

Adherence to Wearing Prescription Custom-Made Footwear in Patients With Diabetes at High Risk for Plantar Foot Ulceration

ROELOF WAAIJMAN, MSC¹
RENSKE KEUKENKAMP, MSC¹
MIRJAM DE HAART, MD, PHD¹

WOJTEK P. POLOMSKI, MD²
FRANS NOLLET, MD, PHD¹
SICCO A. BUS, PHD^{1,3}

OBJECTIVE—Prescription custom-made footwear can only be effective in preventing diabetic foot ulcers if worn by the patient. Particularly, the high prevalence of recurrent foot ulcers focuses the attention on adherence, for which objective data are nonexistent. We objectively assessed adherence in patients with high risk of ulcer recurrence and evaluated what determines adherence.

RESEARCH DESIGN AND METHODS—In 107 patients with diabetes, neuropathy, a recently healed plantar foot ulcer, and custom-made footwear, footwear use was measured during 7 consecutive days using a shoe-worn, temperature-based monitor. Daily step count was measured simultaneously using an ankle-worn activity monitor. Patients logged time away from home. Adherence was calculated as the percentage of steps that prescription footwear was worn. Determinants of adherence were evaluated in multivariate linear regression analysis.

RESULTS—Mean \pm SD adherence was $71 \pm 25\%$. Adherence at home was $61 \pm 32\%$, over $3,959 \pm 2,594$ steps, and away from home $87 \pm 26\%$, over $2,604 \pm 2,507$ steps. In 35 patients with low adherence ($<60\%$), adherence at home was $28 \pm 24\%$. Lower BMI, more severe foot deformity, and more appealing footwear were significantly associated with higher adherence.

CONCLUSIONS—The results show that adherence to wearing custom-made footwear is insufficient, particularly at home where patients exhibit their largest walking activity. This low adherence is a major threat for reulceration. These objective findings provide directions for improvement in adherence, which could include prescribing specific off-loading footwear for indoors, and they set a reference for future comparative research on footwear adherence in diabetes.

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Custom-made footwear is recommended and often prescribed to patients with diabetes, peripheral neuropathy, and foot deformity to prevent foot ulceration and further complications such as infection and amputation (1). Elevated plantar pressures and ill-fitting footwear are important risk factors of ulceration (2,3). Custom-made footwear aims to reduce ulcer risk by reducing foot pressures and providing proper fit (4–6). It is clear that to be effective in ulcer

prevention, prescription footwear should be worn by the patient, in particular when being ambulant (7). Because annual ulcer recurrence rates are high, up to 40% found in one study (8–10), poor adherence may be a factor in this outcome. Patient self-report studies show that only 22–36% of diabetic patients with peripheral neuropathy, vascular disease, or foot deformity wear prescription footwear regularly ($>80\%$ of the day) (11,12). This is unfortunate, since it has been

shown that ulcer recurrence rate can be substantially reduced when patients adhere to wearing pressure-relieving footwear (13). Nonadherence is therefore a major issue in high-risk diabetic patients that determines clinical outcome.

To date, adherence to footwear use has been assessed using subjective methods, including questionnaires, face-to-face interviews, or diaries (11–14). Subjective methods are known to have issues with accuracy and reliability and may lead to a response bias or to missing data (15–17). Furthermore, these methods do not accurately distinguish between active and nonactive periods. In removable below-the-knee walkers used for off loading diabetic foot ulcers, adherence was measured objectively (18), but the accelerometer-based sensors used were not developed to fit inside a shoe. Therefore, we use a new adherence-to-treatment monitoring system (the @monitor, developed at the Academic Medical Center in Amsterdam), which is small enough to fit inside the patients' shoe and has been proven to be valid and reliable in determining moments of donning/doffing and feasible in use in diabetic foot patients (19).

Objective data on footwear adherence in patients who have diabetes and are at high risk for ulceration are not available. Adherence is most appropriately obtained during ambulation, when pressures on the foot are highest. Furthermore, adherence may vary according to where the patient is (at home or away from home) (14) or according to what day of the week or time of day it is. Knowledge about adherence and about what determines adherence is valuable in addressing issues of footwear effectiveness and can direct or may even reform footwear prescription practice. Therefore, the aim of this study was to objectively assess adherence to wearing prescribed custom-made footwear during ambulation in patients with diabetes at high risk for ulceration and to assess the determinants of adherence in this patient group.

From the ¹Department of Rehabilitation, Academic Medical Centre, University of Amsterdam, Amsterdam, the Netherlands; the ²Department of Rehabilitation, Spaarne Hospital, Hoofddorp, the Netherlands; and the ³Department of Surgery, Hospital Group Twente, Almelo, the Netherlands.

Corresponding author: Sicco A. Bus, s.a.bus@amc.uva.nl.

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RESEARCH DESIGN AND METHODS

Patients were selected from the database of a randomized controlled trial on custom footwear effectiveness (DIAbetic Foot Orthopedic Shoe [DIAFOS], clinical trial reg. no. NTR1091), in which patients were consecutively recruited from the outpatient multidisciplinary foot clinics of 10 Dutch hospitals. The first 120 patients in this trial who were assessed for adherence were included in the current study. Inclusion criteria were diagnosed diabetes, loss of protective sensation as confirmed by 10-g Semmes-Weinstein monofilament and vibration perception threshold testing (20), a prior plantar forefoot or mid-foot ulcer that healed in the 18 months before inclusion in the trial, and prescription custom-made footwear. Exclusion criteria were bilateral amputation proximal to the tarso-metatarsal joint, nonambulatory status, unlikelihood to survive 18 months' follow-up, and inability to follow the study instructions. Written informed consent was obtained from each patient prior to inclusion in the trial, which was approved by all involved local research ethics committees.

Footwear

Patients wore fully custom-made footwear (i.e., custom insoles in custom shoes) or semi-custom-made footwear (i.e., custom insoles in off-the-shelf extra-depth shoes). The footwear was prescribed by a rehabilitation medicine specialist and manufactured by a shoe technician, both of whom were experienced in treating diabetic foot patients. Shoes were mostly ankle high or boot style and were in some cases tibia high. The footwear generally had a stiffened rubber outsole with roller configuration and multidensity insoles.

Instrumentation

Data on footwear use were collected using a temperature-based adherence-to-treatment monitor, the @monitor, which has previously been described in detail (19). In short, the @monitor measures 35 × 15 × 5 mm (length × width × height) and integrates two digital-to-digital temperature sensors (one on each flat side of the monitor), a battery, and a data logger. The @monitor samples temperatures at a maximum 1-min interval giving a 14-day collection period. The @monitor is placed in a plastazote foam pad and taped to the inner lateral shoe border just below ankle level. Only thin adhesive tape (covering

the @monitor) and the patient's sock separate the @monitor from the leg. Because the temperature difference across the @monitor when wearing the footwear is unequal to the temperature difference when not wearing the footwear, footwear use can be determined. Response of the @monitor to donning and doffing footwear is immediate, with temperature change present at the next measurement sample. The @monitor has been shown to be accurate in determining moments of donning and doffing of footwear (mean 0.4-min difference with an accurately kept log [95% CI 0.2–0.6]) and feasible for use by high-risk diabetic patients (19). Using a docking station and custom software, start date and time, number of days of data collection, and sample frequency are defined. Temperature readouts are exported to a text file after data collection.

Ambulatory activity was recorded using a step activity monitor (StepWatch; Orthocare Innovations), which was strapped to the lateral side of the leg above the ankle. The step activity monitor stores the number of steps per minute over a maximum period of 14 days. Measurement accuracy is optimized by personalizing body height and type of gait of the patient (normal, fast, and slow) in the settings of the monitor and verified by a light on the monitor that blinks at each of the first 40 steps taken by the patient after initialization. The error between counted steps and measured steps with the StepWatch is 0.3% (21).

Procedures

At baseline, demographic, socioeconomic, disease-related, and foot complication history data were collected and a foot examination was performed. Each patient received brochures and standard verbal information from the researcher on diabetic foot care and the need to wear prescribed footwear as much as possible, preferably with each step taken. Because of the break-in period of footwear, data on adherence were collected a minimum of 3 months after footwear delivery. Three months after footwear delivery, perceived footwear aesthetics and comfort were scored on a visual analog scale using the Questionnaire of Usability Evaluation (22).

To avoid change in behavior of the patient during the measurement, patients were informed that foot temperature (not adherence) would be measured. The sample frequency of the @monitor was set at the maximum one sample per minute.

Both the @monitor and the step activity monitor were synchronized to local time on the same personal computer before each measurement. Shoes were equipped with the @monitor, and the step activity monitor was strapped to the ankle. If a patient had more than one pair of prescription custom-made shoes, a second pair was also equipped with the @monitor. If a patient had more than two pairs of prescription shoes, the patient was asked to wear only those two pair equipped with the @monitor. Each patient was asked to wear the step activity monitor for seven consecutive full days, at all times, except when taking a shower or bath or when discomfort was felt. Patients were also instructed not to remove the @monitor from the shoes. Additionally, they were asked to write down in a daily log the time periods (from [hh:mm] to [hh:mm], where h is hour and m is minute) that they were away from home, were cycling, or did not wear the step activity monitor. Patients returned the monitors and log after the measurement through postal mail.

Data analysis

Recordings with <4 days of step activity or without a weekend day included were considered incomplete and were excluded from analysis. The @monitor and step activity monitor data were analyzed using Matlab R2011a software (MathWorks, Natick, MA) (19). For patients with two pairs of custom-made shoes in the study, data were accumulated. For each measurement day, step count and total wearing time were calculated. Adherence was calculated from the cumulative number of steps over the full measurement period as follows:

$$\text{Adherence} = \frac{\sum \text{steps wearing prescribed footwear}}{\sum \text{steps}}$$

When step activity was recorded during periods that the @monitor did not record footwear use, it was assumed that the patient walked either barefoot or in non-prescription footwear. The reported time periods in the daily log for cycling were used to filter the step count data to keep walking-only data. Reported time in the daily log for being away from home was used to separate step count, wearing time, and adherence data for periods at home and for periods away from home. Subgroup analyses were done for patients

with adherence $\geq 80\%$ (adherence_{high}) and adherence $< 60\%$ (adherence_{low}). To compare outcomes with previous studies that used subjective methods, we also calculated adherence as percentage of daytime that the prescription footwear was worn. We assumed out-of-bed daytime to be 16 h.

Determinants of adherence

As potential determinants of adherence, the following factors were taken into account: age, sex, education level (low, medium, and high), living status, employment, diabetes type, diabetes duration, cumulative months of past ulceration, history of amputation, presence of peripheral arterial disease, BMI, HbA_{1c}, severity of foot deformity, daily step count, variation in daily step count over the measurement period, type of footwear, and perceived footwear aesthetics and footwear comfort.

Statistical analysis

All statistical analyses were performed using IBM SPSS Statistics version 19 (SPSS, Chicago, IL). Mann-Whitney *U* tests assessed baseline differences between included and excluded patients. Descriptive analyses were done on baseline patient characteristics and on outcomes for wearing time, adherence, and step activity. Paired *t* tests assessed differences in adherence between being at home and away from home and between weekdays and weekend days. One-way ANOVA tested for differences in adherence between participating centers and between patient subgroups (adherence_{high} vs. adherence_{low}). Pearson correlation coefficients were calculated between adherence and wearing time and between adherence and daily step

count. For all of the above tests, a significance level of $P < 0.05$ was used. Univariate regression analysis ($P < 0.10$) was used to assess the association between variation in step count and time away from home and to assess factors significantly associated with adherence. Significant univariate factors were entered in a multivariate regression analysis of adherence (with backward selection, $P < 0.10$).

RESULTS—Thirteen of the 120 included patients were excluded from analysis because of incomplete (< 4 days) step activity data ($N = 10$), technical failure ($N = 2$), or refusal to wear the step activity monitor ($N = 1$). Baseline characteristics did not differ significantly between excluded and analyzed patients, except for sex (relatively more women were excluded, $P = 0.018$).

Of the remaining 107 patients, 93 (87%) were men, 103 (96%) were Caucasian, 76 (71%) had type 2 diabetes, and 89 (83%) wore fully custom-made footwear. Mean \pm SD age was 63.8 ± 9.6 years and diabetes duration 17.3 ± 11.9 years. Thirty-five patients had one pair of prescription custom-made shoes, and 72 had two pairs. Footwear age at assessment of adherence was 1.4 ± 0.9 years. We had 6.5 ± 0.9 days of analyzed data per patient. Seventy-nine patients (74% of total group) had complete reports of time spent away from home. The step activity monitor was not worn during $3.5 \pm 9.6\%$ of the day, and nonuse occurred mostly at night. Patients donned and doffed their footwear 1.3 ± 0.9 times/day.

Outcome data for step count and adherence are shown in Table 1. Footwear adherence was $71 \pm 25\%$ (range 10–100%). When patients were at

home, adherence was significantly lower than when away from home ($P < 0.001$), while daily step count was significantly higher at home ($P < 0.001$). Adherence was $< 60\%$ between 8 P.M. and 10 A.M. and below 40% between midnight and 8 A.M. (Fig. 1). Both adherence and step count were significantly lower during weekend days than weekdays ($P < 0.001$). Adherence and daily step count were not significantly correlated ($r = 0.14$, $P = 0.16$). Correcting for cycling had a negligible effect on adherence.

Patients wore their prescribed footwear 9.4 ± 4.4 h/day, at home 6.4 ± 4.6 h, and away from home 3.5 ± 2.7 h. Wearing time was $59 \pm 27\%$ of daytime. Twenty-nine percent of patients wore their prescription footwear $> 80\%$ of daytime. Wearing time was significantly correlated with adherence ($r = 0.87$, $P < 0.001$). Adherence was not significantly different between participating centers ($P = 0.16$), and neither was daily step count ($P = 0.35$) or wearing time ($P = 0.59$). Day-to-day variation in step count increased significantly when patients were more away from home ($\beta = 181$ steps/h [95% CI 80–282], $P < 0.001$).

Thirty-three percent of the patients had adherence $< 60\%$ (Fig. 2). In this adherence_{low} group, adherence was $40 \pm 15\%$ and was 2.5 times higher for away from home than for at home (Table 1). In the adherence_{high} group, adherence was $85 \pm 12\%$ and was 1.1 times higher for away from home than for at home. Daily step count was not significantly different between the adherence subgroups ($P = 0.19$) (Table 1).

In the univariate regression analysis, a lower BMI, a history of amputation, more severe foot deformity, more variation in

Table 1—Data on daily step count and adherence

	Daily step count			Adherence (%)		
	Total group	Adherence _{low} group	Adherence _{high} group	Total group	Adherence _{low} group	Adherence _{high} group
Full measurement period (N = 107)	6,397 \pm 3,494	5,849 \pm 3,720	6,885 \pm 3,543	71 \pm 25	40 \pm 15	92 \pm 6*
Walking only (N = 107)	5,967 \pm 3,129	5,505 \pm 3,301	6,300 \pm 3,199	71 \pm 25	40 \pm 15	91 \pm 7*
Cycling only (N = 28)	1,642 \pm 1,647	1,507 \pm 1,388	1,790 \pm 1,813	78 \pm 37	44 \pm 39	94 \pm 24*
At home (N = 79)	3,959 \pm 2,594††	3,988 \pm 2,131††	3,917 \pm 2,947	61 \pm 32††	28 \pm 24††	83 \pm 17*†
Away from home (N = 79)	2,604 \pm 2,507	1,867 \pm 2,661	3,051 \pm 2,441	87 \pm 26	69 \pm 31	95 \pm 22*
Weekday (N = 107)	6,686 \pm 3,573	5,959 \pm 3,543	7,252 \pm 3,761	72 \pm 25	42 \pm 17	92 \pm 6*
Weekend day (N = 107)	5,734 \pm 3,628#	5,542 \pm 4,160	6,056 \pm 3,545#	66 \pm 30#	34 \pm 24	89 \pm 11*#

Data are means \pm SD. Adherence_{high} group, adherence $\geq 80\%$; adherence_{low} group, adherence $< 60\%$. * $P < 0.001$, significantly different from the adherence_{low} group. † $P < 0.05$. †† $P < 0.01$, significantly different from away from home. # $P < 0.05$, significantly different from weekday.

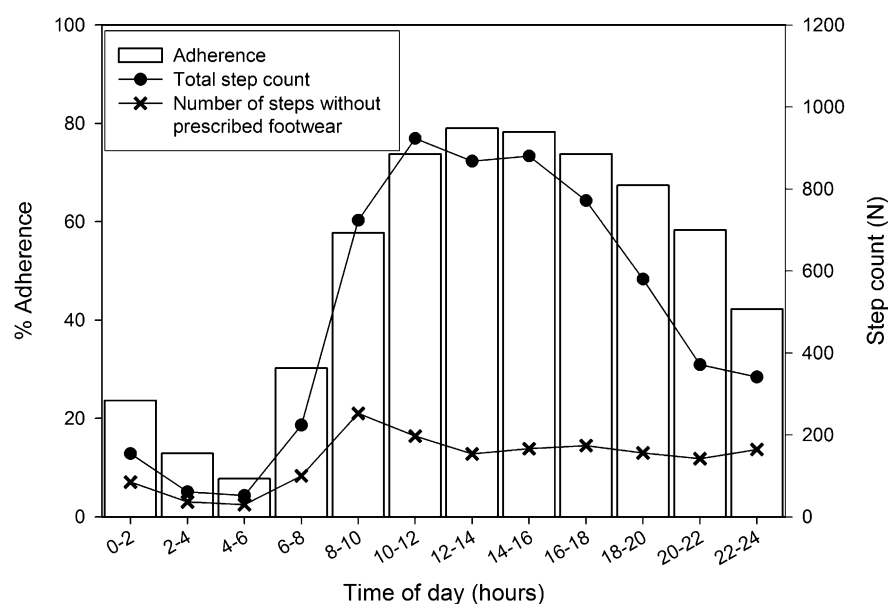


Figure 1—Mean adherence, total step count, and the number of steps taken without wearing prescribed footwear during 2-h time slots over the day.

daily step count, and a better perception of footwear aesthetics were significantly associated with higher adherence (Table 2). In the multivariate analysis, all of these factors except history of amputation remained significant ($R^2 = 0.18$, $P < 0.10$) (Table 2).

CONCLUSIONS—Adherence to wearing prescription custom-made footwear is important to prevent ulceration in

high-risk patients with diabetes. With use of objective methods to measure adherence, the study results showed that 71% of the steps taken were in prescription custom-made footwear, while, among individuals, differences in adherence were large (10–100%). Adherence was much lower at home than away from home, which substantiates earlier studies that use subjective data (14). In particular, in the patient group with low

adherence (<60%), adherence at home was poor (28% compared with 69% away from home). Patients were significantly more active at home than away from home, which corresponds with previous data (23). This further amplifies the problem of footwear use at home, increasing the cumulative stress on an inadequately protected foot. Therefore, interventions aimed to increase adherence should primarily target the home situation, e.g., through the prescription of special off-loading footwear for indoors.

When calculating adherence in similar units to what most previous studies did, our results show that 29% of the patients wore their prescribed footwear >80% of the daytime. This is comparable with earlier studies that used mailed questionnaires (with a less-than-optimal response rate) and face-to-face interviews and that showed that 22–36% of diabetic patients at risk for ulceration wear their prescription footwear all day (11,12) or for at least >80% of daytime (14). These consistent outcomes across studies reinforce the problem of nonadherence in this patient group. Furthermore, they show that interpretations may vary based on which method is chosen to report adherence (percentage of daytime versus percentage of steps). A major disadvantage of subjective methods is that they lack the sensitivity, accuracy, and reliability to measure adherence during ambulant and non-ambulant periods added with the risk of reporting bias. Therefore, these methods lack the ability to accurately assess adherence when it is most important, namely, when the foot is loaded most. This strongly supports the use of objective methods to assess true adherence in a patient. Using these methods, our study still showed that on average, 29% of steps were taken without wearing custom-made footwear. Nonadherence was largest during the late-evening, night, and early-morning hours, when patients may walk more on a hard bathroom or kitchen floor. This further increases the risk for ulcer recurrence.

The multivariate regression analysis showed that patients with more severe deformity had higher adherence to prescribed footwear—maybe because these patients have no other choice than to wear custom-made footwear or because they are more aware of its benefits. Patients with higher BMI were less adherent, which may reflect overall difficulty with adhering to a healthy lifestyle in overweight or obese patients. More day-to-day variation in activity was positively associated with adherence, probably because patients who spent

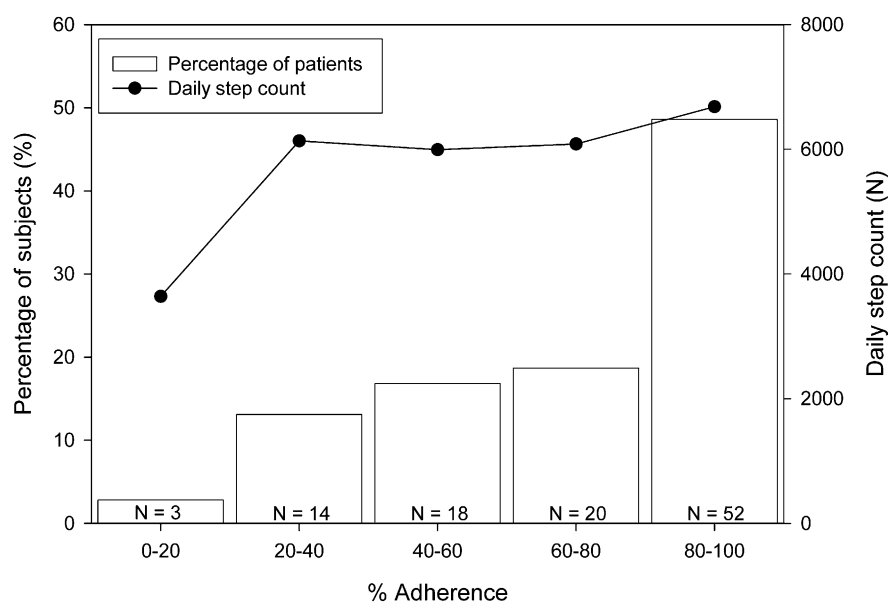


Figure 2—Distribution of patients across five subgroups of adherence. Also shown is the mean daily step count for each subgroup.

Table 2—Outcomes for the univariate and multivariate regression analysis on determinants of adherence

Variable	N or means ± SD	Univariate regression		Multivariate regression	
		β (95% CI)	P	β (95% CI)	P
Age (years)	63.8 ± 9.6	0.120 (−0.380 to 0.620)	0.639		
Sex (male/female)	93/14	4.263 (−9.833 to 18.359)	0.555		
Diabetes type (1/2)	31/76	−5.408 (−15.855 to 5.039)	0.313		
Diabetes duration (years)	17.3 ± 11.9	0.080 (−0.324 to 0.484)	0.701		
BMI (kg/m ²)	31.1 ± 6.0	−0.939 (−1.717 to −0.161)	0.020*	−0.747 (−1.544 to 0.051)	0.066*
PAD grade (I/II) ^a	60/45	7.324 (−2.288 to 16.936)	0.138		
HbA _{1c} (%)	7.4 ± 1.4	0.297 (−3.284 to 3.878)	0.871		
Cumulative past ulcer months [log(months)]	2.00 ± 1.18	0.491 (−3.639 to 4.621)	0.816		
History of amputations (no/yes)	69/38	11.017 (1.291–20.743)	0.029*		
Severity of deformity (no/mild/moderate/severe) ^b	4/37/50/16	8.615 (2.464–14.766)	0.006*	6.831 (0.545–13.118)	0.034*
Education level (low/medium/high)	63/21/23	−1.796 (−7.629 to 4.037)	0.548		
Living with others (no/yes)	29/78	4.16 (−6.524 to 14.844)	0.447		
Employed (no/yes)	82/25	−3.44 (−14.807 to 7.923)	0.549		
Daily step count (per 1,000 steps)	6,397 ± 3,494	0.985 (−0.901 to 2.870)	0.158		
Variation in daily step count (per 1,000 steps)	2.101 ± 1.411	3.956 (0.651–7.261)	0.021*	3.655 (0.307–7.003)	0.033*
Type of footwear (fully custom made/semi-custom made)	89/18	−1.747 (−14.621 to 11.127)	0.788		
Perceived footwear aesthetics (VAS score)	6.8 ± 2.6	1.861 (−0.025 to 3.747)	0.056*	1.975 (0.176–3.775)	0.032*
Perceived footwear comfort (VAS score)	8.1 ± 1.8	−0.226 (−2.988 to 2.536)	0.873		

Data are N or means ± SD for descriptive data and unstandardized linear regression coefficients (95% CIs) for regression analysis. PAD, peripheral arterial disease; VAS, visual analogue scale. *Significant association (P < 0.10). ^aPresence of peripheral arterial disease was classified according to a diabetic foot ulcer classification system for research purposes (ref. 27). ^bSeverity of deformity was classified as “no,” “mild” (i.e., presence of pes planus, pes cavus, hallux valgus, hammer toes, or lesser toe amputation), “moderate” (i.e., hallux or ray amputation, prominent metatarsal heads, or claw toes), or “severe” (i.e., Charcot deformity or [fore]foot amputation). The most severe deformity present determined classification.

more time away from home (higher adherence) were the ones more variable in activity. Finally, patients who perceived their footwear as more attractive were more adherent, which seems intuitive, although previous studies are inconclusive on this association (14,24). Despite these significant associations, overall explained variance in adherence was only 18%, which implies that optimizing any of these predicting factors may have a limited effect on adherence. More research is needed to further elucidate why patients are adherent or not.

The objective data collected on adherence provide an excellent basis for further exploration of predictors of adherence and have great value in guiding footwear prescription practice and diabetic foot treatment. In many chronic diseases, adherence to treatment is a major problem and influenced by social and economic factors, the health care team, disease characteristics, therapy, and patient-related factors (25). Therefore, objective footwear adherence data could be used to assess patient groups with different social-economic or cultural backgrounds, ethnicity, or past experiences with foot

complications. Assessment of adherence in different regions or at different centers may provide information on more or less successful prescription and health care practices. Effects of patient education and other interventions can be accurately determined. Finally, objective adherence data could be used to explore reasons for non-adherence and to individualize type and frequency of footwear prescription (19). Effectively, these analyses could shape and potentially reform the prescription and use of specialist diabetic footwear.

Some limitations apply. First, we did not measure adherence while standing, even though patients spend twice as much time standing than walking (26) and forces equal to body weight are applied to the foot. Custom-made footwear was worn 9.4 h/day and was strongly associated with adherence. We therefore suggest that adherence may be as high in standing as in walking. Second, we measured adherence objectively, but we were still dependent on daily kept logs to determine periods of cycling, being away from home, and nonuse of the step activity monitor. This increases the chance for

missing data or unreliable data. More objective ways to evaluate these events should be further explored, as well as methods to assure that patients do not take off the step activity monitor during measurement. Nonuse of the step activity monitor may under- or overestimate adherence. We verified from the daily kept logs that nonuse occurred only during 3.5% of the day, suggesting a negligible impact on the adherence values. Third, we attempted to avoid a conscious change in behavior by blinding the patient for the goal of the measurement, but we have no confirmation of whether we succeeded. Finally, we did not measure adherence to wearing nonprescription footwear (e.g., off-the-shelf shoes, sandals, slippers), and therefore we lack information on the amount of barefoot walking, which is the most hazardous walking condition.

In conclusion, the results show that adherence to wearing prescribed custom-made footwear is insufficient in neuropathic diabetic patients with prior foot ulceration, in particular at home where they exhibit their largest walking activity. This low adherence is a major threat for

reulceration in this high-risk patient group. Improvement of adherence could therefore include the prescription of specific protective footwear for indoors, while the importance of wearing prescription footwear should be further promoted. The objective data collected on adherence have great value in guiding clinical practice and provide an excellent basis to further explore predictive factors of adherence, to perform comparative research, and to investigate interventions that aim to improve adherence.

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