The Effect of a Heel to Toe Rocker Sole on Walking in Patients with Type 2 Diabetes: A Pilot Study

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Submitted: 2020-04-02; **Accepted**: 2020-06-18; **Doi:** https://doi.org/10.22037/jcpr.v5i3.29277

Abstract

Introduction: Rocker-soled shoes are usually used to help for preventing foot problems in the diabetic population. However, different designs of rocker sole exist, there is limited knowledge regarding their effect on gait parameters in diabetic patients. **Methods and Materials:** Six subjects with type 2 diabetes (4 males, and 2 females) walked in a gait laboratory setting. A three-dimensional motion capture system was used to acquire gait data when walking barefoot, with un-adapted footwear, or footwear adapted with a heel-to-toe rocker sole**.** The gait variables were as follows: spatiotemporal parameters (walking speed, cadence, percentage of stance phase, and stride length) and sagittal range of motion of ankle, knee, and hip joints. **Results:** Among spatiotemporal parameters, only the stance phase percentage was significantly increased when the subjects walked with the rocker-soled footwear (12%) and un-adapted footwear (10.7%) compared with barefoot walking, but not significant difference between 2 footwear conditions. There were no significant differences between the three test conditions in hip, knee or ankle joint ranges of motion in the sagittal plane. **Conclusion:** This pilot study demonstrated that footwear can potentially be adapted with a rocker sole profile in diabetic patients without significantly affecting hip, knee and ankle sagittal plane kinematics.

Key words: Diabetes; Footwear; Heel-to-toe Rocker Sole; Walking

Please cite this paper as: Gordahani SAA, Arazpour M. The Effect of a Heel to Toe Rocker Sole on Walking in Patients with Type2 Diabetes: A Pilot Study. J Clin Physio Res. 2020; 5(3): e20. Doi: https://doi.org/10.22037/jcpr.v5i3.31712

Introduction

Recent estimates have predicted that total diabetic population worldwide will reach 300 million in 2025 and 366 million in 2030 (1) with 50% subjects also developing peripheral neuropathy (2, 3). Patients with diabetes are advised to wear rocker-soled footwear as a preventative measure if they are at risk of developing plantar neuropathic foot ulceration or indeed if neuropathic ulcers have previously developed which have since healed (4, 5). They are designed to decrease loading on the forefoot by limiting the sagittal plane range of motion (ROM) of foot joints and reduce the externally-applied sagittal plane dorsiflexor moments acting during stance phase as well as plantar foot pressures (6). The magnitude of reduction in movement and plantar pressures depends on the design of rocker profile utilized in the footwear and its apex position (5).

Gait parameters in people with diabetes may differ from that of those with normal walking patterns (2, 7, 8). Walking speed is reduced in this patient population, along with the reduction in stride length and cadence. An increase in double support time can also occur (2, 9, 10) as well as an alteration to the magnitude of ground reaction forces(11). When compared to healthy control subjects, diabetic subjects also show a decreased plantar flexion ROM at ankle, as well as reduced flexion at knee(12-14).

Previous studies have evaluated the effect of rocker soles on gait kinematics and kinetics in diabetic people(5), but the most have indicated that limited alterations of ankle and hip joint motion at sagittal plane may be expected when healthy adults walked with the most commonly-used rocker sole designs used in clinical practice (15-18). With regards to the effect of rocker soles on diabetic people, investigations have shown that wearing types of rocker shoes can decrease plantar pressures during walking.

Figure1. The un-adapted bootee; A) and bootee adapted with the heel to toe rocker sole; *B*) used in this study

However, for gait parameters, most studies have assessed the influence of toe-only rocker shoe in individuals with diabetes(19, 20). A recent study indicated that cadence and step length were significantly increased and ROM of ankle, knee, and hip joints was significantly reduced while walking with toe-only rocker shoe compared with standard shoe in patients with type 2 diabetes(19). One of most popular rocker style shoes is heel to toe rocker sole (the sole curves upward at the front towards the toes and also at the back towards the heel). This rocker can reduce peak plantar pressures in the medial forefoot, central forefoot, and toe regions in comparison of the flatter style footwear, thereby decreasing the risk of ulcerations in the foot. However, to the best of your knowledge, there is no study to investigate the effect of footwear with heel to toe rocker sole profile on gait parameters in individuals with diabetes. Therefore, the present study aimed to investigate gait parameters of diabetics using heel to toe rocker sole shoe. We hypothesize that subjects with diabetes wearing a shoe with multi-curve heel-to-toe rocker sole adaptation will elicit difference in spatiotemporal gait parameters and hip, knee and ankle joint kinematics compared to wearing a shoe without rocker sole adaptation.

Methods and Materials

Subjects

Six subjects with type 2 diabetes [4 males, 2 females; aged 55.33 (11.32) years, of height 168.16 (6.11) cm, and weight 73.53 (5.73) kg], who were previously referred from physicians to receive orthotic intervention, participated in this pilot study. The inclusion criteria were the presence of type 2 diabetes, and being able to wear off-the-shelf shoes with no current evidence of neuropathic foot ulceration. Diabetic subjects who had limited walking capability, or concurrent diseases (e.g. hallux limitus, hallux rigidus, first metatarsal head dorsal exostosis, sesamoiditis, metatarsal head fractures, mid tarsal joint osteoarthritis, rheumatoid metatarsal head pain and dysfunction, osteoarthritis of the ankle, rheumatoid arthritis affecting the rear foot and ankle joint, Achilles tendon injuries, and plantar fasciitis), which would affect the lower extremity, were excluded from the study. *The written and informed consent* was obtained from all subjects before being enrolled in the present study. Approval for performing the study was obtained from the ethics committee of the University of Social Welfare and Rehabilitation Sciences. Finally, six patients undertook the pilot walking trials.

Two pairs of booties were provided for each subject after the assessment for shoe size by an expert orthotist (Figure1). The footwear sizes supplied ranged between size 38 and 43. The uppers were made from cotton lined with neoprene. The booties had a removable 4mm plastazote inlay inserted for protection of the plantar surface of the feet.

The un-adapted bootee (flat sole) incorporated a wedge-style sole unit, with a shallow rocker shape to the midfoot and was manufactured to provide a toe spring profile equivalent to a 7- degree rocker angle. The heel-to-toe rocker sole profile which formed the other footwear test condition was designed with more pronounced shaping to provide additional rocking motion. It had a relatively small radius in the heel portion, and an anterior toe rocker curve with a larger radius to provide a gradual roll forwards at the forefoot. The toe rocker portion started at 65% of shoe length relative to the back of the heel. The apex of the central portion was positioned at 50% of shoe length from the back of the heel to provide a rocking motion and also offer increased stiffness when compared to the baseline shoe(5). The sole units were all manufactured using the same microcellular rubber with a shore value of 35–40 (shore Adurometer) and a sole strip was added to ensure reduction of bending of the sole unit during ambulation.

Table 1. Mean (SD) andinter-quartile range (first and third) of the spatial-temporal parameters in using the two types of interventions in this study compared to barefoot (* P<0.05)

	Stance phase (%)		Cadence (step/min)		Stride length (m)		Walking Speed (m/s)	
	Mean (SD)	**Inter-quartile range**	**Mean (SD)**	**Inter-quartile range**	**Mean (SD)**	**Inter-quartile range**	**Mean (SD)**	**Inter-quartile range**
Barefoot (B)	51.99 (1.43)	50.74,53.56	88.48 (9.31)	79.12, 97.37	1.15 (0.03)	1.11,1.18	0.81 (0.15)	0.66,0.92
Baseline footwear (BF)	57.57 (3.16)	55.10,60.15	86.81 (7.51)	80.22, 94.23	1.19 (0.06)	1.15,1.34	0.78 (0.17)	0.68,0.92
Heel-to-toe rocker soled footwear (RF)	58.13 (4.16)	55.89,61.29	84.39 (10.32)	74.99, 96.64	1.18 (0.05)	1.13,1.22	0.77 (0.15)	0.68,0.86
power	0.032		0.048		0.039		0.029	
Effect size	0.092		0 .268		0.181		0.062	
***P*-value for comparison between conditions B and BF**	0.007*		0.564		0.203		0.339	
***P*-value for comparison between conditions B and RF**	0.005*		0.257		0.182		0.63	
***P*-value for comparison between conditions BF and RF**	0.773		0.532		0.846		0.254	

Table 2. Mean (SD) andinter-quartile range (first and third) of the hip, knee and ankle kinematics during walking in the two types of interventions compared to barefoot

	Hip joint ROM		Knee joint ROM		Ankle joint ROM	
	Mean (SD)	Inter-quartile range	Mean (SD)	Inter-quartile range	Mean (SD)	Inter-quartile range
Barefoot (B)	44.53 (6.3)	38.72, 51.74	50.49 (11.08)	37.77, 59.94	31.27 (7.78)	23.11, 36.59
Baseline footwear (BF)	47.46 (4.53)	39.02, 50.48	56.89 (5.08)	51.26, 60.16	30.43 (4.54)	25.83, 31.55
Heel-to-toe rocker soled footwear (RF)	45.55 (6.24)	40.73, 53.05	54.75 (4.76	49.95, 59.14	31.71 (9.45)	24.75, 33.72
power	0.024		0.037		0.035	
Effect size	0.350		0.434		0.172	
***P* value for comparison between conditions B and BF**	0.154		0.1854		0.759	
***P* value for comparison between conditions B and RF**	0.846		0.496		0.393	
***P* value for comparison between conditions BF and RF**	0.654		0.939		0.800	

Gait analysis

The subjects were asked to walk in a gait laboratory at the University of Social Welfare and Rehabilitation Sciences in order to facilitate data capture of gait parameters. A short time of adaptation was permitted before testing each test condition. Prior to testing each of the test conditions, thus, the participants were asked to walk at a normal speed in the laboratory environment for 5 minutes in order to adapt to each footwear. Kinematic data were integrated with force plate data using a Vicon digital motion capture system (Oxford Metrics, UK, 640), using six cameras (Vicon, Infrared) at a frequency of 100 HZ. Reflective markers were placed over specific bony landmarks including: the top of the sacrum (L4-L5), bilaterally on the anterior superior iliac spines (ASIS), greater trochanter, knee joint sagittal plane lateral centre, laterally over both fibular head, lateral malleoli, the calcaneus, and the head of the first and fifth metatarsals. The putting surface markers on the shoes to represent the foot in different gait analysis techniques may provide a further source of error. We forced to provide three holes to put the foot markers on the shoe because we could not access to foot. One person was put the markers directly over the anatomical landmarks on the calcaneus, and the head of the first and fifth metatarsals portions on the shoe. Classical methods describing distal segment orientation relative to the next proximal segment were employed.

Five trials were performed for each test condition (walking barefoot, walking with the un-adapted footwear or walking with footwear adapted with the heel-to-toe rocker sole) at the subject's self- selected walking speed in a randomised order. The mean of these trials was considered for each walking condition. Only motion analysis of the joint kinematics (in sagittal plane) was reported in this study.

Data Processing

Dominant right-side limb data were extracted for the analysis of all participants. The lower limb joints angels (hip, knee, and ankle) were calculated by measuring the relative angles between reference frames defined on each body segment such as trunk, thigh, shank, and foot. The frames in turn were defined using the markers put on the body segments. Joints ROMs were calculated as the difference between the maximum and minimum values in a gait cycle. Data were processed at 100 Hz with VICON Body Builder (Oxford Metrics, Oxford, UK) using the standard lower limb model included in the software. The data was then analysed using MATLAB (Math Works, Natick, MA). The primary variables of interest were as follows: spatiotemporal gait parameters (walking speed, cadence, percentage of stance phase, and stride length) and sagittal ROM of ankle, knee, and hip joints.

Statistical Analysis

The Willcoxon test was applied instead of the t-test because of low sample size. This was used to compare the effect of the heel-to-toe rocker sole and un-adapted shoe and also two footwear conditions and barefoot walking condition on the specified gait parameters. SPSS statistical software version 17 was used for data analysis. A $P<0.05$ was regarded as significant level.

Results

Table 1 demonstrates the mean stance phase percentage, walking speed, stride length, and cadence when walking in three test conditions. There was no statistically significant difference in walking speed, cadence or stride length when comparing barefoot walking with both of the footwear conditions along with no significant different between two footwear. There was only a significant increase in the stance phase percentage when comparing barefoot walking in comparison of both footwear conditions (un-adapted shoe 5.58%, heel-to-toe rocker sole: 6.32%), with no statistically significant difference when comparing the footwear conditions.

Figure 2 and Table 2 show the hip, knee and ankle joint kinematics when walking with three test conditions. At heel strike (Figure 2), the subjects had similar hip joint flexion angles, but at terminal stance, heel-to-toe rocker profile produced greater hip joint extension to some extent compared to the un-adapted footwear. The maximum knee flexion in swing phase was also increased in the rocker footwear condition compared to using the un-adapted footwear, but knee extension in midstance was decreased. The heel-to-toe rocker profile induced a dorsiflexion shift in the kinematic data at initial contact and during mid-stance compared to the un-adapted footwear. Although there were the differences among graphs in three test conditions, ankle, knee, and hip joint sagittal plane ROMs were not statistically significantly altered in all conditions (Table 2, $p> 0.05$).

Discussion

This pilot study was designed to obtain a first indication of the clinical relevance of adding a specific rocker sole profile to footwear to ascertain its effect on walking parameters in diabetic subjects. This paper focused on spatiotemporal gait parameters as well as hip, knee and ankle kinematics These parameters have clinical relevance for the quality of life of diabetic patients and their ability to undertake daily activities (21).

The walking speed of people with diabetes has been shown to range from 0.7 to 1.24 m/s; which is significantly lower than that of control healthy subjects (0.9 to 1.47 m/s). Step length values range from 1.38 to 1.54 m for healthy controls, and from 1.08 to 1.38 m in diabetic subjects(21). Several factors such as subject's height, lower limb length, and age can influence gait speed as well as the existence of pathology. The subjects in this study had an average walking speed of 0.8 m/s in the barefoot walking which is within the typical range noted for diabetic patients (0.7 to 1.24 m/s), (21). The use of un-adapted and the rocker-soled footwear both caused a reduction in the walking speed (3% and 4% respectively) and cadence (2% and 4% respectively) and an increase the stride length (4% and 3% respectively) compared to barefoot walking in this study, but those did not reach a significant difference. However, stance phase percent was ~52% in barefoot condition which was significantly shorter than both footwear conditions. This rate is below the 63% associated with unimpaired walking. It seems that this rate is a feature of barefoot gait in patients with diabetes. One of reason for the increase of stance phase and no significant difference of other spatiotemporal using shoes can be due to added weight of shoes during gait compared with barefoot walking.

Diabetic mellitus is one of the clinical indications for using rocker sole profiles in footwear, where the primary objectives are to reduce plantar foot pressures by limiting sagittal plane ankle joint and metatarsophalangeal joint motion (5). Previous studies have reported that the toe-only rocker shoe could affect people's gait with diabetes(19, 20). In this study, the heel-to-toe rocker

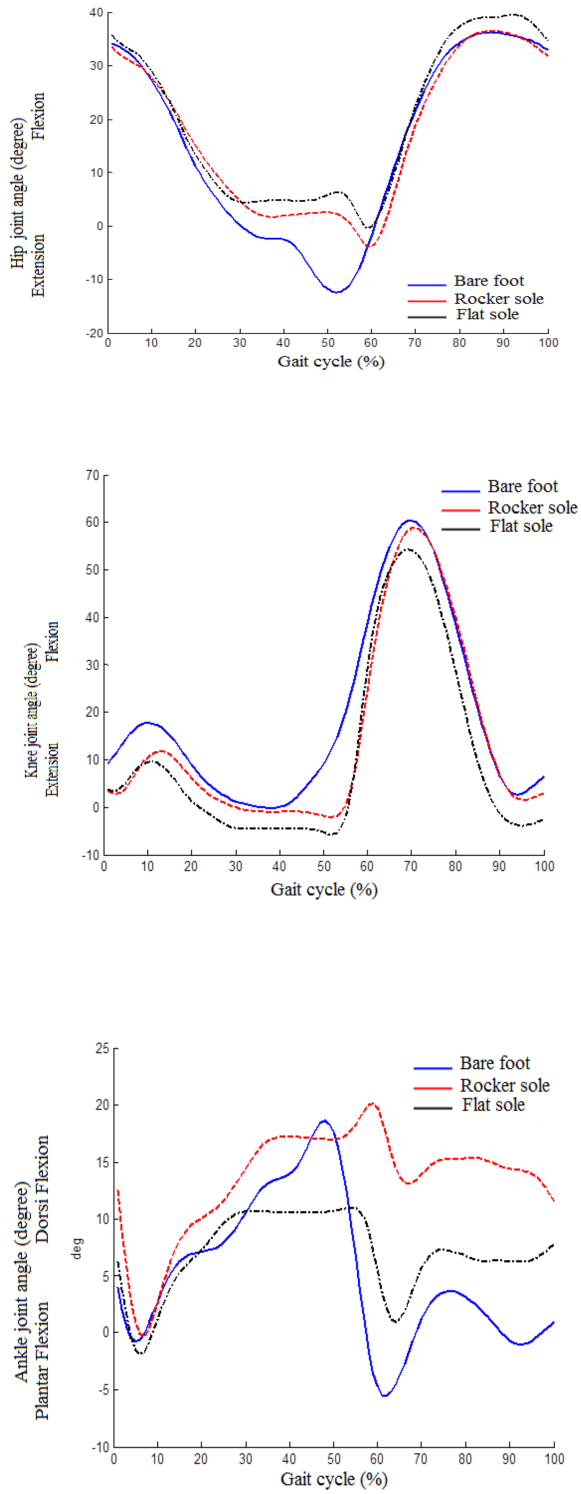

Figure 2. Hip, knee and ankle joint sagittal plane kinematics for the three test conditions Joint angle: positive numbers=flexion/dorsiflexion; negative numbers=extension/plantar flexion

profile induced a dorsiflexion shift in the kinematic data during mid-stance compared to the un-adapted footwear (Fig.2). On the other hand, using either rocker sole profile did not significantly change sagittal plane ankle, knee, and hip joint ROM compared to walking in the barefoot test condition. The rocker apex was positioned at 50% of shoe length on the heel-to-toe rocker profile. Due to production of a virtual negative shaping posterior to this, therefore, diabetic subjects were probably able to roll forwards so effectively. Another possible reason can be due to lack of adaptation time wearing heel-to-toe rocker sole footwear during daily living which requires further investigation in associated with the balance evaluation.

The small number of subjects (n = 6) who participated in the study was a limitation of this study. Both the subjects and the assessors were also un-blinded. In addition, kinetics and muscle activity data were not analysed in this study. Moreover, the adaptation time with the footwear was so short. However, the results from this pilot study gave the authors a confidence to proceed into a larger study involving more participants to more fully understand the mechanism behind the results of this pilot study. For such comparisons, the statistical power was under 80% and the effect size was small in this study. So, an appropriately larger sample size could reveal significant differences.

Conclusion

This pilot study demonstrated that footwear can be adapted with rocker sole profiles in diabetic patients without significantly affecting lower limb kinematics at the hip, knee, and ankle in diabetic subjects.

Acknowledgements

We would like to thanks Dr Ali Ajdarkosh, MD, CED of Daniellee holding for your support to perform this study.

Conflict of interest:
None

Funding support:
None

Authors' contributions:
All authors made substantial contributions to the conception, design, analysis, and interpretation of data.

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