Chapter 1

Introduction and outline of this thesis

Major lower limb amputations occur in the Netherlands with an incidence of 18.5 to 19 per 10,000 persons, resulting in 3200 to 3300 amputations annually, primarily at trans-tibial level.[1] Primary reasons for amputation are peripheral vascular disease (95%), but amputation as a result of trauma (4%) and cancer (1%) also occur.[2] After amputation, optimal patient prosthesis satisfaction, for example in regaining ambulation, is a major goal in the prescription of lower limb prostheses.[2,3]

In the past, primitive prostheses were fabricated from wood and metal with few moving parts. These prostheses were heavy and fitted poorly to the residual limb, resulting in limited functioning with the prosthesis.[4,5] With advanced technologies and introduction of new materials, for example silicon liners[6], prosthesis fit and functioning with the prosthesis improved.[5] However, prosthesis satisfaction is often not achieved to full potential. Many patients experience pain in the residual limb during prosthesis use and are not satisfied with the comfort of the prosthesis socket.[7,8] Osseointegration, or bone-anchored limb prosthesis, is an alternative that makes the socket possibly obsolete.[9] But this technique is not suitable for most patients and a majority of the persons with an amputation still use a prosthesis socket for fixation of the prosthesis to the residual limb.[10]

Research questions

Hand function and prosthesis donning in relation to residual limb skin problems

The skill of adequately donning prosthesis components is a factor that significantly influences prosthetic wear, use and comfort.[11] Different methods of fitting and suspension require different donning techniques, and all require an adequate hand function for a good and safe result.

With the increased use of silicon liners in trans-tibial prostheses, proper prosthesis donning is even more essential to ensure adequate functioning of the prosthesis.[12] Improper liner donning may result in skin problems caused by an uneven distribution of liner material over the residual limb and creasing in the liner. Additionally, air trapping under the liner may result in blistering of the skin.[13,14] It is essential that the liner is evenly distributed over the residual limb with minimal elastic tension to prevent shearing forces. Not all patients are skilled in liner use and this may result in inadequate donning and doffing, causing residual limb skin problems and wounds. This phenomenon is illustrated in a case report entitled "A patient with donning related stump wounds: a case report" (Chapter 2a).

This case report also shows that hand function impairments may result in liner related residual limb skin problems because of inadequate liner donning.

The first research question: *"How does impaired hand function relate to liner related residual limb skin problems",* is addressed in chapter 2b.

Silicon liner use in prosthesis fit

Silicon liners are increasingly used in fitting trans-tibial prostheses since their introduction.[6] Liners with a variety of material properties have been introduced since then and advantages have been propagated by producers of the silicon liners regarding prosthesis fit and suspension compared to the "standard" prosthesis with a supracondylar fitting, Kondyl Bettung Munster (KBM) fitting, patella tendon bearing (PTB) fitting, or conventional type prosthesis fitting.[6,15-17] The liner also offers skin protection and diminishes friction between the socket and the residual limb surface, improving comfort in wearing the prosthesis. It is claimed that, with the silicon liner socket, the prosthesis appearance is more pleasing and easily accepted by persons with an amputation.[13,18] Advantages of silicon liner use in trans-tibial prosthesis have not been investigated systematically.

The second research question: *"What are the advantages of silicon liner use in trans-tibial prostheses",* is addressed in chapter 3.

Prosthesis fit

A good prosthesis fit is a prerequisite for functioning with a prosthesis and an important goal in prosthetic care of persons with a trans-tibial amputation.[19,20]

Prosthesis socket fit is not clearly defined in literature. A good prosthesis socket fit, or biomedical fit, ensures adequate fixation of the prosthesis to the residual limb. Expert opinions and case reports indicate that the biomedical fit should be comfortable and maintain the integrity of the residual limb tissues including skin, muscles, blood vessels and nerves while the prosthesis is worn and used.[5,7,8,12] Furthermore, the biomedical fit allows for adequate knee range of motion while performing activities such as cycling and climbing stairs.[20] Sixty-five percent of people with a trans-tibial amputation report skin problem of the residual limb[21] which may be related to a suboptimal biomedical fit. In people with a trauma-related amputation, more than half of them is dissatisfied with the comfort of the prosthesis fit and almost 25% report skin irritation and wounds.[8] This data shows that although a good biomedical fit is sought after, it is not always achieved and continues to present a major challenge in prosthetic care.[22-27]

Aside from the physical changes experienced after amputation and subsequent fitting of a prosthesis, the amputation also has a psychological and social impact on the person with an amputation.[28] The person's perception of themselves and ideas and expectations regarding the prosthesis and the acceptance of the prosthesis being part of them, as well as the attitude of others towards the amputation and prosthesis, has influence on the fit of a prosthesis in a psychosocial sense.[28-35] As such, the psychosocial fit of the prosthesis is the way the prosthesis fits a person with an amputation both psychologically and socially.

Pain reported by people with a trans-tibial amputation is a complex issue. Residual limb pain may be the result of a poor biomedical fit and has a negative psychological effect on the prosthesis user. More than 80% of the people with traumatic amputations experience (phantom or residual limb) pain, and they report significantly higher emotional distress than those without pain.[35-37] Furthermore, the experience of pain may be an expression of dissatisfaction with the prosthesis when no apparent problem with the biomedical fit can be found.[35]

Factors supposed to influence prosthesis fit have been described in literature only in general terms and studied fragmentarily and to a limited extent, giving insufficient base for a systematic and comprehensive assessment of prosthesis fit.[8,19,29,30,32,38-42]

The third research question: *"What factors influence the biomedical and psychosocial prosthesis fit",* is addressed in chapter 4.

Prosthesis satisfaction

Between 40 to 60 % of people with an amputation is not satisfied with their prostheses. Of these persons, 75% is dissatisfied with the comfort and over 50% reports pain while using their prostheses.[7,8] Factors related to dissatisfaction with the prosthesis are: displeasing appearance, poor function, a prosthesis that is to heavy and an inadequate socket fit resulting in residual limb discomfort and pain.[7,8,35,43] Factors associated with residual limb discomfort are prosthesis socket problems, residual limb sweating, skin problems and (phantom) pain.[7,8,21,35] Dissatisfaction with the prosthesis can ultimately result in rejection of the prosthesis, which may occur in up to 30% of prostheses prescribed in some patient groups.[7] Hence, prosthesis (dis)satisfaction is a highly relevant issue in the care of persons with a lower limb amputation.[8,43]

Prosthesis satisfaction is the patient's individual appreciation of the prosthesis and influenced by aspects of the prosthesis and residual limb. Psychosocial factors are relevant for they also influence the patient's attitude towards the prosthesis. For example, comments made by the

patient's partner regarding the prosthesis can influence this patient's satisfaction with their prosthesis. Therefore, satisfaction with the prosthesis is a biopsychosocial construct and is influenced by many factors.[3,44-46]

A comprehensive overview of factors influencing satisfaction with the prosthesis is currently missing. Such an overview may help clinicians to systematically assess these factors and target them to improve outcomes.

The fourth research question: *"What factors influence patient prosthesis satisfaction",* is addressed in chapter 5.

Assessing prosthesis satisfaction

Prosthesis checking is a procedure in which the certified prosthetist orthotist (CPO) assesses prosthesis fit, use and function and takes inventory of the prosthesis user's problems and (dis)satisfaction with the prosthesis and residual limb. In practice this is often performed in a non-standardized manner by the CPO.[47] More standardization may improve efficiency and quality of CPO consultation. This standardization can be achieved by using a checklist. Because of the many factors influencing prosthesis satisfaction and fit, it is possible that systematic checking of these factors by using a checklist may be beneficial in improving prosthesis satisfaction and prevent residual limb skin problems and pain. Checklists use is known to improve quality of health care by facilitating the preparation of procedures and aiding memory in performing complex procedures.[48,49]

The fifth research question: *"What are benefits of systematically checking the prosthesis and residual limb using a checklist during CPO consultation",* is addressed in chapter 6.

Aims of this thesis were:

1. To assess the influence of hand function impairments on the occurrence of liner related residual limb skin problems.
2. To identify in literature advantages of silicon liner use in trans-tibial prostheses.
3. To assess expert opinions regarding factors influencing trans-tibial prosthesis fit.
4. To identify in literature factors that influence trans-tibial prosthesis satisfaction.
5. To assess the benefits of systematically checking factors influencing prosthesis satisfaction by the CPO using a checklist.

Outline of this thesis is as follows:

In chapter 2a, a case report is presented illustrating that impaired hand function was associated with liner related residual limb skin problems.

In chapter 2b, the results of a historic cohort study are presented concerning the influence of hand function on the occurrence of liner related residual limb skin problems.

In chapter 3, the results of a systematic review are presented regarding the advantages of silicon liner use in trans-tibial prostheses.

In chapter 4, the results of a Delphi survey are presented regarding expert opinions on factors influencing prosthesis fit.

In chapter 5, the results of a systematic review are presented regarding factors influencing prothesis satisfaction.

In chapter 6, the results of research are presented regarding the use of a checklist for systematic evaluation of factors influencing prosthesis satisfaction.

In chapter 7, the general discussion and clinical implications of this thesis are discussed, followed by recommendations for future research.

Chapter 8, summary/samenvatting.

Chapter 9, dankwoord, curriculum vitae and list of peer-reviewed publications and book contributions.

References

1.Rommers GM, Vos LD, Groothoff JW, Schuiling CH, Eisma WH. Epidemiology of lower limb amputees in the north of The Netherlands: aetiology, discharge destination and prosthetic use. Prosthet Orthot Int 1997;21(2):92-99.

2.Fortington LV, Rommers GM, Postema K, van Netten JJ, Geertzen JH, Dijkstra PU. Lower limb amputations in Northern Netherlands: unchanged incidence from 1991-1992 to 2003-2004. Prosthet Orthot Int 2013;37(4):305-310.

3.Kark L, Simmons A. Patient satisfaction following lower-limb amputation: the role of gait deviation. Prosthet Orthot Int 2011;35:225–233.

4.Van der Meij WKN. No leg to stand on. Historical relation between amputations surgery and prostheseology. University of Groningen Thesis 1995.

5.Laferrier JZ, Gailey R. Advances in lower-limb prosthetic technology. Phys Med Rehabil Clin N Am 2010;21(1):87-110.

6.Kristinsson O. The ICEROSS concept: a discussion of a philosophy. Prosthet Orthot Int 1993;17:49-55.

7.Berke GM, Fergason J, Milani JR, Hattingh J, McDowell M, Nguyen V. Comparison of satisfaction with current prosthetic care in veterans and service members from Vietnam and OIF/OEF conflicts with major traumatic limb loss. JRRD 2010;47(4):361-371.

8.Dillingham TR, Pezzin LE, MacKenzie EJ, Burgess AR. Use and satisfaction with prosthetic devices among persons with trauma-related amputations: a long-term outcome study. Am J Phys Med Rehabil 2001;80(8):563-571.

9.Thesleff A, Brånemark R, Håkansson B, Ortiz-Catalan M. Biomechanical Characterisation of Bone-anchored Implant Systems for Amputation Limb Prostheses: A Systematic Review. Ann Biomed Eng 2018;46(3):377-391.

10.Cadth rapid response report: summary with critical appraisal. Osseointegrated prosthetic implants for lower limb amputation: a review of critical effectiveness, cost effectiveness and guidelines.
Project Number: RC0856-000, Version 1.0, February 27, 2017.

11.Gauthier-Gagnon C, Grisé MC, Potvin D. Enabling factors related to prosthetic use by people with transtibial and transfemoral amputation. Arch Phys Med Rehabil 1999;80:706-713.

12.Mak AFT, Zhang M, Boone DA. State-of-the-art research in lower-limb prosthetic biomechanics-socket interface: a review. J Rehabil Res Dev 2001;38:161-174.

13.Lake C, Supan TJ. The incidence of dermatological problems in the silicon suspension sleeve user. J Prosth Orthot 1997, 9, 97-106.

14.Wetz HH, Bellmann D, M'Barek BA. Erfahrungen mit dem silikon-soft-socket im unterschenkel-kurzprothesenbau. Med Orth Tech 1992;112:256-263.

15.Klute GK, Glaister BC, Berge JS. Prosthetic liners for lower limb amputees: a review of the literature. Prosthet Orthot Int 2010;34(2):146-153.

16.Fillauer CE, Pritham CH, Fillauer KD. Evolution and development of the silicon suction socket (3S) for below-knee prostheses. J Prosthet Orthot 1989;1: 92-103.

17.Fitzlaff G, Heim S. Socket technology and prosthetic alignment. In: Lower limb prosthetic components; design, function and biomechanical properties. Dortmund, ISPO Verlag Orthopäedie-Technik 2002:13-28.

18.Kapp S. Suspension systems for prosthesis. Clin Orthop 1999;361:55-62.

19.Pezzin LE, Dillingham TR, MacKenzie EJ, Ephraim P, Rossbach P. Use and satisfaction with prosthetic limb devices and related services. Arch Phys Med Rehabil 2004;85:723-729.

20.Sansam K, Neumann V, O'Connor R, Bhakta B. Predicting walking ability following lower limb amputation: a systematic review of the literature. J Rehabil Med 2009;41:593-603.

21.Meulenbelt HE, Geertzen JH, Jonkman MF, Dijkstra PU. Determinants of skin problems of the stump in lower-limb amputees. Arch Phys Med Rehabil 2009;90:74-81.

22.Sewell P, Noroozi S, Vinney J. Andrews S. Developments in the trans-tibial prosthetic socket fitting process: a review of past and present research. Prosthet Orthot Int 2000;24:97-107.

23.Van der Linde H, Hofstad CJ, Van Limbeek J, Postema K, Geertzen JH. Use of the Delphi Technique for developing national clinical guidelines for prescription of lower-limb prostheses. J Rehabil Res Dev 2005;42:693-704.

24.Abrahamson MA, Skinner HB, Effeney DJ, Wilson LA. Prescription options for the below knee amputee. A review. Orthopedics 1985;8:210-220.

25.Collins DM, Karmarkar A, Relich R, Pasquina PF, Cooper RA. Review of research on prosthetic devices for lower extremity amputation. Crit Rev Biomed Eng 2006;34:379-438.

26.Lilya M, Johansson T, Öberg T. Movement of the tibial end in a PTB prosthesis socket. A sagittal X-ray study of the PTB prosthesis. Prosthet Orthot Int 1993;17:21-26.

27.Polliack AA, Craig DD, Sieh RC, Landsberger S, McNeal DR. Laboratory and clinical tests of a prototype pressure sensor for clinical assessment of prosthetic socket fit. Prosthet Orthot Int 2002;26:23-34.

28.Gallagher P. Introduction to the special issue on psychosocial perspectives on amputation and prosthetics. Disabil Rehabil 2004;26:827-830.

29.Legro MW, Reiber G, del Aguila M, Ajax MJ, Boone DA, Larsen JA, Smith DG, Sangeorzan B. Issues of importance reported by persons with lower limb amputations and prosthesis. J Rehabil Res Dev 1999;36:155-163.

30.Murray CD, Fox J. Body image and prosthesis satisfaction in the lower limb amputee. Disabil Rehabil 2002;24:925-931.

31.Desmond D, MacLachlan M. Psychological issues in prosthetic and orthotic practice: a 25 year review of psychology in Prosthetics and Orthotics International. Prosthet Orthot Int 2002;26:182-188.

32.Fisher K, Hanspal R. Body image and patients with amputations: does the prosthesis maintain the balance? Int J Rehabil Res 1998;21:355-363.

33.Gallagher P, MacLachlan M. The Trinity Amputation and Prosthesis Experience Scales and quality of life in people with lower-limb amputation. Arch Phys Med Rehabil 2004;85:730-736.

34.Lee WC, Zhang M. Using computational simulation to aid in the prediction of socket fit: a preliminary study. Med Eng Phys 2007;29:923-929.

35.Desmond D, Gallagher P, Henderson-Slater D, Chatfield R. Pain and psychosocial adjustment to lower limb amputation amongst prosthesis users. Prosthet Orthot Int 2008;32:244-252.

36.Desmond DM, MacLachlan M. Affective distress and amputation-related pain among older men with long-term, traumatic limb amputations. J Pain Symptom Manage 2006;31:362-368.

37.Borsje S, Bosman JC, van der Schans CP, Geertzen JH, Dijkstra PU. Phantom pain: a sensitivity analysis. Disabil Rehabil 2004;26(14-15):905-910.

38.Murray CD. The social meanings of prosthesis use. J Health Psychol 2005;10:425-441.

39.Legro MW, Reiber GD, Smith DG, del Aguila M, Larsen J, Boone D. Prosthesis Evaluation Questionnaire for persons with lower limb amputations: assessing prosthesis-related quality of life. Arch Phys Med Rehabil 1998;79:931-938.

40.Schaffalitzky E, Gallagher P, MacLachlan M, Wegener ST. Developing consensus on important factors associated with lower limb prosthetic prescription and use. Disabil Rehabil 2012;34(24):2085-2094.

41.Schiff A, Havey R, Carandang G, Wickman A, Angelico J, Patwardhan A, Pinzur M. Quantification of shear stress within a transtibial prosthetic socket. Foot Ankle Int 2014; 35(8):779-782.

42.Gholizadeh H, Abu Osman NA, Eshraghi A, Ali S. The effects of suction systems on transtibial amputees´ gait performance. PLoS One 2014;9(5).e94520.

43.Gailey R, McFarland LV, Cooper RA, Czerniecki J, Gambel JM, Hubbard S. Unilateral lower-limb loss: Prosthetic device use and functional outcomes in servicemembers from Vietnam war and OIF/OEF conflicts. JRRD 2010;47(4):317-331.

44.Batbaatar E, Dorjdagva J, Luvsannyam A, et al. Conceptualisation of patient satisfaction: a systematic narrative literature review. Perspect Public Health 2015;135:243–250.

45. Batbaatar E, Dorjdagva J, Luvsannyam A, et al. Determinants of patient satisfaction: a systematic review. Perspect Public Health 2017;137:89–101.

46.MohdHawari N, Jawaid M, MdTahir P, et al. Case study: survey of patient satisfaction with prosthesis quality and design among below-knee prosthetic leg socket users. Disabil Rehabil Assist Technol 2017;10:868–874.

47.NHS Report: Improving the quality of orthotics services in England. NHS England 19 November 2015.

48.Thomassen Ø, Espeland A, Søfteland E, Lossius HM, Heltne JK, Brattebø G. Implementation of checklists in health care; learning from high-reliability organisations. Scand J Trauma Resusc Emerg Med. 2011;19:53.

49.Kohler F, Xu J, Silva-Withmory C, Arockiam J. Feasibility of using a checklist based on the International Classification of Functioning, Disability and Health as an outcome measure in individuals following lower limb amputation. Prosthet Orthot Int. 2011;35(3):294-301.