Chapter 7

General discussion and conclusions

General discussion

The aim of this thesis was to identify and assess factors influencing trans-tibial prosthesis fit and satisfaction. Advanced prosthesis components, for example silicon liners, are increasingly used without systematic assessment of their advantages or required donning skills for safe and proper use in achieving a good prosthesis fit.[1-5] Improper liner donning can cause residual limb skin problems and may result in problems with prosthesis fit and patient dissatisfaction with the prosthesis. Prosthesis satisfaction is an important goal in prosthesis prescription and is influenced by prosthesis fit .[6-9] Factors influencing fit have thus far been studied fragmentarily and a complete overview of fit and satisfaction influencing factors was lacking.[10-19] Furthermore, systematic assessment of the prosthesis and residual limb is important in achieving and maintaining satisfaction.

Hand function and silicon liner use

Silicon liner use in lower limb prostheses has increased during the years improving prosthesis suspension, while adequate hand function is important for liner donning. A case study illustrated residual limb skin problems caused by improper liner donning as a result of impaired hand function (Chapter 2a). This case report shows that blister wounds may occur when the liner is not donned correctly. Thus, adequate hand function is required for a proper liner donning technique in achieving a good prosthesis fit. To systematically assess hand function impairments in relation to liner related residual limb skin problems, a historic cohort study was performed (Chapter 2b). This historic cohort study showed that impaired hand function increased the risk of liner related residual limb skin problems, compared to no hand function impairment. In practice, the silicon liner must be rolled inside out fully before applying it to the residual limb. Subsequently, the liner is placed onto the distal end of the residual limb and slowly rolled on, preventing air trapping between the liner and residual limb surface (Figure 1). When a pin is used, special care must be given to correct positioning of the pin for easy placement in the shuttle lock system (Figure 1 (2-4)). Incorrect positioning may force the pin in the shuttle lock system, resulting in a sheering force on the distal end of the residual limb and causing skin problems and pain. All these donning steps require an adequate hand function. Therefore, hand function should be assessed prior to considering a prosthesis with silicon liner fitting. Additionally, proper donning instructions should be given to prevent liner related residual skin problems and to achieve a good prosthesis fit.

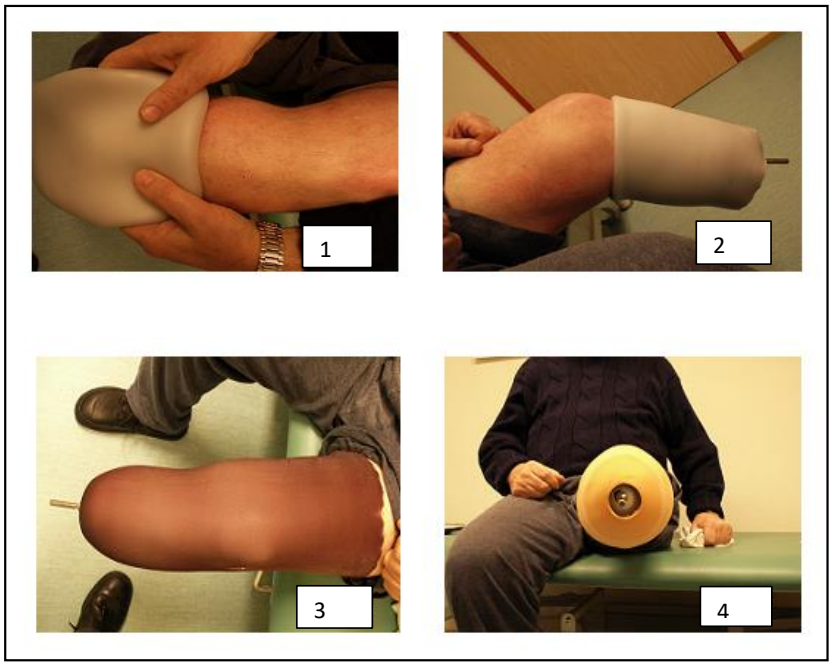

Figure 1. Proper liner donning

Prosthesis fit and satisfaction

The results of a literature review regarding possible advantages of silicon liner use (Chapter 3) showed that liner use improves prosthesis suspension and walking function, but sometimes at the cost of causing skin problems.

In a Delphi survey among experts (Chapter 4) regarding factors influencing prosthesis fit, consensus was reached on most psychosocial factors, but limited consensus was reached on biomedical factors. For example, consensus was reached on statements concerning "prosthesis support and suspension" but no consensus was reached on statements concerning "movement of the residual limb in the socket" or "skin problems and pain". Prior to the study it was assumed that more consensus on biomedical factors would be reached since biomedical factors are more tangible and easier to assess. An explanation may be that experts are more experienced in assessing biomedical factors and have a stronger opinion about them than about psychosocial factors, which are more generally formulated. Experts stated that poor hygiene and medical

conditions, for example diabetes, may result in skin problems independent of prosthesis use. Furthermore, persons with an amputation may vary in their wishes concerning prosthesis fitting techniques. For example, some prosthesis users prefer a tighter fit and some a looser one. The preferred fit influences the movement of the residual limb in the socket. Differences in patient preferences may be reflected in the opinions of the experts.

In clinical practice and literature, it was found that many prosthesis users are not satisfied with their prosthesis, sometimes resulting in prosthesis rejection.[15,20,21] These experiences and findings make prosthesis satisfaction an important issue. The results of a systematic review (Chapter 5) showed that many factors influence trans-tibial prosthesis satisfaction. Satisfaction however is operationalized differently in studies, making comparison of results between studies difficult.

Prosthesis checking and assessment of factors influencing prosthesis satisfaction using a checklist

Results of a study assessing prosthesis satisfaction of prosthesis users using a checklist during CPO consultation (Chapter 6) showed that checklist use identified more factors of dissatisfaction than mentioned by the prosthesis user prior to consultation. An explanation may be that for prosthesis users it is easier to confirm problems and dissatisfaction with the prosthesis when the CPO enquires for them than when he or she must come up with problems beforehand. Also, choosing items from a checklist may be easier than mentioning them from memory. Prosthesis users mentioned fit problems mainly regarding movement of the residual limb in the socket (16%) and pressure points on the skin (26%). Movement of the residual limb in the socket is generally caused by residual limb shrinkage and atrophy, resulting in subsequent fit problems with pressure points on bony prominences in the socket. These problems are frequent reasons for CPO consultation, explaining these outcomes. CPO's evaluated that the checklist helped them somewhat in getting additional information, improved the atmosphere during consultation and contact with the prosthesis users and made them feel more professional. Other CPOs mentioned that checklist use cost them more time and even hindered the consultation procedure. A new consultation procedure asks flexibility from the CPO and some CPOs were probably more fixed in their routine, making checklist use more time consuming for them. The benefits of the checklist may be limited when assessing simple problems during routine control visits.

Prosthesis users evaluated that the checklist made them felt more understood by the CPO. Other prosthesis users mentioned that the consultation mainly took longer. They rated the CPO's consultation high (mean 8.8 on a ten-point scale). However, they may have been reluctant to give a low score even when they were dissatisfied because of their dependence on the CPO for prosthesis service. Generally, patients may tolerate unsatisfactory aspects of health care when care in general is satisfactory.[22,23]

Study methods used in this thesis

Different study methods were used to identify factors influencing prosthesis fit and satisfaction.

In a historic cohort study, residual limb skin problems and hand function were investigated (Chapter 2b). This is a quick method of investigating a predetermined group of patients to assess the possible relationship between a risk factor and disease outcome. An advantage was that records were recorded in one rehabilitation center and recorded by the same physician with expertise in the care of persons with an amputation. Disadvantage of this method is that the quality of the data is often dependent on the accuracy of keeping medical records. Data is not collected based on a protocol and interpretation of data may in part be subjective. In this historic cohort study, hand function in patients was not assessed directly using a validated instrument and residual limb skin assessment was not systematically performed or noted, possibly causing errors in interpretation and recording.

In an electronic Delphi survey, factors assumed to influence trans-tibial prosthesis fit were identified and presented to experts (Chapter 4). The Delphi survey method was used because relevant research specifically concerning prosthesis fit or factors influencing prosthesis fit was not available. The Delphi survey method is a consensus-based method by which participants participate anonymously and fill in forms at their own convenience, facilitating participation. Participants are uniformly instructed on how to reply to questions and statements. The Delphi survey has the advantage of reaching a large group of participants regardless of their location, facilitating response, with about 50 participants being an optimal number.[24] Statements were constructed based on factors identified in literature and clinical practice. Defining consensus is a cornerstone in the Delphi study method. Consensus was defined as 75% or more participants completely agreed and fewer than 25% completely disagreed with a statement as previously proposed.[25] During three rounds, saturation of opinions and consensus was reached. Literature

mentions no preferred number of rounds in the survey.[25] The uniform method of presenting statements during the survey has the advantage that the investigator and individual participants have no influence on the responses of other participants. Disadvantages of this method is that participants never meet and cannot hear other opinions directly and discus them, possibly delaying consensus formation. Also, interpretation errors regarding the precise intention of the statements may occur, affecting responses.[24] In our survey, response rate was high and consensus was reached on the majority of the presented statements. Also, by assessing the responses, additional insight was gained in opinions on issues mentioned in the statements.

Possible advantages of silicon liner use (Chapter 3) and factors influencing trans-tibial prosthesis satisfaction (Chapter 5) were identified in one literature review and one systematic review. Database searches have the advantage of being able to collect a large body of literature, that can successively be assessed along criteria for inclusion and methodological quality.[26] Disadvantage of (systematic) reviews are the presence of bias. Types of information bias within studies are: (1) writing bias, for not all subjects are qualified for scientific research, (2) publication bias, for studies may be judged unsuitable for publication by reviewers and editors of journals, (3) selection bias, for a selection of databases is made, only peer reviewed studies are considered and language restrictions are often applied and (4) information/observational bias, for researchers only study items easy to record or in areas where they expect positive results. Regarding selection bias, in the (systematic) reviews of this thesis the most relevant databases were searched giving a substantial number of publications. Most scientific literature is published in English, while Dutch and German language studies were also included in the research for this thesis, diminishing language bias. Methodological assessment of studies was done by using known quality criteria lists and these were applied by two researchers independently.[27,28]

A checklist was constructed to assess prosthesis satisfaction in prostheses users (Chapter 6). The use of checklists can improve quality of care by promoting consistent preparation of procedures and facilitating teamwork and communication between professionals.[29,30] Furthermore, checklists have been used as outcome instruments to measure functional improvement in persons with an amputation [29] and in standardization of processes. Prosthesis checking is a process by which the CPO assesses prosthesis use, function and patient's problems, complaints and (dis)satisfaction. In practice this is often performed in an individual, non-standardized manner. Standardization of this process may improve systematic collection of patient information and facilitate zeroing in on issues and factors causing problems with the

prosthesis or residual limb, thus improving efficiency and quality of CPO consultation and ultimately patient satisfaction with the prosthesis. Disadvantage of checklist use is that the regular consultation procedure may be hindered by only focusing on checklist items, negatively affecting the personal contact with the patient and the quality of consultation. The checklist procedure asks flexibility from the user in implementing it in practice. Furthermore, items outside the checklist may not be identified because the user only focuses on checklist items.

Limitations of this thesis

It should be noted that hand function was not formally evaluated clinically in Chapter 2b. Clinical evaluation of hand function in patients using liners may show more concise relationships between hand function impairments and liner donning problems. A diversity of hand function tests are available and choosing the appropriate test is difficult.[31-33] Additionally, persons with hand function impairments may compensate for this impairment and be able to donn the liner adequately regardless of the limitations in hand function. Research has shown that compensation strategies are used when muscle fatigue occurs in the hand and fingers.[32] Thus, making the distinction between adequate compensation in the presence of hand function impairments for liner donning in relation to increased risk of residual limb skin problems will be challenging.

Regarding the identification of factors influencing prosthesis fit, a Delphi survey among experts in the Netherlands was performed. Defining experts working mainly in the Netherlands may introduce bias and limitations that influence outcome for the findings of this research, because only the opinions of these experts were assessed. One expert worked outside the Netherlands. Cross cultural differences existed when determining the validity of the Orthotics and Prosthetics Users' Survey (OPUS).[34] Differences were seen in prosthesis and orthosis financing systems in relation to prescription and repair.[34] A broader inclusion of experts, for example from other countries, may yield additional insights and factors influencing fit. The scope of this thesis was limited to identifying known factors influencing prosthesis fit and satisfaction from expert opinions and literature. The opinions of persons with an amputation were included to a limited extent in the checklist study (Chapter 6). Unknown or new factors relevant for prosthesis users may not have been fully identified which may limit the generalizability of the outcomes of this thesis.

Patient satisfaction, generally defined as matching patient expectations with experiences, has been studied in relation to health care and is important in evaluating the quality of health care services.[8,9] Prosthesis satisfaction was thus far not clearly defined in literature. This thesis clearly operationalizes prosthesis satisfaction and identifies factors influencing prosthesis satisfaction (Chapter 5). The operationalization of prosthesis satisfaction formulated in this thesis may present a base for future research in this field.

Response in our checklist study (Chapter 6) was limited. The organizational structure of the participating centers probably contributed to non-response. This finding is in accordance with results found in research studying difficulties in implementation of checklists in high-reliability organizations and health care mentioning difficulties caused by top down implimentation.[35,36] Motivating the CPOs to use the checklist was challenging because some seemed to be fixed in their consultation routine. This tendency/fixation was also seen in the evaluation. Some CPOs mentioned that checklist use hindered consultation and increased the time needed for consultation without apparent benefits. Furthermore, not all forms were adequately filled in possibly because of unclear instructions. Additionally, limited available time to complete the checklist may be a reason for non-response. More involvement of CPOs in the developmental phase might have increased responses.[37]

Implications for clinical practice

Some implications for clinical practice can be given for professionals caring for persons with an amputation, based on the results of this thesis. Silicon liners are frequently used in prosthesis fitting, giving advantages in prosthesis suspension when they are properly applied. The latter requires an adequate hand function. Improper donning may result in improper prosthesis fit and can cause residual limb skin problems and wounds. In clinical practice it is advised to perform a brief hand function assessment, including grip strength, hand and finger mobility and coordination, prior to contemplating a prosthesis with silicon liner fitting. This may be done by asking the patient to apply a silicon liner to his or her residual limb and assess the quality of the donning technique. When donning quality is poor, prosthesis fit may be compromised and liner use may not be advised.

Prosthesis fit is not clearly defined in literature. A Delphi survey study has defined factors influencing prosthesis fit using expert opinions, thus creating an overview of these factors grouped in biomedical and psychosocial factors. When assessing prosthesis fit, this overview

is useful in determining the quality of prosthesis fit in individual patients. Given that prosthesis fit is closely associated with prosthesis satisfaction, optimizing fit will have a positive effect on prosthesis satisfaction. Therefore, early improvement of fit factors and systematic evaluation of these factors when problems arise will be beneficial for early targeting of factors and for creating problem-solving strategies.

This thesis shows that many factors influence prosthesis satisfaction and the relevance of specific factors may be individually determined. These factors should be evaluated regularly to achieve and maintain satisfaction, for a change in patient characteristics or circumstances may change the relevance of factors for the individual patient. When the patient is dissatisfied with the prosthesis, systematic evaluation of factors, using the checklist studied in this thesis, may improve zeroing in on specific problems and factors causing dissatisfaction.

Future research

This thesis has given answers related to prosthesis fit and satisfaction, but also poses new questions.

1.Optimalization of prosthesis donning

As shown in this thesis, silicon liner donning is influenced by hand function. Hand function impairments increase the risk of developing liner related residual limb skin problems. Liner donning requires an adequate hand function and is important for achieving a good fit and preventing residual limb skin problems and wounds. Further prospective investigation of prosthesis components, including liner types, suspension systems (pin, vacuum) and socket types (KBM, PTB, full contact) in relation to donning techniques and hand function requirements is needed. Increasing age of persons with an amputation results in an increased incidence of hand function impairments and vascular insufficiency, affecting the contralateral limb and cognition. Technological advances in prosthesis fitting techniques increasingly require specific donning skills, making donning potentially more difficult for the elderly patient group. These issues stress the need for more research in this field.

2.Improving prosthesis fit

This thesis showed that a variety of biomedical and psychosocial factors influence prosthesis fit. An overview of these factors is provided, giving a base for assessing the quality of prosthesis

fit. Prosthesis fit was previously not clearly defined and only studied fragmentarily, while a good fit is a prerequisite for good functioning with the prosthesis. Biomedical and psychosocial factors influencing fit should receive more consideration in future research, with inclusion of homogenic patient groups in relation to amputation level, residual limb characteristics and level of activity.

3.Improving prosthesis satisfaction

This thesis showed that many factors influence prosthesis satisfaction and that these factors are dependent on patient characteristics such as gender, age, employment and activity level. An overview of known factors is provided, however this overview may not be complete. Further research investigating factors influencing prosthesis satisfaction is warranted. It would be interesting to qualitatively and quantitatively study, in a cross-sectional design, prosthesis satisfaction in patients and assess associations with patient characteristics, including age, gender, marital status, raising children, living conditions, performing specific activities, types of employment, hand function, co morbidity, residual limb characteristics and functioning of the contralateral leg. These characteristics may influence the individual relevance of satisfaction factors. More insight in the effects of these factors may provide information to further optimize prosthesis satisfaction.

4.Developement of lower limb prostheses

The findings of this thesis provided insights that can be used in prosthesis development to improve fit and prosthesis satisfaction. To improve prosthesis fit, biomedical and psychosocial factors should be taken into consideration and to improve prosthesis satisfaction, both prosthesis and residual limb related factors should be taken into account. Systematic development, by the prosthesis industry, of various prostheses types is needed, accounting for ease of donning and doffing in relation to hand function and considering the relevance of individual fit and satisfaction influencing factors.

General conclusions

Silicon liner use improves prosthesis fit by improving prosthesis suspension, but impaired hand function increases the risk of liner related residual limb skin problems.

Prosthesis fit is a multifactorial phenomenon, including both biomedical and psychosocial factors. Prosthesis satisfaction is influenced by factors that have been studied fragmentarily with different operationalizations. Literature shows that many patients are not satisfied with their prosthesis fit and experience discomfort, residual limb wounds and pain. This thesis provides a comprehensive list of factors influencing prosthesis fit and satisfaction, facilitating the systematic evaluation of these factors when problems arise. For this purpose, a checklist was developed for use in clinical practice. Checklist use identified more issues and factors of dissatisfaction than previously mentioned by the prosthesis user. To further optimize prosthesis fit and satisfaction in lower limb prosthesis users, more research is needed.

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