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Plantar pressures in diabetic patients with foot ulcers which have remained healed

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Abstract

Aims The recurrence of foot ulcers is a significant problem in people with diabetic neuropathy. The purpose of this study was to measure in-shoe plantar pressures and other characteristics in a group of neuropathic patients with diabetes who had prior foot ulcers which had remained healed.

Methods This was an epidemiological cohort study of patients from diabetes clinics of two Swedish hospitals. From a database of 2625 eligible patients, 190 surviving patients with prior plantar ulcers of the forefoot (hallux or metatarsal heads) caused by repetitive stress were identified and 49 patients agreed to participate. Barefoot and in-shoe plantar pressures were measured during walking. Data on foot deformity, activity profiles and self-reported behaviour were also collected.

Results Mean barefoot plantar peak pressure at the prior ulcer site (556 kPa) was lower than in other published series, although the range was large (107–1192 kPa). Mean in-shoe peak pressure at this location averaged 207 kPa when measured with an insole sensor. Barefoot peak pressure only predicted ~35% of the variance of in-shoe peak pressure, indicating variation in the efficacy of the individual footwear prescriptions (primarily extra-depth shoes with custom insoles).

Conclusions We propose that the mean value for in-shoe pressures reported in these patients be used as a target in footwear prescription for patients with prior ulcers. Although plantar pressure is only one factor in a multifaceted strategy to prevent ulcer recurrence, the quantitative focus on pressure reduction in footwear is likely to have beneficial effects.

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Keywords barefoot pressure measurement, in-shoe pressure measurement, neuropathy, threshold

Introduction

Foot ulcers and their recurrence are a serious concern to people with diabetes. Approximately 15% of diabetic patients in the USA will experience a foot ulcer at some point in their lifetime [1]. Diabetic patients who have had a previous foot ulcer are at high risk of developing new foot ulcers [2]. Ulcers are a leading cause of non-traumatic lower limb amputation in diabetic patients, with a foot ulcer preceding 85% of such amputations [3,4]. Diabetic foot ulcers generally develop because of loss of protective sensation associated with neuropathy [5] and are commonly located at the plantar surface of the toes and forefoot [3,6]. It is believed that most neuropathic ulcers are caused by high plantar foot pressures at sites of foot deformity [7], perhaps in combination with inadequate or ill-fitting footwear [8].

Diabetic patients with a history of foot ulcers have higher barefoot peak plantar pressures than diabetic patients without foot ulcers [9]. Authors have speculated on the magnitude of loads on the foot that are likely to cause tissue damage [7,9]. A retrospective study reported a sensitivity of 70.0% and a specificity of 65.1% for peak barefoot plantar pressure as a predictor of ulceration [9]. Additionally, unusual changes in the level of activity in a given patient may be a precursor of foot injury [10,11].

The above studies, however, have measured plantar pressures only during barefoot walking. Diabetic individuals, especially those at risk for foot ulceration, are advised against barefoot walking and are often prescribed therapeutic footwear. This

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footwear is designed to redistribute the plantar pressures of the foot, thus attenuating peak pressures in at-risk regions. Few randomized controlled trials have investigated the influence of therapeutic footwear on ulcer recurrence [12–15]; most, but not all [14], show a reduced number of re-ulcerations in patients with therapeutic footwear compared with control patients with diabetes. Thus, a study of the footwear of patients who do not re-ulcerate may offer insight regarding what constitutes 'adequate' plantar offloading.

Current technology allows normal (or vertical) plantar pressures to be measured at the foot–footwear interface during walking in footwear [16]. The measurement of shear stress inside the shoe remains elusive [17] despite recent advances in barefoot plantar shear measurement [18,19]. It would be advantageous to define a peak in-shoe plantar pressure threshold below which the risk of ulceration is reduced. While there is likely to be a complex relationship between plantar pressure at the foot–footwear interface and ulceration because of behavioural issues (i.e. level of activity, amount of barefoot walking, etc.), the purpose of the present study is to provide insight into in-shoe pressures for a unique group of patients with prior ulcers.

Patients and methods

Subjects

Forty-nine subjects (38 men and 11 women; age 62.9 ± 10.3 years; height 177 ± 8 cm; weight 88.1 ± 17.5 kg) participated in the study. Participants were recruited from diabetes databases of two Swedish hospitals. Information within these databases was compiled over an 18-year period and included approximately 2625 diabetic patients. Inclusion criteria for the study were patients with known diabetes, treated at a multidisciplinary diabetic foot centre because of a foot ulcer (Wagner grade 1–5) and followed until healing, with annual follow-up for a minimum of 5 years. From this sample, 190 surviving patients were identified with prior plantar ulcers of the forefoot (hallux or metatarsal heads) from repetitive stress. Only patients aged 30–80 years with ulcers that were of predominantly neuropathic aetiology and who had remained healed for at least 90 days were included. The patients' medical records were examined to confirm this information. Exclusion criteria were major vascular disease, hallux blood pressure < 35 mmHg, trauma as cause of ulceration, Charcot fracture, prior foot surgery involving amputation of more than one toe or resection of a metatarsal head, and the inability to walk. Patients were contacted by telephone to verify the inclusion and exclusion criteria and to ascertain their willingness to participate. Forty-nine participants provided written informed consent.

Protocol

The experimental session consisted of a foot examination, interviews regarding activity level and compliance and measurement of plantar pressures during barefoot walking and within the patients' most commonly worn shoes (typically prescription footwear).

Foot examination

Investigators verified prior ulcer site and date of healing. Also recorded were the patients' ability to detect a 10-g monofilament proximal and distal to the prior ulcer site, the presence or absence of dorsalis pedis and posterior tibial pulses, hallux blood pressure, the range of motion of the first metatarsophalangeal joint of the unloaded foot and foot deformities (i.e. hammer toes, hallux valgus, etc.).

Activity profile

An activity score was compiled based on self-reported hours of sleeping, sitting, standing, walking and time on the feet other than standing or walking (e.g. doing housework). Activity score was calculated as [total standing hours + (2 × total walking hours)]. Weight-bearing time was further categorized into hours wearing shoes and hours barefoot.

Level of compliance

This 15-item questionnaire was based on the daily foot-care routine (Table 1). Patients received one point for each affirmative response to questions 1–5, 8 and 11 and one point for each negative response to the remaining questions. Scoring was based on the sum of the points, with 15 points representing excellent foot care and compliance.

Measurement of plantar pressures

Three separate measures of plantar pressure were collected for each subject. Barefoot plantar pressures were collected using an

Table 1 Results of compliance questionnaire (n = 49)

Do you…	True (n)
have a daily foot care routine? (Q1)	27
look at your feet daily? (Q2)	28
examine all surfaces daily? (Q3)	21
moisturize your feet daily? (Q4)	24
have professional care every 6 months? (Q5)	35
occasionally cancel appointments? (Q6)	2
often cancel appointments? (Q7)	0
break in new shoes? (Q8)	22
ever walk barefoot? (Q9)	26
often walk barefoot? (Q10)	14
wear shoes to the toilet at night? (Q11)	21
ever take a shower barefoot? (Q12)	44
sometimes ignore a foot problem? (Q13)	13
occasionally treat a foot problem yourself? (Q14)	23
often treat a foot problem yourself? (Q15)	8

emed® platform and in-shoe plantar pressures were measured using both pedar® and pliance® flexible pressure-sensitive arrays (http://www.novel.de). Each of these sensor types has elements with different average single sensor areas (50, 185 and 19.4 mm^2 for emed®, pedar® and pliance®, respectively).

For emed® plantar pressure testing, barefoot patients stood with the foot of interest directly in front of the platform. Five successful first-step trials were collected on each subject. For in-shoe plantar pressure testing, patients wore their most frequently used shoes. Pedar® insoles, which cover the entire plantar surface of the feet, were placed inside the patients' shoes. Pressure data from approximately 30 foot contacts were collected as patients walked across the laboratory. Patients chose their own speed of walking during the in-shoe trials, but, once established, this speed (± 5%) was used for all trials [20]. Although walking speed can alter measured plantar pressure, a self-selected comfortable speed was chosen to represent conditions typically encountered in each patient's life.

The pliance® array was attached using paper tape over the site of the patient's healed prior ulcer. The subject's sock and shoe were donned. Pressure data from approximately 30 foot contacts were collected as patients walked across the laboratory with the same speed constraints as for pedar® measurements. For all three measures, the magnitude of peak pressure in the region of the healed ulcer was determined from mask analysis [21].

Results

The first metatarsal head and the hallux were common sites of prior plantar ulceration (n = 18 and 17, respectively), followed by the second metatarsal head (n = 5). On average, ulcers had been healed 3.6 ± 3.4 years with a range of 0.4–14.4 years (median = 3.0 years). Two patients were able to detect the monofilament both proximal and distal to their prior ulcer site, with one additional patient detecting the monofilament proximal to the prior ulcer site. Forty-two patients had at least one foot deformity (hammer toes, claw toes, hallux valgus, bunions, prominent metatarsal heads, midfoot or other prominence).

Most patients reported spending a majority of their time (in hours) sleeping (8.7 ± 1.8; range 5–15) and sitting (7.1 ± 3.2; range 0–16). Walking was the dominant reported activity requiring patients to be on their feet (5.9 ± 3.1; range 0–15). Remaining time was spent standing (2.1 ± 1.9; range 0–8) and performing other weight-bearing activities (0.2 ± 0.5; range 0–3). Most standing, walking and other weight-bearing activities were performed while wearing shoes (1.8 ± 1.7, 5.3 ± 3.0 and 0.2 ± 0.5, respectively). For approximately 50% of the hours spent walking or standing, patients reported wearing the same shoes worn during the pressure measurement session. Based on the activity profile, patients had an average activity score of 14 ± 6 (range 2–31).

The average compliance score was 9.0 ± 2.6 (range 2–13; Table 1). Fifty-five per cent of patients claimed to have some type of daily foot-care routine and 71% reported seeking professional care for their feet every 6 months.

Mean peak plantar pressure in the forefoot during barefoot walking (emed®) was 566 ± 316 kPa (Table 2), demonstrating significant variability in the group, with a range from 107 to 1192 kPa. Peak pressures in some trials were above the saturation level of the pressure sensor.

Prescription footwear can be expected to attenuate peak pressures and this is reflected by the peak in-shoe pressure results (with limitations regarding comparison of different sensor sizes mentioned below). Pedar® values were, on average, 36.5% of barefoot values (Table 2), with a gradient of 0.123 characterizing the relationship between in-shoe and barefoot pressure (Fig. 1a; note that comparisons are not corrected for effects of sensor size). Pliance® values were, on average, 51.4% of barefoot values (Table 2), with a gradient of 0.249 (Fig. 1b). Ranked in-shoe peak pressure data are shown in Fig. 2 and the pairs of in-shoe and barefoot plantar pressures for each subject are shown in Fig. 3.

The r^2 of the regression equations between the activity scores and in-shoe pressures were 0.07 and 0.005, respectively, for pedar® and pliance® measurements. This reflects the absence of a relationship between activity and in-shoe plantar pressure, thus negating the expectation that patients with higher in-shoe pressures would have to be less active to stay healed.

Discussion

Subjects in this study represent an important subset of diabetic people with neuropathic foot ulcers. Despite having experienced a plantar foot ulcer that was caused by repetitive injury rather

Table 2 Average peak pressures (kPa) at prior ulcer sites during barefoot walking (emed®) and during shod walking using two in-shoe methods (pedar® and pliance®)

		Emed® (barefoot)		Pedar® (in-shoe)		Pliance® (in-shoe)	
	n	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	Range
Hallux	17	486 ± 242	205–1060	214 ± 71	122–337	304 ± 124	112–513
MTH1	18	664 ± 342	144–1192	202 ± 62	108–325	300 ± 132	48–671
MTH2–5	14	537 ± 347	107–1180	204 ± 75	96–319	263 ± 145	60–575
All sites	49	566 ± 316	107–1192	207 ± 68	96–337	291 ± 132	48–671

As expected, pliance® values are larger than pedar® measurements because of the smaller pliance® sensor size.
MTH, metatarsal head; SD, standard deviation.

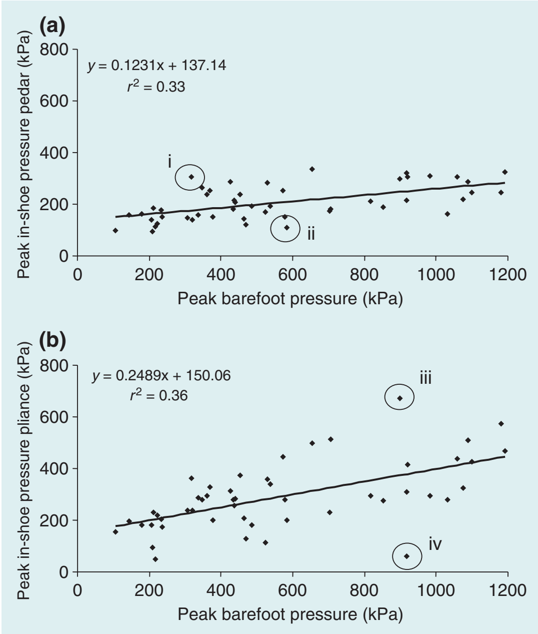

FIGURE 1 (a) Peak barefoot pressure vs. pedar® in-shoe pressure. Note the gradient of 0.123 and relatively low r^2 of 0.33. Peak pressure from an unsuccessful footwear intervention (point i) in which peak pressure has only been reduced from 317 to 304 kPa; peak pressure from a more successful prescription (point ii) in which peak pressure has been reduced from 583 to 108 kPa. (b) Peak barefoot pressure vs. pliance® in-shoe pressure. The gradient of 0.249 is approximately double that seen with pedar® sensors, although r^2 remains low at 0.36. Peak pressure from an unsuccessful footwear intervention (point iii) has been reduced from 899 kPa to only 691 kPa; peak pressure from a successful prescription (point iv) has been reduced from 918 to 60 kPa. Note: points iii and iv do not represent the same patients as those identified as points i and ii.

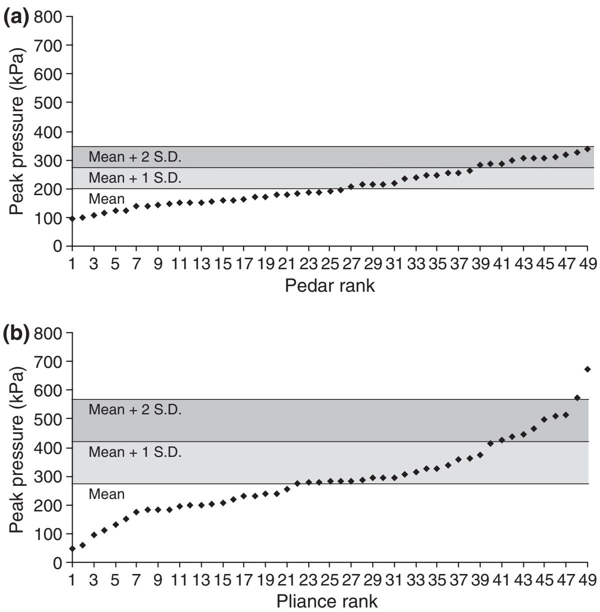

FIGURE 2 Ordered in-shoe peak pressure at prior ulcer sites for (a) pedar® sensor measurements and (b) pliance® sensor measurements. Shading shows mean + 1 and mean + 2 standard deviations.

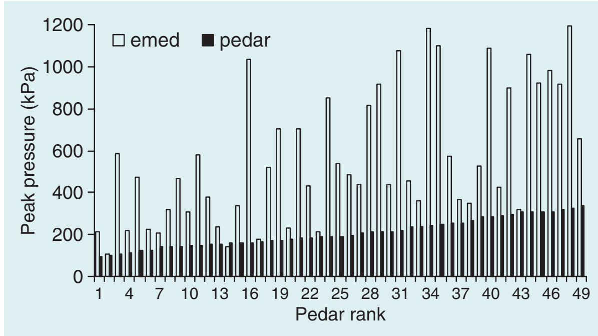

FIGURE 3 A comparison of barefoot (emed®) and in-shoe (pedar®) pressures at the prior ulcer site for each subject in the study. Data are ranked by in-shoe pressure, allowing the effectiveness of individual footwear prescriptions to be evaluated. Note: many subjects with in-shoe pressures in the mid-range (close to 200 kPa) exhibit high barefoot pressures.

than by a single traumatic event, these individuals had remained healed at the time of the study for an average of 3.6 years. In the literature, reported recurrence rates for neuropathic foot ulcers are between 28% at 12 months and 100% at 40 months [12,13]. Further, Pound *et al.* [22] found that 32.7% of patients in a consecutive series of 370 patients with 1031 ulcers never became ulcer-free after a minimum follow-up of 6 months. Thus, subjects in the present study can be considered to have an ulcer-free survival that was longer than typical. This implies that their characteristics—the combination of feet, footwear (i.e. typically an extra-depth shoe with custom-moulded insoles and a custom-moulded sandal for indoor use) and behaviours (i.e. counselled never to walk barefoot)—were sufficient to prevent reulceration.

While some subjects were at relatively low risk of recurrence based on their barefoot plantar pressure—probably because osteomyelitis or significant debridement altered the underlying bone—47% had ulcer site barefoot pressures of > 500 kPa and 35% had pressures of > 600 kPa. While Armstrong *et al.* [9] proposed an at-risk cut-point of > 700 kPa, many patients with prior ulcers in that study also had prior ulcer site pressures below that value. Furthermore, our platform had a larger sensor size than that used in the Armstrong *et al.* study (50 vs. 25 mm²—a larger sensor can potentially underestimate the pressure), so a direct comparison of pressure is not possible. In any case, some patients in our survey did have 'at-risk' pressure at the prior ulcer site.

There was great variability in the reduction of plantar pressure by the prescribed footwear. Thus, shoes that are made by following similar principles and using similar materials, as was the case in this small geographic area, offload the at-risk regions of the foot differently. This reflects the inherent difficulty in making therapeutic footwear with the traditional approach of using skilled experts but without incorporating the measurement of pressure [23].

An absolute comparison of plantar pressures during barefoot and shod walking is complicated by different sensor areas in barefoot vs. in-shoe devices. Mathematical approximations can be made, but it is not possible to accurately reconstruct the true peak pressure without knowing the geometry of the bone in contact with the sensor (because pressure from a small boney prominence is averaged by a large sensor across the sensor area [6]). We have therefore chosen to present the relationships directly as measured and comparisons that are made must be considered with this in mind. Independent of the scaling issue, barefoot peak pressure is a poor predictor of peak in-shoe pressure, as reflected by low r^2 values in the regressions of pedar® and pliance® on emed® (Fig. 1; 0.33 and 0.36, respectively). This observation suggests that in-shoe pressure is a key variable that should be examined when foot ulcer risk in diabetic patients is being considered.

Maximum values for in-shoe pressure in this group of patients were 337 and 671 kPa for pedar® and pliance®, respectively. Currently, there are no in-shoe plantar pressure targets or thresholds available in the literature to guide clinical practice in the prescription of footwear and no data are available from patients who cannot maintain a healed state. Guldemond *et al.* [16], using similar instrumentation, reported mean peak forefoot pressure values between 134 and 275 kPa (depending on site) in ulcer-free patients. We therefore propose that a reasonable conservative goal would be to aim for footwear that attenuates in-shoe plantar pressures to values close to the mean seen in our group of patients who have remained healed. Pedar® in-shoe sensors are much more common than pliance® devices and this recommendation translates to a peak pressure value of approximately 200 kPa as measured by pedar®. Even although most medical tests use the 95% confidence intervals to define normal ranges, the use of such an approach would lead to the acceptance of extremely high in-shoe pressures as 'normal' (see Fig. 2). This observation is similar to results from Armstrong *et al.* [9], who found that mean + 2 standard deviations for peak barefoot pressure in ulcer-free patients resulted in a value near the saturation level of the platform (1115 kPa), which was not useful to discriminate those at risk for ulcer from those who were not. Thus, confidence intervals should not be used to define pressure thresholds for ulceration in this patient group.

Our recommendation that 200 kPa be provisionally adopted until more data are available acknowledges that plantar pressure is only one important factor in preventing re-ulceration. Other factors, such as activity level, consistent use of prescription footwear, appropriate preventive care and others not considered in this study (e.g. tissue properties, microvascular status) may have played a role in preventing ulceration in our subjects with plantar pressures in the two upper quartiles.

In this study we attempted to examine behavioural factors that might have contributed to patients remaining ulcer free. We expected that patients with relatively high in-shoe pressures would have relatively low physical activity and that patients with relatively high barefoot pressures would have higher compliance with footwear use for all activities and higher self-care scores. However, we were unable to document any of these anticipated relationships, possibly because our assessment methods were not sensitive enough or because of the well-understood biases of self-reporting. Self-reports of activity are subject to substantial inaccuracies [24], indicating that a performance- or observation-based approach is needed.

Periods of barefoot standing and walking were reported to be relatively brief, (i.e. 53% admitted to 'ever' walking barefoot and 42% claimed to use shoes to walk to the bathroom during the night). As custom-moulded sandals were provided to many patients, this relatively high number is at least plausible for this population. Almost all subjects reported taking showers barefoot, despite this activity being mentioned by experts as a risk factor for ulceration. Importantly, these subjects were reasonably active, so lack of reulceration cannot be attributed to severely limited activity. Although they reported spending, on average, 15.8 h sleeping or sitting down, the mean time reported spent walking (5.9 h) is relatively high, but plausible given the typical dependence in Sweden on public transportation.

An unpublished validation study reported by Lemaster *et al.* [25] found an intra-class correlation between a self-reported activity questionnaire and a 'continuously worn step-activity monitor' to be only 0.47. Additionally, Lemaster *et al.* [25] concluded that the questionnaire showed no association between activity and the risk of ulceration, although their measure of ulceration (a lesion not healed in 30 days) was conservative.

Subsequently, Lemaster *et al.* [26] conducted an exercise intervention study by examining inactive diabetic people with peripheral neuropathy (n = 97). Using activity monitors and a more robust measure of foot injury, they reported that daily step-counts were increased in the exercise group (14%) and decreased in the control group (6%), yet there were no significant differences in foot ulcer occurrence.

Although self-reports of compliance with foot-care routines are subject to the same limitations discussed above for self-reported activity, quantitative approaches to monitor self care are not readily available. Future studies should further examine the relationship of quantitative measures of activity and adherence to self-care behaviour to the maintenance of healing.

The traditional view that repetitive stress is a leading cause of foot ulceration [27] has recently been re-examined. Mueller and Maluf [28] have hypothesized that the soft tissue of the plantar aspect of the foot may actually accommodate and respond positively to repeated loading similar to the way in which muscle and bone tissues respond. This is an intriguing hypothesis that remains to be quantitatively tested and identified with a particular molecular mechanism.

In summary, the characteristics of a group of patients with prior plantar diabetic neuropathic foot ulcers who had remained healed were examined. In some patients, plantar pressures were no longer high enough for these patients to be at risk. Many, however, still had extremely high pressures at prior ulcer sites and, based on in-shoe pressure data, we propose a conservative provisional in-shoe pressure goal of < 200 kPa using pedar® sensors. Studies have shown that in-shoe pressures can be systematically reduced to the 200 kPa range with appropriately designed prescription footwear interventions [23,29,30]. Although footwear is frequently prescribed on a trial-and-error basis, the use of in-shoe pressure measurement with the proposed value as a target for reduction could lead to significantly improved footwear for patients at-risk for ulceration or re-ulceration [23].

Competing interests

PRC and JSU own stock in DIApedia LLC (State College, PA, USA) and are inventors on US patents 6 610 897, 6 720 470 and 7 206 718 which elucidate a load-relieving dressing and a method of insole manufacture for offloading diabetic feet. DIApedia receives royalties from a licensing agreement with Acor Orthopaedic. PRC is also a recipient of grants from the National Institutes of Health and has received honoraria from Merck, Eli Lilly and ConvaTec. AK is employed as the Director of Biomechanics in the Novel GMBH, which is a company in Munich, Germany which developed and manufactured the system used for pressure distribution measurement (emed®, pedar® and pliance®) and the software used for the evaluation of the pressure data within this study.

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References

1 Palumbo PJ, Melton LJ. Peripheral vascular disease and diabetes. *Diabetes in America: Diabetes Data Compiled 1984 (NIH 85-1468)*. Washington, DC: US Government Printing Office, 1985: XV-1–XV-21.
2 Apelqvist J, Larsson J, Agardh CD. Long-term prognosis for diabetic patients with foot ulcers. *J Intern Med* 1993; **233**: 485–491.
3 Reiber GE, Vileikyte L, Boyko EJ, del Aguila M, Smith DG, Lavery LA *et al.* Causal pathways for incident lower-extremity ulcers in patients with diabetes from two settings. *Diabetes Care* 1999; **22**: 157–162.
4 Larsson J, Apelqvist J, Agardh CD, Stenstrom A. Decreasing incidence of major amputation in diabetic patients: a consequence of a multidisciplinary foot care team approach? *Diabet Med* 1995; **12**: 770–776.
5 Brand PW. Repetitive stress in the development of diabetic foot ulcers. In: Levin ME, O'Neal LW, eds. *The Diabetic Foot*. St Louis: C V Mosby, 1988: 83–90.
6 Cavanagh PR, Ulbrecht JS. The biomechanics of the foot in diabetes mellitus. In: Bowker JH, Pfeifer MA, eds. *Levin and O'Neal's The Diabetic Foot*. St Louis: Mosby, 2008: 115–184.
7 Veves A, Murray HJ, Young MJ, Boulton AJ. The risk of foot ulceration in diabetic patients with high foot pressure: a prospective study. *Diabetologia* 1992; **35**: 660–663.
8 Cavanagh PR. Therapeutic footwear for people with diabetes. *Diabetes Metab Res Rev* 2004; **20**: S51–S55.
9 Armstrong DG, Peters EJ, Athanasiou KA, Lavery LA. Is there a critical level of plantar foot pressure to identify patients at risk for neuropathic foot ulceration? *J Foot Ankle Surg* 1998; **37**: 303–307.
10 Armstrong DG, Lavery LA, Holtz-Neiderer K, Mohler MJ, Wendel CS, Nixon BP *et al.* Variability in activity may precede diabetic foot ulceration. *Diabetes Care* 2004; **27**: 1980–1984.
11 Lott DJ, Maluf KS, Sinacore DR, Mueller MJ. Relationship between changes in activity and plantar ulcer recurrence in a patient with diabetes mellitus. *Phys Ther* 2005; **85**: 579–588.
12 Uccioli L, Faglia E, Monticone G, Favales F, Durola L, Aldeghi A *et al.* Manufactured shoes in the prevention of diabetic foot ulcers. *Diabetes Care* 1995; **18**: 1376–1378.
13 Chantelau E, Haage P. An audit of cushioned diabetic footwear: relation to patient compliance. *Diabet Med* 1994; **11**: 114–116.
14 Reiber GE, Smith DG, Wallace C, Sullivan K, Hayes S, Vath C *et al.* Effect of therapeutic footwear on foot reulceration in patients with diabetes: a randomized controlled trial. *J Am Med Assoc* 2002; **287**: 2552–2558.
15 Busch K, Chantelau E. Effectiveness of a new brand of stock 'diabetic' shoes to protect against diabetic foot ulcer relapse. A prospective cohort study. *Diabet Med* 2003; **20**: 665–669.
16 Guldemond NA, Leffers P, Sanders AP, Schaper NC, Nieman F, Walenkamp GH. Daily-life activities and in-shoe forefoot plantar pressure in patients with diabetes. *Diabetes Res Clin Pract* 2007; **77**: 203–209.
17 Mackey JR, Davis BL. Simultaneous shear and pressure sensor array for assessing pressure and shear at foot/ground interface. *J Biomech* 2006; **39**: 2893–2897.
18 Yavuz M, Botek G, Davis BL. Plantar shear stress distributions: comparing actual and predicted frictional forces at the foot–ground interface. *J Biomech* 2007; **40**: 3045–3049.
19 Yavuz M, Erdemir A, Botek G, Hirschman GB, Bardsley L, Davis BL. Peak plantar pressure and shear locations: relevance to diabetic patients. *Diabetes Care* 2007; **30**: 2643–2645.
20 Rosenbaum D, Hautmann S, Gold M, Claes L. Effects of walking speed on plantar pressure patterns and hindfoot angular motion. *Gait Posture* 1994; **2**: 191–197.
21 Cavanagh PR, Rodgers MM, Iiboshi A. Pressure distribution under symptom-free feet during barefoot standing. *Foot Ankle* 1987; **7**: 262–276.
22 Pound N, Chipchase S, Treece K, Game F, Jeffcoate W. Ulcer-free survival following management of foot ulcers in diabetes. *Diabet Med* 2005; **22**: 1306–1309.
23 Owings TM, Woerner JL, Frampton JD, Cavanagh PR, Botek G. Custom therapeutic insoles based on both foot shape and plantar pressure measurement provide enhanced pressure relief. *Diabetes Care* 2008; **31**: 839–844.
24 Smith DG, Domholdt E, Coleman KL, del Aguila MA, Boone DA. Ambulatory activity in men with diabetes: relationship between self-reported and real-world performance-based measures. *J Rehabil Res Dev* 2004; **41**: 571–580.
25 Lemaster JW, Reiber GE, Smith DG, Heagerty PJ, Wallace C. Daily weight-bearing activity does not increase the risk of diabetic foot ulcers. *Med Sci Sports Exerc* 2003; **35**: 1093–1099.
26 Lemaster JW, Mueller MJ, Reiber GE, Mehr DR, Madsen RW, Conn VS. Effect of weight-bearing activity on foot ulcer incidence in people with diabetic peripheral neuropathy: feet first randomized controlled trial. *Phys Ther* 2008; **88**: 1385–1398.
27 Hall OC, Brand PW. The etiology of the neuropathic plantar ulcer: a review of the literature and a presentation of current concepts. *J Am Podiatry Assoc* 1979; **69**: 173–177.
28 Mueller MJ, Maluf KS. Tissue adaptation to physical stress: a proposed 'Physical Stress Theory' to guide physical therapist practice, education, and research. *Phys Ther* 2002; **82**: 383–403.
29 Mueller MJ, Lott DJ, Hastings MK, Commean PK, Smith KE, Pilgram TK. Efficacy and mechanism of orthotic devices to unload metatarsal heads in people with diabetes and a history of plantar ulcers. *Phys Ther* 2006; **86**: 833–842.
30 Lott DJ, Hastings MK, Commean PK, Smith KE, Mueller MJ. Effect of footwear and orthotic devices on stress reduction and soft tissue strain of the neuropathic foot. *Clin Biomech* 2007; **22**: 352–359.