

Activity Patterns of Patients With Diabetic Foot Ulceration

Patients with active ulceration may not adhere to a standard pressure off-loading regimen

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OBJECTIVE — To evaluate the activity of patients with diabetic foot ulcerations and their adherence to their pressure off-loading device.

RESEARCH DESIGN AND METHODS — We enrolled 20 subjects treated for neuropathic diabetic foot wounds corresponding to University of Texas grade 1 stage A. All were off-loaded using a removable cast walker (RCW). We recorded the total activity (measured in activity steps per day) taken on a waist-worn computerized accelerometer. We subsequently correlated this to activity recorded on an RCW-mounted accelerometer, which was not readily accessible to the patient.

RESULTS — There were a mean $1,219.1 \pm 821.2$ activity units (steps) taken per patient per day. Patients logged significantly more daily activity units with the protective RCW off than with it on (873.7 ± 828.0 vs. 345.3 ± 219.1 , $P = 0.01$). This amounts to only 28% of total daily activity recorded while patients were wearing their RCW. Although a total of 30% of the patients in the study recorded more daily activity units while wearing the device, this subset most adherent to their off-loading regimen still only wore the device for a total of 60% of their total daily activity.

CONCLUSIONS — Subjects with diabetic foot ulcerations appear to wear their off-loading devices for only a minority of steps taken each day. This may partially explain the poor results reported from many trials of agents designed to help speed the healing of these wounds. Control of this important aspect of care with less easily removable devices may increase the prevalence of healing.

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In the presence of neuropathy, patients with diabetes generally develop ulcers on the sole of the foot at areas of moderate or high pressure and shear that are exposed to repetitive injury, which is primarily related to normal walking during

the course of daily activity. We have previously shown that the majority of activity in high-risk patients with diabetes occurs inside their home. One of the mainstays of ulcer prevention and treatment involves the use of prosthetics, casts, and braces to

reduce pressure and shear forces on the sole of the foot and protect the foot from repetitive injury (1,2).

In 2001, we published results of a randomized controlled trial comparing the proportion of healing of ulcers treated with three commonly used modalities: the total-contact cast (TCC), the removable cast walker (RCW), and the half shoe (3). In this study, a significantly greater percentage of subjects treated with the TCC healed within 12 weeks compared with the other two modalities. Interestingly, however, subjects using the TCC and the RCW had similar activity profiles in this study. Previous gait laboratory studies have suggested that the TCC and RCW reduce pressure to approximately the same extent on the sole of the foot (4,5). If activity and pressure reduction are approximately the same in these two groups, one might question what other feature of the TCC has led to its apparent superiority in facilitating wound healing. We have postulated that this might be related to poor compliance with recommendations to wear special devices to off-load and protect the foot with removable modalities such as the RCW. We are unaware of any reports in the medical literature objectively detailing the frequency of use of off-loading modalities. Therefore, the purpose of this study was to evaluate the activity of subjects with diabetic foot ulcerations and their adherence to their pressure off-loading device.

RESEARCH DESIGN AND METHODS

— We enrolled 20 subjects with diabetes for participation in this prospective longitudinal study. All subjects had a noninfected nonischemic superficial diabetic foot ulcer corresponding to University of Texas grade 1 stage A, as diagnosed by the treating physician (6). All patients were dispensed a standardized RCW (Royce Medical, Camarillo, CA) to reduce plantar pressure during ambulation and healing.

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Abbreviations: RCW, removable cast walker; TCC, total-contact cast.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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See accompanying editorial, p. 2689.

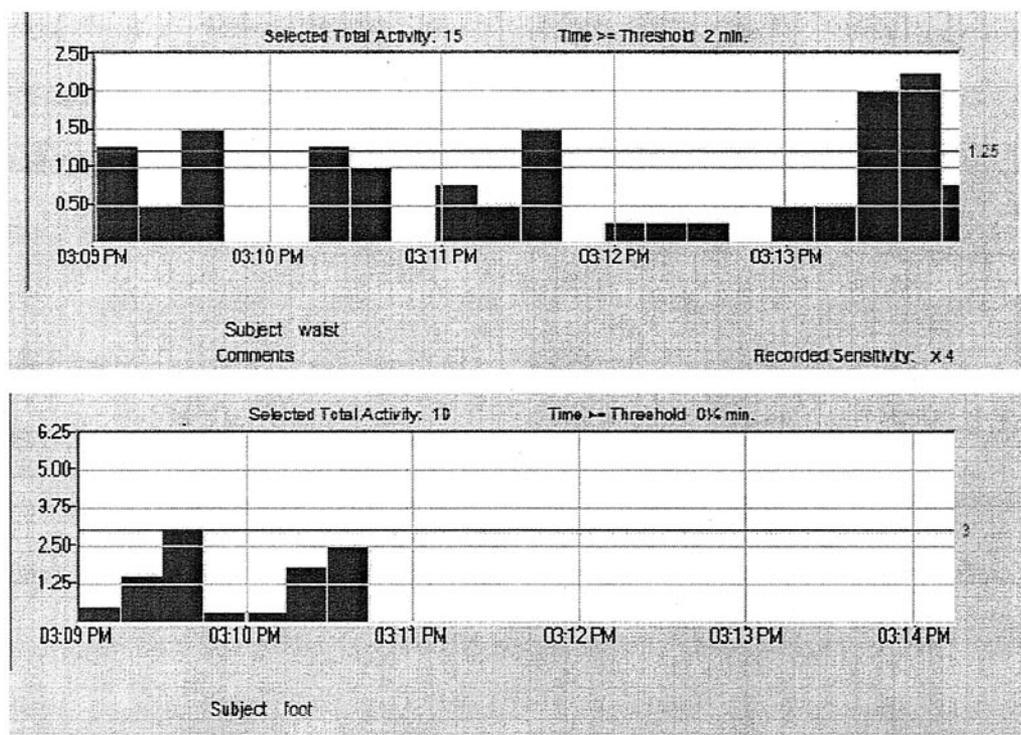


Figure 1—Example of graphic output of waist- and RCW-worn activity monitors. The top graph represents output from the waist-worn activity monitor, and the bottom represents the RCW-worn device. Note that at 3:11 P.M., the patient's RCW monitor fails to register, whereas the waist-worn device continues to record activity, implying removal of the RCW at that time.

All patients were dispensed a computerized accelerometer/pedometer (Bio-trainer Pro; IM Systems, Boston, MA). The device is designed to measure the activity of people taken over a period of time. It also records the time of day when that activity occurred, allowing for the identification of clusters of activity. The mechanism in the device has been previously calculated to be 96% for brisk walking, 92% for slow walking, 96% for ascending stairs, and 98% for descending stairs (7). All pedometers were calibrated by a clinician, who instructed the enrolled participants as to appropriate operation of the devices. The patient was instructed to wear the device at all times during the day and night for 7 days. A similar device was attached to the posterior aspect of the RCW and fixed in place with adhesive in a manner preventing ready access by the patient. The data from these devices were then downloaded by study personnel.

We recorded the total activity (measured in activity units or steps per day) taken on the waist-worn device. We subsequently correlated this to any recorded activity on the RCW-mounted device. Any movement recorded on the RCW-mounted device that correlated with activity on the waist-worn device was considered "active use." Subjects were telephoned on a daily basis by study per-

sonnel to ensure that they were wearing their waist-worn activity monitor. Activity that was registered on the RCW-mounted device and not on the waist-worn device was not counted as activity because there was no viable method against which to measure it. This was identified for a total of 870 of the total 201,600 total min (0.4%) recorded in all patients during the period of study. This small amount of motion may have been attributable to moving or carrying the RCW when it was not being worn by the study subject. An example of the graphical output created by the waist- and RCW-mounted devices is outlined in Fig. 1.

For analysis of activity based on steps

taken during active use of the RCW versus activity without the RCW worn, we used a Wilcoxon's signed-ranks test for paired samples. All data are reported as means \pm SD, unless otherwise specified.

RESULTS — We enrolled 20 patients, 70% male, with a mean age of 65.0 ± 7.6 years. Subjects had a mean duration of diabetes of 12.5 ± 5.2 years. All had University of Texas grade 1 stage A wounds measuring an average 3.0 ± 2.3 cm². There were a mean $1,219.1 \pm 821.2$ activity units (steps) taken per patient per day.

Study subjects took significantly more steps per hour when they were wearing their device than when the device

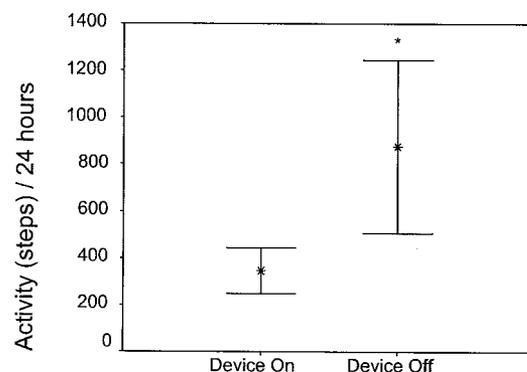


Figure 2—Activity of patients with ulcers with and without protective off-loading device. *P = 0.01. Error bars represent SE of mean.

was removed (92.9 ± 44.8 vs. 46.1 ± 40.3 , $P = 0.008$). However, subjects took more total steps each day when they were not using the prescribed off-loading device (873.7 ± 828.0 vs. 345.3 ± 219.1 , $P = 0.01$). Only 28% of total daily activity occurred while subjects wore the removable cast boot (Fig. 2).

We dichotomized the study population into two groups based on the amount of time they wore the RCW. High utilizers were defined as subjects that used the RCW for more than half of their total activity. Low utilizers wore the prescribed RCW for less than half of their average daily activity. Only 30% of study subjects were high utilizers, whereas 70% were low utilizers. On average, high utilizers only wore the prescribed off-loading device for a total of 60% of their daily steps.

CONCLUSIONS— The results of this study suggest that patients with diabetic foot ulcerations wear their off-loading devices for only a minority of the steps taken each day. To our knowledge, this is the first report in the medical literature evaluating the activity of subjects with wounds both in and out of their primary off-loading device.

Over the past decade, there have been a number of large trials and analyses of wound healing agents designed for the treatment of diabetic foot wounds. These have included bioengineered tissues, recombinant growth factors, oxidized regenerated cellulose, and a host of physical modalities (8–16). Whereas all of these modalities have, to one degree or another, shown promise in treating segments of this population, the overall prevalence of healing has been disappointing.

Although we were not surprised by the overall findings with this study, we were alarmed by the surprisingly high percentage of steps taken without adequate plantar protection. Nearly 75% of the steps taken per day in these patients were taken without adequate pressure relief. Because this is a novel methodology to assess adherence, we have tried to contemplate potential methodological reasons why this number could be as low as it is. Certainly, there may be built-in inaccuracies in the activity monitoring devices. However, all of these devices were tested for function accuracy by both the factory and our team both before and after the tests. If there were significant inaccuracies,

we would presume that these would be more or less proportionately the same for all devices used and could not explain the enormous difference in readings. Furthermore, we were using the waist-worn device as a measure of total activity and the RCW-attached device as merely a measure of “active” or “not active.” Therefore, we cannot explain this difference based on the physical location of the device.

In conclusion, it appears as though patients with neuropathic diabetic foot wounds do not wear a commonly prescribed pressure-relieving modality for the vast majority of activity taken each day. These results may help to at least partially explain the less-than-impressive outcomes reported from many trials that have not used effective off-loading strategies. Failure to adequately off-load the foot or modulate activity exposes the wound to repetitive stress during activity of the same magnitude that precipitated the wound in the first place (17). We postulate that tight control of both pressure reduction and activity may increase the prevalence of healing significantly.

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