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Lower-extremity dynamics of walking in neuropathic diabetic patients who wear a forefoot-offloading shoe

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ABSTRACT

Background: A forefoot-offloading shoes has a negative-heel rocker outsole and is used to treat diabetic plantar forefoot ulcers, but its mechanisms of action and their association with offloading and gait stability are not sufficiently clear.

Methods: Ten neuropathic diabetic patients were tested in a forefoot-offloading shoe and subsequently in a control shoe with no specific offloading construction, both worn on the right foot (control shoe on left), while walking at 1.2 m/s. 3D-instrumented gait analysis and simultaneous in-shoe plantar pressure measurements were used to explain the shoe's offloading efficacy and to define centre-of-pressure profiles and left-to-right symmetry in ankle joint dynamics (0–1, 1:maximum symmetry), as indicators for gait stability.

Findings: Compared to the control shoe, peak forefoot pressures, vertical ground reaction force, plantar flexion angle, and ankle joint moment, all in terminal stance, and the proximal-to-distal centre-of-pressure trajectory were significantly reduced in the forefoot-offloading shoe ($P < 0.01$). Peak ankle joint power was 51% lower in the forefoot-offloading shoe compared to the control shoe: 1.61 (0.35) versus 3.30 (0.84) W/kg (mean (SD), $P < 0.001$), and was significantly associated with forefoot peak pressure ($R^2 = 0.72$, $P < 0.001$). Left-to-right symmetry in the forefoot-offloading shoe was 0.39 for peak ankle joint power.

Interpretation: By virtue to their negative-heel rocker-outsole design, forefoot-offloading shoes significantly alter a neuropathic diabetic patient's gait towards a reduced push-off power that explains the shoe's offloading efficacy. However, gait symmetry and stability are compromised, and may be factors in the low perceived walking discomfort and limited use of these shoes in clinical practice. Shoe modifications (e.g. less negative heel, a more cushioning insole) may resolve this trade-off between efficacy and usability.

1. Introduction

Foot ulcers are a serious complication of diabetes mellitus. They increase risk for infection and hospitalization and precede the vast majority of non-traumatic lower limb amputations in diabetes (Armstrong et al., 2017). Most plantar foot ulcers occur in the forefoot and are caused by a combination of loss of protective sensation and elevated levels of mechanical stress (Monteiro-Soares et al., 2012; Prompers et al., 2007). Management focuses on adequately offloading the ulcer by redistribution of pressure to other foot regions. Non-removable offloading, such as with the total contact cast, is the current gold standard treatment (Bus et al., 2016a; Lewis and Lipp, 2013; Morona et al., 2013). However, these devices have drawbacks: they are time consuming to apply, require a skilled technician for safe application, are contraindicated when daily wound assessment is needed, and they provide restrictions in ADL and sleep discomfort (Bus et al., 2016a; Bus et al., 2016b). As a result, they are underused in patient care (SC et al., 2008). Prefabricated and removable knee-high walkers, felted foam and shoe modifications are the most commonly used methods for treating foot ulcers (Raspovic and Landorf, 2014; SC et al., 2008).

Forefoot-offloading shoes (FOS) are prefabricated shoes designed to offload the plantar forefoot. The FOS is commonly used for foot ulcer treatment in some countries, but hardly at all in others. The FOS is a relatively cheap lightweight shoe that is easy to don and doff and that has a sole that, in contrast to the traditional “half shoe”, extends across the entire foot surface (Fig. 1). The FOS transfers load from the forefoot to more proximal foot regions (Bus et al., 2009). It has been suggested that this load transfer is achieved by (a) a rocker-bottom stiff outsole which pivots at the level of the metatarsal base and acts to limit dorsiflexion of the toes, and (b) a negative-heel configuration, i.e. where the toes are elevated compared with the heel, which limits the progression of body weight to the forefoot (Brown et al., 2004). We

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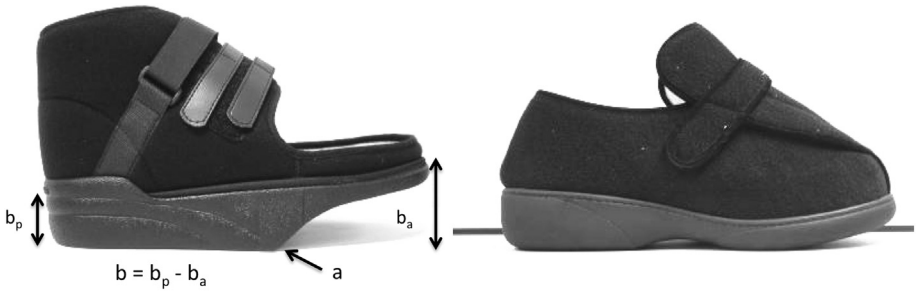

Fig. 1. Left: the forefoot-offloading shoe, with (a) representing a rocker bottom outsole with pivot point located at 60% of shoe length and (b) a negative heel with a 3-cm height difference between the most posterior (heel) and most anterior (tip) part of the support surface of the shoe. Right: Pulman shoe, which was the control shoe that was worn on the right and left foot in the control condition and on the left foot in the FOS condition.

previously showed in neuropathic diabetic patients that the FOS effectively reduces peak pressure in the forefoot with 38–58% when compared to a control shoe (Bus et al., 2009). In a recently completed randomized controlled trial the FOS showed to be similarly effective as ankle and knee-high removable casting devices in healing plantar forefoot ulcers in patients with diabetes (Bus et al., in press).

The biomechanical mechanisms by which the FOS offloads the foot in neuropathic diabetic patients are not sufficiently known; studies that simultaneously measure gait dynamics and plantar pressure in these patients do not exist. Apart from its offloading effect, we previously showed that comfort of walking is compromised in the FOS (Bus et al., 2009). From indications in the literature and clinical experience, the FOS may also cause problems with postural and gait stability in patients who have lost protective sensation, which increases their risk of falls (Crews et al., 2013; Paton et al., 2013). These drawbacks may be the effect of the same design features and biomechanical mechanisms that are thought to explain the effective offloading. Such a trade-off between biomechanical efficacy of the FOS on the one side and perceived usability and possible gait stability on the other may explain its limited widespread use in the treatment of plantar forefoot ulcers.

The purpose of this study was to identify alterations in the lower extremity dynamics of walking in neuropathic diabetic patients who wear the FOS and explore associations with in-shoe plantar pressure that can explain the offloading effect of these shoes and may provide indications for the compromise in walking comfort known to be present with wearing these shoes. These insights may help to determine if modifications to the FOS are needed to improve acceptance and use in clinical practice.

2. Methods

2.1. Study design

The study was designed as a cross-sectional study with a within-subject comparison between two footwear conditions.

2.2. Study participants

Ten persons with diabetes mellitus and loss of protective sensation due to peripheral neuropathy participated in the study. Patients were at high risk of developing a foot ulcer, defined either by having a history of foot ulceration or a foot deformity. Loss of protective sensation was confirmed present by the inability to sense a 10-g Semmes–Weinstein monofilament at, at least, one of the three plantar foot sites tested (hallux, first and fifth metatarsal head) or the inability to sense a vibration of 25 V at the great toe as measured with a Biothesiometer (Biomedical Instruments, Newbury, OH) (Pham et al., 2000). Patients with an active foot ulcer, inability to walk a distance of 20 m repeatedly without walking aid, a lower-extremity amputation, an active neuro-osteoarthopathy, or Charcot or equines foot deformity were excluded from participation. The local ethics committee approved the study protocol and each subject gave written informed consent before inclusion.

2.3. Footwear

The two footwear conditions tested were 1) a FOS worn on the right foot with a standard shoe worn on the left foot (FOS condition) and 2) both feet fitted with the standard shoe (control condition). The FOS was a Rattenhuber Talus (www.rattenhuber.de, Germany), which is used for offloading plantar forefoot ulcers in patients with diabetes (Fig. 1). It consists of a rocker outsole with a pivot point location of the rocker at 60% of the total shoe length measured from the heel (a, Fig. 1). The FOS also contains a negative heel outsole, with a difference in height from the ground between heel and forefoot of 3.0 cm (b, Fig. 1). The FOS is worn with a flat 13-mm dual-density cushioning insole placed inside the shoe. The standard shoe was a Pulman shoe (www.fld.fr, France), normally fitted to treat patients who require a spacious internal shoe environment to accommodate felted foam or a wound dressing (Fig. 1). The Pulman shoe has a flexible rubber outsole, moderate heel lift and soft upper that was chosen as control shoe because it has no known specific biomechanical function (Bus et al., 2009).

2.4. Procedures

Data were recorded on demographics, health history, neuropathic status and foot deformities. Participants were tested first at a preferred walking speed and then at a controlled walking speed of 1.2 m/s. Walking speed was measured using photocells positioned along the walkway (Tag-Heuer, La Chaux-de-Fonds, Switzerland), and was standardized between trials within a testing condition (maximum ± 5% deviation from the average speed measured). The order of shoe condition tested was randomized within the speed condition. Patients walked forth and back along a 12-m walkway. In each footwear condition, a convenience sample of four practice trials were used for the patients to become accustomed to walking in the tested shoe. Four valid trials of undisturbed walking were recorded.

An 8-camera motion capture system (MX1.3, VICON, Oxford, UK), operating at a sample frequency of 100 Hz was used to record the 3-dimensional trajectories of 14-mm adhesive reflective passive body markers that were placed on anatomical landmarks on the lower extremity and pelvis of the subject, and on the shoe where they were reinforced with sports tape Ground reaction forces were measured at 1000 Hz sample frequency using two sequentially placed AMTI force plates that were set flush in the middle of the walkway (OR6–7, AMTI, Watertown, MA, USA.). A valid gait trial was one in which (i) each foot landed individually on a force plate without targeting, as confirmed by the researcher, and (ii) all body markers were reconstructable from first heel strike on the force plate to subsequent ipsilateral heel strike.

Simultaneously with above measurements, in-shoe plantar pressure was measured at 50 Hz sampling rate using the Pedar-X system (Novel GmbH, Munich, Germany). The system consists of 2-mm thick capacitance-based measurement insoles containing 99 pressure-sensing sensors at a spatial resolution of approximately one sensor per square centimetre. The insoles are placed between the shoe insert and the sock of the patient and are connected to a waist-worn data logger that transmits pressure data real time to a PC through Bluetooth connection.