Optimizing Prosthetic Gait

Balancing capacity and load

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General Introduction
Introduction

Lower limb amputation, the surgical ablation of a lower limb or part thereof, has been one of the first surgical procedures ever performed. The level at which a lower limb amputation can be performed can vary from the toes up until as high as the pelvis. In this thesis I will focus on the amputations performed at the level of the tibia and femoral. Not surprisingly, the presence of a lower limb amputation drastically affects the quality of life [63, 164, 198]. A difference in the quality of life between etiology groups exists; larger physical disability and greater social isolation have been reported for people amputated due to vascular deficiency compared to people amputated after trauma [43]. Impairments in body function due to the loss of part of a limb can substantially hamper daily activity and functioning, and hence, can restrict active participation in the community [42]. In recent years technological advancements in operational techniques, prosthetic developments, and post-operative care of people after amputation, have paved the way for significant improvements in functioning and the quality of life of these patients. These developments are mediated by scientific research yielding a continuous growing body of knowledge on the biomechanical abnormalities and compensational strategies used by amputees [35].

Despite these scientific and clinical developments, people with a lower limb amputation still face many problems and challenges, especially when it comes to walking with the prosthesis. In the following sections the rationale behind the research, presented in this thesis is outlined. In this section it will be argued why it is important to restore walking ability, and it will be elucidated which factors can serve as important determinants for walking ability with a lower limb prosthesis. Before elaborating on the problems people face regaining mobility, the following paragraph will briefly discuss the number and characteristics of the people faced with a lower limb amputation.
Prevalence and incidence

No one will dispute that undergoing a lower limb amputation is a life-changing surgery. Unfortunately, a substantial number of people are faced with this operation every year. Reported incidence rates vary largely between geographical areas \cite{105, 153}, reported values range between 1 per 100,000 women in Japan \cite{65} up to 47.2 per 100,000 for inhabitants of the United States \cite{48}. In war torn countries, land mines account for the vast majority of all amputations performed \cite{199}. In developmental countries, 34% of all extremity amputations performed are due this type of trauma \cite{204}. Conversely, in developed countries, the vast majority (87-94%) of lower limb amputations is performed due to vascular deficiency \cite{48, 167, 179}, whereas a substantially smaller number of amputations are performed due to trauma (3-4.6%) \cite{48, 65, 179}. An even smaller number of people undergo amputation due to congenital limb deficiency \cite{65}, or malignant cancer \cite{60}. The population studied in this thesis stems from developed countries (The Netherlands and Italy), and from here on forward this thesis will focus on this population. Most of the patients who undergo amputation due to vascular deficiency have been previously diagnosed with peripheral arterial disease or diabetes mellitus. In the UK one in every three amputations performed involves patients with diabetes mellitus, whilst almost half of the people in Australia who undergo amputation are diabetic \cite{153}. Unfortunately, the overall total number of people that undergo amputation has increased over the years. In western countries, this increase is primarily caused by an increase in vascular deficiency related amputation \cite{48}. Moreover, because incidence rates increase with age \cite{48} and more people are likely to survive to old age, the older vascular amputee has become an increasingly important subgroup within the total population in need of prosthetic rehabilitation \cite{74}.

In the developed countries, incidence rates are expected to aggravate even further in the coming years as lifestyle-related diseases like peripheral vascular disease and diabetes mellitus become more common \cite{242}. This increase is thought to happen despite recent improvements in surgical intervention techniques, aimed at salvaging the limb. While intuitively one might think that undergoing a lower limb amputation is a last resort, and more drastically reduces the quality of life than limb salvage surgery, scientific research has failed to substantiate this. Studies examining the quality of life between these two populations of patients show no differences in quality of life scores \cite{16, 63, 173, 202, 239}. Some studies actually report less pain when walking \cite{16}, less anxiety and depression \cite{119}, and less post-operative complications \cite{16, 63, 119, 202} after amputation compared to limb salvage surgery. Furthermore, although subjects with an amputation have a lower subjective rating of mobility \cite{39, 63, 120}, objective measures of functional mobility in terms of walking speed and oxygen cost do not differ between both groups \cite{202}. 
Chapter 1

Mobility

The level of mobility is an important determinant for the quality of life as it strongly influences the extent to which patients are able to regain much of the daily activities performed prior to the amputation. The relationship between mobility and quality of life has been investigated by Pell and colleagues (1993) [164]. They found that, despite larger social isolation and emotional distress in people with an amputation, impaired mobility was the only parameter associated with the quality of life after an amputation. Furthermore, early postoperative mobilization is strongly advocated in order to avoid deleterious effects of immobility, especially in the older persons [34].

Mobility is a term that encompasses a plentitude of different features. Based on the categorical differentiation of items related to mobility reported by van Bennekom and colleagues (1995) [211], Bussmann and colleagues (1998) made mobility explicit by stating that: “Mobility is the process of moving oneself, and of changing and maintaining postures” [19]. This definition is fairly broad, and in this context mobility can imply simply moving a leg while lying in bed or performing an activity like walking. In this thesis I focus on mobility in the latter context, more specifically, mobility in terms of subjects’ ability to walk with a prosthesis. Throughout the literature different parameters have been used to quantify walking ability ranging from the timed-up-and-go test [188, 214], functional walking distance [80], adaptability [111], functional scales [75, 182], ambulatory activity monitors [17, 77, 108], to self-reported scales [150, 188]. In this thesis subjects’ walking ability has been quantified by walking speed and walking economy (i.e. the energy expenditure needed to walk a given distance).

There are a number of determinant factors negatively associated with subjects’ walking ability, for instance, a low cognitive capacity [184, 214], age [99, 188], functionality prior to amputation [99, 184, 214], and the level of amputation [99, 184, 214]. While some studies also suggest a likewise negative association between comorbidity and walking ability, a recent review by Sansam and co-workers (2009) did not support this [184]. The presence of a vascular amputation is associated with a lower walking ability after amputation, but whether this can be attributed to the older age or the presence of comorbidity in these patients is unknown [184]. In conjunction, this study and clinical experience indicate that the older patients with a vascular trans-femoral amputation are assumed to have the lowest probability to regain and maintain walking.

The framework

To classify the limitation in walking ability that people might face after lower limb amputation, the International Classification of Functional, Disability and
Health (ICF) framework \cite{232} can be used. The ICF provides a universal language for understanding human functioning and disability, and as such, provides a guideline for the description and classification of functioning in the context of health \cite{176}. The ICF is based on three domains; 1) body functions and structures, 2) activities and 3) participation (Figure 1). The limitations in walking ability are classified as a limitation within the activity domain. The factors associated with a poor walking ability are predominantly related to impairments within the domain of body functions and structures \cite{97}, and to external factors like prosthetic design and environmental factors (Figure 1). Ergo, the current thesis focuses on the impairments in the body functions and structures domain (e.g. aerobic capacity) and external factors (prosthetic push-off power) and relates this to the walking ability in terms of walking speed, oxygen cost and balance. These measures are often used in both scientific and clinical practice economy \cite{163}, and provide an objective evaluation of subjects’ walking ability.

Insight into factors associated with subjects’ walking ability (such as the aforementioned factors like age, cause and level of amputation) is pivotal for intervention management and determining the likelihood of successful

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure1.png}
\caption{The International Classification of Functioning, Disability and Health (ICF).}
\end{figure}

The ICF is a framework that provides a universal language for understanding human functioning and disability. Problems associated with walking are categorized as a limitation in the activity domain. Causes for the limitation in subjects’ walking ability are predominantly caused by impairments within the domain of body functions and structures and external factors.
ambulation after amputation. However, merely assessing correlations between these factors and walking ability does not provide information about the underlying mechanisms, and hence does not reveal direct targets for intervention. While there are different mechanisms that may limit walking ability (e.g. wounds on the stump or limited motivation), this thesis takes a more bio-physical approach in that it focuses on the importance of maintaining a balance between the physical capacity and the physical load imposed while walking.

Capacity versus load: the balloon analogy

Imagine a balloon being filled with water. The more water is in the balloon the more strain will be put on the balloon, up until the moment the stress on the walls of the balloon is too much and the balloon bursts. Importantly, the larger the balloon the more water it can hold before it bursts. This analogy readily illustrates the balance between the capacity humans possess (i.e. the size of the balloon) and the load that is imposed when walking (i.e. the amount of water in the balloon): the lower the available capacity, the lower the load that can be comfortably handled. When the load exceeds a reasonable portion of the available capacity, the balance will be disturbed and walking will take great effort and might even prove impossible (i.e. the balloon bursts).

The term capacity can encompass various aspects of human functioning. The focus in my thesis is on the physical capacity of the subject. Physical capacity is a complex concept and is sub-divided, by the American College of Sports Medicine into five different components: aerobic power, anaerobic power, muscle strength, flexibility and neuromuscular control. While all of these aspects are thought to be in some way affected in people with a lower limb amputation, the focus in this thesis lays on the aerobic capacity. The peak aerobic capacity is the maximal metabolic power that can be derived from the oxidative pathways and is defined as the maximal amount of oxygen that can be utilized during exercise. The term aerobic load is the amount of oxygen that is utilized while performing an activity, which in this thesis is walking.

Relative aerobic load

People walking with a lower limb amputation are not only at risk of having a reduced aerobic capacity (i.e. smaller balloon), they also have to deal with an increased aerobic load while walking (i.e. more water). The notion that the aerobic load while walking with a prosthesis is substantially increased is a notion firmly entrenched and supported by numerous studies. The high stresses on the balloon, through a combination of low
capacity and high loads, render walking with a prosthesis a formidable challenge. Subjects may adapt to the higher strain by reducing their walking speed since this reduces the imposed load and resultantly, makes walking less demanding. From the above we can deduce that subjects’ ability to ambulate at normal speed with a prosthesis might be related to whether sufficient aerobic capacity is available (i.e. whether the size of the balloon is adequate) to compensate for the higher aerobic load imposed when walking. The exact ratio between aerobic load and aerobic capacity is currently unknown. The imposed load divided by the available capacity provides us with a quantitative measure for this balance, namely the relative aerobic load. Valid information about the relative aerobic load is imperative as it provides a firm scientific ground on which the necessity and structure of training regimes can be based.

In order to pinpoint the mechanism causing the limitations in walking ability of people with an amputation, and to provide evidence for adequate rehabilitation, information about the balance between capacity and load must be explored. In the following paragraphs an outline will be given on how different impairments of the body potentially influence the relative aerobic load. Initially the importance of sufficient physical capacity is argued. Secondly, the focus is shifted away from the physical capacity and directed towards understanding the mechanisms responsible for the higher load when walking with a prosthesis.

**Figure 2. The balloon analogy.**

The balance between aerobic capacity and aerobic load while walking can be visualized using the concept of a water balloon. The more water in the balloon the more strain (represented by yellow stripes) will be put on the balloon, up until the moment the stress becomes too much and the balloon will burst. The left balloon represents the situation when there is sufficient capacity and the aerobic load while walking is low. The right balloon might be the situation amputees face; the capacity is low (small balloon) and the load imposed when walking (the amount of water) is high. Resultantly, walking takes great effort and is perceived as strenuous.
Aerobic capacity

The aerobic capacity is subject to both the ability of the cardiovascular and respiratory system to supply oxygen to the muscles, as well as the ability of the skeletal muscles to utilize this oxygen. The magnitude of peak aerobic capacity is, aside from a genetic predisposition, dependent on subjects’ activity level, sex, and is known to decline with age [115]. Most of the people undergoing lower limb amputation are older adults and have had long periods of immobility preoperatively followed by a long period of convalescence due to, for example, delayed wound healing [185]. Hence, these patients are likely to have a severely reduced aerobic capacity compared to their non-amputated healthy counterparts [207]. But also those amputated at a young age are confronted with a perioperative period of limited physical activity, which also puts them at risk for reduced aerobic capacity. The reduced aerobic capacity might predispose subjects to poor walking ability [24-25, 184, 224, 226]. This has long been acknowledged by rehabilitations physicians and many rehabilitation interventions incorporate some form of aerobic training. Remarkably though, only a limited number of scientific studies report on peak aerobic capacity in amputees, and even fewer have focused on the elderly amputee most at risk of a reduced aerobic capacity [216]. Hence, it is difficult to establish which role aerobic capacity plays in the process of regaining and maintaining walking ability in people with a prosthesis.

The paucity of articles reporting measured aerobic capacity of people after lower limb amputation might be attributed to the problems encountered when performing a maximal exercise test in this specific patient group. The impaired motor system, reduced muscle mass, balance problems, local problems in the stump as well as the contra-lateral limb, and the high prevalence of secondary coronary arterial diseases makes standard graded exercise testing [83] unsuitable [66, 210]. A valid and safe exercise test can provide the clinician with important information concerning the cardiac condition of these patients [66, 180], and adjustments to the rehabilitation program or medication intake can be made accordingly.

Aerobic load

Aside from improvements in the aerobic capacity, efforts aimed at reducing the elevated aerobic load can improve the ability to ambulate, as this reduces the relative aerobic load. However, the mechanisms responsible for the higher aerobic load in prosthetic gait are poorly understood. Two possible explanations have been proposed [103]. First, energetically costly biomechanical adaptations in the remaining joints are required to compensate for the absence of active ankle power during prosthetic push-off [35, 98, 194], and secondly, energy is needed for compensational muscular activity to ensure stability while walking with a prosthesis [110, 192, 217-218].
Aerobic load for propulsion

To understand the importance of sufficient push-off power on the overall metabolic energy cost, human gait may be modeled as a double inverted pendulum (Figure 3). This so-called dynamic walking model was originally described by McGeer and colleagues (1990) [144] and has been further elaborated upon by Kuo and colleagues [129-131]. According to this model, the overall metabolic energy cost while walking is closely related to the work performed during the step-to-step transition [57]. Moreover, the cost for the step-to-step transition can partly explain the higher metabolic energy cost found in people walking with a lower limb prosthesis [110]. The most efficient way of reducing the step-to-step transition cost, and consequently reducing the metabolic energy cost, is by generating a push-off power along the trailing leg through ankle plantar flexion [129] immediately preceding heel strike of the leading leg [181]. In normal walking, this push-off power is primarily generated by the biological ankle [158, 234]. Unfortunately, the push-off power that can be generated by the prosthetic ankle is profoundly reduced, hence, step-to-step transition cost is higher and subjects with an amputation need to revert to other, less efficient, strategies to remain walking at the same walking speed [6, 110, 152]. In recent years, lower limb prosthetic developments have progressed exponentially. These new developments aim at designing a prosthesis that is able to more closely mimic human ankle power during gait, thereby, reducing the step-to-step transition cost and concomitantly the metabolic energy cost while walking. Insight into the efficacy of these newly developed prostheses can be obtained using dynamic walking models. These models are particularly attractive because of their simplicity and ability to provide insight into net mechanical work performed during the step-to-step transition; moreover, they provide helpful insight into the metabolic cost while walking with different prosthesis.

Figure 3. The dynamic walking model.

In this model human walking is modeled as an inverted pendulum. During the step-to-step transition the center of mass (COM) velocity has to be redirected. This is accomplished with negative impact work performed by the leading leg and positive push-off work performed by the trailing leg. The work is calculated as the dot product of the forces under each limb and the center of mass velocity.
Aerobic load for balance

Simplifying metabolic cost to the mechanical work associated with the step-to-step transition, though very insightful, overlooks important other contributors to the overall metabolic energy cost. An important factor overlooked is the energy required to ensure stability while walking (i.e. the ability to recover from and adapt to perturbations) [134]. Alteration in the energy required for the control of balance might explain why some studies find a reduction in step-to-step transition cost, while the associated reduction in metabolic energy cost is either absent [192], or lower than expected [98]. The human ability to walk without falling, i.e. to remain in balance, depends on the interaction between the passive dynamics of the musculoskeletal system and the active control by the central nervous system. Human walking is, to some extent, passively stable in the direction of progression; however, it requires active balance control in lateral direction [57, 128]. Gross control of lateral stability is predominately ensured by proper lateral foot placement [128], while more refined adaptations are realized by lateral ankle movements after placement of the foot [102]. While the use of the lateral foot placement strategy is not compromised in people with a lower limb amputation, they lack the ability for more refined adaptation in the prosthetic ankle [102] and might be forced to use less economic balance control strategies. To sum, in order to determine which factors contribute to the aerobic load imposed on the body while walking with a lower limb amputation information about both the effect of prosthetic ankle power and balance control is eminent.

Aim and research questions

The general aim of this thesis is to enhance our knowledge regarding the aerobic capacity and aerobic load while walking of people with a unilateral lower limb amputation and provide insight into how these factors influence the ability to regain and maintain walking. By doing so, this thesis aims to provide recommendations that can optimize rehabilitation, prosthetic prescription and development, and improve functioning and the quality of life of people after lower limb amputation.

More specifically this thesis aims to answer the following research questions:

- What is the relative aerobic load of people walking with a lower limb amputation and how does this relative aerobic load affect the walking ability?
- What is the aerobic capacity of people with a lower limb amputation and how can this be reliably determined?
- Which factors can be influenced in order to reduce the aerobic load while walking with a prosthesis?
General Introduction

Outline of thesis

A schematic representation of how the aforementioned influencing factors may relate and interact with one another is depicted in Figure 4. In the following paragraphs, I will briefly delineate how these factors will be addressed in subsequent chapters. The data presented in Chapter 2 till 4 are collected during one experimental cohort study. In each of these chapters specific research questions were addressed separately.

In Chapter 2 of this thesis, a detailed description of a newly developed standardized test for assessing the peak aerobic capacity of people with a unilateral lower limb amputation is given. In addition, information is presented about the feasibility and validity of this test.

Based on the results obtained from the study presented in Chapter 2, the proposed test is used to determine the peak aerobic capacity of older adults with a lower limb amputation in Chapter 3. In this chapter the association between the presence, level and cause of amputation on peak aerobic capacity is determined. This study augments the limited body of knowledge on peak aerobic capacity of elderly amputees with a lower limb prosthesis due to either trauma or vascular deficiency.

In Chapter 4 the peak aerobic capacity of people with a lower limb amputation is combined with the aerobic load measured while walking at different speeds to gain insight into the relative aerobic load while walking with a lower limb prosthesis. Again the association between the presence, level and cause of the amputation was investigated. Moreover, the relationship between relative aerobic load and walking economy and walking speed was determined. Furthermore, a data-driven model is constructed to gain insight into the potential effect of an increased aerobic capacity on the relative aerobic load, walking economy and walking speed.

Chapters 5 and 6 concentrate on potential factors that contribute to the higher aerobic load while walking with a prosthesis. In Chapter 5 the mechanical cost of walking with the energy storage and return prosthesis is compared to the cost when walking with the more conventional soft ankle cushioned heel prosthesis. This has been realized by applying the principles of dynamic walking by calculating the step-to-step transition cost. Possible differences in step-to-step transition cost between both feet are explained by close examination of the following parameters: step length, push-off power and roll-over shape.

The aim in Chapter 6 is to determine whether strategies applied for balance control can contribute to the overall metabolic cost of walking in able-bodied people. As very little is known on the energy cost for balance control, this chapter
is more fundamental in nature and involves healthy able-bodied controls. The energy cost for balance control is studied by enforcing a walking pattern similar to subjects’ unconstrained gait. By enforcing a gait pattern subjects can no longer rely on a stepping strategy to control balance in lateral direction, and balance is perturbed. Because global gait characteristics are set, changes in metabolic energy cost are a consequence of changes in the balance control strategies applied.

In Chapter 7 the main findings of the previous chapters are recapitulated and discussed. Based on the information deduced from the reported studies, future research recommendations are proposed. Finally, implications for clinical practice are presented and possible suggestions on how these results may be incorporated in the clinical prosthetic rehabilitation are provided.

Figure 4. Schematic representation of factors influencing prosthetic walking.

The imposed aerobic load while walking divided by the aerobic capacity provides us with a qualitative measure for the effort experienced while walking, namely the relative aerobic load. The topics studied in this thesis are indicated by their chapter number.
General Introduction