



Full length article

Three-curve rocker-soled shoes and gait adaptations to intermittent claudication pain: A randomised crossover trial

Alastair R. Jordan^{a,*}, Garry A. Tew^b, Stephen W. Hutchins^{c,1}, Ahmed Shalan^d, Liz Cook^e, Andrew Thompson^d^a School of Sport, York St John University, Lord Mayor's Walk, York, YO31 7EX, United Kingdom^b Department of Sport, Exercise and Rehabilitation, Northumbria University, Newcastle upon Tyne, NE1 8ST, United Kingdom^c Directorate of Prosthetics and Orthotics and Podiatry, School of Health Sciences, University of Salford, Frederick Road, Salford, M6 6PU, United Kingdom^d General Surgery Department, York Hospitals Foundation Trust, Wigginton Road, York, YO31 8HE, United Kingdom^e York Trials Unit, Department of Health Sciences, University of York, York, YO10 5DD, United Kingdom

ARTICLE INFO

Keywords:

Peripheral arterial disease
Walking gait
Biomechanics
Footwear
Peripheral artery disease
Rocker shoes

ABSTRACT

Background: Intermittent claudication (IC) is a symptom of peripheral arterial disease where a cramp-like leg pain is exhibited during walking, which affects gait and limits walking distance. Specifically-designed rocker-soled shoes were purported to mechanically unload the calf musculature and increase walking distances until IC pain.

Research questions: Do three-curve rocker-soled shoes increase walking distance and what are the biomechanical differences during pain-free walking and IC pain-induced walking, when compared with control shoes?

Methods: Following NHS ethical approval, 31 individuals with claudication (age 69 ± 10 years, stature 1.7 ± 0.9 m, mass 83.2 ± 16.2 kg, ankle-brachial pressure index 0.55 ± 0.14) were randomised in this crossover trial. Gait parameters whilst walking with rocker-soled shoes were compared with control shoes at three intervals of pain-free walking, at onset of IC pain (initial claudication distance) and when IC intensifies and prevents them walking any further (absolute claudication distance). Two-way repeated measures ANOVA were performed on gait variables.

Results: When compared with control shoes, rocker-soled shoes reduced ankle power generation (mean 2.1 vs 1.6 W/kg, respectively; $p = 0.006$) and altered sagittal kinematics of the hip, knee and ankle. However, this did not translate to a significant increase in initial (138 m vs 146 m, respectively) or absolute (373 m vs 406 m, respectively) claudication distances. In response to IC pain, similar adaptations in temporal-spatial parameters and the sagittal kinematics were observed between the shoe types.

Significance: The three-curved rocker shoes, in their current design, do not augment gait sufficiently to enhance walking distance, when compared with control shoes, and therefore cannot be recommended for the intermittent claudication population.

Clinical Reg No. (ClinicalTrials.gov): NCT02505503.

1. Introduction

Intermittent claudication (IC) is the most common symptom of peripheral arterial disease [1]. Atherosclerosis of the lower limb arteries commonly results in ischaemic pain in the calves during physical activity; which is relieved by rest [2–4]. Individuals with IC report a reduced quality of life due to an impairment of physical functions and IC pain which adversely affect gait, limits walking distances and encourages a sedentary lifestyle which has poor cardiovascular and

illhealth outcomes [5–12]. Current treatments for IC include surgery and/or conservative interventions such as smoking cessation, drug management and supervised exercise programmes [5,13,14]. However, these treatments can be costly and offer no guarantee of improved walking distance or reduction in the severity of IC pain [15]. Adaptations to footwear could improve walking ability and increase walking distance until the onset of IC pain (initial claudication distance (ICD)) and when the pain intensifies and prevents them walking any further (absolute claudication distance (ACD)) [16]; however the support from

* Corresponding author at: School of Sport, York St John University, Lord Mayor's Walk, York, YO31 7EX, United Kingdom.

E-mail address: a.jordan1@yorks.ac.uk (A.R. Jordan).

¹ Present address: Institute of Ergotherapy and Orthopaedic Engineering, Oslo Metropolitan University, Pilestredet 46, 0167, Oslo, Norway.

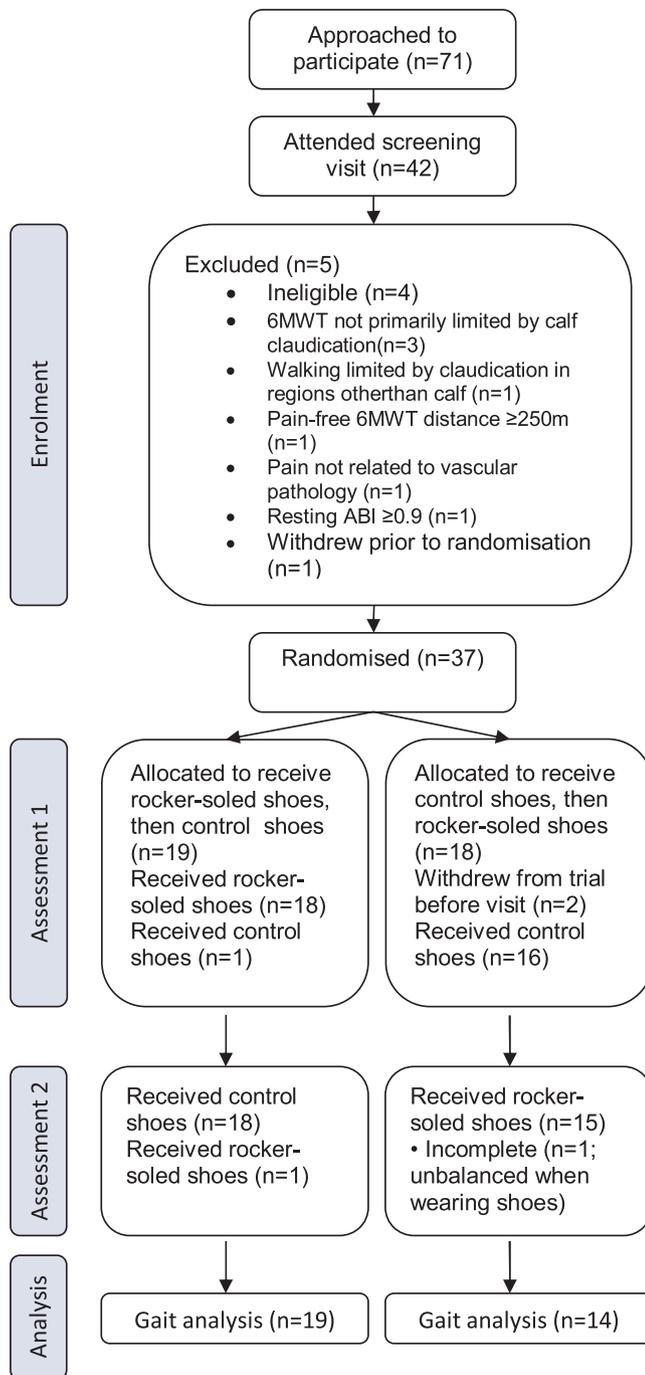


Fig. 1. CONSORT flow diagram of the recruitment to the study.

literature is sparse and unclear [13,17–19]. Rocker-soled shoes have been shown to increase the ICD in individuals with IC when compared with standard shoes (+77 m; $p < 0.01$ and +89 m; $p < 0.01$, respectively) [19]. It is hypothesised that a rapid plantarflexion in the early stance phase, which is a gait characteristic of individuals with IC [20], could hinder the natural rocker of the foot and increase the demand on lower limb musculature. Rocker-soled shoes could facilitate or reinstate the natural rocker of the foot, therefore reducing the demands on lower limb musculature and improving ICD and ACD. A recent pilot study by Hutchins et al. [13] found that a three-curve rocker-soled shoe (Fig. 1) doubled the pain-free walking distance and reduced the intensity of IC pain by 43% when compared with stock therapeutic shoes ($n = 8$). Hutchins et al. [13] hypothesised that rocker-soled shoes might reduce the metabolic demands and mechanically unload the calf

musculature by 25% when compared with un-adapted shoes, thus allowing individuals to increase ICD. This evidence of an unloading effect was from unpublished thesis data [21] and found in healthy participants ($n = 12$). The applicability of these findings to the IC population is questionable due differences in gait between individuals with IC and age-matched healthy controls, even when walking without IC pain [20,22–24]. In contrast to Richardson [19] and Hutchins et al. [13], our research group has previously reported no difference in ICD during usual pace walking ($n = 34$) between rocker-soled shoe design and standard shoe (164 ± 132 m vs 160 ± 88 m, respectively) [25]. Direct comparison of the rocker shoe literature in IC is difficult due to subtle differences in shoe design, walking assessments and variation in the description of IC pain given to individuals with IC (e.g. 'bothered by pain' [19] and 'onset of pain' [13,25]). Lastly, the effect of rocker-soled shoes on ACD, which is a key indicator of walking ability, was not considered by Hutchins et al. [13] or by our group, previously [25]. Therefore the aim of this study was to identify the effect of three-curve rocker shoes on walking distance and the biomechanics of walking whilst pain-free, at ICD and ACD.

2. Methods

2.1. Participants

The study was approved by the NRES Committee for Yorkshire & The Humber - Leeds West (Ref: 15/YH/0107), and prospectively registered (ClinicalTrials.gov: NCT02505503). Participants were recruited from vascular outpatient clinics of a teaching hospital and provided written informed consent to participate. Inclusion criteria were: aged ≥ 16 years; stable symptoms of IC for ≥ 3 months; resting ankle-brachial pressure index (ABPI) ≤ 0.9 and/or imaging evidence of peripheral arterial disease; pain-free walking distance < 250 m on 6-minute walk test with walking limited primarily by calf IC (assessed at screening visit). Those with critical limb ischemia; absolute contraindications to exercise testing; lower-limb amputation; co-morbidities that limit walking before IC pain (e.g. lower-limb osteoarthritis); ambulation limited by IC in regions other than the calf; major ankle or foot pathology, and; current or previous (within 6 months) use of orthoses, lower-limb braces or customised shoes prescribed by a health professional were excluded from the study. Further information on the recruitment to the study is presented in the CONSORT flow diagram (Fig. 1).

2.2. Shoes and randomisation

After participant eligibility was confirmed in the screening visit, shoe size was assessed and both the rocker-soled and control shoes were ordered from an established shoe manufacturer (Chaneco; www.chaneco.co.uk). The rocker-soled shoe was a trainer-type shoe with a black leather upper section, laces, and a specially-designed rocker sole (Patent no.: GB2458741B) (Fig. 2B). The rocker-soled shoes were adapted from the design used in Hutchins et al. [13] but still maintained the same fundamental design of three circular curves. The arcs of these curves were formed from radii centred on the sagittal plane anterior-posterior position of the ankle, hip and knee during a standing position and assuming a vertical line between them all. This design purports to position the ground reaction force lines of action closer to lower limb joint centres, and thus joint moments and powers might be reduced. This would only be true when the lower limb is in vertical position, or at mid-stance. The apex position of the intervention shoe was in line with the anterior-posterior position of the anatomical ankle joint. The control shoe had a through-wedge rocker sole, toe-only curved rocker (Fig. 2A) and an apex positioned proximal to the first metatarsal head. As the control shoe shared characteristics of a typical trainer shoe and was similar in appearance and weight to the rocker-soled shoe, both researchers and participants were blinded.

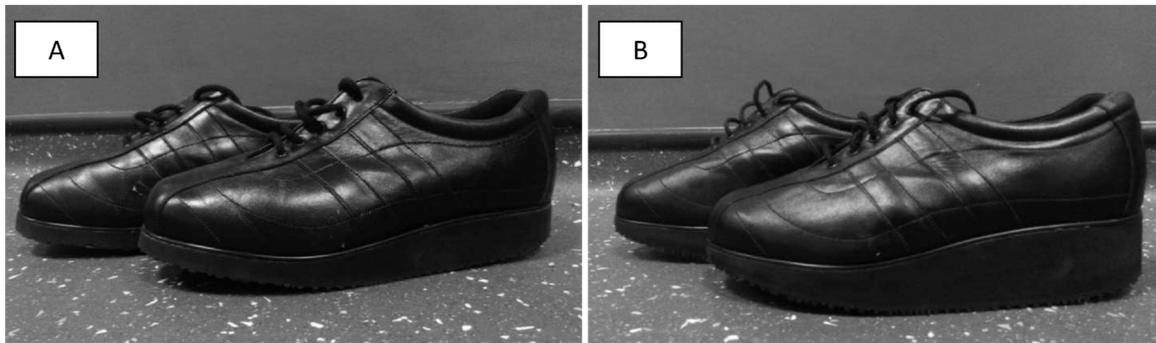


Fig. 2. Control shoe (A) and three-curve rocker shoe (B) used in this study.

The order of testing for each participant (i.e., rocker-soled shoes first then control shoes, or vice versa) was determined using a computer-generated randomisation sequence (blocked randomisation with a block size of 8) created by an otherwise uninvolved statistician. The allocations were blinded (i.e. labelled AB and BA) to the statistician and researchers. Once a participant had completed the screening visit, participants were assigned to the next available randomised allocation.

2.3. Walking gait assessment

Participants visited the gait laboratory on two occasions separated by a minimum of 48 h. On each visit, participants were allowed to habituate to wearing the allocated pair of shoes for 3045 min before commencing the walking gait assessment [26]. Three-dimensional optical motion analysis was used to analyse the gait of participants whilst walking on a level surface, along a 20 m figure-of-8 circuit. Eleven Oqus 300 cameras (Qualisys, Gothenburg, Sweden) tracked the coordinate data (200 Hz) of spherical retroreflective markers adhered to the skin or tight fitting clothing overlying landmarks of the lower limbs in a six-degrees-of-freedom model. Markers were positioned on both legs on the anterior superior iliac spine, posterior superior iliac spine, greater trochanter, medial and lateral femoral epicondyle, medial and lateral malleoli, calcaneus, and the superior aspect of the foot, plus the 1st and 5th metatarsal heads. Cluster markers (markers on a rigid baseplate) were positioned on the lateral aspect of the thigh and shanks. Following a static capture, the medial and lateral femoral epicondyles, medial and lateral malleoli and greater trochanter markers were removed prior to the walking trials. Participants were naive to a piezoelectric force plate (9281B, Kistler, Switzerland) embedded in the floor in the central 10 m straight portion of the circuit and captured kinetic data. Participants were asked to walk continuously at their own self-selected walking pace and indicated when ICD and ACD occurred.

2.4. Data analysis

Marker coordinate data and kinetic data from two passes through the 10 m capture volume (two trials) of pain-free walking, two trials immediately after ICD and the final two trials before ACD were processed and analysed. The markers were labelled in Qualisys Track Manager software (Qualisys, Gothenburg, Sweden) and exported to Visual 3D motion analysis software (CMotion, Rockville, MD, USA) for processing and analysis. Raw marker coordinate data was interpolated and filtered using a zero-lag fourth order low-pass Butterworth filter with a cut-off frequency of 6 Hz [24]. Kinetic data was subject to a low pass filter with a cut-off frequency of 15 Hz [27]. Kinematic and kinetic data were computed, cropped and normalised to 100% gait cycle with 0% indicating initial foot contact [7]. Only the limb affected by IC was analysed. Temporal-spatial parameters of interest included walking velocity, step length, cadence and contact times. Kinematic and kinetic variables of interest at the hip, knee and ankle included joint range of motion, peak joint angles, joint angles at toe off, peak sagittal plane

joint moments and powers, and moment and power at toe off.

2.5. Statistical analysis

IBM SPSS Statistics for Windows, Version 20 (SPSS, IBM Corp., Armonk, NY, USA) software was used in two-sided statistical tests at the 5% significance level. A two-way repeated measures ANOVA test with post-hoc analysis (Bonferroni pairwise comparisons) was used to compare walking distances and the gait variables between the two shoe types and at the instances of pain-free walking, ICD and ACD.

3. Results

Thirty-one participants completed the gait analysis in both shoes. The participant group comprised of 25 men and 6 women with a mean age 69 ± 10 years, stature 1.7 ± 0.09 m, mass 83.2 ± 16.2 kg and ankle-brachial pressure index 0.55 ± 0.14 .

3.1. Temporal-spatial parameters

Temporal-spatial parameters are presented in Table 1. A main effect for shoes was not observed in any of the temporal-spatial parameters. A main effect for time was observed and post-hoc analysis indicated a decreased velocity, step length, and a decrease in double limb support as IC pain intensified from pain-free to ICD and ACD. A decrease in cadence was found between ICD-ACD and pain-free-ACD, and gait cycle time increased between pain-free-ACD.

3.2. Kinematics

Sagittal plane kinematics of the pelvis, hip, knee and ankle are presented in Table 2. Main effects were observed between shoes. When compared with the control shoe, the rocker-soled shoes increased pelvic transverse plane rotation range of motion and peak plantarflexion, but reduced sagittal plane range of motion at the hip, knee and ankle; knee flexion at toe-off and peak knee flexion during the swing phase. A main effect for time was observed and post-hoc analysis indicated an increased pelvic tilt and a reduced dorsiflexion in swing, plantarflexion at toe-off as IC pain intensified from pain-free to ICD and ACD. An increased hip angle at toe off, and a reduction in knee range of motion and peak plantarflexion were found between ICD-ACD and pain-free-ACD.

3.3. Kinetics

Joint powers of the hip, knee and ankle are presented in Table 3. A main effect was observed between shoes and indicated a reduced peak ankle power generation in the rocker-soled shoes when compared with the control shoes. A main effect for time indicated a decrease in hip power generation at toe off and peak knee power generation, however the significance level of 5% was met, marginally ($p = 0.042$ and

Table 1

Mean (standard deviation) temporal-spatial parameters of individuals with IC wearing control (A) and rocker-soled (B) shoes during the three time intervals of pain-free (PF), initial claudication distance (ICD) and absolute claudication distance (ACD). Significance level set at $p < 0.05$ and significant changes represented by shaded boxes. A significant 'main effect of shoe' indicates difference between control and rocker-soled shoe and a significant 'main effect of time' indicates difference across three time intervals.

	PF				ICD				ACD				P value (main effect of shoe)	P value (main effect of time)	Post hoc (PF-ICD, ICD-ACD, PF-ACD)	P value (shoe and time interaction)
	A		B		A		B		A		B					
Distance (m)					138	(72)	146	(94)	373	(227)	406	(212)	0.393	<0.001	- , <0.001, -	0.607
Velocity (m/s)	1.16	(0.26)	1.17	(0.26)	1.13	(0.27)	1.12	(0.27)	1.07	(0.25)	1.06	(0.25)	0.798	<0.001	0.001,<0.001,<0.001	0.330
Step length (m)	0.63	(0.11)	0.64	(0.11)	0.62	(0.11)	0.62	(0.11)	0.60	(0.10)	0.61	(0.10)	0.977	<0.001	0.022, 0.008,<0.001	0.230
Step candence (steps/min)	111.1	(10.0)	110.7	(10.9)	110.3	(10.4)	109.1	(10.8)	108.1	(11.4)	107.2	(10.9)	0.678	<0.001	0.102, 0.001, <0.001	0.120
Gait cycle time (s)	1.09	(0.09)	1.09	(0.11)	1.10	(0.10)	1.11	(0.12)	1.12	(0.13)	1.12	(0.13)	0.973	0.003	0.180, 0.072, 0.025	0.189
Stance time (% gait cycle)	64.1	(2.0)	63.8	(2.0)	64.5	(2.6)	64.0	(2.2)	64.4	(2.8)	64.6	(2.6)	0.290	0.092	0.371, 0.909, 0.209	0.600
Double limb support (% gait cycle)	28.2	(4.1)	28.0	(3.8)	29.1	(4.2)	28.6	(3.7)	30.0	(4.4)	29.6	(3.7)	0.153	<0.001	0.004, 0.002,<0.001	0.923

$p = 0.050$). Post-hoc analysis was unable to establish significant differences between time intervals.

4. Discussion

This study aimed to identify the effect of three-curve rocker shoes on walking distance and the biomechanics of walking whilst pain-free, at ICD and ACD. Our data suggests that three-curve rocker shoes reduced plantarflexor power generation and altered kinematics of the hip, knee and ankle when compared with the control shoes. Many changes in temporal-spatial parameters and sagittal plane kinematics were observed between pain-free, ICD and ACD whereas few kinetic variables were observed; especially at the ankle. Despite the differences between shoes, the key finding of this study was that the three-curve rocker shoes did not significantly increase ICD or ACD.

The three-curve rocker design has previously demonstrated a doubling of ICD in a pilot study by Hutchins et al. [13]. Our study found a small but non-significant increase in continuous walking ICD (+8 m) and ACD (+33 m) whilst wearing rocker-soled shoes when compared

with control shoes. In our previous study [25], ICD was measured during self-paced walking and during a 6-minute walking test. Both walking tests were performed over 30 m lengths, rather than 10 m lengths used in this study, and also found no differences in walking distances whilst wearing the rocker-soled shoes when compared with the control shoes. Therefore, this study agrees with previous research regarding this specific rocker design and we can confirm that the assessment task did not affect the main finding.

The three-curve rocker shoe was purported to mechanically unload the calf musculature in healthy individuals and it was hypothesised that this could allow individuals with IC to walk further before experiencing pain [13]. In our study, peak ankle power generation was reduced in the three curve rocker-soled shoes, which could be indicative of more passive placement of the foot into a plantarflexed position at toe off due to a potential reduced mechanical load on the calf musculature and/or a load-sharing co-activation of other lower limb musculature. Greater peak plantarflexion in the early stages of swing was observed and could be due to a continuation of the rocker effect of the shoes. Despite greater peak plantarflexion, ankle ROM was reduced in the rocker-soled

Table 2

Mean (standard deviation) sagittal plane kinematics of individuals with IC wearing control (A) and rocker-soled (B) shoes during the three time intervals of pain-free (PF), initial claudication distance (ICD) and absolute claudication distance (ACD). Significance level set at $p < 0.05$ and significant changes represented by shaded boxes. A significant 'main effect of shoe' indicates difference between control and rocker-soled shoe and a significant 'main effect of time' indicates difference across three time intervals.

	PF				ICD				ACD				P value (main effect of shoe)	P value (main effect of time)	Post hoc (PF-ICD, ICD-ACD, PF-ACD)	P value (shoe and time interaction)
	A		B		A		B		A		B					
Anterior pelvic tilt ROM (°)	3.4	(1.5)	3.5	(1.3)	3.7	(1.4)	3.7	(1.3)	4.1	(1.5)	4.3	(1.8)	0.456	0.001	0.047, 0.050, 0.010	0.723
Pelvic rotation ROM (°)	5.5	(2.6)	7.5	(3.4)	5.9	(3.3)	8.0	(4.7)	5.7	(3.0)	8.4	((4.1)	<0.001	0.143	0.454, 1.000, 0.047	0.515
Hip at toe off (°)	7.9	(5.8)	8.0	(5.7)	8.0	(5.5)	7.6	(7.1)	9.4	(5.6)	9.8	(7.3)	0.969	0.002	1.000, 0.010, 0.017	0.715
Hip flexion in swing (°)	34.6	(6.6)	35.4	(7.5)	35.0	(6.8)	34.3	(8.0)	34.7	(6.3)	35.6	(7.8)	0.733	0.131	0.518, 0.387, 1.000	0.460
Hip range of motion (°)	37.4	(6.1)	36.8	(5.9)	37.6	(6.6)	34.0	(9.1)	35.8	(6.0)	35.1	(5.4)	0.015	0.112	0.268, 1.000, 0.097	0.122
Knee at toe off (°)	44.2	(5.2)	41.7	(4.2)	44.0	(4.8)	42.7	(4.3)	44.5	(5.2)	41.8	(5.3)	0.003	0.703	1.000, 1.000, 1.000	0.185
Peak knee flexion in swing (°)	60.2	(4.9)	58.2	(4.9)	60.4	(4.7)	58.4	(5.1)	59.8	(5.1)	57.7	(5.3)	0.002	0.055	1.000, 0.048, 0.526	0.923
Knee range of motion (°)	62.2	(4.7)	59.9	(5.1)	62.1	(5.8)	59.9	(5.5)	61.0	(5.6)	58.4	(5.9)	<0.001	0.009	1.000, 0.022, 0.047	0.503
Ankle at toe off (°)	-4.0	(4.7)	-4.5	(4.3)	-2.3	(4.6)	-3.3	(4.4)	-0.8	(4.0)	-1.1	(4.5)	0.356	<0.001	0.006, 0.003, <0.001	0.462
Peak plantarflexion (°)	-9.0	(5.0)	10.9	(4.7)	-9.1	(4.2)	10.0	(4.8)	-6.9	(4.0)	-8.2	(4.6)	0.020	<0.001	0.859,<0.001, 0.004	0.219
Dorsiflexion in swing (°)	3.6	(2.7)	2.7	(2.9)	3.0	(3.0)	2.1	(3.3)	2.4	(3.3)	2.0	(3.3)	0.098	<0.001	0.011, 0.043, 0.002	0.216
Ankle range of motion (°)	24.6	(3.7)	23.7	(3.5)	25.6	(2.8)	23.9	(3.2)	25.2	(2.9)	24.1	(3.0)	<0.001	0.329	0.350, 1.000, 1.000	0.175

Table 3

Mean (standard deviation) joint moment and power values of individuals with IC wearing control (A) and rocker-soled (B) shoes during the three time intervals of pain-free (PF), initial claudication distance (ICD) and absolute claudication distance (ACD). Significance level set at $p < 0.05$ and significant changes represented by shaded boxes. A significant 'main effect of shoe' indicates difference between control and rocker-soled shoe and a significant 'main effect of time' indicates difference across three time intervals.

	PF				ICD				ACD				P value (main effect of shoe)	P value (main effect of time)	Post hoc (PF-ICD, ICD-ACD, PF-ACD)	P value (shoe and time interaction)
	A		B		A		B		A		B					
Hip power at toe off (W/kg)	0.7 (0.3)	0.7 (0.2)	0.8 (0.3)	0.8 (0.3)	0.9 (0.4)	0.9 (0.2)	0.591	0.042	0.089, 0.194, 0.500	0.388						
Peak hip power generation (W/kg)	1.0 (0.4)	1.0 (0.3)	1.0 (0.4)	0.9 (0.4)	0.8 (0.5)	0.9 (0.3)	0.895	0.123	0.089, 0.194, 0.412	0.422						
Peak hip power absorption (W/kg)	0.5 (0.2)	0.6 (0.5)	0.5 (0.2)	0.5 (0.1)	0.6 (0.2)	0.5 (0.2)	0.933	0.917	0.665, 0.704, 0.382	0.618						
Knee power at toe off (W/kg)	0.6 (0.3)	0.6 (0.4)	0.8 (0.6)	0.5 (0.1)	0.6 (0.2)	0.4 (0.3)	0.296	0.591	1.000, 1.000, 0.807	0.755						
Peak knee power generation (W/kg)	0.8 (0.6)	0.7 (0.6)	0.7 (0.5)	0.6 (0.4)	0.6 (0.3)	0.5 (0.4)	0.266	0.050	0.135, 1.000, 0.219	0.518						
Peak knee power absorption (W/kg)	1.4 (0.5)	2.1 (1.7)	1.6 (0.5)	1.4 (0.5)	1.4 (0.4)	1.2 (0.3)	0.665	0.144	1.000, 0.074, 0.329	0.135						
Ankle power at toe off (W/kg)	2.1 (0.5)	1.5 (0.7)	1.7 (0.4)	1.5 (0.4)	1.4 (0.5)	1.4 (0.5)	0.082	0.093	0.680, 0.333, 0.128	0.217						
Peak ankle power generation (W/kg)	2.3 (0.8)	1.7 (0.8)	2.2 (0.4)	1.6 (0.3)	1.8 (0.4)	1.6 (0.4)	0.006	0.073	1.000, 0.067, 0.229	0.124						
Peak ankle power absorption (W/kg)	1.1 (0.3)	1.0 (0.4)	1.2 (0.5)	1.2 (0.3)	1.3 (0.5)	1.2 (0.4)	0.331	0.084	0.318, 1.000, 0.139	0.634						

shoes and must be a result of a reduced dorsiflexion as the tibia advances in the latter stages of the stance phase and attributable to the rocker placing the foot into a more plantarflexed position.

The purpose of ankle power generation and plantarflexion is to propel the lower limbs into the swing phase, advancement of the lower limb and to ensure adequate foot clearance from the floor [28,29]. There is no evidence of compensatory mechanisms for the reduced ankle power generation in the joint moments or powers at the knee or hip whilst wearing the rocker-soled shoes. Similarly, no differences were detected in the hip angle or ankle sagittal plane angle. However, the knee was less flexed at toe-off and in swing phase, and the rotation range of motion at the pelvis was greater in the rocker-soled shoes. The increased rotation range of motion at the pelvis is a strategy to enhance limb advancement and the reduced knee flexion were likely a result of reduced propulsion at toe off and attributable to the position of the apex and 'rocking' effect of the rocker-soled shoes. The reduced knee flexion in the swing phase could reduce the foot clearance of individuals with IC, therefore any rocker-soled shoe should be designed to ensure adequate foot clearance to reduce tripping and falls risk, and allow individuals with IC to negotiate obstacles.

As IC pain intensified from pain-free walking, ICD and ACD, many changes in temporalspatial parameters and sagittal plane joint kinematics were observed. However, kinetic changes were restricted to the hip and knee. Reductions in velocity, step length, cadence, and increase in gait cycle time were also observed. It has been reported previously that individuals with IC tend to walk slowly as a result of lower cadence and shorter stride length, greater stance time, double stance, and reduced single stance and these are exacerbated with the progression of pain [4,7,12,30]. A slower walking speed and higher proportion of time spent in contact with the ground is a strategy to enhance balance and reduce the likelihood of falling at the expense of walking velocity [4,7,30] and has been demonstrated in our study. Our study reflects previous research, where individuals with IC wore their own shoes, 'stock' or 'laboratory standard' shoes, and found that kinematic adaptations to IC pain were observed at the pelvis and hip, with few at the knee and most notable adaptations being observed at the ankle [7,20,24]. Interestingly, ankle joint kinetics did not change in response to IC pain, which contradicts the findings of Koutakis et al. [23] who found a reduction in ankle power generation during walking with IC pain. In our study, there is some evidence of compensatory changes at the hip which could have reduced the demands on the ankle. As IC pain increased, hip flexion angle at toe off increased, which is reflective of the increase in hip power generation. These changes at the hip likely compensated for the reduction in knee power generation, also observed by Koutakis et al. [23], and reduced the demand on the calf

musculature to propel the lower limb as IC pain intensified; hence there were no changes in ankle power generation. This compensatory mechanism was observed in both shoe test conditions and therefore, in response to IC pain, rocker-soled shoes were unable to alter the kinematic and kinetics of walking gait significantly when compared with the control shoes.

5. Limitations

The shape of the rock-soled shoe was the same as Hutchins et al. [13], however the bulk of the sole was reduced under the rearfoot to blind the participants and researchers. In reducing the bulk, it is likely that the apex of the shoe was moved anteriorly and this reduced the rocker effect. Therefore, direct comparisons with the study by Hutchins et al. [13] are problematic. The gait analyses were carried out during continuous walking of 10 m lengths, due to laboratory size, involved many turns and could have affected the metabolic load on calf musculature. This study assessed the affected limb only and does not address the gait asymmetries which have been reported previously [4,7,12,30].

6. Conclusions

There is evidence that the rocker soled shoe altered key gait parameters, however there was no clinical benefit to individuals with IC in terms of walking distances when compared with the control shoes. Consequently, there is little evidence to support the current design of the rocker-soled shoe for individuals with IC. The rocker-soled shoes showed some promise as ankle power generation was reduced which could be indicative of a reduction in or sharing of the load on calf musculature. Further investigation is required to optimise the rocker effect, potentially by moving the apex of the shoe posteriorly, to enhance walking distances in individuals with IC.

Conflict of interest statement

The authors declare no conflicts of interest.

Declarations of interest

None.

Acknowledgements

This study was supported by grants from the Yorkshire Vascular and

Surgical Research Fund, York Teaching Hospital Charity, and the University of York. The Sponsor was York Teaching Hospital NHS Foundation Trust. Sponsors did not have any role in study design; data collection, analysis or interpretation; in the writing of the report; or in the decision to submit the article for publication.

References

- [1] M.M. McDermott, P. Greenland, K. Liu, J.M. Guralnik, M.H. Criqui, N.C. Dolan, C. Chan, L. Celic, W.H. Pearce, J.R. Schneider, Leg symptoms in peripheral arterial disease: associated clinical characteristics and functional impairment, *JAMA* 286 (2001) 1599–1606.
- [2] M. Condoirelli, G. Brevetti, Intermittent claudication: an historical perspective, *Eur. Heart J. Suppl.* 4 (2002) B2–B7.
- [3] R.M. Schainfeld, Management of peripheral arterial disease and intermittent claudication, *J. Am. Board Fam. Pract.* 14 (2001) 443–450.
- [4] R.G. Crowther, W.L. Spinks, A.S. Leicht, F. Quigley, J. Golledge, Intralimb coordination variability in peripheral arterial disease, *Clin. Biomech.* 23 (2008) 357–364.
- [5] L. Egberg, S. Andreassen, A.-C. Mattiasson, Experiences of living with intermittent claudication, *J. Vasc. Nurs.* 30 (2012) 5–10.
- [6] R.A. Gohil, K.A. Mockford, F. Mazari, J. Khan, N. Vanicek, I.C. Chetter, P.A. Coughlin, Balance Impairment, Physical Ability, Its link with disease severity in patients with intermittent claudication, *Ann. Vasc. Surg.* 27 (2013) 68–74, <https://doi.org/10.1016/j.avsg.2012.05.005>.
- [7] K.A. Mockford, N. Vanicek, A. Jordan, I.C. Chetter, P.A. Coughlin, Kinematic adaptations to ischemic pain in claudicants during continuous walking, *Gait Posture* 32 (2010) 395–399.
- [8] H.R. Scott-Okafor, K.K. Silver, J. Parker, T. Almy-Albert, A.W. Gardner, Lower extremity strength deficits in peripheral arterial occlusive disease patients with intermittent claudication, *Angiology* 52 (2001) 7–14.
- [9] N. Vanicek, S.A. King, R. Gohil, I.C. Chetter, P.A. Coughlin, Computerized dynamic posturography for postural control assessment in patients with intermittent claudication, *J. Visual. Exp.* 82 (2013) e51077.
- [10] M.M. McDermott, K. Liu, L. Ferrucci, L. Tian, J.M. Guralnik, Y. Liao, M.H. Criqui, Greater sedentary hours and slower walking speed outside the home predict faster declines in functioning and adverse calf muscle changes in peripheral arterial disease, *J. Am. Coll. Cardiol.* 57 (2011) 2356–2364.
- [11] B.Q. Farah, R.M. Ritti-Dias, G.G. Cucato, P.S. Montgomery, A.W. Gardner, Factors associated with sedentary behavior in patients with intermittent claudication, *Eur. J. Vasc. Endovasc. Surg.* 52 (2016) 809–814.
- [12] A.W. Gardner, P.S. Montgomery, The relationship between history of falling and physical function in subjects with peripheral arterial disease, *Vasc. Med.* 6 (2001) 223–227.
- [13] S.W. Hutchins, G. Lawrence, S. Blair, A. Aksenov, R. Jones, Use of a three-curved rocker sole shoe modification to improve intermittent claudication calf pain—a pilot study, *J. Vasc. Nurs.* 30 (2012) 11–20.
- [14] S. Spronk, J.V. White, J.L. Bosch, M.M. Hunink, Impact of claudication and its treatment on quality of life, *Semin. Vasc. Surg.* (2007) 3–9 Elsevier.
- [15] S. Degischer, K.-H. Labs, J. Hochstrasser, M. Aschwanden, M. Tschöepf, K.A. Jaeger, Physical training for intermittent claudication: a comparison of structured rehabilitation versus home-based training, *Vasc. Med.* 7 (2002) 109–115.
- [16] L.M. Kruidenier, S.P. Nicolaï, E.M. Willigendael, R.A. de Bie, M.H. Prins, J.A. Tejjink, Functional claudication distance: a reliable and valid measurement to assess functional limitation in patients with intermittent claudication, *BMC Cardiovasc. Disord.* 9 (2009) 9.
- [17] D. Chavatzas, C.W. Jamieson, The doubtful place of the raised heel in patients with intermittent claudication of the leg, *Br. J. Surg.* 61 (1974) 299–300.
- [18] T. Gorely, H. Crank, L. Humphreys, S. Nawaz, G.A. Tew, “Standing still in the street”: experiences, knowledge and beliefs of patients with intermittent claudication—a qualitative study, *J. Vasc. Nurs.* 33 (2015) 4–9.
- [19] J.K. Richardson, Rocker-soled shoes and walking distance in patients with calf claudication, *Arch. Phys. Med. Rehabil.* 72 (1991) 554–558.
- [20] R. Celis, I.I. Pipinos, M.M. Scott-Pandorf, S.A. Myers, N. Stergiou, J.M. Johanning, Peripheral arterial disease affects kinematics during walking, *J. Vasc. Surg.* 49 (2009) 127–132.
- [21] S. Hutchins, The Effects of Rocker Sole Profiles on Gait: Implications for Claudicants, PhD Thesis, University of Salford, 2007.
- [22] S.A. Scherer, J.S. Bainbridge, W.R. Hiatt, J.G. Regensteiner, Gait characteristics of patients with claudication, *Arch. Phys. Med. Rehabil.* 79 (1998) 529–531.
- [23] P. Koutakis, I.I. Pipinos, S.A. Myers, N. Stergiou, T.G. Lynch, J.M. Johanning, Joint torques and powers are reduced during ambulation for both limbs in patients with unilateral claudication, *J. Vasc. Surg.* 51 (2010) 80–88.
- [24] S.-J. Chen, I. Pipinos, J. Johanning, M. Radovic, J.M. Huisinga, S.A. Myers, N. Stergiou, Bilateral claudication results in alterations in the gait biomechanics at the hip and ankle joints, *J. Biomech.* 41 (2008) 2506–2514.
- [25] G.A. Tew, A. Shalan, A.R. Jordan, L. Cook, E.S. Coleman, C. Fairhurst, C. Hewitt, S.W. Hutchins, A. Thompson, Unloading shoes for intermittent claudication: a randomised crossover trial, *BMC Cardiovasc. Disord.* 17 (2017) 283.
- [26] M. Dhyani, D. Singla, I. Ahmad, M.E. Hussain, K. Ali, S. Verma, Effect of rocker soled shoe design on walking economy in females with pes planus, *J. Clin. Diagn. Res.* 11 (2017) YC01.
- [27] S.L. King, N. Vanicek, T.D. O'Brien, Joint moment strategies during stair descent in patients with peripheral arterial disease and intermittent claudication, *Gait Posture* 62 (2018) 359–365.
- [28] H. Chiba, S. Ebihara, N. Tomita, H. Sasaki, J.P. Butler, Differential gait kinematics between fallers and non-fallers in community-dwelling elderly people, *Geriatr. Gerontol. Int.* 5 (2005) 127–134.
- [29] K. Sato, Factors affecting minimum foot clearance in the elderly walking: a multiple regression analysis, *Open J. Ther. Rehabil.* 3 (2015) 109.
- [30] A.W. Gardner, D.E. Parker, P.S. Montgomery, A. Khurana, R.M. Ritti-Dias, S.M. Blevins, Gender differences in daily ambulatory activity patterns in patients with intermittent claudication, *J. Vasc. Surg.* 52 (2010) 1204–1210.