Do rocker-sole shoes influence postural stability in chronic low back pain? A randomised trial.

Corresponding Author:
C Sian MacRae,
College of Health and Life Sciences, Mary Seacole Building, Brunel University, Kingston Lane, Uxbridge, United Kingdom, UB8 3PH
Email: Sian.Macrae@Brunel.ac.uk
Tel: 07730 954598

Duncan Critchley:
Academic Department of Physiotherapy & Division of Health and Social Care Research, King's College London, London, United Kingdom

Matthew Morrissey:
Faculty of Health Sciences University of Ljubljana, , Ljubljana, Slovenia,

Adam Shortland:
Guy's and St Thomas' NHS Foundation Trust, One Small Step Gait Laboratory, London, United Kingdom,

Biomedical Engineering, King's College London, London, United Kingdom

Jeremy S Lewis:
Department of Allied Health Professions, University of Hertfordshire, Hatfield, United Kingdom

Musculoskeletal Services, Central London Community Healthcare NHS Foundation Trust, London, United Kingdom.

Keywords:
Footwear, chronic low back pain, postural stability, rocker sole shoe

Word count (excluding title page, abstract, references, figures and tables): 2954

ABSTRACT

Background

People with chronic low back pain (CLBP) demonstrate greater postural instability compared to asymptomatic individuals. Rocker-sole shoes are inherently unstable and may serve as an effective balance training device. This study hypothesised that wearing rocker-sole shoes would result in long-term improvement in barefoot postural stability in people with CLBP.

Methods

20 participants with CLBP were randomised to wear a rocker- or flat-soles for a minimum of two hours each day. Participants were assessed barefoot and shod, over three 40 second trials, under four posture challenging standing conditions. Primary outcome was postural stability assessed by root mean squared error of centre of pressure (CoP) displacement ($CoP_{RMSE\ AP}$) and mean CoP velocity (CoP_{VELAP}), both in the antero-posterior direction, using force plates. Participants' were assessed without knowledge of group allocation at baseline, six weeks, and six months (main outcome point). Analyses were by intention-to-treat.

Results

At six months, data from 11 of 13(84.6%) of the rocker-sole and 5 of 7(71.4%) of the flat-sole group was available for analysis. At baseline, there was a mean increase in $CoP_{RMSE\ AP}$(6.41[2.97]mm, p<0.01) and CoP_{VELAP}(4.10[2.97]mm, p<0.01) in the rocker-sole group when shod compared to barefoot; there was no difference in the flat-sole group. There were no within- or between-group differences in change in CoP parameters at any time point compared to baseline i) for any barefoot standing condition ii) when assessed shod eyes-open on firm ground.

Conclusions

Although wearing rocker-sole shoes results in greater postural instability than flat-sole shoes, long-term use of rocker-sole shoes did not appear to influence postural stability in people with CLBP.

INTRODUCTION

Differences in postural control during standing have been reported in people with chronic low back pain (CLBP).[1-9] During more challenging standing conditions, defined as standing on compliant ground with visual occlusion, people with CLBP demonstrate increased centre of pressure (CoP) displacements and velocities, thought to indicate a reduced ability to maintain postural stability.[10] These differences in postural control have been proposed as underpinning mechanisms in the presence and recurrent nature of CLBP.[7, 11]

Greater CoP displacements, interpreted as increased postural instability, are reported during standing wearing rocker-sole compared to traditional flat-sole shoes [12-14] suggesting rocker-sole shoes may act as a balance training device. Rehabilitation with proprioceptive or balance training has demonstrated clinical benefits in people with functional ankle instability and anterior cruciate ligament deficient knees [15-16] and is recommended as a CLBP treatment.[17] To the authors' knowledge, no published study has investigated both the short and long-term influence of rocker-sole shoes on postural stability in people with CLBP. Hence, the following hypotheses were investigated:

H1: Standing in rocker-sole shoes will promote a greater postural instability than standing in flat-sole shoes in the antero-posterior direction compared to barefoot standing.

H2: Individuals presenting with CLBP who wear rocker-sole shoes as part of their rehabilitation programme will improve their barefoot standing stability in the antero-posterior direction in the shorter (6 weeks) and longer term (6 months) against those who wear standard flat-sole trainers.

METHODS

This randomised trial with repeated measures recruited participants from a study investigating the influence of footwear on CLBP.[18]

Participant recruitment, consent and randomisation

Following ethical approval from Outer North London Research Ethics Committee (REC: 10/H0724/7), twenty participants, previously consented and block randomised in a clinical study investigating the effects of footwear on CLBP,[18] were invited to take part by SM. Inclusion criteria were: aged 18 to 65 years, with a three month or greater history of LBP. Exclusion criteria were as the main trial,[18] excluding constant LBP, specific spinal diagnosis inappropriate for physiotherapy interventions (for example spinal fracture of infection); any condition inappropriate for exercise physiotherapy (for example severe cardiovascular or metabolic disease) or for wearing rocker-sole footwear (for example Morton's neuroma, peripheral neuropathy); and participants who had previously used rocker sole shoes.

Interventions

On consenting and entering the current study, participants were already allocated either the rocker-sole (Masai Barefoot Technology [MBT] Chapa Caviar, Masai GB Limited, London, United Kingdom) or the flat-sole shoe (Gel 1140, ASICS, Warrington, United Kingdom) (Figure 1.).[18]

Participants had been fitted with their allocated footwear type and taught how to walk in their shoes (Appendix 1). They were instructed not to wear their allocated shoes prior to baseline biomechanical assessment, then wear them for a minimum of two hours per day whilst standing or walking for the study duration. Between baseline and six week assessment participants attended a four week LBP exercise group (fulfilling methods of the main clinical study participants were recruited from [18]).

Data collection

Data collection occurred at the 'One Small Step Gait Laboratory', Guys' Hospital, London. Demographic, back-pain disability (Roland-Morris Questionnaire) and pain scores (numerical rating scale) were recorded at baseline.

Biomechanical assessment

Participants were assessed wearing short trousers and vest or no top. Participants' anthropometric measurements (pelvic width; leg length; knee width; ankle width; height;

and weight) were recorded to inform the mechanical model formulated for each participant in Vicon's Nexus (1.8.1) motion capture software [Vicon Motions systems, Oxford, UK]).

Participants were assessed barefoot and shod, with their feet on adjacent force plates (FP5000, AMTI Inc., Massachusetts, USA), during four posture-challenging standing conditions involving manipulation of visual input and support surface: (1) firm surface, eyes-open; (2) firm surface, eyes-closed; (3) compliant surface, eyes-open; (4) compliant surface, eyes-closed. Compliant surface was achieved by placing an AirexTM cushion (48.5 x 40.0 x 6.4 cm, 0.7kg, high density (50kg/m-3), closed-cell foam) (l-group, St. Louis, MO) over each force plate (Figure 2.).

Barefoot assessment

Participants stood barefoot, feet approximately pelvis width apart and were instructed to keep their eyes focused on a red sticker at eye height on a tripod three metres in front of them.[19] Participants were assessed for three 40 second trials (shown to produce acceptable reliability [20]) for each standing condition. The middle 30 seconds of each trial was analysed to avoid possible initial sway errors and effects of participant fatigue or anticipation of a trial ending.

Each participant received the same instructions at the start of each trial:

"When I say 'Go' I want you to stand and maintain your balance until you hear the instruction to rest. Each trial will last for 40 seconds. Focus on the red sticker on the tripod ahead of you. Keep your arms relaxed by your sides."

A rest period of 20 seconds occurred between each 40 second trial. Sufficient trials were performed to enable three valid sets of data to be recorded. A test was invalidated if the participant: 1) moved their foot position during the test; 2) changed their arm starting position or; 3) opened their eyes during an eyes-closed task.

Shod assessment

Study shoes were then put on. The shod assessment protocol was conducted as described in the *Barefoot Assessment*. Shod assessment protocol was conducted by AS; shoes were concealed from SM to maintain assessor blinding in the main trial.[18]

Outcome measures

The following postural stability primary outcomes were assessed at baseline, six weeks and six months: i) Root mean squared error and ii) velocity of the CoP in the antero-posterior direction ($CoP_{RMSE\ AP}$ and $CoP_{VEL\ AP}$ respectively). Equations, demonstrating how CoP data were calculated are presented in Appendix 2.

Sample size

A sample size calculation was not conducted due to the lack of reported data of minimal clinically important difference for the primary outcome measures (CoP parameters).

Data extraction

Industry-standard motion capture files (.c3d) containing force data were extracted. Force plate data was filtered with a low pass (10Hz) Butterworth filter. CoP parameters ($CoP_{RMSE\ AP}$ and COP_{VELAP} were calculated using a proprietary programm writer Visual Basic for Application (Microsoft Excel, Reading, UK)

Data analysis

The primary analysis was by intention-to-treat, including all eligible randomised participants who provided follow-up data. Two-way mixed model (between-within) analysis of variances were conducted with one within-subject (assessment time points) and one between-group factor (footwear type) to compare the influence of footwear type over time and one within-subject (standing condition) and one between-group factor (footwear type) to compare baseline data between groups. Analysis of variance utilised data from participants with full data sets (rocker-sole group n=13, flat-sole group n=7 for baseline comparisons and immediate effect of footwear; rocker-sole group n=11, flat-sole group n=5 for long-term follow-up). Macuhly test of sphericity assumption and Levene's test of equality of variances assumption were considered for within-subject and between-subject effects, respectively. The alpha level for determining statistical significance was set at 0.05. Data were analysed using IBM SPSS version 20.0.0 (IBM, Armonk, New York). Results are presented as means (standard deviations (SD)) unless otherwise stated.

RESULTS

20 participants (from 38 who showed interest in the study) were recruited into the study from June 2010-November 2010 (the final 6 months of main study recruitment [18]). Seven participants had been pre-randomised to receive the flat-sole and 13 to receive the rocker-sole shoe.[18] There were no differences between the groups in demographic or outcome measures (Table 1) at baseline.

Table 1. Baseline characteristics of the study participants

	Flat-sole group (n=7)	Rocker-sole group (n=13)	P-value
Gender : Male	3 (42.9 %)*	6 (46.2 %)*	0.89†
: Female	4 (57.1 %)*	7 (53.8 %)*	
Age (years)	37.9 (13.0)	42.6 (12.5)	0.43
Weight (kg)	82.4 (22.0)	70.3 (11.3)	0.12
Height (cm)	173.8 (7.3)	173.5 (9.5)	0.95
Roland Morris Disability Questionnaire (0-24; 0=best)	7.9 (1.8)	5.7 (3.3)	0.13
Numerical rating score for pain (0-10; 0=best)	6.3 (1.5)	5.7 (1.7)	0.48

Summary measures represent means (SD) or *numbers (percentages). Data analysed with independent t-test or Chi-squared test†.

Baseline barefoot CoP parameters are presented in Table 2. There were no differences between the groups in $CoP_{RMSE\ AP}$, $CoP_{VEL\ AP}$ for any of the four standing conditions ($F(3,51)=0.31$, $p=0.82$, $\eta^2=0.02$; $F(1.76,29.94)=0.15$, $p=0.83$, $\eta^2=0.01$ respectively).

Table 2. Barefoot antero-posterior centre of pressure and postural strategy parameters at baseline

Standing condition	Group	$CoP_{RMSE\ AP}$ [mm]	$CoP_{VEL\ AP}$ [mm/s]
Eyes open firm surface	Flat sole shoe	4.80 (2.47)	7.33 (2.01)
	Rocker sole shoe	4.39 (1.84)	7.19 (1.13)
Eyes closed firm surface	Flat sole shoe	4.98 (1.87)	7.54 (1.44)
	Rocker sole shoe	4.05 (1.26)	7.50 (1.12)
Eyes open compliant surface	Flat sole shoe	10.06 (2.87)	11.89 (1.18)
	Rocker sole shoe	8.63 (2.61)	12.67 (4.38)
Eyes closed Compliant surface	Flat sole shoe	11.06 (2.86)	17.94 (4.32)
	Rocker sole shoe	10.62 (2.66)	17.75 (4.12)

Summary measures represent means (SD). RMSE: root mean squared error, VEL: velocity, AP: antero-posterior.

Participant attrition and retention during the study are presented in Figure 3. At 6 months, sixteen (80%) participants were reassessed.

Comparison of centre of pressure parameters when standing barefoot and standing shod

Standing in rocker-sole shoes, with eyes-open on firm surface, resulted in a mean increase in $CoP_{RMSE\ AP}$ of 6.41mm ($t(12) = 7.77$, $p < 0.01$) and $CoP_{VEL\ AP}$ of 4.10mm/s ($t(12) = 7.14$, $p < 0.01$) when compared to standing barefoot (Table 3). There was no difference in $CoP_{RMSE\ AP}$ or $CoP_{VEL\ AP}$ when standing in flat-sole shoes compared to barefoot (Table 3.).

Table 3. Sagittal plane centre of pressure parameters during barefoot and shod standing, with eyes open on firm surface

	Flat sole shoe group (n=7)		Rocker sole shoe group (n=13)	
	CoP $_{RMSE\ AP}$ [mm]	CoP $_{VEL\ AP}$ [mm/s]	CoP $_{RMSE\ AP}$ [mm]	CoP $_{VEL\ AP}$ [mm/s]
Barefoot	4.78 (2.26)	7.03 (2.00)	4.39 (1.84)	7.19 (1.13)
Shod	5.61 (2.33)	7.11 (1.27)	10.79 (3.01)	11.28 (1.93)
Difference between means	0.84 (2.03)	0.07 (1.20)	6.41 (2.97)*	4.10 (2.07)*

Summary measures represent means (SD) or percentages where indicated (%).* Significant difference within groups between barefoot and shoe conditions ($p < 0.01$). RMSE: root mean squared error, VEL: velocity, AP: antero-posterior.

Influence of long-term shoe wear on barefoot sagittal plane centre of pressure parameters

Neither the rocker-sole nor the flat-sole group demonstrated change in $CoP_{RMSE\ AP}$ or $CoP_{VEL\ AP}$ when assessed barefoot during the most challenging standing condition (eyes-closed, compliant ground), at any follow-up point (rocker-sole group $F(2,20)=2.28$, $p=0.13$, $\eta^2=0.19$ and $F(2,20)=2.69$, $p=0.09$, $\eta^2=0.21$ respectively; flat-sole group $F(2,8)=1.89$, $p=0.21$, $\eta^2=0.32$ and $F(2,8)=0.27$, $p=0.70$, $\eta^2=0.06$ respectively) (Table 4.). Furthermore, there were no differences between-groups in $CoP_{RMSE\ AP}$ or $CoP_{VEL\ AP}$ at any follow-up point during the most challenging standing condition ($F(2,28)=1.80$, $p=0.19$, $\eta^2=0.11$ and $F(2,28)=0.28$, $p=0.76$, $\eta^2=0.02$).

Table 4. Change in barefoot centre of pressure parameters during standing, eyes closed on compliant surface at reassessment points

	Centre of pressure parameter	Assessment: Baseline	6 weeks	6 months	P-value
Flat-sole shoe group (n=5)	$CoP_{RMSE\ AP}$ [mm]	10.80 (2.85)	10.70 (3.40)	9.29 (1.95)	0.21
	$CoP_{VEL\ AP}$ [mm/s]	21.61 (3.48)	20.66 (4.82)	20.19 (5.85)	0.70
Rocker-sole shoe group (n=11)	$CoP_{RMSE\ AP}$ [mm]	10.43 (2.85)	9.35 (2.62)	9.75 (3.08)	0.13
	$CoP_{VEL\ AP}$ [mm/s]	17.85 (4.59)	15.28 (3.64)	15.77 (4.26)	0.09

Summary measures represent means (SD).

No difference in $COP_{RMSE\ AP}$ or $CoP_{VEL\ AP}$ were found for the three less challenging standing conditions assessed within- or between-shoe groups at any follow-up point.

Influence of long-term shoe wear on postural control assessed when shod.

When standing in study shoes, with eyes-open on firm surface, no significant differences where observed in $CoP_{RMSE\ AP}$ or $CoP_{VEL\ AP}$ for either shoe group at any reassessment point (rocker-sole group: $F(2,20)=1.35$, $p=0.28$, $\eta^2=0.12$, and $F(2,20)=1.84$, $p=0.19$, $\eta^2=0.15$ respectively; flat-sole group: $F(2,8)=0.74$, $p=0.51$, $\eta^2=0.16$, $F(2,8)=0.63$, $p=0.56$, $\eta^2=0.14$). Furthermore, whilst wearing study shoes there were no differences between-groups in change in $CoP_{RMSE\ AP}$ or $CoP_{VEL\ AP}$ at any reassessment point ($F(2,28)=1.18$, $p=0.32$, $\eta^2=0.08$, and $F(2,28)=0.37$, $p=0.70$, $\eta^2=0.03$ respectively) (Table 5.).

Table 5. Change over time in antero-posterior centre of pressure parameters during shod standing, eyes open on firm surface

	Centre of pressure parameter	Assessment Baseline	6 weeks	6 months	P - value
Flat-sole shoe group (n=5)	$CoP_{RMSE\ AP}$ [mm]	5.20 (1.52)	6.03 (2.95)	5.29 (2.22)	0.51
	$CoP_{VEL\ AP}$ [mm/s]	7.28 (2.04)	6.22 (1.16)	6.29 (1.97)	0.56
Rocker-sole shoe group (n=11)	$CoP_{RMSE\ AP}$ [mm]	10.17 (2.84)	9.54 (2.79)	11.07 (3.89)	0.28
	$CoP_{VEL\ AP}$ [mm/s]	9.39 (2.24)	9.10 (3.25)	8.24 (1.81)	0.19

Summary measures represent means (SD).

DISCUSSION

This study investigated the influence of rocker sole shoes on postural stability in people with CLBP. The results were concordant with Hypothesis 1; that is that the wearing of rocker sole shoes provides a less stable surface to stand on than flat-sole shoes. However, the results do not support Hypothesis 2; there were no differences in barefoot CoP parameters within- or between-groups during barefoot trials at six weeks or six months, compared to baseline, for any standing condition. Furthermore, there were no changes from baseline in CoP parameters in the rocker-sole group when shod at six weeks and six months. These findings suggest that adaptation of the postural control system did not occur following long-term wear of rocker-sole shoes. Alternatively, the outcomes assessed were not appropriate to detect any potential training effect offered by the rocker-shoes.

Antero-posterior centre of pressure parameters.

The current study demonstrated similar barefoot baseline CoP parameters between shoe groups. When compared to the findings of other studies investigating CLBP with the same outcome measures under similar protocols, this study demonstrated increased postural stability during less challenging standing conditions,[6, 11, 21] and reduced postural stability during more challenging standing conditions.[11, 21-22] These differences may be due to a number of methodological and demographic differences reported to influence outcome, namely: number of trials; [10] trial durations; [10] participant age;[23-26] body weight; [27-28] body height;[27-28] and gender.[25] However, the consistent increase in CoP parameters from stable to more challenging standing conditions in the current study concurs with other studies.[7,11]

Reduction in a CoP parameter is interpreted as an improvement in postural stability.[10] It was hypothesised that due to the increased proprioceptive input from wearing rocker shoes [12] a greater reduction in barefoot and shod postural excursion may occur at reassessment in the rocker-sole compared to the flat-sole group. However, neither group demonstrated a significant change in CoP parameters at any follow-up compared to baseline when barefoot or shod. This lack of change suggests that the rocker-sole footwear either i.) provided an additional postural challenge, however the type of challenge did not result in long-term improvements in sensori-motor function, ii.) provided an appropriate postural challenge but 'dosage' was insufficient for a training effect to occur, or iii.) influenced proprioceptive deficits, however, improvements were not detected.

The first explanation, suggesting that the increased postural challenge from rocker-sole shoes does not influence long-term improvements in sensori-motor function compared to wearing flat-sole shoes, concurs with the findings of other studies.[29-30] Nigg et al. investigated the influence of rocker-sole footwear on balance in golfers with LBP [29] and in people with knee osteoarthritis.[30] In support of the current study findings, Nigg et al. concluded that no differences in balance performance were detected between the intervention (rocker-sole group) or control group (normal shoes) at six[29] and twelve weeks.[29] The current study adds to Nigg et al's conclusions by demonstrating that longer term use of rocker-sole shoes (six months) has no further influence on postural stability.

The second explanation suggests a greater postural challenge may have resulted in a measured training effect. When compared to standing barefoot, the rocker shoes demonstrated a 57-146% increase in the CoP parameters assessed. Introducing additional postural challenge in an attempt to increase the CoP parameters further may not only be unsafe or impractical in a CLBP population, but may also, in the absence of evidence to support a relationship between increased postural challenge and change in CoP parameters or clinical change, be inappropriate.

The third explanation suggests that the null hypothesis was incorrectly accepted and study conclusions are incorrect. This may have been due to an underpowered sample, poor reliability of the outcome variables or an insensitivity to detect genuine changes in postural control. The reliability of the outcome variables may be improved by increasing the duration and number of trials. However, of the numerous CoP parameters regularly reported in research assessing postural stability, the two parameters chosen in the current study have been reported as highly reliable.[10]

Although changes in CoP parameters have been suggested as appropriate outcome measures to detect clinical change,[31] to the authors knowledge, measurements of the standard error of CoP parameters, during challenging standing conditions, have yet to be reported in the literature for people with CLBP. The differences in postural instability outcomes during challenging standing conditions for both shoes types in the current study are less than the reported standard errors of the same CoP parameters assessed in reliability studies investigating elderly participants (who also demonstrate poor postural stability).[32] Changes in CoP parameters following an intervention may be too small to reliably determine whether change in postural stability has occurred.

The clinical study investigating the effects of rocker-sole footwear on CLBP,[18] from which the current participants were recruited, demonstrated clinically important statistically significant reductions in disability and pain (in both rocker and flat sole shoe groups) at follow-up, however, the current study demonstrates no change in postural parameters. This study and the findings of Kuukkanen and Malkia [33] (who in the presence of improvement in function in patients with LBP, found no improvement in postural stability at six months following an exercise intervention) suggest that CoP parameters may be insensitive to real changes in postural control or that there may be no significant changes in control. If the latter, the use of any mechanical indices as outcome measures would be inappropriate; if the former, alternative mechanical outcome measures need to be developed and tested.

Limitations

A systematic review investigating acceptable reliability for CoP parameters in asymptomatic individuals, published subsequently to the start of the current study, recommended a minimum trial duration of 90 seconds – a greater duration than that applied in this clinical trial.[34] However, in the current study, prolonged standing may have aggravated symptoms, and negatively influenced attrition rates.

The authors recognise the small sample size of this study may have resulted in a Type II error. Although the study sample is small (n=20), when compared to participants in the clinical study[18] from which study participants were recruited (n=115), there were similar reductions in pain and disability at six week and six month follow-up (disability: rocker-sole group $F(2,106) = 0.20$, $p = 0.82$, $\eta 2 = 0.001$; flat-sole group, $F(1.53,73.4) = 0.24$, $p = 0.73$, $\eta 2 = 0.01$; pain: rocker-sole group, $F(1.70,90.10)=0.01$, $p=0.99$, $\eta 2 <0.01$; flat-sole group, $F(2,96) = 1.04$, $p = 0.36$, $\eta 2$ 0.02) suggesting that this sub-group was a representative sample of a larger CLBP population, hence reducing the likelihood of a type II error.

It is unclear what effect either shoe type may have on CoP parameters in people with more severe CLBP, greater postural instability at baseline or if worn for greater than six months.

Conclusions

This is the first randomised trial with long-term follow-up comparing the influence of rocker-sole and flat-sole shoes on standing CoP parameters in a CLBP population. Long-term use of rocker-sole or flat-sole shoes in addition to attendance to a four week exercise group does not appear to influence barefoot postural control, as determined by CoP parameters, during standing in people with CLBP.

What are the new findings?

- Standing in a rocker-sole shoe reduced postural stability compared to standing barefoot whereas standing in a flat-sole shoe did not influence postural stability.
- Long term use of rocker or flat-sole shoes do not influence postural stability in barefoot standing.

How might it impact on clinical practice in the near future?

This study questions the belief that balance rehabilitation, especially when delivered in standing using rocker-sole shoes, will result in a long-term influence on postural control in people with CLBP. Treatment approaches directed towards influencing or 'normalising' altered CoP parameters may not be appropriate for people with CLBP.

Acknowledgements

We would like to thank all participants for their contributions to this study. We would also like to thank Tanya Forster, Andrew Lewis, and Jonathan Noble for their assistance during the data collection and analysis process. We thank all physiotherapy departments who participated in this trial, namely: Balance Performance Physiotherapy, Clapham, London, UK, SW4; Chelsea and Westminster Hospital, Chelsea, London, UK, SW10; Queen Mary's Hospital, Roehampton, UK, SW14; and St. George's Hospital, Tooting, UK SW18.

Funding and Competing Interests

The clinical study from which participants in the current study were recruited was funded by a Masai GB Ltd. project grant. Masai GB Ltd had no role in the writing of the manuscript, data collection, analysis or interpretation; trial design; patient recruitment; or the decision to submit for publication. The authors have not been paid to write this article. The corresponding author had full access to all data in the study and had final responsibility for the decision to submit for publication.

References

1. Moseley G, Hodges P. Are the changes in postural control associated with low back pain caused by pain interference? Clin J Pain 2005; 21:323-29.

2. Luoto S, Taimela S, Hurri H, et al. Psychomotor Speed and Postural Control in Chronic Low Back Pain Patients: A Controlled Follow-Up Study. Spine 1996;21:2621-27.

3. Byl N, Sinnott P. Variations in Balance and Body Sway in Middle-Aged Adults: Subjects with Healthy Backs Compared with Subjects with Low-Back Dysfunction. Spine 1991;16:325-30.

4. Mientjes M, Frank J. Balance in chronic low back pain patients compared to healthy people under various conditions in upright standing. Clin Biomech 1999;14:710-16.

5. Takala E, Korhonen I, Viikari-Juntura E. Postural sway and stepping response among working population: reproducibility, long-term stability, and associations with symptoms of the low back. Clin Biomech 1997;12:429-37.

6. Della Volpe R, Popa T, Ginanneschi, F, et al. Changes in co-ordination of postural control during dynamic stance in chronic low back pain patients. Gait Posture 2006; 24:349-55.

7. Mok N, Brauer S, Hodges P. Hip Strategy for Balance Control in Quiet Standing Is Reduced in People With Low Back Pain. Spine 2004;29:E107-12.

8. Mann L, Kleinpaul J, Pereira Moro A, et al. Effect of low back pain on postural stability in younger women: influence of visual deprivation. Journal of Bodywork and Movement Therapies 2010;14:361–6.

9. Yahia A, Jribi S, Ghroubi S, et al. Evaluation of the posture and muscular strength of the trunk and inferior members of patients with chronic lumbar pain. Joint Bone Spine 2011;78:291–7.

10. Ruhe A, Fejer R, Walker B. Center of pressure excursion as a measure of balance performance in patients with non-specific low back pain compared to healthy controls: a systematic review of the literature. Euro Spine J 2011;20: 358-68.

11. Brumagne S, Janssens L, Knapen S, et al. Persons with recurrent low back pain exhibit a rigid postural control strategy. Euro Spine J 2008; 17:1177-84.

12. Nigg B, Hintzen S, Ferber R. Effect of an unstable shoe construct on lower extremity gait characteristics. Clin Biomech 2006; 21:82-88.

13. Buchecker M, Pfusterschmied J, Moser S, Müller E. The effect of different Masai Barefoot Technology (MBT) shoe models on postural balance, lower limb muscle activity and instability assessment. Footwear Science. 2012; 4:93-100.

14. Nigg B, Federolf PA, von Tscharner V, Nigg S. Unstable shoes: functional concepts and scientific evidence. Footwear Science. 2012; 4:73-82.

15. Tropp H, Askling C. Effects of ankle disc training on muscular strength and postural control. Clin Biomech 1988;3:88-91.

16. Fitzgerald G, Axe M, Snyder-Mackler L. The Efficacy of Perturbation Training in Nonoperative Anterior Cruciate Ligament Rehabilitation Programs for Physically Active Individuals. Phys Ther 2000;80:128-40.

17. Johanssen F, Remvig L, Kryger P, et al. Exercise for chronic lower back pain: a clinical trial. J Orthop Sports PhysTher 1995;22:52-59.

18. MacRae CS, Lewis J, Shortland A, et al. Effectiveness of Rocker Sole Shoes in the Management of Chronic Low Back Pain. A Randomised Clinical Trial. Spine 2013;38:1905-12.

19. Ivanenko Y, Grasso R, Lacquaniti F. Effect of gaze on postural responses to neck proprioceptive and vestibular stimulation in humans. J Physiol 1999;519:301-14.

20. Salavati M, Hadian M, Mazaheri M, et al. Test-retest reliability of center of pressure measures of postural stability during quiet standing in a group with musculoskeletal disorders consisting of low back pain, anterior cruciate ligament injury and functional ankle instability. Gait Posture 2009;29;460-64.

21. Brumagne S, Cordo P, Verschueren S. Proprioceptive weighting changes in persons with low back pain and elderly persons during upright standing. Neurosci Lett 2004:366;63-66.

22. Lafond D, Champagne A, Descarreaux M, et al. Postural control during prolonged standing in persons with chronic low back pain. Gait Posture 2009;29: 421-27.

23. Era P, Heikkinen E. Postural Sway During Standing and Unexpected Disturbance of Balance in Random Samples of Men of Different Ages. J Gerontol 1985;40:287-95.

24. Doyle T, Dugan E, Humphries B, et al. Discriminating between elderly and young using a fractal dimension analysis of centre of pressure. Int J of Med Sci 2004;1:11-20.

25. Hageman P, Leibowitz J, Blanke D. Age and gender effects on postural control measures. Arch Phys Med Rehab 1995;76:961-65.

26. Hasselkus B, Shambes G. Aging and Postural Sway in Women. J Gerontol 1975;30;661-67.

27. Chiari L, Rocchi L, Cappello A. Stabilometric parameters are affected by anthropometry and foot placement. Clin Biomech 2002;17:666-77.

28. Hue O, Simoneau M, Marcotte J, Berrigan F, et al. Body weight is a strong predictor of postural stability. Gait Posture 2007;26:32-38.

29. Nigg B, Davis E, Lindsay D, et al. The Effectiveness of an Unstable Sandal on Low Back Pain and Golf Performance. Clin J Sport Med 2009;19:464-70.

30. Nigg B, Emery C, Hiemstra L. Unstable Shoe Construction and Reduction of Pain in Osteoarthritis Patients. Med Sci Sport Exer 2006;38:1701-08.

31. Ruhe A, Fejer R, Walker B. Is there a relationship between pain intensity and postural sway in patients with non-specific low back pain? BMC Musculoskel Dis 2011;12:162.

32. Salehi R, Ebrahimi-Takamjani I, Esteki A, et al. Test-retest reliability and minimal detectable change for center of pressure measures of postural stability in elderly subjects. Med J Islam Repub Iran 2010;23:224-32.

33. Kuukkanen T, Malkia E. An experimental controlled study on postural sway and therapeutic exercise in subjects with low back pain. Clin Rehab 2000;14;192-202.

34. Ruhe A, Fejer R, Walker B. The test-retest reliability of centre of pressure measures in bipedal static task conditions - A systematic review of the literature. Gait Posture 2010;32:436-45.

Figure legends

Figure 1. Study shoes: Rocker sole shoe (top); Flat sole shoe (bottom).

Figure 2. Participant standing on foam cushions over-lying force plates.

Figure 3. Flow of participants through trial.

Figure 1. Study shoes: Rocker sole shoe (top); Flat sole shoe (bottom).
(Gel 1140, ASICS, Warrington,
99x76mm (300 x 300 DPI)

Figure 2. Participant with infra-red reflective markers in situ standing on foam cushions over-lying force plates.
bilateral Iliac crests, and po
76x103mm (300 x 300 DPI)

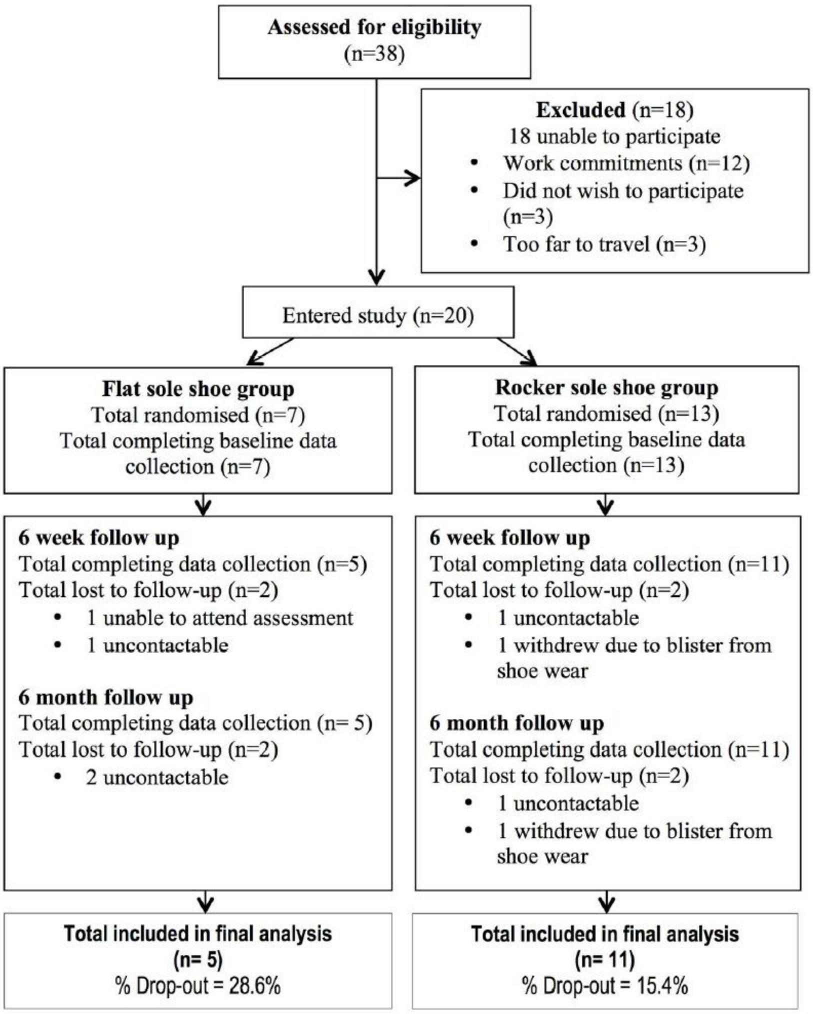


Figure 3. Flow of participants through trial.
and retention during the study
161x201mm (300 x 300 DPI)

Appendix 1

Standing and walking instructions for study shoes

ROCKER SOLE SHOE (wording as recommended by shoe manufacturer)

Walking Technique:

“Begin by walking naturally on a flat surface.”

Cues:

- (Good speed): “Walk at a brisk pace.”

- (Short steps): “Shorten the stride length.”

- (Good posture) “Walk with good posture…”

  - (Draw up crown of head): “Lengthen your spine by drawing the crown of your head up.)
  - (Proper gaze): “Look straight ahead.”
  - (Tummy in): “Pull your lower abdominal muscles in to help activate your core stability.”
  - (Shoulders back): “Bring your shoulders back and in line with your ears and hips.”

- (Swing arms with proper trunk movement): “Gently swing your arms and move your torso as you walk.”

- (Roll through): “Make sure you roll through the feet with every step.”

  - (Demonstrate proper roll through)
  - (Demonstrate where the heel sensor should hit): “Your foot should contact at the heel. As your foot rolls through from heels to toes, roll through the centre of the foot. When your foot pushes off, the weight in your toes should be evenly distributed so that the pressure is from the middle rather than to one side.”

Standing Exercise:

- (Foot position): “Stand with your feet parallel and shoulder width apart.”

- (Rock through the feet): “Roll forwards and backwards through the feet and ankles…

- (Find the Pivot Area): “…feeling the pivot area just in front of the heels.”

- (Heels and toes off floor): “Come to rest on the Pivot area. You should feel that your heels and toes are slightly off the floor.”

- (Posture): “Draw up your posture, lengthening your spine, gently drawing your shoulders back and softening your knees.”

Correction of Wrong Technique: "When wearing your shoes, certain mistakes can occur. Be aware that you are walking properly in your shoes to gain the maximum benefit."

- (Watching feet): "Do not watch your feet or the floor – look straight ahead when wearing your shoes."

- (Slouched posture): "Walk and stand with good posture at all times."

- (Poor core control): "Remember to engage your core muscles."

- (Stiff arms): "Walk with a relaxed, natural gait letting your arms swing gently and your torso move."

- (Over-pronation): "Do not let your feet roll in when you stand or walk."

- (Flat foot-strike): "Roll through the foot to get the full benefit of the shoes."

- (Pain): "Walking should feel comfortable and natural. If you have pain, stop and check your technique or consult with your physiotherapist."

Fitting: "Always make sure your shoes are snug on the instep, tight on the heel and comfortable on the toes."

- **Should not**: "Your shoes should not slip at all, squeeze or rub the toes, press on the tips of your toes, rub against the ankle bones or cause you any pain.

- **General medical precautions**: "When you first start wearing your shoes you may experience certain short-term effects. These include tingling in the feet and toes and general aches in the muscles. These effects normally stop within one to two weeks of wearing them."

- **Build up the amount of time you wear your shoes**: Start wearing the shoes for 15 to 30 minutes per day building up daily over the first week to two hours**.** Progress only as your comfort allows, to wearing a minimum of two hours per day.

- **Comfort:** If you encounter any problems with wearing your shoes, please contact your physiotherapist to discuss.

FLAT SOLE SHOE (wording altered from rocker sole shoe instructions above to apply to the flat sole shoe)

Walking Technique:

"Begin by walking naturally on a flat surface."

Cues:

- (Good speed): "Walk at a normal pace."

- (Normal stride): "Walk with your normal stride length."

- (Good posture) "Walk with good posture…"

- (Draw up crown of head): "Lengthen your spine by drawing the crown of your head up.)
- (Proper gaze): "Look straight ahead."
- (Tummy in): "Pull your lower abdominal muscles in to help activate your core stability."
- (Shoulders back): "Bring your shoulders back and in line with your ears and hips."

- (Swing arms with proper trunk movement): "Gently swing your arms and move your torso as you walk."

- (Roll through): "Make sure you roll through the feet with every step."

- (Demonstrate proper roll through)
- (Demonstrate where the heel should hit): "Your foot should contact at the heel. As your foot rolls through from heels to toes, roll through the centre of the foot. When your foot leaves the floor, push off through your big toe"

Standing Exercise:

- (Foot position): "Stand with your feet parallel and shoulder width apart."

- (Heels and toes on floor): "You should feel that your weight is evenly distributed over both feet."

- (Posture): "Draw up your posture, lengthening your spine, gently drawing your shoulders back and softening your knees."

Correction of Wrong Technique: "When wearing your shoes, certain mistakes can occur. Be aware that you are walking properly in your shoes to gain the maximum benefit."

- (Watching feet): "Do not watch your feet or the floor – look straight ahead when wearing your shoes."

- (Slouched posture): "Walk and stand with good posture at all times."

- (Poor core control): "Remember to engage your core muscles."

- (Stiff arms): “Walk with a relaxed, natural gait letting your arms swing gently and your torso move.”

- (Over pronation): “Do not let your feet roll in when you stand or walk.”

- (Flat foot-strike): “Roll through the foot to get the full benefit of the shoes.”

- (Pain): “Walking should feel comfortable and natural. If you have pain, stop and check your technique or consult with your physiotherapist.”

Fitting: “Always make sure your shoes are snug on the instep, tight on the heel and comfortable on the toes.”

- **Should not**: “Your shoes should not slip at all, squeeze or rub the toes, press on the tips of your toes, rub against the ankle bones or cause you any pain.

- **General medical precautions**: “When you first start wearing your shoes you may experience certain short-term effects. These include tingling in the feet and toes and general aches in the muscles. These effects normally stop within one to two weeks of wearing them.”

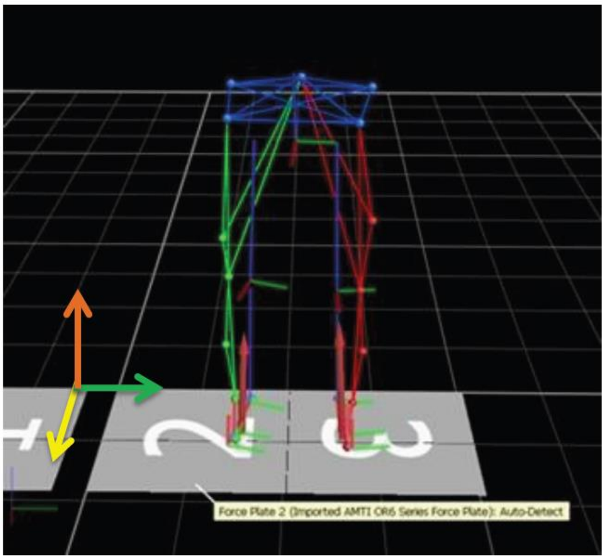
- **Build up the amount of time you wear your shoes**: Start wearing the shoes for 15 to 30 minutes per day building up daily over the first week to two hours**.** Progress only as your comfort allows, to wearing a minimum of two hours per day.

- **Comfort:** If you encounter any problems with wearing your shoes, please contact your physiotherapist to discuss.

Appendix 2

Centre of pressure calculations

Centre of pressure (CoP) calculations were made from the output from two force plates inset in the laboratory floor. The figure below demonstrates the x, y and z axes of the force plates. Yellow arrow represents the x-axis; green arrow, the y-axis; and orange arrow, the z-axis.



The x-coordinate of the CoP was calculated under each limb from the moments and forces produced by each plate with respect to the origin of the laboratory space, as follows:

$$x_{CoPl\_i} = \frac{-M_{yl\_i}}{F_{zl\_i}} + plate\ origin_{xl}$$

$$x_{CoPr\_i} = \frac{-M_{yr\_i}}{F_{zr\_i}} + plate\ origin_{xr}$$

where x_{CoPl_i}, x_{CoPr_i} are x- coordinates of the CoP under the left and right feet at time point i, and M_{yl_i}, M_{yr_i}, F_{zl_i}, F_{zr_i} are directional components of the moments and forces acting on the body from each force plate. These coordinates are expressed relative to the global coordinates of the laboratory space by a translation between the origin of the force plate and the origin of the laboratory (*plate origin*$_{xl}$, *plate origin*$_{xr}$) .

The x-coordinate of the CoP of the whole body was calculated by multiplying the x-coordinate of the CoP for each limb by the fraction of the total vertical force (F_z) acting through that limb, and adding the two terms together, as follows:

$$x_{CoP\_i} = x_{CoPl\_i} * \left(\frac{F_{zl\_i}}{F_{zl\_i} + F_{zr\_i}}\right) + x_{CoPr\_i} * \left(\frac{F_{zr\_i}}{F_{zl\_i} + F_{zr\_i}}\right)$$

where x_{CoP_i} is the x-coordinate of the CoP of the whole body.

Calculation of the root mean squared error of the centre of pressure in the antero-posterior direction ($CoP_{RMSE\ AP}$)

The root mean squared error of the CoP in the antero-posterior direction (x-direction) is given by:

$$CoP_{RMSE\_AP} = \sqrt{\sum_{i}^{N} \frac{\left(x_{CoP\_i} - \overline{x_{CoP\_i}}\right)^2}{N}}$$

where $\overline{x_{CoP\_i}}$ is the mean position of the x-coordinate of the CoP, and N is the number of time points in the trial.

Calculation of centre of pressure velocity in the antero-posterior direction ($CoP_{VEL\ AP}$)

The mean velocity of the CoP in the antero-posterior direction (x-direction) is given by:

$$CoP_{VEL\_AP} = \sum_{i} \frac{\left|x_{CoP\_i} - x_{CoP\_i-1}\right|}{N} * f_s$$

where f_s is the data sampling frequency.