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This is the Accepted version of the following publication

The publisher's official version can be found at
https://www.tandfonline.com/doi/abs/10.1080/00140139.2021.1918351?journalCode=terg20
Note that access to this version may require subscription.

A shoe-insole to improve ankle joint mechanics for injury prevention among older adults

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Abstract

Technologies to assist senior individuals with active walking are important. This experiment aimed to investigate whether a customised insole geometry would reduce the risk of falls and locomotive injuries. The tested insole incorporated a built-in inclination to assist ankle dorsiflexion ($2.2°$) and eversion ($4.5°$). Twenty-six older adults and 30 younger counterparts undertook gait assessment with and without the experimental insole while 3D motion capture and force plates recorded gait. The insole increased swing foot-ground clearance, with.43 cm for the older adults' dominant foot. The insole also prevented excessive lateral centre of pressure movement. The main insole effects on foot contact mechanics were: (i) prolonged time to foot-flat (.015s) and (ii) improved energy efficiency (2%). Reduced knee adduction moment (> 15%) was observed in the older group. Shoe insoles to provide dorsiflexion and eversion support may have the potential to reduce the risk of falls and locomotion-related injuries for older adults.

150 words

Practitioner Summary

Using 3D gait assessment techniques this research investigated shoe-insoles incorporating ankle dorsiflexion and eversion support features. It was shown that falls risk and locomotive injuries

could be reduced by the application of orthotics to support ankle dorsiflexion and eversion.

Shoe-orthotics may provide practical low-cost solutions to correcting gait impairments.

49 words

Introduction

Recent advances in medical science combined with healthier lifestyles and improved social security have contributed dramatically to life expectancy but, as a result, 'ageing' is becoming a serious public health problem in developed countries (Crimmins 2015). Rather than focusing primarily on life expectancy we are beginning to appreciate that 'healthy ageing' is important, not only for older individuals themselves but also for the community due to the increasing healthcare costs of an ageing population (Banks, 2008). Locomotor function is fundamental to a healthy, active, life but walking is increasingly compromised with ageing (Shafrin et al., 2017). Modifications to gait patterns can potentially reduce the impact of ageing on everyday mobility.

Falls are the major cause of locomotion-related acute injuries and one in three older adults fall annually, with approximately 20% of cases leading to serious injury (Stevens et al. 2006). Of the many falls-related factors, balance loss due to tripping has been reported to account for approximately half of all falls incidents (Blake et al. 1988; Smeesters et al. 2001). Tripping can be defined as unintentional contact of the swing foot with either the walking surface, or objects on it, sufficient to destabilise the walker. Biomechanically, tripping risk is highest at an event midway through swing phase, known as Minimum Foot Clearance (MFC) (Begg et al. 2007). At this point toe-ground clearance is very low, only 1 to 2 cm, and in the

event of tripping, balance must be recovered rapidly to avoid falling. Balance control is highly influenced by the foot centre of pressure (CoP), influencing stability (Ganesan et al. 2014; Ganesan et al. 2014). As a consequence, measures to improve dynamic balance are important in minimising the risk of falls and associated injuries (Nagano et al. 2015).

Insoles also have the potential to relieve problems due to long-term suboptimal joint mechanics. Excessive adduction moments, i.e. forces directed outward when walking, are a common cause of bone-on-bone contact at the medial knee (Rana et al. 2016). Knee pain due to osteoarthritis (OA), for example, is more prevalent with ageing and health-related costs due to OA are increasing rapidly (Heidari, 2011; Wallace et al., 2017). Raising the outer part of an insole, known as a 'lateral-wedge', has been reported to be effective for knee OA prevention (Radzimski et al. 2012). In addition to improving knee alignment, corrective insoles also provide ankle support, changing joint orientation to reduce knee loading by assisting the absorption of foot-ground impact forces.

While customised insole geometry can influence ankle motion (Hellstrand Tang et al. 2014; Lehmann et al. 1987) the mechanism by which specialised insoles change foot orientation to assist gait control requires further investigation. The current research focus was how a specialised insole would affect gait mechanics via ankle dorsiflexion and eversion. Dorsiflexion is the primary joint motion to increase swing foot clearance and reduce tripping risk

(Moosabhoy and Gard 2006). At heel contact, greater dorsiflexion is also beneficial in preventing flat-foot contact and improving foot-ground impact-force distribution (Silver-Thorn et al. 2011; Ventura et al. 2011). Dorsiflexion at heel contact reduces impact shock via elastic energy absorption by the extended Achilles tendon, relieving stresses on the knee (Lichtwark and Wilson 2006; Ventura et al. 2011).

Ankle eversion immediately following heel contact has been shown to correct Varus knee misalignment and reduce knee adduction moments, effective in the prevention of knee osteoarthritis (OA), already widely applied using the lateral-wedge insole (Radzimski et al. 2012). Eversion support may also regulate lateral CoP movement to stabilise the centre of mass and enhance medio-lateral stability (Ganesan et al. 2014). Lateral CoP deviation may also affect stability in older adults due to reduced stimulation of mechanoreceptors and attenuated afferent feedback (Nurse et al. 2005). Strong onset of CoP on the lateral part of the foot also increases the risk of inversion sprain that can often directly lead to falls (Willems et al. 2005).

Despite strategies to prevent falls and reduce knee pain, older adults tend not to independently engage in long-term interventions without immediate benefits and cost advantages (Yardley et al. 2007). Insoles are highly cost effective and easily adopted compared to exercise programmes and hazard reduction measures via home modifications. Our purpose in the current research was to investigate a biomechanically designed, ankle-supporting insole to

determine whether it would change gait patterns in a way that can reduce the risk of falling and alleviate damaging stresses on the knee joint. If shown to be effective wearable orthotics have considerable advantages as a population-level falls prevention and knee joint remediation intervention.

Materials and Methods

Insole technology (Patent Reference: WO2016015091)

The experimental insole was designed to apply dorsiflexion and eversion of approximately 2.2° and 4.5°, respectively (Figure 1, the insole geometry for 26cm size). In this design the target eversion angle is applied across the entire insole surface by constructing the outermost edge 0.5cm higher than the inner section under the heel (26cm size). The insole surface against the shoe is flat and the construction material (EVA) has sufficient stiffness to maintain the required inclination. The most anterior inner surface is elevated 1.0cm relative to the inner heel and the highest section (1.5cm) is the most lateral and anterior surface under the toe. Based on the 26cm insole, the same geometry was applied to different foot sizes (i.e. 27cm-29cm).

Insert Figure 1 about here

Participants

Participants were 30 healthy young males (23.8 ± 3.5 yrs) and 26 healthy older males (72.0 ± 7.7 yrs): height - young: 1.77 ± .06m, older: 1.74 ± .07m and mass - young: 75.7 ± 3.5kg, older: 76.7 ± 7.9kg. Young participants were university community volunteers while the older group was recruited through advertisements in a local newsletter. Five of the young and four older participants were left limb dominant, determined by the previously used procedure (Seeley et al. 2008). Older participants were physically active and capable of walking continuously for 30 minutes or more. They reported no falls in the past two years and no traumatic injuries that would affect their gait. Volunteers were confirmed to have a shoe-size between 26cm and 29cm and the same shoes (standard NIKE running shoes) were provided to eliminate any potential shoe effects on gait. All participants provided informed consent using procedures approved and mandated by the Victoria University Human Research Ethics Committee.

Protocol

Participants first walked at preferred speed without the insole, followed by an insole walking trial. To reduce fatigue effects, adequate rest was provided between the two conditions. Three Optotrak (Optotrak®, NDI, Canada) camera units were set up around an 8m walkway in which two force plates (AMTI) were embedded to record the ground reaction forces (GRF) of each foot independently. The Optotrak motion analysis camera system tracked infra-red light emitting

diodes (IREDS) attached to lower limb joint anatomical landmarks in three dimensions at 100Hz (Figure 2c) and the GRF data were sampled by the forceplates at 1000Hz. Thirty walkthrough trials were completed to collect the required minimum 60 strides' gait data from each participant.

Insert Figure 2 about here

As shown in Figure 2c, a technical frame comprising a set of three IREDs formed clusters that were firmly attached to each body segment. Raw position-time data from the IRED clusters was then used to reconstruct virtual marker locations to define the lower body kinematics using conventional modelling methods within Visual 3D (C-motion). Pelvis segment was defined by anterior superior iliac spines, posterior superior iliac supines and greater trochanters. The femur model was based on the locations of the greater trochanter, quardrate tubercle, lateral and medial epicondyles. The shank was defined by the lateral and medial condyles and lateral and medial malleolus of the tibia. The foot complex was built using the heel, the 2nd and 5th metatarsal heads, toe (the superior distal end of the foot) and lateral and medial malleolus (Nagano et al. 2011). Thus, a 6-DOF lower body model was established to calculate joint kinematics and kinetics. Obtained raw data were first interpolated to compensate any occluded

signals using a window of up to 10 frames (0.1s). A 4th order zero-lag Butterworth Filter with a cut-off frequency of 6 Hz was then applied to smooth the position-time data. To determine the gait cycle phases and obtain spatio-temporal parameters, toe-off and heel contact were identified by applying kinematic conventions for the detection of these events (O'Connor et al. 2007). Vertical velocity of foot centre of gravity was monitored and the maximum value within a gait cycle was identified as toe-off, while the second local minimum from toe-off was determined as heel contact.

Examined Parameters

The stride cycle was defined as the interval from heel contact to the following heel contact of the same foot, divided into single and double support phases. As gait asymmetry is an age-associated phenomenon (Nagano et al. 2011) both the dominant and non-dominant limbs' gait functions were analysed separately. Dominance of gait parameters was based on the lead limb, in which the contact foot defines the dominance of spatio-temporal parameters following heel contact. Spatial and temporal data from the toe and heel defined the spatio-temporal variables (Nagano et al. 2012). Step length and width were displacements between two consecutive heel contacts in anterior-posterior and medio-lateral directions, respectively. Double support time was the temporal period from heel contact of one limb to contralateral toe-off, when both feet were on the walking surface. Step velocity was average horizontal velocity of

swing foot from toe-off to heel contact.

Maintaining sufficient toe-ground clearance at MFC has been reported to be a fundamental adaptation to reduce the risk of tripping falls. As illustrated in Figure 2a, MFC was defined as the local minimum vertical distance of the toe from the walking surface during mid-swing, described statistically using the median ± interquartile range (IQR) (Begg et al. 2007).

Maximum lateral CoP displacement during single support (from heel contact) was obtained as a key variable for determining medio-lateral balance and the risk of inversion sprain. Ankle angle was defined as in Figure 3 (top) (Winter 1991), such that relative to a 90° neutral position, positive and negative angles indicated dorsiflexion and plantarflexion, respectively. Foot flat was identified at the initial frame where the vertical toe location after heel contact reduced to vertical toe height obtained during the static (quiet standing) trials recorded for 3D modelling. To separate noise from the actual foot-flat instance, the minimum of 5 consecutive frames (.05s) were consistently lower than the toe height during the static trial. Time was recorded from heel contact to foot flat. Time was recorded from heel contact to foot flat. Knee adduction moment was computed by inverse dynamics as a net internal moment based on 3D modelling of the lower limb joints. Rotational torque as illustrated in Figure 3 (bottom) was used to define knee adduction moment. Initial peak knee adduction moment during stance was monitored as a kinetic marker for OA risk (Schmitz and Noehren 2014). Knee adduction moment was

normalised by body mass (N.m/kg). Recovery rate was used to quantify efficient mechanical energy transfer during loading, indicating the energy transferred to oscillate the loading response (Cavagna et al. 1976; Collett et al. 2007). More efficient loading is only possible by utilising shock at heel contact to initiate toe-off.

$$\text{Recovery rate } (\%) \; = 100 * [\Delta KE + \Delta PE - \Delta(KE + PE)]/(\Delta KE + \Delta PE)$$

where KE and PE are kinetic energy and potential energy; ΔKE, ΔPE and Δ(KE+PE) indicating increments in mechanical energy during double support – i.e. only the sum of increased amounts (Cavagna et al., 1976).

PE and KE were based on pelvis centre of gravity kinematics, adequate for the assumption of inverted pendulum movement for human walking, which was modelled on the linkage of the pelvis and foot by the one rigid limb (Kuo, 2007). PE and KE were computed by the following equations.

$$PE = body \; mass \; \times gravitational \; acceleration \; \times pelvis \; height$$

$$KE = \frac{1}{2} \times body \; mass \; \times pelvis \; velocity^2$$

Recovery rate reflects the reliance on external energy input indicated by Δ(KE+PE) relative to the entire mechanical energy state of walking. A higher recovery rate accompanies less voluntary push-off, generally reducing the burden on lower limb joints (Cavagna et al., 1976).

Insert Figure 3 about here

Design and Analysis

A repeated measures (general linear model) Insole x Age x Limb (2 x 2 x 2) Analysis of

Variance (ANOVA) design was applied to test insole effects on gait parameters, accounting for

any interaction effects of age and limb dominance. Statistical significance was accepted when

the computed p-value for the ANOVA F-ratio was less than 0.05 (SPSS Inc). Significant

interaction effects were examined further using Tukey's test for between-mean comparisons.

Results

Spatial-temporal Gait Parameters (Table 1)

The insole did not significantly influence spatio-temporal gait parameters but compared to

younger counterparts, older adults demonstrated shorter step length ($F_{1, 54} = 30.7$, $p < 0.001$);

slower step velocity ($F_{1, 54} = 37.6$, $p < 0.001$) and longer double support time ($F_{1, 54} = 21.7$, $p <$

0.001).

Insert Table 1 about here

Minimum Foot Clearance (MFC)

As illustrated in Table 2, the insole increased MFC overall by .36cm ($F_{1, 54}$ = 96.7, p < 0.001) but as indicated by an Insole x Age x Limb interaction ($F_{1, 54}$ = 10.7, p = 0.001) the primary influence was found to be the older adults' dominant limb, with MFC .43cm greater when wearing the insole. Furthermore, an Age x Limb ($F_{1, 54}$ = 14.7, p < 0.001) interaction revealed that older adults' dominant MFC was lower than for their non-dominant limb.

Insert Table 2 about here

Lateral Centre of Pressure (CoP) Displacement

Maximum lateral CoP displacement decreased ($F_{1, 54}$ = 8.4, p = 0.005) when wearing the insole (Figure 4). Dominant CoP displacement was greater than for the non-dominant side ($F_{1, 54}$ = 21.9, p < 0.001) and as indicated by an Age x Limb interaction ($F_{1, 54}$ = 6.5, p < 0.013) older adults also showed higher CoP variability in the dominant limb.

Insert Figure 4 about here

Foot Contact Angle

The insole increased ankle dorsiflexion at MFC by 0.7° (reduced plantarflexion) as indicated in

Figure 4 ($F_{1, 54} = 4.7$, p = 0.035). The insole also increased foot contact angle ($F_{1, 53} = 5.9$, p = 0.019) but this effect was more clearly seen in the older group, exceeding 2° (Insole x Age: $F_{1, 53} = 5.4$, p = 0.024). Foot contact angle was 3.5° lower in the older group ($F_{1, 53} = 13.0$, p < 0.001).

Insert Figure 5 about here

Loading Response

The insole prolonged time to foot flat by .015s ($F_{1, 54} = 39.0$, p < 0.001) and knee adduction moment was affected by an Insole x Age interaction ($F_{1, 54} = 19.9$, p < 0.001) with a remarkable reduction of 0.12 N.m/kg in older adults when wearing the insole (Figure 5, middle panel). The bottom panel of Figure 5 also confirms an increased recovery rate of 2% in insole walking ($F_{1, 54} = 4.1$, p < 0.048).

Discussion

Our sample of older participants showed gait characteristics consistent with comparable cohorts in previous reports (e.g., Winter 1991), showing that step length was shorter, leading to slower step velocity and longer double support time compared to their younger counterparts. Consistent with Begg et al. (2007) and Nagano et al. (2011), no ageing effects on MFC height were observed. Maximum lateral CoP displacement was larger in the older group

implying less lateral stability but this effect was not significant. Foot contact angle of the older group was lower than for the young, as shown in previous reports (Nagano et al. 2011; Perry et al. 2007). It is interesting to consider how these age-specific gait changes could be compensated by an insole, with minimal disturbance to natural gait. The device maintained gait fundamentals, described by spatio-temporal parameters, while also effecting relatively small but functionally significant changes to ankle joint motion that improved initial ground-contact loading and facilitated swing limb control at MFC, where every 1° increase in ankle dorsiflexion is predicted to add .3cm to MFC height, a significant increment relative to previously reported critical obstacle heights of approximately 1cm (Begg et al., 2007; Fotios and Uttley, 2018; Moosabhoy and Gard, 2006; Nagano et al., 2015). When standing the insole structure provided dorsiflexion support of 2.2° but when walking the insole provided an additional 0.7° dorsiflexion at MFC, contributing to increased ground clearance at MFC. An overall 0.36cm increment in MFC due to the insole was an additional ground clearance that would reduce toe-ground contact probability (Moosabhoy and Gard 2006). Furthermore, the insole increased MFC in the older adults' dominant limb, previously shown to have an asymmetrically greater risk of ground contact at MFC (Nagano et al. 2011).

While increased MFC is effective in reducing tripping risk, maintaining balance is also important in the event of swing foot contact. Ageing per se has not been identified as the critical factor to reduce MFC but dynamic balance control impairs with age (Shafrin et al., 2017). For prevention of tripping falls, therefore, dynamic balance control is important in case of forward balance loss due to tripping (Pijnappels et al., 2008). Previous studies (Ganesan et al. 2014) reported that CoP excursion affects dynamic balance. In the present study eversion support by the insole reduced lateral CoP displacement; this feature may improve balance and also help in preventing inversion sprains (Ganesan et al. 2014; Maki et al. 2008; Zehr et al. 2014).

Ankle dorsiflexion and eversion are designed to absorb impact during the early loading response (Silver-Thorn et al. 2011). In the insole condition the ankle was more dorsiflexed at heel contact, increasing time to foot flat and distributing impact forces over a prolonged interval. These combined effects could also enhance mechanical energy efficiency, i.e. a 2% increase in recovery rate, such that a larger proportion of foot contact impact can be utilised to activate toe-off, while reducing mechanical energy that may damage the knee (Mazumdar et al. 2016; Silver-Thorn et al. 2011).

Reduced knee adduction moment for older people in the insole condition also supports potential benefits for OA prevention. Incorporating eversion support into a shoe insole to reduce knee adduction moment for OA prevention has been already recognised in the Lateral Wedge

Insole (Rafiaee and Karimi 2012). Nakajima et al. (2009) reported that eversion support reduced knee adduction moment by 7.7%-13.3%. The current insole reduced knee adduction moment by more than 15%, implying that eversion combined with dorsiflexion may be more effective in reducing knee adduction moment. Individuals with excessive knee adduction moment could, therefore, benefit from wearing the insole. In future studies, other factors such as knee flexion and extension moment should be examined to more fully understand the role of dorsiflexion and eversion in mitigating the effects of knee osteoarthritis and reducing injury to the knee.

A combination of dorsiflexion and eversion support has been found to reduce the risk of falls and enhance efficient loading but further developments can be considered. First, the experimental insole provided inclination from the inner heel toward the outer toe, which may not leave sufficient space at the toe, causing a tight fit. This structure could also disturb adequate supination during mid to late stance, possibly causing overpronation (De la Cruz et al. 2014). One solution is to limit inclination from the heel to metatarsals and incorporate declination from the metatarsal region toward the toe to create space and allow functional supination. Such ankle joint support may not, however, have the same effects as revealed in the current study and further validation would be necessary.

Incorporation of textures to guide the ideal CoP path for adequate cutaneous stimulation could be a further development of the insole. Priplata et al. (2003) suggested

improving balance by using vibrating insoles to stimulate the plantar region. Nurse et al. (2005) also raised the possibility of using a textured insole to enhance proprioceptive reactions. Additional texture around the plantar surface is, thus, a potential development to control CoP and promote tactile sensation.

The results also revealed important limb dominance effects to be recognised in designing insoles because the same insole may not be appropriate for both feet. It was found that non-dominant foot MFC was higher, consistent with previous findings (Nagano et al. 2011). In contrast, greater lateral CoP movement with higher variability was found in the dominant limb. These two asymmetrical features suggest that the dominant foot has a greater risk of either tripping or balance disturbance, perhaps reflecting a safety mechanism by protecting the less confidently employed non-dominant limb.

In summary the insole showed effects on gait mechanics by (i) maintaining adaptive spatio-temporal parameters; (ii) increasing MFC due to ankle dorsiflexion (reduced plantarflexion) especially for older adults; (iii) reducing lateral CoP movement; (iv) enhancing efficient stance foot loading; and (v) reducing knee adduction moment for older adults. Although the current insole designs may be useful for injury prevention, further trials are essential before the device is more widely adopted. As described previously, dorsiflexion and eversion support angles of 2.2° and 4.5°, respectively, are unlikely to cause overuse injuries.

Silver-Thorn et al. (2012), for example, reported that an additional dorsiflexion up to 5° does

not affect gait fundamentally and Radzimski et al. (2012) also confirmed that eversion angles in

the range 5°-15° are commonplace. These observations are supported by the results above but

further investigation of the insole effects, including long-term use, should be monitored. A wider

range of populations should be examined in future work, utilising a variety of insole designs

including different geometrical structures and materials.

3393 words

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Tables

Table 1.   Insole effects on spatio-temporal parameters (mean ± SD)

Spatio-temporal parameters		Dominant		Non-dominant	
		Non-insole	Insole	Non-insole	Insole
Young	Step Velocity (m/s)	1.33 ± 0.11	1.35 ± 0.10	1.32 ± 0.10	1.34 ± 0.11
	Step Length (cm)	74.35 ± 4.44	75.49 ± 3.98	74.29 ± 4.30	74.70 ± 3.99
	Step Width (cm)	9.02 ± 2.71	6.46 ± 2.58	8.82 ± 2.49	6.99 ± 2.66
	Double Support Time (s)	0.13 ± 0.02	0.13 ± 0.03	0.13 ± 0.03	0.13 ± 0.02
Older	Step Velocity (m/s)	1.13 ± 0.09	1.10 ± 0.08	1.13 ± 0.08	1.08 ± 0.09
	Step Length (cm)	66.91 ± 4.55	64.99 ± 3.95	67.13 ± 4.94	64.31 ± 4.17
	Step Width (cm)	10.61 ± 3.47	9.44 ± 2.66	10.10 ± 3.31	9.81 ± 2.56
	Double Support Time (s)	0.15 ± 0.02	0.16 ± 0.03	0.15 ± 0.02	0.16 ± 0.02

Table 2.   Insole effects on MFC (median ± IQR); Group data comparison.

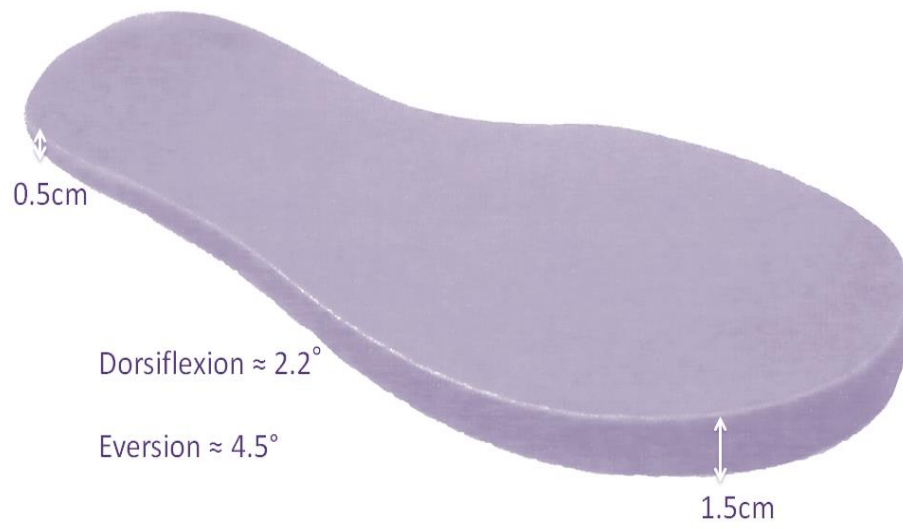| MFC (cm)	Dominant		Non-dominant	
	Non-insole	Insole	Non-insole	Insole
Young	1.46 ± 1.00	1.87 ± 1.49	1.57 ± 1.18	1.97 ± 1.28
Older	1.65 ± 1.00	2.15 ± 1.16	2.08 ± 1.11	2.40 ± 1.51

Figures

Figure 1

0.5cm

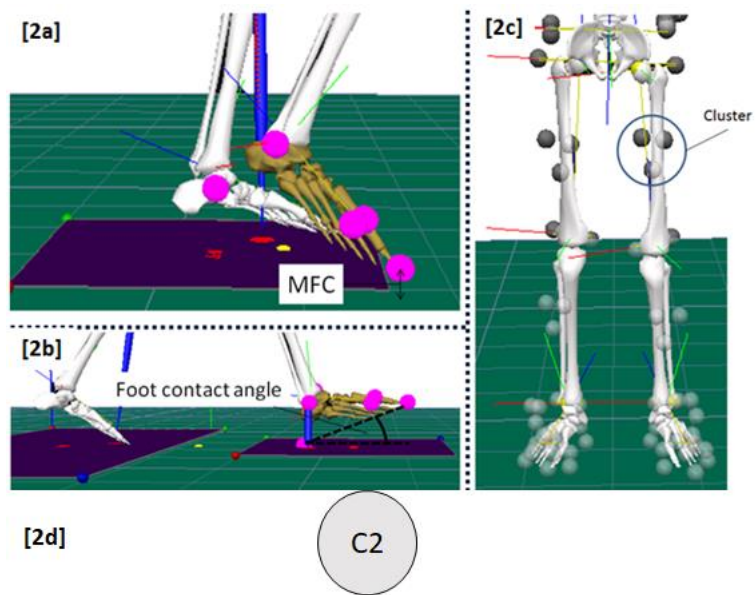Dorsiflexion ≈ 2.2°

Eversion ≈ 4.5°

1.5cm
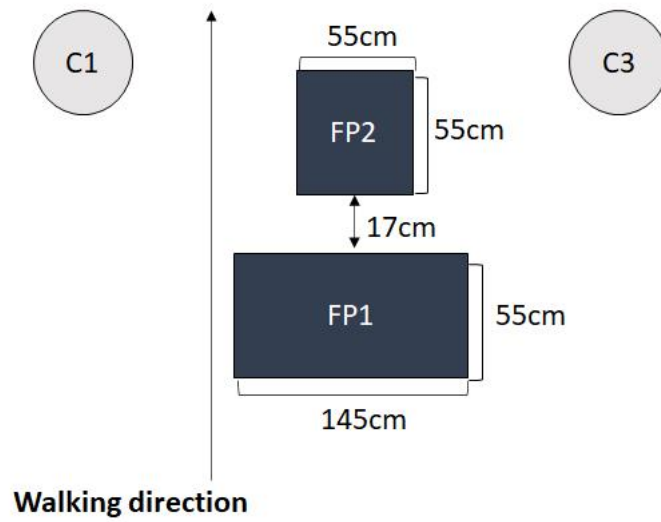
Figure 2
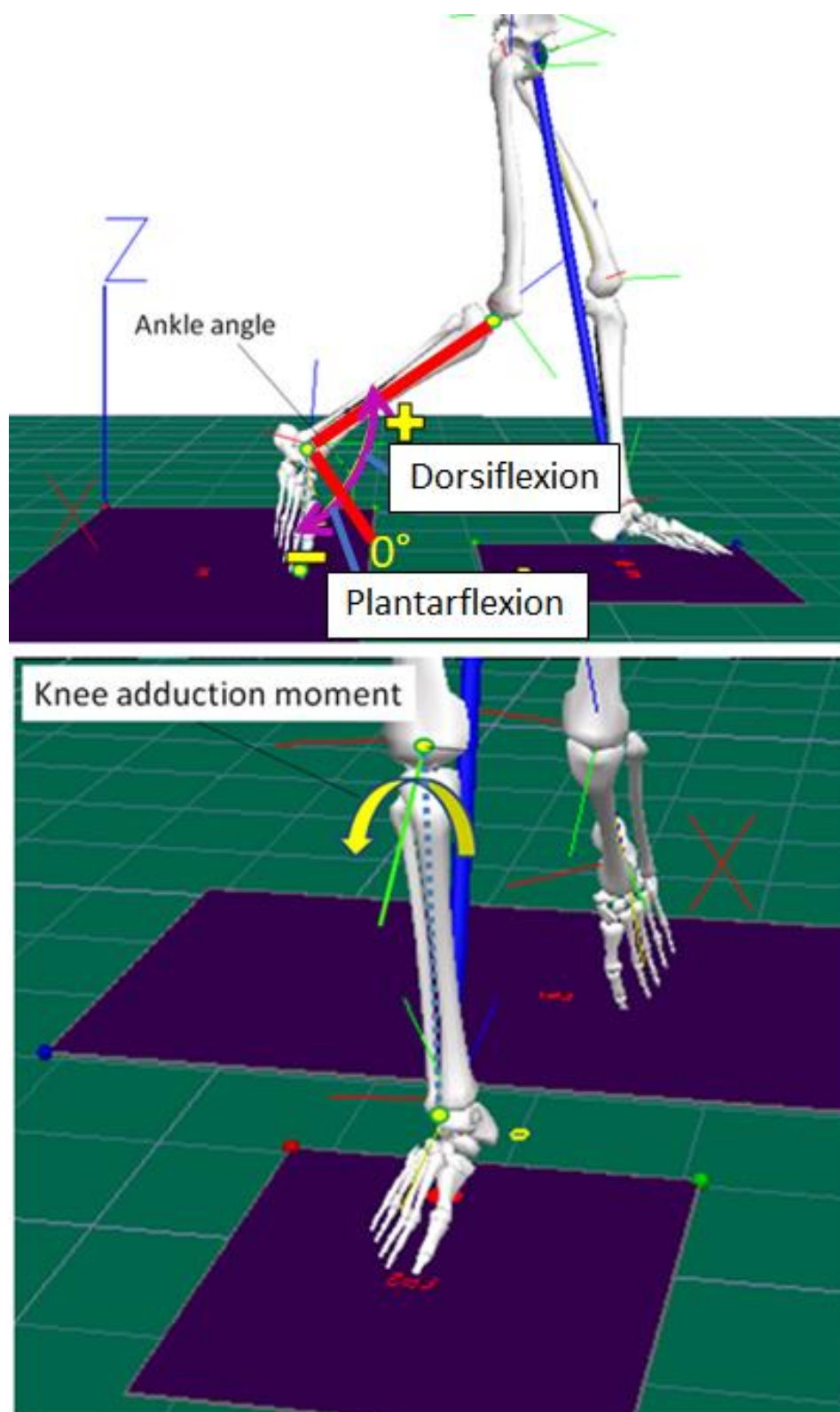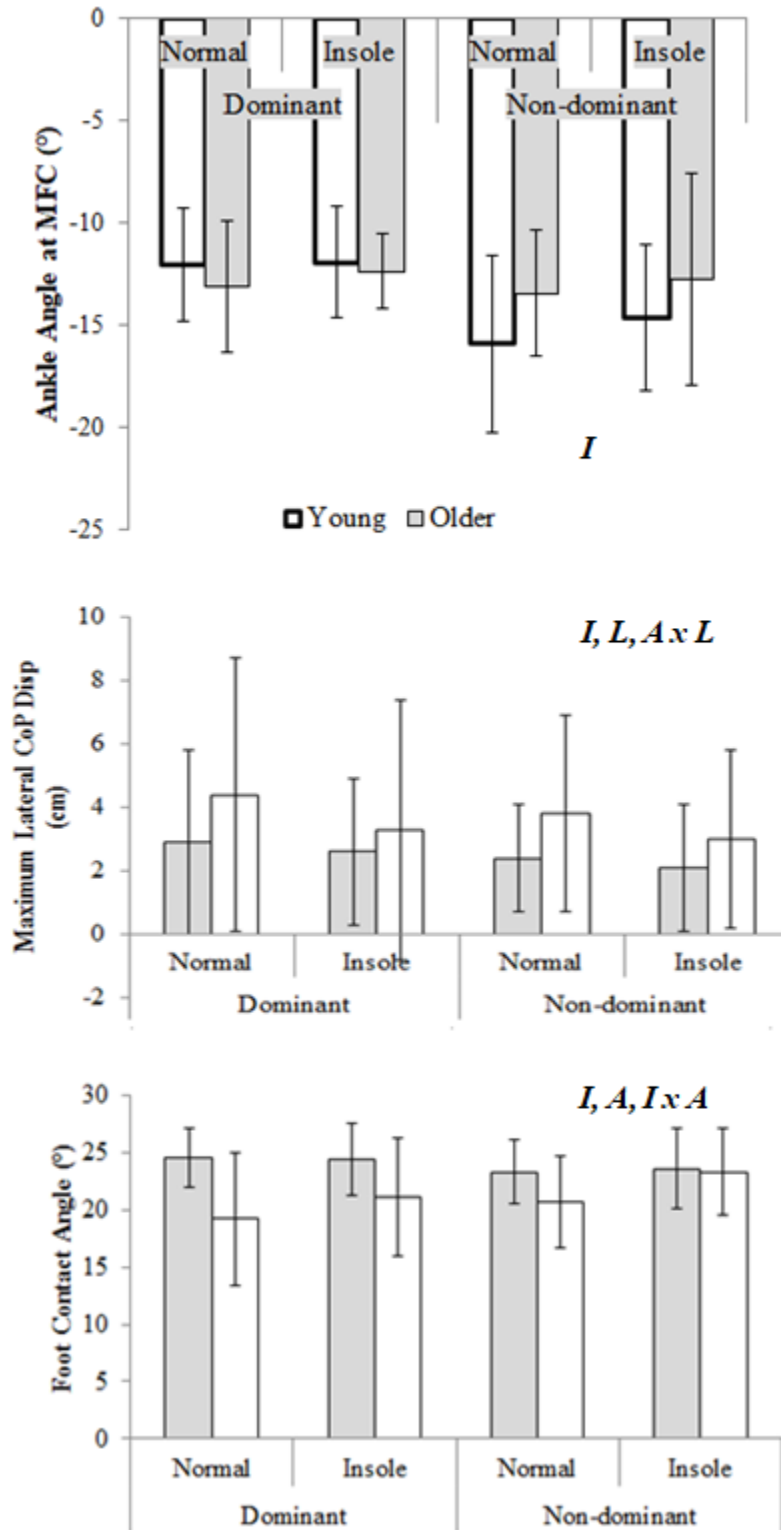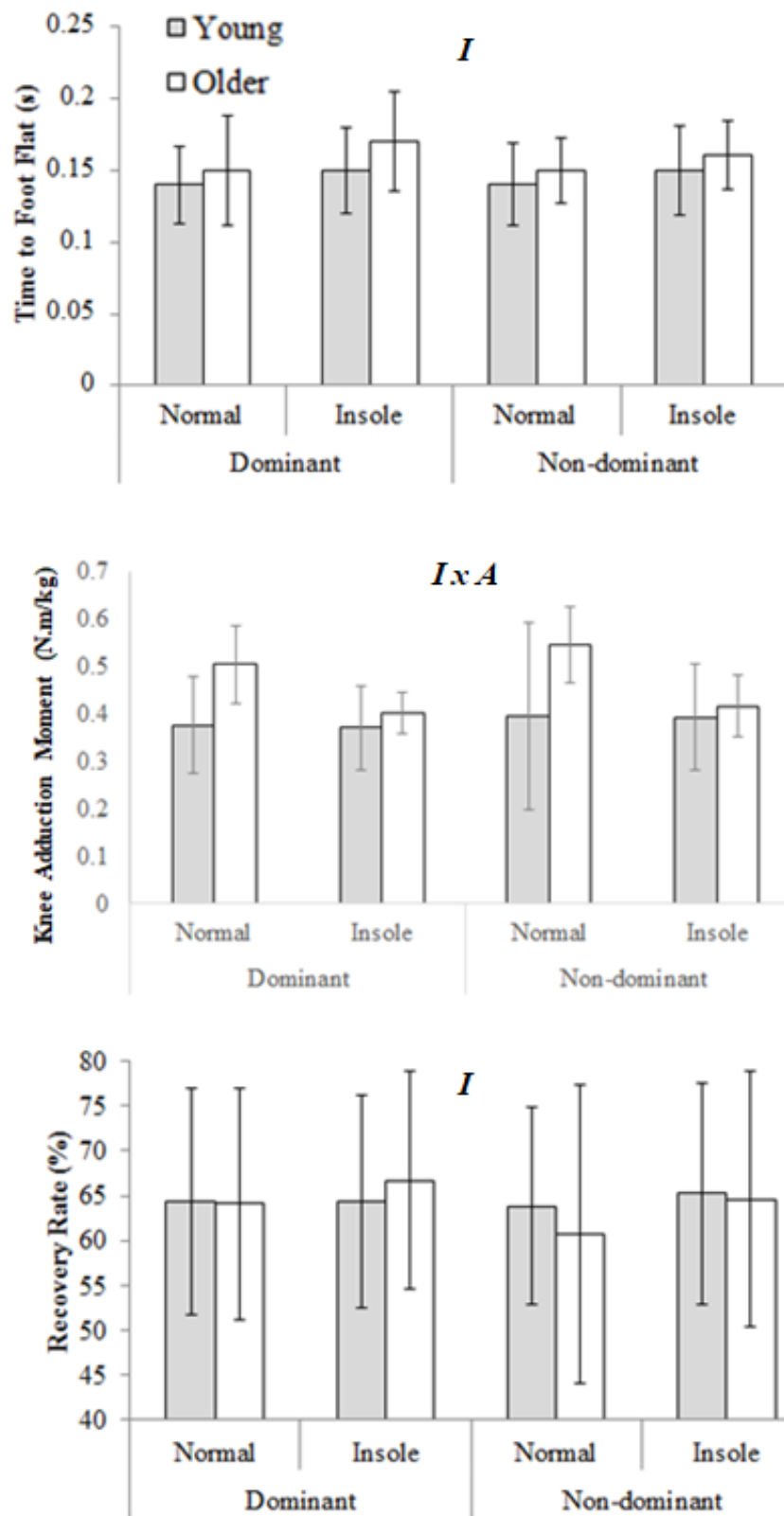
Figure 3

Figure 4.

Figure 5.

Figure Captions

Figure 1.   Specification of insole used in the current research.

Figure 1. Alt Text. Insole geometry to support 2.2° dorsiflexion and 4.5° eversion (26cm size) controlled by applying different thickness to the shoe-insole.

Figure 2.   Definitions of examined parameters based on 3D motion capture system utilising virtual marker function.

Figure 2 Alt Text. (a) Image of minimum foot clearance (MFC); (b) Definition of foot contact angle. Angle formed between toe-heel-walking surface; (c) Lower body marker setup. (Nagano et al., 2011). (d) Overground gait testing setup. FP1 and FP2 indicating Force plate 1 & 2, respectively; C1, C2 and C3 indicating Optotrak camera tower 1, 2 and 3.

Figure 3.   Definitions of ankle angle in the sagittal plane and knee adduction moment.

Figure 3. Alt Text (Top) Ankle angle definition relative to 90° (shank-foot segment) positive and negative indicating dorsiflexion and plantarflexion, respectively; (Bottom) knee adduction moment, expressed in absolute value, the rotational torque around the anterior-posterior axis.

Figure 4.   Insole effects on ankle joint control between young and older adults; dominant and non-dominant limbs.

Figure 4. Alt Text (Top) Insole increased dorsiflexion ankle angle at MFC; (Middle) Insole reduced maximum lateral CoP displacement; (Bottom) Insole increased foot contact angle. Significant effects indicated by bold italic as *I* (insole effect)*, A* (ageing effect)*, L* (limb effect); interaction effects indicated by *x.*

Figure 5.   Insole effects on loading response between young and older adults; dominant

Figure 5. Alt Text (Top) Insole increased time to foot flat; (Middle) Insole reduced knee adduction moment; (Bottom) Insole increased recovery rate. Significant effects indicated by bold italic as *I* (insole effect)*, A* (ageing effect)*, L* (limb effect); interaction effects indicated by *x.*