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Preliminary Evaluation of a Cycling Cleat Designed for Diabetic Foot Ulcers

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Abstract

Background—Offloading devices for diabetic foot ulcers (DFU) generally restrict exercise. In addition to traditional health benefits, exercise could benefit DFU by increasing blood flow and acting as thermotherapy. This study functionally evaluated a cycling cleat designed for forefoot DFU.

Methods—Fifteen individuals at risk of developing a DFU used a recumbent stationary bicycle to complete one 5-minute cycling bout with the DFU cleat on their study foot and one 5-minute bout without it. Foot stress was evaluated by plantar pressure insoles during cycling. Laser Doppler perfusion monitored blood flow to the hallux. Infrared photographs measured foot temperature before and after each cycling bout.

Results—The specialized cleat significantly reduced forefoot plantar pressure (9.9 kPa versus 62.6k Pa, $P < .05$) and pressure time integral (15.4 versus 76.4 kPa/sec, $P < .05$). Irrespective of footwear condition, perfusion to the hallux increased (3.97 ± 1.2 versus 6.9 ± 1.4 tissue perfusion units, $P < .05$) after exercise. Infrared images revealed no changes in foot temperature.

Conclusions—The specialized cleat allowed participants to exercise with minimal forefoot stress. The observed increase in perfusion suggests that healing might improve if patients with active DFU were to use the cleat. Potential thermotherapy for DFU was not supported by this study. Evaluation of the device among individuals with active DFU is now warranted.

One-third or more of the costs associated with treating diabetes and its complications in the United States have been associated with the treatment of diabetic foot ulcers (DFU).¹ The most dire consequence of these wounds, and a source of great financial burden,² is lower-extremity amputations. Thus healing these wounds in a timely manner is of great

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importance. Recently, a number of animal and human studies in aged and obese populations have indicated that exercise may be able to play a role in supporting wound healing.^{3–5} Even in the absence of direct DFU benefit, exercise would provide other diabetes-related benefits to patients with DFUs.^{6–8} However, the etiology of DFUs makes exercise a challenge for these patients. The etiology of DFUs typically includes repetitive trauma associated with weightbearing activity in the presence of peripheral neuropathy.^{9,10} Therefore, a key component to the healing of these wounds is the mitigation of physical stress to the wounds, referred to as offloading,^{11,12} which is generally accomplished with specialty footwear. In addition to offloading DFUs, this footwear typically limits the patient's physical activity.

Removable cast walkers and total contact casts have been shown to provide the greatest amount of offloading to the foot.¹³ However, these devices are large and difficult to maneuver in,^{14,15} which likely accounts for the reduction in physical activity seen in patients who use these devices.¹² Decreased physical activity will in turn likely lead to cardiac decompensation, weight gain, and increased blood glucose levels. This is particularly problematic as obesity is highly prevalent in these individuals¹⁶ and these changes could further inhibit wound healing ability for the patient.^{17–19} In contrast, exercise has been shown to improve glycemic control, induce weight loss, and improve cutaneous perfusion to the feet of persons with diabetes.^{20–22} One study that focused specifically on individuals with diabetes and foot complications showed significant improvements in diabetes control (decreased HbA_{1c}), muscle strength, and participants' perceived limitations in functioning.²³ The exercise intervention in that study incorporated moderate aerobic exercise (40%–65% heart rate reserve) consisting of cycling, walking, and/or arm ergometry that was paired with resistance training with a 'generic fitness apparatus.'

In the case of DFUs, there are a number of potential mechanisms by which exercise could benefit the ulcers. As core temperature increases with exercise, a temperature threshold is reached at which point skin blood flow begins to rise.²⁴ This would be beneficial as diminishment in the microcirculation system, which serves as the key oxygen and nutrient delivery system with regards to the entire skin surface,²⁵ have been previously shown to be a risk factor for DFU.²⁶ In considering active DFU, improved pedal microcirculation might not only improve nutrient and oxygen delivery to the wound but it might also result in improved inflammatory responses at the DFU site. Previous work in mice models has suggested that exercise may improve wound healing in old mice (18–22 months) via an anti-inflammatory response.²⁷ Increased inflammation has been highlighted as one of several factors contributing to major regulatory misallocation that leads to stagnation in wound healing.^{28,29} However, the anti-inflammatory cytokine IL-6 markedly increases after exercise.^{30, 31} IL-6 increases in part due to skeletal muscle fibers.³⁰ Not only do muscles produce IL-6, but their contraction helps to release it into the blood stream. Thus increased perfusion to the foot elicited by exercise may result in increased IL-6 within the foot, which may help mitigate chronic inflammation within the ulcer. Lastly, exercise might promote DFU healing by initiating localized warming at the site of the wound. Previous research has suggested that externally warming the foot aids in DFU healing,^{32,33} and it might be possible for exercise to generate heat within the foot that results in similar benefits.

Although there are numerous potential benefits of exercise for persons with DFU, the necessity of offloading the wounds significantly limits patients' exercise options. Most forms of exercise will result in the application of physical stress to DFUs. Some of the more common options to provide aerobic exercise without loading the foot, such as upper-extremity ergometry, exclude the lower extremity and therefore may have some limitation in benefits. Although the lower extremities are incorporated with swimming, it poses other challenges to the open wound such as possible infection and cross contamination.^{34,35}

Initial work in the development of a device designed to allow individuals with forefoot DFU to safely exercise using their lower extremities, yielded promising results.³⁶ This study demonstrated that healthy individuals could use a specially designed cycling DFU cleat (CLEAR Cleat) to significantly reduce the stress to the forefoot (most common site of DFU) during stationary cycling. However, no studies to date have evaluated the DFU cleat in individuals with diabetes. Prior to exposing individuals with active DFU to the device, the purpose of this study was to perform an initial evaluation of the DFU cleat in persons at risk of DFU. The offloading and thermal and vascular responses to cycling with the cleat were evaluated. Promising results of the functionality of the device among individuals at risk of developing a DFU would warrant further investigation in the more vulnerable population of individuals with active DFU.

Materials and Methods

Participants

Fifteen individuals (Table 1) were recruited by study staff from the Scholl Foot and Ankle Center (North Chicago, Illinois). Adults with diabetes and a DFU risk grade 1 or higher (scale ranges from 0–3, with 3 being the highest risk category³⁷) were eligible to participate. Individuals were excluded if they had a DFU either at the time of screening or within the previous 4 weeks. Additionally, individuals were excluded from participating if they were being treated for any chronic cardiovascular conditions including, but not limited to, coronary heart disease, congestive heart failure, chronic obstructive pulmonary disease, or chronic bronchitis. All participants read and signed an informed consent form approved by the Rosalind Franklin University Institutional Review Board prior to participation.

The sample size was based upon expected offloading outcomes using data from Lavery et al.³⁸ With an expected difference in peak pressure of 40 kPa between means and an SD of 20 kPa, seven observations would have been required per condition at a power of 80 and $\alpha = 0.05$ to demonstrate a difference. In order to allow for exploration of secondary outcomes, 15 participants were recruited.

Procedures

The study procedures consisted of a single study visit during which each participant completed two cycling bouts of approximately 5 mins each on a recumbent stationary bicycle (Lifecycle 9500R; Life Fitness, Rosemont, Illinois). The stationary recumbent bicycle was used for two reasons. Because patients with diabetic foot ulcers are commonly obese, it was believed that the back support and large seat would maximize comfort.

Concerns regarding limited mobility and diminished balance of participants provided additional rationale for the use of the stationary recumbent bicycle. During one bout the participant used the bicycle's standard pedals in tandem with standardized athletic shoes (New Balance, Boston, Massachusetts). During the other bout the participant used the DFU cleat with their right foot and retained the standardized athletic shoe on their left foot. The order of the cycling conditions was randomized for each participant for the purpose of preventing any data biases due to the order in which the cycling conditions were tested. Participants were asked during the first bout to obtain a moderate intensity they would feel comfortable maintaining for 30 minutes. They were allowed to alter their cadence and the bicycle's resistance level in order to find the desired intensity of effort. Once they felt they had reached the correct effort level they were asked to maintain constant cadence (revolutions per minute were visually displayed for participants) and were not allowed to modify the resistance level. The participants were asked to replicate this same cadence and resistance level when completing the second cycling bout. Heart rate (HR) was also measured while cycling to ensure that the effort level was similar in each bout. The two cycling bouts were separated by approximately 20 mins of rest.

The DFU cleat is similar in design to a removable cast walker and similarly immobilizes the ankle at 90 degrees (Fig. 1). The DFU cleat differs from short leg walkers in that the base of the cleat is truncated at the level of the midfoot. The cleat secures the heel of the cyclist's foot directly over the pedal, while allowing the forefoot to protrude freely with no fixed base beneath it. This design allows only the heel of the participant's foot to be in contact with the DFU cleat, which further ensures that the forefoot is exposed to only nominal pressures. A specialized offloading insole (Active Offloading Insole; Össur, Reykjavik, Iceland) was used in conjunction with the cleat.

Outcome Measures

The primary outcome of the study was the peak pressure and pressure time integral values associated with the different cycling conditions. Each participant was fitted for appropriately sized plantar pressure monitoring insoles (PedarX; Novel, Munich, Germany). Data were collected at 100 Hz while cycling. For analysis purposes, mean values for 10 consecutive cycling revolutions collected near the end of each trial were used.

Secondary variables included thermal and vascular responses to the cycling. An infrared photograph was taken of the feet prior to and immediately after each cycling session using a Ti25 infrared camera (Fluke; Everett, Washington). Smart view 3.0 software (Fluke) and a custom Matlab (MathWorks, Inc, Natick, Massachusetts) code³⁹ to isolate the foot from the thermal image were used to analyze changes in plantar foot temperature associated with the cycling (Fig. 2). The plantar surface was divided into forefoot (distal 40% foot length), midfoot (intermediate 30% foot length), and heel (proximal 30% foot length) sections to compare temperature in each section. A laser Doppler perfusion monitor (Transonic Systems Inc, Ithaca, New York) was used to assess the vascular response of the plantar tissue of the hallux to the cycling. Before the first cycling session, the surface flowprobe was attached to the plantar surface of the right hallux by an adhesive sticker. The placement on the foot was outlined with a marker to provide reproducible placement. Perfusion was monitored for

approximately 1 min. The probe was removed prior to cycling (as cycling with the probe may have harmed the foot) and then reattached immediately after taking the post-cycling infrared photograph. This procedure was repeated for measuring tissue perfusion during the second cycling bout.

Results

Offloading

Offloading analyses were limited to the right foot (the foot that used the DFU cleat during one of the two trials, Fig. 3). For analysis purposes the pressure data were analyzed for three distinct foot regions by using masking software (MultiMask, Novel). The regions included the heel (proximal 30% foot length), midfoot (intermediate 30% foot length), and forefoot (distal 40% foot length). Repeated measures analyses of variance (ANOVA) with main effects of foot region and footwear condition were used to assess the peak pressure and pressure time integral data. For each set of data both the footwear condition and the interaction of footwear condition with foot region were found to be significant. Therefore, paired *t* tests were used to look at the effect of footwear within each foot region. The results of the *t* tests are presented in Figure 4.

Vascular Response

The tissue perfusion data were also evaluated with a repeated measures ANOVA with main effects of time (pre- versus post-cycling) and footwear condition. The main effect of time was found to be significant. After exercise, the perfusion to the hallux increased 73.9% (3.97 ± 1.2 versus 6.9 ± 1.4 tissue perfusion units). Neither the main effect of footwear nor the interaction of time by footwear was found to be significant.

Thermal Response

Paired *t* tests and repeated measure ANOVA on the temperature readings from the infrared imaging demonstrated no significant changes in the whole foot as well as all subsections of the plantar surface in association with cycling. The right foot temperature for all participants averaged $29.1 (\pm 1.6)^{\circ}\text{C}$ before cycling and recorded $29.4 (\pm 1.8)^{\circ}\text{C}$ after cycling for all conditions.

Exercise Intensity

Ability to maintain consistent exercise intensity was also evaluated. As the resistance level of the ergometer was fixed at each patient's self-selected value, differences in revolutions per minute (RPM) and HR were analyzed. Repeated measures ANOVA with main effects of time (1 min versus 5 min into trial) and footwear condition were used to evaluate RPM and HR data. There were no significant findings for the RPM data, thus participants were able to maintain a consistent speed both within and across the different footwear conditions. The HR data indicated that neither the main effect of footwear condition nor the interaction of footwear condition $\times$ time were significant. However, the main effect of time was found to be significant ($P = .018$) with the mean $\pm$ SD heart rate increasing from minute 1 ($98 \pm 5.6/\text{min}$) to minute 5 ($105 \pm 7.6/\text{min}$). In an effort to estimate exertion levels, the percentage of age-predicted maximum HR⁴⁰ was calculated for the final HR measurements in each of the

footwear conditions. A paired *t* test indicated that the mean $\pm$ SD percentage of maximum HR did not differ between cycling with standard shoes ($61\% \pm 4\%$) versus cycling with the cleat ($61\% \pm 5\%$).

Discussion

In comparison to cycling with standardized athletic shoes, the peak pressure and pressure time integral data both indicated that the DFU cleat was able to significantly reduce forefoot stress during the cycling exercise. While the reduction in peak pressure indicated a drop in the maximum amplitude of stress, the pressure time integral reduction indicated a drop in the total stress imparted over each cycling revolution. Although this was the first study to assess the device with participants at risk for DFU, the results are in agreement with an initial study that used healthy participants.³⁶ Both studies suggest that patients with an active DFU would be able to exercise without incurring appreciable trauma at the site of their wounds. The peak pressure applied to the forefoot in the present study (10 kPa) during cycling with the specialized cleat was well below the values recorded in other studies that assessed loading during walking in offloading devices (66–134 kPa).^{14,41}

The increased laser Doppler values at the hallux following the cycling bout suggest improved microcirculation within the foot and are suggestive of a potential therapeutic benefit should individuals with active DFU perform the exercise. In addition to the oxygen and nutrients²⁵ to be delivered to the surface of the foot, the increased microcirculation should result in increased anti-inflammatory cytokine IL-6 within the foot.^{30,31} The increased IL-6 may in turn oppose a detrimental state of chronic inflammation at the DFU site.^{28,29}

As physical stress-induced site-specific inflammation is associated with increased temperatures⁴² the lack of increased temperature of the foot in the present study indicates that there were no immediate signs of cycling-induced inflammation.^{42,43} While trauma-associated inflammation at bony prominence sites was not anticipated in the DFU cleat condition, it was thought to be a possibility in the forefoot during the standard shoe condition. Furthermore, it was anticipated that the exercise would result in a generalized increase in the temperature of the foot. The results of this study did not support the potential for a thermotherapy^{32,33} effect upon DFU to be elicited by cycling with the DFU cleat. It is possible that such a generalized increase might have been elicited if the exercise period had been longer than 5 mins or if the participants had been exercising at a higher exertion level. The mean $\pm$ SD heart rate after cycling of 105 ± 29 /min in the DFU cleat condition and 105 ± 31 /min in the standard shoe condition suggests that the participants were exercising at a low exertion level.

In addition to the limitation of the short duration of the cycling protocol, there were other inherent limitations in this investigation. As participants only participated in a single visit, there was no evaluation of how individuals would respond to regular use of the device in association with an intervention program. Similarly, as participants were asked to cycle at a moderate intensity that they would feel comfortable maintaining for 30 minutes, but only cycled for two 5-min bouts, participants may have modified their selected cadence or

resistance if they had actually cycled for 30 mins. If a validated exertion scale had been used within the study's protocol there would have been a greater understanding of participants' perceived exertion during the study's two cycling bouts. However for the purposes of this study, the most important factor regarding cycling intensity was ensuring that it was kept consistent between the two cycling conditions to ensure a fair comparison between the different cleat options.

Although this study saw increased perfusion to the hallux of participants, no additional vascular tests such as calculation of the ankle brachial index were conducted for the purpose of describing the sample of participants. Thus it is not possible to state how the results might differ in individuals of varying severity of peripheral vascular disease. Lastly, the use of at-risk patients as opposed to patients with active DFU was a limitation. This was done to maintain a cautious progression in the evaluation of the specialized cleat. Although it is highly unlikely that the offloading results would differ, it is possible the vascular and thermal responses might differ in individuals with active DFU.

Conclusions

In conclusion, this study demonstrated that the specialized cleat was able to offload the forefoot of individuals who are likely to develop DFU. In addition to minimizing stress to the forefoot, exercising with the device elicited an increase in blood flow to the foot. These results suggest that in addition to providing a safe means of exercise for individuals with DFU, ulcer healing might actually benefit from the exercise. However, the study failed to provide support to the theory that cycling with the cleat may provide a thermotherapeutic benefit for individuals with DFU. Evaluation of the device in individuals with active DFU is warranted.

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Conflict of Interest: Mr. Crews and Dr. Wu are named on a patent for the cleat evaluated (US 8,105,257 B2). However, neither of these individuals directly participated in data collection. They also remained blinded regarding trial conditions during data analyses. Only after data analyses were complete were trial conditions unblinded.

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Figure 1. Diabetic foot ulcer cycling cleat. In contrast to a standard cycling cleat, this specialized cleat fixes the rearfoot over the pedal.

Figure 2.
Temperature analysis of the plantar surface of the foot. A, Regular image of a participant's right foot; B, infrared image; and C, edge detection using custom Matlab code.

Figure 3.

Representative three-dimensional pressure profiles. A, Pressure distribution while cycling with bilateral athletic shoes; B, pressure distribution while cycling with DFU cleat on the right foot and athletic shoe on the left foot.

A **B** **Figure 4.**

Peak pressure (A) and pressure time integral (B) offloading results. An asterisk is indicative of a significant ($P < 0.05$) difference between the two footwear conditions for the region of interest.

Table 1

Demographics of Study Participants

Sex, M/F (No.)	7/8
Age (mean $\pm$ SD [years])	53 $\pm$ 8
BMI (mean $\pm$ SD [kg/m ²])	33.7 $\pm$ 4.9
Duration of diabetes (mean $\pm$ SD [years])	10.3 $\pm$ 7.2
Diabetic foot ulcer risk grade ^a	
Grade 1	n = 2
Grade 2	n = 8
Grade 3	n = 5

Abbreviation: BMI, body mass index.

^a Grade 0 is lowest risk and Grade 3 represents a history of previous diabetic foot ulcer and is the highest risk classification