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Factors Influencing Physical Activity in Patients with Venous Leg Ulcer

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Doctoral Thesis

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‘The time is always now’
Viktor IV, Amsterdam

ABSTRACT

Background and Aim. Venous leg ulcer is a chronic condition characterized by a cyclical pattern of healing and recurrence leading to pain, disability, inactivity and reduced health. Physical activity is beneficial for venous circulation and general health, but knowledge is needed of determinants of physical activity and of possibilities for patients with leg ulcer to be physically active. The overall aim of the present work was, in terms of the International Classification of Functioning, Disability and Health (ICF), to identify and illuminate factors influencing patients' possibilities to be physically active, and to gain deeper understanding of how physical activity is perceived and understood in patients with present or previous venous leg ulcer.

Patients and Methods. Thirty-four female patients aged 60–85 years and 27 age-matched control subjects were recruited to *Study I*, which had a descriptive, cross-sectional design. Clinical tests and structured interviews were used to collect the data. In *Study II*, a survey study with a descriptive, cross-sectional design, data were collected with a postal questionnaire from 98 patients, 62 women, aged 60–86 years. In *Study III*, an experimental, cross-sectional study, six patients and 22 control subjects, 2/12 women, aged 67 (58–83) years, were included. For data collection, clinical tests, structured interviews and treadmill walking were used. In *Study IV*, using a qualitative semi-structured in-depth approach, interviews were conducted with 22 patients, 13 women, aged 75 (60–85) years.

Results. In *Study I*, leg ulcer patients showed reduced ankle range of motion, calf-muscle strength, walking speed, mobility, primary and extended ADL and physical activity as compared to control subjects. Pain and functional limitations seemed to persist despite wound healing. Patients suffering from active ulceration were more negatively affected than their post-ulcer fellows. By contrast, general health and global life satisfaction were rated similarly by the two groups. In *Study II*, fear-avoidance beliefs were present in 83% of the patients and 41% had strong fear-avoidance beliefs. Odds ratios (OR) for low physical activity was about three times higher for patients with strong fear-avoidance beliefs (OR 3.1, 95% confidence interval 1.1–8.3; $p = 0.027$) than for patients with weak fear-avoidance beliefs. *Study III* showed that total ankle range of motion was decreased by 3–4% with multi-layer high-compression bandaging. Walking with compression showed no change in oxygen cost as compared to walking at the same speed without bandaging. In *Study IV*, four categories of descriptions of physical activity were identified; (i) 'self-management', (ii) 'instructions and support', (iii) 'fear of injury' and (iv) 'a wish to stay normal'. Patients displayed poor understanding of the underlying pathology and chronicity of the disease. No or contradictory information regarding physical activity was given patients from caregivers.

Conclusions. Factors influencing physical activity were identified in most components of the ICF. Disabilities seemed to persist despite wound healing. Strong fear-avoidance beliefs were present and associated with low physical activity. Use of multi-layer high-compression bandaging decreased ankle range of motion but did not increase oxygen cost of walking. Whether or not the patients had understood the chronic nature of the underlying pathology was an important aspect of various ways of perceiving physical activity. Disabilities were found to impede, but not preclude physical activity. Certain environmental factors such as compression bandaging and inappropriate walking shoes and personal factors such as dysfunctional fear of movement and poor knowledge of the chronicity of the underlying disease were the greatest obstacles to physical activity.

LIST OF PAPERS

This thesis is based on the following original papers, which are referred to in the text by their Roman numerals:

Study I **Roaldsen KS**, Rollman O, Torebjörk E, Olsson E, Stanghelle JK. Functional ability in female leg ulcer patients - a challenge for physiotherapy. *Physiotherapy Research International* 2006; 11 (4): 191-203.

Study II **Roaldsen KS**, Stanghelle JK, Elfving B, Talme T, Mattsson E. Fear-avoidance beliefs and pain as predictors for low physical activity in patients with leg ulcer. *Physiotherapy Research International* 2009; 14 (3): 167-180.

Study III **Roaldsen KS**, Elfving B, Stanghelle JK, Mattsson E. Effect of multi-layer high-compression bandaging on ankle range of motion and oxygen cost of walking. In manuscript.

Study IV **Roaldsen KS**, Biguet G, Elfving B. Physical activity in patients with venous leg ulcer – between engagement and avoidance. A patient perspective. Submitted.

Study I and II are reprinted with kind permission from *Physiotherapy Research International*.

Study III and IV may undergo changes before journal publication.

CONTENTS

1 INTRODUCTION	1
1.1 CHRONIC VENOUS INSUFFICIENCY AND VENOUS LEG ULCER	1
1.1.1 Definitions, etiology, risk factors, pathophysiology, effects on daily life and provision of care	1
1.1.2 Classification of venous disease	3
1.1.3 Venous circulation and the effect of the calf-muscle pump	3
1.1.4 Dysfunction of the calf-muscle pump	6
1.2 TREATMENT AND MANAGEMENT OF VENOUS LEG ULCER	6
1.2.1 Compression	7
1.2.2 Leg elevation	8
1.2.3 Leg exercise and walking	8
1.2.4 Adherence to treatment regimens	9
1.3 INTERNATIONAL CLASSIFICATION OF FUNCTIONING, DISABILITY AND HEALTH (ICF)	10
1.4 PHYSICAL ACTIVITY AND EXERCISE	12
1.4.1 Definitions and concepts	12
1.4.2 Health benefits of physical activity	12
1.4.3 Assessment of physical activity	13
1.4.4 General recommendations	13
1.4.5 Theoretic relationship among physical activity, exercise and disability	14
1.4.6 Physical activity in patients with venous leg ulcer	14
1.5 PHYSIOTHERAPY IN PATIENTS WITH VENOUS LEG ULCER	15
1.6 FEAR OF MOVEMENT AND AVOIDANCE BEHAVIOR	15
1.6.1 The fear-avoidance model of pain	15
1.7 RATIONALE FOR THE PRESENT WORK	16
2 AIMS	17
3 MATERIAL AND METHODS	18
3.1 STUDY DESIGNS	18
3.2 PARTICIPANTS AND DATA COLLECTION	18
3.2.1 Inclusion criteria	18
3.2.2 Study I	18
3.2.3 Study II	18
3.2.4 Study III	19
3.2.5 Study IV	19
3.3 METHODS	19
3.3.1 Body functions and structures	20
3.3.2 Activities and participation	24

3.3.3 Environmental and personal factors	26
3.3.4 Demographic particulars and disease-related data	27
3.4 ANALYSIS	27
3.4.1 Quantitative analysis	27
3.4.2 Qualitative analysis	28
3.5 ETHICS APPROVAL	29
4 RESULTS	30
4.1 IMPAIRMENTS, ACTIVITY LIMITATIONS AND PARTICIPATION RESTRICTIONS	30
4.1.1 Study I	30
4.1.2 Study II	31
4.1.3 Study III	32
4.2 FEAR OF MOVEMENT AND AVOIDANCE BEHAVIOR	33
4.2.1 Study II	33
4.2.2 Study IV	35
4.3 EFFECT OF COMPRESSION	35
4.3.1 Study III	35
4.4 PERCEPTIONS OF PHYSICAL ACTIVITY	37
4.4.1 Study IV	37
4.5 ADDITIONAL RESULTS	39
5 DISCUSSION	40
5.1 PHYSICAL ACTIVITY	40
5.2 DISABILITIES INFLUENCING PHYSICAL ACTIVITY	40
5.3 CONTEXTUAL FACTORS AS FACILITATORS OR BARRIERS FOR PHYSICAL ACTIVITY	43
5.4 THE RELATIONSHIP BETWEEN PHYSICAL ACTIVITY, DISABILITY AND CONTEXTUAL FACTORS	45
5.5 METHODOLOGICAL CONSIDERATIONS	46
5.5.1 Samples and study design	46
5.5.2 Methods	48
5.6 CLINICAL IMPLICATIONS	52
6 SUMMARY	53
7 CONCLUSIONS	54
8 ACKNOWLEDGEMENTS	55
9 REFERENCES	58

Study I-IV

DEFINITIONS

Activity limitations	Individual difficulties in executing activities (ICF) ¹
Disability	Umbrella term for impairments, activity limitations and participation restrictions (ICF) ¹
Fear of movement	A specific fear of movement and physical activity that is (wrongfully) assumed to cause reinjury (Vlaeyen et al., 1995)
Fear-avoidance beliefs	Fear-avoidance in the context of pain refers to avoidance of movements and activities based on fear (Lundberg, 2006)
Functioning	Umbrella term for body functions and structures, activities and participation (ICF) ¹
Health-enhancing physical activity	Any form of physical activity that benefits health and functional capacity without undue harm or risk (Foster, 2000)
Impairments	Problems in body function and structure (ICF) ¹
Participation restrictions	Individual problems experienced in involvement in life situations (ICF) ¹
Physical activity	Any bodily movement produced by skeletal muscles that result in energy expenditure (Caspersen et al., 1985)
Physical exercise	Planned, structured, and repetitive bodily movement done to improve or maintain one or more components of physical fitness (Caspersen et al., 1985)
Venous insufficiency	Failure of venous drainage and increased venous pressure in the lower legs (Alguire and Mathes, 1997)
Venous leg ulcer	A venous leg ulcer located below the knee with duration of at least six weeks caused by chronic venous insufficiency (Callam, 1992)

¹**ICF:** Domains and components of the International Classification of Impairments, Disability and Health (WHO, 2001)

ABBREVIATIONS

Terms and concepts are consistently written out the first time they are used, with abbreviations in brackets. However some terms and concepts are more known as their abbreviations than in their full length.

ADL	Activities of daily living
Ankle ROM	Total ankle range of motion, i.e. the sum of ankle plantar flexion and dorsiflexion
BMI	Body mass index
CVI	Chronic venous insufficiency
ICF	International Classification of Functioning, Disability and Health
FABQ	Fear-avoidance Beliefs Questionnaire
FABQ-physical	Fear-avoidance Beliefs Questionnaire, physical activity subscale
Max VO ₂	Maximal oxygen consumption
Md	Median
OR	Odds ratio
WHO	World Health Organization
VAS	Visual analogue scale

1 INTRODUCTION

Venous leg ulcer is a chronic condition characterized by a cyclical pattern of healing and recurrence leading to pain, disability, inactivity and reduced health. Although not recognized as such, the condition represents a pressing health-care problem based on its prevalence, cost and impact on quality of life (Cullum, 2001b). In Sweden, annual costs of venous leg ulcers are approximately 1-2 billion SEK or equivalent with 1-2 % of total health-care resources (Fagrell, 2005). Physical activity is beneficial for venous circulation and general health. Knowledge of factors influencing patients' possibilities to be physically active with venous leg ulcer is essential to develop intervention programmes tailored for the specific needs of this group of patients.

1.1 CHRONIC VENOUS INSUFFICIENCY AND VENOUS LEG ULCER

1.1.1 Definitions, etiology, risk factors, pathophysiology, effects on daily life and provision of care

Approximately 70% of leg ulcers proximal to the ankle are caused by chronic venous insufficiency (CVI) (Nelzén et al., 1994) which is a progressive, troublesome condition and an important public health problem. Chronic venous insufficiency is a consequence of damage to the valves in the veins of the legs. It results from post-thrombotic syndrome, varicose veins or venous malformation, leading to failure of venous drainage and increased venous pressure (Alguire and Mathes, 1997). The failure of venous drainage leads to serious pathological changes in the skin and underlying tissue which starts to emerge long before any actual ulcer appears. Patients may be asymptomatic with only minor cosmetic concerns or may be plagued with leg aches, heaviness, and cramping associated with oedema, chronic eczema, pigmentation, fibrosis, and ulceration. As defects in venous drainage cannot be reversed in the majority of patients, continuing episodes of ulceration seem to be inevitable.

By definition, a venous leg ulcer is located below the knee with a duration of at least six weeks, and is caused by chronic venous insufficiency (Callam, 1992). The most typical ulcer location is the area around the malleolus of the ankles (gaiter area) (Figure 1). Venous leg ulcer is also called varicose, stasis or difficult-to-heal ulcer.

The prevalence of venous insufficiency in industrialised countries is high, 10-15% of men and 20-25% of women. However, the prevalence of venous leg ulcers is fortunately low, estimated to 0.5-1% in men and 1-1.5% in women at

some time during life (Callam, 1992). The overall prevalence (healed + open) between different countries and over time is relatively stable (Nelzén, 2008). The point prevalence of open ulcers is more variable, 0.1-0.3%, depending on whether people who treat their ulcers themselves are included. There is a marked increase in venous ulcer with advancing age. With a growing proportion of elderly people in the population, venous leg ulcers are becoming an increasing public health problem. The prevalence in Sweden is about 50 000 patients (Nelzén et al., 1994).



Figure 1. Venous leg ulcer (www.thefreedictionary.com/lip+and+leg+ulcer)

Venous ulcers are chronic and recurrent with healing periods lasting several years, sometimes even decades. According to patient recall, up to 50% of venous ulcers may be present for 7-9 months, and between 8% and 34% may be present for more than five years (Baker et al., 1991). Recurrence rates are as high as 45% (Harrison et al., 2001).

Known risk factors for venous insufficiency are family history of maternal venous insufficiency, increasing age, history of deep vein thrombosis, frequent or regular prolonged standing at work, heat exposure, low physical activity and (for women) more than four pregnancies (Gourgou et al., 2002; Bérard et al., 2002).

Leg ulcers are a chronic, disabling and life-limiting condition with detrimental effect on quality of life (Lindholm et al., 1993; Hyland and Thomson, 1994; Briggs and Flemming, 2007). The effects are physical, social and psychological, but the physical emerges as the most dominant theme, particularly pain, activity limitation and inactivity (Persoon et al., 2004).

A significant proportion of leg ulcers in Sweden is managed by patients themselves without involving professional health-care. This is particularly true among younger patients (Nelzén, 2008). Health-care treatment and management is given mainly in primary care, generally as the responsibility of community health-care nurses or nurses at dermatological outpatient clinics,

and this accounts for much of the associated costs. District nurses spend up to half their time caring for patients with ulcers (Faresjö et al., 1997; Simon et al., 2004). Physiotherapists are not involved in leg-ulcer care in Sweden on a regular basis (Socialstyrelsen, 2005).

1.1.2 Classification of venous disease

The most used and helpful tool for diagnosing venous dysfunction is colour Doppler ultrasound. Alternative techniques giving more limited and less detailed information are plethysmography and hand-held Doppler assessment (Nelzén, 2008).

Classification and grading of venous disease may be helpful for documentation of the severity of the disease and for communicating results. Severity is classified according to the seven grades of the Clinical severity, Etiology, Anatomy, Pathophysiology (CEAP) classification (Porter and Moneta, 1995). These are: no evidence of venous disease (0), superficial spider veins (1), varicose veins (2), ankle oedema without skin changes (3), skin pigmentation in the gaiter area (4), a healed venous ulcer (5), an open venous ulcer (6).

Some degree of arterial disease occurs in up to 25% of venous-ulcer patients (Nelzén et al., 1994). Arterial disease is important to diagnose to avoid complications due to inappropriate compression therapy. A useful screening test is the ankle-to-brachial blood pressure ratio (ankle/brachial pressure index, ABPI). An ABPI of 0.9 or higher is normal. Patients with claudication usually have an ABPI of 0.5 to 0.9 and where there is resting ischaemic pain it is usually < 0.5 (Alguire and Mathes, 1997). Venous insufficiency with $ABPI \geq 0.8$ is generally classified as ulcers of predominantly venous cause with a minor arterial component.

1.1.3 Venous circulation and the effect of the calf-muscle pump

Two main mechanisms that aid blood flow from the legs back towards the heart against the force of gravity, are the pumping action of leg muscles and the foot pump (the venous pump system of the foot and calf), and respiration (Stranden, 2004). See Figure 2 for function of the venous pump system. The venous pump system is often referred to only as the calf-muscle pump as the action of the calf muscles is the most important mechanism. The major venous plexus in the lower leg and foot are anatomically positioned so that they are compressed during normal walking, thus pumping venous blood towards the heart.

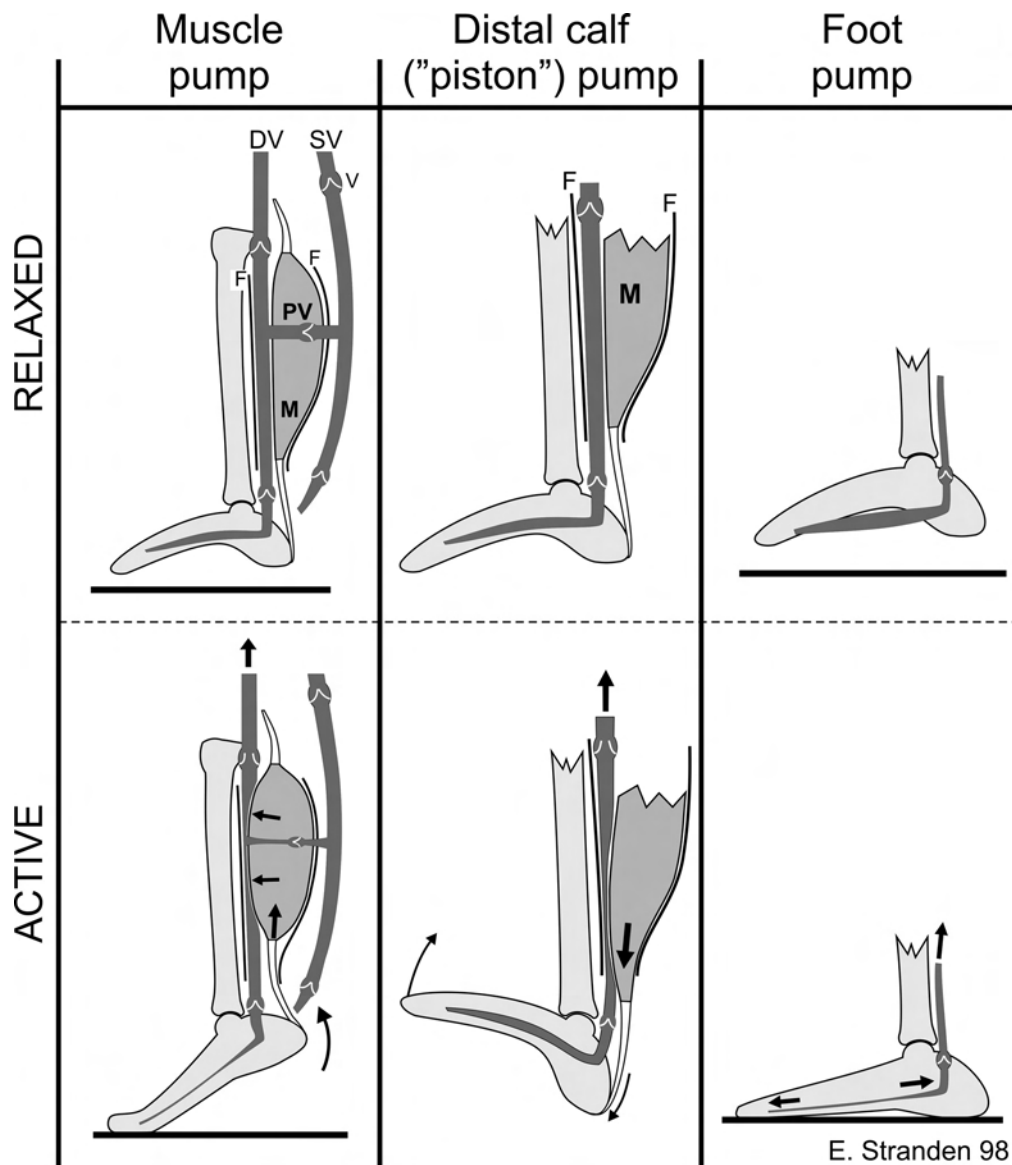


Figure 2. The venous pump systems of the foot and calf in relaxed and active states (Illustration with kind permission from Einar Stranden).

LEFT: The muscle pump consists of muscles (M) ensheathed by a common fascia (F) and veins within the same compartment. Contraction of the calf muscles, as in plantar flexion of the ankle joint during walking (above), expels blood into the proximal collecting vein (below). During relaxation blood is drained from the superficial veins (SV) into the deep veins (DV) in addition to the arterial inflow, making the pump ready for the subsequent ejection. V: venous valve.

MIDDLE: Distal calf pump. On dorsiflexion of the ankle (passive or active), the bulk of the calf muscle (M) descends within the fascial sheath (F), and expels blood in the distal veins like a piston.

RIGHT: Foot vein pump. The plantar veins are connected like a bow-string from the base of the fourth metatarsal in front to the medial malleolus. On weight-bearing the tarsometatarsal joints are extended and the tarsal arch is flattened. Thus the veins are stretched, causing them to eject their content of blood (Stranden, 2000).

Venous valves are generally bicuspid and direct flow from superficial to deep veins and from distal to proximal veins. There are more valves distally where the venous pressure is highest (Alguire and Mathes, 1997). If the valves are not functioning properly, blood runs back rapidly into the veins (reflux). The venous refilling time exceeds 20 seconds in people with healthy veins and reduces to below 10 seconds in venous insufficiency (Figure 3). The shorter the time, the more marked is the venous dysfunction (Stranden, 2004).

The normal pressure in the superficial leg veins during walking (ambulatory venous pressure), measured at the ankle, is maintained between 25 and 30 mmHg by the action of the foot and calf-muscle pump and competent venous valves, but progressively increases to 60 to 90 mmHg in the presence of valvular incompetence or venous obstruction (Stranden, 2004) (Figure 3). Repetitive muscle contractions, like walking, reduce venous pressure to a lower level than during just one muscle contraction.

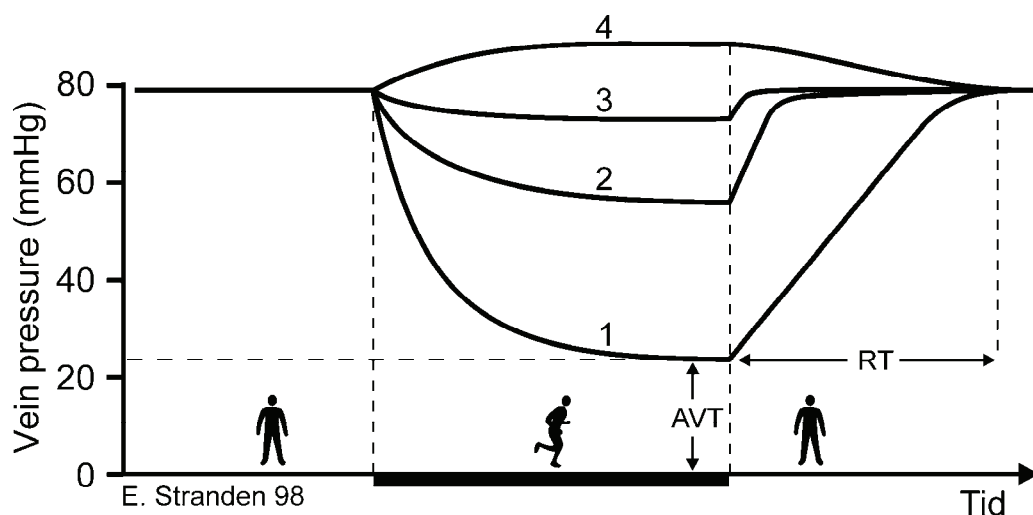


Figure 3. The venous pressure at rest and during walking (Illustration with kind permission from Einar Stranden).

1. Healthy subjects, 2. Subjects patients with superficial and perforant venous dysfunction, 3. Patients with additional deep venous dysfunction, and 4. Patients with deep venous outflow obstruction. The ambulatory venous pressure (AVT) represents the lowest mean pressure during walking at the site of measurement, and the recovery time (RT) is the time interval between the end of walking until the vein pressure reaches the pressure level in passive standing (Stranden, 2004).

An ambulatory venous pressure higher than 25-30 mmHg constitutes venous hypertension. The ambulatory venous pressure is used to measure the effectiveness of the calf-muscle pump. Normal functioning of the calf-muscle

pump needs normal ankle range of motion. Reduced ankle range of motion and low degree of leg-muscle activity or reduced leg muscle mass is found to reduce the efficacy of the calf-muscle pump (i.e. decreased venous emptying) in healthy legs during walking (Kügler et al., 2001).

1.1.4 Dysfunction of the calf-muscle pump

The two major biomechanical components of dysfunction of the calf-muscle pump in patients with long-term venous ulcer are reduced ankle range of motion (Dix et al., 2003) and reduced calf-muscle strength (Back et al., 1995). However, it is not known whether the weakened calf muscles and reduced ankle range of motion are a consequence of venous ulceration or if venous ulceration is a consequence of weakened calf muscles and reduced ankle range of motion.

The crucial role played by the calf-muscle pump in the pathogenesis of venous ulcer was demonstrated by Araki et al. (1994), who showed that venous insufficiency (i.e. reflux) was a necessary, but not a sufficient cause of venous ulceration. The status of the calf-muscle pump plays a key role in whether the patients with chronic venous insufficiency get ulcers (Araki et al., 1994).

1.2 TREATMENT AND MANAGEMENT OF VENOUS LEG ULCER

Most venous leg ulcers could be healed if patients were admitted to hospital for continuous leg elevation (Simon et al., 2004). This once popular approach is now rarely used due to high costs and the complications of bed rest.

General treatment aims for venous ulcers are to reduce oedema, eliminate skin changes, and heal the ulcers. Treatment options are often divided into drugs, surgical, and physical treatments, i.e. leg elevation, compression, leg exercise.

In the evidence-based guidelines and literature about the treatment of venous leg ulcer, compression therapy, pain management and lifestyle advice (e.g. performing leg exercise and leg elevation) are recommended (Scottish Intercollegiate Guidelines Network, 1998; CREST, 1998; Wound Ostomy and Continence Nurses Society, 2005; Royal College of Nursing, 2006). The basis for effective treatment for venous leg ulcers based on best evidence was outlined by Simon et al., (2004): Four layer compression bandaging, leg elevation, improving mobility, reduce obesity, improve nutrition, skin grafting in selected patients and venous surgery in selected patients (Simon et al., 2004).

According to a systematic review from the Swedish Council on Technology Assessment in Health-care on venous leg-ulcer-care in Sweden (SBU, 2003) and description of leg ulcer care from the Swedish National Board of Health

and Welfare (Socialstyrelsen, 2005), treatment focus is largely on choice of wound dressing and compression bandaging. There is less attention being paid to lifestyle advices and the importance of ankle range of motion and therapeutic activation of the calf-muscle pump through exercise. To our knowledge there are no national guidelines for the management of venous leg ulcer in Sweden. However, there are some regional guidelines (Socialstyrelsen, 2005).

1.2.1 Compression

Applying gradient compression stockings or bandages is considered the cornerstone of venous leg treatment (Cullum et al., 2001a). These bandages or stockings need to be worn as long as there is evidence of venous disease, which often implies a lifelong treatment. Compression is most beneficial if the patient is ambulatory and using the calf-muscle pump (Cullum et al., 2001a, 2001b).

It is not clear how compression produces the beneficial effects. Diminished venous reflux, increased blood flow velocity in the deep veins, and improved venous ambulatory pressures is demonstrated in patients with chronic venous insufficiency (Alguire and Mathes, 1997). Compression probably also improves the cutaneous microcirculation and lymphatic flow, and it may be an important mechanism in reducing fibrosis (Agu et al., 2003). Effective compression apply the greatest amount of pressure at the ankle and gradually decrease pressure up the leg (e.g. 40-30-20 mmHg). Multi-layered high compression is reportedly more effective than single-layer compression (Cullum et al., 2001a). Compression stockings are available with varying degrees of compression; Class I. 18-21 mmHg, II. 25-35 mmHg, III. 36-46 mmHg and IV. >46 mmHg (Lindholm, 2007).

When ulcers are present, compression therapy is applied by using primarily low elasticity (short-stretch) bandages with a high working pressure and low resting pressure. These bandages should be worn 24 hours a day and should be changed once or twice a week (Heinen et al., 2007a). When the wound has healed, patients are encouraged to wear compression stockings or high elasticity (long-stretch) bandages on a daily basis. High-compression hosiery is found to be more effective than moderate compression in preventing ulcer recurrence (Cullum et al., 2001b).

In excessive overweight or oedema, standard compression stockings and bandaging may be ineffective. An alternative is to use intermittent pneumatic compression (IPC) pumps. These devices consist of flexible plastic cuffs that encircle the lower leg. Periodically the air chambers inflate and compress the leg, and then deflate (Cullum et al., 2001a).

1.2.2 Leg elevation

The rationale behind leg elevation is that the oedema will be reduced as the blood flows back to the heart with the aid of gravity (Simon et al., 2004). Leg elevation is advised in brochures for patients with venous leg ulcers for 30 minutes a day, or three or four short periods during the day (Abadi et al., 2007). In a sitting position legs are placed above hip-level and in a prone position above heart level. Heinen et al. (2004) conclude that elevating the leg above the heart for 10-30 degrees was beneficial for skin oxygenation without compression, but that high compression with leg elevation can have a negative effect on skin oxygenation and wound healing. Dix et al. (2005) used an accelerometer to measure how often patients elevated their legs and found poor correlation between ulcer healing and minutes of elevation. Heinen et al. (2004) suggest that the combination of high compression and leg elevation may not improve ulcer healing. Patients should receive instructions on leg elevation in accordance with the kind of compression they use. The compression they receive should be appropriate to their ability to mobilize (Heinen et al., 2004).

1.2.3 Leg exercise and walking

In absence of randomized, controlled, longitudinal clinical studies, real evidence for the effectiveness of physical activity and leg exercise in leg ulcer healing is lacking (Abadi et al., 2007). However, it is often assumed that exercise contributes to the healing and/or prevention of leg ulcers (Heinen et al., 2004). Thus, walking and leg exercises in combination with compression therapy is generally recommended in venous leg ulcer based on the assumption that physical activity reverses the effects of venous hypertension, hastens wound healing time and prevents wound recurrence and post-ulcer disabilities (Araki et al., 1994; Franks et al., 1995; Padberg et al., 2004; Uden et al., 2005).

It is known that not exercising the calf-muscle pump may result in venous hypertension (Donovan et al., 2005) and that leg exercise increases leg-muscle strength and calf-muscle pump function (i.e. hemodynamic) (Heinen et al., 2004). A number of studies have investigated the effect of exercise of the lower leg.

- Klyszcz et al. (1995) found a positive effect on calf-muscle pump function, tissue oxygenation, plantar flexion and dorsiflexion by a supervised exercise program twice a week in six weeks in 16 patients.
- Yang et al. (1999) found positive effect on muscle pump function of a home-based six-week program with heel rises (tip-toe exercise) on

alternate days in 20 patients, but no significant effect on calf muscle strength.

- Kan and Delis (2001) studied the effect of seven days of supervised strengthening exercises of the calf muscles in 10 patients and 11 matched controls. Plantar flexion was performed in six minutes in sets of three with five minutes breaks between the sets with gradually increasing the repetitions during the week. The result showed positive effect on calf-muscle pump function and calf muscle endurance. The authors concluded that isotonic exercise performed in this study was able to restore the pumping action of the calf muscle within seven days.
- Padberg et al. (2004) found improved strength and calf muscle function of a three months' structured, supervised exercise programme.
- Davies et al. (2007) concluded that a simple, home-based exercise programme is effective in achieving gains in ankle range of motion and may help to reduce pain in 11 patients. The exercise regime consisted of a twice-weekly 5-10 minutes programme, using elastic resistance bands. The study lasted for 24 weeks and had a 6-month follow up.

There are no studies on the effect of walking on ulcer healing. However, Ibegbuna et al. (2003) found optimal function of the calf-muscle pump while walking on a treadmill with compression at low walking speeds ($1.0-2.5 \text{ km}\cdot\text{h}^{-1}$) in patients with primary venous insufficiency (CEAP 2 and 4). Walking without compression did not produce a statistical improvement (Ibegbuna et al., 2003).

1.2.4 Adherence to treatment regimens

Despite the obvious need for evidence-based leg-ulcer-care to reduce the effects of the condition, discrepancy between evidence and practice has been reported indicating that patients with leg ulcer receive less than optimum care (Lorimer et al., 2003; Van Hecke et al., 2008). Pain medication is often not prescribed. Patients do not always receive compression therapy. Conflicting life-style advices is given from different health-care professionals, if given at all (Van Hecke, et al., 2008). Patients find it difficult to combine leg elevation instructions with other daily responsibilities and do not know how to do this or for how long (Hyland and Thompson, 1994; Douglas, 2001). Care related to problems encountered by the patient such as outdoor mobility and problems finding appropriate footwear, appears to be insufficient (Heinen et al., 2007a).

Adherence to long-term lifestyle regimens (e.g. compression, leg elevation and exercise) is reportedly to be a major problem in patients with venous leg ulcer (Van Hecke et al., 2008). Adherence to physical activity is generally low, though there is some evidence that adherence to leg exercise is higher than adherence to walking exercise (Heinen et al., 2007b). There is evidence that

the use of compression stockings (class III) improves adherence compared with short-stretch bandages. For patients with healed leg ulcers class II stockings are preferred (Van Hecke et al., 2009). There is no well-documented evidence that health-care interventions, such as leg-clubs and leg ulcer clinics contribute to patient adherence. Educational programmes have a positive effect on adherence to leg elevation, but not on adherence to compression therapy (Van Hecke et al., 2009).

1.3 INTERNATIONAL CLASSIFICATION OF FUNCTIONING, DISABILITY AND HEALTH (ICH)

The effects of venous leg ulcer on physical activity is related to patients' functioning. To be able to describe and illuminate factors influencing physical activity in these patients, there is a need for a multidimensional conceptual framework of functioning and disability.

The WHO provides a multidimensional model and classification in the International Classification of Functioning, Disability and Health (ICF) (WHO, 2001) (Figure 4). The model is based on a bio-psycho-social model of health in human functioning, which can be described in two directions, the 'salutogenic' functioning and the 'pathogenic' disability. The positive and negative aspects of functioning are described in three dimensions: impairments at body level, activity limitations at personal level and participation restrictions at social level. Patients' functioning and disability are seen as a dynamic interaction between health condition and contextual factors. Contextual factors include both external environmental factors and internal personal factors. Environmental factors and personal factors play the role as barriers to or facilitators of functioning.

The ICF consists of two main parts, the model, as described in Figure 4, and the classification system with a list of domains within the components body functions and structures, activity/participation and environmental factors. The list of classifications does not distinguish between activity and participation, and personal factors are not classified at all.

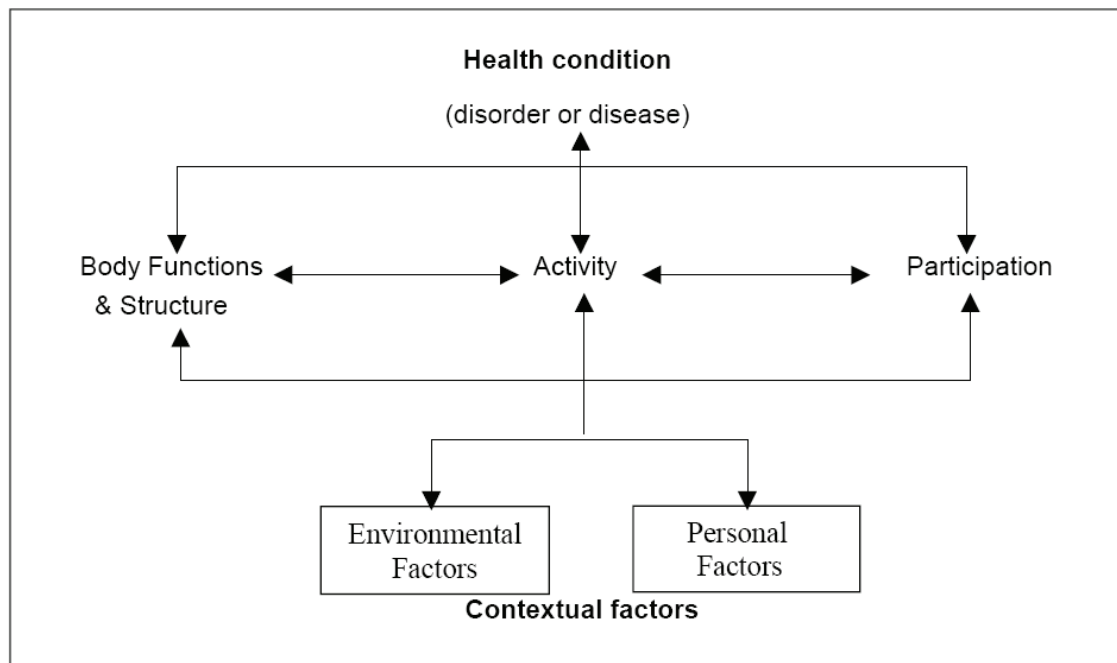


Figure 4. The International Classification of Functioning, Disability and Health (ICF) (WHO, 2001) model: Interaction between the three levels of human functioning classified by ICF; functioning at the level of body or body part (body functions and structures), the whole person (activity), and the whole person in a social context (participation) interacting with health conditions and contextual factors (WHO, 2001).

The overall goal of the classification is to establish a common language and framework for describing functional states associated with health conditions (diseases, disorders and injuries) and to improve communication among health-care workers, society and people with disabilities. In addition, it provides a systematic coding scheme to enhance the development of a scientific base for assessing the impact of health conditions on life situations and for enabling comparison of data across countries, health-care disciplines and social services. Thus, the ICF can be used both as a conceptual framework, as in this thesis, and as a classification- and code system.

The classification may also be used to discuss the complex relationships between impairments, activity limitations, participation restrictions and the role of environmental and personal factors at a particular level of disability. To our knowledge, no studies report on possibilities of using the ICF in work with patients with venous leg ulcer.

1.4 PHYSICAL ACTIVITY AND EXERCISE

1.4.1 Definitions and concepts

Physical activity is defined as ‘any bodily movement produced by skeletal muscles that result in energy expenditure’ (Caspersen et al., 1985). It is thus a very broad term that includes almost everything a person does during waking hours. Inactivity, on the other hand, is time spent doing things that do not increase energy expenditure markedly. Energy expenditure is usually expressed as the oxygen required per time unit based upon measurements of oxygen consumption (VO_2) ($\text{l} \cdot \text{min}^{-1}$ or $\text{ml} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$).

Physical exercise is a less broad term than physical activity and is defined as ‘planned, structured, and repetitive bodily movement done to improve or maintain one or more components of physical fitness’ (Caspersen et al., 1985). Physical capacity (fitness) is defined as ‘a set of attributes that individuals possess or achieve that relates to their ability to perform physical activity’ (e.g. strength, aerobic capacity, balance, flexibility). Physical activity, exercise and physical capacity are interrelated factors influencing health.

The concept of health-enhancing physical activity (HEPA) highlights the fact that all activity during transport, at work, during household or leisure time at moderate intensity or above, can give health benefits (Foster, 2000).

1.4.2 Health benefits of physical activity

Physical activity reportedly gives substantial health benefits, even in patients with chronic diseases (Pedersen and Saltin, 2006). Thirty minutes of moderately intensive physical activity on most days of the week decreases the risk of all-cause mortality and chronic conditions such as cardiovascular disease, non-insulin-dependent diabetes, obesity, colon cancer, mental diseases and osteoporosis, and improves wellbeing and health (Pate et al., 1995; FYSS, 2008).

Physical activity is related to health benefits in the ‘dose-response relationship’. The dose of physical activity is often described by intensity, duration and frequency. For general health benefits the lowest intensity required is activity of at least moderate intensity, equivalent to 51-69% of maximal aerobic capacity ($\text{VO}_2 \text{ max}$) which is at least equivalent to brisk walking and 12-13 on Borg’s RPE Scale.

The recommendations are general and, depending on the aim of the physical activity and the expression or consequences of different chronic diseases, the dose-response relationship can differ for general health and for different disabilities or diseases (Haskell et al., 2007; FYSS 2008). For example a person with very low physical capacity might gain health benefits already at low intensity walking for 30 minutes, or bouts for at least 10 minutes x 3, while 60-90 minutes at moderate intensity is required to prevent weight regain in former obese individuals (FYSS, 2008).

There are to our knowledge no disease-specific recommendations for patients with venous leg ulcer.

1.4.3 Assessment of physical activity

Physical activity can be assessed either as behaviour or as energy cost of movement using direct or indirect measures (La Monte and Ainsworth, 2001). Direct measures include doubly-labelled water which is considered to be the gold standard in the assessment of physical activity. This is a valid, but expensive method unsuitable for large studies. Other direct methods include calorimetry, observation, physical activity logs and remote sensing systems. Motion detectors such as pedometers or accelerometers are useful, but cannot be used in all aspects of all physical activity. Indirect methods such as oxygen-uptake and heart-rate monitors are often complex and expensive. Other indirect measures include 24-hour recall and physical activity questionnaires (Welk, 2002).

The most common method used is self-reporting by questionnaire. Questionnaires are easy to administer and cost-effective, but are hampered by low accuracy related to factors such as social desirability, recall bias, the complexity of the questionnaire, seasonal variations, length of the period surveyed and the subject's age (Sallis and Saelens, 2000). When using questionnaires it is important that physical activity involved in transport, leisure time activities and housework is included, as this improves the accuracy of assessment of physical activity, particularly in women (Ainsworth and Levy, 2004).

1.4.4 General recommendations

The recommendations for maintaining good health through physical activity were updated in 2007 and suggest including 30 minutes of moderate intensive physical activity, such as brisk walking, five times per week or 20 minutes of vigorous intensity, such as jogging, three times per week (Haskell et al., 2007). The 30 minutes can be accumulated in several bouts of at least ten minutes duration. Additional to these activities, ten strength training exercises, eight to

ten repetitions of each exercise twice a week should be applied. The recommendations stress that these activities are in addition to routines of daily living such as self-care and cooking or other activities lasting less than ten minutes, such as walking around home or office, or walking from a parking lot.

The recommendations distinguish healthy adults (50-64 years) and older adults (> 64 years) from adults and older people with chronic conditions. The recommendations for healthy physical activity are over all the same for all age groups, with adaptation of intensity with age. However, recommendations for older adults and those with chronic conditions or physical limitations, also includes activities that maintain or increase flexibility twice a week for at least ten minutes each time and balance exercise for older adults in risk of falling. In addition, older adults should have an individually tailored activity plans to obtain a sufficient level of physical activity to maintain health (Nelson et al., 2007).

About 1/5 of the adult population in Sweden is sufficiently active to reach health benefits. Women are less active than men and subjects with low income levels are less active than subjects with higher (FYSS, 2008).

1.4.5 Theoretic relationship among physical activity, exercise and disability

There is strong evidence that physical activity levels are related to the development of disability in older adults (Fiatarone Singh, 2002; Nelson et al., 2007) on these conceptions; 1) Physical activity may retard the biological aging process, 2) Physical activity can modify risk factors for disability-related diseases, 3) Physical activity can alter the expression or consequences of diseases that are already present and 4) Physical activity can indirectly affect other modifiers of disability, such as psycho-social functioning (Fiatarone Singh, 2002).

An overlap exists between the identifiable risk factors for disability and the consequences of inactivity. Physical activity influences the development of and expression of functioning and disability – and vice versa.

1.4.6 Physical activity in patients with venous leg ulcer

Low physical activity is found to be one of many risk factors for recurrence of venous leg ulcers (Finlayson et al., 2009). In a study on ulcer related problems and health-care needs in 141 patients with leg ulcers, one-third of all patients judged their own level of physical activity to be insufficient (Heinen et al. 2007a, 2007b). Approximately, one-quarter of all patients walked outdoors only once a week or less. In a study of 150 patients, leg exercises were conducted by only one-third of the patients (Heinen et al. 2007a, 2007b). Thus,

there is a reason to believe that physical activity should be stimulated in patients with leg ulcers to meet general recommendations and disease-specific challenges to gain functioning and health.

1.5 PHYSIOTHERAPY IN PATIENTS WITH VENOUS LEG ULCER

The role of physiotherapy in wound care, seem to vary greatly from country to country. In the US physiotherapists have an extensive role, while physiotherapists in the UK and Sweden are secondary to the role of other health professions (McCulloch, 1998; Coleridge Smith, 1999). According to Coleridge Smith (1999) physiotherapy management should focus on impairments, activity limitations and participation restrictions that may result from the presence of a wound, restoring physical functioning, preventing wound recurrence and further post-ulcer limitations:

- Patient education, health promotion/education, lifestyle counselling
- Reduction of oedema
- Pain relief
- Improving calf-muscle pump function and ankle range of motion
- Restoring normal gait
- Adaptation of adequate walking aids, foot wear, and clothes
- Selection of wound dressings and compression garments to facilitate functioning and physical activity

1.6 FEAR OF MOVEMENT AND AVOIDANCE BEHAVIOUR

Fear as a psychological factor that has received much attention in the case of explaining (chronic) pain and associated disability (Leeuw et al., 2007). In venous leg ulcer, some studies, primarily from the perspective of the patient, with a qualitative research approach (Hyland and Thomson, 1994; Walshe, 1995; Chase et al., 1997; Hyde et al., 1999; Ebbeskog and Ekman, 2001), have reported of fear of pain, fear of activities and fear of (re)injury, primarily in patients suffering from ulcer-related pain, but also in those with no current but previous ulcer-related pain experiences. Patients reported that they were afraid of exposing the leg to strain and that they avoided situations that aggravated pain, such as standing, walking and going out.

1.6.1 The fear-avoidance model of pain

Based on previous work (Lethem et al., 1983; Philips, 1987; Waddell et al., 1993) Vlaeyen et al., 1995 and Vlaeyen and Linton (2000) proposed a cognitive behavioural model of chronic low back pain now known as the fear-avoidance model. The model provides an explanation of why chronic pain

problems and associated disability develop in some patients and not in others. The basic assumption of the model is that the way pain is interpreted may lead to two different pathways, either confrontation or avoidance (Vlaeyen and Linton, 2000).

When pain is perceived as non-threatening, patients are likely to maintain engagement in daily activities that promote functional recovery. In contrast, (mis)interpretation of pain as threatening gives rise to pain-related fear and associated safety-seeking behaviour, such as avoidance of movements and hyper-vigilance that can be adaptive in the acute pain stage, but worsen the problem in the case of long-lasting pain (Leeuw et al., 2007). Disuse and disability may in turn lower the threshold at which pain will be experienced. As a response to acute injury, avoidance behaviour is adaptive (Phillips, 1987). In persistent pain, however, avoidance behaviour is considered exaggerated maladaptive behaviour influenced by pain-related fears and wrongly held disability beliefs. Fear of movement has been reported to be strongly associated with activity limitations in patients with chronic musculoskeletal pain (Vlaeyen et al., 1995; Crombez et al., 1999).

Several questionnaires have been developed to assess the phenomenon, including the Fear-Avoidance Beliefs Questionnaire (FABQ) (Waddell et al., 1993). This seeks to quantify beliefs as to physical activity affects pain and whether it should be avoided.

1.7 RATIONALE FOR THE PRESENT WORK

Physical activity in combination with compression therapy is generally recommended in patients with venous leg ulcer on the assumption that physical activity reverses the effects of venous hypertension, decreases wound healing time, and prevents wound recurrence and post-ulcer disabilities.

Knowledge of determinants for physical activity and of possibilities being physically active with leg ulcer is essential to develop intervention programs tailored for the specific needs of this patient group. It is therefore of great importance to identify and illuminate factors that influence patients possibilities to be physically active with leg ulceration. To accomplish changes in lifestyle and physical activity, it is crucial to explore the different ways patients perceive and understand physical activity, as this influences physical activity behaviour.

2 AIMS

The overall aim of the present work was, in terms of the International Classification of Functioning, Disability and Health (ICF), to identify and illuminate factors influencing patients' possibilities to be physically active, and to gain deeper understanding of how physical activity is perceived and understood in patients with present or previous venous leg ulcer.

The specific aims were:

- Study I** to describe and quantify disease consequences in female patients with healed or active venous leg ulcer using the nomenclature of the International Classification of Functioning, Disability and Health (ICF),
- Study II** to describe the occurrence of fear-avoidance beliefs and the role of fear-avoidance beliefs and pain severity in predicting level of physical activity in patients with healed or active leg ulcer,
- Study III** to investigate the effects of multi-layer high-compression bandaging on ankle range of motion, oxygen cost of walking, subjective walking ability and walking shoe comfort, and
- Study IV** to identify and elucidate the qualitative variations in how physical activity is perceived and comprehended in individuals with healed or active leg ulcer.

3 MATERIAL AND METHODS

3.1 STUDY DESIGNS

An overview of the designs and participants of Study I-IV is given in Table 1.

3.2 PARTICIPANTS AND DATA COLLECTION

3.2.1 Inclusion criteria

The patients were recruited from the Department of Dermatology, Akademiska Hospital, Uppsala, Sweden (Study I) and from the Department of Dermatology, Karolinska University Hospital (Studies II-IV). Control subjects were recruited from the Department of Dermatology, Akademiska Hospital, (Study I) and through colleagues, friends and neighbours (Study III).

Inclusion criteria for the patients were age 60-86 (Studies I, II and IV), 55-85 (Study III) years, a diagnosis of venous insufficiency and current or previous venous leg ulcer with no or a minor arterial component, for example ankle-brachial pressure index (ABPI) above 0.7, and ability to cooperate and to communicate in Swedish. Exclusion criteria were acute ulcer (Studies I-III: ulcer duration <3 months, Study IV: ulcer duration <1 month), foot ulcers and ulcers due to diabetes mellitus. In Study III further inclusion criteria were; healed ulcer, good or excellent self-reported mobility, no walking aids and being able to walk on a treadmill.

Inclusion criteria for control subjects in Study I were patients with minor dermatology complaints aged 60–85 years referred to the same hospital units as the patients, with localized, mild-to-moderate skin disease and no history of venous leg ulcer. In Study III further inclusion criteria were; good or excellent self-reported mobility, no walking aids and being able to walk on a treadmill.

3.2.2 Study I

In Study I, female patients were invited to participate. Thirty-seven patients were enrolled. Three dropped out for health or personal reasons. Thus, 34 patients were included. In parallel, 27 non-ulcer patients with minor dermatological complaints were invited to participate as control subjects (Table 1).

3.2.3 Study II

In Study II, a questionnaire was mailed to 146 patients. The response rate was 75% (110/146) after two reminders. Incomplete information that could not be supplemented by a phone interview necessitated the exclusion of 11

individuals. One was excluded because of missing sociodemographic data, leaving 98 patients (67%) to constitute the study group (Table 1).

3.2.4 Study III

Patients who had participated or had been invited to participate in Study II or IV, had agreed to be contacted again and fulfilled the inclusion criteria (six from Study II and five from Study IV), were asked to participate in Study III. In addition, three patients from the Department of Dermatology, Karolinska University Hospital, were invited to participate. A total of six patients accepted the invitation, two women and four men (two from Study II, three from Study IV and one from the Department of Dermatology (Table 1). In parallel to patient inclusion, a total of 22 healthy adults were invited to participate as control subjects, 10 women and 12 men (Study III) (Table 1).

All measurements were performed by a physiotherapist, a bio-engineer and a nurse, at the Movement Laboratory at the Department of Physiotherapy, Karolinska University Hospital, on two different days with a median of 6 (0.5-57) days apart.

3.2.5 Study IV

All those participants in Study II (n=98) who had given permission to be contacted again (n=69), were informed by letter and asked to participate in Study IV. In addition, two patients were recruited directly from the Department of Dermatology, Karolinska University Hospital. Forty-seven answered the letter (68%), twenty-nine accepted the invitation (42%) while 18 declined or wanted additional information. Two patients were excluded due to cognitive impairments, leaving 29 in the eligible group.

The first author scheduled interview meetings 2-10 days ahead of the interviews. The recruitment ended when no new aspects of the phenomenon arose in the interviews. Finally the study sample comprised of 22 patients, 13 women and nine men (Table 1).

3.3 METHODS

The International Classification of Functioning, Disability and Health (ICF) (WHO, 2001) constituted the framework for organising the data and guided the selection of measurement instruments in the four studies. All ICF components were included; 'body functions and structures', 'activities and participation', and 'environmental and personal factors'. Outcome properties, measurement instruments and units used in the different studies are presented in Table 2 in terms of the ICF (WHO, 2001).

Table 1

Table 2

3.3.1 Body functions and structures

Pain

Pain was assessed in two different ways:

- Intensity of general pain and leg-ulcer pain was rated on a 100 mm visual analogue scale (VAS) from 0 (no pain) to 100 (worst possible pain) (Carlsson, 1993) and was used as an outcome measure in Study I.

- Intensity of leg-ulcer pain was scored on a six-graded scale (Melzack and Torgerson, 1971); '0 = none, 1 = mild, 2 = discomforting, 3 = distressing, 4 = horrible and 5 = excruciating'. Pain was dichotomised into no or mild pain (scores 0–1) and pain (scores 2–5). The scale was used as an outcome measure in Study II.

Ankle range of motion

Ankle range of motion was measured in two different ways:

- Ankle range of motion (degrees) was measured with goniometry during maximal voluntary plantar flexion and dorsiflexion in a reclined position with the knees slightly bent (Miller, 1985). The test was used as an outcome measure in Study I.

- Loaded dorsiflexion of the ankle (degrees) was measured with goniometry in a standing position with one leg on the floor and the examined leg on a 30-cm-high box (Lindsjö et al., 1985) (Figure 5). Plantar flexion was measured with the patient sitting on the edge of a chair with the investigated leg stretched forward with the sole placed so that the medial part of the forefoot was just in contact with the floor (Nilson et al, 2003). The test was used as an outcome measure in Study III.



Figure 5. Measuring loaded ankle dorsiflexion

Calf muscle strength and dorsiflexor strength

Maximal isometric voluntary contraction (MVC) (Ns) was measured in patients and control subjects in Study I during plantar flexion and dorsiflexion of the ankles. The subject lay supine on a specially designed bench equipped with mechanical arrangements for fixing the trunk, extremities and joint angles in standardized positions. Muscle force was measured with a strain gauge connected to a sling attached to the forefoot at a fixed distance to the ankle axis. On a given signal, the subjects were strongly encouraged to exert maximal force in the tested muscle group for 10 s. While performing the test, the force signal was graphically displayed on a computer screen being visible to the patient. MVC was defined as the force area under the curve generated during a single 10-sec test of maximal voluntary contraction (Lindahl et al., 1988). The test was used as an outcome measure of patients and controls in Study I, but the results have not been previously published.

Estimated maximal oxygen capacity

Maximal oxygen capacity ($\text{VO}_2 \text{ max}$) was estimated using a sub-maximal bicycle ergometry test according to Åstrand and Rhymin (1954). The subjects cycled at the final workload for at least six minutes to reach steady state. Heart rate was monitored using a heart rate monitor with a chest transmitter (Polar, Polar Oy, Kempele, Finland). Maximal oxygen capacity ($\text{VO}_2 \text{ max}$, $\text{l} \cdot \text{min}^{-1}$) was calculated according to the nomogram and the factors provided by Åstrand and Rhymin (1954) and Åstrand and Rodahl (1977). Relative $\text{VO}_2 \text{ max}$ ($\text{ml} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$) was calculated from absolute $\text{VO}_2 \text{ max}$ ($\text{l} \cdot \text{min}^{-1}$) and body weight (kg). The test was used as a background variable in Study III.

Oxygen cost

Oxygen consumption, VO_2 ($\text{l} \cdot \text{min}^{-1}$) was measured after six minutes at steady state, the subject walking on a treadmill (Cardio Rehab-Hill 3175, Cardionics Försäljning AB) at a speed as close as possible to the self-selected walking speed in the corridor. Metamax II (Serial nos. M II 53229901) was used for assessing oxygen consumption (Medbø et al., 2002). During the experiments the data collected were immediately transferred to and stored in a computer, calculating the oxygen cost in $\text{ml} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$ and in $\text{ml} \cdot \text{kg}^{-1} \cdot \text{m}^{-1}$. Heart-rate was monitored with a heart-rate monitor with a chest transmitter (Polar, Polar Oy, Kempele, Finland). The test was used as an outcome measure in Study III (Figure 6).

Compression pressure

A sub-bandage pressure transducer (Kikuhime, Biomedical Systems Engineering, large probe) was used to measure level of compression under compression bandages. The probe was placed in a slide that made it possible to ensure that sub-bandage pressure was 40 (38-42) mmHg at the lateral

malleolus and 20 (19-21) mmHg under the knee. The test was used to ensure accuracy of the measurements in Study III (Figure 7).

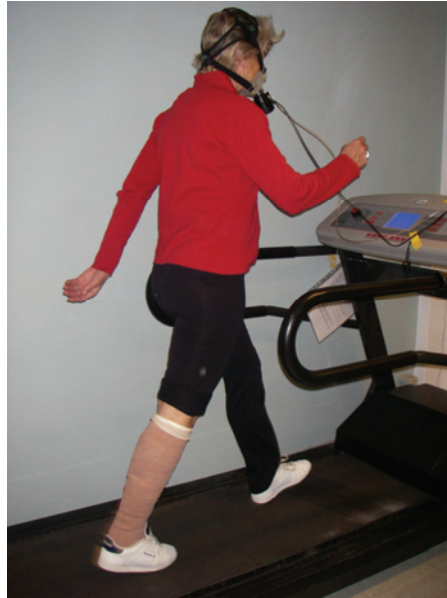


Figure 6. Measuring oxygen consumption while walking on a treadmill with multi-layer high-compression bandaging on one leg



Figure 7. Measuring sub-bandage compression

3.3.2 Activities and participation

Walking speed

Walking speed was measured in two different ways:

- Self-selected walking speed ($\text{m} \cdot \text{s}^{-1}$) was calculated from a three-minute walk along a 20-m walking track in a calm indoor corridor with marks every metre

on the side of the walkway (Butland et al., 1982). The test was used as an outcome measure in Study I.

- Self-selected walking speed ($\text{m}\cdot\text{s}^{-1}$) was assessed using a modified six-minute walking test (6MWT) (Butland et al., 1982; Guyatt et al., 1985). The subjects walked along a 35 m walking track in a calm indoor corridor with marks every metre on the side of the walkway. The test was used as an outcome measure in Study III.

Walking endurance

The total distance walked in three minutes at self-selected walking speed on a 20-m walking track in a calm indoor corridor with marks every metre on the side of the walkway (Butland et al., 1982), was used as an indicator of walking endurance. The test was used as an outcome measure in Study I.

Ratings of perceived exertion during walking

Perceived exertion was assessed using the Ratings of Perceived Exertion Scale 6–20 (Borg's RPE Scale) (Borg, 1982). The test was used as an outcome measure in Study I and Study III.

Mobility

Mobility was assessed in three different ways:

- Timed Up and Go (TUG) was used as an outcome measure in Study I (Podsiadlo and Richardson, 1991). The subjects were instructed to rise from a chair (height 44 cm), walk three metres, turn around a mark on the floor and walk back and sit again. The activity was repeated three times and timed with a stop-watch.
- The Rivermead Mobility Index (Collen et al., 1991) assesses fundamental aspects of mobility in 15 items: turning over in bed, lying-to-sitting, sitting balance, sitting-to-standing, standing unsupported, transfer, walking indoors with aid, walking indoors unaided, climbing stairs, walking outdoors, picking off floor, walking on uneven ground outdoors, bathing, up and down four stairs, and running. A score of 1 is given for each 'yes' answer, giving a maximum of 15 points, indicating a high level of mobility. The test was used as an outcome measure in Study II.
- Self-rated mobility was assessed by asking the patients to rate their mobility as 1 = poor, 2 = fair, 3 = good or 4 = excellent. The question was developed to fit the patient group. The test was used as an outcome measure in Study I and as a background variable in Study II-IV.

Primary and extended activities of daily living

The Barthel ADL Index (Mahoney and Barthel, 1965) was used to assess primary activities of daily living (ADL). The index consists of 10 items - personal hygiene, bowels, bladder, toilet use, feeding, transfer, mobility, dressing, stairs and bathing. A sum score of 0–20 was calculated. High scores indicate a high degree of independence. The test was used as an outcome variable in Study I and as a background variable in Study II.

The Functional Status Questionnaire, part I (FSQ) (Jette et al., 1986) was used to assess extended ADL. A maximum of 52 points reflects how health problems affect both basic ADL, such as self-care and walking, and extended ADL, such as household work, shopping and participating in community activities. The test was used as an outcome variable in Study I.

Physical activity

Physical activity was rated on a six-graded scale including both physical training/exercise and household/domestic activities (Mattiasson-Nilo et al., 1990; Frändin and Grimby, 1994). The test was used as an outcome measure in Study I-II and as a background variable in Study III-IV.

3.3.3 Environmental and personal factors

Use of walking aids and community services

The use of walking aids, indoors and outdoors was reported by the patients and used as a background variable in Study I-IV.

Satisfaction with life

Satisfaction with life was rated with the Life Satisfaction Scale (LiSat) (Fugl-Meyer et al., 1991). This contains one global question (satisfaction with life as a whole) and eight domain-specific questions related to different aspects of life. Two questions were slightly modified to fit the study group. Scores ≥ 5 are classified as satisfaction with life. The test was used as an outcome measure in Study I.

Self-rated general health

Self-rated general health was rated using the question: ‘Would you say that your health is excellent, good, fair or poor?’ (Kaplan and Camacho, 1983). The test was used as an outcome measure in Study I.

Fear-avoidance beliefs

The physical activity subscale of the Fear-Avoidance Beliefs Questionnaire (FABQ) (Waddell et al., 1993) was used to assess fear-avoidance beliefs for

physical activity. The FABQ-physical is a five-item self-report questionnaire aimed at quantifying beliefs about how physical activity affects pain and whether it should be avoided. The subscale is scored on a Likert scale of 0–6, from ‘strongly disagree’ to ‘strongly agree’, where higher sum scores indicate stronger fear-avoidance beliefs. The questionnaire was used as an outcome measure in Study II.

3.3.4 Demographic particulars and disease-related data

In addition to the outcome and background variables mentioned, demographic and disease-related data were collected. Age, gender, BMI (‘personal factors’) and current medical status (‘body function and structure’) are described in Study I-IV. Study I, II and IV. They also include disease duration, leg ulcer-status (‘body function and structure’) and use of walking-aids (‘environmental factors’). In Study I use of community services (‘environmental factors’) is also described (Table 2).

3.4 ANALYSIS

3.4.1 Quantitative analysis

Statistical methods used in this thesis are listed in Table 4. All statistical analyses was performed using SPSS, version 14.0-15.0 (SPSS Inc., Chicago, IL, USA). The significance level was set to $p \leq 0.05$.

Table 3. Statistical methods used in Study I-IV

	Study I	Study II	Study III	Study IV
Descriptive statistics				
Median and range	x	x	x	x
Number/frequencies	x	x	x	x
Methods of analysis				
Chi-square test	x	x		
Fisher’s exact test	x			
Mann-Whitney U-test	x	x		
Wilcoxon’s rank sum test	x			
Wilcoxon’s signed rank test	x		x	
Spearman’s rank correlation		x		
Simple and multiple logistic regression		x		

In all the studies, continuous data are presented by median and range and categorical data by numbers/frequencies. For continuous variables differences between groups were compared with the Mann–Whitney U-test and

Wilcoxon's rank sum test. Wilcoxon's signed rank test was used for matched and paired data. For categorical values differences between groups were compared with Fisher's exact test and the Chi-square test. The Spearman rank order correlation coefficient was used to check for correlations between variables. Correlation coefficients were judged according to Domholdt (2005): $r=0.00-0.25$, little, if any; $r=0.26-0.49$, low; $r=0.50-0.69$, moderate; $r=0.70-0.89$, high; and $r=0.90-1.00$, very high. Multiple logistic regression analyses, with low/high physical activity as dependent variable, were performed for variables showing significance in the simple analyses. Odds ratios and 95% CI intervals were calculated for low level of physical activity. Age, number of chronic conditions and ulcer status were considered important to use as confounders on logical grounds. All statistical analyses were performed using SPSS version 15.0-17.0 (SPSS Inc., Chicago, IL, USA). A p value of ≤ 0.05 was considered statistically significant.

3.4.2 Qualitative analysis

Qualitative research approach can be helpful for understanding the complexities of human health and behaviour (Gibson and Martin, 2003). It is thus useful when studying patients' understanding of phenomena in health-care, such as physical activity. These methods include in-depth qualitative interviews, observation, focus groups and ethnographic fieldwork. Given the range of data types, there are diverse approaches to data analysis, including grounded theory, content analysis, phenomenology and phenomenography. The identification and refinement of thematic categories is a major aspect of qualitative analysis.

In venous leg ulcer, studies with a qualitative research approach have been used to increase understanding of the influence of leg ulcer on everyday life and of the patients' experiences of living with leg ulcer. (Walshe, 1995; Chase et al., 1997; Hyde et al., 1999; Douglas, 2001; Ebbeskog and Ekman, 2001).

Phenomenography

Phenomenography is a qualitative research approach that originates from educational research (Marton, 1981; Bernard et al., 1999) and has become fairly well known in health-care research (Sjostrom and Dahlgren, 2002). Phenomenography aims at identifying and describing differences and similarities in how individuals experience, understand and conceptualise phenomena. It assumes that there is a limited number of qualitatively different ways of understanding or experiencing phenomena which are shared by different people in a similar situation. The outcome of a phenomenographic research approach is a set of logically related categories that outline the perceptions of the phenomenon. These categories and the logical relations

between them provide the final outcome space for the research (Dahlgren and Fallsberg, 1991; Marton and Booth, 1997). The semi-structured interview is a common data-collection method in phenomenographic research (Dahlgren and Fallsberg, 1991).

Phenomenography must not be confused with *phenomenology* where the aim is to describe the essence of a phenomenon, and not the qualitatively different ways people experience and understand the phenomenon.

In Study IV, transcripts from the 22 interviews were analysed using a phenomenographic approach. The analysis followed the seven steps of the phenomenographic analysis procedure described by Dahlgren and Fallsberg (1991);

1. *Familiarization*. Each transcript was read several times.
2. *Condensation*. A short summary of each interview was established.
3. *Comparison*. The preliminary themes and their associated statements were compared to find similarities and differences in content.
4. *Grouping*. Seven preliminary categories were identified by grouping themes with similar content and synthesized into four discrete categories of descriptions.
5. *Articulating*. Each category of description was described and illustrated with quotations.
6. *Labelling*. The categories were 'labelled' with a suitable metaphor.
7. *Contrasting*. The categories were compared to find a structure that could relate them to each other.

3.5 ETHICAL APPROVAL

Participants in all studies received written information about the method and aims of the studies and participants in Study I, III and IV received additional oral information. The participants were informed that the participation was voluntary and could be terminated at any time without stating a reason and without affecting care. Written informed consent was obtained from all participants prior to entry into the studies. Ethical approval was obtained from the Ethical Committee at Uppsala University (Dnr 98258) for Study I and from the Regional Ethical Review Board in Stockholm (Dnr 04-565/2) for Study II-IV.

4 RESULTS

4.1 IMPAIRMENTS, ACTIVITY LIMITATIONS AND PARTICIPATION RESTRICTIONS

4.1.1 Study I

An overview of impairments, activity limitations and participation restrictions in patients (n=34) and in controls (n=27) in Study I is shown in Table 5.

Table 4. Impairments, activity limitations and participation restrictions in patients (P) with active ulcer (A), healed ulcer (H) and in control subjects (C) (Study I). Median (range) or number (percent) are presented.

	Patients P		Controls C		p-values	
	Active ulcer n=21 A	Healed ulcer n=13 H	n=27 C	AC	HC	AH
Body functions and structures						
Ulcer pain (mm)	40 (0-66)	0 (0-42)				<0.001
Ankle range of motion (ROM) (degrees)	41 (10-63)	50 (29-67)	61 (42-85)	<0.001	0.002	0.039
Plantar flexion	33 (10-49)	40 (31-55)	48 (36-65)	<0.001	0.012	0.009
Dorsiflexion	8 (-8-15)	10 (-9-14)	13 (5-20)	0.012	0.002	0.753
Calf muscle strength and dorsiflexion (Ns)	3659 (2473-6854)	4409 (2928-6090)	5752 (3236-7958)	<0.001	0.012	0.308
Plantar flexion	2107 (1112-4400)	2392 (1644-4292)	3667 (2284-4905)	<0.001	0.009	0.345
Dorsiflexion	1712 (825-3052)	1841 (868-2606)	2044 (927-3053)	0.024	0.203	0.472
Activities and participation						
Walking speed (m/s)	0.9 (0.4-1.2)	1.1 (0.7-1.6)	1.3 (0.9-1.8)	<0.001	0.014	0.027
Walking endurance (m)	150 (60-200)	197 (116-260)	210 (128-260)	<0.001	0.168	0.008
Perceived exertion (points)	13 (11-15)	11 (10-15)	11 (7-15)	<0.001	0.014	0.080
Timed Up and Go (s)	13 (9-29)	11 (8-24)	10 (7-13)	<0.001	0.120	0.082
Primary ADL (points)	19 (10-16)	20 (15-20)	20 (18-20)	<0.001	0.015	0.076
Extended ADL (points)	30 (22-43)	37 (22-43)	42 (31-50)	<0.001	0.424	0.120
PC						
Self-rated, good/excellent, n (%)	5 (24)	5 (38)	22 (82)		<0.001	
Physical activity 1-2, n (%) ¹	13 (38)	0 (0)	0 (0)		<0.001	
Physical activity (≥4), n (%) ¹	0 (0)	4 (31)	14 (52)		<0.001	
Environmental and personal factors						
Walking aids, n (%)						
Indoor	5 (24)	2 (15)	1 (4)		0.054	
Outdoor	14 (67)	4 (31)	1 (4)		<0.001	
Community services, n (%)						
Transportation	11 (52)	3 (23)	2 (7)		0.003	
Domestic help	5 (24)	1 (8)	1 (4)		0.092	
Life Satisfaction (≥5), n (%) ²						
Daytime activities	6 (29)	8 (62)	17 (63)		0.036	
Contact with friends	14 (67)	13 (100)	22 (82)		0.041	
Independence in ADL	11 (52)	10 (77)	23 (85)		0.016	
Economy	10 (48)	7 (54)	13 (48)		0.843	
Leisure time	10 (48)	8 (62)	18 (67)		0.347	
Family life	17 (81)	10 (77)	22 (82)		0.763	
Physical health	5 (24)	5 (39)	10 (37)		0.425	
Psychological health	15 (72)	10 (77)	19 (70)		0.938	
Life as a whole	14 (67)	8 (62)	17 (63)		0.946	
Self-rated general health, good/excellent, n (%)	16 (76)	9 (69)	22 (83)		0.738	

¹Physical activity: 1 'Hardly any physical activity', 2 'Mostly sitting, sometimes a walk, sometimes light domestic work'; ≥4 'Moderate exercise, 1-2 hours/week' or more. ²Life Satisfaction: ≥5 'satisfied' or 'very satisfied'.

Patients with leg ulcer showed significantly reduced values for ankle range of motion, calf-muscle and dorsiflexor strength, walking speed, walking endurance, self-perceived exertion while walking, mobility, ADL, physical activity and health-related life satisfaction as compared to control subjects. Use of community services (transport and home help) was significantly more frequent in the patient group. Patients suffering from active ulceration were more negatively affected, and more of them had pain than their post-ulcer fellows. Patients with healed ulcers also had significant disabilities as compared to controls. Self-rated general health and satisfaction with life as a whole were similar in the patient group and in the control group (Table 4).

Half of the patients in Study I, 17 (50) were mostly sitting, sometimes a walk (score 1-2) (Table 8). Only 4 (12%) patients had moderate physical activity (score 4). None of the controls were mostly sitting and 14 (51%) had moderate physical activity or more (score ≥ 4).

4.1.2 Study II

In Study II, the most common physical activity score was 3) 'Light physical exercise for 2-4 hours a week, responsibility for light domestic work' (Figure 8). Only 18 (18%) of the patients had moderate physical activity or more (score ≥ 4).

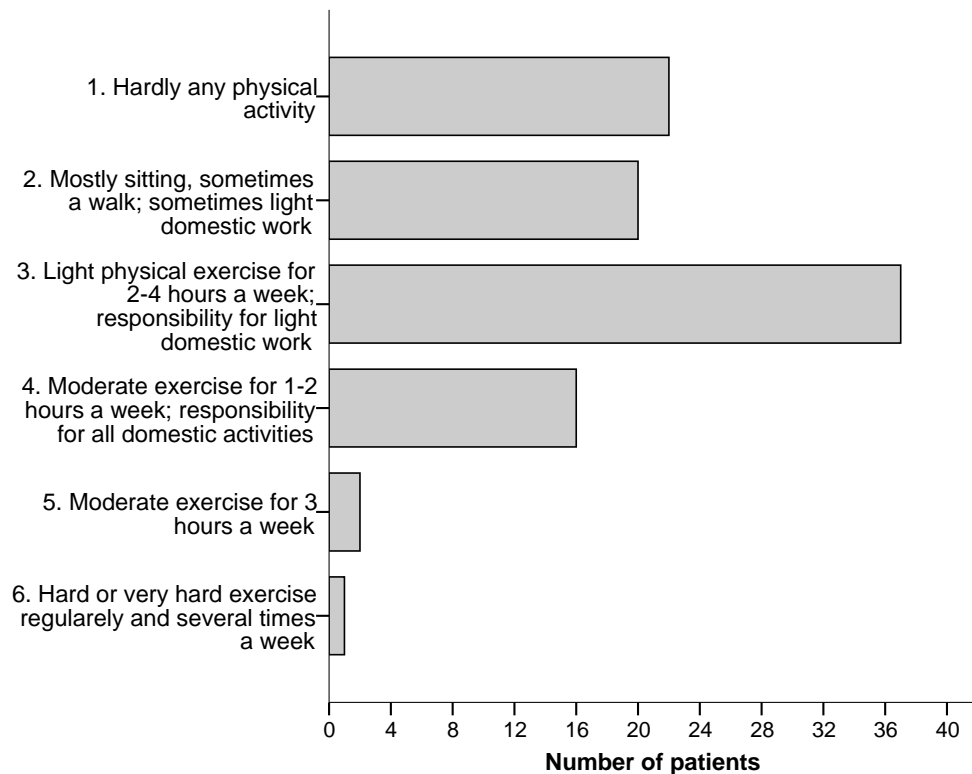


Figure 8. Number of patients (n=98) scoring the different items of the physical activity scale (Frändin and Grimby, 1994; Mattiasson-Nilo et al., 1990).

In all, 42 patients were classified as having low physical activity (scores 1-2) and 56 as having higher (scores 3-6). There were no significant differences in physical activity due to age, gender, BMI, ulcer status or number of chronic conditions. Patients with low physical activity had significantly stronger fear-avoidance beliefs and more severe pain than patients with high physical activity (Table 5).

Table 5. Characteristics, impairments and activity limitations in patients with active and healed ulcer (n=98) (Study II). Data are presented as median (range) or as numbers. P-values are given for differences between groups with low physical activity versus high.

Differences between groups with low physical activity versus high.				
	Whole group n=98	Low physical activity (score 1-2) n=42	High physical activity (score 3-6) n=56	p- value
Body functions and structures				
Ulcer status (active/healed)	55/43	26/16	29/27	0.318
Number of chronic conditions	4 (1-8)	5 (1-8)	3 (1-8)	0.121
Pain				
None	42	10	32	<0.001
Mild	14	6	8	
Discomforting	21	12	9	
Distressing	12	6	6	
Horrible	7	6	1	
Excruciating	2	2	0	
Activities				
Barthel ADL Index	18 (5-20)	16 (5-20)	20 (14-20)	<0.001
Rivermead Mobility Index	13.5 (2-15)	9 (2-15)	15 (8-15)	<0.001
Self-rated mobility				
Poor	27	21	6	<0.001
Fair	37	15	22	
Good	24	5	19	
Excellent	10	1	9	
Personal factors				
FABQ-physical	12	8.5	16.5	<0.001
Gender (male/female)	36/62	16/26	20/23	0.809
Age (years)	77 (60-86)	77 (60-86)	75 (61-85)	0.108
BMI (kg·m ⁻²)(n=88)	26.5 (16.5-48.3)	26.3 (16.3-45.9)	26.7 (16.0-48.3)	0.809

BMI=body mass index.

Pain=The Six-point verbal rating scale for pain assessment (Melzack and Torgerson, 1971).

ADL=Activities of daily living.

FABQ-physical= the Fear-avoidance beliefs questionnaire, physical activity subscale (Waddell et al., 1993).

In all, 42 patients were classified as having pain (scores 2–5) and 56 patients as having no or mild pain (scores 0–1). Patients with active ulceration had more severe pain ($p < 0.001$) than non-ulcer patients. Patients with pain reported significantly more chronic conditions, activity limitations and a lower level of physical activity than those with no or mild pain ($p < 0.05$).

4.1.3 Study III

An overview of characteristics, impairments and activity limitations in patients (n=6) and controls (n=22) in Study III is given in Table 6 and Figure 10. The

patients had significantly higher BMI, more chronic conditions, reduced ankle range of motion and increased oxygen cost of walking than controls did ($p < 0.05$).

Table 6. Characteristics and disabilities in patients (n=6) and control subjects (n=22) (Study III).

	Patients n=6 Median (range)	Controls n=22 Median (range)	p-value
Body functions and structures			
Chronic conditions, n, md (range)	2 (1-4)	1 (0-4)	0.012
<i>Ankle range of motion</i>			
Ankle range of motion (ROM) (degrees)	69 (59-81)	87 (69-108)	<0.001
Plantar flexion (degrees)	41 (29-49)	51 (39-61)	0.008
Dorsiflexion (degrees)	30 (22-34)	36 (24-49)	0.010
<i>Bicycle ergometry test</i> ¹			
Work load (kpm·min ⁻¹)	600 (300-750)	450 (375-900)	0.832
Heart rate (beats·min ⁻¹)	123 (117-131)	128 (102-147)	0.113
Maximum oxygen capacity, VO ₂ max			
l·min ⁻¹	2.24 (1.18-2.90)	1.7 (1.3-3.1)	0.524
ml·kg ⁻¹ ·min ⁻¹	24.3 (12.8-30.5)	28.8 (19.0-45.5)	0.165
Activities			
<i>Floor walking</i>			
Self-selected walking speed (m·s ⁻¹)	1.39 (1.22-1.57)	1.47 (1.17-1.69)	0.112
Perceived exertion (6-20)	11 (9-13)	11 (9-13)	0.165
<i>Treadmill walking</i>			
Self-selected walking speed (m·s ⁻¹)	1.11 (0.92-1.36)	1.32 (1.11-1.50)	0.078
Perceived exertion (6-20)	11 (9-13)	11 (9-13)	0.512
Oxygen cost, VO ₂ ·kg ⁻¹ (ml·kg ⁻¹ ·m ⁻¹)	0.204 (0.16-0.23)	0.156 (0.13-0.23)	0.003
Oxygen cost (%)	59 (43-98)	43 (29-77)	0.033
Physical activity, ≥3, n (%)	6 (100)	22 (100)	0.764
Physical activity, ≥4, n (%)	3 (50)	13 (59)	
Personal factors			
Gender, female, n (%)	2 (33)	10 (46)	0.682
Age, years, md (range)	66 (58-83)	67 (63-83)	0.764
BMI (kg·m ⁻²)	28 (23-37)	24 (19-27)	0.001

¹ The test was performed in five out of six patients

4.2 FEAR OF MOVEMENT AND AVOIDANCE BEHAVIOUR

4.2.1 Study II

Fear-avoidance beliefs were present in 81 (83%) of the patients (Table 5). Forty patients (41%) had strong fear-avoidance beliefs. Patients with fear-avoidance beliefs above the median (n = 40) reported significantly more chronic conditions, pain, activity limitations and a lower level of physical activity ($p < 0.005$) than those with weak fear-avoidance beliefs (n = 58). One-third of the patients with healed ulcers had strong fear-avoidance beliefs.

Fear-avoidance beliefs in patients with pain were stronger than in those with no or mild pain ($p<0.001$) (Figure 9). There were no significant differences in fear-avoidance beliefs because of age, gender, BMI or ulcer status.

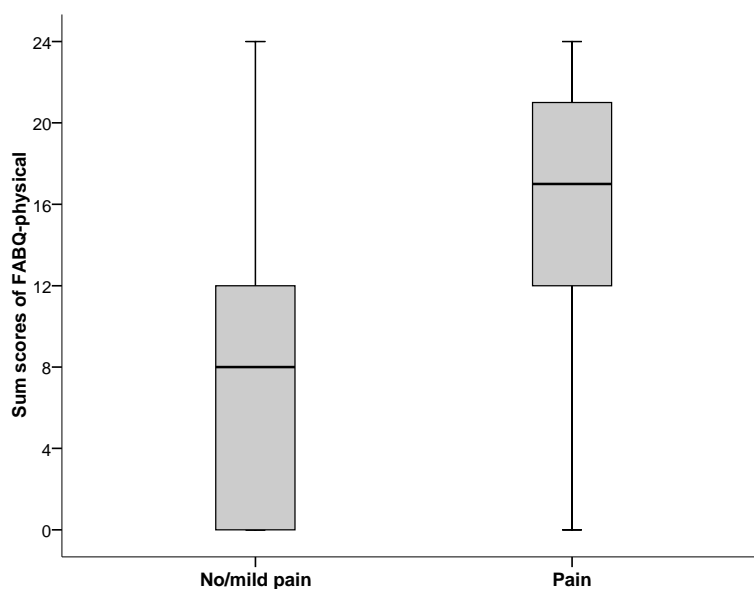


Figure 9. Box and whiskers plot with median, first and third quartile and range of sum scores (0-24) for the Fear-Avoidance Beliefs Questionnaire, physical activity subscale (FABQ-physical) (Waddell et al., 1993) in patients with no/mild pain (score 0 'No' and score 1 'Mild') and pain (score 2 'Discomforting', score 3 'Distressing', score 4 'Horrible' and score 5 'Excruciating') (Melzack and Torgerson, 1971), respectively ($p<0.001$) ($n=98$). Patients with pain had significant stronger fear-avoidance beliefs (Study II).

Logistic regressions analyses were conducted with physical activity (low/high) as dependent variable and pain intensity and fear-avoidance beliefs as independent variables. In simple logistic regression analyses the possible predictors of low physical activity were tested one by one, alone and in combination with confounders (age, number of chronic conditions and ulcer status). Both pain intensity and fear-avoidance beliefs were significant and evaluated further in the multiple logistic regression analysis. Fear-avoidance beliefs remained significant in the adjusted model (odds ratio, OR 3.1; 95% confidence interval, CI 1.13-8.26; $p=0.027$) while pain lost its significance (OR 2.8; 95% CI 0.94-8.28; $p=0.066$). Odds ratios (OR) for low physical activity were about three times higher for patients with strong fear avoidance beliefs.

4.2.2 Study IV

In Study IV, ‘fear of injury’ represented one out of four categories of descriptions. In this category physical activity involved fear of increased pain and fear of (re)injury. Physical as well as social activities were viewed as risk-taking actions to be postponed until the ulcer was healed. To prevent injury, the individuals seemed to use their skill in recognizing threats known to damage the skin on their legs. When interacting with other people, they appeared to be watchful and pre-occupied with their own safety and protection. Leg ulcer seemed to be experienced as an acute condition that would pass off once the ulcer had healed. When leg ulcers occurred the individuals had problems understanding why this was happening to them. Responsibility for treatment was handed over to the specialists.

4.3 EFFECT OF COMPRESSION

4.3.1 Study III

Total ankle range of motion (ROM) was decreased by 4% with compression in controls and by 3% in ulcer patients (Tables 7a and 7b). Walking with multi-layer high-compression bandaging showed no change in oxygen cost as compared to walking at the same speed without bandaging in either groups (Figure 10, Tables 7a and 7b).

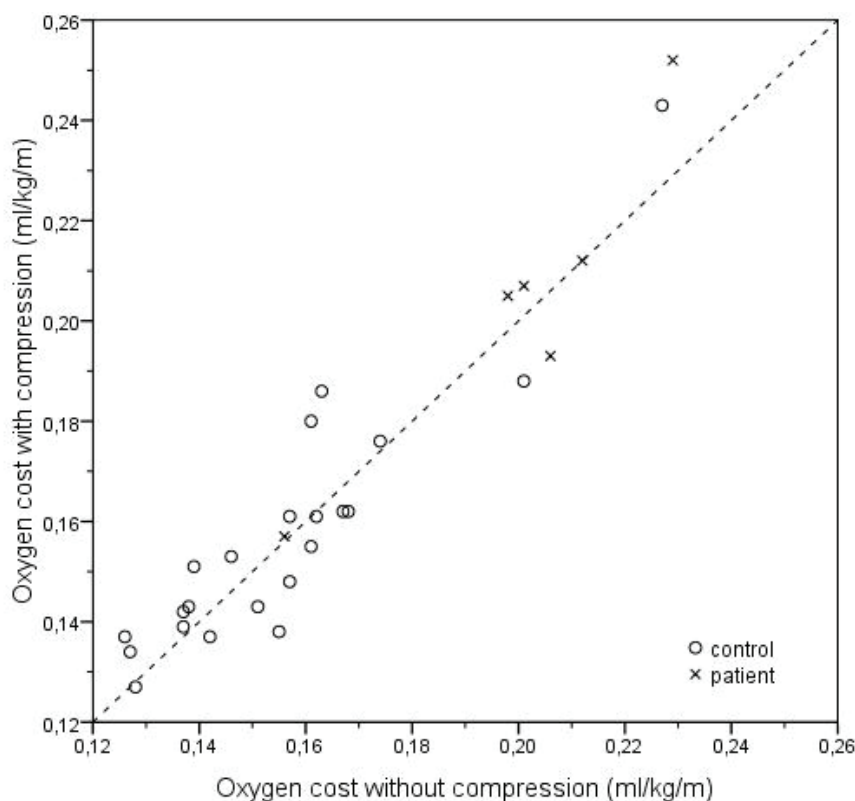


Figure 10. Oxygen cost ($\text{ml} \cdot \text{kg}^{-1} \cdot \text{m}^{-1}$) in patients ($n=6$) and controls ($n=22$) walking with and without multi-layer high-compression bandaging.

The relative oxygen cost of treadmill walking, % VO_2 max of walking $[(\text{VO}_2 \text{ walking} / \text{VO}_2 \text{ bicycling}) \times 100]$ (Åstrand and Rodahl, 1977) was higher in patients than in controls with and without compression ($p=0.016/p=0.033$) (Table 7, Figure 10). The relative oxygen cost of walking in patients was calculated to 60% (43-108) % with compression as compared to 43% (27-72) % in controls. Four of five patients used 50% or more of their maximal oxygen capacity as compared to 7 of 22 patients.

Table 7a. Impairments and activity limitations with and without compression in patients (n=6).

Patients, n=6	Without compression	With compression	p-value
	Median (range)	Median (range)	
Ankle range of motion			
Ankle range of motion (ROM) (degrees)	69 (59-81)	64 (59-74)	0.016
Plantar flexion (degrees)	41 (29-49)	39 (30-47)	0.531
Dorsiflexion (degrees)	30 (22-34)	26 (22-32)	0.063
Treadmill walking			
Self-selected walking speed (m·s ⁻¹)	1.11 (0.92-1.39)	1.11 (0.92-1.39)	-
Oxygen consumption, VO ₂ (l·min ⁻¹)	1.21 (0.82-1.49)	1.26 (0.79-1.55)	0.463
Oxygen cost, VO ₂ /kg			
ml·kg ⁻¹ ·min ⁻¹	12.8 (11.5-15.4)	13.45 (12.0-15.6)	0.463
ml·kg ⁻¹ ·m ⁻¹	0.204 (0.16-0.23)	0.206 (0.16-0.25)	0.345
Oxygen cost (%)	59 (43-98)	60 (43-108)	0.665
Heart rate (beats·min ⁻¹)	102 (87-121)	102 (81-122)	0.854
Perceived exertion (6-20)	11 (9-13)	11 (9-13)	0.317

Table 7b. Impairments and activity limitations with and without compression in controls (n=22).

Controls, n=22	Without compression	With compression	p-value
	Median (range)	Median (range)	
Ankle range of motion			
Ankle range of motion (ROM) (degrees)	87 (69-108)	83 (68-105)	0.001
Plantar flexion (degrees)	51 (39-61)	50 (34-60)	0.175
Dorsiflexion (degrees)	36 (24-49)	34 (22-47)	0.004
Treadmill walking			
Self-selected walking speed (m·s ⁻¹)	1.32 (1.11-1.50)	1.32 (1.11-1.50)	-
Oxygen consumption, VO ₂ (l·min ⁻¹)	0.86 (0.49-1.94)	0.84 (0.54-1.49)	0.974
Oxygen cost, VO ₂ ·kg ⁻¹			
ml·kg ⁻¹ ·min ⁻¹	11.9 (9.42-17.03)	12.2 (9.7-18.2)	0.465
ml·kg ⁻¹ ·m ⁻¹	0.156 (0.13-0.23)	0.152 (0.13-0.24)	0.505
Oxygen cost (%)	43 (29-77)	43 (27-72)	0.987
Heart rate (beats·min ⁻¹)	87 (70-113)	86 (71-117)	0.182
Perceived exertion (6-20)	11 (9-13)	11 (9-14)	0.491

Compression bandaging negatively affected walking shoe comfort in nine controls (41%), and five subjects (23%) expected that walking distance would be impaired. Five of the ulcer patients (83%) complained about reduced shoe

comfort due to compression and 3 (50%) expected that walking distance would be impaired.

4.4 PERCEPTIONS OF PHYSICAL ACTIVITY

4.4.1 Study IV

Four qualitatively different categories of perception and comprehension of physical activity were identified and described. The categories could be interpreted using a two-dimensioned construct: (1) the understanding of leg ulcer as a chronic or acute condition (chronic versus acute) and (2) the way patients met dilemmas and hindrances regarding physical activity in daily life (confront versus avoid) (Figure 11). Irrespective of category information regarding physical activity was insufficient or contradictory. Thus, most participants displayed poor understanding of the physiology and the pathology of the underlying disease or the effect of physical activity on venous circulation.

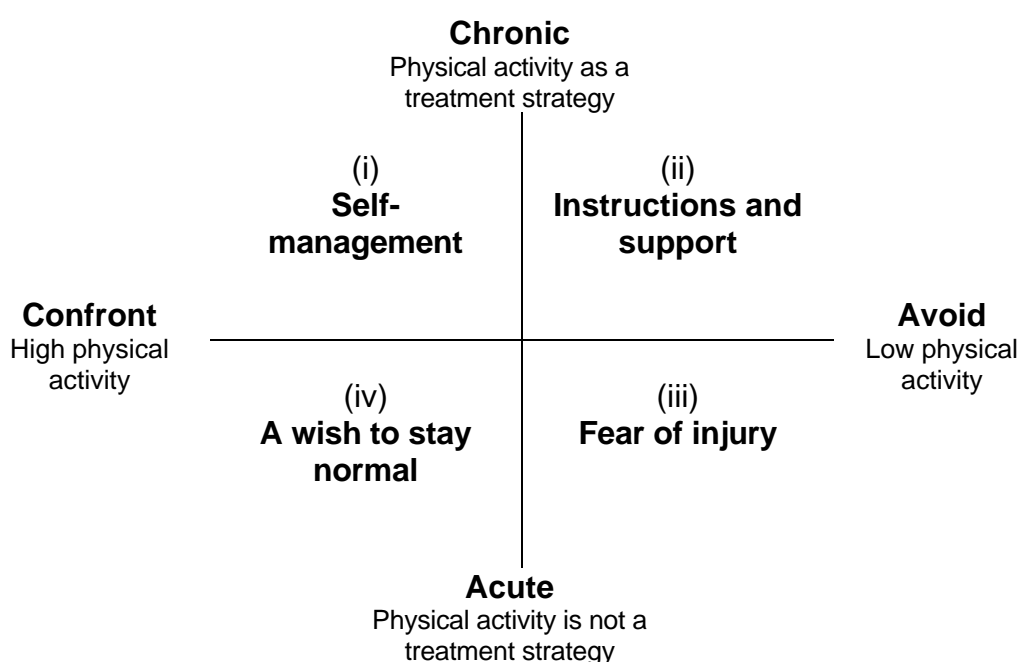


Figure 11. The categories for perception of physical activity in patients (n=22) related to their view of leg ulcer as a chronic or acute condition and how they met barriers related to physical activity and venous leg ulcer in daily life.

The first category of description, '*self-management*' comprised an understanding of physical activity as a life-long treatment strategy to increase circulation. Physical activity was described as a necessity to be able to live with the disease and as an important factor to regain and maintain functioning and health despite the inconvenience of venous leg ulcer. As no long-term

negative effects were experienced, the individuals chose to trust themselves and stay physically active despite of contradictory advices from care givers.

...the only way is to keep moving and improve your circulation. And then you improve everything in your body (P9).

In the second category, ‘instructions and support’ physical activity required external support and reminders, as individuals lacked initiative or discipline or were overwhelmed by barriers. Lack of initiative was reinforced by insufficient and contradictory information. Physical activity was understood as the responsibility of care-givers, leading to a wish for someone else to take the responsibility. The respondents were disappointed in health-care providers who focused solely on ulcer care and not on the patient’s wellbeing.

Actually I’m a bit lazy, I’d need someone to say ”now it’s ten o’clock, now we’re going for a walk”. Someone who gets you going, you get ... once the ulcer has healed, then it’s fine (P3).

In the third category, ‘fear of injury’ physical activity involved fear of increased pain and fear of injury. Physical as well as social activities were viewed as risk-taking action to be postponed until the ulcer was healed. Leg ulcer was experienced as an acute condition that would pass off once the ulcer had healed.

Oh yes, I’m ever so careful. Definitely. If there’s too many people, I don’t join in. Well, if I get kicked or something happens, then it’s likely I’ll get an ulcer again. So I’m very, very careful (P17).

In the fourth category, ‘a wish to stay normal’ comprised an understanding of physical activity as maintaining an identity as a normal person. Physical activity was used to gain well-being and distract pain, not as a treatment strategy. Adherence to compression therapy was poor and inconsistent, given the lack of knowledge of the chronic nature of the underlying disease and the fact that using compression stockings threatened one’s identity as a normal person.

Many of my neighbours here don’t know I’ve got leg ulcers. Why should I tell them? I don’t want anyone to feel sorry for me. Even the bloke I sometimes go fishing with doesn’t know (P5).

Compression stockings is something I don’t want to know about. I wasn’t quite alert enough, it just wasn’t my style to have compression stockings. Elderly ladies were the ones who had them (laughter) (P16).

4.5 ADDITIONAL RESULTS

Some common characteristics in patients in Study I-IV are shown in Table 8.

Table 8. Some common characteristics of patients in Study I-IV.

	Study I n=34	Study II n=98	Study III n=6	Study IV n=22
Body functions and structures				
Disease duration ¹ , years, md (range)	5 (0.7-52)	5.9 (0.3-57)	5.5 (2-11)	8 (0.1-51)
Active ulcer, n (%)	21 (62)	55 (56)	0 (0)	10 (46)
Chronic conditions, n, md (range)		4 (1-8)	2 (1-4)	4 (2-7)
Pain is a problem, n (%)	17 (50)	42 (43)	0	7 (32)
Ankle ROM, degrees	53 (10-85)		69 (59-81)	
Activities				
Walking speed, m/s, md (range)	1.1 (0.4-1.8)		1.4 (1.2-1.6)	
Physical activity 1-2, n (%)	17 (50)	42 (43)	0 (0)	16 (73)
Physical activity ≥4, n (%)	4 (12)	18 (18)	3 (50)	6 (27)
Self-rated mobility, good/excellent, n (%)	10 (29)	35 (36)	5 (83)	12 (55)
Environmental and personal factors				
Gender, female (%)	34 (100)	62 (63)	2 (33)	13 (59)
Age, years, md (range)	77 (60-85)	76 (60-86)	66 (58-83)	75 (60-86)
BMI, kg·m ⁻²	25 (19-41)	27 (17-48)	28 (23-37)	24 (19-36)
Walking aids, outdoor, n (%)	18 (53)	53 (54)	0	10 (46)

¹Physical activity: 1 'Hardly any physical activity', 2 'Mostly sitting, sometimes a walk, sometimes light domestic work'; ≥4 'Moderate exercise, 1-2 hours/week' or more.

5 DISCUSSION

By combining clinical investigation with a set of physical test procedures and questionnaires, a broad apprehension of impairments, activity limitations and participation restrictions was attained. The evaluation was done within the framework of ICF since its standardised language seems particularly useful in understanding functioning and disability in chronic disease states like venous leg ulcer. To our knowledge no other study has focused on so many aspects regarding functioning and disabilities in this patient group, and ICF is applied for the first time in this field.

5.1 PHYSICAL ACTIVITY

Physical activity level

Most 76-year-olds in Sweden have a physical activity level of 4) 'moderate exercise 1-2 hours a week, responsibility for all domestic activities' (Frändin and Grimby, 1994). In our studies the most common scores were 2) 'mostly sitting, sometimes a walk, sometimes light domestic work' and 3) 'light physical activity for 2-4 hours a week, responsibility for light domestic work'. In Study I and II (n=132), 45% of the patients had score 1 and 2, 'hardly any physical activity' and 'mostly sitting, sometimes a walk' and only 17% had score 4 or more. Heinen et al., (2007a) also found a lower level of physical activity in the patient group as compared to the Dutch adult population an only 13% of the patients walked for 30 minutes on at least 5 days a week. Clearly, patients with venous leg ulcer have a low level of physical activity and spend little time walking. This is worrying as walking effectively activates the calf-muscle pump and reduces venous hypertension in combination with compression (Ibegbuna et al., 2003). Evidently, physical activity and leg exercise levels in patients with leg ulcers need to be stimulated, in the short term to increase leg-muscle strength and calf-muscle pump output, and in the long term to increase physical fitness (increase maximal oxygen capacity) and prevent ulcer-recurrence and post-ulcer functional limitations.

5.2 DISABILITIES INFLUENCING PHYSICAL ACTIVITY

Pain

The proportion of patients with pain problems in Study I and II was in accordance with other studies on pain in venous leg ulcer (Hofman et al., 1997; Hyland and Thomson, 1994). In line with Hofman et al. (1997) and Phillips et al. (1994) we found that 67% of the active ulcer patients experienced pain as a problem, while only 38% reported pain the day of investigation, which support the impression of pain being an intermittent problem much dependent on ulcer-status. Several studies indicate that pain intensity in these patients is strongly

related to activity limitations (Persoon et al., 2004). Pain-related fear of movement and associated avoidance behaviour has for the first time been described in these patients (Study II) and must also be considered. The median level of fear-avoidance beliefs in our patients was similar to levels in patients with chronic musculoskeletal pain (Pfungsten et al., 2000; Crombez et al., 1999; Waddell et al., 1993). In these patients, fear-avoidance beliefs are found to be one of the most potent predictors of low physical activity and self-reported disability and have been put forth as a central mechanism in the development of a chronic problem. It seems important to optimize pain-relief in patients with pain problems in order to enhance physical activity and leg exercise. As ulcer pain is intermittent, pain treatment has to be focused upon flexible pain-reduction procedures.

Ankle range of motion

In Study I and III we found a significant reduction in ankle range of motion (ROM) on both the ulcerated leg and the unaffected leg both in patients with current leg ulcers and those with previous ones. Patients with active ulcers had lower median values than healed patients supporting findings by Back et al. (1995) and Dix et al., (2003) who concluded that limbs with chronic venous insufficiency (CVI) had significantly reduced ankle ROM, which became more pronounced with progression in clinical severity of CVI. Reduced ankle ROM is found to reduce the efficacy of the calf-muscle pump and decrease venous emptying of the leg during walking (Kügler et al., 2001). The negative effect of reduced ankle ROM on ulcer-healing was demonstrated by Barwell et al. (2001) who found that only 13% of patients with below 35 degrees ankle ROM, had healed in 24 weeks compared to 60% of those with more than 35 degrees. It is generally agreed that dorsiflexion past the 90 degree "neutral" position is needed for a normal walking motion and full activation of the calf-muscle pump, as are adequate footwear and an adequate push-off phase (Araki et al., 1994). High-heeled shoes are therefore not recommended in patients with venous leg ulcer. In Study I, however, high heeled shoes made walking possible in some patients with a negative dorsiflexion.

Ankle range of motion can be reduced by several factors such as inactivity, high age, pain, skin changes and arthritis. Study III showed that ankle ROM was reduced with compression both in patients and in control subjects. Ankle ROM is dependent on the integrated function of nerves, muscles, tendons, capsules, ligaments, and cartilages. Thus, ankle ROM may be altered by conditions that affect the functional capability of any of these components. Davies et al. (2007) found that a simple, home-based exercise programme was effective in improving ankle ROM, and Klyszcz et al. (1995) demonstrated the effect of a structured out-patient exercise programme on ankle ROM. Thus, the ankle-restricting effect of compression should be counteracted with a regular

exercise programme prescribed with the compression garment. Compression stockings, which cause little restriction of ankle range of motion, are preferable to bandages when appropriate.

Calf muscle strength and dorsiflexor strength

Calf muscle strength was reduced in both legs, whether involved by an ulcer or not, and in both the active ulcer and healed ulcer groups (Study I). Patients with active ulceration, however, showed a larger reduction in muscle strength than healed patients irrespective of duration of leg ulcer disease. We found that the calf muscle antagonist, dorsiflexion, was also weakened. Our findings are consistent with those of Yang et al. (1999) and Uden et al. (2005) who reported impaired calf muscle function in patients with venous leg ulcer compared to healthy subjects. Bed rest and inactivity particularly affects muscles in the lower leg, both plantar flexors and the dorsiflexor and should therefore be avoided in this patient group. Musculoskeletal dysfunction of the leg is associated with poor function of the calf-muscle pump both in healthy people (Kügler et al., 2001) and in leg ulcer patients (Araki et al., 1994; Back et al., 1995) and should thus be counteracted with a structured leg exercise programme in addition to regular walking.

Oxygen cost of walking

The relative oxygen cost of walking in patients ($\% \text{VO}_2\text{max} \cdot \text{kg}^{-1}$) was higher than in controls as a result of a low maximal aerobic capacity ($\text{VO}_2\text{max} \cdot \text{kg}^{-1}$). This means that walking is hard work. The relative oxygen cost of walking with and without compression in patients was calculated to 59-60% of VO_2max both with and without compression. Walking requires little effort as long as it taxes less than 50% of VO_2max (Waters and Mulroy, 1999). With compression, four out of five patients used 50% or more of their maximal oxygen capacity. According to Waters and Mulroy (1999) the rate of oxygen consumption at self-selected walking speed requires 48% of the VO_2max of a subject 75 years of age. If a high percentage of maximal oxygen capacity is used during an activity the person will experience high exertion after some minutes of walking and will thus probably not reach the recommended daily 30 minutes of physical activity. This was demonstrated by Mattsson et al. (1997) in obese women where walking was a very exhausting activity. In the tested patients with venous disease, walking at a self-selected walking speed will probably not be tolerated for 30 minutes to enhance health benefits. To achieve health benefits patients should be encouraged to walk in bouts of at least 10 minutes three times a day. To achieve increased venous circulation, even slow walking and walking for shorter periods of time have a positive effect.

Walking speed and walking endurance

Our findings of reduced walking speed and walking endurance accord with those of Uden et al. (2005), who also found disturbances in gait-variables such as cadence and stride length compared to controls. Normal walking is a most efficient way to optimize the effect of the calf-muscle pump on venous return in combination with compression therapy (Ibegbuna et al., 2003), even at low walking speeds. Walking more briskly and taking larger steps, might make the foot-, ankle- and calf pump mechanisms work more effectively, but can affect venous pressure negatively as a result of exercise hyperaemia and lymphatic leak. Stick et al. (1992) found that venous pressure during fast walking ($6 \text{ km}\cdot\text{h}^{-1}$) and running ($10 \text{ km}\cdot\text{h}^{-1}$) increased compared to that during walking at $3 \text{ km}\cdot\text{h}^{-1}$. Vigorous exercise has been found to increase the likelihood of the development of the first time venous ulcer (Bérard et al., 2002), probably due to high gravity effect and increased venous pressure. Thus, adaptation and monitoring of walking and other physical activities seem to be important. A dynamic activity at moderate intensity and low impact and gravity effect in combination with compression, might probably be advocated.

5.3 CONTEXTUAL FACTORS AS FACILITATORS OR BARRIERS FOR PHYSICAL ACTIVITY

Fear of movement and avoidance behaviour

To our knowledge Study II is the first study on fear of movement and associated avoidance behaviour in patients with venous leg ulcer. It showed that fear-avoidance beliefs were present in a majority of patients and that strong fear-avoidance beliefs were a predictor of low physical activity. Even a third of the patients with healed ulcers reported elevated scores on fear-avoidance beliefs. In Study IV, 'fear of injury' represented one out of four categories of descriptions of physical activity. Physical activities as well as social were viewed as risk-taking actions to be postponed until the ulcer had healed. Patients used their skill in recognising threats known to damage the skin on their legs and were watchful and pre-occupied with safety and self-protecting. Safety-seeking behaviour and hyper-vigilance are well-known phenomena in avoidance in avoidance behaviour, as discussed by (Leeuw et al., 2007) leading to low physical activity. Leg ulcer seemed to be experienced as an acute condition that would pass off once the ulcer had healed.

Patients with chronic venous disease live in uncertainty knowing the danger of re-ulceration. In the acute stage, when the pain is a result of an open leg ulcer or infection, fear and associated avoidance behaviour are likely to be adequate as they will direct attention towards the injury, enhance necessary care and facilitate healing. A slight decrease in physical activity or adapted physical activity with an unhealed ulcer can therefore be adequate in the acute stage.

However, when leg ulcers are healed or are slowly healing, fear of movement and avoidance behaviour becomes dysfunctional if they go beyond protecting the leg from trauma through compression treatment and clothing. It seems important to identify the patients with dysfunctional fear of movement and avoidance behaviour, as avoidance behaviour might have a profound negative effect on physical activity. An early identification and treatment of patients with dysfunctional fear of movement and associated avoidance behaviour could lead to better preventive interventions.

Perceptions of physical activity

Although physical activity is recommended for patients with venous leg ulcer, the patient perspective on physical activity has not previously been studied. Four qualitatively different ways of perceiving and understanding physical activity were described. Whether or not leg ulceration was viewed as a chronic or an acute event was an important aspect of various ways of perceiving and understanding physical activity. The participants who understood the chronic nature of venous insufficiency as the cause of leg ulcer saw physical activity as a plausible treatment strategy, as seen in the categories 'self-management' and 'instruction and support'. This was in contrast with patients with conceptions of leg ulceration as an acute event, as in 'fear of injury' and 'a wish to stay normal'. Understanding of the potential effect of physical activity on ulcer-healing and the prevention of recurrence was generally poor, as was understanding of the importance of adherence to compression therapy to optimize the effect of physical activity on venous circulation. The findings are consistent with those of Edwards et al. (2002), who reported that patients' knowledge of their condition was poor, with little understanding of the underlying pathology and those of Flaherty (2005). Flaherty found that the patients who were fairly well-informed made conscious decisions about lifestyle changes, including exercise, whereas those who displayed poor understanding of the disease and the treatment, especially of the chronicity of venous insufficiency, viewed their previous ulceration as an acute episode that had healed and considered themselves cured. Briggs and Flemming (2007) and Van Hecke et al. (2008) suggest that a change in the focus of leg-ulcer care is needed, from viewing leg ulcer as an acute event with wound healing as the only desirable outcome to viewing it as a chronic condition in need of long-term care. The shift from specialists' healing-rates to self-care and symptom management (reducing pain and improving physical activity), may in turn affect healing, as also argued by Persoon et al. (2004).

Irrespective of category, few of our participants had been encouraged by health-care providers to consider physical activity as an optional treatment strategy or to find ways to exercise despite the inconveniences of venous insufficiency and recurrent leg ulcer.

Vague and inaccurate life-style advice such as ‘live as usual’ and contradictory exercise advice, as found through the present study, are not fruitful strategies. Health professionals’ ability to impart clear-cut and consistent information must be strongly improved, likewise their ability to support and encourage physical activity.

Walking aids and community services

The frequent use of walking aids and utilisation of community services demonstrates a high degree of disability, but also that relatively simple adaptations in daily life can be favourable for functioning as they foster participation.

Four-layer high-compression bandaging

The compression system tested in Study III was a four-layer high-compression bandage in everyday use to treat venous leg ulcer. Multi-layer compression systems are effective and widely used (Cullum et al., 2001a). Their effect on ankle joint mobility or gait capacity has to our knowledge not been studied before. Our finding that ankle range of motion was decreased with compression is in accordance with the study of Lentner et al. (1997), who demonstrated that compression bandaging restricted ankle joint mobility between 7 and 32% in healthy subjects, and that thick bandages led to a larger decrease than thin ones. The reduction in our study (3-4%) was significant, but more modest. However, Lentner et al. (1997) used a passive measurement without loading on the foot, since we used a loaded method as it is considered to be the clinical test that correlates best with end results after ankle problems such as immobilization and fractures (Nilson et al., 2003). A three to four percent reduction in ankle mobility is probably of minor clinical significant in healthy subjects with normal ankle range of motion, but might have considerable significance for leg-ulcer patients. Artificially restricting the movement of the ankle joint is reported to decrease the effectiveness of the calf muscle pump in healthy subjects (Kügler et al., 2001). This is probably also the case for leg ulcer patients. Thus, partial immobilization with compression should be counteracted with a regular exercise programme.

Walking shoe comfort with compression

Reduction of walking-shoe comfort and walking ability was frequently reported by patients and controls. To facilitate recommended physical activity in patients with venous leg ulcer, the use of appropriate walking shoes in combination with compression garments should be stressed.

Adequate footwear and an adequate push-off phase are necessary for an effective calf-muscle pump function (Araki et al., 1994).

5.4 THE RELATIONSHIP BETWEEN PHYSICAL ACTIVITY, DISABILITY AND CONTEXTUAL FACTORS

To get a more comprehensive picture of factors influencing physical activity in the present work, disabilities, known risk factors for disability (Fiatarona Singh, 2002); gender, age, disease duration, chronic conditions and BMI, and contextual factors from Study I-IV were categorized according to the components of the ICF (Table 9).

Factors unmodifiable by physical activity such as gender and age, and disease related factors like disease duration and chronic conditions, had the least influence on physical activity in the present work. Further, factors that are more likely to be modified by physical activity such as pain, ankle range of motion, calf muscle strength, oxygen cost of walking and walking speed, were found to impede physical activity, but not preclude physical activity.

Main obstacles to physical activity were external influences from environmental factors such as compression bandaging, inappropriate walking shoes and poor or lacking support. Additional obstacles to physical activity were found in personal factors such as dysfunctional fear of movement and poor or lacking knowledge of the chronicity of the underlying disease and the effect of physical activity in venous leg ulcer. This accords to Heinen et al. (2007b) who found that pain, lack of knowledge and inaccurate beliefs, lack of social and professional support and low self-efficacy for enhancing physical activity were predictors for physical activity. In opposition to their findings, multi-morbidity seemed not to be the main obstacle to physical activity in the present work.

Recognition of the role of fear-avoidance beliefs, disease and health education, lifestyle counselling and exercise and physical activity in prevention and treatment of patients with venous leg ulcer is vital to optimal management of this problem. A high level of adherence to long-term therapies is, according to the World Health Organization review (Sabate, 2003), associated with factors as knowledge of the severity of the disease and belief in the efficacy of treatment, adequate social support, and trust in the care-givers. Thus, addressing these factors is a main challenge in the management of venous leg ulcers. The patients have a medical condition for which physical activity is therapeutic and beneficial and should therefore perform physical activity in a manner that both treats the condition and reduces the risk of developing long-term post-ulcer functional limitations and reduced health. This approach might be associated with reduced costs, both for society and for the individual patient.

Table 9. Relationship between physical activity, disability and contextual factors in patients with venous leg ulcer in relation to the components of the ICF (WHO, 2001). Variables listed with study numbers in brackets.

Influence on physical activity	Body functions and structures	Activity/ participation	Environmental Factors	Personal factors
I Factors with the least influence on physical activity	Number of chronic conditions (I-IV)			Gender (I-IV)
	Disease duration (I-IV)			Age (I-IV)
				BMI (I-IV)
II Factors impeding but not precluding physical activity	Ulcer status (I, II, IV)	Walking speed (I, III)	Facilitators to physical activity	
	Pain (I, II, IV)	Walking endurance (I, III)	Walking aids (I)	Knowledge of the chronic nature of the underlying disease (IV)
	Ankle range of motion (I, III)	Perceived exertion (I, III)	Appropriate walking shoes (III)	Knowledge of the effect of physical activity in venous leg ulcer (IV)
	Calf-muscle strength (I)	Mobility (I, II)	Community services (I)	Confronting barriers to physical activity (IV)
	Oxygen cost of walking (III)	Primary ADL (I, II)	Support and encouragement (IV)	Satisfaction with - Life as a whole - Economy - Physical health - Psychological health (I)
		Extended ADL (I)		Perception of general health as good (I)
		Dissatisfaction with - dependence in ADL - daytime activities - contact with friends (I)		
		Satisfaction with - leisure time - family life (I)		
			Barriers to physical activity	
			Four-layer high-compression bandaging (III)	Dysfunctional fear of movement and associated avoidance behaviour (II)
III Factors that are great obstacles to physical activity			Inappropriate walking shoes (III)	Avoiding barriers to physical activity (IV)
			Poor or lacking support (IV)	Poor or lacking knowledge of the chronic nature of the underlying disease (IV)
				Poor or lacking knowledge of the effect of physical activity in venous leg ulcer (IV)

5.5 METHODOLOGICAL CONSIDERATIONS

5.5.1 Samples and study design

In this thesis all patients were included from outpatient dermatology clinics. In Sweden, most patients with uncomplicated venous leg ulcer are treated by general practitioners and/or nurses from community health-care and home health-care organizations. Patients with poorly healing wounds, recurrent wounds, or wounds related to more complicated aetiology are referred to outpatient dermatology clinics (Socialstyrelsen, 2005). As a result, the generalization of our findings may be limited to patients with more severe venous leg ulcer concerns. However, given the characteristics of the patients included and the insight that qualitative research does not aim at generalize results, the results might be considered transferable to patients with venous leg ulcer in outpatient clinics in general.

The fact that a number of patients declined participation in Study II, III and IV may have created a selection bias. The prevalence of patients with health-enhancing physical activity was higher in Study II, III and IV as compared to Study I, - where only three patients declined participation. The increasing number of persons with moderate intensity physical activity in Studies II-IV might indicate that patients that declined the invitation to participate had even more severe venous leg ulcer concerns. Generally, studies involving/discussing physical activity probably attract individuals who have a special interest in physical activity, exercise and health. Therefore the result of Study II, III and IV might mainly be considered valid for patients holding this special interest. The results in patients from Study III should be interpreted with caution due to the low number of patients.

In Study IV, purposeful sampling was not performed as discussed by Rolfe (2006). However, to secure a wider variation in length of leg ulcer disease, inclusion criteria was slightly changed to include patients with short-time leg ulcer concerns (<6 weeks). One might argue that a strategic, purposeful sampling would have been preferred to secure a wide variation in perceptions of the phenomenon studied. However, the patients that accepted the invitation to participate represented a wide variation regarding to important factors as gender, age, BMI, previous history of leg ulcer and length of leg ulcer disease to secure variation of perceptions and richness of detailed information. The decliners in Study II differed slightly from the participators in gender as significantly more women declined. This may have influenced the result. The results of Study II-IV may therefore be valid preferably for male and female patients holding a special interest in physical activity in relation to venous leg ulcer.

The cross sectional design of the studies is a limitation. To be able to draw any causal relationships, longitudinal studies are needed using objective and subjective measures of physical activity together with outcomes of functioning, disability, healing rates and recurrence rates. This could lead to a better understanding of the relationship between physical activity, disability, ulcer healing and ulcer recurrence. This could also bring knowledge of the dose-response relationship of physical activity in venous ulceration. The preferable mode, intensity, duration and frequency of physical activity in venous leg ulcer have to be illuminated in further studies.

5.5.2 Methods

The methods in this thesis have both strengths and limitations. The use of several methods, such as self-reported data, validated questionnaires and data from medical files, clinical tests and in depth-interviews is a strength. One limitation is that none of the assessment methods have been validated for this specific patient population. However, all but one of the chosen assessment methods is valid and reliable outcome measures frequently used in rehabilitation in adult patients with other chronic diseases. The use of the International Classification of Functioning, Disability and Health (ICF) as a conceptual framework is a strength, however we have few outcome measures related to ‘participation’ and ‘participation restrictions’ which is a limitation.

One outcome measure was designed to fit the patient group, self-rated mobility. We wanted a short and simple measure of mobility based on the assumption that the way an individual rate, comprehend and perceive their own functioning, influence their actual performance, i.e. what the individual really does in his or her current environment (WHO, 2001). In all studies self-rated mobility showed the same tendency as validated measures of functioning and disability, strengthening the face validity of this simple measure. Thus, having an obvious face validity, further validity and reliability has to be established.

In all studies, level of physical activity is reported by self-reports using a standardized questionnaire. One limitation with using self-report instruments for physical activity is the complex nature of physical activity itself. Physical activity is a construct of body movement and can be assessed either as the behaviour, or as the energy costs of the body movement (LaMonte and Ainsworth, 2001). Another limitation is that it is potentially liable to different measurement biases (Sallis and Saelens, 2000; Ainsworth and Levy, 2004). One is recall, which may differ among individuals. Strength of the present studies is the cross sectional designs which reduce recall bias. In Study I, however, the patients were asked to recall the impact of leg ulcer on general health in retrospect and one can argue that this is biased. One important measurement bias is the individual perception of what physical activity

comprises. To reduce bias, all subjects in Study I and IV were interviewed using a structured questionnaire enabling additional information about what physical activity comprises. In Study III self-reports of physical activity was discussed with each person against measures of VO_2 and health counselling. In Study II the concept of physical activity was explained in the question heading to reduce bias. Another possible bias is desirability and the possibility of over-report of physical activity in Study II. However, more patients in Study II reported 'hardly any physical activity' (score 1) than in the other studies, indicating that this was probably not the case. It is strengthening that physical activity in his thesis was reported using a questionnaires where physical activity involved in transport occupation and housework were included, as this improves the accuracy of assessment of physical activity, particularly in women (Ainsworth and Levi, 2004).

In Study IV several strategies were used to establish and maintain trustworthiness (Rolfe, 2006). Physical activity is complex and action was taken to secure that the interviewed patients had the same understanding of the concept. Therefore, physical activity was discussed and defined early on in the interviews, as 'all daily activities that increased metabolism, such as household activities, shopping, transport, walking, exercising etc'. The participants had no relationship with the interviewer and were not in any position of dependence, which might reduce desirability bias. One important question is whether the full variation of perceiving and understanding physical activity was captured in the categories described. We felt that no new information was revealed during the last interviews and therefore judged that the 22 interviews were sufficient to capture satisfactory variations in understanding of physical activity in this patient group. This is in line with recommendations in phenomenography (Marton, 1981).

In Study III VO_2 during walking was calculated from the predicted VO_2 max from a sub-maximal bicycle ergometry test according to Åstrand and Rodahl (1977). A maximal test or a sub-maximal walking test on a treadmill had been preferable. This was not done, for convenience's sake and from a wish to expose the subjects to a minimum of effort. One can argue that a sub-maximal test is preferable in this patient population as it is hard to motivate chronic patients to perform until exhaustion and also a risk for complications. The potential problem with a sub-maximal test is the potential inaccuracy of maximal VO_2 values. A maximal test would probably be ended before predicted maximal heart rate was achieved due to muscular limitation. Thus, the maximal VO_2 values in Study III may be overestimated. However, since these patients were their own controls, the potential false estimations have minor significance.

In Study III we chose to measure energy expenditure at a controlled walking speed on a treadmill to guarantee the same speed both with and without compression. Self-selected walking speed differs greatly among patient populations depending on the extent of disability (Waters and Mulroy, 1999). Patients with gait disabilities, often seen in leg ulcer patients, have difficulties adjusting to walking on a treadmill. It might be preferable to test patients on a track, allowing them to select their preferred walking speed and use their customary walking aids. However, the walking speed would be difficult to standardize under those conditions.

In Study I calf-muscle strength and dorsiflexor strength was measured using maximal isometric voluntary contraction (MVC) (Ns) by strain gauge connected to a sling attached to the forefoot in a supine position. The clinical relevance of a strength test of the ankle at unloaded state may be questioned. Though not well documented this in-house method for measurement of muscle strength has obvious face validity which is strengthened by the fact that all other mobility variables pointed in the same direction.

5.6 CLINICAL IMPLICATIONS

- Physical activity should be prescribed for disability prevention and treatment, adapted and adjusted to the patients' resources and the expression of the disease. Simple and socially acceptable activities that are easily transferable to daily life should be encouraged. These would include activities like leg exercise and walking combined with compression and leg elevation while resting in accordance with the kind of compression in use.
- Pain-relief must be optimized to enhance physical activity.
- An early identification and treatment of patients with dysfunctional fear of movement and associated avoidance behaviour could lead to better preventive interventions.
- The restricting effect of multi-layer high compression bandaging on ankle range of motion should be counteracted with a regular exercise programme prescribed together with the compression garment. Compression stockings, causing little restriction of ankle range of motion, should preferably be used when appropriate.
- The use of appropriate walking shoes in combination with compression garments is important.
- Health professionals have to improve their ability to impart clear-cut information about the pathology and chronicity of the underlying disease, the effect of physical activity and the benefits of adherence to compression therapy.
- The high relative oxygen cost of walking, as a result of a low maximal aerobic capacity, means that walking is hard work. If walking for 30 minutes is not tolerated, walking in bouts of 10 minutes x 3 should be recommended to enhance health benefits.
- Normal walking is a most efficient way to optimize the effect of the calf-muscle pump on venous return in combination with compression therapy even at low walking speeds.
- Dynamic activities with low impact and gravity effect, as walking, Nordic-walking, swimming, cross-country skiing, should probably be advocated to activities with high impact and gravity effect like jogging.
- Physical activity offers a low-cost alternative with largely health related side-effects which benefits both venous circulation and general health. Effort should be made to involve patients in their care and to teach them to live with their chronic condition.
- Physiotherapists might have an important role in initiating and implementing physical activity and leg exercise as a treatments strategy in patients with venous leg ulcer.

6 SUMMARY

- To our knowledge no other study has focused on so many aspects regarding functioning and disabilities in this patient group, and the International Classification of Functioning, Disability and Health (ICF) (WHO, 2001) is applied for the first time in this field. Factors influencing physical activity were identified in most components of the ICF. Patients with active ulcer were more negatively affected than post-ulcer patients and had significant pain problems. Disabilities persisted despite wound healing. Disabilities experienced by the patients in consequence of the ulcer were profound and can aggravate the actual healing through inactivity.
- Fear-avoidance beliefs were present in 81 (83%) of the patients. Forty patients (41%) had strong fear-avoidance beliefs. Patients with low physical activity had significantly stronger fear-avoidance beliefs and more severe pain than patients with high physical activity. Odds ratio (OR) for low physical activity were about three times higher for patients with strong fear avoidance beliefs than for patients with weak fear-avoidance beliefs.
- Total ankle range of motion was decreased by 3% in patients and with 4% in controls with a multi-layer high-compression bandaging. Walking with compression showed no change in oxygen cost as compared to walking at the same speed without compression. Half the subjects reported that compression bandaging negatively affected walking-shoe comfort and 1/3 expected walking distance to be reduced with compression. The relative oxygen cost of walking, $\% \text{VO}_2\text{max} \cdot \text{kg}^{-1}$, was higher in patients than in controls as a result of low maximal aerobic capacity, $\text{VO}_2\text{max} \cdot \text{kg}^{-1}$.
- Whether or not the patients had understood the chronic nature of the underlying pathology of venous leg ulcer was an important aspect of various ways of perceiving physical activity. Four categories of descriptions of physical activity were identified; (i) 'self-management', (ii) 'instructions and support', (iii) 'fear of injury' and (iv) 'a wish to stay normal'. Irrespective of category, the participants reported that information from care-givers regarding physical activity was insufficient or contradictory. Written information or exercise programmes were not obtained regularly and not at all in primary care.

7 CONCLUSION

Factors influencing physical activity were identified in most components of the International Classification of Functioning, Disability and Health (ICF). Patients with active ulcer were more negatively affected than post-ulcer patients and had significantly more pain problems. Disabilities persisted despite wound healing. Strong fear-avoidance beliefs were present and associated with low physical activity. Use of multi-layer high-compression bandaging decreased ankle range of motion but did not increase oxygen cost of walking. Whether or not the patients had understood the chronic nature of the underlying pathology was an important aspect of various ways of perceiving physical activity. Disabilities impeded, but did not preclude physical activity. Certain environmental factors such as compression bandaging, inappropriate walking shoes and lack of support, and personal factors such as dysfunctional fear of movement and poor or no knowledge of the chronicity of the underlying disease and the effect of physical activity were the greatest obstacles to physical activity.

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9 REFERENCES

- Abadi S, Nelson EA, Dehghani A. Venous ulceration and the measurement of movement: a review. *J Wound Care* 2007; 16: 396-402.
- Ainsworth BE, Levy SS. Assessment of health-enhancing physical activity. Methodological issues. In Oja P, Borms J (Eds.) *Health enhancing physical activity*. Oxford UK: Meyer & Meyer Sport 2004, pages 239-270.
- Agu O, Baker D, Seifalian AM. Effect of graduated compression stockings on limb oxygenation and venous function during exercise in patients with venous insufficiency. *J Vasc Surg* 2003; 12(1): 69-78.
- Alguire PC, Mathes B. Chronic venous insufficiency and venous ulceration. *J Gen Int Med* 1997; 12: 374-383.
- Araki CT, Back TL, Padberg FT, Thompson PN, Jamil Z, Lee BC, Duran WN, Hobson RW 2nd. The significance of calf-muscle pump function in venous ulceration. *J Vasc Surg* 1994; 20: 872-879.
- Back TL, Padberg FT, Araki CT, Thompson PT, Hobson RW. Limited range of motion is a significant factor in venous ulceration. *J Vasc Surg* 1995; 22: 519-523.
- Baker SR, Stacey MC, Jopp-McKay AG, Hoskin SE, Thompson PJ. Epidemiology of chronic venous ulcers. *Brit J Surg* 1991; 78: 864-867.
- Barwell JR, Taylor M, Deacon J, Davis C, Whyman MR, Poskitt KR. Ankle mobility is a risk factor for healing of chronic venous leg ulcer. *Phlebology* 2001; 16: 38-40.
- Bérard A, Abenhaim L, Platt R, Kahn SR, Steinmetz O. Risk factors for the first-time development of venous ulcers of the lower limbs: The influence of heredity and physical activity. *Angiology* 2002; 53: 647-657.
- Bernard A, McCosker H, Gerber R. Phenomenography: A qualitative research approach for exploring understanding in health-care. *Qual Health Res* 1999; 9: 212-226.
- Borg GAV. Psychophysical bases of perceived exertion. *Med Sci Sports Exerc* 1982; 14(5): 377-381.
- Butland RJA, Pang J, Gross ER, Woodcock AA, Geddes DM. Two, six, and 12-minute walking tests in respiratory disease. *BMJ* 1982; 284: 1604-1608.
- Briggs M and Flemming K. Living with leg ulceration: a synthesis of qualitative research. *J Adv Nurs* 2007; 59: 319-328.
- Callam MJ, Harper DR, Dale JJ, Ruckley CV. Chronic ulcer of the leg: clinical history. *BMJ* 1987; 294: 1389-1391.
- Callam M. Prevalence of chronic leg ulceration and severe chronic venous disease in western countries. *Phlebology* 1992; (suppl 1): 6-12.
- Carlsson AM. Assessment of chronic pain. Part I: Aspects of reliability and validity of the visual analogue scale. *Pain* 1993; 16: 87-101.

- Caspersen CJ, Powell KE, Christenson GM. Physical activity, exercise, and physical fitness: definitions and distinctions for health-related research. *Public Health Rep* 1985; 100: 126-131.
- Chase SK, Melloni M, Savage A. A forever healing: The lived experience of venous ulcer disease. *J Vasc Nurs* 1997; 15: 73-78.
- Coleridge Smith PD. The management of chronic venous disorders of the leg: an evidence-based report of an International Task Force. *Phlebology* 1999; 14 suppl.1: 72-76.
- Collen FM, Wade DT, Robb GF, Bradshaw CM. The Rivermead Mobility Index: a further development of the Rivermead Motor Assessment. *Int Disabil Stud* 1991; 13(2): 50-54.
- Crombez G, Vlaeyen JWS, Heuts PHTG, Lysens R. Pain-related fear is more disabling than pain itself: Evidence on the role of pain-related fear in chronic back pain disability. *Pain* 1999; 80: 329-339.
- Cullum N, Nelson EA, Fletcher AW, Sheldon TA. Compression for venous leg ulcer. *Cochrane Database of Systematic Reviews* 2001a, Issue 2.
- Cullum N, Nelson EA, Flemming K, Sheldon T. Systematic reviews of wound care management: (5) beds; (6) compression; (7) laser therapy, therapeutic ultrasound, electrotherapy and electromagnetic therapy. *Health Technol Assess* 2001b; 5: 1-221.
- CREST. Guidelines for the assessment and management of leg ulceration. Recommendations for Practice 1998. <http://www.n-i.nhs.uk/crest> (Access 7 June 2009)
- Dahlgren LO, Fallsberg M. Phenomenography as a qualitative approach in social pharmacy research. *J Soc Adm Pharm* 1991; 8: 150-156.
- Davies JA, Bull RH, Farrelly IJ, Wakelin MJ. A home-based exercise programme improves ankle range of motion in long-term venous ulcer patients. *Phlebology* 2007; 22: 86-89.
- Dix FP, Brooke R, McCollum CN. Venous disease is associated with an impaired range of of ankle movement. *Eur J Vasc Endovasc Surg* 2003; 25 (6): 556-561.
- Dix FP; Reilly B, David MC, Simon D, Dowling E, Ivers L, Bhowmick A, McCollum CN. Effect of leg elevation on healing, venous velocity and ambulatory venous pressure in venous ulceration. *Phlebology* 2005; 20(2): 87-94.
- Domholdt E. *Rehabilitation Research. Principles and Application*. Third Edition. Elsevier Saunders, St.Louis, Missouri, USA, 2005, page 358.
- Donovan KJ, O'Keeffe DT, Grace PA, Lyons GM. Accelerometer based calf-muscle pump activity monitoring. *Med Eng Phys* 2005; 27 (8): 717-722.
- Douglas V. Living with a chronic ulcer: an insight into patients' experiences and feelings. *J Wound Care* 2001; 10: 355-360.

- Ebbeskog B, Ekman S-L. Elderly persons' experiences of living with venous leg ulcer: living in a dialectal relationship between freedom and imprisonment. *Scand J Car Scien* 2001; 15(3): 235-243.
- Edwards L, Moffatt CJ, Franks PJ. An exploration of patient understanding of leg ulceration. *J Wound Care* 2002; 11: 33-39.
- Etris MB, Pribble J, LaBrecque J. Evaluation of two wound measurement methods in a multi-center, controlled study. *Ostomy Wound Manage* 1994; 40(7): 44-48.
- Faresjö T, Frödin T, Vahlquist C, Klevbrand M, Elfström J, Leszniewska D, Larsson A. Costs of the treatment of leg ulcers: initiating a quality assurance process. *Int j Health Care Quality Assurance* 1997; 10(3): 125-130.
- Fagrell B, Om... Venös insufficiens och dess komplikationer. *Medicinsk Access* maj 2005; 4: 44-47.
- Fiatarone Singh M. Exercise to prevent and treat functional disability. *Clin Geriatr Med* 2002; 18: 431-463.
- Finlayson K, Edwards H, Courtney M. Factors associated with recurrence of venous leg ulcers: A survey and retrospective chart review. *Int J Nurs Stud* 2009; 46: 1071-1078.
- Flaherty E. The views of patients living with healed venous leg ulcer. *Nurs Stand* 2005; 19: 78-89.
- Foster C. Guidelines for health-enhancing physical activity promotion programmes. The UKK Institute for Health Promotion Research, Tampere, Finland, 2000.
- Franks PJ, Mofatt CJ, Connolly M, Bosanquet N, Oldroyd M, Greenhalgh RM, McCollum C. Factors associated with healing leg ulceration with high compression. *Age and Aging* 1995; 24: 407-410.
- Frändin K, Grimby G. Assessment of physical activity, fitness and performance in 76-years olds. *Scand J Med Sci Sports* 1994; 4: 41-46.
- FYSS. Physical activity in the prevention and treatment of disease. Statens folkhälsoinstitut, Elanders 2008, pages 11-194. In Swedish.
- Fugl-Meyer AR, Brenholm I-B, Fugl-Meyer K. Happiness and domain-specific life satisfaction in adult northern Swedes. *Clin Rehab* 1991; 5: 25-33.
- Gibson BE, Martin DK. Qualitative research and evidence-based physiotherapy practice. *Physiotherapy* 2003; 89: 350-358.
- Gourgou S, Dedieu F, Sancho-Garnier H. Lower limb venous insufficiency and tobacco smoking: a case-control study. *Am J Epidemiol* 2002; 155: 1007-1015.
- Guyatt GH, Sullivan MJ, Thompson PJ, Fallen EL, Pugsley SO, Taylor DW, Berman LB. The 6-minute walk. A new measure of exercise capacity in patients with chronic heart failure. *Can Med Assoc J* 1985; 132: 919-923.

- Harrison MB, Graham ID, Friedberg E, Lorimer K, van der Velde CS. Assessing the population with leg and foot ulcers. *Canadian Nurses* 2001; 10: 18-23.
- Haskell WL, Lee IM, Pate RR, Powell KE, Blair SN, Franklin BA, et al. Physical activity and public health: updated recommendations for adults from the American College of Sports Medicine and the American Heart Association. *Med Sci Sports Exerc* 2007; 39: 1423-1434.
- Heinen MM, van Achterberg T, Reimer WS, van der Kerkhof PC, de Lat E. Venous leg ulcer patients: a review of the literature on lifestyle and pain-related interventions. *J Clin Nurs* 2004; 13: 355-366.
- Heinen MM, Van der Vleuten CJ, de Rooij MJM, Uden CJT, Rvers AWM, van Achterberg T. Physical activity and adherence to compression therapy in patients with venous leg ulcer. *Arch Dermatol* 2007a; 143: 1283-1288.
- Heinen MM, Evers AW, Uden CJT, Van der Vleuten CJ, Van de Kerkhof PC, van Achterberg T. Sedentary patients with venous or mixed ulcers: determinants of physical activity. *J Adv Nurs* 2007b; 60: 50-57.
- Hofman D, Ryan TJ, Arnold F, Cherry GW, Lindholm C, Bjellerup M et al. Pain in venous leg ulcers. *J Wound Care* 1997; 6: 222-224.
- Hyde C, Ward B, Horesfall J, Winder G. Older women's experience of living with chronic leg ulceration. *Int J Nurs Pract* 1999; 5(4): 189-98.
- Hyland ME, Thomson B. Quality of life of patients with leg ulcers; questionnaire and preliminary findings. *J Wound Care* 1994; 3(6): 294-298.
- Ibegbuna V, Delis KT, Nicolaides AN, Aina O. Effect of elastic compression stockings on venous hemodynamics during walking. *J Vasc Surg* 2003; 37: 420-425.
- Jette AM, Davies AR, Cleary PD, Celkins DR, Rubenstein LV, Fink A, Kesecoff J, Young RT, Brook RH, Delbaco TL. The Functional Status Questionnaire: reliability and validity when used in primary care. *J Gen Intern Med* 1986; 1: 143-149.
- Kan YM, Delis, KT. Hemodynamic effects of supervised calf muscle exercise in patients with venous leg ulceration: a prospective controlled study. *Arch Surg* 2001; 136: 1364-1369.
- Kaplan GA, Camacho T. Perceived health and mortality: a nine-year follow-up of the human population laboratory cohort. *Am J Epidemiol* 1983; 117: 292-304.
- Klyscz T, Nicolaus M, Mohr C, Horstman T, Steins A, Hahn M. Clinical improvement in patients with chronic venous incompetence (CVI) with an intensified 6-week long physical training programme. *Phlebology* 1995; Suppl.1: 900-903.

- Kügler C, Strunk M, Rudofsky G. Venous pressure dynamics of the healthy human leg: role of muscle activity, joint mobility and anthropometric factors. *J Vasc Res* 2001; 38: 20-29.
- La Monte MJ, Ainsworth BE. Quantifying energy expenditure and physical activity in the context of dose response. *Med Sci Sports Exerc* 2001; 33: 370-378.
- Lentner A, Späth F, Wienert V. Limitation of movement in the ankle and talocalcaneonavicular joints caused by compression bandages. *Phlebology*; 1997; 12: 25-30.
- Lethem J, Slade PD, Troup JDG, Bentley G. Outline of a fear-avoidance model of exaggerated pain perception – I. *Behav Res Ther* 1983; 21: 401-408.
- Leeuw M, Goossens MEJB, Linton SJ, Crombez G, Boersma K, Vlayen JWS. The fear-avoidance model of musculoskeletal pain: Current state of scientific evidence. *J Behav Med* 2007; 30 (1): 77-94.
- Lindholm C, Bjellerup M, Christensen OB, Zederfeldt B. Quality of life in leg ulcer patients. An assessment according to the Nottingham Health Profile. *Acta Derm Venerol (Stockh)* 1993; 73: 440-43.
- Lindholm C. Sår, 2nd ed. Studentlitteratur, Narayana Press, Denmark 2007, pages 31-59.
- Lindahl O, Bäcklund T, Karlsson S, Söderberg T. Measuring hand muscle function with strain gauge. *Phys Med Biol* 1988; 33 (Suppl 1): 277.
- Lindsjö U, Danckwardt-Lilliestrom G, Sahlstedt B. Measurement of the motion range in the loaded ankle. *Clin Orthop Rel Res* 1985; 199: 68-71.
- Lorimer KR, Harrison MB, Graham ID, Friedberg E, Davis B. Venous leg-ulcer care: how evidence-based is nursing practice? *J Wound Ostomy Continence Nurs* 2003; 30: 132-142.
- Lundberg, M. Kinesiophobia. Various aspects of moving with musculoskeletal pain. Thesis. Göteborg, Sweden 2006, pages 18-26.
- Mahoney FI, Barthel DW. Functional evaluation: the Barthel Index. *Maryland Medicine* 1965; 14: 61-65.
- Marton F. Phenomenography – describing conceptions of the world around us. *Instr Sci* 1981; 10: 177-200.
- Marton F, Booth S. Learning and Awareness. Mahwah, New Jersey, USA: Lawrence Erlbaum Associates, Publishers 1997, pages 117-128.
- Mattiasson-Nilo I, Sonn U, Johannesson K, Gosman-Hedström G, Persson GB, Grimby G. Domestic activities and walking in elderly; evaluation from a 30-hour heart rate recording. *Aging* 1990; 2: 191-198.
- Mattsson E, Evers Larsson U, Rössner S. Is walking for exercise too exhausting for obese women? *Int J Obesity* 1997; 21: 380-386.
- McCulloch JM. The role of physiotherapy in managing patients with wounds. *J Wound Care* 1998; 7(59): 241-244.
- Medbø JI, Mamen A, Welde B, von Heimburg E, Stokke R. Examination of the Metamax I and II oxygen analysers during exercise studies in the laboratory. *Scand J Clin Lab Invest* 2002; 62: 585-598.

- Melzack R, Torgerson WS. On the language of pain. *Anesthesiology* 1971; 34: 50-59.
- Miller PJ. Assessment of Joint Motion, in Rothstein J (Ed.) *Measurement in Physical Therapy*, Churchill Livingstone, New York 1985, pages 103-136.
- Nelson ME, Rejeski WJ, Blair SN, Duncan PW, Judge JO, King AC, et al. Physical activity and public health in older adults: recommendations for adults from the American College of Sports Medicine and the American Heart Association. *Med Sci Sports Exerc* 2007; 39: 1435-1445.
- Nelzén O, Bergqvist D, Lindhagen A. Venous and non-venous leg ulcers: clinical history and appearance in a population study. *Brit J Surg* 1994; 81(2): 182-187.
- Nelzén O. Prevalence in venous leg ulcer: the importance of the data collecting method. *Phlebology* 2008; 15(4): 143-150.
- Nilsson G, Nyberg P, Ekdahl C, Eneroth M. Performance after surgical treatment of patients with ankle fractures – 14-month follow-up. *Physiother Res Int* 2003; 8: 69-82.
- Padberg FT, Johnston MV, Sisto SA. Structured exercise improves calf-muscle pump function in chronic venous insufficiency: a randomized clinical trial. *J Vasc Surg* 2004; 39: 79-87.
- Pate RR, Pratt M, Blair SN, Haskell WL, Macera CA, Bouchard C et al. Physical activity and public health. A recommendation from the Centers for Disease Control and Prevention and the American College of Sports Medicine. *JAMA* 1995; 273: 402-407.
- Pedersen BK, Saltin S. Evidence for prescribing exercise as therapy in chronic disease. *Scand J Med Sci Sports* 2006; 16 Suppl 1: 3-63.
- Persoon A, Heinen MM, van der Vleuten CJ, de Rooij MJ, van de Kerkhof PC, van Achterberg T. Leg ulcers: a review of their impact on daily life. *J Clin Nurs* 2004; 13(3): 341-354.
- Pfingsten M, Kroner-Herwig B, Leibing E, Kronshage U, Hildebrandt J. Validation on the German version of the fear-avoidance beliefs questionnaire (FABQ). *European Journal of Pain* 2000; 4: 259-266.
- Philips HC. Avoidance behaviour and its role in sustaining chronic pain. *Behav Res Ther* 1987; 25(4): 273-279.
- Phillips T, Stanton B, Provan A, Lew R. A study of the impact of leg ulcers on quality of life: Financial, social, and psychologic implications. *J Amer Acad Dermatol* 1994; 31: 49-53.
- Podsiadlo D, Richardson S. The timed «up and go»: A test of basic functional mobility for frail elderly persons. *J Amer Geriatr Soc* 1991; 39: 142-148.
- Porter JM, Moneta GL and An International Consensus Committee on Chronic Venous Disease. Reporting standards in venous disease: An update. *J Vasc Surg* 1995; 21 (4): 635-645.

- Rolfe G. Validity, trustworthiness and rigour: quality and the idea of qualitative research. *J Adv Nurs* 2006; 53: 304-310.
- Royal College of Nursing. Clinical Practice Guidelines – The nursing management of patients with venous leg ulcers - Recommendations, Royal College of Nursing 2006
http://www.rcn.org.uk/data/assets/pdf_file/0003/107940/003020.pdf
 (Access 7 June 2009)
- Sabate E. Adherence to long-term therapies: evidence for action. Geneva, Switzerland: World Health Organization; 2003: 17-39.
- Sallis JF, Saelens BE. Assessment of physical activity by self-report: status, limitations, and future directions. *Res Q Exerc Sport* 2000; 71: 1-14.
- SBU. The Swedish Council on Technology Assessment in Health-care. Evidensbaserad eldrevård: Hudsår – venösa bensår, diabetiska fotsår och trycksår, 2003, pages 217-231 – www.sbu.se (Access 2 November 2009). In Swedish.
- Scottish Intercollegiate Guidelines Network. The care of patients with chronic leg ulcer: A national clinical guideline. Scottish Intercollegiate Guidelines Network, Edinburgh 1998.
- Simon DA, Dix FP, McCollum CN. Management of venous leg ulcers. *BMJ* 2004; 328: 1358-1362.
- Sjostrom B, Dahlgren LO. Applying phenomenography in nursing research. *J Adv Nurs* 2002; 40: 339-345.
- Socialstyrelsen. The National Board of Health and Welfare in Sweden. Hemsjukvården - ett steg före? Ben- och fotsårsbehandling i hemsjukvård. Artikelnr 2005-109-22 - Publicerad - www.socialstyrelsen.se - , oktober 2005 (Access 2 November 2009). In Swedish.
- Stick C, Jaeger H, Witzleb E. Measurements of volume changes and venous pressure in the human lower leg during walking and running. *J Appl Physiol* 1992; 72: 2063-2068.
- Stranden E. Dynamic leg volume changes when sitting in a locked and free-floating tilt office chair. *Ergonomics* 2000; 43 (3): 421-433.
- Stranden E. Patofysiologi. I Nordberg L (Red), Vensjukdomar, Studentlitteratur, Lund 2004, pages 69-73. In Norwegian.
- Uden CJT, Vleuten CJM, Kooloos JGM, Haenen JH, Wollersheim H. Gait and calf muscle endurance in patients with chronic venous insufficiency. *Clin Rehabil* 2005; 19: 339-344.
- Van Hecke A, Grypdonck M, Defloor T. A review of why patients with leg ulcers do not adhere to treatment. *J Clin Nurs* 2009; 18: 337-349.
- Van Hecke A, Grypdonck M, Beele H, De Bacquer D, Defloor T. How evidence-based is venous leg-ulcer care? A survey in community settings. *J Adv Nurs* 2008; 65 (2): 337-347.

- Vlaeyen JW, Kole-Snijders AMJ, Boeren RGB, van Eek H. Fear of movement/(re)injury in chronic low back pain and its relation to behavioural performance. *Pain* 1995; 62: 363-372.
- Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain; a state of the art. *Pain* 2000; 85: 317-332.
- Yang D, Vandongen YK, Stacey MC. Effect of exercise on calf-muscle pump function in patients with chronic venous disease. *Brit J Surg* 1999; 86: 338-341.
- Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A fear-avoidance beliefs questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain* 1993; 52: 157-168.
- Walshe C. Living with a venous leg ulcer: a descriptive study of patients' experiences. *J Adv Nurs* 1995; 22: 1092-1100.
- Waters RL, Mulroy S. The energy expenditure of normal and pathological gait. *Gait and Posture* 1999; 9: 207-231.
- Welk GJ. Physical activity assessments for health-related research. Human Kinetics, Champaign, IL, 2002.
- WHO, World Health Organization. International Classification of Functioning, Disability and Health (ICF). Geneva 2001.
- Wound Ostomy and Continence Nurses Society. Guideline for the management of wounds in patients with lower-extremity venous disease. *J Wound Ostomy Continence Nurs*, Glenview 2005.
- Åstrand PO, Rhyming I. A nomogram for calculation of aerobic capacity (physical fitness) from pulse rate during sub-maximal work. *J Appl Physiol* 1954; 7: 218-221.
- Åstrand PO, Rodahl K. Textbook of Work Physiology. Physiological Bases of Exercise 2nd ed. McGraw Hill: New York, 1977.

Table 1. Designs, participants and demographics in Study I-IV

Study	I		II	III	IV
Study design	Descriptive, cross-sectional		Descriptive, cross-sectional	Experimental, cross-sectional	Explorative, cross-sectional
Data sources	Functional tests and structured interviews		Postal questionnaire	Functional tests and structured interviews	Semi-structured interviews
Analysis	Quantitative (Chi-square test, Fisher's exact test, Mann-Whitey U test, Wilcoxon's signed rank test)		Quantitative (Chi-square, Mann-Whitey U test, Logistic regression, Spearman's rank corr)	Quantitative (Wilcoxon's signed rank test)	Qualitative (Phenomenography)
	Patients	Control subjects		Patients	Control subjects
Participants, n	34	27	98	6	22
Gender, female/male (%)	34/0 (100/0)	27/0 (100/0)	62/36 (63/37)	2/6 (33/67)	10/12 (46/54)
Age, years, md (range)	77 (60-85)	76 (62-85)	76 (60-86)	66 (58-83)	67 (63-83)
Diagnosis	Active and healed venous leg ulcer	Minor dermatological complaints	Active and healed venous leg ulcer	Healed venous leg ulcer	Healthy adults
Disease duration², years, md (range)	5 (0.7-52)		5.9 (0.3-57)	5.5 (2-11)	
Active ulcer, n (%)	21 (62)		55 (56)	0 (0)	
Physical activity¹, n (%)					
1-2	17 (50)	0 (0)	42 (43)	0 (00)	0 (0)
≥4	4 (12)	14 (51)	18 (18)	3 (50)	13 (59)
Self-rated mobility, good/excellent, n (%)	10 (29)	22 (82)	34 (35)	5(83)	21 (96)
					12 (55)

¹Frändin and Grimby, 1994: 1) 'Hardly any physical activity', 2) 'Mostly sitting, sometimes a walk, sometimes light domestic work'; ≥4 'Moderate exercise, 1-2 hours/week' or more. ²Time from onset of the first ulcer.

Table 2. Assessments: Outcome properties, outcome measures and units used in the different studies in the relation to International Classification of Functioning, Disability and Health (ICF).

Outcome	Measurement instruments (ref)	Unit	Study I	Study II	Study III	Study IV
property/quality						
Body functions and structures						
Current medical status	Medical records ^a and self-report	-	X ^a	X	X	X
Disease duration	Medical records ^a and self-report	-	X ^a	X		X
Ulcer status	Medical records ^a and self-report	-	X ^a	X		X
Ulcer size	Digital imaging analysis (Olympus DP-Soft, Soft Imaging System GmbH, Germany) of acetate film tracings (Etris et al., 1994)	Metry (m ²)	X			
Pain	Visual Analogue Scale (Carlsson, 1993)	Scale (mm) 0-100	X	X		
	Six-point verbal rating scale for pain assessment (Melzack and Targerson 1971)	Classification 0-5	X			
Ankle range of motion	Goniometer (Miller, 1985)	Test (degrees)	X		X	
Calf-muscle and dorsiflexor strength	Strain gauge (Lindahl et al., 1988)	Test (Ns)	X			
Aerobic capacity	Åstrand-bicycle test (Åstrand and Rodahl, 1977)	Test (ml•kg ⁻¹ •min ⁻¹)			X	
Oxygen consumption	Metamax (Medbø et al., 2002)	Test (ml•kg ⁻¹ •min ⁻¹)			X	
Compression pressure	Kikuhime (Biomedical Systems Engineering)	Test (mmHg)			X	
Activities and participation						
Walking speed	Walking speed: 20 m walking (Butland et al., 1982)	Test (m/s)	X			
	Modified Six Minute Walking test (6MWT) (Butland et al., 1982; Guyatt et al., 1985)	Test (m/s)			X	
Walking ndurance	Timed Walking Tests: 3 minutes walking (Butland et al., 1982);	Test (m)	X			
Perceived exertion	Borg's Rating of Perceived Exertion Scale (Borg's RPE Scale) (Borg, 1982)	Scale 6-20	X		X	
Mobility	Timed Up and Go (Podsiadlo et al., 1991)	Test (sec)	X			
	The Rivermead Mobility Index (Collen et al., 1991)	Sumscore 0-15		X		
Primary ADL	Self-rated mobility; Questions designed to fit the study	Classification 1-4	X	X	X	X
Extended ADL	The Barthel ADL Index (Mahoney and Barthel, 1965)	Sumscore 0-20	X			
Physical activity	Functional Status Questionnaire, part 1 (Jette et al., 1986)	Sumscore 0-52	X			
	Physical activity in the elderly (Mattiasson-Nilo et al., 1990; Frändin and Grimby, 1994)	Classification 1-6	X	X	X	X
Environmental and personal factors						
Use of walking aids	Self-report	-	X	X		X
Utilization of community services	Self-report	-	X	X		X
Satisfaction with life	Life Satisfaction Scale (LiSat) (Fugl-Meyer et al., 1991)	Classification 1-6	X			
Self-rated general health	General question of self-rated health (SRH) (Kaplan and Camacho, 1983)	Classification 1-4	X			
Fear-avoidance beliefs	The Fear-Avoidance Beliefs Questionnaire, physical activity subscale (FABQ-physical) (Waddell et al., 1993)	Sumscore 0-24		X		
Own opinions	Self-report		X		X	X

