The effect of textured insoles on balance and gait in people with multiple sclerosis: an exploratory trial

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Abstract

Objectives The primary aim of this study was to investigate the immediate effects of textured insoles on balance and gait in people with MS. The secondary aim was to explore any effects after two weeks of wear.

Study Design Within-session repeated-measures design with an exploratory follow-up period.

Setting Hospital gait laboratory

Participants Forty-six participants with MS (34 female), age mean (SD) 49 (7) years, who could walk 100m unassisted or using one stick/crutch.

Intervention Participants were tested wearing three types of insole in a randomised order: control (smooth insole), texture 1 (Algeos UK Ltd) or texture 2 (Crocs^{TM}). Participants were then randomly allocated to wear one of the textured insoles for two weeks, after which they were retested.

Main outcome measures Standing balance (centre of pressure excursions and velocity) was measured with eyes open and closed on a Kistler force platform. Spatio-temporal parameters of gait were measured using a GAITRite system.

Results The textured insoles had no significant immediate effects on balance or gait, apart from an increase in anterior-posterior sway range with eyes open in texture 2 (mean difference 4.5 mm, $p<0.05$). After two weeks, balance was not significantly different, but both textured insoles showed statistically significant effects ($p<0.05$) on spatio-temporal parameters of gait, with mean stride length increases of 3.5 cm (texture 1) and 5.3 cm (texture 2) when wearing the insoles.

Conclusions

After two weeks of wear there were improvements to spatio-temporal parameters of gait. However, whether this was a placebo or learning effect is unclear.

Keywords: multiple sclerosis, textured insoles, gait, spatio-temporal parameters, balance, double-limb standing

Clinical trial registration number: ISRCTN02778739

Background

Impairments of balance and gait are common problems in people with multiple sclerosis (MS) [1, 2]. Findings in other populations beyond MS show that wearing textured insoles, or standing on textured surfaces, can affect balance, theoretically by way of increased stimulation to the plantar surface of the feet [3-10]. Some studies have reported that textured insoles reduce postural sway during standing in healthy young [3, 4] and older people [4, 7, 9], representing an improvement in balance. Other studies have shown no clear benefit in healthy people [6, 11] and older fallers [10] during similar balance tasks. However, there has been limited research in people with MS. Dynamic foot orthoses (contoured to the sole of the foot) were reported to have an initial destabilising effect on standing balance, followed by an improvement in balance after wearing the orthoses for 4 weeks, in adults with MS [12]. It was proposed that these alterations in balance could be due, in part, to an increase in plantar stimulation and long-term sensory-motor training effect [12], thus supporting the idea of investigating textured insoles. Another small study of 14 people with MS, reported some effects of wearing textured insoles, constructed from sandpaper, on gait kinematics and kinetics, including benefits to knee and hip excursion, and ground reaction forces [13].

One common limitation of all previous studies that report benefits from textured insoles is the use of a within-session research design, with no longitudinal component [3, 7, 9]. Therefore it remains unclear whether improvements in balance would be retained or accrue over time. This is an important clinical consideration.

The primary aim of the current study was to determine if there were any immediate effects of textured insoles on double-limb standing balance and gait in people with MS. The secondary aim of this study was to explore any effects after two weeks of wear, to provide pilot data on whether any immediate effects of textured insoles were maintained over time.

Methods

Design

This study consisted of two parts. In part one, related to the primary aim, a within-session design was used to investigate the immediate effects of wearing insoles. All participants were tested under each of three conditions defined by the type of insole: control, texture 1 and texture 2, the order of which was randomised. In part two of the study, related to the secondary aim, participants were randomised to be given either texture 1 or texture 2 insoles and reassessed after two weeks wear.

Participants

Men and women aged between 18-65 years with a clinical diagnosis of MS who were able to walk 100 metres unassisted or with the use of one stick or crutch were recruited. Exclusion criteria included relapse of MS symptoms in the previous three months, self-reported neuromuscular disease (other than MS); stroke, musculoskeletal injury in the previous 6 weeks, peripheral sensory neuropathy of a degree that would preclude them perceiving the textures (tested on first attendance using monofilaments) and; an inability to understand instructions (judged by either of the two research assistants present during testing). Participants were recruited from a hospital MS service and MS support groups in the community. All participants gave written informed consent.

Sample size was calculated for the primary aim and outcome of centre of pressure (CoP) velocity, based on figures from the study of foot orthoses and balance in people with MS by Ramdharry et al. [12] : power = 0.8, alpha=0.05; mean (SD) CoP velocity = 22.58 $mm.s^{-1}$ (8.96), mean change of 3.9 $mm.s^{-1}$. A simple calculation for two related groups gave a figure of n=42. To plan for an attrition rate of 20% by the second testing session we aimed to recruit up to 50 people, which would also allow group sizes of around 20-25 in each of the two groups in the follow up part of the study, sufficient in our view for an exploratory investigation in that part of the study.

Randomisation

Simple randomisation using a computer system (www.randomizer.org), whereby a research assistant contacted the University to receive the relevant allocation, was used: to determine the sequence in which the three insoles were first worn; to allocate participants to wear either of the textured insoles for the two week follow-up; and to determine the sequence in which that allocated textured insole and the control insole were worn in the retest at two weeks. For purposes of concealment the randomisation lists were held centrally and not shown to the researcher and the researcher was only told the allocation to either insole for the two week follow up after the first within-subject tests had been completed.

Materials

Three types of insoles were used, as shown in Figure 1. The control insole had a smooth surface (Medium Density EVA, 3mm thickness, shore value A50, black, OG1304; Algeos UK Ltd., Liverpool, United Kingdom). Texture 1 insole had small, pyramidal peaks with centre-to-centre distances of approximately 2.5mm (Evalite Pyramid EVA, 3mm thickness, shore value A50, black, OG1549; Algeos UK Ltd., Liverpool, United Kingdom) and had been used in our previous studies [6, 7, 10, 11]. These two insoles were cut to a range of men's and women's standard UK shoe sizes, at a local orthotic manufacturing workshop (Peacocks Medical Group, Newcastle-upon-Tyne, UK). Texture 2 was a commercial insole – the Crocs™ Silver insole. This EVA insole has small nubs about 1mm in height and 2 mm in diameter (see Figure 1), a shore value of A25, a curved arch and heel cup. It was used to investigate whether a relatively cheap, commercially available insole would have comparable effects to Texture 1, because previous studies have shown that effects may depend on the texture type [6, 7]. However we were aware of the limitation that the design of this insole differed from Texture 1 and the control in properties other than the texture.

Double-limb standing balance was measured using a Kistler force platform (Model 9286AA, Kistler Instruments Ltd., Hampshire, UK), sampled at 50 Hz. Level, over-ground walking was measured using the GAITRite system (CIR Systems, Inc., Havertown, PA 19083, USA), a 4.57m long portable electronic walkway with an active area 3.66m long by 0.61m wide. The GAITRite instrumentation has been shown to have high reliability [14, 15]. A start and finish line were marked on the floor 2m in front and 2m behind the walkway to allow participants to accelerate and decelerate outside the walkway [14].

Procedure

Prior to testing participants completed a short telephone questionnaire detailing demographic details. At baseline assessment participants completed the 12-Item World Health Organization Disability Assessment Schedule II (12-Item WHODAS II) [16], and the 12-item Multiple Sclerosis Walking Scale (MSWS-12) questionnaire [17]. Peripheral sensation was tested using a 10g monofilament: participants who were unable to feel the monofilament at ≥4 sites on each foot were excluded [18].

Before data collection, each participant had a practice standing balance and walking trial wearing the control insoles, to ensure familiarity with the procedures. Each participant put the first allocated insole into their normal shoes under the supervision of a research assistant to provide help and verify that the correct insole was being used. Thereafter, a second research assistant, who was blind to the insole condition, began data collection. Testing was carried out wearing no hosiery in order to optimise contact between the indentations on the upper surface of the textured insoles and sensory receptors on the plantar surface of the feet. Participants were not blinded to the insole condition.

Participants were asked to stand on the force platform and adopt their preferred, comfortable, quiet standing position, with arms hanging by their sides, whilst looking straight ahead at a circular black target of 10cm diameter, fixed 3m away and at eye level. Foot positioning was standardised throughout, using individual foot templates to eliminate confounding effects of altered joint kinetics. Each participant performed three trials of double-limb standing over 30 seconds, with eyes open and eyes closed (i.e. 6 trials per condition, 18 trials in total). Rest periods were provided between visual conditions.

Following tests of standing balance, a 5 minute seated rest period was provided to prevent fatigue. Participants then walked unassisted, at their normal, self-selected pace, along the GAITRite walkway mat, whilst being supervised by a research assistant. One gait trial was completed for each of the three insole conditions in a randomised sequence

Once all three insoles had been tested the non-blinded research assistant gave the participant their randomly allocated textured insole (Algeos or Crocs^{TM}) to wear in their shoes over the two week intervention period. Participants were allowed to wear hosiery over this period, in order to replicate usual apparel conditions. The participants were encouraged to wear the insoles as often as possible but the actual frequency and duration of wear was at the discretion of the participant.

Reassessment of standing balance and gait was completed after two weeks using the same procedures as at the first assessment. However, testing was conducted under only two insole conditions: wearing the textured insole that had been worn during the intervention period and the smooth control insole (the latter to explore the necessity of wearing the textured insole to show any effect after two weeks).

Outcome measures

Double-limb standing balance outcome measures were the range and standard deviation of the CoP excursion in the mediolateral (ML range and MLSD) and anterior-posterior direction (AP range and APSD), and CoP velocity. All measures were taken with eyes open and eyes closed. Gait measurements were velocity, cadence, stride length, step length, cycle time, double-limb support time, swing time, and base of support.

ML and AP CoP excursion variables (mm) were extracted from the force platform using Bioware software. CoP velocity (mm.s^{-1}) was calculated using previous methods [19]. Gait measurements were produced using the GAITRite software.

Data Analysis

Data were analysed with SPSS version 16.0 (SPSS Inc, Chicago, IL, 60606, USA). In part 1 of the study, for each balance and gait variable, the immediate effects of the insoles were analysed with a repeated-measures ANOVA. Where the assumption of sphericity was violated, a Greenhouse–Geisser correction was applied. Post hoc pairwise comparisons were used to identify where specific differences occurred, with Bonferroni adjustments for the use of multiple comparisons. In part 2 of the study, the exploratory analysis of the effects of the insoles after two weeks (including the dependence of effects on actually wearing the insole at testing) was on an *as randomised* basis. Paired t-tests were used to compare baseline control measures with measures at two weeks while wearing the textured insole; and to compare baseline control measures with measures at two weeks while wearing the control insole. 95% confidence intervals were calculated for all comparisons. All tests were two-tailed with alpha set at p=0.05.

Results

Participants

Fifty four individuals with MS were assessed for eligibility, however, 4 declined to take part and 4 did not meet the criteria. 46 participants took part (34 female), age mean (SD) 49 (7) years. The mean (SD) MSWS-12 score for all 46 participants at baseline was 3.09 (0.96), on a scale of 1-5, with 5 being a high level of limitation. The mean (SD) 12-item WHODAS II disability score was 1.47 (0.76), on a scale of 0-4, with 4 being a high level of disability.

For the two week exploratory intervention period, 24 participants were randomised to the Algeos insole, and 22 to the Crocs™ insole. The 2 groups did not differ in WHODAS II or MSWS-12 scores at baseline (p=0.99 and 0.65 respectively). No participants were lost to follow-up and all 46 returned and completed the study (Figure 2). However not all participants could complete all tests due to fatigue (details are below).

Study Part 1: the immediate effects of wearing textured insoles (Primary Aim)

Balance (Table 1)

A statistically significant increase in AP range during double-limb standing with eyes open was observed when wearing the Crocs™ insole compared to control ($p<0.05$). The mean difference (95% CI) was 4.5 (0.6 to 8.4) mm. No other significant between-condition differences were observed.

Gait (Table 2)

Neither of the textured insoles had a statistically significant immediate effect on gait variables, compared to control (all $p >0.05$).

Study Part 2: Exploration of the effects after 2 weeks (Secondary Aim)

Balance (Table 3)

There were no statistically significant effects on standing balance variables (all p>0.05).

Gait (Table 4)

Stride length in both legs significantly increased in both textured insole groups, relative to the baseline control condition. This increase occurred irrespective of whether the test was carried out wearing the textured or control insole.

With two exceptions, step length in both legs increased significantly in both groups regardless of whether the textured or control insoles were worn during testing. The exceptions were non-significant effects in the right leg while wearing the Crocs insole and in the left leg wearing the Algeos insole.

Double support time was reduced significantly in the Crocs™ group whether the test was carried out wearing the textured insole or the control insole, except in the right leg while wearing the textured insole where there was a clear indication of a trend towards a reduced time (p=0.06). There were no such effects in the Algeos group.

Left leg cycle time also reduced significantly in the Crocs™ group, both with and without the textured insole in place during testing. No significant effects were observed in the Algeos group

Base of support was only affected in the Algeos group. The left base of support was reduced significantly when the test was carried out wearing the control insole, but not when the textured insole was worn.

Other measures of gait did not change significantly in either group.

Discussion

The primary aim of this study was to investigate the immediate effects of wearing two different textured insoles on double-limb standing balance and gait in people with MS. The secondary aim was to explore any effects after two weeks of wear, to see if any immediate effects of textured insoles were maintained over time.

There was partial evidence of an immediate increase in sway in the AP direction when wearing the Crocs™ insole. There were no other significant immediate effects on either balance or gait. This observation of increased sway is consistent with previous research investigating the immediate effects of wearing dynamic foot orthoses on balance in people with MS [12] where an initial detrimental effect on balance was seen. This could be an immediate destabilising effect [12] or it could be that participants felt greater freedom or confidence to increase their excursions in the AP direction. Whatever the cause, although statistically significant, this immediate effect is relatively small in magnitude, being a mean increase of about 10%. A lack of immediate improvement in balance is also consistent with recent studies on textured insoles in adults with chronic ankle instability and older people, who commonly present with impaired balance at baseline [8, 10]. As previous studies on healthy people have shown immediate improvements in balance [3, 7, 9] this is an important clinical finding. It is possible that the presence or magnitude of the textured effect may be dependent upon an individual's balance ability at baseline, thus explaining the conflicting findings between healthy and clinical groups.

After two weeks of wear, we found no effects of textured insoles on standing balance. However we did observe effects on gait, including increased stride and step length. Similar changes in these gait variables have been reported after physiotherapy or exercise interventions in MS [20, 21], and are viewed as beneficial effects, suggesting a more confident gait pattern. The magnitude of the changes seen in this study (3-5%) is small. Due to differences in outcome measures used it is difficult to compare directly between studies. This is the first study, to date, to explore the longitudinal effects of textured insoles in adults with MS. Our baseline gait data compare well with previously published values in MS, for example being similar to the velocity, cadence and step length reported by Givon et al. [1], suggesting that the functioning level of participants within the current study concurs with previous research studies. Improvements in gait after 2 weeks were found both when wearing the textured insole and when wearing the control insole, i.e. the observations were independent of wearing the textured insole at the time of testing. This points to the suggestion that textured insoles may possibly provide a sensory-motor training effect, giving an improvement in walking that is still exhibited without the textured insole, rather than just a mechanical effect that would be dependent on having the insoles in the shoes at the time of testing. In addition, we noted that stride length changes were uniform but step length changes were more mixed. This could possibly indicate an effect related to limb dominance, but further work would be needed to explore that in more depth. However, it is important to note that in the exploratory longitudinal part of our study there were two textured insole groups but no control group. We used this design to explore whether any immediate effects were maintained whilst retaining an adequate sample size in the follow-up section. Therefore, it is possible that a placebo or learning effect may have produced the effects on gait rather than the actual insoles. This remains to be determined, but our exploratory data provide important preliminary evidence which can inform future investigations using a robust randomised controlled trial design.

The current findings raise some important issues for future studies investigating textured insoles in people with MS. While the two weeks intervention period showed effects on gait, it will be important that future studies use a control group. It also raises the question as to whether these effects may accrue or additional effects be seen if the insoles were worn over a longer period. It is recommended that a larger study should measure participants at multiple time points over a period of months to determine if and when habituation to the sensory stimulus occurs, and whether benefits in other gait measures are seen over longer time periods. In addition it will be important to quantify if any effect is related to these insoles reducing the volume of space within the shoe, and so increasing pressure on the foot, rather than only due to plantar stimulation from the texture. Also, our sample size at follow up was relatively small, which may have impeded our ability to detect statistically significant effects.

The results suggest that the type of textured insole may be important. This may be due to differences in the geometric textured pattern of the insoles, which concurs with findings from our previous research strategies in healthy young and older people [6, 7]. If the type of texture is important then our results are only applicable to these two types of textures and a larger range of textures would need to be tested to determine an optimal geometric pattern, including the depth, shape and spacing of indentations.

We encouraged participants to wear the textured insoles as often as they could during the intervention period. The mean number of days wearing the insoles was reported as 11 (SD 4, range 3-14) days. From our preliminary discussions with people with MS we believe that the voluntary wear of insoles would best reflect real-life practice. However, future work would benefit from obtaining precise details of the frequency of insole wear by way of diaries. Our sample had relatively intact plantar sensation and it would be unwise to extrapolate our findings to those with marked peripheral sensory problems.

Future studies should also collect information on: how confident people feel when walking in the insoles, comfort, and acceptability, which could help us to better understand how textured insoles bring about their effects on balance and gait. This information would help refine what could be the most effective textured footwear intervention for people with MS.

Conclusions

We found no immediate improvements to either standing balance or gait from the textured insoles. After two weeks of wear, standing balance had not improved, but there were improvements to some aspects of gait, specifically stride length and step length. However, it is unclear whether this was a placebo or learning effect. Our preliminary data suggests the need for an in-depth investigation into the effects of prolonged wearing of textured insoles on gait, and how this affects function and, ultimately, self-management in MS.

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Tables

Table 1 Immediate effects of wearing insoles: balance

	Mean (SD) n = 44			
	Control insole	**Algeos insole**	**Crocs™ insole**	**p value**
EO CoP velocity (cm/sec)	23.6 (11.8)	23.8 (10.2)	23.7 (9.0)	0.946
EO AP range (mm)	44.3 (16.6)	45.4 (16.9)	48.8 (16.9) *	0.042
EO AP SD (mm)	8.2 (3.8)	8.0 (3.5)	8.8 (3.5)	0.145
EO ML range (mm)	32.9 (16.8)	35.5 (23.0)	36.3 (24.7)	0.744
EO ML SD (mm)	5.2 (3.2)	5.5 (3.3)	5.5 (3.0)	0.701
EC CoP velocity (cm/sec)	33.2 (16.8)	33.6 (16.6)	34.9 (17.7)	0.177
EC AP range (mm)	55.2 (24.4)	55.0 (23.2)	57.9 (26.5)	0.164
EC AP SD (mm)	9.9 (4.9)	10.2 (4.9)	10.6 (5.7)	0.095
EC ML range (mm)	28.9 (16.3)	30.5 (17.6)	31.7 (18.7)	0.309
EC ML SD (mm)	5.0 (3.1)	5.4 (3.4)	5.5 (3.3)	0.254

EO, eyes open; EC, eyes closed; CoP, centre of pressure; AP, anterior-posterior; ML, mediolateral. Only 44 of 46 participants completed the tests in all insole conditions as some participants had to stop due to fatigue. * indicates significant difference compared to control condition.

Table 2 Immediate effects of wearing insoles: gait

	Mean (SD) n=36			
	Control insole	**Algeos insole**	**Crocs™ insole**	**p value**
Velocity (cm/sec)	77.5 (25.8)	75.4 (28.2)	76.3 (24.2)	0.319
Cadence (steps/min)	91.5 (15.0)	90.0 (17.0)	90.4 (14.4)	0.269
Stride length L (cm)	99.8 (21.9)	97.8 (24.2)	99.5 (22.0)	0.148
Stride length R (cm)	99.5 (21.8)	98.0 (24.0)	99.8 (21.6)	0.240
Step length L (cm)	48.5 (12.5)	47.8 (13.4)	48.7 (12.0)	0.297
Step length R (cm)	50.8 (9.7)	49.9 (11.1)	50.7 (10.1)	0.323
Cycle time L (sec)	1.3 (0.3)	1.4 (0.4)	1.4 (0.3)	0.151
Cycle time R (sec)	1.3 (0.3)	1.4 (0.4)	1.4 (0.3)	0.091
Double support time L (sec)	0.5 (0.2)	0.5 (0.3)	0.5 (0.2)	0.097
Double support time R (sec)	0.5 (0.2)	0.5 (0.3)	0.5 (0.2)	0.116
Swing time L (sec)	0.4 (0.1)	0.4 (0.1)	0.4 (0.1)	0.379
Swing time R (sec)	0.4 (0.1)	0.5 (0.1)	0.4 (0.1)	0.322
Base of support L (cm)	13.3 (5.2)	13.7 (4.7)	13.1 (5.1)	0.217
Base of support R (cm)	13.3 (5.0)	14.1 (4.5)	13.4 (5.1)	0.107

Only 36 participants completed the gait tests in all insole conditions as some participants had to stop due to fatigue.

Table 3 Effects of wearing the insoles for two weeks: balance.

Balance Measurement	**Algeos Group**				**Crocs Group**			
	Control (2 weeks) – Control (baseline)		**Texture (2 weeks) – Control (baseline)**		**Control (2 weeks) – Control (baseline)**		**Texture (2 weeks) – Control (baseline)**	
	Mean difference (95% CI)	*P* value	Mean difference (95% CI)	*P* value	Mean difference (95% CI)	*P* value	Mean difference (95% CI)	*P* value
EO CoP velocity (cm/sec)	-0.8 (-6.7 to 5.1)	0.78	-1.0 (-6.8 to 4.8)	0.72	0.5 (-0.9 to 1.9)	0.48	1.0 (-0.3 to 2.9)	0.30
EO AP range (mm)	2.5 (-3.2 to 8.3)	0.37	1.4 (-3.5 to 6.2)	0.57	0.3 (-5.6 to 6.3)	0.91	-0.9 (-4.1 to 2.3)	0.56
EO AP SD (mm)	-0.6 (-2.0 to 0.9)	0.41	-0.4 (-1.8 to 1.0)	0.53	0.1 (-0.8 to 1.0)	0.84	-0.2 (-0.8 to 0.4)	0.49
EO ML range (mm)	1.3 (-5.7 to 8.3)	0.70	-5.5 (-12.6 to 1.6)	0.12	0.6 (-7.8 to 9.1)	0.88	-4.3 (-10.5 to 1.8)	0.16
EO ML SD (mm)	-0.4 (-1.8 to 0.9)	0.51	-0.9 (-2.4 to 0.6)	0.22	0.2 (-0.6 to 1.0)	0.64	-0.1 (-0.8 to 0.6)	0.72
EC CoP velocity (cm/sec)	1.3 (-1.4 to 4.1)	0.33	0.5 (-2.8 to 3.9)	0.75	-1.3 (-3.6 to 1.0)	0.25	2.1 (-1.1 to 5.3)	0.18
EC AP range (mm)	-2.4 (-9.0 to 4.2)	0.46	-4.6 (-1.2 to 2.9)	0.21	-1.4 (-6.4 to 3.6)	0.58	2.8 (-2.6 to 8.3)	0.29
EC AP SD (mm)	-0.4 (-1.4 to 0.7)	0.50	-0.9 (-2.2 to 0.4)	0.15	-0.3 (-1.1 to 0.6)	0.48	0.6 (-0.2 to 1.3)	0.12
EC ML range (mm)	1.7 (-3.2 to 6.6)	0.48	0.1 (-5.4 to 5.6)	0.97	2.1 (-5.8 to 9.9)	0.59	1.6 (-2.0 to 5.2)	0.36
EC ML SD (mm)	0.1 (-0.8 to 1.0)	0.83	0.1 (-1.1 to 1.2)	0.93	0.2 (-0.9 to 1.3)	0.72	0.1 (-0.7 to 1.0)	0.72

Table 3 shows, for each of the textured insoles, mean differences and their 95% confidence intervals for two comparisons. Control (2 weeks) – Control (baseline) tested if any effects were seen without having to wear the textured insole during testing. Texture (2 weeks) – Control (baseline) tested if any effects were seen while the participant wore the specific textured insole during testing. EO, eyes open; EC, eyes closed; CoP, centre of pressure; AP, anterior-posterior; ML, mediolateral; SD, standard deviation.

For each variable, data for control at baseline were provided by 24 participants for Texture 1 (Algeos) and 22 participants for

Texture 2 (Crocs). However, data at two weeks were not available for all participants. Hence, for the paired comparisons in this table n = between 17 and 20.

Table 4: Effects of wearing insoles for two weeks: gait

Gait Measurement	**Algeos Group**				**Crocs Group**			
	Control (2 weeks) – Control (baseline) n=20		**Texture (2 weeks) – Control (baseline) n=20**		**Control (2 weeks) – Control (baseline) n=19**		**Texture (2 weeks) – Control (baseline) n=17**	
	Mean difference (95% CI)	*P* value	Mean difference (95% CI)	*P* value	Mean difference (95% CI)	*P* value	Mean difference (95% CI)	*P* value
Velocity (cm/sec)	3.0 (-2.6 to 8.7)	0.27	-0.5 (-6.7 to 5.8)	0.88	3.4 (-3.0 to 9.7)	0.28	2.4 (-5.3 to 10.1)	0.52
Cadence (steps/min)	-0.7 (-5.7 to 4.4)	0.70	-3.9 (-11.6 to 3.7)	0.30	0.3 (-6.8 to 7.5)	0.93	-1.0 (-8.9 to 7.0)	0.80
Stride Length L (cm)	4.4 (1.4 to 7.5)	0.01*	3.3 (0.8 to 5.8)	0.01*	4.7 (1.9 to 7.5)	<0.01*	5.3 (1.1 to 9.5)	0.02*
Stride Length R (cm)	5.8 (2.2 to 9.4)	<0.01*	3.6 (0.5 to 6.7)	0.02*	4.6 (1.8 to 7.4)	<0.01*	5.2 (1.0 to 9.4)	0.02*
Step Length L (cm)	2.5 (0.6 to 4.4)	0.01*	0.9 (-0.9 to 2.7)	0.31	2.2 (0.9 to 3.6)	<0.01*	2.9 (1.1 to 4.6)	<0.01*
Step Length R (cm)	2.7 (0.9 to 4.5)	0.01*	2.6 (1.1 to 4.2)	<0.01*	2.6 (0.8 to 4.4)	<0.01*	2.4 (-0.5 to 5.3)	0.10
Cycle time L (sec)	-0.01 (-0.08 to 0.05)	0.65	0.1 (-0.1 to 0.4)	0.32	-0.05 (-0.09 to -0.02)	<0.01*	-0.04 (-0.09 to 0.00)	0.05*
Cycle time R (sec)	0.1 (-0.1 to 0.4)	0.30	0.1 (-0.1 to 0.4)	0.25	0.05 (-1.6 to 0.3)	0.65	0.1 (-0.2 to 0.3)	0.50
Double support time L (sec)	-0.03 (-0.08 to 0.02)	0.20	0.01 (-0.1 to 0.1)	0.84	-0.04 (-0.07 to -0.02)	<0.01*	-0.03 (-0.06 to -0.002)	0.04*
Double support time R (sec)	-0.02 (-0.08 to 0.03)	0.32	0.01 (-0.1 to 0.1)	0.88	-0.05 (-0.07 to -0.02)	<0.01*	-0.03 (-0.06 to 0.00)	0.06
Swing time L (sec)	0.00 (-0.02 to 0.01)	0.87	-0.01 (-0.04 to 0.02)	0.41	0.00 (-0.03 to 0.02)	0.64	0.00 (-0.02 to 0.02)	0.70
Swing time R	0.02 (-0.01 to	0.19	0.01 (-0.02 to	0.47	0.00 (-0.01 to	0.93	0.00 (-0.02 to	0.81

(sec)	0.04)		0.04)		0.01)		0.03)	
Base of support L (cm)	-1.7 (-3.0 to -0.3)	0.02*	-0.1 (-2.2 to 0.2)	0.09	0.6 (-0.7 to 1.9)	0.37	0.09 (-0.8 to 2.7)	0.29
Base of support R (cm)	-0.7 (-2.2 to 0.8)	0.35	-0.5 (-1.8 to 0.8)	0.43	0.4 (-0.9 to 1.7)	0.48	1.1 (-0.7 to 3.0)	0.21

Table 4 shows, for each of the textured insoles groups, the mean differences and their 95% confidence intervals for two comparisons. Control (2 weeks) – Control (baseline) tested if any effects were seen without having to wear the textured insole during testing. Texture (2 weeks) – Control (baseline) tested if any effects were seen while the participant wore the specific textured insole during testing.

* highlights differences that were statistically significant at alpha = 0.05. For each variable, data for control at baseline were provided by 24 participants for Texture 1 (Algeos) and 22 participants for Texture 2 (Crocs). However, data at two weeks were not available for all participants.

Figures

Figure 1. Insoles. From top: Control; Algeos (Texture 1); Crocs^{TM} (Texture 2); detail of Crocs^{TM} textured surface

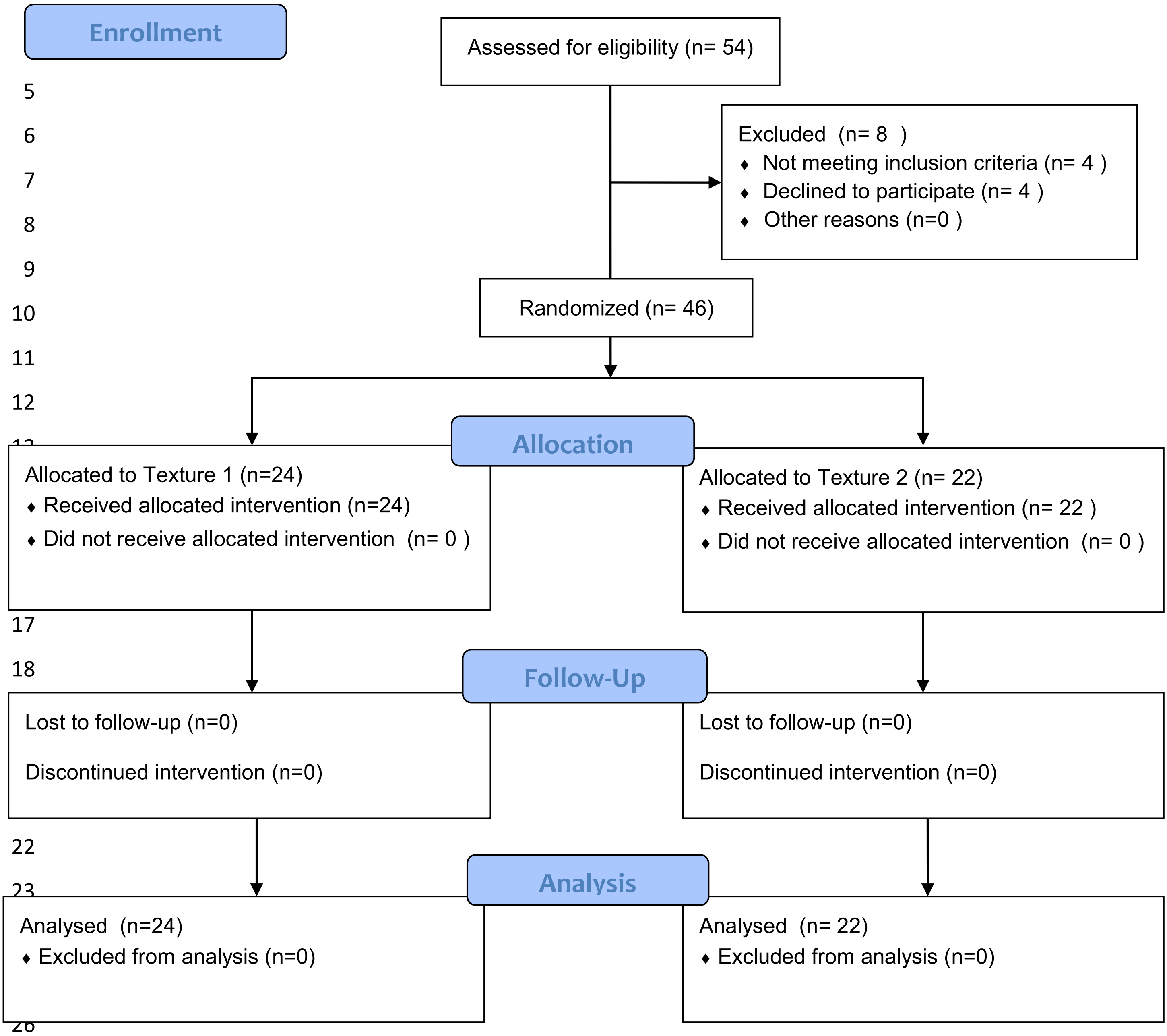

Figure 2. Flowchart of study outline