Custom-made footwear in diabetes: Offloading, usability and ulcer recurrence
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Chapter 1

General introduction
THE DIABETIC FOOT

Epidemiology and complications
Diabetes is one of the most common chronic diseases. In 2012, approximately 370 million people worldwide suffered from diabetes, representing approximately 8.3% of the world’s adult population. Because of the strong increase in the percentage of elderly people and people with obesity, this number is expected to rise above 552 million in the next 20 years. In the Netherlands, 882,000 people had diabetes in 2011, a number that is expected to increase to 1.1 million in 2030. The economic burden of diabetes is substantial. Over 814 million euro was spent on diabetes-related health care in the Netherlands in 2005. Costs will further increase markedly in future years.

A prevalent and debilitating complication of diabetes is foot ulceration, as shown in Figure 1.1a. The lifetime risk for ulceration in diabetic patients is 15-25%. Diabetic foot ulcers are a major cause of morbidity and are the most frequent reason for hospitalization. They significantly increase the risk for infection and amputation. Globally, every 30 seconds a limb is lost due to diabetic foot disease. Eighty-five percent of these amputations are preceded by a foot ulcer. Once a patient has had a foot ulcer, the risk for recurrence is substantially increased (relative risk 1.6 to 5.3). Prevention and appropriate management of foot ulcers are therefore of paramount importance to decrease both the patient and economic burden of diabetic foot disease.

Etiology of diabetic foot ulcers
Diabetic foot ulcers result from the simultaneous action of multiple contributing causes. Often reported underlying pathologic conditions such as vascular dysfunction and peripheral nerve damage contribute to the development foot ulcers. Peripheral vascular disease is present in about 50% of diabetic patients with a foot ulcer. In combination with minor trauma, peripheral vascular disease leads to tissue breakdown and impairs healing of foot ulcers because blood perfusion of the foot is affected. The key factor in diabetic foot ulceration is peripheral neuropathy, which is present in approximately 30% - 50% of all diabetic patients. As a result of neuropathy, patients have loss of sensory, motor, and/or autonomic nerve function. Sensory nerve dysfunction impairs protective sensation in the foot, and hampers the patient’s ability to perceive increased mechanical load, friction, pain or heat. Skin damage may occur and remain unnoticed. Loss of motor nerve function can result in muscle atrophy in the foot muscles and subsequent changes in the shape of the foot. Finally, a dry skin and hyperkeratosis, which are common pre-signs for diabetic foot ulcers, and also edema, leading to a poor fit of shoes, may be a consequence of autonomic nerve damage. Overall, peripheral neuropathy greatly increases the risk for foot ulceration in diabetic patients (relative risk 2.2).
In the presence of neuropathy, elevated plantar pressure is considered one of the most important risk factors of foot ulceration in diabetic patients. Figure 1.1b shows excessively high peak pressure at the second metatarsal head in a patient walking barefoot. The location of the high-pressure peak corresponds with the location of the ulcer shown in Figure 1.1a. Repetitive exposure to high plantar pressure under bony prominences during unprotected ambulatory activity may lead to local skin breakdown.

The association between elevated plantar pressure during barefoot walking and ulcer development has been confirmed by several authors, but there is no consensus on the exact pressure threshold for tissue breakdown. This may be explained by the fact that although the likelihood of ulceration increases with increased plantar pressure, factors such as severity of neuropathy, level of foot deformity and limited joint mobility contribute to ulceration, which complicates ulcer prediction on an individual level. Furthermore, barefoot pressures do not represent the true mechanical load exposed to the foot, as patients often wear offloading footwear. The addition of in-shoe plantar pressures may therefore better indicate the actual load on the foot in these patients. Although a pressure level that reflects an individual peak pressure threshold for ulcer development has proven elusive to determine to date, a level <200kPa was found to be indicative for ulcer-free survival in diabetic patients who have had a previous foot ulcer. Until a better individual threshold is determined, achieving a in-shoe peak pressure level below 200kPa may be an effective target in footwear prescription.
Elevated plantar pressures are strongly associated with the presence of foot deformity and a history of amputation. Hammer toes or claw toes are among the most prevalent deformities in patients with diabetes (32% to 46%). Bus and co-workers showed that claw and hammer toe deformity is associated with a distal displacement and subsequent thinning of the sub-metatarsal head fat pads, which subsequently leads to increased plantar pressure under the metatarsal heads increasing the risk for ulceration. Other prevalent types of foot deformity in patients with diabetes are hallux valgus (33%) and limited joint mobility of the first metatarso-phalangeal joint (23% to 35%), both leading to local bony prominences and associated with increased plantar peak pressure under the hallux and the first metatarsal head. Although Charcot foot deformity is not very prevalent, it is considered to be the most severe structural deformity of the diabetic foot. A Charcot foot is a progressive condition characterized by pathological fractures, dislocation of joints, and often debilitating deformity, leading to increased plantar foot pressures mainly in the midfoot area. Finally, plantar pressure is markedly increased in patients with partial foot amputations, possibly due to biomechanical compensation or high prevalence of deformity and limited joint mobility in these patients.

Thus, diabetic patients with neuropathy, foot deformity and/or partial foot amputation who show elevated plantar pressures are at high risk for the development of plantar foot ulcers. This statement is supported by the fact that inappropriate footwear (cramped toe box, inadequate offloading), has been reported to be an important factor in the development of foot ulcers in diabetic patients, as various authors have identified footwear as the root cause of 21 to 76% of ulcers and/or amputations. Thus, these patients require adequate footwear that distributes these pressures across the foot to reduce pressure at “at-risk” foot regions.

**OFFLOADING WITH CUSTOM-MADE THERAPEUTIC FOOTWEAR**

**Custom-made footwear**

Custom-made therapeutic footwear is recommended and often prescribed to high-risk diabetic patients to prevent ulcer development. For this, the footwear should reduce and redistribute mechanical pressure. To relieve mechanical pressure (also called ‘offloading’) at high-pressure locations, custom insoles aim to redistribute the load from high-pressure locations to adjacent foot regions.

In the Netherlands, two types of custom-made footwear are generally prescribed. These are semi-customized shoes (i.e. custom-made insoles worn in extra-depth off-the-shelf shoes) and fully customized shoes (i.e. custom-made insoles worn in custom-made shoes). In several studies, custom-made total-contact (i.e. accommodating) insoles have been found to
be effective in the reduction of peak plantar pressure (range 16% - 32%), compared to control conditions \(^{51-59}\). Additional relief can be achieved by further modifying and individualizing the insole, e.g. with adding a metatarsal pad or bar (16% to 39%) \(^{51, 60-63}\). Substantial offloading effects have also been reported for the use of a rocker or roller configuration of the shoe outsole \(^{64-67}\). However, despite the positive effect on foot pressure of these custom interventions, large individual differences in offloading effect are common and many uncertainties exist on the effective application of footwear design elements in individual patients \(^{52, 57, 63, 68}\). This concerns, for example, the optimal pivot point location and toe spring angle \(^{67, 69}\). A more structured and evidence-based approach to footwear prescription and objective evaluation of the offloading success would probably reduce this variability in offloading effect and will assist prescribers to design properly offloaded footwear for diabetic patients \(^{52, 57, 68}\).

Effectiveness
Despite widespread prescription of custom-made therapeutic footwear, evidence for its effectiveness to prevent ulcer recurrence is still meagre and conflicting results are present in the literature \(^{70}\). In a prospective cohort study of Busch and Chantelau \(^{71}\), and a randomized controlled trial of Uccioli et al. \(^{72}\), reduced ulceration rates were shown in patients who wore custom-made therapeutic footwear compared to patients who wore their own (standard) footwear. Reiber et al., however, showed no significant benefit in ulcer recurrence prevention of custom-made footwear compared to off-the-shelf footwear in a large randomized controlled trial \(^{73}\). The differences in these outcomes are difficult to explain, but may be because of a wide variety of methods and materials used in footwear prescription. None of the studies indicated whether their intervention footwear was effective in reducing pressure compared to the control footwear, nor was any accurate estimate of the patient’s adherence to their prescribed footwear provided. In view of this, three systematic reviews confirm that there is still limited evidence to support the use of custom-made footwear in the prevention of foot ulcers and pointed out the need for well-designed prospective trials in which adequate offloading of footwear is assured \(^{50, 70, 74}\).

Plantar pressure assessment
To design adequate offloading footwear that can prevent ulcer occurrence, high-pressure regions need to be identified, and pressure in these regions needs to be effectively reduced. Based on clinical evaluation, however, identification of such foot regions seems difficult \(^{75}\). In clinical practice in the Netherlands, foot pressure prints on carbon paper sheets are commonly used to locate plantar foot regions with excessively high pressures. Although with this method pressure areas can be localized, the major disadvantage is that the load is not quantified. In the last 2 decades, more advanced equipment has been developed to assess dynamic pressures while walking barefoot and in shoes. With such equipment, high-pressure
spots on the plantar site of the foot can be accurately identified and quantified. Additionally, offloading efficacy of custom-made therapeutic shoes can be evaluated.

Although these systems are used more frequently nowadays in research and clinical practice, specific guidelines on how to obtain valid and reliable data are not widely available. Bus et al. reported that at least 3 walking trials with a two-step approach to a pressure platform is most reliable for obtaining barefoot plantar pressures in neuropathic diabetic patients. Such recommendations are not available for in-shoe pressure measurements in these patients. Kernozek et al. showed that a minimum 8 steps per foot were required for reliable in-shoe pressures data, but they tested healthy subjects walking in standard footwear on a treadmill at controlled speeds. A guideline on the required number of steps for reliable and valid in-shoe pressure data in neuropathic diabetic patients with foot deformity wearing custom-made footwear and walking over ground is needed to avoid collecting too many steps that may increase patient burden or too few steps that may compromise data quality.

**Offloading improvement**

Custom-made footwear design and evaluation of its effectiveness is generally based on a trial-and-error approach, meaning that ineffective footwear is primarily indicated when an ulcer recurs. Due to the lack of a structured conceptual approach in footwear prescription and evaluation as described above, offloading success is mostly dependent on the clinical experience and skills of the prescribing physician and shoe technician. The result of this trial-and-error approach is that offloading efficacy varies considerably between patients. Although methods for a more quantitative approach to footwear design are available, such as by using 3D foot scanning techniques, computer assisted design and manufacturing systems and foot pressure systems, these technologies are still not frequently used in clinical practice (situation in 2008). Offloading success may be improved and inter-subject variation may be reduced by the use of these technologies, which may potentially reduce the risk for foot ulceration. Moreover, the use of in-shoe plantar pressure assessment has been proven a valuable tool to evaluate the offloading efficacy of custom-made footwear and to guide modifications to the footwear that can reduce pressure at high-risk regions. Bus et al. showed this approach to be successful by improving offloading compared to baseline with on average 30% in a relatively small group of diabetic patients wearing custom-made footwear. Confirmation of these promising data is needed in a larger more homogeneous group of at-risk diabetic patients.

**Use and usability**

Besides that footwear should adequately offload at-risk foot regions to effectively contribute to ulcer prevention, custom-made footwear needs to be worn. Chantelau and col-
leagues showed that, when protective footwear is worn for at least 60% of daytime, the risk for foot ulcer recurrence can be significantly reduced in diabetic patients. It is therefore worrying that several studies showed that therapeutic footwear is not often worn in this patient population: only 22 to 36% of patients use their footwear frequently. The risk for ulcer development is therefore markedly elevated in these patients. Several authors reported the influence of perceived usability aspects of footwear on its actual use, including weight, appearance and comfort of the shoes. Also the perceived benefit of using therapeutic footwear is an important factor in a patient’s decision to wear the shoes. How diabetic patients with a high risk of ulceration, for whom wearing their prescription footwear is most important, perceive the usability of their footwear is not known, nor is the influence of this perception on footwear use. Insight in the perceived usability will contribute to the understanding and eventually improvement of patient’s behaviour in wearing therapeutic footwear.

THE DIABETIC FOOT ORTHOPAEDIC SHOE (DIAFOS) TRIAL

In an ‘ideal’ approach to footwear prescription and evaluation, footwear is objectively evaluated, for example by using in-shoe pressure analysis, and, if needed, modified to improve offloading. Furthermore, in such an approach the footwear should be monitored over time as used materials may be subject to wear and tear or foot structure may change over time. The effectiveness of such an approach in the prevention of foot ulceration has not been assessed before. The Department of Rehabilitation Medicine of the Academic Medical Center in Amsterdam collaborated with nine other hospital-based multidisciplinary diabetic foot clinics and nine orthopedic footwear companies across the Netherlands in a multicenter randomized controlled trial on custom-made footwear effectiveness called the DIAFOS trial (Diabetic Foot Orthopedic Shoe trial). The data on which the current thesis is based mainly originate from this trial. In the DIAFOS trial, neuropathic diabetic patients with a recently healed plantar foot ulcer were randomly assigned to an intervention group that had their custom-made footwear evaluated using in-shoe plantar pressure measurement and, if needed, modified based on this evaluation with the goal to improve offloading, or a control group that had their custom-made footwear evaluated according to usual practice in which in-shoe plantar pressure measurements are not used. All patients in the trial were followed for 18 months or until foot ulcer recurrence. The primary outcome was the percentage of patients with a recurrent plantar foot ulcer in 18 months. Secondary outcomes of the trial that have been the subject of separate studies described in this thesis were (a) the offloading efficacy of the delivered footwear, (b) the pressure relieving effect and preservation of different types of footwear modification, and (c) the use and perceived usability of custom-made footwear.
AIMS OF THIS THESIS

The general aim of this thesis was to expand the knowledge on the effectiveness of custom-made footwear to prevent plantar foot ulcer recurrence in diabetic patients, by applying objective measurements of offloading.

Specific aims were:

1. To determine the minimum number of collected steps that is required to obtain representative in-shoe plantar pressure data in diabetic patients with neuropathy.

2. To assess the offloading efficacy of custom-made therapeutic footwear in high-risk diabetic patients.

3. To assess the value of using in-shoe plantar pressure assessment for evaluating, improving and preserving the offloading properties of newly prescribed custom-made footwear.

4. To assess the effect of footwear modifications on in-shoe plantar pressure in custom-made footwear for high-risk diabetic patients.

5. To evaluate the perceived usability of custom-made therapeutic footwear among high-risk diabetic patients and to assess how it is related to footwear use.

6. To assess whether offloading-improved custom-made footwear reduces ulcer recurrence in diabetic patients with neuropathy.

OUTLINE OF THE THESIS

Chapter two describes a study in which the number of footsteps required to obtain valid and reliable in-shoe plantar pressure data in diabetic patients with neuropathy wearing custom-made footwear is determined.

In-shoe plantar pressure analyses were used in chapter 3 to evaluate to what extent offloading is adequate in the custom-made footwear worn by diabetic patients with neuropathy and a history of plantar foot ulceration. The contributing role of different types of foot deformity to footwear efficacy was specified in this study.

Chapter 4 presents a study which aimed (1) to assess the value of using in-shoe plantar pressure analysis for improving the offloading properties of custom-made footwear and (2) to
evaluate whether improved offloading results can be maintained over a 1-year period when compared with a control group.

Where chapter 4 focused on ‘if’ offloading capacity can be improved, **chapter 5** evaluated ‘how’ this can be done. In this chapter the offloading efficacy of the many footwear modifications performed in the DIAFOS trial were studied. These data were summarized in an offloading effect-matrix to assist footwear prescribers in the design and modification of adequately offloading footwear for high-risk diabetic patients.

How diabetic patients with neuropathy, foot deformity and previous foot ulcers perceive the usability of their footwear and whether there are parameters associated with footwear use was shown in **chapter 6**.

**Chapter 7** describes the results of the DIAFOS randomized controlled trial in which we examined the effectiveness of offloading-improved custom-made footwear on plantar foot ulcer recurrence in comparison with usual care (i.e. non-improved custom-made footwear). In addition, we evaluated whether adherence to wearing custom-made footwear influenced ulcer recurrence.

Finally, in **chapter 8**, the main findings of the studies in this thesis are discussed, the used methodology in the different studies is critically reviewed and implications for clinical practice and future research are presented.
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