Improving footwear to prevent ulcer recurrence in diabetes: Analysis of adherence and pressure reduction
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Chapter 3

NEW MONITORING TECHNOLOGY TO OBJECTIVELY ASSESS ADHERENCE TO PRESCRIBED FOOTWEAR AND ASSISTIVE DEVICES DURING AMBULATORY ACTIVITY

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ABSTRACT

Objective: To assess the validity and feasibility of a new temperature-based adherence monitor to measure footwear use.

Design: Observational study.

Setting: University medical center and participants’ homes.

Participants: Convenience sample of healthy subjects (n = 11) and neuropathic diabetic patients at high risk for foot ulceration (n = 14).

Interventions: In healthy subjects, the validity of the in-shoe attached adherence monitor was investigated by comparing its registrations of donning and doffing of footwear during 7 days to an accurately kept log registration. In diabetic patients, the feasibility of using the adherence monitor for seven days in conjunction with a time-synchronized ankle-worn step activity monitor to register prescribed footwear use during walking was assessed. Furthermore, a usability questionnaire was completed.

Main Outcome Measures: For validity, the mean time difference and 95% confidence interval (CI) between moments of donning/doffing footwear recorded with the adherence monitor and in the log were calculated. For feasibility, technical performance, usability, and the percentage of steps that the footwear was worn (adherence) were assessed.

Results: The mean time difference between the adherence monitor and log recordings was 0.4 minutes (95% CI, 0.2 - 0.6 min). One erroneous and 2 incomplete recordings were obtained in diabetic patients. Three patients reported discomfort with the step activity monitor, and 4 patients would not favor repeated testing. Patients used their footwear for between 9% and 99% of their walking steps.

Conclusions: The adherence monitor shows good validity in measuring when footwear is used or not, and is, together with instrumented monitoring of walking activity, a feasible and objective method to assess treatment adherence. This method can have wide application in clinical practice and research regarding prescribed footwear and other body-worn assistive devices.
INTRODUCTION

In different fields of medicine, patient adherence to prescribed treatment is important to assure treatment efficacy. This includes the use of assistive devices in rehabilitation, such as prescription footwear, removable offloading devices, and upper and lower limb orthoses. In patients with diabetic foot disease, studies have shown that only 22% to 28% of these patients wear their prescribed footwear more than 80% of the daytime\textsuperscript{1,2}. Also, in cases of active foot ulceration, diabetic patients may wear their prescribed cast walker only 28% of the steps taken during the day\textsuperscript{3}. Possibly, this reduced adherence explains the lower efficacy of these devices to heal foot ulcers when compared to nonremovable offloading devices\textsuperscript{3,4}. Clearly, nonadherence is a problem in patients with diabetic foot disease.

Adherence is traditionally assessed through patient reporting, diary recordings, or by observing wear and tear of the worn device. These subjective or semiquantitative methods, however, lack sensitivity and increase the risk of reporting bias and missing data\textsuperscript{5-7}. Several objective methods, mostly based on temperature or pressure readings, have previously been developed, in particular for assessment of spine orthosis use in scoliosis patients\textsuperscript{5,8-10}. In offloading treatment of the diabetic foot, accelerometer-based activity monitors have been used for this purpose\textsuperscript{3,11}. However, because to their weight and size, these monitors were not intended for use inside footwear. The Department of Medical Technological Innovation and Development of the Academic Medical Centre in Amsterdam developed and manufactured an adherence to treatment monitor, which is small enough to fit inside the patients’ shoe and potentially can be used with almost any other body worn assistive device. The system incorporates 2 temperature sensors, a data logger, and a battery in the same plastic housing. The adherence monitor can be combined with existing methods of activity monitoring to determine adherence to treatment during weight-bearing ambulatory activity.

For the adherence monitor to have wide application in research and clinical practice, it must accurately discriminate between time periods of use and nonuse of the assistive device. This requires sensitive sensors, sufficiently high sample frequencies, multiple day measurements, and protection against loads from the body. Furthermore, the adherence monitor should be safe and easy to use and should measure what it intends to measure, namely treatment adherence. The goal of this study was to assess the validity of the adherence monitor to measure footwear use in healthy subjects and to assess the feasibility of using the adherence monitor together with a step activity monitor in diabetic patients at high-risk for plantar ulceration who wear prescribed footwear.

METHODS

Study design

This proof of principle study was an observational study with a maximum of 7-day follow-up of subjects.
Subjects

The validity of the adherence monitor was assessed in a convenience sample of well-instructed healthy subjects to assure accurate log recordings of footwear use. Feasibility was assessed in a convenience sample of diabetic patients at high risk for ulceration, one of the intended groups of users of the system. The diabetic patients were measured in a patient care setting. After examination of the study description, the local ethics committee waived the requirement for ethical review of the study under the Medical Research Involving Human Subjects Act in the Netherlands. However, informed consent was still obtained from participating subjects.

Adherence monitor

The adherence to treatment monitor (@monitor) is a temperature-based monitoring system and is shown in Figure 1. The @monitor measures 35x15x5 mm (length x width x height). It consists of a plastic housing integrating a digital-to-digital temperature sensors on each of the largest flat sides of the @monitor, a battery, and a data logger. The temperature sensors measure ambient temperature with a resolution of 0.063°C. Sample frequency can be set at a maximum of 1 sample per minute and a minimum of 1 sample per 30 minutes. The data logger stores data from 14 to 300 days of recording, dependent on sample frequency. The life of the 2.5-V battery varies between 40 and 150 days, dependent on sample frequency and ambient temperature. The @monitor is attached to the inner surface of the body-worn assistive device (footwear, upper limb or lower limb orthosis), which means that 1 of the 2 sensors of the @monitor is close to the skin. By measuring the temperature difference across the 2 sensors, with $\Delta T_{\text{non-use}} \neq \Delta T_{\text{use}}$, the use of the assistive device is determined. Using a docking station and custom software, start date and time, number of days of data collection, and sample frequency are defined. At readout after data collection, the temperatures from both temperature sensors for each time sample are exported to a text file for further analysis. The @monitor can be used as a stand-alone monitor to assess the duration of use of the assistive device, or combined with a step activity monitor to specifically determine use during ambulation, which is of primary interest in diabetic patients who wear prescribed footwear in order to reduce risk of ulceration caused by repetitive loading of the foot.

Testing protocol

Healthy subjects wore low-cut or bottine shoes (Oxford style, canvas, sport) or high boots; patients wore fully or semicustomized footwear with a low, bottine or high shaft. Eight prototypes of the @monitor were used and set to the maximum frequency of 1 sample per minute. The @monitor was placed in a plastazote foam pad with trimmed edges to avoid excessive pressure on the skin or the @monitor (see Figure 1). One thin layer of adhesive tape was placed over the @monitor and pad to avoid it dropping into the shoe. The pad was taped to the inner surface of the lateral shoe border using adhesive athletic tape, at a level just distal to the lateral malleolus. One of the shoes was fitted with the @monitor. The @monitor was initialized to start recording before it was inserted in the shoe to help event recognition (shoe on/off) in data analysis.
Objective monitoring of footwear use

The healthy subjects were instructed to don/doff their shoes several times while wearing the @monitor for 1 day in a climate controlled hospital setting. Subjects kept a record of the exact time moments (1-minute resolution) of these events in a log using a digital clock that was time synchronized with the internal clock of the PC from which the @monitor was initialized. A subset of healthy subjects were instructed to wear the @monitor between 4 and 7 days, again recording the exact time moments of donning/doffing their shoes in a log.

The diabetic patients were tested with the @monitor in their prescription footwear for a 7-day period. Patients additionally wore a step activity monitor (Stepwatch) around the ankle to assess walking activity. The step activity monitor was initialized on the same PC as the @monitor, and measurement accuracy was optimized by personalizing body height, body mass and type of gait (normal, fast, slow). These personal settings were confirmed to be correct by a light on the step activity monitor that flashed with each of the first 40 steps taken by the subject. Patients were instructed to wear the activity monitor at all times except when taking a bath or shower but including time spent in bed to catch any ambulatory activity at night. They were also instructed to complete a daily diary for periods of sleeping, riding a bicycle, being away from home and for not wearing the step activity monitor, if this occurred. After testing, patients returned the @monitor, step activity monitor, and diary via postal mail or at their next clinic visit.

Figure 1. (A) The @monitor, (B) which is fitted inside a plastazote foam pad, (C) covered with a thin layer of cellophane tape to prevent it from falling out, and (D) then taped to the inner surface of the shoe using adhesive athletic tape, at a level just distal to the lateral malleolus.
whichever came first.

To assess usability with the @monitor and step activity monitor, patients completed a short questionnaire after data collection addressing complications or practical issues encountered during the 7 days of monitoring.

**Data analysis**

Using custom MATLAB software, the data were checked for completeness and errors. The readouts from the 2 temperature sensors of the @monitor were normalized to each other using the temperature offset measured in the first few samples of registration (shoe off). To assess the cutoff point for shoes being on or off, first the average temperature difference between both temperature sensors was calculated in all samples that showed a ≥0.3°C difference. Subsequently, the shoes were classified as being worn when the temperature difference between sensors in a sample was >25% of this average temperature difference, and not worn when the difference was <25%. This 25% cutoff level was defined based on pilot tests. Validity of the @monitor was assessed for 1-day and multiple-day recordings in the healthy subjects. For this purpose, the time instances for donning and doffing the shoes were compared to the log recorded time instances using descriptive analyses in SPSS (version 16.0). The mean difference between @monitor and log readings and the 95% confidence interval (CI) of this mean difference was calculated to assess the limits of agreement between the 2 methods. These mean time differences were compared between donning and doffing using independent sample t tests with a significance level of P = 0.05. Using the same tests, mean temperature differences from the @monitor were compared between study groups.

If in the diabetic patients less than 4 days were recorded by either the @monitor or step activity monitor, data collection was considered a failure. Readouts of the @monitor and step activity monitor were matched on date and time using MATLAB software. Periods of reported cycling (7% of total number of steps in the study) were filtered in the data, because we were only interested in weight-bearing ambulatory activity. Periods of reported nonuse of the step activity monitor were also filtered. For each day of data collection, the number of steps taken and the total time in hours that the footwear was worn were calculated. Adherence was calculated as the percentage of daily steps that the prescribed footwear was worn by the patient and averaged over the number of data collection days (range, 0%-100%).

**RESULTS**

Eleven healthy subjects (8 men, 3 women, mean age ± SD, 42.0±9.4y) and 14 diabetic patients (11 men, 3 women, mean age ± SD 56.2±12.9y) with peripheral neuropathy, foot deformity, and a history of plantar foot ulceration were tested.

A total 62 events (donning and doffing of shoes) were registered in the 1-day recordings of the 11 healthy subjects. The mean time difference in minutes between the @monitor and log recordings was 0.0 minutes (95% CI, -0.2 to 0.3min). For donning alone, this was -0.3 minutes (95% CI, -0.6 to 0.0min). For doffing, this was 0.3 minutes (95% CI, -0.1 to 0.7min). Mean time differences were significantly different between donning and
doffing ($P < 0.05$). In 30 of 62 events, the time difference between @monitor and log recordings was 0 minutes, in 24 events plus or minus 1 minute, in 7 events plus or minus 2 minutes, and in one event 3 minutes.

Multiple-day recordings in a subset of 7 healthy subjects lasted on average 6.3±1.1 days. A total 108 events (donning and doffing of shoes) were registered. The mean time difference in minutes between @monitor and log recordings was 0.4 minutes (95% CI, 0.2 to 0.6min), for donning alone, this was 0.1 (95% CI, -0.1 to 0.3min). For doffing alone, this was 0.8 (95% CI, 0.5 to 1.0min). Mean time differences were significantly different between donning and doffing ($P<.001$). In 56 of the 108 events, the time difference between @monitor and log recordings was 0 minutes, in 40 events plus or minus 1 minute, in 9 events plus or minus 2 minutes, and in one event each 3, 4, and 5 minutes.

The average temperature difference measured from the @monitor while wearing footwear was a mean ± SD 1.5°C±0.3°C (range, 1.0 - 1.7) in the healthy subjects, and a mean ± SD of 1.8°C±0.6°C (range, 1.0 - 2.9) in the diabetic patients. This difference was not significantly different between groups ($P=.30$).

Figure 2. Example readout of temperature and activity data for 1 subject during 1 day of recording. On the horizontal axis is time of day. Dotted and dashed line curves show the raw temperature data from both temperature sensors of the @monitor. Continued line curve shows the temperature difference between sensors after offset correction. The vertical spikes show the weight-bearing activity data from the step activity monitor expressed in number of steps per minute. The straight horizontal lines show the periods that the shoes were on and off after data analysis. In this subject, shoes were worn between 13.35 and 20.12 hours and between 21.18 and 22.53 hours, but not during activity between 8.00 and 13.34 hours.
Data from 3 diabetic subjects were excluded from analysis. One recording in a patient with the @monitor showed an error, and from 2 patients less than 4 days of step activity monitor data were collected because these patients removed the step activity monitor and forgot to put it back on. Figure 2 shows a graphical presentation of temperature and activity data in 1 patient. The mean number of daily steps ± SD in the group of diabetic patients was 8294±4794. Patients wore their prescribed footwear on average 8.5 hours per day. Adherence ranged from 9% to 99% across patients. Eleven out of 14 patients documented time spent away from home. Figure 3 shows an example report of adherence constructed from the @monitor, step activity monitor, and diary data.

None of the healthy subjects reported any irritation or discomfort from wearing the @monitor in the shoe. Eleven of the diabetic patients did not encounter any discomfort from wearing the @monitor or step activity monitor; 3 patients reported discomfort with wearing the step activity monitor. Skin complications were not encountered. Two patients reported difficulty with removing the foam pad with the @monitor from the inner shoe, 2 others reported glue remains after removal. Two patients forgot to return the @monitor and step activity monitor to the clinic. When asked about willingness to wear the monitors for repeated testing in the future, 10 patients had no objection. Four patients did not favor repeated testing; in 3 this concerned wearing the step activity monitor.

![Figure 3. Example data showing adherence over a 7-day period for 1 of the diabetic patients in the study. Adherence data are expressed as percentage of steps that the patient wears the prescribed footwear. Data are shown for overall adherence, adherence at home, and adherence away from home. The dashed horizontal line represents the average adherence over 7 days. Shown are also the average number of steps per day and the at-home activity ratio (= number of steps at home/ total number of steps).](image)

**DISCUSSION**

Adherence to treatment is an important factor that affects the efficacy of treatment. The results of this study show that as an objective monitoring tool, the @monitor provided valid and feasible data on adherence to wearing footwear. The @monitor showed no under- or overestimation for instances of donning/doffing for the 1-day recordings, and only 0.4 minutes overestimation for the multiple-day recordings. Instances of doffing shoes were overestimated with respect to donning shoes, which can be corrected by adjusting the cutoff level in the calculation algorithm. In any case, all 95% CIs were small (within 1 minute). The recordings with the @monitor and step activity monitor in the
diabetic patient group were of good quality (only 1 error) and mostly complete (only 2 < 4-day recordings). Data on treatment adherence could be obtained. There were few issues with usability, and the majority of patients had no objection to repeated testing. These valid and feasible data suggest that the @monitor is a valuable system for obtaining objective data on footwear adherence.

The @monitor is the first documented objective adherence monitoring system for use with footwear. Hunter et al. tested temperature and pressure sensors for monitoring spinal orthoses use and found a weak association between monitor and log recordings (r = .34-.65) together with a large over- or underestimation of total wearing time (4-38min). Validity can be greatly improved when multiple pressure sensors are used at once. The use of off-the-shelf accelerometer-based activity monitors showed good correspondence with log recordings (intraclass correlation coefficient = .93) for assessing the use of removable cast walkers. The highly accurate outcomes in the current study may be explained by the fact that not just temperature, but temperature difference between the 2 temperature sensors of the @monitor was measured. This may improve sensitivity to temperature change when the device comes in contact with the body and limits the influence of normal variation in ambient temperature. Although @monitor validity was not assessed in the diabetic patients, the measured temperature differences between the temperature sensors during recording (mean 1.8°C) were comparable to the healthy subject group (mean 1.5°C), which suggests a high sensitivity for defining shoes on/off in diabetic patients. A practical advantage of the @monitor is that it is small and lightweight. This supports the use of the @monitor not only in prescribed footwear, but also in upper and lower limb orthoses that often allow only limited space between the device and the skin.

One of the @monitors showed an error resulting in loss of data that we have encountered occasionally (~5% of cases) in other measurements that we have performed to date with the @monitor (unpublished data, patient care data and Netherlands Trial Register 1091 study data, 2010-2011). Presumably, the failure is due to contact loss of the battery because of above-threshold mechanical pressure on the @monitor, which depletes battery energy. Strengthening the plastic housing of the @monitor or improving the absorbing properties of the foam pad in which the @monitor is placed may solve this issue. A more common issue that can cause incomplete data for treatment adherence is the removal or incorrect placement of the step activity monitor by the patient. This may be avoided by making the step activity monitor nonremovable (the StepWatch is waterproof), or by sending text message alerts during data collection. Another aspect that may bias data is that cycling activity can not be automatically filtered from ambulatory activity in the StepWatch data, necessitating its recording in a diary, which is more prone to errors or missing data. Three patients reported discomfort from wearing the step activity monitor by stating: “uncomfortable at night in bed” or “feels like a detention monitor”. Four of the 14 diabetic patients were not in favor of repeated testing, but in only 1 patient this concerned the @monitor, showing that this is a user-friendly system that does not limit the patient in daily life activities.

Assessing the validity and feasibility of the @monitor was important for its future application in research and clinical practice. We are currently assessing treatment adher-
ence to prescribed footwear in a large group of high-risk diabetic patients (Netherlands Trial Register 1091), which may provide important insight into the role of adherence in ulcer development. Furthermore, determinants of poor adherence can be studied. For these purposes, objective data recording is much more valuable than subjective data recording. For clinical practice, objective recording of adherence could be used to (1) help explain (lack of) treatment efficacy in a given patient, (2) explore reasons for non-adherence, (3) individualize type and frequency of footwear prescriptions, and (4) evaluate educational interventions aimed at improving adherence. It could also be used as a quality assurance method for hospitals and for footwear and insurance companies. Further development may include an adherence reminder system to notify patients when they are active and not wearing the prescribed treatment. Crews et al. proposed some potential ethical dilemmas related to who has access to patient adherence data and for what purpose: Can this be considered an invasion of privacy? Should adherence be factored into determining reimbursement for assistive devices? These dilemmas should be discussed and resolved before implementation. Nevertheless, the potential for the use of objective adherence monitoring is high.

**Study limitations**
The study was limited in that validity of the @monitor was not tested under challenging climate conditions. Therefore, we do not have full knowledge of system performance in all possible environments. We, however, performed measurements in July (summer) and in November (autumn, in The Netherlands), with no difference in performance found between these two months. Furthermore, the highest sample frequency of the @monitor is 1 sample per minute, which means that when footwear is donned and doffed within a 1-minute interval, this change may not be registered. Such rapid donning and doffing seems, however, unlikely, even when patients get out of bed at night to visit the bathroom. Finally, we only tested the @monitor in footwear and not in other assistive devices. Space to fit the @monitor in a total contact device may be a challenge. However, when close contact of the @monitor with the skin is assured, valid measurements in other assistive devices are expected to be as likely as in footwear.

**CONCLUSIONS**
The study showed that valid data can be acquired when using the @monitor to assess footwear use in healthy subjects, and that together with step activity monitoring, its use is feasible in neuropathic diabetic subjects. Therefore, the @monitor is a valuable system for objective assessment of treatment adherence to prescribed footwear that can benefit both research and clinical practice. Besides footwear, the @monitor may have wider application in settings where patients wear removable body worn assistive devices.

**Suppliers**
- Orthocare Innovations, 840 Research Pkwy, Ste 200, Oklahoma City, OK 73104
- The MathWorks Inc., 3 Apple Hill Dr, Natick, MA 01760
- IBM Corp, 1 New Orchard Rd, Armonk, NY 10504
REFERENCES


