee mechanisms. Prescription criteria are becoming clearer; therefore professionals advise or prescribe these knee units for an increasing number of patients. However, the costs of these knee-units and the related insurance aspects to provide these components are limiting the prescription. On the other hand professionals are forced to formulate more solid prescription criteria for costly prosthetic components, which in the long run will benefit both consensus opinion and guideline development. The question is if these rapid changes in professional opinion will have implications for the guideline development. To deal with these rapid changes the guideline has to be based on general prescription criteria only. On the other hand it requires an ongoing process of updating the guideline.

The next step was the integration of formal, clinical and technical knowledge by way of a formal consensus procedure.

Delphi-procedure

What are the results and limitations?

The Delphi procedure is a structured communication aimed at producing detailed critical examination and discussion, not at exacting a quick compromise. A Delphi procedure in general may be characterised as a method for structuring a group communication process, so that the process enables a group of individuals to deal with complex problems [6]. There are several modifications of the method and the computer based or electronic version is one of them. An important property of the computer based Delphi method is that members of a group can participate in an asynchronous manner. A participant can take part in the group communication process when they want and only contribute to those aspects to which they feel best able to contribute. In a face-to-face approach the participants have to take a sequential path through a group problem solving process. The Delphi method allows the individual participant to express a personal judgment [7].

Perhaps the property that most characterizes the Delphi method for most people is the anonymity in responding. The objective of this is to allow the introduction and evaluation of ideas and concepts by removing some of the common biases normally occurring in a face-to-face group process [7]. For example, it means that a participant does not have to feel embarrassed if he or she does not feel able to contribute to a specific statement. On the other hand an important factor is that the participants are informed about who is actually involved in the group of respondents. On beforehand this aspect motivates participation [7].

In this respect the method used in this consensus procedure is adequate (AGREE 8). The participants were informed about the group of respondents. In the Netherlands this was the first time the three key disciplines in the field of amputation and prosthetics participated in such a group process. Their motivation and participation was very promising. In the two postal rounds there was a maximum response; all the invited participants responded. Looking at the amount of comments on the various statements there was much positive reaction. With these comments statements were adjusted or changed further and posted again on the electronic platform. The project group was not able to get all the participants to take part in the round table session following the postal rounds due to unforeseen circumstances. However, 60 per cent of the original group was present and this was considered acceptable. The reaction of the participants was enthusiastic with regard to design and procedure and the overall results of the round table session. This implies that the next phases in the guideline development process may be carried out successfully.

The final result of the consensus procedure was a format with 37 statements categorised according to general aspects of prosthetic prescription or to a specific prosthetic component they were assigned to. At first sight this could come across as a rather a poor result of such a procedure and could, therefore, be seen as a limitation of the study result. On the other hand an agreement with a rate of 75 per cent or more on 37 statements regarding prosthetic prescription obtained from 32 participants of three different disciplines can be seen as a positive and promising result.

After the round table conference the project team modified the statements format into a draft scheme (see addendum 2, 3 and 4). When the level of amputation is known the level of activity forms the starting point from which choices can be made for the prosthetic components. Criteria regarding personal characteristics of the amputee determine the first prescription (body structure and function level). Adjustments are made based on specific items related to daily life circumstances and, if applicable, aspects of the employment situation (participation level) (AGREE 13 and 14). In a second round table conference this practical scheme will be discussed and refined where necessary (AGREE 15).

Guideline development

Potential harms and limitations (AGREE 9)

A potential harm of a clinical guideline in general can be found for patients. If guidelines are inflexible they leave insufficient room for clinicians to tailor care and, hence, in the assessment of the individual patient may be the wrong choice[2]. In the guideline process for prosthetic prescription, however, as mentioned above, specific individual characteristics and levels of activity serve as a starting point. Secondly, the inventory of the participation level can be a guide for further adjustments. These criteria for prosthetic prescription take care that the needs of the individual amputee are guaranteed. However, in chapter 7 we concluded that there might be a discrepancy between the expectations of patients and what they experienced in their contact with clinical professionals as the most important dimension. A third limitation of guidelines in general as mentioned in the introduction is related to this aspect, namely that patients' needs may not be the only priority in making recommendations [2]. The service demand, however, should be the starting point of a clinical procedure, e.g. the prescription of a prosthesis. For the continuation of the guideline procedure we recommend that the patient's opinion is incorporated and that they take part in an external review process.

A potential harm of a guideline in general regarding clinicians can also be found if scientific information and clinical advice are inaccurate and compromise the quality of care as a result. On the other hand clinicians may find them inconvenient and time-consuming to use [2]. However, the clinicians who are meant to use this guideline were involved in the development process and are presenters of the three key disciplines in prosthetic prescription, namely Medical Doctors in Physical and Rehabilitation Medicine (MD P&RM), Certified Prosthetists (CP) and Physical Therapists (PT) (Agree 4 and 16).

Finally a guideline in general can potentially harm health-care systems. For example health insurance companies or the government may be harmed by a guideline if it leads to costly interventions [2]. In case of underuse, e.g. of prosthetic care, a guideline can force up the costs of care. Therefore, the use of a guideline does not automatically lead to 'cost-containment'. As one of the main goals of this project is to obtain guidelines that are transparent it is stated that these parties are able to get more insight into prosthetic prescription. On the other hand overuse of care may be prevented this way. Therefore, the guideline can still lead to a certain cost control, although this was not the aim of this guideline development process (AGREE 18).

Dissemination and implementation

In the end a successful outcome will depend on the implementation of the guideline. This requires a broad support by potential users. This support has to be generated in an early phase of the guideline development process. Potential users should be able to formulate their expectations and give their opinion on concept versions. The potential users are:

- Clinical professionals (MD P&RM, CP, PT)
- Patient groups
- Health insurance companies and government.

Feedback was given on several occasions during the development process in multidisciplinary conferences. In these conferences most of the interested parties were present, namely the government, health insurance companies, medical doctors, producers and suppliers of prosthetics and patient groups.

Guidelines do not implement themselves [8]. We recommend that a multidisciplinary panel should supervise the various steps of dissemination and implementation.

Participants from the guideline procedure might form this panel. There is a range of effective dissemination and implementation strategies the choice of which depends on the nature of the guideline and which group is being targeted [9], for example:

- Producing short summaries for use in a range of forums, including internet and websites
- Potential users of the guideline should be involved in the development process
- Publishing articles about the guideline process and the final result in professional journals to promote the clinical guideline
- Mobilising educational institutes, professional organisations and patient groups
- Incorporating the guideline in routine procedures such as quality control of institutions and organisations
- Pilot studies in clinical practice.

The more educational the dissemination strategy is the greater the probability that the guidelines are incorporated in clinical practice. The format of the guideline should be clear and comprehensible for the potential users. Different versions must be provided, for example one for professionals and one for patients. However a simple dissemination will not be sufficient for the definite implementation. Interventions most likely to induce change are those that require the clinicians' participation [10]. The following strategies have proved effective in changing the behaviour of clinicians and can therefore be used in the implementation process [9].

- Media marketing
- The use of opinion leaders
- Endorsement by clinical groups
- Practice visits from leading experts
- Education of patients
- Seminars and conferences about the subject
- Reminder systems in daily practice
- Local adaptation and incorporation by institutes or multidisciplinary teams.

A combination of several of these strategies is recommended for the implementation process of the guideline on prosthetic prescription. Practice visits from experts in the field and the local adaptation and incorporation of the guideline may be the most relevant strategies for the implementation of the prosthetic prescription guideline (AGREE 19). The management of different clinics

have a responsibility also in this matter. They have to facilitate the implementation by offering time and resources during the implementation phase.

The continuation

What comes next in the prosthesis guideline development process?

First an external review has to be performed by clinical professionals and experts on guideline development who were not involved in the guideline process (Agree 11). Representatives of patient groups could be involved in this review process too.

The concept guideline should be disseminated among the clinical professionals who will then be given the opportunity for adjustments. These adjustments will have to be discussed during a plenary session with these professionals and can only be applied after reaching consensus by anonymous voting, i.e. identical to the first plenary session in the Delphi procedure.

This will have to be followed by a phase of testing the usability of the guideline in clinical practice on several locations throughout the Netherlands. Clinical practices that were involved in the observational study are suitable for the test procedure (AGREE 17 and 21). This process needs to be guided by the project group and by giving detailed information on how to use the guideline. This phase will be followed by a widespread implementation round.

Test and implementation phases will be followed by another adjustment round which will result in the presentation of the definitive guideline on prosthetic prescription for a lower limb prosthesis. It is presumed that this last round can be carried out through an Internet procedure similar to the Delphi procedure (AGREE 20). This final result should form a solid basis for further evidence-based research in the future.

The presentation of a definitive guideline for prosthetic prescription, however, will not be the end of the process. Guideline development must be seen as an ongoing process. The rapid changes of options for various prosthetic components have already been mentioned. The information of future research could also be a motive for adjustments in the guideline. Therefore, a project group consisting of the key disciplines should be formed which is responsible for updating the guideline (AGREE 12). The patients' opinions should be incorporated in this process as well.

Recommendations

Besides these steps in the guideline development process some specific recommendations for future training, research and clinical practice can be made.

Several authors state that the most important indicator for making choices in the prescription process is the functional ability of the amputee [11-14]. In our opinion the use of a classification based on these functional abilities has to be recommended therefore. In addition, it seems appropriate to look at aspects of activities of daily life, such as employment-related factors, to complete the intended use [15].

As stated in chapter 4 there is a wide range of prosthetic components in clinical practice and a lack of consensus among clinicians regarding prosthetic prescription criteria. The level of training and the experience of the prosthetic team members may partly cause this. For example, the training level of the prosthetists has been of a lower category (level II of the International Society of Prosthetics and Orthotics, see chapter 4) up to now compared to other developed countries. The introduction of a university course for prosthetists could offer more consistent information for the clinical team on functional aspects of prosthetic components. Recently the upgrading of the prosthetists' level of training has been started in the Netherlands. Therefore, it has been proposed that the prosthetist should have a more important role in the prescription process than this has been the case up to now. Secondly, the continuing education of the MDs in P&RM is necessary in order to assure consistency in knowledge about possible medical problems and functional abilities of the amputees.

The recommendations for future research have already been emphasized. Furthermore, as stated in chapters 4 and 5, classification of amputees according to their level of activity is of interest with regard to the prosthetic prescription. Various classifications are available and in this study we have primarily used the 5-level functional classification of the US Health Care Financing Administration (HCFA) [16]. Nevertheless there are other classifications that could be of interest, e.g. the SIGAM mobility scale [17].

As mentioned before the ambulatory monitoring of human activity can provide objective and valid data about (changes in) human motor behaviour [3]. However, the research for relevant outcome measures for prosthetic users within the framework of prosthetic prescription is still of interest.

To a certain extent functioning with a prosthesis may depend on the early phase after amputation. Whether early or immediate fitting influences functioning in the long term is still an open question. One could hypothesize that an early loading of the prosthetic limb decreases the loss of balance and walking skills compared to loading several weeks later for example. On the other hand the effects of various postoperative stump treatment methods could influence the ability to function with a prosthesis later on. More research on these aspects is recommended.

Conclusion

The study resulted in a draft clinical guideline for the prescription of a lower limb prosthesis. The knowledge of clinical professionals was a greater contribution in the guideline development process than the evidence based knowledge found in the literature. This difference in contribution, however, had been expected from the start of the procedure and was the motive for the set up of a consensus procedure. Therefore, the term 'opinion-based guideline' is more appropriate than 'evidence-based guideline'. The draft has led to a practical format, which can be used in clinical practice. It gives the involved disciplines, patients and third parties the opportunity to get insight into the prescription process (transparency).

More research is needed on various aspects of amputation and prosthetics in order to get better arguments for prescription criteria. Objectives for research that are recommended are ambulatory monitoring of human activity and functional comparisons between different prosthetic components, which take the categorisation of the level of activity into account. Additionally, functional outcomes in these studies should be assessed for various aspects of mobility.

The Delphi method as a tool to form an opinion based guideline seems highly adequate. This procedure is recommended in the implementation process of this guideline and for similar research projects, e.g. on orthotics. The incorporation of the patient's opinion early in the development process of such procedures is of importance.

In the provision of a prosthesis the future functioning of the amputee should be matched with the prosthetic components and the use of the whole prosthesis. Therefore, for clinical practice it is recommended that the functional ability of the amputee forms the starting point in formulating the prescription of a lower limb prosthesis. For this a mobility classification, such as the HCFA classification, can be used. However, assessment of other classifications, e.g. SIGAM or modifications of this scale, could be taken into consideration. Adjustments can be made based on circumstances in the individual patient's daily life situation.

The implementation process of the draft clinical guideline will be the next step in the development process. This phase is essential for a successful result and it needs the cooperation of the clinical professionals who have been involved in the process so far. The enthusiasm and motivation of these professionals is very promising for the continuation of the guideline development process for lower limb prosthetics.

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Addendum 1

Appraisal Instrument for Guidelines, Research and Evaluation in Europe (AGREE-instrument)

Range and aims

1. The general aim of the guideline is described in detail (Chapter 1).
2. The clinical question to be answered is described in detail (Chapter 1).
3. The patients who the guideline is applied to are specifically described (Chapter 1).

Involvement of interested parties

4. The guideline development group consists of participants of all relevant disciplines.
5. The expectations and preferences of patients are investigated (Chapter 7).

Carefulness of development

6. Systematic methods are used for evidence based information, e.g. Medline, Embase and the Cochrane Library (Chapters 2 and 3).
7. The criteria for the selection of scientific information are described in detail (Chapters 2 and 3).
8. The method for formulating the recommendations is described, e.g. the use of a consensus method such as the Delphi technique.
9. The profits for health care and harms and limitations are considered making the recommendations.
10. There is an explicit relation between the recommendations and the underlying scientific evidence.
11. Before the publication of the guideline an external review has to be carried out by an expert panel.
12. The procedure for revision of the guideline is described.

Transparency and presentation

13. The recommendations are specific and unambiguous, they are concrete and precise regarding the measures that have to be taken.
14. All the options for the clinical problem are clearly mentioned.
15. The most important recommendations can be identified easily, e.g. by using tables or flow charts.

Applicability

16. The potential users of the guideline are clearly described.
17. The potential organizational limitations are mentioned, e.g. where the guideline will be used be used.

18. The potential implications for costs when the recommendations are used.
19. The applicability of the guideline is supported with aids, e.g. education, patient information or electronic guidance.
20. The guideline offers review criteria for evaluation and feedback.
21. The guideline has been tested for clinical use on patients.

Independence of the guideline development group

22. The project group is independent of the financier of the guideline development (Chapter 1).
23. Conflicting interests of the project group are mentioned if applicable (Chapter 1).

Addendum 2

Patient characteristics

Level of amputation
TRANS-FEMORAL

K-level ***K4 (active walker)***		**Product characteristics** **Socket**	**Weightbearing**	**Suspension**	**Knee mechanism**	**Ankle-foot mechanism**
Stump characteristics	**Normal stump**	Hard socket	Hybride system, a combination of NML- and QUAD-principle	Vacuum suction	5- or 7-axes or electronic stance-phase and swing-phase control	Dynamic ElasticResponse Foot Multiflex foot
	Long stump	*Hard socket*	*NML/QUAD-principle*	*Vacuum*	*5- or 7-axes or electronic control*	*Dynamic Elastic Response Foot* *Multiflex foot*
	Scars	*Hord socket* gel-liner	*NML/QUAD-principle*	*Vacuum* if necessary + gel-liner	*5- or 7-axes or electronic control*	*Dynamic Elastic Response Foot* *Multiflex foot*
	Soft tissue surplus	*Hord socket* if necessary with gel-liner	*NML/QUAD-principle*	*Vacuum* if necessary + gel-liner	*5- or 7-axes or electronic control*	*Dynamic Elastic Response Foot* *Multiflex foot*
	Sensory loss	*Hard socket*	*NML/QUAD-principle*	*Vacuum* if necessary + gel-liner	*5- or 7-axes or electronic control*	*Dynamic Elastic Response Foot* *Multiflex foot*
	Soft tissue atrophy	*Hard socket* if necessary with gel-liner	QUAD-principle	Hip joint and pelvic belt if necessary + gel-liner	*5- or 7-axes or electronic control*	*Dynamic Elastic Response Foot* *Multiflex foot*
	Short stump	*Hard socket*	QUAD-principle	Vacuum or hip joint and pelvic belt	*5- or 7-axes or electronic control*	*Dynamic Elastic Response Foot* *Multiflex foot*

Addendum 3

Patient characteristics						
Level of amputation *TRANS-TIBIAL*		**Product characteristics**				
K-level *K3 ("community walker")*		**Socket**	**Weightbearing**	**Suspension**	**Knee mechanism**	**Ankle-foot mechanism**
Stump characteristics	**Normal stump**	Gel-liner	Total surface bearing	Cord fixation Vacuum suction	Not applicable (n.a.)	Opportunity for walking on uneven level, higher walking speed, more freedom of dorsal/plantarflexion movement. Mobile foot: flexibility at the ankle-joint (DER) or in the foot (Flex-foot)
	Long stump	*Gel-liner*	*Total surface bearing*	*Cord fixation* *Vacuum suction* No penfixation	*n.a.*	*Mobile foot: flexibility at the ankle-joint (DER) or in the foot (Flex-foot)*
	Scars		*Total surface bearing*	*Cord fixation* *Vacuum suction* No penfixation	*n.a.*	*Mobile foot: flexibility at the ankle-joint (DER) or in the foot (Flex-foot)*
	Pressure soars	*Gel-liner*	*Total surface bearing*	*Cord fixation* *Vacuum suction*	*n.a.*	*Mobile foot: flexibility at the ankle-joint (DER) or in the foot (Flex-foot)*
	Allergy	*Gel-liner*	*Total surface bearing*	*Cord fixation* *Vacuum suction*	*n.a.*	*Mobile foot: flexibility at the ankle-joint (DER) or in the foot (Flex-foot)*
	Skin problems (general)	*Gel-liner*	*Total surface bearing*	*Cord fixation* *Vacuum suction*	*n.a.*	*Mobile foot: flexibility at the ankle-joint (DER) or in the foot (Flex-foot)*

Addendum 4

Adjusting prosthetic prescription based on patient characteristics - participation level

Everyday life	Employment	Sitting, standing, rotational movements, uneven levels
	Home situation	Thresholds, floor surface, stairs, walking space
	Hobbies	Sitting, rotational movements
	Sports	Walking, running, jumping, cycling, rotational movements, uneven levels
Experience	Comfort	Sitting comfort, perspiration in the socket
	Cosmetics	Cosmetic aspects of the prosthesis

Summary

Summary

In the year 2000 a Prosthetics and Orthotics Guideline Development Group within the Dutch Society of Physical and Rehabilitation Medicine (VRA) was commissioned by the Dutch College of Health Care Insurances (CvZ) and the Ministry of Health Care to develop a clinical guideline on prosthetic prescription in lower limb amputation. The aim of this *Prosthesis Guideline Development* project (Proguide) is to obtain a guideline on a scientific basis. In the Netherlands a prosthesis is prescribed in clinical practice by a medical doctor in Physical and Rehabilitation Medicine (MD in P&RM) in collaboration with a Certified Prosthetist (CP) and sometimes on the advice of a Physical Therapist (PT). Experience plays an important role in an adequate prescription. This means that a clear evidence-based motivation for the choices made cannot always be given. Therefore, It can lead to local prescription variations as to the overuse or underuse of prosthetic care and a lack of transparency for consumers and health insurance companies. Hence, a clinical guideline will lead to a more consistent and efficient clinical practice and more uniform high-quality care.

Guidelines rely on systematic literature reviews, which were either published previously or created de novo by guideline developers. Systematic reviews can aid in guideline development because they involve searching for, selecting, critically appraising, and summarizing the results of primary research. However, not all aspects of treatment and care will have been the subject of research. In cases where randomized controlled trials have not been conducted we have to rely on other sources of evidence. Accordingly, clinicians can provide 'expert opinion' and patients can also take part in developing guidelines to provide an 'expert patient opinion' on care options. In general the definition of clinical guidelines is as follows: systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. This definition emphasizes the clinical guideline as a practical instrument for everyday practice and, therefore, as a support in taking decisions in specific clinical situations both for professional and patient.

In the Proguide project the guideline development was restricted to the adult population (over 18 years of age) with a trans-tibial (TT), knee disarticulation (KD) or trans-femoral (TF) amputation level. Prescription criteria of importance for a lower limb amputee deal with body structure and body functions and with specific aspects related to everyday life. Therefore, besides aspects of the amputation stump, general condition of the patient, co-morbidity and level of activity in home and employment situation are of interest in prosthetic prescription. There is a

growing awareness that the prosthetic prescription has to match the intended use of a prosthesis.
The integration of knowledge from research together with the expert opinions of clinical professionals and the opinions and wishes of consumers can form a solid basis for a procedure on guideline development for prosthetic prescription.

Literature review (Chapters 2 and 3)
A systematic literature review was performed to obtain evidence-based information about the effects of different prosthetic components on human functioning with a lower limb prosthesis. This should provide an objective starting point for further development of consensus-based criteria for prosthetic prescription in the Netherlands. The first step is to extract as much scientifically based knowledge from the literature as possible. In this respect, two types of studies can be distinguished: (a) clinical studies focusing on motor performance or daily functioning with a lower limb prosthesis and, (b) technical studies focusing on the mechanical characteristics of prosthetic components without specifically human functioning. In view of prosthetic guideline development, only studies addressing motor performance and human functioning with a lower limb prosthesis were considered relevant.
The studies were identified by a systematic search using the Medline Database, Current Contents, The Cochrane Database, and Psyclit. The following keywords and their synonyms were used: lower limb prosthesis, lower limb amputation, prosthetic prescription, prosthetic foot, prosthetic knee, prosthetic suspension, stump, socket, and physiological and biomechanical parameters. The quality of the studies was assessed using predetermined methodological criteria.
Out of 356 potentially relevant studies, 40 studies eventually qualified for final methodological analysis and review. From these publications 28 focused on the prosthetic foot, 5 on the prosthetic knee, 1 on the prosthetic socket, and 6 studies focused on the effect of prosthetic mass. Four studies satisfied all the criteria and were labeled as A studies. Twenty-six publications received a B label, and 10 studies were labeled as C studies. Limited unbiased information can currently be obtained from studies on the effects of different prosthetic components on human functioning with a lower limb prosthesis for evidence-based prosthetic prescription.
There is some evidence that energy-storing feet result in a comfortable walking speed and stride length that are about 7-13% higher than with a conventional foot in both traumatic and vascular TT amputees. Possibly, such feet also facilitate the symmetry of gait. These considerations seem important particularly for the active

prosthetic user. Inactive prosthetic users may benefit from an early foot-flat mechanism to facilitate weight transfer onto their prosthesis.
With regard to the prosthetic knee active prosthetic users may profit from the advanced characteristics of swing-phase controllers, whereas the geriatric vascular patient may still profit from the stance-phase stability that is provided by a conventional locked knee unit.
Despite a huge amount of literature, there are considerable gaps in our formal clinical knowledge concerning the effects of different prosthetic components and their mechanical characteristics on human functioning with a lower limb prosthesis.

Prosthetic prescription in clinical practice (Chapter 4)
Prosthetic prescription for lower limb amputees and the used methodology are primarily based on empirical knowledge. Clinical expertise plays an important role that can lead to an adequate prescription; however, a clear evidence-based motivation for the choices made cannot be given. An observational study of clinical practice in the Netherlands was performed to get insight into potential similarities in prescription criteria and the influence of the level of activity on prosthetic prescription. In a multi-centred, cross-sectional study the prescription data were collected from 151 amputees with a TF amputation, KD or TT amputation.
A multiple logistic regression analysis showed no relationship between the activity level and any of the variables included in the equation such as the hospital or MD in P&RM, prosthetic components, age of the amputee or reason of amputation. The criteria used are merely based on the clinical expertise and local experience whereas the actual prescriptions differ from location to location. There is some agreement on several prescription criteria and the level of activity is an important factor when prescribing a prosthesis in lower limb amputees. However, explicit criteria are at our disposal when matching the functional ability of the prosthetic user with the functional properties of prosthetic components or the complete prosthesis.

Interview with professionals (Chapter 5)
Besides the evidence-based knowledge from literature and the explicit knowledge form clinical practice the more implicit knowledge from clinical experts is of importance for guideline development. In order to obtain this information an interview study with 11 clinical experts from the three key disciplines (MD in P&RM, CP and PT) in this field was performed. A semi-structured interview method was carried out, structured around the three levels of amputation, i.e. TT, KD and

TF. For each level of amputation the options were inquired about for each prosthetic component given a certain patient situation, based on stump aspects like stump length and skin aspects. For these patient characteristics the primary options were asked regarding different prosthetic components, i.e. socket, knee and prosthetic foot, i.e. in the first prescription.
The prescription criteria given in these semi-structured interviews appeared divided with regard to various options in the prescription of a lower limb prosthesis. Prosthetic prescription criteria seem to be based on local experience and partly on assumptions regarding characteristics of prosthetic components. However, also the implicit knowledge is of importance for the consensus procedure on guideline development.

The consensus procedure (Chapter 6)
A Delphi procedure in general may be characterised as a method for structuring a group communication process, so that the process enables a group of individuals to deal with complex problems. The Delphi method allows the individual participant to express a personal judgment. Perhaps the property that most characterizes the Delphi method for most people is the anonymity in responding.
In this study the "Modified Delphi Technique" was used, which has been developed by the RAND Corporation. This is the most commonly used method for clinical guidelines. This formal consensus method consists of two postal rounds and a final consensus meeting. The two postal rounds were conducted by the internet. An advantage of the Computer Mediated Delphi Method, is "collective intelligence". This is the ability of a group to produce a result that is of higher quality than any single individual in the group could achieve on their own. Preferably, guidelines should be developed and disseminated by a group, team, or organisation which is perceived by the target group of clinicians. Therefore, the participants in this project were physicians, prosthetists or physical therapists, specialized in both amputees and prostheses. In this project we formed a participant group of 32 members, representing the above-mentioned key disciplines.
The statements for the Delphi process were developed by combining the information of the systematic review, the survey of clinical practice on prosthetic prescription and the interviews with professionals.
This resulted in 45 statements about prosthetic prescription. After two postal rounds the views of the national expert panel were then combined with a consensus development conference.

The participants of the Delphi process achieved consensus about 37 statements on the prosthetic limb for lower limb amputees, which are applicable in the prescription process. Eventually, after dividing and prioritising these statements, a specific format for the draft of the guideline was developed.
In this format the statements were divided according to the amputation level and split up into different domains. These domains represent the different prosthetic components, socket, knee mechanism and ankle-foot mechanism and general aspects of prescription. The total process resulted in the development of a draft clinical guideline comprising guidance for the tasks of prescribing prostheses for the lower limb.

Patient satisfaction (Chapter 7)
Traditional questionnaires compiled by providers of health care do not reflect the true experience of patients about the quality of the care provided. Due to a lack of specific questions general answers and high satisfaction scores are obtained. A study was performed to obtain information about the wishes and experiences of patients with a lower limb amputation with regard to prosthetic prescription and their exchange of information with the health care providers.
In analogy with the Quote questionnaires a focus group technique was used. Based on the structure of this questionnaire 24 specific items are formulated which are of importance according to the prosthetic users. The items are divided into 4 categories: (1) service demand, (2) formulation of the prosthetic prescription, (3) training, information and aftercare, (4) claim and insurance aspects. The questionnaire consists of two sets (A and B) of 24 items. Part A rates the importance of each item, part B rates the experience in daily practice with the same items.
One hundred and thirteen questionnaires were mailed with a response of 73 per cent. The outcomes of the questionnaires result in 2 sets of information: one concerning the importance of several items in the process of prosthetic prescription, the other the experience of the prosthetic user. In both sets high mean values were observed, which suggests that the respondents meet with a high level of expertise among care providers. By multiplying the scores on importance by the percentage of negative experience per item (impact score) points of improvement for clinical practice were formulated.
A discrepancy was noticed between the needs of patients and what they experience in their contacts with clinical professionals as the most important dimension. The results of this questionnaire are useful in the process of guideline

development for prosthetic prescription. A questionnaire with specific items for a homogeneous target group is a good method to formulate points of improvement for daily practice in health care.

Discussion and conclusion (Chapter 8)

The aim of this study was to create a draft clinical guideline for the prosthetic prescription of a lower limb prosthesis in the Netherlands. The starting point was the gathering of evidence and opinion based knowledge to create a basis for further discussion with clinical experts. There are considerable gaps in our formal clinical knowledge concerning the effects of different prosthetic components. Therefore, evidence-based knowledge has a lesser contribution to the concept guideline than the knowledge of clinical experts. To improve the long-term guideline more explicit knowledge is needed.

Through observations in daily practice and interviews with professionals quite a lot of knowledge about the functioning of amputees and prosthetic components is available. A wide range of prosthetic components was used for TF, KD and TT amputees in the observational study and also suggested in the interviews with clinical experts. With agreement on several items explicit criteria are at our disposal for prosthetic prescription. The level of activity is mentioned as an important factor when prescribing a prosthesis in lower limb amputees. With the knowledge available on several locations a further development of the draft clinical guideline can be performed. During the guideline development process we noticed that opinions about prosthetic prescription can change rapidly. To deal with these rapid changes the guideline has to be based on general prescription criteria only. On the other hand it requires an ongoing process of updating the guideline.

The formal, clinical and technical knowledge was integrated by way of a formal consensus procedure. With the structuring of the group communication process, the possibility to express personal judgment and its anonymity as property the Delphi method was adequate for this procedure. In the Netherlands this was the first time the three key disciplines in the field of amputation and prosthetics participated in such a group process. The reaction of the participants was enthusiastic with regard to design and procedure and the overall results of the round table session. This implies that the next phases in the guideline development process may be carried out successfully.

During the round table conference the project team modified the statements format into a draft scheme. When the level of amputation is known the level of

activity forms the starting point from which choices can be made for the prosthetic components. Criteria regarding personal characteristics of the amputee determine the first prescription. Adjustments are made based on specific items related to daily life circumstances and, if applicable, aspects of the employment situation.
In the end a successful outcome will depend on the implementation of the guideline. We recommend that a multidisciplinary panel should supervise the various steps of dissemination and implementation. Practice visits from experts in the field and the local adaptation and incorporation of the guideline may be the most relevant strategies for the implementation of the prosthetic prescription guideline. The management of different clinics have to facilitate the implementation by offering time and resources during the implementation phase.
Continuation of the guideline development process starts with an external review of the guideline by clinical experts. The concept guideline should then be disseminated among the clinical professionals who will be given the opportunity for adjustments. This will have to be followed by a phase of testing the usability of the guideline in clinical practice on several locations throughout the Netherlands. Test and implementation phases will be followed by another adjustment round which will result in the presentation of the definitive guideline on prosthetic prescription for a lower limb prosthesis.
More research is needed on various aspects of amputation and prosthetics in order to get better arguments for prescription criteria. Objectives for research that are recommended are ambulatory monitoring of human activity and functional comparisons between different prosthetic components, which take the categorisation of the level of activity into account. Additionally, functional outcomes in these studies should be assessed for various aspects of mobility.
The study resulted in a draft clinical guideline for the prescription of a lower limb prosthesis. The knowledge of clinical professionals was a greater contribution in the guideline development process than the evidence-based knowledge found in the literature. The Delphi method as a tool to form an opinion-based guideline seems highly adequate. This procedure is recommended in the implementation process of this guideline and for similar research projects, e.g. on orthotics. The incorporation of the patient's opinion early in the development process of such procedures is of importance.

Samenvatting

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In 2000 werd aan de commissie prothese en orthese richtlijnen (PORO) van de vereniging voor physische en revalidatiegeneeskunde (VRA) de opdracht verstrekt door het College voor Zorgverzekeringen (CVZ) om een richtlijn te ontwikkelen voor het voorschrijven van een prothese voor de onderste extremiteit. Het doel van dit Prosthesis Guideline Development project (Proguide) is het verkrijgen van een richtlijn op wetenschappelijke basis. In Nederland wordt een beenprothese in de dagelijkse praktijk doorgaans voorgeschreven door een revalidatiearts in samenwerking met een prothesemaker en soms ook met het advies van een fysiotherapeut. Ervaring speelt hierbij een belangrijke rol voor een adequaat voorschrift. Dit betekent dat een duidelijke evidence-based motivatie voor de gemaakte keuzes niet altijd gegeven kan worden. Dit kan dan ook leiden tot lokale variaties in het prothesevoorschrift als ook tot over- of onderbehandeling met betrekking tot de geboden zorg. Tevens ontstaat hierdoor een gebrek aan transparantie voor zowel de patiënt/consument als voor zorgverzekeraars. Geconcludeerd wordt dan ook dat een klinische richtlijn kan leiden tot een consistente en efficiënte dagelijkse praktijkvoering en een meer uniforme zorg met een hogere kwaliteit.

Richtlijnen worden in het algemeen vooral gebaseerd op systematische literatuur reviews die reeds eerder zijn gepubliceerd of nieuw opgezet worden in het kader van de betreffende richtlijn. Systematische reviews kunnen bijdragen aan de richtlijn ontwikkeling, omdat deze betrekking hebben op het zoeken naar, het selecteren van en het kritisch beoordelen en samenvatten van de resultaten van primaire research. Het is echter wel zo, dat niet alle aspecten van zorg en behandeling onderwerp zijn geweest van wetenschappelijk onderzoek. Voor die zorgaspecten waarin geen gerandomiseerde en gecontroleerde onderzoeken zijn uitgevoerd, zullen we aldus moeten vertrouwen op andere informatiebronnen. Dienovereenkomstig kunnen klinische professionals een 'expert mening' geven en patiënten hun 'expert patiënten mening' met betrekking tot verschillende zorg opties. In het algemeen kan een richtlijn als volgt worden gedefinieerd: 'systematisch ontwikkelde mededelingen die zowel professionals als patiënten ondersteunen bij het maken van de meest gepaste keuze uit de verschillende zorgopties in specifieke klinische omstandigheden'. Deze definitie benadrukt de waarde van de klinische richtlijn als een praktisch instrument voor de dagelijkse praktijk.

In het Proguide project is de richtlijn ontwikkeling toegespitst op de populatie van volwassenen (18 jaar of ouder) met een transtibiaal, knie of transfemoraal

amputatieniveau. De voorschrijfcriteria, van belang voor patiënten met een beenamputatie, betreffen lichaamsfunctie, lichaamsstructuur en specifieke aspecten gerelateerd aan aspecten van het dagelijkse leven van de patiënt. Naast de specifieke aspecten van het geamputeerde been betreft het dan ook de algemene conditie van de beengeamputeerde, co-morbiditeit en het activiteitenniveau in de eigen woonomgeving en werksituatie. Er is een toenemend begrip voor het met elkaar in overeenstemming brengen van het beoogde gebruik van de prothese en het prothesevoorschrift.
De integratie van kennis afkomstig uit onderzoek, de expert mening van klinische professionals en de wensen van consumenten, vormt een solide basis voor het ontwikkelen van een richtlijn voor het voorschrijven van een beenprothese.

Literatuur review (hoofdstukken 2 en 3)
Er werd een systematische literatuur review uitgevoerd om 'evidence based' informatie te verkrijgen betreffende de effecten van verschillende prothesecomponenten op het functioneren van een patiënt met een amputatie van de onderste extremiteit. Deze informatie zou moeten dienen als een objectief uitgangspunt voor de verdere ontwikkeling van op consensus gebaseerde criteria voor het prothesevoorschrift in Nederland. De eerste stap is het verkrijgen van zoveel mogelijk wetenschappelijke kennis uit de literatuur. In dit opzicht kunnen er twee typen studies onderscheiden worden: (a) klinische studies gericht op motorische prestatie en dagelijks functioneren met een beenprothese, en (b) meer technische studies betreffende de mechanische karakteristieken van prothesecomponenten los van het specifieke functioneren van de prothesegebruiker. In het licht van prothese richtlijn ontwikkeling werden alleen de studies betreffende motorische prestatie of functioneren van de prothesegebruiker relevant geacht.
De studies werden geïdentificeerd middels een systematische zoektocht met gebruikmaking van de Medline database, Current Contents, de Cochrane database en Psyclit. De volgende synoniemen en sleutelbegrippen werden gebruikt: 'lower limb prosthesis', 'lower limb amputation', 'prosthetic prescription', 'prosthetic foot', 'prosthetic knee', 'prosthetic suspension', 'stump', 'socket', en fysiologische en biomechanische parameters. De kwaliteit van de studies werd beoordeeld met gebruikmaking van vooraf bepaalde methodologische criteria.
Uit een aantal van 356 potentieel relevante studies werden uiteindelijk 40 studies gekwalificeerd als geschikt voor een uitgebreidere methodologische analyse. Van deze publicaties handelden 28 over de prothesevoet, 5 over de protheseknie, één

over de prothesekoker en 6 studies betroffen de invloed van het prothesegewicht. Vier studies voldeden aan alle gestelde criteria en werden gekwalificeerd als A studies. Een B niveau werd toegekend aan 26 studies, een C niveau aan 10 studies. Objectieve informatie voor een 'evidence based' prothesevoorschrift kan dus maar uit een relatief beperkt aantal studies verkregen worden met betrekking tot het functioneren met een beenprothese of over de eigenschappen van verschillende prothesecomponenten.
Er is enige evidentie dat de zogenaamde 'energy storing' prothesevoeten een 7 tot 13% hogere comfortabele loopsnelheid en 'stride length' kunnen geven in vergelijking met een conventionele prothesevoet bij patiënten met een transtibiale amputatie, zowel als gevolg van een trauma als bij een vasculaire oorzaak van de amputatie. Waarschijnlijk vergemakkelijken deze voeten ook de symmetrie van het lopen. Deze overwegingen lijken vooral van belang voor de meer actieve prothesegebruiker. De meer inactieve protheseloper zou meer kunnen profiteren van een vroege 'foot flat' mechanisme om het over brengen van gewicht op het prothesebeen te vergemakkelijken.
Bij het gebruik van een protheseknie kunnen actieve protheselopers baat hebben bij het gebruik van de meer geavanceerde karakteristieken van een zwaaifase controle mechanisme, terwijl oudere (vasculaire) beenprothesegebruikers meer kunnen profiteren van de standfase stabiliteit van bijvoorbeeld een conventionele knie met slotmechanisme.
Ondanks de grote hoeveelheid beschikbare kennis in de literatuur, zijn er belangrijke tekortkomingen in de objectieve klinische kennis betreffende de effecten van verschillende prothesecomponenten en bijbehorende mechanische karakteristieken op het functioneren met een beenprothese.

Het prothesevoorschrift in de klinische praktijk (hoofdstuk 4)
Het voorschrijven van een beenprothese en de daarbij gebruikte methodologie is voornamelijk gebaseerd op empirische kennis. De klinische expertise speelt een belangrijke rol en kan leiden tot een adequaat voorschrift. Een duidelijke 'evidence based' motivatie voor de keuzes kan echter niet gegeven worden. Er werd een observatie uitgevoerd in de 'klinische praktijk' in Nederland om inzicht te krijgen in potentiële overeenkomsten in voorschrijf criteria en tevens in de invloed van het niveau van functioneren van de patiënt op het prothesevoorschrift. Middels een multicentrum, crossectionele studie werden de voorschrijf criteria verzameld bij 151 patiënten met een transfemorale amputatie, een knie-exarticulatie of transtibiale amputatie. Een multipele logistische regressie analyse

liet geen duidelijke correlatie zien tussen het activiteitenniveau en één van de andere variabelen, waaronder locatie kliniek, revalidatiearts, prothese-componenten, leeftijd patiënt of de reden van amputatie. De gebruikte criteria waren voornamelijk gebaseerd op de klinische expertise en de lokale ervaring , waarbij de voorschriften variëren van locatie tot locatie. Wel is er enige overeenstemming voor enkele voorschrijf criteria en met name wordt het activiteitenniveau van de amputatiepatiënt genoemd als een belangrijk criterium. Er zijn aldus wel enkele expliciete criteria voorhanden voor het matchen van de functionele mogelijkheden van de prothesegebruiker en de functionele eigenschappen van prothesecomponenten of een volledige prothese.

Interview met professionals (hoofdstuk 5)
Naast de 'evidence based' kennis uit de literatuur en de expliciete kennis uit de klinische praktijk, is de meer impliciete kennis van klinische experts van belang voor de ontwikkeling van een richtlijn. Er werd een interview methode toegepast waarin 11 klinische experts afkomstig uit de drie sleutel disciplines (revalidatiearts, prothesemaker en fysiotherapeut) participeerden. Deze semi-gestructureerde methode was opgezet rondom de drie amputatieniveaus transtibiaal, knie-exarticulatie en transfemoraal. Voor elk amputatieniveau werd gevraagd om de opties voor de verschillende prothesecomponenten te benoemen in een patiëntsituatie met zogenaamde standaard stompkenmerken met betrekking tot lengte en huidaspecten. Bij deze patiënt kenmerken werden de primaire keuzes gegeven voor de verschillende prothesecomponenten, stompkoker en knie- en voetmechanisme, in een eerste prothesevoorschrift voor de betreffende patiënt.
De criteria voor de keuze van de verschillende componenten, gegeven in deze interviews, vertolken uiteenlopende meningen. Prothesevoorschrift criteria lijken ook hier vooral gebaseerd te zijn op lokale ervaringen en deels ook op aanname van verschillende eigenschappen zonder objectief bewijs. Toch blijft deze impliciete kennis wel van belang voor de consensus procedure in het kader van de richtlijnontwikkeling.

De consensus procedure (hoofdstuk 6)
Een Delphi procedure kan in het algemeen gekarakteriseerd worden als een methode waarmee een groepscommunicatie proces zo gestructureerd wordt, dat het proces de groep van individuen in staat stelt om complexe problemen te behandelen. De methode geeft de individuele deelnemer de mogelijkheid om een persoonlijke mening te geven. Waarschijnlijk is de gewaarborgde anonimiteit bij

het beantwoorden van vragen de meest karakteristieke eigenschap van de Delphi methode.
In deze studie werd een gemodificeerde Delphi techniek gebruikt zoals ontwikkeld door de RAND organisatie. Deze methode is in het algemeen de meest gebruikte methode voor de ontwikkeling van klinische richtlijnen. Deze formele consensus methode bestond uit twee postale rondes via het internet en een afsluitende plenaire bijeenkomst. Het voordeel van een met de computer ondersteunde Delphi methode is de zogenaamde 'collectieve berichtgeving'. Dit is de mogelijkheid van een groep van individuen om een resultaat te genereren dat van een hogere kwaliteit is dan wanneer ieder individu afzonderlijk zou kunnen bereiken.
Ontwikkeling en verspreiding van een richtlijn moet bij voorkeur worden uitgevoerd door een groep of organisatie die is samengesteld uit de uiteindelijke doelgroepen. De participanten in deze procedure waren dan ook revalidatieartsen, orthopedisch instrumentmakers en fysiotherapeuten, allen met als specifiek aandachtsgebied de amputatie en prothesiologie. In dit project werd een deelnemersaantal van 32 geformeerd die representatief leken voor de drie genoemde sleuteldisciplines.
De stellingen voor de Delphi procedure werden opgesteld middels het combineren van de informatie uit de verschillende informatiebronnen, systematische literatuur review en het werkveldonderzoek met observatie en interview. Dit resulteerde in 45 stellingen met betrekking tot het voorschrijven van een beenprothese. Na het beantwoorden van deze stellingen in de internet rondes werd de procedure afgesloten met de plenaire bijeenkomst.
De deelnemers aan de Delphi procedure bereikten overeenstemming over 37 stellingen met betrekking tot de prothesevoorziening voor beenprothese gebruikers die toepasbaar zijn in het voorschrijfproces. Vervolgens werd tijdens de plenaire bijeenkomst een format opgesteld waarin de stellingen over verschillende domeinen werden verdeeld. Deze domeinen representeren de verschillende prothesecomponenten, prothesekoker, kniemechanisme, enkel-voet mechanisme en algemene aspecten van belang bij het voorschrijven. Daarna werd de prioriteit van de verschillende stellingen binnen elk domein bepaald. Het totale proces resulteerde uiteindelijk in een concept klinische richtlijn die als gids kan dienen wanneer een beenprothese wordt voorgeschreven.

Vragenlijst voor patiënten (hoofdstuk 7)
In traditionele vragenlijsten, waarin de items zijn opgesteld door zorgverleners, komt de daadwerkelijke ervaring van patiënten met betrekking tot de kwaliteit van

de geboden zorg niet tot uiting. Als gevolg van een gebrek aan specifieke vragen worden algemene antwoorden gegeven en worden vervolgens hoge tevredenheidscores bereikt. Er werd een onderzoek uitgevoerd met als doel het verkrijgen van informatie over de wensen en ervaringen van patiënten met een beenamputatie aangaande de procedure van protheseverstrekking en de uitwisseling van informatie met de verschillende zorgverleners.
In analogie met de Quote vragenlijsten werd de focusgroep techniek gehanteerd. Gebaseerd op de structuur van deze vragenlijsten werden 24 items geformuleerd die van belang zijn voor prothesegebruikers. De items werden verdeeld over vier categorieën: (1) hulpvraag, (2) formuleren van het prothesevoorschrift, (3) training, informatie en nazorg, (4) aanspraak en verzekeringsaspecten. De vragenlijst bestaat uit twee delen (A en B) van 24 items. Deel A heeft betrekking op de belangrijkheid van ieder item en deel B op de ervaring in de dagelijkse praktijk betreffende dezelfde items.
Van 113 verstuurde vragenlijsten werd 73 procent geretourneerd. De uitkomst van deze lijsten resulteerde in twee sets met informatie: één betreffende de belangrijkheid toegekend aan de verschillende items in het proces van protheseverstrekking, de ander betreffende de ervaringen van de prothesegebruiker. In beide sets werden hoge gemiddelde scores waargenomen, hetgeen suggereert dat de respondenten een hoog niveau van expertise ervaren bij zorgverleners. Door de scores op belangrijkheid te vermenigvuldigen met het percentage negatieve ervaring per item (zogenaamde impactscore) konden verbeterpunten worden geformuleerd voor de klinische praktijk.
Er werd een discrepantie waargenomen tussen de wensen van patiënten en de aspecten die door professionals als belangrijk worden aangegeven. Deze resultaten zijn van belang voor de richtlijn ontwikkeling. Het gebruik van een vragenlijst met specifieke items voor een homogene doelgroep is een goede methode voor het formuleren van verbeterpunten voor de dagelijkse praktijk.

Discussie en conclusie (hoofdstuk 8)
Het doel van deze studie was het creëren van een concept klinische richtlijn voor het voorschrijven van een beenprothese in Nederland. Het verzamelen van wetenschappelijk bewijs in combinatie met de kennis uit het werkveld vormde het uitgangspunt voor een verdere discussie met klinische experts. Er blijken forse tekortkomingen te zijn in onze formele klinische kennis betreffende de effecten van het gebruik van diverse prothesecomponenten. De 'evidence based' heeft daarom een veel beperktere bijdrage geleverd aan de richtlijn ontwikkeling dan de

kennis van klinische experts. Om de richtlijn op langere termijn te verbeteren is meer expliciete kennis noodzakelijk.
Middels de observaties in de klinische praktijk en de interviews met professionals is er veel kennis beschikbaar gekomen met betrekking tot het functioneren van prothesegebruikers en de verschillende prothesecomponenten. Er blijkt echter een breed palet aan protheseonderdelen te worden gebruikt voor de drie beschreven amputatieniveaus. Met de overeenstemming op een aantal onderdelen staan er meerdere expliciete criteria voor het voorschrijven tot onze beschikking. Het niveau van functioneren van de amputatiepatiënt wordt genoemd als een belangrijke factor. Met de beschikbare kennis op verschillende locaties kan het concept van de richtlijn verder uitgewerkt worden.
Tijdens het richtlijn ontwikkelingsproces is gebleken dat de meningen met betrekking tot protheserecеptuur snel kunnen veranderen. Voor de richtlijn betekent dit dat deze vooral gebaseerd moet zijn op algemene voorschrijfcriteria. Daarnaast vraagt dit ook om een voortgaand proces van aanpassing van de richtlijn.
De formele, klinische en technische kennis werd geïntegreerd middels een formele consensus procedure. De Delphi methode bleek hiervoor een adequate procedure, met name door het bieden van structuur voor het groepscommunicatie proces, het bieden van de mogelijkheid van persoonlijke beoordeling en het waarborgen van anonimiteit. In Nederland was dit de eerste keer dat de drie belangrijke disciplines op het terrein van amputatie en prothesiologie participeerden in zo'n groepsproces. De reacties van participanten waren zeer enthousiast met betrekking tot de opzet en het verloop van de procedure en de uiteindelijke resultaten van de plenaire bijeenkomst. Dit betekent ook dat de volgende stappen in de richtlijn procedure een goede kans van slagen hebben.
Na de plenaire bijeenkomst van klinische experts werd het format met stellingen door de richtlijn projectgroep omgezet in een meer praktisch te hanteren schema, hetgeen ook als uitgangspunt kan dienen voor een hulpmiddelenkompas. Bij een bepaald amputatieniveau vormt het activiteitenniveau van de patiënt het uitgangspunt voor de criteria behorend bij de keuze voor de verschillende prothesecomponenten. Criteria betreffende specifieke patiëntkenmerken bepalen dan in eerste instantie het prothesevoorschrift. Vervolgens kunnen aanpassingen op dit voorschrift van toepassing zijn op basis van specifieke eisen die gesteld worden aan de dagelijkse omstandigheden of bezigheden van de betreffende patiënt, of wanneer van toepassing, op basis van de arbeidssituatie.
Een succesvolle uitkomst van de richtlijn wordt uiteindelijk ook bepaald door de implementatie ervan in de dagelijkse praktijk. Het wordt hierbij aanbevolen om

verspreiding en implementatie te laten superviseren door een multidisciplinair panel. Zogenaamde praktijk visites door klinische experts en lokale adaptatie en incorporatie van de richtlijn lijken in deze de meest relevante strategieën voor de implementatie van de prothese richtlijn. Het management van de diverse klinieken dient deze implementatie dan wel te faciliteren door het verschaffen van voldoende tijd en middelen.

Het vervolg van de richtlijn procedure start met een externe review door klinische experts die tot nu toe niet betrokken zijn geweest bij de procedure. De concept richtlijn dient dan op kleine schaal verspreid te worden om de bruikbaarheid voor de dagelijkse praktijk te beoordelen, waarna aanpassingen kunnen worden gemaakt. Daarna kan de implementatie van de definitieve richtlijn plaatsvinden.

Er is meer onderzoek gewenst op het terrein van amputatie en prothesiologie om betere argumenten te verkrijgen voor de voorschrijfcriteria. Onderzoek zou zich meer kunnen richten op ambulante meting van activiteiten van patiënten en een meer functionele vergelijking van verschillende prothesecomponenten, waarbij het activiteitenniveau wordt inbegrepen. Daarnaast zouden de functionele uitkomsten van deze studies ook gemeten moeten worden voor verschillende aspecten van activiteit en mobiliteit.

In conclusie kan gesteld worden dat de studie heeft geresulteerd in een concept richtlijn voor het voorschrijven van een beenprothese. De kennis van klinische experts had hierin een groter aandeel dan het wetenschappelijke bewijs dat in de literatuur werd gevonden. De Delphi methode is een adequaat instrument voor het verkrijgen van een 'opinion based' richtlijn. De procedure wordt daarom ook aangeraden voor het te volgen implementatieproces en voor vergelijkbare onderzoeksprojecten, zoals bijvoorbeeld voor orthesiologie. De incorporatie van de wensen en de mening van de patiënt in het richtlijn ontwikkelingsproces in dergelijke procedures is van groot belang.

Dankwoord

Dankwoord

Dit onderzoek is tot stand gekomen met de medewerking van velen. Een dankwoord aan een ieder is dan ook op z'n plaats. Het zijn er echter bijna te veel geweest om allemaal te noemen, maar ik zal een poging ondernemen. Naast begeleiding, directe medewerking en stuwende krachten, is er ook veel aanmoediging geweest. En die aanmoediging is nodig, want hoewel promoveren heel leuk kan zijn, gaf het onderzoek toch menigmaal aanleiding tot verzuchting. Een promotieonderzoek verrichten naast klinische werkzaamheden op drie locaties valt niet altijd mee.

Mijn belangrijkste medewerkster is Cheriel Hofstad, steun en toeverlaat gedurende het gehele onderzoekstraject. Cheriel, jou ben ik de meeste dank verschuldigd. Meegedacht, meegereisd, meegeschreven, mee gegeten, ondersteunend bij het opzetten van menige presentatie en de uiteindelijke afwerking van het proefschrift, met veel tijd en aandacht voor de lay-out. Jouw hulp was onontbeerlijk. Dat je nu je eigen promotietraject bent gestart doet mij dan ook deugd en ik wens je daarbij veel succes.

Dan de directe begeleiding. De beide promotores Klaas Postema en Jan Geertzen en de co-promotor Jacques van Limbeek dank ik voor hun begeleiding en aanmoediging op diverse momenten in het onderzoekstraject. Klaas, jij was degene die het projectvoorstel heeft geschreven en je hebt ondanks je drukke werkzaamheden in het Groningse ook nog tijd vrij kunnen maken voor je eerste promovendus. Jacques, mijn dank ook aan jou, vooral ook voor de aanmoediging, 'dat het allemaal zou gaan lukken' en de colleges statistiek die ik er ongevraagd bij kreeg. Jan, je bent een begeleider eerste klas! Pas later bij het onderzoek betrokken, maar een belangrijke 'vlottrekker' in een cruciale fase van het promotietraject. Je bent in die zin zeer belangrijk geweest voor het verdere verloop van het onderzoek en met name voor het op gang brengen van het publiceren. Met name de aanhef bij menig telefoontje was indrukwekkend. En dan natuurlijk ook dank aan Klazina en Inge als onmisbare schakels in het contact met de promotores.

Als het om de 'vlottrekkers' in de moeilijke fasen van het onderzoek gaat, dan heeft ook Sander Geurts een belangrijke rol gespeeld. Sander mijn dank, in de eerste fase van het onderzoek wist je een artikel weer op de juiste wijze te redigeren, waardoor de eerste publicatie tot stand is gekomen. De samenspraak en samenwerking blijft een belangrijke stimulans.

Tevens dank ik Lieselotte Toelle voor haar onmisbare bijdrage, door het lezen en corrigeren van de hoofdstukken.

Dan zijn er de 'professionals' die in meerdere fasen van het onderzoek hun medewerking hebben verleend, revalidatieartsen, orthopedisch instrumentmakers en fysiotherapeuten, die zich in hun dagelijkse praktijk lieten observeren, zich lieten interviewen en vooral ook om hun zeer enthousiaste medewerking aan de consensusprocedure. Mijn dank voor jullie inzet en geduld, het resultaat is nu eindelijk daar (zie addendum). Aansluitend hierbij wil ik ook de Stichting Informatie Voorziening Zorg (IVZ) en zijn medewerkers bedanken voor hun belangrijke bijdrage aan de Delphi procedure.
Dick Rijken en Theo Bougie, jullie hebben een belangrijke rol gespeeld bij het bepalen van de uitgangspunten voor de richtlijn. Jullie inzet is van groot belang voor de implementatie van de richtlijn en daarmee een belangrijke ondersteuning bij mijn onderzoek. De strijd is overigens nog niet gestreden.

Voordat een onderzoek in combinatie met klinische werkzaamheden kan starten moet er ook de gelegenheid voor worden gegeven. Dit kan alleen maar als anderen werkzaamheden overnemen. In die zin ben ik dank verschuldigd aan mijn collega's in het netwerk revalidatiegeneeskunde Nijmegen. Gedurende een aantal jaren hebben jullie meerdere collega's de gelegenheid gegeven om een promotieonderzoek af te ronden. Marion, Margriet, Viola, Frits, Albert, Dirk, Sander en Nique, mijn dank voor jullie ondersteuning. Dat geldt natuurlijk ook voor mijn promoverende en gepromoveerde collega's Peter en Henk. De aanmoedigingsprijzen zijn echter voor Henk (van 'Op de Boesch') voor zijn enthousiaste aanmoedigingen en voor Mirjam (van 'Breukelen') voor de gedeelde smart en het regelmatig relativeren. Mirjam, het gaat lukken! Rest er nog één collega om te bedanken en dat is Barbara Lo-A-Njoe. Barbara, naast de ondersteuning in het CWZ, het waarnemen tijdens regelmatige afwezigheid, was er vooral de ontspanning door de grappen en grollen, onze gezamenlijke blik op de medische wereld en nog wat van die dingen. En daarbij hoort natuurlijk ook 'onze' Ans, dank jullie voor de ondersteuning en aanmoediging.
En dan zijn er nog al die vrienden en een paar 'kennissen' die bewust of ongemerkt en misschien wel ongewild voor aanmoediging hebben gezorgd. Frank, Ivo, Nicole, Tilly, Jim, Brigitte, Inge, Tom, Sandra, Roger, Paul, Els, Wilco, Frans, Marian, Cees, Lizette, Charlotte, moeder Elizabeth Petronella (genaamd Bep), Gusta en Elisabeth, en nog menig ander, jullie ga ik vooral nog bedanken in de toekomst. Dat laatste geldt dan ook voor de beide paranimfen, Cheriel Hofstad, reeds genoemd, en Geert Smits. Het leven is een feest!

april 2004

Dank voor de medewerking aan Proguide:

- Henk Arwert
- Sebastiaan Beeker
- Annemarijke Boonstra
- Marcel Conradi
- Jos Deckers
- José van Dijk
- Jenny van Dorp
- Cees Emmelot
- Eugene Evers
- Theo Evers
- Hepke Grupstra
- Peter ten Hengel
- Willem Hokken
- Hennie Huiskes
- Peter Janssens
- Bert Kap
- Ed van Laar
- Fred de Laat
- Harald Laman
- Elly Nossent
- Rein van der Ploeg
- Woitek Polomski
- Frans Rings
- Clemens Rommers
- Tjerk de Ruiter
- Tanneke Schoppen
- Mariët Schreibers
- Cock Vergeer
- Luc Vos
- Jaap de Vries
- Bob Wester
- Evert Wieman
- Henk Zijlstra

Curriculum Vitae

Curriculum Vitae

Harmen van der Linde werd op 8 december 1955 geboren te Steenwijkerwold. In 1979 behaalde hij het diploma fysiotherapie aan de opleiding te Deventer. Daarna was hij een jaar werkzaam als fysiotherapeut in het instituut voor verstandelijk gehandicapten De Lathmer te Wilp en vervolgens gedurende drie jaar in het St. Jozef ziekenhuis te Deventer. Van 1983 tot 1990 studeerde hij geneeskunde aan de Katholieke Universiteit te Nijmegen.

Na afronding van de studie geneeskunde was hij gedurende de periode van één jaar werkzaam als arts-assistent heelkunde in het Rijnstate Ziekenhuis te Arnhem. Vanaf april 1991 was hij vervolgens werkzaam in de revalidatiegeneeskunde in de St. Maartenskliniek te Nijmegen. Vanaf september 1992 tot september 1996 was hij in opleiding voor het betreffende specialisme in het circuit Nijmegen met als opleider R.A.J. Rijken.

Na afronding van de opleiding bleef hij werkzaam in het revalidatienetwerk Nijmegen. Momenteel werkt hij in het Canisius Wilhelmina Ziekenhuis en is aldaar opleider revalidatiegeneeskunde. Tevens heeft hij klinische deeltaken in het Radboud Universitair Medisch Centrum en de St. Maartenskliniek. De revalidatiegeneeskundige aandachtsgebieden zijn amputatie en bijbehorende prothesiologie en de traumatologie. Hij heeft diverse nevenfuncties, waaronder een bestuurlijke in de Nederlandse afdeling van de International Society for Prosthetics and Orthotics en is hij lid van de werkgroep gezondheid van de stedenband die de stad Nijmegen heeft met Masaya in Nicaragua.