Effect of a Forefoot Off-loading Postoperative Shoe on Muscle Activity, Posture, and Static Balance

Joanne S. Paton, PhD*
Katherine Thomason, FRCS (T&Q)†
Karl Trimble, FRCS†
James E. Metcalfe, FRCS (Orth)†
Jonathan Marsden, PhD*

Background: We investigated whether a forefoot off-loading postoperative shoe (FOPS) alters standing posture, ankle muscle activity, and static postural sway and whether any effects are altered by wearing a shoe raise on the contralateral side.

Methods: Posture, ankle muscle activity, and postural sway were compared in 14 healthy participants wearing either a FOPS or a control shoe with or without a contralateral shoe raise. Participants were tested under different sensory and support surface conditions. Additionally, reductions in peak pressure under the forefoot while walking were assessed with and without a contralateral shoe raise to determine whether the FOPS continued to achieve its primary off-loading function.

Results: Compared with the control condition, wearing a FOPS moved the center of pressure posteriorly, increased tibialis anterior muscle activity, and reduced ankle plantarflexor activity. These changes decreased when a contralateral shoe raise was added. No difference in postural sway was found between footwear conditions. Forefoot peak pressure was always reduced when wearing the FOPS.

Conclusions: The posterior shift in center of pressure toward and behind the ankle joint axis is believed to result in the increase in tibialis anterior muscle activity that now acts as the primary stabilizer around the ankle. Instability may, therefore, increase in patients with weak tibialis anterior muscles (eg, diabetic neuropathy) who need to wear off-loading devices for ulcer management. We suggest that the addition of a contralateral shoe raise fitted with a FOPS may potentially be beneficial in maintaining stability while off-loading the forefoot in this patient group. (J Am Podiatr Med Assoc 103(1): 36-42, 2013)

The forefoot off-loading postoperative shoe (FOPS) is a category of prefabricated, easy-to-fit, and widely available footwear designed to immobilize the forefoot and reduce the mechanical stress transmitted to the area. The shoe is used to assist in the treatment of forefoot trauma when off-loading the forefoot is essential for healing but patient ambulation must be maintained. For example, after many forefoot surgical procedures, a period of complete or partial reduction in forefoot load is required to decrease the risk of postsurgical complications, such as loss of fixation, malunion, and nonunion.1,2 Similarly, FOPSs are routinely used in the management of neuropathic forefoot ulceration as one method of reducing mechanical plantar tissue stress, crucial to creating the optimum healing environment.3 Moreover, the International Working Group of the Diabetic Foot recommends forefoot off-loading shoes as the preferred alternative in diabetic foot ulcer treatment when above-the-ankle devices cannot be used.4

FOPS Design and Mode of Action

A variety of different FOPSs are available for purchase; however, most share the following design characteristics intended primarily to reduce forefoot loads:
• A rocker sole unit with the fulcrum positioned behind the metatarsal heads. The positioning of the fulcrum relative to the plantar foot is crucial for functional success. To maximize forefoot and toe peak pressure reduction, the apex of the rocker must be located posterior to the metatarsal heads.5
• A rigid sole unit to immobilize the forefoot. In gait, during active propulsion when maximum loads are transmitted through the forefoot, the rigid sole unit of the FOPS functions to limit forefoot involvement by resisting metatarsophalangeal joint dorsiflexion.6
• A negative heel wedge to transfer body weight and plantar loads posteriorly.3 The negative heel wedge positioned posterior to the metatarsal heads inhibits the proximal progression of body weight and transfer of plantar loads onto the forefoot.
• Minimal contact area between the sole unit and the floor to support midfoot and rearfoot regions only.7 Bus and colleagues3 found that 40% of forefoot load was transferred to the midfoot when FOPSs with a proximally reduced contact area between the sole unit and the floor and a negative heel were worn.

Evaluation of the design features inherent to the FOPS has focused largely on its proven ability to successfully reduce forefoot pressures, until recently without consideration of possible adverse effects or implications for patient adherence,2,3,8 a vital aspect of intervention clinical efficacy.4 Bus and colleagues3 used a visual analog scale to compare the walking comfort of four different FOPSs with that of control shoes, and Schuh and colleagues1 used a 5-point satisfaction score to rate the comfort, stability, and rolling characteristics of several different postoperative shoes, including one FOPS. Both studies report that participants view the FOPS as significantly less comfortable compared with other footwear conditions. Moreover, although FOPSs were found to be most effective in reducing forefoot pressures, they were also perceived by wearers to be the most unstable. Both studies conclude that the FOPS design features, although effective in reducing forefoot pressures by radically modifying gait kinematics, were also liable to adversely affect patient-perceived comfort and stability.1,3

The FOPS and Muscle Activation and Balance

There is limited evidence to suggest that insoles and orthopedic shoes can affect balance in people with peripheral neuropathy and older people.7,8 In addition, a study of 20 healthy young adults found that rocker-bottom shoes and shoes with a negative pitch had a destabilizing effect compared with a control shoe, thus increasing the potential for imbalance.9 Rocker-bottom shoes are also a feature of commercially available “unstable shoes,” such as the “Masai Barefoot Technology,” and increases in sway are also seen in healthy people when these are first worn.10,11 Given that these same design features are magnified and combined in the FOPS, it seems plausible to expect that the effect of the FOPS on standing posture and stability might be greater. We aimed to investigate the effect of the FOPS not only on posture and sway but also on muscle activation. Some patient groups, such as those with diabetes who may use off-loading devices for the management of ulceration, may have associated peripheral neuropathy and ankle muscle weakness. This may limit their ability to use certain muscle groups to maintain balance.

It is common practice for patients to wear only one FOPS, on the side to benefit from off-loading, thereby creating a substantial asymmetry in postural alignment and gait kinematics, which may increase instability and the need to activate lower-limb muscles to maintain balance. We, therefore, also assessed whether wearing a contralateral shoe raise affects the impact of the FOPS on postural sway, posture, muscle activation, and peak pressure.

Therefore, the purposes of this preliminary investigation were 1) to compare the effect of the FOPS (Darco OrthoWedge; Darco International Inc, Huntington, West Virginia) with a control shoe on static balance, posture, and muscle activity, and 2) to determine how that effect might be altered by using a contralateral shoe raise. Additional clinically relevant information assessing the magnitude of forefoot peak pressure reduction with and without the contralateral shoe raise is also reported, as this is the primary aim of the shoe.

Methods

Participants

Fourteen asymptomatic volunteers (11 females and 3 males; mean ± SD age, 36 ± 10.8 years) were recruited from a convenience sample of staff and students attending Plymouth University, Plymouth, England. Participants were excluded from the study if younger than 18 years or self-reporting a history of lower-limb surgery, trauma, or neurologic disease that may affect standing balance. Written consent
was obtained from participants after explanation of the study. Ethical approval was sought and granted by the Plymouth University ethics committee.

**Footwear Conditions**

Each participant was fitted with three footwear conditions, tested in a random order: 1) a pair of standardized lace-up neutral Kappa training shoes (control); 2) the FOPS, a Darco OrthoWedg worn on the left side, with the control shoe on the right side (FOPS); and 3) a repeat of footwear condition 2 but with the addition of a shoelift device (Evenup; Evenup LLC, Buford, Georgia). The shoelift device consists of a 5-cm removable through-shoe raise attached to the outsole of the right control shoe to even up leg length while wearing the FOPS (FOPS + raise).

**Protocol**

This study was a repeated-measures experimental design; all within-subject measures were performed in a single session. Standing balance, posture, and muscle activity under different sensory and support surface conditions were assessed, followed by a measure of foot pressure while walking (see later herein). The order of the three footwear conditions was randomized using a Latin square design. Participants rested in a sitting position between conditions. The environment in which measurements were taken was standardized; heating and lighting were set at comfortable constant levels, and noise was kept to a minimum.

**Measurement of Standing Balance, Posture, and Muscle Activity.** Participants were instructed to stand “as still as possible” on the force plate (9286AA; Kistler Instruments Ltd, Hampshire, England) while looking straight ahead with their arms by their sides and their feet aligned along the anteroposterior axis of the force plate, 5 cm apart. Foot position was constrained to minimize variability in sway between participants and across conditions due to changes in stance width and foot angle. Participants performed the standing test under four different conditions: eyes open and eyes closed while standing on a firm surface and a compliant surface (a 15-cm-thick medium foam mat; density, 69 kg/m³). A 28-second trial was performed for each condition.

**Standing Balance.** Body sway was measured in two ways. Signals from the force plate were analog-to-digital converted at 200 Hz (CODAmotion, Leicestershire, England). Movement of the center of pressure (COP) in the anteroposterior and mediolateral directions was calculated offline. The COP data were then exported into MATLAB (The Mathworks Inc, Cambridge, England) and filtered with a fourth-order 5-Hz low-pass Butterworth filter and the velocity of COP data in the anteroposterior and combined anteroposterior and mediolateral directions (total COP), calculated as described previously. A second measure, the velocity of body sway (C7 velocity), was calculated by recording the motion of a marker placed at the level of the C7 spinous process using three-dimensional motion analysis (CODAmotion). Movement of the marker in the horizontal plane provided a combined measure of anteroposterior and mediolateral motion.

**COP Position.** The COP position relative to the foot was calculated from the COP position collected with the force plate and referenced to the position of a marker placed in line with the tip of the lateral malleolus captured by the three-dimensional motion analysis. The COP position relative to the foot was analyzed only when standing on a firm surface. The COP position was not measured while standing on foam because the foam obscured the foot markers.

**Muscle Activity.** Surface electromyography (MTS; Medical Research Ltd, Leeds, England) was performed on the left gastrocnemius and tibialis anterior muscles. Electrodes were placed longitudinally over the belly of each muscle with a 2.5-cm interelectrode distance according to SENIAM guidelines (http://www.seniam.org/). Signals were amplified (×1000) and were sampled at 2 kHz. In MATLAB, signals were filtered (30 Hz–1 kHz) and rectified, and the mean amplitude over the length of each standing condition was calculated.

**Measurement of Foot Pressure While Walking.** Reduction in mean peak forefoot pressure data for the left side were collected using an in-shoe pressure measurement system (F-Scan, version 6.3x; Tekscan, South Boston, Massachusetts) at a sampling frequency of 50 Hz. The sensors were cut to the appropriate size and fitted into the test footwear, and the participant was then weighed and the sensor calibrated. Dynamic in-shoe pressure data were recorded by the F-scan while participants walked 10 m at a self-selected speed to enable the collection of a minimum of three midgait steps. Using standard F-scan masking software, maximum mean peak pressure was calculated at two plantar sites: 1) the region under the hallux and 2) the region under the first metatarsophalangeal joint. It is recognized that the F-scan in-shoe measurement system has limitations, in particular in terms of absolute data values; however, several studies have suggested that the system is adequate for determin-
ing the rank order of data and, therefore, was considered appropriate for use in this study.\textsuperscript{15,16}

**Data Analysis**

The effects of the three footwear conditions on COP and C7 velocity, COP position relative to the foot, muscular activity, and peak pressure while walking were analyzed with repeated-measures analysis of variance. For the walking trials, the factor was shoe condition (n = 3), and for the standing trials, the factors were footwear condition (n = 3), vision (n = 2, eyes open versus eyes closed), and surface (n = 2, firm versus foam). A Greenhouse-Geisser correction was used to correct for significant differences in sphericity. Post hoc analyses compared the FOPS and FOPS + raise conditions with the control condition.

Based on amplitude-of-sway data from a study distinguishing between elderly fallers and nonfallers,\textsuperscript{17} a sample size of 13 was estimated to give 95% power to yield a statistically significant result at $P = .05$.

**Results**

**Effects on Postural Sway**

There were no significant differences in anteroposterior sway or total COP velocity (COP anteroposterior: $F_{2,26} = 3.8, P > .05$; COP total: $F_{2,26} = 0.7, P > .05$) among the three footwear conditions investigated (Fig. 1A). For anteroposterior COP velocity and total COP velocity, there were significant differences among the four standing test conditions (Fig. 1A). There was a significant effect of vision (COP anteroposterior: $F_{1,13} = 125.1, P < .001$, Fig. 1A), with sway being higher with eyes closed, and a significant effect of surface (COP anteroposterior: $F_{1,13} = 225.9, P < .001$; COP total: $F_{1,13} = 432.6, P < .001$, Fig. 1A), with sway being higher when standing on foam.

There was also a significant vision $\times$ surface interaction (COP anteroposterior: $F_{2,26} = 160.2, P < .001$; COP total: $F_{2,26} = 166.8, P < .001$), with the increase in sway with eyes closed being greater when standing on foam (Fig. 1A).

No significant effect was apparent in anteroposterior C7 velocity or total C7 velocity between footwear conditions (C7 anteroposterior: $F_{2,26} = 1.2, P > .05$; C7 total: $F_{2,26} = 0.04, P > .05$). However, a significant difference was found in anteroposterior C7 velocity and total C7 velocity between the four standing test conditions (Fig. 1B), with greater sway being seen with the eyes closed (C7 anteroposterior: $F_{1,13} = 47.5, P < .001$; C7 total: $F_{1,13} = 73.9, P < .001$) and when standing on foam (C7 anteroposterior: $F_{1,13} = 90.5, P < .001$; C7 total: $F_{1,13} = 166.4, P < .001$). The effects of closing the eyes were larger when standing on foam (C7 anteroposterior: $F_{2,26} = 80.7, P < .001$; C7 total: $F_{2,26} = 150.8, P < .001$, Fig. 1B).

**COP Position**

When standing on a firm surface, there was a tendency for the COP position to move posteriorly when wearing the FOPS compared with the control shoe; this tendency was less when wearing the shoe raise (mean $\pm$ SD: FOPS versus control = $-10.2 \pm$...
12.9 mm; FOPS + raise versus control = −3.8 ± 13.5 mm, \( F_{2,26} = 3.2, P = .056 \). There was a small but consistent mean ± SD posterior shift of 2.1 ± 3.2 mm in the COP when closing the eyes (\( F_{1,13} = 5.7, P < .05 \)).

**Effects on Muscle Activity**

Mean tibialis anterior muscle activity was altered by footwear condition (\( F_{2,26} = 6.8, P < .005 \), Fig. 2A). Post hoc comparisons showed that the activity was significantly higher in the FOPS condition compared with the control condition (\( F_{1,13} = 11.4, P < .01 \)). There was no difference between the control and the FOPS + raise conditions. There was a significant surface \( \times \) condition interaction (\( F_{2,26} = 5.5, P < .01 \)); when standing on foam, electromyographic activity decreased in the FOPS + raise and FOPS conditions and increased in the control condition (Fig. 2A).

Mean gastrocnemius muscle activity was altered by condition (\( F_{2,26} = 6.4, P < .05 \)), with activity being significantly higher in the control condition compared with the FOPS and FOPS + raise conditions (Fig. 2B).

Tibialis anterior and gastrocnemius muscle activity was significantly higher with the eyes closed (tibialis anterior muscle: \( F_{1,13} = 28.6, P < .001 \); gastrocnemius muscle: \( F_{1,13} = 30.5, P < .001 \)), and the increase in activity with eyes closed was greater when standing on foam (tibialis anterior muscle: \( F_{2,26} = 6.28, P < .05 \); gastrocnemius muscle: \( F_{2,26} = 9.16, P < .05 \), Fig. 2). Gastrocnemius muscle activity was enhanced when standing on foam (\( F_{1,13} = 8.5, P < .05 \), Fig. 2B).

**Peak Pressure While Walking**

There was a significant effect of footwear condition on peak pressure under the first metatarsophalangeal joint (\( F_{2,26} = 10.9, P < .001 \)) and under the hallux (\( F_{2,26} = 38.8, P < .001 \)). Post hoc comparisons showed that the pressure was significantly reduced in the FOPS and FOPS + raise conditions compared with the control condition (hallux: FOPS versus control: \( F_{1,13} = 46.6, P < .001 \); FOPS + raise: \( F_{1,13} = 32.9, P < .001 \); metatarsophalangeal: FOPS versus control: \( F_{1,13} = 413.7, P < .005 \); FOPS + raise: \( F_{1,13} = 9.7, P < .005 \), Table 1).

**Discussion**

The present results confirm previous findings that FOPSs are effective in reducing peak pressures at the first metatarsal head and hallux. Furthermore, the effect was maintained with the addition of a contralateral shoe raise. These sites are highly susceptible to ulcer formation and often require surgical intervention and, therefore, are areas frequently in need of protection and off-loading.\(^1,3\) Despite reports that FOPSs are perceived by wearers as unstable, there is little in the literature to support that claim or to investigate the effect of wearing FOPSs on muscle activation. This study additionally found that wearing a FOPS resulted in a posterior shift of the COP, a significant increase in

![Figure 2](image-url)
tibialis anterior muscle activity, and a decrease in ankle plantarflexor muscle activity. There was, however, no increase in overall postural sway, even when balance was challenged by reducing the sensory cues available and decreasing the stability of the support surface.

Normally, the COP and the center of mass lie anterior to the ankle joint axis, and the body tends to sway like an inverted pendulum, being mainly controlled by the action of the ankle plantarflexors. One explanation for the present results is that owing to the rocker design of the FOPS, the COP moves backward toward and posterior to the ankle joint axis, which requires an increase in tibialis anterior muscle activity to maintain stability. In the healthy participants used in the present study, the tibialis anterior muscle was able to maintain postural stability to the same degree as the ankle plantarflexors normally do when the COP and the center of mass lie anterior to the ankle joint, as seen in the control condition.

Shoes with a rocker sole, such as the FOPS, are commonly used by people with diabetes to off-load the forefoot to help manage ulceration. Previous work has shown that people with diabetes and current ulceration also do not show an increase in postural sway when wearing rocker shoes, contrary to subjective reports that they often feel more unstable. This result is in contrast to other studies that have investigated commercially available “unstable” shoes, such as the “Masai Barefoot Technology” shoe, where significant increases in sway are seen when they are first worn. This finding may reflect factors such as the smaller base of support in the latter shoes compared with the postoperative shoe tested in the present study and differences in rocker positioning and design.

Studies in people with diabetes have also demonstrated a similar posterior shift in the COP as reported herein, although muscle activity was not measured. The finding that the posterior shift in the COP is accompanied by an increase in tibialis anterior muscle activity in the present study suggests that balance may be compromised in people with diabetes with additional peripheral neuropathy and weakness in the tibialis anterior muscle. In these circumstances, one may predict that postural sway increases when wearing the FOPS, particularly when sensory cues and support surface properties are altered, or that the postural control strategy may alter the more proximal muscles and that motion would be required to maintain balance.

This study further suggests that one potential way of reducing the shift in the COP and the increase in tibialis anterior muscle activity may be to provide a contralateral shoe raise. Schuh and colleagues suggest that the posterior shift in the COP was responsible for the perceived discomfort and instability reported by their participants wearing the Darco OrthoWedge postoperative shoe. If this were true, then a contralateral shoe raise in conjunction with the FOPS may also improve acceptability of the intervention while still reducing forefoot peak pressure.

Only healthy individuals without foot abnormalities were recruited; therefore, the potential concurrent effect of foot pain and pain avoidance on balance could not be observed; this should be recognized before generalizing findings to a patient population. Despite this limitation, the information presented is of use and suggests two important areas warranting further investigation: 1) to determine the effect of the FOPS on the postural stability and balance strategy in patients with tibialis anterior muscle dysfunction and 2) to determine whether the decreased differences observed with the addition of a contralateral shoe raise were of clinical value in terms of patient-perceived comfort, stability, and compliance.

A further limitation of this study is that the effect of the FOPS on stability was evaluated only during static stance. Although the measurements of postural stability selected for use in this study have been widely used elsewhere to investigate balance and can predict fall risk, patients may experience greater balance difficulties while wearing these FOPSs during ambulation. In addition, the data

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Table 1. Peak Pressures Under the Hallux and Under the First Metatarsophalangeal Joint for the Different Footwear Conditions

<table>
<thead>
<tr>
<th>Location</th>
<th>Control Condition</th>
<th>FOPS Condition</th>
<th>FOPS + Raise Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hallux</td>
<td>136.5 ± 18.7</td>
<td>138.3 ± 14.5</td>
<td>232.1 ± 39.1</td>
</tr>
<tr>
<td>First metatarsophalangeal joint</td>
<td>44.2 ± 10.3</td>
<td>67.3 ± 18.0</td>
<td>204.1 ± 28.3</td>
</tr>
</tbody>
</table>

Abbreviation: FOPS, forefoot off-loading postoperative shoe.
collection in this study occurred shortly after fitting of the footwear condition and, therefore, is representative only of the immediate effect of the device on balance. Research using a longitudinal study design is, therefore, recommended to determine the effect of the FOPS on balance and walking over time.

Conclusions

The results of this study indicate that use of the FOPS leads to a posterior shift in COP position and a concurrent increase in tibialis anterior muscle activity. However, there was no overall increase in whole-body sway compared with the control condition, even when sensory cues were reduced and the support surface was made more unstable. This finding suggests that in healthy participants, the tibialis anterior muscle is able to control standing bipedal balance as adequately as the ankle plantar-flexors. In people with weakness in the tibialis anterior muscle who use rocker-type shoes for the management of ulceration (eg, neuropathic individuals with diabetes), balance may, therefore, be compromised. The present findings suggest that one potential solution is to wear a shoe raise on the contralateral side to move the COP forward and reduce the activity in the tibialis anterior muscle. This may also be accompanied by a reduction in subjective feelings of imbalance and improve compliance.

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References