Transfemoral Amputation, Quality of Life and Prosthetic Function

Studies focusing on individuals with amputation
due to reasons other than peripheral vascular disease,
with socket and osseointegrated prostheses

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Contents

Abstract

Background: Individuals who have undergone a transfemoral amputation (TFA) due to causes other than peripheral vascular disease (PVD) constitute a sub-group of all amputees. This group is usually of young age at the amputation. Conventionally, prosthetic suspension is achieved with a socket. Using the osseointegration method, prostheses can be attached directly to the bone (OI prostheses) without a socket.

Aim: The overall aim was to investigate the health-related quality of life (HRQL) and prosthetic function in persons with a unilateral TFA, due to causes other than PVD, with socket prostheses and OI prostheses.

Material, methods and results: General HRQL was assessed using the SF-36. For condition-specific HRQL, a new self-report questionnaire was constructed: the Questionnaire for Individuals with a Transfemoral Amputation (Q-TFA). It provides results for four scores (prosthetic use, prosthetic mobility, problems and global health) and adequate levels of validity and reliability were demonstrated (Paper II). Physical assessments included measurement of the energy cost using the Physiological Cost Index and hip range of motion (ROM).

The HRQL and prosthetic function are described for 97 persons (62% male, 38% female, mean age 48 years, mean time since amputation 22 years, cause: 55% trauma, 35% tumour, 10% other) (Paper I). The energy cost was investigated for 41 individuals with socket prostheses (Paper III), while hip ROM was investigated for 43 persons with socket prostheses and 20 with OI prostheses (Paper IV). Finally, prospective results at the two-year follow-up for the first 18 consecutive patients treated with an OI prosthesis within a clinical investigation are reported (Paper V).

For the study group (Paper I), the general HRQL was reduced compared with healthy norms. Daily use of the socket prosthesis was reported by 82%. A large number of subjective complaints reducing the HRQL were reported. The most common were heat/perspiration (72%) and sores/skin irritation (62%) with the socket. Further, 48% reported phantom limb pain, 47% back pain and 44% uncomfortable sitting with the prosthesis. The energy cost was increased by 77% compared with controls. The hip ROM was reduced with the socket prosthesis, while individuals with an OI prosthesis had no restriction in hip ROM. Prospective results for the treatment with OI prostheses revealed that 17/18 used the prosthesis and reported an increase in general physical HRQL and more prosthetic use, better prosthetic mobility, fewer problems and better global health at the two-year follow-up compared with the preoperative situation.

Conclusions: For persons with an established TFA, for reasons other than PVD, the general HRQL is lower than that of healthy norms and a considerable number of specific problems are perceived. The Q-TFA is a valid and reliable tool for assessments of this population. Treatment with OI prostheses represents a promising development in the rehabilitation of individuals with TFA who report improved general and condition-specific HRQL at the two-year follow-up.

Keywords: Artificial limb, Energy cost, Health-related quality of life, Lower limb amputation, Osseointegration, Prosthetics, Range of motion, SF-36, Transfemoral amputation

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List of publications

I. Consequences of non-vascular trans-femoral amputation: a survey of quality of life, prosthetic use and problems.
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    Prosthet Orthot Int 2001, 25 (3), 186-194

II. Questionnaire for Persons with a Transfemoral Amputation (Q-TFA): Initial validity and reliability of a new outcome measure.
    K Hagberg, R Brånemark, O Hägg
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    K Hagberg, E Häggström, R Brånemark
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IV. Socket versus bone-anchored trans-femoral prostheses: Hip range of motion and sitting comfort.
    K Hagberg, E Häggström, M Uden, R Brånemark
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V. Osseointegrated transfemoral amputation prostheses: Prospective results of general and condition-specific quality of life in 18 patients with 2-year follow-up.
    K Hagberg, R Brånemark, B Gunterberg, B Rydevik
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Abbreviations and Definitions

In this thesis, the following abbreviations and definitions are used

BMI	Body Mass Index. The index was approximated by adding 12% of the weight of the individual with TFA (without wearing the prosthesis) to the formula
CI	Confidence interval
CWS	Comfortable walking speed
Energy cost	A measure describing the efficiency of walking by the amount of oxygen consumed per unit distance walked
IC socket	Ischial containment socket design
ICC	Intraclass Correlation Coefficient
HRQL	Health-Related Quality of Life
KD	Knee disarticulation, amputation through the knee joint
LCI	Locomotor Capability Index
LLA	Lower limb amputation
MD	Median
Non-elderly	Person with amputation performed at younger ages, in contrast to the group of geriatric amputees
Non-vascular	Amputation performed due to causes other than PVD, including diabetes
OI prosthesis	Osseointegrated prosthesis, i.e. a bone-anchored prosthesis using the method of osseointegration
OPRA	Osseointegrated Prostheses for the Rehabilitation of Amputees. Name of a clinical investigation
Osseointegration	Direct anchorage of an implant by the formation of bony tissue around it without growth of fibrous tissue at the bone-implant interface (Dorland and Anderson 2003)
PCI	Physiological Cost Index
Phantom limb pain	Painful sensation perceived in the missing limb
Prosthetic user	A person who wears a prosthesis at least once a week
PVD	Peripheral vascular disease
QL socket	Quadrilateral socket design
Q-TFA	Questionnaire for Persons with a Transfemoral Amputation
ROM	Range of motion
SD	Standard deviation

SF-36	Short Form 36 Health Survey. Includes eight scales and two summary measures:
	PF = Physical Functioning
	RP = Role Physical Functioning
	BP = Bodily Pain
	GH = General Health
	VT = Vitality
	SF = Social Functioning
	RE = Role Emotional Functioning
	MH = Mental Health
	PCS = Physical Component Score
	MCS = Mental Component Score
TFA	Transfemoral amputation, amputation above the knee, through the femur
TTA	Transtibial amputation, amputation below the knee, through the tibia/fibula
VO$_2$	Oxygen uptake

Background

1. Lower limb amputation and prosthetics

An amputation is defined as "the removal of a limb or other appendage or outgrowth of the body" (Dorland and Anderson 2003). The amputation of a limb is one of the oldest described surgical procedures. The history and evolution of limb amputation surgery follows the history of war to large extent. After World War II, the progression of prosthetic design and specific rehabilitation programmes for individuals with limb loss was intensified (Hierton 1980; Bowker and Pritham 2004). Back in 1949, the American surgeon D.B. Slocum summarised what is still regarded as being of profound importance in the rehabilitation process following a lower limb amputation:

"While the primary objective of amputation surgery is to remove an extremity which is useless or which endangers the life or health of the individual, the ultimate goal is the successful rehabilitation of the patient back into the normal life of his community. This goal can only be realized when a satisfactory, durable stump has been formed; a comfortable well-constructed prosthesis has been selected and properly fitted; and the amputee has been diligently trained in its effectual use and has been carefully guided toward a healthy mental attitude. These four factors – the good stump, the functional, well fitted prosthesis, proper training in the use of the artificial limb, and sound psychological adjustment – are mutually interdependent, and it cannot be overemphasized that each is of profound importance".

(Slocum D.B., 1949, An Atlas of Amputations, St Louis, USA, The C.V. Mosby Company, page 17)

A lower limb amputation (LLA) can be divided into a major or minor amputation. A major amputation is one performed through or proximal to the ankle joint and a minor amputation is subsequently performed distal to the same joint. The three most common levels for a major LLA are transtibial amputation (TTA), transfemoral amputation (TFA) and knee disarticulation (KD) respectively. Today, the majority of all LLA are performed due to peripheral vascular disease (PVD) and the reported annual incidence ranges between 12 and 44 per 100,000 persons, with the highest risk among persons with diabetes mellitus (Ephraim et al. 2003). In Scandinavia, as well as in the rest of the western world, PVD with or without diabetes mellitus constitutes the reason for an amputation in about 80-90% of cases (Pohjolainen et al. 1989; Ebskov 1992; Rommers et al. 1997; Witso and Ronningen 2001; Ephraim et al. 2003; Eskelinen et al. 2004; Johannesson et al. 2004). For this group of patients, the mean age at the amputation is above 70 years (Pohjolainen et al. 1989; Pohjolainen and Alaranta 1998; Eskelinen et al. 2004; Johannesson et al. 2004) and the mortality rate within two years has been reported to be between 52% and 60% (Pohjolainen et al. 1989; Eneroth and Persson 1992; Hermodsson 1999; Eskelinen et al. 2004; Johannesson et al. 2004). A different group comprises the substantially smaller number of persons undergoing an LLA due to trauma, tumour, congenital limb deficiency, infection or other reasons without any element of PVD. This group accounts for about 10% of all major amputations and the largest number of cases are traumatic (including war victims), followed by malignancy (Ebskov 1992; Ebskov 1994; Dillingham et al. 2002; Ephraim et al. 2003). The male to female ratio within traumatic amputations has been reported to be 2:1 (Ebskov 1994).
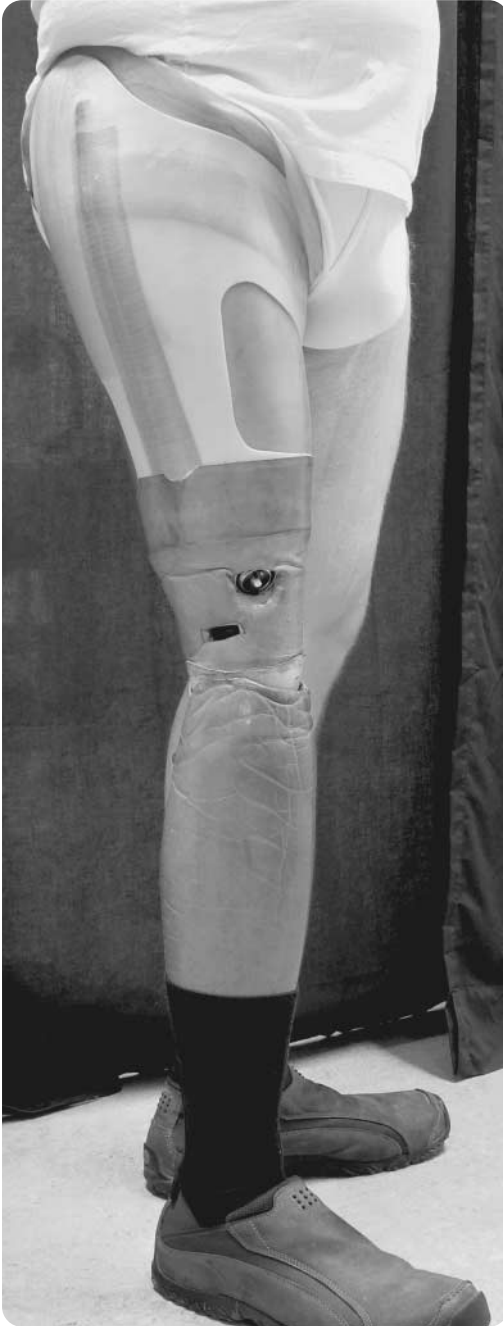
Owing to the discrepancy between different groups of individuals with LLA, it has been argued that the different subgroups should be reported separately (Hermodsson et al. 1994; Pernot et al. 1997; Kent and Fyfe 1999). This thesis focuses on increasing the general body of knowledge on the subset of persons with an established TFA for reasons other than PVD. This subset could be approximated as accounting for fewer than 3% of all major LLA (Ebskov 1992; Rommers et al. 1997; Pohjolainen and Alaranta 1999; Dillingham et al. 2002; Eskelinen et al. 2004) but representing an important group of younger persons with a life-long locomotor disability. Clinical experience indicates that there is a general lack of understanding of the specific living conditions this particular group of persons have to deal with in their everyday lives.

The most important difference between a TTA and a TFA is related to the loss of the knee joint. In addition to the lack of the human knee, the TFA also affects the strength and muscle balance around the affected hip joint (Ryser et al. 1988; Jaegers et al. 1995; Gottschalk 1999). The degree of atrophy of the hip muscles is related to the length of the residual limb (Jaegers et al. 1995). Moreover, insufficient muscle strength, pain and immobility following the amputation increase the risk of developing hip muscle contractures (Gailey and Clark 2004), most commonly in flexion. An established contracture counteracts the correct alignment of the prosthetic limb and reduces the torque of the involved muscles (Murnaghan and Bowker 2004), leading to a reduction in the prerequisites for prosthetic walking capacity. To create the best possible conditions for prosthetic walking, the surgery should include stabilisation of the remaining muscles to the shaft of the femur (Gottschalk and Stills 1994; Jaegers et al. 1996; Gottschalk 1999).

The conventional way to attach a prosthetic limb to the body is with a socket (Kapp 1999; Mak et al. 2001). The very first socket prosthesis was introduced during the 16th century by the French surgeon Ambroise Paré

(Bowker and Pritham 2004). The aim of the socket is to distribute the load from the residual limb to the prosthetic components. The basic goals for prosthetic fitting are to provide "comfort, function, stability and cosmesis" (Schuch and Pritham 1999) and, in order to accomplish these goals, the best possible fit of the socket to the residual limb is essential (Lilja 1998; Legro et al. 1999; Kapp 2000; Marks and Michael 2001). A TFA socket normally contains the total residual limb to the groin and its suspension is most commonly achieved by either suction or a silicon liner (Kapp 2000; Marks and Michael 2001) (Figure 1). In some cases, additional support from a waist belt to secure the retention of the socket could be needed, especially if the residual limb is short. During the last decades, two main TFA socket designs have been used; the quadrilateral socket (QL socket) and the ischial containment socket (IC socket) (Schuch and Pritham 1999; Kapp 2000). The most important differences between them are the contours of the proximal brim in which the ischium is outside the QL socket and is contained in the IC socket. Additional components of TFA prostheses are the prosthetic knee and foot with various constructions (Cochrane et al. 2001; Marks and Michael 2001; Friel 2005). The decision regarding the type of socket and the other components which are going to be used is based on the needs of the individual patient and the empirical knowledge of the clinician (van der Linde et al. 2004). A prosthetic limb may need to be replaced over the years due to factors such as residual limb volume changes, bad fit, broken parts or other reasons. Recently, it has been shown that about one fifth of individuals with LLA were fitted with a new prosthesis at least once a year (Pezzin et al. 2004) and, among individuals with LLA due to trauma, a need to be supplied with a new prosthesis every two to three years has been reported (Hoaglund et al. 1983; Dillingham et al. 2001). Finally, for individuals with TFA due to tumour, the mean cost of "maintaining a functioning prosthesis" has been reported to be USD 4,225 per year

(computed in 1998 dollars) (Hoffman et al. 2002). In Sweden, the cost of the prosthetic device is financed through the public health system and subsequently no costs are charged directly to the patient. In this thesis, no analyses of different prosthetic components and their relationship to function or costs have been performed.

Figure 1A. Example of a TFA socket prosthesis with vacuum suspension.
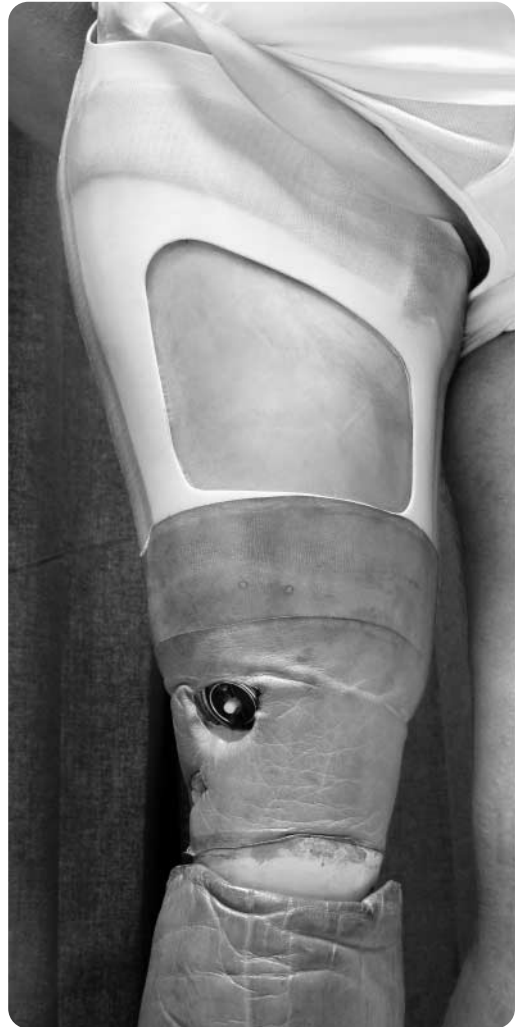
Figure 1B. Close-up of the prosthetic socket, which contains the recidual limb to the groin.

2. Prosthetic function

In 1989, Moore and co-workers defined successful prosthetic ambulation as "prosthetic usage for ambulation on a daily basis with or without external support" (Moore et al. 1989). A few years later, a prosthetic user was defined as "a person who wears a prosthesis at least once a week" (Grise et al. 1993).

There are some general findings that are frequently reported regarding prosthetic function; the group of dysvascular amputees use the prosthesis less than the non-vascular cases and those with TFA use the prosthesis less than those with TTA (Kegel et al. 1978; Hoaglund et al. 1983; Moore et al. 1989; Pernot et al. 1997; Gauthier-Gagnon et al. 1999). Furthermore, individuals with TFA generally have poorer functional capacity than those with TTA (Kegel et al. 1978; Hoaglund et al. 1983; Holden and Fernie 1987; Medhat et al. 1990; Walker et al. 1994; Gauthier-Gagnon et al. 1998; Gauthier-Gagnon et al. 1999). There are, however, some frequent problems when it comes to interpreting and comparing the results of prosthetic function in the existing literature due to the lack of consensus about the outcome measures that should be used, different periods of follow-up and mixed groups of patients with amputations reported on together (Pernot et al. 1997; Kent and Fyfe 1999; Geertzen et al. 2001; Deathe et al. 2002). For example, individuals with amputations of the upper and lower extremities are reported together (Nielsen 1991; Nicholas et al. 1993; Sherman 1999; Pezzin et al. 2004) and cases with amputations due to PVD are mixed with cases with non-vascular causes (Medhat et al. 1990; Nicholas et al. 1993; Gauthier-Gagnon et al. 1999; Matsen et al. 2000). Moreover, those with KDA, TFA and amputations at the hip are grouped together (Kegel et al. 1978; Medhat et al. 1990) and patients with newly performed amputations are reported together with those with an established situation (Kegel et al. 1978; Matsen et al. 2000). As a result, in the existing literatu-

re, it is often difficult to extrapolate the findings that relate to the subset of individuals with an established TFA due to reasons other than PVD and there is a need to investigate this group separately.

Prosthetic use and perceived complaints

One outcome that is commonly reported is the amount of prosthetic use during the day or week, often described as the mean number of hours. For the majority of individuals with a non-vascular LLA, prosthetic use has been reported to be at least 10 hours/day (Walker et al. 1994; Burger et al. 1997; Dillingham et al. 2001; Hoffman et al. 2002) (Table 1).

Several studies have shown that wearing a prosthetic socket is often linked with problems occurring on the residual limb in terms of discomfort, sores, rashes and pain (Hoaglund et al. 1983; Nielsen 1991; Walker et al. 1994; Sherman 1999; Lyon et al. 2000; Matsen et al. 2000; Dillingham et al. 2001; Gallagher et al. 2001; Gallagher and Maclachlan 2001). Further, prosthesis comfort has been stated to be of very great importance among artificial limb users (Nielsen 1991; Legro et al. 1999; Gallagher and Maclachlan 2001). In two separate investigations performed on US veterans with LLA, the authors concluded that "the most striking finding was the high incidence of residual limb discomfort" (Hoaglund et al. 1983) and that "there are significant problems with current methods for attaching prostheses that need to be addressed" (Sherman 1999).

Another commonly reported problem is phantom limb pain (Hill 1999; Smith et al. 1999). Among 104 persons with a major LLA, 69% reported experiencing phantom limb pain and the pain situation was worse for those with TFA compared with TTA (Gallagher et al. 2001). Pain from other body sites, such as back pain and pain in the joints of the contralateral limb, has also been described as occurring frequently (Friberg 1984; Walker et al. 1994; Ehde et al. 2000; Pezzin et al. 2000). Among 92 individuals in another study (major LLA), 63% had experienced phantom limb pain, 76% residual

limb pain and 71% back pain during the last four weeks and close to half had had all three types of pain (Smith et al. 1999). Further, back pain was more common and more bothersome among persons with TFA than with TTA (Smith et al. 1999). In the long term, an increased risk of osteoarthritis in the ipsilateral hip and contralateral knee joint (Kulkarni et al. 1998) and a frequent finding of osteopenia in the ipsilateral hip (Rush et al. 1994) has been reported for individuals with TFA.

Using a prosthetic limb has also been described as causing a variety of other perceived complaints that affect everyday life, including difficulty donning and doffing ("do on" and "do off") the prosthesis, not being able to rely on the prosthesis being securely suspended, difficulties with the choice and/or wear of apparel and shoes, smell and noise emanating from the artificial limb and, of course, difficulties relating to mobility with the device (Grise et al. 1993; Nicholas et al. 1993; Legro et al. 1999; Gallagher and Maclachlan 2001; Miller et al. 2001). Again, there is a lack of research reporting separately on the perceived complaints for persons with TFA for reasons other than PVD.

Prosthetic walking

Walking with a TFA prosthesis is often performed with a characteristic limp (Sjödahl Hammarlund 2004). In addition to analyses of the gait pattern, the outcome of different aspects of prosthetic walking is described in the literature in terms of use of walking aids, walking or mobility skills (e.g. being able to walk on stairs, slopes, uneven terrain and so on), walking distances, walking speed and walking efficiency. Again, there is no clear consensus on how to define functional walking and how to present the results (Pernot et al. 1997). Table 1 illustrates some outcomes reported for individuals with LLA due to trauma or tumour according to various issues with regard to prosthetic use, function and problems. As shown in Table 1, limited walking distances are commonly reported. Not being able to walk 500 m with a prosthetic limb has been shown to be related to poorer quality of life (van der Schans et al. 2002).

Another aspect of prosthetic walking is related to velocity. There is a large amount of research showing that individuals with TFA have a slower self-selected, or comfortable walking speed (CWS) than healthy controls. For non-vascular TFA cases, the CWS has been reported to be between 45 and 75 m/min (James and Oberg 1973; Waters et al. 1976; Huang et al. 1979; Harris et al. 1990; Boonstra et al. 1993; Jaegers et al. 1993; Boonstra et al. 1994; Chin et al. 1999; Waters and Mulroy 1999), while, in the case of healthy persons, it has been reported to be between 60 and 100 m/min (Huang et al. 1979; Waters et al. 1988; Harris et al. 1990; Boonstra et al. 1993; Bohannon 1997; Waters and Mulroy 1999; Sunnerhagen et al. 2000).

Finally, the efficiency of prosthetic gait can be described in terms of energy cost (also known as metabolic cost or oxygen cost), which describes the metabolic consequences of walking in relation to the distance travelled (Czerniecki 1996). The golden standard for the assessment is to perform direct measurements of the volume of oxygen uptake (VO_2) and express the cost as VO_2 per unit of distance walked. In normal walking, the highest efficiency exists when walking at CWS (Pagliarulo et al. 1979; Donn and Roberts 1992; Waters and Mulroy 1999). For persons with a TFA socket prosthesis, the energy cost has been shown to increase by 40-67% compared with the normal level (Waters et al. 1976; Huang et al. 1979; Boonstra et al. 1994; Schmalz et al. 2002). The analysis of direct uptake of VO_2 is a cumbersome method which requires advanced equipment, limiting the assessment to being primarily performed within small groups and in a laboratory setting. Another, more simple, method for estimating the energy cost based on the registration of heart rate is the Physiological Cost Index (PCI) (MacGregor 1981).

There is a need for research reporting performance-based measures of prosthetic walk-

Table 1. Examples of outcomes reported for individuals with LLA due to reasons other than vascular disease. Wherever possible, data for individuals with TFA are reported separately.

	Prosthetic use	Use of walking aids	Walking distance	Reported problems
Hoaglund 1983 TTA and TFA trauma, n=112 (TFA=38) 100% men, mean age 47 yr 1–39 yr since amp	(TTA+TFA) 14% < 8 h/day 86% all day	(TTA+TFA) 24% use cane part of time 61% no aid	(TTA+TFA) 8% none or only in home 45% 1–6 blocks 47% > 6 blocks	(TFA separately) 71% perspiration 61% phantom limb pain 58% back pain 50% pain with prosthesis 45% socket problems
Walker 1994 TFA trauma, n=24 83% male, mean age 29 yr Mean 15 yr since amp	4% < 4 h/day 25% 8–12 h/day 63% > 12 h/day	Not reported	56% 1/4 mile on the flat	75% phantom limb pain 45% skin breakdown problem 50% consider themselves as being quite to very disabled
Burger 1997 Major LLA trauma, n=223 (TFA=89) 80% men, mean age 54 yr Mean age at amp 24 yr	1% no use 14% < 7 h/day 25% 7–10 h/day 60% 10 h/day	31% use aid indoors 48% use aid outdoors	TTA: 33% < 500m TFA: 50% < 500m	Not reported
Dillingham 2001 LLA trauma, n=78 (TFA=16) 87% men Mean age at injury 33 yr Mean time since injury 7.5 yr	95% have a prosthesis Mean use: 80 h/week	32% use a cane or crutches most of the time	Not reported	57% not satisfied with prosthetic comfort 24% phantom limb pain 24% skin irritation and wounds 23% perspiration 17% pain from contralateral limb
Hoffmann 2002 TFA, tumour, n=35 54% men, mean age 43 yr 2–30 yr since amp	17% not daily 26% < 12 h/day 57% > 12 h/day	46% use a cane or crutches, 49% no aid	Not reported	37% mild phantom limb pain 11% severe phantom limb pain
Refaat 2002 LLA tumour, n=66 (TFA=34) 62% men, mean age 52 yr Mean age at amp 40 yr	91% use prosthesis	83% use aid	Not reported	30% required pain medication 26% periodic depression 35% with TFA not satisfied with current status

ing for individuals with TFA due to reasons other than PVD and the results of the PCI have rarely been reported for any individuals with LLA.

3. Health-Related Quality Of Life

In 1948, the World Health Organisation declared health to be "a state of complete physical, mental and social well-being, and not merely the absence of disease" (WHO 1978). Today, any evaluation of a new treatment should include evidence of its impact on health and quality of life (Jackowski and Guyatt 2003). Quality of life is a normative concept that could mean different things to different people (Fayers and David 2000; Cella and Nowinski 2002). Within health outcome research, the concept has been compiled to focus on those aspects that are more directly affected by a health condition and facets relating to factors such as economic status or social surroundings have been excluded. This confined concept is called "health-related quality of life" (HRQL) and it has been defined to include the perception of an individual of his or her degree of physical, psychological and social well-being and the effects that illness and treatment have on daily life (Jette 1993; Muldoon et al. 1998; Patrick and Chiang 2000). It is considered especially important to study HRQL in groups with chronic conditions when the goal of care is "to make the patient's life as comfortable, functional and satisfying as possible" (Sullivan et al. 1999).

Generic and condition-specific measurements of HRQL

There are two main types of HRQL measure; general or generic measures and disease- or condition-specific measures (Streiner and Norman 1995; Fayers and David 2000; Cella and Nowinski 2002; Domholdt 2005). A generic tool gives a broader perspective and could be used on healthy persons as well as on persons with different kinds of health problem. The value of the generic measure is that it can be used for comparisons of different categories of people. The condition-specific tool is designed for a targeted group of patients or conditions and gives a more detailed perspective of HRQL for that specific group. In most cases, the targeted measure is more sensitive to detecting changes within the specific group than the generic tool (Fayers and David 2000; Cella and Nowinski 2002; Beaton and Schemitsch 2003). One common piece of advice is to use both kinds of measure in order to best capture the overall situation and change in health due to an intervention (Beaton et al. 1997; Hays et al. 2002; Beaton and Schemitsch 2003).

The study of HRQL is always a patient-based measure, simply because the patient is the key source of information and the preferred format to capture the patient's subjective experience is self-report questionnaires (Bussmann and Stam 1998).

In orthopaedic and rehabilitation research, the relationship between HRQL and physical function is obvious. The amputation of a limb is a dramatic change in the life situation of the person involved and limb loss is without doubt a chronic condition. Several studies have reported a reduction in general HRQL (Pell et al. 1993; Smith et al. 1995; Legro et al. 1999; Demet et al. 2003), an increased incidence of depression (Kashani et al. 1983) and increased social discomfort (Rybarczyk et al. 1992) among individuals with LLA. The impact of the amputation on the general and the specific HRQL in the particular subset of individuals with TFA for reasons other than PVD is, however, not clear.

4. Outcome measures targeted at individuals with LLA

Over the years, a number of measures have been used to describe prosthetic function and mobility. The most common have been simple classification scales in which the level of mobility is registered by the investigator, with no proof of validity or reliability of the scales (Rommers et al. 2001; Deathe et al. 2002). In 1981, the Amputee Activity Score, which is a validated tool designed to be used in direct interviews with the patient, was published (Day 1981). More specific self-report questionnaires, involving examinations of the HRQL and capturing the patients' own view, have been requested (Kent and Fyfe 1999; Geertzen et al. 2001; Rommers et al. 2001).

Today, one internationally established self-report instrument, with proven validity and reliability, is the Locomotor Capability Index (LCI), which is included in a larger questionnaire called the Prosthetic Profile of the Amputee (Gauthier-Gagnon and Grise 1994; Gauthier-Gagnon et al. 1998). However, the high ceiling effect of the LCI makes this index more suitable for use on individuals with lower prosthetic mobility capabilities, such as those with LLA due to PVD (Miller et al. 2001). Moreover, aspects of HRQL are not included in this tool. Another instrument, in which issues of HRQL are represented, is the Prosthesis Evaluation Questionnaire (PEQ) (Legro et al. 1998), which was developed to "measure small differences in prosthesis function and major life domains related to prosthesis function".

No self-report questionnaire has been designed to address the needs of non-elderly persons with a TFA and their condition-specific HRQL.

5. Osseointegration

The number of problems related to the suspension and comfort of conventional socket prostheses have led to a desire to have the artificial limb attached directly to the residual skeleton and, over the years, surgical attempts have been made to achieve this (Mooney et al. 1971; Hall et al. 1976; Hall 1977; Mooney et al. 1977; Hall 1985).

The discovery that implants made of commercially pure titanium could provide a stable anchorage for the implant in the bone tissue was made by Professor Per-Ingvar Brånemark during the 1950s and the concept of osseointegration has been in successful clinical practice for dental applications since 1965 (Brånemark et al. 1977; Brånemark 2005) and more than two million dental patients have been treated according to the concept worldwide. The word osseointegration is defined as the "direct anchorage of an implant by the formation of bony tissue around it without growth of fibrous tissue at the bone-implant interface" (Dorland and Anderson 2003). At the present time, the method is, for example, also used successfully for treatment with bone-anchored hearing aids, other defects in the head and neck area (Tjellström 1989; Tjellström and Håkansson 1995), finger joint prostheses (Lundborg et al. 1993; Möller et al. 2004) and thumb amputation prostheses (Lundborg et al. 1996). Treatment with major bone-anchored amputation prostheses using osseointegration (OI prostheses) has been performed in Sweden since 1990 (Brånemark et al. 2001) and more recently also in the United Kingdom (Sullivan et al. 2003; Robinson et al. 2004). In 1999, a prospective clinical investigation named OPRA (Ossseointegrated Prostheses for the Rehabilitation of Amputees) was started at the Sahlgrenska University Hospital in Göteborg, Sweden, on patients treated with TFA OI prostheses. In accordance with the OPRA protocol, patients are treated in two surgical sessions followed by rehabilitation, with a total treatment period of approximately 12 months. At the first surgery (S1), a titanium implant (fixture) is inserted in the residual bone and left unloaded for about six months. At the second surgery (S2), a titanium rod (abutment) is inserted into the distal end of the

fixture and then penetrates the skin (Figures 2 and 3). Prosthetic suspension is obtained by connecting the OI prosthesis to the abutment with a specific attachment device (Figures 4 and 5). After S2, the patient undergoes a period of rehabilitation for four to six months with gradually increased weight-bearing and prosthetic activity (Hagberg 2005). The OPRA protocol includes a wide range of assessments performed prior to S1 and at defined time points after S2 until the two-year follow-up; they include radiography, registration of complications, hip range of motion, energy cost while walking, computerised gait analyses, as well as general and specific HRQL measurements.

It is of major importance to report the outcome in terms of HRQL for a new treatment, such as the TFA OI prosthesis.
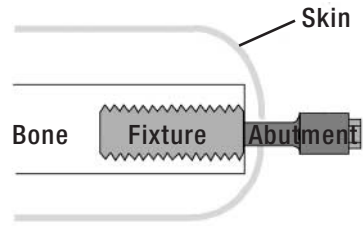

Figure 2. Schematic view of the implant system for anchorage of an amputation prosthesis according to the osseointegration method.
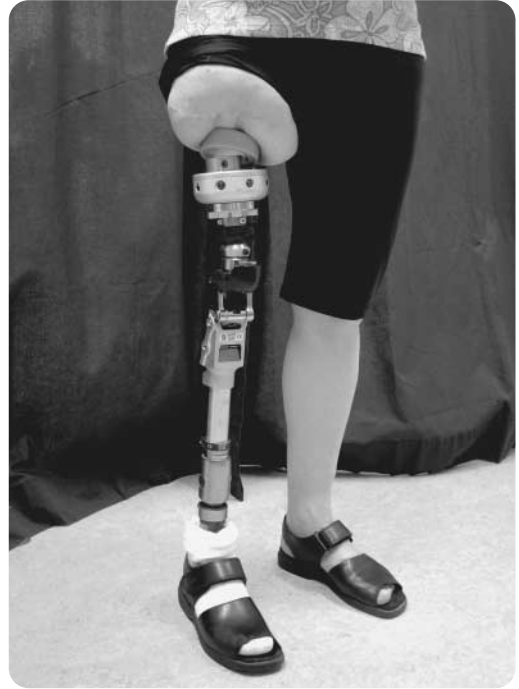

Figure 3. The transcutaneous titanium abutment as seen at the distal end of the residual limb.

Figure 4. Attaching the OI prosthesis. The attachment device is secured to the abutment with a hex key.

Figure 5. Example of a TFA OI prosthesis without the cosmetic cover.

Aims

The overall aims of this thesis were:

1. To investigate the HRQL and prosthetic function in persons with an established TFA due to causes other than peripheral vascular disease (PVD).

2. To investigate the outcome of treatment with OI prostheses regarding HRQL and prosthetic function.

The specific aims were:

Paper I: to describe HRQL, prosthetic use and problems for individuals with an established TFA due to causes other than PVD.

Paper II: to assess the measurement properties of the "Questionnaire for persons with a Trans-femoral Amputation" in individuals using TFA socket prostheses.

Paper III: to assess the energy cost, using the PCI, and prosthetic walking performance for individuals using a TFA socket prosthesis as compared with healthy controls.

Paper IV: to study hip joint motion when wearing and not wearing TFA socket prostheses, to study discomfort while sitting when using the prosthesis and to compare the results between individuals using socket or OI prostheses.

Paper V: to present prospective results of general and condition-specific HRQL for individuals with TFA treated with OI prostheses in the OPRA study.

Material and Methods

Study Population

Individuals with a socket prosthesis

The basic inclusion criteria for the study population in Papers I –IV were:

- Having a unilateral TFA for at least two years
- Being between 20-70 years of age
- Being able to read and understand the Swedish language

The basic study population was collected in two phases:

1. Letters with invitations to participate in the study were distributed nationally in 1999. The invitations were sent from two Swedish associations for amputees and six orthopaedic workshops and/or rehabilitations units. Those who agreed to participate answered the investigators directly.

2. Individuals fulfilling the basic criteria and who were prosthetic users living in the county of Västra Götaland were invited between 2000 and 2002. The invitations were distributed with the assistance of all four prosthetic workshops within the county. Those who had undergone amputation for reasons other than PVD and who could walk continuously for at least 100 m were also asked to come for physical assessments at the Sahlgrenska University Hospital.
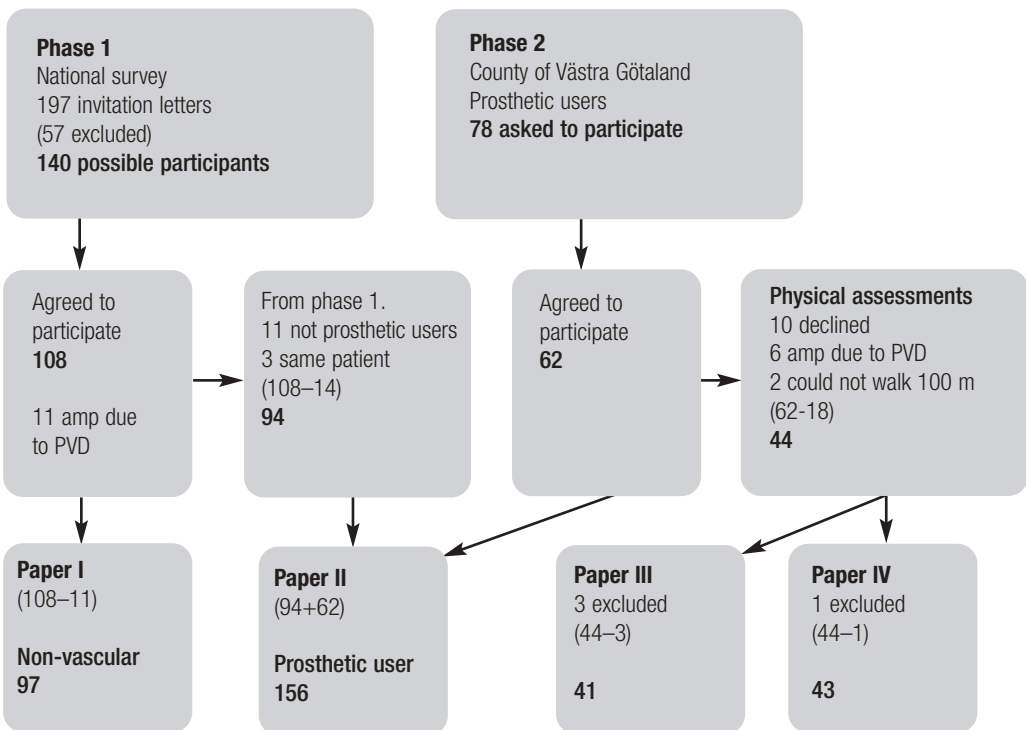

Phase 1
National survey
197 invitation letters
(57 excluded)
140 possible participants

Phase 2
County of Västra Götaland
Prosthetic users
78 asked to participate

Agreed to
participate
108

11 amp due
to PVD

From phase 1.
11 not prosthetic users
3 same patient
(108–14)
94

Agreed to
participate
62

Physical assessments
10 declined
6 amp due to PVD
2 could not walk 100 m
(62-18)
44

Paper I
(108–11)

Non-vascular
97

Paper II
(94+62)

Prosthetic user
156

Paper III
3 excluded
(44–3)

41

Paper IV
1 excluded
(44–1)

43

Figure 6. Diagram describing the study population with TFA and socket prostheses for Papers I-IV.

Figure 6 illustrates the procedure of gathering the study population with TFA and socket prostheses for Papers I-IV. In phase 1, letters with invitations were distributed to 197 individuals. In phase 2, another 78 individuals were invited to take part. From the first phase, 108 participants fulfilling the inclusion criteria were recruited, while 62 were recruited from the second. A total of 44 participants underwent the physical assessments.

Paper I includes individuals with TFA due to causes other than PVD from the population collected in phase 1.

Paper II includes all individuals collected in phases 1 and 2 who were prosthetic users. Three individuals turned out to be registered from both phases and were subsequently excluded from the material from phase 1. The test-retest subgroup was taken from the 62 individuals collected in phase 2. Five failed to answer the test-retest questionnaire and nine were excluded due to reported changes in condition between test and retest.

Papers III and IV include those individuals from phase 2 with amputation due to causes other than PVD, who reported being able to walk 100 m without stopping and who agreed to undergo physical assessments at the Department for Prosthetics and Orthotics at Sahlgrenska University Hospital. In Paper III, three individuals were excluded (2 for medical reasons, 1 was unable to follow the instructions for the test). In Paper IV, one patient was excluded for medical reasons.

Individuals with an OI prosthesis

Paper IV includes individuals with unilateral TFA treated with an OI prosthesis before the start of the OPRA study, aged between 20 and 70 years, with amputation for reasons other than PVD, who were prosthetic users with the ability to walk continuously for at least 100 m.

Paper V includes all patients included consecutively in the OPRA study that had passed the two-year follow-up before April 2006.

Healthy controls

Paper I includes a group of 1,067 healthy controls taken from the Swedish population-based norm for the SF-36 consisting of 8,930 individuals (Sullivan et al. 1994). The controls were matched according to age and gender with the study population of individuals with TFA in Paper I.

Paper III includes 22 healthy controls taken from an investigation of the PCI method performed on 74 healthy individuals of which 42 had been assessed identically to the TFA group. The group of controls was taken from these 42 and matched according to age and gender with the study population of individuals with TFA in Paper III.

Description of the study population included in Papers I-V

An overview of the demographic data for participants with TFA for each paper is shown in Table 2.

In **Paper II,** the participants in the retest subgroup were older (p=0.011), had a longer interval since amputation (p=0.001) and a higher percentage had a prosthetic socket with vacuum suspension (p=0.039) than the remaining study sample (n=108). There were no other statistically significant differences in demographic variables between the groups.

In **Paper III,** the TFA group had a higher body mass index than the controls (27.1 vs 25.0, p=0.017). There were no statistically significant differences in any other variable between the groups.

In **Paper IV**, three of the cases in the OI group were treated and investigated in the United Kingdom, while all the others were investigated in Sweden. The follow-up time since receiving the bone-anchored prosthesis in the OI group was between three and 10 years (MD 5 years). The mean time since the amputation was longer in the S group than in the OI group (29 versus 19 years, p=0.010), as was the mean residual limb length (22 versus 16 cm, p<0.001, measured from the ischial tuberosity to the end of the residual femur). There were no statistically significant differences in any other variable between the groups.

In **Paper V**, 16 of the 18 cases had a unilateral TFA and two had bilateral TFA. For each patient with bilateral amputations, only one limb was included in the OPRA study. Four, out of the 18 patients, are also included in the material of individuals with socket prostheses, with the assessments performed prior to the inclusion in the OPRA study (two patients in Papers I and II and two patients in Papers II, III and IV).

Table 2. Description of the study group of individuals with TFA in Papers I-V. Values are expressed in percent, mean and min-max.

	I	II		III	IV		V
		Total	Retest group	TFA group	S group	OI group	At inclusion
Number	97	156	48	41	43	20	18
Age	48 20-69	51 20-70	55 32-70	49 28-70	51 28-70	46 26-67	45 22-62
Gender: **% male** **% female**	62% 38%	67% 33%	73% 27%	73% 27%	74% 26%	75% 25%	44% 56%
Cause of amputation: **Trauma** **Tumour** **Other *** **Vascular disease**	55% 35% 10% –	55% 31% 6% 8%	63% 25% 4% 8%	71% 24% 5% –	70% 25% 5% –	70% 20% 10% –	67% 28% 0% 5%
Years since amputation	22 2-52	25 2-56	32 2-56	27 2-56	29 2-56	19 6-46	15 10 months – 33 yrs
Prosthetic users	93%	100%	100%	100%	100%	100%	83%

* Other non-vascular amputation cause.

Measurements and Procedures

1. Self–report questionnaires

Short Form-36 Health Survey (Papers I, II and V)

The Short Form 36 Health Survey (SF-36) is a widespread generic self-report measure with documented validity and reliability, which was developed for the assessment of HRQL within population surveys (Ware and Sherbourne 1992; Beaton et al. 1997; Hemingway et al. 1997; Andresen and Meyers 2000). The results are presented in eight separate scales, each representing different dimensions of HRQL; Physical Functioning (PF), Role Functioning from a physical perspective (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role Functioning from an emotional perspective (RE) and Mental Health (MH). Each scale provides a value between 0 and 100 and a higher value represents better health. The PF, RP, BP and GH scales mainly represent physical health domains, while the VT, SF, RE and MH scales primarily represent domains of emotional well-being. By using an algorithm, the results from the eight scales can also be presented in two summary measures, the Physical Component Score (PCS) and the Mental Component Score (MCS) (Ware et al. 1995) (Figure 7), in which the results are standardised to apply to the general population with a mean score of 50 and a standard deviation (SD) of 10.

The SF-36 is commonly used within orthopaedic research (Garratt et al. 2002; Beaton and Schemitsch 2003) and has previously been used in studies of individuals with amputations (Smith et al. 1995; Dagum et al. 1999; Davis et al. 1999; Legro et al. 1999; Pezzin et al. 2000). In this thesis, the validated Swedish version of the SF-36 was used (Sullivan et al.
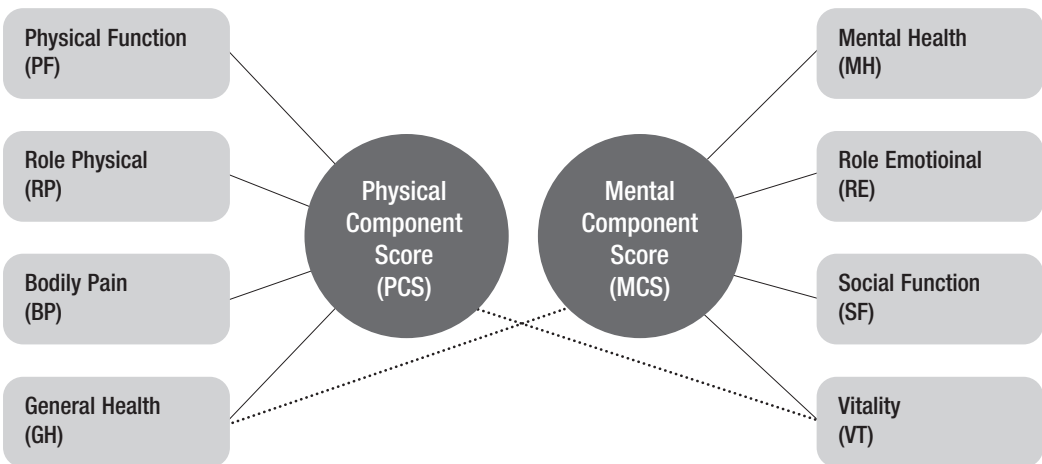

Figure 7. Schematic view of the eight scales of the SF-36 and their relationship to physical and mental components of health. For details see http://www.sf-36.org/tools/SF36.shtml.

1994). In Paper I, the SF-36 was used for descriptive analyses and for comparisons with the normal population. In Paper II, it was used for assessments of the criterion validity of the scores on the Q-TFA and, in Paper V, the tool was used for prospective studies of the outcome of treatment with OI prostheses.

Questionnaire for individuals with a Transfemoral Amputation (Q-TFA) (Papers I-V)

The Q-TFA is a targeted self-report outcome measure designed to reflect current prosthetic use, prosthetic mobility, problems and global health. Primarily designed for non-elderly persons with TFA, the Q-TFA was also developed to study outcome when changing from a conventional socket prosthesis to a bone-anchored prosthesis. The questionnaire consists of 70 questions and it takes approximately 20 minutes to complete it (appendix). Using a scoring system, 54 of the 70 questions are condensed into four separate scores: the Prosthetic Use score, the Prosthetic Mobility score, the Problem score and the Global score. Each score has a range of 0-100 (appendix in Paper II). The Q-TFA is available in Swedish and English.

Prosthetic Use score (2 items). Prosthetic use is defined as the amount of normal prosthetic wear per week. A Prosthetic Use score of one hundred indicates that the prosthesis is normally worn every day for more than 15 hours a day.

Prosthetic Mobility score (19 items). Prosthetic mobility is defined as the capability and performance of moving oneself and of changing and maintaining postures when using the prosthesis. The score consists of three sub-scores, each ranging from 0–100: Capability (12 items), Walking aids (2 items) and Walking Habits (5 items). The average of the three sub-scores generates the total Mobility score. Capability items consist of questions on the ability to perform activities with the prosthesis. The sub-scores for walking aids and walking habits are estimates of prosthetic performance rather than capability. A result of 100 in the sub-score for walking aids means that, in general, no walking aids are used indoors or outdoors in connection with prosthetic use. The Walking Habit sub-score estimates how often (daily, several days a week, once a week, more seldom or never) different walking distances outdoors have been accomplished, without stopping, during the last three months. The distances that are asked about are 50 m, 200 m, 500 m, 2 km and 5 km or more. A Walking Habit sub-score of 0 implies that 50 m of continuous walking has never been performed and 100 indicates that a distance of 5 km has been accomplished every day. To summarise, the Mobility score consists of the average of three sub-scores (Capability, Walking aids and Walking habits) and a score of 100 indicates the best possible prosthetic mobility as measured with the Q-TFA.

Problem score (30 items). Problems are defined as the extent of specific problems related to the amputation and the prosthesis and their impact on quality of life. Each item consists of a paired question: the first asks about the extent of a specific problem during the last four weeks and the second about the impact on quality of life of that specific problem. Ten items relate to problems regardless of prosthetic use and 20 to problems associated with prosthetic use. Answers are given on a five-point Likert scale. The score is reversed, which means that a higher figure indicates more serious problems with a larger reduction in quality of life, while a lower score reflects a better situation with less reduction in quality of life.

Global score (3 items). Global health is defined as the perception of function and problems with the current prosthesis and the per-

ception of the current overall amputation situation. The score is a summary of three questions where answers are given on a five-point Likert scale. A Global score of 100 indicates the best possible overall situation as measured by the Q-TFA.

The aim of the Q-TFA is to reflect the situation for persons using a prosthesis. However, for those not using a prosthetic limb, the Prosthetic Use score, the first 10 questions in the Problem score with no connection to prosthetic usage and the final overall question in the Global score could be analysed separately.

In this thesis, the separate questions on the Q-TFA, without any scores, were analysed in Paper I. In Paper II, the development and scoring system of the Q-TFA was described and the initial validity and reliability of the scores were assessed. In Papers III and IV, questions on prosthetic use were taken from the Q-TFA. In addition, the Walking Habit sub-score was used in Paper III and the separate question on sitting comfort was analysed in Paper IV. Finally, the scores on the Q-TFA were used to investigate the outcome of the treatment with OI prostheses in Paper V. Some additional results from the Q-TFA, not analysed or reported on earlier, are also presented in this thesis.

Procedure

Both questionnaires (SF-36 and Q-TFA) were sent by mail to all the participants in Papers I and II, together with questions relating to demographic characteristics and baseline information. Those who did not answer received two reminders. In the event of uncertainty about a question, the participant and the investigator could contact each other by phone or mail. Participants from phase 2 (Figure 6) were also asked to participate in the test-retest reliability study of the Q-TFA; two weeks after receiving the questionnaires, the Q-TFA was mailed a second time, along with four additional questions on important chang-

es in health condition and condition of the prosthesis to verify a stable situation since the first mailing. In Paper V, the questionnaires were answered at the Department for Prosthetics and Orthotics at Sahlgrenska University Hospital prior to surgery S1 and at the two-year follow-up after surgery S2.

2. Physical assessments

Physiological Cost Index (Paper III)

The Physiological Cost Index (PCI) was introduced by MacGregor to estimate the energy cost in walking (MacGregor 1981). The method is based on the linear relationship between VO_2 and heart rate (HR) (Åstrand and Rodahl 1986; Strath et al. 2000) and requires simply recording of HR at rest and while walking at CWS. For this reason, the method could be suitable for use in a normal clinical setting. The PCI describes the amount of extra heartbeats required per metre walked and is calculated using the formula:

$$PCI = \frac{MeanHR_{at\ work} - MeanHR_{at\ rest}}{Gait\ speed\ (m/min)}$$

The correlation of PCI measurements and VO_2 has been shown to be high in children with amputations and non-disabled (Engsberg et al. 1994) and in six adults with TFA (Chin et al. 1999). Several studies have demonstrated adequate reliability of PCI measurements (Nene 1993; Bailey and Ratcliffe 1995; Graham et al. 2005), but others have revealed that the error of the measurement can be too large (Boyd et al. 1999; Ijzerman and Nene 2002).

Mean PCI values for healthy adults have been reported to be between 0.23 and 0.42 (MacGregor 1981; Nene 1993; Tofts et al. 1998; Graham et al. 2005). PCI values have also been reported for groups of patients with different locomotion disorders (Ijzerman et al. 1999; Taylor et al. 1999; Avramidis et al. 2003; Kavlak et al. 2003), but, for persons walking with an artificial limb, the number of reports are sparse (Herbert et al. 1994; Hachisuka et al. 1999).

Figure 8. Performance of the PCI test with the tester walking behind the patient. For details: see text.

Procedure

In this thesis, the PCI was assessed by five minutes of continuous indoor walking at CWS. The participant had an HR monitor attached around the chest and the receiver was attached between the shoulders with a safety pin on the clothes. Before registering HR at rest, the participant was seated in silence for about five minutes. The resting HR was then recorded each minute for the following five minutes. Prior to the walking part of the test, a short distance was walked in order to warm up. Walking was then performed on a 90 m long level indoor floor track, marked every 2.5 m, with the shape of a long figure of eight. Individuals with TFA were asked to use the walking aid they would normally use for support if walking continuously for a few hundred metres. Walking was carried out for five minutes with the tester walking behind to record the HR at work every 30 seconds (Figure 8). A stopwatch was used for all time-keeping and the investigator recorded HR and the distance walked (to the nearest metre) on a protocol. All the participants were instructed to avoid the intake of tobacco, coffee/tea or a large meal at least two hours prior to the test.

Hip Range of Motion (Paper IV)

For examinations of joint motion, the use of a standardised protocol is recommended (Lea and Gerhardt 1995) and it should be documented whether the assessment relates to a passive or active motion (Boone and Azen 1979; Ekstrand et al. 1982; Roaas and Andersson 1982; Roach and Miles 1991; Lea and Gerhardt 1995). The error in measurements of joint motion has been reported to be below 4° when the same tester measures the same movement (Boone and Azen 1979) and comparisons between the motion of the sound limb with the affected side have been shown to be adequate (Boone and Azen 1979; Roaas and Andersson 1982).

Procedure

In this thesis, active hip range of motion (ROM) was measured bilaterally and recorded according to the method described by the American Academy for Orthopaedic Surgeons (AAOS 1965). One trained physiotherapist from Sweden and one from the UK performed the measurements using the same standardised protocol. A goniometer with long lever arms was used and aligned as described by Norkin and White (Norkin and White 2003). The values were recorded to the nearest five degrees in concordance with earlier studies (Roaas and Andersson 1982; Roach and Miles 1991). All assessments were performed on a firm treatment table. The affected limb was first measured when wearing the prosthesis and then without wearing it. Hip flexion, extension, abduction and adduction were investigated in the supine position. Flexion was measured with the examined knee flexed and the contralateral limb extended on the table. For extension, the participant was positioned diagonally on the edge of the table with the examined limb placed over the edge and was asked to take a firm grip around the flexed contralateral knee to minimise the lordosis of the spine, i.e. in the Thomas Test position. Abduction and adduction were measured with the knee extended. For adduction, the contralateral leg was positioned in some hip and knee flexion to allow full motion. Rotation was measured when seated, with the whole femur supported by the table. Rotation was not measured when not wearing the artificial limb.

3. Measurement properties

The adequate properties of a measurement tool are based on evidence that the tool is substantially free from errors, that it measures what it is supposed to measure and that it is able to detect differences between groups or within individuals after an intervention. These basic instrument properties are known as reliability, validity, sensitivity to change and responsiveness.

Reliability

The term "reliability" relates to the degree of error that is inherent in a measurement, e.g. within the instrument itself, between different observers or testers or within the same observer or tester using the instrument (Streiner and Norman 1995; Domholdt 2005). There are two different components of reliability; absolute and relative reliability (Finch 2002; Domholdt 2005). Absolute reliability specifies "the extent to which a score varies on repeated measures" (Domholdt 2005), while relative reliability relates to the description of "the measure's ability to distinguish among clients" (Finch 2002) and exists when the individual measurement position within a group is maintained on repeated tests (Domholdt 2005). Another aspect of reliability is the internal consistency which relates to the homogeneity within a multi-item scale (Streiner and Norman 1995; Fayers and David 2000). In this thesis, reliability analyses of the Q-TFA have been performed for absolute and relative reliability using a test-retest procedure as well as analyses of the internal consistency (Paper II).

Validity

Measurement validity relates to the ability of the tool to measure what it is supposed to measure, its meaningfulness and utility (Domholdt 2005). The evaluation of validity is an ongoing process in which evidence is collected over time to support the usefulness of a tool. There are several different aspects of validity and the terminology that is used is complex. Most commonly, the concept has been divided into three main topics; content validity, criterion validity and construct validity (Streiner and Norman 1995; Fayers and David 2000; Kocher and Zurakowski 2004). The term "content validity" implies that "the measure is composed of a comprehensive sample of items that completely assess the domain of interest" (Finch 2002), criterion validity relates to the extent to which it presents results that are consistent with a gold standard, such as another well-established tool, and construct validity means providing results in line with hypothesised theories (Fayers and David 2000). However, several more terms are used for different aspects of validity and the interpretations differ in the literature (Streiner and Norman 1995; Fayers and David 2000; Finch 2002; de Vet et al. 2003; Domholdt 2005). It has even been stated that "one of the most difficult aspects of validity testing is the terminology" (Streiner and Norman 1995).

In Paper II, the process of validating the Q-TFA is started. The content validity is discussed in terms of "clinical sensibility" and "face validity" to describe the relevance of its content, while the criterion validity is assessed through analyses of associations between scales on the SF-36 and scores on the Q-TFA.

Sensitivity and responsiveness

The terms "sensitivity to change" and "responsiveness" have often been used interchangeably and reflect the ability of a measure to detect changes (Streiner and Norman 1995). Fayers and David (2000) distinguished

the two by describing sensitivity as the ability of a tool to detect differences between different groups and responsiveness as the ability to detect changes within individuals after an intervention or treatment. Responsiveness has also been described as focusing on the ability of a measure to detect small and clinically important differences (Finch 2002; Jackowski and Guyatt 2003) and this ability depends on the reliability and the validity of the measure (Domholdt 2005).

To be able to capture changes, the measurement scale must have scope for improvements and deteriorations at its upper and lower end. If an instrument is not sufficiently able to register an improvement, it is said to have a "ceiling effect" and the opposite, when a decline cannot be recorded, is termed "floor effect" (Domholdt 2005).

In Paper II, floor and ceiling effects are reported for the Q-TFA and, in Paper V, the responsiveness of the tool is discussed.

Statistical analyses

Throughout the thesis, descriptive statistics have been used and analyses of differences have been performed using non-parametric statistical methods. All the tests are two-tailed and the significance level was set at $p<0.05$ in all the analyses, apart from those of hip ROM in Paper IV, for which the significance level was set at $p<0.01$. An overview of the statistical methods used for each paper is presented in Table 3.

In Paper II, the absolute test-retest reliability was determined by descriptive statistics for each occasion and the differences between them, calculations of intra-individual SD and the measurement error (Bland and Altman 1996). The intra-individual SD was calculated by dividing the within-person variance by the number of participants. The measurement error was calculated using the formula 1.96 x √2 x intra-individual SD. The relative test-retest reliability was assessed with intra-class correlation (ICC), which is a measure of the strength of agreement between repeated measurements, assuming values between 0-1 (Shrout and Fleiss 1979). An ICC of 0.70 or more is recommended for comparisons between groups, while 0.90 is recommended when evaluating individual patients (Fayers and David 2000). The reliability of the scores on the Q-TFA was further analysed according to the internal consistency using Cronbach's alpha and the corrected item total correlation (Streiner and Norman 1995). An alpha coefficient of 0.70 is generally recommended to reflect the relationship between items within a score (Fayers and David 2000). The corrected item total correlation between each item or sub-score and its overall score was calculated using Pearson's product-moment correlation for descriptive purposes (Streiner and Norman 1995). A correlation of $r=0.4$ or higher has been shown to be acceptable (Fayers and David 2000).

In Paper IV, a logistic regression was performed to analyse variables associated with discomfort when sitting. A forward stepwise method was used and variables with a p-value <0.1 were included in the model as possible predictors.

Table 3. Statistical methods used in each paper in the thesis.

METHODS	I	II	III	IV	V
Descriptive statistics					
Mean	X	X	X	X	X
SD		X	X	X	X
Median		X	X	X	
Min-max	X	X	X	X	X
Differences between groups					
Fisher's exact test		X		X	
Chi-square test			X	X	
Fisher's non-parametric permutation test	X				
Mann-Whitney U-test		X	X	X	
Differences within groups					
Wilcoxon's Signed Rank Test		X		X	X
Sign test					X
Reliability					
Intra-individual SD		X			
ICC		X			
Cronbach's alpha		X			
Pearson's product-moment correlation		X			
Association					
Spearman's correlation coefficient		X			
Logistic regression				X	

All the statistical calculations were performed using the SPSS Software for Windows, version 10.0-13.0, manufactured by SPSS Inc. Chicago, Illinois, USA.

Ethical Approval

The participants in this thesis received oral and written information and gave their written informed consent. The studies were approved by the Human Research Ethics Committee at the Sahlgrenska Academy, Göteborg University, Sweden.

Results and comments

In the following presentation, the results from this thesis have been divided into sections based on the content rather than a presentation of one paper at a time. In addition, some supplementary results which have not previously been presented have been added.

1. HRQL as measured by SF-36 (Papers I and V)

The study population with TFA in Paper I had statistically significantly lower scores compared with the healthy controls in all eight dimensions of the SF-36. The largest differences were seen in three of the scales focusing on physical health (PF, RP and BP). The results in Paper V show that, for the 18 patients treated with OI prostheses, the PF, RP, BP scales and the PCS were statistically significantly improved at the two-year follow-up compared with the preoperative situation. The differences between the assessments in the other scales were all non-significant. Scores for the study population with TFA in Papers I and V, together with analyses of differences after treatment with OI prostheses, are reported in Table 4. Mean scores for the SF-36 for the entire study population in Paper I, together with the subset of 15 patients with unilateral TFA using the OI prosthesis at follow-up from Paper V, are illustrated in Figure 9.

Table 4. SF-36 scores for individuals with TFA due to reasons other than PVD (Paper I) and the first 18 patients in the OPRA study (Paper V).

SF-36	Paper I n=97, 93% prosthetic users	Paper V Preop n=18, 83% prosthetic users	Paper V Follow-up n=18, 94% prosthetic users	p-value differences Paper V
PF	46	34	57	0.001
RP	49	38	65	0.004
BP	50	57	71	0.046
GH	65	79	81	0.529
VT	56	64	66	0.420
SF	77	83	86	0.719
RE	71	80	78	0.732
MH	73	77	78	0.722
PCS	-	31	42	0.001
MCS	-	56	52	0.435

COMMENTS

The SF-36 was chosen to measure general aspects of HRQL because of its capacity to describe physical function and changes in health due to injury (Kopjar 1996), the presence of norms for the Swedish population
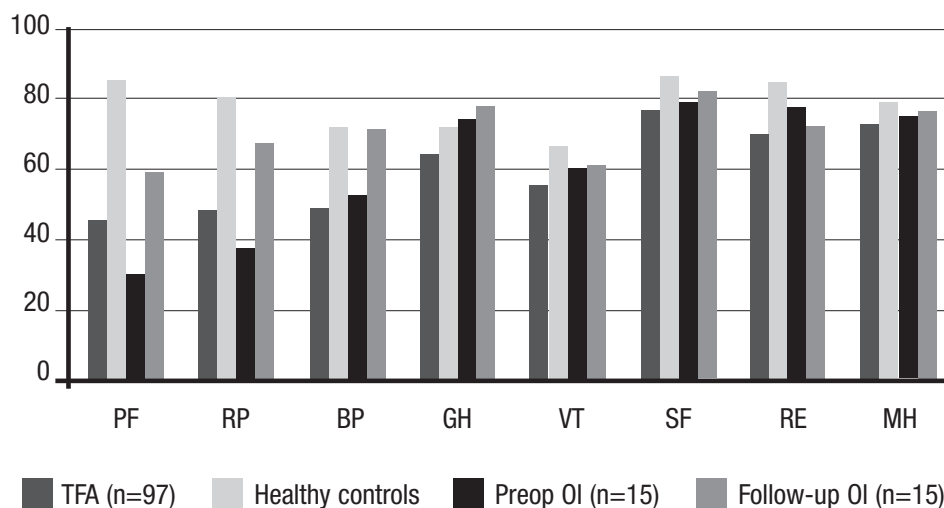
Figure 9. Mean scores on the SF-36 in Papers I and V.
Paper I: Mean scores for 97 individuals with unilateral non-vascular TFA and age- and gender-matched healthy controls taken from the Swedish norm (n= 1067). Paper V: Mean scores preoperatively and at the two-year follow-up for the subset of 15 patients with a unilateral TFA using the OI prosthesis at the two-year follow-up.
For abbreviations on the SF-36, see Figure 7 and the list of abbreviations and definitions.

(Sullivan et al. 1994) and the possibility to compare the results with other investigations and groups of patients. The results for the SF-36 obtained in Paper I are in accordance with those reported elsewhere in the literature for individuals with LLA (Smith et al. 1995; Hart 1999; Legro et al. 1999; Pezzin et al. 2000; Dougherty 2003) with generally lower scores in the scales reflecting physical health and functioning than in those reflecting mental health and emotional well-being. The agreement between the scores presented in Paper I and results more recently reported for US male war veterans with TFA (Dougherty 2003) are illustrated in Figure 10. Furthermore, the SF-36 scores in Paper I are in line with a series of Swedish individuals with traumatic spinal cord injury (Westgren and Levi 1998), which further underlines the impact a TFA has on the general life situation.

The improvements in HRQL reported in Paper V were all in the scales that expose mainly physical function domains. The lower mean values in the preoperative PF and RP scales,

compared with those presented in Paper I, indicate that patients selected for treatment had a poorer preoperative physical situation than most individuals with TFA. This is in accordance with the inclusion criteria for the OPRA study, in which patients experiencing problems with socket prostheses were to be included. At follow-up, the PF and RP scales were well above the scores presented in Paper I (Table 4).
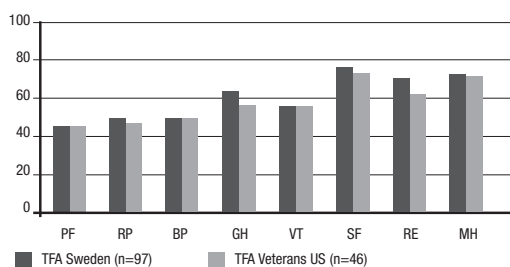

Figure 10. Mean scores on the SF-36 in Paper I and for TFA war veterans (Dougherty (2003)).
For abbreviations on the SF-36, see Figure 7 and the list of abbreviations and definitions.

2. Measurement properties of Q-TFA (Papers II and V)

The distribution of the scores on the Q-TFA from Paper II is presented in Table 5. There was a skewed distribution in the Prosthetic Use score, shown by the difference between the mean and MD value and caused by a small number of individuals with low prosthetic use affecting the mean value.

Validity

The clinical sensibility of the Q-TFA is supported by the development procedures that were used. They included expert opinions, reviews of the literature, semi-structured interviews with experienced prosthetic users and testing of the questionnaire on the target population. Criterion validity is supported by the associations between the scales on the SF-36 and the scores on the Q-TFA (Table 6).

Reliability

The results of the test-retest assessment are presented in Table 7. The overall agreement between tests reveals that the scores on the Q-TFA are reliable. The interpretation of the measurement error reveals that a difference larger than 12 in the Prosthetic Use score, 10 in the Prosthetic Mobility score, 16 in the Problem score and 19 in the Global score is required to claim a real difference, above the noise, on repeated assessments with 95% confidence. Internal consistency, shown by Cronbach's alpha, was 0.80 in the Prosthetic Mobility score, 0.94 in the Problem score and 0.83 in the Global score. The corrected item total correlations ranged from 0.39 to 0.83. Within the Prosthetic Mobility score, Cronbach's alpha was 0.78 in the Walking aid sub-score, 0.86 in the Capability sub-score and 0.85 in the the Walking habit sub-score.

Table 5. Analyses of the distribution and floor and ceiling effects of the scores on the Q-TFA for 156 individuals using socket prostheses.

	Prosthetic Use	Prosthetic Mobility	Problem	Global
Mean	79	67	34	60
MD	90	71	30	58
Min/max	2 / 100	3 / 98	1 / 84	0 / 100
% floor	0	0	0	1
% ceiling	31	0	0	5

Table 6. Analyses of Spearman's correlation coefficient between scores on the SF-36 and Q-TFA.

SF-36	Prosthetic Use	Prosthetic Mobility	Problem	Global
PF	0.36***	0.79***	-0.65***	0.59***
RP	0.26**	0.49***	-0.59***	0.53***
BP	0.24**	0.55***	-0.62***	0.52***
GH	0.27**	0.38***	-0.48***	0.50***
VT	0.16 ns	0.20*	-0.43***	0.42***
SF	0.30***	0.44***	-0.61***	0.52***
RE	0.11 ns	0.32***	-0.34***	0.34***
MH	0.23**	0.22**	-0.45***	0.40***
PCS	0.34***	0.70***	-0.68***	0.62***
MCS	0.19 ns	0.10 ns	-0.30***	0.27**

*p<0.05, ** p<0.01, *** p<0.001, ns=non-significant

Table 7. Test-retest reliability of the scores on the Q-TFA when completed on occasions 1 and 2, n=48. Mean (SD)

Score	Occasion 1	Occasion 2	Diff 2-1	p-value	IISD*	Measurement error **	ICC
Prosthetic Use	85.0 (17.5)	86.7 (17.6)	1.7 (5.8)	0.028	4.2	12	0.94
Prosthetic Mobility	70.7 (18.2)	71.0 (19.2)	0.4 (4.9)	0.39	3.5	10	0.97
Problem	28.0 (17.7)	25.4 (17.7)	-2.7 (7.8)	0.026	5.8	16	0.89
Global	62.7 (21.3)	63.4 (19.9)	0.7 (9.7)	0.08	6.8	19	0.89

* IISD=Intra-individual SD ** Measurement error = 1.96 x $\sqrt{2}$ x IISD

Responsiveness

The floor and ceiling effects of the scores are shown in Table 5. The responsiveness of the scores, when changing from a socket to an OI prosthesis, is denoted in Paper V by the fact that the improvement at follow-up was larger than the respective measurement error for each of the four scores. The clinical importance of the improvement is supported by the concurrent improvement shown in the PF scale and PCS on the SF-36.

Using Q-TFA for illustrating individual profiles

The Q-TFA could also be used to illustrate the outcome with an individual profile. Profiles of this kind, preoperative and at the two-year follow-up, for three of the patients following treatment with an OI prosthesis (Paper V) are illustrated in Figure 11.

COMMENTS

Determining clinical sensibility is a matter of qualitative analysis rather than statistical testing. When developing a new questionnaire, the item generation process should include input from specialists from the area of interest, a review of the existing literature and interviews with patients to ensure that the content of the questionnaire covers relevant and important issues (Fayers and David 2000). These requirements were taken into consideration in the development of the Q-TFA.

For criterion validity between abstract constructs, like those in generic HRQL measures, and a new instrument, correlation coefficients ranging from 0.4-0.8 have been stated to be adequate (Streiner and Norman 1995). A very high association indicates that a new instrument is not needed to capture the phenomena of interest. A very low association, on the other hand, indicates that the two instruments do not measure the same construct. Most of the associations between the scores on the SF-36 and Q-TFA were in the desirable range, but the Prosthetic Use score displayed generally weak associations with the scores on the SF-

1. Male born 1976
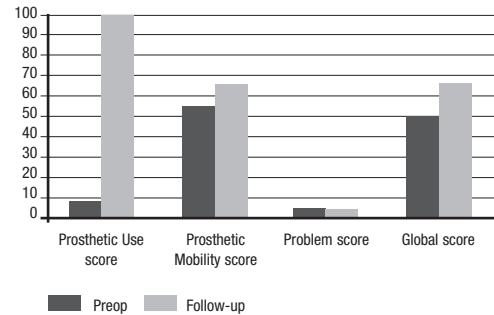
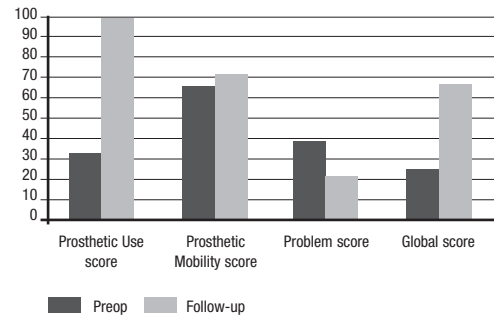
2. Female born 1954
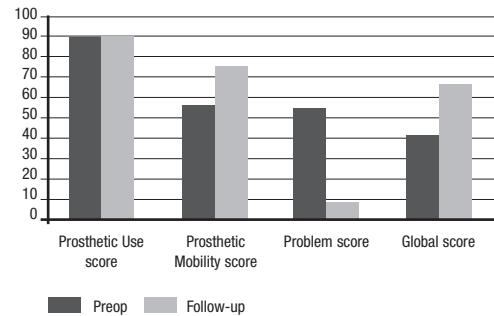
3. Male born 1963

Figure 11. Illustration of Q-TFA scores as reported preoperatively to surgery S1 and at the two-year follow-up for three individual patients in Paper V.

1. *Male born 1976, TFA due to trauma four years before treatment.*
2. *Female born 1954, TFA due to trauma 31 years before treatment.*
3. *Male born 1963, TFA and contralateral foot impairment due to trauma at war 18 years before treatment.*

36 (Table 6). High prosthetic use does not therefore appear to correspond to a high level of physical function as measured in the SF-36. For this reason, presenting the results for prosthetic use is not enough to capture the topic of functioning with a prosthetic limb and should therefore be complemented with the other scores on the Q-TFA. As illustrated in Figure 11, there is a large variation between individuals with regard to the distribution of the scores on the Q-TFA.

For statistical analyses of the reliability of a tool, the use of both the Bland and Altman test and the ICC has been recommended (Rankin and Stokes 1998). In overall terms, the results reveal adequate reliability of the scores on the Q-TFA with satisfactory values on the ICC, small changes in mean values between test and retest and desirable values for the internal consistency. When performing test-retest reliability analyses, the purpose is to study the agreement between two assessment occasions in stable conditions. For this reason, the second mailing of the Q-TFA included a sheet of questions to verify whether any important change in condition had occurred since the first mailing. The 48 individuals in the test-retest part of the study reported no such changes. We cannot, however, claim with any certainty that we really captured a stable situation in all the cases. The clinical experience is that a true stable condition for persons using a prosthetic limb is rare and that changes in the condition of the residual limb could appear frequently, sometimes daily, and this could have influenced the test-retest result. The measurement error was larger in the Problem and Global scores than in the Prosthetic Use and Mobility scores. Questions on prosthetic use and mobility reflect more objective issues than those relating to problems (and their impact on quality of life), as well as those relating to the global situation. A more subjective item could be expected to depend more on the mood of the person answering the questionnaire on that specific day, leading to a larger variation at retest.

The responsiveness of the Q-TFA when changing from a socket to an OI prosthesis is suggested by the data in Paper V. However, further research is needed to provide evidence of the sensitivity and responsiveness of the Q-TFA in other interventions.

3. Prosthetic Use
(Papers I, II and V)

Of the 97 participants in Paper I, daily prosthetic use was reported by 82%, 11% used a prosthesis, but not on a daily basis, and 7% never used a prosthesis. As a result, 93% of those with an established unilateral TFA for reasons other than PVD were prosthetic users. Table 8 shows details of the degree of use of the prosthesis, as well as values for the Prosthetic Use score for the study population in Papers II and V. One patient in Paper V did not use the OI prosthesis at the two-year follow-up due to severe pain and subsequent loosening of the implant. Analyses of the differences in the Prosthetic Use score in Paper V revealed increased prosthetic use (mean increase: 32 points; p=0.013) after treatment with the OI prosthesis.

In Paper I, one third of the prosthetic users reported having been forced to refrain from wearing the prosthesis for a whole day or more during the last three months. The most common reasons for abstaining from wearing the prosthetic limb were skin problems on the residual limb, bad fit of the socket, pain in the residual limb, a broken prosthesis and phantom limb pain.

COMMENTS

Recently, a mean prosthetic use of 11 h/day for individuals with amputations due to trauma or tumour in the upper and lower extremities was reported (Pezzin et al. 2004; Graham et al. 2006). A high degree of prosthetic use is also confirmed among individuals with TFA due to tumour (83% daily use, 57% > 12 h/day) (Hoffman et al. 2002). In conjunction with

Table 8. Details of prosthetic use in Papers II and V.

	Paper II	Paper V Preop	Paper V Follow-up
Prosthetic Use score	n=156*	n=18	n=18
Mean (SD)	79 (25)	51 (42)	83 (27)
MD (min-max)	90 (2-100)	52 (0-100)	100 (0-100)
Of the users: % (n)**	n=156	n=15	n=17
> 15 h/day	31% (49)	27% (4)	53% (9)
13-15 h/day	35% (54)	20% (3)	18% (3)
10-12 h/day	11% (17)	6% (1)	18% (3)
< 10 h/day	12% (19)	27% (4)	5.5% (1)
Not daily	11% (17)	20% (3)	5.5% (1)

* Prosthetic use was a criterion for inclusion.
** Additional results are presented.

the results relating to the use of socket prostheses, Graham et al. (2006) reported that 60% had substantial stump pain and that the pain was statistically significantly associated with hours of prosthetic use. Further, only a weak correlation has been found between hours of use and overall satisfaction with the prosthesis (Pezzin et al. 2004) and, in another study, no relationship was found between prosthetic use and satisfaction with the prosthesis (Gallagher and MacLachlan 2000). The lack of relationship was discussed by the authors and they hypothesised that it might be the case that "irrespective of how the artificial limb may fit or appear, an uncomfortable prosthesis is better than no prosthesis".

Patients using a TFA OI prosthesis reported a very high degree of prosthetic use, with the majority (53%) using it for more than 15 hours each day (Table 8). The high level of prosthetic use is also confirmed by 90% (18/20) using the OI prosthesis for 10 hours daily in Paper IV.

To summarise, a high degree of prosthetic use merely indicates that the individual chooses to use the prosthesis and outcome variables relating to mobility, discomfort or complaints have to be reported along with prosthetic use to give a more complete picture of the situation for the patient.

4. Subjective complaints
(Papers I, II, IV and V)

At least one third of the participants in Paper I reported having had a "moderate or worse problem" that had led to a "moderate or worse" reduction in quality of life in 23 of the 30 questions included in the Problem score on the Q-TFA (Table 9).

Details of the results of the Problem score on the Q-TFA in Papers II and V are presented in Table 10. For 14 of the 18 patients treated with an OI prosthesis, the Problem score could be analysed and the results showed a reduction in problems (mean decrease: 21 points; p=0.002) at follow-up. In addition, separate results, not reported in Papers II and V, are presented in Table 10 to describe the percentage of individuals who report having perceived at least a moderate problem with five selected problem areas: heat/perspiration problems on the residual limb when using the prosthesis, sores/skin irritation on the residual limb when using the prosthesis, back pain, phantom limb pain and discomfort sitting when using the prosthesis.

Table 9. Percentage of individuals with TFA socket prostheses in Paper I who report having had a moderate or worse problem leading to at least a moderate reduction in quality of life during the last four weeks.

%	Problems *
72	Heat/perspiration on the residual limb**
62	Sores/skin irritation on the residual limb
61	Inability to walk in wood and fields
59	Inability to walk quickly
53	Fatigue of the residual limb while walking
52	Being troubled by the way of walking (limping)
51	Pain in the residual limb while standing and walking
48	Phantom limb pain
47	Difficulty feeling the surface one is standing/walking on
47	Difficulty using public transport
47	Back pain
46	Pain in the other leg
44	The prosthesis making it uncomfortable to sit down
44	The prosthesis causing increased wear on clothes
40	Being with other people without wearing a prosthesis
39	Hands not free when using walking aids
38	Pain from the shoulders
38	Being forced to refrain from using the prosthesis
37	Being troubled by the prosthesis feeling heavy
36	Pain in the residual limb when not wearing the prosthesis
34	Not relying on the prosthesis being securely fastened
34	The appearance of the prosthesis
33	Difficulty directing and keeping control of the prosthesis

* 23 of 30 problems from Paper I ** Question relates to last summer.

Sitting comfort

Problems associated with uncomfortable sitting with the socket prosthesis were reported by 44% in Papers I and IV separately. The results from Paper IV also revealed that uncomfortable sitting is more frequently reported among those with less than 90° of active hip flexion motion than those with 90° or more (69% vs 30%, p=0.025). The risk of discomfort when sitting increased more than six times for individuals with less than 90° of hip flexion when wearing their socket prosthesis (odds ratio 6.59, p=0.044, CI 1.48 – 29.60). No difference in

comfort was shown among those individuals with a QL or IC socket (p=1.0).

Discomfort when sitting was reported by 5% of individuals with an OI prosthesis in Paper IV. The percentage reporting discomfort sitting in Paper V decreased from 80% with the socket prosthesis to 12% with the OI prosthesis (Table 10).

COMMENTS

The large number of perceived problems, including bothersome pain, among individuals with LLA is confirmed in several more recent investigations (Ehde et al. 2001; Pezzin et al. 2004; Ephraim et al. 2005; Kulkarni et al. 2005). Good comfort while using a prosthetic limb is an issue not only while standing and walking but also while sitting (Legro et al. 1999). The comfort of the prosthesis has also been shown to be the most important amputation-related factor according to the successful job reintegration of people with LLA (Schoppen et al. 2001). Our results revealed that close to 50% had had back pain and pain in the contralateral limb, reducing their quality of life. Recent publications indicate an even higher incidence of back pain problems, with

81% of those with a traumatic TFA suffering from low back pain (Kulkarni et al. 2005) and a prevalence of 70% among men and 84% among women with TFA (Stam et al. 2004). Another recent publication has reported that individuals with TFA are more than three times as likely as healthy controls to develop pain in the remaining knee (Norvell et al. 2005).

When it comes to phantom limb pain, our findings are in line with a recent publication in which 46% reported having phantom limb pain at least a few times every month and 45% reported the impediment of the pain to be moderate or worse (Borsje et al. 2004). Further, HRQL has been shown to be lower for those with phantom limb pain (van der Schans et al. 2002). The same kind of relationship between HRQL and phantom limb pain could well be present in the population reported on in this thesis, but this has not been investigated.

For patients treated with an OI prosthesis in Paper V, the number of problems affecting quality of life, as reported in the Problem score on the Q-TFA, was significantly reduced at follow-up. One interesting finding is the fact that the increased use of the bone-anchored prosthesis was not accompanied by the percep-

Table 10. Details of the Problem score on the Q-TFA and the percentage of participants reporting a selection of common problems.

	Paper II	Paper V Preop	Paper V Follow-up
Problem score	n=156	n=14	n=14
Mean (SD)	34 (20)	39 (18)	18 (11)
MD (min-max)	30 (1-84)	41 (5-63)	18 (4-39)
Number with problems*, **:			
Heat/perspiration	82%	87% (13/15)	18% (3/17)
Sores/skin irritation	71%	53% (8/15)	6% (1/17)
Back pain	55%	44% (8/18)	39% (7/18)
Phantom limb pain	57%	44% (8/18)	44% (8/18)
Discomfort when sitting	55%	80% (12/15)	12% (2/17)

* *Number reporting having had at least a moderate problem during the last four weeks. Heat and perspiration problems relate to last summer.*
** *Additional results are reported.*

tion of more problems, as illustrated in Tables 8 and 10 and Figure 11. The rate of phantom limb pain problems remained the same, however, and the percentage of individuals reporting back pain problems was not notably lower for the patients in the OPRA study (Table 10). In contrast, problems with heat/perspiration, sores/skin irritation and discomfort sitting when using the prosthesis showed a large decrease. These three perceived complaints all originate from the socket. In the future, it will be interesting to analyse several more detailed results on a larger group of patients treated with OI prostheses, to evaluate which kind of problems can be solved or reduced with a bone-anchored prosthetic limb.

5. Prosthetic mobility, walking performance and PCI (Papers I, II, III and V)

Eighty-four per cent in Paper I did not utilise any walking aid for support while walking at home, while 40% normally used an aid while walking outdoors. Preoperatively, 64% of the unilateral TFA prosthetic users in Paper V walked unaided at home, while 67% walked unaided at follow-up. For outdoor walking, the figures were 29% and 20% respectively.

When it came to non-stopping walking distances outdoors, 35% in Paper I and 32% in Paper III stated that they had accomplished a distance of 500 m on more occasions than once a week during the last three months. Among the healthy controls, 82% reported the same accomplishment (Paper III).

The results for the Prosthetic Mobility score and the Walking habit sub-score on the Q-TFA from Papers II, III and V are presented in Table 11. For the patients treated with an OI prosthesis in Paper V, both scores had improved to a statistically significant degree at follow-up (mean improvement: 17 points; p=0.001 and 18 points; p=0.013, respectively).

The estimated energy cost while walking, as measured by the PCI (Paper III), showed that individuals with TFA had a 77% higher energy cost than the healthy controls. The mean PCI value was 0.55 ± 0.19 in the TFA group and 0.31 ± 0.09 for the controls (p<0.001). The CWS was 62 m/min ± 12.6 and 90 m/min ± 12.8 respectively (p<0.001). There was a statistically significant difference in CWS between those walking with or without the support of a walking aid in the test (51 m/min vs 67 m/min, p<0.001) but not for the PCI (0.58 vs 0.53, p=0.705).

COMMENTS

Capability and performance are two different perspectives of mobility reflecting issues of "can do" in the first and "do do" in the second (Young et al. 1996; Bussmann and Stam 1998; Cohen and Marino 2000). The Mobility score on the Q-TFA is intended to reflect both perspectives in which the normal use of walking aids (Walking aid sub-score) and walking distances performed outdoors (Walking habit sub-score) reflect performance and the Capability sub-score reflects capability. The ability to walk at least 600 m has been shown to be required in order to be regarded as "an independent community ambulatory" in the USA (Lerner-Frankiel et al. 1986). In a more recent study, the ability to walk at least 500 m was stated to be required to facilitate adequate independence in daily life for individuals with LLA (Geertzen et al. 2005). Only about one third of our series reported that they had walked 500 m outdoors, without stopping, on more occasions than once a week during the last three months. Using a step activity monitor, it has recently been shown that the majority of activity sessions for persons using TTA or TFA prostheses were short periods, of one to two minutes and only about once a day was walking that lasted for ~10 minutes performed (Klute et al. 2006). These results, together with those from other investigations presented in Table 1, support our findings that longer walking distances are rarely performed among non-elderly individuals with TFA prostheses.

Table 11. Details of the Prosthetic Mobility score and the Walking habit sub-score.

	Paper II	Paper III	Paper V Preop	Paper V Follow-up
	n=156	n=41	n=14	n=14
Prosthetic Mobility score	67 (21) 71 (3-98)	Not reported	56 (15) 56 (19-80)	74 (10) 74 (53-87)
Walking habit sub-score	Not reported	48 (19) 50 (10-85)	39 (18) 38 (0-65)	57 (17) 63 (30-85)

Mean (SD), MD (min-max)

Another performance-based measure is CWS, which is considered to be a reliable measure highly correlated to other aspects of walking (Witte and Carlsson 1997; Bernardi et al. 1999; Horemans et al. 2004; Flansbjer et al. 2005). Our mean CWS value for persons with TFA (62 m/min, Paper III) is in line with previous results (Waters et al. 1976; Harris et al. 1990; Boonstra et al. 1993) and close to the speed of 57 m/min that has been reported to be the most efficient speed for a group of healthy males walking with TFA prostheses on a treadmill (Jaegers et al. 1993). However, it is considerably lower than the CWS of the control group (90 m/min), as well as the velocity needed to cross a signal-controlled pedestrian traffic intersection (79-84 m/min) (Lundgren-Lindquist et al. 1983; Lerner-Frankiel et al. 1986). One effort during prosthetic rehabilitation is to achieve efficient walking with a more normal walking speed. By taking part in a specific gait re-education training programme, a small group of persons using TFA prostheses (n=9) were shown to increase their free walking speed from 57 to 84 m/min (Sjodahl et al. 2002). This is a very interesting finding since it indicates that it is possible for this group of individuals to achieve a CWS within the normal range.

The speed of walking should be considered in relation to the effort required. An increased energy cost of 40-67% compared with normal has been shown for non-vascular cases walking at CWS with TFA prostheses by measuring the direct VO_2 uptake (Waters et al. 1976; Huang et al. 1979; Boonstra et al. 1994; Schmalz et al. 2002). In most of these studies, the included cases were selected as those with a good socket fit, with no stump swelling or sores, and those with the ability to perform the test without the support of a walking aid. Further, the majority of cases were younger males. All these circumstances may explain the larger increase in energy cost (77%) shown in Paper III. Another explanation could be the PCI test itself, which is an estimate of the energy cost (MacGregor 1981) and not the golden standard for the assessment. For the PCI, the only equipment that is needed is a standard heart rate monitor, a stopwatch and a measured floor track where continuous walking can be carried out, making this assessment very suitable for most clinical settings. Our mean PCI value for the TFA group (0.55) is comparable to those previously reported for 12 TFA cases for comparisons of two different socket designs (mean PCI 0.48 and 0.55 respectively) (Hachisuka et al. 1999). The PCI for our healthy controls averaged 0.31 (0.17-0.49), which is comparable to the values reported by MacGregor for healthy individuals (mean PCI 0.31, 0.11-0.51) (MacGregor 1981) but somewhat lower than those reported by Nene (mean PCI 0.36, 0.2–0.55) (Nene 1993). Further research to investigate the relationship between prosthetic walking speed, energy cost, use of walking aids and specific training would be of major interest.

6. Global score and overall situation (Papers I, II and V)

The results for the Global score from Papers II and V are presented in Table 12. The Global score was statistically significantly improved for the patients treated with OI prostheses (mean improvement: 36 points; p=0.002) as compared to the preoperative situation. The results for the single question concerning "the perception of the current overall situation as an amputee" for the participants in Papers I and V are reported in Figure 12. The improvement in the overall situation for patients treated with OI prostheses in Paper V was statistically significant (p=0.039).

siderable number feel that they have a poor or extremely poor situation. The results in Table 12 indicate that the patients included in the OPRA study rated a lower global amputation situation preoperatively and that, at follow-up, they regarded their situation as better than the average for those individuals with a socket prosthesis. A similar finding is illustrated in Figure 12, in which those who are not prosthetic users are also included. For the one patient with loosening of the implant in Paper V, the overall situation had deteriorated at follow-up and was rated as poor.

Table 12. Details of the Global score on the Q-TFA.

	Paper II n=156	Paper V Preop n=14	Paper V Follow-up n=14
Global score	60 (21) 58 (0-100)	36 (14) 33 (17-58)	72 (17) 67 (33-100)

Mean (SD), MD (min-max)
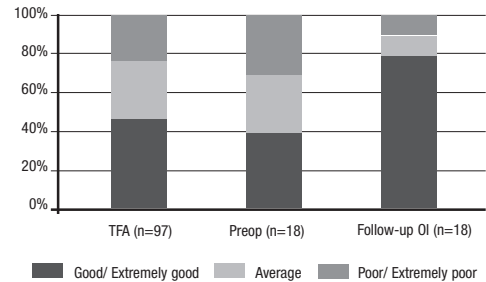
Figure 12. Illustration of the perception of the overall situation as reported in Papers I and V.

COMMENTS

Different ratings for the overall status and/or satisfaction with prostheses, for patients with LLA, have previously been reported (Harris et al. 1990; Walker et al. 1994; Matsen et al. 2000; Refaat et al. 2002; Pezzin et al. 2004), but due to differences in the wording of the questions and the different study samples, the findings are difficult to compare. One limitation of the Global score on the Q-TFA is that prosthetic use is a requirement for the score. For this reason, the single question on the overall amputation situation within the score is also accounted for. The results in Table 12 and Figure 12 demonstrate that the overall amputation situation for many people is rated as good or extremely good but also that a con-

7. Hip range of motion (Paper IV)

The results for active hip motion for the group of patients with socket prostheses (S group) and OI prostheses (OI group) from Paper III are presented in Table 13. The range of normal values was taken from three different studies (AAOS 1965; Boone and Azen 1979; Roaas and Andersson 1982).

Table 13. Active hip motion when wearing and not wearing prostheses, comparisons within and between groups. Mean (min – max)

Motion (normal values)	S GROUP (n=43)				OI GROUP (n=20)				Group diff*
	Without Prosth.	With Prosth.	Diff	p-value	Without Prosth.	With Prosth.	Diff	p-value	p-value
Flexion (113-121)	106 90 – 120	91 75 – 105	-15 -35 – 0	<0.001	113 95 – 135	115 95 –130	2 -10 – 10	0.099	<0.001
Extension (10-28)	15 -10 – 30	6 -25 – 20	-8 -30 – 0	<0.001	9 -15 – 25	12 -5 – 20	2 -5 – 15	0.058	<0.001
ROM flex-ext	121 90 – 150	97 75 – 125	-24 -55 – 0	<0.001	123 95 – 145	127 105 – 150	4 -10 – 20	0.017	<0.001
Abduction (39-48)	31 20 – 45	27 15 – 40	-4 -15 – 5	<0.001	28 15 – 40	29 20 – 40	1 -5 – 5	0.206	<0.001
Adduction (26-31)	20 5 – 30	17 5 – 25	-3 -15 – 5	<0.001	20 15 – 30	19 15 – 25	-1 -10 – 5	0.527	0.032
ROM abd-add	52 35 – 70	45 25 – 60	-7 -25 – 5	<0.001	48 35 – 60	48 35 – 55	1 -5 – 10	0.614	<0.001
Int rotation (33-45)	-	0 0 – 5	-	-	-	24 15 – 40	-	-	<0.001
Ext rotation (33-45)	-	0 0	-	-	-	24 10 – 35	-	-	<0.001
ROM rotation	-	0 0 – 5	-	-		48 35 – 60	-	-	<0.001

* Between-group analyses are based on the analyses of the within-group difference except for measurements of hip rotation where the difference in motion with prostheses has been analysed.

Results within each group

The mean motion was reduced in all the measured directions when using socket prostheses (Table 13). In ROM flexion-extension, the socket reduced motion by a mean of 24°. Thirty-seven per cent (16/43) had less than 90° of hip flexion motion when wearing the socket prosthesis. Within the OI group, no restricted hip motion when using the prosthesis was shown and no individual had less than 90° of hip flexion.

Results between groups

There were no differences in motion between the S group and OI group on the contralateral hip. On the affected side, when not wearing prostheses, the S group had less motion in flexion (-7°, p=0.007) and larger motion in extension (5°, p=0.019) than the OI group. When wearing the prosthesis, the OI group had larger hip motion in all directions compared with the S group (Table 13) and the differences remained when adjusting for the baseline differences when not wearing the prosthesis.

COMMENTS

Although there is general clinical experience that TFA socket prostheses tend to limit hip joint motion, we were not able to find any study that had actually investigated this phenomenon. However, it has recently been shown that the ischium-socket interface limits hip extension when walking (Rabuffetti et al. 2005).

To conduct the study of hip joint motion when wearing TFA prostheses, we had to adapt the standardised protocols for hip joint measurements to some degree (AAOS 1965; Lea and Gerhardt 1995). In our protocol, active motion was measured, since the force of a passive motion could hurt the individual due to the pressure from the brim of the socket or cause the loosening of its suspension. Moreover, we measured hip extension in the supine position instead of the prone position. Lying prone and performing an active hip extension when wearing TFA prostheses could not be considered either clinically relevant or comfortable. Moreover, measurement of hip extension in a supine position has been recommended when a hip flexion contracture could be assumed (Ekstrand et al. 1982; Greene and Heckman 1994).

The measurement error for joint motion, reported in the literature, varies between the different movements that are measured and the position of the subject (Boone et al. 1978; Ekstrand et al. 1982; Bierma-Zeinstra et al. 1998). So, when comparing our values with those reported elsewhere, the measurement protocol we used should be noted.

The findings demonstrate that individuals wearing a TFA socket prosthesis to a high degree have less hip flexion motion on the affected limb than those wearing an OI prosthesis. The S group also had reduced motion compared with that of healthy persons reported elsewhere in the literature (Table 13). No single person, of those with a socket prosthesis, had the amount of hip flexion motion (112-129°) that has been described as necessary for tying a shoe, getting up and down from a chair or picking up an object from the floor (Johnston and Smidt 1970).

The measurement protocol for hip ROM used in this thesis could be adapted in future research to investigate whether new TFA-socket designs could fulfil the desire to normalise hip ROM when using the prosthesis.

General Discussion

This thesis provides evaluation of non-elderly individuals with an established locomotion disability. The basic inclusion criteria for patients were having a unilateral TFA for at least two years and being between 20 and 70 years of age. The age limit of 70 years at inclusion was set to exclude most cases with amputations due to PVD but also to harmonise with the inclusion criteria for the OPRA study. Age over 70 years at the amputation has recently been shown to predict poorer functional outcome (Taylor et al. 2005) and, in our study population, no individual aged 68 years and above at the time of the amputation was included. The interval of two years since the amputation has previously been recommended for assessments of established prosthetic users, since the situation for the individual cannot be assumed to be stable during the first postoperative year (Smith et al. 1995).

There is currently no national registration of persons with an LLA in Sweden and potential participants were therefore identified through associations for amputees and selected orthopaedic workshops or rehabilitation units. In order to assess whether the study group in Paper I was representative, an analysis of the non-respondents was performed. Fifteen of the 43 non-participants (13 men, 2 women) who fulfilled the inclusion criteria but declined participation were analysed. Of these 43, ten individuals answered the overall question with a response rate harmonising with that of the study group (good/extremely good 50% vs. 46%, average 30% vs. 29% and poor/extremely poor 20% vs. 25%). The way in which participants with socket prostheses were recruited for this thesis might still be a source of error since individuals without membership of an amputee association and infrequent contact with an orthopaedic workshop may not have been reached at all. On the other hand, this could include both persons with good or poor quality of life and those with excellent or poor prosthetic function. Due to the limited number of persons with non-vascular TFA in Sweden, it is reasonable to assume that a sufficient number was reached for the investigations in this thesis. The small number of non-vascular TFA cases performed every year in Sweden is confirmed by figures for 2004 derived from the Swedish National Board of Health and Welfare. In that year, fewer than 3% of all major LLA that were registered were at the transfemoral level and were performed because of causes other than PVD. In addition, fewer than a quarter of the cases were females (the Swedish National Board of Health and Welfare, personal communication). It should, however, not be forgotten that there is also another group of individuals with LLA in Sweden, which is not included in these figures, namely refugees with traumatic limb loss from war in their home countries. In the global perspective, this group could be expected to grow due to the situation of ongoing wars and conflicts in different parts of the world.

SF-36

The SF-36 was originally designed for a healthy population and there has been some criticism regarding the wording of some of the questions when the tool is used on persons with locomotion disabilities (Fayers and David 2000; Meyers and Andresen 2000). For instance, it has been suggested that the word "walk" should be replaced by the word "go" to make the questions in the PF scale more meaningful for persons that do not walk but move around using a wheelchair, for example (Meyers and Andresen 2000). Moreover, for a person with an established amputation, answering a question about "work and activities in relation to the normal situation" could be difficult,

since the normal situation for a long time has been a life without the limb. Another criticism of the SF-36 has related to the two role functioning scales (the RP and RE scales), which have been shown to have a larger standard deviation and lower reliability than the other scales (Beaton et al. 1997; Andresen and Meyers 2000). Currently, a revised version of the questionnaire, the SF-36 Version 2.0, is available. Recently, improved measurement properties were shown for the role functioning scales in the Swedish SF-36 Version 2.0 (Taft et al. 2004). When setting up a new study, the SF-36 version 2.0 should be used to increase the reliability and sensitivity of the assessment.

Adjacent to the SF-36, there are also other tools that could be used for measurements of general HRQL. The most well known are the Sickness Impact Profile (Bergner et al. 1981), the Nottingham Health Profile (Hunt et al. 1981) and the Patient Generated Index (Ruta et al. 1994). All of them have been used for evaluations of health in individuals with LLA (Pell et al. 1993; Fusetti et al. 2001; Hoogendoorn and van der Werken 2001; Bosse et al. 2002; Callaghan and Condie 2003; Demet et al. 2003; MacKenzie et al. 2004; Whyte and Carroll 2004). One common shortcoming of all these tools is their limited utility for health economic evaluation analyses. There is one general HRQL measure that can be used for such analyses, namely the EuroQol (Brooks 1996), which generates a single health index. So far, however, a very limited amount of research using the EuroQol on individuals with LLA has been published (Ragnarson Tennvall and Apelqvist 2000) and it has not been possible to find any study using the instrument on non-elderly individuals with LLA.

Psychometrics and clinimetrics

The development of self-report tools and the assessment of their measurement properties can take two somewhat different perspectives; a psychometric approach or a clinimetric approach (Feinstein 1987; Fayers and David 2000). In the psychometric approach, a single construct is measured with multiple items and the internal consistency of the scale is based on statistical analyses of the relationships between the items. In the clinimetric approach, the aim is to measure "clinical phenomena that are generally believed to comprise several unrelated patient characteristics or attributes" (Marx et al. 1999). The emphasis in clinimetrics is more directed towards clinical sensibility, a comprehensive coverage of items and items that patients rate as important and experience frequently (Fayers and David 2000). In clinimetrics, high internal consistency is less relevant and the reliability relies on good agreement between test and retest.

In the development of the Q-TFA, we were influenced by both these approaches and it has been suggested that the two approaches could be complementary rather than conflicting strategies in the development of health measurement scales (Marx et al. 1999). This viewpoint was recently supported (de Vet et al. 2003; Fava and Belaise 2005). Consequently, in concordance with the clinimetric approach (Feinstein 1987; Fayers and David 2000), we included items that could be expected to be important to the target population, regardless of their influence on the consistency of each score. The importance of the items included in the Q-TFA was supported by the large number of participants reporting that they had perceived each specific problem and that every response alternative was chosen. The adequate levels of internal consistency that were found for the scores on the Q-TFA in Paper II were thus an additional benefit of its measurement properties.

Self-report measures targeted at individuals with LLA

Over the years, various measures have been used to assess individuals with LLA. A useful compilation of the tools for outcome measurements in LLA rehabilitation was presented by Gauthier-Gagnon and Grisé at the 10th World Congress of the International Society for

Prosthetics and Orthotics in 2001 (Gauthier-Gagnon and Grisé 2001). In this handbook, the tools are categorised into terms of classification scales, generic and specific HRQL tools and generic and specific functional health status tools and, for each one, the intended use and measurement properties are provided. Since then, a number of new reports on targeted self-report instruments for individuals with LLA have been published. Table 14 gives a compilation of self-report outcome tools for which the measurement properties have been examined. As illustrated in Table 14, the majo-

rity of the more recent instruments include examinations of HRQL and/or perceptions of satisfaction with the prosthesis (Legro et al. 1998; Bilodeau et al. 1999; Gallagher and MacLachlan 2000; Panesar et al. 2001; Callaghan and Condie 2003; Heinemann et al. 2003; Gallagher and Maclachlan 2004; Hagberg et al. 2004). Other instruments, like the Locomotor Capabilities Index (LCI) (Gauthier-Gagnon et al. 1998), the Houghton scale (Houghton et al. 1989), the Amputee Activity Score (AAS) (Panesar et al. 2001) and the so-called SIGAM mobility grades (Ryall et

Table 14. Self-report outcome measures targeted at individuals with LLA for which measurement properties have been explored.

Authors (year)	Name	Specifics of the tool	Scores	Include HRQL issues
Gauthier-Gagnon and Grisé (1994)	*PPA: Prosthetic Profile of the Amputee	To evaluate factors associated with prosthetic use	-	No
Gauthier-Gagnon et al (1998)	*LCI: Locomotor Capabilities Index (included in the PPA)	To evaluate ambulatory skills with a prosthesis	1	No
Legro et al. (1998)	PEQ: Prosthesis Evaluation Questionnaire	To measure differences in prosthesis function and major life domains	10	Yes
Bilodeau et al. (1998)	SAT PRO: Satisfaction face à la prothèse	To evaluate satisfaction with the prosthesis	1	Yes
Fisher and Hanspal (1998)	AAOL: Attitude to Artificial Limbs Questionnaire	To measure attitudes to the artificial limb	1	Yes
Gallagher and MacLachlan (2000)	*TAPES: Trinity Amputation and Prosthesis Experiences Scales	To assess the adjustment to LLA prostheses	9	Yes
Houghton et al. (1992)	Houghton Scale	To capture prosthetic wearing habits	1	No
Panesar et al. (2001)	AAS: Amputee Activity Score Questionnaire	To look at the level of activity with a prosthetic limb	1	No
Ryall et al. (2003)	SIGAM mobility grades	To describe simple, clinically meaningful functional levels of mobility	1	No
Heinemann et al. (2003)	OPUS: Orthotics and Prosthetic Users Survey	To measure functional status, HRQL and client satisfaction	4	Yes
Callaghan et al. (2003)	PGI: Patient Generated Index adapted for amputees	To capture areas or activities of life affected by the amputation	1	Yes
Hagberg et al. (2004)	*Q-TFA: Questionnaire for persons with TFA	To reflect current prosthetic use, mobility, problems and global health	4	Yes

* *Available in Swedish*

al. 2003), measure only prosthetic use and/or mobility. Even though the Houghton scale, the AAS and the SIGAM mobility grades were first published long ago, their measurement properties were not established until more recently (Miller et al. 2001; Panesar et al. 2001; Devlin et al. 2004). In order to avoid the high ceiling effect of the LCI, a new scaling (LCI-5) was recently introduced (Franchignoni et al. 2004) with improved psychometric properties compared with the standard LCI. The LCI-5 could therefore be a more useful measure for non-elderly individuals with higher prosthetic mobility in future research.

In order to apply a self-report questionnaire, a validated translation to the language in which it is intended to be used is needed. The number of tools to choose from in languages other than English is still unfortunately more limited. For example, only three of the tools described in Table 14, the PPA, the LCI and the TAPES, have been translated from English to Swedish and as yet none of these translations has been published in the literature. The Q-TFA was developed and validated on a Swedish population. To enable the Q-TFA to be used in the OPRA study, it has been translated into English and, at the present time, the English version is being used for English-speaking patients within the study. However, the measurement properties of the English version of the Q-TFA have not been evaluated. Future work is required to translate, adapt and assess the Q-TFA in languages other than Swedish.

To summarise, there is now a fairly large number of available targeted self-report outcome tools that meet the required standards of measurement validity and reliability. Future research comparing these tools with each other would be helpful when it comes to choosing the right combination of measurements for a specific research question.

Sitting comfort and hip ROM

The assessment of discomfort when sitting and using the prosthesis in this thesis was limited to analyses of a single question from the Problem score on the Q-TFA. No further questions on the perception of different aspects of sitting comfort were asked. Not surprisingly, less than 90° of hip flexion motion when wearing the prosthesis is obviously one factor that affects sitting comfort. Contrary to Hachisuka and co-workers (1999), we found no relationship between socket design (QL or IC socket) and discomfort when sitting. Nor could we find any relationship with regard to the socket material that is used. However, the results relating to socket design and material were drawn from small sub-groups. Another possible factor that might be important when it comes to discomfort when sitting is the lack of hip rotation when sitting with a socket prosthesis. With an OI prosthesis, sitting in more normal positions, such as with the legs crossed, is possible.

To date, the issue of comfort when sitting when using prosthetic limbs has attracted very little attention in the literature. Future research should focus more on possible variables related to discomfort when sitting and on finding solutions to improve socket comfort without jeopardising the suspension to the residual limb.

PCI and prosthetic walking performance

There are some limitations to the PCI assessments performed in the present thesis. First, it has been discussed whether it is important or not to obtain steady state conditions at the walking part of the test (Bailey and Ratcliffe 1995). We noticed that steady state was not reached among all our participants walking with TFA prostheses and the same phenomenon has been described among children with severe diplegia (Boyd et al. 1999). However, none of our healthy controls displayed a similar pattern. Second, there is no published reliability test of the PCI in persons with LLA and the reliability of the method has been questioned for individuals with a spinal cord injury (Ijzerman et al. 1999). In the study from which the controls in the healthy group were taken (Paper III), the results show high reliability on repeated tests, with a measurement error of 0.08 (Hagberg et al. 2006).

Recently, the test-retest reliability of the PCI on healthy adults was confirmed, but in the same study the validity of the test was not possible to confirm (Graham et al. 2005). Future studies of the PCI are recommended in order to further investigate its validity, reliability, the importance of achieving steady state and to explore values for the measure for different groups of patients.

There are also a number of other methods for assessing prosthetic walking performance that are of major interest, but they have not been used in the current thesis. The first is the scale of perceived exertion (Borg 1982) that could have been used in combination with the PCI test. This is also an easily performed, low-cost test that is suitable for use in a clinical setting. Second, the two-minute and six-minute walking tests (Brooks et al. 2001; Gailey et al. 2002) are both easy to assess. None of them could, however, be used for analyses of the PCI due to the way in which the instructions are given ("walk as far as you can" vs "walk at your normal self-selected speed"). Third, more convenient, portable equipments are currently available for direct measurements of oxygen consumption (Bowen et al. 1998; Boyd et al. 1999). Due to the cost of such equipment, it is still most accessible within a laboratory or research location. Finally, measurements of prosthetic activity and performance over a period of days could be performed using a step activity monitor (Coleman et al. 1999; van Dam et al. 2001; Bussmann et al. 2004; Klute et al. 2006). In particular, investigations with a step activity monitor to further investigate prospective differences in walking performance after treatment with OI prostheses would be of major interest.

Differences due to gender or amputation cause

Throughout Papers I-V in this thesis, very few analyses of sub-groups of the study populations were made, as statistical analyses of smaller groups have limited value. However, it would be very interesting to shed more light on possible differences in outcome according to gender, since most research on individuals with

LLA has focused on male cases. A poorer functional prosthetic outcome and less satisfaction with the artificial limb for females than males has previously been indicated (Legro et al. 1998; Hermodsson 1999; Pezzin et al. 2004). It has also been shown that female cases rate the importance of various issues relating to prosthetic use more highly than males (Legro et al. 1999) and that females have a higher incidence of low back pain (Stam et al. 2004). Moreover, within the general Swedish population, males report better health than females on all scales of the SF-36 (Sullivan et al. 1994). With the aim of investigating whether there were any differences in the results on the SF-36 and Q-TFA due to gender in this thesis, the study population in Paper II was divided into the 95 males and 48 females with TFA due to causes other than PVD. There were no statistically significant differences between the two groups in terms of mean age, age at the amputation or years since the amputation. However, the reason for amputation differed (p=0.003), with more males with TFA due to trauma (males; 70% trauma, 27% tumour, 3% other; females; 42% trauma, 46% tumour, 12% other). It was found that the female group rated their HRQL lower in three of the SF-36 scores (PF p=0.006, BP p=0.023, VT p=0.002) and the PCS (p=0.013), as illustrated in Figure 13. Moreover, the female cases were found to have a statistically significant lower mean Mobility score on the Q-TFA than the male cases (72 vs 62 score points, p=0.002).

The next question in this context was whether there were any differences in outcome between those with TFA due to tumour or due to trauma. Again the study population from Paper II was divided into two groups; tumour (n=48) and trauma (n=86). There were no statistically significant differences between the groups according to mean age, age at the amputation or years since the amputation, but a difference in gender was found (tumour; 54% males; 46% females, trauma; 77% males, 23% females, p=0.007). The results for the SF-36 are illustrated in Figure 14. The VT score was statistically significantly lower for the tumour
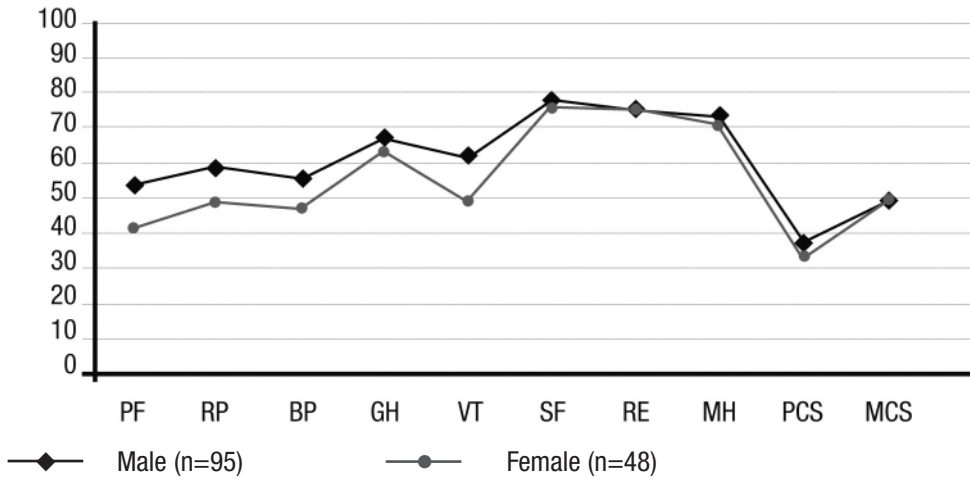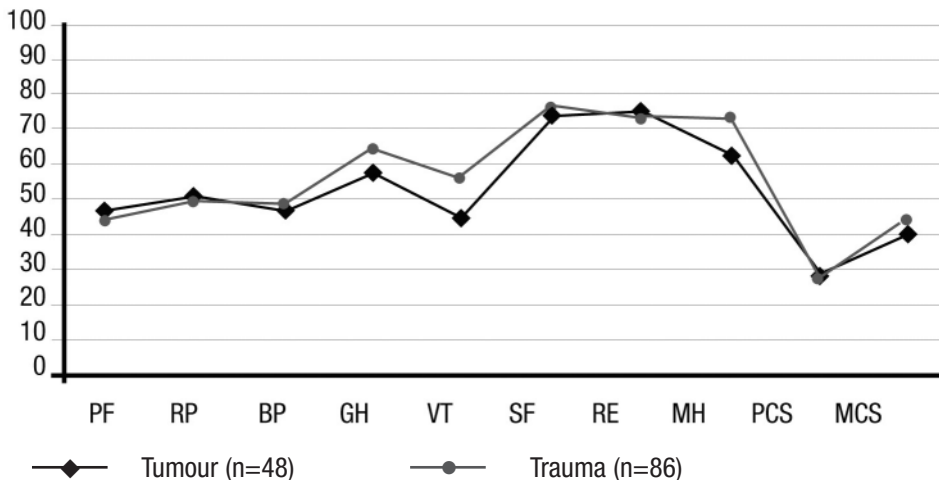
Figure 13. Illustration of mean SF-36 scores in Paper II separated for male and female cases (additional results). For abbreviations on the SF-36, see Figure 7 and the list of abbreviations and definitions.

group as compared to the trauma group (p=0.024). In contrast, the trauma group had a lower mean Prosthetic Mobility score on the Q-TFA than the tumour group (66 vs 73, p=0.04). No other score was shown to be different in statistically significant terms between the groups.

In the above analyses, the finding of the lower VT score on the SF-36 for both females and tumour cases could not be separated due to the higher rate of females in the tumour group and vice versa. The results do, however, indicate that there could be interesting differences due to gender and amputation cause that require more in-depth studies.

Figure 14. Illustration of mean SF-36 scores in Paper II separated for TFA due to tumour or trauma (additional results). For abbreviations on the SF-36, see Figure 7 and the list of abbreviations and definitions.

TFA vs limb-sparing surgery

There is an ongoing debate about the advantages of limb-sparing surgery compared with amputations and several studies support salvage of the limb (Ham et al. 1998; Dagum et al. 1999; Davis et al. 1999; Pardasaney et al. 2006). Davis and co-authors (1999) investigated individuals with LLA due to tumour with a matched group of limb-sparing cases and found increased disability and a higher level of handicap for the LLA group but concluded that the "differences in disability between amputation and limb sparing patients are smaller than anticipated". Several other investigations have, however, failed to show important differences favouring one of the two treatment alternatives (Weddington et al. 1985; Harris et al. 1990; Postma et al. 1992; Hoogendoorn and van der Werken 2001; Bosse et al. 2002; Refaat et al. 2002; Nagarajan et al. 2004).

In some investigations, assessments of HRQL using the SF-36 have been performed and the results could therefore be compared with the study population in this thesis. Figure 15 illustrates scores for the SF-36 reported for four different studies, three for limb-sparing surgery (Davis et al. 1999; Malo et al. 2001; Conroy et al. 2003) and one for the Van Ness Rotationplasty (Veenstra et al. 2000), along with the scores for the 15 unilateral cases successfully treated with an OI prosthesis from Paper V. It is interesting to note that the figures for the patients with OI prostheses are in line with the others. The results presented in Figure 15 should, however, be interpreted with caution, since there are various differences in the study populations. During the coming years, however, treatment with bone-anchored TFA prostheses could be another alternative to limb-sparing surgery in specific cases.
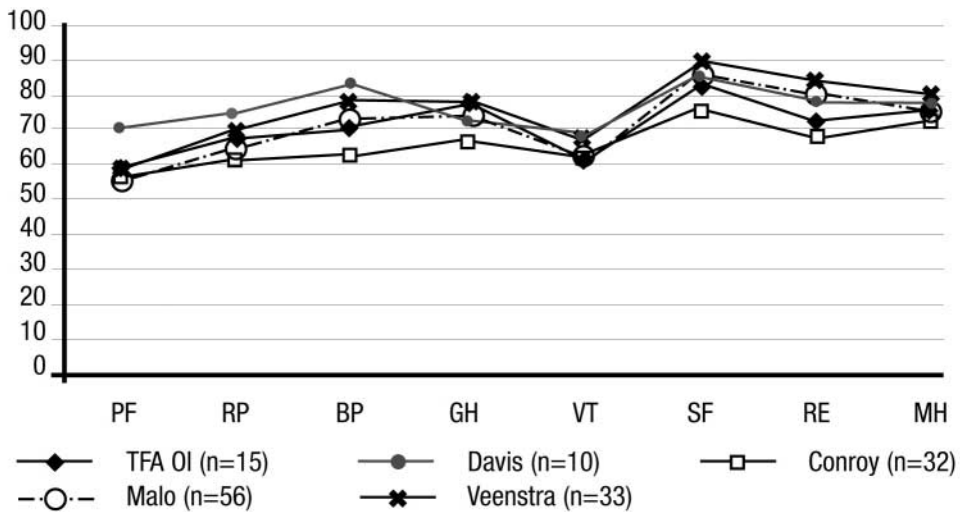
Figure 15. Examples of mean SF-36 scores in other investigations (limb sparing surgery* and Van Ness Rotationplasty**), together with the results in Paper V for patients using a unilateral TFA OI prosthesis
*Davis et al. (1999), Malo et al. (2001), Conroy et al. (2003).
**Veenstra et al. (2000).
For abbreviations on the SF-36, see Figure 7 and the list of abbreviations and definitions.

The OPRA study and bone-anchored prostheses

Treatment with TFA OI prostheses has been performed in Sweden since 1990 and the OPRA study started in 1999. Another surgical method for bone anchorage of TFA prostheses has been presented from Germany (Staubach and Grundei 2001; Aschoff and Grundei 2004), but no prospective results from that procedure have as yet been reported. There was a clinical development period of almost 10 years before the OPRA study started; this was critical in order to standardise the procedure of the treatment. The selection of patients is crucial and for this reason the inclusion of patients in the OPRA study has been prolonged. The prospective results relating to HRQL improvements are very encouraging and there is international interest in learning more about this treatment which justifies the current report, even if the study is still ongoing. Due to earlier attempts with poor results (Mooney et al. 1971; Mooney et al. 1977), there is also scepticism regarding the treatment, e.g. due to the potential risk of infections and loosening of the implant.

One limitation of Paper V is the modest number of patients that have been followed for two years, which is a fairly short period in this context. However, this is the first prospective study reporting on patients with a TFA OI prosthesis. We continue to follow all the patients included in the OPRA protocol, with the aim of reporting the entire protocol, as well as the long-term results, in a large group of patients over the coming years. At the moment (August 2006), 38 patients and 41 limbs have been included in the OPRA study in Sweden. As reported, 18 patients have currently passed the two-year follow-up (Paper V) and 17 of these 18 are using the OI prosthesis. Further, at this time, nine of these 17 patients have also passed three years and seven have passed five years since surgery S2; they are all continuing to use their OI prosthesis. Of the remaining 20 patients, another 13 are using the OI prosthesis, but they have not yet been followed for two years, while seven patients are in the treatment process (three patients are in the process of prosthetic rehabilitation and four patients are scheduled for the second surgery). Currently, there is one case with loosening of the implant among all the included 41 limbs in 38 cases.

Within this thesis, the aim has been to evaluate HRQL and prosthetic function. There is, however, a large amount of both ongoing and necessary research within other areas in the field of osseointegrated amputation prostheses. They include aspects of loading of the implant system (Frossard et al. 2004), the phenomenon of osseoperception (Jacobs et al. 2000; Rydevik et al. 2005), gait analyses (Tranberg et al. 2004) and infections at the skin penetration area (Sooriakumaran et al. 2004; Hagberg et al. 2006). Studies of health-economic evaluations of the treatment would also be of considerable interest in the future.

Bone-anchored prosthetic limbs, using the method of osseointegration, will most probably become a realistic alternative for an increasing number of patients with amputations during the coming years and it is to be hoped that the results presented in this thesis will be useful in future research in this area.

Future Research

It is suggested that future investigations within the field covered by this thesis should focus on the following issues.

- Investigations of differences in HRQL and prosthetic function due to gender among individuals with LLA

- Health-economic evaluations of different prosthetic and rehabilitation treatments

- Further analyses of problems related to discomfort when sitting with lower limb prosthetics

- Investigations of everyday prosthetic walking performance using a step activity monitor

- Further investigation of the measurement properties of the Q-TFA

- Investigation of the reliability of the PCI on individuals walking with a prosthetic limb

- Further research on the prospective outcome for patients treated with bone-anchored amputation prostheses

Conclusions

1. Measurement of the amount of prosthetic use is not sufficient in order to describe the situation for individuals using a prosthetic limb. The evaluation should also include assessments of quality of life, mobility and problems. The targeted self-report questionnaire, the Q-TFA, is a new tool with adequate measurement properties which enables assessments of this kind in non-elderly individuals using TFA prostheses.

2. Individuals with non-vascular TFA with socket prostheses:

- Report reduced general HRQL as compared to healthy controls, with a pronounced decrease in physical health compared with mental health.
- Use the prosthetic limb to a high degree but report considerable problems related to the prosthesis and the amputation. About two thirds report socket-related problems with heat/perspiration and sores/skin irritation on the residual limb, which reduce their HRQL.
- Have restriction in the active hip joint motion when using the socket prosthesis; about one third have less than 90° of hip flexion.
- Frequently report discomfort when sitting with the socket prosthesis. The risk of discomfort when sitting increases if the hip flexion motion with the prosthesis is less than 90°.
- Have a 77% increase in the energy cost compared with healthy controls as measured with the PCI.
- Report that limited walking distances outdoors are accomplished.

3. Individuals treated with a TFA OI prosthesis:

- Have no restriction in the active hip joint motion when using the prosthesis.
- Have few problems with discomfort when sitting.
- One patient of 18 was not able to use the OI prosthesis at the two-year follow-up and reported a poorer overall situation.
- Seventeen of 18 patients were using the OI prosthesis at the two-year follow-up and reported considerable improvements in the general and the condition-specific HRQL as compared to the preoperative situation. The prospective results show more prosthetic use, better prosthetic mobility, fewer problems and better global health at the two-year follow-up.

Svensk sammanfattning

Summary in Swedish

Bakgrund

Vid lårbensamputation, av annan anledning än perifer kärlsjukdom, sker oftast amputationen vid yngre år. Konventionell protesförsörjning sker med protes med hylsa (hylsprotes). Genom osseointegrationsmetoden kan en protes istället fästas direkt till kvarvarande skelett (OI-protes).

Syfte

Det övergripande syftet med studierna var att undersöka hälsorelaterad livskvalitet (HRQL) och protesfunktion hos personer med ensidig lårbensamputation, av annan orsak än kärlsjukdom, med hylsprotes och OI-protes.

Material, metoder och resultat

Generell HRQL undersöktes med SF-36. För undersökning av sjukdomsspecifik HRQL konstruerades ett nytt frågeformulär "Questionnaire for Individuals with a Transfemoral Amputation" (Q-TFA) som består av fyra skalor (Prosthetic Use score, Prosthetic Mobility score, Problem score, Global score). I studie II undersöktes reliabilitet och validitet hos Q-TFA och dess mätegenskaper befanns vara adekvata. Fysiska undersökningar omfattade mätning av energikostnad vid gående med metoden Physiological Cost Index samt mätning av höftrörlighet med och utan protes på.

I studie I beskrivs generell HRQL och protesfunktion hos 97 personer (62% män, 38% kvinnor, medelålder 48 år, genomsnitt 22 år sedan amputationen, orsak; 55% trauma, 35% tumör, 10% annan). Energikostnad vid gående undersöktes hos 41 personer med hylsprotes (studie III) och höftrörlighet mättes hos 43 personer med hylsprotes och 20 personer med OI-protes (studie IV). Prospektiva resultat, vid två års uppföljning, vad gäller generell och specifik HRQL redovisas för de första 18 patienterna som behandlats med OI-protes inom ramen för en klinisk prövning (studie V).

Resultaten visar att generell HRQL, mätt med SF-36, var lägre hos undersökningsgruppen (studie I) jämfört med svensk norm. Daglig användning av protesen angavs av 82%. Gruppen rapporterade att de besvärades av ett stort antal problem som medförde försämrad livskvalitet. Vanligast förekommande var värme och svettning (72%) samt sår och skav (62%) på amputationsstumpen vid användning av hylsprotes. Vidare angav 48% besvärande fantomsmärtor, 47% besvärande ryggsmärtor och 44% rapporterade obekväm sittkomfort med protes. Energikostnaden vid gående var 77% högre hos personer med protes jämfört med en frisk kontrollgrupp. Höftrörligheten begränsades vid användning av hylsprotes men inte med OI-protes. Prospektiva resultat, vid behandling med OI-protes, visade att 17/18 använde OI-protesen vid två års uppföljning och de angav förbättrad generell fysisk HRQL, mer protesanvändning, bättre protesfunktion, färre problem samt förbättrad övergripande situation jämfört med den preoperativa situationen (studie V).

Slutsatser

Personer med ensidig lårbensamputation, av annan anledning än perifer kärlsjukdom, har sämre hälsorelaterad livskvalitet än en normalbefolkning. Trots hög grad av protesanvändning anger gruppen betydande specifika problem som hänför sig till amputationen och protesen och som medför försämrad livskvalitet. Frågeformuläret Q-TFA har adekvata mätegenskaper för undersökning av denna grupp. För rehabilitering av personer med lårbensamputation utgör behandling med skelettförankrad amputationsprotes en lovande utveckling med förbättrad hälsorelaterad livskvalitet rapporterad vid två års uppföljning.

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Appendix

QUESTIONNAIRE FOR PERSONS WITH A TRANSFEMORAL AMPUTATION (Q-TFA)

Welcome!
You should answer the questions by entering a cross or a figure in the appropriate box. If you require additional information, please contact your physiotherapist.

EMPLOYMENT SITUATION

Level of employment (please give figures):

Work_____ %   Education _____ %   Unemployment_____%

Sick leave_____ %   Disability pension _____ %   Retired _____%

Type of work:_____

If you are in employment, approximately what proportion of your working day is made up of work that is...

	0%	25 %	50 %	75 %	100 %
Sitting	☐	☐	☐	☐	☐
Moving, slight	☐	☐	☐	☐	☐
Moving, considerable	☐	☐	☐	☐	☐

LEVEL OF EDUCATION

☐ Primary School
☐ Secondary School
☐ Exam from University

CIVIL STATUS

☐ Single
☐ Married/Cohabiting

If you have any other points of view you would like to share with us after completing the questionnaire, please write them in your own words on the reverse of this page.

1. **How many days per week, on average, do you wear the prosthesis?**
Number of days:

  0   1   2   3   4   5   6   7
☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

2. **How many hours per day, on average, do you wear the prosthesis?**

☐ 0 – 3 hours
☐ 4 – 6 hours
☐ 7 – 9 hours
☐ 10 – 12 hours
☐ 13 – 15 hours
☐ more than 15 hours

3. **Approximately what proportion of the time you are at home, on average, do you wear the prosthesis?**

0%   **25 %**   **50 %**   **75 %**   **100 %**
☐   ☐   ☐   ☐   ☐

4. **Approximately what proportion of the time you are outdoors, on average, do you wear the prosthesis?**

0%   **25 %**   **50 %**   **75 %**   **100 %**
☐   ☐   ☐   ☐   ☐

5. **Approximately what proportion of the time you are at work or place of study, on average, do you wear the prosthesis?**

0%   **25 %**   **50 %**   **75 %**   **100 %**
☐   ☐   ☐   ☐   ☐

If you do not work or study, enter a cross here: ☐

6. **Do you normally prefer to wear the prosthesis or not during the following activities?**

	Wear	Do not wear
a) Cooking or similar	☐	☐
b) Cleaning, gardening or similar	☐	☐
c) Driving or travelling by car	☐	☐
d) Socialising in your own home	☐	☐
e) Socialising in public places/other people's homes	☐	☐

7. **What is/are your primary reason/s for choosing not to wear the prosthesis?**
(Feel free to enter more than one cross)

- ☐ It hurts to wear the prosthesis.
- ☐ It is strenuous wearing the prosthesis.
- ☐ I move about too slowly when I am wearing the prosthesis.
- ☐ My hands are not free when I am wearing the prosthesis.
- ☐ I feel that my life is simpler without the prosthesis.
- ☐ I do not like the prosthesis.
- ☐ I have experienced other difficulties that make it hard to wear the prosthesis.
- ☐ Other reason (please specify): _____

If you <u>always</u> choose to wear the prosthesis, cross here: ☐

8. **Over the past three months, have you been forced to refrain entirely from wearing the prosthesis for a whole day or more?**

Yes ☐ Please answer questions 9-11 as well
No ☐ Please proceed to section B, question 12

9. **Please specify the total number of days off and working days (or school days) on which you have been forced to refrain from using the prosthesis over the past three months?**

	1	2-3	4-6	7-15	>15 days
Days off	☐	☐	☐	☐	☐
Working days	☐	☐	☐	☐	☐

10. **Did this entail having to stay home from work or school?**

☐ ☐
Yes No

11. **Which problem/s forced you to refrain entirely from wearing the prosthesis?** (Feel free to enter more than one cross)

Phantom pain ☐
The prosthesis did not fit well ☐
Skin problems ☐
Pain in the residual limb (stump) ☐
Fault in the prosthesis/broken prosthesis components ☐
Other reason (please specify): _____ ☐

YOUR CURRENT LEVEL OF FUNCTION
WITH THE PROSTHESIS

12. **Which walking aid do you normally use when walking in your home wearing the prosthesis?**

☐	☐	☐	☐	☐
Walking frame or similar	2 crutches or 2 sticks	1 crutch or 1 stick	Nothing	Other

If other, please specify:_____

13. **Which walking aid do you normally use when walking outdoors wearing the prosthesis?**

☐	☐	☐	☐	☐
Walking frame or similar	2 crutches or 2 sticks	1 crutch or 1 stick	Nothing	Other

If other, please specify:_____

14. **Approximately what proportion of all your movements from one place to another, when you are wearing the prosthesis, do you make sitting in a wheelchair?**

0%	25%	50%	75%	100%
☐	☐	☐	☐	☐

15. **Can you perform the following movements wearing the prosthesis and with the support of your normal walking aid?** Please feel free to try the movement if you are unsure of your answer.

	Yes	**No**	Not tried
a) Walking up and down stairs without a handrail:	☐	☐	☐
b) Walking up a hill:	☐	☐	☐
c) Walking down a hill:	☐	☐	☐
d) Walking over uneven terrain, e.g. on forest trails or fields:	☐	☐	☐
e) Walking quickly over a distance of 50 metres:	☐	☐	☐
f) Walking while carrying a bag of food shopping or light suitcase:	☐	☐	☐

16. **Can you do the following when wearing the prosthesis?** Please feel free to try if you are unsure of your answer.

Yes No Not tried

a) Standing up for 10-15 minutes without support and without discomfort: ☐ ☐ ☐
b) Walking across the room carrying a tray with both hands: ☐ ☐ ☐
c) Sitting comfortably in a low armchair or in the back seat of a car: ☐ ☐ ☐
d) From a seated position, bending down and tying your shoelaces: ☐ ☐ ☐
e) Easily sitting down on the floor and standing up again: ☐ ☐ ☐
f) Cycling: ☐ ☐ ☐

17. **Can you use the following means of transport when wearing the prosthesis?**

Yes No Not tried

a) Bus / Tram ☐ ☐ ☐
b) Aeroplane ☐ ☐ ☐
c) Train / Underground ☐ ☐ ☐
d) Car / Taxi ☐ ☐ ☐

18a.Over the past three months, how often have you used the prosthesis to continuously walk outdoors any of the distances shown below? (Enter <u>one</u> cross for <u>each</u> distance)

	Daily	Several times/week	Once/week	Less than once/week	Never
10 m:	☐	☐	☐	☐	☐
50 m:	☐	☐	☐	☐	☐
200 m:	☐	☐	☐	☐	☐
500 m:	☐	☐	☐	☐	☐
2 km:	☐	☐	☐	☐	☐
5 km or more:	☐	☐	☐	☐	☐

18b. Over the past three months, have you ever fallen while wearing the prosthesis?

☐ ☐
Yes No

18c. Please specify the total number of falls caused by reasons related to the prosthesis and those caused by other reasons not related to the prosthesis.

a) Number of falls caused by reasons related to the prosthesis during the last three months:

_____

b) Number of falls caused by other reasons during the last three months:

_____

19. **Over the past four weeks, have you been troubled by any of the following?**
Please specify how much trouble you have had and how this trouble has affected your quality of life. Enter a figure between 0 - 4 in the box for trouble and a figure between 0 - 4 in the box for quality of life.

Trouble	**Quality of life**
0 = No trouble	0 = No reduction in quality of life
1 = Slight trouble	1 = Slight reduction in quality of life
2 = Moderate trouble	2 = Moderate reduction in quality of life
3 = Considerable trouble	3 = Considerable reduction in quality of life
4 = Great deal of trouble	4 = Extreme reduction in quality of life

Trouble regardless of prosthesis usage

Trouble

1a Have you experienced phantom pains? ☐ **Quality of life**

1b How has this affected your quality of life? ☐

2a Have you had pain in your residual limb (stump) when not wearing the prosthesis? ☐

2b How has this affected your quality of life? ☐

3a Have you experienced back pain? ☐

3b How has this affected your quality of life? ☐

4a Have you had pain in your shoulders? ☐

4b How has this affected your quality of life? ☐

5a Have you experienced pain in your other leg? ☐

5b How has this affected your quality of life? ☐

6a Have you been troubled by the appearance of your residual limb (stump)? ☐

6b How has this affected your quality of life? ☐

7a Have you been troubled by being with other people without your prosthesis? ☐

7b How has this affected your quality of life? ☐

Trouble

8a Have you had difficulty using public transport? ☐

Quality of life ☐

8b How has this affected your quality of life?

9a Have you had difficulty visiting public places such as the cinema,

theatre, museum or sports ground? ☐

9b How has this affected your quality of life? ☐

10a Have you been troubled by not being able to have your hands free

when using a walking aid? ☐

10b How has this affected your quality of life? ☐

Trouble in connection with prosthesis usage

Trouble

11a Have you had pain in your residual limb (stump) when standing and walking? ☐

Quality of life ☐

11b How has this affected your quality of life?

12a Have you had difficulty putting on (donning) or removing (doffing)

the prosthesis? ☐

12b How has this affected your quality of life? ☐

13a Have you been unable to rely on the prosthesis being securely fastened? ☐

13b How has this affected your quality of life? ☐

14a Have you been troubled by noises from the prosthesis' socket? ☐

14b How has this affected your quality of life? ☐

15a Has the prosthesis made it uncomfortable to sit down? ☐

15b How has this affected your quality of life? ☐

16a Has the prosthesis made it troublesome to sit on the toilet? ☐

16b How has this affected your quality of life? ☐

17a Has the prosthesis given rise to sores, chafing or skin irritation? ☐

17b How has this affected your quality of life? ☐

Trouble	**Quality of life**
0 = No trouble	0 = No reduction in quality of life
1 = Slight trouble	1 = Slight reduction in quality of life
2 = Moderate trouble	2 = Moderate reduction in quality of life
3 = Considerable trouble	3 = Considerable reduction in quality of life
4 = Great deal of trouble	4 = Extreme reduction in quality of life

18a Have you had trouble maintaining good hygiene on your
residual limb (stump)?

Trouble ☐

Quality of life

18b How has this affected your quality of life? ☐

19a Has the prosthesis caused increased wear on your clothes? ☐

19b How has this affected your quality of life? ☐

20a Have you had difficulty directing and keeping control of the prosthesis? ☐

20b How has this affected your quality of life? ☐

21a Have you been unable to walk quickly? ☐

21b How has this affected your quality of life? ☐

22a Have you been unable to walk in woods or fields? ☐

22b How has this affected your quality of life? ☐

23a Have you been troubled by the way you walk (e.g. limping / waddling)? ☐

23b How has this affected your quality of life? ☐

24a Have you had difficulty feeling what type of surface you are
standing/walking on? ☐

24b How has this affected your quality of life? ☐

25a Does your residual limb (stump) become tired when walking
with the prosthesis? ☐

25b How has this affected your quality of life? ☐

26a Have you been troubled by the prosthesis feeling heavy? ☐

26b How has this affected your quality of life? ☐

27a Have you been troubled by the appearance of the prosthesis (colour,
shape, surface)? ☐

27b How has this affected your quality of life? ☐

28a Have you been forced to refrain entirely from using the prosthesis? ☐

28b How has this affected your quality of life? ☐

Trouble
0 = No trouble
1 = Slight trouble
2 = Moderate trouble
3 = Considerable trouble
4 = Great deal of trouble

Quality of life
0 = No reduction in quality of life
1 = Slight reduction in quality of life
2 = Moderate reduction in quality of life
3 = Considerable reduction in quality of life
4 = Extreme reduction in quality of life