The Diabetic Foot

Assessment and assistive devices

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The Diabetic Foot

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Ineko

"Bra" fötter betyder väldigt mycket. Frihet, dans, promenader, bilkörning. Mina fungerar perfekt sedan jag fått helfotsinlägg och fotvård. Nu har jag fötter utan hälsprickor.

Person som lever med diabetes

"Good" feet mean a lot. Freedom, dancing, walking and I can drive my car. My feet are in perfect condition since I was supplied with insoles and get regular foot care. Now, I have feet without heel cracks.

Person living with diabetes

Abstract

Foot ulcers are a serious complication in diabetes and the most common factor leading to lower extremity amputation. The Swedish National Guidelines for Diabetes Care recommend an annual foot check for all 400,000 patients in the country, to identify patients at risk of developing diabetic foot ulcers (DFU). In the identified patients, preventive intervention and acute treatment should be initiated. Assistive devices, an annual foot check, risk classification of the feet, podiatry service, information and access to medical specialists should all be included in a well-designed prevention and care programme. However, there are regional differences in Sweden. The current lack of risk classification routines is leading to a situation in which patients at risk of developing DFU are likely not to be detected and, when they are detected, the necessary interventions may be delayed. This thesis focuses on health-care providers at departments of prosthetics and orthotics and methods that accurately assess the risk of developing DFU are presented. Moreover, the effects of assistive devices (foot orthoses and shoes) were evaluated.

The patients that were studied in this thesis (n = 216) were all referred to a department of prosthetics and orthotics with the aim of being provided with protective assistive devices, as their feet were in the risk zone for developing DFU. Clinical tests, surveys and in-shoe pressure measurements were used to assess the type and frequency of risk factors that were present in the studied group. Several risk factors were found to be present, e.g. foot deformities, calluses and neuropathy.

An eHealth tool, named the D-Foot, was constructed and its validity and reliability were assessed. The web program, the D-Foot, includes a series of foot assessments. After completing the assessments, an objective foot ulcer risk is displayed on the screen. The D-Foot gives recommendation for the prevention and care of DFU, based on the current guidelines.

In-shoe pressure measurements showed that the plantar peak pressure using foot orthoses (prefabricated and custom-made) inserted in normal walking shoes was approximately 200 kPa under the sole of the foot. The individual variation in peak pressure was large.

The conclusions of this thesis are that the D-Foot should be recommended as a clinical tool to assess the risk of foot ulcers in diabetes. Moreover, foot measurements and plantar pressure measurements are assessments that facilitate the provision of assistive devices. It is expected that early identification and rapid intervention with prevention and care will reduce the number of DFUs and amputations, leading to positive effects for the individual and society.

Keywords: assessment, assistive devices, diabetic foot, diabetic foot ulcers, costs, eHealth, foot anthropometrics, foot deformity, risk factors, orthoses, insoles, pressure measurements, prevention, quality of life

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Sammanfattning på svenska

Fotsår är en vanlig orsak till amputation hos patienter med diabetes. Enlig Socialstyrelsens rekommendationer bör Sveriges 400,000 personer med diabetes årligen genomgå en grundlig fotundersökning för att fastställa om personen har risk att utveckla fotsår. Lämpliga skor, tillgång till fotvård samt remiss till medicinska specialister är insatser som bör erbjuds patienter med förhöjd/akut risk att utveckla fotsår. Regionala skillnader föreligger i vad mån patienter erhåller rekommenderad prevention. En av orsakerna till att patienter i riskzonen inte upptäcks i tid är avsaknaden av enhetlig rutin för fotundersökning i landet, vilket leder till att riskgraderingen blir subjektiv.

Avhandlingen riktar sig primärt till personal inom ortopedteknisk verksamhet och en ny metod för objektiv riskgradering av fötterna presenteras. Vidare har ortopedtekniska hjälpmedel (fotinlägg och skor) för prevention av fotsår studerats. Riskfaktorer för att utveckla fotsår registrerades i den studerade patientgruppen och egenskaper hos inlägg och skor undersöktes. Patienter med diabetes (n=216) remitterade till någon av de ortopedtekniska avdelningarna i Västra Götalandsregionen ingick i studierna. Kliniska test, frågeformulär och mätning av trycket under fotsulan användes för att fastställa typ och förekomst av riskfaktorer. Ett flertal riskfaktorer t.ex. fotdeformiteter, förhårdnader och nervskador identifierades i den studerade populationen.

Ett eHälsoverktyg, D-Foot, avsett att bidra till en enhetlig och objektiv sårriskgradering skapades och dess tillförlitlighet utvärderades. Web programmet D-Foot innehåller en serie strukturerade fotundersökningar. Efter att undersökningarna slutförts visades patientens riskgrad på dataskärmen. Även behandlingsrekommendationer, i enlighet med riktlinjer för prevention av fotsår vid diabetes, visades på samma sätt.

I en studie jämfördes trycket under fotsulan när patienter använde endera prefabricerade eller individuella inlägg (hårda eller mjuka). Inläggen var anpassade till promenadskor. Trycket på utvalda områden under foten låg runt 200 kPa. Den individuella variationen av plantart tryck var dock stor. Sammanfattningsvis är D-Foot ett användbart och tillförlitligt kliniskt beslutsstöd. Kvantitativ mätning av fotlängd, fotbredd, tåhöjd och plantart tryck ger information av betydelse vid utprovning av ortopedtekniska hjälpmedel. För att minska antalet sår och amputationer bör patienter i riskzonen fotundersökas, riskgraderas och erbjudas de rekommenderade insatserna vilka inkluderar regelbundna fotkontroller, råd om egenvård, tillgång till hjälpmedel och fotvård. Vidare bör konsultation i egenvård erbjudas samt, vid behov, multidisciplinär service. Varje sår som förhindras ger positiva effekter för både individ och samhälle

List of papers

This thesis is based on the following studies, referred to in the text by their Roman numerals.

I. Hellstrand Tang U, Zügner R, Lisovskaja V, Karlsson J, Hagberg K and Tranberg R. Foot deformities, function in the lower extremities, and plantar pressure in patients with diabetes at high risk to develop foot ulcers. Diabetic Foot & Ankle, 2015; 6.

II. Hellstrand Tang U, Siegenthaler J, Hagberg K, Karlsson J and Tranberg R. Foot anthropometrics in individuals with diabetes compared with the general Swedish population - implications for shoe design.
Submitted.

III. Hellstrand Tang U, Tranberg R, Zügner R, Karlsson J, Lisovskaja V, Siegenthaler J and Hagberg K. The D-Foot, an eHealth tool useful in risk classification and foot assessment in diabetes - construction and reliability.
Submitted.

IV. Hellstrand Tang U, Zügner R, Lisovskaja V, Karlsson J, Hagberg K and Tranberg R. Comparison of plantar pressure in three types of insole given to patients with diabetes at risk of developing foot ulcers – A two-year, randomized trial. Journal of Clinical & Translational Endocrinology, 2014; 1(4):121-132.

Contents

Abbreviations

AFO	Ankle foot orthosis
CPO	Certified prosthetist and orthotist
BMI	Body mass index
DFU	Diabetic foot ulcer
DPO	Department of prosthetics and orthotics
EVA	Ethylene vinyl acetate
GRF	Ground reaction force
HRQL	Health-related Quality of Life
IWGDF	The International Working Group on the Diabetic Foot
NCD	Non-communicable disease
LoE	Level of evidence
NDR	The National Diabetes Register in Sweden
PP	Peak pressure
PREM	Patient-reported experience measurement
PROM	Patient-reported outcome measurement
ROI	Region of interest
ROM	Range of motion
SFI	The Swedish Shoe Industry's Research Institute
Sh	Shore
VGR	Region Västra Götaland (in Sweden)
WHO	World Health Organisation

Brief Definitions

Anthropometry	Measurements of the human body or its parts. From the Greek anthropos, "human", and metron," measure [1]
Assistive devices	Any item, piece of equipment, or product, whether it is acquired commercially, modified, or customised, that is used to increase, maintain, or improve the functional capabilities of individuals with disabilities [2]
Biomechanics	The study of biological systems using methods of mechanical engineering [3]
Callus	Hyperkeratosis caused by excessive mechanical loading [4]
Charcot foot (neuro-osteoarthropathy)	Non-infectious destruction of bone and joints associated with neuropathy; in the acute phase, associated with signs of inflammation [4]
Content validity	The extent to which a measurement is a complete representation of the concept of interest [5]
Diabetic neuropathy	The presence of symptoms or signs of peripheral nerve dysfunction in people with diabetes, after the exclusion of other causes [4]
Foot deformity	Structural abnormalities of the foot, such as hammer toes, mallet toes, claw toes, hallux valgus, prominent metatarsal heads, residuals of neuro-osteoarthropathy, or sequelae after foot surgery, including amputations [4]
eHealth	The use of information and communication technology for health [6]
EQ-5D	A standardised measurement of health status developed by the EuroQol Group in order to provide a simple, generic measurement of health for clinical and economic appraisal [7]
Foot lesion	Any abnormality associated with damage to the skin, nails or deep tissues of the foot [4]
Foot ulcer	Full-thickness lesion of the skin of the foot [4]

Insole	The terms "insoles" and "foot orthoses" are used interchangeably in this thesis. An insole is a device that is inserted in a shoe with the aim of supporting the three-dimensional shape of the foot and thereby redistributing and equalising the plantar pressure.
High risk	Presence of characteristics indicating a greatly increased probability of developing a specific condition or an event [4]
Kinematics	Describes motion [3]
Kinetics	The study of force, moments, mass and acceleration [3]
Low risk	Low probability of developing a specific condition or event [4]
Orthoses	Orthosis; orthotic device: "Externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal systems" [8]
Intra-rater reliability	The "consistency with which one rater assigns scores to a single set of responses on two occasions" [5]
Inter-rater reliability	The "consistency of performance among different raters or judges in assigning scores to the same objects or responses .... it is determined when two or more raters judge the performance of one group of subjects at the same point in time" [5]
Neuro-osteoarthropathy (Charcot foot)	Non-infectious destruction of bone and joint associated with neuropathy, in the acute phase associated with signs of inflammation [4]
Pressure time integral	A measurement used to quantify pressure over time
Prosthesis	Prosthesis; prosthetic device; "externally applied device used to replace wholly, or in part, an absent or deficient limb segment" [8]
SF-36	A measurement of functional health and well-being from the patient's point of view [9]
Shoe last	A shoe last is a three-dimensional reproduction of the approximate shape of the foot. Shoes are built on shoe lasts [10]
Therapeutic footwear	"Some form of customisation to the patient's foot regarding a combination of insole, shoe, and/or orthosis" [11] or "Generic term for footwear designed to allow some form of treatment to be applied to the foot that cannot be applied by or in a conventional shoe. Extra depth shoes, custom-made shoes and so on are all examples of therapeutic shoes (Greek therapeutikos, from therapeuein to attend, treat)" [12]

This thesis has been influenced by my clinical experience as a certified prosthetist and orthotist (CPO) and podiatrist. Over a period of 35 years, I have assessed more than 500,000 toes and 50,000 feet. Several patients with diabetes have told me that their feet have not been assessed in a structured manner or at an annual foot check. They also commonly request information about the type of intervention health care can offer and they ask about self-care to prevent foot problems.

In this thesis, the term "The Diabetic Foot" was chosen because it is an expression known worldwide to describe the field of research related to foot complications present in patients with diabetes. I interpret the term "The Diabetic Foot" as the foot belonging to a person diagnosed with diabetes. The definition of "The Diabetic Foot" described by the International Working Group on the Diabetic Foot (IWGDF) is more specific and is: "Infection, ulceration or destruction of tissues of the foot associated with neuropathy and/or peripheral artery disease in the lower extremity of people with diabetes" [4].

1. Introduction

The prevention and care of diabetic foot problems (ulcers and amputation), when successful, are beneficial to the patient, his/her family, the health-care system and society [13]. However, national figures from Sweden show that there are regional differences in terms of the number of people diagnosed with diabetes who undergo amputations [14]. It is also evident that the amputation level (e.g. transtibial, knee exarticulation, transfemoral) is dependent on where you live in the country [15]. This indicates that some parts of the country have a prevention and care strategy for diabetic foot ulcers (DFU) of high quality, while other regions are less successful. Promising results have shown that early screening and intervention can reduce the number of DFUs and subsequent amputation [16, 17]. The recommended interventions are based on long-term research and international collaboration [11, 16, 18]. Back in the 1950s, Dr. Paul Brand found that ulceration in leprosy was due to peripheral neuropathy and tissue breakdown due to pressure and overloading. Dr. Brand and his team introduced an intervention using a total contact cast to off-load the foot. By using this treatment, plantar neuropathic ulcers were more likely to heal [19]. The result was astonishing and this new strategy, i.e. using off-loading modalities, was introduced, studied and is now (in the 2000s) the recommended treatment for plantar forefoot pressure-induced ulcers occurring in patients with diabetes [12, 20]. Several studies have shown that a below-knee total contact cast and ankle foot orthoses (AFO) to off-load the foot are effective in the treatment of plantar forefoot DFUs [21]. The positive effect of using assistive devices (footwear and orthoses) to prevent and heal DFUs has been globally recognised [21]. The IWGDF and the World Health Organisation (WHO) strongly recommend the use of footwear and orthoses to prevent and treat DFUs [22]. However, the efficacy of these assistive devices needs to be further evaluated [23-27].

The list of main interventions recommended by the IWGDF includes:

- The early recognition of patients at risk of developing DFU. Every patient with diabetes should undergo a yearly foot assessment
- Swift management (prevention and treatment) for patients who are identified as running an increased risk of developing DFU
- A set of interventions should be offered to patients. These interventions should include access to podiatry, the use of appropriate footwear and orthoses and offer patients access to information about self-care
- Patients with severe foot lesions should be referred to multidisciplinary diabetic foot teams
- A knowledge of how to prevent and manage DFU should be conveyed to patients and health-care givers.

Even if studies and clinical practice have shown that well-designed prevention and care can reduce the number of DFUs, more effort still needs to be

made [25, 28]. There are several examples of patients with severe foot complications that have passed undetected until a late stage (sometimes too late), when the DFU is already established. They have not been offered adequate footwear and orthoses and have no access to podiatry. One possible reason for this is that foot problems, in general, are assigned low priority in the health-care system. Another reason is the lack of assessment tools and structured routines to assess the risk of developing foot ulcers. Taken together, this has led to a situation in which patients at risk of developing DFU are likely not to be detected and, when they are detected, the necessary interventions are delayed.

Several medical specialists are involved in the care of patients with diabetes. The focus of this thesis is the prevention and care of foot problems provided at the departments of prosthetics and orthotics (DPO). The unresolved issue of how to perform a structured foot ulcer risk classification at the DPO is discussed in this thesis. Questions relating to the efficacy of footwear and foot orthoses, used in the prevention and care of DFU, are addressed. Moreover, the prevalence of risk factors for developing DFU needs to be assessed in detail. This thesis bridges a gap in the knowledge of how the CPO assess the risk of foot ulcers in patients with diabetes. One aim of the thesis was to construct a valid eHealth tool that generates an objective risk classification. Another aim was to test the reliability of the eHealth tool. Moreover, the efficacy of assistive devices in the prevention of the first DFU was investigated. More specifically, methods for evaluating foot problems in patients with diabetes referred to a DPO need to be evaluated and the assistive devices that are used need to be studied.

Topics that have been examined in the current thesis include:

- The prevalence of different risk factors (e.g. neuropathy, foot deformities and callosities) in patients referred to a DPO
- How is the plantar pressure influenced by the above-mentioned risk factors?
- Does the three-dimensional shape of the foot in a patient with diabetes differ compared with the foot of a person representing the general population?
- The construction of a valid tool that can be used safely to classify the risk of foot ulcers and to test the reliability of the tool
- Does the plantar peak pressure (PP) of custom-made foot orthoses differ from that of prefabricated foot orthoses?

Moreover, the following topics are of interest and are touched on in this thesis:

- The experience of health-related quality of life (HRQL) in patients with diabetes and foot problems
- The extent to which patients at risk of developing DFU have access to podiatry?
- The costs of assistive devices

1.1 EPIDEMIOLOGY

The prevalence of diabetes in the world is rapidly increasing [29]. The number of patients with diabetes was 415 million in 2015 and it is estimated that it will rise to approximately 600 million in 2035 [30]. In Figure 1, the estimated prevalence at global, national, regional and local level is illustrated. Type 1 diabetes and type 2 diabetes involve most of the patients, even if other less frequent types exist. Of these two, type 2 diabetes is the most common, caused by a defect in insulin secretion that increases the blood sugar level [31, 32]. In type 1 diabetes, the insulin production in the pancreas is deficient.

Several co-existing risk factors contribute to the development of a DFU and include lifestyle factors, co-morbidity and late complications of the disease. Peripheral vascular disease, neuropathy in combination with foot deformities and high plantar pressure are some of the risk factors that increase the risk of developing DFUs [16, 33-35]. Moreover, poor vision and greater body mass have been shown to be related to the development of DFUs [16, 35, 36].

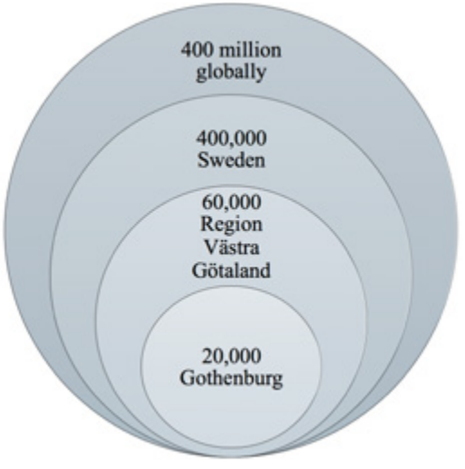


Figure 1. Local, regional, national and global estimates of the number of patients with diabetes in 2015 [37-39]. The prevalence of diabetes was 4% in Sweden in 2015 [39].

Foot ulcers are preventable and early intervention is essential to avoid serious complications. It is estimated that, every 20 seconds, a person in the world undergoes an amputation due to the effects of diabetes [38]. Moreover, in 2015, the disease caused five million deaths [38]. Taken as a whole, the complications of diabetes including sick-leave and health-care costs have a major impact on the global economy [17, 40, 41]. An estimate of the global costs for the treatment of one of the complications, namely DFUs, is presented in Table 1.

The WHO has recognised diabetes as one of the non-communicable diseases (NCD), prioritises the prevention of the disease and its complications and supports the national strategies for prevention. The challenges of fighting NCDs and promoting good health are on the global agenda [43, 44]. The health-promotion activities include healthy living with physical activities and smoking cessation [45].

Table 1. Estimated cost of diabetic foot ulcers.

Level	Number of patients with DFU	Costs/ patient USD	Health-care costs million USD
Regional	3,000	5,000	15
National	20,000	5,000	100
Global	20,000,000	5,000	100,000

An estimate of costs related to treatment in non-infected and non-ischaemic DFUs at regional, national and global level. The estimates are based on a prevalence of DFUs of 5% and the number of patients diagnosed with diabetes in the Region Västra Götaland (60,000 persons), Sweden (400,000), and global (400 million) [37-39]. The cost of the treatment of a DFU was estimated at 5,000 US dollars (1990 price level) [42].

Studies have shown that the well-designed prevention and care of DFUs and amputation is cost saving and improves HRQL [28, 46, 47]. The prevention of DFUs starts with the identification of the patients that are at risk. Risk factors that need to be assessed are distal neuropathy, distal vascular disease, foot deformities, high plantar pressure, skin pathologies and a history of earlier DFU or amputation. Neuro-ischaemic factors (neuropathy and vascular dysfunction), common in diabetes, increase the risk that DFUs will become infected. The combination of vascular dysfunction, neuropathy and infection prolongs the healing time, with an increased risk of lower extremity amputation. The most common preceding factor for lower extremity amputation is DFUs [48]. The likelihood of a lower extremity amputation is up to 46 times higher in patients with diabetes than in those without [49,50]. However, the numbers differ between studies and are to some extent explained by differences in the studied populations, diagnostic criteria, study settings and geographical location [15].

In Sweden, a positive trend with a decreasing number of amputations above the ankle has been noted during the last few decades. In 1993, the number of amputations above the ankle in patients with diabetes was approximately 1,500/year compared with 732/year in 2012 [14, 51]. In Figure 2, the decreasing trend, reported by the National Board of Health and Welfare, for the number of amputations above the ankle for 2008-2012 is presented.

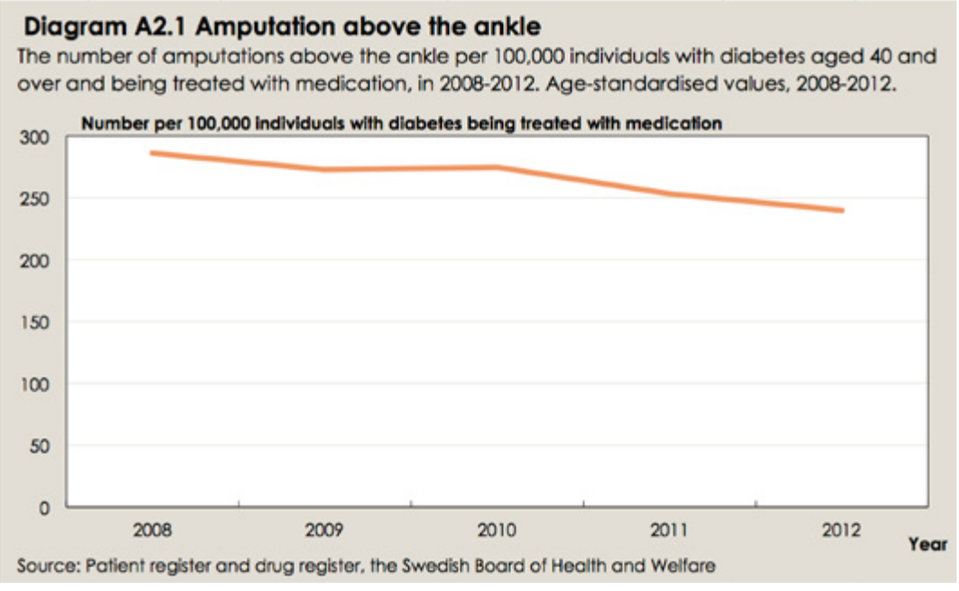


Figure 2. A declining trend in amputation levels in Sweden in 2008-2012[1] among patients with diabetes [14].

The regional differences in amputation rates are presented in the report and are shown in Figure 3. The region of Blekinge had the lowest amputation rate (180 per 100,000 patients with diabetes) and the region of Gotland had the highest (395 amputations per 100,000 patients with diabetes). The other 19 counties reported numbers between 180-395 per 100,000 patients (aged > 40 years and under medical treatment for diabetes).

[1] *Age-specific values for first-time amputees per 100,000 patients with diabetes in 2008-2012. The patients were > 40 years old and under medical treatment for diabetes.*

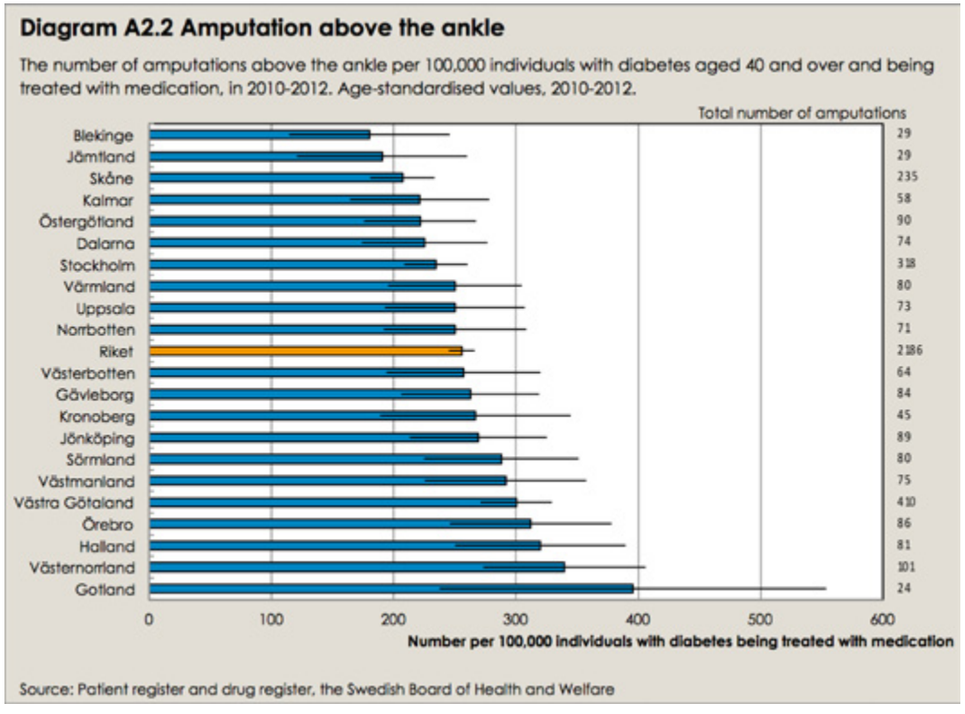


Figure 3. The figure shows the regional differences in lower extremity amputations in Sweden among patients with diabetes (2008-2012) [14].

Foot ulcers

The risk of developing DFUs among patients with diabetes is estimated to be approximately 6%-38%, considering a duration of the illness of 10 years. The estimation is based on a population-based annual incidence of DFUs of 1.0-7.2% [52-56]. One prerequisite when planning for good quality and equal access to prevention and care is to know the prevalence of DFUs in a given population and the corresponding numbers of DFUs. No such robust national statistics exist in Sweden. However, an estimate gives us an insight into the magnitude of the problem. The number of patients estimated as presenting with a DFU annually in Sweden is 20,000, based on a prevalence of DFU of 5%. Five per cent is a mean value based on the reported prevalences from the scientific literature ranging from 1.7%-10.0 % [55, 57, 58]. In Table 1, an estimate of the number of patients with DFUs is presented at regional, national and global level. The national estimate in this thesis (20,000) contrasts with the numbers reported from the National Diabetes Register in Sweden (NDR). In the NDR (2015), 3,000 of 393,000 registered patients (0.8%) were listed as having severe foot complications (DFU and severe Charcot foot) [39].

Three important risk factors for developing DFUs are peripheral vascular disease, neuropathy and foot deformities.

Peripheral vascular disease

Peripheral vascular disease with micro-vascular changes, increased permeability, impaired autoregulation of blood flow and vascular tone increases the risk of DFU and amputation [48, 59-61]. Disturbanc-

es in the blood flow are common in patients with DFUs. In a large European study, it was found that approximately 50% of the patients with DFUs had peripheral vascular disease [62]. The reported prevalence of peripheral vascular disease in patients with diabetes varies and national numbers are not well presented. From a study including patients from primary care setting, it was found that one third of patients (including patients aged > 50 years with diabetes or a history of smoking) had peripheral artery disease [63].

Neuropathy

Diabetic peripheral neuropathy is one of the leading causes of the onset of DFU. The increased risk of developing DFUs in the presence of neuropathy is suggested to be seven-fold compared with having diabetes without neuropathy [34]. Signs of neuropathy (the sensory loss, tingling sensation, numbness, hyperesthesia, dry feet and muscle weakness) could affect as many as 200 million patients worldwide. This means that 50% of the patients with diabetes in the world are affected by neuropathy [17, 64]. If this assumption is correct, the need for information about self-care, access to podiatry, access to DPOs and medical specialists is enormous. An illustration of the number of patients with peripheral neuropathy is shown in Figure 4. That the assumption is based on 50% having neuropathy can be discussed, but it appears to be reasonable, based on the reported prevalence of neuropathy; 16-87% [57, 58, 64-67].

The aetiology of peripheral neuropathy is not well clarified. One assumption is that peripheral neuropathy is related to high glucose levels and vascular dysfunction in combination with metabolic change [68-70]. Hitherto, the only treatment delaying the damage to the nerve system is adequate insulin therapy [66, 69].

The three major expressions of diabetic neuropathy are sensory neuropathy, motor neuropathy and autonomic neuropathy [71, 72]. These factors often co-exist. Signs of sensory neuropathy are a tingling sensation in the feet, numbness, a pricking sensation and/or a deep, aching or burning pain in the legs [73, 74]. Autonomic neuropathy can affect heart rate frequency and intolerance of exercise. Moreover, orthostatic hypotension, constipation, gastroparesis, erectile dysfunction, impaired neurovascular function and sudomotor dysfunction (dry skin) are expressions of autonomic neuropathy [75-77].

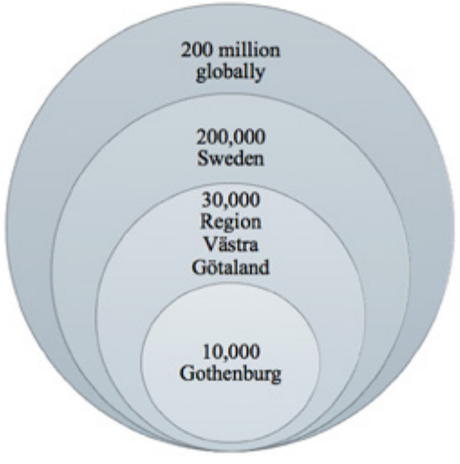


Figure 4. Local, regional, national and global estimates of the number of patients with diabetes at risk of developing foot ulcers, based on the prevalence of neuropathy. The number is based on the assumption that 50% of all patients with diabetes have signs of neuropathy [58, 65, 66].

If the motor function, a complex interaction between nerves, muscles, tendons and ligaments, is disturbed, the underlying cause might be motor neuropathy [78, 79]. Signals from the nerves (proprioception[2]) start a series of reactions in muscles and tendons to balance and maintain an upright position when walking on the ground. By adjusting movements and acceleration, the body is kept in an appropriate position. In the presence of motor neuropathy, balance and gait pattern are affected. Moreover, impaired joint motion sensation has been reported [79-83] and weakness of the distal muscles has been shown to affect up to 50% of patients with diabetes [84-86]. Motor neuropathy affecting muscle strength and reflexes is a predictor of the development of DFUs [52].

Foot deformities

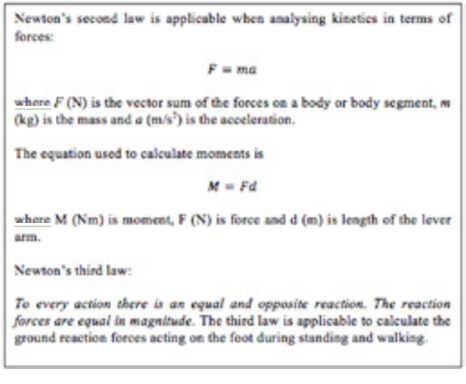
The presence of foot deformities is defined not only as the presence of hammer toes and hallux valgus, it also includes small muscle wasting, limited joint mobility, a prominent metatarsal head and bony prominences [33, 57]. Obviously, Charcot foot deformity with its bony prominences is identified as a risk factor for developing DFUs [16, 35, 36]. In one study, the presence of foot deformity was assessed and defined as being present if the patient had a combination of three or more of the above-mentioned findings [57]. No national numbers of foot deformities present in the general population or in the subgroup of patients with diabetes are available. In studies of patients with or without a history of DFU, foot deformities were reported in 47-87% [87-89]. The studies differ in the number of participants (49-398) and only one [87] reported the overall prevalence of foot deformities in the studied group.

■

[2] *Proprioceptors are muscle spindles signaling the position of joints, tendons and muscles to the brain.*

2. The Foot

The locomotion of humans was described by the Weber brothers in the 1830s. The three brothers (Ernst, Wilhelm and Eduard) used basic mechanical laws of force, moments and reaction forces to explain the biomechanics of locomotion. They described human locomotion as a forward falling due to gravity, maintaining the body in an upright position and with a pendulum swing of the limb [90]. The study of biological systems by the methods of mechanical engineering and Newton's natural laws is the subject area called biomechanics (Figure 5) [3].


Newton's second law is applicable when analysing kinetics in terms of forces:

$$F = ma$$

where F (N) is the vector sum of the forces on a body or body segment, m (kg) is the mass and a (m/s^2) is the acceleration.

The equation used to calculate moments is

$$M = Fd$$

where M (Nm) is moment, F (N) is force and d (m) is length of the lever arm.

Newton's third law:

To every action there is an equal and opposite reaction. The reaction forces are equal in magnitude. The third law is applicable to calculate the ground reaction forces acting on the foot during standing and walking.

Figure 5. Newton's laws are applicable in the study of locomotion and gait.

Mechanical models and new innovations in mechanics were the foundation of the industrial revolution starting in the 1800s. The Weber brothers linked knowledge of anatomy and theories of mechanics into their research on human locomotion. Later in the 1800s, Fischer and Braune supplemented the theoretical three-dimensional model of human gait in their publication Der Gang der Menschen [91]. Their contribution was the identification of the centre of gravity for body segments and the addition of a three-dimensional co-ordinate system in the measurement volume. By investigating cadavers, the centre of gravity for body segments was identified and was described for the first time in history. For these body segments, they calculated the corresponding magnitude of moments of inertia. The experimental parts of Braune and Fischer's research were performed during the night to avoid the disturbance of daylight during the innovative experiments on human walking. Their test subject was dressed in an illuminated suit while walking in the test volume. Two cameras identified the illuminated individual and in this way the displacement of the centre of gravity of the body segments could be calculated. Braune and Fischer's contribution to the framework of gait analysis included the addition of a three-dimensional co-ordinate system corresponding to the anatomical planes [91]. Marey and Muybridge contributed to the illustration of human motion and animal gait [92, 93]. In the late 1800s, they presented a piece of cinematic art of human and animal animation to a large audience. The audience was impressed. This was the first example of animation, the innovation that has led to the existence of widespread cinema art.

Gait cycle

The gait cycle (stance phase and swing phase) is the term used to describe the sequences of human walking (Figure 6) [3]. It begins and ends with

heel contact by one and the same leg. The stance phase as described in this thesis consists of: a) heel contact, b) foot flat, c) mid-stance and d) toe-off. Generally, 60% of the gait cycle occurs in the stance phase and 40% in the swing phase.

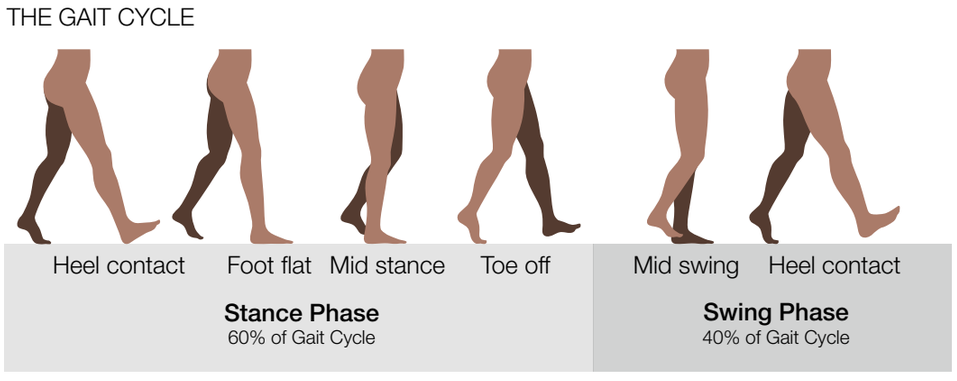


Figure 6. The gait cycle is generally divided into two phases; the stance phase and the swing phase, with a proportion of 60/40% of the gait cycle. It begins and ends with heel contact by one and the same leg.

The six determinants of gait

Forward motion in gait has been described and explained by the "the six determinants of gait" presented in the 1950s by Saunders [94]. The principle was based on the kinematic features of locomotion. The main characteristic of the six determinants of gait is to minimise the vertical displacement of the centre of gravity of the body by the foot and ankle movement, the knee movement, the hip rotation, the hip tilt and the lateral displacement of the hip [3, 94]. In another model (dynamic walking that has been tested using walking machines), the kinematics and forces are ignored and a mechanical approach to walking is suggested. In this model, the stance leg moves in a more circular arc rather than in the horizontal plane [95].

2.1 BIOMECHANICS AND ANATOMY

Biomechanics is the study of a biological system by methods of mechanical engineering considering the effects of forces on human bodies (kinetics) and motion (kinematics) [3]. Kinetics is the study of forces, moments, mass and acceleration applied to a rigid body with an identified centre of pressure. The magnitude and direction of the external forces, ground reaction forces (GRF), are commonly measured with force platforms embedded in the floor [96]. Aspects of kinematics (human movements and their patterns) can be expressed as linear and angular displacements, velocity and acceleration [96, 97]. Equipment used to capture kinematics, often present in gait laboratories, are goniometers, accelerometers, video imaging cameras and digital optical tracking systems. Measurements of kinetics (e.g. magnitude of external forces) and kinematics (e.g. velocity and acceleration) are used to calculate gait parameters such as reaction forces and muscle moments.

The human foot is constructed to resist forces, strains, to maintain balance and to co-ordinate movements in static and dynamic conditions. An estimation of the cumulative daily load of the foot is 750 tonnes, assuming 10,000 steps a day and a body weight of 75 kg (Figure 7) [78]. With a frequency of 10,000 steps a day, it will take a person eleven years to walk a distances covering one lap around the earth.

Figure 7. The accumulated daily load transmitted through the foot is approximately 750 tonnes, assuming a body weight of 75 kg and 10,000 steps/day.

To increase the muscle effect in humans and animals, long lever arms are needed. The insertion of muscle tendons optimises the required moments used during human gait [98] (Figure 8). The lever arm of the Achilles tendon is approximately 38 mm (in adults). The gastrocnemius muscle with its prolongation into the Achilles tendon makes it possible to generate the moment that is required at toe-off [98, 99].

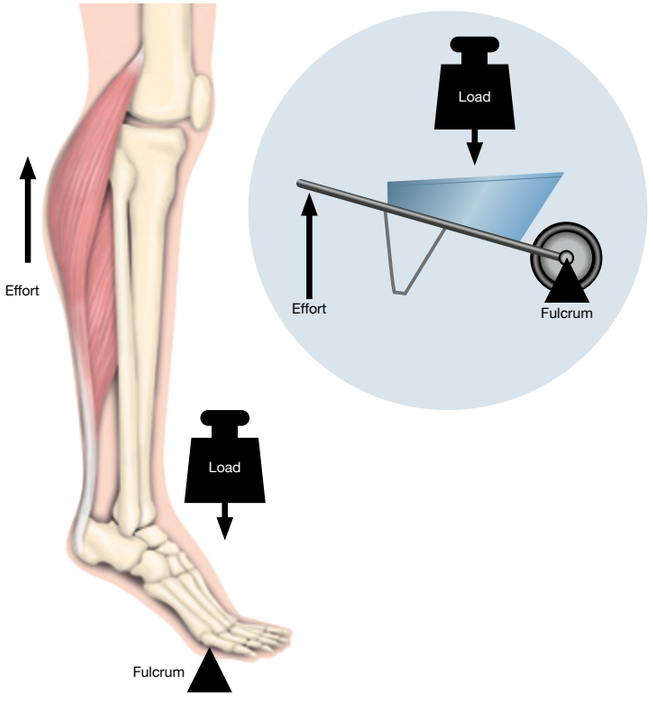


Figure 8. The gastrocnemius and Achilles tendon act as a wheel-barrow. The forces acting around the ankle are balanced and are illustrated by the principle of how a wheel-barrow works.

The foot acts on the ground and the ground acts on the foot. At toe-off, an opposite force, the GRF, is transmitted through the metatarsal joint. The amplitude of the GRF is dependent on body weight, velocity and the force generated by the calf muscles. The greater the body weight and the higher the muscle force, the greater the GRF and the higher the plantar pressure transmitted through the forefoot (Figure 9) [78].

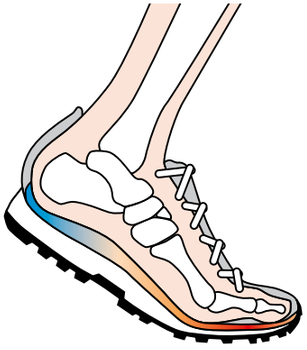


Figure 9. The foot is constructed to sustain the compressive forces and shear forces that are repeatedly transmitted through the forefoot at every toe-off.

Anatomy

The foot consists of 26 bones, two sesamoid bones and 33 joints [100]. According to Montgomery and Lidström [101], the foot can be divided into three parts: the forefoot, the midfoot and the hindfoot. In Figure 10, the bones in the three parts are presented.

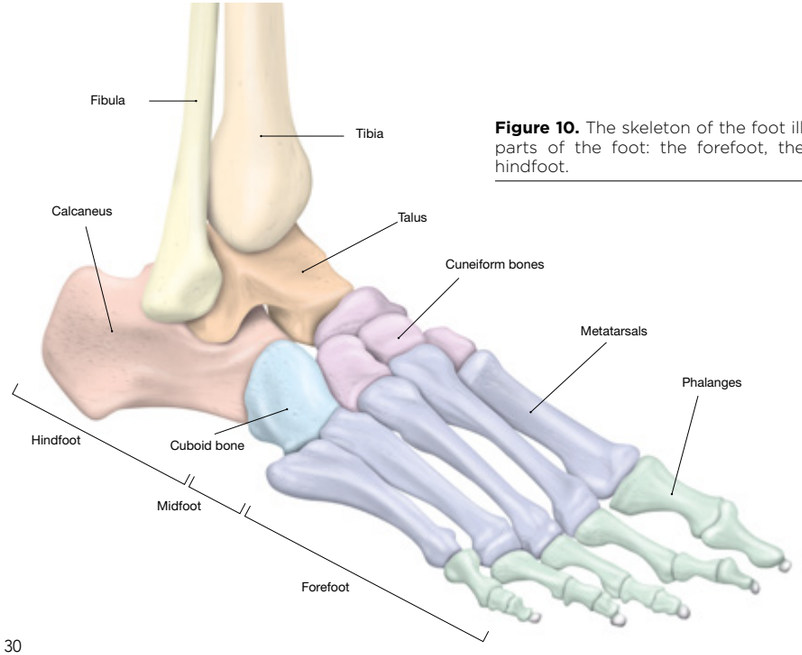


Figure 10. The skeleton of the foot illustrating the three parts of the foot: the forefoot, the midfoot and the hindfoot.

The main motions occur at the ankle joint (plantar and dorsal flexion) and can be recorded in the sagittal plane (Figure 11). The ankle is stabilised by strong ligaments [102]. The multiaxial motion in the ankle and foot includes the inversion and eversion of the calcaneus and the abduction and adduction of the forefoot.

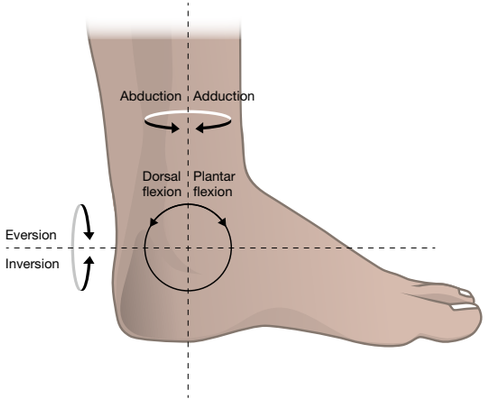


Figure 11. Illustration of the major motions in the foot: plantar and dorsal flexion of the foot, eversion and inversion of the calcaneus and abduction and adduction of the forefoot.

Ankle plantar flexion ranges from 0° to 50° and dorsal flexion from 0° to 20° (Figure 12).

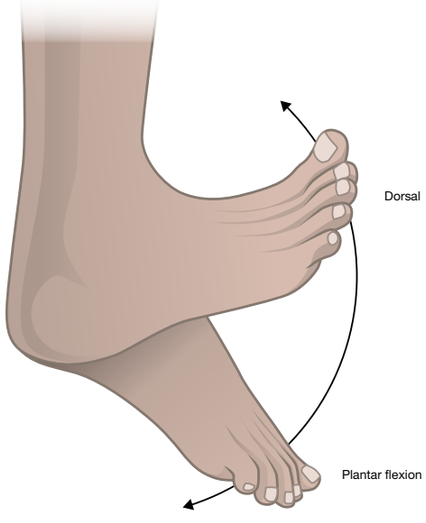


Figure 12. Plantar flexion (0°-50°) and dorsal flexion (0°-20°) occur in the sagittal plane. Plantar flexion and dorsal flexion of the toes occur at the metatarsal joints.

Isolated abduction and adduction of the forefoot occur mainly at the metatarso-phalangeal joints. In the pronated foot, the forefoot is abducted, the foot is dorsally flexed, the ankle and subtalar joints are in the valgus position and the calcaneus is everted (Figure 13, to the left). The rotation of the foot affects the hallux and the metatarsals in an inward rotation. In the supinated foot, the forefoot is adducted, the foot is plantar flexed, the ankle and subtalar joints are in the varus position and the calcaneus is inverted (Figure 13, to the right).

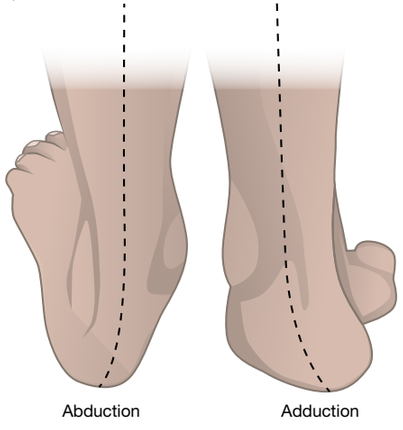


Figure 13. Pronation and supination of the foot.

The linked movements of pronation and supination are necessary during walking, as they enable the body to adapt to irregularities on the ground. Pronation and supination engage several joints; the most important are the ankle joint, the subtalar joints and the metatarsal joint. Inversion at the subtalar joint ranges from 5° to 25° and eversion at the subtalar joint ranges from 5° to 15° [102]. In addition to adaptations to irregularities in the ground, the flexible foot also acts as a shock absorber at heel strike. At toe-off, the foot is a stable construction with a long and rigid lever arm that generates the required force in the forward propulsion of the body. This change in function is achieved by the "locking mechanism" occurring between the medial and lateral parts of the foot (Figure 14).

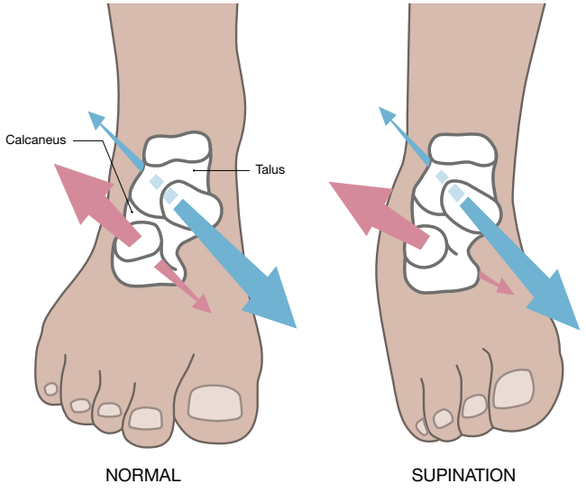


Figure 14. When the subtalar joints run parallel to each other, the foot is "unlocked" (to the left). This allows the foot to pronate and be flexible. In the supinated position, the subtalar joints are "locked" and the foot is formed as a stable and rigid lever arm. This is present at toe-off.

In the flexible and relaxed position (the normal position to the left in Figure 14), the subtalar joints run parallel.

The skeleton of the foot is protected by the skin and tissues consisting of subcutaneous fat pads, vessels and nerves (Figure 15). The shock-absorbing fat pads (~15 mm thick) protect the structures (skin, profound tissues and bones) from trauma caused by external forces [78].

Figure 15. The skin and fat pads protect the skin, deep tissues and bones from external forces transmitted through the foot during walking and standing. The fat pads consist of a network of fibro-elastic tissues that are richly innervated with thermoreceptors and mechanoreceptors. The blood supply in the healthy fat pad is good.

2.2 PLANTAR PRESSURE

All bodies on the earth load the ground due to the gravity force. Our bodies load the ground in the lying, sitting, standing and walking position. The counter-acting force, GRF, is transmitted through our bodies and is felt as pressure. Forces acting over small areas produce high pressure, whereas a larger area (with equal force) reduces the pressure following the equation for pressure:

$$P = F / A$$

where P (Pa) is pressure, F (N) is force and A (m^2) is area.

A high PP damages skin, other soft tissues and underlying structures. The receptors in the nerve system receive impulses when a high PP damages the tissue. "The gift of pain", as described by Dr. Brand, is the solution by which the nervous system warns of the presence of high PP. As a result, protective behaviour is initiated, for example, to exchange ill-fitting shoes for better-fitting ones, to remove sharp items/edges from footwear or to rest when the foot is exhausted [19]. Not only an external high PP may lead to skin breakdown, bony prominences and the malalignment of body segments can also cause high pressure, especially if the force is distributed over a small area. An example of bony prominences is hammer-toe deformity. The change in the positions of the metatarsal heads and interphalangeal joints, as seen in patients with hammer-toe deformity, exposes the metatarsal heads, the dorsal interphalangeal joint and the tip of the toe to high PP (Figure 16) [89, 103]. The risk of high PP is further increased in the presence of hypotrophic plantar fat pads.

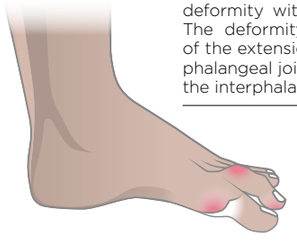


Figure 16. A hammer-toe deformity with areas of high PP. The deformity is a combination of the extension of the metatarsal phalangeal joint and the flexion of the interphalangeal joints.

The abduction of the forefoot that occurs during foot pronation increases the pressure on the lateral side of the forefoot and on the navicular area due to the valgus position. Moreover, the inward rotation of the first metatarsal and the hallux increases the pressure on the medial side of the first metatarsal head and the hallux. Hallux valgus and limited range of motion (at the ankle joint, subtalar joints and metatarsal joints) have been shown to increase the risk of developing DFUs due to higher PP [89, 104-107]. Repeated plantar pressure (steps per time unit), even at moderate levels, has also been suggested to be a risk factor for the development of DFUs [108, 109].

Plantar pressure is mainly measured in gait laboratories and at well-equipped DPOs. One of two techniques is mainly used, barefoot measurements and in-shoe pressure measurements. The design of the barefoot measurement platforms varies - some are large and can register several steps (Figure 17, page 34), while others measure single steps. The pressure measurement systems vary in sensor types and design and are based on different technologies (capacitive, resistive, piezoelectric and piezoresistive) [110-112]. When force is applied to the sensors, an electrical signal is triggered. The signal is proportional to the measured pressure. Caution should be taken when the results of pressure measurements are interpreted. The results are dependent on the systems and techniques that have been used [87, 110]. Moreover, accurate calibration, equilibration of the sensors and the appropriate handling of the equipment are all required to obtain valid, reliable measurements [113].

In-shoe pressure measurement measures the pressure acting on the sole of the foot while the patient uses his/her shoes. A thin sensor is adjusted to fit into the shoe (Figure 36, page 57). In-shoe measurements allow the patient to move over a larger area. If a wireless system is used, the patient can move outdoors while the pressure is registered.

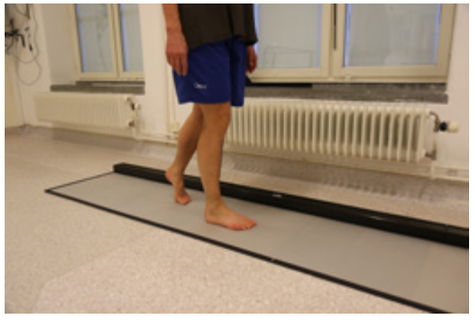


Figure 17. The plantar pressure platform registers several steps while the patient walks barefoot (the Walkway™ gait analysis system (Tekscan, Inc., Boston). Photographer Roy Tranberg.

Several variables are used to describe plantar pressure, namely PP, maximum peak pressure and pressure time integral [114]. During the trial reported in this thesis, the test subject walked 8-10 steps across the gait laboratory. The first step (acceleration) and the last step (deceleration) of each trial were excluded from the analyses. The pressure, measured in predefined boxes of 2*2 cm, of the remaining five to seven footsteps was averaged and presented as the PP. Maximum PP is the highest pressure measured within the predefined boxes recorded over the same number of footsteps used in the PP calculation. The pressure time integral calculates the integral of the PP over time during the same number of footsteps. In Studies I and IV, the F-Scan® in-shoe pressure measurement system and 6.62 software (Tekscan, Inc., Boston) were used.

Shear forces

Technical devices measuring the shear forces are not yet as widespread in clinical practice and research as devices registering the vertical forces with pressure mapping systems [115]. Even if several shear sensors have been tested (transducer, magneto-resistors, optical methods, strain gauges and capacitive sensors), they all have limitations in terms of sensitivity to temperature changes and fragility [116]. When further developed, the shear force measurement devices will add useful information about the forces acting on the sole of the foot, contributing to the understanding of the pathway to the onset of DFU [117].

■

3. Assessment

Studies have shown that using structured routines in clinical practice has several advantages and that the use of uniform validated routines facilitates the establishment of an accurate diagnosis [118-120]. The digital meta-data collected, when structured routines are used in the foot ulcer risk assessment, can help to predict ulcer development and ulcer healing [120]. Moreover, structured routines increase the amount and consistency of documentation in the medical record system [118].

The ulcer risk classification systems are mainly the same all over the world and range from "no risk", "low risk" "and "moderate risk" to "high risk". These levels of risk are sometimes expressed in risk classes 1-4 [26, 120, 121].

In the VGR, a four-level risk classification system has been used since 2008 [35] and consists of the following risk classes:

- diabetes and no further risk factors (risk grade 1)
- signs of distal neuropathy or peripheral vascular disease (risk grade 2)
- signs of distal neuropathy or peripheral vascular disease, previous foot ulceration/amputation, foot deformity, skin pathologies (e.g. calluses, fissures) (risk grade 3)
- presence of foot ulcer, osteoarthopathy (Charcot foot) or severe pain syndrome (risk grade 4)

These risk levels correspond to the risk classification system used in the NDR [39].

A description of assessements that are available to evaluate risk factors, such as distal neuropathy, peripheral vascular disease, foot deformities, skin pathologies, previous foot ulceration/amputation, Charcot foot and severe pain syndrome, follows.

Neuropathy

The presence of distal neuropathy can be assessed in many ways and they include the 10 gram monofilament test, the vibration test using a 128 Hz tuning fork, the pinprick sensation test, tests of ankle reflexes and/or the vibration perception threshold test [26, 72, 122]. The Semmes Weinstein 10 gram monofilament (a single-fibre nylon thread) examination is a rapid, easy test of sensory loss measured on the plantar hallux and the third and the fifth metatarsal heads [123]. Another tactile sensation test is the Ipswich Touch Test [124]. The Ipswich Touch Test is a simple, reliable sensory test, which involves touching the first, third and fifth toes. The advantage of the Ipswich Touch Test is that no equipment is required other than the clinician's own fingertips. Moreover, patients' self-perceived experience provides useful information in the assessment of peripheral neuropathy. A positive answer to the question "Do you perceive a tingling sensation/numbness or pain in the lower limb" assesses signs of diabetic neuropathy [16].

Motor neuropathy is assessed by testing the Achilles tendon reflexes and/or tests of motor

function in the lower extremities. In a sitting position, the patient is asked to dorsiflex the foot and, in a standing position, he/she is asked to walk on the toes and on the heel [26, 72, 73]. Through visual assessment of the skin (dry skin) or by measuring the electrochemical skin conductance, signs of autonomic neuropathy are assessed [75, 125, 126]. Peripheral neuropathy is defined as being present if any of the above-mentioned tests is positive.

Foot deformities

Foot deformities are, according to the definition of the IWGDF, "structural abnormalities of the foot such as hammer toes, mallet toes, claw toes, hallux valgus, prominent metatarsal heads, residuals of neuro-osteoarthropathy, amputations or other foot surgery" [4].

All the above-mentioned structural abnormalities might lead to an increase in PP. Taken together, foot deformities, limited range of motion, altered biomechanics, malalignment, altered gait, the presence of drop foot and length discrepancies are factors that might lead to high PP [26, 27, 33, 35, 127]. In the visual gait analysis, limited range of motion in the lower extremity joints is assessed. Malalignment, altered gait, the presence of drop foot and length discrepancies can be assessed visually and in further detail using an optical tracking system [97]. Visual gait analysis is an inexpensive method and the assessment is made with the patient in the standing position and during walking.

Assessments of foot anthropometrics (foot length, foot width and toe heights) are used to identify patients in need of customised footwear [128-130]. An inspection of the footwear used by the patients is another source of information about malalignment. Moreover, an inspection of footwear provides information on the type of footwear the patient is likely to use (Figure 18) [128].

Figure 18. An example of a shoe that has been frequently used by the patient. Photographer Jan Johansson.

Skin

Calluses and heel cracks are identified by visual inspection and by palpation. Areas exposed to calluses caused by excessive pressure are identified and skin pathologies such as heel cracks, fissures and foot ulcers are registered [26, 35, 131].

Peripheral vascular disease

The palpation of foot pulses is recommended even if the validity of this method has been questioned [27, 36, 132-134]. Moreover, the patients should be asked whether they have a history of claudication and resting pain in the legs [63].

■

4. Assistive devices

History

Early findings relating to assistive devices show that splints were used to stabilise fractured body segments in Egypt around 5,000 years ago [135]. These orthoses, made of bark wrapped in linen, were shaped as a tube and attached around the limb [135]. An ancient assistive device, the first example of a prosthesis[3], has been found in Egypt and is approximately 3,000 years old. The prosthesis was a well-designed hallux prosthesis, with a beautiful carved nail used by an Egyptian woman with a hallux amputation [136, 137].

Sandals and shoes have been used for thousands of years to protect the feet from cold, wet and sharp items on the ground. Early findings have been reported from America, 9,000 years ago [138]. Nowadays, it is natural and comfortable to wear shoes designed for the left and the right foot respectively. However, during the 16th century, shoes were built symmetrically due to limitations in the industrial production of lasts. A pair of shoes was built on a standard last, the same for both feet. The fitting and comfort of these shoes have been questioned.

The issue of well-fitting shoes for the Swedish people was a national task in the middle of the 1900s. Between 1940 and 1990, the benefits of wearing functional, well-fitting shoes were acknowledged at the highest political level. "An appropriate shoe design is mandatory to promote foot health" (translated by the author). This statement was published in 1951 in the report entitled SHOES from the Commerce Department in Sweden [139]. At that time, Sweden had a shoe industry of great importance. With governmental support, the shoe industry strove to implement a national strategy to increase the quality of shoe production and to spread the knowledge and awareness that well-fitting shoes were a key factor in improving good foot health. The Swedish Shoe Industry's Research Institute (SFI) conducted several investigations to optimise the shoe last, shoe fitting and shoe production during the same period (1940-1990). Large-scale tests that included the registration of the foot anthropometrics of more than 16,000 persons were performed. The feet were measured and size was classified and transferred into a new last system aimed to improve shoe making and shoe fitting. Some of the raw data on foot measurements from the SFI, stored at ArkivCentrum in Örebro, Sweden, have been used in this thesis. These measurements represent the foot anthropometrics of the general Swedish population.

Global

Today, "assistive device" is used as an umbrella term covering different types of equipment used to improve, maintain or increase a patient's function and participation in social life [2]. The devices cover a wide range of products from hearing aids to crutches, orthoses and prostheses [140, 141]. Three agreements have been made between the United Nations and the member states related to assistive devices. The first is the Priority Assistive Product List consisting of 50 priority items. All member states are, as a minimal level, recom-

[3] Prosthesis; externally applied device used to replace wholly, or in part, an absent or deficient limb segment

mended to provide people in need with these 50 much-needed assistive products [22]. Therapeutic footwear designed to prevent DFUs is one of the 50 priority assistive devices. The second document is the Convention on the Rights of Persons with Disabilities, article 1: "The purpose of the present Convention is to promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities, and to promote respect for their inherent dignity. Persons with disabilities include those who have long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others" [140]. The third is the agreement in "the 2030 Agenda for Sustainable Development", Goal 3, with the goal to "Ensure healthy lives and promote well-being for all at all ages" [142]. Taken as a whole, these agreements support the right of any person in need to have access to therapeutic footwear, orthotics and prosthetics to ensure their full participation in society, promoting well-being and healthy living. Assistive devices and products can reduce inequalities experienced by people of all ages living with impairments, including those living with chronic conditions and functional decline, by enabling them to be productive and participate in all areas of life [143].

Assistive devices in prevention and care of DFU

The assistive devices discussed in this thesis are footwear, orthoses and prostheses supplied by the DPOs (in Swedish covered by the term "ortopedtekniska hjälpmedel"). Interventions with assistive devices in patients with diabetes aim to prevent and treat foot problems within the framework of national laws following recommendations [27, 144-149] and regional frameworks [35, 150].

Assistive devices used to compensate for functional loss in the lower extremities are frequently supplied by the DPOs and cover approximately 50% of the total service [151], among which a large number have diabetes. High pressure on the medial, lateral and dorsal parts of the foot is often caused by ill-fitting shoes that are too narrow or have a toe box that is too low [11, 152, 153]. The overall aim of the provision of shoes and foot orthoses is to promote good foot health and prevent DFUs. This is achieved by:

- preventing the future loss of function or ability,
- improving or preserving function or ability and
- compensating for deteriorated or lost function or the ability to cope with daily life [27, 151, 154].

The main steps in the provision of assistive devices to patients with diabetes and foot problems include: a) assessing the need, b) selecting an assistive device, c) discussing the choice and the needs with the patient (or his/her peers), d) giving instructions and information about the donning and doffing of the device and the potential risks of the devices and e) making a plan for follow-up. At the follow-up, the function and effectiveness of the device should be evaluated [155]. The patient's participation and integrity in health care has been strengthened by law in Sweden and encourages patients and health-care givers to co-operate as equal partners. When evaluating the need for assistive devices, consideration should be taken of the way the device is able to facilitate participation in daily living, socially, culturally and physically [147]. High priority for the use of assistive devices in the prevention and care of foot problems in patients with diabetes can be found in the Swedish National Guidelines for Diabetes Care, launched in 2015 [27]. The guidelines have recommendations for the use of assistive devices aiming to prevent and treat foot problems [27]. The range of priority is 1-10, with 1 representing the highest priority.

- Preventive foot therapy (intervention with a structured programme comprising regular examinations, medical foot treatment, staff or patient education and training and assistive devices (shoe supplies)) is recommended for patients running a high risk of developing DFUs (priority 2).
- Prescription of assistive devices to patients with foot deformities (such as Charcot foot) with impaired circulation and/or sensitivity (priority 2).
- Prescription of assistive devices to patients with diabetes with foot deformities with normal circulation and sensitivity (priority 7).
- Care in a multidisciplinary team, including assistive devices, for patients with severe foot problem such as deep DFUs and the presence of infection (priority 1).
- Treatment with a non-removable ankle foot orthosis for patients with severe plantar forefoot ulcers (priority 2).
- Treatment with assistive devices (foot orthoses, shoes and ankle foot orthoses named "Walker" (Figure 22, page 45) for patients with severe plantar forefoot ulcers (priority 4),
- Routine examination of the feet, in patients with diabetes, to identify the occurrence of foot deformities (priority 2).

A variety of foot orthoses, footwear and footwear adjustments are available at the DPOs. However, still more evidence is needed to evaluate the effects of these interventions that are traditionally based on empirical experience and the individual skill of the clinicians [156-158]. In the following text, examples of assistive devices used in the prevention and care of foot problem in diabetes are presented.

Foot orthoses

A variety of foot orthoses, custom-made and prefabricated, inserted in appropriate footwear, are available at the DPOs and aim to compensate for loss of function, to protect the feet from trauma and to redistribute high PP. Several materials and combinations of materials are available. Hard material (e.g. carbon fibre or hard plastic materials) is used when a rigid construction is required (Figure 19). Softer material (e.g. ethyl vinyl acetate (EVA) and polyurethane foams) has a cushioning effect [159]. The properties and the hardness of the material are measured with a durometer and reported in shore A. A higher shore A represents a harder material.

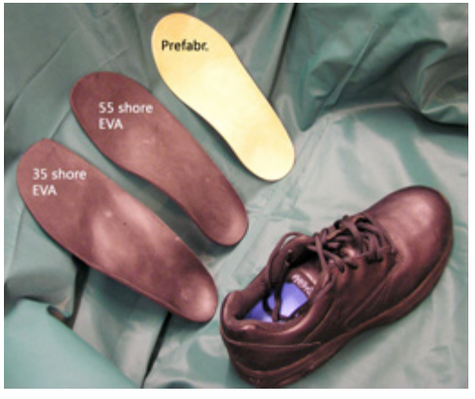


Figure 19. The custom-made foot orthoses are made of 35 shore and 55 shore EVA respectively. The prefabricated foot orthoses have a core of a mixture of thermoplastic, polyurethane, polyester and polycarbonate. The core supports the medial arch and the metatarsal reinforcement. The top layer is made of urethane polymers. The cover is a 2-mm layer of microfibre, consisting of polyester and polyurethane with a hardness of 12 shore A. Foot orthoses are only useful if they are adapted to and inserted in an accurate shoe. The shoe in the figure is an example of a standard walking shoe (Opara Deluxe men 809159, ladies 8807159; Erimed, Stockholm, Sweden). Photographer Ulla Hellstrand Tang.

Casting, foam boxes and foot scanning are equipment's and techniques that are used to capture the shape and morphology of the feet (Figure 20). These impressions, manual or digital, are used in the production of custom-made foot orthoses. Based on the digital data, foot orthoses can be automatically produced by carving out the orthoses from a block or by 3D printing [160].

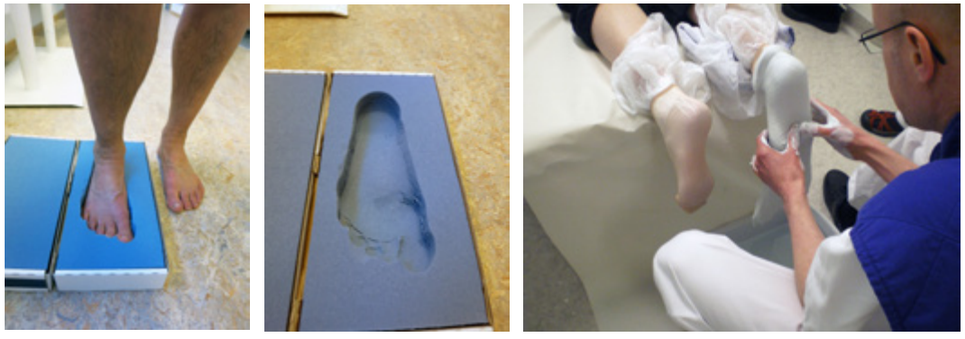


Figure 20. The foot shape is captured using a foam box (to the left). To the right, the casting technique. Photographers Klas Bildsten and Ulla Hellstrand Tang.

In this thesis, the custom-made orthoses that were tested were produced on the basis of individual positive casts and produced in a traditional manner using vacuum heating and grinding (Figure 21).

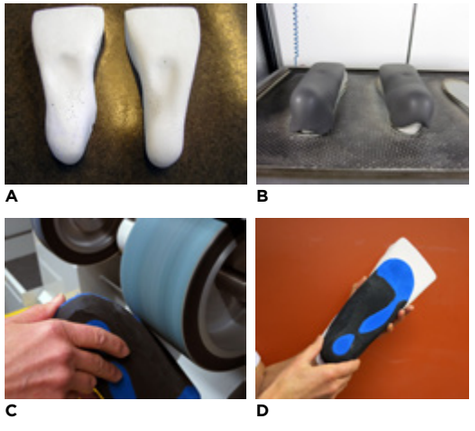


Figure 21. Production of foot orthoses. A. Positive cast. B. The thermoplast is heated and vacuum shaped over the positive cast. C. The final shape and function are achieved by grinding the material. D. The foot orthoses and the corresponding positive cast. Photographer Klas Bildsten.

The scientific literature presents conflicting information on how prefabricated foot orthoses and custom-made foot orthoses respectively redistribute pressure when they are used by patients with diabetes. Better evidence to support the positive effect of the pressure redistribution, the pressure properties, of foot orthoses is required [23, 24, 161]. In a systematic review based on cross-sectional studies, it was shown that a reduction in PP was achieved by using custom-made foot orthoses [103]. In a randomised, controlled study (n = 119), no significant differences in regional PP were found at baseline and at the six-month follow-up when comparing prefabricated insoles (at lower costs) with custom-made insoles supplied to patients with diabetes and neuropathy [162]. However, contrasting findings were reported in a randomised study (n = 61), where a significant difference in PP reduction appeared, favouring custom-made insoles compared with prefabricated insoles inserted in walking shoes [163].

Adjustments

In clinical practice, adjustments of foot orthoses are common to achieve the goal of minimising PP in high-risk zones and aligning the lower extremities into an appropriate position. Common adjustments include adding to or removing material from the surface of the foot orthoses and adjustments to the metatarsal pad. The evaluation is often subjective, without quantitative measurements, and based on trial and error. It has recently been recommended that an in-shoe plantar pressure analysis should be used to evaluate and quantify the effect of the adjustments [164].

Ankle foot orthoses (AFO)

An AFO is a below-the-knee device that affects the ankle and the foot. The use of a non-removable AFO, a Walker, is recommended by the IWGDF to promote the healing of plantar forefoot DFUs (not infected or ischaemic) (Figure 22) [21, 165, 166].

Figure 22. An ankle foot orthosis (AFO is) recommended by the IWGDF in the treatment of plantar forefoot ulcers. To the left, a Walker and, to the right, a custom-made AFO made of carbon fibre. Foot orthoses can be inserted in the AFO with the aim of supporting the foot and redistributing the plantar pressure. Photographer: Roy Tranberg.

A special type of AFO is a pressure-relieving orthosis designed to relieve pressure in the heel region (Figure 23). Caution should be taken as, even at low levels, long-term pressure occurring during bedrest can result in an ulcer. The posterior part of the calcaneus is a critical area at special risk of developing heel ulcers.

Figure 23. A pressure-relieving AFO. The heel is elevated and relieved from pressure. Photographer: Roy Tranberg.

Footwear

Two definitions of therapeutic footwear are suggested by the IWGDF: "Some form of customization to the patient's foot regarding insole, shoe, and/or orthosis" [11] and "Generic term for footwear designed to allow some form of treatment to be applied to the foot that cannot be applied by or in a conventional shoe. Extra depth shoes, custom-made shoes, etc. are all examples of therapeutic shoes (Greek therapeutikos, from therapeuein to attend, treat)" [12].

A few attempts have been made to standardise the provision of footwear to patients at risk of developing DFU, but further standardisation is still needed [21, 128, 129, 167]. A standardisation suggested by Dahmen et al. included a terminology for shoe characteristics: shaft height, outsole and insole material. These characteristics, useful in shoe production, were linked to different expressions of neuropathy [168]. Moreover, a set of objectives for shoe provision for patients with diabetes has been suggested by Janisse and Janisse [167]. They suggested the following objectives for shoe provision; protection, pressure relief, shock reduction, shear reduction, accommodation to deformities, stabilization, support and accommodate the use of foot orthoses and AFOs.

The efficacy of footwear to prevent a recurrence of DFUs was evaluated in a longitudinal study, with a nine-month follow-up, comprising 241 patients with diabetes and neuropathy [169]. The results showed that the use of therapeutic sandals with insoles reduced the PP by approximately 7 kPa compared with the use of the patients' own footwear that generally increased the pressure by 20 kPa. The occurrence of new DFUs was increased by 4% in the group of patients that used their own footwear. Moreover, the effect of footwear with either custom-made foot orthoses or prefabricated insoles relating to PP and pain was evaluated in patients with diabetes experiencing weight-bearing pain (n = 61) [163]. In both groups, the pain decreased and the function increased. Moreover, the study showed that the custom-made insoles reduced PP compared with the prefabricated ones.

A variety of shoes are available at the DPOs. Assessments of the patients' foot anthropometrics (foot length, foot width and toe heights) are used to identify those in need of customised footwear [128-130].

A shoe designed to protect the feet from trauma during warm weather is illustrated in Figure 24.

Figure 24. An example of a perforated shoe that protects the feet from external trauma. A foot orthosis with a thickness of 3-5 mm is inserted in the shoe, designed to support the foot and redistribute the pressure. Photographer: Lars Ahlstrand.

An example of a shoe with padded shaft edges and a rigid rocker bottom sole is shown in Figure 25.

Figure 25. A shoe with a padded shaft edge and a rigid rocker bottom sole constructed to be used with a foot orthosis with a thickness of 5-8 mm. Photographer: Ulla Hellstrand Tang.

Shoe modifications

The overall purpose of shoe modifications is to keep the foot in balance in static and dynamic conditions. The biomechanical properties of a shoe can be changed by applying medial or lateral flares (Figure 26), medial or lateral wedges or rocker bottom soles. Wedges are used to tilt the foot around the longitudinal axis. A medial wedge tilts the foot into supination and a lateral wedge tilts the foot into pronation. The rocker bottom sole decreases the weight-bearing forces applied to the metatarso-phalangeal joints. Moreover, rocker bottom soles improve gait function without requiring a normal ROM at the ankle, subtalar or metatarso-phalangeal joints.

In the presence of leg length discrepancy, compensation is made by incorporating an extra outer sole in the shoe [156]. The effects of shoe modification are preferably evaluated using in-shoe plantar pressure analysis and gait analysis [164].

Figure 26. Above, the medial flare increased the base of support on the medial side with the aim of resisting pronation. Below, a lateral flare. Photographers: Ulla Hellstrand Tang and Roy Tranberg.

eHealth

eHealth is the use of information and communication technology for health [6]. The WHO recognises the use and spread of eHealth as a technology useful to improve global health through integrated solutions in the promotion of health and well-being [170-173]. Telehealth, electronic health records, the use of eLearning in health science, mhealth (e.g. appointment reminders, treatment adherence, decision support systems) and the way national government uses big data in the health-care sector are all examples of eHealth [171]. In a European report from the WHO, it was shown that 22/53 (49%) of the member states have developed government-supported mHealth programmes [174]. Twenty-nine (66%) of the member states use eLearning for students of health sciences and six (13%) of the member states have a national strategy that regulates the use of big data in the health-care sector. The universal goal is to make eHealth tools accessible to patients and health-care personnel and, at the same time, secure the integrity and safety of the personal data that are handled and stored. The Swedish government has set an ambitious goal, Vision for eHealth 2025, in terms of eHealth and digital technology [175].

> *"Vision for eHealth 2025: In 2025, Sweden will be best in the world at using the opportunities offered by digitisation and eHealth to make it easier for people to achieve good and equal health and welfare, and to develop and strengthen their own resources for increased independence and participation in the life of society."*

Digitisation offers great opportunities for social services and health and medical care and it will make it easier for individuals to be involved in their own health and social care. In Study III, an eHealth solution was used. The rationale of using a digital solution was the potential advantage offered by digital techniques in terms of data recording, data processing, data storage and the feasibility of visualising the test results on the screen. Moreover, the use of big data in the prevention and care of foot problems will hopefully increase the understanding of predictors of the onset of DFU.

■

5. Aims

There is a need to construct tools and adopt routines that facilitate the early recognition of patients at risk of developing DFUs. The national presence of potential risk factors, such as peripheral neuropathy, foot deformities and a history of DFU and amputation, is not known in Sweden. Moreover, assistive devices used in the prevention and care of DFUs require further in-depth evaluation.

The specific aims of the four papers included in this thesis were to:

I. Examine the prevalence of risk factors for the onset of DFUs in patients with diabetes and to explore the influence of these risk factors on plantar pressure

II. Examine whether foot anthropometrics differ between patients with diabetes compared with the general population and, if so, what reasons may be plausible for these differences

III. Construct a valid, reliable routine for foot assessment and risk classification in patients with diabetes designed to be used by CPOs.

IV. Compare the plantar pressure in three types of insole used by patients with diabetes.

■

6. Study Design and Methods

This section starts with an overview of the population and a summary of the study designs, inclusion criteria, outcome variables and level of evidence (LoE) (Table 2). A description of the methods and the accuracy of the methods used are presented in Table 3. The statistics that were used in studies I-IV are presented in Table 4.

Population

The patients with diabetes, with and without DFUs, included in Studies I-IV were patients referred to a DPO in VGR, Sweden. In Study II, a control group, representing the general population in Sweden, was created from studies of body anthropometrics [176, 177] (Figure 27).

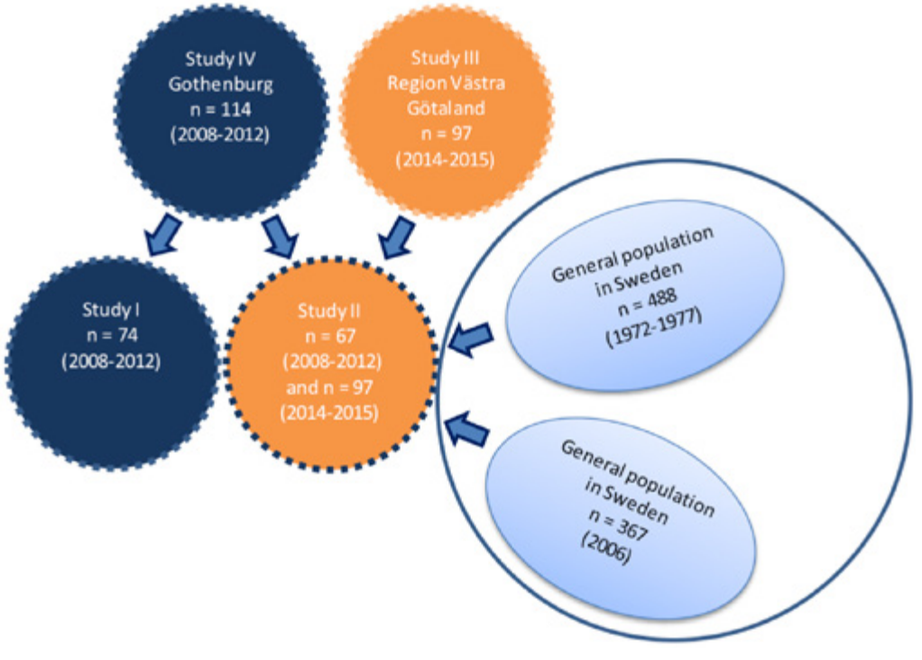


Figure 27. A flow chart of participation in Studies I-IV. The cohorts of patients with diabetes are illustrated in the four dashed circles. The large blue circle contains two oval figures that illustrate the cohorts of participants drawn from the general population [176, 177]. The places where the studies took place and the year of inclusion are presented. The arrows indicate the sources from which the participants originate.

The designs, inclusion criteria and main outcomes for the four studies included in the thesis are presented in Table 2. The studies were mainly quantitative and included a RCT, a cross-sectional, a retrospective and a methodology study.

Table 2. A presentation of the study designs, inclusion criteria, outcome variables and LoE in Studies I-IV.

Study	Study design	Study population	Inclusion criteria	Variables	LoE of the outcome
I	Cross-sectional	Patients with diabetes without DFUs referred to a DPO, derived from Study IV	Age >18 years, patients with diabetes, no DFUs, able to understand and follow instructions in Swedish and able to walk independently	Presence of foot deformity and neuropathy, function in the lower extremities, plantar pressure and HRQL	LoE: Fair to poor E: Descriptive study A: The type and combination of risk factors are necessary information when patients are provided with assistive devices designed to prevent and heal DFUs. The influence on PP of these risk factors needs to be confirmed in future studies. Patient-reported outcome measurements are of importance in descriptive studies. F: Useful results in clinical practice
II	Retrospective cohort	Patients with diabetes referred to a DPO and a control group representing the general population from anthropometry studies	The group of patients with diabetes is the same as in Study I.	Differences between the groups in terms of foot length, foot width and maximum toe height	LoE: Fair to poor E: Descriptive study A: The finding of potential risk factors (large toe height and wide forefoot width) for developing DFUs is useful in clinical practice F: As A
III	Methodology study	Patients with diabetes referred to a DPO	Age >18 years, able to understand and follow instructions given in Swedish	Evaluation of content validity and inter-rater and intra-rater reliability of an internet-based program used for risk classification and foot assessment in diabetes	LoE: N/A E: N/A A: Good F: Good
IV	Longitudinal RCT	Patients with diabetes without DFUs referred to a DPO	Age >18 years, no DFUs, able to understand and follow instructions given in Swedish and able to walk independently	The pressure redistribution properties of three types of foot orthosis were evaluated using the F-Scan® in-shoe pressure measurement system. All adjustments of the orthoses that were made during the two-year study and the wear and tear of the assistive devices were recorded.	LoE: Good E: The intervention works A: The intervention was accepted by the patients F: The results are useful in clinical practice when the CPO suggests an appropriate type of foot orthosis

Note: The studies presented are cross-sectional, retrospective, methodological or longitudinal randomised, controlled studies.
LoE; Level of evidence according to Evans' "Hierarchy of evidence" with the levels: excellent, good, fair and poor [178].
E; effectiveness, A; appropriateness, F; feasibility, RCT; randomised, controlled study, PP; peak pressure, CPO; certified prosthetist and orthotist
n/a, not applicable

Methods

The assessments and variables used to describe the population and to answer the research questions are presented in Table 3. A series of photographs that illustrate the clinical tests are presented in Figures 28-34.

Table 3 (Pages 53–55). Description of the accuracy and reliability of the methods used in the studies.

Study	How	Details	Accuracy and reliability
		Demography	
I + III	Self-reported assessment	Type of diabetes, duration of the disease, glucose level, medication for high blood pressure, medication for heart disease, nicotine use and self-perceived ability to walk normally	Reasonable level of reliability [179]
		Descriptive/diagnostic	
III	Self-reported assessment	Height and weight, self-perceived ability to a) walk normally, b) have good balance and c) have normal sensation in the feet	Reasonable level of reliability [179]
III	Self-reported assessment	Numbing/tingling sensation in the feet Less sweaty feet now as compared with recent years as a sign of peripheral neuropathy [36, 58, 69, 180]	Reasonable level of reliability [179]
III	Self-reported assessment	Self-perceived pain and history of foot ulcers	Reasonable level of reliability [179]
II	Clinical assessment	Height and weight	Accuracy height measurement: ± 2 mm and accuracy digital weight measurement: ± 0.1 kg [176]
I	Clinical assessment of foot deformities	Visual inspection and palpation, presence of hallux valgus, hallux limitus/rigidus, pes planus, pes cavus, low forefoot arch and hammer toes, hypotrophic fat pad and nail deformities	There is meagre evidence to support these measurements being accurate and reliable. One study shows low inter-rater reliability of static biomechanical assessments of the foot [181, 182].
I + III	Clinical assessment of skin pathologies	Visual inspection and palpation to assess the presence of skin callosities and heel fissures (Figure 28)	N/A
I + III	Clinical assessment of skin pathologies	Visual inspection and palpation to assess the presence of areas of excessive pressure with callosities	There is meagre evidence to support these measurements being accurate and reliable.
I + III	Clinical assessment of skin pathologies	Visual inspection to evaluate the presence of foot ulcers	N/A
I + III	Clinical assessment of foot deformities	The height of the hammer toes was measured with a ruler (Figure 29).	Measurement error of toe height measurement using a ruler: ± 0.18 mm [183]
I + III	Clinical assessment of foot deformities	Foot length and foot width were measured using a calliper (Figure 30).	The reliability of foot length and foot width measurements expressed as inter-correlation coefficient has been reported to be very good (> 0.97) [184, 185].

***Table 3** continues on pages 54–55.*

III	Clinical assessment of foot deformities	Passive range of dorsal flexion at metatarso-phalangeal joint (Figure 31)	There is meagre evidence to support these measurements being accurate and reliable. The reports from different studies give conflicting results in terms of reliability [181, 182, 186].
III	Clinical assessment of foot deformities	The maximum dorsiflexion angle at the ankle joint was measured with a goniometer in a standing position with the knee extended (Figure 32)	Measurements of the maximum dorsiflexion angle at the ankle joint have been shown to be of moderate reliability [187, 188].
III	Clinical assessment of foot deformities	Visual inspection and palpation to study the presence of Charcot foot deformity	N/A
III	Clinical assessment of foot deformities	Visual inspection and palpation to study the presence of calcaneus valgus/varus	There is meagre evidence to support these measurements being accurate and reliable. One report shows low inter-rater reliability of static biomechanical assessments of the foot [181, 182].
III	Clinical assessment of foot deformities	Visual inspection and palpation to study the presence of abduction/adduction of the forefoot	There is meagre evidence to support these measurements being accurate and reliable. One report shows low inter-rater reliability of static biomechanical assessments of the foot [181, 182].
III	Clinical assessment of foot deformities	Visual inspection and palpation to study the presence of prominent, superficial bony structures on the plantar area	There is meagre evidence to support these measurements being accurate and reliable.
III	Clinical assessment of foot deformities	Visual inspection and palpation to study toe and/or foot amputation	N/A
III	Clinical assessment of foot deformities	Navicular drop test	Reliable measurement [189]
III	Clinical assessment of foot deformities	Insufficient function of the toes and the metatarsal phalangeal joints	N/A
II	Foot anthropometrics	Foot length measurements using the foot measurement apparatus (Figure 39, page 68)	Measurement error: ± 0.14 mm [183]
II	Foot anthropometrics	Foot length measurement	Rigid measurement tape: ± 2 mm [176]
II	Foot anthropometrics	Foot width measurement using the foot measurement apparatus (Figure 39, page 68)	Measurement error: ± 0.06 mm [183]
II	Foot anthropometrics	Foot width measurement	Rigid measurement tape: ± 2 mm [176]
I	Clinical assessment of gross motor function	The function of the lower extremities was tested by asking the patient to walk on his/her toes and heels (Figure 33 and Appendix 1) [72].	N/A
I	Clinical assessment of gross motor function	Assessment of passive range of motion at the knee and hip joints (Appendix 1)	N/A
I	Clinical assessment of gross motor function	Balance test (Appendix 1)	Good to acceptable reliability [190]
I	Clinical assessment of gross motor function	Five-minute walking test	High reliability when using the six-minute walking test in elderly people [191]
III	Clinical assessment of gross motor function	Gait deviation, foot flap or toe drag	There is meagre evidence to support these measurements being accurate and reliable.
III	Clinical assessment of gross motor function	Gait deviation affected from hip/knee	There is meagre evidence to support these measurements being accurate and reliable.
III	Footwear	Excessively worn-out shoes	There is meagre evidence to support these measurements being accurate and reliable.
III	Footwear	Inappropriate footwear	There is meagre evidence to support these measurements being accurate and reliable.
I	Clinical assessment of neuropathy	Four techniques for measuring distal peripheral neuropathy were used; a tuning fork C128 Hz, a 10g Semmes Weinstein monofilament, the slight touch of a pencil and different positioning of the hallux (Figure 34 and 35). A positive result from one of these assessments was defined as a sign of peripheral neuropathy [36, 123].	The monofilament examination has been shown to a varying degree to be effective in diagnosing peripheral neuropathy [123]. The monofilament test is recommended to assess the risk factor of peripheral distal neuropathy [57, 192, 193].
III	Clinical assessment of neuropathy	The Ipswich Touch Test	Valid and reliable [124, 194]
		Patient-related experience measurements	
III*	Self-perceived experience	Access to podiatry, information about self-care involving foot examination was registered using a tablet.	Reasonable level of reliability [179]
III*	Self-perceived experience	Satisfaction with and use of the assistive device were assessed at the three-month follow-up interview.	Reasonable level of reliability [179]
		Patient-reported outcome measurements	
I + III*	Health-related quality of life	EQ-5D (Appendices 3 and 4)	A valid, reliable measurement [195]
I	Health-related quality of life	SF-36 (Appendix 2)	A valid, reliable measurement [196-199]
		Plantar pressure measurement	
IV	In-shoe pressure measurement	In-shoe pressure measurement (Figure 36)	Reliable and accurate measurements require equilibration and calibration according to the recommendation from the manufacturers [110, 113, 200].
		Other	
IV	Adjustments	Registration of adjustments and exchange of foot orthoses due to wear and tear were assessed.	n/a

N/A: not applicable, meaning that no evidence relating to the validity or reliability of the method was found
**Additional work, not yet published or submitted*

Examples of the clinical assessments that were used in the studies (Figures 28-35)

Figure 28. Callosities were assessed by visual inspections and by palpation. Photographer: Lovisa Tang.

Figure 29. The height of hammer toes was measured using a ruler. Photographer: Klas Bildsten.

Figure 30. Foot length and foot width were measured using a foot caliper. Photographer: Lovisa Tang.

Figure 31. Passive range of dorsal flexion at the metatarso-phalangel joints. Photographer: Klas Bildsten.

Figure 32. Maximum dorsiflexion at the ankle joint was measured using a goniometer in a standing position with the knee extended. Photographer: Lovisa Tang.

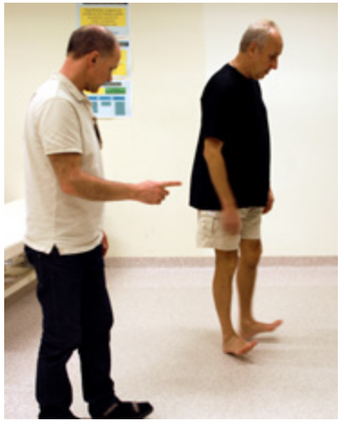


Figure 33. Function in the lower extremities was tested by asking the patient to walk on his/her toes and heels. Photographer: Lovisa Tang.

Figure 34. Distal peripheral neuropathy was assessed using several tests. This photo illustrates the 10-gram Semmes Weinstein monofilament test.

Figure 35. Vibration test. Distal peripheral neuropathy was assessed. A tuning fork, C128 Hz, was used in the vibration test. Photographer: Lovisa Tang.

In Studies I, II and IV, in-shoe pressure measurements were obtained using resistive sensors, software and the F-Scan® system (Tekscan, Inc., Boston, Figure 36).

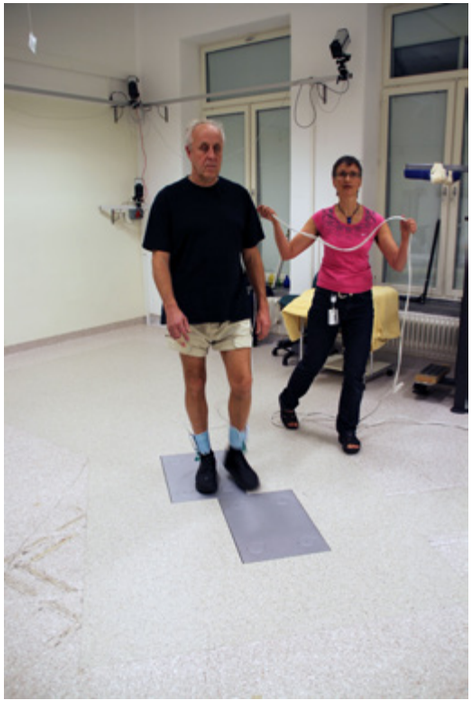


Figure 36. In-shoe pressure measurements were obtained using the F-Scan® system (Tekscan, Inc., Boston) that included resistive sensors and software. Above, the sensor is placed over the insole in the shoe. Below, the patient walks at a self-selected speed across the gait laboratory. The system registers the plantar pressure at 50 Hz in eight seconds. Photographer: Lovisa Tang.

HRQL was measured using the SF-36 (Study I). The SF-36 is a generic instrument widely used to "capture practical, reliable and valid information about functional health and well-being from the patient's point of view" and consists of 36 questions [9, 196-199] (Appendix 2).

In Study III, the eight observers were asked to answer a System Usability Scale survey (SUS) [201], regarding how they perceived using the new internet-based program, the D-Foot. The SUS is a survey used to collect ten subjective answers about how users rate the use of an interactive technology. The English version has good validity and reliability [201]. The Swedish version was translated by the authors of Study III (Appendix 5). The Swedish version has not yet been tested for validity and/or reliability.

Statistics

Descriptive statistics were used to describe the studied population regarding variables such as age, gender and body mass index (BMI). The results for the dichotomous variables were presented as numbers and percentages. Continuous variables were presented as mean values and standard deviation when the distribution was assessed as being normally distributed; otherwise, the median values were presented. Exploratory analyses and graphs were used to illustrate the distribution and variation, e.g. the pressure over long-term use of the foot orthoses at interesting regions on the sole of the foot (Figure 37 and 44). Comparative statistical tests were used to answer the research question(s).

The methods chosen to measure the probability of detecting the differences in the outcomes were dependent on the research questions, the main outcomes and the type of variables studied and these methods are presented in Table 4. Moreover, the t-test was used to compare differences between groups in terms of variables such as age and BMI.

Power, the number of study participants and main outcome are strongly related [5]. A typical way of designing a trial is to construct a null hypothesis with a corresponding alternative, fix a certain level of power at which this hypothesis will be tested and subsequently choose the sample size that will give the desired power. In order to decide which hypotheses are appropriate for evaluation, prior knowledge and/or expert input is required.

In Study III, the results of a pilot study (n = 14) were used for the initial evaluation of the agreement of the 22 assessments that were consequently included in the D-Foot. Several possibilities were discussed by the expert group and the statistician, arriving at the following set-up:

- For discrete responses (often yes/no), the main outcome was evaluated by using the proportion of patients on which the two observers agree. This proportion was then used to estimate the probability of agreement, p_i
- An agreement will be considered to be "good" if p_i is larger than or equal to 0.8
- One foot per person should be considered, because there is a possibility that the observers are likely to judge the right and the left foot dependently of the contralateral foot
- A power of 0.80 is acceptable
- In the pilot study, several measurements showed an agreement as good as 0.9. It was then decided to design the study mainly for these measurements, thus assuming p_i = 0.9 for power calculations.

Formally, the hypothesis of the type: $H_{0i} : p_i \leq 0.8$ and $H_{1i} : p_i > 0.8$ was considered. If H_{0i} is rejected, good agreement is claimed. Using the fact that, for relatively large sample sizes, the proportion will be approximately normally distributed with expectation p_i, the following expression relating to power and sample size was used:

$$power = 1 - F(c + z_{1-a}\sqrt{\frac{c(1-c)}{n}}; p_i, (1-p_i)/n$$

$F(a;\mu,\sigma^2)$ stands for the cumulative distribution function of a normal distribution, with an expected mean value μ and a variance σ taken at point a.

The other items in the equations were:
c; an "acceptable agreement", set at 0.8
z_{1-a}; 0.05, an appropriate quantile from a standard normal distribution
p_i; the probability that, for an assessment i, the two observers agree
n; number of participants

In order to determine the number of participants to include, the power equation was used and "n" was solved and was found to be approximately 100. An acceptable level of agreement was deemed to be present if several of the assessments included in the D-Foot had an agreement of > 0.80.

The sample size in Study IV was based on an effect size of 30 kPa, a two-sided a=0.05, a power of 0.80 and a drop-out rate of 15%. The effect size was based on the differences in PP between custom-made insoles of 35 Shore A versus 55 Shore A that have previously been presented [202].

Table 4 (Pages 59-60). A summary of the statistical analyses used in Studies I-IV.

Study	Research question	Main outcome	Type of outcome	Statistical analysis	Comments
I	What type, and frequencies, of risk factors related to DFUs were present in the cohort?	Type and frequencies of risk factors (number, per cent, mean, SD)	Discrete and continuous	Descriptive	
I	What were the associations, in seven plantar regions of interest (ROI), between risk factors for developing DFUs and plantar PP?	Order of priority of the risk factors and the proportion of the risk factors that were re-sampled. Magnitude and direction of factors associated with PP	Discrete and continuous	Linear mixed model with random effects and re-sampling using Aikaike information criteria	Untransformed and logarithmic data were used.
II	Did foot anthropometrics differ in patients with diabetes as compared with the general population?	Differences in foot length, foot width, $index_{FL/FW}$ and maximum toe height between the four groups respectively: 1) patients with diabetes with neuropathy, 2) patients with diabetes without neuropathy, 3) controls measured in the 1970s, 4) controls measured in the 2000s	Continuous	Differences between groups were calculated using ANOVA, followed by multiple comparisons.	
II	If differences exist between groups according to foot anthropometrics, what were the plausible reasons for these differences?	The estimated foot length, foot width, $index_{FL/FW}$ and maximum toe height adjusted for the covariates of age, gender and BMI	Continuous	Linear model with fixed effect for background variables: age, gender and BMI	For maximum toe height, the logarithmic values were used.
III	To describe the construction of an eHealth tool useful in the risk classification and assessment of the feet of patients with diabetes	The construction of an internet-based program	N/A	N/A	Content validity

Table 4 continues on page 60.

III	To assess the inter-rater and intra-rater reliability of the eHealth tool	Agreement	Discrete and continuous	For discrete variables: percentage of agreement and Cohen's kappa statistics For continuous variables Pearson's correlation coefficient and intra-class correlation coefficient (ICC) were used.	
IV	Does the plantar pressure distribution, studied in seven ROIs, differ between three types of commonly used foot orthosis?	PP, maxPP and PTI	Continuous	Linear model with random intercept. The main effects were: type of foot orthosis and time since the last change of foot orthoses	The intercept factor denotes a baseline, i.e. the estimated mean PP for new prefabricated foot orthoses
IV	How does the redistribution pattern vary in the seven ROIs during two years' use of the foot orthoses?		Continuous	Descriptive and exploratory analysis of the changes in PP in seven ROIs (illustrated with graphs)	
IV	What type and frequencies of adjustment occurred?		Discrete and continuous	Registration of adjustments	
IV	How much had the patients used the prescribed foot orthoses and footwear and how satisfied were they with the devices?		Continuous	Self-reported experience	Scale 0-100, a higher value represents more frequent use and greater satisfaction

Note: The table presents the main research questions that were addressed in the studies, the type of variables that were analysed, the main outcomes and the statistical analyses used.
SD; standard deviation,
$Index_{FL/FW}$; the index foot length/foot width
N/A; not applicable
PP; peak pressure
maxPP; maximum peak pressure
PTI; pressure time integral

7. Summary of results

A general description of the patients included in Studies I-IV revealed that a larger number of patients were diagnosed with type 2 diabetes than type 1 (Table 5). The mean age ranged from 58-60 years and the duration of disease was 12-17 years. The majority (> 65%) were being treated for high blood pressure. The mean BMI value was 27-28 kg/m^2. The presence of neuropathy varied between 38% and 77%.

The foot assessments revealed that > 30% of the patients had pes planus, a deviation of the calcaneus, a deviation of the forefoot and/or superficial bony structures. The ability to walk was generally good, based on the clinical assessments, although some patients walked with a foot flap, toe drag and/or had dysfunction in the hip/knee joints. The PP of the sole of the foot, measured at the heel, MTH5, MTH2, MTH1 and/or the hallux, ranged from 136-292 kPa.

More than 28% of the patients wore shoes that were worn out or inappropriate. The presence of skin pathologies varied (19-66% presence of calluses and/or heel fissures).

A full presentation of the included patients is presented in Table 5. The table is organised in the following topics: medical history, anatomy, kinesiology, mobility and gait, biomechanical stress, skin, lifestyle, anthropometrics and neuropathy.

Table 5 (Pages 63-65). Description of the patients in Studies I-IV.

Category	Variables	Outcome	Studies I-IV	Comments
Medical history				
	Type I diabetes	27%, 34%, 27%	I, III, IV	The prevalence (as a percentage) is presented for each of the studies respectively.
	Women	50%, 43%, 46%	I, III, IV	
	Age (yrs.)	60 yrs., 64 yrs., 58 yrs.	I, III, IV	
	Duration of diabetes	15 yrs., 17 yrs., 12 yrs.	I, III, IV	
	HbA1c mol/mmol	60 mol/mmol	III	
	HbA1c (%)	5.8%, 6.7%, 6.4%	I, III, IV	
	Medication for high blood pressure and or heart disease	74%, 65%	I, IV	
	Medication for high blood pressure	76%	III	
	Medication for heart disease	32%	III	

***Table 5** continues on pages 64-65.*

	Ability to walk normally (self-perceived)	74%, 64%, > 70%	I, III, IV	
	Using walking aid(s)	21%	III	
	Normal sensation (self-perceived)	56%	III	
Anatomy				
	Amputation	0%	III	
	Charcot deformity	1%	III	
	Hallux valgus	23%, 26%	I, III	
	Hallux rigidus	18%	I	
	Pes planus	34%	I	
	Pes cavus	10%	I	
	Low forefoot arch	77%	I	
	Calcaneus valgus/varus	33%	III	
	Forefoot abduction/adduction	35%	III	
	Prominent superficial bony structures of the plantar area	35%	III	
Kinesiology				
	Maximum dorsiflexion at the ankle joint (degree)	27°, 22°	I, III	
	Passive range of dorsal flexion at the hallux (degree)	54°	III	
Mobility and gait				
	Ability to walk normally	74%	I	
	Ability to walk on toes and heel	100%	I	
	Balance	84%	I	
	Five minutes' walking (m)	373 m	I	
	Walking speed m/s	1.2 m/s	I	
	Dysfunction of hip/knee joints	23%	I	
	Gait deviation, foot flap or toe drag	10%	III	
	Gait deviation affected by hip/knee dysfunction	36%	III	
	Insufficient forefoot function	34%	III	
Biomechanical stress				
	Heel, PP (kPa)	175 kPa; 159 kPa;237 kPa	IV	Soft; hard; prefab. resp
	MTH5, PP (kPa)	141 kPa; 136 kPa; 151 kPa	IV	Soft; hard; prefab. resp
	MTH2, PP (kPa)	255 kPa; 294 kPa; 292 kPa	IV	Soft; hard; prefab. resp
	MTH1, PP (kPa)	195 kPa; 211 kPa; 237 kPa	IV	Soft; hard; prefab. resp
	Hallux, PP (kPa)	200 kPa; 232 kPa; 206 kPa	IV	Soft; hard; prefab. resp
	Medial/lateral collapsed heel counter	29%	III	
	Excessively worn-out sole	28%	III	
Skin				
	Areas of excessive pressure with callosities	45%	III	
	Callosities	19-38%, 45%	I, III	At any of MTH1, MTH2 or MTH5 areas
	Callosities, heel	53%	I	
	Heel fissures	66%	I	
	Hypotrophic fat pad	47%	I	
	Nail deformities	32%	I	
	Foot ulcer prevalence (%/year)	11%, 0.9%	III, IV	
Lifestyle				
	Use of nicotine products	17%, 27%, 24%	I, III, IV	
	Inappropriate footwear	31%	III	
Anthropometrics				
	BMI (kg/m^2)	27, 28, 28	I, III, IV	
	Foot length (mm)	247 vs. 265 mm*, 258 mm	I, III	*Women and men resp.
	Foot width (mm)	97 vs. 102 mm* , 101 mm	I, III	*Women and men resp.
	Index foot length/width	2.56 vs. 2.59 mm*	I	*Women and men resp.
	Hammer toe height (mm)	28 vs. 30 mm*, 26.7 mm	I, III	*Women and men resp.
Neuropathy				
	Neuropathy	38%, 77%, 38%	I, III, IV	

Note: The table presents the patients included in Studies I-IV. Risk factors that might be related to the development of foot ulcers are presented. The prevalence of dichotomous variables is presented as a percentage and continuous variables are presented as a mean value. The distribution for continuous variables is presented in the original articles. All the patients were derived from two main studies; a two-year longitudinal randomised controlled study, Study IV, (2008-2012) [203], and a multicentre cohort study, Study III, (2014-2015) [204]. The result from the medical histories is information given by the patients. The results for the right foot are presented.
MTH; metatarsal head
PP; peak pressure
Soft; soft (35 Shore) custom-made foot orthoses
Hard; hard (55 Shore) custom-made foot orthoses
Prefab; prefabricated foot orthoses

7.1 STUDY I

Foot deformities, function in the lower extremities, and plantar pressure in patients with diabetes at high risk to develop foot ulcers

Foot deformities, dysfunction of the lower extremities, callosities and neuropathy are, among other risk factors, important risk factors for the onset of the first DFU. Little is known about the prevalence of these serious risk factors and their influence on PP.

The aim of the study was to assess the prevalence of potential risk factors for the onset of DFUs, e.g. foot deformities, function of the lower extremities, callosities and neuropathy. The aim was also to explore the association between these risk factors and plantar PP. The cohort studied comprised patients without a known history of DFUs visiting the DPO for the first time, n = 74 (Figure 27, page 51).

The presence of foot deformities and dysfunction and pain in the lower extremities was assessed by several clinical tests, the in-shoe plantar pressure measurement system (F-Scan®) and surveys including the SF-36 health-related quality-of-life assessment (Appendices 1 and 2). The PP was assessed in seven ROIs (Figure 37).

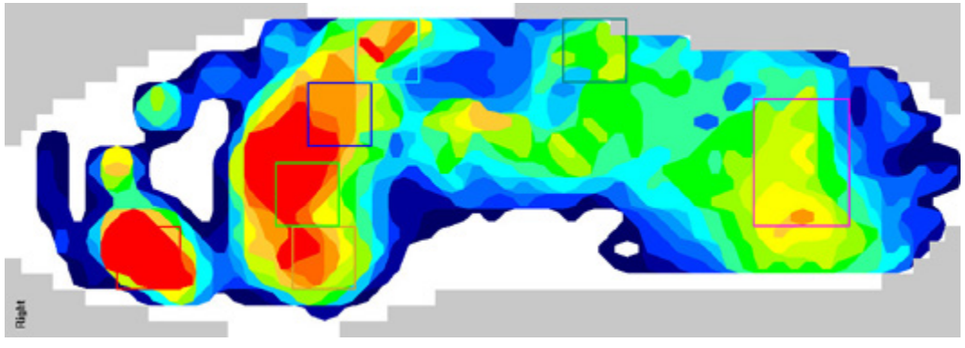


Figure 37. The pressure was analysed at seven ROIs. The boxes indicate the ROIs: the heel, lateral midfoot, MTH5, MTH4, MTH2, MTH1 and the hallux.

More than 50% of patients had one or more of the risk factors, callosities/fissures at the heel and/or pes planus. Twenty-eight (38%) of the patients had neuropathy. Gait-related parameters such as the ability to walk on the forefoot or the heel were normal for the whole group. Twenty per cent had a loss of function and/or pain at the hip and knee joints. The presence of hallux valgus and/or hallux rigidus was associated with an increase in the PP of the medial forefoot. An increment in BMI and the presence of calluses were associated with increased lateral forefoot PP.

The results from the SF-36 (Figure 38) reflect good self-experienced physical function expressed in the domain of physical functioning (mean 76 ± 22). There was a large between-individual variation. Taken together, the Physical Component Score (44 ± 10) was lower than the mean value of 50, which is in line with previous studies [205]. The Mental Component Score was close to the value for the general population (49 ± 12 vs. 50 ± 10). The large variation presented in the eight domains reflects the fact that the group comprised patients with a wide range of mental and physical abilities at different ages (22-85 years old).

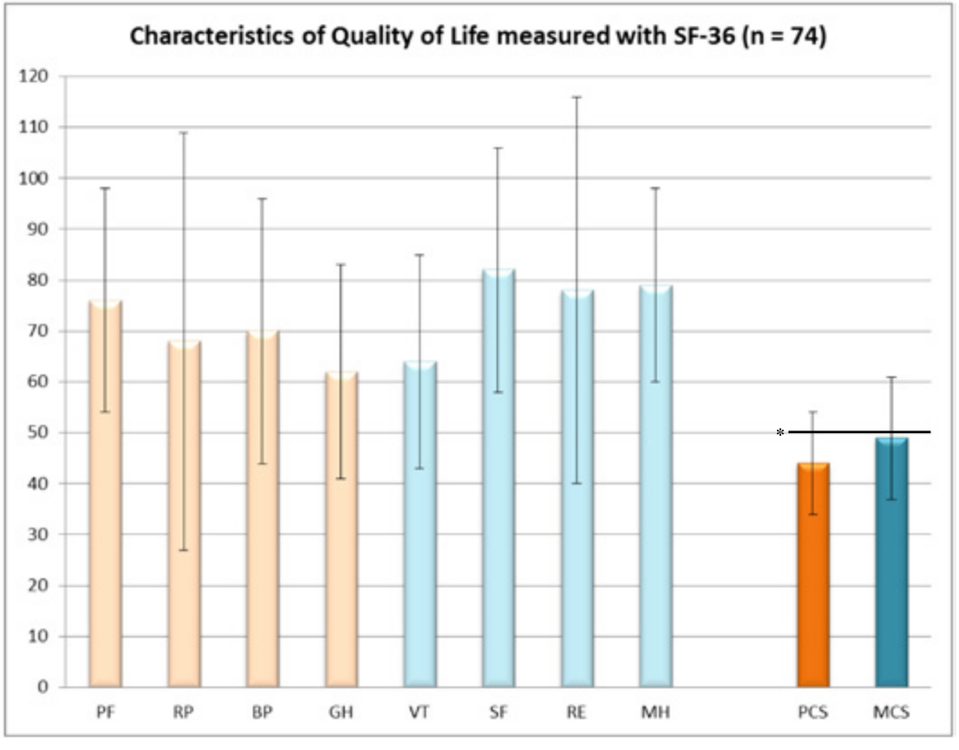


Figure 38. Results of the SF-36 with bars (mean ± SD) showing the eight domains for (SF-36 Version 1 Scale Scores). PF, physical functioning; RP, role physical; BP, bodily pain; GP, general health; VT, vitality; SF, social role functioning; RE, emotional role functioning; and MH, mental health. The two summary scores are presented on the right: the Physical Component Score (PCS) and the Mental Component Score (MCS).
*The results for the PCS and MCS are normalised against a Swedish population (n=8,000) with a mean of 50 ± SD 10 [206].

Taken together, patients with diabetes visiting a DPO for the first time had several risk factors for developing DFUs. Foot deformities such as hallux valgus and/or hallux rigidus appeared to increase medial plantar PP and a higher BMI, as well as the presence of calluses, appeared to increase lateral plantar PP. The results support the theory that changes in biomechanics due to limited range of motion and changes in the alignment of the skeleton and joints have an impact on the pressure distribution on the plantar area of the foot. In order to confirm the influence of risk factors such as foot deformities and dysfunction of the lower extremities on plantar pressure, larger studies are needed.

■

7.2 STUDY II

Foot anthropometrics in individuals with diabetes compared with the general Swedish population – implications for shoe design

Therapeutic footwear used in the prevention of DFUs is the subject of rigorous demands regarding function and fitting. The shoes must correspond well to the three-dimensional shape of the foot in terms of foot anthropometrics, such as foot length, foot width and toe height. The literature gives limited information about foot anthropometrics in patients with diabetes, although these measurements are of importance in shoe fitting.

The aim of the study was to examine whether foot anthropometrics differ between patients with diabetes compared with the general population and, if so, what reasons for these differences may be plausible.

Foot anthropometrics were measured in 164 patients with diabetes visiting a DPO in VGR, Sweden. The control group consisted of 855 participants without known diabetes (Figure 27, page 51). Foot anthropometrics were compared between the following groups: patients with diabetes with and without neuropathy and controls consisting of participants measured in the 1970s and the 2000s. The foot measurements were obtained using foot callipers, a rigid measurement tape and special foot measurement apparatus (Figure 39).

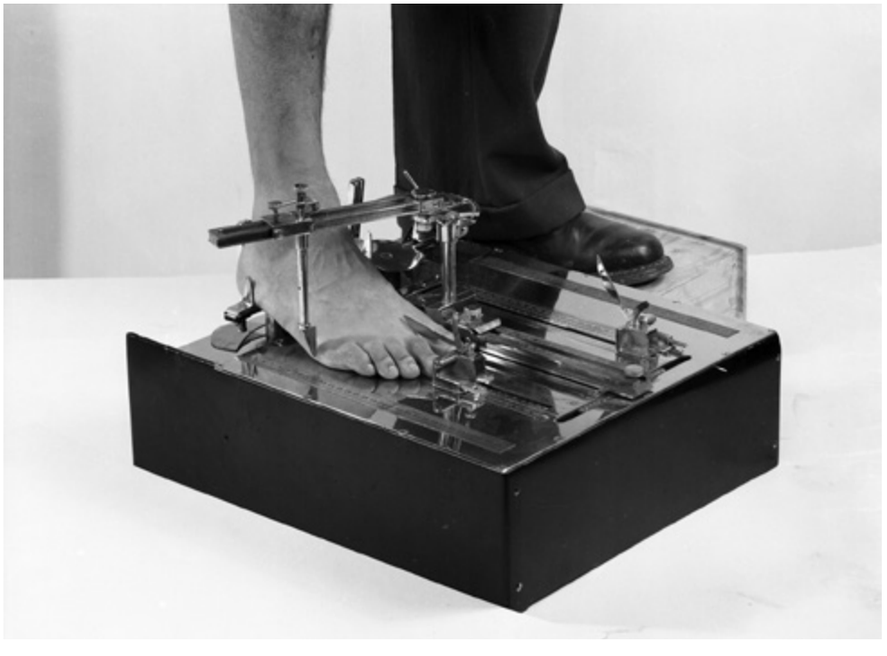


Figure 39. Special foot measurement apparatus, developed by Nils Haraldsson, was constructed to measure foot anthropometrics (lengths, heights and angles). In combination with a measurement tape, a total of 21 foot measurements were recorded. This apparatus was used by the Swedish Shoe Industry's Research Institute during the period 1940 to 1990. The feet of 16,000 people in Sweden were measured. The right foot was placed without shoes and stockings and with the sole of the foot horizontally on the measurement device and fixed with a metal plate between the hallux and the second toe. The posterior part of the heel rested against a bar. Subjects stood with their weight equally distributed between both feet. Foot length was measured with a bar mounted perpendicular to a longitudinal scale. All measurements at the SFI were performed with the same measurement device. Photographer: Curt Götlin 1951/Örebro stadsarkiv. Homepage available 2016-04-22 http://www.orebro.se/5025.html

The results showed that foot anthropometrics (foot length, foot width and maximum toe height) differed between the four groups before adjusting for the co-variates of age, gender and BMI. The individual variation was high (foot length 194-306 mm, foot width 74-132 mm and maximum toe height 15-45 mm). Maximum toe height, adjusted for age, differed between groups of patients with and without neuropathy (25.6 v. 24.4 mmm), ($p = 0.034$). The foot index, calculated as foot length/foot width (adjusted for age, gender and BMI), was lower (2.58) in patients with diabetes without neuropathy than controls from the 2000s (2.63), ($p = 0.018$). Patients with diabetes with neuropathy had wider feet (98.6 mm) compared with controls measured in the 2000s (97.0 mm), ($p = 0.047$).

In conclusion, age, gender, BMI, diabetes and neuropathy have an effect on foot anthropometrics. The individual variations were large. Detailed consideration of the foot anthropometrics of each individual patient with diabetes is recommended before he/she is provided with footwear designed to prevent the development of a DFU.

■

7.3 STUDY III

The D-Foot, an eHealth tool useful in risk classification and foot assessment in diabetes – construction and reliability

The regular structured foot assessment and risk classification of the feet is recommended in the strategy to prevent the development of DFUs. However, at the time of Study III, there was no reliable routine that facilitated an objective risk classification of the feet in diabetes.

The aim of the study was to describe the construction of an eHealth tool, the D-Foot, programmed to generate an objective judgement of foot ulcer risk. The reliability of the D-Foot was tested.

The content validity was assured by a consensus process in the regional expert group. The expert group included CPOs, physiotherapists, an orthopaedic shoemaker and an orthopaedic surgeon. Collaboration with the diabetes association was established and the content of the D-Foot was discussed with its representatives. The judgement for an item to be included in the internet-based program, the D-Foot, was based on scientific literature, current guidelines and clinical experience. The series of foot assessments that were included in the internet-based program should be quick and easy to perform. Based on the discussion that took place during six meetings, a series of 22 foot assessments and four patient questions were included in the eHealth tool, the D-Foot. The following risk factors were identified: neuropathy, foot deformities, skin pathologies, history of earlier ulcers/amputation, ulcers and osteoarthropathy (Charcot foot).

Inter-rater (n = 97) and intra-rater (n = 82) reliability were assessed by eight CPOs at four different DPOs in VGR. The agreement was tested by calculating the agreement and kappa statistics for the discrete variables. The inter-rater and intra-rater agreement for the continuous variables was calculated using Pearson's correlation coefficient and the intra-class correlation coefficient (ICC).

As a result of Study III, an eHealth tool, the D-Foot, was constructed. In Figure 40, some examples of the illustrative manuals that were incorporated in the D-Foot are presented. The content validity of the internet-based program was assured by the consensus process.

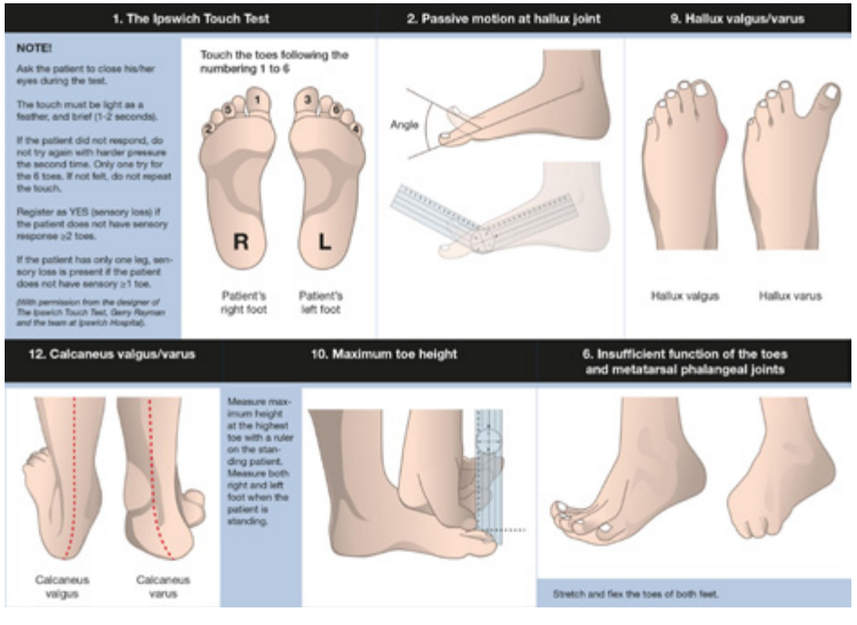


Figure 40. Examples of assessments that were included in the eHealth tool, the D-Foot.

A one-page guideline that illustrated the risk classes, the symptoms and the recommended intervention was created and was incorporated into the internet-based program (Figure 41).

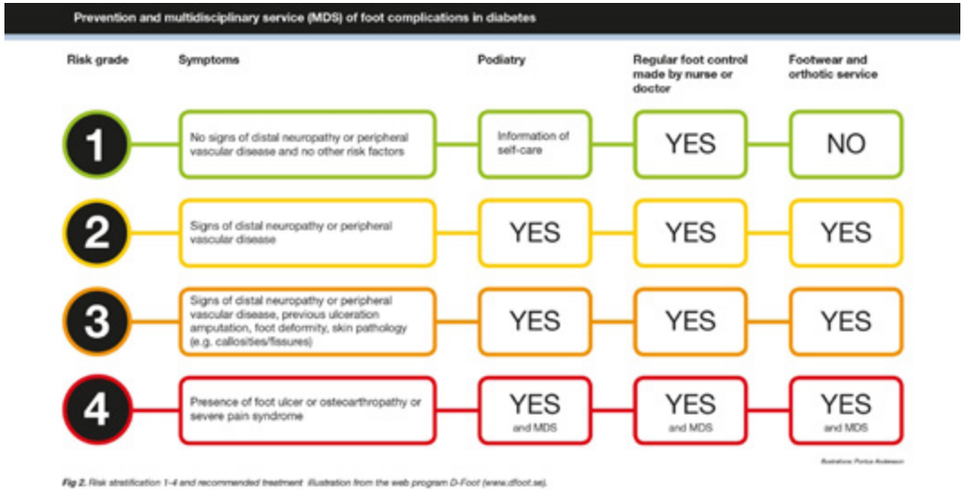


Figure 41. The one-page guideline illustrates the risk classes, the symptoms and the regional recommended interventions [35]. The text is a translation from the Swedish version of internet-based program, the D-Foot version 2014.01, with the additional text "and multidisciplinary service".

The test of reliability revealed that the risk grade and the risk factors of foot ulcer, gait deviation, hallux valgus/varus, amputation and Charcot deformity had an inter-rater agreement of > 0.80. The inter- and intra-rater agreement for the discrete measurements was > 0.59 and > 0.72 respectively. For continuous measurements, the inter- and intra-rater correlation varied (0.33-0.98 and 0.25-0.99 respectively). The following risk factors had a kappa value of > 0.50; the Ipswich Touch Test, amputation, Charcot foot and hallux valgus/varus. Risk factors with a Pearson's r of > 0.50 were: maximum toe height, passive range of dorsal flexion at metatarso-phalangeal joint I and maximum dorsal flexion at the ankle joint. Large variability between the observations made at the four different DPOs was found (Figure 42).

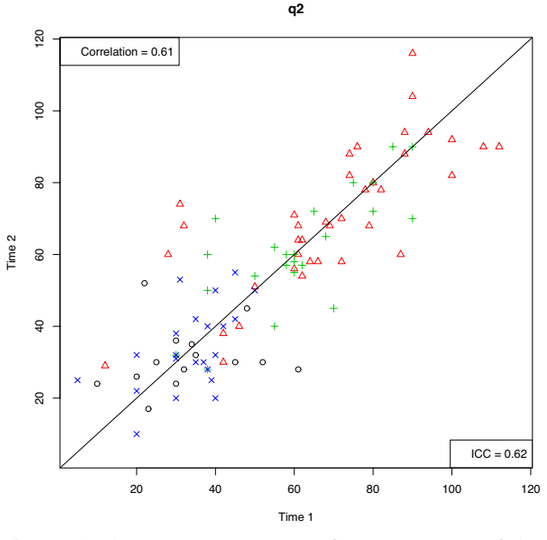


Figure 42. The inter-rater agreement for passive range of dorsal flexion of the metatarso-phalangeal joint I revealed site-dependent differences that indicated systematically lower values at different sites. DPO_B and DPO_D measured the ROM at the hallux joint as smaller values (20°-50°) compared with DPO_A and DPO_C (50°-150°). Triangle = DPO_A, circle = DPO_B, plus = DPO_C and cross = DPO_D.

To summarise, the level of agreement for risk classification and the assessments for identifying foot ulcers, amputations and Charcot deformity was high. The risk factor of foot deformity was defined and methods for identifying foot deformities were established. One limitation was that the presence of peripheral vascular disease was not included in this version of the D-Foot.

The patients appeared to appreciate the interaction that took place when the D-Foot was used in the foot assessments. They were engaged in the process, answered the surveys and, when the result was shown on the screen, a motivational talk was initiated related to self-care, shoes and the risk factors that should be considered.

The national vision for Sweden to be in the front line when using digitisation and eHealth in 2015 is promising and, with this national initiative, solutions like the D-Foot have the potential to be supported and to be spread. The use of eHealth tools can facilitate the prevention and care of foot problems in diabetes [175]. In the future, solutions might appear that will facilitate the patients' self-screening of their feet that might be a good support in the self-care of the feet [207].

Finally, the D-Foot is recommended for clinical use at a DPO. The D-Foot assesses an objective foot ulcer risk, gives recommendations for prevention and might be useful in promoting good foot health.

■

7.4 STUDY IV

Comparison of plantar pressure in three types of insole given to patients with diabetes at risk of developing foot ulcers – A two-year, randomized trial

Foot orthoses, designed to distribute high plantar PP and inserted in shoes, are frequently used to prevent DFUs. However, the scientific literature provides limited evidence relating to the pressure distribution properties of commonly used foot orthoses designed to prevent the development of the first DFU.

The aim of the study was to compare the redistribution of pressure between three commonly used foot orthoses inserted in walking shoes. The secondary aim was to explore the redistribution pattern of PP in seven ROIs under the sole of the foot during two years of use.

One hundred and fourteen patients with diabetes were included in a two-year study (Figure 27, page 51). The patients who were included were referred to a DPO with the aim of being provided with assistive devices with the purpose of protecting the feet from DFUs. The patients were randomised to use one of following foot orthoses: a) soft custom-made orthoses composed of EVA with 35 Shore A hardness, b) hard custom-made orthoses composed of EVA with 55 Shore hardness or c) prefabricated foot orthoses composed of a hard core with a top layer of soft microfibre. The plantar PP was measured using the F-Scan®, an in-shoe pressure measurement system, at seven ROIs at baseline and subsequently every six months. After completion of the study, a survey revealed the extent to which the patients had had access to podiatry, had used the assistive devices and how satisfied they were with the devices. A total of 86 (75%) of the patients completed the four follow-ups. In Figure 43, the reasons and the number of patients that dropped out are presented.

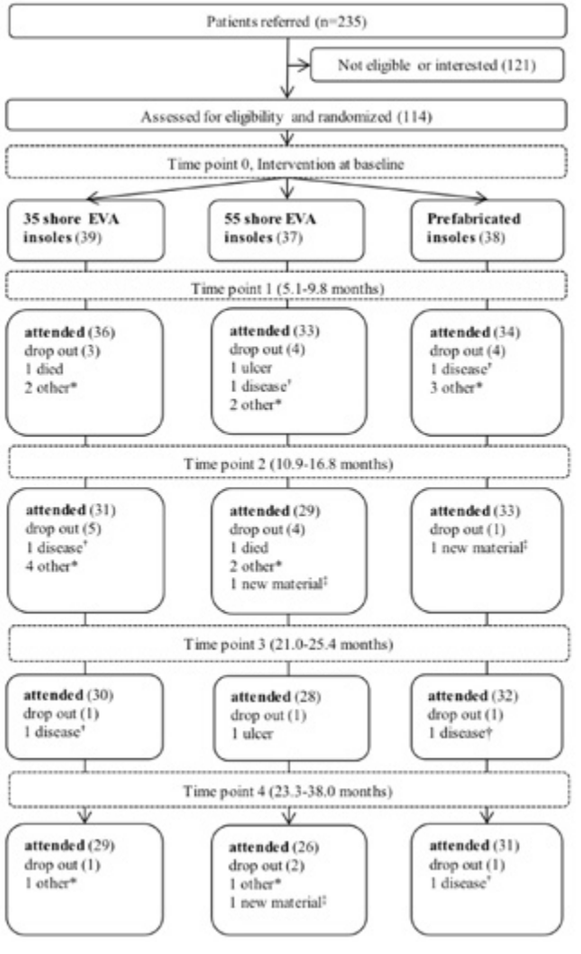
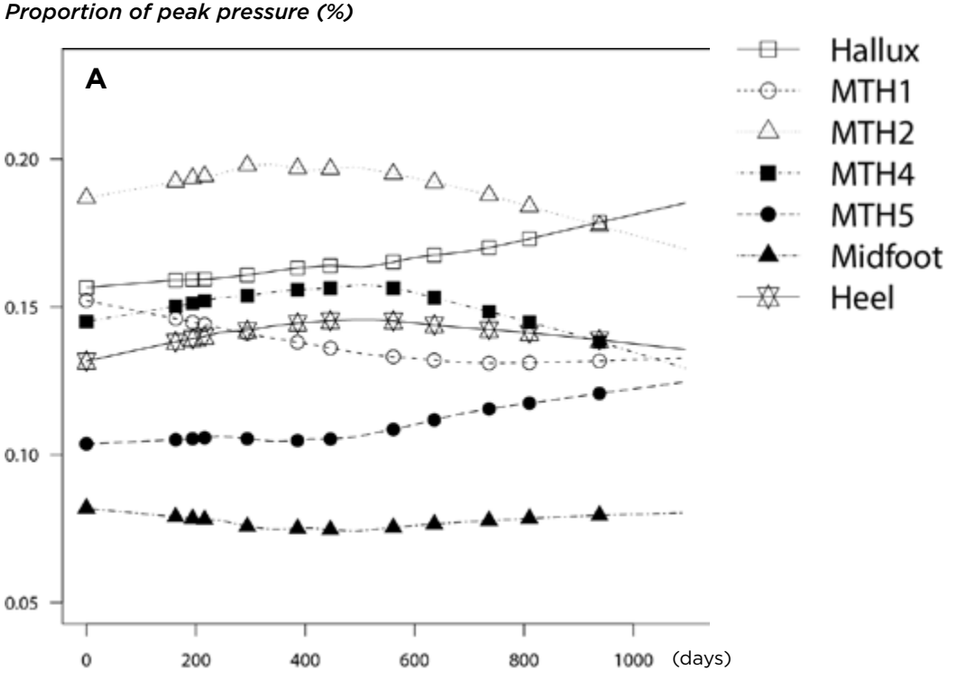


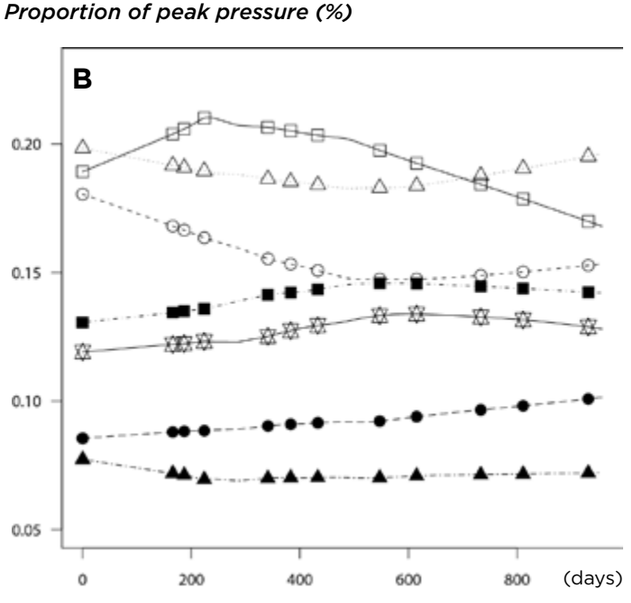
Figure 43. Flow chart for the participants in the study and the reasons for study drop-outs. The "measurement time point" reflects the time interval and is reported as a range (minimum to maximum). The numbers of participants are presented in parentheses. Reasons for dropping out are explained as follows: *participant drop-out for personal reasons; †other disease made participation impossible; ‡ participant wanted to change material of the insoles or the participant was prescribed another insole material.

A mixed-model analysis estimated the differences in pressure considering the different types of foot orthosis and the time since the foot orthosis was changed, thus taking account of the fact that the effect on PP might change as the foot orthoses be-

come worn-out. The individual variation in PP was high. The mixed-model analysis estimated a lower PP value in the heel regions for the 35 Sh EVA and 55 Sh EVA insoles (171 ± 13 and 161 ± 13 kPa respectively) than for the prefabricated insoles (234 ± 10 kPa) ($p < 0.001$). Moreover, for some of the other six ROIs, differences in PP could be observed. The PP ranged from 82 to 294 kPa. The standard deviation was high; < 145 kPa.

The redistribution of peak PP for all the foot orthoses was stable at the midfoot, while the proportion of load on the distal area changed during the study period (Figure 44). The graphs indicate that, when patients use soft custom-made foot orthoses, the proportion of PP at baseline is highest at MTH2 and lower at the hallux. However, as time passes, the pressure curves for these two ROIs comes successively closer and, during the latter part of the study, graphs for MTH2 and the hallux coincided. The opposite pattern was observed for patients that used the hard custom-made foot orthoses. Patients using the hard custom-made foot orthoses had had a higher proportion of PP at the hallux in the first part of the study; this did, however, change over time to a location at the MTH 2. This is an illustration of the complex interacting distribution of pressure that occurs over time. In Table 6, the results from the patients' survey in terms of their satisfaction and use of the assistive devices revealed that the satisfaction was 85 and the use was 79, measured on a 0-100 scale (higher values mean greater satisfaction and more frequent use). Forty-nine (66%) of a total of 74 patients who answered the surveys reported that they had had access to podiatry during the last 12 months.





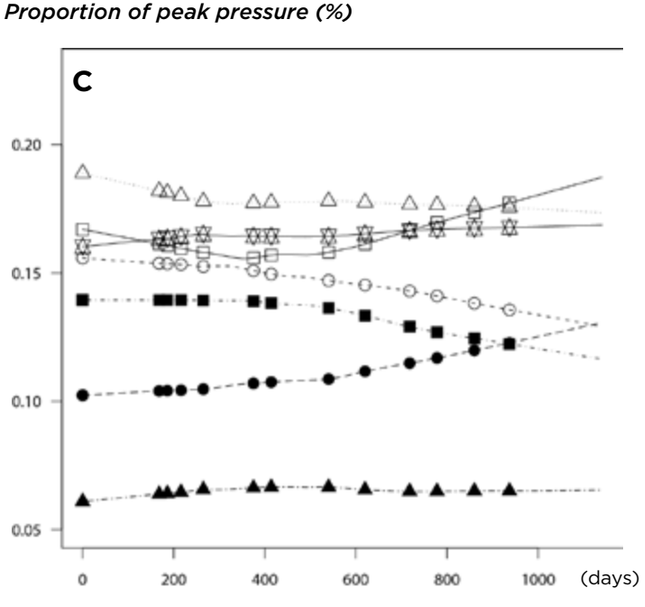


Figure 44. The distribution of PP for seven ROIs is illustrated for patients that used soft 35 Shore EVA foot orthoses during a two-year period (A), patients that used hard 55 Shore EVA foot orthoses (B) and patients that used prefabricated foot orthoses (C). The changes over time and the distribution of the plantar PP are presented as the proportion of load for each region of interest. The proportional loads are high at metatarsal head 2 and the hallux. The figure was originally published in Hellstrand Tang et al. 2014 [203].
MTH1-5; metatarsal heads 1-5.

Table 6. Patient-reported use and satisfaction with the foot orthoses and the footwear.

Details	Values	Comments
Self-reported use of the foot orthoses inserted in appropriate shoes	79	Scale 0-100, a higher value represents more frequent use.
Self-reported satisfaction with the foot orthoses inserted in appropriate shoes	85	Scale 0-100, a higher value represents greater satisfaction.
Exchange of foot orthoses/year	43	Eighty-three pairs during two years' provision of foot orthoses
Lifetime/foot orthoses (days)	327-260	Hard and soft foot orthoses respectively
Adjustments during the two-year study	14	

In conclusion, custom-made foot orthoses used in combination with walking shoes contributed to lower PP at the heel region. The use of foot orthoses with high edges surrounding the heel that fitted tightly and were made of EVA (35 EVA and 55 EVA) reduced the pressure under the heel significantly compared with prefabricated foot orthoses that had lower edges and were made of thinner material. For the remaining six ROIs, indications of differences between types of foot orthosis in terms of the PP could be observed. All three types of foot orthoses that were used showed a PP value of around 200 kPa for the seven ROIs. The individual variation in plantar pressure was high. The patients were likely to use foot the foot orthoses inserted in appropriate shoes and, moreover, they were satisfied with the equipment. All the foot orthoses maintained their pressure redistribution properties over long periods and only a few adjustments were needed during the study period.

■

8. Discussion

One important contribution to this thesis, The Diabetic Foot - assessment and assistive devices, is the presentation of a new eHealth tool, the D-Foot, designed for use in diabetic foot ulcer risk classification. Another contribution is the detailed presentation of the variety of risk factors that are present in a cohort of patients visiting the DPO. Moreover, an attempt has been made to investigate the extent to which patients in need of interventions in terms of podiatry, assistive devices, annual foot checks and information about the self-care of the feet have been offered or have received the recommended interventions.

These topics have been studied:

- The prevalence of different risk factors (e.g. neuropathy, foot deformities and callosities) in patients referred to a DPO
- How is the plantar pressure influenced by the above-mentioned risk factors?
- Does the three-dimensional shape of the foot in a patient with diabetes differ compared with a foot of a person representing the general population?
- The construction of a valid eHealth tool, the D-Foot, which safely classifies the risk of foot ulcers and the inter-rater and intra-rater reliability of the tool
- The plantar pressure of custom-made foot orthoses and prefabricated foot orthoses.

Moreover, the following topics are presented and discussed:

- The patients' HRQL
- To what extent do patients at risk of developing DFU have access to podiatry?
- The cost of assistive devices

The recommendations for the prevention and care of DFUs are a consequence of long-term research and international collaboration [11, 16, 18]. Starting in the 1950s, Dr. Paul Brand introduced treatment with a total contact cast to heal plantar neuropathic ulcers [19]. Since then, casting and off-loading are two of the treatments that are available in many multidisciplinary services. Further initiatives to fight high amputation rates in diabetes took place in 1989, when an agreement was made between representatives from patient associations and the European governments [208], which resulted in the target of reducing the numbers of lower extremity amputations, due to diabetes, by 50% during a five-year period. This inspired national strategies and the improvement of health-care pathways. Promising results in the treatment of DFUs have been demonstrated as a result of early recognition and action [209] and access to multidisciplinary service [27, 210]. However, the efforts and resources to prevent and treat foot complications in diabetes vary around the world and are dependent on national strategies, economic conditions, health-care systems and traditions. The IWGDF has been successful in its

efforts to spread the knowledge that every patient with diabetes should have his/her feet risk classified, preceded by structured foot assessments. A variety of foot assessment forms and routines have been developed. Few of them, to the best of my knowledge, has been tested for reliability [35, 55, 119, 211-216].

The prevalence of different risk factors (e.g. neuropathy, foot deformities and callosities) in patients referred to a DPO

Several types of risk factor were present in the patients participating in Studies I and III (Table 5) and, in Figure 45, these risk factors are illustrated and shown to belong to nine areas. As recommended in Swedish regional guidelines, the risk factors, here presented in any of the nine areas, need to be assessed by the CPO prior to the prescription of an assistive device [150]. Only thereafter can the CPO consider and recommend a type of appropriate footwear and assistive device(s) for each individual patient [35, 150].

The insight that assessments of risk factors, such as foot deformities, are important in regular screening has also been presented in a retrospective study of 243 patients with type 2 diabetes [88]. The prevalence of potential risk factors, such as foot deformities (38% calluses, 49% hallux valgus, 39% hallux valgus and 44% bony prominences) was high and the authors stated that these risk factors need to be recognised to prevent the development of DFUs and amputations. Moreover, the frequent presence of foot deformities (86%) was reported in a study by Owings et al., assessing foot deformities in patients whose DFUs had remained healed [87].

The aim for Study III was to construct a tool that identified risk factors that have previously been shown as being assessed as "risk factors for the onset of DFU" [27, 33, 35, 36, 39, 57, 119, 158, 180, 217, 218].

Figure 45. A model of the nine potential risk areas where the risk of developing a DFU need to be identified [35, 150].

All the patients in Studies I and II were classified as risk group 3 based on the presence of foot deformities, skin pathologies and/or neuropathy. In Study III, the presence of neuropathy was higher, 77%, compared with Studies I and IV (38%). In contrast to Studies I and IV, Study III also included patients with and without DFU. Damage to the peripheral nervous system is often present in patients with DFUs and this might explain the higher presence of neuropathy. In Studies I and IV, the patients were first-time visitors to a DPO and probably had less damage to the nervous system.

How is plantar pressure influenced by the risk factors of neuropathy, foot deformities, dysfunction in the lower extremities and body anthropometrics?

In Study I, neuropathy was present in 38% of the patients and 53% had callosities in the heel region. Neuropathy was not associated with high PP. Moreover, a low forefoot arch was present in 77% and gait-related parameters, such as the ability to walk on the forefoot or the heel, were normal in all patients. Eighty per cent had normal function at the hip and knee joints and gait velocity was 1.2 ± 0.2 m/sec. All patients were stratified to risk group 3.

Hallux valgus and hallux rigidus were associated with higher PP in the medial forefoot. A higer BMI and callosities was also associated with higher PP at metatarsal heads 4 and 5. Pes planus was associated with lower PP at MTHI 1.

The access to techniques to measure plantar pressure has facilitated the research of plantar pressure and to access high PP as predictors of DFU development. The research related to the relationship between high PP and the development of DFU has grown rapidly the last decades due to the development of advanced techniques for measuring plantar pressure.

By using barefoot measurements and in-shoe plantar pressure measurements, researchers have found that the presence of foot deformities such as Charcot foot deformity, hammer toe deformity, hallux valgus, limited joint motion, prominent bony structures and small muscle wasting, increases the risk of developing DFUs because their presence has been linked to high PP and they might accordingly be regarded as predictors of DFU development [104, 107, 108, 161, 180]. However, larger studies are needed to determine whether some types of foot deformity or the severity of foot deformity may be associated with a higher risk of developing DFU.

Taken together, several potential risk factors for the onset of diabetic foot ulcers have been identified in Studies I and III. Hallux valgus and hallux rigidus were associated with higher PP under the medial forefoot and a high BMI increased the PP under the lateral forefoot. This indicates that there is a need to construct a simple, valid and reliable assessment routine, to be used in clinical practice, in order to detect potential risk factors for the onset of DFU. Larger studies are needed to establish data sets that make it possible to evaluate the complex relationship between the risk factors (e.g. neuropathy, foot deformities, dysfunction in the lower extremities, limited ROM and foot anthropometrics) and high PP. The findings in the current thesis indicate that the high forces transmitted through the foot when sitting, standing and walking should be considered and, as much as possible, be redistributed to acceptable levels with the use of assistive devices.

Does the three-dimensional shape of the foot in a patient with diabetes differ compared with a foot of a person representing the general population?

As a result of Study II, it was found that age, gender, BMI, diabetes and neuropathy have an effect on foot anthropometrics (foot length, foot width and maximum toe height). Not surprisingly, the present findings are in line with earlier studies showing that gender, age and body mass has an effect on foot anthropometrics [219-221]. New findings in Study II are the presentation of the effects of age on maximum toe height (increased toe height with age) and foot width (wider forefoot width with age). These results were found when BMI was excluded from the statistical model. The effect of neuropathy on foot length, foot width and maximum toe height has not been clarified and needs to be studied in more detail. The individual variations in foot anthropometrics were large. This thesis emphasises the importance of detailed consideration of the foot anthropometrics of all patients with diabetes in order to provide them with therapeutic shoes. Standards for measurements of foot length, foot width and toe height should be prepared and introduced into daily work at the DPOs.

The construction of a valid eHealth tool, the D-Foot, which safely classifies the risk of foot ulcers and the inter-rater and intra-rater reliability of the tool

The main contribution of this thesis is the presentation of a new eHealth tool, the D-Foot, which, based on a series of foot assessments, is programmed to provide an objective foot ulcer risk classification on the screen. The standardised foot assessment routine and the risk classification are in line with the aims in the national and regional guidelines [27, 35]. In contrast to current routines, the D-Foot gives a more objective and reliable classification of foot ulcer risks [35, 222-230]. However, Study III revealed that some assessments had low inter-rater reliability, implying that these assess-

ments need to be revised, or even removed from the D-Foot in future versions. Assessments that showed low reliability were tests of insufficient function of the metatarso-phalangeal joints and the toes, the navicular drop test, assessments of areas of excessive pressure with callosities and the assessment of gait deviation affected by the hip/knee. Moreover, assessments that examine the presence of peripheral vascular disease and skin pathologies need to be added to future versions [36, 231].

The Swedish National Guidelines for Diabetes Care, launched in 2015, recommend a regular annual examination of the feet to detect foot deformities, which correspond to a priority of 2 on the 1-10 scale. So, what is a foot deformity? Among clinicians, the answer to this question varies. The risk factor of "foot deformity" is by definition "structural abnormalities of the foot such as hammer toes, mallet toes, claw toes, hallux valgus, prominent metatarsal heads, residuals of neuro-osteoarthropathy, or foot surgery including amputations" [4]. Some researchers have included limited range of motion in the definition of foot deformity [33, 57], measured as the presence of a "lack of contact between any of the metacarpo-phalangeal joints during prayer sign" or by assessing the prevalence of hallux limitus/rigidus [33, 57].

In Study III, the expert group clarified the expression foot deformities by studying the current guidelines and the scientific literature. Several expressions of foot deformity were described (with words and with illustrations) and were programmed in the internet based program, the D-Foot. The manual, which is included in the software, included details on how to measure these foot deformities (amputation, Charcot deformity, hallux valgus/varus, abduction/adduction of the forefoot, prominent superficial bony structures on the plantar area, gait deviation with drop foot, malalignment, hammer toes and limited ROM at the hallux joint and at the ankle joint (Figure 40, page 70). Moreover, to clarify and make the assessment of the foot deformity of "hammer toe" easier, a measurement of maximum toe height was introduced. A hammer toe height exceeding 25 mm was set as the threshold value. The relevance of setting 25 mm as a threshold was based on commonly used toe-box heights of 22-26 mm for off-the-shelf shoes (for adults) [183, 232].

Peak pressure as a risk factor

In the current version of the D-Foot, indirect signs of high PP indicating calluses and areas of high pressure were assessed and direct measurements of PP were not included. The reason that direct measurements of PP were not made was that these assessments would be time consuming and the exclusion of plantar pressure measurements was therefore obvious. Moreover, a routine measurement of plantar pressure requires equipment which is desirable but not yet common at the DPO. However, in clinical practice, pressure measurements are important, especially in patients that require a further evaluation to optimise their assistive devices [164]. One advantage of using dynamic plantar pressure is that the pressure is quantified, documented and visualised.

A comparison of the barefoot plantar measurement and the in-shoe plantar pressure provides valuable information on the extent to which the assistive devices redistribute the pressure from areas with high PP [87, 164]. It is possible to ask whether there is a "true" threshold value of PP that should not be exceeded to minimise the risk of developing DFUs? The answer is simple: "No, there is no true value". However, several authors have made qualified attempts to investigate the relationship between high plantar pressure and the risk of developing DFUs. Armstrong et al. measured barefoot PP using an emed® platform and found that a PP of > 700 kPa yielded high sensitivity[4] and specificity[5] (> 65%) in the screening of patients at risk of developing DFUs [109]. The study comprised 219 patients with diabetes and neuropathy (Figure 46) [109]. Lavery et al. used the same type of platform in a study of 1,666 diabetes patients running a high risk of DFUs and found that a PP of > 850 kPa assessed patients running a high risk of DFUs (sensitivity 64% and specificity 46%) [108]. Similar results were presented in a study by Bolton et al., where they used an optical pressure measurement system [233]. They tested barefoot PP in patients with and without neuropathy and with and without previous DFUs (total n = 123) and found that a PP of > 1080 kPa was more often found in those with previous DFUs [233]. However, a lower value with a PP = 566 kPa was reported by Owings et al. in 49 patients with diabetes, neuropathy and healed DFUs [87]. The pressure was measured using an emed® platform. All the above-mentioned studies assessed the PP in groups of patients with ongoing DFUs or healed DFUs. In Figure 46, the differences in the suggested threshold values are presented.

The suggested threshold values, measured using an in-shoe pressure measurement system, are lower than barefoot measurements. Owings et al. suggested a fixed in-shoe PP value of 200 kPa that could serve as a threshold value to avoid ulcer recurrence [87]. A relative measurement of successful intervention has been suggested by Bus et al. [158]. They suggested a reduction in plantar pressure of 30% as the target for a successful intervention by wearing therapeutic footwear compared with standard shoes.

There are, however, several important limitations to consider when the results of plantar pressure measurements are compared. Differences in terms of study design, the pressure measurement system and/or models for the calculation of pressure (PP, maxPP or PTI) make comparisons risky. Moreover, the shoe types, type of insoles, the patient's gait velocity during measurement, the number of steps used in the calculation and, not least, the handling of the measurement system and equipment will also influence the results. All these factors must be considered when the results of PP are interpreted [110, 234].

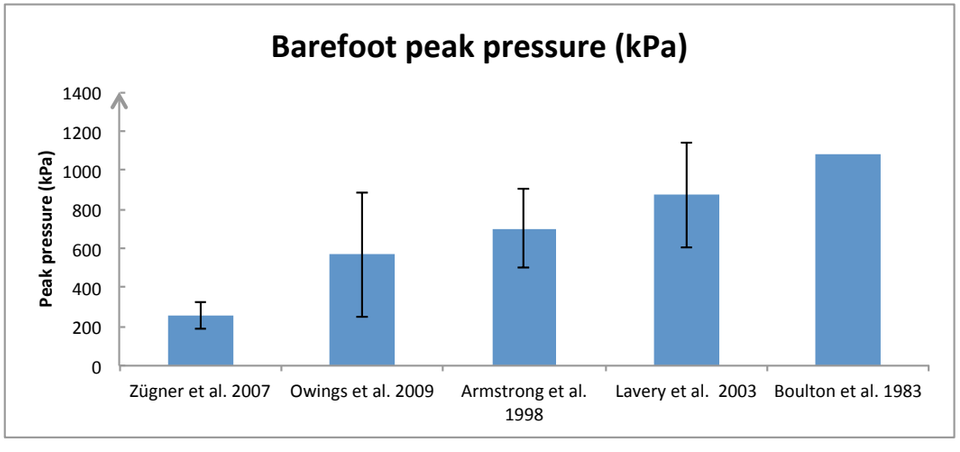


Figure 46. Barefoot PP in patients with diabetes and with healed or ongoing foot ulcers. The four bars to the right represent threshold values that should not be exceeded to minimise the risk of developing DFUs. In the study of Boulton et al. the standard deviation was not presented. The study to the left is an example of the plantar pressure level of barefoot measurement in a small cohort of patients without a known history of DFUs [202].

Plantar pressure of custom-made foot orthoses and prefabricated foot orthoses

Previous research has shown that high plantar pressure can be reduced and/or redistributed by using custom-made or contoured foot orthoses, in combination with special footwear [169, 235-237]. It is widely debated among clinicians whether or not all patients with diabetes should have custom-made foot orthoses and whether custom-made foot orthoses constructed from softer

[4] *Sensitivity; a true positive rate*
[5] *Specificity, a true negative rate*

material are more effective in reducing the pressure in areas where there is a high risk of ulcer development. In Study IV, different types of foot orthoses and the impact of foot orthoses on plantar pressure were evaluated. The patients were followed for two years with regard to differences in the PP for three different types of foot orthoses. The mixed-model analysis estimated lower PP values in the heel regions for the soft 35 Sh EVA and the hard 55 Sh EVA foot orthoses (171 and 161 kPa respectively) compared with prefabricated foot orthoses (234 kPa) ($p < 0.001$). Moreover, for some of the other six ROIs, indications of differences in PP or PTI were observed. Custom-made foot orthoses used in combination with stable walking shoes resulted in lower pressures at the heel region. Systematic differences in plantar pressure for the remaining six ROIs were not observed. In a patient with no present DFUs and no risk factors in the heel area, prefabricated foot orthoses can be regarded as a relevant alternative to custom-made foot orthoses. However, the prescription should include an individual assessment of all the potential risk factors that might be present.

■

8.1 ADDITIONAL WORK

HRQL

Two patient-reported outcome measurements (PROM) were used to determine the well-being and functional health of patients. In Study I, the SF-36 and the EQ-5D (Appendix 3) were used and, in Study III, the EQ-5D (Appendix 4) was used. The following section presents additional results related to the EQ-5D.

EQ-5D

The EQ-5D is a standardised, reliable and valid measurement of health status developed by the EuroQol Group in order to provide a simple, generic measurement of health for clinical and economic appraisal [195]. It consists of two parts. The first part is a health state description comprising five questions (representing the domains of mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Originally, answers were given on a three-level scale (EQ-5D-3L, Appendix 3) [238] and a five-level scale was subsequently developed (EQ-5D-5L, (Appendix 4) [239]. The EQ-5D-5L was developed to improve the sensitivity of the instrument and to reduce the ceiling effect. In both versions, the answers can be transformed to a single index-based utility score of HRQL. The utility index is widely used in economic evaluations [240] and is interpreted from 1 (full life) to 0 (death) and values of < 0 are considered worse than death [241]. Part two consists of an EQ-VAS scale (0-100) with the endpoints of 'Best imaginable health state' and 'Worst imaginable health state' (Appendices 3-4).

In Study I, more that 70% of the patients reported "I have no problems..." for all domains except for pain/discomfort, in which 40% reported no problems (Table 7). Moreover, 74% of the patients perceived that they had the ability to walk normally and they were all able to walk on their toes and heels (Table 5). These results are supported by the EQ-5D results in terms of mobility, self-care and general activities.

Table 7. The EQ-5D-3L results for patients with diabetes, but without foot ulcers, referred to a DPO, Study I (n = 74).

Level	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety/depression
1	55 (76%)	72 (100%)	65 (90%)	29 (40%)	53 (74%)
2	17 (24%)	-	7 (10%)	41 (57%)	17 (2%)
3	-	-	-	2 (3%)	2 (3%)
Missing values	2	2	2	2	2
Total	74	74	74	74	74

Note: The patients answered the EQ-5D-3L, in printed format (Appendix 3). The distribution of the answers (levels) is presented as the number and percentage for each domain. Level 1) I have no problems..., level 2) I have some problems..., level 3) I am unable to...

In Study I, the patients were first-time visitors to a DPO and were offered assistive devices to prevent DFUs, probably at an early stage of the disease, and reported good HRQL in four of the five domains.

Study III revealed that more than 60% of the patients reported no problems in terms of self-care, usual activities and anxiety/depression (Table 8). Moreover, 46% of the patients reported no problems in the domain of mobility and 21% had no problem related to pain/discomfort. A sub-group analysis of the 13 patients that were classified as risk group 4 revealed that they rated their health lower in all five domains than those that were classified as lower risk grades (Table 9). Moreover, 62% per cent of the patients in risk group 4 reported moderate or severe problems with mobility.

Table 8. The EQ-5D-5L results, obtained from a cohort of patients with diabetes with and without foot ulcers referred to a DPO.

Level	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety/ depression
1	41 (46%)	72 (81%)	53 (60%)	19 (21%)	56 (63%)
2	19 (21%)	10 (11%)	16 (18%)	22 (25%)	22 (25%)
3	21 (24%)	7 (8%)	9 (10%)	37 42%)	4 (4%)
4	8 (9%)	-	10 (11%)	7 (8%)	7 (8%)
5	-	-	1 (1%)	4 (4%)	-
Missing value	8	8	8	8	8
Total	97	97	97	97	97

Note: The patients in Study III answered the EQ-5D-5L in digital format (Appendix 4). The distribution of the answers (levels) is presented as the number and percentage in each domain. The levels were: Level 1) I have no problems..., level 2) I have slight problems..., 3) I have moderate problems...,4) I have severe problems...,5) I am unable to...

Table 9. The EQ-5D-5L results, from the sub-group analysis for the thirteen patients with DFUs (Study III).

Level	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety/ depression
1	4 (31%)	7 (54%)	3 (23%)	1 (8%)	8 (62%)
2	1 (8%)	3 (23%)	7 (54%)	4 (31%)	4 31%)
3	7 (54%)	3 (23%)	1 (8%)	7 (54%)	-
4	1 (8%)	-	2 (15%)	1 (8%)	1 (8%)
5	-	-	-	-	-
Total	13	13	13	13	13

The value of physical activities and daily walking has been emphasised at any stage of the disease [27, 242]. However, several patients with DFUs are recommended not to load the foot and to avoid walking. For the individual patient, these two conflicting pieces of advice are frustrating. It is worth to notice that even for patients with foot problems, customised physical training can be tailored to improve physical function, improve well-being and keep glucose levels balanced [242].

The EQ-5D index in Studies I and III was 0.81 and 0.78 respectively and the EQ VAS was > 70 in both groups (Table 10). These findings are in line with previous results showing that patients with diabetes experience poorer HRQL compared with the general population [205, 243]. Moreover, in the presence of DFUs, the HRQL has been shown to be even lower [244-248]. The individual variation in HRQL was large in the studies included in the thesis.

Table 10. Results for the EQ-5D VAS and EQ- 5D utility indices, Studies I and III.

Groups		EQ VAS		EQ-5D index		EQ-5D-5L cross-walk index*	
	N	Mean ± SD	Min Max	Mean ± SD	Min Max	Mean ± SD	Min Max
Study I. Diabetes without foot ulcers (EQ-5D-3L)	74	75.8 13.7	30 100	0.81 0.20	0.09 1.00		
Study III. Diabetes with and without foot ulcers (EQ-5D-5L)	89	70.4 19.2	0 100	0.78 0.21	0.00 1.00	0.69 0.23	-0.01 1.00

N; number
SD, standard deviation
Min, minimum value
Max, maximum value
** The cross-walk index values are the converted utility index for the EQ-5D-5L that are comparable with the utility index for the EQ-5D-3L [239, 249]. The index values are based on the TTO (time trade-off) value set from the United Kingdom [250].*

Pain

By interviewing the patients in Study I (n = 67), the level of pain was assessed. The patients were asked to rate the pain from 0-10 (0 = no pain, 10 = extreme pain). The registered level of pain was then multiplied by a factor of 10, giving a possible result ranging from 0-100. In Study I, it was shown that the self-perceived pain was 10 (± 24), minimum 0 to maximum 90. The reason for the large variation was that several patients (n = 55) had no foot pain at all.

In Study III, self-reported pain was registered on a visual analogue scale using a tablet (Figure 47). The end-points were 0 = "no pain" and 100 = "extreme pain", with all other possible integers lying in between these values. The right foot was analysed.

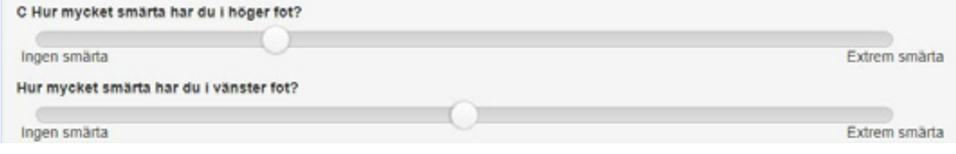


Figure 47. A pain scale was incorporated in the internet-based program, the D-Foot. The patients registered the level of pain by touching the screen. The question was "How much pain do you experience in your foot (right and left respectively)?"

In Study III (n = 97), the self-perceived pain was 26 (± 28), minimum 0 to maximum 100. In this cohort, the majority (54%) reported a low pain level < 20 and a few (n = 15) reported values of > 60, which indicates the large spread of self-perceived pain on the pain scale. The presence of pain, presented in Study III, is further confirmed by the results of the "pain/discomfort" domain in the EQ-5D-5L, in which 79% experienced some problems with pain/discomfort (Table 8). The underlying causes of the pain, to varying degrees, perceived by the majority of the patients in Study III are not known. One possible explanation is that the pain is related to damage to the nervous system [251]. In Studies I and III, some patients perceived extreme pain.

The presence and level of pain vary in the results found in the scientific literature. In this thesis, quantitative measurements (0-100 scale) to measure pain were used, thereby creating an opportunity to examine the variation in perceived pain and the mean pain level. Quantitative measurements are not as common as pain reported as discrete or dichotomous (yes/no) results. One example of a

discrete three-level pain score (no pain, moderate, extreme) can be found in the study by Bair et al. (n = 11,689 participants) [252]. These authors found that 58% of the patients experienced extreme to moderate pain. Moreover, 55% of the patients said their physical activities were limited because of the pain. In a study by Smide, 28% of a total of 145 participants answered that they had pain in their feet [253]. In a third study, discomfort/pain in the feet was reported in 88% (214 of a total of 243 patients) of patients examined in a primary care setting [254].

Taken together, the thesis and the above-mentioned studies confirm that pain is a factor that is present (to varying degrees) in patients with diabetes. In Studies I and III, some individuals experienced extreme pain (maximum value of 90 and 100 respectively). Severe pain syndrome leads to a risk classification in level 4, according to the regional guidelines from VGR [35]. Patients with severe pain syndrome should preferably be referred to multidisciplinary service for further examination, have access to podiatry and be provided with assistive devices (Figure 41, page 71). The conclusion of the HRQL measurements is that the studied cohort generally experienced good HRQL, but large variations existed. Moreover, it is important to assess the presence of pain prior to the provision of assistive devices, as this has large-scale implications for the design of the devices.

PREM

Patient-reported experience measurements (PREM) have been shown to influence the patients' HRQL and are regarded as an important measurement that is necessary for improvements in the care of foot problems in patients with diabetes [255, 256].

We are moving away from a health-care tradition based on hierarchy towards person-centred care, where the patient is considered more as a partner than as a patient. In this new type of partnership, the patient/person and the health-care providers plan, monitor, implement and evaluate the relevant interventions [257]. A positive outcome in DFU prevention using assistive devices is possible if, and only if, the devices are used and accepted by the patient [258]. The general term used to describe how much a patient uses the prescribed assistive devices is the term "adherence". The WHO definition of adherence is "the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health-care provider" [259]. Assistive devices protect the feet if they are well-fitting, are accepted by the patient and if the patients adhere to using them [260]. Little is known about how patients perceive the prescribed assistive devices and the extent to which they adhere to using the device.

Two surveys were used in this thesis to answer these questions. At the two-year follow-up in Study IV, the patients reported how much they had used the foot orthoses and how satisfied they were with the devices (Table 6). As shown in Study IV, a high level of use and satisfaction with the assistive devices was reported, scored as 79 and 85 respectively on the 0-100 scale. One hundred represents more frequent use and a higher level of satisfaction on the scale.

In Study III, 86 patients (response rate 89%) with and without DFUs participated in a telephone interview three months after they had received their foot orthoses and/or therapeutic footwear [204]. They were asked to recall their last visit to the DPO. On their last visit, the interviewed patients had been provided with therapeutic footwear and/or foot orthoses and/or counselling with the aim of preventing the development of DFUs. On this visit, the patients' feet were assessed using the internet-based software, the D-Foot. On this visit, the patients played an active part in the assessment by answering a patient survey that was incorporated in the web-based software. The results of the foot assessment and the risk classification were discussed with the CPO (Figure 41, page 71) and led to a talk on self-care and the types of footwear and foot orthosis that would be optimal for his/her need. The interviewer, a dedicated research assistant, followed a structured protocol consisting of eight questions (Appendix 6). In addition, any comments related to the visit and/or the assistive devices were welcomed. The comments were categorised into four themes; "season", "outdoors", "follow-up" and "foot complication" (Table 11). If the patient reported any complaints relating to the devices, he or she was recommended rapidly to make contact with the DPO for a new appointment. Eighty-two (95%) of the patients were content or very content with the consultation with the CPO on the last visit (Appendix 6). More than 70% of those who had received foot orthoses and/or footwear stated they had used the devices often or all the time. More than 80% were content or very content with the foot orthoses and/or the footwear.

Twenty-nine patients made comments and examples of these comments are presented in Table 11. Seven of the comments were categorised as complaints related to the assistive devices, such as "The shoe appears to be too large" or "The foot orthoses are not good". Ten patients reported that the use of footwear and/or foot orthoses was dependent on the season and location (indoors or outdoors). Two patients were discontented because they had not been provided with any foot orthoses or footwear and one patient felt discomfort with the orthoses and declined to take them home from the visit.

Taken as a whole, the majority of the patients were satisfied with the consultation at the DPO and reported that they used the assistive devices frequently. Several factors appear to matter when it comes to adherence in using the devices. One is obviously that footwear, for instance, must be suitable for the season and for use outdoors and indoors respectively. The clinical implication is that the CPO should take the time to talk to the patient in terms of his/her habits, as well as considering the special requirements for footwear in different situations. Additional methods to further strengthen the patients' participation at a DPO visit should be developed in line with the intention of the new Swedish law "patientlagen" (patient law) [144]. This law states that the patients' rights and the role of being an active partner in his/her treatment are strengthened. Before any decision relating to a treatment plan is made by a health-care professional, a dialogue with the patient should take place and symptoms and treatment should be discussed [27, 35, 144-147, 150, 261].

Table 11 (Page 89-90). Examples of comments from the patients, Study III.

Comments	Category
Has developed an ulcer on his/her toe, but it is not because of the shoes. The patient hit his/her little toe.	Foot complication
Broke her toe in the summer and has not used the insoles since then. Before that, however, she used the insoles all the time.	Foot complication
Has not used the shoes because of the hot summer but will use them in the autumn.	Season
Because of the summer, the patient has been wearing sandals into which the insoles did not fit.	Season
Thinks the shoes are heavy, wishes there were colours other than black, especially during in the summer.	Season
Uses the insoles all the time outside but not indoors.	Outdoors
Only uses the insoles outside, no longer has pain.	Outdoors
She did not test the insoles as they did not feel better.	Other
Given slippers on the visit to the DPO. Already had shoes.	Other

Table 11 continues on page 90.

Has not collected the insoles for financial reasons. Was not told that he/she would have to pay for them.	Other
I am in heaven! The insoles have given me a new life.	Other
No insoles were delivered.	Other
Very satisfied! "I can walk again."	Other
Thought the visit was actually truly fantastic!	Other
Only uses the shoes and insoles indoors not outdoors.	Indoors
Pinch marks on the back of the foot, but he/she will very soon be coming for adjustments.	Follow-up
Have advised the patient to contact OTA again, as he was not satisfied with the insoles and shoes.	Follow-up
The shoe feels too large. The patient was advised to contact the DPO.	Follow-up
The shoes are loose. The patient was advised to make an appointment at the DPO as soon as possible.	Follow-up
Does not like the insoles. The patient was advised to make an appointment at the DPO as soon as possible.	Follow-up
Thinks the insoles hurt. The patient was advised to make an appointment at the DPO as soon as possible.	Follow-up
She was dissatisfied when she did not have a chance to try out the shoes. The insoles do not fit her own shoes properly.	Complaints no shoes

Access to podiatry

National and regional guidelines state that all patients with diabetes should have their feet checked annually [27, 35, 262] and that those at risk should preferably be offered prevention with podiatry, information about self-care and have the DPO for consulting and/or to be provided with assistive devices. There is, however, some albeit limited information as to whether these guidelines are followed in Sweden [263]. According to the NDR, > 90% of registered patients in 2015 had had their feet checked [39]. However, the criteria to be assessed as "foot checked" are not described in detail. For patients classified into risk groups 1-4, a referral to podiatry for information about self-care is recommended (Figure 41, page 71).

A survey originating from the Swedish National Board of Health and Welfare revealed that only 28% of the municipalities and districts offered podiatry designed to prevent the development of DFUs [14]. Alongside this thesis, data relating to the opportunity to have access to podiatry were obtained from the VGR (Figure 48). They showed a large variation of 8-53%, depending on where patients were living. Moreover, the results from Study III showed that 89% had undergone a foot check during the last 12 months, 76% had obtained information about self-care and 60% had had access to podiatry. The access to podiatry, reported in Study IV, was 66% and all patients were classified in risk group 3.

Patients whose feet are not checked might present with several risk factors, such as calluses, heel fissures, neuropathy, unguis incarnates, nail deformities and a history of amputation/DFU that should have led to interventions. The findings from the present research that some of the patients are not offered the recommended interventions are supported by the results of a survey (601 responses from hospitals and diabetic foot clinics in the Nordic countries) that questioned whether guidelines in diabetes care were implemented in the Nordic countries [263]. The author presented striking results; 24% answered that the team/centres did not, as a matter of routine, examine the patients' feet (144/601). Seventy-five per cent (277/366) and 30% (110/366) of the team/centres did not always have a CPO, a podiatrist/chiropodist respectively participating in the multidisciplinary team [263]. Moreover, 35% did not use the current guidelines in their prevention and care of foot problems in diabetes. These findings support the urgent need for structure and the monitored implementation of current guidelines in order to work based on evidence-based practice [264, 265].

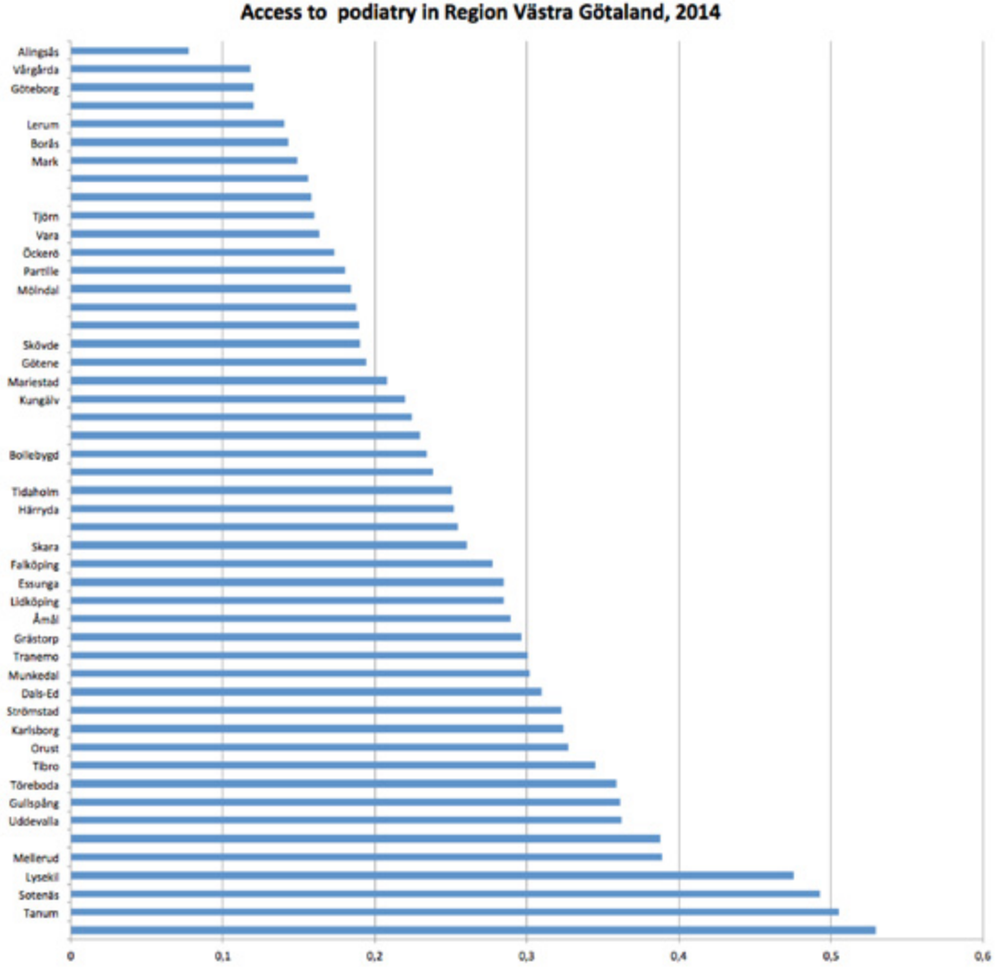


Figure 48. Patients' opportunity to access podiatry in the VGR for patients with type 2 diabetes in the 49 municipalities in the region.

Taken together, the access to podiatry for patients with type 2 diabetes varied in the VGR and more than one third of patients at risk of developing DFUs and referred to a DPO to prevent DFUs had not had the opportunity to access podiatry (Studies III and IV). The monitoring of how well the health-care system is able to offer podiatry and consultation in terms of self-care is essential in the

evaluation of how well needs are fulfilled. With this in mind, it appears clear that an appropriate DFU prevention and treatment plan, including self-care, should be prepared and decided upon in a dialogue between the patient and the health-care givers [16, 27, 144, 145].

The cost of assistive devices

Well-designed studies that include the cost of the interventions and assess the patients' HRQL have been requested and are thought to be of great importance in making continuous improvements to the prevention and care of foot problems in diabetes [23, 27, 165, 266]. The presentation of the overall cost of the prevention and care of DFUs and amputations in a Swedish context originate from the 1990s [28, 42, 46, 47, 210, 267]. In 2008, a European study presented the direct and indirect costs of healed/unhealed DFUs and the costs of major amputations (8,218 USD, 9,209 USD and 26,842 USD respectively) [268]. These figures were based on data obtained in the Eurodial study and included figures from Swedish centres [217, 269].

An estimate of the costs of DFU treatment at regional, national (Sweden) and global level is presented in Table 12. These numbers provide an estimate of the national costs (Sweden 100 million USD, 1990 prices) and figures and they are on a par with the estimates presented in a Swedish report in 1998 [51] and figures from the Eurodial study (4,804 USD[6] to heal a DFU, no infection or peripheral artery disease [268]).

It is well known that a more severe DFU will lead to higher treatment costs [268]. The total cost of DFUs treated in multidisciplinary setting (1997 prices) per patient/year for patients healed at one year has been reported to be 143,300 SEK (mean), range 26,300-543,600 SEK [267]. For patients whose DFUs had not healed at one year, the costs were 248,400 SEK, 167,200-421,500 SEK [267]. However, only 4% (6,500 SEK) of the total costs for patients with DFU that healed or did not heal accounted for assistive devices (walking casts, handmade orthopaedic shoes, individually fitted insoles and custom-made treatment shoes) [267]. In the Eurodial study (n = 821 patients with DFUs), the cost of assistive devices/patient (casts, insoles, orthoses and footwear) was 5% (4,333 SEK[7], 2005 prices) [268]. The total direct cost was 89,555 SEK and the total indirect cost was 6,115 SEK per patient.

Little is known about the costs of assistive devices to prevent and treat DFUs in Sweden today. In Study III (n = 38) and Study IV (n = 114), the direct costs of foot orthoses and footwear were registered. In accordance with the regional framework, all patients were charged for the visit (100 SEK/visit[8]) and for the devices, but the footwear was subsidised at 800 SEK/pair. However, foot orthoses for patients in risk groups 2-4 were free of charge, as was footwear for those in risk group 4 [150]. Patients did not pay for a visit that included a consultation not leading to any devices. The cost of prefabricated foot orthoses was 900 SEK/pair and, for custom-made foot orthoses, 1,500 SEK/pair (2015 prices) in Study IV. The mean cost per person in Study III was 1,856 SEK for the devices (foot orthoses and shoes) that the patients were provided with during the study period. The mean cost per person and year (including the costs of shoes) in Study IV was 1,225 SEK. In Study III and IV, some patients used their foot orthoses in their own shoes.

Moreover, due to foot problems, 6% of the patients were on sick leave and 34% visited health-care units other than DPOs during the last 12 months prior to the survey (Study III).

Taken together and given that prefabricated foot orthoses serve a useful purpose, the prefabricated orthoses are 40% cheaper than custom-made orthoses. This finding is supported by another study comparing the costs and the pressure redistribution effects of prefabricated and custom-made foot orthoses [162]. In addition to the benefits with lower costs, the prefabricated foot orthoses can be supplied to the patient during one visit to the DPO. The custom-made foot orthoses require at least two visits at the DPO.

Moreover, strengthened by regional and national initiatives, health-care departments are encouraged to report the international classification of diseases and to report the costs of the services provided at the DPOs [270] by using the Swedish "KVÅ" (Klassifikation av VårdÅtgärder, classification of care measures) classification. The KVÅ includes the classification of surgery and non-surgical procedures. The surgical procedures in the KVÅ are generally the same as the procedures in the NCSP[9], but the medical procedures are national in scope. Establishing the KVÅ procedures at the DPOs at regional and national level will make it possible to facilitate the mapping of the services health-care givers offer to patients in need of the prevention and care of DFUs in Sweden [256].

Table 12. Estimated local, national and global costs of a halved prevalence of DFU.

Level	Patients with DFU	Costs/patient USD	Health-care costs million USD	Saved health-care costs million USD
Regional	3,000	5 000	15	8
National	20,000	5,000	100	50
Global	20,000,000	5,000	100,000	50,000

Note: A calculation of the effects, in terms of "saved costs" with a halved prevalence of DFU. The estimated reduction in the cost of healing DFUs (not considering the higher cost of severe DFUs and amputations) is based on the assumption that, in 2016, the prevalence of DFUs is 5% and the prevalence of diabetes globally is 400 million, in Sweden 400,000 and in the VGR 60,000 people [36-39]. The cost of healing a DFU (not ischaemic) is estimated at 5,000 U.S. dollars (1990 price) [42]).

Limitations and strength

The strength of this thesis is that it presents comprehensive scientific information relating to assistive devices, in an area of paramount interest; the prevention and care of foot problems in diabetes. Two hundred and sixteen patients with diabetes and 855 participants representing the general population were included. In contrast to other European studies [164, 258, 271], the majority of our patients (93%, 201/216) visited the DPO with the aim of preventing DFUs and were, at the time of their visit, free from DFUs. The detailed description provides new and useful information regarding the presence of risk factors in the nine risk areas (Figure 45 page 80) and the need to assess these risk factors. A two-year RCT was included and the study evaluated the long-term effects of foot orthoses on plantar pressure in a cohort of patient without a known history of DFU.

An holistic approach was adopted with the aim of making a thorough investigation of the multifaceted aspects of existing foot problems and evaluating the interventions to prevent DFU. The assistive devices (footwear and foot orthoses) were evaluated using analyses of plantar pressure, PROM and PREM. An evaluation of the cost of assistive devices was made. The illustrations used in the thesis are designed to be inclusive and easy to understand for readers from all over the world.

One obvious problem, the lack of structured methods to assess the foot ulcer risk, was tackled and the solution, the eHealth tool, the D-Foot, was constructed and presented. The manual that was included in the D-Foot (Figure 40, page 70) is an example of the overall emphasis on making the internet-based program easy to understand and to use.

Studies I-IV have been evaluated according to their LoE [178] and by the IWGDF standard for reporting studies in terms of DFUs [266]. By setting the LoE and considering the guidance of standards for reporting studies, improvements in study quality are expected, thereby facilitating comparisons of study results, between studies [272].

Study design and methods are addressed in Tables 2 and 3 (pages 52-55). The LoE of each study

[6] *Converted from euros to US dollars (2016-01-15). The original figures represent 2005 prices.*
[7] *Converted from euros to Swedish crowns (2016-01-14).*
[8] *Patients with a "free card" were not charged for the visit. A "free card" means that the patient has reached a defined level of costs for health-care visits, during the last 12 months, and thereafter the visits are free.*
[9] *NCSP, NOMESCO Classification of Surgical Procedures.*

is included in Table 2 and represents the aspects of effectiveness, appropriateness and feasibility rated as excellent, good, fair and poor [178]. In Table 3, the accuracy and reliability of the assessments are presented. One third of the assessments had limited evidence to support their being accurate and/or reliable and several methods had a limited or a reasonable level of accuracy and/or reliability. Further methodological studies are needed to improve and evaluate the validity and reliability of the included tests.

By assessing the effectiveness, as presented in Table 2, of an intervention, the researcher presents the LoE for the study. The level of evidence shows whether the intervention was efficient in relation to the benefits and harm and addresses the question that would benefit from the tested intervention. Appropriateness takes account of the perspectives of the patient and his/her experience. Is the health issue that is addressed important to the patient and does the patient feel that the intervention is beneficial? Issues such as the economic implications of using an intervention and methods for the implementation and allocation of resources for a new intervention are addressed using the term feasibility. Studies with an "excellent to good" LoE are a sound basis for clinical practice. An intervention rated as "good" needs to be evaluated further. If the score is "fair", there is not enough evidence for implementation in clinical practice and the study is seen as an initial exploration and gives guidance to set the research agenda. Finally, the level "poor" indicates important gaps in the research field and might be of help in prioritising future research. However, descriptive and exploratory studies are also important, especially in research areas that are not yet being explored [272].

The evidence level in Study I was judged as "fair to poor", due to weaknesses in the methods used to assess foot deformities and to assess the function of the lower extremities. These methods have not yet been evaluated according to validity and/or reliability. There is an urgent need to conduct methodological studies that evaluate methods that are accurate and reliable to assess foot deformities and function in the lower extremities [273, 274].

Study II was an exploratory study. The LoE was judged as "fair to poor".

Study III was a methodological study. The content validity of the D-Foot was secured by the consensus process and, at six meetings, the expert group studied the current guidelines and the scientific literature to find evidence for an assessment to be included in the D-Foot. One important problem, the subjective foot ulcer risk classification, was resolved and the method that had been constructed, the internet-based software, the D-Foot, was shown to be reliable. The LoE was rated as "good". The eHealth tool, the D-Foot, needs, however, to be implemented, evaluated and improved, preferably by an expert group that includes representatives with diabetes.

The requests from patient associations that their members should have their feet checked in an appropriate manner are numerous and they demand health care that provides good, equal service. An objective foot ulcer risk classification for everyone is a right for patients with diabetes and leads to further necessary actions such as referrals to podiatry and to the DPO. Local and regional differences in the access to prevention (e.g. podiatry and information about self-care) are not acceptable.

Study IV, a two-year longitudinal prospective RCT study, aimed to evaluate the differences between three types of foot orthosis was rated as having a "good" LoE. The results have already changed clinical practice, at least one DPO, in favour of using prefabricated foot orthoses, when relevant.

Moreover, the quality of the studies (I-IV) in the thesis has been assessed with the help of the standards suggested by the IWGDF, Table 13 [266].

Table 13 (Page 95-96). Core details in studies of DFUs.

Entity	Aspect	Study	Not included in current thesis
	Person		
	Age, gender and ethnicity	I-IV	Not ethnicity
	Diabetes type, duration and adequacy of glycaemic control	I, II, III, IV	
	Comorbidities (e.g. established renal failure, heart failure, immobility, impaired vision)	I, IV	Not established renal failure, heart failure, impaired vision
	DFU risk classification: low, medium, or high	I, II, III, IV	
	Ambulatory status	I, III, IV	
Limb			
	Peripheral artery disease: minimal assessment by palpation of pulses and ankle-brachial, pressure index, or toe blood pressure, or both		No
	Neuropathy: minimal assessment by determining loss of protective sensation (e.g. with a 10 g monofilament or vibration perception)	I, II, III, IV	
	Foot deformity (type or severity, or both)	I, II, III, IV	
	History of previous foot ulceration and amputation	I, II, III, IV	
	Interventions		
	All interventions: details of interventions (including duration and frequency); person or team providing foot care; setting of the study	IV	
	Footwear: details on design, customisation and materials used; evidence of pressure-reducing efficacy if study relates to plantar ulceration	IV	
	Education or behavioural change: whether aimed at patients, carers, or health-care professionals		No
	Outcome		
Foot and limb			
	DFU (defined according to existing guidelines) incidence expressed as a proportion of a population at a fixed time, or time to ulceration, or both	IV	
	First ever ulcer	IV	
	Adherence to the intervention (e.g. wearing footwear, self-care, or education, preferably measured objectively	III, IV	Self-reported (III: additional work)
	Foot pressure reduction (following provision of footwear or surgical interventions, or both)	I, IV	No baseline barefoot measurement
	Ambulatory activity level (for footwear studies), quantitatively assessed if possible		No

Table 13 continues on page 96.

Amputation (major or minor, defined according to existing guidelines	III	
Person		
Survival	IV	Death reported as drop-outs in the flow chart of the study population (Figure 43, page 73)
Health-related quality of life	II, III	III: additional work
Adverse events or adverse device effects, or both	IV	Adverse events reported as drop- outs in the flow chart of the study population (Figure 43, page 73)
Surrogate*		
Incidence of pre-ulcerative lesions (e.g. hyperkeratotic tissue, haemorrhage, blister, inflammation, each of which requires definition)	I, III	Prevalence of pre-ulcerative lesions (e.g. callosities)
Change in plantar foot pressures	I, IV	
Change in adherence	No	
Foot examination skill (patient, carer, health-care professional)	III	
Patient satisfaction and well-being	I, IV	I: HRQL IV: Satisfaction

** Potential surrogate outcome measurements for studies in which ulcer incidence is not the primary outcome*

The standards include a set of 21 questions developed by the IWGDF to be used as a quality marker in the performed studies. The answers to the 21 questions are shown below. A "yes" is the desired answered and gives a score of 1. The scores in the thesis, according to the 21-point scoring system, are as follows.

Study design

1. Are appropriate definitions included for the terms "ulcer", "healing" and all other required aspects of the population and the outcomes? Yes = 1.

2. Was the choice of study population appropriate for the chosen intervention and the stated conclusions? Yes = 1.

3. Was there a control population that was managed at the same time as those in the intervention group or groups? (In Study IV, the group that received prefabricated foot orthoses was assessed as the control group). Yes = 1.

4. Is the intervention sufficiently well described to enable another researcher to replicate the study? Yes = 1.

5. Are the components of other aspects of care described for the intervention and comparative groups? Yes = 1.

6. Were the participants randomised into intervention and comparative groups? (Study IV). Yes = 1.

7. Were the participants randomised by an independent person or agency? No (Study IV).

8. Was the number of participants studied in the trial based on an appropriate sample size calculation? (Studies III-IV). Yes = 1.

9. Was the chosen primary outcome of direct clinical relevance? (Study IV). Yes = 1.

10. Was the person who assessed the primary outcome or outcomes blinded to group allocation? No.

11. Were either the clinical researcher who cared for the wound on research visits or the participants blinded to group allocation? No (Study IV).

Study conduct

12. Did the study complete recruitment? (Study IV). Yes = 1.

13. Was it possible to document the primary outcome in 75% or more of those recruited? No (Study IV assessed the primary outcome in 72% of those recruited).

14. Were the results analysed primarily by intention-to-treat analysis? No (we used a mixed model analysis).

15. Were appropriate statistical methods used throughout? Yes = 1.

Outcomes

16. Was the performance in the control group of the order that would be expected in routine clinical practice? (Study IV). Yes = 1.

17. Are the results from all participating centres comparable? Answer "yes" if the study was conducted at only one centre. (Studies I, III, IV). Yes = 1.

Study reporting

18. Is the report free from errors of reporting - e.g. discrepancies between data reported in different parts of the report? Yes = 1.

19. Are the important strengths and weaknesses of the study discussed in a balanced way? Yes = 1.

20. Are the conclusions supported by the findings? Yes = 1.

21. Is the report free from any suggestion that the analysis or the conclusions could have been substantially influenced by people with commercial or other personal interests in the findings? Yes = 1.

From a total score of 21, a score of 16 was obtained. The IWGDF has not yet presented any general guidance on how to interpret the results from the 21-point system. An improvement in Study I would have been to add two control groups to assess the prevalence of foot deformities and dysfunction in the lower extremities in groups of patients not provided with assistive devices. An analysis of whether the prevalence of foot deformities and dysfunction in the lower extremities differed between groups (representing the general population and a general population of patients with diabetes) would have been of great interest.

In Study IV, a large variation (49-145 kPa) in plantar pressure was found. The variation in PP is, however, in line with previous findings [87, 275, 276].

Finally, in Table 14, the statistical considerations are addressed, with the aim of providing guidance for further research in the area. The challenge when it comes to measuring plantar pressure, accurately and reliably, is due to the multifaceted aspects of dynamic walking. Improvements are, however, possible by using structured study protocols, correct handling of the equipment and by standardisation (e.g. using the same types of socks and shoes). This will strengthen the con-

clusions that are drawn in terms of the effects of using different types of assistive device. As mentioned earlier, comparisons with barefoot measurements and comparisons of plantar pressure with the pressure recorded in control groups will increase the opportunity to draw conclusions about plantar pressure reduction and/or redistribution achieved by using foot orthoses and appropriate shoes.

Table 14. A summary of statistical considerations.

Study	Consideration	Comment
I	No power calculation	The patients in Study I were also included in Study IV.
	Raw data and logarithmic data are presented	The result captures different aspects of the pressure distribution. The logged data fit better in the model and give more reliable results, while, at the same time, downplaying the importance of very high PP.
I	Exploratory analysis	In the model selection, the Akaike information criteria were used. It is possible that the use of other criteria (e.g. Bayesian information criteria) could have led to a somewhat different result).
II	No power calculation	This was a retrospective study.
II	Raw data and logarithmic data are presented	To better fit to the model, the logged data were used for the variable of "maximum toe height".
II	Multiple comparisons	No correction was made for multiple comparisons. The authors chose to allow the results to be transparent and to present the full set of p-values, thus making it easier for readers to interpret the results themselves.
II	Comparisons between groups	The three comparisons (ANOVA analysis and the following two analyses of covariance) did not include all four groups due to missing values.
III	Power calculation	Is presented in the "statistics" section
III	Kappa statistics	A limitation in the kappa statistics appears when the result is unbalanced (the observers are likely to choose one of the alternatives). This leads to a low pooled kappa value, even if the agreement was high.
III	Multiple comparisons	The agreement was calculated for several assessments. No correction was made for multiple comparisons. The authors chose to allow the results to be transparent and to present the confidence interval for the discrete variables.
IV	Power calculation	Is presented in the "statistics" section
IV	Analysis of pressure	One of the six trials (17%) was randomly chosen for the analyses of plantar pressure. The reason for this was time limits. An optimal solution would have been for the software, to deliver the results automatically.
IV	There was large variation in PP, max PP and PTI	The above-mentioned limitation that not all data were processed and analysed is one reason for the variation.

Note: The table presents statistical considerations in Studies I-IV.

9. Conclusions

The main recommendation presented in this thesis, relating to the prevention and care of foot problems in diabetes, is to use valid, reliable methods when the feet of the patients are assessed and the foot ulcer risk is evaluated. An eHealth tool, the D-Foot, has been constructed and has been found to be valid and reliable in assessing the foot ulcer risk. Studies I-IV showed that the prevalence of potential risk factors in cohorts of patients referred to a DPO was high and multifaceted. The nine areas of risk were assessed by the medical history, foot anatomy, kinesiology, mobility and gait, the biomechanical stress, the skin, lifestyle factors, body anthropometrics and neuropathy. Several of the risk factors appeared to influence the plantar pressure and to have implications for the provision of assistive devices. There was large inter-individual variation, however. The patients' needs, as well as their condition and function, have to be considered when assistive devices are prescribed and service is offered at a DPO. This service should include the provision of adequate assistive devices and consultations about self-care and shoe advice.

Moreover, this thesis presents unique information in terms of the pressure redistribution properties of foot orthoses and shoes tested in a cohort of patients without previous DFUs. The plantar pressure was approximately 200 kPa under seven interesting regions on the sole of the foot. The large variation between individuals implies that all patients need to be carefully assessed on an individual level in order to find an optimal solution for their needs. Moreover, plantar pressure measurements are recommended to confirm the effects of the assistive devices in terms of pressure redistribution on the sole of the foot.

Clinical relevance

The D-Foot is recommended for use in clinical practice at DPOs. It is hoped that the use of the D-Foot will improve patient safety, as it generates an objective risk classification based on a series of foot assessments. The digital solution facilitates the storage, documentation, analysis and evaluation of the provision of assistive devices. This is necessary for continuous improvements to the health-care service. The first implementation of the D-Foot in clinical practice is planned in 2017 at the DPO at Sahlgrenska University Hospital. The advantages and disadvantages of using the D-Foot will be evaluated with regard to the following aspects:

- how do patients experience being assessed following the routine in an interactive web program?
- how do the CPOs experience using a new interactive web program when assessing feet?
- how can the meta-data generated in the D-Foot database be used at the DPO to monitor and evaluate their interventions to prevent and treat foot problems in diabetes?

The widespread use of the D-Foot to meet the demand for foot screening in primary care and at medicine clinics is proposed. To comply with the

regional and national recommendations for annual foot screening, the D-Foot should be further accommodated according to regional and national recommendations. It is suggested that some risk areas in the current version of the D-Foot for the DPOs should be removed (kinesiology, biomechanical stress and mobility and gait) and other areas with potential risk factors, such as signs of peripheral angiopathy and metabolic control, should be added (Figure 49).

Figure 49. A model of the nine potential risk areas that increase the risk of developing a DFU. These nine risk areas can be assessed during the annual foot examination using a revised version of the D-Foot. The nine risk areas are identified by the medical history and by assessing the foot anatomy, tissues and muscles, the presence of infection, the presence of angiopathy, the skin, lifestyle factors, the metabolism and the presence of neuropathy.

In line with current regional guidelines, a patient who, at the annual foot check, is assessed as being in risk classes 2-4 should preferably be referred to a DPO, to podiatry and to medical specialists for further examination. The use of standard routines and prompt referrals for patients in need, even at an earlier stage, are expected to reduce the number of DFUs and amputations. However, this expectation needs to be further evaluated at national level.

■

10. Future Perspectives

In addition to the implementation and evaluation of the D-Foot at the DPO at Sahlgrenska University Hospital, a follow-up study of patients included in Study IV is planned. The 114 patients in Study IV were recruited between 2008 and 2010 and were at that time free from DFUs. In 2018, a 10-year follow-up of the cohort will begin with the aim of recording the progress and/or changes in the patients' risk factors for developing DFU. Moreover, the patients' HRQL, their gait parameters and their plantar pressure (in-shoe and barefoot measurements) will be measured. Optionally, a control group will be included. This will be the first time patients with diabetes who are provided with assistive devices are followed over 10 years. The results will bring a new insight into the development of DFUs in their multicomplex context. The accumulated costs, in 2008-2018, of the treatment with assistive devices will be calculated.

Moreover, further studies are needed to identify vulnerable groups and direct actions for those individuals in great need of prevention and care. For example, it has been shown that men are more often affected by DFUs than women [277-279] and that patients with a low income run a higher risk of developing DFUs [278, 280-284]. However, these indications need to be confirmed and other vulnerable groups need to be identified and studied.

Finally, data collected in Studies I-IV will serve as a basis to present a general model to evaluate health care in the context of "sustainable health care" [285, 286]. This model will present key figures for the ecological, economic and social footprints of the interventions with assistive devices in accordance with and of relevance to realise the sustainable development goals [142, 143, 287].

■

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■

Appendix 1

Undersökningsformulär – Diabetesprojekt (DB-100)

Datum **Kontroll månad (0, 6, 12, 18, 24)**
Namn **Remiss från**
Född **Övriga sjd**
Adress
Tel/Mobil
Email

			Höger	Vänster
Passivt rörelseomfång i nedre extremiteten (ua, lätt, måttlig, uttalad)		Höftleder		
		Knäleder		
(rörligheten i fotledens dorsalflex. mäts stående)		Fotleder		
Styrka i fotleder (Klarar ja/nej		Tågång		
		Hälgång		
Sensibilitet (ua, nedatt, obefintlig)	ytlig i fot	Fot		
	djup i stortå alt. fotled	Fot		
Monofilament (Under stortå, MTP 1, MTP 2, MTP 5, häl)		Fot		
Balans (barfota på 1 ben, ua, nedsatt, kan ej		Fot		
Vibration- (stämgaffel-C128), medilt stortå o malleol		Fot		
Mag-tarm problem		Ja		Nej

Kommentar:

Appendix 2

Hälsoenkät

Instruktion: Detta formulär innehåller frågor om hur Du ser på Din hälsa. Besvara frågorna genom att markera det svarsalternativ Du tycker stämmer bäst in på Dig. Om Du är osäker, markera ändå rutan som känns riktigast. Sätt ett kryss i rutan, så här ☒.

1.	**I allmänhet, skulle Du vilja säga att Din hälsa är:**	Utmärkt ☐	Mycket god ☐	God ☐	Någorlunda ☐	Dålig ☐

2.	**Jämfört med för ett år sedan, hur skulle Du vilja bedöma Ditt allmänna hälsotillstånd nu?**	Mycket bättre nu ☐	Något bättre nu ☐	Ungefär detsamma ☐	Något sämre nu ☐	Mycket sämre nu ☐

3. **De följande frågorna handlar om aktiviteter som Du kan tänkas utföra under en vanlig dag. Är Du på grund av ditt hälsotillstånd begränsad i dessa aktiviteter nu? Om så är fallet, hur mycket?**

	Ja, mycket begränsad	Ja, lite begränsad	Nej, inte alls begränsad
a. **Ansträngande aktiviteter**, som att springa, lyfta tunga saker, delta i ansträngande sporter	☐	☐	☐
b. **Måttligt ansträngande aktiviteter**, som att flytta ett bord, dammsuga, skogspromenader eller trädgårdsarbete	☐	☐	☐
c. Lyfta eller bära matkassar	☐	☐	☐
d. Gå uppför **flera** trappor	☐	☐	☐
e. Gå uppför **en** trappa	☐	☐	☐
f. Böja Dig eller gå ner på knä	☐	☐	☐
g. Gå **mer än två kilometer**	☐	☐	☐
h. Gå **några hundra meter**	☐	☐	☐
i. Gå **hundra meter**	☐	☐	☐
j. Bada eller klä på Dig	☐	☐	☐

4. **Under de senaste fyra veckorna, har Du haft något av följande problem i Ditt arbete eller med andra regelbundna dagliga aktiviteter som en följd av Ditt kroppsliga hälsotillstånd?**

	Ja	Nej
a. Skurit ned den **tid** Du normalt ägnat åt arbete eller andra aktiviteter	☐	☐
b. **Uträttat mindre** än Du skulle önskat	☐	☐
c. Varit hindrad att utföra **vissa** arbetsuppgifter eller andra aktiviteter	☐	☐
d. Haft **svårigheter** att utföra Ditt arbete eller andra aktiviteter (t ex genom att det krävde extra ansträngning)	☐	☐

5. **Under de senaste fyra veckorna, har Du haft något av följande problem i Ditt arbete eller med andra regelbundna dagliga aktiviteter som en följd av känslomässiga problem (som t ex nedstämdhet eller ängslan)?**

	Ja	Nej
a. Skurit ned den **tid** Du normalt ägnat åt arbete eller andra	☐	☐
b. **Uträttat mindre** än Du skulle önskat	☐	☐
c. Inte utfört arbete eller andra aktiviteter så **noggrant** som vanligt	☐	☐

6. **Under de senaste fyra veckorna, i vilken utsträckning har Ditt kroppsliga hälsotillstånd eller Dina känslomässiga problem stört Ditt vanliga umgänge med anhöriga, vänner, grannar eller andra?**

Inte alls	Lite	Måttligt	Mycket	Väldigt mycket
☐	☐	☐	☐	☐

7. **Hur mycket värk eller smärta har Du haft under de senaste fyra veckorna?**

Ingen	Mycket lätt	Lätt	Måttlig	Svår	Mycket svår
☐	☐	☐	☐	☐	☐

8. **Under de senaste fyra veckorna, hur mycket har värken eller smärtan stört Ditt normala arbete (innefattar både arbete utanför hemmet och hushållssysslor)?**

Inte alls	Lite	Måttligt	Mycket	Väldigt mycket
☐	☐	☐	☐	☐

9. **Frågorna här handlar om hur Du känner Dig och hur Du haft det under de senaste fyra veckorna. Ange för varje fråga det svarsalternativ som bäst beskriver hur Du känt Dig.**

Hur stor del av tiden under de senaste fyra veckorna har Du...	Hela tiden	Största delen av tiden	En hel del av tiden	En del av tiden	Lite av tiden	Inget av tiden
a. känt Dig riktigt pigg och stark?	☐	☐	☐	☐	☐	☐
b. känt Dig mycket nervös?	☐	☐	☐	☐	☐	☐
c. känt Dig så nedstämd att ingenting kunnat muntra upp Dig?	☐	☐	☐	☐	☐	☐
d. känt dig lugn och harmonisk?	☐	☐	☐	☐	☐	☐
e. varit full av energi?	☐	☐	☐	☐	☐	☐
f. känt Dig dyster och ledsen?	☐	☐	☐	☐	☐	☐
g. känt Dig utsliten?	☐	☐	☐	☐	☐	☐
h. känt Dig glad och lycklig?	☐	☐	☐	☐	☐	☐
i. känt Dig trött?	☐	☐	☐	☐	☐	☐

10. **Under de senaste fyra veckorna, hur stor del av tiden har Ditt kroppsliga hälsotillstånd eller Dina känslomässiga problem stört Dina möjligheter att umgås (t ex hälsa på släkt, vänner, etc)?**

Hela tiden	Största delen av tiden	En del av tiden	Lite av tiden	Inget av tiden
☐	☐	☐	☐	☐

11. **Välj det svarsalternativ som bäst beskriver hur mycket vart och ett av följande påståenden STÄMMER eller INTE STÄMMER in på Dig.**

	Stämmer precis	Stämmer ganska bra	Osäker	Stämmer inte särskilt bra	Stämmer inte alls
a. Jag verkar ha lite lättare att bli sjuk än andra människor	☐	☐	☐	☐	☐
b. Jag är lika frisk som vem som helst av dem jag känner	☐	☐	☐	☐	☐
c. Jag tror min hälsa kommer att bli sämre	☐	☐	☐	☐	☐
d. Min hälsa är utmärkt	☐	☐	☐	☐	☐

Appendix 3

Hälsoenkät

Svensk version för Sverige

(Swedish version for Sweden)

Markera, genom att kryssa i en ruta i varje nedanstående grupp (så här ☑), vilket påstående som bäst beskriver Ditt hälsotillstånd i dag.

Rörlighet

Jag går utan svårigheter ❑

Jag kan gå men med viss svårighet ❑

Jag är sängliggande ❑

Hygien

Jag behöver ingen hjälp med min dagliga hygien, mat eller påklädning ❑

Jag har vissa problem att tvätta eller klä mig själv ❑

Jag kan inte tvätta eller klä mig själv ❑

Huvudsakliga aktiviteter *(t ex arbete, studier, hushållssysslor, familje- och fritidsaktiviteter)*

Jag klarar av mina huvudsakliga aktiviteter ❑

Jag har vissa problem med att klara av mina huvudsakliga aktiviteter ❑

Jag klarar inte av mina huvudsakliga aktiviteter ❑

Smärtor / besvär

Jag har varken smärtor eller besvär ❑

Jag har måttliga smärtor eller besvär ❑

Jag har svåra smärtor eller besvär ❑

Oro / nedstämdhet

Jag är inte orolig eller nedstämd ❑

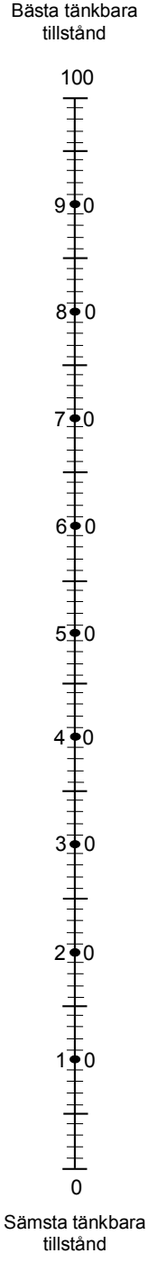
Jag är orolig eller nedstämd i viss utsträckning ❑

Jag är i högsta grad orolig eller nedstämd ❑

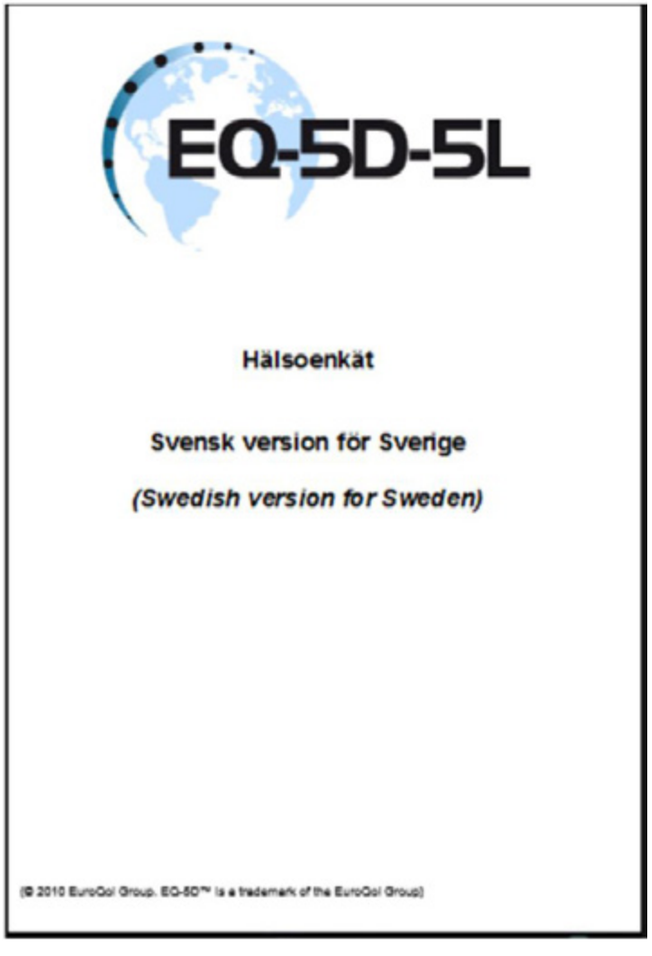
Till hjälp för att avgöra hur bra eller dåligt ett hälsotillstånd är, finns den termometer-liknande skalan till höger. På denna har Ditt bästa tänkbara hälsotillstånd markerats med 100 och Ditt sämsta tänkbara hälsotillstånd med 0.

Vi vill att Du på denna skala markerar hur bra eller dåligt Ditt hälsotillstånd är, som Du själv bedömer det. Gör detta genom att dra en linje från nedanstående ruta till den punkt på skalan som markerar hur bra eller dåligt Ditt nuvarande hälsotillstånd är.

Ditt nuvarande hälsotillstånd



Appendix 4


EQ-5D-5L
Hälsoenkät
Svensk version för Sverige
(Swedish version for Sweden)
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EQ-5D 5L
Klicka bara i EN ruta som bäst beskriver din hälsa IDAG.
RÖRLIGHET
Jag har inga svårigheter med att gå omkring
Jag har lite svårigheter med att gå omkring
Jag har måttliga svårigheter med att gå omkring
Jag har stora svårigheter med att gå omkring
Jag kan inte gå omkring
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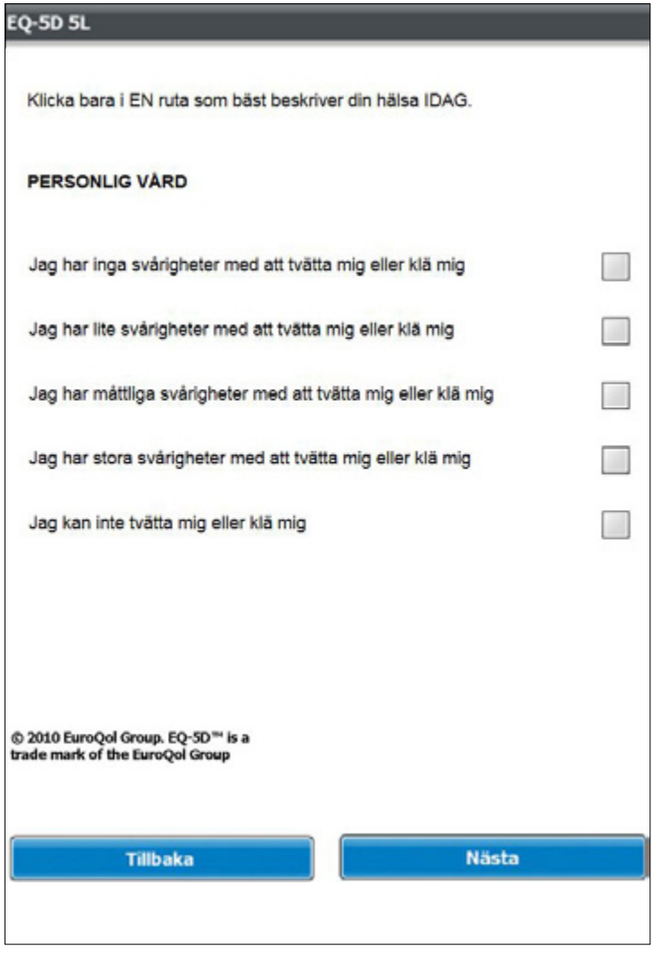
Tillbaka
Nästa


EQ-5D 5L
Klicka bara i EN ruta som bäst beskriver din hälsa IDAG.
PERSONLIG VÅRD
Jag har inga svårigheter med att tvätta mig eller klä mig
Jag har lite svårigheter med att tvätta mig eller klä mig
Jag har måttliga svårigheter med att tvätta mig eller klä mig
Jag har stora svårigheter med att tvätta mig eller klä mig
Jag kan inte tvätta mig eller klä mig
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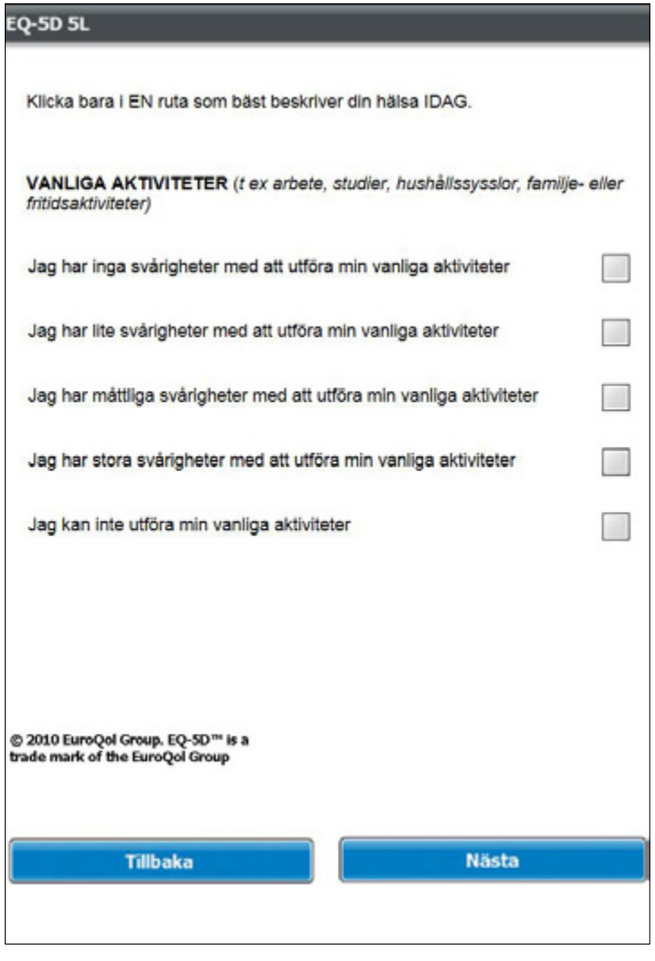
Tillbaka
Nästa


EQ-5D 5L
Klicka bara i EN ruta som bäst beskriver din hälsa IDAG.
VANLIGA AKTIVITETER (t ex arbete, studier, hushållssysslor, familje- eller fritidsaktiviteter)
Jag har inga svårigheter med att utföra min vanliga aktiviteter
Jag har lite svårigheter med att utföra min vanliga aktiviteter
Jag har måttliga svårigheter med att utföra min vanliga aktiviteter
Jag har stora svårigheter med att utföra min vanliga aktiviteter
Jag kan inte utföra min vanliga aktiviteter
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Nästa


EQ-5D 5L
Klicka bara i EN ruta som bäst beskriver din hälsa IDAG.
SMÄRTOR/BESVÄR
Jag har varken smärtor eller besvär
Jag har lätta smärtor eller besvär
Jag har måttliga smärtor eller besvär
Jag har svåra smärtor eller besvär
Jag extrema smärtor eller besvär
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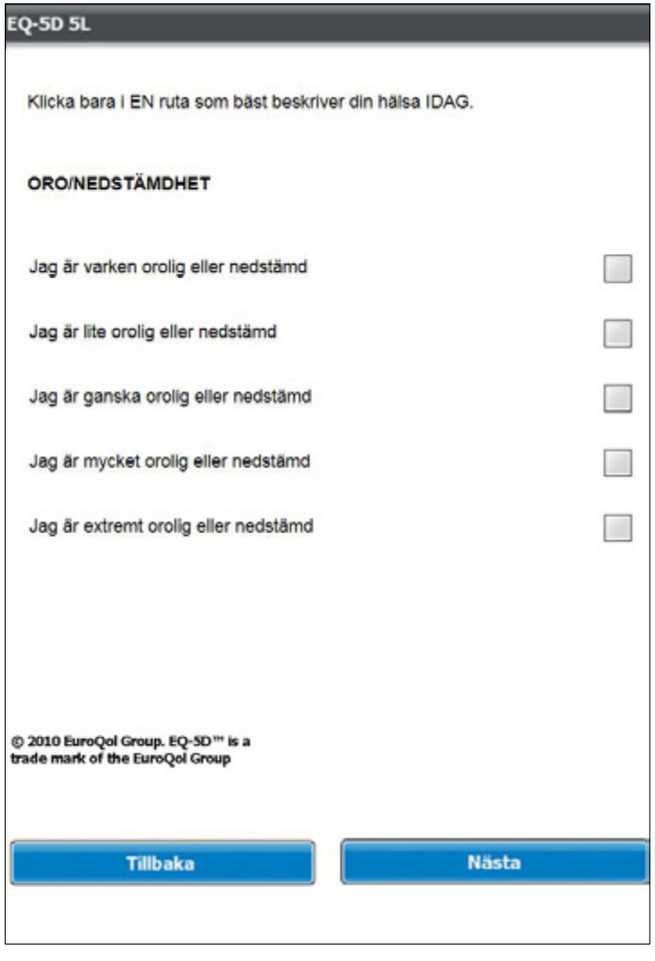
Nästa


EQ-5D 5L
Klicka bara i EN ruta som bäst beskriver din hälsa IDAG.
ORO/NEDSTÄMDHET
Jag är varken orolig eller nedstämd
Jag är lite orolig eller nedstämd
Jag är ganska orolig eller nedstämd
Jag är mycket orolig eller nedstämd
Jag är extremt orolig eller nedstämd
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Tillbaka
Nästa


Bästa hälsa du kan tänka dig
Vi vill veta hur bra din hälsa är IDAG.
Den här skalan är numrerad från 0 till 100.
100 är den bästa hälsa du kan tänka dig.
0 är den sämsta hälsa du kan tänka dig.
Klicka på skalan för att visa hur din hälsa är IDAG.
DIN HÄLSA IDAG
73
100
90
80
70
60
50
40
30
20
10
0
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Sämsta hälsa du kan tänka dig
Tillbaka
Nästa

Appendix 5

System Usability Scale (SUS), with the Swedish title “Hur var det att använda D-Foot?” (How did you experience using the D-Foot?)

The 10 questions in the SUS are presented in Swedish, followed by the original English text *(http://www.measuringu.com/sus.php, downloaded 20151106*).

1. Jag tror att jag kommer vilja använda D-Foot ofta. *I think that I would like to use this system frequently.*
2. Jag tyckte D-Foot är onödigt komplicerat. *I found the system unnecessarily complex.*
3. Jag tyckte D-Foot var enkelt att använda. *I thought the system was easy to use.*
4. Jag tror jag kommer behöva teknisk support för att kunna använda D-Foot. *I think that I would need the support of a technical person to be able to use this system.*
5. Jag tyckte att de olika funktionerna i D-Foot var välfungerande. *I found the various functions in this system were well integrated.*
6. Jag tyckte att D-Foot var ologiskt uppbyggt. *I thought there was too much inconsistency in this system.*
7. Jag tror att de flesta snabbt kommer kunna lära sig att använda D-Foot. *I would imagine that most people would learn to use this system very quickly.*
8. Jag tyckte att D-Foot var besvärligt att använda. *I found the system very cumbersome to use.*
9. Det kändes pålitligt att använda D-Foot. *I felt very confident using the system.*
10. Jag behövde lära mig många nya saker innan jag kunde börja använda D-Foot. *I needed to learn a lot of things before I could get going with this system.*

The Swedish response format was:
1) Håller absolut inte med, 2) Håller inte med, 3) Håller varken med eller inte med, 4) Håller med and 5) Håller fullkomligt med.

The English response format was:

Strongly Disagree 1	2	3	4	Strongly Agree 5
○	○	○	○	○

Appendix 6

Patients self-reported experience of the services at the DPO and the assistive devices

Level of content/ usage	How did you experience the consulta-tion with the CPO at the last visit to the DPO?	Have you developed foot ulcers since the last visit to the DPO?	Were you provided with foot orthoses?	If Yes, how much have you used your foot orthoses?	How content are you with the foot orthoses?	Were you provided with shoes?	If Yes, how much have you used your shoes?	How content are you with the shoes?
Yes/No Yes (%)		3/83 (4%)	80/6 (93%)			30/56 (35%)		
Discon-tent/never	1 (1%)			1 (1%)	3 (4%)		2 (7%)	1 (3%)
Somewhat discontent/ seldom	-			6 (8%)	2 (2%)		3 (10%)	2 (7%)
Neither content or discontent/ sometimes	3 (4%)			10 (13%)	5 (6%)		4 (13%)	4 (14%)
Content/ often	30 (35%)			19 (24%)	28 (35%)		9 (30%)	11 (38%)
Very content/all the time	52 (60%)			43 (54%)	41 (52%)		12 (40%)	11 (38%)
Missing values	1	1	1	8	8	1	57	58
Total number	87	87	87	87	87	87	87	87

Note: A the three-month follow-up of the patients were interviewed in terms of how they perceived to use the assistive devices that they had received from the DPO and how they perceived the services at the DPO. The answers are the interviewer's translation of the patients' answers in terms of the amount of time they have used their shoes and insoles, their perception of the shoes and insoles and their answers to the question of whether they have developed ulcers on their feet since the visit.