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# Gait Efficiency and the Use of Insolia® Flex to Promote First Metatarsophalangeal Joint Dorsiflexion

**by Sarah A. Curran, PhD, BSc(Hons), FCPodMed, FHEA [1], Janette Davis[1], Joanna L. Tozer[1], Laura Watkeys[2]**

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***Background:*** *Dorsiflexion of the first metatarsophalangeal (MTP) joint during walking is an important characteristic that assists efficient forward progression. In spite of a range of foot orthoses used to encourage motion at this joint, little is known how they influence energy efficiency during walking. The aim of this study was to determine if a mass market, insole modification (Insolia® Flex) influenced energy consumption and improved forefoot comfort.*
***Materials and Method:*** *Fifteen healthy male volunteers (mean age 29 years) were randomly assigned 2 pairs of identical and commercially available footwear, one of which contained the Insolia® Flex. Heart rate (HR), volume of oxygen consumed in liters per kilogram ($VO_2$/kg), respiration exchange ratio (RER), physiological cost index (PCI) and the number of steps (NoS) were monitored whilst walking on a treadmill at a speed of 4.2km/hour and 0% incline for 20 minutes. The Footwear Comfort Scale was also completed following each condition.*
***Results:*** *Paired t tests showed that HR, $VO_2$/kg and the PCI were significantly reduced for the Insolia® Flex condition ($p<0.001$). No significant differences ($p>0.05$) were noted for the RER ($p<0.05$), but significantly less NoS were taken during the Insolia® Flex condition ($p<0.001$). A significantly improved overall and forefoot comfort rating ($p<0.001$) was noted for the Footwear Comfort Scale.*
***Conclusions:*** *The findings of this study show that energy consumption measures (i.e. HR and VO2/kg) and the PCI (a proxy measure) are influenced by first MTP joint function and suggests that efficiency is improved with the use of a modified insole that promotes function at this joint. Further research is required to clarify these findings.*

**Key words:** Energy consumption, First metatarsophalangeal joint, First metatarsal, Insolia® Flex, Comfort.

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During human bipedal walking, the storage and exchange of potential and kinetic energy in compliant structures is considered an important energy saving mechanism.[1-3] Approximately 10,000 steps is the target value that should be taken each day by the average person, and is achieved by a style of gait that progresses the body forward in a safe and efficient manner.[4] Whilst numerous and complex mechanisms are involved, the energy provided during subsequent steps is a result of momentum and pulling action of the swinging limb and stability of the stance limb. Critical to achieving this, is hip extension of the swinging limb and adequate dorsiflexion at the first metatarsophalangeal (MTP) joint of the stance limb.

**Address correspondence to**: Sarah A. Curran PhD, BSc(Hons), FCPodMed, FHEA. Senior Lecturer, Wales Centre for Podiatric Studies, University of Wales Institute, Cardiff, Western Avenue, Cardiff, CF5 2YB, UK. Email: scurran@uwic.ac.uk; Phone +44 (0) 29 2041 7221.

[1] Wales Centre for Podiatric Studies, University of Wales Institute, Cardiff, Western Avenue, Cardiff, CF5 2YB, UK..
[2] Centre for Biomedical Sciences, University of Wales Institute, Cardiff, Western Avenue, Cardiff, CF5 2YB, UK.

This latter view is based on the reliance of the first MTP joint to engage in a series of autosupport mechanisms (i.e. Hicks windlass,[5,6] high [transverse] propulsion[7,8]) which act in a timely manner during terminal stance to provide stability of the foot for efficient forward advancement of the body. [9-14]

Whilst normal walking requires 65° - 75º of dorsiflexion for efficient forward momentum of the body, the key to understanding the importance of first MTP joint motion is the recognition of first metatarsal function and stability.[15,16] Although the initial 20° of hallux dorsiflexion is achieved without motion of the first metatarsal during stance, to obtain further motion, the hallux relies upon first metatarsal plantarflexion, which couples approximately 1° of plantarflexion for every 3° of hallux dorsiflexion.[17] A dorsiflexed first metatarsal is frequently implicated as a contributing factor to limited mobility of the first MTP joint and include conditions such as functional hallux limitus, hallux limitus and hallux rigidus. This is supported by various forms of foot orthoses that attempt to reposition the first metatarsal (i.e. encourage plantarflexion).[18-21]

Although several studies have shown the kinematic and kinetic improvements of these devices, the effects of these orthoses on energy efficiency are unknown. This is an important omission since normal function at the 1st MTP joint is considered essential for an efficient and fluent gait pattern. Previous studies have shown that methods used to record energy consumption such as volume of oxygen consumed in liters per kilogram ($VO_2$/kg), heart rate (HR), the Physiological Cost Index (PCI) and the frequency of steps taken are responsive allowing differences between various conditions to be determined.[4,22-31] These observations include alterations in high heeled footwear alone;[31-33] high heeled footwear and pre-fabricated foot orthoses,[34] as well as patients with post cerebral vascular accident and rheumatoid arthritis.[35]

The following study attempts to address this imbalance and at the same time explores the influence of a mass market, insole modification – Insolia® Flex. This new product is designed to permit both plantarflexion and eversion of the first metatarsal head during the latter part of the stance phase of walking. The combination of plantarflexion and eversion facilitates improved first metatarsal function and the prevention and development of conditions such as functional hallux limitus and hallux limitus. The aim of this present study therefore was to examine if Insolia® Flex changed energy consumption and improved perceived comfort at the forefoot.

## Methods

*Participants and materials*

A total of 15 male university staff and students volunteered to take part in the study. The mean age was 28.9 years (standard deviation [SD] 7.7, range 19 – 48 years), mean weight of 81.2 kilogram (kg) (SD 14.6, range 57.2 – 105.5 kg), mean height of 171.3 centimeters (cm) (SD 8.2, 158.5 – 190.5cm), and mean shoe size of 7.8 (SD 2.1; range 4.5 – 11.5). Ethical approval was sought from the School of Health Sciences Ethics Committee, University of Wales Institute, Cardiff before the study began. The study's purpose and procedures was fully explained to each participant. Informed consent was obtained from all participants before taking part.

All participants were screened to ensure they had adequate range of dorsiflexion (extension) at the first MTP joint. Participants with <15° (i.e. hallux rigidus) did not take part in the study. The following inclusion criteria was met for all participants: no reported history of injury to the lower extremity within the last 12 months; no reported history of cardiovascular or neurological problems (i.e. angina, high blood pressure, dizziness); experience of walking on a treadmill; must be able to wear the allocated standardized

standardized footwear (female UK sizes 4.5, 5.5, 6.5 or 7.5, and male UK sizes 8.5, 9.5, 10.5 or 11.5). Finally, all participants had to tolerate wearing a mask which covers the mouth and nose (oxygen consumption measurement).

The footwear used in this study was commercially available (Bostonian, USA). (Fig. 1) Two pairs of each available size were provided, and one pair had the Insolia® Flex (Insolia®/HBN Shoe, LLC, Salem, New Hampshire, USA) built within the main insole. (Fig. 2) Insolia® Flex is manufactured as a gel component to approximate the same softness of the plantar fat pad of the foot. Specifically, under the 1st metatarsal head, there is a subtle depression within the device. This is, however, not round, but rather a skewed ovoid, in which the plantar surface is tapered to evert the 1st metatarsal head. The combination of plantarflexion and eversion facilitates improved 1st metatarsal function. In order to blind the process, participants were not informed as to whether they were wearing footwear with or without Insolia® Flex. The order of assessment for each experimental condition was randomly assigned for each participant.

**Figure 1** Standardized footwear used in the study.

*Equipment*

A Woodway (Desmo, Germany) treadmill was used. The $VO_2$/kg and RER were collected and calculated at one minute intervals using a Metalyzer 3B-R2 (Cortex, Germany). (Fig. 3) The RER is the carbon dioxide ($CO_2$) divided with $O_2$ consumption. HR was monitored using a VFIT monitor (Polarexpress Ltd, London), which was attached to the participant's chest by a strap. This telemetry system records the electrical signals generated from the heart by the transmitter worn on the chest and displayed on a wristwatch receiver.

A pedometer was used to record the NoS taken (WSG™ Digital Pedometer). The sensitivity of the pedometer was determined using the *'shake test'* as described by Vincent and Sidman[24] before data collection began. The pedometer was found to be within 3% of the actual number of shakes. The pedometer was positioned according to manufacturer's instructions, and before data began the step number was cleared.

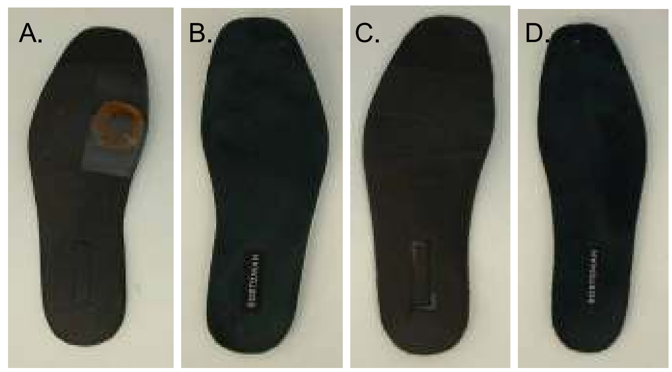


**Figure 2** Example of male insole removed from two identical pairs of footwear. Photo A shows the underside of the insole with the gel component (Insolia® Flex) in situ and photo B illustrates the top surface. Photos A and B provide a visual representation of the underside (C) and topside (D) of the non-modified insole.

**Figure 3** Experimental set up showing the treadmill and Metalyzer 3B-R2 used to record HR, $VO_2$/kg and the RER.

*Footwear Comfort Scale*

Following each walking trial the Footwear Comfort Scale[36] was used to determine the perceived comfort for the 2 conditions. This scale has been used by various authors[37,38] and is based on a series of 8 questions that focus on specific areas of the footwear. Perceived comfort is rated using a 15mm visual analogue scale (VAS), with 0 (= 0 comfort point) labeled as *'not comfortable at all'* and 15 as the *'most comfortable condition imaginable'* (= 15 comfort points).

Since this current project focused on first metatarsal/ray function, only questions 1 (overall comfort) and 3 (forefoot cushioning) were analyzed. For consistency, each participant was advised not to take into account the style and cosmetics of the footwear during comfort rating. In addition, on completion of both sets of experiments, each participant was asked the following question: *Which footwear would you choose if you had to walk all day?* (i.e. condition 1 or condition 2).

*Procedures*

Data was collected in a quiet physiology laboratory set at an ambient temperature in 1 session and lasted approximately 80 minutes. Prior to testing, the order for each experimental condition was randomly assigned to the participant to eliminate order effects. Each participant was given a 5 minute acclimatization period on the treadmill for each of the 2 experimental conditions before data collection began. The speed of walking was standardized to 4.2km/hour with a 0% incline. This speed was chosen since it falls within the mean comfortable speed for females and males.[28,38-40]

Following acclimatization, data were collected over a further 20 minutes at the same standardized speed. To minimize fatigue, each participant was allowed a 10 minute rest between each experimental condition and/or until their HR returned to its resting value. Each participant was instructed to look straight ahead whilst walking on the treadmill. The procedure was terminated if data failed to be recorded or the participant felt uncomfortable, showed an unsteady gait, signaled to stop or when the walking period was completed.

*Data and statistical analysis*

The mean, SD and range were calculated for all of the measures investigated. The PCI was calculated using the following equation: Walking heart rate – resting heart rate divided by speed (m/min).[29] A series of Kolmogorov-Smirnov tests were performed and showed all data to have a normal distribution ($p<0.001$). All variables were analyzed using paired *t* test and 95% confidence intervals (CI) to establish differences between each of the two conditions. The software package SPSS® (version 17.0, London, UK) was used to analyze the data and the significance level was set at $p<0.05$.

## Results

*Differences: Metabolic variables and efficiency*

The mean, SD and range values produced from the male group for HR, $VO_2$/kg, RER, NoS and PCI for each of the experimental condition are summarized in table 1. Significant differences were observed between the two experimental conditions for HR (95% CI -6.26707 to -3.53293; t=-8.000; *df* 14, $p<0.001$); $VO_2$/kg (95% CI -1.95845 to -.82155; t=-3.452; *df* 14; p=0.004), and the PCI (95% CI -.15187 to -.02546; t=-3.009, *df* 14; p=0.009). It was noted that HR, $VO_2$/kg, and the PCI was reduced by 6.1% (5.3), 9.7% (1.3) and 25.8% (0.08) respectively. A reduction of 6% (4.5 beats/min) for heart rate, 10.6% (1.4 ml/min/kg) for $VO_2$/kg and 20% (0.07) for PCI was noted for the Insolia® Flex condition. Whilst no significant differences were noted for the RER (95% CI -.02964 to .00897; t=.797; *df* 14; p=0.1219), the NoS taken by males were significantly differently with 7.4% (143 steps) (95% CI 37.11719 to 248.11719; t=2.898; *df* 14; p=0.012) increase noted for the Insolia® Flex condition.

| | Insolia® Flex<br>Mean ± SD (range) | No Insolia® Flex<br>Mean ± SD (range) |
|---|---|---|
| **HR (beats/min)*** | 86 ± 10.6 (69 – 109) | 91.3 ± 11.4 (72 – 117) |
| **$VO_2$/kg (ml/min/kg)*** | 13.4 ± 1.4 (12 – 14) | 14.7 ± 1.6 (12 – 18) |
| **RER** | 0.81 ± 0.0 (0.7 – 0.95) | 0.81 ± 0.0 (0.72 – 1.00) |
| **PCI (beats/min)*** | 0.31 ± 0.1 (0.05 – 0.52) | 0.39 ± 0.1 (0.12 – 0.74) |
| **NoS*** | 1778 ± 281 (1150 – 2077) | 1921 ± 274 (1513 – 2891) |

**Table 1** Mean, SD and range of each condition and variable measured for the male group (*significant differences p<0.05, paired *t* test).

*Footwear Comfort Scale*

Significantly higher rating values were noted for the male group for *'overall comfort'* (95% CI .50693 to 4.29307; t=2.719, *df* 14, p=0.017) and forefoot cushioning (95% CI 1.31402 to 7.61931; t=3.0339; *df* 14; p=0.009) for the Insolia Flex® condition. Overall comfort increased by 29.6% (2.4), whilst forefoot comfort showed a higher increase of 49.5% (4.5) Figure 4 illustrates the comparison of perceived comfort ratings for each of the two conditions. Eleven males chose the Insolia® Flex condition to walk all day (no Insolia Flex®: *n* = 4). (Fig. 4)

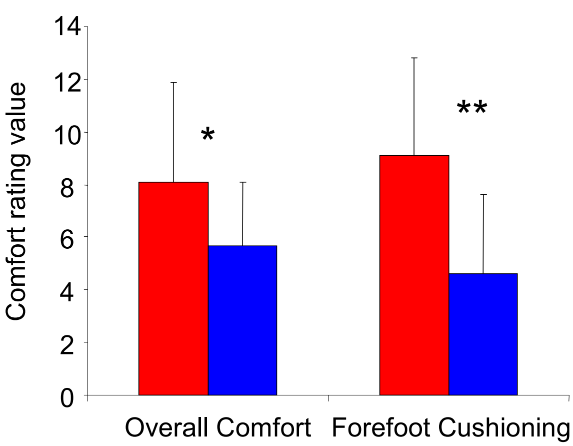


**Figure 4** Comparisons for ratings of overall comfort and forefoot rating (Insolia® Flex ■; no Insolia® Flex ■). Indicates significant differences at p<0.05* and p<0.01**).

## Discussion

The aim of this study was to investigate if Insolia® Flex changed energy consumption and improved perceived comfort at the forefoot. The findings of this study suggest that traditional measures of energy consumption (i.e. HR and VO2/kg) and a proxy measure (i.e. PCI) are influenced by 1st metatarsal function suggesting that efficiency is improved.

*Energy efficiency measures and the number of steps*

For this study, a range of energy efficiency variables namely HR, $VO_2$/kg, RER and PCI were analyzed during treadmill walking for a period of 20 minutes. This is a popular method employed by many [34,43 44] and provides a controlled experiment condition (i.e. speed of walking). Whilst treadmill walking could be criticized for being *'unnatural'*, previous evidence does suggest is that walking on a treadmill identical to routine walking.[45] The only difference however comes from air resistance which can be considered as insignificant during normal speed walking. HR, $VO_2$/kg and PCI were all significantly reduced for the Insolia® Flex condition. Whilst direct comparisons cannot be made with other studies due to the nature of the product investigated (Insolia® Flex), the findings of the present study does share similarities with a previous study that showed that insoles can improve energy efficiency.[34]

During level walking at a constant speed, the mechanical work undertaken at the beginning of stride acts to lift the centre of mass (CoM). When the CoM is lowered (referred to as negative work), the potential energy attributable to the rise in the CoM is turned into kinetic energy.[10,13,14,46] Contact of the foot with the supporting surface uses some of this energy to raise the CoM, and can be illustrated as two curves which are symmetrical and out-of-phase.[47] Studies of 'normal' weight individuals have shown that walking is less efficient when mass is placed on the lower legs or thighs compared with waist loads.[48] This increase could be due to the mechanical work required to swing the limb forwards which essentially have an increased mass and moment of inertia.[49] In this study, it was found that the Insolia® Flex significantly reduced the NoS. This perhaps was a surprise finding, since a significant reduction in HR, VO2/kg and PCI was observed it was thought that there would be a change in the NoS taken. There could however be a number of reasons for this. For example, the speed of the treadmill for the males which was set at 4.2 km/hour may have been too slow. Nevertheless, the Insolia® Flex condition may have allowed for a longer stride and more efficient (negative energy) phase as more motion was afforded at the 1st MTP joint. This is may have corresponded with enhanced hip extension and initiated an improvement in the foot's autosupport mechanisms (i.e. Hicks windlass, calcancaneocuboid joint locking).

*Perceived comfort and standardized footwear*

Perceived overall comfort and forefoot comfort for the Insolia® Flex showed a significant difference. It was noted that the mean comfort value improved from 2.1 to 8.1 for overall comfort, and 4.6 to 9.1 for forefoot comfort. The increase for the latter rating could be due to an increased in space within the forefoot as well as the cushioning effect from the product. Seventy three percent of the males preferred the Insolia® Flex condition.

*Limitations of the study and future work*

The equipment used in this study was simple and the method employed was clear, however, it is acknowledged that there were inherent limitations. For example, whilst a relatively long period of walking was undertaken to obtain the energy measures (i.e. 20 minutes), the time can be considered as a snapshot, which may not represent an overall picture of efficiency. In acknowledging the limitations previously discussed, future work should be undertaken to clarify the findings presented in this study. For example, it would particularly useful to examine kinematic changes at the hip, knee and ankle with the Insolia® Flex as well as the pressure distribution using an in-shoe plantar pressure measurement system (i.e. Pedar®, Novel, Munich, Germany, GmbH). Moreover, providing a strict inclusion criteria is devised, further inquiry could be undertaken using participant's own footwear. This should provide a more global understanding of Insolia® Flex, particularly as it will be promoted as a mass market, insole modification. Further work could also explore the use of this new product on individuals who have limited 1st MTP joint mobility (i.e. functional hallux limitus). This could be coupled with walking on a 5% incline on a treadmill to determine the efficiency and influence of Insolia® Flex on high (transverse) gear propulsion, a component of the foot's autosupport mechanism.

## Conclusion

This study set out to explore the differences in energy efficiency and comfort of a mass market, insole modification that improves plantarflexion/eversion of the 1st metatarsal and 1st MTP joint function. The findings revealed that the Insolia® Flex improved efficiency during a period of 20 minutes (HR, VO2/kg, PCI). Although the NoS were only significantly reduced with Insolia® Flex, there are some logical reasons why this may have happened and include the role of stride length and the standardized speed used to collect the data. future work should explore the role of this new modified insole in participants with limited 1st MTP joint dorsiflexion whilst wearing their own footwear.

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## Competing interests

SAC is the Chief Editor of the *Foot and Ankle Online Journal* and was removed from the peer review process and editorial decision for this manuscript.

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