Continuous Activity Monitoring in Persons at High Risk for Diabetes-Related Lower-Extremity Amputation

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This study evaluated the magnitude and location of activity of diabetic patients at high risk for foot amputation. Twenty subjects aged 64.6 ± 1.8 years with diabetes, neuropathy, deformity, or a history of lower-extremity ulceration or partial foot amputation were dispensed a continuous activity monitor and a log book to record time periods spent in and out of their homes for 1 week. The results indicate that patients took more steps per hour outside their home, but took more steps per day inside their homes. Although 85% of the patients wore their physician-approved shoes most or all of the time while they were outside their homes, only 15% continued to wear them at home. Focusing on protection of the foot during in-home ambulation may be an important factor on which to focus future multidisciplinary efforts to reduce the incidence of ulceration and amputation. The ability to continuously monitor the magnitude, duration, and time of activity ultimately may assist clinicians in dosing activity just as they dose drugs. (J Am Podiatr Med Assoc 91(9): 451-455, 2001)

Many of the neuropathic ulcerations and subsequent amputations that occur every year among patients with diabetes can be prevented. While the pathogenesis of diabetic foot ulceration is complex, the fundamental pathway is consistent and includes neuropathy and repetitive stress on a high-pressure area through activity. Repetitive stress, which is caused by thousands of steps taken daily, leads to inflammation and ultimately catastrophic failure of the skin and ulceration.[1]

Most treatment regimens focus on reducing or mitigating the areas of high pressure, or attempt to reduce or modify activity. Over the past generation, numerous reports have detailed the scope and range of normal and abnormal plantar pressures in patients with neuropathy and diabetes.[2-7] However, the authors are unaware of any reports in the medical literature evaluating the degree and location of activity in patients with diabetes at high risk for lower-extremity amputation. Therefore, the purpose of this study was to evaluate the magnitude and location of activi-

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ty of patients with diabetes at high risk for diabetic foot ulceration.

Materials and Methods

Twenty subjects with diabetes were selected for participation in this prospective longitudinal project. All of the subjects were men, with a mean (± standard error of the mean [SEM]) age of 64.6 ± 1.8 years and diabetes mellitus of 13.4 ± 1.3 years' duration. The patients were enrolled from the high-risk diabetic foot clinic at the Southern Arizona Veterans Affairs Medical Center in Tucson, Arizona. The diagnosis of diabetes was made prior to enrollment and confirmed by communication with primary care providers or by reviewing medical records. Sensory neuropathy was evaluated with a 10 g Semmes-Weinstein monofilament wire using methods previously described.[8]

All of the patients enrolled in the study were defined as either University of Texas Risk Category 2 (neuropathy with deformity) or Category 3 (history of ulcer or amputation).[9, 10] Patients not falling into these categories were excluded from the study. Patients who were unable to walk without assistance from another individual or were not capable of independent living also were excluded from the study.

The study participants were dispensed an activity monitor (Sportbrain.com, Sunnyvale, California), a device that measures the number of steps taken over a period of time and records the time that each step is taken. The monitor is worn on the waistband and automatically activates when a step is taken. There are no buttons or displays on the monitor. The device stores activity for up to 10 consecutive days, after which the information is uploaded to a centralized computer server.[11] The accuracy of the mechanism used in this device has been previously calculated to be 96% for brisk walking, 92% for slow walking, 96% for ascending stairs, and 98% for descending stairs.[12] The patients were instructed by one of two clinicians in the appropriate operation of the device and were instructed to wear the activity monitor at all times, including while sleeping, except when bathing, swimming, or showering. The subjects also were given a one-page log form and were instructed to record the times when they entered and left their homes. Patients were followed in this manner for 1 week. Patients were given a two-question interview, by the same clinician, upon their return to the clinic. The first question was: "When outside your home, do you wear your shoes a) more than half of the time? or b) less than half of the time?" The second question was: "When inside your home, do you wear your shoes a) more than half of the time? or b) less than half of the time?"

For an analysis of activity based on location of activity (outside home *versus* inside home), a Wilcoxon signed-ranks test for paired samples was used. All data were reported as mean ± SEM.

Results

Patients were most active during late morning and mid-afternoon hours (Fig. 1). As expected, patients took more steps per hour outside the home than inside (371.6 ± 57.8 *versus* 130.2 ± 24.9, $P = .001$). However, patients took more steps per day inside their homes than they did outside (2,380.6 ± 421 steps inside home *versus* 2,167.4 ± 570.2 steps outside home, $P = .033$) (Table 1). Even though 85% of the patients indicated that they wore their physician-approved shoes most or all of the time while outside the home, only 15% continued using the shoes when they were at home.

Discussion

The results of this study suggest that patients with diabetes who are at high risk for diabetic foot ulceration may be at least as active at home as they are outside their home. To the authors' knowledge, this is the first report in the medical literature to make this comparison. Most previous clinical studies using pedometers were unable to measure accurately the rate

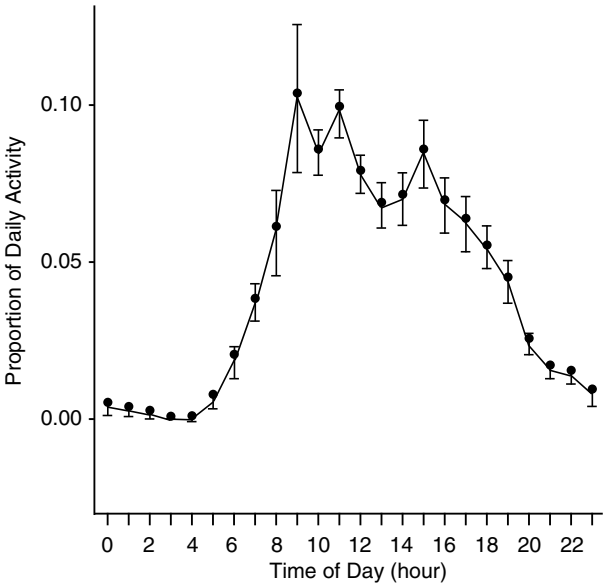


Figure 1. Proportion of activity by time of day. The error bars represent the SEM.

Table 1. Activity of Patients at High Risk for Diabetic Foot Ulceration (mean ± SEM)

	Outside the Home	Inside the Home	Total
Daily activity(steps)	2,167.4 ± 570.2	2,380.6 ± 421	4,548 ± 779.3
Time spent (hours)	5.3 ± 0.5	18.7 ± 0.5	24

and time of activity because they only counted steps. The device used in this study was able to record both the number and the time when activity occurred. In the authors' opinion, the ability to monitor continuously the magnitude, duration, and time of activity, as done in this study, ultimately may assist physicians in dosing activity just as they dose drugs.

Overall, patients in this study appear to have had similar activity levels when compared to previous studies that have evaluated walking patterns in patients without diagnosed diabetic neuropathy or a history of lower-extremity ulceration,[13-15] in patients with a history of joint-replacement surgery,[12] or those being treated for chronic obstructive pulmonary disease.[16] Caution should be taken when making direct comparisons across pedometer trials, however, because while intradevice differences are generally negligible, differences in duration of monitoring and specific differences in pedometer design can affect the absolute number of steps recorded.[17, 18]

A mainstay of programs designed to reduce ulcer occurrence or recurrence involves the use of therapeutic shoes with viscoelastic insoles to accommodate high-pressure areas on the sole of the foot. These devices represent a relatively inexpensive intervention strategy that can make a substantial impact on the prevalence of pathology.[19-23] Congressional legislation has provided funding for Medicare recipients with diabetes to receive one pair of therapeutic shoes and three pairs of insoles each year.[24, 25]

The recent attention of clinicians and policy makers to the importance of diabetic footwear highlights an appreciation that protection of high-risk diabetic feet may lead to fewer complications. Chantelau and Haage[26] reported in a study of 51 high-risk patients that those who were compliant with wearing therapeutic footwear were significantly less likely to ulcerate than subjects who did not. The results of the present study indicate that therapeutic shoes are worn primarily during periods outside the home, with little attention paid to the time period when the patient is inside the home, a period amounting to at least one-half of the daily activity of these high-risk patients. The more attention that is paid to accommodation of these patients during nonworking hours through the use of modalities such as accommodative slippers or sandals may be an effective way to improve compliance with this potentially effective prophylactic regimen. As mentioned, Medicare beneficiaries currently are eligible for one pair of therapeutic shoes annually.[24, 25] Approximately $986,844 was charged to Medicare for 18,303 billable episodes for such shoes in 1999.[27] As the 2-year cost of treating one diabetic foot ulcer can approach $30,000,[28] the prevention of just a very small number of wounds by the funding of two pairs of shoes per year (one pair of outdoor shoes, one pair of indoor sandals) would seem, at first glance, to be both wise and economically feasible.

Data from the present study may be used cautiously to evaluate the rationale for the effectiveness of offloading strategies designed to heal wounds. Currently, the most widely acknowledged standard in offloading the plantar diabetic foot ulcer is the ambulatory total contact cast,[1] which has been shown to be at least as effective in offloading the foot as any other modality to which it has been compared.[29-31] Fully acknowledging its ability to mitigate pressure, it may be postulated that the element of forced compliance with total contact casting may be the single most significant attribute that has led to its consistent healing of superficial foot ulcers in the range of 6 to 8 weeks.[32-39] In a randomized clinical trial, Armstrong et al[40] reported that although patients who wore a total contact cast took a similar number of steps per day as patients who wore a removable cast walker, patients with a total contact cast healed significantly faster. Certainly some of this difference may be attributed to the forced compliance that a total contact cast imposes on the patient. Perhaps monitoring activity, or designing pressure-relieving modalities that monitor activity, and adherence to therapy may assist in motivating the patient and informing the clinician.

Conclusion

Patients with diabetes who are at high risk for diabetic foot ulceration may be at least as active during periods of time spent at home as when they are out-

side their home. However, the data in this study suggest that subjects typically do not wear their prescribed, protective footwear while at home. Focusing on protection of the foot while the patient is inside the home may be an important factor on which to focus future multidisciplinary efforts to reduce the incidence of ulceration and amputation.

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