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RESEARCH: COMPLICATIONS

Foot ulcer recurrence, plantar pressure and footwear adherence in people with diabetes and Charcot midfoot deformity: A cohort analysis

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Abstract

Aims: To investigate people with Charcot midfoot deformity with regard to plantar pressure, footwear adherence and plantar foot ulcer recurrence.

Methods: Twenty people with diabetes, Charcot midfoot deformity, plantar foot ulcer history and custom-made footwear were assessed with regard to barefoot and in-shoe plantar pressures during walking, footwear adherence (% of daily steps over 7-day period) and plantar foot ulcer recurrence over 18 months. In a cohort design, they were compared to 118 people without Charcot foot (non-Charcot foot group) with custom-made footwear and similar ulcer risk factors.

Results: Median (interquartile range) barefoot midfoot peak pressures were significantly higher in the Charcot foot group than in the non-Charcot foot group [756 (260–1267) vs 146 (100–208) kPa; $P<0.001$]. In-shoe midfoot peak pressures were not significantly higher in the Charcot foot group [median (interquartile range) 152 (104–201) vs 119 (94–160) kPa] and significantly lower for all other foot regions. Participants in the Charcot foot group were significantly more adherent, especially at home, than participants in the non-Charcot foot group [median (interquartile range) 94.4 (85.4–95.0)% vs. 64.3 (25.4–85.7)%; $P=0.001$]. Ulcers recurred in 40% of the Charcot foot group and in 47% of the non-Charcot foot group ($P=0.63$); midfoot ulcers recurred significantly more in the Charcot foot group (4/8) than in the non-Charcot foot group (1/55; $P=0.001$).

Conclusions: Effective offloading and very high footwear adherence were found in people with diabetes and Charcot midfoot deformity. While this may help protect against plantar foot ulcer recurrence, a large proportion of such people still experience ulcer recurrence. Further improvements in adherence and custom-made footwear design may be required to improve clinical outcome.

1 | INTRODUCTION

Charcot neuro-osteoarthropathy is a complex and severe condition that can have devastating consequences for affected feet.[1,2] Diabetes is the most common cause of Charcot neuro-osteoarthropathy,[3] which occurs exclusively in those people affected by peripheral neuropathy. Without appropriate treatment, the condition may result in gross alteration of foot structure and function.[1,2] Moreover, Charcot neuro-osteoarthropathy has a profound negative effect on quality of life[4] and is

associated with significant morbidity and premature mortality.[1,5] It is considered a rare complication, with an incidence ranging from 0.1% to 0.3% among people with diabetes,[1,6] although it may be more prevalent due to difficulties with diagnosis.[1,7]

Evidence-based treatment for acute Charcot neuro-osteoarthropathy does not exist. Treatment primarily aims to achieve a stable and plantigrade foot that remains ulcer-free, through immobilization and offloading with a total contact cast or removable walker.[2,8–11] Delay in diagnosis and continued weight-bearing without total contact cast support may lead to severe deformity.[2,12] Deformity occurs mostly in the midfoot and frequently as rocker-bottom, which is a significant risk factor for ulceration.[13] Typical management following the acute stage includes gradual weight-bearing and continued offloading with custom-made footwear in order to prevent (recurrent) ulceration.[7,14,15] However, only few non-comparative studies exist on the efficacy of offloading management of the Charcot foot beyond the acute phase.[14,16] Ulceration rates of 49% and 65% over a 4- to 9-year follow-up were reported in people with Charcot foot wearing accommodative or custom-made footwear.[15,17] Furthermore, 1-year ulcer incidence was found to drop from 73% to 10% in people with Charcot foot after provision of custom-made footwear.[18] However, none of these studies measured the offloading characteristics of the footwear prescribed.

The presence of Charcot foot deformity is often an exclusion criterion in ulcer prevention trials, and thus hardly studied. Charcot foot deformity was recently identified as the single greatest predictor of high barefoot plantar pressures in the midfoot region in people with diabetes and a history of ulceration.[19] Furthermore, objective measures show that adherence to wearing custom-made footwear is insufficient in people with diabetes at high risk of foot ulceration, which has implications for ulcer recurrence.[20,21] A literature review shows that the risk of developing a recurrent foot ulcer is 40% within 1 year after healing;[22] therefore, this group in remission is an important one to target for ulcer prevention. Footwear offloading and adherence have, however, not been investigated in the Charcot foot population. Neither has ulcer recurrence after recent healing for which custom-made footwear is prescribed. The aim of the present study, therefore, was to assess barefoot and in-shoe plantar pressures, footwear adherence and plantar foot ulcer recurrence in people with diabetes, Charcot midfoot deformity and plantar foot ulcer history, and to compare these outcomes to those in people with the same risk factors but without a Charcot foot.

What's new?

- Acute Charcot neuro-osteoarthropathy is treated through foot immobilization and offloading, but minimal data exist on offloading management and clinical outcome beyond the acute phase.
- Barefoot midfoot peak pressures during walking were significantly higher in participants with than without Charcot foot. In-shoe midfoot peak pressures were comparable between groups and all other foot regions showed significantly lower in-shoe peak pressures in participants in the Charcot foot group.
- The Charcot foot group was close to optimally adherent to wearing custom-made footwear and had significantly higher adherence than the non-Charcot foot group.
- Incidence of plantar foot ulcer recurrence was as high in the Charcot foot group as in the non-Charcot foot group.
- The Charcot foot group had very high adherence to wearing effectively offloading footwear, which may reduce plantar foot ulcer recurrence risk compared to when these conditions are not met. However, the Charcot foot group still experienced ulcer recurrence at a high rate, comparable to that of the non-Charcot foot group that had lower footwear adherence. Further improvements in footwear design and adherence may be required, among other options.

2 | PARTICIPANTS AND METHODS

2.1 | Study design

We conducted a cohort analysis of data obtained from a multicentre randomized controlled trial on the effectiveness of custom-made footwear to prevent plantar foot ulcer recurrence in people with diabetic foot disease (the Diabetic Foot Orthopedic Shoe (DIAFOS) trial).[20] Reporting is carried out according to the recommendations set out in the STROBE checklist for cohort studies (https://www.strobe-statement.org/).

2.2 | Participants

Participants from 10 outpatient clinics in the Netherlands were enrolled if they met the following inclusion criteria: type 1 or type 2 diabetes; age ≥18 years; loss of protective foot sensation as a result of peripheral neuropathy; and a recently healed plantar foot ulcer (<18 months prior to study entry). All participants received newly prescribed fully or semi custom-made footwear at study entry. Fully custom-made footwear comprises custom-made insoles worn in custom-made shoes, whereas semi custom-made footwear comprises custom-made insoles worn in off-the-shelf

diabetes-specific shoes. People with bilateral amputation proximal to the metatarsals, inability to walk unaided and comorbidity that would make 18 months' survival (i.e. the length of follow-up) unlikely, were excluded. Participants were randomized to either pressure-improved and preserved custom-made footwear, as guided by 3-monthly in-shoe plantar pressure measurements, or to usual care (i.e. non-improved custom-made footwear).

2.3 | Procedures

On entry into the trial, demographic and disease-related data were collected, a foot assessment was undertaken and barefoot and in-shoe plantar foot pressures were measured. In the participants with pressure-improved footwear, recorded in-shoe pressures were used to identify a maximum of three regions of interest per foot that were targeted for pressure improvement. These regions were the previous ulcer location and the two highest peak pressure locations in the forefoot or midfoot. If peak pressure exceeded 200 kPa, the footwear was subject to a maximum three rounds of modifications, with the goal of reducing peak pressure by at least 25% or to an absolute level below 200 kPa.[20] A detailed description of the modification protocol can be found elsewhere.[23] For the present study, the in-shoe pressure data *after* footwear modification at entry were used for analysis for the participants with pressure-improved footwear. For the usual care participants, the single measured in-shoe pressure data at entry were used. Each participant was followed for 18 months or until plantar foot ulcer recurrence. A foot ulcer was defined as a cutaneous erosion through the dermis without reference to time present.[24] Ulcer recurrence for the study was defined as an ulcer appearing on any plantar site on either foot in a person whose plantar foot ulcer had previously healed.

2.4 | Foot assessment

History of plantar foot ulceration and Charcot neuro-osteoarthropathy were confirmed via medical records that included foot and ankle radiographs. Midfoot Charcot deformity was diagnosed from clinical assessment by the participant's physician and from consensus between four investigators who assessed photographs of the foot. With the participant's foot weight-bearing, these photographs were taken from a medial, lateral, anterior and posterior view, and non-weight bearing from a medial, anterio-lateral and anterio-medial view. Other commonly encountered foot deformities were recorded in a similar fashion. The presence of peripheral neuropathy was diagnosed using methods and definitions described elsewhere.[20]

2.5 | Custom-made footwear

Participants wore and were tested for plantar pressure in their newly prescribed custom-made footwear and in the custom-made footwear they already possessed. Footwear was prescribed by a rehabilitation specialist and manufactured by a shoe technician in each of the participating centres; both specialist and technician were experienced in the management of people with diabetic foot disease. See elsewhere for technical details on the custom-made footwear.[20]

2.6 | Plantar pressure measurement and analysis

Barefoot dynamic plantar pressures were measured with an Emed-X pressure platform (Novel, Munich, Germany) at a 100-Hz sampling rate. The two-step method at a self-selected speed over five walking trials for each foot was used.[25] In-shoe dynamic plantar pressures were recorded at a 50-Hz sampling frequency using a Pedar-X in-shoe pressure measurement system (Novel, Munich, Germany). A minimum of 12 midgait steps per foot were collected at a self-selected walking speed, independent from the speed chosen for barefoot pressure measurement.[26] Pressure analysis was undertaken using Novel multimask software (version 13.3.65). The mean peak pressures at the previous ulcer location and, in case of ulcer recurrence, the new ulcer location, were used for analysis, as well as mean peak pressures for four anatomical foot regions: the heel, midfoot, forefoot (i.e. metatarsal 1–5) and toes (hallux, digits 2–5).

2.7 | Adherence

Footwear use and daily step activity were assessed objectively at least 3 months after baseline for 7 continuous days. Footwear use was measured with the @monitor (Department of Medical Technology and Innovation, Amsterdam UMC, Amsterdam, The Netherlands). This is a small temperature-based sensor that was placed inside the two pairs of custom-made shoes that the participant used most. The @monitor provides valid and reliable data.[27] Daily step activity was recorded simultaneously using an activity monitor strapped above the ankle (StepWatch; Orthocare Innovations LLC, Oklahoma City, OK, USA). Participants were instructed to wear the StepWatch at all times, except when having a shower or bath. Footwear adherence was calculated from these measurements and expressed as the percentage of cumulative steps taken in the 7-day period that custom-made footwear was worn. Participants recorded time spent away from home so that adherence could be calculated for both at-home and away-from-home periods.[21]

2.8 | Selection of participants and feet

Of the 171 trial participants, those wearing semi-custom-made footwear (n=28) were excluded for the present study, to match study groups on participants only wearing fully custom-made shoes. Participants with missing barefoot plantar pressure data (n=5) were also excluded. The remaining 138 participants were divided into two groups: those with Charcot midfoot deformity (Charcot foot group) and those without (non-Charcot foot group). All participants with Charcot foot diagnosis had midfoot deformity. One foot per participant was selected for barefoot and in-shoe pressure analysis. The foot with the highest degree of deformity was selected for the non-Charcot foot group. Foot deformity was classified as 'absent', 'mild' (i.e. pes planus, pes cavus, hallux valgus or limitus, hammer toes, lesser toe amputation), 'moderate' (i.e. hallux rigidus, hallux or ray amputation, prominent metatarsal heads, claw toes) or 'severe' (i.e. forefoot amputation and pes equines).[20] In case of equal degree of deformity, the foot with the highest barefoot peak pressure, irrespective of location, was chosen. Where both feet saturated the pressure platform at 1275 kPa, the left foot was selected. For the Charcot foot group, the affected foot was selected. One participant had bilateral Charcot; in this case, the foot with the highest barefoot peak pressure was included.

2.9 | Statistical analysis

Participant characteristics, barefoot and in-shoe peak pressure, footwear adherence and daily step activity were summarized using descriptive statistics. For normally distributed data, expressed as mean ± SD, independent sample t-tests were used to compare differences between study groups; for non-normally distributed data, expressed as median [interquartile range (IQR)], Mann–Whitney U-tests were used. Proportions of participants with a foot ulcer were compared using Fisher's exact test. P values <0.05 were considered significant, with Bonferroni correction applied in case of multiple testing of dependent variables. Statistical analyses were performed using SPSS 24.0 (SPSS Inc., Chicago, IL, USA).

2.10 | Ethics

All participants provided written informed consent prior to entering the trial. Ethical approval was obtained from the medical ethics committee of Amsterdam UMC, University of Amsterdam (project MEC07/133).

3 | RESULTS

3.1 | Group characteristics

Twenty participants in the Charcot foot group and 118 in the non-Charcot foot group were analysed and compared. Eight Charcot foot participants (40%) and 63 non-Charcot foot participants (53%) had pressure-improved custom-made footwear. Demographic and disease characteristics are shown in Table 1; no significant differences (after Bonferroni adjustment) were found between study groups, except for location of previous ulcers. Most previous ulcers in the non-Charcot foot group were found at the hallux and metatarsal head regions, and none in the midfoot. In the Charcot foot group, most previous ulcers were found at the metatarsal head 1 region and at the midfoot.

3.2 | Plantar pressure

Barefoot and in-shoe plantar pressure data are summarized in Table 2. Median (interquartile range) barefoot peak pressures in the midfoot were significantly higher in the Charcot foot group than the non-Charcot group [756 (260–1267) kPa vs 146 (100–208) kPa; P<0.001). No other region showed a significant group difference in barefoot peak pressure. In-shoe peak pressure at the midfoot was non-significantly higher in the Charcot foot group than non-Charcot group: 152 (104–201) kPa vs 119 (94–160) kPa. In-shoe peak pressures in the heel, forefoot, toes, and at the new ulcer location were significantly lower in the Charcot foot group (P<0.01).

3.3 | Adherence

Median (IQR) overall adherence to wearing the prescribed custom-made footwear was significantly higher in the Charcot foot group than the non-Charcot foot group: 95.3 (80.3–98.5)% vs 75.9 (54.9–90.2)%; P<0.001 (Table 3). In particular, adherence at home was different between groups: 94.4 (85.4–95.0)% for the Charcot foot group vs 64.3 (26.4–85.7)% for the non-Charcot foot group (P=0.001). Groups exhibited a comparable daily step count of approximately 6600 steps (P=0.82).

3.4 | Ulcer recurrence

Table 4 summarizes the data on plantar foot ulcer recurrence. Eight of the 20 participants (40%) in the Charcot foot group had a recurrent plantar ulcer in 18 months, vs 55 of the 118 (47%) participants in the non-Charcot foot group (P=0.63).

TABLE 1 Baseline participant characteristics

Characteristic	Charcot foot group	Non-Charcot foot group	*P*
Participants, *N*	20	118	-
Age, years	61.6 ± 8.8	63.2 ± 10.5	0.46
Male gender, *n* (%)	15 (75)	100 (85)	0.33
Median (IQR) BMI, kg/m^2	29 (26–33)	31 (27–34)	0.34
Type 2 diabetes, *n* (%)	13 (65)	84 (71)	0.60
Median (IQR) diabetes duration, years	18 (9–25)	12 (7–26)	0.48
HbA_{1c} (*N*=129)			
mmol/mol	68 ± 15	59 ± 15	0.02
%	8.4 ± 1.3	7.5 ± 1.4	0.02
Loss of protective sensation[b], *n* (%)			
Based on abnormal SW monofilament	20 (100)	116 (98)	1.00
Based on vibration perception threshold >25 volts (*N*=132)	17 (89)	98 (87)	1.00
Vibration perception threshold, volts (*N*=131)[c]	50 (48–50)	50 (43–50)	0.98
Peripheral artery disease (*N*=131)[d] , *n* (%)	5 (28)	40 (35)	0.79
Location previous ulcer, *n* (%)			
Hallux	3 (15)	32 (27)	0.40
Digits 2-5	3 (15)	23 (19)	0.77
Metatarsal 1	7 (35)	27 (23)	0.27
Metatarsal 2-5	0	31 (26)	<0.01[a]
Heel	0	1 (0.8)	1.00
Medial midfoot	5 (25)	0	<0.001[a]
Lateral midfoot	2 (10)	0	0.02
Base metatarsal 1-2	0	4 (3.4)	1.00

Abbreviations: IQR, interquartile range; SW, Semmes-Weinstein.

Data are expressed as mean ± SD, unless otherwise indicated.

[a]Significantly different between study groups ($P<0.01$, after Bonferroni correction).

[b]Loss of protective sensation was confirmed present in both feet by the inability to sense the pressure of a 10-g SW monofilament at any of the three plantar foot sites (hallux, first and third metatarsal head) or a vibration of 25 volts at the hallux from a biothesiometer (maximum measurable value 50 volts).

[c]In nine participants, the vibration perception threshold could only be measured in one foot because of hallux amputation.

[d]Peripheral artery disease was confirmed as present when pedal pulses were non-palpable and the ankle–brachial index was <0.9 in the foot that was selected for analysis. In seven participants, peripheral arterial disease data were missing.

In the Charcot foot group, seven of eight (88%) ulcers recurred in the same foot as where the previous ulcer was present, of which four (57%) recurred at the previous ulcer site. Four of the eight ulcers (50%) were in participants with pressure-improved footwear. In the non-Charcot foot group, 45 of 55 (82%) ulcers developed in the same foot as where the previous ulcer was present, of which 35 (78%) recurred at the previous ulcer site. Twenty-nine of 55 ulcers (53%) were in participants with pressure-improved footwear. In the Charcot foot group, significantly more plantar ulcers recurred at the midfoot than in the non-Charcot foot group (four of eight vs. one of 55, respectively; $P=0.001$). Two of four midfoot ulcers (50%) in the Charcot foot group and the midfoot ulcer in the non-Charcot foot group developed in participants with pressure-improved footwear.

4 | DISCUSSION

This study was a comprehensive analysis of biomechanical factors, treatment adherence behaviour, and plantar foot ulcer recurrence in people with Charcot midfoot deformity

TABLE 2 Barefoot and in-shoe plantar peak pressure data

	Charcot foot group	*n*	Non-Charcot foot group	*n*	*P*
Barefoot peak plantar pressure					
New ulcer location	752 (491–1079)	8	849 (503–1186)	55	0.82
Heel	299 (258–407)	20	327 (245–409)	118	0.66
Midfoot	756 (260–1267)	20	146 (100–208)	118	<0.001[a]
Forefoot	1066 (716–1253)	19	1091 (822–1238)	118	0.64
Toes	186 (83–447)	20	223 (95–331)	113	0.98
In-shoe peak plantar pressure					
New ulcer location	141 (92–190)	7	219 (167–306)	55	<0.01[a]
Heel	153 (125–197)	20	190 (163–223)	118	<0.01[a]
Midfoot	152 (104–201)	20	119 (94–160)	118	0.03
Forefoot	195 (125–216)	20	219 (178–287)	118	<0.01[a]
Toes	100 (65–165)	20	153 (114–202)	118	<0.01[a]

Data are expressed as median (interquartile range).

[a]Significantly different between study groups ($P<0.01$, after Bonferroni correction).

TABLE 3 Adherence and daily step count data

	Charcot foot group	*n*	Non-Charcot foot group	*n*	*P*
Adherence[b], %	95 (80–99)	17	76 (55–90)	103	<0.001[a]
Adherence at home[c], %	94 (85–95)	12	64 (26–86)	68	0.001[a]
Adherence away from home[c], %	100 (100–100)	12	99 (93–100)	68	0.03
Mean ± SD daily step count	6592 ± 3145	16	6600 ± 3447	111	0.82

Data are expressed as median (interquartile range), unless otherwise indicated.

[a]Significantly different between study groups ($P<0.02$, after Bonferroni correction).

[b]Adherence was not measured in 18 participants due to drop out ($n=4$), development of an ulcer during the trial ($n=9$), refusal to participate ($n=1$) or for other reasons ($n=4$).

[c]In an additional 40 participants, data on being at home or away from home, which was completed through daily logs, were missing.

compared with those without. Participants with Charcot midfoot deformity showed a significant 5.2-fold greater median barefoot peak pressure at the midfoot and a non-significant 1.3-fold greater median in-shoe peak pressure at the midfoot than non-Charcot foot participants. In-shoe midfoot peak pressures in the Charcot foot group were 80% lower than their barefoot peak pressures and nearly all were <200 kPa. At all other foot regions, in-shoe peak pressures in the Charcot foot group were significantly lower than in the non-Charcot foot group. The Charcot foot participants were significantly more adherent in wearing their custom-made shoes than the non-Charcot foot participants. This was especially the case when at home, with median values close to 100% in the Charcot foot group. The combination of low in-shoe peak pressure and very high footwear adherence in the Charcot foot participants may have helped reduce the incidence of ulcer recurrence. Still, a large proportion of Charcot foot participants had plantar foot ulcer recurrence, similar to the non-Charcot foot group; significantly more midfoot ulcers developed in the Charcot foot group.

The significantly higher barefoot and non-significantly higher in-shoe peak pressures found in the midfoot in the Charcot foot group can be expected from the major change in foot architecture. By losing the plantar arch as a result of bone, joint and soft-tissue damage, deformity occurs at the midfoot. This extends to the typical rocker bottom foot,[1] which was found in some of the Charcot foot participants in the study. Such midfoot (rocker bottom) deformity changes the structural weight-bearing surface and leads to increased load on the skin. This is attributable to, among other factors, an absence of a cushioning subcutaneous fat-pad. This can ultimately result in ulceration. The midfoot deformity is the characteristic difference between the

TABLE 4 Plantar foot ulcer recurrence data

	Charcot foot group (*N*=20) *n* (%)	Non-Charcot foot group (*N*=118) *n* (%)	*P*
Ulcer recurrence	8 (40)	55 (47)	0.63
Same foot, same site	4 (50)	35 (64)	
Same foot, other site	3 (38)	10 (18)	
Contralateral foot	1 (13)	10 (18)	
Location ulcer recurrence			
Hallux	0	16 (29)	0.10
Digits 2–5	0	5 (9)	1.00
Metatarsal 1	2 (25)	12 (22)	1.00
Metatarsal 2–5	2 (25)	21 (38)	0.70
Heel	0	0	
Medial midfoot	4 (50)	1 (2)	0.001*
Lateral midfoot	0	0	
Base metatarsal 1–2	0	0	

*Significantly different between study groups ($P<0.01$, after Bonferroni correction).

Charcot foot and non-Charcot foot groups, and possibly the sole biomechanical difference, as barefoot peak pressures in other foot regions were similar between groups. The highest barefoot and in-shoe peak pressures in both groups were found under the metatarsal heads, as observed previously.[28] This suggests that, while the midfoot is targeted for offloading in people with Charcot midfoot deformity, pressure redistribution over the entire plantar surface is important. Our data show this can be effectively achieved with custom-made footwear.

Footwear adherence in the Charcot foot group was significantly higher than in the non-Charcot group, especially when participants were at home. Overall median adherence was close to 100% in the Charcot foot group, with some non-adherence only found when participants were at home. A possible explanation for the very high adherence may be that, with midfoot deformity, the base of support is reduced when barefoot. This may further increase the balance disturbance already caused by the neuropathy. Therefore, by necessity, these people may increase their base of support by wearing their custom-made footwear. Alternatively, the prolonged periods of casting in the acute phase of Charcot neuro-osteoarthropathy (up to 9 months) may have made this group more aware of the risk of complications, the loss of mobility and decline of quality of life, and thus more motivated to wear their prescribed footwear.

Incidence of plantar foot ulcer recurrence was not significantly different between groups and similar to rates found in other studies of high-risk people with diabetes.[22] Comparisons with other studies in people with Charcot foot are hampered by a wide variation in follow-up periods, patient inclusion criteria and footwear provided.[15,17,18] More ulcers in the Charcot foot group recurred at the midfoot than in the non-Charcot foot group: 50% vs 2%. The higher midfoot peak pressures, combined with previous ulcer history at the midfoot in 35% of Charcot participants best explains this. The other 50% of foot ulcers in the Charcot foot group recurred at the metatarsal heads, where barefoot peak pressures were also high. The trial from which the present data were obtained showed that high footwear adherence, in combination with improved and low in-shoe peak pressures, substantially reduces risk for plantar foot ulcer recurrence in high-risk people with diabetes.[20,29] Thus, the close to optimal footwear adherence and seemingly low in-shoe peak pressures may have protected against ulcer recurrence compared to when these conditions would not have been met. Nevertheless, the incidence of ulcer recurrence in the Charcot foot group was still high and not different from that in the non-Charcot foot group. A number of factors may play a role here. Firstly, while the in-shoe midfoot peak pressures were reduced by 80% from barefoot, they still may have been too high to help prevent ulceration effectively. A target pressure that is advocated for footwear provision is 200 kPa,[20,29,30] but this pressure threshold was defined based on pressures measured in the forefoot. A different threshold may apply to the midfoot, being more vulnerable after a major change in foot architecture and lack of protective subcutaneous fat tissue present. Secondly, despite the close to optimal adherence outcomes, the few percent non-adherence remaining at home may have left the Charcot foot participants unprotected and with increased risk for ulcer recurrence. Further improvements in midfoot offloading and footwear adherence may be needed and should be further investigated. Also other factors related to bone, joint and soft tissue involvement (i.e. strength, movement, extensibility), shear and vascular components,

and the effect of surgical reconstruction of the foot should be further studied. Clinicians should therefore regard offloading and adherence as only two of a number of issues that need to be addressed to help prevent plantar foot ulcer recurrence in people with Charcot midfoot deformity.

A strength of the present study is that objective biomechanical and behavioural measures are used in a comprehensive analysis of plantar foot ulcer recurrence in a homogeneous group of people with Charcot midfoot deformity. Few studies exist on the management of the Charcot foot beyond the acute phase, despite its importance given the associated morbidity and mortality. The limitations of the study mainly originate from using existing data from a randomized controlled trial on footwear efficacy.[20] This determined the imbalance between groups, with 20 Charcot foot participants and 118 non-Charcot foot participants. This is, however, in line with the low incidence of Charcot neuro-osteoarthropathy in the diabetes population. Furthermore, being a clinical trial, we did not randomly include people with Charcot foot from the general patient population; neither did we include people with Charcot foot who had no plantar foot ulcer history. These factors may affect footwear adherence and ulcer outcome. Also, we relied heavily on peak pressure as an outcome of Charcot midfoot deformity. While many bony and soft tissue changes will show as a change in peak pressure, factors such as shear and small vessel blood flow are probably also important in skin breakdown. Finally, approximately half of the participants had pressure-improved footwear, which potentially biases the in-shoe pressure results within study groups, in particular, in the already-small Charcot foot group. This is not expected, however, to influence the comparison between study groups as the proportion of participants with pressure-improved footwear was comparable between groups and because peak pressures in improved and non-improved footwear showed substantial overlap.

In conclusion, our findings show effective offloading of pressures inside custom-made footwear and very high adherence to wearing this footwear in people with diabetes at high risk of foot ulceration who have Charcot midfoot deformity. While this may have reduced plantar foot ulcer recurrence incidence compared to less effective or less worn footwear, incidence of recurrence was comparable to high-risk people without Charcot foot who showed higher in-shoe peak pressures and lower adherence. Further improvements in adherence and custom-made footwear design that include the use of region-specific target pressures may be required, among other options, to improve clinical outcomes in people with diabetes and Charcot midfoot deformity.

COMPETING INTERESTS

None declared.

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