



Decreasing an Offloading Device's Size and Offsetting Its Imposed Limb-Length Discrepancy Lead to Improved Comfort and Gait

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OBJECTIVE

Patient adherence is a challenge in offloading diabetic foot ulcers (DFUs) with removable cast walkers (RCWs). The size and weight of an RCW, changes to gait, and imposed limb-length discrepancies may all discourage adherence. This study sought to determine whether RCW size and provision of a contralateral limb lift affected users' comfort and gait.

RESEARCH DESIGN AND METHODS

Twenty-five individuals at risk for DFUs completed several 20-m walking trials under five footwear conditions: bilateral standardized shoes, a knee-high RCW with shoe with or without an external shoe lift contralaterally, and an ankle-high RCW with shoe with or without an external shoe lift contralaterally. Perceived comfort ratings were assessed through the use of visual analog scales. Spatial and temporal parameters of gait were captured by an instrumented walkway, and plantar pressure was measured and recorded using pedobarographic insoles.

RESULTS

The bilateral shoes condition was reported to be most comfortable; both RCW conditions without the lift were significantly less comfortable ($P < 0.01$). In contrast to the ankle-high RCW, the knee-high RCW resulted in significantly slower walking (5.6%; $P < 0.01$) but greater offloading in multiple forefoot regions of the offloaded foot (6.8–8.1%; $P < 0.01$). Use of the contralateral shoe lift resulted in significantly less variability in walking velocity (52.8%; $P < 0.01$) and reduced stance time for the offloaded foot (2.6%; $P = 0.01$), but it also reduced offloading in multiple forefoot regions of the offloaded foot (3.7–6.0%; $P < 0.01$).

CONCLUSIONS

Improved comfort and gait were associated with the ankle-high RCW and contralateral limb lift. Providing this combination to patients with active DFUs may increase offloading adherence and subsequently improve healing.

A key tenet in healing plantar diabetic foot ulcers (DFUs) is the reduction of physical stress on the DFU, that is, “offloading” (1–3). Although a total contact cast is traditionally considered the gold standard in offloading, recent recommendations have shifted from exclusive use of total contact casts toward the use of either total contact casts or removable cast walkers (RCWs) that are irremovable through the use of casting tape or other means (2). While RCWs are able to provide offloading of wounds

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similar to that provided by total contact casts (4,5), their use has been associated with poorer healing than that seen with total contact casts (5,6). The diminished healing with RCWs has been attributed to insufficient adherence compared with total contact casts, which essentially force adherence because they cannot be removed. The first study to objectively monitor the adherence to RCWs by patients with DFUs found that study participants used their RCW during only 28% of their daily steps (7). A subsequent study looking at RCW adherence demonstrated a direct association between RCW adherence and DFU healing (8). Despite recommendations for the use of irremovable devices, removable devices are reported to be used much more often (9,10). In addition to being more commonly used, removable devices are sometimes recommended. For example, a recent set of practice guidelines regarding management of the diabetic foot recognizes that some patients require frequent dressing changes and recommends the use of RCWs in such cases (11). Research is needed to better understand means to improve both adherence to removable RCWs and the user experience with RCWs that are rendered irremovable.

RCWs are a burden for users not only because of their size and weight but also because of their potential impact on gait kinematics and postural stability (12–14). RCWs are not designed with these functional aspects in mind, which is particularly problematic for individuals with DFUs, who tend already to have an increased risk of falls as a result of decreased ankle and foot proprioception (13,15). The importance of postural instability to RCW adherence was highlighted in a previous study that objectively demonstrated the positive association between offloading adherence and DFU healing (8). That study evaluated a number of potential predictors of adherence (e.g., wound severity, patient demographics, and patient-reported factors), and self-reported neuropathic postural instability was the most predictive variable assessed. With regard to the impact of RCWs on gait, their potential to increase asymmetry should also be considered, as greater variability of gait has been shown to be a discriminating factor between those who fall and those who do not fall (16).

An induced limb-length discrepancy (LLD) is another problem often associated with RCWs that may contribute to patient

nonadherence. LLDs are known to cause several musculoskeletal problems, such as joint pain, and can affect gait and balance (13,17–20). After dispensing an RCW, physicians commonly hear reports from patients of knee and low-back pain as well as problems walking, which are related to the LLD imposed by the offloading boot (18). A study of patients with DFUs by Nahas et al. (21) found that peak pressure of the total foot on the short limb was increased with a footwear-induced LLD of 20 mm or more. They also found that peak pressure was especially high under the second through fifth metatarsal heads and that maximum vertical force was increased beneath the third through fifth metatarsal heads (21). Thus a person using an LLD-inducing offloading device to heal a DFU may increase the risk of ulceration on the contralateral limb. Furthermore, an artificially induced 2-cm LLD in older adults has been shown to increase oxygen consumption and perceived exertion while walking on a treadmill (17). This is particularly concerning because individuals with DFUs are already physically deconditioned compared with nonulcerated individuals with diabetic peripheral neuropathy (22).

A previous investigation regarding the height of RCWs found that an ankle-high RCW provided forefoot offloading similar to that provided by a more traditional knee-high RCW, yet it weighed 17% less than the knee-high RCW (23). The purpose of the current study was to compare these two RCWs in combination with a contralateral limb lift (Fig. 1). We hypothesized that the different footwear conditions would lead to differences in comfort, kinematic gait parameters, and offloading amplitude. Any identified changes would have potential implications for improving the patient experience with RCWs and for increasing RCW adherence in DFU patients.

RESEARCH DESIGN AND METHODS

Subjects

We recruited 25 adults (13 women, 12 men) with type 1 ($n = 2$) or type 2 ($n = 23$) diabetes and a risk grade of 1 or higher on the diabetic foot risk classification system of the International Working Group on the Diabetic Foot (3 adults with grade 1 risk, 17 adults with grade 2 risk, and 5 adults with grade 3 risk) (24). The mean age \pm SD of participants was 56 ± 11 years, the mean duration of diabetes \pm SD was 15 ± 13 years, and the



Figure 1—Offloading footwear: the knee-high RCW (A), the ankle-high RCW (B), and the standardized shoe with an external shoe lift attached (C).

mean BMI \pm SD was 34 ± 9 kg/m². Subjects with active DFUs were excluded from participation as a precautionary measure to avoid potentially causing a DFU to deteriorate further in response to study activities. All subjects were capable of ambulating without assistive devices such as walkers or crutches. One subject had a history of stroke (~ 5 years before study participation), and the other participants had no history of significant neuromuscular disease or deficits (other than complications associated with diabetes). In addition, none of the patients had previously sought or received any care for an LLD. Before participation in this study, all subjects read and signed an institutional review board–approved consent form.

Footwear

Each participant completed walking trials under five different conditions: 1) bilateral standardized athletic shoes (New Balance, Boston, MA), 2) a standardized athletic shoe on one foot and an ankle-high RCW on the other foot, 3) a standardized athletic shoe plus an external shoe lift (Evenup LLC, Buford, GA) on one foot and an ankle-high RCW on the other foot, 4) a standardized athletic shoe on one foot and a knee-high RCW on the other foot, and 5) a standardized athletic shoe plus an external shoe lift on one foot and a knee-high RCW on the other foot. To prevent fatigue (or other possible confounding variables that would be affected by the order in which footwear conditions were evaluated) from influencing the results, the testing order of the footwear conditions was randomized for each subject. A single investigator (J.C.) was responsible for securing and removing the offloading devices and athletic shoes for each subject. RCWs were placed on the foot that was classified to be at higher risk

for DFU according to the diabetic foot risk classification system of the International Working Group on the Diabetic Foot (24). If both feet were at equivalent risk, then the right foot received the RCW.

Walking Trials

In each footwear condition, subjects were asked to walk for 2–3 min to acclimate themselves before data collection. Following acclimatization, subjects completed two 20-m walking trials, during which data were collected. In each trial, subjects were instructed to walk as they would normally walk at a self-selected speed. For a trial to be considered successful, the subject needed to complete the entire 20-m walk without pausing or stopping. Analyses were based on data from the second trial for each footwear condition.

No efforts were made to ensure subjects walked at equivalent speeds with each device. Although speed does influence the plantar pressure generated during walking, the intent of this study was to assess the differences in gait parameters associated with the different footwear conditions. If walking speed had been controlled, the results obtained might not represent the gait that subjects would exhibit if they were not being observed.

Perceived Comfort Ratings

Following completion of all walking trials, participants were asked to rate the overall comfort of each footwear condition through the use of a 12-cm visual analog scale (25). As was done in a study by Mills et al. (25) that identified clinically meaningful tools for measuring perceived comfort of footwear, the visual analog scale was anchored by the terms “not comfortable at all” to “most comfortable imaginable.” Participants were instructed to “rate each footwear condition by placing a single vertical line on each scale (one horizontal scale was provided for each footwear condition) with regard to each condition’s overall comfort.”

Spatial and Temporal Parameters of Gait

To assess spatial and temporal parameters of gait, subjects walked over a 7.3-m-long instrumented carpet (GAITRite; CIR Systems Inc., Franklin, NJ) that had been placed in the middle of the 20-m walkway. The system uses a series of pressure sensors to identify spatiotemporal parameters of gait based on identification of the timing and location of each footstep.

The software for the system automatically calculates mean values for numerous variables from each trial. Mean walking velocity represents the distance along the length of the walkway between the initial heel strike and the last heel strike of a trial, divided by the time elapsed between first contact of the initial and last steps of the trial. The velocity of a single step was calculated as the distance along the horizontal axis of the walkway from the geometric heel center of the current footfall to the geometric heel center of the previous footfall on the opposite foot, divided by the time elapsed between the first contact of each foot with the walkway. Individual data for step velocity were used to determine within-trial variability of velocity. The coefficient of variability of participants’ step velocities for each trial was calculated as the SD of the trial’s step velocity divided by the trial’s mean step velocity.

Plantar Pressure Recordings

Pressure insoles (Pedar-X; Novel, München, Germany), were fitted to each of the subjects’ feet and placed inside each piece of footwear. While subjects walked, plantar pressures were recorded at a sampling frequency of 100 Hz. In addition to looking at plantar pressure parameters with reference to the entire foot, plantar pressure data were analyzed for four specific forefoot regions (hallux, medial forefoot, intermediate forefoot, and lateral forefoot) corresponding to common sites where DFUs occur.

Analyses

The plantar pressure and gait data collected in the trials with athletic shoes on both feet were used to normalize the data collected for each of the RCW conditions. The normalized values from the four RCW conditions were then compared through the use of two-way (RCW height \times contralateral limb lift) repeated-measures ANOVA.

Comfort ratings were analyzed with a one-way (footwear condition) repeated-

measures ANOVA, allowing each of the four offloading conditions to be contrasted with the bilateral athletic shoe condition. A Sidak adjustment for multiple comparisons was used for pairwise comparisons.

In all analyses $P < 0.05$ was considered significant. Reported effect sizes represent partial η^2 values. Statistical analyses were conducted with the statistical software package SPSS version 24 (IBM Corporation).

RESULTS

Perceived Comfort Ratings

Significant differences in perceived comfort were found between the different offloading options ($P < 0.0005$; effect size = 0.30). Both the ankle-high RCW with no lift and the knee-high RCW with no lift resulted in poorer comfort than the athletic shoes (Table 1). Neither of the offloading conditions in which the external shoe lift was used differed from the athletic shoes.

Spatial and Temporal Parameters of Gait

Mean walking velocity was significantly reduced ($P = 0.006$; effect size = 0.27) with the knee-high RCW. As a percentage relative to walking in the control condition of bilateral athletic shoes, use of the knee-high RCW showed a 5.6% (95% CI 1.7–9.5%) greater reduction than the ankle-high RCW. Mean velocity was not affected by use of the contralateral lift or the interaction of RCW height with lift use. In contrast to the mean velocity data, variability in walking velocity (step-by-step coefficient of variability) was significantly altered ($P = 0.006$; effect size = 0.27) by use of the contralateral lift. As a percentage relative to walking in the control condition of bilateral athletic shoes, use of the contralateral lift showed 52.8% (95% CI 16.3–89.3%) less variability in step velocity. Variability in step velocity was not affected by RCW height ($P = 0.21$).

Table 1—VAS perceived comfort ratings

	Mean \pm SE (cm)	P value
Athletic shoes (reference)	11.3 \pm 0.6	NA
Ankle-high RCW + lift	10.4 \pm 0.8	0.765
Knee-high RCW + lift	8.6 \pm 0.8	0.051
Ankle-high RCW	8.2 \pm 0.7	0.003*
Knee-high RCW	7.0 \pm 0.8	<0.0005*

NA, not applicable. *Significant difference ($P < 0.05$) in comfort between offloading condition and the reference condition of bilateral athletic shoes.

Table 2—Reductions in peak pressure for the offloaded foot

	Lift use				RCW height			
	No lift	Lift	<i>P</i> value	Effect size	Ankle	Knee	<i>P</i> value	Effect size
Total foot	23.3 ± 4.1	22.9 ± 4.3	0.751	0.004	21.5 ± 4.5	24.7 ± 4.0	0.088	0.116
M-FF	52.1 ± 2.4	50.5 ± 1.9	0.224	0.061	47.3 ± 2.5	55.4 ± 2.4	0.007*	0.265
I-FF	56.2 ± 1.5	51.7 ± 1.7	0.001*	0.382	49.7 ± 2.0	58.3 ± 1.7	<0.0005*	0.407
L-FF	54.3 ± 1.7	48.3 ± 2.1	<0.0005*	0.519	47.9 ± 2.2	54.7 ± 2.0	0.004*	0.304
Hallux	53.4 ± 3.5	49.7 ± 3.0	0.002*	0.343	48.6 ± 3.7	54.5 ± 3.3	0.051	0.150

Values are the mean ± SE percentage reduction relative to the control condition of bilateral athletic shoes. Effect size statistic is partial η^2 value. I-FF, intermediate forefoot; L-FF, lateral forefoot; M-FF, medial forefoot. *Significant difference ($P < 0.05$) between offloading conditions.

nor by the interaction of RCW height with lift use ($P = 0.83$).

Stance time for the foot using the RCWs was significantly affected by lift use ($P = 0.011$; effect size = 0.25) but was not affected by RCW height ($P = 0.095$) or the interaction of lift use with RCW height ($P = 0.077$). As a percentage change relative to walking in the control condition of bilateral athletic shoes, wearing the contralateral lift caused a 2.6% (95% CI 0.7–4.5%) smaller increase in stance time.

Neither the main effects of RCW size ($P = 0.68$; mean difference 1.1%; 95% CI –4.5 to 6.8%) and lift use ($P = 0.46$; mean difference 1.9%; 95% CI –7.1 to 3.3%), nor their interaction ($P = 0.37$) significantly altered the heel-to-heel base of support for the offloaded limb. In a similar way, RCW size did not significantly affect double support time for the offloaded limb ($P = 0.22$; mean difference 2.0%; 95% CI –5.2 to 1.2%), lift use ($P = 0.77$; mean difference 0.44%; 95% CI –3.5 to 2.6%), or the interaction of RCW size and lift use ($P = 0.20$).

Plantar Pressure

No significant interactions occurred between the main effects of RCW height and contralateral lift use; independently, however, each significantly affected the loading of both the offloaded foot and the contralateral foot. Multiple regions

of the offloaded foot saw significantly greater reductions in peak pressure with the knee-high RCW (Table 2). Multiple regions of the offloaded foot also had significantly greater reductions in peak pressure when the contralateral lift was not used (Table 2). The peak pressure data from the contralateral foot exhibited a significant effect only in association with lift use. However, the relation was opposite to that within the offloaded foot (Table 3). Multiple regions of the contralateral foot had lower peak pressure values with the use of the lift.

CONCLUSIONS

Although a positive association exists between adherent use of offloading RCWs and DFU healing (8), objective monitoring of adherence indicates that patients only wear these devices during 28–59% of their physical activity (7,8). To date, the primary means of addressing this problem has been to force compliance by making RCWs irremovable (26–28). However, simply making RCWs irremovable does nothing to address the reason(s) why patients are nonadherent. This study sought to evaluate whether the size of RCWs and induced LLD influence users’ comfort and gait.

Subjects rated the ankle-high RCW with contralateral lift as the most comfortable offloading condition, and their rating of its comfort did not significantly differ from

their comfort rating for the control condition of bilateral athletic shoes. By contrast, the least comfortable offloading option of knee-high RCW without a contralateral limb lift was reported as being significantly less comfortable than the control condition. This is important, as a previous study concerning custom-made footwear used to prevent DFUs found that patients identified comfort as the highest priority when determining footwear usability (29). The changes in gait velocity within the current study may have been secondary indicators of differences in comfort, which add further support to the self-reported comfort ratings that designated the ankle-high walker paired with the contralateral lift as the most comfortable offloading option.

The recently reported finding that self-reported neuropathic postural instability is highly predictive of RCW adherence (8) adds substantial weight to the importance of the differences in gait parameters identified in this study. Previous studies of older adults with diabetes found that individuals with greater fear of falling also walk at slower velocities (30,31). In specifically investigating the influence of self-perceived unsteadiness during gait, Reeves et al. (32) found gait velocity to be strongly correlated with self-perceived unsteadiness ($r = -0.57$; $P = 0.0001$). That finding fits well with the premise put forth by Dingwell et al. (33)

Table 3—Reductions in peak pressure for the contralateral foot

	Lift use				RCW height			
	No lift	Lift	<i>P</i> value	Effect size	Ankle	Knee	<i>P</i> value	Effect size
Total foot	1.7 ± 3.5	10.2 ± 3.3	<0.0005*	0.621	6.8 ± 3.1	5.1 ± 3.7	0.299	0.045
M-FF	1.0 ± 3.2	5.2 ± 3.2	0.036*	0.170	3.7 ± 2.7	2.5 ± 3.6	0.528	0.017
I-FF	4.7 ± 2.4	12.3 ± 2.3	0.001*	0.382	7.4 ± 2.0	9.6 ± 2.4	0.084	0.119
L-FF	1.6 ± 3.2	13.5 ± 2.7	<0.0005*	0.510	5.7 ± 2.9	9.4 ± 3.0	0.082	0.120
Hallux	3.7 ± 4.1	10.0 ± 3.7	0.002*	0.339	6.9 ± 3.6	6.8 ± 4.4	0.969	0.000

Values are the mean ± SE percentage reduction relative to the control condition of bilateral athletic shoes. Effect size statistic is partial η^2 value. I-FF, intermediate forefoot; L-FF, lateral forefoot; M-FF, medial forefoot. *Significant difference ($P < 0.05$) between offloading conditions.

that reductions in walking speed by individuals with diabetic neuropathy are a compensatory strategy used to maintain dynamic stability of the upper body. Furthermore, additional studies of older adults found greater gait variability to be a discriminating factor between those who fall and those who do not fall (16), as well as a predictor of frailty status (34). Taking into consideration the findings of previous research with regard to the changes in gait noted in the current study, knee-high RCWs and the LLD caused by RCWs may increase the fear of falling and subsequently be a primary basis for RCW nonadherence. Additional work to evaluate the effect of RCW size and imposed LLDs on users' self-reported measures of fear of falling (e.g., Activities-specific Balance Confidence scale) are warranted to confirm this hypothesis.

The offloading results in this study indicate that the best offloading profile for the foot using the RCWs was the knee-high RCW without the contralateral lift. Several forefoot regions had significantly lower peak pressures with use of the tall walker (mean difference 6.5%) and absence of the contralateral lift (mean difference 4%). As previous work demonstrated a positive association between walking speed and peak plantar pressures (35), it is worth reiterating that participants walked significantly slower in the tall walker. Therefore, the reduced pressures observed with the tall walker were likely due in part to the slower walking speed and not exclusively to a greater capacity for offloading than that provided by the short walker.

Although the amplitudes of the differences in peak pressures between footwear conditions seem rather modest, the impact of such differences on DFU healing is unknown. If the improved comfort and stability associated with the ankle-high RCW paired with a contralateral lift lead to higher RCW adherence, it is conceivable that the higher adherence would more than make up for any detriments to wound healing associated with the slightly smaller amplitude in offloading capacity. Such a phenomenon may help explain why a recent study of offloading by Piaggese et al. (36) obtained results that seem to contradict those of previous works by Armstrong et al. (26) and Katz et al. (27). Piaggese et al. randomized 60 patients with DFUs to either a traditional knee-high total contact cast, an

ankle-high cast walker rendered irremovable, or the same ankle-high cast walker that could be removed. After 90 days they found no differences in DFU healing between the three groups. However, the study by Armstrong et al., with a similar study size, found that a removable knee-high cast walker provided poorer healing than the same knee-high walker rendered irremovable. The study by Katz et al. compared a knee-high walker rendered irremovable with a traditional knee-high total contact cast and found that the two options resulted in equivalent healing rates. The likely explanation for the conflicting results between Piaggese et al. and the other two studies is that patients were more adherent to using ankle-high than knee-high removable walkers.

The present study had limitations due to its single-visit, laboratory-based design. It is possible that perceptions regarding the different offloading options may evolve over the course of treating an active DFU for a period of weeks or months. A larger randomized controlled trial or repeated-measures crossover study in which patients use the varied offloading options for a prolonged period of time would allow for extensive evaluation of patients' experiences. Using tools such as a technology acceptance model and the NeuroQol survey, it would be possible to look at participants' perceptions of benefit, ease of use, and attributes of benefit with regard to the offloading devices, as well as whether the devices had differing effects on users' quality of life (37–39). A better understanding of users' perceptions of RCWs may lead to the development of improved educational interventions for future users (40).

In conclusion, the use of an ankle-high walker and provision of a contralateral limb lift resulted in the best self-reported comfort and improved gait parameters, in contrast to a knee-high walker and absence of a contralateral lift. We anticipate that if this offloading option were provided to individuals with active DFUs, their offloading adherence would improve. Additional research aimed at improving patient experience with offloading of DFUs may lead to improved health outcomes and reductions in health care expenditures.

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