The acute effects of pre-fabricated insoles on running mechanics and perceived footwear comfort of endurance runners

by

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PLAGIARISM DECLARATION

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I, Ernest Hobbs, declare that this dissertation, which I hereby submit for the degree MSc Sports Science (Biomechanics) at the University of Pretoria, is my own original work and has not previously been submitted by me for a degree at this or any other tertiary institution. Where secondary material is used, this has been carefully acknowledged and referenced in accordance with university requirements.

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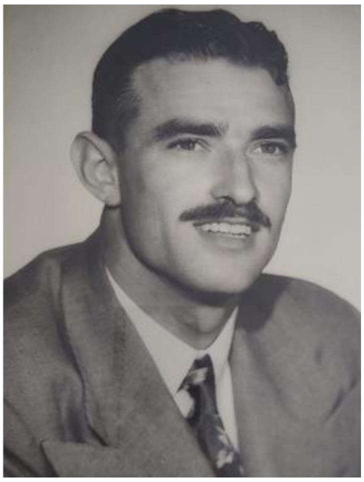

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Glossary of terms

Antero-posterior	relating to both the forwards/backwards movement
Axial	situated in, on, or along the longitudinal axis
Braking impulse	the horizontal impulse during the deceleration period during the stance phase of running
Cadence / Stride frequency	the rate at when strides are taken, measured as strides per minute
Centre of mass	the point at which the mass of a system could be concentrated
Cushioning	the compliance of an absorptive material
Foot inclination	the inclination of the foot in the sagittal plane measured relative to horizontal
Ground reaction force	the force applied back to the object colliding with the ground by virtue of Newton's third law of motion
Impact peak	the passive peak in the vertical ground reaction force after impact during running
Impact shock	the force applied to a structure at the moment of collision
Kinematics	the study of mechanics concerned with the motion of objects without reference to the forces which cause the motion
Kinetic chain	an interrelated group of body segments, connecting joints, and muscles working together to perform movements
Kinetics	the study of mechanics concerned with the motion of bodies under the action of forces

Loading magnitude	the magnitude of the ground reaction force after impact
Loading rate	the rate of increase in vertical ground reaction force after impact during running, calculated by dividing the maximal vertical force by the time to the maximal vertical force
Medio-lateral	relating to lateral movements, forces, and accelerations
Propulsion peak	the vertical active ground reaction force during the propulsion phase of running stance
Resultant	a result vector composed of vertical, antero-posterior, and medio-lateral vectors
Shock attenuation	the act of slowing down the frequency of impact shock as it travels upwards through tissue
Spatiotemporal	factors related to distance and time, such as stride length and stride frequency
Stance phase	the period during which body weight is supported on the relevant limb, beginning at touchdown and concluding at toe-off
Step length	the distance between individual steps between left and right foot
Stride length	the distance between individual strides of the same foot
Tibial acceleration	a proxy measurement for the impact forces experienced at the tibia by virtue of Newton’s second law of motion (F = ma)
Touchdown	the instant at which contact is made between the body and the running surface

List of symbols and abbreviations

AC	Arch Cushioned insole
AT	Athlete insole
BW	Body weight
BW/s	Body weights per second
CON	Control condition
g	Acceleration due to gravity
GRF	Ground reaction force
ICC	Interclass correlation coefficient
IMU	Inertial measurement unit
m/s	Metres per second
ms	Milliseconds
mm	Millimetres
N	Newton
PAR-Q	Physical activity readiness questionnaire
PTA	Peak tibial acceleration
ROM	Range of motion
WR	Walker Runner insole

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Abstract

Title:	The acute effects of pre-fabricated insoles on tibial acceleration and kinematics of endurance runners
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Tibial acceleration is a prominent biomechanical consideration associated with common running-related injuries, such as tibial stress injuries. Cushioning insoles are proposed to be capable of reducing tibial acceleration, though there is conflicting evidence. Perceived comfort, primarily through enhanced cushioning, has shown some association with peak axial tibial acceleration, however the magnitude of this correlation has been found to be low. Changes in footwear cushioning have been associated with adjustments in running mechanics that may mask the effect of the cushioning material or potentially increase the risk of injury by altering the biomechanical variables associated with running-related injuries. The majority of research related to running mechanics has historically occurred in laboratory environments, thus compromising ecological validity. The purpose of this study was to investigate the effects of pre-fabricated insoles on running mechanics and footwear comfort in a field setting.

Twenty-nine recreational runners (age: 31.8 ± 6.5 y) completed four separate laps of an athletics track while wearing running shoes containing either the ordinary sock liner (CON), or pre-fabricated insoles namely Sofsole Athlete (AT), Spenco Arch Cushioned (AC), and Spenco Walker Runner (WR) (Implus LLC, Durham, North Carolina, USA). Participants were fitted with seven inertial measurement units (IMUs) (Noraxon,

Scottsdale, Arizona, USA). Each IMU included a tri-axial accelerometer, gyroscope, and magnetometer in order to capture segment and joint kinematics in all three planes of motion. Spatiotemporal data was collected using a 10 m length of an optical measurement system (OptoJump by Microgate, Bolzaho, Italy). Subsequent to each lap, the participant completed the Footwear Comfort Assessment Tool comprising of nine 100 mm visual analogue scales. Biomechanical and perceived comfort variables were compared in R using a linear mixed model with main effect for condition. Pairwise comparison between condition was conducted post-hoc with Tukey adjustments for the p-values.

No significant differences for spatiotemporal parameters, tibial acceleration, shock attenuation, knee flexion, hip flexion, or shin inclination were observed. Foot pitch angle was significantly greater between WR versus AC, AT versus CON, and WR versus CON ($p < 0.001$), as was ankle dorsiflexion at touchdown between WR versus AC and WR versus CON ($p < 0.001$). Peak ankle dorsiflexion was significantly greater between WR versus AC and WR versus CON ($p = 0.006$), while ankle dorsiflexion ROM was significantly reduced between WR versus CON and AC versus CON ($p = 0.007$). Overall comfort was significantly greater for AT versus AC, AT versus WR, and AC versus CON ($p = 0.002$), and shoe length comfort was significantly less for WR versus CON ($p = 0.33$).

The pre-fabricated insoles investigated in this study did not result in any significant acute changes to peak acceleration or shock attenuation, however significant and clinically relevant changes regarding ankle dorsiflexion, foot inclination, and overall footwear comfort did occur. Runners should be aware that enhanced cushioning of pre-fabricated insoles may be negated by adjustments to ankle dorsiflexion and foot strike pattern during touchdown. Runners may therefore be advised to select pre-fabricated insoles based on their perceived comfort.

Keywords – Biomechanics, footwear comfort, inertial measurement units, recreational runners, running footwear, running mechanics, perceived comfort, pre-fabricated insoles, sagittal plane kinematics, tibial acceleration.

Chapter one: Introduction

1.1 Background information

Running has gained popularity amongst both recreational and competitive participants, as can be seen by the growth of fun runs and marathons (1, 2). It is estimated that 8% - 13% of adults world-wide and 9% of adults in Africa choose running as their physical activity of choice (3). Endurance running has been associated with a number of health-related benefits, including improved blood glucose levels, cholesterol fraction concentrations, lean body mass, and bone density in previously inactive adults (4, 5). Overall, running is associated with a 30% reduction of all-cause mortality, and a 50% reduced risk of mortality due to cardiovascular events and chronic health problems, including cardiovascular disease (6-8). Despite the health benefits, running has also been associated with an increased risk of injury when compared to other forms of aerobic exercise, such as walking (9).

A running-related injury has been defined as a musculoskeletal pain situated predominantly in the lower limbs attributed to running, which results in (a) a stoppage of running, (b) a restriction in running duration, speed, distance, or training for at least 3 consecutive scheduled training sessions or 7 days, or (c) a consultation with a physician or other health professional (10, 11). Injury not only impacts a runner's quality of life, but also interrupts their training and participation, and increases their financial burden through healthcare costs. At any given time, 25% of endurance runners may be experiencing a running-related injury and approximately 50% of endurance runners will experience interrupted training due to a running-related injury during a calendar year (12). Running-related injuries most commonly affect the lower leg, including the knee, shank, ankle, and foot. A recent systematic review indicated that up to 78% of men (31% at the knee, 26% at the ankle foot, and 21% at the shank) and 75% of women (40% at the knee, 19% at the ankle-foot, and 16% at the shank) have reported running-related injuries at or below the knee (13).

A number of factors that potentially increase the risk of running-related injuries have been identified. These have been sub-divided into categories such as anatomical (foot morphology and Q-angle), physiological (older age and greater body mass index), training-related (low running experience, low or high training frequency, low or high weekly running mileage), and biomechanical factors (e.g. high ground reaction force magnitude and loading rate, lower limb joint flexion angles, foot and shin inclination at touchdown, cadence, and stride length) (14-17). Measures of ground reaction force (GRF) magnitude, instantaneous- and average vertical GRF loading rate, and tibial acceleration (PTA) have been associated with tibial bone stress injuries in runners, when compared to age and mileage matched controls (18, 19).

More specifically, it has been reported that greater stride lengths and reduced stride frequencies are associated with a more extended knee at impact and a greater foot inclination. Impact is thus made with the heel of the foot, resulting in greater knee flexion during the stance phase. This leads to larger (i) vertical GRF impact peaks, (ii) average vertical GRF loading rates, (iii) instantaneous vertical GRF loading rates, (iv) and higher tibial accelerations. Each of these variables may contribute to a variety of running related injuries (20, 21). At similar running speeds, a 10% and 20% increase in stride length has been reported to result in a 30% and 85% increase in tibial acceleration respectively. Additionally, impact shock attenuation increased by 8.2% and 18.36% respectively (22). In another study, increasing stride length by 10% and reducing stride frequency by 10% resulted in a 4% increase in impact shock attenuation brought on by larger tibial acceleration. Alternatively, a 10% decrease in stride length with a subsequent 10% increase in stride frequency brought about a 15% decrease in impact shock attenuation due to reduced tibial acceleration (23).

Over the past few decades there has been much interest regarding the effect of footwear on running mechanics and running-related injuries. The cushioned heel and midsole of a typical running shoe reduces peak GRF, GRF loading rates, and tibial acceleration by passively attenuating impact shock (24, 25). Pre-fabricated and custom-made cushioning insoles may improve comfort, provide arch support, and enhance cushioning. In the case of custom-made insoles, this allows for fabrication to the requirements of the individual, while pre-fabricated insoles offer a more cost-effective solution to a generalised population. Cushioning insoles are generally used by runners to increase the cushioning of their running shoes or reinstate cushioning in older shoes that may have limited midsole cushioning as a result of general wear. However, changes in cushioning properties may cause alterations in their stride parameters, segment orientation, and joint motion during stance phase (25).

Investigations into the effectiveness of pre-fabricated insoles on biomechanical variables that are associated with lower limb injuries have yielded mixed results. In one study, cushioning pre-fabricated insoles have been associated with reductions of 16% in PTA, 7% in peak vertical GRF, and 8% in peak vertical GRF loading rates during overground running (26). In another study, there were no significant differences in PTA between custom-made insoles and a control group, with pre-fabricated insoles slightly increasing PTA by 3% and 11% before and after a fatiguing run respectively (27). Between the orthotic conditions, vertical GRF loading rates increased by a non-significant 1.5% and decreased by a more significant 7%, compared to the control condition under nearly identical spatiotemporal parameters. However, non-significant reductions in vertical GRF of 2% in both the orthotic conditions were observed (28). In contrast, a softer footwear condition was reported to yield a 5% increase in vertical GRF during the active peak while reducing the average vertical GRF loading rate by 11% when compared to a control condition (29). The effect of perceived comfort of pre-fabricated insoles on running biomechanics has also received some attention, again with inconsistent findings. Custom-made orthotics consisting of thermoplastic polyurethane and ethylene-vinyl acetate have both been determined to be more comfortable than a control condition, particularly with improved arch height- and medio-lateral control comfort. Following a review of the current literature there appears to be little agreement related to the effectiveness of insoles in reducing lower limb injuries and the variables commonly considered responsible for these injuries.

Several studies have investigated the effects of footwear conditions on impact and GRF loading rate and magnitude, however many of these have demonstrated common limitations to their research. For one, these investigations are typically performed in a laboratory setting, often using an instrumented treadmill to capture kinetic data with the use of force plates. Although a well-designed and maintained instrumented treadmill is believed to be very capable of providing similar results, there are subtle yet significant differences compared to overground running (30). Cadence has been found to be significantly higher, while stride length and stride time was significantly shorter. More specifically, treadmill running may result in reduced knee flexion, and greater peak medial and anterior GRF compared to overground running (30). From a meta-analysis perspective, it has been found that sagittal plane kinematics, particularly at touchdown, may differ substantially, with motorised treadmills producing a ~10° decrease in foot pitch, ~2° increase in knee flexion, ~6° decrease in knee flexion range of motion (ROM), and ~4° decrease in hip flexion at touchdown. Interestingly, ankle dorsiflexion ROM collected on a motorised treadmill was greater compared to running on a concrete surface, but was lower when compared to running over a lab runway (31). Thus, evidence suggests the use of a treadmill may alter a runner's natural running technique. A recent systematic review and meta-analysis of cross-over studies compared running biomechanics between motorized treadmills and overground running. It was reported that stride length and stride frequency remained largely unchanged. Additionally, peak vertical GRF, and PTA were not significantly different or were of trivial magnitude. Sagittal, frontal, and transverse plane angles of the ankle during initial contact were not significantly different. Furthermore, only peak frontal plane ankle angles during stance were significantly different, while differences in sagittal and transverse plane angles of the ankle at peak during stance were not significant. Peak sagittal, frontal, and transverse plane knee angles during stance were not significantly different. Although sagittal plane knee flexion at initial contact increased significantly by an average of 2.3° and knee flexion ROM decreased significantly by 6.3°, frontal and transverse knee ROM and angles during initial contact were not significantly different. Lastly, all sagittal, frontal, and transverse plane hip angles during initial contact and stance phase were not significantly different. It is important to note that motorised treadmills may increase ground contact time by a significant margin of 5ms, while more powerful motors have been found to increase stride time. With respect to lower limb kinematics, motorised treadmills were reported to significantly reduce the foot-ground angle at contact by an average of -9.8°, resulting in contact being made with the foot in a less inclined position. The extent of these differences were believed to potentially impact training, research, and clinical practice (31).

The treadmill surface may also not accurately mimic real-world conditions. Alternatively, laboratory settings have also made use of a short overground running area, ranging from 15 meters (26, 32, 33) to 22 meters (34-37). The limited space may also compromise the kinematic data captured in these settings. The capture volume of motion capture systems used in laboratory-based overground running studies usually only allows for 1-2 strides to be analysed. Thus, such volumetric restrictions may be inadequate for a subject to reach their true running pattern. A laboratory setting may, therefore, limit the ecological validity of research findings. Furthermore, research on the assessments of footwear comfort has suggested that running trials should typically exceed 2 minutes in duration. This would allow subjects adequate time to adjust their running stride and determine perceived comfort (38, 39). Many overground studies, however, do not allow for this adjustment time. Additionally, many studies investigating tibial acceleration neglect to also measure changes in kinematics and spatiotemporal parameters which may further inform the findings and allow for a more comprehensive interpretation of any effect.

1.2. Defining the research problem

Studies have reported reductions in loading magnitudes, loading rates, and PTA by increasing stride frequency, reducing stride length, or both. It has, however, also been noted that any change in running gait, such as manipulation of spatiotemporal parameters may bring about an increased risk of injury in other forms (40). The use of insoles may potentially assist in reducing impact-related variables such as tibial acceleration and impact shock attenuation without requiring any alteration to running technique. To date, this has only been investigated in a laboratory environment, and evidence under real-world conditions is sparse.

Information gained through this study may reveal with greater clarity the relationship between footwear conditions and impact-related variables during running. The effect of pre-fabricated insoles on lower limb biomechanics during running in recreational runners may contribute to the pool of knowledge on this relationship pertaining to injury related variables. This may further inform the advice clinicians and other healthcare professions offer runners pertaining to the use of insoles.

1.3. Research question

Do pre-fabricated insoles alter tibial acceleration, shock attenuation, lower limb kinematics, spatiotemporal parameters, and perceived comfort during outdoor running on a track?

1.4. Aim and objectives

The aim of this study is to investigate if three types of pre-fabricated insoles (namely Sofsole Athlete, Spenco Arch Cushioned, and Spenco Walker Runner, all by Implus LLC, Durham, North Carolina, USA) alter selected running mechanical variables (tibial acceleration, shock attenuation, lower limb kinematics, spatiotemporal parameters) and perceived comfort experienced by endurance runners when running outdoors on a track.

Objectives:

1. Determine whether tibial acceleration and shock attenuation differ when running in three types of pre-fabricated insoles and conventional running shoes using inertial measurement units.
2. Determine whether lower limb kinematics and spatiotemporal parameters differ when running in three types of pre-fabricated insoles and conventional running shoes using inertial measurement units.
3. Determine whether perceived comfort differs when running in three types of pre-fabricated insoles and conventional running shoes using the Footwear Comfort Assessment Tool (FCAT), composed of nine Visual Analogue Scales (VAS) (38).

The findings of the research will be used to provide recommendations regarding the effectiveness of pre-fabricated insoles in reducing mechanical load during running.

1.5. Research design

The current study involved a quantitative research approach. An experimental study by means of a repeated measures cross over design was followed: 1) to investigate the effect of pre-fabricated insoles on tibial acceleration, shock attenuation, and sagittal plane kinematics of the hip, knee, and ankle, and 2) to examine the perceived comfort of the pre-fabricated insoles during and immediately after running.

1.6. Structure of the dissertation

Chapter 2 will review the existing literature in order to discuss previous findings and highlight limitations with the intent to identify a plausible opportunity for further investigation. Chapter 3 will be presented in a manuscript format containing introduction, methods, results, and discussion sections. This will include a description of the participants, the equipment used, and the standardised procedures followed. Chapter 4 will consist of a concise summary of the study, focussing specifically on the key findings and recommendations for future research.

Chapter two: Literature review

2.1. Introduction

The factors responsible for excessive cumulative load that leads to running-related injuries is believed to be multifactorial in nature and involves anatomical-, biomechanical-, physiological-, and training-related factors (14-16). As the foot makes contact with the ground during running it decelerates and briefly comes to a complete halt, which propagates a shock wave through the musculoskeletal system (22, 41). The magnitude of this impact shock is directly related to the magnitude- and rate of acceleration (42). These components, as well as the number of loading cycles, contribute to the cumulative load on the tissues of the musculoskeletal system. Repetitive cumulative load may exceed the tissue’s capacity to manage the load (43) or provide insufficient time for repair and remodelling of injured tissue such as bone, tendons, and skeletal muscle between loading periods (44, 45). This may result in cumulative microtrauma to the musculoskeletal system, which may progress towards gradual onset injury if loading is not reduced (11). Excessive cumulative load places runners at a higher risk of sustaining running-related injuries such as tibial stress fractures (46). Medial tibial stress syndrome and tibial stress fractures typically accounts for 9.5% and 4.5% of running-related injuries respectively (47). Endurance runners are believed to be at an increased risk of stress fractures due to the repetitive nature and impact associated with the activity (45). Amongst NCAA cross country athletes stress fractures accounted for 30% and 58% of severe running injuries in men and women respectively (48). The magnitude of acceleration may be influenced by the orientation and alignment of the lower extremity at the moment of touchdown, with imprecise running technique contributing to increased magnitude- and rate of loading (46, 49). While there is value in studying biomechanical variables of kinetics and kinematics in isolation, there may be greater value in examining the relationships between these variables, particularly since altering one variable may result in change of another. As a result, through investigating the effect of footwear on both kinetics and kinematics it would be possible to determine whether changes in impact-related variables such as tibial acceleration are as a result of altered kinematics or due to the shock attenuation properties of footwear.

The following section will review the biomechanical variables of interest, as well as current literature on footwear, and will conclude with a brief review on the relationship between perceived comfort and variables discussed in the section.

2.2 Running mechanics

Running mechanics is defined as the interaction of motions, loads, and stresses applied to the body during running. The complex coordination between muscle force production, joint flexion, and segment orientation within the musculoskeletal system through the three planes of motion influences the quality and efficiency of movement, including potential risk of injury. The study of running mechanics investigates spatiotemporal stride parameters, the internal and external forces acting on the body, and motion of the joints, segments and centre of mass. The main external force is the collision force between the ground and the foot-and-ankle complex. The GRF produced during this collision represents the sum of all segment masses multiplied by their acceleration.

For the purpose of this study this review will focus on GRF, tibial acceleration, shock attenuation, spatiotemporal parameters, and lower limb sagittal plane kinematics. The spatiotemporal parameters of interest include stride length, cadence, and running speed. The sagittal plane kinematics will specifically include foot and shank pitch, and ankle, knee, and hip flexion.

2.2.1 Ground reaction forces

During running, as the foot strikes the ground, the foot applies a force to the ground, the centre of mass lowers, and a portion of the body decelerates to a velocity of zero meters per second. The portion of the body which decelerates to zero meters per second is referred to as the effective mass. In response, a GRF is applied back to the foot, resulting in an impact shock wave which propagates up the kinetic chain through the skeletal system (41, 50, 51).

Although the antero-posterior- and medio-lateral GRF may contribute to running-related injuries, the vertical GRF component is the most widely studied due to its correlation with running-related injuries. The vertical impact peak and the propulsion peak of vertical GRFs have also been investigated. Of great interest to researchers are the instantaneous- and average vertical GRF loading rates, both of which have been linked to running-related injuries (18, 19, 52, 53). The shape of the vertical GRF curve during running, as seen in Figure 2.1, typically consists of a vertical impact peak and a propulsive peak.

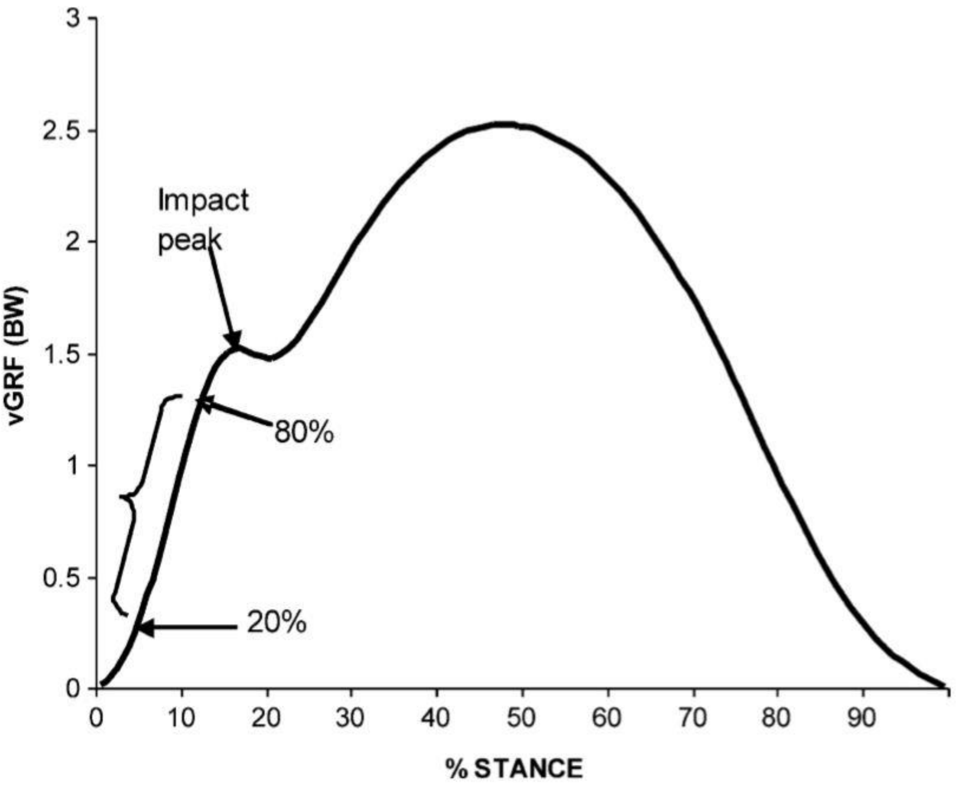

Figure 2.1: *Example of the vertical ground reaction force curve. The average vertical GRF loading rate was calculated as the slope of the curve between 20% and 80% of the time until impact peak, reproduced from (19).*

The vertical impact peak represents the passive vertical impact and the propulsive peak represents the vertical active force during the propulsion phase. The instantaneous- and average vertical GRF loading rates are calculated from the 20-80% portion of the graph between contact and vertical impact peak (19, 40). The vertical GRF is relatively easy to measure by means of force platforms and provides an approximate measure of the load exerted on the lower extremity in response to the load applied to the running surface.

The vertical impact peak of a rear foot strike occurs within 50 ms into early stance phase after touchdown with the ground, and typically reaches magnitudes of 1.5 – 2 times body weight (BW) at running speeds between 3 and 5 m/s (25, 40, 54). GRF impact magnitude is significantly correlated to running speed (r = 0.34) and the foot angle relative to horizontal at the moment initial contact with the ground is made (r = 0.24), while impact peak- and active peak magnitudes is significantly correlated to dorsiflexion (r = 0.31 and r = 0.32 respectively) and stride length (r = 0.29 and r = 0.31 respectively) during stance phase (55).

Runners with a history of tibial stress fractures have a 36% increase in vertical GRF and significantly higher vertical impact- and propulsive- peaks compared to runners with no stress fracture history (53, 56). The stress fracture group also exhibited significantly higher posterior-, medial-, and lateral force peaks. It is postulated that these increased force peaks may cause significantly greater bending moments on the tibia, which may have contributed to the stress fractures (56). During the early stages of a fatiguing run, uninjured runners have demonstrated vertical GRF 8% greater than runners with a history of tibial stress fractures. It was noted, however, that the vertical GRF increased in the previously injured group as running continued whereas the vertical GRF of the uninjured group remained largely unchanged (57). Meanwhile, a number of studies have reported no significant difference in vertical GRF between previously injured and uninjured runners (58-60). Three-dimensional gait analysis, investigating each of the subject’s running kinematics, is needed to establish the cause of these greater external loads since the orientation and alignment of joints and segments have been shown to influence the magnitude of peak GRF (20).

Perhaps of greater importance than vertical GRF loading magnitude are vertical GRF loading rates, as this has been more closely linked to the development of running-related injuries. A number of kinematic variables also influence vertical GRF loading rates. An increase in speed from 3m/s to 6m/s has been reported to raise instantaneous vertical GRF loading rate from 8 BW/s to 30 BW/s (61). In addition, knee flexion ROM ($r = -0.621$, $p<0.001$), knee joint stiffness ($r = 0.579$, $p<0.001$), ankle sagittal plane angle at touchdown ($r = -524$, $p<0.001$), and shank inclination at touchdown ($r = -0.656$, $p<0.001$) have been found to reveal moderate- to strong correlations with instantaneous vertical GRF loading rate (62). A meta-analysis found that loading rates were significantly higher in stress fracture groups compared to control groups – in 7 out of 13 studies that examined GRF loading rate reported (46). A methodological quality checklist was used to rate included studies (18 studies with 496 cases and 676 controls) in a similar meta-analysis, investigating the relationship between vertical GRF and running-related injuries. Vertical GRF loading rates were 10-15% greater in runners with a history of tibial stress fractures when compared to runners with no history of stress fractures. No significant difference in the magnitude of either vertical GRF impact- or active peak were found between the injured and uninjured runners (63). Therefore, it may be more pertinent to study vertical GRF loading rates and surrogate measures closely correlated to vertical GRF loading rates when investigating relationships between running mechanics, tibial load, and running-related injuries such as medial tibial stress syndrome and tibial stress fractures.

Impulse is the product of force and time, represented by the area under the vertical GRF force-time curve. In running, vertical impulse refers to the impulse produced by the vertical component of the GRF, between contact and vertical impact peak, and has been hypothesized to be a risk factor for musculoskeletal injuries (64). Since vertical impulse is dependent on force and time, it can be altered by adjusting time to impact peak or vertical impact peak magnitude. By increasing the vertical impact peak magnitude or extending the time to impact peak, a larger vertical impulse is generated. The stiffness of footwear has been shown to achieve this by extending the time for the midsole to deform during impact (32, 65). This increase in vertical impulse, although associated with a decrease in GRF loading rate, may place a runner at an increased risk of repetitive stress injuries (64). Thus, there does appear to be a trade-off between reducing impact loading rate and increasing impulse, as represented in Figure 2.2.

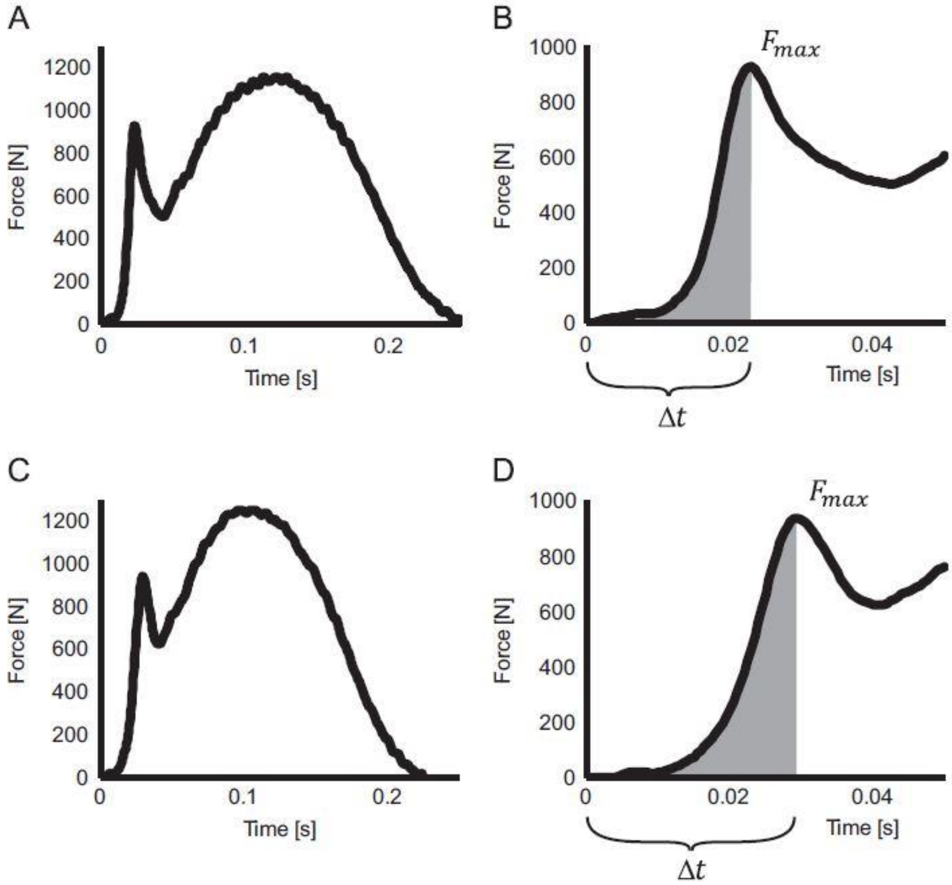

Figure 2.2: *The vertical ground reaction force curve of a barefoot rear foot strike runner on a hard surface (A) with a focus on the vertical impact peak (B) in comparison to the vertical ground reaction force curve of a rear foot strike runner in soft footwear (C) with emphasis on the corresponding vertical impact peak (D). The time to impact in footwear increased substantially, resulting in a larger effective mass, which in turn resulted in a larger vertical impulse, represented as the shaded area in B and D, reproduced from (64).*

To summarise, GRF is an approximate measure of the load the musculoskeletal system is subject to when the foot collides with a running surface. The impact- and propulsion peaks of vertical GRF have been correlated to ankle dorsiflexion, stride length, and tibial stress fractures. However, the vertical GRF loading rates might be a better measure of the load applied to the lower extremities, and have themselves been shown to correlate closely with foot- and shank inclination at touchdown, as well as tibial stress fractures. The collection of GRF data in field settings, as opposed to laboratory settings, is limited. Therefore, our understanding of GRF production, and in particular GRF rate of loading, in field settings during running activities is limited. Surrogate measures, such as tibial acceleration, have grown in prominence for its ease of data collection in both laboratory and field settings.

2.2.2 Tibial acceleration

As the foot impacts a running surface, the foot and lower leg decreases in velocity to 0 m/s. This rapid deceleration can be measured by means of accelerometers placed on the lower limbs, commonly on the distal anteromedial tibia. Acceleration of the tibia takes place in three dimensions according to the local tibial coordinate frame: axial, antero-posterior, and medio-lateral (66). A resultant acceleration accounts for all three of the acceleration components by which tibial acceleration is measured, thus creating a single metric of greater magnitude than any of the individual axes which constitute it. For the purpose of this dissertation, peak resultant tibial acceleration will be referred to as peak tibial acceleration (PTA). Historically, the axial component has been the most commonly reported by use of a uniaxial accelerometer. This requires the sensitive axis to be aligned with the long axis of the tibia in order for axial data to be accurately recorded.

Significant positive correlations between vertical GRF loading rates and tibial acceleration have been identified. Peak axial tibial acceleration has been correlated to both average ($r = 0.70$) and instantaneous ($r = 0.73$) vertical GRF loading rates in forefoot striking runners. Similarly, in rearfoot striking runners, peak axial tibial acceleration revealed correlations with both average- ($r = 0.47$) and instantaneous ($r = 0.70$) vertical GRF loading rates (67). An unspecified component of PTA has also previously demonstrated a very strong correlation ($r = 0.95$) with instantaneous vertical GRF loading rate. As a result, instantaneous vertical GRF loading rate was described as a good predictor of tibial accelerations (68).

Results from a cross-sectional study also showed that runners with a history of tibial stress fractures demonstrated significantly greater vertical GRF loading rates and peak axial tibial acceleration compared to uninjured controls. This further supports the relationship between vertical GRF loading rates and tibial accelerations, indicating that an increase in vertical GRF loading rate may be associated with a similar increase in PTA (19). By means of a binary logistic regression it has also been found that peak axial tibial acceleration was able to predict a history of tibial stress fractures in 70% of the runners assessed. The likelihood of a previous tibial stress fracture was determined to increase by a factor of 1.361 for every 1g increase in peak axial tibial acceleration (19). Both GRF and PTA measurements have been proposed to be accurate measures by which to evaluate the cushioning properties of athletic footwear (68). It has, however, been suggested that peak axial tibial acceleration provides a more direct estimate of mechanical load acting on the tibia (19). Additionally, peak axial tibial acceleration may be a more appropriate variable to measure when screening large numbers of runners due to its sensitivity and limited set-up, and could be a more sensitive discriminator of runners at increased risk of injury (19).

With the introduction of triaxial accelerometers, acceleration through the vertical, medio-lateral, and antero-posterior axes could be collected. Additionally, these three components could be combined into a resultant acceleration. Solely assessing axial tibial acceleration may inaccurately estimate the impact shock experienced at the tibia (69). A resultant calculation of tibial acceleration may be a more precise measure of impact shock than axial tibial acceleration on its own, since the transverse plane acceleration may contribute substantially (70). Triaxial accelerometers do not require to be accurately aligned with the long axis of the tibia, which means that the resultant tibial acceleration may offer superior repeatability and be a more reliable measure of tibial acceleration between testing sessions (71). Peak tibial acceleration refers to the maximal positive acceleration experienced by the tibia during early stance phase, shortly after impact. Similar to vertical GRF loading rate and vertical impact peak, this typically occurs within the first 50 ms following contact, as seen in Figure 2.3 (19, 40).

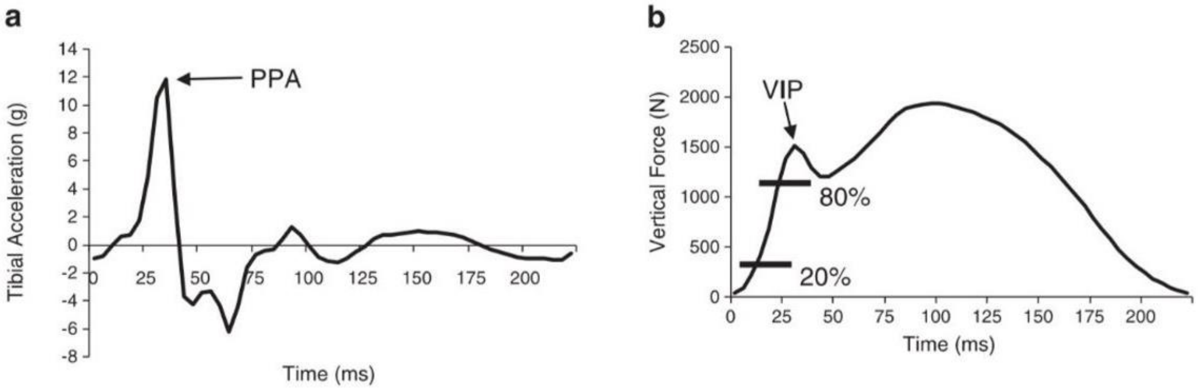

Figure 2.3: *Peak tibial acceleration (PTA) from the tibial acceleration curve (a) alongside the ground reaction force curve (b). Generally, both PTA and vertical impact peak (VIP) of ground reaction force occur within the first 50 ms of stance phase, reproduced from (40).*

The position and alignment of the lower extremities at contact may affect tibial acceleration, since these are associated with joint stiffness and effective mass (49). The configuration of joint segments at the end of the swing phase affects the velocity of the foot and lower leg in the moments prior to impact. These further influences the force applied to the ground, the resulting GRF, as well as the rate of deceleration required to bring the foot and lower leg to a downwards velocity of 0 m/s during touchdown with the ground. As a result, the impact shock magnitude and the frequency at which peak power occurs is also affected (72). Since rearfoot strike running is believed to increase axial tibial acceleration compared to forefoot strike running, it has been suggested that increased ankle compliance during forefoot strike running may contribute to reducing the rate of tibial acceleration (72). During rearfoot strike running, peak axial tibial acceleration was previously shown to be greater in magnitude than antero-posterior- and medio-lateral tibial acceleration, whilst during forefoot strike running both the antero-posterior- and resultant tibial accelerations were seen to be larger than the peak axial tibial acceleration (69). Resultant tibial acceleration was shown to decrease from 13.2g to 9.5g when habitual forefoot striking runners adjusted their running technique in order to make contact with the rearfoot. Similarly, resultant tibial acceleration increased from 9.4g to 11.3g when habitual rearfoot striking runners adjusted their running technique in order to make contact with the forefoot (69). There is further evidence that forefoot strike running increases axial tibial acceleration, while rearfoot strike running increases acceleration along the transverse axis during downhill running (67, 70).

Tibial acceleration has also been found to correlate with running velocity, where an increase in running velocity from 3.3 m/s to 5.0 m/s and 1.25 m/s to 5.0 m/s resulted in significant increases in axial tibial acceleration across a range of footwear conditions and different running surfaces (35, 73). Further investigations reported increases in all components of tibial acceleration (axial, antero-posterior, and medio-lateral) when running velocity increased from 3.5 m/s to 4.7 m/s (74). A recent study found that resultant tibial acceleration increased from 7.8g – 12.9g when running velocity increased from 2.7 m/s – 3.7 m/s (71). Finally, a regression analysis has shown that a 0.1m/s increase in running velocity is associated with a 0.38g increase in resultant tibial acceleration. This indicates that a positive linear relationship between running velocity and resultant tibial acceleration may exist (75). During this study the majority of participants demonstrated a consistent increase in resultant tibial acceleration with each incremental increase in running velocity. A number of their participants produced lower resultant tibial accelerations when running at an increased velocity. It was proposed that these runners may have a preferred set of functional coordination patterns at higher speeds, resulting in reduced tibial acceleration (75).

In summary, tibial acceleration has been closely correlated with vertical GRF loading rates. Tibial acceleration has been suggested to be a more direct measure of mechanical load acting on the tibia, while its sensitivity and ease of set-up makes it a more appropriate variable to measure. Triaxial accelerometers are able to accurately measure acceleration in all three planes of motion, with the single resultant tibial acceleration single metric constituting acceleration data from all three planes. Tibial acceleration is dependent on running speed, as well as joint flexion and segment orientation.

2.2.3 Impact shock attenuation

In order to maintain a stable field of vision by which to identify environmental information for safe navigation, head accelerations remain largely stable across a range of walking speeds, stride frequencies, stride lengths, and combinations of these (76, 77). This is accomplished through attenuation of the accelerations experienced during impact. Impact shock attenuation is the change in high frequency acceleration between distal segments (typically the lower leg) and proximal segments (typically the head or sacrum) (41). A number of factors may influence the magnitude of tibial acceleration during running, including spatiotemporal characteristics (stride length, stride frequency, and result running velocity) and running kinematics, such as foot inclination at touchdown. As impact shock increases, so does the need to attenuate this shock.

Impact shock is dampened by means of active and passive attenuation as it moves upwards from the point of contact. The predominant passive attenuation mechanisms include, skin, bone, ligaments, tendons, cartilage, and the fat pad in the heel (78).

Active attenuation mechanisms involve the eccentric contraction of muscles around the ankle, knee, and hips joints (22). The attenuation mechanisms only filter out a portion of the impact shock and slow down the advancement of the shock wave as it continues to travel up the kinetic chain. When impact shock is applied over short periods of time it has been shown to be harmful, thus the attenuation of impact shock plays an important role in extending the initial period of force application at the point of contact, as well as slowing the rate of travel up the kinetic chain (79). The shock wave still affects various structures and tissues as continues up the kinetic chain, and may be influenced by lower limb kinematics. An increased horizontal distance between the centre of mass and the point of touchdown results in increased ankle joint stiffness but reduced knee joint stiffness (80). An increase in ankle joint stiffness has been found to results in a larger braking impulse during initial contact, while reduced knee joint stiffness has been reported to increase the vertical displacement of the centre of mass (81). The increase in braking impulse results in greater vertical GRF, while increased knee flexion produces greater knee joint loads and external knee flexion moments. Greater active attenuation through increased joint flexion reduces knee joint pressure, gradually reducing the distance between the centre of mass and the point of contact, lowering the centre of mass, and dissipating the vertical GRF through greater knee flexion ROM (82-85). Passive shock attenuation mechanisms will be discussed in greater depth when reflecting on footwear, while the following pages will address active shock attenuation mechanisms.

Eccentric muscle contraction provides the greatest contribution to active impact attenuation, however high magnitudes of eccentric muscle contractions, particularly over time, has been associated with muscle damage and increased oxygen consumption, resulting in reduced running performance (22, 86-88) . Shock attenuation has generally been calculated using acceleration data from accelerometers attached to the shank and the head to give an indication of systemic attenuation. However by utilising the data from accelerometers fixed to the shank and the sacrum, shock attenuation of the lower limbs can be calculated (89).

The lower limbs are able to reduce the magnitude of impact and rate of vertical GRF loading, and thus the impact shock transmitted through the body from foot to head. If touchdown is made with little flexion the impact force is more likely to pass through the joint centres of the lower extremity. As a result, the shock wave travels a more direct route through the body, bypassing much of the active shock attenuation mechanisms, increasing the demands on the passive mechanisms to attenuate these loads. However, should there be greater flexion in landing, the impact force vector is directed away from the joint centres, allowing the eccentric muscular contraction to actively absorb a portion of the load. This results in greater acceleration of the more distal segments and lower accelerations on the proximal segments and trunk (42).

Although flexion about the hip and ankle contribute to shock attenuation, the knee is believed to play a far larger role (90). This is due to the relative size and strength of the quadriceps crossing over the knee which have the greatest potential to eccentrically contract under load as the knee is flexed from touchdown to mid stance, at which point knee flexion is at its greatest (42). The magnitude of attenuation through knee flexion is influenced by the perpendicular distance between the knee joint centre of rotation and the line of action of the resultant GRF. A greater perpendicular distance would require a greater knee extensor moment in order to prevent a collapse of the knee, resulting in a larger magnitude of energy absorbed at the knee (23). An increase in stride length results in a greater perpendicular distance between the knee joint centre of rotation and the line of action of the resultant GRF at impact, which increases shock attenuation. This suggestion is supported by studies which reported a relationship between the impact response and knee flexion angle at impact, inferring that knee flexion angle would influence shock attenuation (74, 81, 88, 91). A 10% increase in stride length with a 10% decrease in cadence whilst running at 3.8m/s has been reported to result in a 4.2% increase in shock attenuation. Conversely, reducing stride length by 10% and increasing in cadence by 10% was associated with a 14.7% reduction in shock attenuation (92).

Considering that pelvic and head accelerations remain relatively stable as running velocity increases, it can be surmised that shock attenuation should increase as tibial acceleration increases in order to maintain stable head accelerations. Shock attenuation increases as a function of running velocity, and as a result tibial acceleration, increases proportionately (93). When running at increased speed, a runner would need to increase their stride length, cadence, or both. While maintaining similar cadence, running at 4.4 m/s with a 15% increase in stride length has been reported to produce 43% more shock attenuation compared to running at 3.3 m/s with a 15% decrease in stride length. Much smaller changes in shock attenuation were reported when stride length remained constant, but cadence was increased by 15% while running at 4.4 m/s versus a 15% reduction in cadence while running at 3.3 m/s (23). As stride length changes, so may knee flexion angle and the foot inclination at impact. Increased stride length on all surface gradients has been associated with increased energy absorption at the knee and hip resulting in greater impact shock attenuation. When stride length was increased by 10%, it resulted in a 90% increase in impact shock attenuation, while reducing stride length by 10% was associated with a 68% decrease in shock attenuation (94). Although a 10% increase in preferred stride length was associated with larger tibial acceleration, it was also noted that a 10% decrease in preferred stride length yielded larger sacral acceleration, indicating reduced shock attenuation when stride length was reduced (94). Stride length influences both knee flexion and foot inclination, both of which have been found to affect GRF impact peaks, with every degree change in knee flexion and foot inclination being associated with a change of 68N and 85N respectively (91).

To summarise, shock attenuation mechanisms filter out high frequency acceleration as it moves up the musculoskeletal system. Active shock attenuation of the lower limbs primarily occurs through the eccentric contraction of the muscles surrounding the knee during flexion whist under load, allowing impact forces to be directed away from joint centres. Shock attenuation is influenced by the perpendicular distance between the point of ground contact and the body’s centre of mass, thus increased stride length would require greater shock attenuation through increased joint flexion. Therefore, by measuring the tibial acceleration, which is functionally coupled with knee and lower limb motion, as well as pelvic acceleration it is possible to determine the magnitude of active shock attenuation taking place during the early stages of stance phase when running.

2.2.4 Spatiotemporal parameters and lower limb kinematics

Spatiotemporal stride parameters such as stride length have been shown to have a direct relationship to lower limb sagittal plane kinematics. Studies attempting to reduce stride length, whether directly or indirectly by increasing cadence, found that shorter stride lengths may be associated with increased knee flexion and reduced ankle dorsiflexion at touchdown (20, 95, 96). Increased stride length was reportedly associated with reduced knee flexion at touchdown and increased ankle dorsiflexion, resulting in greater angling of the shank towards the body (97). It has been reported that running at a higher cadence with a shorter stride length may result in increased knee flexion at touchdown, but reduced knee flexion during mid-stance. The increased knee flexion at touchdown results in reduced tibial acceleration, with the reduced knee joint flexion during the stance phase results in active shock attenuation at the knee (20).

Rearfoot striking runners make touchdown with the ankle joint in dorsiflexion. Forefoot striking runners demonstrate reduced stride length compared to rearfoot striking runners, and make touchdown with the running surface in a plantar flexed position (72). As a result of the reduced stride length, cadence increases and contact time tends to decrease (98). Forefoot striking runners reportedly make touchdown with the ankle in 12.5° of plantar flexion and the shank at a 2° angle of inclination, while rearfoot striking runners demonstrate 1.2° of ankle dorsiflexion and a shank inclination angle of 8° at touchdown (99).

Lower limb kinematic adjustments typically influence lower limb kinetics. Earlier research has shown that shorter stride lengths are associated with reduced vertical GRF loading rate (95) and lower peak vertical GRF (20). This was attributed to increased knee flexion and reduced ankle dorsiflexion during initial contact. It has been observed that forefoot strike running yields a smaller impact peak and reduced vertical GRF loading rate compared to rearfoot striking running (25, 67). By reducing stride length and increasing cadence a runner may be able to reduce vertical GRF loading rates (20). Forefoot striking runners have been shown to produce a less prominent vertical GRF impact peak in a time domain GRF signal compared to rearfoot striking runners. Additionally, the vertical GRF active peak occurs roughly 12% later in forefoot striking runners in comparison to rearfoot striking runners (100). It has been reported that a statistically linear relationship between stride length and axial tibial acceleration exists. Axial tibial acceleration decreased by 5.6g when stride length was reduced from 20% greater than preferred stride length to 20% shorter than the preferred stride length (22). It is difficult to associate such a reduction in tibial acceleration to running-related injury rate since there is a dearth of longitudinal research apart from case studies, however a 1-year follow-up of a randomised control trial following a 2-week gait retraining program has yielded interesting results. 320 novice runners were allocated to either the control group or the intervention group following a stratified randomisation. Although there are no details regarding stride length or stride frequency during the gait retraining program, the intervention group were able to significantly reduce average- and instantaneous vertical GRF loading rates at both 8km/h and 12km/h following a 2-week gait retraining program where they were instructed to “run softer”. At a 12-month follow-up the intervention group reported a 62% decrease in running related injuries in comparison to the control group (101). It should be noted that alteration in stride length and stride frequency may have consequences related to muscle recruitment patterns and injury due to a redistribution if musculoskeletal strain. Additionally, reducing stride length has been associated with a significant decrease in running economy by potentially increasing oxygen cost by 7-8%, although other studies have indicated a nearly negligible increase following a 10% increase in cadence at the same running speed (95, 102). Considering the prolonged nature of endurance running, any potential increase in the cost of locomotion should be kept in mind.

The magnitude of vertical GRF loading rates are dependent on running velocity, with studies reporting an increase in average vertical GRF loading rates of 77.2 BW/s at 3.0 m/s to 113.0 BW/s at 5.0 m/s (54). Unfortunately, no description was provided of either stride length or stride frequency, both of which have been found to impact vertical GRF and are required to change with an increase in running speed. Stride length and the resulting adjustment to kinematics have also been found to influence tibial acceleration during running. Increased stride length has been shown to reduce joint flexion at touchdown during running. This resulted in higher vertical GRF loading rates and increased PTA (97). A probabilistic model assessing the effects of stride length and running mileage on the risk of sustaining a stress fracture determined that a 10% reduction in stride length may result in a corresponding reduction in tibial contact force, decreasing the likelihood of suffering a tibial stress fracture (103). Increasing cadence in order to reduce stride length has been reported to reduce tibial acceleration (41), however there is evidence to suggest that making touchdown with the forefoot may significantly increase PTA compared to rearfoot strike running (67). The increase in PTA when running with a forefoot striking pattern has been attributed to (i) reduced passive shock attenuation in the anterior of the foot and shoe, and (ii) an increase in knee stiffness. The plusher midsole and thicker fat pad in the heel are more capable of dampening accelerations during initial contact, thus making initial contact on the forefoot reduces the passive attenuation of shock compared to making initial contact with the heel. Although ankle stiffness during forefoot strike running decreases, knee stiffness substantially increases. Since the knee has been identified to play a far larger role in active shock attenuation, this increase in knee joint stiffness reduces overall leg compliance, resulting in increased PTA during initial contact (67, 104).

Although PTA is affected by spatiotemporal factors, research has shown that PTA may be moderated by footwear (35, 105). It is believed that the plush midsole of conventional running shoes, particularly in the heel of the shoe, may encourage runners to make touchdown with the heel. This would be achieved by an increase in foot inclination through an increase in stride length. As a result, this would lead to further adjustments in joint and segment orientations. Thus, knee flexion at touchdown may be reduced, leading to the shank assuming a less vertical angle at touchdown and angling more towards the body. During stance phase knee flexion increases, resulting in a larger knee- and ankle sagittal plane ROM. Forefoot strike running does not passively utilise the fat pad in the heel and the cushioning of the rear of the shoe. This may increase the reliance on kinematics and eccentric muscle contraction to reduce impact (72). Although adopting shorter strides to make contact on the forefoot may increase knee joint flexion at initial contact, as mentioned earlier, this may increase knee joint stiffness and reduce knee joint shock attenuation during the remainder of early stance phase until mid-stance is reached. As a result, the knee may not provide the shock attenuation required during forefoot strike running to adequately dampen the impact shock traveling upwards from the lower leg.

In essence, as stride length increases at a set stride frequency, running speed increases as a result. An increase in stride length is associated with increased ankle dorsiflexion but reduced knee flexion at touchdown. This results in increased angling of the shank towards the body, leading to increased tibial acceleration. This establishes a direct association between running speed and adjustments to stride length with tibial acceleration.

2.3 Footwear

The midsole of a running shoe comprises the soft material found above the rugged outsole of the shoe. This is often claimed by manufacturers to reduce impact during running through increased cushioning and shock attenuation, inferring a reduced risk of running-related injuries associated with impact. Insoles, a soft material inserted on top of the midsole and directly under the foot, have claimed to do the same. It is important to mention that running-related injury rates have not significantly decreased over the last few decades. This may be due to the population of frequent runners shifting from mostly competitive to predominantly recreational or the varying definition of running-related injuries (106). Furthermore, the midsole hardness has been found to have little influence on running-related injury frequency (107). Since running-related injuries are multi-factorial, the influence of differing footwear characteristics on running mechanics also require investigation.

The impact shock absorbing properties of footwear are generally assessed in bench top material tests. A mass with a specified impact velocity is dropped from a specified height onto the material, in this case the midsole or insole of a shoe. The effectiveness of the material to passively attenuate impact shock is determined by the magnitude of reduction in impact peak (108, 109). The passive impact shock attenuation through the midsole or insole has been proposed to reduce pain associated with various running injuries, such as medial tibial stress syndrome and patellofemoral pain syndrome (110). Since footwear is the interface between the running surface and the foot, it may play a significant role in altering biomechanical parameters such as tibial acceleration, which have been associated with common running injuries.

The midsole of running shoes play a large role in the passive attenuation of shock. As a result, significant research has been directed at investigating the shock attenuation capabilities of the midsoles. Thicker midsoles are suggested to increase the contact time during early stance phase by increasing the time required for the thicker midsoles to be deformed during impact (32, 65). It has been demonstrated that the midsole of a conventional running shoe could reduce GRF loading rate from 463.1 BW/s during barefoot running to 69.7 BW/s while running in conventional running shoes (25). Several studies have indicated that conventional running shoes with cushioning midsoles produce lower peak tibial acceleration while also increasing the time to peak tibial acceleration in comparison to barefoot running (24, 33-35, 65, 105, 111). One study in particular investigated the effect of four running shoes of differing double density ethylene-vinyl acetate variations in comparison to barefoot running. The PTA was reported to differ significantly between barefoot and shod conditions (barefoot = 14g, shod = 9-10g), as was the time after touchdown to reach PTA (barefoot = 18ms, shod = +/- 34.5ms). Notably, no significant differences between the shod conditions were reported (111).

It has previously been reported that cushioned footwear may alter sagittal plane kinematics by increasing ankle dorsiflexion at contact and ankle joint stiffness, as well as increasing peak sagittal plane knee flexion and ROM (24, 32-35, 67, 105). Shod runners display a significant increase in stride length compared to barefoot runners, even when barefoot runners were instructed to make touchdown with the rear foot (33). Additionally, it has been proposed that minimalist running shoes (characterised by a very thin midsole offering reduced cushioning in comparison to conventional running shoes) encourage a non-rearfoot strike with an increase in cadence resulting from the decrease in stride length (112). Studies investigating the combined effects of footwear and spatiotemporal parameters on knee joint stress have yielded interesting results. In one example, a 10% reduction in stride length has been associated with 12.2% decrease in peak knee extensor moment, while minimalist footwear resulted in a 6.3% reduction in peak knee extensor moment. When combining a 10% reduced stride length with minimalist footwear the peak knee extensor moment was reduced by 17.7% (113). Similarly, a 10% increase in cadence was associated with a 16% reduction in patellofemoral joint stress while running in a minimalist shoe reduced patellofemoral joint stress by 15%. When incorporating minimalist footwear with a 10% increase in cadence, patellofemoral joint stress was reduced by 29% (114).

Development in footwear has also produced a maximalist running shoe, featuring a thicker midsole which is claimed to provide increased cushioning compared to conventional running shoes. As a result, this has encouraged recent investigations comparing the effects of these running shoes on GRF and PTA. Conventional footwear produced lower instantaneous vertical GRF loading rates and PTA compared to minimalist footwear (58.3% and 29.5% respectively). Likewise, maximalist footwear produced lower instantaneous vertical GRF loading rates and PTA compared to minimalist footwear (53.6% and 16.3% respectively). No significant differences were, however, found between conventional and the maximalist shoes, suggesting minimal difference between cushioned conditions (105). This is partially supported by a study reporting that increasing midsole thickness was associated with decreased average vertical GRF loading rate, which has been associated closely with PTA, as midsoles increased in size from 1mm in width to 25mm in thickness. Interestingly, 29mm thick insoles increased the average vertical GRF loading rate (65). A similar study investigated the effects of shoes of varying midsole thickness (of 0mm, 2mm, 4mm, 8mm, and 16mm) on average vertical GRF loading rate and PTA between barefoot running and shod running. No significant differences were found between any of the footwear conditions. Contact time was seen to increase as midsole thickness increased, with the 16mm thick midsole being significantly longer in duration than both barefoot and 0mm midsole stance durations. Additionally, ankle stiffness, foot inclination, and ankle dorsiflexion angle at touchdown in the barefoot condition was significantly less than all shod conditions. Furthermore, ankle dorsiflexion ROM in the barefoot condition was significantly greater than all the shod conditions. Finally, the barefoot condition displayed significantly reduced knee flexion ROM compared to shod conditions with midsoles between 2mm and 16mm in thickness (32). There is evidence to support the belief that cushioned running shoes are capable of reducing tibial acceleration and the time to PTA, however it appears that exceptionally thick midsoles do not further promote a reduction in these variables. It has been noted that highly cushioned footwear may increase impact loading and peak patellofemoral force and pressure through greater knee- and ankle joint stiffness when compared to less cushioned footwear (115-117).

When an insole is inserted into a conventional running shoe, the midsole of the shoe remains the primary source of shock absorption, with the insole contributing a far smaller amount (66). Custom-made insoles are carefully manufactured to fit an individual's foot however, these are costly as they are customised according to the needs of a runner. Pre-fabricated insoles are mass-produced and commercially available at a more affordable price, but are not customised to cater to the needs of an individual. Pre-fabricated insoles inserted into the athletic footwear and defence boots of naval recruits lowered injury rate by 34% compared to a control group wearing flat insoles. These injuries were predominantly medial tibial stress syndrome, patellofemoral pain syndrome, Achilles tendonitis, and plantar fasciitis (118). Conflicting evidence from a meta-analysis indicate that shock-absorbing insoles may have no effect on the risk of either lower limb stress fractures or overall injuries. It was, however, indicated that custom made orthotics may reduce the risk of overall injuries by 28%, with a 41% reduction in lower limb stress fractures (119). While these injuries are associated with high GRF loading rates, direct correlations between tibial acceleration and pre-fabricated insoles are needed to draw any conclusive statements regarding its capacity to attenuate shock. Although the purpose of insoles varies, there is limited research focused on its influence on tibial acceleration. Studies investigating the effects of pre-fabricated insoles on PTA following a one- or two-week adjustment period have reported no significant difference compared to a control condition (27, 67). However, conflicting evidence has shown that pre-fabricated insoles may significantly reduce tibial acceleration, GRF loading rate, and GRF impact peak relative to control conditions (26). This is partially supported by evidence indicating a 16% reduction in peak vertical GRF loading rates when comparing pre-fabricated insoles to control conditions. Although stride length and stride frequency were not reported, running speed and knee flexion remained similar between trials, suggesting no significant difference in stride length or stride frequency. Since active impact attenuation through decreased knee joint stiffness was ruled out, the reduction in peak vertical GRF loading rates were attributed to the passive impact attenuation properties of the insoles. It should be noted that ankle dorsiflexion angle was also not reported, and could contribute to these findings. Additionally, only 8 of the 15 participants experienced biomechanically relevant reductions of ≥ 10% (110).

Any kinematic adjustments made as a result of footwear choice may vary per individual. Thinner midsoles may not significantly reduce stride length or increase cadence. As a result, some runners may continue to make touchdown with the rearfoot regardless of the midsole thickness. Such runners may demonstrate increased average- and instantaneous vertical GRF loading rates when running in thinner midsoles compared to shoes with a more moderate midsole thickness (65). Additionally, reduced stride length results in a greater number of loading cycles. This has previously been reported to increase the cumulative loading at the metatarsophalangeal- and ankle joints (113).

In summation, the cushioning material in footwear act as a passive shock attenuation mechanism during impact. Although there is evidence to indicate that cushioned running shoes are able to significantly reduce tibial acceleration compared to minimalist and barefoot condition, there appears to be no significant difference between cushioned conditions. Research related to the effect of pre-fabricated insoles in tibial acceleration has yielded conflicting results. It should also be noted that increased cushioning may increase stride length, ankle dorsiflexion angle at touchdown, and knee flexion range of motion during stance phase.

2.4 Perceived footwear comfort and biomechanical variables

When selecting running footwear, comfort has been identified as the deciding factor (120). Evidence suggests that increased footwear comfort may not only increase running performance through enhanced running economy, but may also reduce the risk of running-related injuries (121, 122). Perceived comfort is a highly subjective measure of which several aspects may play a role, however cushioning has been highlighted as one of the leading characteristics by which to define perceived footwear comfort (38). A number of studies have investigated the effects of perceived footwear comfort on kinetic and kinematic variables commonly associated with running-related injuries, such as vertical GRF and tibial acceleration. Although perceived comfort may not be associated with a change in peak vertical GRF, a significant inverse correlation with vertical GRF loading rate has been shown to exist. Thus, an increase in perceived comfort may be significantly correlated to a decrease in vertical GRF loading rate (29, 123). Additionally, although perceived comfort may not significantly correlate with peak axial tibial acceleration, there is evidence to suggest that an increased sense of comfort may be associated with an increase in vertical GRF impact peak (123). There is, however, evidence disagreeing with this finding. The footwear comfort assessment tool was used to correlate perceived comfort in four different running shoes to vertical GRF peaks and vertical GRF loading rates. Perceived comfort did not reflect a significant correlation with either vertical GRF peaks or vertical GRF loading rates (124). In contradiction to this, increasing perceived comfort has been significantly correlated with reduced peak axial tibial acceleration. It is, however, important to note that the magnitude of this correlation was low ($r = 0.23$) (125). Since vertical GRF loading rates have previously been shown to correlate with tibial acceleration, findings focusing on the inverse correlation between perceived comfort and vertical GRF loading rates may lend some support to those suggesting that increasing perceived comfort may reduce tibial acceleration. Considering that perceived comfort plays such a prominent role in the selection of footwear it may be of value to further examine the relationship between perceived footwear comfort and running biomechanics. Cushioning has been identified as a prominent facet in footwear comfort, thus continued research studying the effect of cushioning on biomechanical variables such as tibial acceleration, shock attenuation, sagittal plane kinematics, and spatiotemporal factors may shed greater light in areas where there is conflicting evidence.

2.5 Limitations of previous research

A survey of the current literature indicates several limitations, which include: running surface, running space, running speed, and population of runners. Also, a number of studies only report findings related to running kinetics and tibial acceleration, with no reflection on kinematic adjustments.

2.5.1 Running surface as a limitation

Several studies utilised a short running track to record overground running data, with the running space often limited to roughly 20 meters in length and a restricted capture volume around the middle of this length. This distance may be insufficient, and may not allow runners to accurately simulate their natural running pattern (30). As a result, this may bring the ecological validity of the data into question. Very often only data from a single step may be collected in the limited capture volume. Researchers would need to repeat each trial numerous times in order to collect data from a sufficient number of steps to compile a sample to study. This is time consuming, and prevents researchers from acquiring biomechanical data from sequential steps. Foot strikes averaged across different trials and between subjects has previously been identified as a limitation of statistical power, thus reducing the strength of the data and the conclusions drawn there from (126-129). With perceived footwear comfort in mind, it is also suggested that subjects require at least two minutes in a footwear condition to adequately adjust to their natural running pattern and determine the level of comfort following a trial (38, 39).

2.5.2 Running space as a limitation

The use of an instrumented treadmill is proposed to facilitate more repeatable patterns of movement from stride to stride compared to repeated short discontinuous overground running trials (130). Continuous running on a treadmill may be more suited to acquiring multiple steps and detecting small differences in vertical GRFs and kinematics while running as it allows for continuous collection of data during movement (131, 132). Instrumented treadmills may offer a few benefits compared to overground running in limited lab space, such as standardising test conditions and the ability to accurately reproduce running speeds. There have, however, been concerns regarding the validity of data collected on treadmills. Overground running has been found to produce significantly lower knee flexion angles at touchdown and significantly greater antero-posterior- and medio-lateral GRF in comparison to treadmill running. Significant differences in sagittal plane kinematics for the hip (reduced hip flexion at contact, peak hip flexion, and ROM), knee (peak knee flexion), and ankle (excursion from contact to peak angle) have been reported during treadmill running compared to overground running. A significant increase in peak eversion angle and a significant decrease in hip internal rotation ROM has also been noted (131). Although vertical GRF between treadmill running and overground running may be highly correlated highly, at similar running speeds runners may prefer a rearfoot contact during overground running but adjust to a non-rearfoot contact during treadmill running (132). This would suggest a decrease in stride length and an increase in stride frequency, which has been supported by reports that treadmill running significantly increases cadence and significantly reduces stride length at similar running speeds. Such changes are likely to affect antero-posterior GRF values (30). Furthermore, even after adjusting for differences in running speed, tibial accelerations have been shown to be significantly higher during field testing and race participation compared to treadmill protocols (133, 134). It has thus been suggested that tibial shock during treadmill-based tests cannot be used to estimate the shock experienced when running outdoors. As a result, field testing using portable devices is likely encouraged as it improves ecological validity, allows ample time for subjects to adjust to their natural running pattern, and provides sufficient time for subjects to determine perceived comfort of footwear (133, 134).

2.5.3 Running speed as a limitation

Several studies have standardised the inter-participant running speed, which may result in more consistent inter-trial spatiotemporal parameters and minimal changes in lower limb kinematics between trials. Since participants are likely to differ in height, running technique, mobility, and preferred running pace, this may result in runners exhibiting running technique different from their natural technique. Constraining participants to a set speed may inhibit runners from attaining their optimal stride frequency, stride length, or both, and in doing so may alter other factors such as contact time (135). Thus, prescribing a standardised running speed may limit the validity of the data, while allowing participants to run at a comfortable self-determined speed may improve repeatability between trials and accuracy of data collected.

2.5.4 Population of runners studied as a limitation

The populations used in previous research vary substantially, from military recruits, to novice runners, and cross-country runners. Although each population may have specific benefits, each may also have its own constraints. Military recruits often have set routines and strictly guided activities, however many studies examining impact and acceleration on military recruits either perform these investigations while recruits wear their combat footwear or athletic footwear, but rarely assess both. Additionally, combat footwear may differ greatly from standard athletic footwear (118). Similarly, the kinematics and kinetics demonstrated by cross country runners during cross country events may not be an accurate portrayal of the kinematics and kinetics exhibited by conventional road runners. Care should be taken when drawing conclusions based on this specific running population, considering the constant change in running terrain and the equally constant change in spatiotemporal parameters as a result. Several studies also make use of novice runners, most notably university students. The level of experience between participants may vary substantially, as may their recent training loads. Less experienced runners may be more prone to inconsistent lower limb kinematics and spatiotemporal parameters within a sample of steps.

2.5.5 Limitations due to incomplete measure of biomechanical variables

A number of studies in the literature investigated GRFs and tibial acceleration without accounting for variations in kinematics and spatiotemporal parameters. Lower limb kinematics, joint stiffness, and stride length alterations may have significant implications on kinetics and tibial acceleration. As a result, it may be of significant importance to assess changes in loading with consideration the potential changes in lower limb kinematics and spatiotemporal parameters.

2.6 Conclusions

Although there is a general consensus in evidence indicating that cushioned footwear may significantly reduce tibial acceleration compared to barefoot running, there is conflict when comparing different shod conditions. Even though increased cushioning has been associated with reduced tibial acceleration, the current literature suggests no significant difference in tibial acceleration between various cushioned footwear conditions. There is also evidence that highly cushioned footwear may increase impact loading, joint stiffness, and patellofemoral pressure. This conflict extends to pre-fabricated insoles, with evidence indicating that shock-absorbing insoles may be capable of reducing tibial acceleration, whilst others report no significant differences.

Additionally, it has been suggested that only a portion of runners may experience biomechanically relevant reductions. Changes in footwear cushioning has been reported to affect lower limb kinematics and spatiotemporal parameters. These adjustments are known to influence tibial acceleration and impact shock attenuation. However, several studies have neglected to investigate lower limb kinematics and spatiotemporal parameters in parallel with tibial acceleration. Additionally, investigations into the effects of pre-fabricated insoles on running mechanics have occurred in laboratory settings by means of instrumented treadmills and short overground capture volumes. Although these methods have advantages, they also risk ecological validity. Field testing allows endurance runners time to adjust their natural running technique while capturing several consecutive steps for examination. Furthermore, field testing provides endurance runners sufficient time to gauge the level of perceived footwear comfort experienced. By means of inertial measurement units it is now possible to collect accurate data in a field setting, thus improving ecological validity. Additionally, the inertial measurement units are capable of collecting acceleration data alongside joint and segment angle data.

Chapter three: Original research article

3.1 Introduction

Endurance running has been associated with health-related benefits such as a 50% reduced risk of mortality due to cardiovascular events and 30% reduction in all-cause mortality (6). However, approximately 50% of endurance runners will experience interrupted training as a result of a running-related injury each year (12, 45). The lower leg is one of the most common sites of injury, with medial tibial stress syndrome and tibial stress fractures accounting for about 9.5% and 4.5% of running-related injuries respectively (47). Repetitive impacts and the associated load experienced by the musculoskeletal system are key components of injury aetiology (45).

Peak tibial acceleration (PTA) during the stance phase has been measured during running in an attempt to understand the nature of these impacts. Increased ground reaction force (GRF) and PTA has been associated with tibial stress injuries both prospectively and retrospectively (18, 19, 25, 38). Through impact shock attenuation, the high frequency acceleration between distal segments such at the tibia and proximal segments such as the pelvis is partially filtered out (41, 42). This dampening of high frequency accelerations is achieved predominantly through the eccentric contraction of muscles around the hip, knee, and ankle as joint flexion increases while under load (22). Increased stride length has been shown to reduce knee flexion and increase foot- and shank inclination at touchdown. A ~10% increase in stride length has previously been associated with a 5% decrease in knee flexion and a 44% increase in foot inclination at touchdown, resulting in a 14% increase in antero-posterior GRF and an 8% increase in vertical GRF (20, 97). Similarly, stride length increases of 10% and 20% at a constant running speed have been associated increases of 30% and 85% in PTA respectively (22).

The cushioning properties of conventional running shoes could reduce PTA by increasing passive shock attenuation upon impact (24, 25). Pre-fabricated cushioning insoles may further enhance this cushioning effect, and have been suggested as a cost-effective solution with the additional benefit of improved comfort. Footwear comfort, of which cushioning plays a major role, has been proposed to reduce the risk of running-related injuries (38, 122). Enhanced perceived comfort has shown significant correlation to reduced peak axial tibial acceleration (125), while greater perceived comfort has been associated with reductions in vertical GRF loading rates, which are closely linked to tibial acceleration (29, 123). Previous research investigating the effect of pre-fabricated insoles on PTA and lower limb kinematics has yielded mixed results. In one study, PTA decreased when wearing a cushioning pre-fabricated insole during a single overground running trial (26). In contrast, following a seven day adjustment period, participants demonstrated an increase in PTA before and after fatiguing run on an instrumented treadmill (27).

Instrumented treadmills used in previous studies have been shown to yield significantly shorter stride length and stride time, with significantly increased stride frequency compared to overground running (30). Stride length is associated with sagittal plane knee- and ankle flexion and shank- and foot inclination, thus a treadmill-based protocol may produce significantly different lower limb joint flexion, segment inclination, and PTA. This could make it difficult to relate laboratory data to real world performance due to an inaccurate account of a runner's natural kinematic and acceleration data. Ankle dorsiflexion has previously been shown to be significantly lower when testing on a treadmill compared to overground measures even when foot strike pattern was controlled (136). Laboratory based overground running trials generally only cover a distance of 15 – 22 metres, allowing optical motion capture systems to only capture one or two strides per trial (26, 32-37). Trials are recommended to exceed two minutes in duration in order to allow subjects adequate time to adjust to their natural running stride and determine perceived comfort (38, 39). Inertial measurement units (IMUs) are able to record accurate acceleration, lower limb joint flexion, and segment inclination in parallel. IMUs also present an opportunity to assess a far larger sample of consecutive steps in a field setting. This further provides runners with more time to settle into their natural stride during a trial and to ascertain the level of comfort they are experiencing in the footwear condition.

The purpose of the current study was to investigate the effect of three different pre-fabricated insoles on (i) lower limb sagittal plane kinematics, tibial acceleration and shock attenuation, and (ii) perceived footwear comfort amongst recreational endurance runners, in a field setting.

3.2 Methods

This was a quantitative, experimental study conducted using a repeated measures cross-over design. Acceleration of the lower limb and pelvis segments, sagittal plane lower limb kinematics, and spatiotemporal variables in the form of stride length, cadence, and running speed were measured under four conditions in a randomised order. The protocol was approved by the University of Pretoria Faculty of Health Sciences MSc committee, as well as the Research Ethics Committee of the Faculty of Health Sciences, University of Pretoria (ethics reference number: 360/2019). All testing took place at the University of Pretoria athletics track, which consists of a Mondo surface. This allowed the current study to be conducted on a level terrain while providing participants sufficient time to adopt their normal running pattern. Conducting the study away from a laboratory setting was believed to improve the ecological validity of the findings.

3.2.1 Participants

Male and female runners who met the following criteria were invited to participate in the study: aged between 20 - 45 years, partook in endurance running at least three days per week with a total weekly mileage of 15 kilometres or more, at an average pace of between 5.5 – 6.5 min/km, and had a minimum of six months running experience prior to their participation in the study. Potential participants were excluded if they had a history of lower limb or spinal surgery, any injury which limited running performance (mileage, speed, or frequency) in the six months prior to participating, or answered ‘yes’ to any of the questions in the Physical Activity Readiness Questionnaire (PAR-Q). It was deemed necessary to keep the population relatively homogenous since variations in lower limb running kinematics and spatiotemporal variables may be attributed to differences in running speed, experience, and age. To ensure that the running shoes used in the control condition was not vastly different between participants, runners were excluded if they made use of insoles in their running shoes, habitually ran barefoot, or in shoes with substantially increased (maximalist) or reduced (minimalist and barefoot-inspired) midsole thickness. Runners who made use of stability- or motion control shoes were also excluded from the study. A convenience sampling approach was used in order to recruit runners from local running clubs. A target of 50 participants was set, however due to restrictions related to the Covid-19 pandemic and resulting testing delays this number was reduced. Twenty-nine runners (13 females and 16 males) voluntarily participated in this study after providing written informed consent. Foot strike pattern was establish following the control trial by means of assessing foot inclination at initial contact, where 27 of the participants were classified as rearfoot striking runners, while the remaining 2 participants were classified as non-rearfoot striking runners. A detailed description of participants is presented in Table 3.1.

Table 3.1: *Descriptors of runners participating in the study*

		Age (years)	**Height (m)**	**Mass (kg)**	**Weekly mileage (km/w)**	**Running experience (months)**	**400m lap time**
Mean (SD)	**Male (n = 16)**	34.2 (6.2)	1.8 (0.1)	82.4 (11.5)	43.6 (24.2)	77.3 (68.8)	119.5 (11.8)
	Female (n = 13)	28.8 (5.7)	1.7 (0.1)	64.9 (10.0)	27.1 (9.8)	60.5 (38.8)	120.2 (11.8)
	Total (n = 29)	31.8 (6.5)	1.7 (0.1)	74.5 (13.9)	36.2 (20.6)	69.8 (57.1)	119.8 (11.6)

3.2.2 Procedures

Each participant received standardised verbal instructions regarding the testing process and were given the opportunity to ask questions regarding the procedures. The participants provided information regarding their age, current active footwear, and recent weekly running mileage. Additionally, their mass and height were measured. Following a self-guided warm-up including at least one warm-up lap at their typical training pace around the athletics track (in an outer lane, ~ 454 m) the participant was instructed to complete another lap at a similar pace after a five-minute rest. Both laps were timed and feedback was given to the participant regarding their pace in order to assist them to maintain their pace in subsequent experimental trials. Experimental trials were deemed acceptable if they were completed within a 5% margin of the average running speed across a 10m stretch, as measured using an optical system

(OptoJump, Microgate, Bolzaho, Italy) situated within the data capture zone (Figure 3.1).

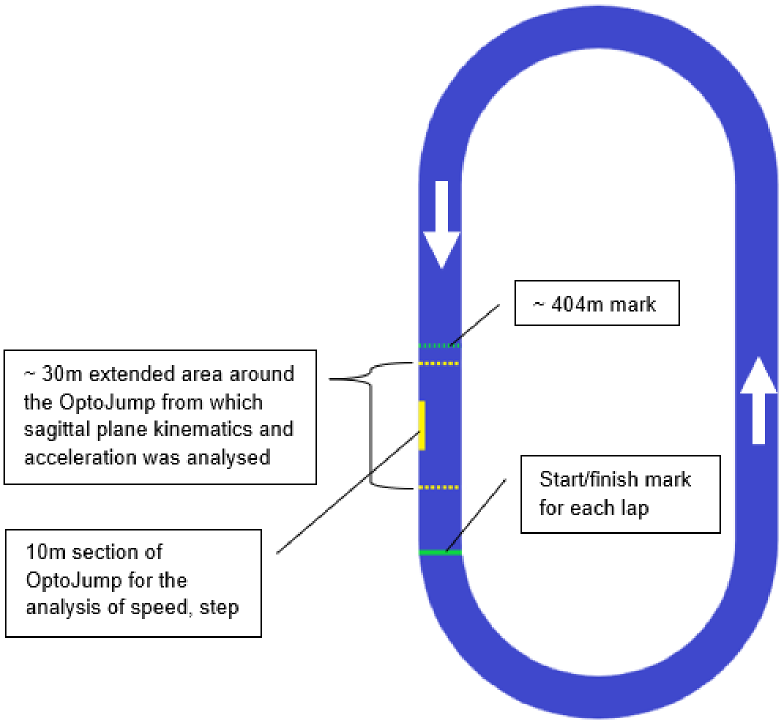

Figure 3.1. *Testing layout on the Mondo track, indicating OptoJump set-up and data capture zone for acceleration and sagittal plane kinematics.*

Biomechanical data were collected by means of IMUs (MyoMotion Research Pro, Noraxon, Scottsdale, USA), each of which contained a tri-axial gyroscope, accelerometer, and magnetometer in order to collect movement and orientation in the three planes of motion. Prior to all experimental trials, calibration procedures were followed, with the participant standing in a neutral posture. Foot placement was standardised during calibration by means of an adjustable platform. Participants then completed a single lap around the Mondo track in the outside lane. At the conclusion of each trial the participants were asked to complete the Footwear Comfort Assessment Tool (FCAT) while in-shoe conditions were changed. This also provided a 5- to 7-minute period of rest. This process was implemented for the control trial, as well as the three experimental conditions. Figure 3.2 depicts the testing procedure.

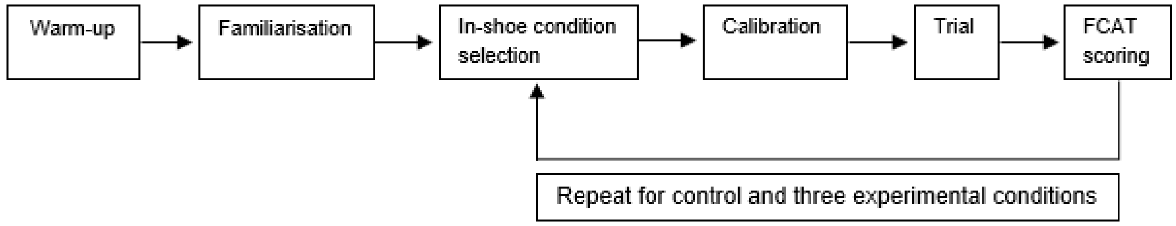

Figure 3.2. *Flow chart of testing procedures.*

In the event that an experimental lap was measured to be beyond the 5% margin in running speed compared to the control trial, sufficient rest was given, followed by re-calibration, and a repeat of that experimental condition. Experimental trials were limited to a maximum of six, allowing for two additional trials to meet the 5% margin criteria. The total number of laps, including warm-up and familiarisation, was therefore limited to nine laps (~4000 m total) to avoid the potential effects of fatigue. Repeated trials were necessary eleven times across all participants (five participants required one repeat trial, three participants required two repeat trials). All participants completed all trials in their own athletic footwear and their choice of active wear. The only change between trials was the in-shoe condition based on the experimental study design.

The pre-fabricated insoles were manufactured by Sofsole and Spenco (Implus LLC, Durham, USA), and were comprised of the Sofsole Athlete (AT), Spenco Arch Cushioned (AC), and Spenco Walker Runner (WR) (Figure 3.3). The primary purpose of the insoles was to enhance comfort and/or improve cushioning. The most prominent difference between the pre-fabricated insoles was the presence and prominence of arch cushioning in two of the insoles, while more modest differences included their cushioning properties and thickness. Table 3.2 provides a full description of the three pre-fabricated insoles used in the experimental conditions during this study.

__Figure 3.3.__ The pre-fabricated insoles used in the current study: Sofsole Athlete (left), Spenco Arch Cushioned (centre), and Spenco Walker Runner (right).

__Table 3.2:__ Details of the pre-fabricated insoles used in the experimental trials.

	Sofsole Athlete	**Spenco Arch Cushioned**	**Spenco Walker Runner**
Purpose	Comfort Cushioning	Comfort	Cushioning
Material	Implus foam Gel (heel and forefoot)	Spencore Polyurethane Polysorb	Spencore Polyurethane Spencore heel plug
Heel thickness	9mm	6.35mm	7.5mm
Forefoot thickness	8mm	4mm	6.8mm
Heel-forefoot offset	1mm	2.35mm	0.7mm
Arch cushion	No	Yes	Yes

3.2.3 Instrumentation

Seven IMUs were used to acquire 3-dimensional lower body joint flexion, segment orientation, as well as tibia and pelvis acceleration data. Data was sampled at 200 Hz and transmitted wirelessly to a receiver in the Noraxon Portable Lab (Noraxon, Scottsdale, USA) that was connected via a cable to a computer. The sensors were affixed by means of elastic straps to seven locations, as depicted in Figure 3.4: over the metatarsals of the left and right foot attached to the shoe laces via a clip and secured with a tight elastic band, the medial border of the left and right tibia below the muscular bulk of the gastrocnemius, the lateral aspect of the left and right thigh over the iliotibial band, and on the sacrum between the left and right posterior superior iliac spine. The validity and reliability of similar IMUs have been shown to be acceptable for tibial acceleration and sagittal plane kinematics, particularly during the stance phase of level walking and running tasks (137-140).

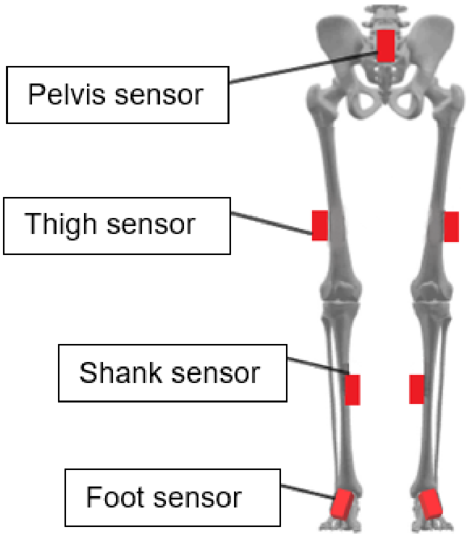

Figure 3.4: *Inertial Measurement Unit (IMU) placement*

Running speed, stride length, and step frequency were measured using an OptoJump optical measurement system over a 10-meter zone. Each 1-meter section of the transmitting bar contained 96 light emitting diodes (LEDs) and was paired with a receiving bar. This enabled the system to detect interruptions or resumptions in communication between the bars, and calculate their duration and location along the 10-meter zone. A Ninox 300C camera (Noraxon, Scottsdale, USA) was connected and synchronised to the IMU data via the Portable Lab in order to identify the first step entering the data capture zone. The video footage was subsequently used along with the OptoJump data to determine which foot initiated the recording of spatiotemporal data, as well as assign subsequent data to the relevant limb.

Perceived comfort for each of the four trials was rated within two minutes after the completion of each trial using the Footwear Comfort Assessment Tool (FCAT) (38). The FCAT was composed of nine 100mm Visual Analogue Scales (VAS), with the far left indicating the lowest possible level of comfort and far right denoting the highest possible level of comfort. The use of VAS has been shown to be reliable in the measure of footwear comfort in the FCAT, with a reported interclass correlation coefficient (ICC) of 0.799 for the FCAT (38). The nine scales assessed perceived footwear comfort according to overall comfort, heel cushioning, forefoot cushioning, medio-lateral control, arch height, heel cup fit, heel width, forefoot width, and shoe length. Without being prompted by a numbered scale or coloured spectrum, participants placed a mark on each of the nine scales, which was subsequently measured from the left to give a value between 0 and 100 for each of the nine comfort variables.

3.2.4 Data reduction

A Kalman filter (a linear quadratic estimation) fused the accelerometer, gyroscope, and magnetometer data together prior to the data being transmitted from each IMU to the Portable lab. The Noraxon MR3 software's automatic step detection identified touchdown and stance phase for each step. The kinematic signals were visually assessed for clear artefact. Ten consecutive steps with the right leg for each condition were identified, and their stance phase time normalised to 101 data points. The mean value over 10 steps was calculated for the following variables in each condition: peak resultant tibial- and pelvic acceleration during the stance phase; foot pitch, shank pitch, ankle plantar/dorsiflexion, sagittal plane knee- and hip flexion angles at touchdown; and peak ankle dorsiflexion, knee- and hip flexion during stance phase. Joint ROM was calculated as the difference between the joint angle at touchdown and peak joint flexion during the stance phase. Impact shock attenuation was calculated as a percentage change between the PTA and peak pelvic acceleration. These variables are summarised in Table 3.3.

3.2.5 Statistical analysis

All biomechanical and perceived comfort variables were compared in R using a linear mixed model with main effect for condition after confirming normal distribution through a Shapiro-Wilk test. A random effect for participant was used to account for within participant correlation. A global Wald-based test was run to test for overall condition effect with statistical significance accepted at $p \leq 0.05$. Pairwise comparison was conducted between condition post-hoc with Tukey adjustments for the p-values. Models were assessed for outliers. The models were also adjusted with speed as a confounder, however no significant differences were observed. The final results are presented without the adjustment for speed. Effect size for pairwise comparison was calculated with < 0.2 being regarded as trivial, 0.2 - 0.59 regarded as a small effect, 0.6 – 1.19 considered as a moderate effect, 1.2 – 2.0 viewed as a large effect size. Data presented in the tables are described by the mean values of each condition for each variable, along with the standard deviation and 95% confidence intervals.

Table 3.3: *Kinematic variables of interest in the current study*

	At touchdown	**During stance phase**
Tibial acceleration		Peak tibial acceleration (PTA) measured in meters per second squared (g)
Pelvic acceleration		Peak pelvis acceleration (PPA) measured in meters per second squared (g)
Shock attenuation		Shock attenuation (SA) between PTA and PPA measured as a %
Foot	Foot pitch (°) measured relative to horizontal	
Shank	Shank pitch (°) measured relative to vertical	
Ankle	Ankle plantar/dorsiflexion (°)	Peak ankle dorsiflexion (°) Ankle dorsiflexion range of motion (°) measured from touchdown until peak ankle dorsiflexion
Knee	Knee flexion (°)	Peak knee flexion (°) Sagittal plane knee range of motion (°) measured from touchdown until peak knee flexion
Hip	Hip flexion (°)	Peak hip flexion (°) Sagittal plane hip range of motion (°) measured from touchdown until peak hip flexion

3.3 Results

3.3.1 Acceleration and attenuation data

A summary of the acceleration and attenuation data is shown in table 3.4.

Table 3.4: *Summary of acceleration and attenuation data*

	Control				**Arch Cushioned**				**Athlete**				**Walker Runner**			
	Mean	SD	95% CI		Mean	SD	95% CI		Mean	SD	95% CI		Mean	SD	95% CI	
Peak Tibial Acceleration (g)	8.3	3.4	7.1	9.5	8.1	3.3	6.9	9.3	7.9	3.0	6.8	8.9	8.3	3.2	7.2	9.5
Peak Pelvis Acceleration (g)	4.1	1.2	3.7	4.6	4.2	1.2	3.8	4.6	4.1	1.2	3.7	4.6	4.1	1.3	3.7	4.6
Shock Attenuation (%)	49.5	15.3	44.0	55.0	47.1	15.2	41.7	52.6	46.7	14.8	41.4	52.0	49.0	17.4	42.8	55.2

No significant differences between conditions

There was no significant effect of insole condition on PTA (p = 0.316), peak pelvic acceleration (p = 0.887) (Appendix A, Figure. A.1), or impact shock attenuation (p = 0.498) (Appendix A, Figure. A.2).

3.3.2 Sagittal plane kinematic data

A summary of the sagittal plane kinematic data is shown in table 3.5.

Table 3.5: *Summary of sagittal plane kinematic data*

		Control				**Arch Cushioned**				**Athlete**				**Walker Runner**			
		Mean	SD	95% CI		Mean	SD	95 %CI		Mean	SD	95% CI		Mean	SD	05% CI	
Ankle (°)	TD	0.6	4.7	-1.1	2.2	1.2	4.4	-0.4	2.8	2.0	4.0	0.5	3.4	2.7 [a b]	4.2	1.3	4.2
	Peak	16.6	4.4	15.1	18.2	16.4	4.3	14.8	17.9	17.8	3.4	16.6	19.1	18.1 [a b]	3.8	16.7	19.5
	ROM	16.1	3.0	15.0	17.2	15.2 [a]	3.3	14.0	16.4	15.9	3.4	14.7	17.1	15.4 [a]	3.4	14.2	16.6
Knee (°)	TD	18.6	5.7	16.6	20.6	19.0	5.1	17.2	20.8	19.1	4.9	17.3	20.8	18.5	5.3	16.6	20.4
	Peak	39.6	4.8	37.9	41.4	39.8	4.1	38.3	41.3	40.6	3.9	39.2	42.0	39.4	4.4	37.8	40.9
	ROM	21.0	4.1	19.6	22.5	20.8	4.5	19.2	22.4	21.6	4.6	19.9	23.2	20.9	4.6	19.3	22.5
Hip (°)	TD	26.3	6.8	23.8	28.7	26.6	4.8	24.9	28.3	27.2	5.9	25.1	29.3	26.1	5.9	24.1	28.2
	Peak	27.3	6.7	24.9	29.8	27.9	4.7	26.2	29.6	28.5	5.9	26.4	30.6	27.4	6.0	25.3	29.6
	ROM	1.1	1.2	0.7	1.5	1.3	1.4	0.8	1.8	1.3	1.3	0.8	1.8	1.3	1.3	0.9	1.8
Foot (°) at TD		6.8	5.3	5.0	8.7	7.4	5.1	5.6	9.2	8.6 [a]	4.2	7.1	10.1	8.9 [a b]	5.2	7.0	10.8
Shank (°) at TD		6.3	3.3	5.1	7.5	6.3	3.1	5.2	7.4	6.7	3.6	5.4	8.0	6.2	3.0	5.2	7.3

a = Significantly different from Control

b = Significantly different from Arch Cushioned

There was a significant effect of condition on foot pitch at touchdown ($p < 0.001$). Post hoc analysis revealed significantly greater foot pitch angle for WR (8.9 ± 5.2°) versus AC (7.4 ± 5.1°) ($p = 0.005$, ES = 0.29), AT (8.6 ± 4.2°) versus CON (6.8 ± 5.3°) ($p = 0.028$, ES = 0.37), and WR versus CON ($p < 0.001$, ES = 0.39) (Appendix A, Figure. A.3). There was no significant effect of insole condition on shank pitch at touchdown ($p = 0.713$).

There was a significant effect of condition on ankle dorsiflexion at touchdown ($p < 0.001$). Post hoc analysis revealed significantly greater ankle dorsiflexion for WR (2.7 ± 4.2°) versus AC (1.2 ± 4.4°) ($p = 0.009$, ES = 0.37) and WR versus CON (0.6 ± 4.7°) ($p < 0.001$, ES = 0.49) (Appendix A, Figure. A.4). There was also a significant effect of condition on peak ankle dorsiflexion ($p = 0.006$). Post hoc analysis revealed significantly greater peak ankle dorsiflexion for WR (18.1 ± 3.8°) versus AC (16.4 ± 4.3°) ($p = 0.011$, ES = 0.43) and WR versus CON (16.6 ± 4.4°) ($p = 0.026$, ES = 0.36). Additionally, there was a significant effect of condition on ankle dorsiflexion ROM ($p = 0.007$), with significantly lower ankle dorsiflexion ROM for WR (15.4 ± 3.4°) versus CON (16.1 ± 3.0°) ($p = 0.03$, ES = 0.22) and AC (15.2 ± 3.3°) versus CON ($p = 0.\ 024$, ES = 0.28).

There was no significant effect of insole condition on knee flexion at touchdown ($p = 0.625$) (Appendix A, Figure. A.5), peak knee flexion ($p = 0.302$), or knee flexion ROM ($p = 0.591$). Similarly, there was no significant effect of insole condition on hip flexion at touchdown ($p = 0.765$) (Appendix A, Figure. A.6), peak hip flexion ($p = 0.698$), or hip flexion ROM ($p = 0.301$).

3.3.3 Spatiotemporal data

Summary statistics for the spatiotemporal variables of interest are presented in table 3.6.

Table 3.6: *Summary of spatiotemporal variables*

	Control				Arch Cushioned				Athlete				Walker Runner			
	Mean	SD	95% CI		Mean	SD	95% CI		Mean	SD	95% CI		Mean	SD	95% CI	
Running speed (m/s)	3.9	0.5	3.8	4.1	4.0	0.6	3.8	4.2	4.0	0.6	3.8	4.2	4.0	0.6	3.8	4.2
Step length (cm)	140.2	17.8	133.9	146.6	139.5	17.9	133.1	145.9	140.9	18.6	134.2	147.5	140.4	18.8	133.7	147.1
Cadence (steps/min)	168.8	10.4	165.1	172.6	169.7	11.5	165.6	173.9	168.9	10.6	165.1	172.7	169.8	10.8	166.0	173.7

No significant differences between conditions

There was no significant effect of insole condition on cadence (p = 0.197), stride length (p = 0.64), or running speed (p = 0.557).

3.3.4 <u>Footwear comfort variables</u>

Summary statistics for the footwear comfort variables of interest are presented in table 3.7.

Table 3.7: *Summary of FCAT data*

	Control				Arch Cushioned				Athlete				Walker Runner			
	Mean	SD	95% CI		Mean	SD	95% CI		Mean	SD	95% CI		Mean	SD	95 %CI	
Overall Comfort	73.1	11.7	68.9	77.3	63.9 $^{a\ b}$	18.8	57.1	70.6	75.0	15.9	69.3	80.7	64.7 ^{b}	17.1	58.6	70.8
Heel Cushioning	70.9	13.1	66.2	75.6	66.5	21.3	58.9	74.2	71.8	18.4	65.2	78.4	71.9	16.8	65.9	78.0
Forefoot Cushioning	67.8	16.4	62.0	73.7	65.7	17.9	59.3	72.1	71.1	15.7	65.5	76.7	68.8	17.8	62.4	75.2
Medio-Lateral Control	62.3	16.9	56.2	68.3	62.1	19.2	55.2	69.0	62.8	23.3	54.5	71.1	68.9	16.0	63.1	74.6
Arch Height	60.8	17.6	54.5	67.1	61.4	23.6	52.9	69.8	67.3	21.1	59.8	74.9	56.3	22.3	48.3	64.3
Heel Cup Fit	71.2	16.2	65.4	77.0	67.7	16.2	61.9	73.4	68.7	21.6	61.0	76.4	66.3	21.7	58.5	74.0
Heel Width	71.1	15.7	65.4	76.7	70.3	15.6	64.8	75.9	71.3	18.8	64.6	78.0	68.0	17.0	61.9	74.0
Forefoot Width	69.5	15.3	64.0	74.9	69.1	15.3	63.6	74.6	65.3	20.4	58.0	72.6	67.3	17.2	61.2	73.5
Shoe Length	77.4	13.8	72.4	82.3	72.9	10.8	69.0	76.8	74.1	14.2	69.0	79.2	69.3 ^{a}	15.2	63.9	74.8

a = Significantly different from Control

b = Significantly different from Athlete

There was a significant effect of condition on overall comfort (p = 0.002). Post hoc analysis revealed significantly greater overall comfort for AT (75.0 ± 15.9) versus AC (63.9 ± 18.8) (p = 0.012, ES = 0.64), AT versus WR (64.7 ± 17.1) (p = 0.025, ES = 0.62), and AC versus CON (73.1 ± 11.7) (p = 0.055, ES = 0.60) (Appendix A, Figure. A.7). There was also a significant effect of condition on the “length” item (p = 0.033). Post hoc analysis revealed significantly shortened perceived length for WR (69.3 ± 15.2) versus CON (77.4 ± 13.8) (p = 0.018 ES = 0.56). Further, there was no significant effect of insole condition on heel cushioning (p = 0.518), forefoot cushioning (p = 0.553), mediolateral control (p = 0.324), arch height (p = 0.042), heel cup fit (p = 0.647), heel width (p = 0.753), or forefoot width (p = 0.705).

3.4 Discussion

The primary purpose of this investigation was to determine whether the use of pre-fabricated insoles resulted in any acute changes to running biomechanics. A secondary purpose was to assess changes in perceived footwear comfort when using each of the three insoles relative to the control condition. Although no significant changes were found with respect to PTA or shock attenuation during the stance phase, there were differences in the sagittal plane kinematics of the foot and ankle between conditions. Furthermore, significant differences in overall footwear comfort and preceived length were also observed. The main findings will be discussed below in relation to the aims and objectives, and in light of the current literature.

3.4.1 Peak tibial acceleration

The magnitude of tibial acceleration is indicative of load experienced by the tissues of the musculoskeletal system (42). Repetitive cumulative load may exceed the tissue’s capacity to manage this load, or provide insufficient time for the structures to repair and remodel between loading cycles (43-45). This may result in microtrauma to the musculoskeletal system, potentially progressing to overuse injuries such as medial tibial stress syndrome and tibial stress fractures (11, 46). These injuries account for 9.5% and 4.5% of running-related injuries respectively (47). Peak tibial acceleration may be influenced by lower extremity joint flexion and segment orientation at the moment of touchdown (46, 49). The magnitude of this acceleration may be attenuated passively through soft tissue and cushioning footwear (78). Since the contributors to tibial acceleration are multifactorial, an investigation into lower limb orientation and alignment should be conducted alongside studies assessing the effectiveness of cushioning insoles to provide this passive attentuation.

The main focus of this study was to determine if pre-fabricated insoles influence tibial acceleration. We found no significant change in PTA between any of the conditions tested. Although there is no consensus in current literature regarding the influnce of insoles on tibial acceleration, several investigations have yielded similar results, thus our findings were largely expected. Following a one- to two week adjustment period to pre-fabricated and custom-made insoles, PTA may not be significantly different in comparison to the control condition (27, 67). This applies to both rearfoot and non-rearfoot striking runners. There have, however, been reports that pre-fabricated insoles may significantly reduce PTA (26). Studies focusing on the cushioning properties of running shoes, without the use of additional insoles, have come to similar conclusions. Evidence suggests that increased midsole thickness may be directly correlated to increased contact time due to an increase in time for the midsole to deform. The increased time to deform, in turn, reduces avereage vertical GRF loading rate, which has been correlated with PTA (32, 65). Despite the increase in contact time and subsequent reduction in vertical GRF loading rates, differences in midsole thickness do not seem to signifficantly affect PTA (32, 105). This trend may also not hold true for midsoles beyond 25 mm in thickness, as there is evidence indicating that exceptionally thick midsoles beyond 25 mm may increase vertical GRF loading rates (65). Thus, there are conflicting findings with regards to the effect that improved cushioning may have on PTA. Furthermore, it has been established that highly cushioned footwear may increase knee- and ankle joint stiffness, thereby potentially increasing impact loading in comparison to less cushioned footwear (115, 116). Although impact shock may be modestly attenuated by footwear cushioning, PTA is largely dependent on segment orientation and joint flexion distal to the tibia, while shock attenuation is influenced by joints flexion proximal to the tibia. These sagittal plane adjustments in response to the pre-fabricated insoles will be further discussed bellow.

3.4.2 Sagittal plane kinematics

Further, we investigated the effect of pre-fabricated insoles on joint angles, segment orientations, and spatiotemporal parameters. Foot pitch at touchdown was significantly greater in the Athlete and Walker Runner insoles compared to the Control condition. Related to this, ankle dorsiflexion at contact was significantly greater in the Walker Runner condition. Peak ankle dorsiflexion was significanly greater in the Walker Runner insole, while ankle joint ROM was significantly lower in the Walker Runner and Arch Cushioned insoles by comparison to the Control condition. No significant differences were seen in shank inclination, nor hip and knee flexion between any of the conditions. These findings were largely expected considering the general trend in the current literature (24, 32-35). When comparing midsoles of varying thicknesses to barefoot running conditions, significant increases in ankle dorsiflexion at touchdown and knee joint ROM have previously been reported, while ankle joint ROM reflected a significant decrease. Although midsoles ranged in thickness from 0mm to 16mm, it was also noted that no significant differences in joint flexion or segment inclination were observed between the any of the shod conditions (32). Following a gradual two week adjustment period, custom-made insoles have been shown to yield a decrease in ankle dorsiflexion at touchdown. Although peak ankle dorsiflexion showed little change, this resulted in an increase in ankle joint ROM (67). Previous studies have reported increased knee flexion at touchdown, whereas we found no significant change to knee flexion. Again, peak knee flexion remained largely unchanged, resulting in a significant reduction in knee flexion ROM in the custom-made insole condition compared to the Control condition (67). Investigations have also compared maximalist, minimalist, and conventional running footwear to determine differences which may be brought on by varying midsole thickness. Significant increases in ankle dorsiflexion angle at touchdown and relative knee flexion ROM have been observed only when comparing maximalist footwear to minimalist footwear, and conventional footwear to minimalist footwear. When comparing conventional footwear to maximalist footwear no significant differences were found. (105). Joint flexion at impact determines the magnitude of shock attenuation. Reduced joint flexion allows impact forces to travel more closely to the joint centres, thus reducing the ability to actively attenuate impact shock. This may place increased demands on passive attenuation mechanisms. Alternatively, increased joint flexion after touchdown directs impact forces away from the joint centres, placing a larger degree of the attenuation burden on the eccentric contraction of muscles (42). The knee plays a large role in shock attenuation, with the eccentric contraction of the quadriceps and resulting knee extensor moment contributing to a substantial amount of energy absorbed at the knee (23, 90). Our results demonstrated both a non-significant change in hip- and knee flexion ROM during stance phase, as well as a non-significant difference in impact shock attenuation between all conditions. The lack of a significant difference in shock attenuation may be attributed to the lack of significant difference in hip- and knee joint flexion ROM. Although foot inclination at initial contact was significantly higher in the Athlete and Walker Runner insole conditions compared to the control condition PTA did not significantly differ between the control and these experimental conditions. It could be inferred that increased cushioning in the Athlete and Walker Runner insoles may have mitigated any increase in impact shock as a result of increased foot inclination at initial contact. This could be attributed to the increased composition of the heel as well as the thickness in the heel of the Athlete and Walker Runner insoles. The Athlete insole included a gel in the heel and measured 9mm in thickness, while the 7.5mm thick heel of the Walker Runner included a Spencore heel plug. Notably, these qualities of the heels of these two insoles were proposed by the manufacturers to increase cushioning.

3.4.3 Spatiotemporal parameters

The spatiotemporal parameters were not significantly different between conditions, however this was the intended outcome as a result of maintaining a running speed within a 5% margin of the control condition. Significant changes in stride length with or without a change in stride frequency would potentially have increase shin inclination, thereby influencing PTA through increased antero-posterior tibial acceleration. Antero-posterior tibial acceleration is a major component in the resultant vector we investigated. In other studies which controlled running speed for this purpose, no significant changes in stride length or stride frequency were reported (27, 116).

3.4.4 Footwear comfort

Footwear comfort is a subjective criteria consisting of multiple factors, however cushioning has been highlighted as one of the leading factors by which footwear comfort is assessed (38). Comfort is considered to be the deciding factor in the selection of footwear, with evidence indicating an inverse relationship between footwear comfort and risk of injury (120, 122). There is conflicting evidence in the current literature regarding the relationships between footwear comfort and biomechanical variables associated with common running-related injuries. A significant correlation between increased perceived comfort and reduced peak axial tibial acceleration has been reported in a previous study, though it was noted that the magnitude of this correlation was low at r = 0.23 (125). Conflicting evidence found no significant correlation between perceived comfort and peak axial tibial acceleration. Increased perceived comfort was, however, associated with an increase in vertical GRF impact peak and reduced average vertical GRF loading rate (123). This is partially supported by an investigation which reported a reduced average vertical GRF loading rate associated with increased perceived comfort. Peak vertical GRF, however, showed little change (29). A further study found no significant correlation between perceived footwear comfort and either peak GRF and vertical GRF loading rates (124). The direct relationship between vertical GRF loading rates and PTA has been established, thus data reflecting correlations to these loading rates may be interpreted to have similar effects on PTA (19).

The footwear comfort assessment in our study identified that the control condition scored significantly higher in the overall comfort scale than the Arch Cushioned condition, while the Athlete condition score was significantly higher in overall comfort than both the Walker Runner and Arch Cushioned conditions, and similar to the control. With respect to the pre-fabricated insoles used in this study, a number of differences may be noteworthy in relation to the comfort scores. Firstly, the Athlete and Arch Cushioned insoles are purported to primarily provide comfort, with the Athlete insole also providing cushioning, while the Walker Runner insole is marketed as a cushioning insole. Although there was no significant difference in the arch height scores, it is possible that the presence of this prominent arch cushion contributed to the lower overall comfort score of the Arch Cushioned insole. The Walker Runner insole, which was primarily suggested to improve the cushioning of impact, also scored significantly lower in the overall comfort scale and contains a small arch cushion as well. Secondly, regarding thickness, the Athlete insole had greater heel (9mm) and forefoot (8mm) thickness with only a 1mm offset. The Arch cushioned insole had the thinnest stack heights of 6.35mm in the heel and 4mm in the forefoot with a more substantial offset of 2.35mm. The Walker Runner insole had the lowest offset at 0.7mm, with a heel stack height of 7.5mm and a forefoot stack height of 6.8mm. Conventional running shoes generally have heel-to-toe offsets between 8mm and 12mm, thus significant changes to the heel-to-toe offset may potentially also result in lower perceived comfort since runners are fairly sensitive to this.

3.4.5 Further considerations

The Athlete and Walker Runner insoles are proposed to enhance cushioning. These insoles also yielded significantly increased foot pitch compared to the control condition and the Arch Cushioned insole. The ankle dorsiflexion at touchdown and peak ankle dorsiflexion during the stance phase was increased in the Athlete insole, however only the Walker Runner insole yielded a significant increase in comparison to the Arch Cushioned and Control conditions. The dorsiflexion ROM, however, was smaller in Walker Runner than Control condition, and similar between Walker Runner and Arch Cushioned. It may be possible that, in order to maintain similar pelvic acceleration, runners adjusted their foot pitch at impact to achieve similar tibial accelerations, thereby negating the enhanced passive shock attenuation of the cushioned pre-fabricated insoles. Based on our research, this appears to be the case during acute response to pre-fabricated insoles, however this might not hold true following a prolonged adjustment period.

3.4.6 Strengths and limitations of the study

This study may have been limited by a number of factors, most notably the running surface used during data collection. We utilised a Mondo athletics track, which had the benefit of being convenient for testing, providing a safe environment, and providing a level running terrain. Endurance running, however, generally occurs on a firmer surface such as asphalt. Since the running surface was level, inferrences regardig the effect of pre-fabricated insoles on incline- and decline running can not be made. This is particularly true for joint angles and segment orientations, as well as the resulting accelleration and shock attenuation.

Participants were instructed to run in their own choice of footwear, and although oversight was presented in order to ensure conventional running shoes were used, it is possible that significant discrepancies in footwear age and mileage exist. As a result,differences in the cushioning properties of running shoe midsoles may lead to significantly different shock attenuation between participants regardless of in-shoe conditions. Although the investigation assessed the insole conditions, the passive attenuation of the footwear condition would have been comprised of the running shoe and the pre-fabricated insole condition together as opposed to the insole in isolation. Although this would only affect inter-runner PTA, it is still worth noting that cushioning capacity between participants may vary. The participants selected shoes in which they felt most comfortable, however, standardising the shoe across all participants may have risked variations in perceived comfort even in the absence of the pre-fabricated insoles.

Although the resultant tibial- and pelvic accelerations investigated in this study were calculated using the antero-posterior, medio-lateral, and vertical accellerations, the joint angles and segment orientations assessed were only in the sagittal plane. The sagittal plane accounts for the majority of the kinematic movements, however inspection of the frontal- and transverse plane kinematics may provide further information as to the effect of pre-fabricated insoles on joint angles and segment orientations in those planes of motion. This would include factors such as rearfoot eversion and hip internal/external rotation.

Running speed was also controlled to be within a 5% margin of the control condition, which limited changes to spatiotemporal parameters, and thus also potential changes to sagittal plane joint angles and segment orientations. Although this was exercised for this very purpose, the possibility exists that adjustments to step parameters in response to the experimental conditions may have lead to significant changes to the biomechanical variables investigated. This, however means that the effect of the experimental conditions would no longer focus on the pre-fabricated insoles in isolation, as we intended to investigate.

Lastly, we investigated the acute effects of the pre-fabricated insoles on the biomechanics of endurance runners, thus the adaptation period to the insoles was limited. Inferences made on the chronic effects of pre-fabricated insoles on running biomechanics should be discouraged.

3.4.7 Summary and conclusion

The three pre-fabricated insoles assessed in this study showed no significant effect on PTA or shock attenuation. Additionally, spatiotemporal parameters did not significantly change. This is likely due to a combination of strict running speed control within a 5% margin and the skill of the participants, aqcuired through experience, to maintain similar stride length and cadence at a set pace. Significant sagittal plane kinematic differences were noted in foot inclination and ankle dorsiflexion at touchdown, as well as peak ankle dorsiflexion during stance, and ankle dorsiflexion ROM. These findings are in alignment with evidence in the current literature. It has previously been found that, although greater cushioning significantly reduces PTA compared to minimalist running shoes, there is no significant difference in PTA between shoes with greater cushioning (105). Likewise, following an adjustment period, no significant difference in PTA has been found when comparing pre-fabricated to a conventional running shoe (27, 67). Additionally, several studies have reported an increase in ankle dorsiflexion and foot inclination at touchdown with increased cushioning (24, 32-35). Furthermore, two of the pre-fabricated insoles were considered to have significantly lower overall comfort than the Control condition, while one yielded a significantly lower shoe length score.

Although the pre-fabricated insoles investigated in this study did not result in any significant acute changes to peak acceleration or shock attenuation, the significant and clinically relevant changes noted regarding ankle dorsiflexion and overall footwear comfort may be of value to runners considering making use of pre-fabricated insoles. Pre-fabricated insoles with enhanced cushioning may increase ankle dorsiflexion and foot inclination at touchdown, encouraging touchdown to be made with the heel. Although there is no effect on tibial acceleration, these changes may cause discomfort as runners adjust to the potential changes in ankle flexion and foot angle at touchdown, particularly if the adjustment period to the pre-fabricated insoles is brief and continuous. These findings may only apply to the acute effects with short-term use, while chronic exposure may result in adjustments to running speed and, stride length, and sagittal plane kinematics. Further research will be required to determine effects of chronic exposure to pre-fabricated insoles on running biomechanics in a field setting.

Since there appears to be no significant short-term influence on tibial acceleration, runners may benefit more from selecting pre-fabricated insoles based on their perceived comfort. Additionally, it may be wise to highlight the importance of an incremental adjustment period to the pre-fabricated insoles in order for runners to progresively adapt to the insoles and the potential changes to ankle dorsiflexion and foot angle at touchdown.

Chapter four: Conclusion

4.1 Conclusion

The purpose of this dissertation was to firstly review the literature on biomechanical variables of interest, and secondly to investigate the effect of three different pre-fabricated insoles on these same biomechanical variables during running. The particular variables of interest included tibial acceleration, shock attenuation, and sagittal plane lower limb joint angles and segment orientation. Additionally, this study investigated the effect on perceived footwear comfort of these three pre-fabricated insoles for endurance runners.

4.1.1 Summary of literature review

Through a review of the literature, it was established that GRF is an approximate measure of the load the musculoskeletal system is placed under when the foot collides with a running surface. The vertical GRF loading rate is an appropriate proxy measure of the load applied to the lower extremities. Vertical GRF loading rates have been shown to closely correlate with foot- and shank inclination at touchdown, as well as tibial stress fractures. Tibial acceleration has also been closely correlated with vertical GRF loading rates, and has been suggested to be a reasonable proxy measure of mechanical load acting on the tibia. The sensitivity of tibial acceleration and ease of using triaxial accelerometers makes it a more appropriate variable to measure. Triaxial accelerometers are able to accurately measure acceleration in all three planes of motion, with the single resultant tibial acceleration single metric constituting acceleration data from all three planes. Tibial acceleration is dependent on running speed, as well as joint flexion and segment orientation at touchdown. As running speed increases stride length increases in response. An increase in stride length is associated with increased ankle dorsiflexion but reduced knee flexion at touchdown. This results in increased shin inclination, leading to increased tibial acceleration. This establishes a direct association between running speed and adjustments to stride length with tibial acceleration.

Shock attenuation is an important function in order to maintain a steady field of vision while moving, and attenuation mechanisms filter out high frequency acceleration as it moves up the musculoskeletal system. Active shock attenuation of the lower limbs primarily occurs through the eccentric contraction of the muscles surrounding the knee during flexion whist under load, allowing impact forces to be directed away from joint centres. Shock attenuation is influenced by the perpendicular distance between the point of ground contact and the body's centre of mass, thus increased stride length would require greater shock attenuation through increased joint flexion. The cushioning material in footwear act as a passive shock attenuation mechanism during impact. Although there is evidence to indicate that cushioned running shoes are able to significantly reduce tibial acceleration compared to minimalist and barefoot condition, there appears to be no significant difference between cushioned conditions. Research related to the effect of pre-fabricated insoles in tibial acceleration has yielded conflicting results. It should also be noted that increased cushioning may increase stride length, ankle dorsiflexion angle at touchdown, and knee flexion range of motion during stance phase.

4.1.2 Summary of results from the current study

We established that:

- pre-fabricated insoles had no significant effect on peak tibial acceleration or shock attenuation
- the Walker Runner pre-fabricated insoles significantly increased foot pitch- and ankle dorsiflexion at touchdown and peak ankle dorsiflexion compared to both the Control- and the Arch Cushioned conditions
- the Athlete pre-fabricated insoles significantly increased foot pitch at touchdown compared to the Control condition
- the Walker Runner- and Arch Cushioned pre-fabricated insoles significantly reduced ankle dorsiflexion ROM compared to the Control condition
- pre-fabricated insoles had no significant effect on shank pitch, knee flexion, or hip flexion
- pre-fabricated insoles had no significant effect on stride length, cadence, or running speed

- the Arch Cushioned pre-fabricated insole significantly reduced overall footwear comfort compared to the Control condition
- the Athlete pre-fabricated insole yielded significantly improved overall footwear comfort scores compared to the Arch Cushioned- and Walker Runner insoles
- the Walker Runner insole significantly reduced perceived footwear length compared to the Control condition

4.2 Practical implications

The acute effects of pre-fabricated insoles on tibial acceleration and lower limb joint kinematics in a field setting appear to be similar to those reported in laboratory settings. Although the pre-fabricated insoles investigated in this study did not result in any significant acute changes to PTA or shock attenuation, the significant and clinically relevant changes noted may be of value to runners considering making use of pre-fabricated insoles. Pre-fabricated insoles with enhanced cushioning may increase ankle dorsiflexion and foot inclination at touchdown, encouraging touchdown to be made with the heel. These changes may cause discomfort as runners adjust to the potential changes in ankle flexion and foot angle at touchdown, particularly if the adjustment period to the pre-fabricated insoles is brief and continuous. In addition, pre-fabricated insoles may significantly alter perceived comfort while running. While one of the pre-fabricated insoles in the current study was statistically considered significantly to be less comfortable than the control condition, a few participants expressed enhanced comfort in the same pre-fabricated insole. Since perceived sense of comfort is subjective in nature, it may still be dependant on factors such as foot structure and foot mechanics. It should also be noted that changes is perceived footwear comfort may, in turn, prompt adjustments in running mechanics which could be to the benefit or detriment of the runner. Since footwear comfort is a significant motivator for choice in footwear, the selection of pre-fabricated insole should carefully consider this. Further investigation may be required to determine the chronic effects on lower limb kinematics and perceived comfort.

These findings may only apply to the acute effects with short-term use. Chronic exposure may result in adjustments to running speed and, as a result, stride length and sagittal plane kinematics. Should it result in reduced stride length, this may be advantageous to runners, allowing greater joint flexion and reduced segment inclination at touchdown, resulting in reduced PTA. Alternatively, this may be detrimental to runners should stride length increase, with a consequent decrease in joint flexion and increase in segment inclination at touchdown, resulting in an increase in PTA. Further research will be required to determine the chronic effects of pre-fabricated insoles on running biomechanics in a field setting.

Since there appears to be no significant short-term influence on PTA, runners may benefit more from selecting pre-fabricated insoles based on their perceived comfort. Significant differences in foot inclination at touchdown and ankle dorsiflexion at touchdown and during stance phase were observed for both the most comfortable and least comfortable pre-fabricated insoles. Creating an awareness of these potential kinematic adjustments and the change to musculoskeletal load they might induce could be of importance to runners choosing to make use of insoles. Thus, it may be wise to highlight the importance of an incremental adjustment period to the pre-fabricated insoles, including a gradual increase in running volume and intensity as with any change in footwear. This allows runners to progresively adapt to the insoles and the potential changes to ankle dorsiflexion and foot angle at touchdown.

4.3 Recommendations for future research

Future research expanding the literature on this topic is greatly encouraged, with specific emphasis on field testing as opposed to laboratory testing and the utilisation of motorised treadmills. In particular, future research should investigate the long-term changes brought about by pre-fabricated insoles. Running on terrain with an incline and decline require adjustments to spatiotemporal parameters and sagittal plane kinematics. For this reason it may also be of interest to determine the effect of pre-fabricated insoles on running biomechanics during uphill and downhill running. Further investigations into frontal and transverse plane kinematics may add a great deal of insight regarding the effect of pre-fabricated insoles on running biomechanics. Since evidence exists that additional weight and alterations in mechanics may increase the cost of locomotion it may be of interest to include such considerations in future research related to pre-fabricated insole. Although practically negligible, the inclusion of pre-fabricated insole may alter the heel- and forefoot stack heights, as well as the heel-to-forefoot offset. Such changes in isolation may alter running mechanics. In addition to an increase in thickness, pre-fabricated insoles may potentially also differ in texture. Such differences may influence foot muscle recruitment and activation patterns. Although research on this exists in laboratory conditions, there is limited information related to field settings. Finally, it may be of interest to investigate the changes in spatiotemporal variables prompted by pre-fabricated insoles at various running speeds.

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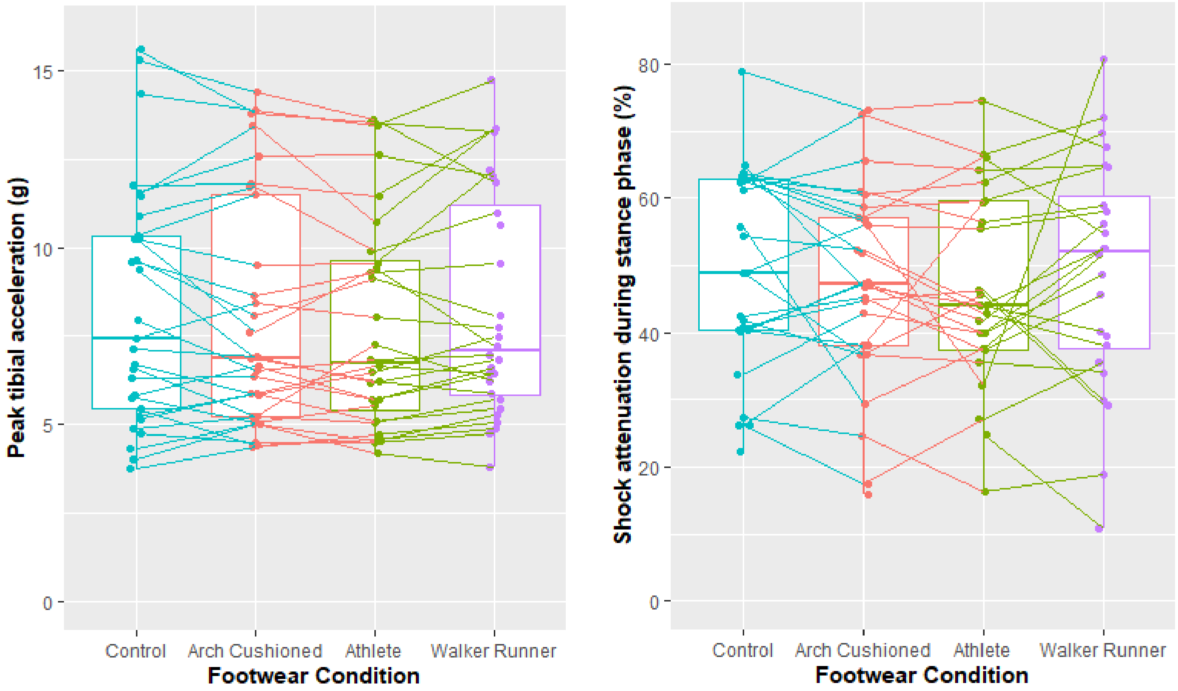
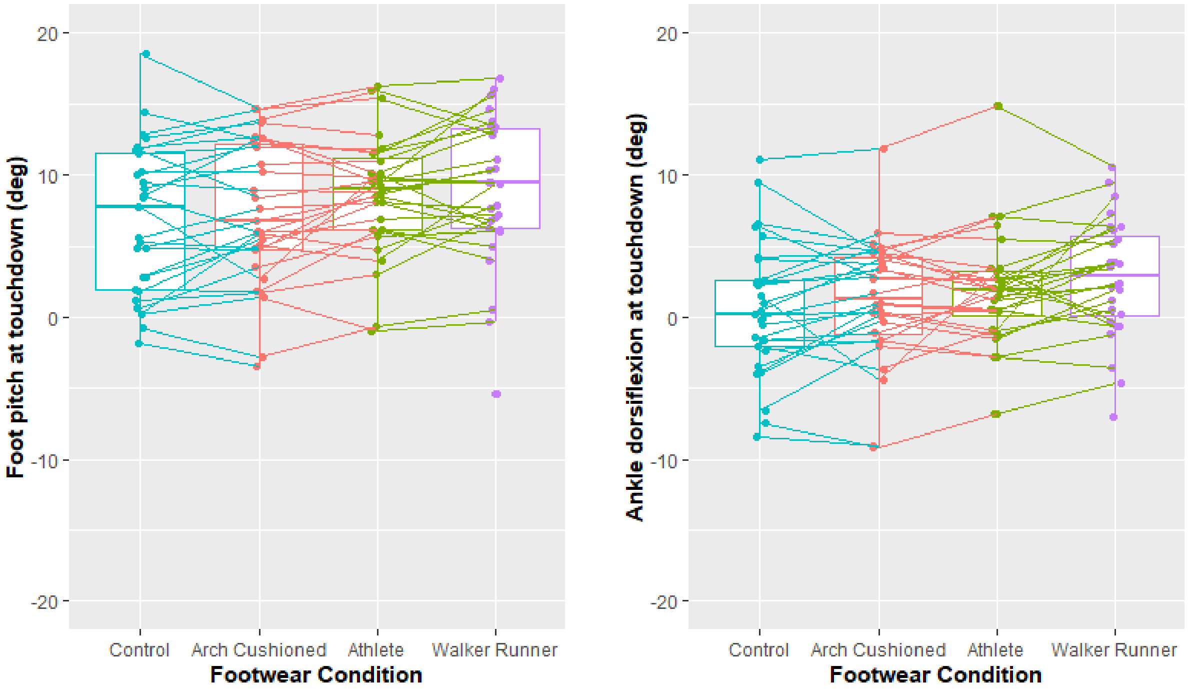
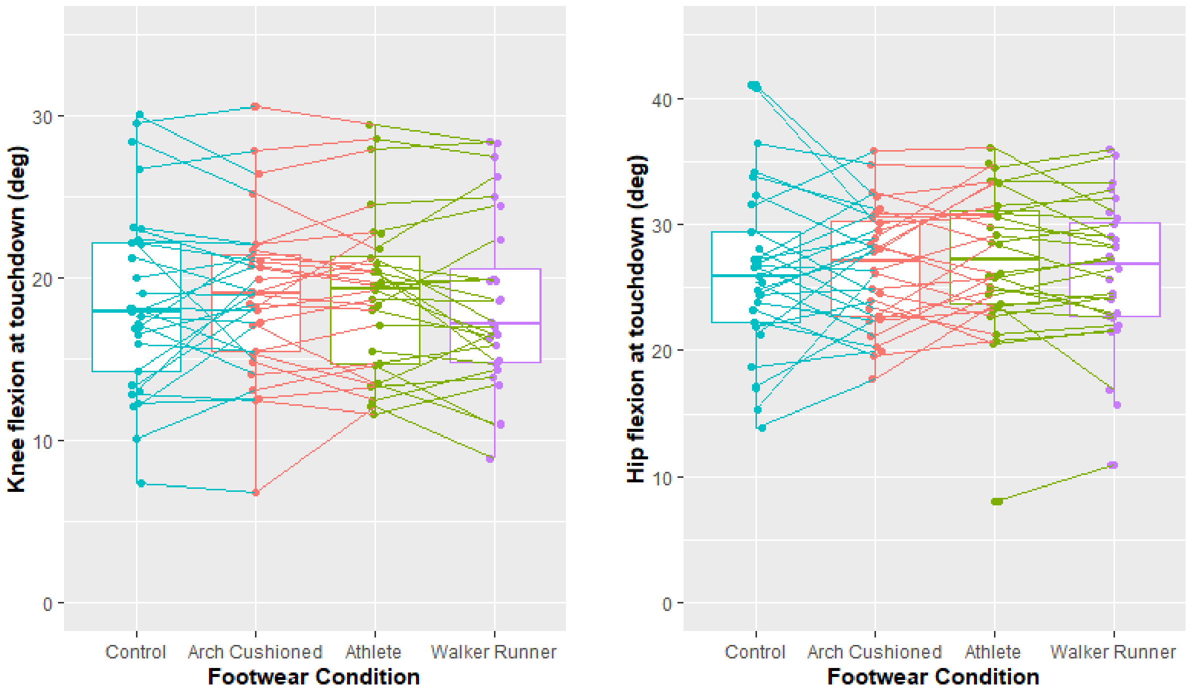
Appendix A: Box plot figures for selected results



***Figures A.1 and A.2:** Mean peak tibial acceleration and mean shock attenuation across control and experimental conditions. No significant differences were found between conditions.*



***Figures A.3 and A.4:** Mean foot pitch at touchdown and mean ankle dorsiflexion at touchdown across control and experimental conditions. Significant foot pitch differences were found between Control and Athlete ($p < 0.05$), Control and Walker Runner ($p < 0.001$), and Arch Cushioned and Walker Runner ($p < 0.01$). Significant ankle dorsiflexion differences were found between Control and Walker Runner ($p < 0.001$), and Arch Cushioned and Walker Runner ($p < 0.01$).*



Figures A.5 and A.6: *Mean knee flexion and mean hip flexion at touchdown across control and experimental conditions. No significant differences were found between conditions.*

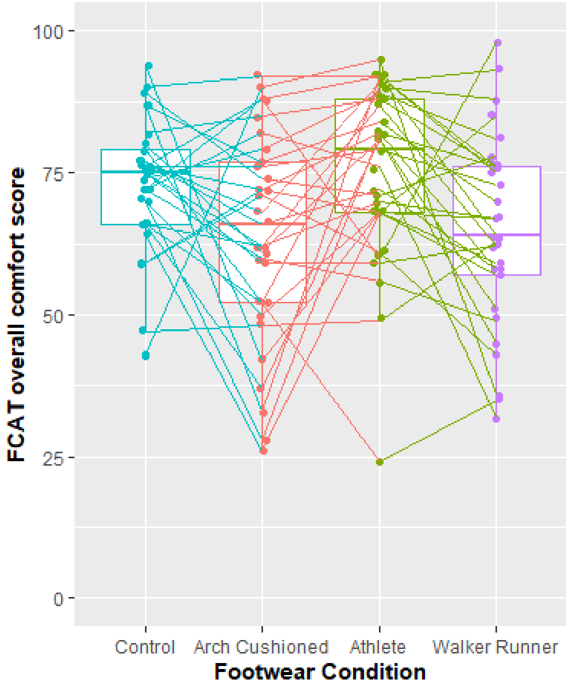


Figure A.7: *Mean overall comfort scores across control and experimental conditions. Significant differences were found between Control and Arch Cushioned ($p < 0.1$), Athlete and Arch Cushioned ($p < 0.05$), and Athlete and Walker Runner ($p < 0.05$).*

Appendix B: Participation information and informed consent form

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ADULT PARTICIPANT INFORMATION AND INFORMED CONSENT DOCUMENT

The Acute Effects of Pre-fabricated Insoles on Tibial Acceleration and Kinematics of Endurance Runners

Introduction

You are invited to volunteer to participate in a research study. This leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions that are not fully explained in this leaflet, do not hesitate to contact the investigators.

The nature and purpose of this study

Researchers from the Sport, Exercise Medicine and Lifestyle Institute at the University of Pretoria will conduct a study entitled “The Acute Effects of Pre-fabricated Insoles on Tibial Acceleration and Kinematics of Endurance Runners”. The study aims to determine if pre-fabricated insoles a) reduce tibial acceleration, b) alter lower limb kinematics, and c) increase perceived comfort in endurance runners.

Explanation of procedures to be followed

Your participation in this research study is entirely voluntary. should you agree to participate, you would be asked to give consent to participate in the following components of the study:

- Seven (7) sensors measuring 3D motion will be attached to your person in the following locations using elasticated Velcro straps: the instep of the left and right foot under the shoe laces, the inside of the left and right shin, the outside of the left and right thigh over the Iliotibial band, and back of the pelvis.
- You will be asked to perform a short calibration by standing still for a few moments in a neutral posture with your feet under your hips and pointing straight forwards.
- You will then be asked to run a single lap around an athletics track in the 8th lane (roughly 454m) at your average training pace in your running shoes with the original sock liner inserted.
- Once the lap is completed, you will be asked to fill a short questionnaire containing nine (9) scales by which to rate the comfort of the shoes and insoles you had just run in.
- You will then receive the same pair of running shoes with one (1) of four (4) inserted, after which will again be asked to perform a short calibration, 454m run at your average training pace, and to complete another questionnaire.
- This sequence will repeat until four (5) successful running trials have been completed within the required pace as determined by your first 454m run. You will be allowed to fully recover for 5 – 8 minutes between each trial.

Potential risks of this study

The completion of questionnaires is not associated with any risk. Questionnaires and other clinical data (paper and electronic) will be kept confidential and secure, and will not be made available to any party other than the research team without the consent of the individual participant.

- The biomechanical assessment requires physical activity which inherently involves some risk of musculoskeletal injury. However, all tasks will involve similar loads and movements that you engage in during regular training and competition. You will be allowed to complete a full warm-up routine of your choice before beginning the testing. All reasonable precautions to reduce the risk of injury will be taken, and all testing will be conducted by appropriately qualified staff.
- You may withdraw from this study at any time without question.
- You may request the removal of your data from this study, during or after completion of the study, at any time without question.

Potential benefits of this study

You will be provided with the results of your impact readings as well as your comfort ratings. This information may be useful in future decisions regarding the use of insoles. The research questions that will be addressed by this study have been identified to have a direct impact on improving injury prevention and management in endurance runners. The anticipated benefits of this study are that the results will further our understanding of the effect pre-fabricated insoles may have on mechanical load and risk of overuse injuries such as shin splints.

Ethical Approval

This Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria (telephone number 012 356 3084) and written approval has been granted by that committee.

Confidentiality

All records obtained whilst in this study will be regarded as confidential. Once we have analysed the information no one will be able to identify you. Results will be published or presented in such a fashion that participants remain unidentifiable.

Contact

Please feel free to contact a member of the research team or the University of Pretoria Health Sciences Research Office should you have any questions related to the study. You can contact the principal investigator on the following number: (012) 420 1804.

Faculty of Health Sciences - Research Ethics Committee
Tswelopele Building, Level 4, Rooms 4-59 and 4-Faculty of Health Sciences, Dr Savage Road, Gezina, Pretoria
Tel: (012) 356 3084 or (012) 356 3085
Fax: (012) 354 1367
Email: manda.smith@up.ac.za / deepeka.behari@up.ac.za / fhsethics@up.ac.za

Consent to participate in this study

I confirm that I have received, read (or had read to me) and understood the above written information regarding the nature, process, risks, discomforts and benefits of the study. I have been given opportunity to submit questions and am satisfied that they have been answered satisfactorily. I agree that research data provided by me or with my permission during the study may be included in a thesis, presented at conferences and published in journals on the condition that neither my name nor any other identifying information is used. I understand that if I do not participate it will not alter my management in any way. I understand that I may withdraw from this study at any time without further question.

I hereby consent to participate in the research study as described in the participant information that I received

Please complete the participant and witness columns:

	Participant	**Witness**	**Investigator**
Name Please Print			To be completed by research team
Signature			To be completed by research team
Date			To be completed by research team

Appendix C: Physical activity readiness questionnaire (PAR-Q), reproduced from (141)

Physical Activity Readiness Questionnaire (PAR-Q)

DATE: __________________

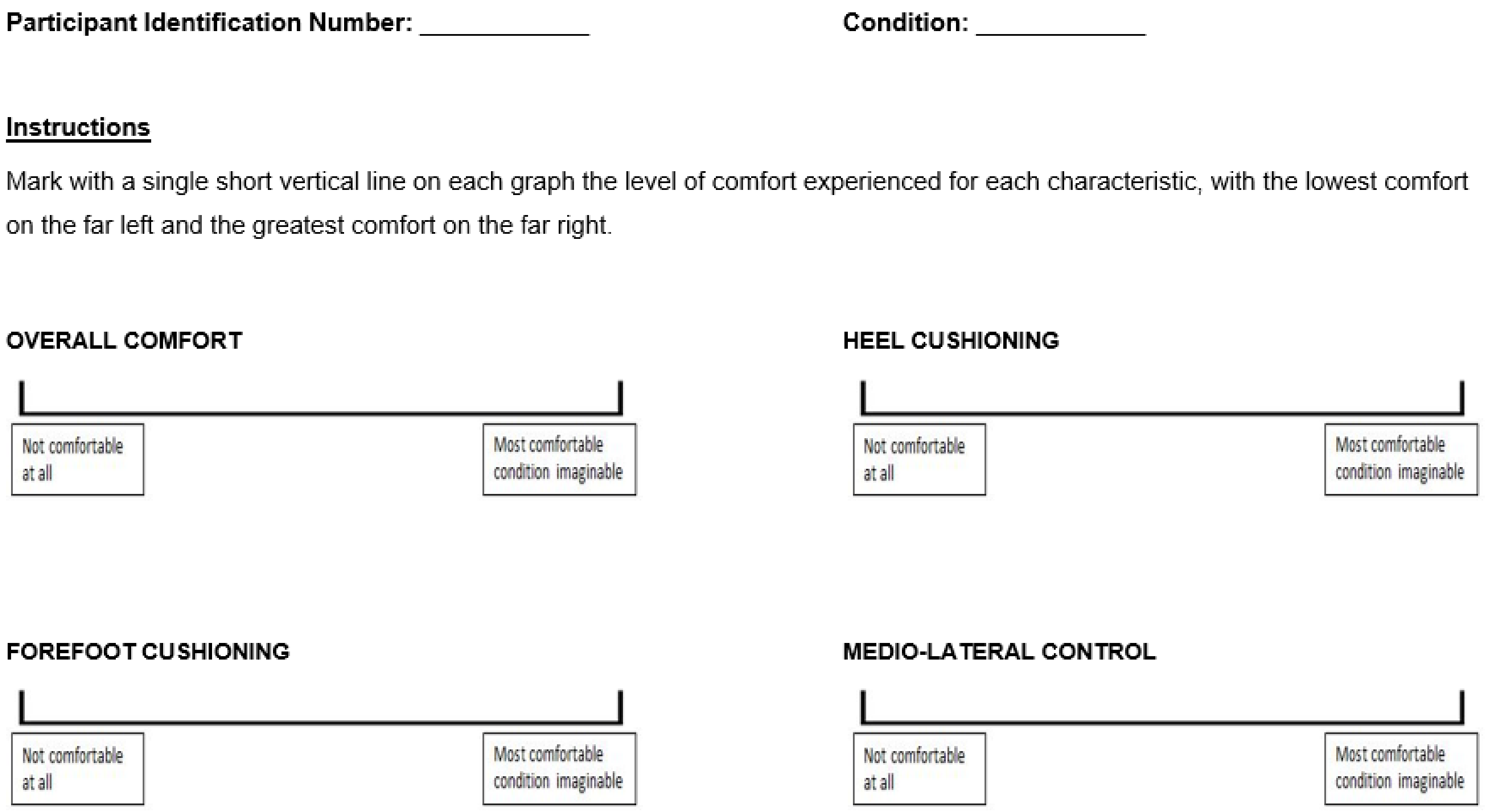
NAME: ____ **AGE:** _______

PHYSICIANS NAME: ______________________________ **PHONE:** _________________

	Questions	**Yes**	**No**
1	Has your doctor ever said that you have a heart condition and that you should only perform physical activity recommended by a doctor?		
2	Do you feel pain in your chest when you perform physical activity?		
3	In the past month, have you had chest pain when you were not performing any physical activity?		
4	Do you lose your balance because of dizziness or do you ever lose consciousness?		
5	Do you have a bone or joint problem that could be made worse by a change in your physical activity?		
6	Is your doctor currently prescribing any medication for your blood pressure or for a heart condition?		
7	Do you know of any other reason why you should not engage in physical activity?		

If you have answered “Yes” to one or more of the above questions, consult your physician before engaging in physical activity. Tell your physician which questions you answered “Yes” to. After a medical evaluation, seek advice from your physician on what type of activity is suitable for your current condition.

Appendix D: Footwear Comfort Assessment Tool (FCAT), reproduced from (38)



Participant Identification Number: ____________ **Condition:** ____________

Instructions

Mark with a single short vertical line on each graph the level of comfort experienced for each characteristic, with the lowest comfort on the far left and the greatest comfort on the far right.

OVERALL COMFORT

Not comfortable at all — Most comfortable condition imaginable

HEEL CUSHIONING

Not comfortable at all — Most comfortable condition imaginable

FOREFOOT CUSHIONING

Not comfortable at all — Most comfortable condition imaginable

MEDIO-LATERAL CONTROL

Not comfortable at all — Most comfortable condition imaginable

ARCH HEIGHT

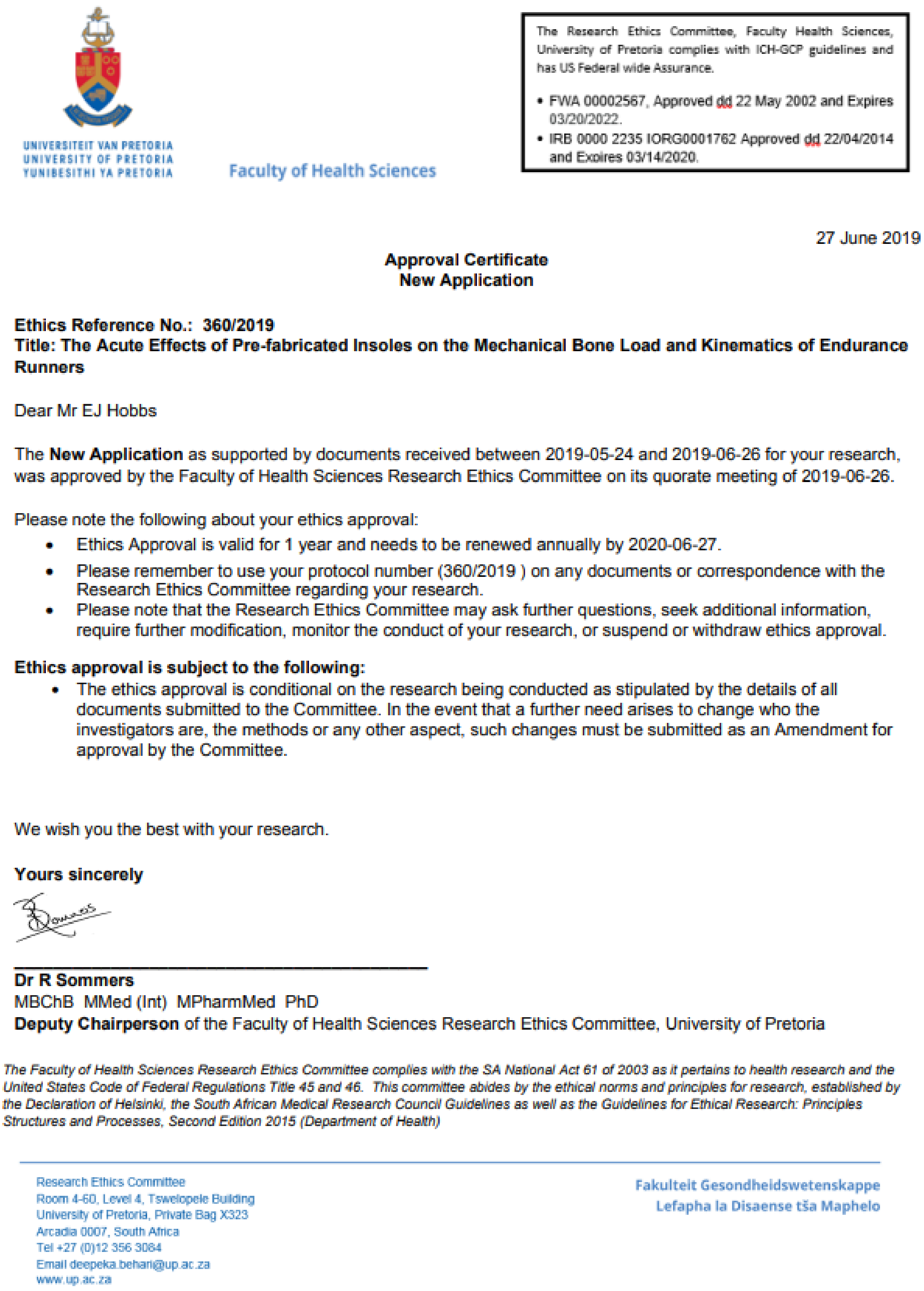
SHOE HEEL WIDTH

SHOE LENGTH

HEEL CUP FIT

SHOE FOREFOOT WIDTH

Appendix E: Letter of approval by the Ethics Committee



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YUNIBESITHI YA PRETORIA

Faculty of Health Sciences

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567, Approved dd 22 May 2002 and Expires 03/20/2022.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 03/14/2020.

27 June 2019

Approval Certificate
New Application

Ethics Reference No.: 360/2019
Title: The Acute Effects of Pre-fabricated Insoles on the Mechanical Bone Load and Kinematics of Endurance Runners

Dear Mr EJ Hobbs

The **New Application** as supported by documents received between 2019-05-24 and 2019-06-26 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 2019-06-26.

Please note the following about your ethics approval:

- Ethics Approval is valid for 1 year and needs to be renewed annually by 2020-06-27.
- Please remember to use your protocol number (360/2019) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

Ethics approval is subject to the following:

- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

Dr R Sommers
MBChB MMed (Int) MPharmMed PhD
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health)

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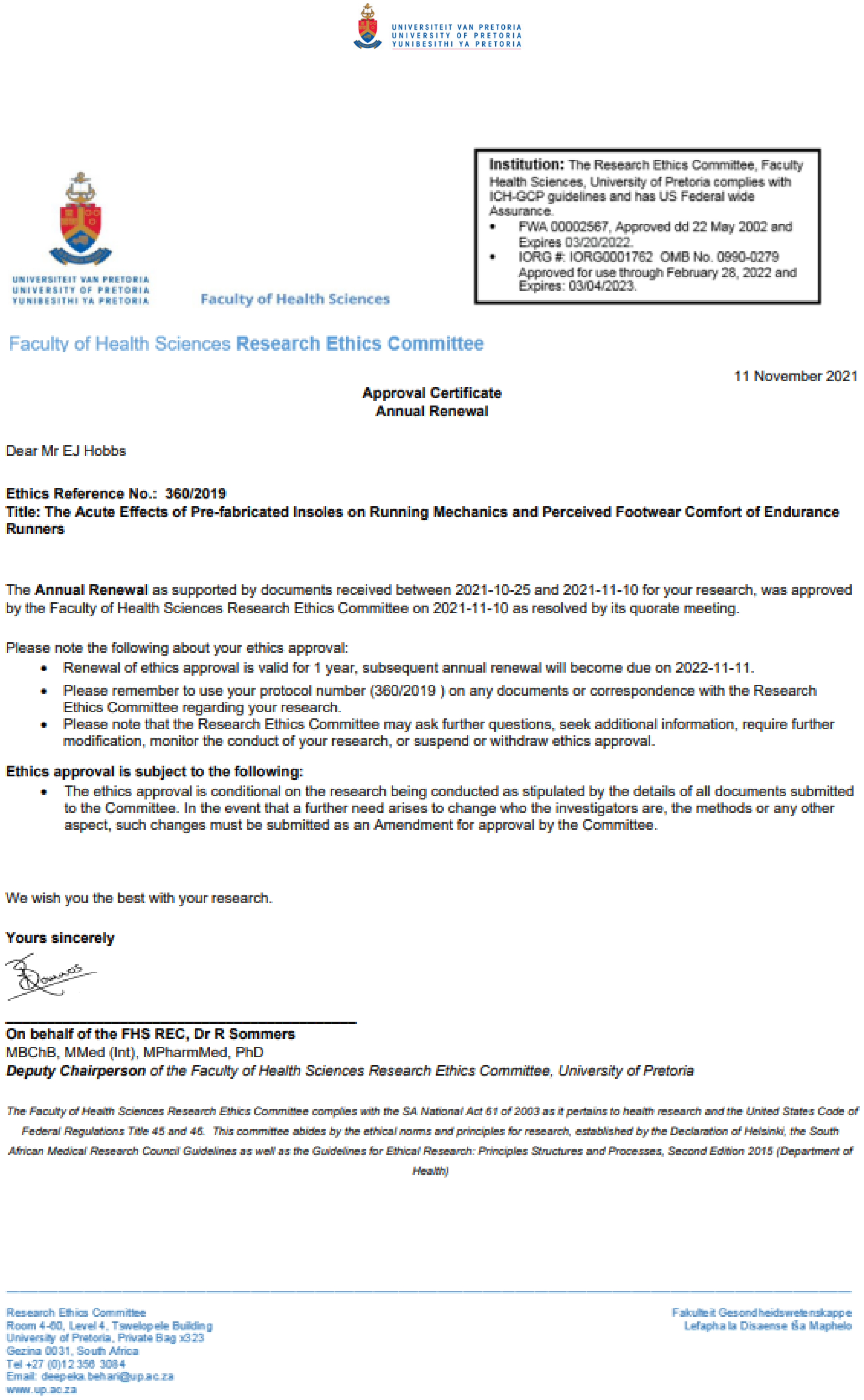
Fakulteit Gesondheidswetenskappe
Lefapha la Disaense tša Maphelo



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Faculty of Health Sciences

Institution: The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567, Approved dd 22 May 2002 and Expires 03/20/2022.
- IORG #: IORG0001762 OMB No. 0990-0279 Approved for use through February 28, 2022 and Expires: 03/04/2023.

Faculty of Health Sciences **Research Ethics Committee**

11 November 2021

Approval Certificate
Annual Renewal

Dear Mr EJ Hobbs

Ethics Reference No.: 360/2019
Title: The Acute Effects of Pre-fabricated Insoles on Running Mechanics and Perceived Footwear Comfort of Endurance Runners

The **Annual Renewal** as supported by documents received between 2021-10-25 and 2021-11-10 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on 2021-11-10 as resolved by its quorate meeting.

Please note the following about your ethics approval:

- Renewal of ethics approval is valid for 1 year, subsequent annual renewal will become due on 2022-11-11.
- Please remember to use your protocol number (360/2019) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

Ethics approval is subject to the following:

- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

On behalf of the FHS REC, Dr R Sommers
MBChB, MMed (Int), MPharmMed, PhD
***Deputy Chairperson** of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria*

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health)

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Fakulteit Gesondheidswetenskappe
Lefapha la Disaense tša Maphelo

Appendix F: Confirmation letter of statistical support for the proposed analysis

saMRC advancinglife

BIOSTATISTICS UNIT

9 April 2019

LETTER OF STATISTICAL SUPPORT

This letter confirms that **E. Hobbs** from the **Department of Physiology, Faculty of Health Sciences of the University of Pretoria** discussed his project: **"The Acute Effects of Pre-fabricated Insoles on the Mechanical Bone Load and Kinematics of Endurance Runners"** with me. I confirm that I will assist with the statistical analysis of the study data.

Data analysis

The descriptive statistics mean, median, standard deviation and inter-quartile range will be used to describe the continuous variables such as kinematic parameters, load and comfort variables. Frequencies and proportions will be used to describe the categorical variables. After examining the data for normality and homogeneity of variances, a one-way repeated measures ANOVA will be used to examine the effect of the condition on the kinematics, load, and comfort variables. using the magnitude thresholds described by Hopkins. Appropriate post hoc tests will be run to determine which conditions differ from each other. Pearson's correlation will be used to measure correlations between different outcome variables. A linear mixed model will be used to compare the conditions controlling for any possible confounders if required. Appropriate graphs such as box plots and bar charts will be used to represent the data graphically. Tests will be evaluated at 5% level of significance. All analysis will be done using STATA 15.

Sample size

The researcher will recruit 45 - 50 participants in the study. A sample of 45 will be powered to detect a difference in paired means of 0.76 with standard deviations in control and treatment group of 1.45 and 1.69 respectively, and correlation between measurements of 0.8 with at least 90% power.

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