VNIVERSITAT DE VALÈNCIA

PhD DEGREE IN PHYSIOLOGY

PhD DISSERTATION

INFLUENCE OF AN INSOLE INTERVENTION ON BIOMECHANICAL PARAMETERS DURING RUNNING WITH AND WITHOUT FATIGUE

A PhD Dissertation presented by:
Mr. ÁNGEL GABRIEL LUCAS CUEVAS

Codirected by:
Mr. SALVADOR LLANA BELLOCH, Ph. D.
Mr. PEDRO PÉREZ SORIANO, Ph. D.

Valencia, 2016

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Submitted to the University of Valencia
in Partial fulfillment of the requirements for the degree of

DOCTOR OF PHILOSOPHY IN PHYSIOLOGY

Departament of Physiology
University of Valencia
Valencia, 2016

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Valencia,

Dr. Salvador Llana Belloch		Dr. Pedro Pérez Soriano		Dr. Mª Carmen Gómez Cabrera

To everyone who has helped me in some way
all these years throughout the
development of this Dissertation.

Acknowledgements

To Dr. Salvador Llana Belloch, for his constant advise throughout the whole dissertation. He has been an important support and his experience and knowledge have been very important for the development of this work. I am very grateful to have him near me.

To Dr. Pedro Pérez Soriano, for his support during this whole work. He has devoted plenty of his time in making me progress and grow within this scientific adventure not only as a student, but also as a person. I really appreciate his constant support.

To Dr. Mª Carmen Gómez Cabrera, for her rigour and advice provided throughout the dissertation. Her suggestions have been extremely useful in the creation of this document. I thank her for being there.

To the podiatrists Dr. Cecili Macian and Dr. Maria Benimeli, who worked very hard to make this study happen. For all those hours analysing the participants and personalising the insoles. For their advice and suggestions in their field of study.

To Dr. Marco Romagnoli and his research team, for their assistance not only during the fatigue protocol but also during the whole study.

To José Priego, José Vicente, Inma, and, in general to all the members of GIBD "Grupo de Investigación en Biomecánica aplicada al Deporte" of the Department of Physical Education and Sports of the University of Valencia, because without their support and help, this study would not have been possible.

To Andrés, Raúl and Daniel, for their assistance throughout the methodology and every time I needed them. They have helped me understand a little bit better their field of expertise and improve the quality of this work with their aid.

To the “Facultad de Ciencias de la Actividad Física y del Deporte” and the “Facultad of Medicina y Odontología” of the University of Valencia for the educational, material and human support received throughout my educational years.

To all the athletes who voluntarily participated in this study. For their energy, involvement and interest in taking part in the project. Without their effort and enthusiasm this study would not have been possible.

To my friends, for all the energy and optimism provided during the whole study and my life, in general.

To Michela, for her patience, unconditional support, and constant understanding. For being there. She has helped me overcome the challenges appearing throughout the whole process.

With special affection, to my family: grandparents, aunts and uncles, cousins and, specially to my parents and brother, Mª Ángeles, Gabriel and Álvaro. They have raised me in the best family and social environment possible, teaching me the most important values in life. I am who I am because of them.

Grants and Funding

This thesis has been supported by the Spanish Ministry of Education and Culture under the Grant FPU12/00574.

This thesis has also been supported by the Spanish Government: Ministerio de Economía y Competitividad, Subdirección General de Proyectos de Investigación, Convocatoria Proyectos I+D “Excelencia”, Subprograma de Generación de Conocimiento (2013), Ref.proyecto: DEP2013-48420-P.

Publications

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- Lucas-Cuevas, A.G., Pérez-Soriano, P., Llana-Belloch, S., Macián-Romero, C., & Sánchez-Zuriaga, D. (2014). Effect of custom-made and prefabricated insoles on plantar loading parameters during running with and without fatigue. Journal of Sports Sciences, 32:1712-1721.
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CONGRESSES

- Lucas-Cuevas, A.G., Camacho, A., Llinares, R, Priego-Quesada, J., García-Pérez, J.A., & Pérez-Soriano, P. *Do foot orthoses and fatigue modify impact acceleration during running?* 25th Congress of the International Society of Biomechanics, Glasgow, 2015.
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- Pérez-Soriano, P., Lucas-Cuevas, A.G., Priego-Quesada, J., & Macián, C. *Presión Plantar influenciada por diferentes tipos de ortesis durante la carrera*. 45

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- Lucas-Cuevas, A.G., Pérez-Soriano, P., Llana-Belloch, S., Aparicio-Aparicio, I., & Giménez-Gil, J.V. *¿Puede el uso de soportes plantares suponer un mecanismo protector en carreras de larga distancia?* VII Congreso Internacional de la Asociación Española de Ciencias del Deporte, Granada, 2012.

ABSTRACT

ABSTRACT (SPANISH)

El uso de soportes plantares está aumentando dentro de la población de corredores por sus demostrados beneficios sobre la redistribución de presiones plantares, la reducción del dolor, y la mejora de la función mecánica de las extremidades inferiores. Sin embargo, en contraposición a los soportes personalizados diseñados por un podólogo, la aparición de soportes prefabricados comercializados sin indicación médica ha provocado una gran controversia. El objetivo de este estudio fue analizar el efecto de soportes plantares (prefabricados, personalizados, control) y el estado de fatiga sobre parámetros espacio-temporales, presiones plantares, impactos de aceleración, y percepción de confort y esfuerzo durante la carrera. Para ello, en tres ocasiones diferentes (para cada uno de los soportes plantares de estudio), 40 participantes (20 hombres y 20 mujeres) fueron analizados antes y después de una carrera fatigante con un sistema de plantillas instrumentadas (Biofoot®) y acelerómetros colocados en tibia y cabeza (Sportmetrics). Además, también se midió la percepción de confort de cada soporte plantar, así como la fatiga percibida durante la carrera.

Los soportes personalizados redujeron la presión plantar en el primer dedo (45%), arco interno (36%) y externo (40%) respecto a los soportes control; y en el talón interno (31%) y externo (53%) respecto a los soportes prefabricados. Además, los soportes prefabricados redujeron la presión en los dedos menores (35%), el arco interno (31%) y externo (31%) en comparación a los soportes control. De igual manera, se observó que los soportes personalizados redujeron la ratio de aceleración en cabeza respecto a los soportes prefabricados (11%) y de control (2%), mientras que los soportes prefabricados condujeron a una mayor ratio de aceleración en tibia (20%). Además, tanto los soportes personalizados como los prefabricados fueron percibidos como más confortables que la condición control.

En conclusión, el uso de soportes plantares personalizados reduce significativamente la carga plantar en zonas de gran importancia para corredores respecto a no llevar soporte y respecto a soportes prefabricados, lo que respalda su uso como estrategia efectiva en la reducción de presiones. Por otro lado, el uso de soportes no alteró de forma significativa los impactos de aceleración, por lo no se debería prescribir su uso con el objetivo de reducir estos impactos. Sin embargo, en los casos donde se prescribe su uso por otras razones (presión plantar, dolor, corrección de la función mecánica, etc.), los soportes personalizados podrían mejorar la transmisión de impactos de aceleración respecto a los soportes prefabricados. Además, el uso de soportes plantares es percibido como algo confortable, lo que favorece la adherencia del corredor a este tipo de soportes.

ABSTRACT (ENGLISH)

The use of insoles is increasing within the running population due to their associated benefits such as reduction of plantar pressures and pain, as well as improvement of the mechanical function of the lower limb. However, in contrast to custom-made insoles designed by a podiatrist in order to face a specific need, the use of prefabricated insoles commercialised without medical prescription is arising a great controversy. The aim of this study was therefore to analyse the effect of insoles (prefabricated, custom-made, control) and the fatigue state on spatio-temporal, plantar pressure, impact acceleration, comfort and fatigue parameters during running. Forty participants (20 men and 20 women) came to the lab on three occasions (each of them corresponding to an insole condition) where spatio-temporal parameters and plantar pressure (Biofoot®), tibial and head impact acceleration (Sportmetrics) were measured before and after a fatiguing run. Moreover, the perception of comfort of each insole and the fatigue perceived during the fatiguing procotol was also analysed.

The custom-made insoles reduced the plantar pressure under the hallux (45%), the medial (36%) and lateral arch (40%) compared to the control condition; as well as under the medial (31%) and lateral heel (53%) compared to the prefabricated insoles. Furthermore, the prefabricated insoles reduced the plantar pressure under the toes (35%), the medial (31%) and the lateral arch (31%) compared to the control condition. Also, the custom-made insoles decreased the head impact rate compared to the prefabricated insoles (11%) and the control condition (2%), while the prefabricated insoles increased the tibial acceleration rate (20%). Finally, both types of insoles (custom-made and prefabricated) were perceived more comfortable than the control condition.

In conclusion, the use of custom-made insoles reduces the plantar loading under areas that are of great interest to runners, what supports their use as an effective strategy to reduce plantar pressures and their potentially role as a strategy to reduce overuse running-related injuries. On the other hand, the use of insoles did not modify impact acceleration and therefore they should not be prescribed with the aim of reducing these impacts. However, in those situations where an insole intervention is needed (to reduce plantar pressure, pain, or correct the mechanical function of the lower limb), the custom-made insoles may provide a greater reduction of the impact accelerations compared to the prefabricated insoles. Moreover, the use of insoles is perceived as comfortable, what favours the adherence to their use.

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ABREVIATIONS

U.S.A.: United States of America

A.C.S.M.: American College of Sports Medicine

B.C.: Before Christ

GRF: Ground Reaction Force

Px: Mean Peak Pressure

TPx: Time to Mean Peak Pressure

PTI: Pressure-Time Integral

PR: Pressure Relative

IBV: Instituto de Biomecánica de Valencia

2D: Two Dimension

3D: Three Dimension

LED: Light-emitting diode

CCD: Charge coupled device

AP: Antero-posterior

ML: Medio-lateral

N: Newton

m²: Square metre

Pa: Pascal

kPa: Kilopascal

cm²: Square centimetre

P: Pressure

F: Force

A: Acceleration

kg: Kilogram

km: Kilometre

m: Metre

cm: Centimetre

mm: Milimetre

h: Hour

min: Minute

s: Second

Hz: Hertz

max: Maximal

VAM: Maximal aerobic velocity

vs: Versus

FPI: Foot Posture Index

mmol: Milimole

µL: Microlitre

BMI: Body Mass Index

N.S.: Non significant

PRE: Running trial before the fatiguing run

POST: Running trial after the fatiguing run

CMI: Custom-made insole

PI: Prefabricated insole

CI: Control Insole (original insole of the shoe)

SUMMARY

(SPANISH)

SUMMARY (SPANISH)

INTRODUCCIÓN

La Actividad Física

La actividad física y el ejercicio regular son prácticas que han experimentado un gran aumento de popularidad en los últimos años y a las cuales han sido asociados numerosos beneficios para la salud. Existe abrumadora evidencia científica que corrobora la asociación entre actividad física y numerosos beneficios para la salud a nivel físico, mental y social. Además, la actividad física ha sido positivamente utilizada como medio clínico preventivo, como tratamiento rehabilitador, y como herramienta orientada a mejorar la salud y calidad de vida de las personas (Garber et al., 2011; Klavestrand & Vingard, 2009). Tales son sus beneficios, que no practicar actividad física ha sido reconocido como un importante factor de riesgo para enfermedades coronarias (Warren et al., 2010), trastornos depresivos (Teychenne, Ball, & Salmon, 2010) y empeoramiento de distintos marcadores de riesgo de enfermedades crónicas (Owen et al., 2010).

La carrera a pie

A día de hoy, el número de corredores tanto profesionales como populares está aumentando de forma significativa e imparable. En Estados Unidos, se estima que la cifra de corredores es alrededor de 30 millones, y el número sigue en aumento (Guo et al., 2006). En España, la carrera es la quinta actividad física más practicada (cerca del 13% de la población), lo que se puede comprobar al observar el aumento de participación en las diferentes maratones y carreras populares del país (García-Ferrando & Llopis-Goig, 2011). Sin embargo, aunque su práctica regular proporciona al organismo múltiples beneficios, también puede generar lesiones en el aparato locomotor.

Las lesiones en el aparato locomotor debidas a la carrera a pie

De entre los diversos tipos de actividad física, la carrera representa un importante porcentaje de los casos de lesiones deportivas por su carácter cíclico y repetitivo (Thijs et al., 2008). Cada vez que el pie contacta con el suelo durante la carrera se produce una fuerza de impacto de entre 1,2 y 4,0 veces el peso corporal. Esa fuerza la produce el cuerpo humano contra el suelo, el cual, por principios mecánicos, devuelve una fuerza de igual magnitud y sentido contrario hacia el cuerpo, que es lo que le permite avanzar y desplazarse. Esa fuerza es atenuada por las estructuras biológicas, quienes gozan de capacidad amortiguadora que permite reducir esos impactos para que no dañen los tejidos del cuerpo humano (Creaby et al., 2011; Llana & Brizuela, 1996). La carrera, debido a su naturaleza repetitiva, puede llevar a un deportista a realizar 600 contactos con el suelo por cada kilómetro recorrido (Guo et al., 2006), cada uno de ellos por debajo del umbral patológico de la capacidad amortiguadora de las estructuras biológicas, pero que en su conjunto y por su carácter acumulativo puede llegar a producir lesiones conocidas "por sobreuso", especialmente en las extremidades inferiores: síndrome patelo-femoral, fracturas de estrés, tendinitis patelar, fascitis plantar, metatarsalgia y tendinitis del talón de Aquiles, entre otras (Derrick, 2004; Lieberman et al., 2010; Tessutti et al., 2010).

Se han descrito numerosas causas como factores que aumentan el riesgo de lesión en corredores y se han dividido en dos categorías: factores intrínsecos y extrínsecos. Entre los más importantes, se ha visto que **factores anatómicos individuales** (diferencias en la morfología del pie o distinta longitud entre los miembros inferiores de una misma persona) (Fields et al., 2010), **errores durante el entrenamiento** (excesivo kilometraje, falta de descanso) (Fourchet et al., 2012), **altas fuerzas de impacto** (debido a su carácter repetitivo y acumulativo durante la carrera) (Willems et al., 2012), las **superficies de entrenamiento** (diferentes terrenos producen diferente amortiguación) (Twomey et al., 2012), o el tipo de **calzado deportivo** (en función de su estructura amortiguadora y del control del movimiento del pie) (Hirschmuller et al., 2011) influyen en el riesgo de lesión en corredores.

Factores que afectan la biomecánica de la carrera

A la hora de analizar la carrera desde un punto de vista biomecánico, es importante identificar aquellos factores que afectan a las diferentes variables para tenerlos en cuenta y tratar de controlarlos lo máximo posible cuando se vaya a evaluar los efectos de una intervención determinada. En este sentido, en el presente trabajo se han presentado y descrito dos factores en concreto y se ha destacado su influencia sobre la biomecánica de la carrera:

- El **estado de fatiga**. Pese a que el estado de fatiga es un fenómeno multifactorial y de difícil análisis debido a los diferentes tipos de fatiga (local, general) (Nigg, MacIntosh, & Mester, 2000) y de las diferentes formas de medirla y controlarla (frecuencia cardiaca (Ament and Verkerke, 2009), consumo de oxígeno (Astorino et al., 2005), concentración de lactato (Wilmore et al., 2007) etc.), su estudio es de vital importancia ya que, cuando el deportista se encuentra fatigado, el riesgo de lesión aumenta (Hreljac, 2004). En este sentido, se ha observado que el estado de fatiga afecta a numerosas variables biomecánicas de la carrera como el **tiempo de contacto** (Nagel et al., 2008), **longitud y frecuencia de zancada** (Hunter and Smith, 2007), **rango articular** (Weist et al., 2004), **fuerzas de impacto** (Gerlach et al., 2005), **activación muscular** (Hanon et al., 2005), **presión plantar** (Rosenbaum et al., 2008), e **impactos de aceleración** (García-Pérez et al., 2014).
- El uso de **soportes plantares**. El estudio del efecto de los soportes plantares sobre la biomecánica de carrera es de vital importancia debido al auge que están teniendo estos soportes tanto a nivel clínico como a nivel preventivo. Su uso a día de hoy se centra en dos campos de actividad (Razeghi & Batt, 2000): en la corrección de la función biomecánica de las articulaciones de la extremidad inferior y en su utilización como herramienta terapéutica para aliviar los síntomas de patologías y lesiones por sobreuso. En este sentido, el uso de soportes plantares ha sido asociado con una **reducción del dolor**, aumento de la **propiocepción** y el **confort**, recuperación de las funciones motoras normales con mayor presteza tras

una lesión, reducción de la **presión plantar** y reducción de los **impactos de aceleración** (Fields et al., 2010; Lee et al., 2012; O'Leary et al., 2008).

Sin embargo, especial controversia ha provocado la aparición de una serie de soportes plantares prefabricados comercializados en numerosas tiendas y centros comerciales, orientados a la prevención de dolores y lesiones para cualquier tipo de consumidor. Podólogos, médicos, entrenadores, preparadores físicos, biomecánicos y especialistas en general del comportamiento del pie durante la carrera han comprobado el aumento de la venta de este tipo de productos donde el consumidor, basándose únicamente en su talla de pie, adquiere un soporte plantar independientemente de cuál sea la morfología de su pie y/o su patrón de marcha y carrera (Werd & Knight, 2010).

Como consecuencia, está surgiendo un creciente interés centrado en comprobar el comportamiento de este tipo de soportes prefabricados frente a aquellos soportes personalizados que son indicados y prescritos por un especialista y que son adaptados a la morfología y comportamiento motor específico del pie en cuestión.

OBJETIVOS DEL ESTUDIO

Por tanto, aprovechando la controversia surgida y el creciente interés tanto de especialistas como de empresas especializadas en el sector de soportes plantares, el presente estudio tiene como objetivos:

1) Analizar el comportamiento de diferentes tipos de soportes plantares (personalizados, prefabricados, control) sobre variables biomecánicas relevantes en la carrera a pie: parámetros espacio-temporales, la presión plantar, los impactos de aceleración, y la percepción de confort y de fatiga.
2) Evaluar el efecto de la fatiga sobre dichas variables (parámetros espacio-temporales, presión plantar, impactos de aceleración, percepción de confort y fatiga) al utilizar los diferentes soportes plantares (personalizados, prefabricados, control) durante la carrera.

MATERIAL Y MÉTODOS

Muestra

En el presente estudio participaron voluntariamente 40 corredores (20 hombres y 20 mujeres) que entrenaban habitualmente, sin lesión previa en las extremidades inferiores en los últimos 6 meses y que no utilizaban soportes plantares previamente. Una vez informados de los pormenores del estudio, proporcionaron un informe consentido de acuerdo con la declaración de Helsinki confirmando su participación. El presente proyecto fue aprobado por el Comité Ético de Investigación en Humanos de la Comisión de Ética en Investigación Experimental de la Universidad de Valencia (número de procedimiento H1411628681304).

Evaluación del tipo de pie y creación de soportes plantares personalizados

Un equipo de podólogos realizó una evaluación del tipo de pie de cada uno de los participantes del estudio usando la escala validada "Foot Posture Index" (FPI-6), que consiste en la valoración de una serie de parámetros funcionales y estructurales para poder determinar el tipo de pie del participante: pie neutro, pie ligeramente pronador, pie muy pronador, pie ligeramente supinador, pie muy supinador (Barton, Menz, & Crossley, 2011).

Una vez realizada la evaluación del pie de los participantes, se realizó un molde de yeso a través de una técnica de moldeado de pie en carga usando un podoneumático durante unas determinadas maniobras de neutralización. Mediante este proceso, se obtuvo un molde de yeso que reproducía la morfología del pie, gracias al cual posteriormente se llevó a cabo la creación del soporte plantar personalizado a cada participante.

Protocolo

La fase experimental se desarrolló en un periodo de tres semanas. En primer lugar, una semana antes de la primera prueba de carrera se distribuyó de forma aleatoria un par de soportes plantares (personalizados/prefabricados). Los participantes intercambiaron las palmillas originales de sus zapatillas deportivas por los soportes proporcionados y se les pidió que mantuvieran su rutina diaria usando las zapatillas, con el fin de que se adaptaran a los soportes del estudio. Transcurrida una semana, los participantes acudieron al laboratorio para realizar la primera prueba de carrera y, a su finalización, los investigadores proporcionaron el segundo par de soportes (en función del orden aleatorio realizado la semana anterior) para dejar transcurrir una nueva semana de adaptación, volviendo a realizar la segunda prueba de carrera una semana más tarde.

Las pruebas del estudio se llevaron a cabo en el Laboratorio de Biomecánica de la Facultad de Ciencias de la Actividad Física y del Deporte, de la Universidad de Valencia. Para las dos pruebas de carrera, los participantes corrieron sobre un tapiz rodante a una velocidad controlada de 12 km/hora y una pendiente de 0% tanto con los soportes de estudio (personalizados o prefabricados) y con los soportes control (las palmillas originales de sus zapatillas deportivas).

Una semana antes del estudio, cuando los participantes acudieron al laboratorio a recoger el primer par de soportes, se les realizó una prueba incremental submáxima de esfuerzo donde se fue aumentando la velocidad (2 km/h cada 3 minutos) mientras se registraba la frecuencia cardiaca mediante un pulsómetro y el nivel de ácido láctico en sangre a través de una punción en el lóbulo de la oreja, con el objetivo de determinar la velocidad individual de estudio (velocidad de estudio para la fatiga) correspondiente al último incremento en el test de esfuerzo antes de sobrepasar el umbral anaeróbico.

Las dos pruebas de carrera tuvieron la misma dinámica. En cada test de carrera se realizaron las siguientes mediciones:

- Calentamiento 7 minutos a 10 km/h (Control/ Soportes A) (aleatorio)
- Carrera PRE 1: 7 minutos a 12 km/h (Control / Soportes A) (aleatorio)
- Carrera PRE 2: 7 minutos a 12 km/h (Soportes A / Control)
- Carrera Fatiga: 12 minutos a velocidad de fatiga (Soportes A)
- Carrera POST 1: 1 minuto a 12 km/h (Control / Soportes A) (aleatorio)
- Carrera POST 2: 1 minuto a 12 km/h (Soportes A / Control) (aleatorio)

En el segundo test de carrera, realizado una semana después del primer test (para asegurar la correcta adaptación de los participantes al nuevo par de soportes plantares), se realizó el mismo protocolo con el segundo par de soportes proporcionado a los participantes y la palmilla de sus zapatillas (soporte control).

Variables de Estudio

Las variables de estudio fueron:

- Parámetros espacio-temporales (Tiempo de contacto, Frecuencia de zancada).
- Presión plantar (Media de la presión máxima, Tiempo hasta la media de la presión máxima, Integral presión-tiempo, Presión relativa).
- Impactos de aceleración (Pico máximo de aceleración (en tibia y cabeza), Ratio de aceleración (en tibia y cabeza), Atenuación.
- Percepción de confort (Confort general, Amortiguación talón, Amortiguación antepie, Control medio-lateral, Altura del arco, Ajuste talón, Anchura talón, Anchura antepié, Longitud zapatilla).
- Percepción de esfuerzo.

Estas variables se registraron para cada una de las siguientes condiciones:

- Soportes Plantares:
  - Control (CI).
  - Personalizados (CMI).
  - Prefabricados (PI).
- Condiciones Fatiga:
  - Descanso (PRE).
  - Fatiga (POST).

Instrumental de medida

Para analizar cada una de las variables mencionadas se utilizaron los siguientes instrumentos:

- Para el análisis de la presión plantar, se utilizó el sistema Biofoot 2001® (IBV, Valencia, España), ampliamente utilizado y validado (Martínez-Nova et al., 2007a; Pérez-Soriano et al., 2011; Pérez-Soriano et al., 2010) y se dividió el pie en 9 zonas para analizar las diferentes variables de presión plantar en cada una de las zonas (García-Pérez et al., 2013; Pérez-Soriano et al., 2011).
- Para el análisis de los impactos de aceleración se colocaron dos acelerómetros triaxiales (Signal Frame, Sportmetrics, Valencia, España): uno en la zona proximal anteromedial de la tibia y otro en la zona central de la frente (Delgado et al., 2013; García et al., 2014).
- Para el estudio de la percepción de confort, los participantes rellenaron una escala analógica visual a través de la cual valoraron los diferentes ítems de confort al correr con cada uno de los soportes plantares (Mündermann et al., 2001).
- Finalmente, los participantes indicaron su percepción de esfuerzo durante el último minuto de la carrera de fatiga sobre una escala de percepción de esfuerzo validada y conocida: la escala RPE 6-20 de Borg (Borg, 1982).

Tratamiento Estadístico

Se utilizó el programa SPSS 18.0 para el tratamiento estadístico. Se comprobó la normalidad de los datos a través de la prueba Kolmogorov-Smirnov y la homocedasticidad mediante el test de Levene. Posteriormente, se llevó a cabo un ANOVA de dos factores de medidas repetidas para los parámetros espacio-temporales, la presión plantar y acelerometría, siendo los factores intra-sujeto los soportes plantares (personalizados, prefabricados, control) y la fatiga (descanso, fatiga). Se utilizó la prueba de Bonferroni para comprobar la existencia de diferencias entre pares de grupos específicos, con el nivel de significación $\alpha = 0.05$.

Además, se realizó un análisis de la varianza (one-way ANOVA) para analizar la percepción de confort de los tres soportes plantares. Por último, puesto que la percepción de esfuerzo no seguía una distribución normal, una prueba no paramétrica (Test de Wilcoxon) se utilizó para comparar las diferencias en la percepción de fatiga entre los dos soportes de estudio (personalizado vs prefabricado).

RESULTADOS

Parámetros espacio-temporales

Ni los soportes plantares ni el estado de fatiga provocaron un efecto significativo sobre los parámetros espacio-temporales del estudio. Independientemente del estado de fatiga, se observó un mayor tiempo de contacto con PI (0,27 seg) en comparación con CMI (0,26 seg) y CI (0,26 seg), aunque no se observaron diferencias significativas ($p > 0{,}05$). Respecto a la frecuencia de zancada, los diferentes soportes tampoco produjeron un efecto significativo, resultando en 157 pasos/minuto con CI, 156 pasos/minuto con CMI y 159 pasos/minuto con PI.

Presión Plantar

El estado de fatiga no produjo diferencias significativas en comparación con las mediciones tomadas en reposo. En relación al efecto de los soportes plantares, se produjo una reducción significativa de la **media de la presión máxima** en el primer dedo, arco interno y arco externo con CMI en comparación con CI (CMI vs CI: 91,23 vs 165,21 kPa, $p < 0{,}05$; 67,74 vs 106,27 kPa, $p < 0{,}01$; y 58,76 vs 97,90 kPa, $p < 0{,}01$, respectivamente). Por otro lado, PI también produjo reducciones significativas de la media de la presión máxima en la zona de los dedos, arco interno y arco externo en comparación con CI (PI vs CI: 126,15 vs 194,22 kPa, $p < 0{,}05$; 73,80 vs 106,27 kPa, $p < 0{,}01$; y 67,49 vs 97,90 kPa, $p < 0{,}01$, respectivamente).

El **tiempo hasta el valor medio de la presión máxima** sufrió incrementos significativos en la zona de los metatarsos externos en la condición CMI en comparación con CI (CMI vs CI: 46,44% vs 41,55%, $p < 0{,}05$). De igual manera, se observaron incrementos significativos de esta variable en la zona del arco externo tanto con CMI como con PI en comparación con CI (CMI vs CI: 25,72%, p < 0,05; PI vs CI: 27,48% vs 20,81%, p < 0,01).

Respecto a la **integral de la presión-tiempo**, se observaron resultados muy similares a los registrados en la media de la presión máxima. En este sentido, la utilización tanto de CMI como de PI produjo disminuciones significativas en la zona del arco externo en comparación con CI (CMI y PI vs CI en arco externo: 3,41 y 2,42 vs 5,22 kPa/s, p < 0,01; respectivamente). Además, CMI redujo la integral de la presión-tiempo bajo la zona del talón externo en comparación con PI y CI (CMI vs PI y CI: 2,70 vs 5,79 y 7,71 kPa/s, p < 0,01).

Finalmente, en relación a la **presión relativa**, tanto CMI como PI redujeron la presión relativa respecto a CI en el arco interno (CMI y PI vs CI 7,23 vs 9,11%, p < 0,05) y externo (CMI y PI vs CI: 4,99 vs 7,09%, p < 0,01). Sin embargo, PI aumentó la presión relativa en comparación con CI en los metatarsos centrales (19,97 vs 15,59%, p < 0,01) y talón interno (14,08 vs 10,60%, p < 0,01).

Impactos de Aceleración

El estado de fatiga no modificó ninguno de los parámetros de impactos de aceleración (p > 0,05). Respecto al efecto de los soportes plantares, ni el **pico máximo de aceleración** ni la **atenuación del impacto** se vieron modificados en ninguna de las condiciones de soporte plantar (p > 0,05). Sin embargo, sí que se observó un reducción de la **ratio de aceleración** en la cabeza al utilizar CMI en comparación con PI y CI (CMI vs PI y CI: 51,73 vs 53,20 y 58,32 G/s, p < 0,05, respectivamente). Además, también se observó una mayor ratio de aceleración en la tibia en PI en comparación con CI y CMI (PI vs CI y CMI: 330,02 vs 264,66 y 261,05 G/s, p = 0,027).

Percepción de Confort

Respecto a la percepción de confort, tanto CMI como PI obtuvieron valores de percepción de confort significativamente mayores que CI en los ítems “Confort general”, “Amortiguación talón”, “Amortiguación antepie”, “Control medio-lateral”, “Altura del arco” y “Ajuste talón”. Además, PI obtuvo también una mejor valoración del ítem “Anchura antepié” en comparación con CI (PI vs CI: 9,49 vs 7,85, p = 0,028).

Percepción de Esfuerzo

Por último, no se observaron diferencias significativas en la percepción de esfuerzo entre la carrera fatigante realizada con CMI y PI (CMI vs PI: 14,2 vs 14,0, p = 0,851).

DISCUSIÓN

Parámetros Espacio-Temporales

Mientras que los valores de tiempo de contacto observados en el presente estudio son similares a los presentados en estudios previos de carrera para la misma velocidad (Alfuth & Rosenbaum, 2011), la frecuencia de zancada es ligeramente menor en comparación con otros estudios (Riley et al., 2008). La reducción de la frecuencia de zancada observada, en comparación con estudios previos para la misma velocidad (3,33 m/s), puede ser debida a diferencias en la técnica y estilo individual de carrera (Ahn, Brayton, Bhatia, & Martin, 2014) y a las diferentes metodologías, equipamientos y protocolos utilizados en cada estudio (García-Pérez et al., 2013). Por otro lado, estos resultados sugieren que los diferentes soportes plantares no modifican los parámetros cinemáticos de la carrera, permitiendo a podólogos y especialistas prescribir este tipo de soportes tanto como herramienta preventiva como tratamiento sin verse modificadas estas dos importantes variables del patrón biomecánico de carrera del deportista.

Presión Plantar

El patrón de presiones plantares observado en el presente estudio es similar a los encontrados por otros autores para la misma velocidad (Queen et al., 2009a). La reducción media de la presión máxima (zona del primer dedo) con el uso de los soportes personalizados es un resultado de gran relevancia, ya que esa zona ha sido señalada como una zona de riesgo involucrada en sobrecargas debido a su papel en la fase final de propulsión (Alfuth & Rosenbaum, 2011). De igual manera, los soportes personalizados redujeron en un 36% y en un 40% la media de la presión máxima en las zonas del arco interno y externo en comparación con la situación control, respectivamente. Este descenso se vio acompañado por una reducción similar del 54% y 35% de la integral presión-tiempo en el arco externo con los soportes personalizados y prefabricados en comparación con la situación control, respectivamente. La integral presión-tiempo ha sido definida como una variable determinante, pues informa no sólo de la carga observada en una zona determinada, sino también del tiempo de exposición de dicha carga, informando del efecto acumulativo del evento compresor (Wegener et al., 2008).

Además, los resultados del presente estudio muestran que ambos soportes plantares de estudio (personalizados, prefabricados) provocaron importantes disminuciones de presión en diferentes zonas (primer dedo, arco, talón) en comparación con la situación control. Las reducciones de presión plantar observadas muestran una tendencia a redistribuir las presiones a las que se ve sometido el pie durante el apoyo en carrera, disminuyendo las presiones en zonas de riesgo y pudiendo resultar en una menor incidencia de lesión por sobrecargas (García-Pérez et al., 2013; Tillman et al., 2002).

Atendiendo a las diferencias entre ambos soportes de estudio, los soportes personalizados redujeron un 31% la media de la presión máxima en la zona del talón interno y un 53% la integral de la presión-tiempo en la zona del talón externo. Este resultado es de especial relevancia pues la sobrecarga del talón puede dar lugar a fascitis plantar, lesión que afecta a un 25% de los corredores (Ribeiro et al., 2011). En consecuencia, la disminución de la sobrecarga producida en esta zona al utilizar los soportes personalizados puede tener especial importancia a la hora de prevenir una lesión tan común entre los corredores como es la fascitis plantar.

Impactos de Aceleración

Los impactos de aceleración se producen cada vez que el pie contacta con el suelo durante la locomoción (marcha, carrera, saltos) y es el resultado de la desaceleración de la masa de los diferentes segmentos corporales en el momento de contacto (Wee & Voloshin, 2013). El análisis de los impactos de aceleración está atrayendo el interés de investigadores y profesionales de la actividad física y del deporte debido a su relación con un mayor riesgo de lesión (Hreljac, 2004; Milner et al., 2006).

En este sentido, un aumento de la magnitud del impacto de aceleración (pico máximo de aceleración) se ha asociado con un aumento del riesgo de lesión, especialmente de fracturas por estrés (Davis et al., 2004; Milner et al., 2006). En uno de estos estudios, Milner y colaboradores (2006) observaron un mayor pico máximo de aceleración en tibia en mujeres corredoras con historial clínico de fracturas de estrés en comparación con corredoras sin historial clínico de fracturas, concluyendo que esta variable podría estar relacionada con un mayor riesgo de lesión.

En el presente estudio, ninguno de los soportes plantares condujo a alteraciones del pico máximo de aceleración, resultados que coinciden con los encontrados por Laughton et al. (2003). Por otro lado, O'Leary y colaboradores (2008) observaron una reducción del pico máximo de aceleración al correr con soportes semi-adaptados específicamente amortiguadores. Sin embargo, se desconoce si la función de atenuación de dichos soportes primaba sobre la función de control del movimiento del retropié (función original de un soporte plantar (Werd & Knight, 2010)) y por tanto es necesario interpretar estos resultados con cautela. Para que un soporte plantar pueda realizar correctamente su función de corrección y control del movimiento, es necesaria una mínima cantidad de rigidez y dureza de los materiales del soporte. Por lo tanto, es importante tener en cuenta que el uso de soportes plantares específicamente construidos para ser amortiguadores podría suponer una reducción de las propiedades de control del movimiento de dichos soportes. En este sentido, sería interesante para futuros estudios analizar en profundidad la relación entre estos dos factores.

Por otro lado, la ratio de impacto también ha sido considerada como un parámetro de gran relevancia en el estudio de los impactos de aceleración y su relación con las lesiones en la carrera. Estudios previos han concluido que cargas repetidas de aplicación rápida (ratio alta) podrían estar asociadas en un mayor grado con degeneración articular que cargas de aplicación lenta (ratio baja) de magnitud de impacto similar o incluso mayor (Radin et al., 1991). En este sentido, en el presente estudio se observó una reducción de la ratio de impacto en la cabeza con el uso de soportes personalizados en comparación con los soportes prefabricados y de control. Esta reducción de la ratio con los soportes personalizados podría suponer un mecanismo protector ya que el sistema musculo-esquelético dispondría de mayor tiempo para lidiar con las cargas de aceleración que se propagan por el cuerpo en cada impacto.

Por último, la atenuación del impacto también es un parámetro de gran interés en el estudio de las cargas de aceleración sobre el cuerpo humano durante la práctica deportiva. Como se ha indicado anteriormente, cada vez que el pie contacta con el suelo, los impactos de aceleración se propagan a través del cuerpo humano desde el pie a la cabeza como resultado de la desaceleración de los segmentos corporales durante el contacto (Enders et al., 2014; Shorten & Winslow, 1992; Wee & Voloshin, 2013). En cada uno de estos contactos, el sistema musculo-esquelético atenúa parcialmente la carga de aceleración con el objetivo de reducir su magnitud y proteger los centros superiores situados en la cabeza (Derrick et al., 1998; Edwards et al., 2012).

En el presente estudio no se observaron alteraciones de los picos máximos de impacto en tibia y cabeza. Por lo tanto, no sorprende encontrar que tampoco se vio alterada la atenuación del impacto para ninguna de las condiciones de soporte plantar. Por extraño que parezca, ningún estudio hasta la fecha ha analizado la atenuación del impacto con el uso de soportes plantares, aunque algunos estudios analizaron parámetros similares. Estos estudios (Laughton et al., 2003; O'Leary et al., 2008) únicamente registraron el impacto de aceleración en tibia, por lo que no es posible conocer la magnitud del impacto de aceleración en la cabeza y por tanto la atenuación del impacto. El hecho de que en el presente estudio no se observaran alteraciones de la atenuación del impacto podría suponer que el sistema musculo-esquelético está lidiando correctamente con la carga de los impactos de aceleración de la carrera sin mayores inconvenientes y que el uso de soportes plantares podría suponer beneficios a otros niveles (presión plantar, cinemática, confort) sin comprometer la capacidad de atenuación de las cargas de aceleración del cuerpo humano.

Percepción de Confort

La percepción de confort es una variable que cada vez se está teniendo más en cuenta dentro del mundo de la investigación en ciencias del deporte. En el presente estudio, los dos tipos de soportes plantares (prefabricados, personalizados) obtuvieron mejores valores de percepción de confort que la situación control.

Aunque los participantes estaban acostumbrados a correr con sus zapatillas deportivas y sin soportes plantares (situación control), el hecho de introducir un soporte plantar fue percibido como algo positivo, lo que contrasta con los resultados de Mündermann et al., (2002) donde la condición de control fue la que obtuvo mayores valores de confort. Los participantes en dicho estudio indicaron que la situación de control era la que más se asemejaba a la situación a la que estaban acostumbrados y el hecho de introducir un soporte plantar alteró dicha percepción.

Existe cada vez un mayor cuerpo de conocimiento reforzando la idea de que la percepción de confort es una variable a tener en cuenta no sólo a la hora de buscar mejoras en el rendimiento (Luo et al., 2009; Mills et al., 2011) sino también como herramienta potencial a utilizar en la predicción y prevención de lesiones (Kinchington et al., 2012; Cheung et al., 2003). Se ha especulado que cuando una situación produce incomodidad (bajos valores de confort), el deportista podría llegar a alterar su patrón natural de movimiento, alterando sus estrategias innatas de activación muscular y de consumo de energía y podría dar lugar a un patrón biomecánico alterado que podría no sólo comprometer el nivel de rendimiento del deportista sino que podría incluso llegar a desembocar en un mayor riesgo de lesión.

Percepción de Esfuerzo

La percepción de esfuerzo durante la carrera fatigante fue similar entre los dos tipos de soporte plantar (personalizado, prefabricado). Éste era un resultado esperado porque hasta la fecha no se han descrito mecanismos por los que el uso de un determinado tipo de soporte plantar podría modificar la percepción de fatiga. Además, en el caso de haber encontrado diferencias en la percepción de esfuerzo entre ambas condiciones, sería ambicioso y atrevido asociar de forma directa la modificación de la percepción de esfuerzo al uso de soportes plantares.

En este sentido, los valores de percepción de esfuerzo fueron utilizados para caracterizar la carrera fatigante y asegurar que los participantes alcanzaban un estado de fatiga similar. El valor reportado de 14 “Duro” indica que los participantes acabaron la carrera de fatiga con un nivel medio-alto de cansancio (objetivo del estudio), un estado similar al cual podríamos encontrar en los minutos finales de un entrenamiento cotidiano en corredores de media distancia.

Por otro lado, el estado de fatiga no modificó ninguno de los parámetros de estudio (parámetros espacio-temporales, de presión plantar, de impactos de aceleración) con independencia del tipo de soporte plantar. En este sentido, y debido a la difícil caracterización de la fatiga (local, general) y de los diferentes niveles de fatiga que una persona puede experimentar (leve, media, grande, extenuación), es muy posible que las discrepancias entre los resultados observados en los diferentes estudios tengan su origen en el distinto estado de fatiga alcanzado por los participantes, así como las diferentes metodologías utilizadas (protocolos de fatiga e instrumentos de análisis) y nivel de los corredores (personas activas, corredores amateurs, profesionales).

Papel del soporte plantar en las lesiones por sobrecarga

Se ha comprobado en numerosos estudios que la utilización de soportes plantares es efectiva en la reducción de impactos de aceleración y presiones plantares en poblaciones muy diferentes como personas de edad avanzada con deformidades en los dedos (Mickle et al., 2011), pacientes con artritis reumatoide y metatarsalgia (Landorf & Keenan, 2000), síndrome patelofemoral (Thijs et al., 2008), atletas con historia previa de lesiones en las extremidades inferiores (Bus et al., 2004), corredoras con historia previa de fracturas de estrés (Milner et al., 2006) y, especialmente, en pacientes diabéticos (Mickle et al., 2011; Paton et al., 2011).

La mayoría de estos estudios concluyen que el efecto acumulado de los cargas mecánicas mantenidas durante largos periodos de tiempo, pueden resultar en sobrecargas en zonas localizadas del pie y desembocar en ulceraciones y empeoramiento de determinados síntomas patológicos, por lo que la reducción de esas sobrecargas es necesaria y los soportes plantares se han mostrado eficaces en ese sentido. Sin embargo, la mayoría de trabajos de investigación están orientados al tratamiento con soportes plantares una vez se ha producido la lesión (tratamiento post-lesión), por lo que el daño ya está hecho y sólo queda tratar de reducir o revertir el daño producido.

Aunque actuar a este nivel es necesario, el desarrollo de estudios que actúen en un estadio previo a la aparición de dicho daño, buscando la prevención en lugar del tratamiento, mediante la localización de los factores dañinos o peligros y la consecuente intervención para controlarlos y limitarlos, es igualmente de vital importancia. Por ello, el presente trabajo se enmarca dentro de esa línea de estudios que buscan la protección de las estructuras biológicas del cuerpo mediante intervenciones preventivas, con el objetivo de actuar antes de que se produzca el daño lesivo y no cuando el deportista se presenta en la clínica con una patología ya desarrollada.

CONCLUSIONES

A. Los parámetros espacio-temporales no se ven modificados por la utilización de los soportes plantares estudiados. En este sentido, una intervención con soportes plantares permitiría a un deportista beneficiarse de las mejoras asociadas a este tipo de soporte plantar (en términos de presión plantar, impactos de aceleración, etc.) sin que se viera afectado su patrón cinemático de carrera.

B. Ambos tipos de soporte plantar (personalizados y prefabricados) reducen la presión plantar en diferentes zonas (primer dedo, 2-5º dedos, arco plantar, talón), lo que implica una reducción de la carga plantar en cada uno de los apoyos del pie en el suelo. Por lo tanto, en carreras de larga distancia donde el número de contactos es elevado, esta reducción de carga en cada paso podría significar una disminución de la carga global acumulativa y por lo tanto del riesgo de lesión.

C. Los soportes personalizados, en comparación con los soportes prefabricados, consiguen reducir la presión bajo el primer dedo y el talón, por lo que son un eficaz medio de descarga de estas zona del pie, tan importante en la fase de contacto y propulsión.

D. Respecto a la atenuación de los impactos de aceleración, no se observan diferencias entre usar o no soportes plantares, lo que indica que el uso de soportes plantares no debería ser considerado como una estrategia específica para reducir los impactos de aceleración durante la carrera a pie.

E. Sin embargo, los soportes personalizados reducen la ratio de aceleración en la cabeza y tibia en comparación con los soportes prefabricados, por lo que cuando a un deportista se le recomienda utilizar soportes para tratar otros síntomas (sobrepresiones, dolor, función mecánica del pie, etc.), los soportes personalizados proporcionan una mayor reducción de los impactos de aceleración.

F. Los dos soportes de estudio (personalizados y prefabricados) han obtenido valores de confort superiores a los registrados con el soporte control. Sin embargo, no ha habido diferencias en cuanto a la percepción de confort entre los dos soportes de estudio.

G. El nivel de fatiga provocado en el presente estudio no modifica ninguno de los parámetros espacio-temporales, de presión plantar, e impactos de aceleración para ninguna de las condiciones de soporte plantar.

1. INTRODUCTION

1. INTRODUCTION

1.1. Physical Activity: Health Benefits

Regular physical activity and exercise are practices very popular all over the world and are associated with numerous physical and mental health benefits. But firstly, the terms of “physical activity”, “exercise” and “physical fitness” are very often used indistinctly and lead to confusion and misunderstanding (Khan et al., 2012; Oja et al., 2015), what makes it necessary to clarify the differences among these concepts.

In this sense, there are some articles that address this problem, providing a common framework for future research (Chodzko-Zajko et al., 2009; Khan et al., 2002; Oja et al., 2015; Thompson et al., 2003). These studies agree to define the aforementioned terms as follows:

- **Physical activity** as any voluntary physiological body movement produced by the skeletal muscles that results in energy expenditure.
- **Exercise** as a subcategory of physical activity, which is planned, structured, repetitive, and with a purpose, in the sense that improvement or maintenance of one or more components of physical fitness is an objective.
- **Physical fitness** as a state of well-being with a low risk of premature health problems and energy to participate in a variety of physical activities. Being physically fit has been defined as "*the ability to carry out daily tasks with vigour and alertness, without undue fatigue and with ample energy to enjoy leisure-time pursuits and to meet unforeseen emergencies*" (President’s Council on Physical Fitness and Sport, 1971). As this definition may be conceptually too general and these variables are not easy to measure, a number of measurable components have been described: (a) cardiorespiratory endurance, (b) muscular endurance, (c) muscular strength, (d) body composition, and (e) flexibility.

Moreover, in order to provide a more complete vision of the topic, it is very important to bear in mind how the lack of physical activity is defined (also known as inactivity or sedentary lifestyle) (Chodzko-Zajko et al., 2009; Garber et al., 2011; Owen, Healy, Matthews, & Dunstan, 2010):

- **Sedentary living** as a way of living that requires minimal physical activity and that encourages inactivity through limited choices, disincentives, and structural or financial barriers. Sitting and low levels of energy expenditure are hallmarks of sedentary behaviour and encompass activities such as television watching, computer use, and sitting in a car or at a desk.

The evidence suggesting that regular physical activity or exercise is beneficial both for the physical and mental health is overwhelming. The beneficial effects of physical activity have been found to be of major importance as a means of clinical prevention (Garber et al., 2011; Morris & Froelicher, 1993; Smith et al., 1995) and as treatment for rehabilitation (O'Connor et al., 1989; Oldridge, Guyatt, Fischer, & Rimm, 1988; Schuler et al., 1992) and improving health condition and quality of life (Conn, Hafdahl, & Brown, 2009; Garber et al., 2011; Klavestrand & Vingard, 2009; Stofan, DiPietro, Davis, Kohl, & Blair, 1998). Such are its benefits that the lack of physical activity is recognised as a risk factor for coronary artery disease (Fletcher et al., 1996; Warren et al., 2010), depression (Teychenne, Ball, & Salmon, 2010), increased waist circumference, elevated blood pressure, depressed lipoprotein lipase activity, and worsened chronic disease biomarkers such as blood glucose, insulin, and lipoproteins (Garber et al., 2011; Healy et al., 2008; Owen et al., 2010).

With respect to **cardiovascular benefits**, regular exercise enhances cardiovascular functional capacity by improving coronary blood flow (Hambrecht et al., 2000), increasing maximum cardiac output (Warburton et al., 2004), decreasing myocardial oxygen demand for the same level of external work performed (Fletcher et al., 1996), lowering blood pressure (USA Department of Health and Human Services, 2008), reducing systemic inflammation (Adamopoulos, Parissis, & Kroupis, 2003), and enhancing the endothelial function (McGavock et al., 2004).

Regarding the **metabolic benefits**, physical activity reduces insulin resistance and glucose intolerance, and possibly hepatic glucose output (Thompson et al., 2001). Further benefits are the improvement in lipoprotein profile by reduction of LDL and the attenuation of the decline in HDL accompanying reduced dietary intake of saturated fat when exercise is combined with weight loss (Durstine et al., 2001).

Regular physical activity also plays an important role in **weight management** (Donnelly et al., 2009; Pate, Ross, Liese, & Dowda, 2015; USA Department of Health and Human Services, 2008), leading to a more favourable body composition profile, including less total and abdominal body fat (Going, Williams, & Lohman, 1995; Warburton, Gledhill, & Quinney, 2001), a greater relative muscle mass (% of body mass) in the limbs (Sugawara et al., 2002), and higher bone mineral density at weight bearing sites (Goodpaster, Costill, Trappe, & Hughes, 1996; Mussolino, Looker, & Orwoll, 2001). Especially important for old people, healthy athletic habits slower the development of disability (Wang, Ramey, Schettler, Hubert, & Fries, 2002), provide salutary effects on fibrinogen levels (Stratton et al., 1991) and preserve bone mass and reduce the risk of falling (American Geriatrics Society, 2001; Nelson et al., 2007).

Psychological state is also positively influenced by physical activity. Evidence suggests that an active lifestyle enhances well-being (Bartholomew, Morrison, & Ciccolo, 2005), and leads to better scores in the satisfaction, comfort, resilience, and achievement dimensions of quality of life (Conn et al., 2009; Klavestrand & Vingard, 2009; Sanchez-Lopez et al., 2009). Healthy physical habits are associated with a lower risk of depressive disorders, anxiety and cognitive decline and dementia (Bibeau, Moore, Mitchell, Vargas-Tonsing, & Bartholomew, 2010; Haskell et al., 2007; Steptoe et al., 1997; Yaffe et al., 2009). Regarding children and adolescents, physical activity has also been related to higher self-esteem (Calfas & Taylor, 1994; Strauss, Rodzilsky, Burack, & Colin, 2001), and academic performance (Shephard, 1997).

Finally, regular physical activity reduces the risk of stroke and type 2 diabetes, osteoporosis (Vuori, 2001), obesity (Wing & Hill, 2001) and breast and colon cancer (Breslow, Ballard-Barbash, Muñoz, & Graubard, 2001; Slattery & Potter, 2002; USA Department of Health and Human Services, 2008).

Engaging physical activity has been stated as an important factor to prevent the development of coronary artery disease and reduce symptoms in patients with established cardiovascular disease (Thompson et al., 2003), thereby being considered as a delaying all-cause mortality activity (Garber et al., 2011).

These health benefits have been related to **different types of exercise** such as cardiovascular (Fletcher et al., 1996; Garber et al., 2011; Morris & Froelicher, 1993; Smith et al., 1995) or resistance exercise (Castaneda et al., 2002; FitzGerald, Kampert, Morrow, Jackson, & Blair, 2004; Garber et al., 2011; Hunter, McCarthy, & Bamman, 2004). Also, regarding the **frequency of practice**, long-term health benefits when considered regular activity (Chodzko-Zajko et al., 2009; Garber et al., 2011; Morris & Froelicher, 1993; Thompson et al., 2003) or short-term effects when practicing acute physical activity (Ho, Dhaliwal, Hills, & Pal, 2011) have also been found.

Finally, what makes physical activity noteworthy is its influence on a great range of the **population**. Positive effects have been found in sedentary people (Blair et al., 1995; Healy et al., 2008), adolescents (Faigenbaum et al., 2009; Sallis et al., 2000; Sanchez-López et al., 2009; Twisk, 2001), adults (Garber et al., 2011; Hakkinen et al., 2010; Vuillemin et al., 2005), old people (over 65 years old) (Chodzko-Zajko et al., 2009; Nelson et al., 2007), and patients with clinical conditions both previous or at the time of study (Fletcher et al., 1996; Ho et al., 2011; McAuley et al., 2009; Schuler et al., 1992), making physical activity a very interesting and powerful tool to be considered when aiming to improve the health condition and quality of life of the population.

Key Points

- Physical activity is associated with numerous cardiovascular, metabolic and psychological benefits.
- Independent of the type and frequency of practice, its benefits are able to influence the entire population.

1.2. Physical Activity: Running

Nowadays, the number of people practising physical activity continues to increase. In the U.S.A, lifestyle reports show that inactive people decreased from 16.0% to 13.5% in the period 2001-2007, leading to an increase in the number of people with recommended levels of physical activity from 45.3% to 48.8% in the same period (Department of Health and Human Services; Guo et al., 2006; Ho et al., 2010). In Spain, the number of active people has also augmented significantly in the last 20 years, especially in the adult and elder populations (Table 1).

Table 1. Evolution of number of people practising at least one sport by age range. In percentage. 1980-2010 (Informe España, 2011. Fundación Encuentro (García-Ferrando & Llopis-Goig, 2011)).

Age range	1980	2010
From 15 to 24 years	52	60
From 25 to 34 years	34	54
From 35 to 44 years	13	44
From 45 to 54 years	8	34
From 55 to 64 years	4	30
Over 65 years	--	19

Among the different types of physical activities, running both in a recreational and competitive way is becoming one of the most popular activities, being practiced today by more people than ever before (Fredericson & Misra, 2007; Fundación Encuentro, 2011;). In the U.S.A. there are more than 54 million of runners (SFIA, 2014), what accounts for 16-20% of the total population. In Spain, a national study carried out in 2010 reported that running was the 5th most practised type of physical activity (García-Ferrando & Llopis-Goig, 2011) (Table 2). According to this study, 12.9% of the population run as a physical activity, what implies an increase of 1.8% from a previous survey in 2005.

Table 2. Evolution of the 10 most practised physical activities in Spain. In percentage. 2005-2010 (Informe España, 2011. Fundación Encuentro (García-Ferrando & Llopis-Goig, 2011)).

2005	%	2010	%
Swimming	32.6	Group classes (Fitness)	34.6
Soccer	26.6	Soccer	24.6
Group Classes (Fitness)	26.3	Swimming	22.9
Cycling	19.1	Cycling	19.8
Outdoors activities	11.9	Running	12.9
Running	11.1	Outdoors activities	8.6
Basketball	9.4	Basketball	7.7
Tennis	8.9	Tennis	6.9
Track and Field	7.2	Track and Fields	6.0
Bodybuilding	6.8	Padel	5.9

All these data confirm the increasing popularity of running, making it a recommended activity by health organisms (Harberg, 2011; USA Department of Health and Human Services, 2008). But to understand better the present situation and role of running in the modern society, it is necessary to find and describe the origins of this practice and the evolution and development that running has been exposed to throughout human history.

Key Points

- Running has experienced an increase in participation in the last years throughout the world.
- In Spain, running has become the 5th most practiced type of physical activity.

1.3. Running History

Since the origin of the human race, walking, running and throwing have accompanied human existence. These skills were developed quickly because the first human communities changed their living place very often and hunted animals to feed themselves, therefore making these skills vital to survive.

But two European races were the first ones to practise athletics regularly in the Bronze Age, about the year 2000 B.C. They were the Irish community of the pre-celtic period and the Greeks of Acvadia, both organising athletic celebrations for religious (even funerary) purposes. Years later (800 B.C.), Homer wrote in the Iliad and the Odyssey about certain running events where people gathered to see the performance of the runners:

"Forthwith uprose fleet Ajax son of Oileus, with cunning Ulysses, and Nestor's son Antilochus, the fastest runner among all the youth of his time. They stood side by side and Achilles showed them the goal. The course was set out for them from the starting-post, and the son of Oileus took the lead at once, with Ulysses as close behind him as the shuttle is to a woman's bosom when she throws the woof across the warp and holds it close up to her; even so close behind him was Ulysses- treading in his footprints before the dust could settle there, and Ajax could feel his breath on the back of his head as he ran swiftly on…"

The Iliad by Homer (800 B.C.) Book XXIII

Figure 1. Runners in the stadion race (520 B.C.) (Miller, 2006).

Afterwards, this same athletic spirit became very popular through the Ancient Games. The Olympic Games were the most famous competition, starting in 776 B.C (Figure 1). The first Olympic Games consisted of one single event, the *stadion*, a race of 192.27 metres long. As the years went by, new races such as the *diaulos* (2 stadions: 380m) in 724 B.C., the *dolichos* (24 stadions: 4615m) in 720 B.C. and the *hoplitodromos* (2 diaulos: 800m) in 520 B.C. were included in the Games, along with non-running events like boxing, wrestling and different types of jumps and throws. Similarly, other athletic Games such as the Isthmian Games (582 B.C.), the Pythian Games (527 B.C.), or the Nemean Games (517 B.C.) also included running races within their events.

In the XVIIth century there were found in England writings addressing new timing methods and describing certain races from village to village, generating the interest of the villagers, especially those involved in gambling. Also in this period and country, some runners who were considered professionals (they were called “running footmen”) were used as communication messengers between villages (Hubiche & Pradet, 1999).

However, it is in the Rugby School, in 1838, where the first cross country running race is held involving their university students. Afterwards, the popularity of running spread within the Public School framework, and the Schools of Cambridge (1857), Eton (1859) and Oxford (1960) followed the initiative (Bravo et al., 1991). Finally, the first official entity, the “Mincing Lane Athletic”, was created in 1861 in England, leading to the formation of the “Amateur Athletic Club” in 1866, being the origin of a wave of athletic federations and associations, firstly in England, and thereafter throughout the world. In Spain, the first official institution was the “Federación Regional Catalana” in 1918, followed in 1919 by the “Confederación Española de Atletismo” that would become the “Real Federación Española de Atletismo” in 1939 (Calzada, 1999).

Key Points

- Running has accompanied the human race since its origin.
- The first organised running events date back to 2000 B.C.
- The main national and international athletic federations started to appear during the XIX-XXth century.

1.4. Running Categories

Running can be divided into two main branches according to the objective of the practice: competitive and recreational running. Whereas the competitive runner focuses on following a rigorous training plan in order to enhance performance and achieve better results usually in official competitions, the recreational runner aims to improve their physical appearance and health status, to be in shape, to relieve stress from the modern lifestyle and, specially, to have fun (García-Ferrando & Llopis-Goig, 2011) (Figure 2).

Figure 2. Crazy race (Moncada), (Las Provincias, 2014).

Although there is a scarcity of formal reports addressing the participation in popular races, an increasing trend can be seen when looking into the number of runners in the different popular races. Even though most of the running events nowadays are increasing their participation rates, there are certain events that have even reached their maximum number of applicants such as the New York City Marathon (the largest marathon in the world), where runners need to enter a lottery system in order to participate in the race. Other examples are the Tokyo's Marathon where during the last 8 years there has been an increase of more than 200,000 applications to take part in the race, or the Marathon of Valencia, a race which more than doubled its participation rate in just four years (Table 3).

Table 3. Participation in different marathon races (official web pages of the different marathon races).

Race	Previous Edition		Last Edition		Increase (participants)
	Year	Participants	Year	Participants	
New York Marathon	2003	34,400	2014	50,504	16,104
Barcelona Marathon	2006	4,425	2015	15,865	11,440
Tokyo Marathon	2007	30,870 (95,044)*	2015	36,030 (302,386)*	5,160 (207,342)*
Valencia Marathon	2010	3,107	2014	11,348	8,241

* Applicants.

Moreover, not only increases in single races have been registered regarding recreational running. According to information published by the "Fundación Deportiva Municipal" of the city of Valencia (2015), the local running league competition comprising 10 races has registered an increase in participation from 550 runners/race in 2005 to 8000 runners/race in 2015, thereby showing a clear trend of increasing participation. These data demonstrate that everyday more and more people engage in recreational races, reaching sometimes excessive participation what makes race organisers establish a limit number of runners in order to ensure the safety and proper development of the event.

Key Points

- Running can be divided into competitive and recreational running.
- Physical appearance, health, relieving stress and having fun are the main reasons why people run.
- In just a few years, national and international running events are increasing their participation rates by thousands.

1.5. Running Technique

Walking and running are natural abilities of the human being. Although both of them may seem very similar, it is necessary to highlight the differences between each other. Whereas walking can be defined as a movement based on a succession of steps where there is a permanent contact with the ground, running is characterised by the existence of a swing or flying phase (no foot touching the ground) in every stride (Leboeuf et al., 2006). Therefore it is important to clarify two new concepts (Aguado, 2015; Novacheck, 1998; Perry & Burnfield, 2010) (Figure 3):

- **Step**: it starts when one foot touches the ground and finishes with the first contact of the next foot.
- **Stride**: it starts when one foot touches the ground and finishes when the same foot contacts the ground again (two steps).

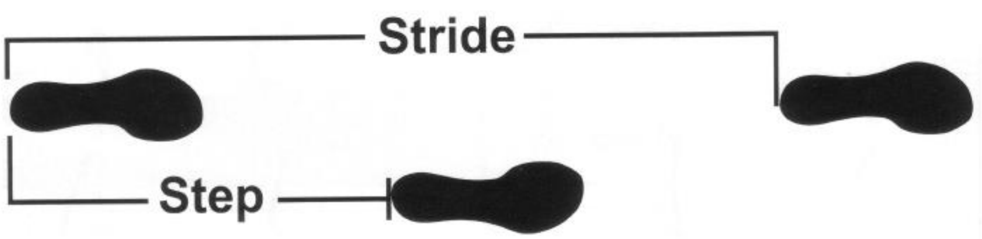


Figure 3. Visual representation of one step and stride (Perry & Burnfield, 2010).

The objective of the runner is to cover a given distance in the least amount of time. The time actually achieved by the athlete in a given event is determined by the distance of the race and by the athlete's average speed over that distance (Equation 1):

$$Time = \frac{Distance}{Speed}$$

Equation 1. Time equation.

Moreover, the speed of the runner is equal to the product of the **stride length** (distance covered with each stride) and the **stride rate** (number of strides in a given time) (Aguado, 2015) (Equation 2):

Speed (m/sec) = Stride length (m/stride) x Stride rate (strides/sec)

Equation 2. Speed equation.

As this equation indicates, in order to reach greater running speeds, the athlete must increase one or both of these parameters (Mercer, Hreljac, & Hamill, 2002) (Figure 4).

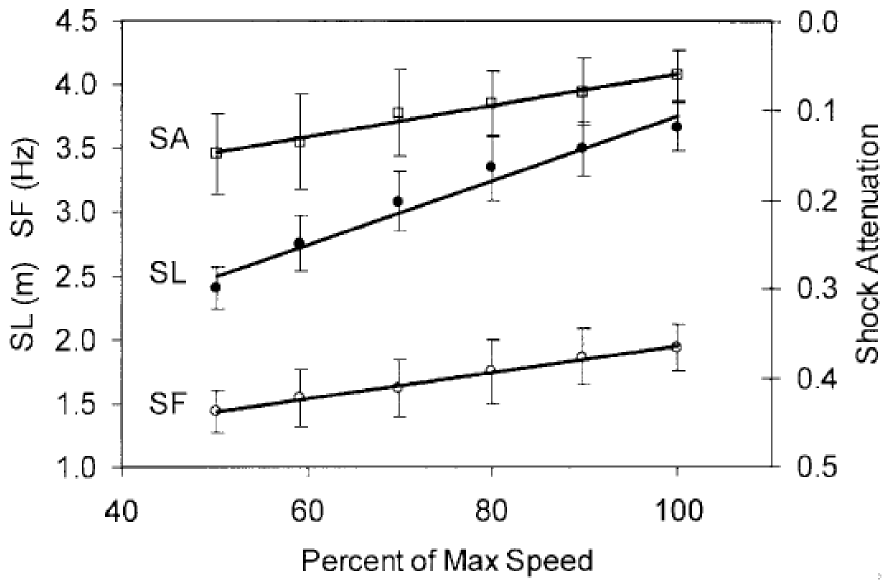


Figure 4. Increase of stride length (SL) and stride frequency (SF) and shock attenuation (SA) as the running speed increases from 40% to 100% of the maximal running speed (Mercer et al., 2002).

At a given speed, it has been demonstrated in the literature that stride length and stride rate are the spatio-temporal parameters that affect the metabolic cost of running the most (Castro, LaRoche, Fraga, & Gonçalves, 2013; Connick & Li, 2014; Hunter & Smith, 2007; Mercer, Doglan, Griffin, & Bestwick, 2008). Athletes adopt an optimal combination of stride length and stride rate that minimizes the metabolic cost of running (Hamill, Derrick, & Holt, 1995; Hunter & Smith, 2007; Mercer et al., 2008). It has been observed that changes of stride length and rate away from the optimal result in increased metabolic cost or poorer economy (Hunter & Smith, 2007; Vernillo et al., 2015). As it can be observed in Figure 5, based on the oxygen consumption measured at different stride frequencies, the authors established the best fit line between these two variables and established the optimal stride frequency (OSF) as the stride frequency that corresponded with the lowest value of oxygen consumption. In this study, it can be seen that experienced runners choose a preferred stride rate which closely matches the predicted optimal stride rate which minimises the metabolic cost.

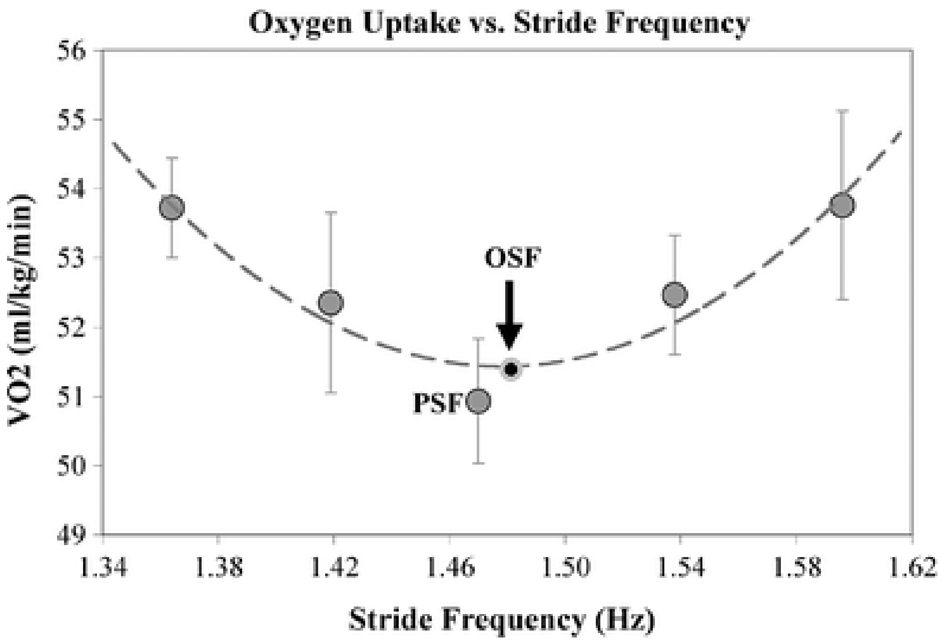


Figure 5. Preferred stride frequency (PSF) chosen by the athletes and optimal stride frequency (OSF) calculated by the best fit of curve from five oxygen uptake samples as a function of stride frequency (Hunter & Smith, 2007).

There is no agreement in the literature as to which of these factors is the critical parameter that influences running economy. In this sense, whereas some studies suggest that stride rate (Martin & Sanderson, 2000) is the key parameter that influences running economy, other studies conclude that stride length (Castro et al., 2013; Slawinski et al., 2008) is the critical factor.

However, there is no doubt that these two parameters are of great importance during running, as it has been demonstrated that increasing or decreasing these parameters alters the running pattern (Table 4) and therefore they should be taken into account when analysing the biomechanics of running.

Table 4. Summary of the effects that occur when stride rate/length is modified.

Increasing stride rate // Reducing stride length	• Increases knee flexion at initial contact (Heiderscheit et al., 2011) • Increases ankle plantar flexion at initial contact (Clarke et al., 1985; Heiderscheit et al., 2011) • Reduces peak knee flexion during stance (Heiderscheit et al., 2011) • Reduces hip peak flexion and hip adduction during loading response (Heiderscheit et al., 2011) • Reduces peak vertical GRF (Heiderscheit et al., 2011; Morin et al. 2007) • Reduces vertical excursion of the centre of mass (Heiderscheit et al., 2011) • Reduces peak tibial acceleration (Derrick et al. 1998) • Reduces ground contact time (Morin et al., 2007) • Reduces peak pressure (Allet et al., 2011) • Reduces knee extension, hip flexion, and ankle plantar flexion moment impulses (Allet et al., 2011)

Moreover, it is also important to take into account that running is a type of physical activity that requires the coordination of the whole body. Whereas the trunk should incline forward to facilitate the movement of the body, the arms, keeping the elbows flexed 90º, accompany the movement of the legs by moving alternatively forwards and backwards (Arellano & Kram, 2014). The action of the legs is cyclic, what means that there is a constant repetition of this technical gesture throughout the performance.

The cycle of running has been divided into different phases depending on the author. In this sense, one of the most popular approaches is the one suggested by Hay (1993) (Figure 6):

1. **Supporting phase**: It starts when the foot touches the ground and ends when the runner's centre of gravity passes forward it. A deceleration of the horizontal velocity and a downwards movement of the centre of mass occurs in this phase.
2. **Driving phase**: It starts when the runner's centre of gravity passes the foot in contact with the ground and ends as the foot leaves the ground. In this phase there is an acceleration of the horizontal velocity and an upwards movement of the centre of mass.
3. **Recovery phase**: It is the time the foot is off the ground and is being brought forward in order to touch the ground again. During the first half of the phase the centre of mass accelerates horizontally and moves upwards until the moment where it reaches the highest point. Immediately after, the centre of mass starts to go downwards and decelerates its horizontal velocity.

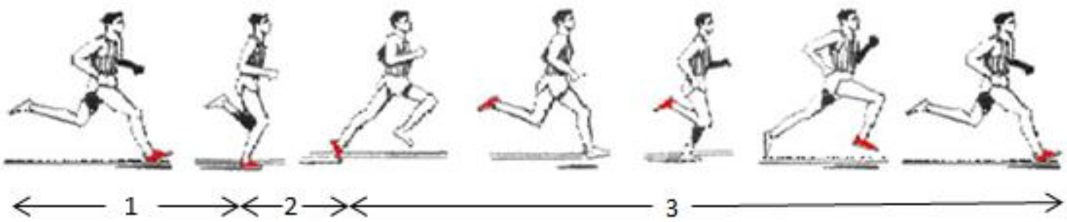


Figure 6. Running cycle gait (Hay, 1993).

However, other authors have divided the cycle into different phases. For instance, Martin and Coe (1998) described up to three ground phases (footstrike, midsupport and take off) and two subphases during the recovery (float follow through and forward swing). Furthermore, Werd and Knight (2010) also divided the running gait in two main phases (stance and swing), each one of them composed by several subphases:

1. **Stance Phase**: Initial contact, Loading, Midstance, Propulsion and Pre-swing.
2. **Swing**: Initial swing, Midswing or Double float and Terminal swing.

All in all, the technical gesture remains the same, and it is the theoretical approach the one that differs from author to author. Albeit the technical description of the running gait is very similar and it is generally considered repetitive and predictable, the runner's characteristics contribute to a higher degree of individual specificity. Inherent differences between individuals such as stature, body proportions, coordination, joint range of motion, musculoskeletal strength, neuromuscular feedback pathways, proprioceptive abilities, and anatomical variations; and extrinsic factors such as the running surface, shoes, insoles and even the socks may trigger individual adaptations resulting in a unique running gait pattern for each runner (Cheung & Ngai, 2015; García-Pérez, Pérez-Soriano, Llana-Belloch, Martínez-Nova, & Sánchez-Zuriaga, 2013; Hong, Wang, Li, & Zhou, 2012; Lieberman, 2014; Werd & Knight, 2010).

Key Points

- Running speed is influenced by stride rate and stride frequency.
- Alterations of these stride parameters influence numerous biomechanical parameters of running.
- Classifying the different actions that occur during running is necessary to understand how external interventions may alter running.

1.6. Running Injuries

1.6.1. Injury Rate and Social Repercussion

Even though the practice of physical activity and exercise provides plenty of benefits for the health and quality of life, it should be taken into account that physical activity is also associated with a certain risk of injury (Foch, Reinbolt, Zhang, Fitzhugh, & Milner, 2015; Gent et al., 2007). When compared with other causes, injures related to sport activities represent a significant figure (Table 5).

Table 5. Different studies describing the rate of sport accidents.

Study	Accidents from Physical Activity	Country
De Löes, 1989	17% of total accidents (compared to working (19%) and traffic (7%))	Sweden
Heiskanen & Kostela, 1994	27% of total injury cases	Finland
Van Galen & Diedricks, 1990	3.3 accidents every 1000h	Netherlands
Schürmeyer et al., 1983	5-10% every day hospital accidents	Germany
Steinbruck & Cotta, 1983	10-15% of total accidents	Germany

Villalba-Cabello, 2004.

The annual medical expenses addressed to sport injuries in the Netherlands are approximately 225 million of dollars, whereas in Germany this figure is estimated to be around 2500 million dollars (Villalba-Cabello, 2004). However, albeit it may seem that practising physical activity and exercise may involve a significant injury risk, athletes who engage in vigorous physical activity have a hospitalization rate 30% lower compared to the inactive population (Villalba-Cabello, 2004). Although there are no studies regarding moderate or light physical activity, according to Villalba et al. (2004) the hospitalization rate may be even lower for this group since the athletes who train and exercise harder are usually the ones getting injured more often. Despite the fact that there are no official data in Spain, these same authors estimated that each person that would stop being sedentary by engaging any physical activity in the region of Andalucía would save the sanitary system approximately 96-159€, which would represent 204-341 million Euros per year for the whole region. Thus, sport injuries can be considered an important economic issue, not only for the athletes but also for the public institutions.

Among the different sports and physical activities, runners are among the most commonly injured athletes (Thijs, DeClercq, Roosen, & Witvrouw, 2008). As presented in the Table 6, the yearly incidence of running injuries is unclear, depending on the author and date of the study.

Table 6. Review of studies analysing injury rate among runners.

Study	% Injury Rate
Daoud et al., 2012	74%
Fields, Sykes, Walker, & Jackson, 2010	50%
Frederick, 1986; Krissoff, & Ferris, 1979; Matheson et al., 1987; Nigg, 2001	37-56%
Hreljac, 2005	27-70%
Nielsen, Ronnow, Rasmussen, & Lind, 2014b	27%
Taunton et al., 2002; Queen, Abbey, Wiegerinck, Yoder, & Nunley, 2010	24-65%
Thijs et al., 2008; VanMechelen, 1992; Wen, Puffer, & Schmalzried, 1997	37-56%
Average of all studies	**48%**

1.6.2. Epidemiology of Running

It is important to highlight that not only the number of runners has increased in every race, but also the number of races available for runners. Twenty years ago the recreational runner trained regularly and competed in a popular race from time to time. Today, due to the popularity of running, the promotion of local races through the media – especially the Internet – and runners joining amateur/recreational clubs facilitate the assistance to events far from the athlete’s living place. As a result, runners have the possibility to participate in an official popular race every week. A good example would be the regional popular running league organised in Albacete, known as “Circuito de Carreras Populares de Albacete” (Figure 7), which in its first edition in 2001 was composed of 6 races all over the region, whereas in the year 2015 it was celebrated the XV Edition, where a runner could participate in up to 48 races (more than one race per week) (Circuito Carreras Populares Albacete, 2015).

Figure 7. Poster of the XV Edition of the Circuito de Carreras Populares de Albacete.

As a consequence of the worldwide popularity of running, increasing the frequency and distance of training and races among runners is considered a relevant risk factor in injury incidence (Gent et al., 2007; Tessutti, Trombini-Souza, Ribeiro, Nunes, & Sacco, 2010; van der Worp et al., 2015). Initial contact between the foot and the ground both during walking and running results in high impact forces acting upon the lower limb (Creaby, May, & Bennell, 2011).

Research using force platforms has showed that ground reaction forces during running are as twice as high as those observed during walking and delivered in less than half of the time (Perry, 1983). As a result, the impact forces imposed on supporting tissues during running are four times greater than walking (Willson & Kernozek, 1999). In other words, the musculoskeletal system absorbs vertical impact forces from 1.2 to 4.0 times the athlete’s body weight every heel strike during running (Bates, Osternig, Sawhill, & James, 1983; Cavanagh & Lafortune, 1980; Creaby et al., 2011; Crossley, Bennell, Wrigley, & Oakes, 1999; Gross, Davlin, & Evanski, 1991;

Lieberman et al., 2010; Lutter, 1980; Withnall, Eastaugh, & Freemantle, 2006). Although joint structures and soft tissues attenuate part of the force, a proportion is transmitted to the skeleton resulting in bone strain or deformation (Lafortune, 1991).

Considering that runners strike the ground approximately 600 times per kilometre, making an accumulative 1.3 million impacts a year when running 34 km/week (Cavanagh & Lafortune, 1980; Crossley et al., 1999; Derrick, Dereu, & McLean, 2002; Frederick, 1986; Gent et al., 2007; Guo et al., 2006; Lieberman et al., 2010; McNeil, 2001; Milner, Ferber, Pollard, Hamill, & Davis, 2006; Moreno De la Fuente, 2005; Pohl, Hamill, & Davis, 2009; Ribeiro et al., 2011; Shorten & Winslow, 1992), bone strain may become excessive as a result of increases in loading magnitude, rate of loading, or number of loading cycles (Crossley et al., 1999; Willson & Kernozek, 1999). Even when the loading is light, the repetitive character of the impacts implies tremendous demands to the musculoskeletal system that may lead to what is called "overuse injuries" (Burnfield, Jorde, Augustin, Augustin, & Bashford, 2007; Derrick, 2004; Dixon, Collop, & Batt, 2000; Gross et al., 1991; Ho et al., 2010; Lieberman et al., 2010; Reeder, Dick, Atkins, Pribis, & Martinez, 1996; Sharkey, Ferris, Smith, & Matthews, 1995; Tessutti et al., 2010; Shorten, 2000; Weist, Eils, & Rosenbaum, 2004; Willson & Kernozek, 1999; van der Worp et al., 2015). At this point, it is necessary to clarify the nature of two concepts whose definitions may vary between studies, but can be commonly defined as following:

- **Running Injury**: A musculoskeletal ailment that is attributed to running that causes a restriction of running speed, distance, duration, or frequency for at least 1 week (Hreljac, 2005; Hreljac, Marshall, & Hume, 2000; Koplan, Powell, Sikes, Shirley, & Campbell, 1982; Lysholm & Wiklander, 1987; Macera et al., 1989).
- **Overuse Injury**: An injury of the musculoskeletal system that results from the combined fatigue effect over a period of time beyond the capabilities of the specific structure that has been stressed (Buist et al., 2010; Hreljac, 2005). These injuries occur when several repetitive forces, each one of them lower than the acute injury threshold of that structure, are applied to a biological structure such as muscles, bones or tendons (van der Worp et al., 2015).

Once it is acknowledged that running injuries are common within the athletic population, getting to know the **most frequent injuries** and their **location** in order to prevent them should be a priority. According to some studies, the most common site of running injury is the knee followed by the foot, lower leg, upper leg, ankle, hip, trunk and upper extremities (Gent et al., 2007) (Figure 8).

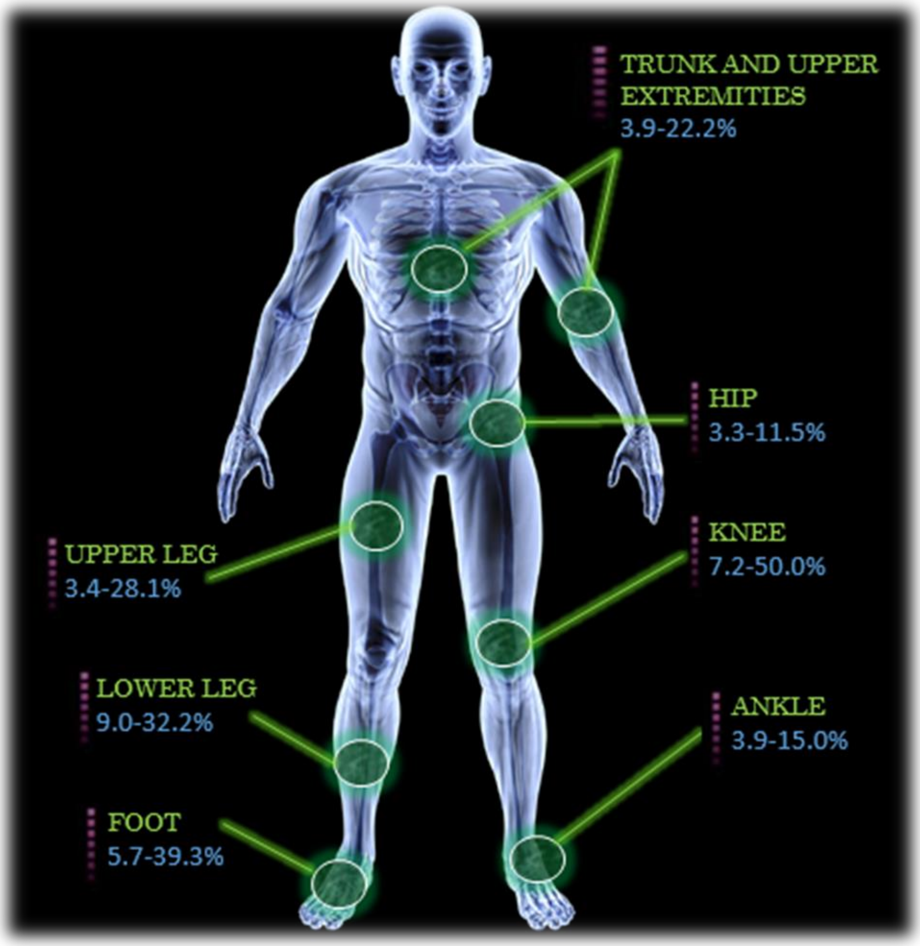


Figure 8. Summary of main injury location in runners.

However, literature regarding this topic is not conclusive. Some authors have stated that approximately 90% of running related injuries occur in the lower extremity (Ho et al., 2010; Marti, Vader, Minder, & Abelin, 1988; Nagel, Fernholz, Kibele, & Rosenbaum, 2008). In the same line of thought, Hreljac (2005) and Queen et al. (2010) also described knee injuries as the most common ones (42-50%). The foot, ankle and lower leg made almost 40% of the remaining injuries that are reported, whereas less than 20% of the running injuries reported occur above the knee.

All these studies suggest that there may be some common mechanisms in the aetiology of running injuries, although there is still no agreement about the specific causes (Gent et al., 2007; Hreljac, 2005; Marti et al., 1988; Queen et al., 2010; Taunton et al., 2002) (Table 7).

Table 7. Review of injury location in different studies

Study	Foot (%)	Ankle (%)	Lower Leg (%)	Knee (%)	Upper Leg (%)	Hip/Pelvis (%)
Nielsen et al., 2014b	14.2*	14.2*	37.0	32.3	3.2	10.6
Rasmussen et al., 2013	32.4*	32.4*	17.6	32.4	5.9	2.9
McKean et al., 2006**	~16	~8	~16	~25	~9	~9
Lun et al., 2004	15.0	3.9	9.0	7.2	9.0	5.0
Taunton et al., 2003	14.0	11.0	26.7	35.2	3.4	9.7
Steinaker et al., 2001 (during training)			16.6	50.0		11.1
Steinaker et al., 2001 (during marathon)	11.1		16.7	33.4		
Wen et al., 1998	16.7	10.7	32.1	31.0	3.6	5.9
Satterthwaite et al., 1996 (during/immediate after marathon)	22.6		16.0	8.8	28.9	
Satterthwaite et al., 1996 (week following marathon)	14.8		20.5	12.7	38.1	
Macera et al., 1989	22.0			24.0		
Walter et al., 1989	15.7	15.0	12.0	26.6	7.2	8.8
Bovens et al., 1989	5.7	12.1	32.2	24.7	6.3	11.5
Jakobsen et al., 1989	6.9	10.8	16.6	26.9	11.4	
Maughan & Miller, 1983	39.3	4.9	13.1	32.0	7.4	3.3

**Foot and ankle measured as the same zone. ** Results only provided in bar graphs: approximated values.*
(Gent et al., 2007).

Although runners do sustain some acute injuries such as ankle sprains and fractures, most running injuries could be classified as overuse injuries (Hreljac, 2005; van der Worp et al., 2015). Within this group of injuries, numerous studies reported different figures of incidence, and indicated that patellofemoral pain syndrome, stress fractures, medial tibial stress (shin splints), patellar tendinitis, plantar fasciitis, metatarsalgia and Achilles tendinitis were the most common overuse running injuries among many others (Foch et al., 2015; Hreljac, 2005; Kahanov, Eberman, Games, & Wasik, 2015; Nielsen et al., 2014b; Queen et al., 2010; Ribeiro et al., 2011; Snyder, De Angelis, Koester, Spindler, & Dunn, 2009; Taunton et al., 2002; Van Ginckel et al., 2009; Willson & Kernozek, 1999) (Figure 9).

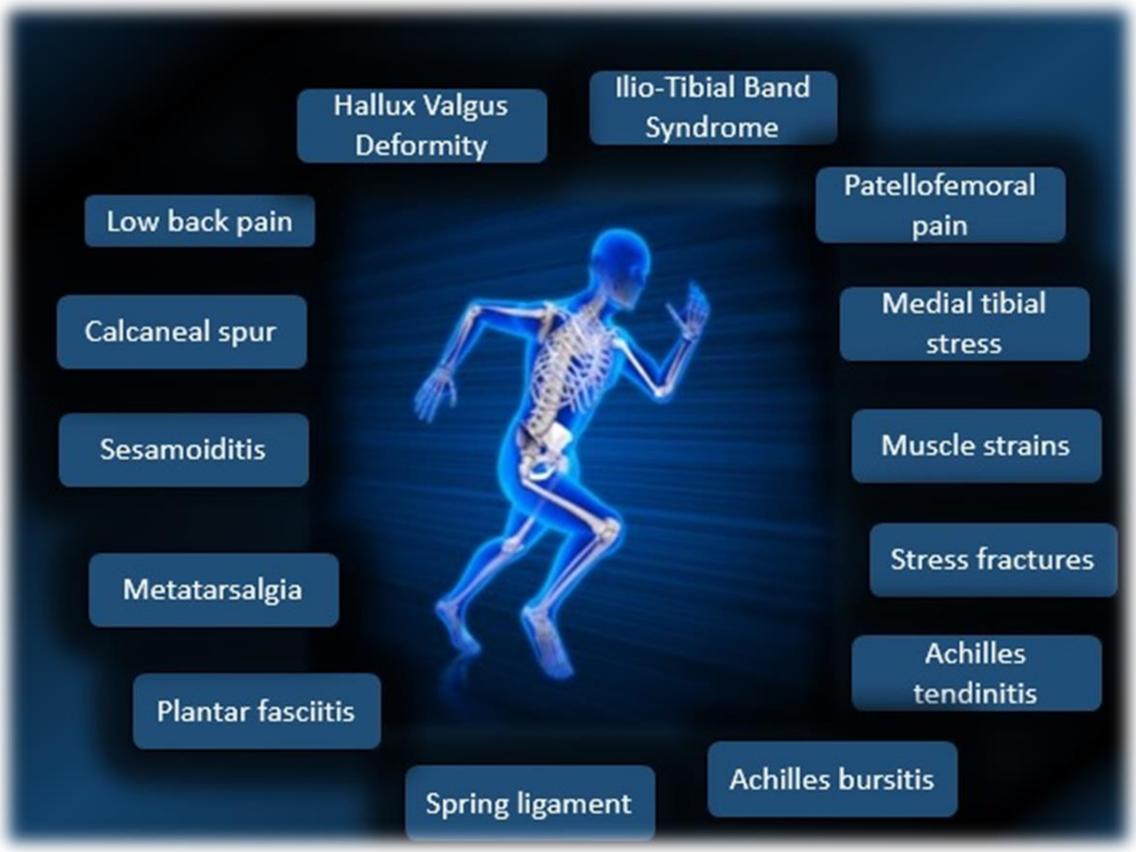


Figure 9. Summary of injuries associated with running (Jonely, Brismée, Sizer, & James, 2011; Moreno De la Fuente, 2005; Nielsen et al., 2014b; Werd & Knight, 2010).

1.6.3. Aetiology of Running Injures

There is strong evidence that practising physical activity and exercise and specifically running provides plenty of benefits for the health state and wellbeing. As stated previously, the greatest concern of runners is the high injury incidence associated with this practice.

Considering the high risk of injury, the prevention of running injuries has become a priority no only for athletes and physicians, but also for coaches, biomechanists, physioterapists, psychologists and, all in all, for the entire team that surrounds the athlete. Despite the great deal of literature that has focused on the subject, scientific research has not been able to verify or refute most of the speculations regarding the aetiology of running injuries. All that can be stated with certainty at this point is that the aetiology of overuse running injuries is multifactorial and diverse (Saragiotto et al., 2014; Willems, De Ridder, & Roosen, 2012). The variables that have been identified as risk factors for running injuries vary slightly from study to study, but they can be placed into two main categories: intrinsic and extrinsic factors.

1.6.3.1. Intrinsic Factors

There must exist some factors that prevent one runner from training for as long, as often, or as intensely as another runner before incurring a running injury. Stated in another way, ‘‘why does each individual runner (and each individual musculoskeletal structure) have a different injury threshold?’’. It is conceivable that two individuals who have comparable anatomic and stride characteristics train together, but only one of the individuals sustains an overuse injury. In this case, and in most cases of overuse running injuries, it is logical to hypothesise that some intrinsic variations between individuals could account for differences in injury susceptibility (Hreljac, 2005). In this sense, the most commonly suggested intrinsic injury factors in the literature are presented in Figure 10.

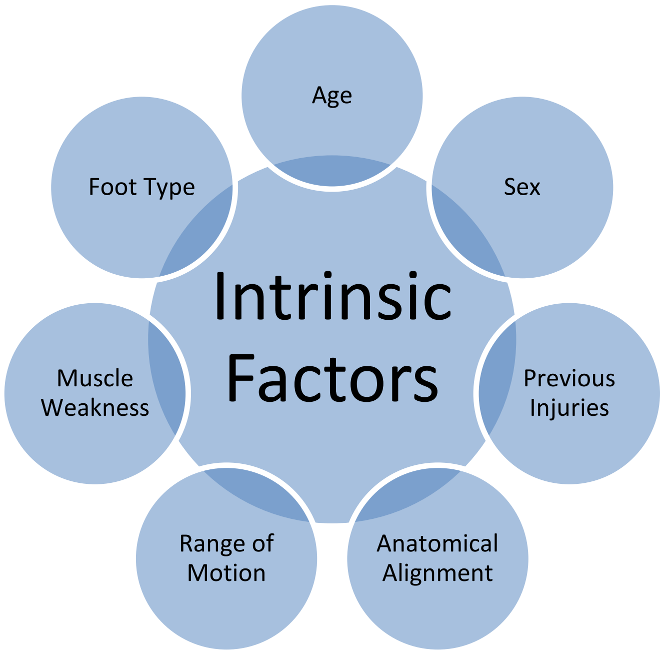


Figure 10. Summary of intrinsic factors predisposing to running-related injuries.

A. **AGE**. The age of the person has been showed to be a risk factor for some diseases such as osteoarthritis (Jorring, 1980). It would be reasonable to believe that older people (where every inner system and organ in the body has experienced greater exposure to physical load) are at greater risk of getting injured compared to young people (Meana, 2008). In this sense, some studies conclude that athletes older than 25 years are at greater injury risk compared to younger athletes (Ostenberg & Roos, 2000). In a study of young athletes aged 6-17 years old, Backous et al. (1988) reported that injury risk doubled after the age of 14. In a recent prospective study, Nielsen et al. (2014b) observed that the age factor (age above 40) was significant for the occurrence of medial tibial stress syndrome and Achilles tendinopathy (Table 8). However, the sex of the athlete also seems to play a role in the relationship between age and injury risk, since males older than 25 years had been suggested to suffer the highest injury rate whereas for females the highest injury rate was observed between the 12th - 15th year of age (Lindenfeld, Schmitt, Hendy, Mangine, & Noyes, 1994). On the other hand, there are also studies that did not find any association between age and injury (Bennell et al., 1996; Soderman, Alfredson, Pietilä, & Werner, 2001). The relationship between these two factors is complex (due to the multifactorial definition of injury and how the injury occurred), and further studies are needed to clarify this relationship.

Table 8. Descriptive data of the types of running-related injuries by age (Nielsen et al., 2014b).

Injury type	All injures (n=254)
	Age (Above 40)
	n (p)
Medial Tibial Stress Syndrome	8 (<0.01)*
Patellofemoral Pain	8 (0.08)
Meniscal Injury (Medial)	7 (0.09)
Achilles Tendinopathy	4 (0.03)*
Plantar Fasciitis	6 (1.00)
Soleus Injury	5 (0.77)
Ilio-Tibial Band Syndrome	2 (0.07)
Patella Tendinopathy	7 (0.55)

B. **SEX**. The relationship between injury risk and sex seems to depend on the type of injury. Several studies have found that women were five times (Myklebust, Maehlum, Holm, & Bahr, 1998) and nine times (Gwinn, Wilckens, McDevitt, Ross, & Kao, 2000) more likely to sustain an anterior cruciate ligament injury compared to men. However, these differences have not been showed in other studies analysing injuries occurring at other locations (Baumhauer, Alosa, Renström, Trevino, &, Beynnon, 1995; Bennell et al., 1996; Beynnon, Renström, Alosa, Baumhauer, & Vacek, 2001; Wiesler, Hunter, Martin, Curl, & Hoen, 1996). Nielsen et al. (2014b) observed that, for a number of running-related injuries, a greater amount of female runners suffered an injury compared to the male runners injured, although only the ilio-tibial band syndrome reached statistical significance (Table 9). Even though the reasons are not clear, it has been speculated that the menstrual cycle (difference in hormones between sexes), bone mineral content and neuromuscular factors (Hewett, 2000; Wiesler et al., 1996) could be some factors accounting for the differences between males and females.

Table 9. Descriptive data of the types of running-related injuries by sex (Nielsen et al., 2014b).

Injury Type	Males (n)	Females (n)	p
Medial Tibial Stress Syndrome	18	20	0.87
Patellofemoral Pain	11	15	0.56
Meniscal Injury (Medial)	10	13	0.68
Achilles Tendinopathy	9	9	1.00
Plantar Fasciitis	6	6	1.00
Soleus Injury	6	6	1.00
Ilio-Tibial Band Syndrome	1	10	0.01*
Patella Tendinopathy	3	8	0.23

C. **HISTORY OF PREVIOUS INJURIES**. The history of previous injury is one of the most commonly suggested factors predisposing to running injury and the one with the greatest body of literature supporting its relationship with injury (Fields, Sykes, Walker, & Jackson, 2010; Hardin, van den Bogert, & Hamill, 2004; Saragiotto et al., 2014; Tenforde, Sayres, McCurdy, Sainani, & Fredericson, 2013; van der Worp et al., 2015). When a body part (muscle, joint, ligament, tendon, bone) gets injured, the injury not only weakens the biological structures (which does not get to become as strong as before the injury) (Fields et al., 2010; Nigg, 2001), but it may also compromise a portion of the neuroceptors that innervate that body location, what may result in a reduction of that area's proprioception (Beynnon et al., 1999). The history of previous injuries becomes especially relevant when the injury is recent (last 12 months) or when it is followed by an inadequate rehabilitation (Milgrom et al., 1991; Saragiotto et al., 2014).

D. **ANATOMICAL ALIGNMENT**. The joint forces occurring between the different segments of the body and the biological structures that must deal with them (ligaments, tendons, articular surfaces, muscles) are related through the anatomical alignment of the joints and the skeletal system (Murphy, Connolly, & Beynnon, 2003). Leg length inequality (Figure 11) has been suspected as a factor in hip, pelvis, iliotibial band syndrome, and low back injury among runners (Fields et al., 2010; Gent et al., 2007; Hreljac, 2005; Johnston, Taunton, Lloyd-Smith, & McKenzie, 2003), although other studies found no relation at all (Hreljac, 2005; Razeghi & Batt, 2000; Wen et al., 1997). Moreover, a significant relationship was observed between increased foot length and width with increased ankle injury risk in military populations (Milgrom et al., 1991). Also, other studies found that increased tibial varum (Beynnon et al., 2001) and increased quadriceps (Q) angle (Q > 15º) (Cowan et al., 1996) seemed to also lead to greater risk of running overuse injuries. However, several studies have reported no association between anatomical alignment (length inequality, knee alignment, Q angle, rearfoot position) and subsequent injury (Soderman et al., 2001; Twellaar, Verstappen, Huson, & van Mechelen, 1997). It has been speculated that abnormal alignment may lead to decreased function and discomfort (Murphy et al., 2003), but to date there is no agreement in the literature regarding their precise influence on the risk of running-related injuries.

Figure 11. Computed radiographic measurement of leg length discrepancy (Sabharwal et al., 2006).

E. **RANGE OF MOTION**. Controversy exists regarding the influence of the range of motion and the risk of injury. In this sense, one study found that knee hyperextension (greater than 10º) was a risk factor for overuse injuries in soccer players, but the ankle dorsiflexion range of motion was not (Soderman et al., 2001). Moreover, Beynnon et al. (2001) suggested that increased calcaneal eversion was a risk factor for ankle sprains only for female runners but not for males. Similarly, another study found that increased hindfoot inversion was associated with greater risk of Achilles tendinitis, but ankle motion was not a risk factor (Kaufman, Brodine, Shaffer, Johnson, & Cullison, 1999). However, several studies observed no relationship between range of motion (ankle, knee and hip range of motion) and injury risk (Milgrom et al., 1991; Twellaar et al., 1997). Finally, whereas foot pronation has been long considered a strong risk factor for running injury (Willems, Witvrouw, De Cock, & De Clercq, 2007; Willems et al., 2006), a recent study has found that foot pronation was not associated with increased injury risk in novice runners (Nielsen et al., 2014a), what leaves a new controversial door open for discussion and further research (Table 10).

Table 10. Number of injuries according to foot posture group (Nielsen et al., 2014a).

Foot posture category	Highly supinated	Supinated	Neutral	Pronated	Highly pronated
Right foot (n=927)					
Legs injury-free	16	160	533	44	5
Legs injured	4	38	111	8	3
Left foot (n=927)					
Legs injury-free	21	145	541	62	7
Legs injured	7	26	107	8	3

F. **MUSCLE WEAKNESS.** Muscle weakness has also been speculated as a risk factor for injury. It is clear that the forces developed by the muscle contractions are important not only for motion but also as a protective mechanism when they are preactivated before ground contact (Boyer & Nigg, 2007). However, it is unclear if muscle weakness (in terms of strength and strength imbalances) is a relevant factor that leads to greater risk of injury. Several studies have suggested that strength imbalances are a risk factor for ankle and knee inury. In this sense, lower ratios of dorsiflexion to plantarflexion, higher ratios of eversion to inversion (Baumhauer et al., 1995) and higher ratios of hamstring to quadriceps strength (Soderman et al., 2001) have been observed in injured athletes compared to healthy ones. On the other hand, other studies did not find quadriceps and hamstring ratios (Ekstrand & Gillquist, 1983; Ostenberg & Roos,

2000) and ankle strength (Beynnon et al., 2001) and quadriceps strength (Milgrom et al., 1991) to be risk factors for injury. Discrepancies regarding the strength measurements (isokinetic measurements at different speeds, isometric measurements) together with the complex interaction of factors that influence strength (muscle reaction time, number of motor units activated, velocity of contractions, etc.) make it very difficult to reach a clear and well-defined relationship between strength and injury risk.

G. **TYPE OF FOOT.** The type of foot has been constantly proposed as a relevant factor that may lead to injury risk (Buldt et al., 2015; Chuckpaiwong, Nunley, Mall, & Queen, 2008; Fields et al., 2010; Hreljac, 2005; Lun et al., 2004; Meana, 2008; Nagel et al., 2008; Razeghi & Batt, 2000; Weist et al., 2004). It is widely believed that a low arched foot (flat or planus) tends to be more flexible and, thus, is subjected to increased pronation (combined motion in all 3 cardinal planes consisting of dorsiflexion, abduction and eversion) (Escamilla, Gómez, Sánchez, & Martínez, 2015; Mademli & Morey, 2015) during the contact phase of walking and running (Figure 12). In contrast, a high arched foot (hollow or cavus) is known to be more rigid and consequently exhibit increased supination (complex triplanar motion consisting of plantar flexion, adduction and inversion) (Mademli & Morey, 2015). A high arched foot is often suggested to be associated with increased injury risk. The runner with high arched feet often has a rigid foot and concomitant problems of decreased ability to absorb the forces occurring during ground contact, which cause an increased injury risk specially on the lateral aspect of the lower extremity such as iliotibial band friction, peroneus tendinitis, femoral and tibial stress fractures and plantar fasciitis (Fields et al., 2010; Hreljac, 2005; McKenzie et al., 1985; Lun et al., 2004; Razeghi & Batt, 2000; Wegener, Burns, & Penkala, 2008; Weist et al., 2004). In contrast, low arched feet have also showed greater energy absorption compared with high arched feet, placing the runner at a higher risk of stress fractures reported in metatarsal bones (Razeghi & Batt, 2000). However, other studies found that arch index was not a major risk factor for running injuries (Fields et al., 2010; Hreljac, 2005; Nielsen et al., 2014a; Wen et al., 1997) and even high arch (Wen, Puffer, &

Schmalzried, 1998) and low arch (Cowan, Jones, & Robinson, 1993; Razeghi & Batt, 2000) index was considered a protective factor against lower-limb injuries.

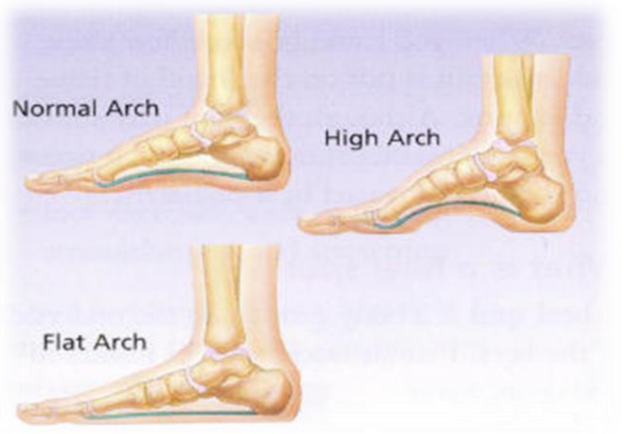


Figure 12. Types of foot arch (Zboinski, 2015).

1.6.3.2. Extrinsic Factors

Even though the genetic and biological factors may account for some of the reasons that could lead to a running-related injury, it is also necessary to describe a number of extrinsic factors (not so related to the human biology but to the environment and the social context) that may also increase the risk of suffering an injury. The most common extrinsic factors are presented in Figure 13.

Figure 13. Summary of the most common extrinsic factors predisposing to running-related injuries.

A. **TRAINING ERRORS**. Several clinical studies have estimated that more than 60% of running injuries could be attributed to training errors (Daoud et al., 2012; Hreljac, 2005). The training variables (errors) that have been identified most often as risk factors for running injuries include **excessive running distance** or **intensity** and **rapid increases in weekly running distance** (Chuckpaiwong et al., 2008; Fields et al., 2010; Fourchet et al., 2012; Gent et al., 2007; Ho et al., 2010; Hreljac, 2005; Macera 1989; Marti et al., 1988; Nigg, 2001; Paty, 1994; Queen et al., 2010; Shorten, 2000). From the 60% of running injures attributed to training errors, it has been suggested that half of them were due to excessive mileage (Jacobs & Berson, 1986; Saragiotto et al., 2014; Worp et al., 2015). Running distances greater than 64 km/week, training more than two days a week or running a whole year through without a break were associated with higher injury risk for men, whereas for women these associations were conflicting (Fields et al., 2010; Gent et al., 2007; Jacobs & Berson, 1986; Tessutti et al., 2010). In contrast, higher training mileage has also showed a protective effect for knee injuries, although they caused hamstring problems (Fields et al., 2010; Satterthwaite, Norton, Larmer, & Robinson, 1999). **Changing the training schedule** such as sudden increases in weekly distance or **changes in the type of training** (interval, hill training) have also been showed to increase injury rate when compared to groups that trained as usual (Fields et al., 2010; Ho et al., 2010).

B. **TRAINING SURFACE**. According to Newton's third Law, when a body makes a contact with the ground, the ground exerts a force equal in magnitude and opposite in direction on the body (Morey & Mademli, 2015). After the initial contact, different surfaces will change the type of reaction due to the specific properties of the surface material, which can influence the load absorption mechanisms of the body structures (Dixon et al., 2000; Ho et al., 2010; Tessutti et al., 2010). Impact forces when running on different surfaces have been commonly studied and running surface has been hypothesised as a potential risk factor for running injuries (Dixon, Collop, & Batt, 2000; Gent et al., 2007; Rome, Handoll, & Ashford, 2005). It has typically been assumed that excessive peak impact forces are associated with the occurrence of overuse injuries, and that cushioning surfaces may reduce these impact forces, resulting in a protective mechanism for the human body based on the idea that compliant surfaces may produce less stresses on the biological structures (Barret, Neal, & Roberts, 1998; Dixon et al., 2000; Fields et al., 2010; Hreljac, 2005; Johnston et al., 2003; Moreno de la Fuente, 2005). This assumption has led to believe that manufacturing sports surfaces that provides increased cushioning will result in a reduced incidence of overuse injuries.

In fact, it has been found that the more compliant the surface, the lower the impact peak and the greater the contact area and contact time of the foot, thereby showing a better load absorption (Tessutti et al., 2010; Twomey, Finch, Lloyd, Elliott, & Doyle, 2012). However, albeit differences in impact forces and loading rates have been found, there is a natural adaptation of the human body in order to reduce or even eliminate these differences. This fact was demonstrated when Dixon et al. (2000), using mechanical tests (impacting the surface material with a specific mass and measuring peak deceleration of the impact device, peak force and surface deformation), found impact forces to be six times greater on asphalt in comparison to rubber. However, these differences were not reproduced when athletes ran on these surfaces, and demonstrate that the musculoskeletal system is capable of absorbing the overloading imposed by a more rigid surface such as asphalt, in contrast to what was observed in the mechanical testing (Razeghi & Batt, 2000). Even though mechanical and computational tests are necessary to provide information that sometimes could not be obtained otherwise, the results of Dixon's study (2000) highlight the importance of researching with human beings when possible, since the human body has showed an amazing ability to adapt to each specific situation in order to maintain its natural state and may surprise us with inexplicably mechanisms that the science is not able to explain and understand yet.

All in all, it has commonly been suggested in the literature that running surface may be associated with injury occurrence. However, with the exception of female runners experiencing higher injury rates when running on concrete

(Fields et al., 2010; Gent et al., 2007; Rauh, Koepsell, Rivara, Margherita, & Rice, 2006), no significant association between running surface and increased injury rate in males has been demonstrated yet. As a consequence, further research is needed to clarify whether there is an actual relationship between running surface and injury incidence when running and the underlying causes involved in the biomechanical mechanisms.

C. **FOOTWEAR**. Early on, shoes were an extremely basic item. With the emergence of competitive and recreational sports, shoes became high-tech and added many more features. Running biomechanists became involved in the creation and design of shoes and due to the abundance of research in this area, running shoes with different foot supporting systems, ventilation systems and shock absorbing systems were and stil are being developed. Selecting running shoes based on foot type and the dynamic biomechanics of the athlete became essential both for enhancing performance and preventing injuries (Gent et al., 2007; Johnston et al., 2003; Morey & Mademli, 2015). Nowadays, running shoes are aim-specific, thereby providing a concrete combination of support and stability depending on the characteristics of the practice and the runner. As a result, there are several types of shoes based on their properties (Werd & Knight, 2010):

- **Cushioning Shoes**: To emphasize cushioning and flexibility. These shoes possess a uniform density midsole, limited shoe stabilising features, and an outsole which promotes flexibility while maintaining good traction. These shoes are best suited for the efficient lightweight runner with a normal to high-arched foot who demonstrates normal lower extremity biomechanics.
- **Neutral Shoes**: To promote adequate cushioning and flexibility with the addition of limited stabilising features. These shoes are best worn by a lightweight runner who exhibits normal lower extremity biomechanics.
- **Stability Shoes**: To augment the natural stability of the foot through all phases of gait. These shoes emphasize adequate cushioning and forefoot flexibility and enhanced motion controlling properties. These shoes are

best worn by lightweight through normal weight runners with normal through moderately abnormal lower extremity biomechanics.

- **Motion control Shoes**: To promote a maximum level of support and influence under the most extreme levels of excessive pronation of the foot during all phases of the running gait cycle. These shoes are better suited for runners with a low arch or a pes planus. These shoes are generally poorly suited for the lightweight runner due to the presence of very firm midsole materials.

Running in the wrong shoes can adversely affect lower extremity alignment, making runners more susceptible to injury (Johnston et al., 2003). Depending on the type of foot and the running biomechanics of the athlete, a different type of shoe should be worn (Escamilla et al., 2015; Morey & Mademli, 2015). Athletes using non-appropriate running footwear has been commonly appointed as a situation that may increase the risk of running-related injuries or, in other words, using proper running shoes adapted to the runner is believed to reduce injury incidence (Fields et al., 2010; Hirschmuller et al., 2011; Hreljac, 2005; Shorten, 2000; Snyder et al., 2009; Zadpoor & Nikooyan, 2010; Zadpoor, Nikooyan, & Arshi, 2007). As explained previously, during the landing phase of the locomotion, the so called "impact force peaks" are produced. If the joints are regularly submitted to such impact force peaks, it has been speculated that subchondral bone and articular cartilage may degenerate, leading to lower back pain and lower limb running injuries in runners (Zadpoor et al., 2007). Based on this idea, sport footwear companies, with the help of biomechanists, podiatrists and sport physicians have been aiming to design sport footwear that is able to reduce the aforementioned force peaks.

Results regarding the effect of different types of shoe and their properties and their association with increased injury rate remain unclear. There is no strong evidence of the role of footwear either as a prevention tool or as a treatment for running-related injuries. However, footwear should still be taken into account when studying the occurrence of injuries in order to find out the role that running shoes actually play.

D. **MIDSOLE PROPERTIES**. Apart from choosing a specific type of shoe adapted to a given foot type and running motion, modifying the midsole hardness is also a very common subject of study that is thought to reduce injury rate in running (Escamilla et al., 2015; Hreljac, 2005; Ly, Alaoui, Erlicher, & Baly, 2010). It has been showed that a reduction of midsole stiffness is associated with a greater attenuation of impact force peaks (Hreljac & Marshall 1999; Ly et al., 2010; Shorten, 2000), whereas other authors concluded that midsole stiffness has no or small influence on the impact force peaks (Ly et al., 2010; Nigg, 2001; Razeghi & Batt, 2000; Zadpoor & Nikooyan, 2010). Hreljac and Marshall (1999) stated that athletes respond uniquely to changes in midsole hardness, thereby implying that a runner should conduct a biomechanical test on each running shoe to determine which shoe attenuates best the impacts for them, what is not a feasible situation. Moreover, these authors concluded that the most important criteria in the selection of running shoes when foot type has already been considered are fit and comfort.

In summary, prevention of injury remains an important goal for athletes, biomechanists, sport coaches, researchers and clinicians. However, in order to reduce the occurrence of injury, the risk factors must be established first. Even though many instrinsic and extrinsic factors have been suggested, at present there is little agreement regarding their actual role and influence on the injury rate.

Among the different previously described factors predisposing to injury, the analysis of **mucle fatigue** (leading to a weakened musculoskeletal system) and the **use of insoles** with special shapes and materials prescribed to correct biological risk factors (foot type, leg length discrepancies) and loading stress factors (control ankle motion, reduce elevated forces, pressures, etc.) are gathering the attention of sport biomechanists due to their potential influence on running biomechanics. Therefore, a more in-depth description of these factors is presented in the following section.

Key Points

- At each foot strike during running the body experiences external forces that may lead to injury.
- Injury intrinsic factors include age, sex, history of previous injuries, anatomical alignments, range of motion, muscle weakness or foot type.
- Injury extrinsic factors include training errors, the running surface, the footwear and the properties of midsoles.

1.7. The importance of Fatigue State and Insoles in Running

Even though running has been associated with plenty of benefits for the health at different levels (cardiovascular, metabolic, psycho-social), the practice of running is also accompanied by an increased risk of overuse injury (Fields et al., 2010; Foch et al., 2015; Kahanov et al., 2015). For this reason, it is of great interest to take into account those mechanisms associated with increased risk of injury and to analyse those strategies suggested to be effective in reducing this risk.

In this sense, most of the studies analysing the biomechanics of running are conducted while running in a non fatigued state. However, although difficult, the study of fatigue is important because it is a regular phenomenon experienced by all runners and it is when most overuse injuries are believed to occur (Hreljac, 2004).

On the other hand, when looking at strategies aiming to reduce the incidence of injury in running, the use of insoles is becoming more and more popular within the running community not only because of their suggested benefits on comfort (Hirschmüller et al., 2011) and performance (Luo, Stergiou, Worobets, Nigg, & Stefanyshyn, 2009), but also due to their role on injury prevention by supporting the rearfoot motion and reducing the loading stress experienced by the musculoskeletal system during running (Dixon, 2007; Dixon, Waterworth, Smith, & House, 2003; Pérez-Soriano, Llana-Belloch, Martínez-Nova, Morey-Klapsing, & Encarnación-Martínez, 2011; Razeghi & Batt, 2000).

Therefore, the aim of the present section is to introduce and provide a deeper insight into these factors and their influence on the main biomechanical parameters during running.

1.7.1. The Fatigue State

Fatigue is a multidimensional response of the human body that occurs when the body is not able to sustain further exercise at a required power or through the reduction in the maximum force that a muscle can exert (Enoka, 2002; Millet & Lepers, 2004).

To a certain degree, it can be considered a defence mechanism which alerts the human body that it has reached its physiological and metabolic limit and therefore it cannot keep performing the activity at the same intensity without compromising the entire system.

In this sense, running as a form of physical activity and exercise involves repeated activation of the skeletal muscles in a coordinated fashion. The intensity of the activity is determined by certain muscle activation parameters including repeat interval, duration of contraction, frequency of activation, and proportion of the total motor unit pool activated for a given muscle (Dotan et al., 2012). All these factors will determine the duration that the body can sustain a given exercise. As a consequence of this limited capacity to properly maintain a given muscle activity over time, fatigue can be considered as a state of alarm or as a defence signal. The human body may show this signal when performing persistent exercise at a given intensity, resulting in general failure (central fatigue) or muscle-specific failure (local fatigue) to sustain that intensity (Paillard, 2012; Nigg, MacIntosh, & Mester, 2000).

During running, the athlete reaches a point where fatigue appears, provoking a multidimensional response affecting the basal physiological and biomechanical characteristics (Paillard, 2012). These changes in running biomechanics are mainly due to modifications in kinetic and kinematic parameters, which are believed to affect running stride and economy (Hunter & Smith, 2007).

Therefore, fatigue plays an important role in running and differences have been found when studying running under fatigue. The main effects of the fatigue state on running are:

A. **HEART RATE AND OXYGEN CONSUMPTION**. These physiological parameters are known to increase with fatigue. As the fatigue develops and the runner gets fatigued, the runner's heart needs to increase the amount of times per minute that pumps blood into the system in order to keep providing oxygenated blood to the rest of the body, thereby increasing heart rate (Ament & Verkerke, 2009). Similarly, as the intensity of the exercise and the concurrent fatigue increases, the muscles increase their rate of oxygen consumption in order to meet the energetic demands to maintain the body in motion. The oxygen consumption increases with fatigue up to a point where it reaches a plateau (maximal oxygen consumption, VO_{2max}), which is considered the maximal rate of oxygen consumption by an active muscle during exercise (Astorino et al., 2005; Draper & Wood, 2005) (Figure 14).

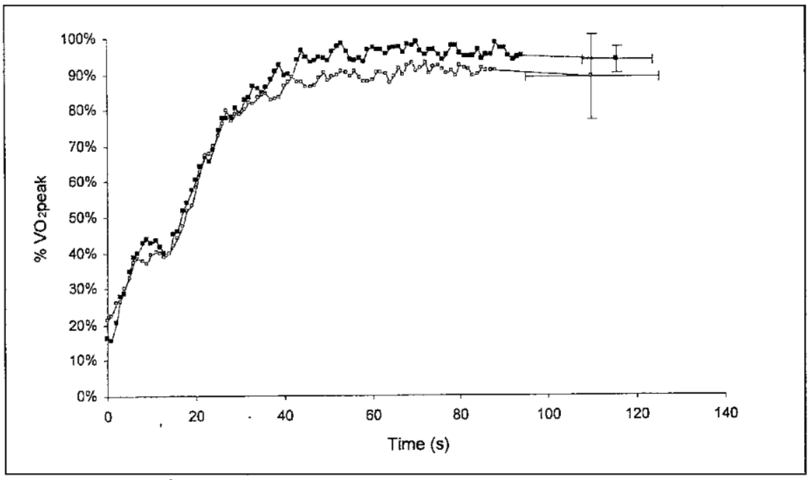


Figure 14. Mean $\dot{V}O_2$ response of sprint (black) and endurance (grey) runners to an exhausting run (Draper & Wood, 2005).

B. **CONTACT TIME**. As contact time is considered a performance marker (shorter contact times have been associated with economical runners (Santos-Concejero et al., 2014)), it is not surprising that the fatigue state has been observed to provoke an increase in contact time during running (Fourchet, Girard, Kelly, Horobeanu, & Millet, 2015; Nicol, Komi, & Marconnet, 1991; Nummela, Vuorimaa, & Rusko, 1992). It has been suggested that fatigue reduces the ability of the musculoskeletal system to deal with the internal loading provoked by the activity and therefore the musculoskeletal system becomes less efficient resulting in adaptations in the running biomechanics away from the optimal patterns (Mizrahi et al., 2012; Verbitsky et al., 1998). However, other studies have not found any difference in contact time as a result of the fatigue state, what could be due to the type of fatigue protocol, the level of fatigue and the type of running (maximal speed [sprint] versus long-distance running technique) (Dutto & Smith, 2002; García-Pérez et al., 2013; Nagel, Fernholz, Kibele, & Rosenbaum, 2008) (Table 11).

Table 11. Contact time after 1 minute (ONSET) and near exhaustion (ENDPOINT) during a treadmill constant velocity run (Fourchet et al., 2015).

Parameter	ONSET	ENDPOINT	p value	% Change
Contact time (s)	0.183 ± 0.13	0.207 ± 0.032	<0.01	13.2 ± 13.1

C. **STRIDE LENGTH AND RATE**. The effect of the fatigue state on stride length and stride rate has showed great variability among studies and fatigue protocols. Whereas some studies have observed a decrease in stride rate (García-Pérez et al., 2013; Gerlach et al., 2005; Hunter & Smith, 2007; Verbitsky, Mizrahi, Voloshin, Treiger, & Isakov, 1998) (Table 12), other studies have found no effect (Derrick, Dereu, & McLean, 2002; Dutto & Smith, 2002) and even an increase in stride rate as a result of the development of fatigue (Elliot & Roberts, 1980). These differences could be explained by the inter-individual adaptations fo fatigue. Whereas some runners are highly sensitive to fatigue and modify their running pattern in an attempt to maintain their optimal running economy, other runners are able to maintain nearly constant physiological and mechanical characteristics of their running pattern as the fatigue develops (Hunter & Smith, 2007).

Table 12. Mean and standard deviation of the effect of fatigue on stride rate (SR) and stride length (SL). Data collected on treadmill and overground. Adapted from García-Pérez et al. (2013).

	3.33 m/s			4.00 m/s		
	Pre-fatigue	Post-fatigue	p	Pre-fatigue	Post-fatigue	p
SR (step/min)	178.6 ± 2.1	177.14 ± 1.85	n/s	194.29 ± 3.10	187.64 ±2.39	0.001*
SL (m)	2.25 ± 0.03	2.27 ± 0.02	n/s	2.51 ± 0.03	2.58 ± 0.03	0.001*

n/s: non significant.

D. **RANGE OF MOVEMENT.** Greater knee flexion and ankle inversion at the time of ground contact have been observed as a result of the fatigue state (Derrick et al., 2002). However, controversy exists since another study found a more pronounced forefoot loading (speculated to be the result of a modified rollover process) leading to a greater pronation as a result of the fatigue state (Weist, Eils, & Rosenbaum, 2004).

E. **IMPACT FORCES**. The fatigue state during running has been associated with a lower impact peak and loading rate of the vertical ground reaction forces (Gerlach et al., 2005) (Figure 15). However, this effect is also unclear since Weist et al. (2004) observed increased local forces measured with instrumented insoles under the metatarsals, the hallux and the toes when running fatigued.

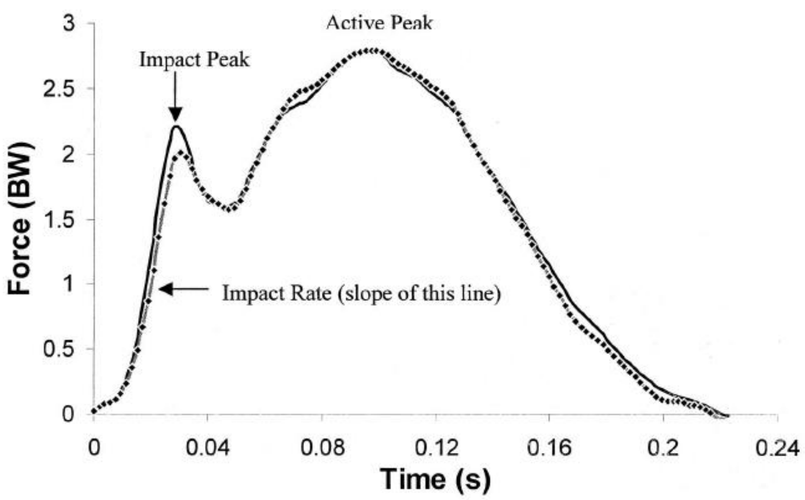


Figure 15. Change in ground reaction forces with fatigue. Prefatigue values (black), Postfatigue (grey) with black diamonds. BW, units of body weight (Gerlach et al., 2005).

F. **MUSCLE ACTIVATION**. A reduction in muscle activity (in terms of the integrated electromyography [iEMG]) during maximal voluntary contractions and during maximal running has been observed after long distance running events (Millet & Lepers, 2004; Millet et al., 2002; Weist et al., 2004) (Figure 16). However, during submaximal exercise, several studies reported no differences (Avogadro, Dolenec, & Belli, 2003) and other studies even found that the amplitude of the muscle activity increased as a result of the fatigue state (Hanon, Thépaut-Mathieu, & Vandewalle, 2005; Nicol et al., 1991; Nummela et al., 1992).

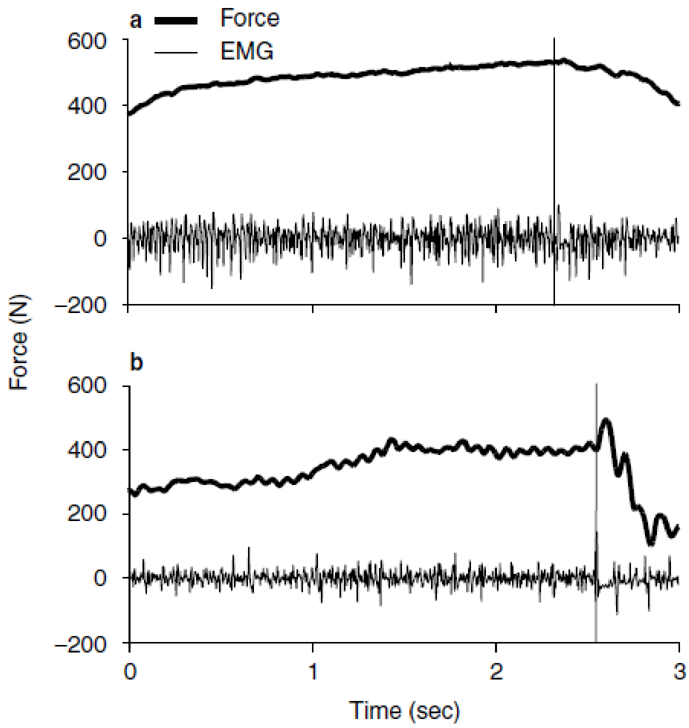


Figure 16. Muscle activation and force of vastus medialis during a knee extension maximal voluntary contraction before and after an ultramarathon (Millet & Lepers, 2004).

G. **PLANTAR PRESSURE**. Several studies have observed a reduction in plantar pressure under the rearfoot and toes together with an increase in pressure under the metatarsal heads with the development of running fatigue as a result of the local fatigue of the toe flexor muscles (Nagel et al., 2008; Rosenbaum et al., 2008; Weist et al., 2004; Willson & Kernozek, 1999) (Figure 17). However, other studies have found no differences in plantar pressure when the athletes ran fatigued compared to a non-fatigued running condition (Alfuth & Rosenbaum, 2011; García-Pérez et al., 2013; Schlee, Milani, & Hein, 2006). The type of fatigue, the level of the runners, how the plantar pressure measurement was carried out (during the last moments of the fatigue protocol vs right after the fatigue, etc.) could account for the differences between studies.

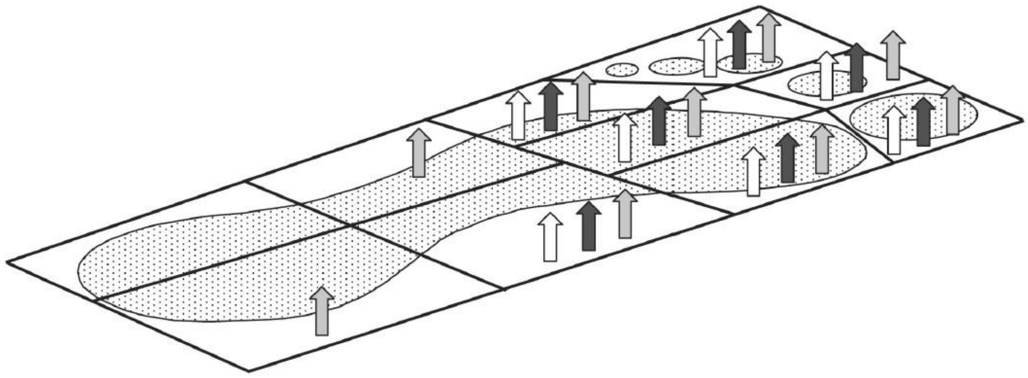


Figure 17. Plantar loading parameters between the fresh and the fatigued condition. Grey arrows = force time integral; black arrows = peak pressure; white arrows = maximum force (Weist et al., 2004).

H. **IMPACT ACCELERATIONS**. Although some investigations have found no effect of the fatigue state on impact acceleration (Abt et al., 2011; García-Pérez, Pérez-Soriano, Llana-Belloch, Lucas-Cuevas, & Sánchez-Zuriaga, 2014; Mercer, Bates, Dufek, & Hreljac, 2003), other studies reported an increase in tibial peak impact acceleration with fatigue (Derrick et al., 2002; Lucas-Cuevas, Priego-Quesada, Aparicio, Giménez, Llana-Belloch, & Pérez-Soriano, 2015; Mizrahi, Verbitsky, & Isakov, 2000; Verbitsky et al., 1998). Moreover, in order to protect the head, the musculoskeletal system adapts itself in order to maintain the accelerations arriving at the head within a healthy range. As a result, since it has been observed that tibial peak impact acceleration increases and head peak acceleration remains the same, the shock attenuation is also found to increase (Derrick et al., 2002) (Figure 18).

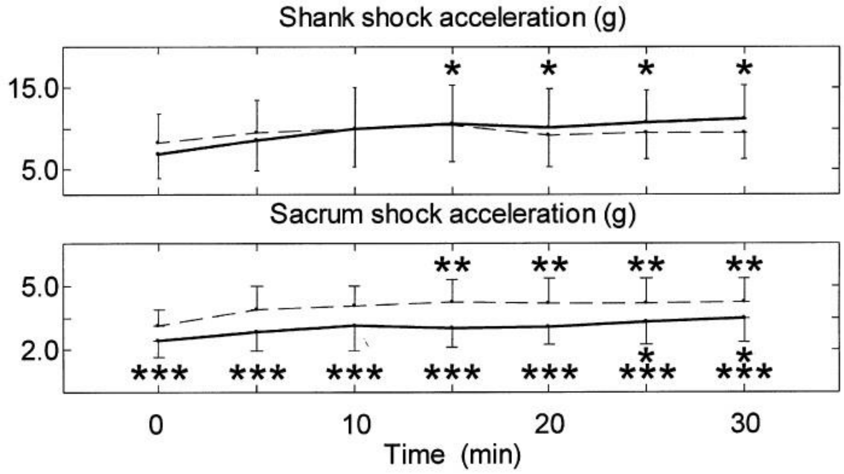


Figure 18. Impact acceleration at a running speed just exceeding the anaerobic threshold. Solid line: level running; dashed line: downhill running.
*** significantly different from data at the beginning of running for level running ($p < 0.05$).**
**** significantly different from data at the beginning of running for decline running ($p < 0.05$).**
***** significantly different between level and decline running ($p < 0.05$).**

The influence of the fatigue state on the aforementioned parameters is not clear and there are big discrepancies among studies (fatigue leading to increased or decreased values of the different variables) almost for any parameter analysed. The main explanation for these discrepancies is the fatigue protocol used in the studies and the subsequent different level and type of fatigue attained by the participants at the moment of measurement.

In this sense, the most common types of tests used in the scientific literature to provoke fatigue are:

A. **REAL AND OFFICIAL RUNNING EVENTS**. In these events, researchers carry out biomechanical analysis “during” or “before and after” the event (Del Coso et al., 2014; Nagel et al., 2008). Although basically any competition guarantees that the athlete will finish fatigued or exhausted, long-distance events such as half-marathons, marathons, half-ironmans, ironmans or ultramarathons are the most appropriated events to provoke general fatigue as a result of prolonged exercise. The main disadvantage of these studies is that researchers have little control over the environment and confounding factors may influence the variables of analysis (and therefore the specific objective of the study) leading to unexpected and difficult-to-explain results. Consequently, it is very difficult for researchers in these studies to analyse and compare the relationship between variables because researchers cannot be sure that other variables are not playing a role in the analysis. On the other hand, it is true that these events are the closest to reality (because in fact they are real running events) and researchers could argue that whatever they are measuring is exactly whatever is happening to the athlete in that situation.

B. **OVERGROUND NON OFFICIAL RUNNING TESTS**. In these events, participants are asked to run a given distance at their own pace or at an established intensity (Alfuth & Rosenbaum, 2011; Rosenbaum, Engl, & Nagel, 2008) or to run for a given time at a relative individual intensity (percentage of maximal aerobic speed, anaerobic threshold) (García-Pérez et al., 2014; García-Pérez et al., 2013). The most common tests are distances of 10 km or durations of 30 minutes, since they represent the middle-point between short-term fatigue events (where anaerobic fatigue [based mainly on energy depletion mechanisms] may be dominant rather than aerobic long-term fatigue [based on a complex interaction of metabolic, neuromuscular and structural changes that occur steadily in order to adapt the individual's running capacity to the increasing stress produced by the event]) and long-term fatigue events (where the time to carry out the experiment is greater than one hour and therefore it becomes a limitation for researchers since it is too time-consuming). These events have the advantage that they are still close to reality (the athlete is running overground with a certain degree of freedom of movement) and there is usually more control over confounding variables compared to official running events.

C. **LABORATORY TESTS**. In these tests, participants run on a treadmill following a specific fatigue protocol while controlling a certain number of parameters of interest (García-Pérez et al., 2013; Voloshin, Mizrahi, Verbitsky, & Isakov, 1998). As it is often said in the scientific jargon, "the more controlled the study, the further from reality". This is especially true in this type of experiments, where a great level of control over specific variables can be done: running speed, running surface stiffness and slope, running pace, physiological variables (heart rate, oxygen consumption, blood lactate concentration, etc.) and environment conditions (temperature, humidity, wind) at the expense of measuring a situation far from reality (no other competitors, no wind, no alteration of the terrain properties, no natural inter-stride alterations as a consequence of stones, curves, etc. in the running path, etc.) (García-Pérez et al., 2014, 2013). This type of tests allows the researcher to better explain the relationship between specific variables but their inference to the real running situation is still unclear nowadays. In this sense, some studies have found differences in biomechanical variables (plantar pressure (García-Pérez et al., 2013), impact acceleration (García-Pérez et al., 2014), muscle activity (Baur, Hirschmuller, Muller, Gollhofer, & Mayer, 2007), energy expenditure (Jones & Doust, 1996), lower extremity kinematics (Riley et al., 2008)) between running on a treadmill and overground and have concluded that running on a treadmill is not exactly the same as running overground.

It is known that the fatigue state plays a very relevant role in the analysis of the biomechanics of running. However, since fatigue is a very complex phenomenon that can be attained as a result of very different situations (type of exercise, intensity, duration, etc.), its analysis becomes difficult and this makes the subsequent interpretation of its effects even more challenging. Nevertheless, nowadays more and more studies are providing strong scientific-based evidence steadily clarifying the different mechanisms that provoke fatigue and every new study helps to increase the body of knowledge around this exciting phenomenon.

1.7.2. Foot Orthoses: Insoles

The anatomical structure of the plantar pad of the foot allows efficient storage and attenuation of mechanical energy through deformation. However, during physical activity, each time the foot contacts the ground, impact forces are produced and transferred upwards to the body (Creaby et al., 2011; Llana & Brizuela, 1996; Wee &

Voloshin, 2013). Even though each one of these impacts can be physiologically absorbed and attenuated by the musculoskeletal system, the repetitive and constant character of these impacts may extenuate the biological structures (van der Worp et al., 2015). Hence, such forces have been commonly associated with overuse injuries (Burnfield et al., 2007; Hardin et al., 2004; van der Worp et al., 2015). As a consequence, professionals of different areas involved in sport injury prevention and coaching, as well as footwear companies have showed an increased interest regarding how to deal with these impacts potentially dangerous for the body. This interest has led sport-specific footwear to be considered as a key element for foot protection and improvement of the performance of athletes (Even-Tzur, Weisz, Hirsch-Falk & Gefen, 2006). An important goal when designing sport shoes is to reduce the impact forces and stresses transferred to the foot and the upper musculoskeletal system during the stance phase, by increasing stress attenuation over the natural attenuation abilities of the heel pad (Daoud et al., 2012; Perkins, Hanney, & Rothschild, 2014).

Apart from modifying the midsole of the shoe and its properties, the use of foot orthoses is being suggested recently to assist in the absorption of skeletal shock transients and reduce peak plantar pressures by lengthening the duration of the deceleration impulses (Creaby et al., 2011; Dixon et al., 2007; Shorten, 2000; Verdejo & Mills, 2004). Werd and Knight (2010, p.19) explained the relevance of foot orthoses in injury prevention and injury treatment as follows:

> *"For the clinician that treats both athletic and non-athletic injuries of the foot and lower extremity, foot orthoses are an invaluable therapeutic tool in the treatment of many painful pathologies of the foot and lower extremity, in the prevention of new injuries in the foot and lower extremity, and in the optimization of the biomechanics of the individual during sports and other weightbearing activities. Because of their therapeutic effectiveness in the treatment of a wide range of painful mechanically based pathologies in the human locomotor apparatus, foot orthoses are often considered by many podiatrists, sports physicians, and foot-care specialists to be one of the most important treatment modalities for these conditions."*

Foot orthoses (often described by the slang word "*orthotics*") are generically defined as (Werd & Knight, 2010, p.20):

> *"An in-shoe medical device which is designed to alter the magnitudes and temporal patterns of the reaction forces acting on the plantar aspect of the foot in order to allow more normal foot and lower extremity function and to decrease pathologic loading forces on the structural components of the foot and lower extremity during weightbearing activities."*

At this point, it is necessary to point out the importance of pathology-specific orthoses such as shoe inserts and insoles that take into consideration the dysfunction of that particular athlete's foot, where considering the activity of the athlete is a pre-requisite to a successful clinical outcome instead of generic foot orthoses that may be inappropriate for the specific case of the athlete (Escamilla et al., 2015). Prescribing the same foot orthosis for patellofemoral pain syndrome and metatarsalgia will not influence the athlete in the same way and therefore the outcome of the treatment may not be successful because each condition has unique and specific functional needs and mechanical origins (Werd & Knight, 2010).

To date, studies on the effect of insoles on overuse injuries can be categorised into two key areas (Crabtree, Dhokia, Newman, & Ansell, 2009; Razeghi & Batt, 2000): the influence on relieving symptoms of overuse injuries and the influence on the biomechanical function of lower extremity joints. Regarding kinematic modifications, insoles have been observed to influence positively the running pattern by better stabilising the rearfoot, reducing maximum overpronation (by bringing pronation of an injured foot closer to that of the normally aligned foot) and time to maximum pronation, reducing maximal external rotation of the tibia, calcaneal eversion and vertical peak reaction forces at the knee (Branthwaite, Payton, & Chockalingam, 2004; Creaby et al., 2011; Escamilla et al., 2015; Mundermann, Nigg, Humble, & Stefanyshyn, 2003; Nawoczenski, Cook, & Saltzman, 1995; Nigg et al., 1987; Razeghi & Batt, 2000; Stacoff et al., 2000). In athletes injured at the time of the study or with special conditions such as pes cavus, treatment with insoles showed earlier improvements in lower limb complaints, pain relief, increased perception of comfort and faster recovery to normal functioning of the affected area (Escamilla et al., 2015; Fields et al., 2010; Gijon-Nogueron et al., 2014; Hirschmüller et al., 2011; Razeghi & Batt, 2000). However, other authors found that insoles didn't provoke dramatic changes in rearfoot motion and frontal plane rotations, thereby concluding that to date there is insufficient evidence to support or refute the use of insoles in controlling lower-limb motion during running to treat running overuse injuries (Gross et al., 1991; Hirschmuller et al., 2011; Razeghi & Batt, 2000).

Besides the role of foot kinematics in running injury incidence, a growing interest has recently been spreading within the scientific community with respect to the relationship between foot pressure loading during running and injury rate. Little has been studied involving the use of insoles and plantar pressure distribution during running, although custom-made insoles built from a mould of the individual's foot print have been proposed as an effective tool to redistribute the pressure beneath the foot and absorb energy in terms of reducing impact forces, thereby preventing overloading in different areas of the foot leading to dangerous excessive impact forces transmitted to the skeletal system (Creaby et al., 2011; Dixon et al., 2003; Escamilla et al., 2015; Fields et al., 2010; Hirschmuller 2011; Gijon-Nogueron et al., 2014; Lee, Lin, & Wang, 2012; Pérez-Soriano, Llana-Belloch, Martínez-Nova, Morey-Klapsing, & Encarnación-Martínez, 2011; Razeghi & Batt, 2000; Shorten, 2000; Wegener et al., 2008; Werd & Knight, 2010; Withnall et al., 2006; Yung-Hui & Wei-Hsien, 2005).

The different types of insoles used and populations involved in the studies make it difficult to provide conclusive and strong evidence regarding the role of custom-made insoles as a possible means of reducing injury incidence or as a preventive tool. Although footwear and insoles focus on controlling and correcting individual running biomechanics and may represent important therapeutic interventions for some athletes, they must remain part of a programme that considers all the aetiological factors (intrinsic and extrinsic factors) in order to prevent the occurrence of overuse running-related injuries from a complete and comprehensive approach.

Key Points

- The analysis of fatigue is important because it is when most injuries are believed to occur.
- Fatigue provokes alterations in the biomechanics of running including alterations in spatio-temporal parameters, accelerations, forces, pressures and muscle activity.
- Insoles are common strategies to prevent and treat running injuries. Insoles influence strongly the biomechanics of running.

1.8. Analysis of Running

Running is a form of physical activity that involves the movement of the entire body while at the same time the different body segments with their corresponding biological structures (tendons, ligaments, bones, muscles) act in a perfectly coordinate manner in order to create an efficient development of the movement (Perry & Burnfield, 2010). Moreover, the different body segments move in different planes of motion (transverse, sagittal and frontal) at different velocities, while the inner organs (heart, lungs, brain, etc.) and systems (cardiorespiratory, musculoskeletal, nervous, etc.) work restlessly to meet the energetic and physical demands of the exercise.

It seems clear that running, even though it is a natural action for humans, involves a complex and synchronized interaction of numerous individual parts that results in the action of running. This act of running is individual-specific and is also called “running technique”. From a biomechanical point of view, it is possible to measure the different individual parameters that take part in the global action and try to explain the manner in which the different parts influence each other in order to identify targets for improvement (and therefore enhance performance) and targets for protection (and therefore prevent or treat injuries). In this sense, the most common physiological and biomechanical parameters analysed in running are presented in Figure 19.

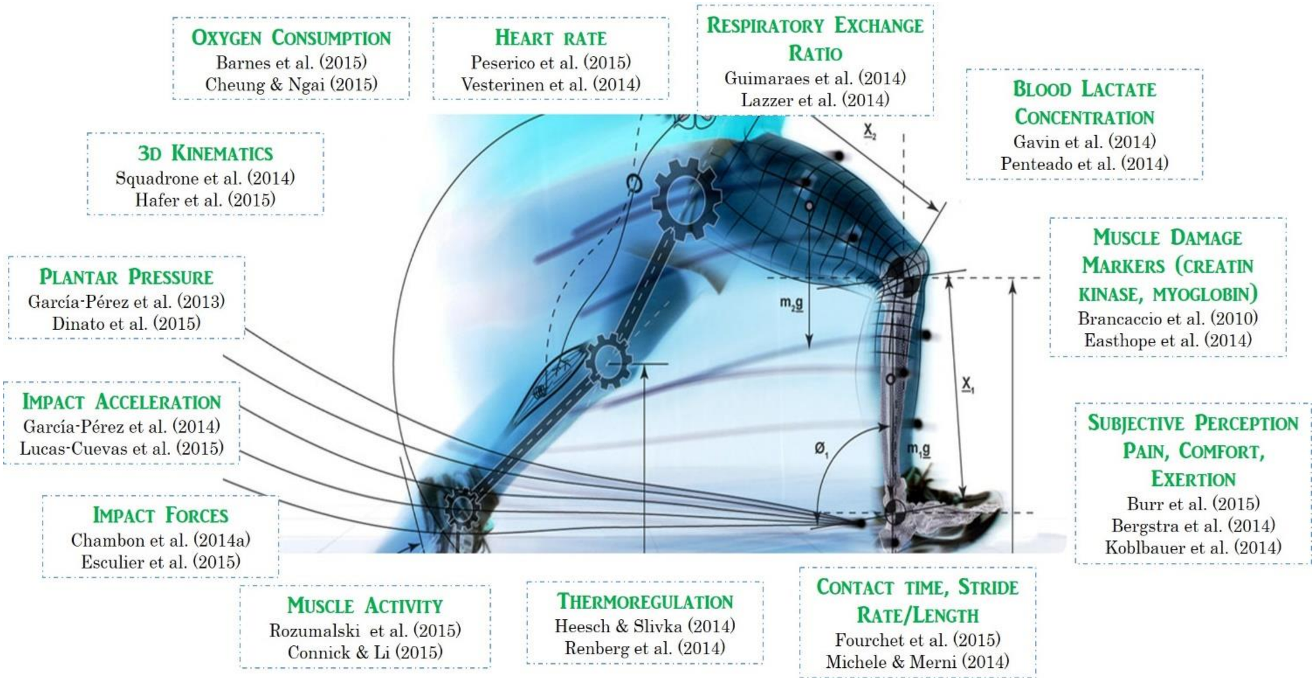


Figure 19. Most common physiological and biomechanical parameters analysed in running.

Among all these parameters, three of the most relevant variables in running are the analysis of the spatio-temporal parameters, plantar pressures and impact accelerations. Spatio-temporal parameters are important because under the same running conditions (running speed, properties of the running surfaces, etc.), a simple alteration of the contact time or stride rate/stride length will directly influence the rest of the parameters (impact forces, muscle activation, impact acceleration, plantar pressure, etc.) and therefore their study and control is of great importante in running (Hanon et al., 2005; Santos-Concejero et al., 2014). On the other hand, plantar pressure and impact acceleration are important parameters because of their association with increased injury rate (Davis, Milner, & Hamill, 2004; Hreljac, 2004; Hreljac, Marshall, & Hume, 2000; Milner, Ferber, Pollard, Hamill, & Davis, 2006; Weist et al., 2004; Willems et al., 2007).

Moreover, since the present work is interested in investigating the effects of an insole intervention and the fatigue state during running, the perception of comfort and the perception of fatigue become essential parameters to take into account in order to have a broad view of the entire picture.

1.8.1. Biomechanical Parameters

1.8.1.1. Analysis of Plantar Pressure

Newton's third law of motion provides a means for indirectly estimating the forces that muscles generate. As the body weight drops onto and moves across the supporting foot when walking (and obviously when running and jumping), vertical and shear (antero-posterior (AP), and medio-lateral (ML)) forces are generated (Aguado, 2015; Morey & Mademli, 2015). The immovable floor reacts with forces of equal intensity but opposite direction to those being produced by the weight-bearing limb. A force plate mounted in the floor can be used to measure and quantify the ground reaction forces (GRF) as vectors with both magnitude and direction (Aguado, 2015; Perry & Burnfield, 2010).

Usually during human motion, a force is distributed over an area of contact (interaction foot sole-ground) rather than a force concentrated at one specific point of application. The sum of the GRF are expressed as a resultant vector with a centre of pressure point. However, these forces are applied through the athlete's shoe or foot during a stance. Therefore, the force vector is in fact distributed over this contact area, and its distribution can be analysed using the concept of **pressure**, defined as the force per unit area applied perpendicularly on the surface of an object, and it is expressed in Newton per square metre ($N \cdot m^{-2}$), also called Pascals (Pa), although Newton per square centimetre ($N \cdot cm^{-2}$) or kilopascals (kPa) are very common units of measure as well (Table 13) (Aguado, 2015; Morey & Mademli, 2015; Robertson et al., 2004):

Table 13. Pressure units and some common pressure measurement equivalences

$$P = F / A \qquad (N \cdot m^{-2} = Pa; \quad N \cdot cm^{-2}; \quad kPa)$$

$$1\ \mathrm{Kg} \cdot \mathrm{m} \cdot \mathrm{s}^{-2} = 1\ \mathrm{N} = 1\ \mathrm{Pa}$$

$$1\ \mathrm{kPa} = 1000\ \mathrm{Pa} = 1000\ \mathrm{N} \cdot \mathrm{m}^{-2} = 0.1\ \mathrm{N} \cdot \mathrm{cm}^{-2}$$

$$1\ \mathrm{Pa} = 1\ \mathrm{N} \cdot \mathrm{m}^{-2} = 0.001\ \mathrm{kPa} = 0.0001\ \mathrm{N} \cdot \mathrm{cm}^{-2}$$

During the stance phase when the foot contacts the ground, an array of force vectors are distributed across the area of contact, each one applied to a unit surface area, for instance, in a 1 mm^2. Some forces within this array are larger than others and the overall pattern of these force vectors constitutes the force distribution across the contact area. The summation of these distributed forces equals the magnitude of the overall force vector measured with a force plate (Robertson et al., 2004).

There are many types of pressure analysis systems with a big variety of sensors. The most common systems are presented in Table 14.

Table 14. Summary of dynamic pressure analysis systems.

Between footwear and ground	Instrumented shoes that include load cells and transducers within the midsole Instrumented shoes that include a metal plate with a strain gauge within the midsole Instrumented shoes that include multiple force cells within the midsole
Between foot and ground	Ink impression matrices Optical techniques. The participant steps on a mat that measures deformity connected to a barograph Electromechanic transducers matrix. A platform with transducers incorporated
Between foot and footwear	Capacitive sensors Strain gauge sensors Conductive sensors Piezoceramic sensors Piezoelectric sensors Hydrocell sensors Resistive sensors Magnetoresistive sensors

Modified from Martínez-Assucena, Pradas-Silvestre, Sánchez-Ruiz, & Peydro de Moya (2005).

The different types of sensors (capacitive, conductive, piezoceramic, hidrocell) are manufactured so that independent cells of equal area are formed, and the circuit is designed to measure the pressure within each cell. Subsequently, thin sheets of these materials can be formed into pressure mats or insoles that are placed inside shoes (Escamilla et al., 2015; Pérez-Soriano, & Llana-Belloch, 2015; Robertson et al., 2004).

In running biomechanics, pressure is measured mainly by two different types of equipment: pressure platforms and instrumented insoles:

A. **PRESSURE PLATFORMS** or stationary pressure mapping “squares” measure pressure distribution under the foot in static and dynamic conditions. It is important to bear in mind that this system only measures the vertical forces, thereby no shear forces are identified using these platforms. Pressure platforms offer useful clinical information about a person’s gait, although several disadvantages should be commented. Firstly, although these platforms can be used for measurements wearing shoes, their usual application lies in barefoot condition as the shoe interface can mask the crucial information about the loading of the anatomical structures of the foot (Escamilla et al., 2015). Also, the measuring area is limited to the dimensions of the platform, thus the athlete must naturally step on it avoiding targeting (Martínez-Nova, Cuevas-García, Sánchez-Rodríguez, Pascual-Huerta, & Sánchez-Barrado, 2008a). Similarly to force plates, these systems can be installed within a gait walkway in order to facilitate the natural running/walking pattern and avoid targeting (Figure 20).

Figure 20. Pressure platform (Novel, 2010).

B. **INSTRUMENTED INSOLES**. Recently, in-shoe pressure measurement systems have become a common tool for analysing load distribution during human motion (Escamilla et al., 2015; García-Pérez et al., 2013; Martínez-Nova et al., 2008a; Pérez-Soriano, & Llana-Belloch, 2015; Pérez-Soriano et al., 2011; Perry & Burnfield, 2010; Shu et al., 2010). Approximately 400 individual pressure cells may register the plantar surface of the foot. To extract the data from such a large number of cells, individual wires would be impractical. Therefore, the insoles are constructed like flexible circuit boards by using thin conductive strips within the insole to carry the signals to a small connecting box worn near the participant's ankle (Robertson et al., 2004) (Figure 21).

Figure 21. Array of sensors embedded into the instrumented insole.

The majority of in-shoe pressure analysis systems function by wearing one or two instrumented insoles linked to a signal amplifier attached to participant's waist, which sends the pressure data to a computer using digital telemetry. These systems generally have a reach around 100-200 metres, allowing the athlete to freely move outside the laboratory, providing the possibility of doing the measurement in the field and measuring multiple steps simulating the actual sequence of locomotion (Cheung & Ng, 2008; Dyer & Bamberg, 2011; Escamilla et al., 2015; García-Pérez, 2013; Martínez-Nova et al., 2008a; Martínez-Nova et al., 2007b; Savelberg & Lange, 1999; Shu et al., 2010; Williams, 2010) (Figure 22).

Figure 22. Analysis of plantar pressure during running using instrumented insoles (Novel, 2010).

An instrumented insole is made of a thin sheet with multiple integrated sensors, thereby enabling the construction of pressure coloured maps where discrete location of pressures within the foot is possible (Figure 23). This system allows for a well understanding of the interactions between shoes and insoles on the athlete's plantar pressure distribution by a continuous pressure analysis curve of both feet over time, since the insoles are measuring throughout the whole motion, enabling the observer to identify the development of the pressures at each phase (Escamilla et al., 2015; Liu et al., 2011). Moreover, using the appropriate computer software, the sensors of the insole can be separated into the different foot areas (heel, medial/lateral midfoot, medial/lateral forefoot or toes), what makes it a useful tool to analyse changes in stepping patterns provoked by a specific insole, injuries or shoes (Perry & Burnfield, 2010; Williams, 2010).

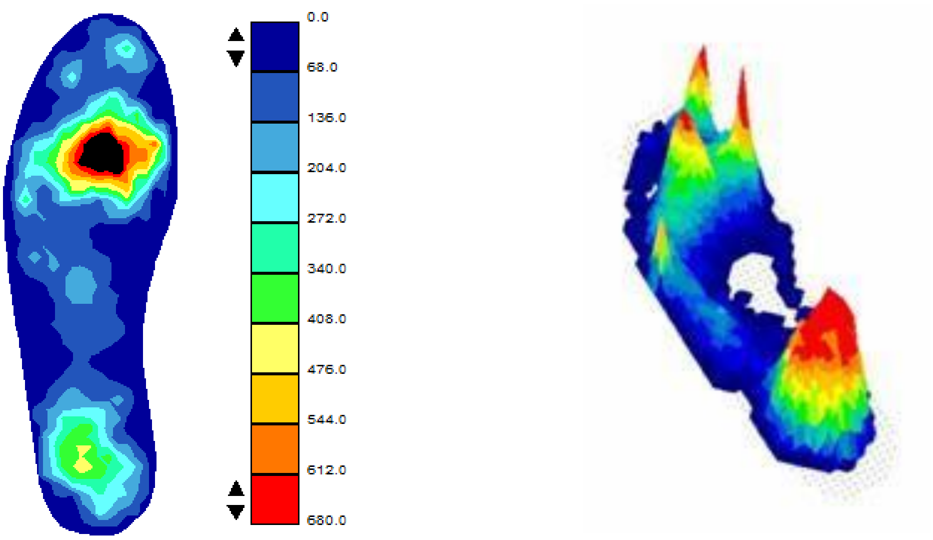


Figure 23. Different pressure coloured maps of the foot using instrumented insoles.

There are several in-shoe pressure analysis systems, of different commercial brands, made of specific type and number of sensors and with different frequencies of measurement (Table 15).

Table 15. Comparison of different plantar pressure systems.

Brand	Type of sensor	Thickness (mm)	Number of sensors	Frequency	Resolution
Novel Electronics (Pedar Insoles)	Capacitance	2.4	256 max	100 Hz	1 N/cm^2
Tekscan (F-Scan system)	Pressure-Sensing Cells	0.2	960 max	165 Hz	4 sensors/ cm^2
Parotec System	Hidrocells	3.0	24	250 Hz (adjustable)	25 N/cm^2
IBV (Biofoot)	Piezoceramic	0.7	64 max	500 Hz (adjustable)	1 N/cm^2

Moreno et al., 2004.

When using one of these systems, no matter which, the researcher must be aware that the pressure distribution on the foot sole during running has been found to be dependent on different factors that will modify the pressure outcome regardless the aim of the study. Hence, it is essential for the researcher to acknowledge them in order to study the pressure distribution during running properly and control as much as possible those confounding factors so that valid and reliable results can be obtained.

During running, the centre of pressure of the body follows a natural path over the plantar surface of the foot. In Figure 24 the dynamic pattern that the centre of pressure follows over the plantar surface during rearfoot running is presented, which is the most common foot strike, observed in 75-90% of the runners (Hasegawa, Yamauchi, & Kraemer, 2007; Larson et al., 2011; Lieberman, 2014). The centre of pressure starts in the heel when the athlete strikes the ground in an inverted position, and then it advances to the lateral aspect of the midfoot as a result of the forefoot going downwards. The centre of pressure moves then to the medial aspect of the foot as a result of the pronation of the foot and the internal rotation of the tibia during the absorption phase. The pronation of the foot is necessary because it unlocks the transverse tarsal joint, increasing the flexibility of the foot and allowing it to function more effectively as a shock absorber. The propulsion phase starts at this point and the foot supinates leading the centre of pressure towards the metatarsal heads and lifting the heel by a forceful contraction of the triceps surae. Finally, as the heel continues to elevate, the centre of pressure moves from the metatarsals to the hallux, which is the last part that remains in contact before the foot finally leaves the ground (González, Alcántara, Gámez, & Alemany, 2008; Novacheck, 1998).

Figure 24. Behaviour of the centre of pressure during rearfoot running (MoveWell, 2015).

Plantar pressure during running has been analysed in the literature in terms of different variables including the peak pressure (Chuckpaiwong, Nunley, Mall, & Queen, 2008; Guldemond et al., 2006; Keijsers, Stolwijk, & Pataky, 2010), the time to the peak pressure (Thijs, Van Tiggelen, Roosen, De Clercq, & Witvrouw, 2007; Warren, Maher, & Higbie, 2004; Willems et al., 2007), the pressure-time integral (Allet et al., 2011; Chuckpaiwong et al., 2008; Warren et al., 2004), and the relative pressure (García-Pérez et al., 2013) (Figure 25).

- The **mean peak pressure** is the average value of the maximum pressures from each step. The peak pressure is the most common pressure parameter reported in the literature since it provides an indication of how severe the plantar loading of an activity is. Increased peak pressure values have been associated with increased injury risk (Chuckpaiwong et al., 2008; Guldemond et al., 2006). By averaging the peak pressures (mean peak pressure), the outcome is more robust against abnormal peak values due to noise of the signal or malfunctioning of a given pressure sensor.
- The **time to peak pressure** is the time from the ground contact to the peak pressure in each foot area. This parameter gives an indication of how fast

the loading is experienced by the foot. In this sense, a shorter time to peak pressure has been associated with increased risk of patellofemoral pain since the musculoskeletal system may not be able to react fast enough to deal adequately with the fast loading (Thijs et al., 2007).

- The **pressure-time integral** is the area beneath the pressure-time curve and indicates how much pressure is being applied on that area over that specific period of time (Mickle, Munro, Lord, Menz, & Steele, 2011). The pressure-time integral has been appointed as a very important variable because it provides information not only about how much load a specific area of the foot is experiencing during a task, but also about how long the load is being applied (Queen et al., 2007; Wegener et al., 2008).

- The **relative peak pressure** is the peak pressure on each region divided by the peak pressure of the entire plantar surface, expressed as a percentage (García-Pérez et al., 2013). Even though this concept has commonly been use to report forces (Fourchet et al., 2012; Weist et al., 2004), it was only until very recently that it has been used to express the relative load for pressures (García-Pérez et al., 2013), providing interesting information of how the pressure is distributed on the plantar surface of the foot.

Figure 25. Example of a representation of the mean peak pressure during Walking (white) and Nordic Walking (grey) (adapted from (Pérez-Soriano et al., 2011)).

1.8.1.1.1. Factors that influence Plantar Pressure

Numerous factors have been suggested to influence the analysis of plantar pressure. The most common ones are presented in Figure 26.

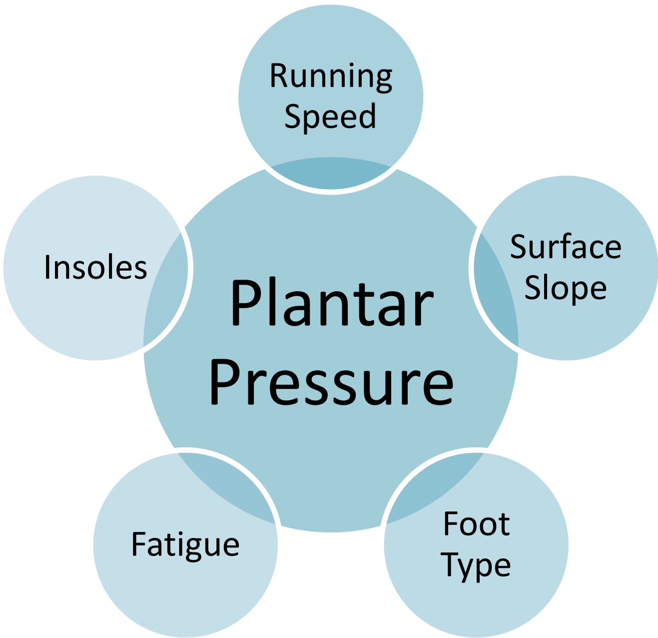


Figure 26. Most common factors that influence plantar pressure.

Regarding the influence of **speed** on plantar pressure, it is essential first to bear in mind that walking is completely different from running from a biomechanical point of view. Although they may seem similar movements, there are plenty of kinetic and kinematic differences between the two types of motion. During walking, there is always at least one foot in contact with the ground, whereas during running there is an alternation between a phase with one foot in contact with the ground and a non-support phase (Lohman III, Balan Sackiriyas, & Swen, 2011; Novacheck, 1998). This difference leads to substantial modifications in kinetics and kinematics, making the two movements completely different when studying their biomechanics (Stolwijk, Duysens, Louwerens, & Keijsers, 2010). In this sense, fast walking is not simply a faster version of walking and fast running is not just a faster version of normal running due to the non linear relationship between velocity and foot motion (Lee, Chou, Liu, Lin, & Shiang, 2008).

The influence of running speed on plantar pressure has been clearly demonstrated. When considering the whole foot, increases in speed have been related to higher plantar pressure distribution (Burnfield, Few, Mohamed, & Perry, 2004; Fourchet et al., 2012; García-Pérez et al., 2013; Ho et al., 2010; Lee et al,. 2008; Lee, Ho, Yang, Wu, & Guo, 2007; Nagel et al., 2008). When dividing the foot into different areas and looking into each one of them individually, there is no total agreement among the researchers. Whereas some authors concluded that there is an increased plantar pressure only at the heel and medial forefoot with greater running speed (Rosenbaum & Becker, 1997), other studies have found higher pressures in all foot regions but the medial forefoot and hallux (Ho et al., 2010) (Figure 27). Also, greater foot contact area (+1.2%) and lower contact time (-20.1%) between the foot and the ground have been associated with increases in velocity (Fourchet et al., 2012), what may explain the aforementioned higher plantar pressure at faster velocities, since the vertical forces are originated and propagated through the body during a shorter amount of time, albeit the interaction area where the force is transmitted (pressure has been defined as the force applied divided by its area of application) increases proportionally but in a much lower rate.

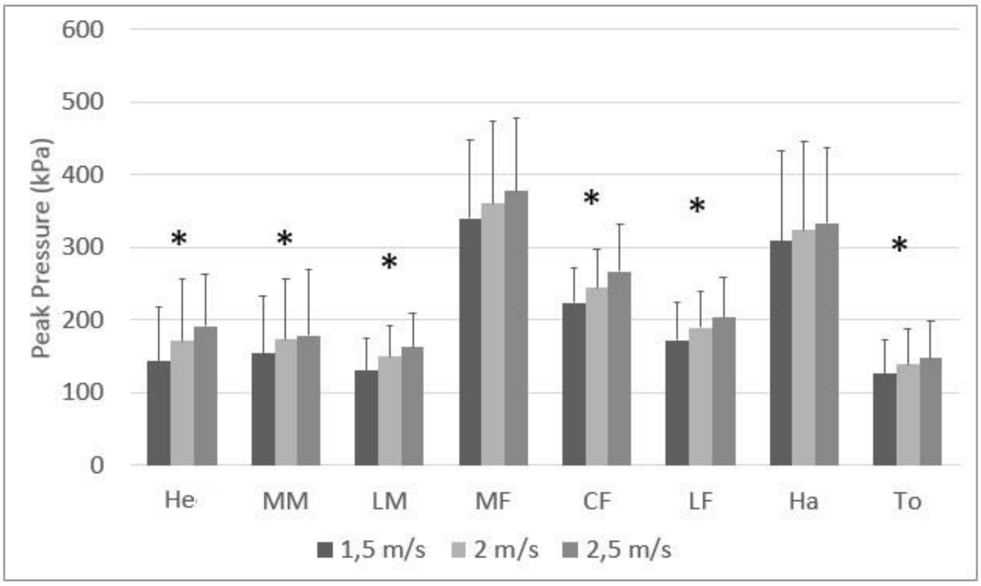


Figure 27. Changes in plantar pressure with running speed (Ho et al., 2010). He: Heel, MM: Medial midfoot, LM: Lateral midfoot, MF: Medial forefoot, CF: Central forefoot, LF: Lateral forefoot, Ha: Hallux, T: Toes.

Moreover, the **slope of the surface** has also been appointed as an important factor that influences plantar pressure. As the angle at which the foot contacts the ground is different when running uphill or downhill, several authors have studied the influence of the slope of the running surface on plantar pressure distribution, although there is not much evidence and future research is necessary. Results of the different studies indicate that when the slope of the surface increases from 5% to 15%, there is a relevant reduction in heel (27%), medial forefoot (15%), hallux (26%) and toes (19%) plantar pressures, whereas there is a trend of increased pressure values on the lateral side of the foot, albeit they are not significant (Ho et al., 2010; Lee et al., 2007) (Figure 28).

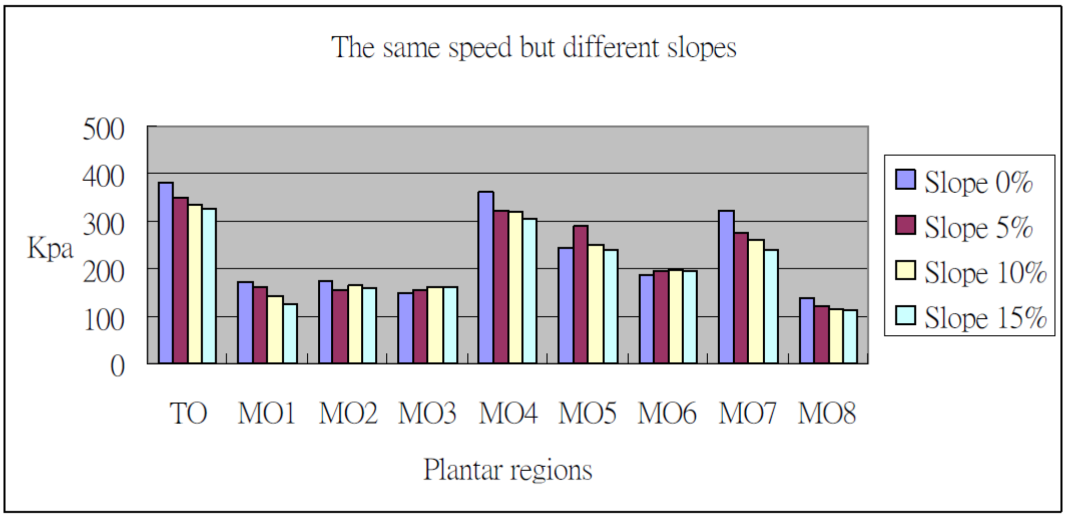


Figure 28. Alterations of peak pressure with slope during running (Lee et al., 2007). TO: Total surface, M01: Heel, M02: Medial midfoot, M03: Lateral midfoot, M04: Medial forefoot, M05: Central forefoot, M06: Lateral forefoot, M07: Hallux, M08: Toes.

This modification in plantar pressure has been related to a decrease in the vertical component of the ground reaction force with increased slope (Ho et al., 2010). In level running, the knee plays an essential role in absorbing the impact shock of the ground reaction force, but since during uphill running the range of motion of the knee is severely reduced, the foot arch provides a very important assistance, leading to more foot inversion as the slope increases and therefore augmenting lateral plantar pressure (Ho et al., 2010). Although several studies involving walking downhill have been carried out (Grampp, Willson, & Kernozek, 2000), to the author's knowledge, no study to date has analysed plantar pressure distribution during downhill running downhill, thereby highlighting the need for research into this topic due to the increasing popularity of recreational cross-country races involving continue uphill and downhill tracks and the injury risk that may accompany running with a constantly changing slope (Creagh, Reilly, & Nevill, 1998).

Several **types of foot** such as normal, high-arched (pes cavus) or low-arched (pes planus) have been previouslu described (see section 1.6.3.1: Intrinsic Factors). As it can be expected, different foot architectures will modify not only the biomechanics of the human locomotion but also the plantar pressure distribution, since the load originated from a movement will be transmitted to the human body by the interface ground-foot. Needless to say, the way the biological foot structures are built will affect how the body receives the load and subsequently how this impact is transmitted and attenuated. Proof of this belief is the evidence suggesting that extreme arch heights lead to increased injury risk (Fields et al., 2010; Hreljac et al., 2000; Williams III, McClay, & Hamill, 2001). Specifically, individuals with a rigid, high arched foot are said to be at greater risk for femoral, tibial and fifth metatarsal stress fractures, anterior knee pain, ankle strains and injuries involving the lateral structures of the lower extremity (Chuckpaiwong et al., 2008; Jonely et al., 2011; Queen et al., 2009a; Teyhen et al., 2009; Williams et al., 2001). On the other hand, people with low arched feet (or flat feet) have been showed to be at increased risk for knee pain, patellofemoral syndrome, iliotibial band, medial tibial stress syndrome, ankle sprains, second and third metatarsal stress fractures and other overuse injuries involving the medial and soft tissue structures of the lower extremity such as patellar tendinitis and plantar fasciitis (Chuckpaiwong et al., 2008; Jonely et al., 2011; Queen et al., 2009a; Teyhen et al., 2009; Willems et al., 2007; Williams et al., 2001). However, the literature is far from reaching an agreement on this matter, since not only there are studies stating that there is no association between arch height and lower extremity injury risk (Chuckpaiwong et al., 2008; Jonely et al., 2011; Queen et al., 2009a; Williams et al., 2001), but also a few authors have suggested that certain foot types may even be protective against some kinds of injuries (Jonely et al., 2011; Wen et al., 1998).

It is reasonable to believe that different foot architecture (high arch versus low arch) will distribute differently the pressure during foot contact and therefore overloading of specific areas may occur (Razeghi & Batt, 2000). Many studies have addressed this topic (Table 16), although only a few of them have studied plantar pressure distribution during shod running (Chuckpaiwong et al., 2008; Queen et al., 2009a), compared to barefoot running (Teyhen et al., 2009) and walking studies (Burns, Crosbie, Hunt, & Ouyrier, 2005; Jonely et al., 2011).

Table 16. Plantar pressure alterations due to foot type in different studies.

Arch Type	Study	Results
HIGH ARCH	Jonely et al., 2011 Queen et al., 2009a Chuckpaiwong et al., 2008 Sneyers et al., 1995	-Lower relative loads under the midfoot compared to normal and pes planus -Greater peak pressure and relative load in forefoot
	Weist et al., 2004	-Greater load on the lateral edge of the foot
	Teyhen et al., 2009	-Greater peak pressure and force-time integral in lateral forefoot during walking
	Jonely et al., 2011 Burns et al., 2005	-Greater rearfoot peak pressure compared to normal feet
LOW ARCH	Jonely et al., 2011 Queen et al., 2009a Chuckpaiwong et al., 2008 Sneyers et al., 1995	-Lower maximum force and peak pressure under lateral and medial forefoot compared to normal feet -Greater peak pressure and force in medial midfoot
	Korpelainen et al., 2001	-Greater loading of the medial longitudinal arch
	Weist et al., 2004	-No correlation between foot type and foot loading

In general, high-arched feet showed lower loading under the midfoot and greater loading under forefoot, whereas low-arched feet tended to reduce the peak pressures under the forefoot and increase the loading under midfoot. However, other studies have found no association between plantar pressures and foot type (Weist et al., 2004). The use of footwear influencing the foot motion during running and the methodology applied to define the foot type for the different studies have been suggested as possible explanations that could have accounted for these differences (Chuckpaiwong et al,. 2008; Queen et al., 2009b). Hence, well developed studies using validated clinical foot evaluations are necessary to further analyse how the different types of foot actually influence the plantar pressure distribution during running.

Also, the **fatigue state** is an important factor to take into account when analysing plantar pressure. Running as a form of physical activity and exercise involves repeated activation of the skeletal muscles in a coordinated fashion. The intensity of the activity is determined by a number of muscle activation parameters including interval, duration of contraction, frequency of activation, and proportion of the total motor unit pool activated for a given muscle (Dotan et al., 2012). All these factors determine the duration that the body can sustain that precise exercise.

During running, the athlete reaches a point where fatigue appears, provoking a multidimensional response affecting the basal physiological and biomechanical characteristics of their movements (Brown, Zifchock, & Hillstrom, 2014). These changes in running biomechanics are mainly due to modifications in kinetic and kinematic parameters, which are believed to affect running stride and economy (Hunter & Smith, 2007). Therefore, fatigue plays an important role in running and differences have been found when studying running under fatigue in physiological variables such as heart rate and oxygen consumption (Avogadro, Dolenec, & Belli, 2003; Rosenbaum, Engl, & Nagel, 2008), and in biomechanical factors including contact time (Elliott & Roberts 1980, Nagel et al., 2008), stride length and stride rate (Gerlach et al., 2005; Hunter & Smith, 2007; Place, Lepers, Deley, & Millet, 2004), range of movement in the different joints (Derrick et al., 2002; Weist et al., 2004), impact forces (Christina, White, & Gilchrist, 2001; Derrick et al., 2002; García-Pérez et al., 2013; Gerlach et al., 2005; Mercer, 1999; Mercer et al., 2003; Mizrahi, Verbitsky, & Isakov, 2001), and plantar pressure distribution (García-Pérez et al., 2013; Nagel et al., 2008; Rosenbaum et al., 2008; Weist et al., 2004; Willson & Kernozek, 1999).

Focusing on modifications in plantar pressure distribution, fatigue has been found to increase peak pressure in the metatarsal heads, midfoot, hallux and toes, although decreases in the same zones have also been stated by other studies (Table 17).

Table 17. Changes in plantar pressure distribution under fatigue.

Study	Fatigue Protocol	Post-Measurement	Plantar pressure modifications
Bisiaux, 2008	30-min run at 80% max aerobic speed	Walking	• Increased peak pressure in 2nd-3rd metatarsal heads immediately after fatigue test. • Decreased peak pressure under medial midfoot and hallux immediately after fatigue test. • Decreased peak pressure under medial heel, medial midfoot, 1st-3rd metatarsal heads measured 30min after fatigue test.
García-Pérez et al., 2013	30-min run at 85% VAM	Running	• Increased relative load under medial arch. • Decreased peak pressure under the hallux and heel.
Nagel et al., 2008	Marathon	Walking	• Increased peak pressures under the 2nd-5th metatarsal heads. • Decreased peak pressure under the toes and hallux.
Rosenbaum et al., 2008	-----------	---------------	• Decreased peak pressure under midfoot.
Stolwijk et al., 2010	Walking 40-50km for 4 days	Walking	• After 1 day: Increased peak, mean pressure and pressure-time integral under the 4th-5th metatarsal heads and heel. • After 4 days: Increased peak, mean and pressure-time integral under the heel compared with Post-test 1. • After 4 days: Decreased peak, mean and pressure-time integral under the toes, and 1st-2nd metatarsal heads compared with Post-test 1.
Weist et al., 2004	Exertion Treadmill protocol	Running	• Increased peak pressure in medial midfoot, 1st-5th metatarsals, toes and hallux.
Willson & Kernozek 1999	Exertion Treadmill protocol	Running	• Increased peak pressure under the 1st metatarsal head. • Decreased peak pressure and pressure-time integral under the heel.

The main explanation about these differences in plantar pressure distribution may be the fatigue protocol, since some studies measured before and after a marathon (Nagel et al., 2008), or a 10 km run (Alfuth & Rosenbaum, 2011), whereas other studies used a known treadmill exertion protocol (Weist et al., 2004; Willson & Kernozek,

1999) to provoke fatigue. Differences in the actual final state of fatigue and the methodology used to achieve it may have affected the results.

Bearing in mind that fatigue induces multiple changes in biomechanical and physiological variables, several authors highlight the importance of a better understanding of how fatigue affects the body’s impact absorption ability during human locomotion since it would provide essential knowledge to be used in footwear design, training surfaces, coaching, etc. that could reduce the harmful effects of these variables and therefore decrease injury rate during running (Clansey, Hanlon, Wallace, & Lake, 2012; Lucas-Cuevas et al., 2015; Mercer et al., 2003; Verbitsky, Mizrahi, Voloshin, Treiger, & Isakov, 1998).

Finally, the **use of insoles** is one of the most common strategies used by podiatrists to modify plantar pressures when an abnormal situation is identified (Escamilla et al., 2015). Insoles are in-shoe devices used to ensure that the static and dynamic functioning of the feet is as close as possible to the ideal (Crabtree et al., 2009). They have been demonstrated to be effective in alleviating symptoms, preventing deformity and enhancing athletic performance (Gijon-Nogueron et al., 2014; Landorf & Keenan, 2000), although most reasoning for their use is anecdotal and scientific evidence to support their effectiveness is needed. However, there is an increasing trend addressing many different types of insoles by modifying their materials, thickness and conformity, and their effect on different populations such as patients with pathologies, athletes, or sedentary people.

Special attention must be paid to the distinction between “over the counter” or prefabricated insoles and custom-made insoles. Sports, shoe, grocery and drugs shops have shelves filled with non-specific insoles in different shapes and sizes for the customer to buy them when “needed”. On the other hand, a custom-made insole is a device derived from a three-dimensional representation of the foot, made by using a mould of the foot while the subtalar joint is in the neutral position (neither pronated nor supinated), in order to subsequently construct a device capable of maintaining the subtalar and midtarsal joints in the corrected position during active gait (Cabtree et al., 2009; Werd & Knight, 2010). It is reasonable to believe that this kind of insoles will better fulfil the person’s expectations than a taken off-the-shelf shoe insert chosen strictly by size of the foot (Bus, Ulbrecht, & Cavanagh, 2004; Goske, Erdemir, Petre, Budhabhatti, & Cavanagh, 2006).

As mentioned before, insoles have been suggested to provide plenty of benefits including pain relief, increased proprioceptive and tactile inputs, improved comfort (Gijon-Nogueron et al., 2014; Lee et al., 2012; Rethnam & Makwana, 2011) and they have specially been identified as a potential tool for decreasing lower extremity injuries by reducing the magnitude and rate of loading and redistributing the pressure across the plantar surface of the foot (Branthwaite et al., 2004; Dixon et al., 2003; Hinz et al., 2008; Lee et al., 2012; Luo, Houston, Garbarini, Beattie, & Thongpop, 2011; Pérez-Soriano et al., 2011; Razeghi & Batt, 2000; Whittle, 1996; Windle, Gregory, & Dixon, 1999; Yung-Hui & Wei-Hsien, 2005) (Figure 29).

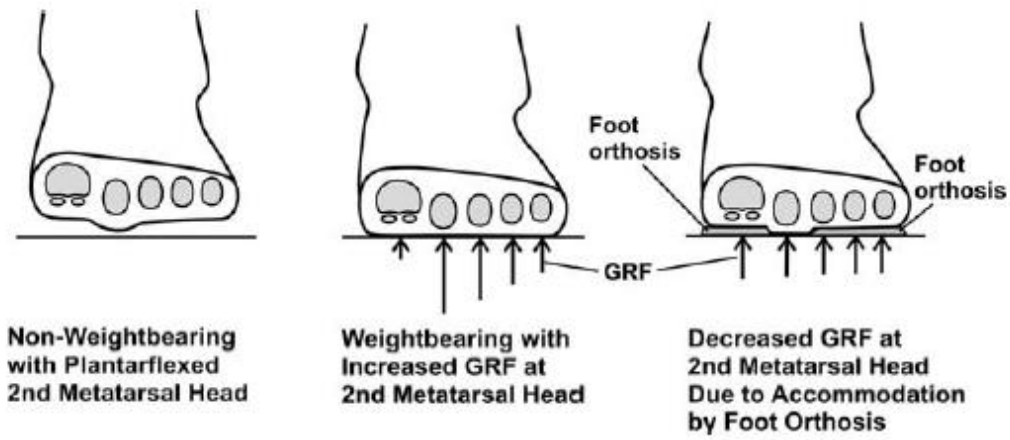


Figure 29. Example of plantar force redistribution by using a foot orthosis (Werd & Knight, 2010).

In this sense, the use of custom-made insoles has been observed to lead to reductions in vertical peak pressure in different studies involving patients with plantar neuropathic ulceration, type II diabetes and metatarsalgia (Werd & Knight, 2010). In pronated feet, a 30-40% reduction under the first metatarsal head and medial heel was found (Razeghi & Batt, 2000), whereas Dixon et al. (2003) observed reduced peak heel pressures while running with military footwear.

Among the numerous parameters that influence how foot orthoses affect plantar pressure, the **shape** and the **materials** are two of the most important factors (Gijon-Nogueron et al., 2014; Lee et al., 2012; Yung-Hui & Wei-Hsien, 2005):

A. **Shape of the insert**. The amount of pathologies that can be addressed with an adequate intervention with inserts is limitless. However, since there are very different types of insoles depending on their shape (length of the insert, amount of layers, areas of extra support and reinforcement), their actual function and goal (pathology to treat) will vary depending on their design. Yung-Hui and Wei-Hsien (2005) reviewed several studies utilising different types of shoe inserts and their effects on plantar pressure (Table 18). As it can be seen in Table 18, depending on the specific situation, reinforcing the support under certain areas can be more profitable in some cases than prescribing a full-length insert. This example highlights that prescribing an insole when a pathology is found is not enough and a deeper knowledge of the properties of the insole is needed to adequately treat a given pathology.

Table 18. Compilation of studies analysing the effects of shoe inserts on plantar pressure.

Shoe insert	Effect	Study
Heel pad	Reduction of heel pressure and magnitude of heel strike impact	Light et al., 1980; Jorgensen & Ekstrand, 1988)
Arch support	Reduction of tension in the plantar aponeurosis	Kogler et al., 1996
Metatarsal pad	Reduction of forefoot pressure and beneficial weight bearing transfer to the longitudinal and metatarsal arches	Lee et al., 2004
Total contact insert	Relief heel and forefoot pressure	Lord & Hosein, 1994; Chen et al., 2003)

Yung-Hui & Wei-Hsien (2005).

B. **Material of the insert**. It has been observed that different materials can increase comfort and pressure distribution during human locomotion (Lee et al., 2012). In Table 19, some of the most common materials used in insole construction are presented.

Table 19. Materials most commonly used in insole construction.

1) Polyurethane elastomers (Cambion, Sorbothane, Viscolas)
2) Polyurethane foams (Cleron, Poron, PPT)
3) Polyethylene foams (Evazote, Frelon, Pelite, Plastazote)
4) Polyvinyl chloride foams (lmplus)
5) Ethylene vinyl acetate (EVA)
6) Synthetic rubber foams (Neoprene, Noene, Spenco, Ucolite, Zdel)
7) Silicone rubber

Whittle, 1996.

However, special attention must be paid to viscoelastic materials (Llana-Belloch & Pérez-Soriano, 2015). Not long ago, Whittle (1996) published a very interesting review describing the properties of these materials and their use in footwear and insoles. According to this review, viscoelastic materials combine two different physical properties. The term "viscous" implies that they deform slowly when exposed to an external force, whereas the term 'elastic' implies that once a deforming force has been removed, they return to their original configuration. On the one hand, purely elastic materials recover from deformation almost instantly and return most of the momentum and energy to the heel during heel strike. Viscoelastic materials, on the other hand, provide greater reduction of the impact forces because they transfer the momentum to the ground and return very little energy to the heel, since the material recovers from deformation over a longer period of time and the energy which was used to deform it is largely converted to heat. Based on these mechanisms, viscoelastic materials are better than purely elastic ones at reducing the peak force at heel strike.

However, other studies have indicated that the material properties of the insoles were not as effective as either the **thickness** or the **conformity** of the insole (Goske et al., 2006). According to these authors, the thicker the insole, the greater the pressure reduction under the whole foot. However, footwear do not provide nowadays enough space to place this type of inserts inside, thereby special footwear should be made in order for this recommendation to become practical. Even though thickness has been found to be effective, it has been considered to be secondary to the conforming profile of the insole, being the full-conforming insole the structural device that provided the greatest reduction of pressure (Bus et al., 2004; Goske et al., 2006; Werd & Knight, 2010).

Several studies analysing how the construction properties inherent to insoles modify pressure distribution during locomotion have been presented so far (Bus et al., 2004; Chen et al., 2003; Goske et al., 2006; Lee et al., 2012; Yung-Hui & Wei-Hsien, 2005; Werd & Knight, 2010). However, the differences among the properties of the insoles affecting different types of locomotion, which can at the same time be analysed in different populations, make it very difficult to reach conclusive results regarding their effect on plantar pressure due to the plurality of studies and situations. A summary of the findings involving the use of insoles and plantar pressure modifications can be found in the annexes (Summary of studies addressing insoles effect on plantar pressure), which may provide a broader view of the numerous possibilities that the use of insoles can have when treating and preventing overuse injuries and, why not, in enhancing sport performance through a better understanding of the factors underlying the overloading of the foot.

Despite all the evidence presented so far supporting the use of custom-made insoles to reduce plantar pressure during human locomotion, to the author's knowledge there is only one study that found no significant reductions of plantar pressure in running shoes using different types of personalised insoles compared to prefabricated insoles (Nigg, Herzog, & Read, 1988). In this study it was suggested that insoles were less effective with footwear that has inherent shock absorbing properties such as running shoes, whereas they may be useful for footwear with limited shock absorption characteristics like military boots or conventional street shoes (Windle et al., 1999).

The relationship between custom-made insoles and decreased plantar pressures as a means of reducing overuse injuries is becoming of major interest for sport and foot specialists. However, there is a dearth of studies addressing the role of custom-made insoles used by athletes with no present pathologies and their possible effect on redistributing the pressure evenly throughout the foot, which may lead to better injury prevention and increased running performance in both recreational and competitive runners. For this purpose, studies involving non-injured runners are necessary to provide a better understanding of the role that insoles play on overuse running injury prevention and treatment.

1.8.1.2. Analysis of Impact Acceleration

Acceleration can be defined as the rate change in velocity over time (acceleration = meter · second^{-2}) (Aguado, 2015; Pelham, Robinson, & Holt, 2006) and it is measured by accelerometers attached to the body in order to calculate segment accelerations during locomotion (Pérez-Soriano & Llana-Belloch, 2015) (Figure 30). Acceleration during human locomotion can be presented either in m · s^{-2} or gravitational units "G" (1 G = 9,8 m · s^{-2}).

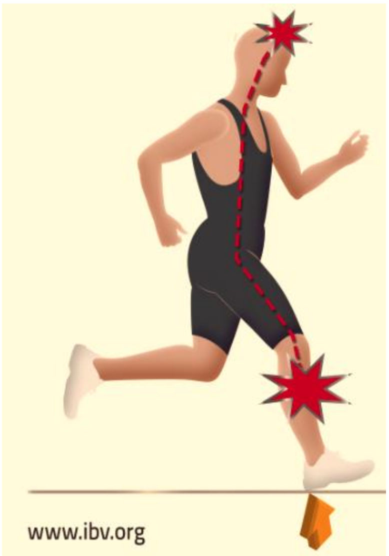


Figure 30. Impact acceleration going through the body during running (IBV, 2013).

Accelerometers are becoming more and more used in locomotion studies due to a series of advantages (Kavanagh & Menz, 2008; Pelham et al., 2006):

a) They are cheaper compared to other pieces of equipment also used for gait analysis such as force platforms.

b) They are lightweight and small and can therefore be placed in many different parts of the human body without altering the natural mechanics of the movement.

c) They are portable and as a result, testing is not restricted to a laboratory environment.

Even though there are many different commercial types of accelerometers depending on the type of sensor (fluid, reluctive, servo, magnetic, etc.), the accelerometers most commonly used in human motion are piezoresistive, capacitive, and piezoelectric (Zheng, Black, & Harris, 2005). The basic mechanism underlying the measurement of acceleration is a mass-spring system that operates under the principle of Hooke's Law ($F = k \cdot x$) and Newton's 2nd Law of motion ($F = m \cdot a$). In this sense, Kavanagh and Menz (2008) described the accelerometer functioning as follows (Equation 3):

> *"When a mass–spring system is submitted to a compression or stretching force due to movement, the spring will generate a restoring force proportional to the amount of compression or stretch. Given that mass, and the stiffness of the spring can be controlled, the resultant acceleration of the mass element can be determined from characteristics of its displacement"*

$$F = k \cdot x = m \cdot a, \qquad \text{thus} \qquad a = \frac{k \cdot x}{m}$$

where
F = Force; k = constant factor characteristic of the spring; x = displacement of the mass; m = mass; a = acceleration of the mass

Equation 3. Functioning of the mass-spring system of an accelerometer based on Hooke's Law and Newton's 2nd Law of motion.

An accelerometer can measure acceleration in one (uniaxial accelerometer) or more axes (e.g. three axes: triaxial accelerometer). Whereas uniaxial accelerometers are usually placed on the heel or on the shoe to measure the moment of ground contact during running or walking (Enders, von Tscharner, & Nigg, 2014; Friesenbichler, Stirling, Federolf, & Nigg, 2011; Selles, Formanoy, Bussmann, Janssens, & Stam, 2005), triaxial accelerometers are placed on different body segments to measure accelerations in the vertical, antero-posterior and medio-lateral axes (Cámara & Llana, 2015; Encarnación-Martínez, Pérez-Soriano, & Llana-Belloch, 2014; García-Pérez et al., 2014; Kavanagh, Barrett, & Morrison, 2004; Kavanagh & Menz, 2008; Lafortune & Hennig, 1992; Llana-Belloch & Pérez-Soriano, 2015) (Figure 31 and 32).

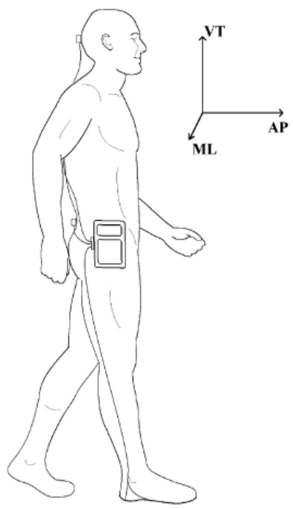


Figure 31. Convention of the acceleration axes (Kavanagh et al., 2004).

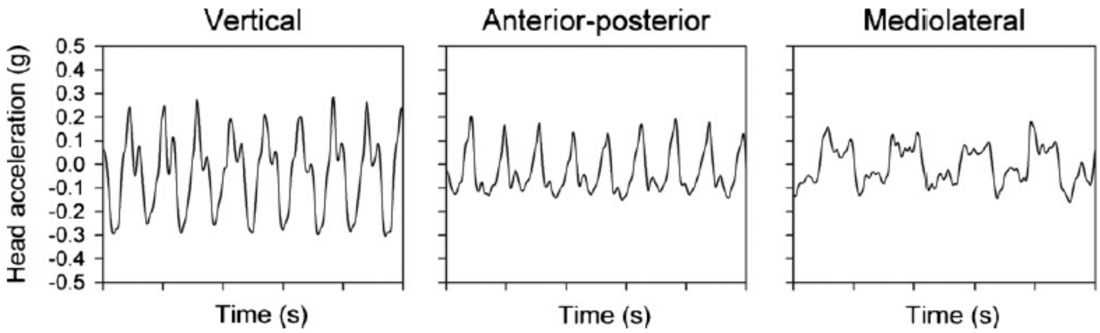


Figure 32. Vertical, antero-posterior and medio-lateral head accelerations taken from a triaxial accelerometer during walking (Kavanagh & Menz, 2008).

Among the three axes, the axis most commonly analysed in the running literature has been the vertical axis since it provides information regarding the transmission and attenuation properties of materials and body segments (Cámara & Llana, 2015; Chambon, Sevrez, Ly, Guéguen, Berton, & Rao, 2014b; Dixon et al., 2000; Encarnación-Martínez et al., 2014; García-Pérez et al., 2014; Gruber, Boyer, Derrick, & Hamill, 2014; O'Leary, Vorpahl, & Heiderscheit, 2008).

The analysis of impact acceleration has been used in the field of sports from very different approaches and aiming to fulfill very different objectives including **attenuation of surfaces** (Bigelow, Elvin, Elvin, & Arnoczky, 2013; Dixon et al., 2000; García-Pérez et al., 2014; Vanhelst et al., 2009), shock absorption properties of **insoles** (O'Leary et al., 2008) and **running shoes** (Chambon et al., 2014b; Chambon, Delattre, Guéguen, Berton, & Rao, 2014a), evaluation of the modification of **sport technique** (Derrick et al., 1998; Edwards, Derrick, & Hamill, 2012; Encarnación-Martínez et al., 2014; Gruber et al., 2014; Wood & Kipp, 2014), **running performance** (Derrick, 2004; Derrick et al., 2002; Verbitsky et al., 1998), **perception of comfort** (Delgado et al., 2013; O'Leary et al., 2008), **running fatigue** (Abt et al., 2011; Derrick et al., 2002; Mercer et al., 2003; Mizrahi, Voloshin, Russek, Verbitsky, & Isakov, 1997; Verbitsky et al., 1998; Voloshin et al., 1998) and **running injuries** (Davis et al., 2004; Hreljac, 2004; Hreljac et al., 2000; Milner et al., 2006).

Even though impact acceleration is measured more accurately by placing an accelerometer through a pin attached directly to the tibial bone (Lafortune, Henning, & Valiant, 1995), this procedure cannot be routinely applied due to its invasive nature. Therefore, the majority of the studies use skin-mounted or surface-mounted accelerometers to measure impact acceleration (Abt et al., 2011; Bigelow et al., 2013; Chambon et al., 2014b; Coventry, O'Connor, Hart, Earl, & Ebersole, 2006; Derrick et al., 1998; Duquette & Andrews, 2010b; Encarnación-Martínez et al., 2014; García-Pérez et al., 2014; Greenhalgh, Sinclair, Leat, & Chockalingam, 2012; Gruber et al., 2014; Laughton, Davis, & Hamill, 2003; Lucas-Cuevas et al., 2013; Mercer et al., 2003; O'Leary et al., 2008; Voloshin et al., 1998).

It has been suggested that in order to minimise the noise produced by mounting an accelerometer on the skin, the protocol of the study should comply with the following conditions (Coventry et al., 2006; Derrick et al., 1998; Gruber et al., 2014; Ziegert & Lewis, 1979):

A. To attach the accelerometer to a location as close as possible to the bone (minimum amount of soft-tissue between the bone and the accelerometer).
B. To use a low-mass accelerometer.

C. To secure the accelerometer with an elastic strap tightened to participant tolerance.

There is some discrepancy in the literature regarding the location where the accelerometer should be placed. Whereas a few studies from 20 and 30 years ago attached accelerometers to the ankle (through a splint moulded around the medial and lateral malleoli of the ankle) (Oakley & Pratt, 1988) or to a bite-bar gripped between the teeth (Shorten & Winslow, 1992), the majority of the studies nowadays place the accelerometer on the tibia and the forehead (Chambon et al., 2014b; Coventry et al., 2006; Delgado et al., 2013; García-Pérez et al., 2014; Gruber et al., 2014) (Table 20). However, when placing the accelerometer at the tibia, there is still no agremeent regarding to which exact place of the tibial bone the accelerometer should be attached.

Table 20. Summary of accelerometer placement among studies.

Placement	Study
Tibia (distal portion)	Butler et al., 2007; Greenhalgh et al., 2012; Laughton et al., 2003; O'Leary et al., 2008.
Tibia (proximal portion)	Chambon et al., 2014b; Duquette & Andrews, 2010; Flynn et al., 2004; Kersting, 2011; Verbitsky et al., 1998.
Head and Tibia (distal portion)	Clansey et al., 2012; Coventry et al., 2006; Delgado et al., 2013; Derrick et al., 2002; Gruber et al., 2014; Hamill et al., 1995; Mercer et al., 2002; TenBroek at al., 2014.
Head and Tibia (proximal portion)	Abt et al., 2011; Encarnacion et al., 2014; García-Pérez, 2014.
Intra-cortical pin to Tibia bone	Lafortune et al., 1995.
Ankle	Oakley and Pratt, 1988.
Teeth	Shorten & Winslow, 1992.
L3 spinous process (lower trunk) and ensiform process (upper trunk)	Kawabata et al. 2013.
L5 vertebra	Bigelow et al., 2013.

It is important to take into account that each time the foot contacts the ground during locomotion (walking, jogging, running, jumping, etc.) there is a rapid vertical deceleration that results in a shock wave that is transmitted throughout the body from the foot to the head (Cámara & Llana, 2015; Shorten & Winslow, 1992; Wee & Voloshin, 2013; Whittle, 1999). In the Figure 33, a common example of tibial and head vertical acceleration signal is presented and it can be observed that a rapid deceleration occurs in the tibia right after ground contact (GC).

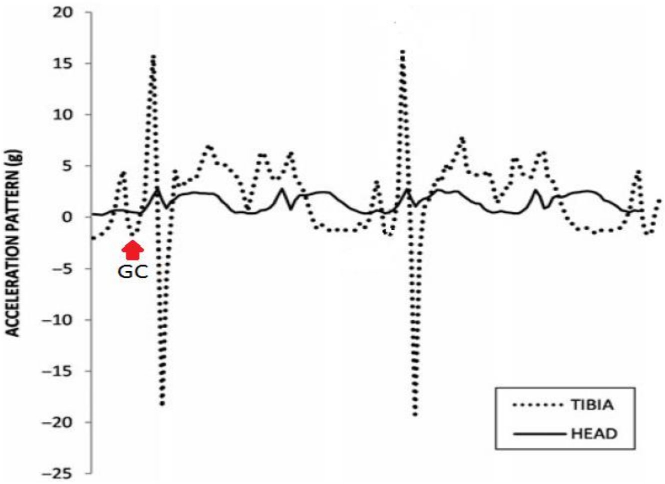


Figure 33. Head (solid line) and tibial (dashed line) vertical accelerations during running. GC: Ground Contact (García-Pérez et al., 2014).

In this sense, running is a cyclical activity that involves the athlete striking the ground hundreds and even thousands of times each training session. As previously stated, the runner will perform around 600 ground contacts per kilometre (involving 3,000 – 6,000 contacts for a 5 km-10 km running session) (Guo et al., 2006). Even though the human body is prepared to deal with each one of those single impacts that occur below the injury threshold, their accumulative and repetitive effect on the human body could lead to overloading and fatigue of the attenuation mechanisms and eventually increase the risk of suffering an injury (Davis et al., 2004; Gent et al., 2007; Hreljac, 2004; Hreljac et al., 2000; Lieberman et al., 2010; Milner et al., 2006; Tessutti, Trombini-Souza, Ribeiro, Nunes, & Sacco, 2010; Wee & Voloshin, 2013). Such is the relevance of this impact acceleration that Radin et al. (1975) even stated that osteoarthritis could even have its origin on poorly handled mechanical load rather than from a disease.

Impact acceleration has been analysed in the literature from very different approaches. Especially as a result of its hypothetical potential relationship with overuse injuries, impact acceleration has been studied in terms of peak impact acceleration (Derrick, 2004; Encarnación-Martínez et al., 2014; Milner et al., 2006; O'Leary et al., 2008; Olin & Gutierrez, 2013), acceleration rate (Chambon et al., 2014b; Duquette & Andrews, 2010b; Shung, de Oliveira, & Nadal, 2009), acceleration magnitude (Laughton et al., 2003), and shock attenuation (Delgado et al., 2013; Mercer et al., 2002; Mizrahi et al., 1997; Verbitsky et al., 1998; Voloshin et al., 1998).

- The **peak acceleration** is the maximum amplitude of the acceleration signal (PA in Figure 34). Peak acceleration is the most common acceleration variable analysed in the literature and it has been suggested to provide information regarding the actual magnitude or stress of the shock wave (Encarnación-Martínez et al., 2014; García-Pérez et al., 2014; Laughton et al., 2003; Lucas-Cuevas et al., 2013; O'Leary et al., 2008). Previous studies have showed a strong correlation between peak tibial acceleration and the ground reaction forces measured by a force plate (Elvin, Elvin, & Arnoczky, 2007; Hennig, Milani, & Lafortune, 1993) and it has been suggested that the higher the peak acceleration observed in a segment (e.g. tibial tuberosity), the greater the loading stress experienced by that segment, what could lead to overloading of the musculoskeletal system and injury occurrence (Clinghan, Arnold, Drew, Cochrane, & Abboud, 2008; Milner et al., 2006).
- **Acceleration Rate** is the ratio or slope between the peak acceleration and the time from ground contact to the peak acceleration (AR in the Figure 34). It is the time derivative of the acceleration/time function and it is calculated from two variables: peak acceleration and time to peak acceleration. As such, a change in any of these variables will ultimately influence the acceleration rate, meaning that a high acceleration rate could be the result of increased values of peak acceleration or shorter times to reach a given value of peak acceleration (Chambon et al., 2014b; Duquette & Andrews, 2010a, 2010b; García-Pérez et al., 2014). Even though this variable was not taken into account in the first studies that focused on the analysis of impact acceleration, it is true that in recent years

the acceleration rate is gaining the attention of researchers due to its increasing potential role in the risk of injury occurrence (Dixon et al., 2000; Ogon, Aleksiev, Spratt, Pope, & Saltzman, 2001; Zadpoor & Nikooyan, 2011). Increases in loading rate may result in a stiffened pathway along which the shock travels (Greenwald, Janes, Swanson, & McDonald, 1998) and may therefore result in a greater risk of overuse injury (Davis et al., 2004; Hansen, Zioupos, Simpson, Currey, & Hynd, 2008). Several studies have suggested that repetitive, rapidly applied loading produce joint degeneration whereas slowly applied loads of equal or even greater magnitude often have no deleterious effects (Radin & Rose, 1975; Radin, Yang, Riegger, Kish, & O'Connor, 1991). Therefore, it seems that the acceleration rate of the shock wave is steadily gaining the attention of the research community and its analysis during locomotion could provide important information of the acceleration load experienced by the athlete.

- **Shock Attenuation** is the reduction in the acceleration signal from one location to another (usually from the tibia to the head). It is analysed by calculating the difference between the tibial peak acceleration and the head peak acceleration expressed as a percentage of the tibial acceleration (Equation 4).

$$\frac{Tibial\ Acc - Head\ Acc}{Tibial\ Acc} * 100$$

Example:
Tibial Acceleration = 8 G
Head Acceleration = 2 G

$$Shock\ Attenuation = \frac{8-2}{8} * 100 = 75\%$$

Equation 4. Calculation and example of shock attenuation.

Shock attenuation is, together with peak acceleration, the variable most commonly analysed and reported in impact acceleration studies (Abt et al., 2011; Coventry et al., 2006; Delgado et al., 2013; Derrick et al., 1998; García-Pérez et al., 2014; Gruber et al., 2014; Laughton et al., 2003; Lucas-Cuevas et al., 2015; Mercer et al., 2003; Mercer et al., 2002). In order to protect the head from excessive acceleration, the shock wave is attenuated by the human body, what results in a constant value of impact acceleration within a healthy physiological range. No matter how high the impact acceleration is at the level of the tibia, the human body adapts itself in order to attenuate this acceleration and prevent the disruption of the vestibular and visual systems as a result of an excessive magnitude of impact acceleration arriving at the head (Derrick et al., 1998; Edwards et al., 2012; Hamill et al., 1995). In this sense, increased values of tibial acceleration are accompanied by increased values of shock attenuation, thereby protecting the head (Derrick et al., 1998; Lucas-Cuevas et al., 2015; Mercer et al., 2002). This shock wave is partly attenuated by many factors including the running surface (Dixon et al., 2000; García-Pérez et al., 2014), running shoes (Chambon et al., 2014a; TenBroek, Frederick, & Hamill, 2014), socks (Blackmore, Ball, & Scurr, 2011), insoles (O'Leary et al., 2008), compressive garments (Doan et al., 2003; Kraemer et al., 1998; Lucas-Cuevas et al., 2015) and the musculoskeletal system (Derrick, 2004; Derrick et al., 1998; Mercer et al., 2002; Verbitsky et al., 1998).

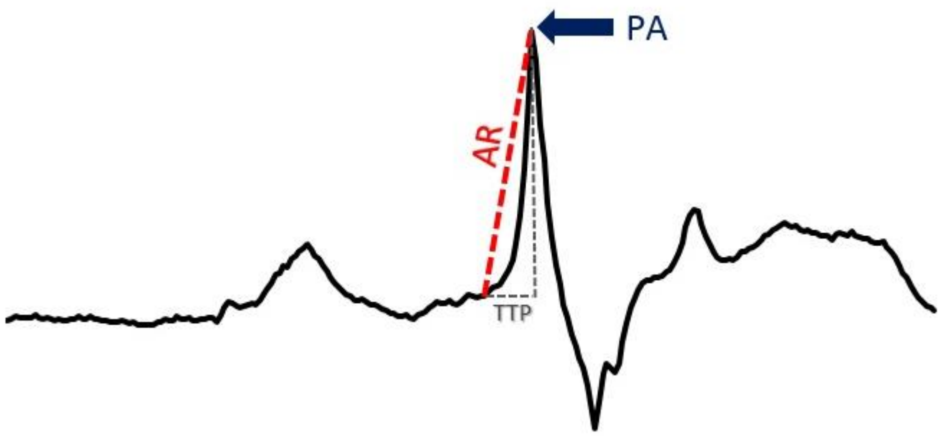


Figure 34. Peak acceleration (PA), time to peak (TTP) and acceleration rate (AR) calculated from the vertical impact acceleration signal measured on the tibia during running.

1.8.1.2.1. Factors that influence Impact Acceleration

Different factors have been identified to influence impact acceleration. The most common ones are presented in Figure 35.

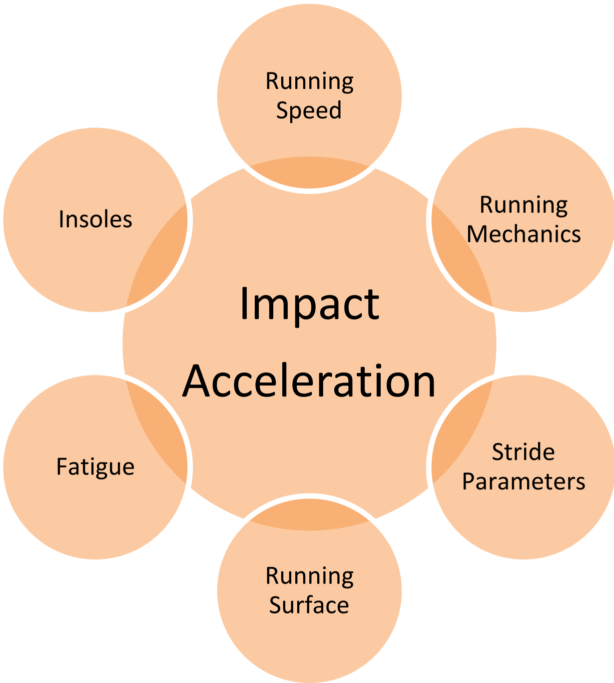


Figure 35. Most common factors influencing impact acceleration.

Among all of them, the **running speed** is the most common factor and the one with the greatest body of literature supporting its influence on impact acceleration (Clarke et al., 1985; Derrick et al., 1998; Greenhalgh et al., 2012; Mercer et al., 2002; Shorten & Winslow, 1992). Similarly to its effect on plantar pressure (Fourchet et al., 2012; García-Pérez et al., 2013) and ground reaction forces (Dorn, Schache, & Pandy, 2012; Keller et al., 1996), increases in running speed lead to greater impact acceleration (Greenhalgh et al., 2012; Mercer et al., 2002). In addition, Clarke et al. (Clarke et al., 1985) found that running speed could modify the tibial vertical peak acceleration by 34% for each 1 m · s^{-1} increase in running speed. Nevertheless, despite large increases in leg acceleration across speeds, the magnitude of the head peak acceleration tends to remain within a narrow range of magnitude (Derrick et al., 1998; Encarnación-Martínez et al., 2014; García-Pérez et al., 2014; Hamill et al., 1995; Lucas-Cuevas et al., 2015; Shorten & Winslow, 1992). It is important to take into account that as the acceleration at the tibia increases, a concurrent increase in shock attenuation of the body exists in order to maintain a constant and healthy level of acceleration arriving at the head (Derrick et al., 1998; Lucas-Cuevas et al., 2015; Mercer et al., 2002) (Figure 36).

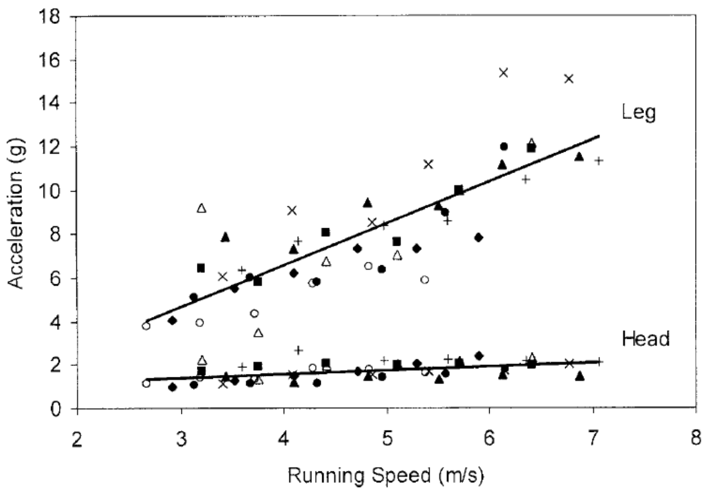


Figure 36. Head and tibial peak accelerations during running at different speeds (Mercer et al., 2002).

Other factors that have been hypothesized to influence impact acceleration are the individual's **running mechanics**. On the one hand, it seems that the musculoskeletal system is able to attenuate impact accelerations via active processes such as adjusting joint stiffness and manipulating kinematics to place body segments in positions that are more adequate to attenuate shock (Hamill et al., 1995). It has been observed that a greater knee flexion at ground contact reduces the effective mass, which is the portion of the total system mass that would be needed to accurately model the impact if a single mass particle were used instead of the total system (human body) with its deforming and rotating segments (Derrick et al., 2004). If every body segment is aligned, the effective mass is essentially the mass of the body and the entire body would accelerate as a single rigid unit (leading to greater ground reaction forces) (Figure 37a). However, if the joints are flexed (flexion of the knee during ground contact), the segments closest to the origin of the shock wave will experience the greatest accelerations, while the rest of the global system will react eccentrically and experience lower ground reaction forces (Figure 37b). In this sense, during running, a greater knee flexion at ground contact will reduce the effective mass of the system and lead to lower ground reaction forces but greater impact acceleration in the tibia (Derrick, 2004; Hamill et al., 1995; Mercer et al., 2002).

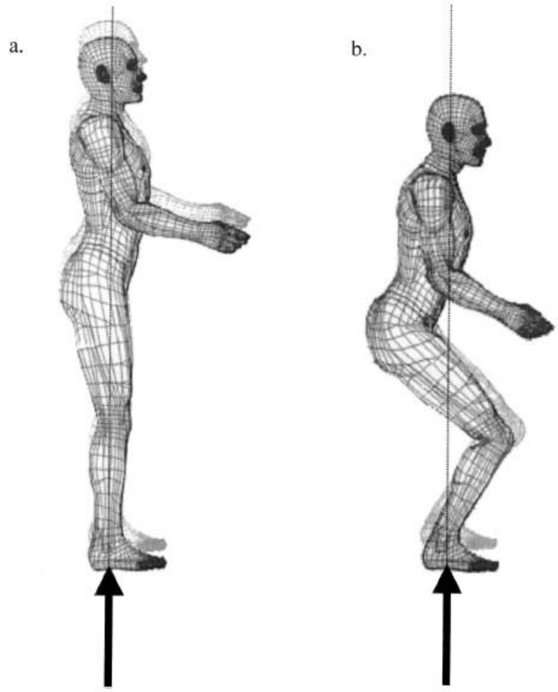


Figure 37. Effect of joint alignment on the effective mass and ultimately on the segments' impact acceleration (Derrick, 2004).

On the other hand, strong evidence exists to explain the effects of **spatio-temporal parameters** (stride rate and stride length) on impact acceleration during running (Derrick et al., 2002; Derrick et al., 1998; Mercer et al., 2002; Mizrahi et al., 2000; Shorten & Winslow, 1992; Verbitsky et al., 1998). Previous studies have suggested that a change in the attenuation properties of the body could be due to alterations in these two parameters to compensate for the change in muscle ability (Derrick et al., 2002; Mercer et al., 2003). Evidence has been found to support that increases in stride length lead to greater impact acceleration (Derrick et al., 1998; Mizrahi et al., 2000; Verbitsky et al., 1998). Two studies carried out by Derrick et al. (1998) and Mercer et al. (1999) independently manipulated stride rate and stride length allowing running velocity to vary, and observed that impact acceleration became greater only when stride length increased. However, these studies required participants to match a given stride length and they were not able to conclude whether impact acceleration would also vary with natural stride length changes (Table 21).

Table 21. Tibial and head mean peak acceleration for each stride length. PSL: Preferred Stride Length (Derrick et al., 1998).

Stride Length	Tibial Acceleration (G)	Head Acceleration (G)
+20%	11.3	1.9
+10%	7.9	1.7
PSL	6.1	1.5
-10%	5.9	1.3
-20%	5.7	1.1

Moreover, increases in impact acceleration are followed by increases in shock attenuation in order to protect the head (Derrick et al., 1998; Mercer et al., 2002). As it would be expected, higher values of impact acceleration as a result of greater stride length are followed by a concurrent increase in shock attenuation (Derrick et al., 1998; Mercer et al., 2002). Even though there could be some controversy regarding which stride parameter, stride rate or stride length, would be dominant on its effect on impact acceleration, stride length has showed a correlation of r = 0.71 with shock attenuation whereas stride length has showed a correlation of r = 0.40, thereby highlighting that shock attenuation seems to be more sensitive to changes in stride rate (Mercer et al., 2002).

Moreover, the **running surface** has also been appointed to alter impact acceleration and attenuation during running due to the different properties among surfaces (Derrick et al., 1998; Dixon et al., 2000; Hardin et al., 2004; Kim & Voloshin, 1992; Riley et al., 2008). Regarding the attenuation properties of different surfaces, running on softer surfaces led to lower impact acceleration compared to harder surfaces (Dixon et al., 2000; Greenhalgh et al., 2012). One of the most popular studies in this area was carried out by Dixon et al. (2000). These researchers measured peak impact acceleration and acceleration rate via mechanical tests and also in athletes during actual running. Interestingly, even though they observed impact accelerations six times greater on asphalt in comparison to rubber during the mechanical tests (Table 22), these differences disappeared when measuring impact acceleration in the actual running condition. It seems that the musculoskeletal system was able to adapt itself (by modifying instinctively their natural running mechanics, kinematics, muscle activation, etc.) in order to keep the accelerations in the body at a constant level.

Table 22. Peak acceleration and acceleration rate for the three running surfaces in the mechanical tests (Dixon et al., 2000).

	Asphalt	Acrylic	Rubber-Modified Asphalt
Peak Acceleration (G)	300	105	55
Acceleration Rate (G/s)	300,000	35,000	13,800

Moreover, there is a between-surface comparison that has caught the attention of the whole running research community: treadmill versus overground running. Treadmills are used in gyms and research laboratories for numerous purposes including improvement of the physical condition and fitness, leisure, rehabilitation, and research, among others (García-Pérez et al., 2014; García-Pérez et al., 2013; Savelberg, Vorstenbosch, Kamman, van de Weijer, & Schambardt, 1998). However, whether treadmill running is representative of natural overground running remains unclear. Regarding impact acceleration, whereas some authors did not find any difference in impact acceleration between these surfaces (Bigelow et al., 2013), a recent study carried out by García-Pérez et al. (2014) observed that running on a treadmill led to lower peak acceleration and acceleration rate in a non-fatigue state compared to running overground. However, the differences between surfaces were not observed when the athletes ran fatigued and the authors concluded that the fatigue state of the athlete should be taken into account when analysing impact acceleration due to its strong influence on the running surface (Table 23).

Table 23. Impact acceleration parameters during overground and treadmill running (García-Pérez et al., 2014).

	Pre-fatigue		Post-fatigue	
	Overground	Treadmill	Overground	Treadmill
Tibial peak acceleration (G)	24.6 ± 10.8	15.3 ± 6.8*	22.2 ± 10.3	17.2 ± 9.5
Tibial impact rate (G / s)	614 ± 245	405 ± 215*	538 ± 234	520 ± 370
Head peak acceleration (G)	3.2 ± 0.7	2.8 ± 0.6*	3.0 ± 0.7	2.7 ± 0.6
Head impact rate (G / s)	41 ± 10	41 ± 8	45 ± 13	41 ± 9
Shock attenuation (%)	82.1 ± 9.7	75.5 ± 20.8	82.4 ± 8.7	77.9 ± 13.9

Taking into account the amount of contacts between the foot and the ground during each training and running event, even a slightly different behaviour of the transmission of impacts could lead to great changes over time (Shorten & Winslow, 1992; Tessutti et al., 2010).

Finally, prolonged exposure to this impact acceleration (such as in long distance running) could fatigue the musculoskeletal system and lead to increased risk of injury (Mizrahi & Daily, 2012; Mizrahi et al., 1997). In this line of thought, **muscle fatigue** may cause modifications in the body dynamics which may lead to the loss of the muscles inherent ability to protect internal tissues from excessive shock waves. Consequently, when the muscle's ability to perform is diminished, articular cartilage and ligaments become more vulnerable to excess dynamic loading (Whittle, 1999).

The effects of fatigue on impact acceleration have been measured mainly by provoking two different types of fatigue:

a) A general whole body fatigue via running tests (García-Pérez et al., 2014; Mercer et al., 2003; Mizrahi et al., 1997; Verbitsky et al., 1998).
b) A local fatigue in given muscles of the lower limb using a human pendulum approach (Duquette & Andrews, 2010b; Flynn, Holmes, & Andrews, 2004; Lafortune & Lake, 1995).

Different changes in the behaviour of the impact acceleration have been observed with the development of the fatigue. One of the greatest effects of fatigue on impact acceleration is a steady increase in tibial peak acceleration as the fatigue develops (Bigelow et al., 2013; Derrick et al., 2002; Lucas-Cuevas et al., 2015; Mizrahi et al., 1997; Mizrahi et al., 2000; Verbitsky et al., 1998; Voloshin et al., 1998) (Figure 38). These authors explained the increase in impact acceleration accompanying the development of fatigue as a result of the reduced ability of the fatigued muscles to properly attenuate the shock waves produced at each ground contact.

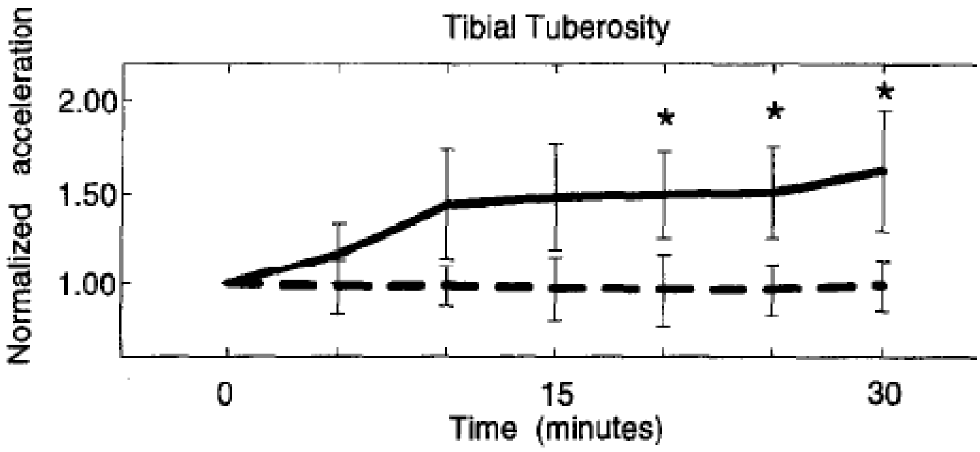


Figure 38. Normalised acceleration (mean (SD)) on the tibial tuberosity for the fatigue group (solid line) and the non-fatigued group (dashed line). * Significantly different (p<0.05) from the data at the beginning of the test (Voloshin et al., 1998).

The fatigue state of the athlete also influences how the human body attenuates these impact accelerations. Different studies have observed that, regardless the increase in the tibial acceleration as a result of the fatigue state of the athlete, the values of impact acceleration remain indeed constant at the head, thereby supporting the idea that increased values of acceleration are accompanied by increased values of shock attenuation in order to maintain the acceleration arriving at the head stable and within a physiological healthy range (Derrick et al., 2002; Mizrahi et al., 1997; Verbitsky et al., 1998; Voloshin et al., 1998). In the Figure 39 it can be observed that the tibial acceleration increased with the development of fatigue, the head acceleration remained constant, and the resulting shock attenuation increased in the same rate as the tibial acceleration did in order to protect the head.

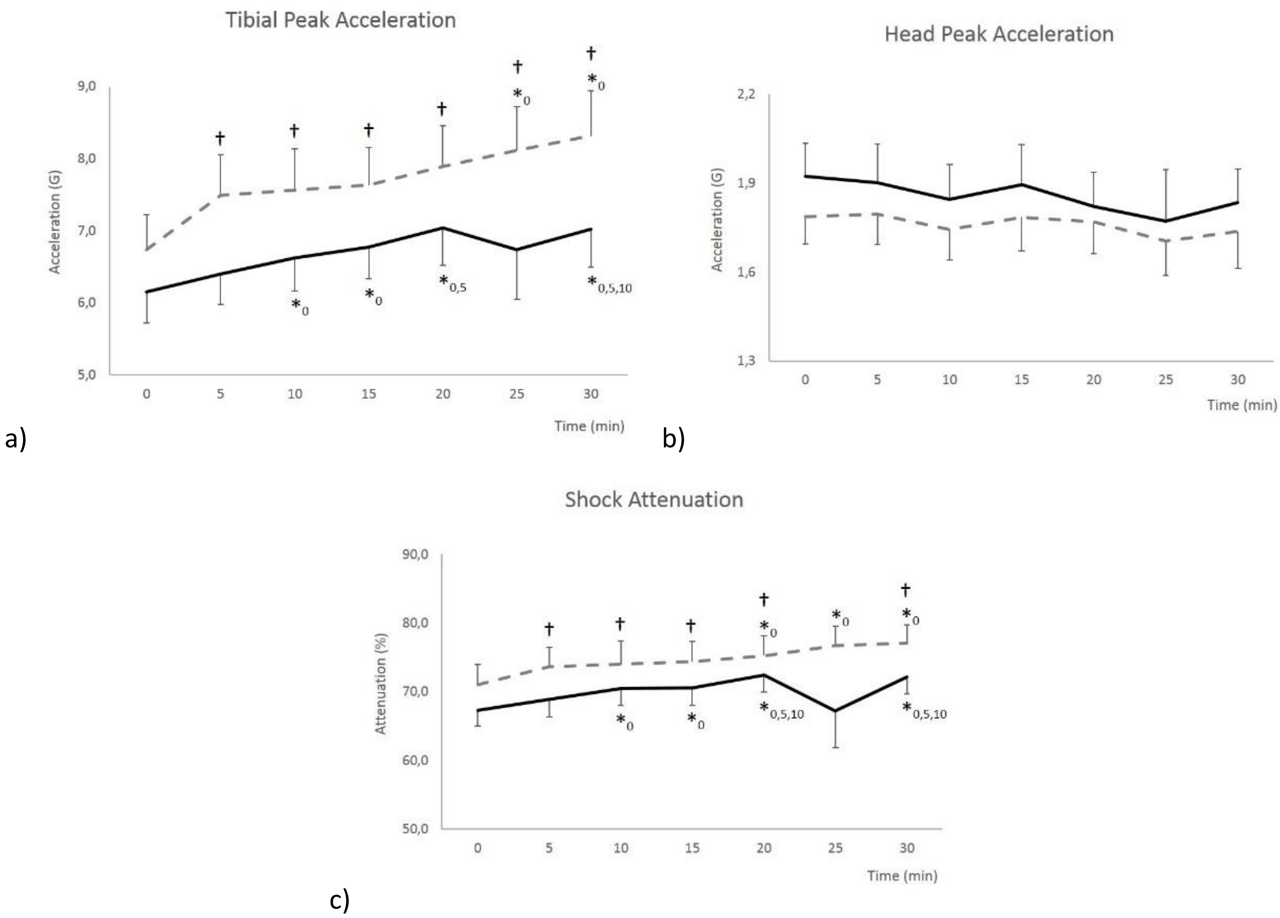


Figure 39. Impact acceleration values (mean (standard error)) during a 30-min fatigue running session with compressive stockings (solid line) and placebo stockings (dashed line).
a) Tibial peak acceleration; b) Head peak acceleration; and c) Shock attenuation (Lucas-Cuevas et al., 2015).

Finally, the use of **insoles** has been also speculated to influence positively the transmission and attenuation of the impacts during running (Dixon, 2007; Nigg, Herzog, & Read, 1988; O'Leary et al., 2008; Shiba, Kitaoka, Cahalan, & Chao, 1995; Windle, Gregory, & Dixon, 1999). However, their effectiveness remains unclear because while some studies have observed beneficial effects (Dixon, 2007; Milgrom et al., 1992; Mündermann, Stefanyshyn, & Nigg, 2001; Schwellnus, Jordaan, & Noakes, 1990), other authors have not found any protective effect with the use of insoles (Gardner et al., 1988; Withnall, Eastaugh, & Freemantle, 2006). In this sense, O'Leary et al. (2008) observed that the use of cushioned insoles led to lower tibial peak acceleration compared to running without insoles. They also found no difference in the time to peak acceleration between the two conditions and, although these authors did not calculate the acceleration rate, the lower peak acceleration and similar time to peak acceleration would also result in a lower acceleration rate when running with insoles (Figure 40).

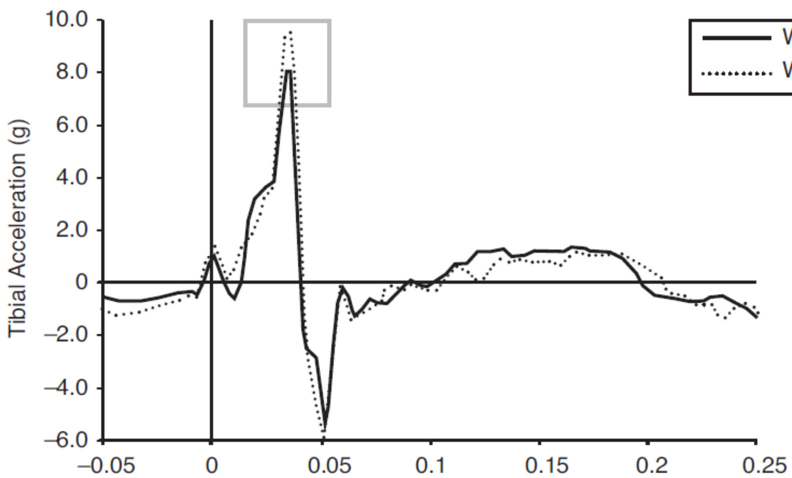


Figure 40. Tibial acceleration during the stance phase of running with and without insoles. The peak values are boxed. Foot ground contact occurs at 0 seconds (vertical line) (O'Leary et al., 2008).

It has been speculated that the magnitude of the attenuation properties of the insoles may depend on the material of the insoles. In this sense, Dixon et al. (2003) compared the attenuation properties of four insoles (commercialised as shock-absorbing insoles) and found a lower loading rate with insoles made of polyurethane foam with an ethyl vinyl acetate (EVA) heel cup compared to Saran® insoles or to insoles made only of polyurethane. Even though these insoles are classified as shock-absorbing, the authors concluded that the different materials composing the insoles could account for the differences in shock attenuation.

1.8.2. Perceptual Parameters

1.8.2.1. Analysis of Comfort

Recently, the perception of comfort has gained the attention of athletes, coaches and biomechanists due to its potential relationship with performance (Luo et al., 2009; Nigg, Nurse, & Stefanyshyn, 1999; Nurse, Hulliger, Wakeling, Nigg, & Stefanyshyn, 2005; Wakeling, Pascual, & Nigg, 2002), and injury occurrence (Anderson, Stefanyshyn, & Nigg, 2005; Che, Nigg, & de Koning, 1994; Kinchington, Ball, & Naughton, 2010a, 2012).

The main problem that surrounds the perception of comfort is that, even though it is a promising tool that may be able to explain and predict different sport indicators related to performance, fatigue and injury, the perception of comfort is still today and ambiguous concept and its definition remains unclear, what makes it difficult for researchers to establish protocols and measurement tools to register and analyse it.

In an attempt to define it, Kolcaba and Kolcaba (1991) described comfort as a subjective response drawn from past experiences and influenced by physical, mechanical, psychological and neurophysiological factors. Moreover, comfort can be a mental and a physical phenomenon and it is also frequently defined as a state of wellbeing or the absence or relief of discomfort or pain (Kolcaba & Kolcaba, 1991; Kolcaba & Steiner, 2000). In this sense, from a physiological point of view, comfort would be the opposite of pain (discomfort) due to the interactive play of nociceptive stimulation and the cerebral cortex (Karoly, Jensen, & Goldstein, 1987). In this line of though, these authors stated that the lack of pain stimuli via the neural networks of the body could also be considered "comfort".

However, following Kolcaba and Kolcaba's idea (1991), comfort would be drawn from interrelated human experiences gathered over a period of time (the person's life). As a result, the holistic perception of all these experiences would be valuable and significant only for that specific person and therefore they would be of no actual value to another person with different past experiences (Kolcaba, 1992). This argumentation ultimately results in comfort being individual-specific, since the very same stimulus can be comfortable for one person and uncomfortable for another (Mündermann, Nigg, Humble, & Stefanyshyn, 2003). Hence, all in all, not only the concept of comfort lacks consensus within the literature but it also has a big inter-individual variability, what makes it even more difficult for researchers to create tools to adequately measure it and to develop scales to standardise it (Mündermann, Nigg, Stefanyshyn, & Humble, 2002; Slater, 1985).

The perception of comfort is becoming a relevant variable to take into account and it is being used in many different areas including the military service (Mündermann et al., 2001), manufacturing industries (Orlando & King, 2004), nursing (Chiu & Wang, 2007), podiatry (Bettoni et al., 2014; Zifchock & Davis, 2008) and sports (Delgado et al., 2013; Hennig, 2014; Kinchington et al., 2012; Lucas-Cuevas et al., 2015).

Focusing on the sports field, the analysis of the perception of comfort is becoming essential due to its aforementioned relationship with fatigue, performance and injury occurrence and the majority of the latest studies evaluating the effectiveness of an intervention with a sport garment provide information about the participants' perception of comfort (Ali, Caine, & Snow, 2007; Dinato et al., 2015; Hennig, 2014; Kinchington et al., 2012; Lucas-Cuevas et al., 2015; Murley, Landorf, & Menz, 2010; Yeo & Bonanno, 2014).

The perception of comfort has been associated with plenty of parameters of interest. Specifically, the sport and exercise literature is currently focusing on the relationship between the perception of comfort and:

- Footwear (Dinato et al., 2015; Hennig, 2014; Jordan & Bartlett, 1995; Kunde, Milani, & Sterzing, 2009).
- Insoles (Anderson et al., 2005; Mündermann et al., 2003; Mündermann et al., 2001; Murley et al., 2010; Nigg et al., 1999).
- Compressive garments (Ali et al., 2007; Lucas-Cuevas et al., 2015).
- Shoe lacing (Hagen, Feiler, & Rohrand, 2011).
- Running technique (Delgado et al., 2013).
- Running surface (Kaalund & Madeleine, 2014).
- Sport performance (Kinchington et al., 2012; Luo et al., 2009).

- Injury prediction (Kinchington et al., 2010a).

These studies provide information not only about biomechanical alterations due to external interventions (shoes, garments, insoles) during a certain activity but also about the participants' perception and opinion of the intervention, which would enable biomechanists and manufacturers to find limitations and deficits of the products and correct them in the future.

It has been previously said that literature lacks consensus regarding the actual definition of comfort and as a result, different tools, questionnaires and scales are being used nowadays to measure it. The most common tools are visual analogue scales (VAS) and Likert scales which can be modified depending on the condition analysed (Table 24).

Table 24. Summary of the comfort scales used and the condition being analysed.

Study	Comfort Measurement	Condition Analysed
Ali et al., 2007	11-point rating	Compressive Garments
Au & Goonetilleke, 2007	7-poiny scale	Footwear
Jordan & Barlett, 1995	5 point scale	Footwear
Delgado et al., 2013	7-point scale	Foot strike pattern
Dinato et al., 2014	100 mm VAS SCALE	Footwear
Hagen et al., 2010	7-point scale	Shoe Lacing
Kinchington et al., 2012	6-point scale	Performance
Kinchington et al., 2010	6-point scale	Injury
Kraemer et al., 2000	120-point scale	Compressive Hosiery
Luo et al., 2009	5-point scale	Footwear
Mündermann et al., 2002	150 mm VAS	Inserts
Mündermann et al., 2003	150 mm VAS	Inserts
Murley et al., 2010	150 mm VAS	Insoles
Salles & Gyi, 2012	150 mm VAS	Insoles
Sterzing et al., 2013	150 mm VAS	Midsoles
Wegener et al., 2008	150 mm VAS	Footwear
Yung-Hui & Wei-Hsien, 2005	100 mm VAS	Footwear
Zifchock & Davis, 2008	100 mm VAS	Insoles

VAS: Visual Analogue Scale.

Both VAS scales (Figure 41) and Likert scales (Figure 42) have advantages and disadvantages. These comfort scales had their origin in pain scales, where the increasing scores represent increased pain. Similarly, in these scales applied to comfort, higher values in the scale represent a greater perception of comfort.

Figure 41. Visual Analogue Scale, VAS (Mündermann et al., 2003).

Name	Place a score 0 to 6 in each box						
Lower limb comfort	**Foot**	**Ankle**	**Calf-Achilles**	**Shin**	**Knee**	**Footwear**	**Sum comfort**
Rank each body area from 0–6 using the comfort descriptors							36 maximum score
Comfort descriptors 0 = extremely uncomfortable (unable to run or jump) 1 2 3 = neither uncomfortable or comfortable (more or less uncomfortable/comfortable) 4 5 6 = zero discomfort (extremely comfortable; best ever feel)							

Figure 42. A 6-point Likert scale (Kinchington, Ball, & Naughton, 2010b).

On the one hand, Likert scales have been showed to have acceptable validity (Lozano, Garcia-Cueto, & Muñiz, 2008), minimal error of measurement and are simple to understand (Dijkers et al., 2002; Miller, Nigg, Liu, Stefanyshyn, & Nurse, 2000). However, these scales are ordinal-based or ranking-based scales, where the person orders a parameter (e.g. comfort) of an object from "least" to "most". Therefore, in these scales there is no indication in an absolute sense of how much comfort an object possesses (Mündermann et al., 2002). Moreover, whereas this scale allows the determination of relative differences, very small differences between conditions cannot be detected due to the discrete spacing between the ratings. Finally, since the answers from this scale are presented in discrete values, it would introduce errors to correlations between the discrete perception of comfort and other biomechanical variables measured on continuous scales (Mündermann et al., 2002).

Based on this argumentation, Mündermann et al. (2002) suggested that visual analogue scales (VAS) of 100 – 150 mm in length have the greatest sensitivity and suggested that this type of scales are less vulnerable to distortions or biases in rating. Moreover, based on the definition of comfort, they concluded that a control condition should always be measured in each test so that the individual could compare the new condition to the control condition. As it can be observed in Table 24, VAS scales have become very popular in the footwear and insoles research field and the number of articles using VAS are now comparable to those using the Likert-scales.

A number of studies have investigated whether the perception of comfort is associated with different biomechanical parameters such as plantar pressure and impact forces (Che et al., 1994; Hagen et al., 2011; Hong, Lee, Chen, Pei, & Wu, 2005; Jordan & Bartlett, 1995; Jordan, Payton, & Bartlett, 1997; Milani, Hennig, & Lafortune, 1997). In this sense, due to the mechanoreceptors placed under the foot, people are more sensitive to pressure and therefore much better able to detect pressure changes rather than changes in the forces acting on the plantar aspect of the foot (Milani et al., 1997). Based on this idea, these authors suggested that, whereas a relationship between comfort and impact forces was very unlikely to exist, alterations in plantar pressure could be associated with comfort and play a significant role in its subjective perception. In this line of thought, whereas some studies have observed that lower values of plantar pressure were associated with increased comfort (Che et al., 1994; Hagen et al., 2011; Hong et al., 2005; Jordan et al., 1997), other studies have not been able to find such association (Dinato et al., 2015; Wegener et al., 2008) and this relationship is not clear yet.

Regarding the analysis of the perception of comfort in sports and especially when looking at the effects of using sport equipment such as insoles, footwear or garments, the perception of comfort plays a very special and relevant role since how an athlete perceives these garments may ultimately affect their actual **performance** and **injury occurrence** (Che et al., 1994; Kinchington et al., 2012; Luo et al., 2009; Mills, Blanch, &

Vicenzino, 2011, 2012; Mündermann et al., 2003, 2002; Mündermann et al., 2001; Vicenzino, Collins, Cleland, & McPoil, 2010). Various studies have suggested that the perception of comfort could be a performance indicator during exercise since the perception of lower extremity discomfort can lead to alterations in the leg's muscular activity and compromise the actual movement, thereby influencing not only performance but also increasing the risk of injury (Kinchington et al., 2012; Nurse et al., 2005; Wakeling et al., 2002).

Finally, of special interest is the influence of insoles on the perception of comfort during exercise. Many studies have been carried out to analyse how different insoles of different materials and properties influenced the perception of comfort during walking and running (Anderson et al., 2005; Au & Goonetilleke, 2007; Che et al., 1994; Healy, Dunning, & Chockalingam, 2010; Kaalund & Madeleine, 2014; Murley et al., 2010; Nigg et al., 1999; Salles & Gyi, 2012; Yeo & Bonanno, 2014; Yung-Hui & Wei-Hsien, 2005; Zifchock & Davis, 2008). Such is the relevance of comfort in the construction of insoles that 30 years ago Campbell et al. (1982) already included the concept of "comfort" when defining the most important characteristics that a good insole should have (Campbell et al., 1982, p.48):

> *"Biocompatibility, ease of use, ease of fabrication, availability, durability, simulation of the mechanical properties of soft tissue, subjective comfort, cost and pressure distributing properties. […] Moreover, to fulfil their defined role, foot orthoses need to have both shock attenuation and movement control characteristics."*

The original role of an insole is to control and support foot motion during locomotion (Werd & Knight, 2010). Interestingly, recent studies have found that the hardness of an insole is a dominant factor in the individual's perception of comfort when assessing an insole (Mündermann et al., 2001). In this sense, whereas softer insoles are considered more comfortable, their ability to support and control motion is therefore compromised (since hard materials and support structures are needed to control motion) (Mündermann et al., 2001). As a result, this discrepancy opens an interesting door ahead for lower limb and insoles biomechanics, since it is necessary that future studies address this issue and provide a deeper insight into how insoles influence the perception of comfort.

1.8.2.2. Analysis of Fatigue

The level of fatigue attained by an athlete has been measured in very different ways by using different tools. Among the most common tools to measure the level of fatigue we can find:

A. **PERCENTAGE OF THE PREDICTED MAXIMAL HEART RATE (HR_{max}).** Many studies calculate the individual's predicted maximal heart rate ("220 – age (years)") and terminate the fatigue protocol when the athlete reaches and arbitrary percentage of their age-predicted maximal heart rate (e.g. 85% - 95% of HR_{max}) (Abt et al., 2011; Benjaminse et al., 2008; Zafeiridis, Sarivasiliou, Dipla, & Vrabas, 2010).
B. **PLATEAU IN MAXIMAL OXYGEN CONSUMPTION (VO_{2max}).** By measuring oxygen consumption (VO_2) through the individual's expired air with gas analysers, researchers are able to measure the maximal rate of oxygen consumption by the active muscles during exercise (VO_{2max}). As the intensity increases and the fatigue appears, the muscles consume more and more oxygen in order to meet the physiological demands of the activity, up to a point where the oxygen consumption reaches its limit and this value plateaus (VO_{2max}), moment that has been considered as a marker of fatigue (Abt et al., 2011; Astorino et al., 2005).
C. **BLOOD LACTATE CONCENTRATION [La].** As the intensity and duration of the exercise increases, so does the concentration of lactate in the human body (Wilmore, Costill, & Kenney, 2007). As a result, measuring blood lactate concentration during a given exercise has been used as a fatigue marker and it has even been used to defined a physiological threshold ("Lactate Threshold") defined as the highest velocity attained prior to the curvilinear increase in blood lactate concentration above the baseline levels (Irving et al., 2006; Weltman

et al., 1990). This threshold has been commonly used to fatigue participants by having them run at this threshold for a given time (Carter, Pringle, Jones, & Doust, 2002; McMorris, Swain, Lauder, Smith, & Kelly, 2006).

D. **RESPIRATORY EXCHANGE RATIO (RER)** is the ratio between the amount of carbon dioxide produced and the oxygen consumed during a given exercise (V_{CO2}/V_{O2}) (Wilmore et al., 2007). This ratio also increases with the exercise intensity (Ramos-Jiménez et al., 2008). The RER indicates the muscle oxidative capacity of the muscles to get energy and it has been used as an objective means of quantifying effort (Nakanishi et al., 2014). Together with the aforementioned parameters (%HR_{max}, VO_{2max}, [La]), this ratio is also used to terminate fatigue protocols when it reaches values greater than 1.0 - 1.1 (Bove et al., 2007; Nemeth et al., 2009).

E. **SCALES OF PERCEIVED EFFORT**. They are scales ranging from 0 to 10 (OMNI scales, CR-10) or from 6 to 20 (6-20 RPE Borg scale) where the lower values of the scales stand for “very light intensity” and the higher values of the scales represent “very hard” and “maximal effort” intensities (Borg, 1982). It is a subjective way of measuring the perception of exertion during a fatigue protocol and it has been validated with other fatigue parameters such as the maximal oxygen consumption, heart rate, or blood lactate concentration (American College of Sports Medicine (ACSM), 2005; Borg, 1982; Irving et al., 2006; Williams, 2014) (Table 25).

Table 25. Summary of the relationship between the percentages of maximal oxygen uptake (%VO_{2max}), maximal heart rate (HR_{max}) and Borg’s rating of perceived exertion (RPE) (American College of Sports Medicine (ACSM), 2005).

%VO2max	<20	20-39	40-59	60-84	≥85	100
%HRmax	<35	35-54	55-69	70-89	≥90	100
RPE	<10	10-11	12-13	14-16	17-19	19-20

1.8.2.2.1. Rating of perceived exertion (RPE)

The rating of perceived exertion (RPE) scale (Figure 43) was developed by Gunnar Borg and accepted as a valid tool within the sports and exercise research field in 1973 (Noble & Robertson, 1996). The general objective of using the RPE is to quantify an individual's subjective perception of exertion in order to determine the intensity at which a given exercise is being performed (Borg, 1982).

6	
7	Very, very light
8	
9	Very light
10	
11	Fairly light
12	
13	Somewhat hard
14	
15	Hard
16	
17	Very hard
18	
19	Very, very hard
20	

Figure 43. 6-20 rating of perceived exertion (RPE) Borg Scale (Borg, 1982).

A common misunderstanding is to assume that changes in heart rate, oxygen consumption and lactate concentration will influence RPE. However, this is not true since previous studies have indicated that the main intrinsic factors that influence RPE are in fact the breathing work, the sensation of muscle pain, the perception of limb speed, the body temperature and the joint strain (Borg, 1982; Chen, Fan, & Moe, 2002; Robertson & Noble, 1997).

On the other hand, since RPE is a subjective tool, some psychological factors and the environment also play a role when an individual determines their perception of fatigue. In this sense, the following factors have been suggested to also modulate this perception: age, gender, the mode of exercise, audio-visual distractions, circadian rhythms, haematological and nutritional status, medications, the physical environment, the psycho-social status, and the competitive milieu of the testing environment (Robertson & Noble, 1997; Williams & Eston, 1989; Winter, Jones, Davison, Bromley, & Mercer, 2006).

The RPE Borg Scale 6-20 (Figure 43) was originally designed for aerobic exercise where subjective perceptions of fatigue were defined to concur with the linear increments in heart rate and oxygen consumption as exercise increased (Borg, 1982; Winter et al., 2006). In this sense, increasing intensity measured by heart rate could be easily identified with an RPE value by the calculation:

$$RPE * 10 = HR$$

Equation 5. RPE and Heart rate relationship.

where an RPE of 7 (Very, very light) would correspond to 70 beats/minute, an RPE of 15 (Hard) would correspond to 150 beats/minute, an RPE of 19 (Very, very hard) would correspond to 190 beats/minute) (Borg, 1982).

The very same researcher, Gunnar Borg, designed a second scale to measure the perception of fatigue called the Borg Category Ratio Scale (Borg CR-10 Scale) (Figure 44). This scale was created using a more familiar range (0 to 10) and it is suggested to be best suited to determine fatigue when there is overriding sensation arising from pulmonary responses or from a specific area of the body such as muscle pain or ache (e.g. fatigue in the quadriceps) (Borg, 1982; Winter et al., 2006).

0	Nothing at all	
0.5	Very, very weak	(just noticeable)
1	Very weak	
2	Weak	(light)
3	Moderate	
4	Somewhat strong	
5	Strong	(heavy)
6		
7	Very strong	
8		
9		
10	Very, very strong	(almost max)
•	Maximal	

Figure 44. Borg Category Ratio scale (Borg CR-10) (Borg, 1982).

Based on Borg's idea to create scales for determining effort during non-specific exercise, different researchers have developed and validated afterwards the OMNI scales which, based on the same principle, are scales with increasing numeration linked to increasing intensity but created and designed for specific types of physical activities such as walking and running (Utter et al., 2004) (Figure 45) or resistance exercise (Robertson et al., 2003) (Figure 46).

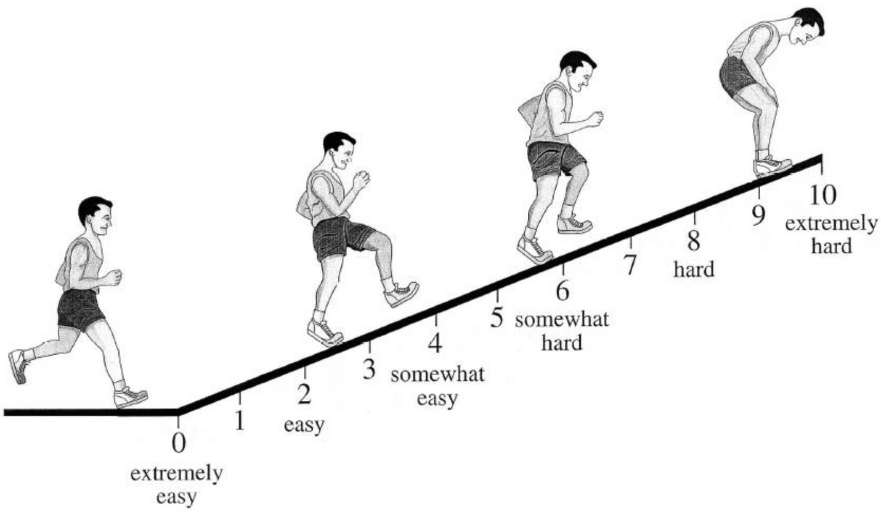


Figure 45. OMNI perceived exertion scale for walking and running (Utter et al., 2004).

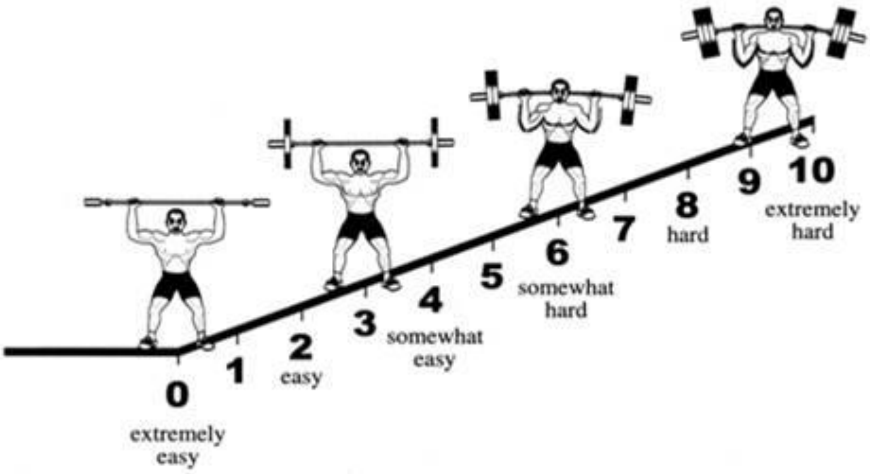


Figure 46. OMNI perceived exertion scale for resistance exercise (Robertson et al., 2003).

All in all, it is important that researchers know that these scales are equally valid tools which can easily provide information regarding the intensity of a given exercise taking into account the individual's perception. As long as the investigator acknowledges its limitations and controls the best as possible the study situation in order to perform the test in the ideal conditions, the perception of fatigue scales are interesting and important tools to use in experimental studies where the fatigue state is involved.

Key Points

- Plantar pressure can be influenced by the running speed, surface and slope, foot type, fatigue state and the use of insoles.
- Impact acceleration can be influenced by the running speed, surface, the mechanics of running, stride variables, the fatigue state and the use of insoles.
- The perception of comfort is individual-specific: the same stimulus can be perceived as comfortable or uncomfortable depending on the person.
- The Borg RPE is an easy, quick and valuable tool to measure the fatigue state.

1.9. Aim of the Study

As presented in the introduction, the use of insoles has been associated with numerous benefits. However, there is nowadays a great controversy that questions whether prefabricated insoles (insoles chosen based solely on the athlete's foot size) would provoke similar effects than custom-made insoles (insoles made by a podiatrist and created from a three-dimensional model of the athlete's foot) on the biomechanics and running pattern during running.

Moreover, the fatigue state has been observed to provoke modifications in performance and in the athlete's running pattern. Moreover, it is when the athlete is fatigued when the majority of overuse injuries are believed to occur.

After doing a broad review of the literature analysing the influence of insoles on the biomechanics of running, a lack of evidence has been identified regarding the effects of using custom-made or prefabricated insoles on spatio-temporal, plantar pressure, impact acceleration, and perception of comfort parameters during running. Moreover, the role that the fatigue state may play in these relationships is also of great interest and to date this role has not been elucidated.

Therefore, the present dissertation has the following aims and hypotheses:

Research Aim 1:

To investigate the influence of the fatigue state and the use of insoles (control insole [CI: the original sock liners of the running shoe], custom-made insoles [CMI] and prefabricated insoles [PI]) on two spatio-temporal parameters (contact time and stride rate).

- **Hypothesis 1 (H1)**: The use of insoles (custom-made, prefabricated) will not influence the spatio-temporal parameters compared to the control condition.

- **Hypothesis 2 (H2)**: The fatigue state (post-fatigue condition) will lead to lower stride rate and to greater contact time compared to the pre-fatigue condition.

Research Aim 2:

To investigate the influence of the fatigue state and the use of insoles (control insole [CI: the original sock liners of the running shoe], custom-made insoles [CMI] and prefabricated insoles [PI]) on plantar pressure during running.

- **Hypothesis 3 (H3)**: The use of custom-made insoles will reduce plantar pressure compared to the control condition and the prefabricated insoles.
- **Hypothesis 4 (H4)**: The fatigue state (post-fatigue condition) will modify the pattern of plantar pressures compared to the pre-fatigue condition.

Research Aim 3:

To investigate the influence of the fatigue state and the use of insoles (control insole [CI: the original sock liners of the running shoe], custom-made insoles [CMI] and prefabricated insoles [PI]) on impact acceleration during running.

- **Hypothesis 5 (H5)**: The use of custom-made insoles will reduce impact acceleration compared to the control condition and the prefabricated insoles.
- **Hypothesis 6 (H6)**: The fatigue state (post-fatigue condition) will lead to greater impact acceleration compared to the pre-fatigue condition.

Research Aim 4:

To investigate the influence of the fatigue state and the use of insoles (control insole [CI: the original sock liners of the running shoe], custom-made insoles [CMI] and prefabricated insoles [PI]) on the perception of comfort.

- **Hypothesis 7 (H7)**: Custom-made insoles will be perceived more comfortable than the control condition and the prefabricated insoles.

- **Hypothesis 8 (H8)**: Both study insoles (custom-made and prefabricated insoles) will be perceived more comfortable than the control condition.

Research Aim 5:

To investigate the influence of the fatigue state and the use of insoles (control insole [CI: the original sock liners of the running shoe], custom-made insoles [CMI] and prefabricated insoles [PI]) on the perception of fatigue (RPE).

- **Hypothesis 9 (H9)**: The use of insoles (custom-made and prefabricated) will not influence the perception of fatigue.

The results of this study may have some important implications in the area of sport biomechanics and sport medicine:

1. **Effect of CMI**: If using custom-made insoles shows a reduction in plantar pressure and impact acceleration during running, this finding may lead to an injury protective mechanism since the overloading of specific foot areas together with the repetitive stresses provoked by the impact accelerations each time the foot contacts the ground have been associated with increased overuse injury incidence.
2. **Effect of PI**: If using prefabricated insoles shows no difference in plantar pressure and impact acceleration compared to the control condition, this finding may imply that "off-the-shelf" insoles do not provide additional support compared to running without insoles.
3. **If there is no difference between CMI and PI,** it may imply that insoles based on a 3D model of the foot provide no further benefits compared to conventional non-personalised insoles.
4. **If there is no difference between CMI and PI versus CI,** it may imply that the use of insoles has no real effect on the studied parameters during running and their effectiveness could be questioned.

2. METHODOLOGY

2. METHODOLOGY

2.1. Experimental Design

In order to fulfill the aforementioned objectives, the following experimental protocol was carried out. The study involved running at 3.33 m · s^{-1} (12 km · h^{-1}) on a treadmill under three different conditions (control condition [CI], custom-made insoles [CMI], and prefabricated insoles [PI]) under two fatigue states (rest and fatigued) where spatio-temporal parameters, plantar pressure, impact acceleration, perception of comfort and fatigue were measured. This project was a double-blind study where neither the participants nor the investigator who measured and analysed the data knew the differences among the insole conditions and therefore possible subjective bias were eliminated.

2.1.1. Participants

The initial sample consisted of 42 athletes, comprising 21 males (50%) and 21 females (50%). Participants were recruited via advertisements in running clubs, running events (Valencia half-marathon and marathon) and University athletic teams. The inclusion criteria to take part in the study were as follows:

1. Minimum of 20 km/week of running mileage.
2. Free of injuries in the last 6 months prior to the study.
3. No lower extremity surgery in the last 2 years prior to the study.
4. No use of insoles prior to the study.

All participants were informed about the protocol and experimental design of the study and subsequently gave written informed consent. The study procedures complied with the Declaration of Helsinki (World Medical Association, 2008) and were approved by the University of Valencia ethics committee (procedure number H1411628681304). Eventually, 2 athletes did not meet the inclusion criteria and were excluded from the study. Therefore a final sample of 40 participants (20 males and 20 females) took part in the study. Some general anthropometric variables were measured the first day of the study with a bioelectrical impedance body composition analyser (Tanita BC-418MA, Tanita Corporation, Arlington Heights, IL, USA) for a better description of the sample (Table 26).

Table 26. Description of the participant characteristics (Mean ± Standard Deviation).

Item	All group (n=40)
Age (years)	30.35 ± 5.21
Body Height (cm)	170.38 ± 9.11
Body Weight (kg)	64.38 ± 10.72
BMI (kg/m^2)	22.00 ± 2.11
Body Fat (%)	17.79 ± 5.56

2.1.2. Assessment of foot type and insole personalization

The foot type of the participants was classified using the Foot Posture Index-6 (FPI-6), which is a validated and commonly used clinical tool for quantifying the degree to which a foot can be considered to be in a pronated, supinated or neutral position (Arnold, Causby, & Jones, 2010; Gijon-Nogueron et al., 2014; Barton, Menz, & Crossley, 2011; Burns et al., 2005; Menz & Munteanu, 2005; Thijs et al., 2008; Wegener et al., 2008; Zammit, Menz, & Munteanu, 2010). This test is intended to be a simple and fast method for scoring various features of foot posture into a quantifiable result, which provides an indicator of the overall foot posture. The participants stood on a podoscope (Podiatech®, Voiron, France) in a relaxed stance position with double limb support, their arms by the side and looking straight ahead (Redmond, Crosbie, & Ouvrier, 2006). By palpation and a series of observations, the weight-bearing foot posture was rated according to a series of predefined criteria. This test comprises six clinical criteria:

1. Palpation of the talar head.
2. Observation of the supralateral and infralateral malleolar curvature.
3. Observation of the calcaneal frontal plane position.
4. Observation of prominence in the region of the talonavicular joint.

5. Observation of the congruence of the medial longitudinal arch.
6. Observation of abduction/adduction of the forefoot on the rearfoot.

Each item can be graded from -2 to +2 (Table 27), so that a global score of “-12” (highly supinated) or “+12” (highly pronated) can be estimated when the scores of each item is combined (Barton et al., 2011).

Table 27. Possible grades of each item in the FPI-6.

-2	Clear signs of supination
-1	Moderate signs of supination
0	Neutral
+1	Moderate signs of pronation
+2	Clear signs of pronation

Redmond et al., 2006.

Generally, literature has agreed to consider the global aggregated score as follows (Table 28):

Table 28. Estimation of the overall foot posture.

-5 to -12	Highly Supinated
-1 to -4	Supinated
0 to +5	Neutral
+6 to +9	Pronated
+10 to +12	Highly Pronated

Thijs et al., 2008; Redmond, Crane, & Menz, 2008; Zammit et al., 2010.

Participants carried out the present study while running with either the original insoles of their running shoes (control condition), a pair of prefabricated insoles selected taking into account solely the athlete’s foot size (prefabricated), and a pair of custom-made insoles adapted directly from a 3D model of the individual’s foot print (custom-made). The characteristics of the insoles are presented in Figure 47.

Custom-made Insoles

- Top layer (blue): Podiamic 160 polyethylene + ethyl-vinyl acetate (EVA), 2.5 mm thick, hardness 30° Shore A.
- Sole reinforcement (white): Polyester resin Transflux® 1.0 mm thick.
- Forefoot insert (green): Synthetic Viscotene® 2.5 mm thick, hardness 30° Shore A.
- Rearfoot insert (grey): Podiaflex® resin 0.9 mm thick.
- Rearfoot reinforcement: Polyester resin Transflux® 1.0 mm thick.

Prefabricated Insoles

- Forefoot reinforcement of polyurethane foam, hardness 15-25° Shore A (red).
- Rearfoot reinforcement of polyurethane foam. hardness 15-25° Shore A (green).
- Extra support under medial arch (10 cm long and 3.5 mm high) of Techcarbon.

Figure 47. Insoles used in the study.

For the personalisation of the custom-made insoles (Figure 48), the podiatrists had each participant standing on a Printlab2 platform (Podiatech®, Voiron, France). This instrument is composed by a pair of silicon vacuum bags filled with polystyrene microspheres connected to a built-in vacuum pump with a filter that enables the recreation of the foot plantar print. While the participants stood on the platform, the podiatrists created a plaster mould of the foot through different manoeuvres of neutralisation with the foot loading the platform. Depending on the FPI-6 outcome, the podiatrists used different manoeuvres to properly imprint the foot plantar structure on the instrument, which consisted of internal and external tibial rotation movements to neutralise the subastragalar joint, manoeuvres of configuration of the medial longitudinal arch through dorsiflexion movements of the first metatarsophalangeal joint, and stabilising lateral movements.

In order to get the foot mould, five sheets of plaster adjusted to the individual's foot size were prepared. Once the plantar foot print was recreated, the plaster sheets were positioned on the Printlab2 platform and the participant stood on the instrument one last time so that a precise mould could be created.

Figure 48. Creation of the foot print plaster mould protocol.
A) FPI-6 Test; B) Manoeuvre of neutralisation; C) PrintLab2 Platform; D) Plaster Sheets on participants foot imprint; E) Recreation of the final foot print plaster mould.

The moulds reproducing the athletes' feet were subsequently filled completely with plaster and left 24 hours so that the mould could properly dry. Finally, using a MobiLab2® heating and thermo-welding system (Podiatech®, Voiron, France) (Figure 49), the custom-made insoles were heated at 110ºC under vacuum conditions for three minutes based on the foot print from the plaster mould. This thermo-conforming procedure enabled the podiatrists to obtain three-dimensional insoles personalised to each athlete's foot.

Figure 49. MobiLab 2 Thermo-welding system.

One week before the first running test, the participants came to the laboratory to receive the first pair of insoles (custom-made or prefabricated, at random) and to perform an incremental submaximal running test in order to determine their individual speed of the fatiguing run (explained in the following section).

2.1.3. Protocol

The experimental phase of the study was carried out during three weeks. Firstly, a pair of insoles (CMI or PI) was randomly given to each participant one week before the first running test for adaptation purposes. During this week prior to the test, the participants were asked to use their sport footwear with the assigned insoles leading their normal daily routine. After the week of adaptation, the participants came to the lab to perform the first running test with those insoles and, after completing the first running test, participants gave the used insoles to the researchers to ensure that they did not mistake them with the new pair of insoles provided by the researchers (PI or CMI, depending on the initial randomisation). After another week of adaptation with the new pair of insoles, participants came again to the lab to carry out the running test (same protocol as the first running test) but with the second pair of insoles (Figure 50).

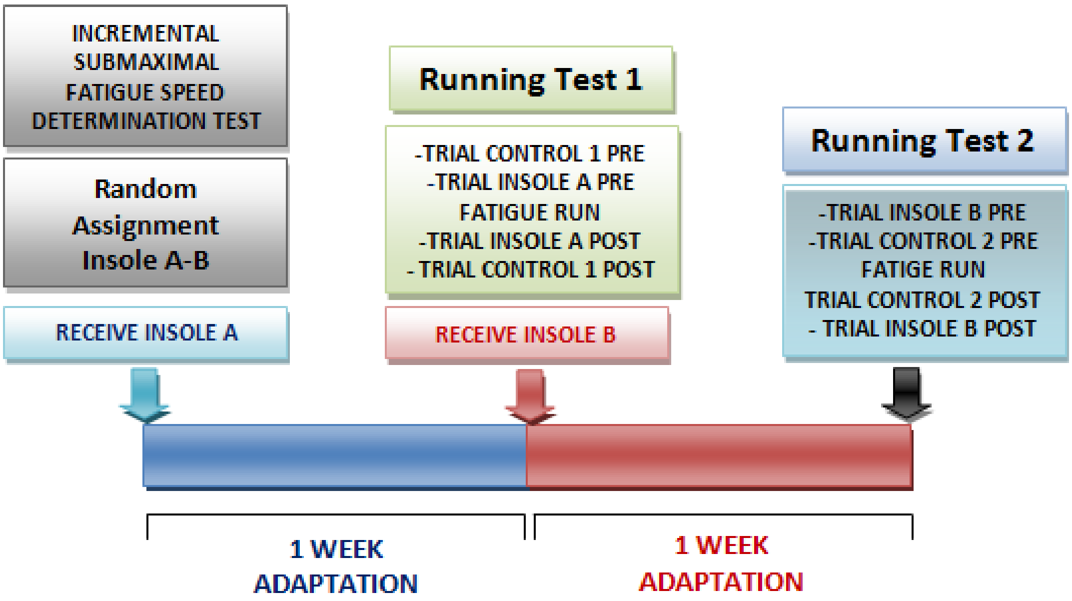


Figure 50. Representation of the experimental phases (example of randomly-assigned INSOLE A first).

All running tests took place in the Laboratory of Biomechanics in the Faculty of Physical Activitiy and Sport Sciences, in the University of Valencia. Participants ran on a treadmill (Excite Run 700, TechnoGymSpA), built in Gambettola (Italy), at a fixed speed and with 0% slope (Figure 51).

Figure 51. Treadmill used in the study.

Each running test consisted of a fatigue run and four running trials. Firstly, the order of the conditions of each running test was randomly established for all participants. When the participants arrived to the lab, anthropometric measurements were taken and afterwards they carried out a standardised warm up (using their running shoes either with the original insoles of the shoes or the study insoles depending on the initial randomisation) for seven minutes at 2.78 m · s^{-1} (10km · h^{-1}). At the 7th minute of warm-up, the speed was increased to 3.33 m · s^{-1} (12km · h^{-1}) (without any pause between warming-up and 1st running trial) and the participants ran for another 7 minutes. Within the last minute, plantar pressure (at 500 Hz during 6 seconds) and impact acceleration (at 500 Hz during 15 seconds) were measured.

During this measuring time, 8-9 steps (plantar pressure) and 20-24 steps (impact acceleration) were registered (first pre-fatigue [PRE] measurement). In order to ensure that no alteration of the running pattern was made during the analysis, no signal was given to the athlete as to the exact moment of measurement.

As soon as the first PRE running trial was finished, participants completed the perception of comfort visual scale while the researchers removed the firstly used insoles and inserted the second pair of insoles. This process took about 1 minute and as soon as the participant was ready, the second PRE running trial began at 3.33 m · s^{-1} for another 7 minutes. Plantar pressure and impact acceleration were measured within the last minute of the trial, whereas the perception of comfort for the second pair was reported right after the end of this trial (Figure 52). After both PRE running trials, a fatiguing run was carried out for 12 minutes and the perception of fatigue was reported during the last minute of the run (fatigue protocol explained next). Immediately following the fatigue run, two 1-minute POST (post-fatigue) running trials at 3.33 m · s^{-1} were done (one POST running trial for each insole condition where plantar pressure and impact acceleration were measured again).

The second running test was carried out one week later (so that participants would use the new pair of insoles for another adaptation week) and consisted exactly of the same protocol, including a second control trial and the new pair of study insoles. Similar to the first running test, the spatio-temporal, plantar pressure, impact acceleration, perception of comfort and fatigue parameters were measured for these conditions.

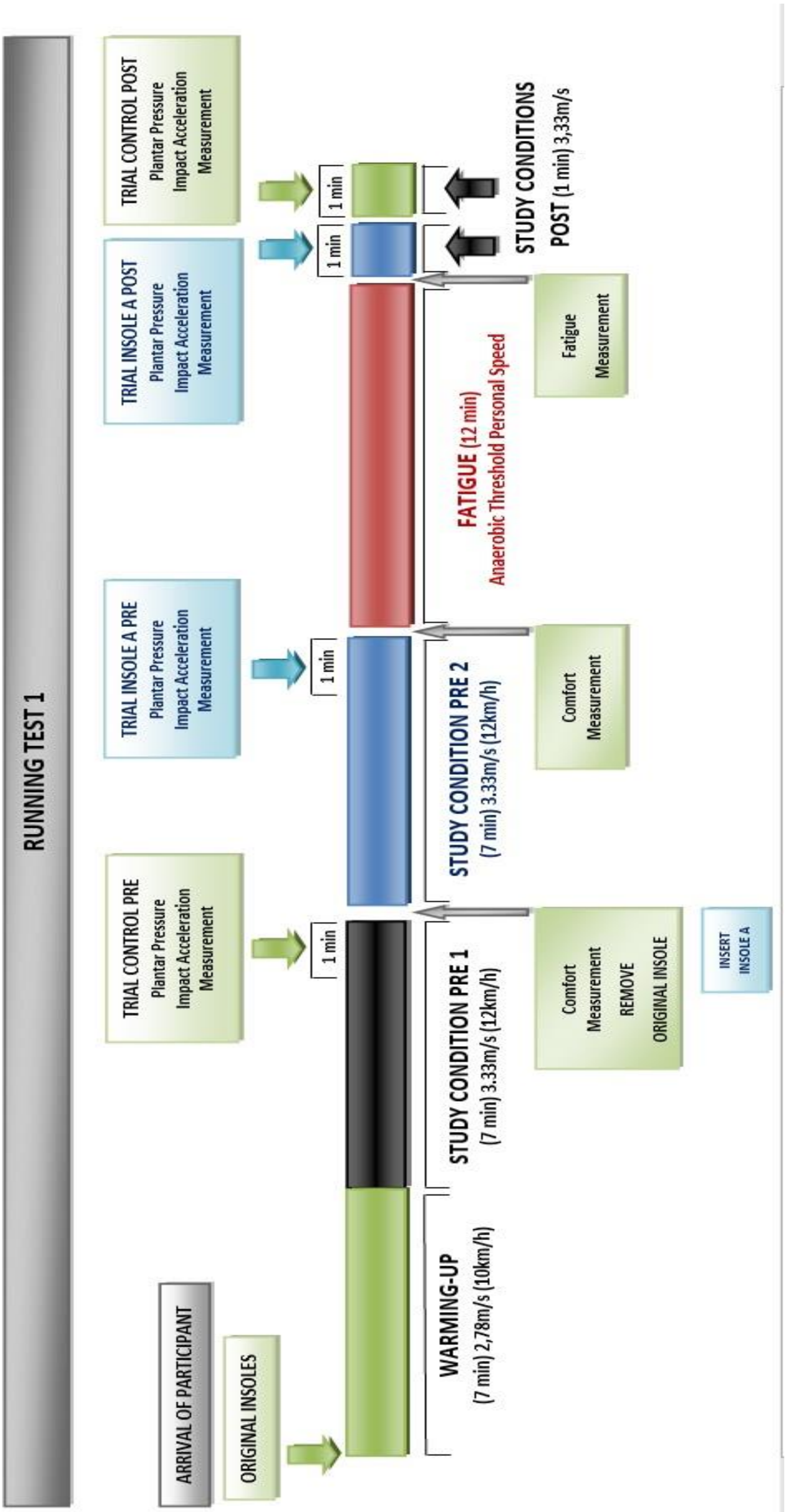


Figure 52. Representation of simulated Running Test 1 (example of randomly-assigned INSOLE A first). *Spatio-temporal parameters were measured together with plantar pressure.

2.1.4. Fatigue Protocol

One week before the beginning of the running tests, the participants came to the laboratory and an incremental submaximal running test was carried out together with the Foot Posture Index test that has been previously explained. The aim of the submaximal running test was to determine the running speed at which each participant could perform just below their specific anaerobic threshold, so that the effect of a similar level of fatigue on the different insole conditions could be analysed.

The incremental submaximal test consisted of a warm-up stage of 5 minutes at 2.78 $m \cdot s^{-1}$ (10 $km \cdot h^{-1}$). At the end of the warm-up, a blood lactate sample was taken, and depending on the lactate accumulation level, the speed was increased to the next stage (2 $km \cdot h^{-1}$ each stage) in order to achieve blood lactate levels close to 4 mmol (López & Fernández, 2006). After three minutes of running at the new assigned speed, another blood lactate sample was taken in order to confirm that the participant was running at the desirable speed (blood lactate levels close but lower than 4 mmol). When the lactate levels were not the expected ones (too low), the speed was increased to the next stage (+2 $km \cdot h^{-1}$) again and a third blood lactate sample was made after three minutes.

Blood lactate level was used as the main physiological variable for determining the fatiguing running speed as it has been previously suggested to be a useful tool to effectively predict exercise performance (McArdle, Katch, & Katch, 2004). However, the fatiguing running speed was confirmed by the exercise physiologists based not only on the blood lactate levels, but also taking into account the participant's heart rate evolution and fatigue symptoms showed by the runners such as breath alteration and facial expression of exhaustion.

The ear lobe was prepared using non-alcoholic mediwipes and capillary blood lactate samples were taken using Lactate Pro® Analyser (Arkay Factory Inc., Shiga, Japan) via pinching with a disposable lancet and filling a reagent strip with at least 5 µl of blood.

Via this incremental submaximal test prior to the experimental phase of the study, the individualised fatiguing running speed was determined for each participant. Later on, during the running trials, the participants ran for 12 minutes at this speed so that an analysis of the effect of the insole conditions under a fatigue state could be measured.

2.1.5. Test Specifications

For both running tests, the same protocol was carried out. In order to minimise the amount of confounding variables and to control the variability between tests, several specifications were established:

1. The order of the participants performing the test and the order of the insole conditions were **assigned at random**.
2. Participants used the assigned insoles during **one week** prior to each running test for **adaptation** purposes. Although to the author's knowledge there is no study specifying the amount of time needed for a person to correctly adapt to newly-prescribed insoles, the podiatrists involved in the study suggested two days would be enough based on their experience. As a consequence, the participants wore the assigned insoles for a whole week to ensure a proper adaptation process to the insole condition.
3. The day prior to the running tests, participants were asked to **avoid any strenuous physical effort, depressive substances or stimulants** in order to perform the tests under "normal" physiological conditions.
4. Each participant underwent both running tests at a **similar time of day**.
5. The running tests were carried out on a **treadmill**. Although some studies have suggested that there may be significant biomechanical differences between running on a treadmill and overground (Baur et al., 2007; Bowtell, Tan, & Wilson, 2009; García-Pérez, 2013, 2014; Hines & Mercer, 2004; Ki-Kwang, Lafortune, & Valiant, 2005; Milgrom et al., 2003; Nigg, De Boer, & Fisher, 1995; Salvador, García, Iranzo, Pérez-Soriano, & Llana, 2011), there is a also a trend of studies agreeing that despite the small variations between both conditions

(similar to those which would appear when running on different overground surfaces), running on a treadmill can be representative to running overground and the use of treadmill in scientific studies could therefore be justified, as long as researchers bear in mind that running on a treadmill will provide comparable but not equivalent results (Fellin, Manal, & Davis, 2010a; Jones & Doust, 1996; Meyer, Welter, Scharhaq, & Kindermann, 2003; Riley et al., 2008).

6. All participants had **previous experience running on a treadmill**. Some studies have stated that runners with no experience in running on a treadmill need 6 minutes of familiarization in order to get valid and reliable results (Lavcanska, Taylor, & Schache, 2005; Paroczai & Kocsis, 2006). Hence, in order to ensure that all participants were familiarised with running on the treadmill and thereby not altering the variables of interest, all the running trials included a 7-min warm up.
7. Participants performed both tests with **their own running shoes** (and using the same shoes throughout the trials). Although some studies have recommended that all participants should use the same footwear to avoid variability among shoes (Dixon et al., 2000; Milner et al., 2006; Mizrahi, Voloshin, Russel, Verbitsky, & Isakov, 1997; Rethnam & Makwana, 2011; Tessutti et al., 2010; Verbitsky et al., 1998), it has also been suggested that athletes running with their own shoes may more accurately reflect a real-life situation, since imposing non-familiar shoes may alter their running biomechanics (Gerlach et al., 2005; Weist et al., 2004). Moreover, the introduction of the insole intervention was already a new situation for the participants, and including a new factor (unknown footwear) could make the interpretation of the results more difficult. Therefore, in this study, certain among-shoe variability was assumed in order to ensure a “natural” running gait performance.
8. The participants were instructed to **lace their running shoes in the same way** throughout conditions, since different shoe lacings may influence impact forces and pressure distribution (Fiedler et al., 2011; Hagen & Hennig, 2008; Werd & Knight, 2010).
9. Participants carried out a 7-min standardised **warm-up** before the study conditions. Warming-up was performed at a lower intensity (2.78 $m \cdot s^{-1}$) than

the study conditions (3.3 m · s^{-1}). Participants warmed-up only once (before the first running trial), since the amount of time between conditions was short (1-2 minutes) and authors considered it was not necessary to repeat the warm-up for the second running trial.

10. All participants **ran at 3.33 m · s^{-1}** both with the control and study insole conditions. This velocity was chosen because it is the most commonly used speed in the running literature (Baur et al., 2004; Baur et al., 2007; Chuckpaiwong et al., 2008; Dixon et al., 2000; Dixon et al., 2003; Fellin et al., 2010a; Fellin, Rose, & Royer, 2010b; García-Pérez et al., 2013, 2014; Hennig & Milani, 1995; Nigg et al., 1995; Queen et al., 2009a; Ribeiro et al., 2011; Tessutti et al., 2010) and, moreover, it has been appointed to match the 3 hr 20 min to 3 hr 45 min marathon time usually reported by recreational runners (Hennig & Milani, 1995).
11. All participants were instrumented and the biomechanical parameters (spatio-temporal, plantar pressure, impact acceleration, comfort, fatigue) were analysed **by the same researcher**.

2.2. Spatio-Temporal and Plantar Pressure Analysis

2.2.1. Equipment

In order to measure the spatio-temporal parameters and the plantar pressure throughout the different study conditions, Biofoot 2001® (IBV, Valencia, Spain) pressure analysis system was used (Figure 53). This system has a sample frequency of 500 Hz (allowing for 6 seconds of measurement at this sample rate) and has been showed to be reliable (Martínez-Nova et al., 2008a). It comprises a series of thin (0.7 mm), flexible, polyester insoles each with 64 piezoelectric sensors of 0.5 mm thickness and 5 mm diameter. The sensors are distributed in accordance with the foot physiology in such a way that there is a greater density of sensors under bony areas where pressures tend to be high, especially under the forefoot (Martínez-Nova, Cuevas-García, Pascual-Huerta, & Sánchez-Rodríguez, 2007a; Martínez-Nova et al., 2007b).

This system is equipped with the following the devices (Figure 53):

A. Instrumented insoles.
B. Signal amplifier.
C. A telemetry transmitter.
D. A data receiver card.
E. A software of analysis.

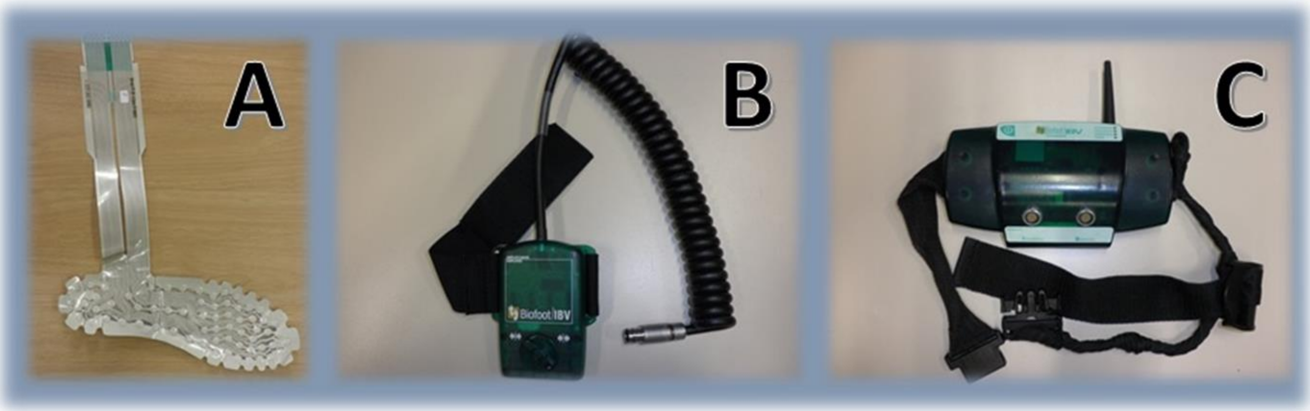


Figure 53. Biofoot 2001® (IBV/Valencia) Pressure Analysis System.
A) Instrumented Insole; B) Amplifier; C) Telemetry transmitter.

The instrumented insole is connected to an amplifier attached to the participant's lower leg, which through a telemetry transmitter placed on the participant's waist sends the data to a receiver (a card inserted into the computer) by digital telemetry, where the signal is logged and can be further analysed by the Biofoot/IVB 6.0 Software (Figure 54).

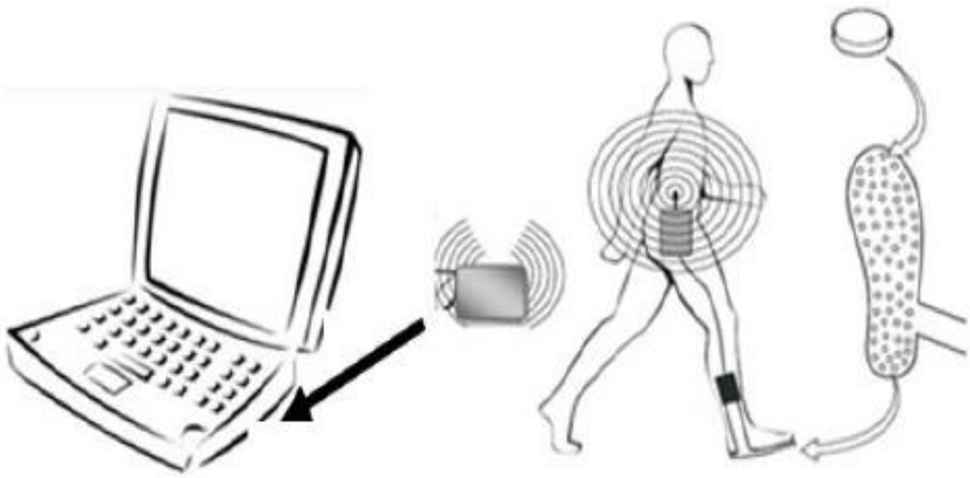


Figure 54. Diagram of Biofoot 2001® Pressure Analysis System functioning. Modified from Vera & Hoyos, 1993 (cited by Pérez, 2004).

2.2.2. Experience Design

Participants' foot size was asked and an instrumented insole according to that size was inserted into the participant's left shoe above the insole. Plantar pressure was measured only in the left foot because previous studies have observed no significant differences in plantar pressures between feet (Baur et al., 2007; Weist et al., 2004; Willson & Kernozek, 1999) and in order not to interfere with the impact acceleration equipment placed on the right leg.

Once the insole was connected to the amplifier located in the participant's waist, the participants walked with all the equipment around the lab for two minutes to warm the insoles, since the pressure sensors within the insole have been showed to be sensitive to temperature and therefore temperature calibration should be done before measurement (Bamberg, Lastayo, Dibble, Musselman, & Raghavendra, 2006; Catalfamo, Moser, Ghoussayni, & Ewins, 2008; Dyer & Bamberg, 2011; Jonely et al., 2011; Luo, Berglund, & An, 1998; Shu et al., 2010). Afterwards, the final step before starting the running trial was the pressure-zero calibration.

At this point, the participants were asked to elevate their left leg in order to put the pressure sensors of the instrumented insole under no load except for the foot and the inherent pressure of the shoe. Participants were asked to remain in this position for 10 seconds while the system carried out the calibration and established that pressure as the zero value. Once all these steps of the calibration process were done (Figure 55), the participants started the warm-up and the rest of the running test was carried out as explained previously.

Figure 55. Calibration process for the Biofoot 2001® Pressure Analysis System.
A) Inserting instrumented insole; B) Connecting instrumented insole to amplifier; C) Amplifier connected to telemetry transmitter; D) Calibration of the system.

2.2.3. Data Analysis

Once the measurements were done, the sole of the foot was divided into 9 zones with the Biofoot Software (Figure 56) as done in previous studies (Cheung & Ng, 2008; Chuckpaiwong et al., 2008; García-Pérez et al., 2013; Lee et al.,2007; Maiwald et al., 2006; Nagel et al., 2008; Pérez-Soriano et al., 2011; Queen, Haynes, Hardaker, & Garret, 2007; Rosenbaum et al., 2008; Weist et al., 2004; Wiegerinck et al., 2009).

H: Hallux
T: Toes
MM: Medial Metatarsal
CM: Central Metatarsal
LM: Lateral Metatarsal
MA: Medial Arch
LA: Lateral Arch
MH: Medial Heel
LH: Lateral Heel

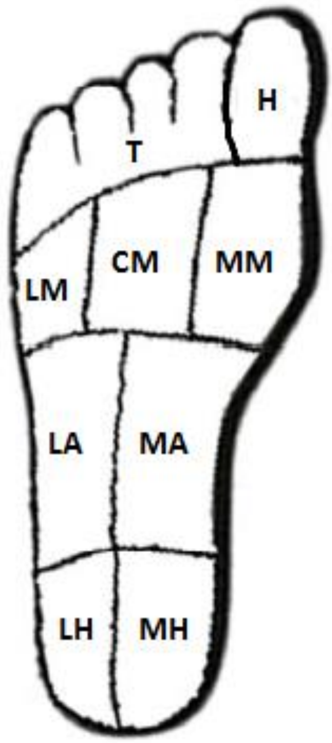


Figure 56. Foot sole divided into 9 areas for plantar pressure analysis.

After the foot was divided into the nine areas of analysis, spatio-temporal parameters and plantar pressure variables within each different area were analysed (Table 29).

Table 29. Spatio-temporal and plantar pressure variables analysed in the study.

SPATIO-TEMPORAL PARAMETERS	1) **Contact Time** (**CT**) (seconds)	Period of time that the foot is in contact with the ground during the stance phase.
	2) **Stride Rate** (**SR**) (stride/minute)	Number of strides per minute.
PLANTAR PRESSURE PARAMETERS	3) **Mean peak pressure** (**Px**) (kPa)	The average value of the maximum pressures from each step recorded over each foot area.
	4) **Time to mean peak pressure** (**TPx**) (%)	Moment where Px occurs expressed as a percentage of the total duration of the stance phase.
	5) **Pressure-Time Integral** (**PTI**) (kPa/second)	The pressure in a given zone per time unit (the area under the pressure-time curve).
	6) **Relative Pressure** (**RP**) (%)	The mean peak pressure of each zone relative to the mean peak pressure of the entire foot.

The data were exported from the Biofoot software to a ".txt" file, and results were subsequently organised and prepared with the Microsoft Excel software (Microsoft Inc. USA) for statistical treatment with SPSS 18 (SPSS Inc., Chicago, IL).

2.3. Impact Acceleration Analysis

2.3.1. Equipment

In order to measure the impact acceleration during running, a pair of lightweight tri-axial accelerometers (Signal-Blt, Sportmetrics, Spain) with a sampling frequency of 500 Hz were used. The acceleration signal was transmitted via Bluetooth to a computer where all the data were registered.

The accelerometry system comprises (Figure 57):

A. Two accelerometers.
B. A data adquisition and transmitted module.
C. A laptop.

Figure 57. Accelerometers and data adquisition module.

2.3.2. Experience Design

In order to measure impact acceleration adequately, the accelerometers were placed on the proximal anteromedial aspect of the right tibia and on the forehead as previously done in numerous studies (Table 20, p.80). The vertical axis of the accelerometer was aligned to be parallel to the long axis of the shank. Before placing the accelerometers, the locations were shaved and cleaned with alcohol in order to reduce the noise coming from the skin. Afterwards, the accelerometers were firmly fixed to the skin with double-side adhesive tape and secure with elastic belts around the leg and forehead (Figure 58).

Figure 58. Accelerometer placement protocol: A) Shaving the location; B) Placing the tibial accelerometer; C) Placing the head accelerometer; D) Securing the head accelerometer; E) Whole-body view.

This protocol complied with the recommendations of previous studies to minimise noise signal and to reduce the amount of error (compared to a bone-pin accelerometer) (Coventry et al., 2006; Gruber et al., 2014; Ziegert & Lewis, 1979):

A. To attach the accelerometer to a location as close as possible to the bone (minimum amount of soft-tissue between the bone and the accelerometer).
B. To use a low-mass accelerometer.
C. To secure the accelerometer with an elastic strap tightened to participant tolerance.

2.3.3. Data Analysis

Acceleration data were registered in the computer as a ".blt" file. These files were treated with Matlab (Version 7.12.0.635, The Math Works Inc., Natick, MA, USA). First, the ".blt" files were transformed to ".mat" format and afterwards, a custom written software filtered the signal. The filter was a low-pass filter with an 8^{th} order lowpass digital Chebyshev Type II filter with stopband edge frequency 50 Hz and stopband ripple 40 dB. After filtering the signal, the software automatically identified and exported the variables of analysis.

From the global acceleration signal, the software was programmed to identify and export the following impact acceleration variables for further analysis:

A. Head and tibial peak acceleration: maximal value of the acceleration signal.
B. Head and tibial acceleration rate: the acceleration slope measured by the acceleration amplitude divided by the time from ground contact to the peak acceleration
C. Shock attenuation: the reduction in the acceleration signal from the tibia (tibial peak acceleration) to the head (head peak acceleration), expressed as a percentage.

With the matlab software, different steps were followed in order to export the final outcome as an excel file (Figure 59):

A. Select the folder of analysis (where all the data from one condition were stored (e.g. custom-made insole pre-fatigue)).
B. Visually identify the general measurement.
C. Check each individual step manually in order to confirm that the program identified the variables correctly.
D. Once all the steps for all the participants for a given condition were confirmed, the software exported the results of the different variables of analysis to an excel file.

A)

B)

C)

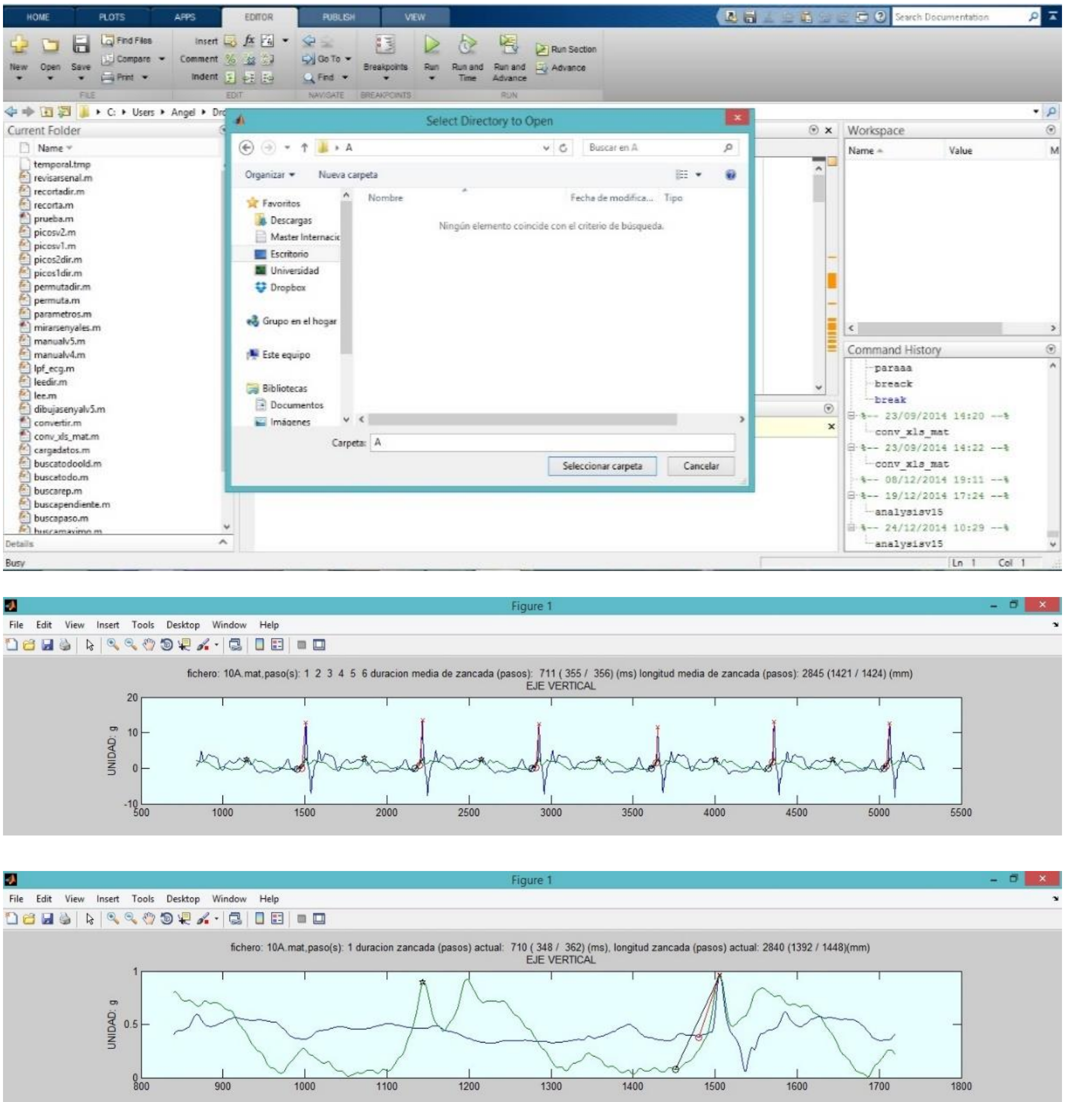


Figure 59. Data analysis with Matlab: A) Selection of the folder with the data; B) Checking the entire signal; C) Checking each individual step.

In the excel file, the results were organised in order to prepare them for the statistical treatment with the SPSS 18 (SPSS Inc., Chicago, IL).

2.4. Comfort Analysis

2.4.1. Equipment

For the analysis of the perception of comfort, a 150 mm visual analogue scale (VAS) was used. This scale has been showed to be a reliable tool to assess comfort (Mündermann et al., 2002) and has been used previously in numerous studies (Table 24, p.96).

For each variable, the scale is labelled at the left end as “not comfortable at all” (0 comfort points) and at the right end as “most comfortable condition imaginable” (15 comfort points) (Figure 60).

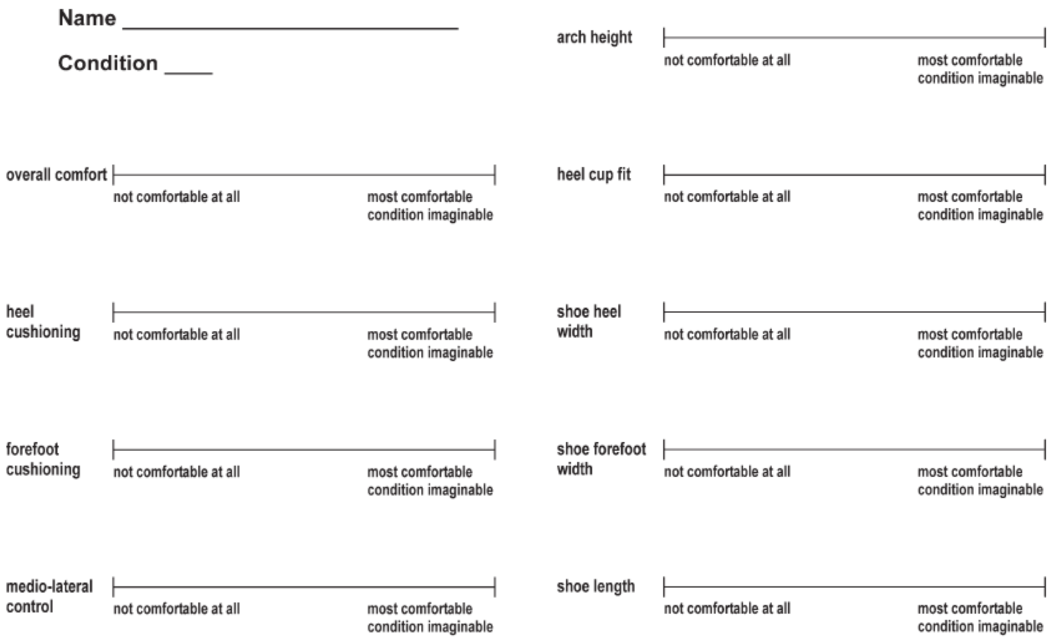


Figure 60. Representation of the VAS from Mündermann et al. (2002).

2.4.2. Experience Design

For an adequate and reliable measuremenf of comfort, previous studies have suggested that giving specific instructions to the participants regarding the definition of eah item will increase the reliability of these scales (Mündermann et al., 2002). Therefore, a document with the following information was read during the 7-min running trials so that the participants could specifically focus on those items (Figure 61).

There are several aspects of shoes which we are interested in measuring:	
Overall comfort	Overall impression of the shoe
Heel cushioning	Softness/hardness of the insole in the heel region
Forefoot cushioning	Softness/hardness of the insoles in the forefoot region
Medio-lateral control	Position of foot controlled by shoe
Arch height	Medial arch height of the insole
Heel cup fit	Fit of the insole in the heel region, i.e. whether the insole is loose or tight
Shoe heel width	Width of the shoe in the heel region
Shoe forefoot width	Width of the shoe in the forefoot region
Shoe length	Length of the shoe
There are scales for measuring each of these aspects of shoes. Although some shoe aspects may be equally comfortable, we would like you to judge the aspects independently. Please mark the line to indicate the relative comfort of a specific shoe condition; the further to the right, the more comfortable the shoe. Similarly, mark the other lines to indicate the comfort of the specific shoe aspects.	

Figure 61. Description of the items read to the participants (adapted from Mündermann et al. (2002)).

Right after the participants finished each one of the two running trials, they were given the comfort scale and were asked to cross with a pen the horizontal line of each item with a small vertical line indicating the amount of comfort perceived during that specific run.

Participants completed the comfort scale while the researchers prepared the participants' running shoes for the next study condition (extracting the first pair of insoles and inserting the second pair). This procedure (perception of comfort measurement and exchange of insoles) took no more than one minute.

2.4.3. Data Analysis

Once the experimental phase finished, the crossings in the comfort scale were measured. Using a ruler, the distance in milimeters between the left end (0 point) and the mark (vertical line) written by the participants was measured. That value in milimiters was considered the value of perception of comfort and was introduced into an excel file.

The variables of perception of comfort analysed in this study were:

A. Overall comfort.
B. Heel cushioning.
C. Forefoot cushioning.
D. Medio-lateral control.
E. Arch height.
F. Heel cup fit.
G. Shoe heel width.
H. Shoe forefoot width.
I. Shoe length.

Finally, the results were organised in an excel file in such a manner so that a further analysis (statistical analysis) could be carried out with SPSS 18 (SPSS Inc., Chicago, IL).

2.5. Fatigue Analysis

2.5.1. Equipment

In order to measure the perception of fatigue, a 15-point rating of perceived exertion scale (6-20 RPE Borg) was used (Figure 62) (Borg, 1982). This scale is a gold-standard tool for measuring the perception of fatigue during exercise and allows for a quick an easy measurement of this parameter.

6	
7	Very, very light
8	
9	Very light
10	
11	Fairly light
12	
13	Somewhat hard
14	
15	Hard
16	
17	Very hard
18	
19	Very, very hard
20	

Figure 62. 6-20 ratings of perceived exertion (RPE) Borg Scale (Borg, 1982).

2.5.2. Experience Design

Depending on the type of exercise and fatigue, the human body is able to return to basal values of the different physiological parameters (heart rate, VO_2, etc.) in a relatively short time (Daanen, Lamberts, Kallen, Jin, & Van Meeteren, 2012). This is specially important for the measurement of the perception of fatigue, because as a result of the body's ability to recover, the athlete will not perceive the intensity of an exercise in the same manner during the last minute of the performance compared to one minute after the performance. For this reason, participants were asked to report their perception of fatigue (RPE) during the last minute of the fatiguing run. When the fatiguing run was about to end (last minute), the researchers showed the RPE scale to the participants and asked them to report a value corresponding to their perception of fatigue at that time.

2.5.3. Data Analysis

The reported values of the perception of fatigue (RPE) for each insole condition were written into an excel file and were organised and prepared to be further analysed (statistical analysis) in SPSS 18 (SPSS Inc., Chicago, IL).

2.6. Statistical Analysis

The data were exported to the statistics software SPSS 18 (SPSS Inc., Chicago, IL) where the corresponding statistical treatment was carried out. After carrying out a descriptive analysis of the sample (age, height, weight, BMI, %Body fat), three different analyses were made (Figure 63):

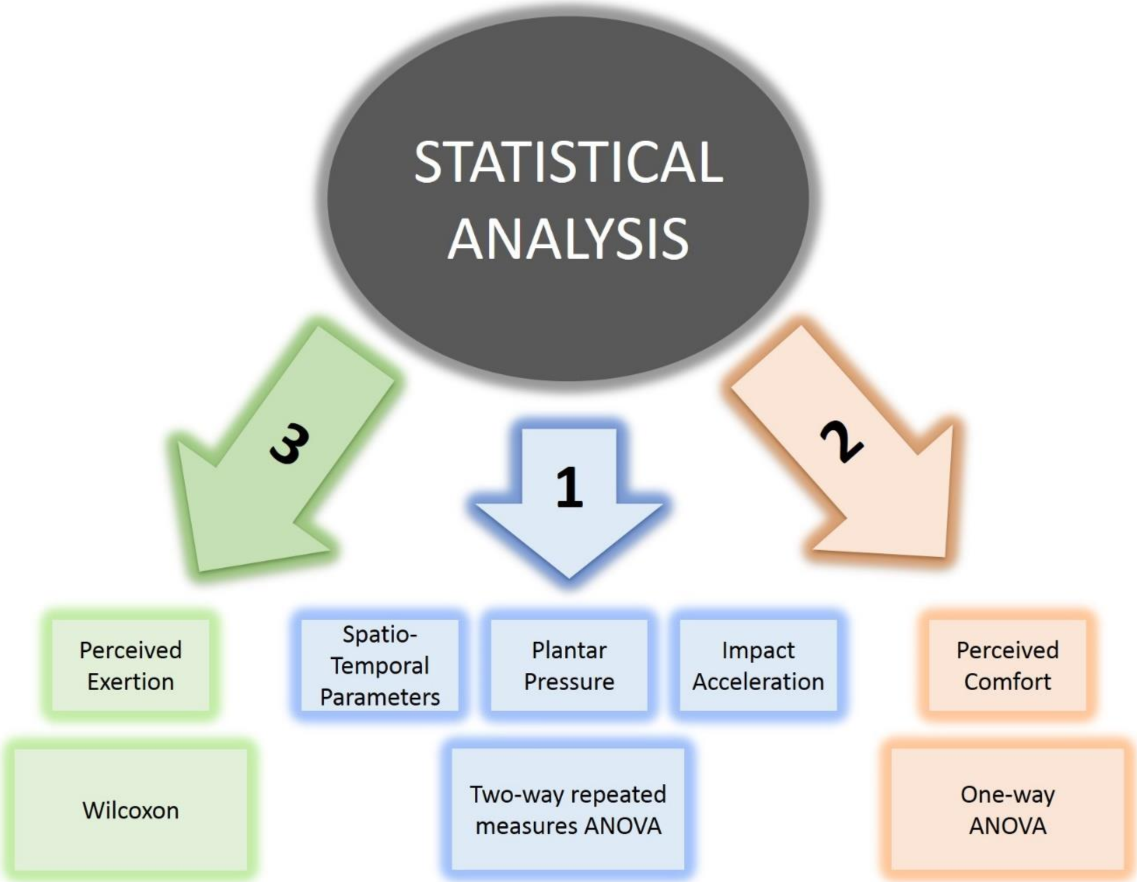


Figure 63. Summary of the Statistical Analysis

1. Effect of the insoles and the fatigue state on spatio-temporal, plantar pressure and impact acceleration parameters

The normality of the spatio-temporal, plantar pressure and impact acceleration variables was checked using the Kolmogorov-Smirnov test. All variables showed a significance value of $p > 0.05$, what indicated that the data was normally distributed and therefore parametric tests were carried out. Therefore a two-way repeated-measures ANOVA considering the insole condition (with three levels: CMI, PI, CI) and the fatigue state (with two levels: PRE and POST) as intra-subject factors was carried out. The dependent variables of this analysis were (Figure 64):

Stride Rate (steps /minute)	**Stride Length** (m)		**Contact Time** (seconds)
Mean Peak Pressure (kPa)	**Time to Mean Peak Pressure** (%)	**Pressure-Time Integral** (kPa / s)	**Relative Pressure Distribution** (%)
Peak Impact Acceleration (G)	**Acceleration Rate** (G / s)		**Shock Attenuation** (%)

Figure 64. Dependent variables of the study.

In order to test whether the sphericity assumption was violated or not, a Mauchly test was performed. When sphericity was established, the analysis of variance (ANOVA) was performed using a univariate approximation. On the other hand, when sphericity was violated, the most powerful approximation among the following was taken: multivariate approximation or degrees of freedom adjustment (Greenhouse-Geisser, the Huynh-Feldt, and the Lower-bound). Finally, a Bonferroni correction was used as post hoc tests for pairwise comparisons with a significance level set at $\alpha = 0.05$.

2. Effects of the insoles on the perception of comfort

To analyse the difference in the perception of comfort among the three insole conditions, the normality of the distribution with the Kolmogorov-Smirnov test was checked and confirmed ($p > 0.05$). Then, a one-way ANOVA was carried out to analyse the nine comfort items for the three insole conditions (CI vs CMI vs PI). Bonferroni correction was used as post hoc tests for pairwise comparisons with a significance level set at $\alpha = 0.05$.

3. Effect of the insoles on the perception of fatigue

The ratings of perceived exertion did not follow a normal distribution (Kolmogorov-Smirnov test, $p < 0.05$) and therefore a non-parametric analysis with the Wilcoxon test was carried out to compare the perceived fatigue when running with custom-made and prefabricated insoles. Significance level set at $\alpha = 0.05$.

3. RESULTS

3. RESULTS

3.1. Analysis of the Spatio-Temporal Parameters

3.1.1. Effects of the Insoles

The effect of the different insole conditions on the spatio-temporal parameters is presented in Table 30. Although no significant differences were found, PI showed a higher contact time (0.27 seconds) compared to CI and CMI (both 0.26 seconds) (p > 0.05). Similarly, regarding stride rate, CMI slightly decreased stride rate (156 steps · minute^{-1}) compared to CI and PI (157 and 159 steps · minute^{-1}, respectively), although these differences were non-significant (p > 0.05).

Table 30. Effect of the insoles on the spatio-temporal parameters.

Parameter / Condition	CI		CMI		PI		*p* value
	Mean	SE	Mean	SE	Mean	SE	
Contact Time (seconds)	0.26	0.01	0.26	0.01	0.27	0.01	N.S.
Stride Rate (steps/minute)	157.00	3.98	155.96	5.86	158.92	4.04	N.S.

SE: Standard Error; N.S.: non significant.

3.1.2. Effects of the Fatigue

No significant differences were found in the spatio-temporal parameters of the study, and furthermore, no clear trend was observed neither in contact time nor in stride rate since increases and reductions among conditions were observed between the pre and post fatigue tests (p > 0.05) (Table 31).

Table 31. Effect of fatigue and insoles on spatio-temporal parameters.

Parameter / Condition	CI Mean (SE)			CMI Mean (SE)			PI Mean (SE)		
	Pre	Post	*p*	Pre	Post	*p*	Pre	Post	*p*
Contact Time (seconds)	0.24 (0.01)	0.28 (0.01)	N.S.	0.25 (0.01)	0.27 (0.01)	N.S.	0.27 (0.12)	0.26 (0.01)	N.S.
Stride Rate (steps/minute)	163.32 (4.80)	150.68 (6.49)	N.S.	155.09 (7.16)	156.84 (5.84)	N.S.	157.44 (5.64)	160.40 (4.75)	N.S.

SE: Standard Error; N.S.: non significant.

3.2. Analysis of the Plantar Pressure

3.2.1. Effect of the Insoles

During the plantar pressure analysis, four variables were measured: Mean peak pressure, Time to mean peak pressure, Pressure-Time Integral, and Relative Pressure. Regarding mean peak pressure (Figure 65), the greatest pressures were found in the central metatarsal area (higher than 200 kPa) and lateral heel (150-220 kPa). PI showed significant lower pressures in toes, medial arch and lateral arch compared to CI (PI vs CI: 126.15 (22.20) vs 194.22 (21.60) kPa, $p < 0.05$; PI vs CI: 73.80 (10.15) vs 106.27 (12.92) kPa, $p < 0.01$; PI vs CI: 67.49 (8.88) vs 97.90 (10.85) kPa, $p < 0.01$, respectively). On the other hand, CMI provoked a significant decrease in mean peak plantar pressure in the hallux, medial arch and lateral arch compared to CI (CMI vs CI: 91.23 (18.72) vs 165.21 (22.59) kPa, $p < 0.05$; CMI vs CI: 67.74 (10.39) vs 106.27 (12.92) kPa, $p < 0.01$; CMI vs CI: 58.76 (10.26) vs 97.90 (10.85) kPa, $p < 0.01$, respectively). Furthermore, CMI decreased mean peak pressure in the medial heel compared to PI (CMI vs PI: 128.22 (20.38) vs 186.64 (20.47) kPa, $p < 0.05$).

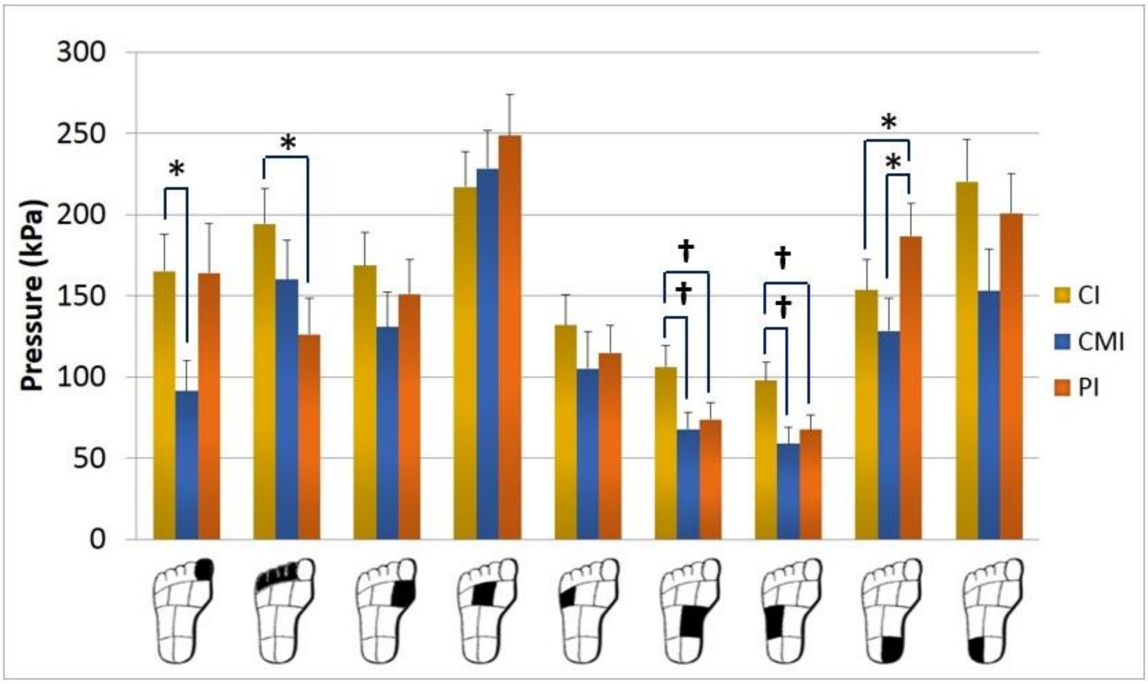


Figure 65. Mean Peak Pressure (mean + standard error) in the three insole conditions. * p < 0.05; † p < 0.01.

The time to mean pressure (expressed as time when the mean peak pressure occurs as a percentage of the whole step) was significantly increased under the lateral metatarsal area by CMI compared to CI (CMI vs CI: 46.44 (1.75) vs 41.51 (1.53) %, p = 0.021) and by both PI and CMI compared to CI under the lateral arch (PI and CMI vs CI: 25.72 (1.92) and 27.48 (2.32) vs 20.81 (1.55) %, p = 0.004 and p = 0.046, respectively) as showed in Table 32.

Table 32. Time to mean peak pressure in the three insole conditions.

Foot Area / Condition	CI		CMI		PI		*p* value
	Mean	**SE**	**Mean**	**SE**	**Mean**	**SE**	
Hallux	56.18	1.93	59.42	2.46	59.20	1.81	N.S.
Toes	49.68	1.81	51.00	2.35	52.64	1.60	N.S.
Medial Metatarsal	50.00	1.42	50.01	1.39	51.05	1.51	N.S.
Central Metatarsal	48.02	1.33	46.84	1.74	48.35	1.56	N.S.
Lateral Metatarsal	41.51	1.53	46.44	1.75	43.90	1.80	$p = 0.021^{a}$
Medial Arch	18.90	1.50	23.58	2.16	22.82	2.03	N.S.
Lateral Arch	20.81	1.55	27.48	2.32	25.72	1.92	$p = 0.046^{a}$ $p = 0.004^{b}$
Medial Heel	18.01	2.85	11.35	1.03	10.85	1.05	N.S.
Lateral Heel	15.64	2.03	15.23	2.35	12.97	1.58	N.S.

SE: Standard Error; N.S.: non significant.
[a] Differences CI vs CMI; [b] Differences CI vs PI; [c] Differences CMI vs PI.

Similarly to mean peak pressure, the highest pressure-time integral value was observed under the central metatarsal (17-20 kPa · s^{-1}) (Figure 66). The analysis of this variable showed that both PI and CMI significantly reduced the pressure-time integral compared to CI condition under the lateral arch (PI and CMI vs CI: 3.41 (0.51) and 2.42 (0.51) vs 5.22 (0.65) kPa · s^{-1}, p < 0.01; respectively). Moreover, CMI also decreased the pressure-time integral under the lateral heel compared to PI (CMI vs PI: 2.70 (0.48) vs 5.79 (0.78) kPa · s^{-1}, p < 0.01) and CI (CMI vs CI: 2.70 (0.48) vs 7.71 (0.67) kPa · s^{-1}, p < 0.01).

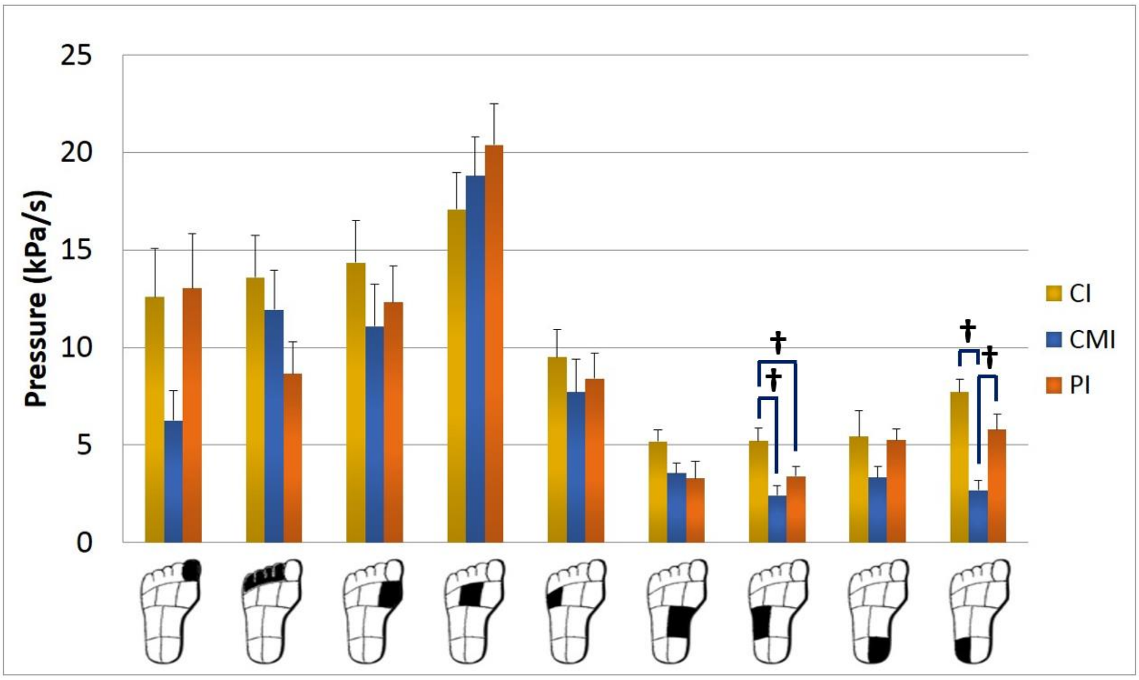


Figure 66. Pressure-time integral (mean + standard error) in the three insole conditions.
*** p < 0.05; † p < 0.01.**

Regarding the relative pressure, PI significantly decreased the pressure under the toes compared to CMI (PI vs CMI: 9.35 (1.37) vs 15.17 (2.19) %, p = 0.021) and under the lateral arch compared to CI (PI vs CI: 5.37 (0.61) vs 7.09 (0.72) %, p = 0.006). On the other hand, CMI reduced the relative load compared to CI under the lateral arch (CMI vs CI: 4.99 (0.60) vs 7.09 (0.72) %, p < 0.001) (Table 33).

Table 33. Relative pressure (%) in the three insole conditions.

Foot Area / Condition	CI		CMI		PI		*p* value
	Mean	SE	Mean	SE	Mean	SE	
Hallux	10.62	1.02	9.08	1.22	10.21	1.26	N.S.
Toes	12.80	1.18	15.17	2.19	9.35	1.37	*p* = 0.021[c]
Medial Metatarsal	11.00	1.21	11.60	1.40	11.01	1.33	N.S.
Central Metatarsal	15.59	1.48	16.34	1.95	19.97	1.88	*p* = 0.001[b]
Lateral Metatarsal	8.15	0.81	8.26	1.13	8.22	1.08	N.S.
Medial Arch	9.11	1.25	7.23	0.96	7.33	1.38	*N.S.*
Lateral Arch	7.09	0.72	4.99	0.60	5.37	0.61	*p* < 0.001[a] *p* = 0.006[b]
Medial Heel	10.60	1.13	12.06	1.81	14.08	1.13	*p* = 0.004[b]
Lateral Heel	15.04	1.64	15.27	1.83	14.46	1.45	N.S.

SE: Standard Error; N.S.: non significant
[a] Differences CI vs CMI.; [b] Differences CI vs PI. ; [c] Differences CMI vs PI.

3.2.2. Effects of the Fatigue

The fatigue state did not influence the mean peak pressure for any of the insole conditions and foot areas (p > 0.05) (Table 34). The highest mean peak pressures were observed under the central metatarsal (194.41 - 258.24 kPa) and lateral heel (141.55 – 217.84 kPa).

Regarding the non-significant trends, the fatigue state reduced the mean peak pressure in the CMI condition under the toes, medial metatarsal, central metatarsal, lateral metatarsal, medial heel and lateral heel, whereas an increase in the mean peak pressure with this insole was observed under the hallux, medial arch and lateral arch. For the PI, a reduction of pressure was observed under the hallux, toes, medial metatarsal, medial arch, medial heel and lateral heel, whereas an increase was observed under the central metatarsal, lateral metatarsal and lateral arch.

Table 34. Effect of the insole conditions and fatigue on mean peak pressure (kPa).

Foot Area / Condition	CI Mean (SE)			CMI Mean (SE)			PI Mean (SE)		
	Pre	**Post**	***p***	**Pre**	**Post**	***p***	**Pre**	**Post**	***p***
Hallux	200.62 (29.26)	129.80 (23.02)	N.S.	90.06 (18.67)	92.41 (20.39)	N.S.	180.49 (37.12)	147.33 (27.68)	N.S.
Toes	213.00 (25.45)	175.44 (25.32)	N.S.	168.73 (28.11)	151.00 (21.61)	N.S.	131.85 (23.16)	120.45 (21.95)	N.S.
Medial Metatarsal	191.84 (22.63)	145.62 (23.63)	N.S.	144.57 (26.03)	116.76 (18.08)	N.S.	151.19 (20.75)	151.08 (22.14)	N.S.
Central Metatarsal	239.33 (25.16)	194.41 (23.97)	N.S.	232.26 (23.31)	224.58 (24.28)	N.S.	238.90 (25.92)	258.24 (28.02)	N.S.
Lateral Metatarsal	147.72 (23.25)	116.20 (18.73)	N.S.	107.68 (22.77)	102.25 (23.45)	N.S.	112.70 (18.49)	116.83 (16.78)	N.S.
Medial Arch	107.74 (15.66)	104.80 (12.99)	N.S.	65.20 (11.05)	70.29 (10.43)	N.S.	76.48 (11.85)	71.13 (9.07)	N.S.
Lateral Arch	99.50 (11.86)	96.30 (13.40)	N.S.	55.86 (9.81)	61.66 (10.98)	N.S.	66.66 (7.82)	68.31 (10.54)	N.S.
Medial Heel	152.80 (19.64)	154.28 (22.92)	N.S.	133.58 (20.80)	122.87 (21.32)	N.S.	189.38 (23.43)	183.90 (20.78)	N.S.
Lateral Heel	222.60 (24.75)	217.84 (35.62)	N.S.	164.41 (25.97)	141.55 (26.04)	N.S.	205.68 (25.06)	195.82 (26.41)	N.S.

SE: Standard Error, N.S.: non significant.

Similarly to mean peak pressure, the fatigue state did not influence any of the pressure-time integral values for any of the insole conditions and foot areas ($p > 0.05$) (Table 35). The highest values were observed under the central metatarsal (16.03 – 21.08 kPa · s^{-1}).

With respect to the trends observed (non-significant), the fatigue reduced the pressure-time integral in the CMI condition under the hallux, toes, medial metatarsal, central metatarsal, lateral metatarsal, medial heel and lateral heel, whereas an increase in this variable was observed under the medial arch and the lateral arch. For the PI, the fatigue led to a non significant reduction of pressure-time integral under the hallux, toes, medial arch and lateral heel, whereas an increase under the medial metatarsal, central metatarsal, lateral metatarsal and lateral arch was observed as a result of the fatigue.

Table 35. Effect of the insole conditions and fatigue on pressure-time integral (kPa · s^{-1}).

Foot Area / Condition	CI Mean (SE)			CMI Mean (SE)			PI Mean (SE)		
	Pre	Post	*p*	Pre	Post	*p*	Pre	Post	*p*
Hallux	15.01 (3.12)	10.18 (2.52)	N.S.	6.49 (1.60)	6.03 (1.57)	N.S.	14.61 (3.30)	11.48 (2.69)	N.S.
Toes	14.20 (2.78)	12.97 (2.21)	N.S.	12.48 (2.35)	11.39 (1.80)	N.S.	8.99 (1.67)	8.33 (4.89)	N.S.
Medial Metatarsal	15.43 (2.17)	13.28 (2.62)	N.S.	12.47 (2.68)	9.71 (1.70)	N.S.	12.14 (1.80)	12.50 (2.18)	N.S.
Central Metatarsal	18.14 (2.06)	16.03 (2.12)	N.S.	18.93 (2.05)	18.65 (2.09)	N.S.	19.67 (2.19)	21.08 (2.38)	N.S.
Lateral Metatarsal	10.04 (1.65)	8.97 (1.45)	N.S.	8.02 (1.71)	7.41 (1.71)	N.S.	8.18 (1.42)	8.63 (1.24)	N.S.
Medial Arch	5.09 (0.82)	5.30 (0.63)	N.S.	3.40 (0.58)	3.71 (0.56)	N.S.	4.12 (0.61)	2.44 (1.50)	N.S.
Lateral Arch	4.59 (0.49)	5.85 (0.95)	N.S.	2.26 (0.56)	2.57 (0.51)	N.S.	3.24 (0.40)	3.58 (0.66)	N.S.
Medial Heel	3.75 (0.53)	7.13 (2.42)	N.S.	3.55 (0.58)	3.13 (0.62)	N.S.	5.25 (0.69)	5.25 (0.57)	N.S.
Lateral Heel	6.29 (1.76)	9.13 (4.22)	N.S.	3.10 (0.54)	2.29 (0.49)	N.S.	6.42 (1.20)	5.16 (0.72)	N.S.

SE: Standard Error, N.S.: non significant.

The fatigue state did not affect the time to mean peak pressure for any of the insole conditions and foot areas either ($p > 0.05$) (Table 36).

Regarding the non-significant trends, the time to the peak pressure for the CMI condition was observed to decrease in the hallux, medial metatarsal, central metatarsal and medial arch; and increase in the toes, lateral metatarsal, lateral arch, medial heel and lateral heel. For the PI condition, the fatigue provoked a non-significant reduction of the time to mean peak pressure in the lateral metatarsal, medial heel and lateral heel, whereas the fatigued provoked an increase of this variable in the central metatarsal, medial arch and lateral arch.

Table 36. Effect of the insole conditions and fatigue on the time to mean peak pressure (%).

Foot Area / Condition	CI Mean (SE)			CMI Mean (SE)			PI Mean (SE)		
	Pre	Post	*p*	Pre	Post	*p*	Pre	Post	*p*
Hallux	56.45 (2.53)	55.91 (2.02)	N.S.	61.75 (3.16)	57.08 (2.63)	N.S.	59.20 (2.06)	59.20 (2.25)	N.S.
Toes	51.93 (2.59)	47.44 (2.43)	N.S.	49.43 (2.38)	52.56 (2.85)	N.S.	52.61 (1.91)	52.67 (2.05)	N.S.
Medial Metatarsal	51.59 (1.87)	48.42 (1.83)	N.S.	50.59 (1.54)	49.43 (1.78)	N.S.	51.00 (1.65)	51.09 (1.81)	N.S.
Central Metatarsal	48.37 (1.35)	47.68 (1.81)	N.S.	46.89 (1.72)	46.79 (1.97)	N.S.	47.90 (1.61)	48.80 (1.91)	N.S.
Lateral Metatarsal	41.79 (2.04)	41.22 (2.03)	N.S.	44.73 (1.92)	48.15 (2.04)	N.S.	44.04 (2.47)	43.76 (1.58)	N.S.
Medial Arch	20.13 (2.55)	17.67 (1.42)	N.S.	24.73 (2.85)	22.43 (2.07)	N.S.	22.31 (1.87)	23.32 (2.42)	N.S.
Lateral Arch	20.13 (2.13)	21.49 (2.29)	N.S.	26.42 (2.65)	28.54 (2.80)	N.S.	24.85 (2.00)	26.59 (2.16)	N.S.
Medial Heel	16.04 (3.00)	19.99 (3.89)	N.S.	10.88 (1.16)	11.83 (1.44)	N.S.	11.78 (1.92)	9.93 (0.59)	N.S.
Lateral Heel	13.54 (2.18)	17.74 (2.75)	N.S.	14.52 (2.08)	15.94 (3.38)	N.S.	14.92 (2.71)	11.01 (0.83)	N.S.

SE: Standard Error, N.S.: non significant.

Finally, similar to the previously described plantar pressure parameters, the fatigue did not affect the relative pressure for any of the insole conditions and foot areas analysed ($p > 0.05$) (Table 37).

With respect to the non-significant trends, while using the CMI, the fatigue provoked a reduction of the relative pressure in the toes, medial metatarsal, medial heel and lateral heel; and an increase in the hallux, central metatarsal, lateral metatarsal, medial arch and lateral arch. Regarding the PI, the fatigue led to a reduction of relative pressure in the hallux, toes, medial metatarsal, medial heel and lateral heel; and an increase in the central metatarsal, lateral metatarsal, medial arch and lateral arch.

Table 37. Effect of the insole conditions and fatigue on relative pressure (%).

Foot Area / Condition	CI Mean (SE)			CMI Mean (SE)			PI Mean (SE)		
	Pre	**Post**	***p***	**Pre**	**Post**	***p***	**Pre**	**Post**	***p***
Hallux	12.09 (1.45)	9.15 (1.27)	N.S.	8.62 (1.11)	9.54 (1.44)	N.S.	10.80 (1.60)	9.62 (1.17)	N.S.
Toes	13.47 (1.47)	12.13 (1.19)	N.S.	15.45 (2.46)	14.89 (2.03)	N.S.	9.53 (1.45)	9.16 (1.27)	N.S.
Medial Metatarsal	11.91 (1.34)	10.08 (1.32)	N.S.	12.51 (1.55)	10.69 (1.28)	N.S.	11.12 (1.36)	10.90 (1.34)	N.S.
Central Metatarsal	14.99 (1.39)	16.20 (1.88)	N.S.	15.62 (2.06)	17.06 (2.09)	N.S.	19.12 (2.04)	20.81 (1.94)	N.S.
Lateral Metatarsal	8.68 (1.10)	7.63 (0.81)	N.S.	8.08 (1.09)	8.44 (1.21)	N.S.	8.08 (1.21)	8.37 (1.00)	N.S.
Medial Arch	7.69 (1.15)	10.53 (1.71)	N.S.	6.95 (0.98)	7.51 (1.03)	N.S.	7.26 (1.47)	7.40 (1.38)	N.S.
Lateral Arch	6.55 (0.78)	7.62 (0.90)	N.S.	4.53 (0.51)	5.46 (0.72)	N.S.	5.18 (0.53)	5.57 (0.79)	N.S.
Medial Heel	10.05 (1.25)	11.15 (1.36)	N.S.	12.40 (1.81)	11.71 (2.02)	N.S.	14.11 (1.39)	14.05 (0.98)	N.S.
Lateral Heel	14.58 (1.67)	15.50 (1.89)	N.S.	15.84 (1.81)	14.70 (2.00)	N.S.	14.80 (1.48)	14.12 (1.60)	N.S.

SE: Standard Error, N.S.: non significant.

3.3. Analysis of the Impact Acceleration

3.3.1. Effect of the Insoles

With respect to peak acceleration, the acceleration value measured at the tibia was significantly different to the value observed at the head, as expected. However, when looking at the values within the same location (tibial peak acceleration with the different insoles and head peak acceleration with the different insoles), no differences in peak impact acceleration were observed between the insole conditions ($p > 0.05$) (Figure 67).

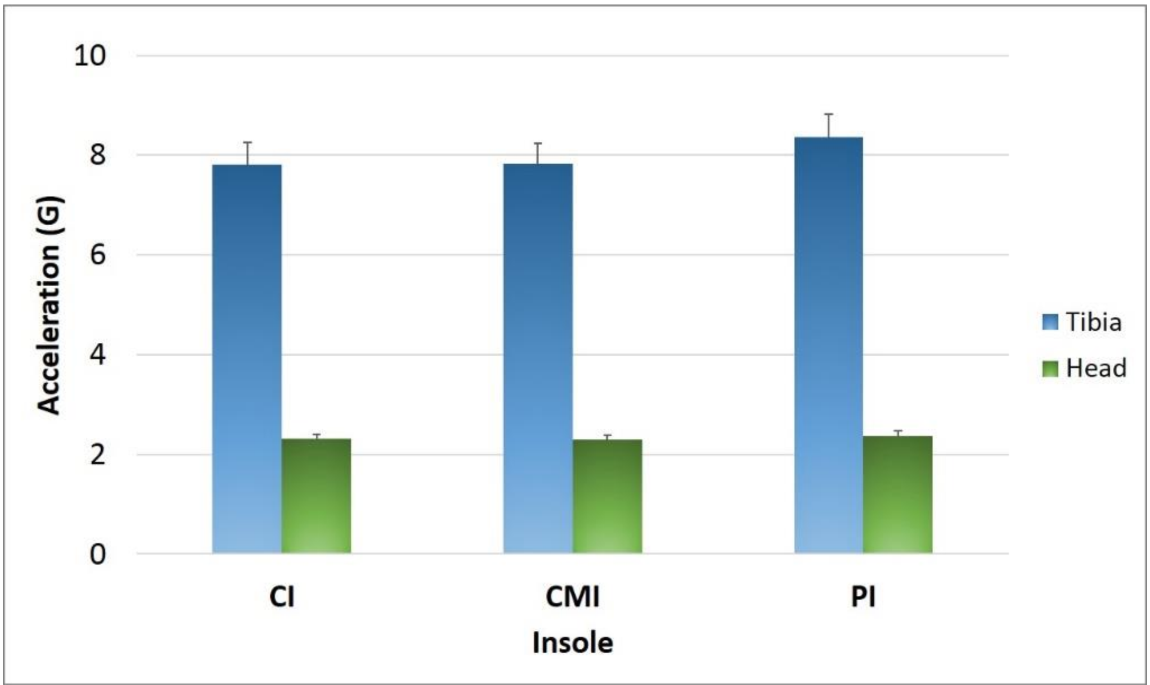


Figure 67. Peak acceleration (mean + standard error) in the three insole conditions.

With respect to the acceleration rate (ratio between the peak acceleration and the time from ground contact to reach the peak acceleration), the head acceleration rate observed when running with CMI was significantly lower compared to the one observed with CI (CMI vs CI: 51.73 (3.43) vs 53.20 (3.17) G· s^{-1}, $p = 0.04$) and with PI (CMI vs PI: 51.73 (3.43) vs 58.32 (4.14) G · s^{-1}, $p = 0.015$) (Figure 68). Moreover, a greater tibial acceleration rate was observed when running with PI compared to CI and CMI (PI vs CI: 330.02 (42.06) vs 264.66 (33.12) G · s^{-1}, $p = 0.027$; PI vs CMI: 330.02 (42.06) vs 261.05 (38.02) G · s^{-1}, $p = 0.036$) (Figure 69).

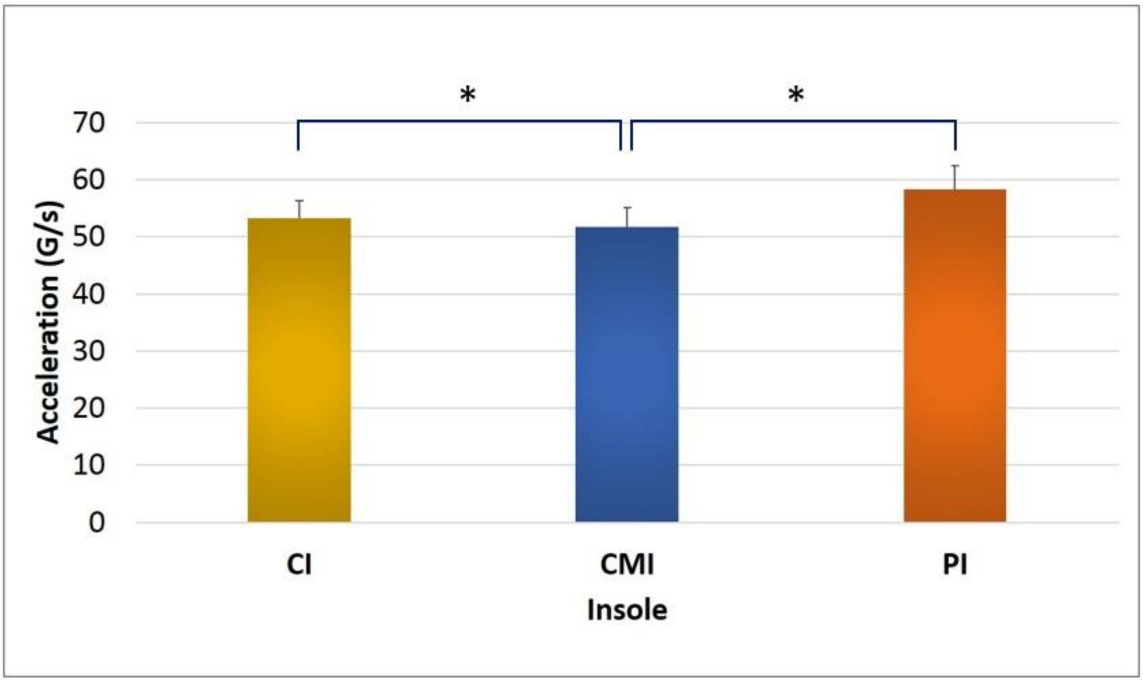


Figure 68. Head acceleration rate (mean + standard error) in the three insole conditions. * $p < 0.05$.

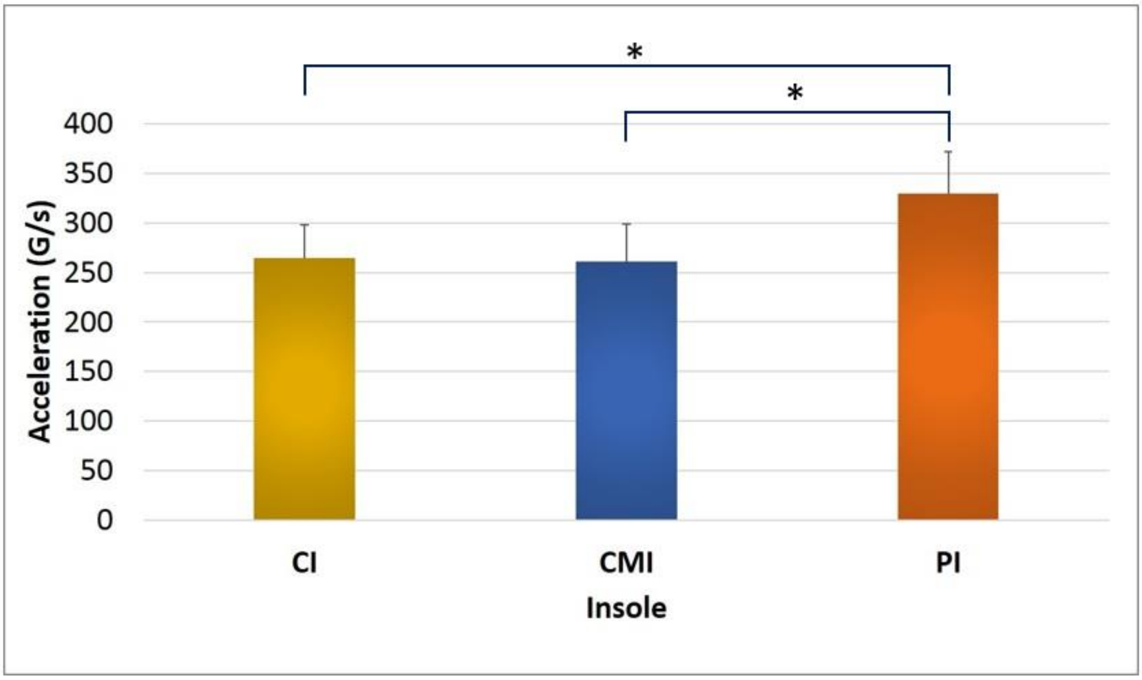


Figure 69. Tibial acceleration rate (mean + standard error) in the three insole conditions. * $p < 0.05$.

Finally, the analysis of the shock attenuation (difference between the acceleration measured at the tibia and the head) resulted in similar values independent of the insole condition ($p > 0.05$) (Figure 70).

However, although non-significant, a lower shock attenuation was observed with CMI compared to CI and PI (CMI vs CI and PI: 65.31 (3.03) vs 66.62 (2.05) and 68.96 (1.85) %, $p > 0.05$).

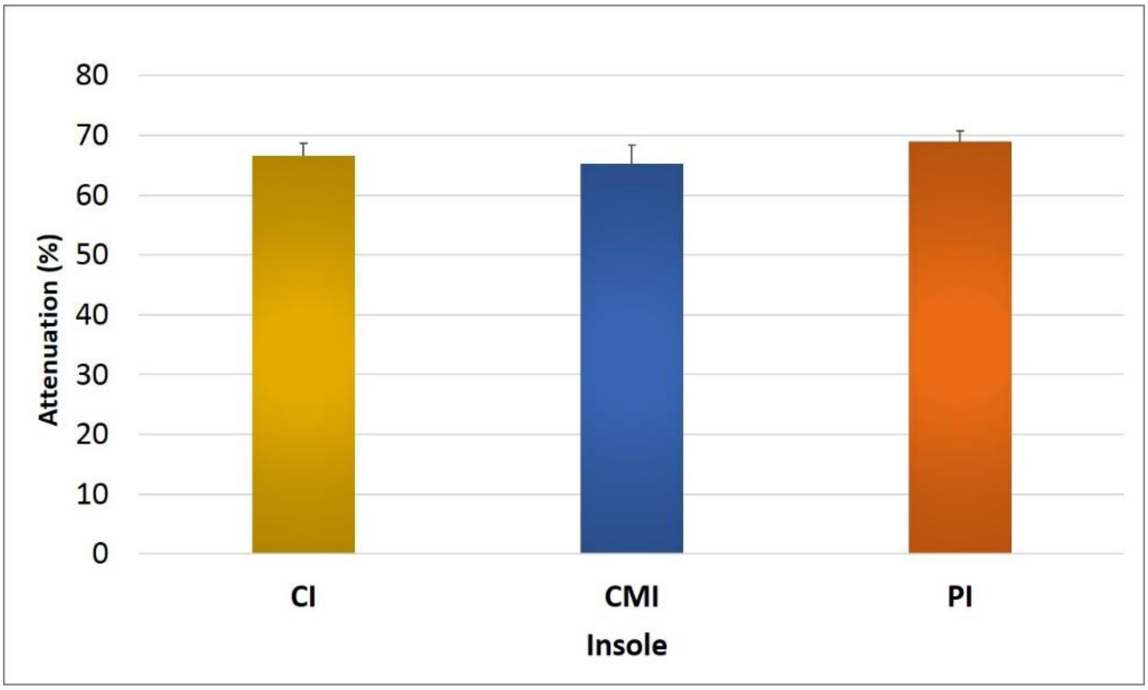


Figure 70. Shock attenuation (mean + standard error) in the three insole conditions.

3.3.2. Effect of the Fatigue

The fatigue state did not influence any of the impact acceleration parameters for any of the insole conditions ($p > 0.05$) (Table 38).

With respect to the non-significant trends, the fatigue provoked the same trend of change for both the CMI and PI. In this sense, the fatigue state led to a reduction of the head peak acceleration and head acceleration rate; and to an increase of the tibial peak acceleration, tibial acceleration rate and attenuation.

Table 38. Effect of the insole conditions and fatigue on the impact acceleration variables.

Variable	CI Mean (SE)			CMI Mean (SE)			PI Mean (SE)		
	Pre	Post	*p*	Pre	Post	*p*	Pre	Post	*p*
Peak Tibia (G)	7.89 (0.44)	7.75 (0.50)	N.S.	7.69 (0.37)	7.96 (0.51)	N.S.	8.13 (0.48)	8.59 (0.51)	N.S.
Peak Head (G)	2.37 (0.08)	2.25 (0.12)	N.S.	2.31 (0.09)	2.27 (0.10)	N.S.	2.38 (0.11)	2.34 (0.14)	N.S.
Rate Tibia ($G \cdot s^{-1}$)	272.28 (35.16)	257.03 (34.84)	N.S.	234.61 (29.99)	257.50 (49.05)	N.S.	319.99 (40.76)	340.06 (50.35)	N.S.
Rate Head ($G \cdot s^{-1}$)	55.05 (2.99)	51.34 (3.67)	N.S.	51.98 (3.46)	51.47 (3.64)	N.S.	58.33 (3.89)	58.31 (4.70)	N.S.
Attenuation (%)	66.43 (1.92)	66.82 (2.51)	N.S.	65.78 (2.68)	65.85 (4.58)	N.S.	67.37 (2.18)	70.55 (1.80)	N.S.

SE: Standard Error; N.S.: non significant.

3.4. Analysis of the Perception of Comfort

A visual analogue scale (VAS) including up to nine items relating to the perception of comfort when running with the different insoles was also provided to the participants. Interestingly, most of the comfort items (overall comfort, heel and forefoot cushioning, medio-lateral control, arch height and heel cup fit) were perceived significantly more comfortable when running with CMI and PI compared to CI (Figure 71). Moreover, greater comfort of "Shoe forefoot width" was also perceived only with PI compared to CI (PI vs CI: 9.49 (0.42) vs 7.85 (0.36), p = 0.028).

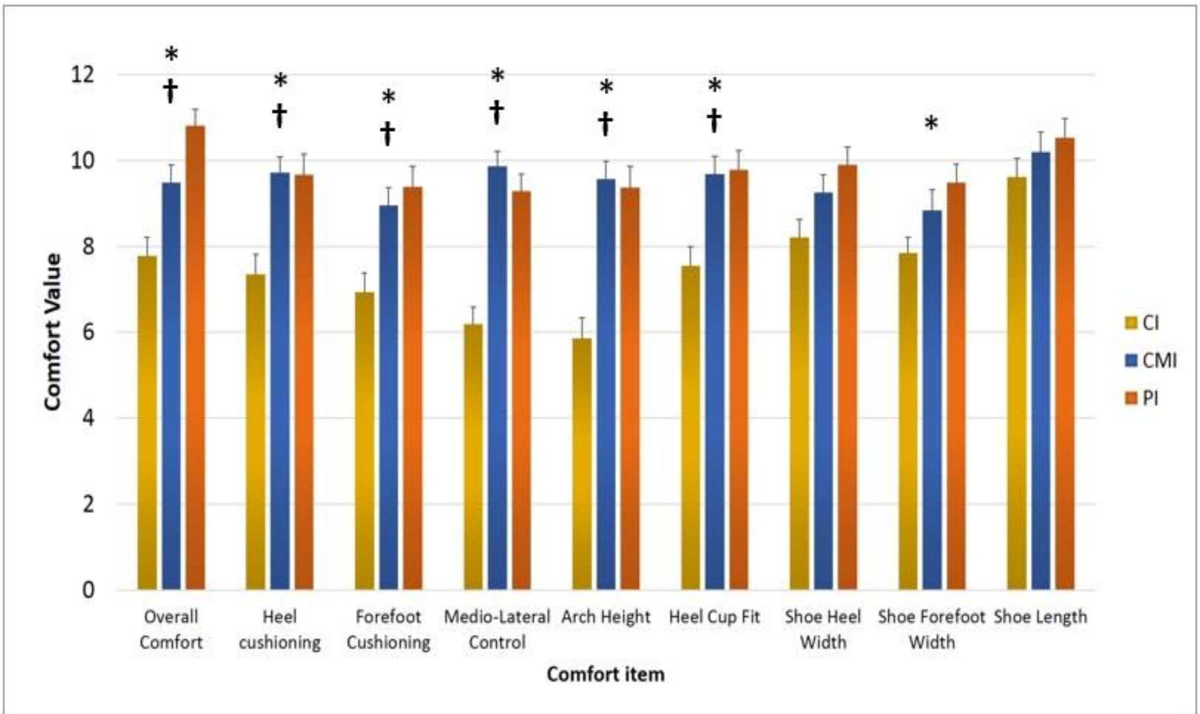


Figure 71. Perception of comfort (mean + standard error) reported with each insole condition.
*** Significant difference PI vs CI (p < 0.05).**
† Significant difference CMI vs CI (p < 0.05).

3.5. Analysis of the Perception of Fatigue

A rating of perceived exertion scale (6-20 Borg scale) was showed to the participants during the last minute of the fatiguing run in order to know how extenuating the fatigue run had been. In the present study, the use of insoles (CMI and PI) did not provoke any difference in the perception of exertion after the fatigue run (CMI vs PI: 14.2 (1.6) vs 14.0 (1.4), p = 0.851) (Figure 72).

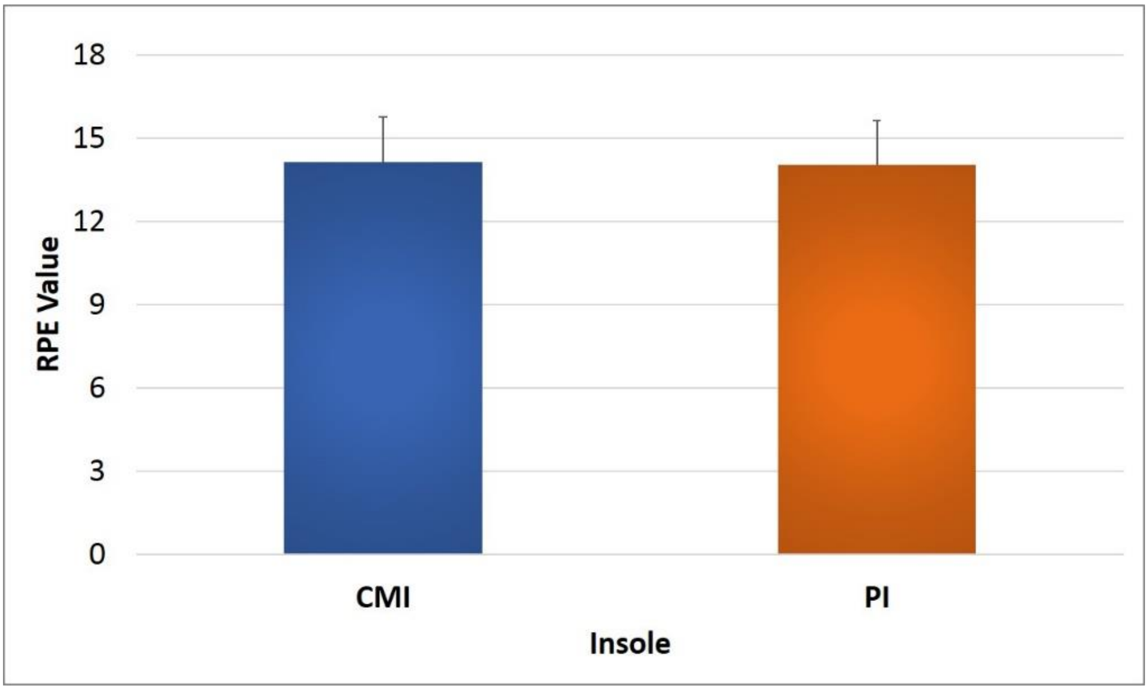


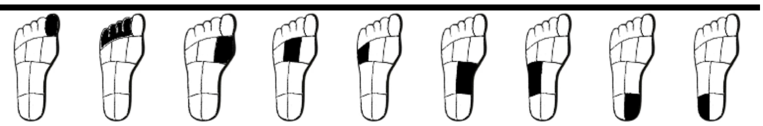
Figure 72. Ratings of perceived exertion (mean + standard error) in each insole condition.

All in all, the results of the study can be summarised as follows:

Table 39. Summary of the spatio-temporal parameters results.

		Custom VS Control	Prefabricated VS Control	Custom VS Prefabricated
S –T PARAMETERS	Contact Time	No difference		
	Stride Rate	No difference		
	Stride Length	No difference		

Table 40. Summary of the plantar pressure results.

Insole comparison / Foot Area										
 Custom VS Control	P_{max}	↓					↓	↓		
	Time to P_{max}					↑		↑		
	Integral							↓		
	$P_{relative}$						↓	↓		
 Prefabricated VS Control	P_{max}		↓				↓	↓	↑	
	Time to P_{max}							↑		
	Integral				↑			↓		
	$P_{relative}$				↑			↓	↑	
 Custom VS Prefabricated	P_{max}								↓	
	Time to P_{max}									↓
	Integral									↓
	$P_{relative}$		↑							

Pmax: Peak plantar pressure; Prelative: Relative Pressure.
Arrows show a significant increment or reduction.

Table 41. Summary of the impact acceleration results.

		Custom vs Control	Prefabricated vs Control	Custom vs Prefabricated
IMPACT ACCELERATION	Accmax Tibia	No difference		
	Accmax Head	No difference		
	Rate Tibia		↑	↓
	Rate Head	↓		↓
	Attenuation	No difference		
COMFORT	Overall Comfort	↑	↑	
	Heel cushioning	↑	↑	
	Forefoot Cushioning	↑	↑	
	Med-Lat Control	↑	↑	
	Arch Height	↑	↑	
	Heel cup fit	↑	↑	
	Heel width	No difference		
	Forefoot width		↑	
	Length	No difference		
RPE	Fatigue	No difference		

Accmax: Peak acceleration, Rate: Acceleration rate, Med-Lat Control: Control Medio-lateral, Length: Shoe length, RPE: Rating of perceived exertion.
Arrows show a significant increment or reduction.

4. DISCUSSION

4. DISCUSSION

Running is a worldwide known type of physical activity with an impressive increasing trend of participants. No matter the age, gender or social status, running is a simple and inexpensive activity associated with plenty of health benefits and available to a great range of the population (Chodzko-Zajko et al., 2009; Garber et al., 2011; Guo et al., 2006; Ho et al., 2010; Oja et al., 2015). However, as a physical activity where the different biological structures and systems are put to work, it involves an inherent risk of damaging the different body tissues depending on the amount and characteristics of the activity being performed. As a result, different areas of study involving not only sport medicine and sport coaching, but also sportswear, footwear, sport materials and surface manufacturing companies, are gathering interest in order to develop new strategies around this popular activity (Fields et al., 2010; Hamstra-Wright et al., 2014; Tessutti et al., 2010; van der Worp et al., 2015).

Among these entities, the footwear industry is making special efforts regarding how to positively influence running via different strategies such as enhancement of running performance and prevention and treatment of injuries associated with running. Whereas the enhancement of running performance through footwear intervention has not been fully addressed and therefore there are still no clear results (Barton, Menz, & Crossley, 2011), the role that footwear and insoles plays on running injury occurrence has been widely studied (Even-Tzur et al., 2006; Fields et al., 2010; Hirchsmuller et al., 2011; Hreljac, 2005; Johnston et al., 2003; Pérez-Soriano et al., 2011; Razeghi & Batt, 2000; Shorten, 2000; Snyder et al., 2009; Werd & Knight, 2010; Zadpoor & Nikooyan, 2010; Zadpoor, Nikooyan, & Arshi, 2007). There is plenty of evidence stating that high impact forces and overloading of the different lower extremity structures lead to increased overuse injury rate, specially patellofemoral pain syndrome, stress fractures, medial tibial stress (shin splints), patellar tendinitis, plantar fasciitis, metatarsalgia and Achilles tendinitis (Hreljac, 2005; Nielsen et al., 2014b; Queen et al., 2010; Ribeiro et al., 2011; Snyder, De Angelis, Koester, Spindler, & Dunn, 2009; Taunton et al., 2002; Van Ginckel et al., 2009; Willson & Kernozek, 1999). Hence, innovative running shoe structures and new midsole materials aiming to provide better shock-absorption and pressure redistribution have been analysed amply with unclear results due to the variability in the runner's foot type and the negative of the footwear companies to build an individually-adapted running shoe for each person (Alcántara, Solaz, & González, 2001; Dixon, 2008; Healy et al., 2012; Kersting & Bruggermann, 2006; Mundermann, Nigg, Stefanyshyn, & Humble, 2002; Nigg et al., 2003; Ogon, Aleksiev, Spratt, Pope, & Saltzman, 2001; Whittle, 1996).

As a result, instead of adapting the whole shoe for each individual, the idea of a neutral running shoe complemented with an orthotic support specifically aimed to improve the deficient pattern of specific foot areas of the runner is increasingly gaining acceptance among specialists. It has been observed that the use of insoles is able to reduce impact forces and positively redistribute plantar pressure during both walking and running (Dixon et al., 2007, 2003; Fields et al., 2010; Hirschmuller 2011; Lee et al., 2012; Pérez-Soriano et al., 2011; Razeghi & Batt, 2000; Shorten, 2000; Verdejo & Mills, 2004; Wegener et al., 2008; Werd & Knight, 2010; Withnall et al., 2006; Yung-Hui & Wei-Hsien, 2005). However, there is a recent controversial matter involving the commercial distribution of prefabricated insoles in a wide variety of stores where the runner can select an insole commercialised as a "running-specific insole" from the shelves of the shop based solely on their foot size, and their effectiveness in preventing and treating running-related injuries and enhancing running performance remains unclear (Goske et al., 2006; Landorf & Keenan, 2000; Paton, Bruce, Jones, & Stenhouse, 2011; Redmond et al., 2000; Werd & Knight, 2010).

Therefore, there is a need to investigate whether there are significant differences in the effect of custom-made and prefabricated insoles on running biomechanics in order to provide further knowledge to support or reject the notion that custom-made insoles adjust better to the athletes' feet and therefore they are more effective in protecting the musculoskeletal system during running.

The present study has aimed to look for these differences by analysing the effect of different insoles and the fatigue state on spatio-temporal, plantar pressure, impact acceleration, comfort and fatigue parameters during running (Figure 73).

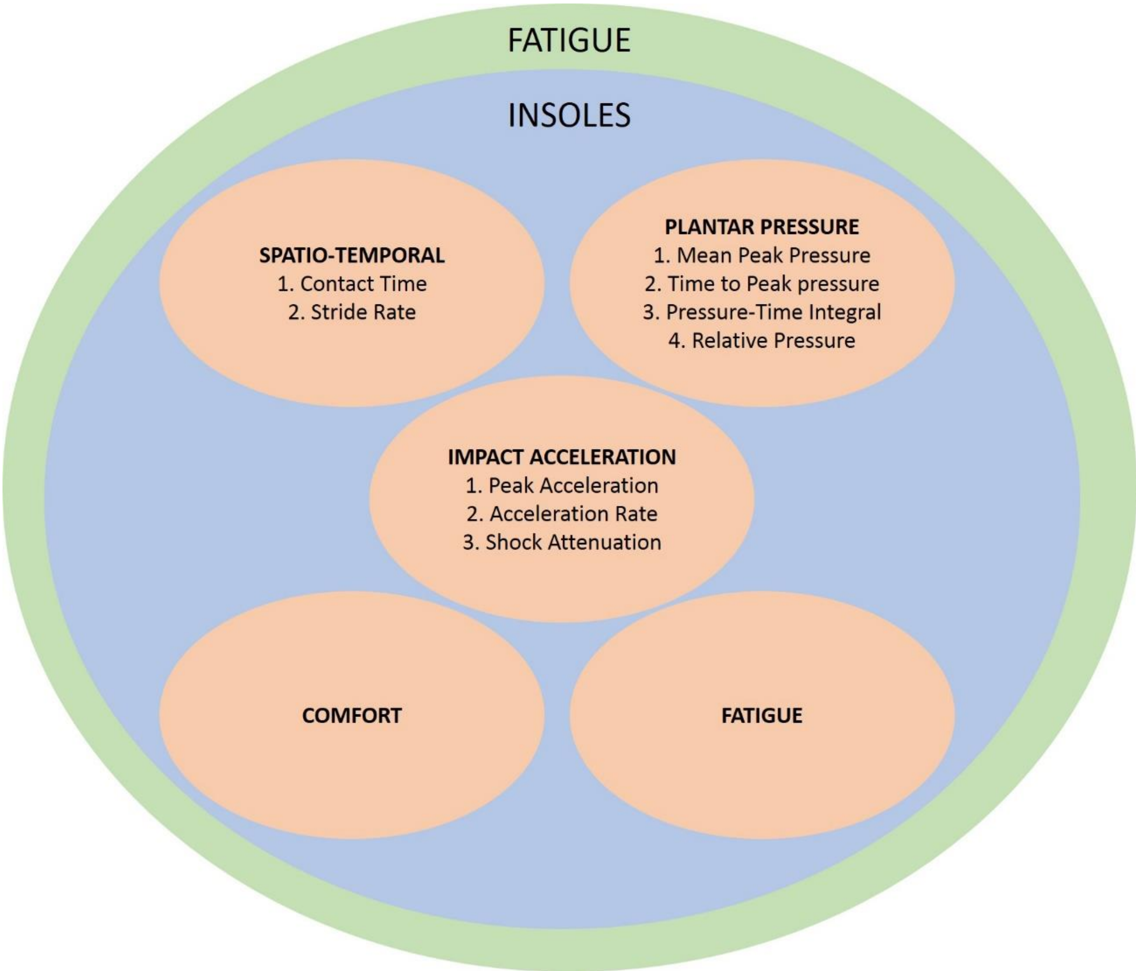


Figure 73. ***Study Design.***

4.1. Analysis of Spatio-Temporal Parameters

The spatio-temporal parameters analysed in this study were the contact time and the stride rate. It has been observed that each athlete selects an optimal and individual-specific combination of stride rate – stride length and a natural instinctive pattern of contact time (which is when the braking and the propulsive forces inherent to running are generated) that minimise their metabolic cost of running (Cavanagh & Williams, 1982; Hamill et al., 1995; Hunter & Smith, 2007). It has been observed that alterations in these parameters could result in increased metabolic cost or poorer economy (Hunter & Smith, 2007; Vernillo et al., 2015). Therefore, it is of great importance to take into account and analyse these parameters since they are good indicators of the musculoskeletal and neuromuscular responses of an athlete to an external intervention such as the use of insoles and the appearance of the fatigue state during running.

4.1.1. Effect of the Insoles

The values of **contact time** observed in this study are very similar to those presented in other studies (Alfuth & Rosenbaum, 2011; García-Pérez et al., 2013) for the same motion (running) and specially for the same velocity of study (3.33 m $\cdot$ s^{-1}), since contact time is strongly affected by speed. As a consequence, greater contact time will produce a slower running gait and, in the same way, lower contact time will result in greater running speed (Bushnell & Hunter, 2007; Chapman et al., 2012; Morin et al., 2012). As to this relationship, Weist et al. (2004) and Leskinen, Häkkinen, Virmavirta, Isolehto, & Kiröläinen (2009) observed lower contact times when analysing stride and plantar pressure parameters during running at faster velocities (3.89 m $\cdot$ s^{-1} and 6.40 m $\cdot$ s^{-1}, respectively), strengthening the aforementioned statement.

Other authors also observed lower contact times even though the athletes in their study ran at the same speed of the current study (Queen et al., 2009b; Ribeiro et al., 2011). However, they measured the contact time in the different foot zones instead of the whole foot, thereby it is reasonable and expected that the whole foot will contact the ground longer that each different foot zone independently.

The second spatio-temporal variable analysed was the **stride rate**, which is the number of strides per minute and is directly related to stride length, being both two the main basic spatio-temporal parameters that influence the metabolic cost of running (Castro et al., 2013; Connick & Li, 2014; Hunter & Smith, 2007; Mercer et al., 2008). The stride rate measured in this study was slightly lower than the one observed by Paroczai & Kocsis (2006) running at 2.95 $m \cdot s^{-1}$, García-Pérez et al. (2013) running at 3.33 $m \cdot s^{-1}$ and Riley et al. (2008) running at 3.80 $m \cdot s^{-1}$. Differences in stride rate are compensated by modifying stride length, and therefore the participants in the present study tended to show a greater stride length compared to the aforementioned studies.

In the present study, neither the custom-made nor the prefabricated insoles modified the stride rate compared to running without insoles. Even though there is a scarcity of studies analysing the influence of an insole intervention in healthy adults during running, the results observed in the present study are in agreement with previous studies that analysed the effect of insoles on the walking gait, where no effect of the insole intervention on the spatio-temporal parameters was observed either (Chen, Lou, Huang, & Su, 2010; Creaby et al., 2011; Haight, Russell Esposito, & Wilken, 2015; Kalron, Pasitselsky, Greenberg-Abrahami, & Achiron, 2015). In this sense, different authors have suggested that runners instinctively adopt an optimal combination of stride rate and length (which minimises the metabolic cost of running) and increases or reductions of any of these two parameters will result in a greater metabolic cost or poorer running economy (Hunter & Smith, 2007; Vernillo et al., 2015). As a result, it is probable that the athletes in the present study tried to maintain their natural (and highly likely “optimal”) stride rate despite the new situation (insoles inside their running shoes) in order not to alter their instinctive running pattern.

All in all, the results of this study imply that the intervention with insoles may be able to modify other biomechanical parameters (plantar pressure, impact acceleration, comfort) without altering the individual running pattern. This would allow athletes to undergo prevention and treatment strategies through orthotic use without suffering any modification in their usual running kinematics parameters.

4.1.2. Effect of the Fatigue

With respect to the interaction of the fatigue state affecting the spatio-temporal variables under the three insole conditions, not only no significant effect of the fatigue state was found but also no clear trend was observed. For CI and CMI, contact time increased after the fatiguing run, whereas exactly the opposite was observed with PI. In general, contact time is believed to increase when the athlete is fatigued because higher contact times have been associated with a decrease in running economy, which is a very typical characteristic of the fatigued condition (Dutto & Smith, 2002; Elliot & Roberts, 1980; Hasegawa, Yamauchi, & Kraemer, 2007; Nummela et al., 2008; Santos-Concejero et al., 2013).

Regarding stride rate, no significant difference was observed between the post-fatigue and pre-fatigue running for any of the insole conditions (control, prefabricated insoles, custom-made insoles). However, the evidence analysing the effect of fatigue on stride rate is unclear. Literature states that running under a fatigued state provokes modifications in the running stride parameters (Hunter & Smith, 2007). Although some studies have found an increased stride rate (Elliott & Roberts, 1980; Place et al., 2004), most studies have found decreases in stride rate when comparing running before and after a fatigue protocol (Candau et al., 1998; Dutto & Smith, 2002; García-Pérez et al, 2013; Gerlach et al., 2005; Hunter & Smith, 2007; Mizrahi, Verbitsky, Isakov, & Daily, 2000; Nummela et al., 2008; Saunders, Pyne, Telford, & Hawley, 2004; Verbitsky et al., 1998). It seems clear that the best running performance at a given speed is at self-selected stride length, and lengthening or shortening it will provoke higher aerobic demands resulting in lower economy and earlier onset of fatigue (Dutto & Smith, 2002; Hunter & Smith, 2007; Santos-Concejero et al., 2013; Saunders et al., 2004).

Therefore, alterations in spatio-temporal parameters seem to be speed-dependent, and the final level of fatigue can also play a major role when analysing these parameters before and after a fatigue protocol. The difference in the results between the present and previous studies may be the type of fatiguing event and the level of fatigue achieved by the runners. In this sense, wheras some studies measured spatio-temporal parameters before and after long-distance event (Vernillo et al., 2015), at the beginning and end of a 5-km run on a track (Nummela et al., 2008) or at the end of an increasing running protocol on a treadmill (Dutto & Smith, 2002), participants in our study carried out a 12-min run below the anaerobic threshold (after having run for 21 minutes taking into account the previous measurements of the session) and the final level of fatigue may have been different. Hence, the type of protocol chosen to reach the fatigue state (short exercise at high intensity versus longer exercises at lower intensity), the level of the participants, the speed of measurement or the running surface may account for the inconsistent results observed in the literature (Dutto & Smith, 2002; Elliott & Roberts, 1980; García-Pérez et al., 2032; Hasegawa et al., 2007; Hunter and Smith, 2007; Nummela et al., 2008; Vernillo et al., 2015; Willson & Kernozek, 1999).

Key Points

- The use of insoles does not affect the spatio-temporal parameters (contact time, stride rate) during running.
- The fatigue state does not influence the spatio-temporal parameters during running independent of the insole condition.

4.2. Analysis of Plantar Pressure

It is important to highlight that the analysis of plantar pressures is gathering an increasing interest within sport physicians, coaches, footwear companies and the very same athletes, who are worried about the fact that the shock wave transmitted through the foot-ground interaction during locomotion is continuously stressing the body structures (bones, muscles, joints). Although the body is prepared to deal with these forces and pressures within a normal range of magnitudes, the accumulative repetition of these stressful events that are produced during running (especially during long-distance events) may provoke local overloading in the foot, which seems to be a relevant risk factor for running injuries (Burnfield et al., 2007; Derrick, 2004; Dixon et al., 2000; Gross et al., 1991; Ho et al., 2010; Jones et al., 1994; Lieberman et al., 2010; McClay & Manal, 1998; Nigg et al., 1987; Reeder et al., 1996; Sharkey et al., 1995; Tessutti et al., 2010; Willson & Kernozek, 1999; Shorten, 2000; van der Worp et al., 2015; Weist et al., 2004). As a consequence, innovative developments in running shoes, sport surface construction and orthotic interventions, among others, are aiming to reduce or prevent the deleterious effects of the repetitive overloading produced during running.

4.2.1. Effect of the Insoles

The **mean peak pressure values** obtained in the current study are similar to those observed in previous studies measuring at similar speed (3.3 m · s^{-1}) ranging from 200 to 350 kPa under the most loaded areas (Alfuth & Rosenbaum, 2011; Chuckpaiwong et al., 2008; Eils et al., 2004; García-Pérez et al., 2013; Queen et al., 2009b; Weist et al., 2004; Wegener et al., 2008; Wiegerinck et al., 2007). Through the analysis of mean peak pressures, it is possible to create a load distribution running pattern based on the highest pressures under each foot area. In the present study, the peak pressure pattern under the foot from the highest to the lowest value when running at 3.3 m · s^{-1} was: Central Metatarsal > Lateral Heel > Toes > Hallux > Medial Heel > Medial Metatarsal > Lateral Metatarsal > Medial Arch > Lateral Arch. This observation is in agreement with other studies where the 1st-3rd metatarsals, the hallux and the heel experienced the greatest pressures and where the arch or midfoot were appointed as the zones with the lowest pressures (Alfuth & Rosenbaum, 2011; Chuckpaiwong et al., 2008; Eils et al., 2004; García-Pérez et al., 2013; Lee et al., 2007; Queen et al., 2009b; Weist et al., 2004; Willson & Kernozek, 1999) (Figure 74).

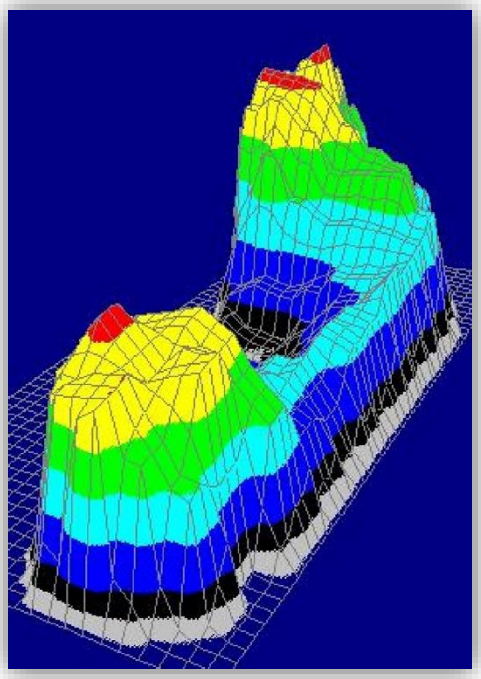


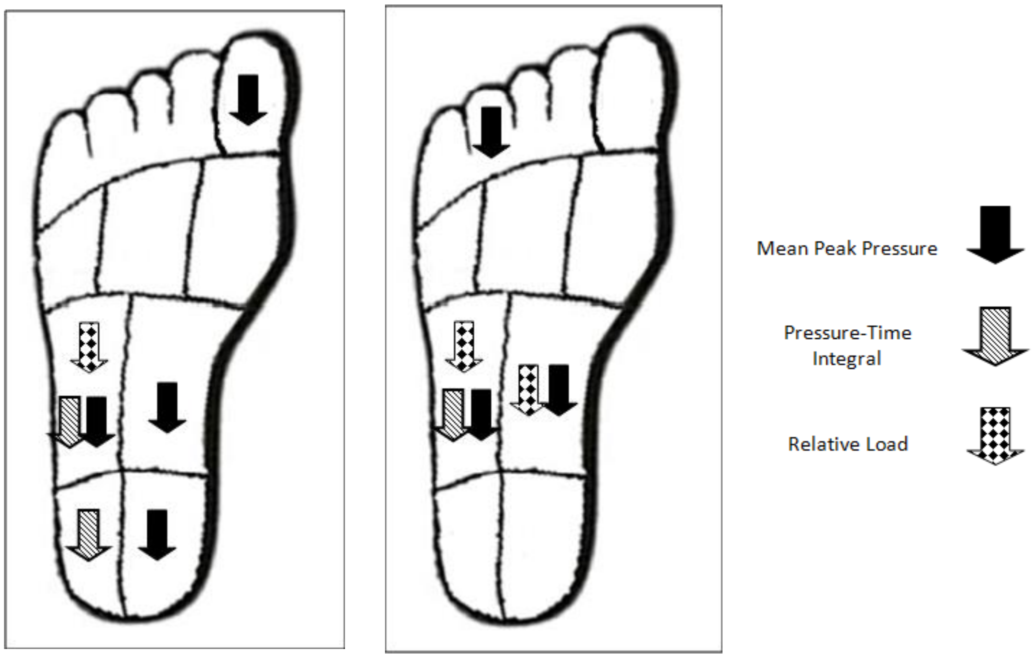
Figure 74. Pressure magnitudes during rearfoot running (Wiegerinck et al., 2009).

Regarding the effect of the different insoles, it is very interesting that CMI decreased mean peak pressure under the hallux by 44.8% and by 44.3% compared to CI and PI, respectively. Previous studies have identified that specific populations such as hallux valgus and hallux rigidus patients or pronated runners experience elevated values of pressure under the hallux (Ledoux & Hillstrom, 2002; Martínez-Nova et al., 2010; Zammit, Menz, Munteanu, & Landorf, 2008). According to Sánchez-Rodríguez et al. (2012), this elevated loading may even "represent a pathological status" and "demonstrate a worse clinical picture". For this reason, taking into account that the hallux is the last part of the foot that contacts the ground before the flying phase of running and due to its relevant role during the push-off phase, relieving almost half of the loading under this zone by using custom-made insoles may imply an important benefit for these specific populations during running (Eils et al., 2004; Martínez-Nova et al., 2010; Sánchez-Rodríguez et al., 2012).

Also, CMI was able to reduce significantly the peak pressure under both the medial arch (36.2%) and lateral arch (40.0%) compared to CI. This finding was seconded by a significant decrease of **pressure-time integral** between both CMI (2.42 kPa · s^{-1}) and PI (3.41 kPa · s^{-1}) compared to CI (5.22 kPa · s^{-1}), resulting in 53.7% and 34.7% reduction of pressure-time integral under the lateral arch, respectively. Since the pressure-time integral describes the cumulative effect of pressure over a measured time in a certain area of the foot, the total load exposure of those areas was lower with CMI and PI compared to CI because the contact time remained the same among conditions (Alfuth & Rosenbaum, 2011; Melai et al., 2011; Putti, Arnold, & Abboud, 2010).

Measuring the pressure-time integral has been appointed as a relevant variable to take into account because it provides information not only about how much load a specific area of the foot is experiencing during a task, but also about how long the force is being applied (Mickle, Munro, Lord, Menz, & Steele, 2011; Queen et al., 2007; Wegener et al., 2008). Burns et al. (2006) found a reduction in pressure-time integral in 154 people with cavus foot using custom-made insoles while walking, which was associated with a 74% decrease in foot pain, whereas Mickle et al. (2011) observed that diabetic patients with claw or hammer toe deformities experienced greater pressure-time integrals than diabetic patients without deformities, thereby highlighting the relevance of this parameter.

The findings of the current study show that both study insoles (CMI, PI) provoked important reductions in loading under the arch (Figure 75), which may imply a better redistribution of pressure over the whole sole for healthy runners during running.



CMI vs CI PI vs CI

Figure 75. Mean peak pressures, Pressure-Time Integral and Relative Pressure differences between conditions.

Interestingly, the custom-made insoles reduced the plantar pressure under the majority of the areas that the centre of pressure follows during the stance phase of running (starting in the heel, moving to the lateral arch, central metatarsal and hallux, Figure 24 in section 1.8.1.1.1, p.62) except for the metatarsal area, where no alteration of the plantar pressure was observed as a result of the insole intervention. These areas of the plantar surface of the foot play a major role during the stance phase because at some point during the motion of the foot they are exposed to a peak of pressure (when the centre of pressure goes over them) and they are therefore the areas at greatest risk of suffering an injury or ulcer resulting from elevated plantar pressures (Bisiaux & Moretto, 2008; Burnfield, Jorde, Augustin, Augustin, & Bashford, 2007; Guldemond et al., 2006; Menz, Lord, & Fitzpatrick, 2003; Pham et al., 2000). Therefore, the reduction of the plantar loading in these areas as a result of the use of insoles may suppose an additional protective mechanism aiding the musculoskeletal system and the footwear to reduce and dissipate elevated plantar loading that could be deleterious for the body.

Attending to the differences between both insole conditions, some remarkable observations should be mentioned. Even though there were not many differences between them (CMI vs PI), CMI were able to decrease mean peak pressure under the hallux compared to CI condition whereas PI did not provoke such reduction. This difference is very important since it has already been explained that the hallux is a critical zone for experiencing overloading. Also, CMI significantly decreased mean peak pressure under the medial heel by 31.3% and pressure-time integral under the lateral heel by 53.5% compared to PI. These results show a pressure pattern indicating that PI provoke greater pressures in the rearfoot compared to CMI, which is the area of the foot that firstly contacts the ground in rearfoot strike runners, who are reported to be the majority of athletes (Alfuth & Rosenbaum 2011; Larson et al., 2011; Laughton et al., 2003; Lieberman et al., 2014). Overloading of this area has been associated with calcaneus spur, plantar heel pain and plantar fasciitis, which is a musculoskeletal disorder that affects 25% of the athletes (Ribeiro et al., 2011). Moreover, as observed in the present study, the rearfoot is an area which experiences a great load during running (García-Pérez et al., 2013; Ribeiro et al., 2011; Willson & Kernozek, 1999) and reducing the amount of load experienced in this area could be a finding of the utmost importance for those runners who show a rearfoot strike pattern.

4.2.2. Effect of the Fatigue

Several studies have suggested that the fatigue state produces a change in the running pattern resulting in a reduction of heel and toes pressure and an increase in forefoot pressure, specifically under the metatarsal heads (Nagel et al., 2008; Rosenbaum et al., 2008; Weist et al., 2004, Willson & Kernozek, 1999). This reduction in heel and toes pressure at the expense of augmented forefoot pressure shows a shift that has been suggested as an increase in local muscle fatigue of the toe flexors, which results in a reduced stabilising and control function of the foot leading to overloading of the metatarsal heads (Nagel et al., 2008; Weist et al., 2004). These authors suggested that the lower involvement of the toes during the push-off phase could be associated with an increased dorsiflexion in the metatarsophalangeal joints, leading to higher pressure values under the metatarsal heads and subsequently to an increased overuse running injury incidence, especially metatarsal stress fractures.

In the current study, a non significant reduction in plantar pressure was found with fatigue. Neither the insoles nor the fatigue seemed to affect the non-fatigued running pattern. These results are in agreement with other studies, where fatigue did not provoke any shift in the plantar pressure distribution during running (Alfuth & Rosenbaum, 2011; García-Pérez et al., 2013; Schlee, Milani, & Hein, 2006). In the current study, participants ran for 12 minutes (after having run 21 minutes taking into account the previous measurements) at a speed close to their individual anaerobic threshold, and therefore it is possible that runners did not reach a fatigue state critical enough to provoke the aforementioned running pattern adaptations (pressure shift from toes to metatarsal head) characteristic of fatigued running.

However, the discrepancy of results between our findings and those observed in previous studies could also be explained by the huge variability among the methodologies used, which may account for the different plantar pressure running patterns obtained among studies (Table 42).

Table 42. Studies analysing plantar pressure distribution after a fatigue run.

	Willson & Kernozek, 1999	Weist et al., 2004	Nagel et al., 2008	Alfuth & Rosenbaum, 2011	García-Pérez et al., 2013
Fatigue Protocol	Ohio State Protocol for graded exercise testing	Running to exhaustion at anaerobic threshold speed	Marathon	10km overground run (20% slower than 10km individual best time)	30min at 85% VAM
Plantar Pressure Analysis Speed	Comfortable speed at rest (later the same for post)	2min after beginning and 2 min before ending	Walking before and after marathon	20% slower than 10km individual best time	At 3.33m/s and 4.00m/s
Plantar pressure Analysis	Shod Running Treadmill	Shod Running Treadmill	Barefoot on plantar pressure platform	Shod Running Treadmill	Shod Running Overground and Treadmill
Population of Study	"Active" Population	Runners and Triathletes	Marathon Runners	Experienced Recreational runners	Recreational runners
Final Fatigue State	Exhaustion	Exhaustion	Within hour of ending marathon	Moderate exhaustion (14.5 Borg Scale)	Exhaustion
Effect of the Fatigue	↓Pmax Heel	↑Pmax Midfoot, M1-M5, H, T2-T5	↑Pmax M2-M5 ↓Pmax H, T2-T5	None	↑Prel MA ↓Pmax LH, H

VAM: Maximal Aerobic Velocity; HR: Heart Rate; Borg Scale: Perceived Exertion test.
Pmax: Peak Pressure; Prel: Relative Pressure.
MA: Medial Arch, LH: Lateral Heel, H: Hallux, M2-5 (2nd-5th metatarsals), T2-T5 (2nd-5th toes).

As it can be observed in Table 42, there were relevant differences in the fatigue protocols (marathon, 10km run, protocol to exhaustion), condition of analysis (barefoot walking, running), participants' training status (active, recreational, experienced runners) and final fatigue state (exhausted, fatigue, up to 1h rest after marathon). As a result, it is very likely that the plantar pressure analyses were carried out under different fatigue states and therefore the results obtained are difficult to be generalised. Therefore, it is essential that future studies define and establish controlled fatigue protocols so that researchers can analyse the plantar pressure behaviour during running under a fatigue state and results can be extrapolated with a higher degree of certainty.

Key Points

- CMI reduce plantar pressure under the hallux, the medial and the lateral arch compared to the control insoles; and under the medial and lateral heel compared to PI.
- PI reduce the plantar pressure under the toes, medial and lateral arch compared to the CI.
- The fatigue state does not influence the plantar pressure in any of the insole conditions.

4.3. Analysis of Impact Acceleration

The analysis of impact acceleration in running is gathering the attention and interest of the running research community due to its potential influence on performance (Derrick, 2004; Derrick et al., 2002; Verbitsky et al., 1998) and injury occurrence (Clinghan et al., 2008; Davis et al., 2004; Hreljac, 2004; Hreljac et al., 2000; Milner et al., 2006). To the author best knowledge, even though a few studies have analysed the effect of cushioned insoles on impact acceleration (Dixon, 2007; Laughton et al., 2003; O'Leary et al., 2008), this is the first study to compare custom-made and prefabricated insoles while analysing in the same study both the effect of an insole intervention and the fatigue state of the runner.

In the next section, the impact acceleration variables most commonly analysed in the literature (e.g. impact peak acceleration, acceleration rate and shock attenuation) will be presented and discussed.

4.3.1. Effect of the Insoles

In the present study it was observed that the use of different insoles (custom-made, prefabricated) partly modified the impact acceleration parameters of recreational runners while running at 3.33 m · s^{-1} on a treadmill. Whereas no difference was observed in the impact peak acceleration, it was indeed observed that the use of insoles affected both the tibial and peak acceleration rate.

Peak impact acceleration is the maximum amplitude of the acceleration signal and is the most common variable analysed in the literature when looking at the severity of the impact during an exercise (Coventry et al., 2006; Derrick, 2004; Duquette & Andrews, 2010b; Encarnación-Martínez et al., 2014; Flynn et al., 2004; García-Pérez et al., 2014; Laughton et al., 2003; Milner et al., 2006; Mizrahi et al., 1997; O'Leary et al., 2008; Olin & Gutierrez, 2013; Voloshin et al., 1998). Taking into account that the external mechanical loading (shock wave) resulting from each foot strike induces internal forces on the natural shock absorbers (soft tissues and bones) in order to attenuate this shock wave (Wee & Voloshin, 2013), even small increases of acceleration at each foot strike may lead to greater risk of injury due to the accumulative effect of the loading stress when maintaining the event over time (Tessutti et al., 2010). In this line of thought, Radin et al. (1982) observed that continuous sub-maximal loading led to degenerative changes in joint structures and cartilage in sheeps during prolonged walking on hard surfaces. Moreover, tibial stress syndrome, spinal injuries and other degenerative changes in joint and articular cartilage in humans have been suggested to occur as a result of the inability of the body to deal with the associated impact accelerations from continuous impacts (McMahon, Valiant, & Frederick, 1987; Mizrahi et al., 1997; Shorten & Winslow, 1992). Finally, recent studies have associated elevated peak acceleration values with an increased risk of suffering tibial stress fractures (Hreljac, 2004; Milner et al., 2006). In one of those studies, Milner et al. (2006) compared the impact peak accelerations of female runners with and without previous tibial stress fractures and provided evidence that suggested a predictive relationship between high tibial acceleration and tibial stress fractures. These studies highlight the importance of analysing impact accelerations during running and encourage future studies to look for strategies that may reduce these accelerations and ultimately decrease the risk of injury.

The use of insoles has been suggested previously as a mechanism to reduce the impact magnitude associated with running, thereby decreasing the risk of injuries (Dixon et al., 2003; Lee, Lin, & Wang, 2012; O'Leary et al., 2008; Windle et al., 1999). However, controversy exists whether a custom-made insole (made directly from a 3D model of the individual's foot) or a prefabricated insole (taken from a store based solely on the individual's foot size) would attenuate impact accelerations during running effectively. In the present study, the use of insoles (either custom-made or prefabricated) did not alter peak impact acceleration during running. This finding indicates that an insole intervention may not provide further protection than the original insoles of the running shoes against injuries associated with elevated accelerations (e.g. stress fractures). This result is in agreement with Laughton et al. (2003), who did not find any difference when comparing a semi-adapted insole condition to a non-insole running condition. On the other hand, O'Leary et al. (2008) did observe that prefabricated cushioned insoles reduced tibial peak acceleration during running, again when compared to a non-insole condition. However, we should be catious since it is unknown whether the insoles used in those studies were specifically designed to be cushioned and if, as a consequence, the motion control characteristics of the insoles (which require a certain amount of hard and stiff materials to support and control the movement) would be compromised in favour of a more shock-absorbing type of insole.

Additionally, it has been suggested that **acceleration rate** is also important in the occurrence of overuse injuries (Milner et al., 2006). Even though impact acceleration has traditionally been the most common acceleration variable analysed in the literature, recent studies are emphasizing the role of loading rate rather than the peak amplitude value as the parameter to take into account when analysing the effects of the resulting shock wave following exercise on the musculoskeletal system (Dixon et al., 2000; Zadpoor & Nikooyan, 2011). These authors stated that repetitive, rapidly applied loads are more associated with joint degeneration than slowly applied loads of equal or even greater magnitude (Radin & Rose, 1975; Radin et al., 1991).

As previously indicated in the introduction ("*Analysis of Impact Acceleration*", section 1.8.1.2), the acceleration rate depends on the peak acceleration and the time to reach that peak acceleration. Since no difference was observed in the tibial and head peak acceleration for any of the comparisons, these results indicate that when a lower acceleration rate was found, the acceleration load needed a longer time to reach it maximal value and it could therefore imply that the musculoskeletal system has more time to attenuate and deal with this loading. It has been speculated that greater acceleration rate could be the consequence of a stiffer pathway along which the impact acceleration travels and could therefore result in a greater risk of injury (Davis et al., 2004; Greenwald et al., 1998; Hansen et al., 2008). Therefore, strategies aiming to reduce acceleration rate may be acting as a protective mechanisms against overuse injuries. In the present study, the custom-made insoles reduced both the tibial and head acceleration rates compared to the prefabricated insoles, what implies that they could be playing a better protective role compared to prefabricated insoles. However, although the custom-made insoles reduced the head acceleration rate compared to the control condition, no difference was observed for the tibial acceleration rate. Consequently, and taking this finding into account together with the absence in differences in peak acceleration also observed between the custom-made and the control condition, the role of insoles as a shock absorbing strategy during running remains unclear. However, if an insole is recommended in order to treat another biomechanical parameter (e.g. plantar pressure, pain, the mechanical function of the foot), these results indicate that a custom-made insole will provide a greater reduction of the acceleration load than prefabricated insoles.

Finally, **shock attenuation** is also considered a very relevant variable when looking at the influence of impact acceleration on the human body during running (Delgado et al., 2013; Mercer et al., 2002; Verbitsky et al., 1998; Voloshin et al., 1998). The shock attenuation ability of the musculoskeletal system is of great relevance because it reduces the magnitude of the impact stress as it goes upwards throughout the body resulting in a decreased acceleration arriving to the head (Abt et al., 2011; Coventry et al., 2006; Delgado et al., 2013; Derrick et al., 1998; García-Pérez et al., 2014; Gruber et al., 2014; Laughton et al., 2003; Lucas-Cuevas et al., 2015; Mercer et al., 2003; Mercer et al., 2002). Previous studies have speculated that reduced values of shock attenuation (as a result of the fatigue, an injury, a running surface) could be dangerous for the musculoskeletal system and thus increase the risk of suffering spinal injuries and joint and cartilage degeneration (Mizrahi et al., 2000).

In this study, no difference in shock attenuation was observed for any of the insole conditions. This result was expected and falls within a rational explanation: since neither the tibial peak acceleration nor the head peak acceleration were influenced by the insole interventions, the athletes' body did not need to change its attenuation to maintain its natural level of acceleration arriving at the head. Strange as it may seem, no study has analysed this parameter while running with insoles. The closest study in this matter was carried out by Dixon et al. (2003), who observed via mechanical test using a drop device that four different types of insoles decreased its impact-absorbing ability after degradation (40,000 impacts) and made a between-insole comparison to see which insole provided the greatest shock-absorption after three weeks of use.

Regrettably, even though their participants used the insoles for three weeks, shock-absorption was measured before and after those three weeks via mechanical tests and it is therefore very difficult to infer their results to a natural running condition where attenuation is measured directly on the athlete's body while using the insoles.

Even though there are two studies that measured impact acceleration while running with insoles (Laughton et al., 2003; O'Leary et al., 2008), they only registered tibial acceleration, and thus it is not possible to know the amount of acceleration arriving to the head and ultimately the shock attenuation resulting from their interventions. Also, Windle et al. (1999) did observe higher "shock attenuation" with different models of insoles, but their concept of attenuation was related to a reduction in plantar pressure instead of a shock attenuation analysed from the impact acceleration signal and their results cannot be compared with the impact acceleration observe in this study.

It is important to bear in mind that shock attenuation is a variable that summarizes what is happening in the body and that provides information related to whether the intrinsic strategies of the human body are working adequately to attenuate the shock being experience at that moment. It was observed in the current work that different insole interventions did not lead to changes in shock attenuation, what may imply that the musculoskeletal system is not experiencing anything unusual compared to the habitual running (control condition) and the athletes may be benefiting from the positive effects of the insoles on other biomechanical parameters (plantar pressure, motion control, comfort) without compromising impact acceleration.

4.3.2. Effect of the Fatigue

Most studies are conducted while running in a non-exerted state. However, although difficult, the study of fatigue is important as it is a regular phenomenon experienced by all runners and is when most injuries are thought to occur (Hreljac, 2004).

The shock wave produced and transmitted throughout the body during running is partly attenuated by the running shoes and the musculoskeletal system (Derrick, 2004; Mercer et al., 2002). However, prolonged exposure to this acceleration loading as in long distance events is believed to lead to increased injury rate as a result of the reduced ability of the fatigued musculoskeletal system to attenuate this loading (Mizrahi & Daily, 2012; Mizrahi et al., 2000). It is believed that when the muscle's ability to perform is diminished, the articular cartilage and ligaments become more vulnerable to excessive dynamic loading (Whittle, 1999). The analysis of this shock wave in terms of peak impact acceleration, acceleration rate and shock attenuation when the musculoskeletal system is fatigued is needed in order to better understand how the body deals with external loadings especially under situations of increased injury risk, such as when fatigue is present (Hreljac, 2004).

It is believed that fatigue hampers the ability of the musculoskeletal system to protect itself from overloading and this loss of protection would be manifested as increased impact accelerations and thus increased risk of injury (Milner et al., 2006; Verbitsky et al., 1998). Numerous studies have observed this increased impact acceleration with fatigue, thereby supporting this theory (Derrick et al., 2002; Lucas-Cuevas et al., 2015; Mizrahi, Verbitsky, Isakov, & Daily, 2000; Mizrahi et al., 1997; Mizrahi et al., 2001; Verbitsky et al., 1998; Voloshin et al., 1998). These authors speculated that when the muscles are fatigued, the amount of energy transmitted to the surrounding bones increases and the probability of injury increases as well (Dufek, Bates, Davis, & Malone, 1991; Fredericson, Jennings, Beaulieu, & Matheson, 2006).

However, in the present study, the fatigue state did not influence peak impact acceleration and acceleration rate independently of the insole condition, what is in agreement with a number of previous studies (Abt et al., 2011; Butler, Hamill, & Davis, 2007; Coventry et al., 2006; Mercer et al., 2003). Moreover, there are other studies that even found a reduction in impact acceleration as a result of the fatigue state (Duquette & Andrews, 2010b; Flynn et al., 2004; Holmes & Andrews, 2006).

It is generally believed that the human body maintains the impact accelerations within a comfortable individual range by making different adaptations, especially alterations in the leg mechanics such as hip, knee and ankle joint positions at contact

(Edwards et al., 2012; Gruber et al., 2014; Lafortune, Lake, & Hennig, 1996; Lieberman et al., 2010; Milner, Hamill, & Davis, 2007) and in the spatio-temporal parameters (García-Pérez et al., 2013; Gerlach et al., 2005; Hunter & Smith, 2007; Verbitsky et al., 1998). As a result, many of the aforementioned studies have tried to control some of these parameters in order to provide further evidence about the individual role of each one of these factors, what may account for the differences between studies.

It is interesting and worth mentioning that in the three studies that found reductions in impact acceleration, the fatiguing protocol had the objective of controlling joint position during ground contact to provoke a local fatigue by placing the participants on a supine position and provoking heel impacts mechanically via a human pendulum apparatus (Duquette & Andrews, 2010b; Flynn et al., 2004; Holmes & Andrews, 2006). These authors observed lower peak acceleration and acceleration rate with the development of fatigue and suggested that the muscle fatigue could have caused the muscle to become less stiff, what would enable a greater impact attenuation due to the dynamics of the wobbling mass. Even though these types of studies are important to see how individual factors (joints position) play a role in the whole mechanism (attenuation of accelerations of the entire musculoskeletal system), these studies miss the part where the body counterbalances the local mechanisms with alternative compensatory strategies. Therefore it is very difficult to extrapolate the results observed in studies where local fatigue is induced to the running motion.

In the present study, an increase in peak impact acceleration during running fatigued was not found for any of the insole conditions, what may indicate that the musculoskeletal system of the participants in this study was able to adequately cope with the continuous acceleration loading of the fatiguing protocol. However, since we did not find any difference between insole conditions, it is both difficult and reckless to relate the behaviour of the impact accelerations during the fatigued run to a hypothetical direct effect of the use of insoles.

Shock attenuation during a fatiguing event is also a relevant indicator of the body's ability to deal with impact acceleration during exercise. Since muscles are thought to play a primary role in shock absorption during ground contact, it has been hypothesized that reduced muscular function as a result of the fatigue state decreases the shock absorbing capacity of the body and can subsequently lead to an increased chance of injury (Verbitsky et al., 1998; Voloshin et al., 1998). However, reports of shock attenuation changes with fatigue have also been inconsistent. Whereas no differences in shock attenuation with fatigue have been observed in agreement with the present work (Abt et al., 2011; García-Pérez et al., 2014), other studies have found both a reduction (Mercer et al., 2003) and an increase (Derrick et al., 2002) in shock attenuation with fatigue. These authors speculated that alterations in the lower leg mechanics (ankle, knee, hip joints), spatio-temporal parameters and the differences in the fatigue protocols may explain the different results among studies.

Nordin and Frankel (1989) hypothesized that the loss of attenuation capacity of the fatigue muscles could be compensated by a change in movement pattern in order to counteract the change in muscle ability. It has been observed that reductions in stride rate (or increases in stride length) have led to increases in impact acceleration (thereby altering impact attenuation) (Mercer et al., 2002; Mizrahi et al., 2000; Verbitsky et al., 1998). This could be explained by the reduction of the effective mass that occurs as the degree of knee flexion increases at the time of ground contact (Derrick, 2004). Derrick et al. (2004) indicated that when the effective mass during running was reduced, the impact acceleration measured at the tibial increased. Since running with longer strides would increase the knee flexion at ground contact and would therefore reduce the effective mass, it is suggested that shorter stride length during running could decrease impact acceleration and therefore aid the musculoskeletal system to attenuate the impact shock during running (Derrick, 2004; Derrick et al., 1998). As presented in the results section (section 3.1. “Analysis of the spatio-temporal parameters”), runners in the present study were able to maintain their optimal stride rate and length and it could partly explain why the impact acceleration and shock attenuation were not modified during the fatigue run with the different insole conditions.

Finally, differences among studies could be also due to the different fatigue protocols and levels of fatigue attained by the participants. Fatigue is such a complex and multifactorial phenomenon that makes it extremely difficult for researchers to recreate situations that provoke similar levels of fatigue, especially when the environmental conditions (treadmill, overground, experimental setup) and the characteristics of the participants (training level, injury vs healthy condition, gender, age, etc.) change from study to study (Table 43).

Table 43. Description of the fatigue protocol in studies analysing the effect of the fatigue state on impact acceleration.

	Fatigue Protocol	Speed of Fatigue ($m \cdot s^{-1}$)	Speed of Measurement ($m \cdot s^{-1}$)	Duration (min)	Acceleration Measurement	Participants
Abt et al., 2011	Running at the ventilatory threshold to exhaustion	3.3	3.3	17.8 ± 5.7	During protocol	Competitive distance
Butler et al., 2007	>85% age specific HRmax or >16 RPE	Self-selected	Self-selected	47 ± 24 (Group 1) 52 ± 25 (Group 2)	Begin and end of protocol	Recreational
Clansey et al., 2012	Two 20 min runs at Lactate threshold (1% gradient)	-----------	4.5	40	Before and after protocol	Highly trained
Coventry et al., 2006	Drop Jumps from 80% max jump height	-----------	-----------	-----------	Before and after protocol	Active
Derrick et al., 2002	Max speed for a 3200-m running at maximal effort	3.40	3.40	15.7 ± 1.7	During protocol	Recreational
Duquette & Andrews, 2010	Local fatigue with human pendulum	Simulation of 1.07 ± 0.05	Simulation of 1.07 ± 0.05	-----------	Before and after protocol	Active
Flynn et al., 2004	Local fatigue with human pendulum	Simulation of 1.00 – 1.15	Simulation of 1.00 – 1.15		Before and after protocol	Active
García-Pérez, 2014	Running at 85% VAM	3.81	4.00	30	Before and after protocol	Experienced
Mizrahi et al., 1997	Running at the anaerobic threshold	2.79 ± 0.29	2.79 ± 0.29	30	During protocol	Active
Mizrahi et al., 2000	Running 5% above the anaerobic threshold	3.53 ± 0.19	3.53 ± 0.19	30	During protocol	Active
Verbitsky et al., 1998	Running at the anaerobic threshold	2.76 ± 0.29	2.76 ± 0.29	30	During protocol	Active

RPE: Rating of perceived exertion (Borg, 1982)*. VAM: Maximal Aerobic Velocity; HR: Heart Rate; Borg Scale: Perceived Exertion test.*

All these differences may very likely result in a different level of fatigue of the participants. As it can be seen in the Table 43, participants were fatigued via very different protocols including running for 30 minutes at a speed 5% higher than their anaerobic threshold (Mizrahi et al., 2000; Voloshin et al., 1998), an incremental maximal effort treadmill run up to the participants voluntary exhaustion (Mercer et al., 2003), or jumping until participants' exhaustion (Coventry et al., 2006). Even though all these studies provided scientific rationale supporting their choice of fatigue protocol, the differences in fatigue protocols make very difficult to reach specific conclusions regarding the role of fatigue on impact acceleration and attenuation during running. However, is it indeed known that fatigue plays an important role, and future studies are encouraged to continue investigating this relationship in order to throw more light into this interesting relationship.

Key Points

- CMI reduce the tibial acceleration rate compared to PI and the head acceleration rate compared to CI and PI.
- PI increase the tibial acceleration rate.
- The fatigue state does not influence the impact accelerations independent of the insole condition.

4.4. Analysis of Comfort

The use of insoles has been confirmed to be an effective way of reducing pain and discomfort (Witana, Goonetilleke, Xiong, & Au, 2009). In the present study, the perception of comfort of nine shoe-related comfort parameters was analysed while running with the original sock liners of the shoe (control condition) and with different insoles (custom-made and prefabricated).

All the comfort parameters were rated higher with the study insoles (custom-made, prefabricated) compared to the control condition. This is coherent with the findings of a previous study (Mündermann et al., 2001). According to Au and Goonetilleke (2007), comfort is a complex phenomenon which can be affected by the properties of the materials used, foot shape, shoe fit, skeletal alignment, within-shoe climate and even factors such as colour and fashion. In this sense, we observed in the present work that perceived comfort can be affected simply by the use of inserts even when the running shoe is left identical.

Although the participants were accustomed to the original sock liners of their running shoes (control condition), the application of a new insert was perceived as a positive element. However, in the study of Mündermann et al. (2002), the control condition was rated the highest. They concluded that the materials of the control condition were more similar to the sock liners commercially available with running shoes, and therefore their participants perceived the new insoles as elements disrupting the natural perception of comfort.

There is a growing body of evidence claiming that comfort can play a major role in sport performance (Luo et al., 2009; Mills et al., 2011; Nigg et al., 1999). Kinchington, et al. (2012) found that rugby football players' performance was compromised when they reported a comfort rating for their legs that was below their usual comfort range and these authors suggested that the perception of comfort could have the potential to be used as a predictive tool for performance and injury prevention.

Moreover, when an external intervention such as an insole is perceived as uncomfortable, it could disrupt the natural biomechanics of the leg and cause the runner to develop compensatory musculoskeletal mechanisms, thus compromising the final performance and increasing the risk of injury (Che et al., 1994; Cheung, Hume, & Maxwell, 2003; Kinchington et al., 2012).

In the present study, the comfort ratings for the custom-made insoles were in general lower than those observed for the prefabricated insoles, although those differences did not reach statistical significance ($p > 0.05$). This unexpected finding is coherent with the observations of Zifchock & Davis (2008) in which high-arched individuals reported a semi-custom insole to be more comfortable than a complete custom insole. It is important to bear in mind that custom-made insoles are prescribed to maintain the subtalar and midtarsal joints in the correct position during active gait (Werd & Knight, 2010) or to treat lower limb pathologies (Gijon-Nogueron et al., 2014). In order to fulfill its purpose and provide good fit and control, the insole's structure needs to be hard and stiff. Prefabricated insoles, however, are made of several layers of foam with less hardness, what gives them a softer structure but less control of movement. It thus appears that, in accordance with previous studies (Finestone et al., 2004; Krumwiede, Konz, & Hinnen, 1998; Mills et al., 2011; Mündermann et al., 2002; Mündermann et al., 2001), the observed differences in comfort may be accounted for by the properties of the materials used in the insoles, with the participants preferring soft (prefabricated insoles) over hard (custom-made insoles) materials. Therefore, since softness of the insert seems to play a major role in comfort perception, it should therefore be considered as a major parameter in the design of footwear insoles.

As expected, the length and width comfort ratings were very similar for all three conditions. Since the length and width of the inserts are matched to shoe size, there is no reason for them to be perceived differently in different insole conditions (Mündermann et al., 2002). In contrast, the most pronounced differences with the control condition found in the present study were in medio-lateral control and arch height. The results may be explained by the different inner properties of the insoles. The custom-made insoles and the prefabricated insoles had several layers of lateral reinforcement, which could explain why, in medio-lateral comfort, both of these insoles were perceived as more comfortable (9.87 and 9.29 comfort points, respectively) than the original insoles (6.19 comfort points). Similarly, the extra support provided by the structure of the study insoles was reflected in higher scores for overall comfort compared to the control condition.

In general terms, both types of insoles (prefabricated and custom-made) were rated as more comfortable during running than the sock liners (control condition) of the running shoe. Even though a custom-made insole is built based on a three-dimensional representation of the individual's foot, a prefabricated insole chosen solely in accordance with the runner's foot size provided similar levels of comfort during running. Although comfort is a subjective attribute that is difficult to measure rigorously, negative comfort or discomfort can lead to inappropriate adaptation of the insoles and even to cessation of the activity, which has led biomechanists, clinicians, sports coaches and the footwear industry to consider comfort as a prognostic indicator of the success of shoe inserts and insoles.

Key Points

- CMI and PI improve the overall, heel cushioning, forefoot cushioning, medio-lateral, arch height and heel cup fit comfort compared to CI.
- PI also improve the forefoot width comfort compared to the CI.
- No differences in comfort exist between CMI and PI.

4.5. Analysis of the Fatigue

In the present work, the 6-20 Borg rating of perceived exertion scale was used to compare the perception of fatigue during the last minute of the fatiguing run when using custom-made and prefabricated insoles.

No differences were observed in the perception of fatigue between the two insole conditions. This was an expected result because even though the use of insoles has been suggested to influence many factors including pain relief, proprioception and comfort (Gijon-Nogueron et al., 2014; Lee et al., 2012), impact forces (Creaby et al., 2011) and plantar loading (Burns, Crosbie, Ouvrier, & Hunt, 2006); there is to date no theory that could explain how the use of insoles could modify the perception of exertion during a fatigue protocol.

Moreover, if differences in the ratings of perceived exertion had been found at the end of the fatiguing run when running with the different insoles, it would be too ambitious and reckless to establish a relationship between a reduction in the perception of exertion and the use of insoles.

Nevertheless, the use of the ratings of perceived exertion scale (RPE Borg Scale) is a useful tool to quantify and control the level of fatigue of the participants throughout a fatiguing protocol. In the current study, an average value of ~14 (~Hard) could indicate that the participants got fatigued to a certain level without reaching the extenuation state, what was the aim of the protocol. It was the author's intention that the fatigue protocol would lead to a fatigue state that would resemble the last minutes of a typical training where maximal exertion may not occur. This issue leaves, however, a door open to further studies that could analyse how the use of insoles would influence different biomechanical parameters (spatio-temporal parameters, plantar pressure, impact acceleration) when running up to greater levels of fatigue or even to extenuation.

Key Points

- No difference in the perception of fatigue during the fatiguing protocol is observed between running with the custom-made and the prefabricated insoles.

5. CONCLUSIONS

5. CONCLUSIONS

5.1. Conclusions of the study

There is strong evidence that associates running to plenty of physical, psychological and social benefits leading to a better health state, quality of life and lower risk for all-causes of mortality. However, running is a cyclical activity that provokes repetitive impacts on the biological structures of the body resulting in an accumulative stress that may lead to injury, especially in the lower extremity.

The use of insoles together with shoe construction developments offer the most directly approach to influence the running technique and potentially reduce these impacts and redistribute the deleterious overloading stress produced during running. Among the different alternatives available to runners, prefabricated (off-the-shelf) or custom-made insoles (personalised to the foot structure) are among the most common strategies to prevent and treat running-related injuries. However, there is a big controversy regarding the effectiveness of these types of insoles during running. In the present study, spatio-temporal parameters, plantar pressure, impact acceleration and the perception of comfort and fatigue have been analysed in a group of recreational runners using the original sock-liners of the running shoes, custom-made insoles and prefabricated insoles during running with and without fatigue. All in all, the main conclusions of the study are:

A. The spatio-temporal parameters (contact time and stride rate) are not modified by the different insoles. As a consequence, intervention with insoles may benefit the runner by protecting the biological structures without altering the individual running performance.

B. Both study insoles (custom-made, prefabricated insoles) reduce significantly the plantar pressure (hallux, toes, arch, heel) compared to the control situation, what implies that the use of insoles may be an important protective tool to reduce the pressure experienced at each foot strike, resulting in a decreased accumulative overloading in long distance runners.

C. Custom-made insoles reduce the plantar pressure under the hallux and the rearfoot compared to the prefabricated insoles. Due to the important role of these areas during the push-off and the heel strike during running, a reduction of pressure in these zones could be of great relevance to runners and may be playing a protective role against overuse injuries.

D. Neither the peak accelerations nor the shock attenuation are influenced by the use of insoles, what indicates that an insole intervention may not provide further protection than the original insoles of the running shoes against injuries associated with elevated impact accelerations.

E. Custom-made insoles reduce tibial and head acceleration rates compared to the prefabricated insoles. As a result, even though insoles should not be recommended to reduce impact accelerations, when an insole is prescribed to treat another biomechanical parameter (e.g. plantar pressure, pain, the mechanical function of the foot, etc.), custom-made insoles will provide a greater reduction of the acceleration load than prefabricated insoles.

F. Both types of insoles (custom-made, prefabricated) are perceived as more comfortable than the control insoles. In this sense, whereas using an insole will improve the running comfort compared to running without insoles, a custom-made insole does not lead to greater perception of comfort than a prefabricated insole.

G. The fatigue state has no effect on the spatio-temporal, the plantar pressure and the impact acceleration parameters independently of the insole condition.

5.2. Limitations of the study

Several limitations have been accounted during the development of the study and need to be mentioned and taken into account when interpreting the results:

1. The use of an in-shoe plantar pressure system to measure the effects of the insoles on running motion. Although instrumented insoles allow the measurement of continuous consecutive steps while the participant moves freely, when participants run on an surface, shearing forces occur (Hreljac, 2005). In this sense, the use of force plates provides shear and propulsion forces during locomotion (Aguado, 2015; Morey & Mademli, 2015), which combined to the information provided by the instrumented insoles, could have resulted in a more accurate and complete vision of the effects of the use of insoles on running biomechanics.

2. The use of a treadmill as the measurement condition instead of a natural running environment. There is controversy whether running on a treadmill really simulates the lower extremity biomechanics of overground running. Since results have been said to be comparable but no equivalent (Fellin et al., 2010a; García et al., 2013; Jones & Doust, 1996; Meyer et al., 2003; Riley et al., 2008), it is important to bear in mind that this study was carried out on a treadmill so the protocol could be better controlled (running speed, slope and stiffness of the surface, etc.), leading to possible biomechanical modifications compared to overground running.

3. Participants used their own running shoes. Although inherent characteristics of running shoes such as midsole stiffness and thickness have been suggested as a factor that may alter impact acceleration and plantar pressure distribution during locomotion (Cole, Nigg, Fick, & Morlock, 1995; De Wit et al., 1995; Hardin, Van den Bogert, & Hamill, 2004; Kersting & Bruggermann, 2006; Ly, Alaoui, Erlicher, & Bali, 2010; Ogon et al., 2001; Qassem, 2003), runners using non-familiar shoes may also modify the running pattern (Gerlach et al., 2005;

Weist et al., 2004). As a result, in this study participants wore their own running shoes to recreate a real-life situation, but it is important to acknowledge that pressure modifications due to footwear may exist.

4. Plantar pressure was measured only in the left foot whereas impact acceleration was measured only in the right leg. In this study, similar loading characteristics between right and left legs were assumed as previously stated in other studies (Liu et al., 2011; Redmond et al., 2000). However, anatomical differences between lower extremities such as foot type may also influence these parameters and should be also taken into account as a limitation (Chuckpaiwong et al., 2008; Queen et al., 2009a; Razeghi & Batt, 2000).
5. The plantar pressure analysis system and the accelerometers may affect running biomechanics. Although to date there is no study to the author’s knowledge analysing whether using these systems may influence the participant’s running pattern, it is important to bear in mind that the participants physically carrying the systems with the additional mass of the equipment may have led to changes in their running pattern.
6. Inherent running pattern of the participants. No identification of the individual running pattern (rearfoot or midfoot strike running pattern) was addressed in this study and plantar pressure and impact acceleration was measured and analysed regardless their running technique, which may have had an effect on these biomechanical parameters (Whittle, 1996).
7. The final level of fatigue of the participants. Due to the fatigue protocol used in this study (12 minutes running below the anaerobic threshold), the participants may have not reached a state of fatigued critical enough to provoke adaptations in their running pattern.

5.3. Future Research

Throughout the development of this study, numerous questions and hypotheses have aroused for further analysis. As a consequence, based on the results obtained in this study and in order to continue in the same line of research, in future studies it would be of great interest to:

1. Analyse how the type of foot (neutral, moderately pronated/supinated and highly pronated/supinated) influence impact acceleration and plantar pressure distribution during running.
2. Investigate whether the different types of running pattern (rearfoot, midfoot strike pattern) show different impact acceleration patterns and plantar pressure distributions during running.
3. Observe via analysis of markers of muscle damage whether the longer use of insoles is able to reduce muscle damage in athletes.
4. Use video analysis systems to observe whether CMI modify running kinematics parameters of the lower extremity compared to PI and CI.
5. Compare the effect of other types of sport equipment such as special "shock-absorbing" running socks on impact acceleration and plantar pressure distribution during running.
6. Corroborate the effect of the insoles while running at greater levels of fatigue (even reaching the extenuation state) and with different fatigue parameters (VO_{2max}, HR_{max}, RER).
7. Study the influence of the use of insoles on the lower limb mechanics and the effective mass and their subsequent effect on impact acceleration during running.
8. Measure through thermographic images whether the different types of insoles have an effect on the thermoregulation of the foot during running.

5.4. Conflicts of Interest

The author declares that there is no conflicts of interest concerning the content of this dissertation.

6. REFERENCES

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7. ANNEXES

7. ANNEXES

1. Summary of studies addressing insole effect on plantar pressure
2. Informed Consent
3. Foot Posture Index

SUMMARY OF STUDIES ADDRESSING INSOLE EFFECT ON PLANTAR PRESSURE (1)

Study	Orthoses analysed	Condition	Results
Lee et al., 2012	- Newly designed insole - Adjustable arch-support insole - Ergo-designed insole - Barefoot	Walking	- **Newly designed**: Lowest pressure in hallux, 2nd-5th phalanges and heel. - **Ergo-designed**: Lowest pressure in 2nd-3rd metatarsal and midfoot. - **Barefoot**: Lowest pressure in 1st and 4th-5th metatarsals.
Healy, Dunning, Chockalingam., 2012	- Low density polyurethane (PU) - medium density PU - low density ethyl vinyl acetate (EVA) - medium density EVA	Walking	Both PU insoles reduced pressure-time integral and increased contact area (pressure redistribution). PU insoles seem more effective than EVA at reducing plantar pressure.
Creaby et al., 2011	Flat-material insole vs Heel-Cup Insole vs No insole	Walking	Reduced Peak Impact force at the knee with flat-material and heel-cup insole.
Hinz et al., 2008	- Synthetic mesh insole (conventional) - EVA foam insole - Neoprene insole - No insole	Walking	Neoprene insoles showed lowest maximum forces and peak pressures under all metatarsals, followed by the EVA insoles. Greatest peak pressures under 1st and 5th metatarsals with conventional insoles. Greatest peak pressures under 2nd-4th metatarsals without insoles.
Goske et al., 2006	27 combinations: Conformity: - Flat - Half-Conforming - Full-Conforming Thickness - 6,3mm - 9,5mm - 12,7mm Materials - Poron Cushioning - Microcel Puff Lite - Microcel Puff	Computational Analysis. Gait simulation.	Conformity the most important variable (44% reduction in plantar pressure with full-conforming compared to barefoot). Insole Thickness secondary to conformity. Peak pressure insensitive to materials change.

SUMMARY OF STUDIES ADDRESSING INSOLE EFFECT ON PLANTAR PRESSURE (2)

Study	Orthoses analysed	Condition	Results
Burns, Crosbie, Ouvrier & Hunt, 2006	Custom orthoses vs sham orthoses (control)	Walking. Cavus feet.	Improved foot pain scores and quality of life compared to control. Decreased plantar pressure under all regions compared to control.
Bus et al., 2004	Custom-made insoles vs flat insoles	Walking	Decreased pressure and force-time integral under 1st metatarsal and heel compared to flat insoles. Increased pressure and force-time integral under medial midfoot.
Lobmann et al., 2001	Special insole support vs conventional (control)	Walk. Diabetic.	30% reduction maximum peak plantar under the whole foot pressure compared to control.
Redmond, Lumb & Landorf, 2000	- Thin-soled shoe (control). - Modified Root cast foot insole - Non-cast insole	Walking	Root orthosis decreased peak pressure under heel and midfoot. Root orthosis decreased pressure-time integral under heel, lateral and medial forefoot. Root orthosis increased peak pressure under hallux. Root orthosis increased contact area (pressure redistribution) under heel, and midfoot. Little difference between non-cast and control.
Li et al., 2000	Foot orthoses vs no orthoses in Rheumatoid and Healthy people	Walking. Rheumatoid Arthritis.	Foot orthoses decreased plantar pressures and loading forces in both groups. Foot orthoses provided greater reduction in the Rheumatoid groups compared to the healthy group.
Windle et al., 1999	- Soborthane insole - Saran Insole - PPT Insole - Cambion Insole - Control Insole	Running	All study insoles decreased peak pressure compared to control insole. Soborthane the most effective for attenuating peak pressure at heel strike and forefoot push-off.

SUMMARY OF STUDIES ADDRESSING INSOLE EFFECT ON PLANTAR PRESSURE (3)

Study	Orthoses analysed	Condition	Results
Hodge et al., 1999	- Prefabricated insoles - Standard custom-moulded insoles - Custom with metatarsal bar - Custom with metatarsal dome - No insole	Walking. Rheumatoid Arthritis.	All insoles decreased pressure under 1st and 2nd metatarsal heads compared to no insole condition. Custom-moulded with metatarsal dome was the most effective reducing subjective rating of pain.
Postema et al., 1998	Custom-moulded insole vs ready made insole with and without Rockerbar	Walk. Metatarsalgia.	Rockerbar decreased by 15,1% force impulse and by 15,7% peak pressure under the central distal forefoot. Custom-moulded insole decreased by 10,8% and 18,2% peak pressure under central and lateral distal forefoot, respectively.
Albert and Rinoie 1994	Custom-made orthosis vs Barefoot	Walking. Diabetic.	30-40% reduction in plantar pressure under 1st metatarsal head and medial heel. Increased total contact area (pressure redistribution).
Nigg et al., 1988	4 different types viscoelastic insoles	Running	No changes in vertical force peak, time of occurrence of vertical force peak, and maximum vertical loading rate.
Boulton et al., 1984	5 mm thick polyurethane elastomer insoles	Walking. Diabetic.	Reduced Pressure under the foot.

INFORMED CONSENT

Estudio de las variables biomecánicas en corredores de fondo

INFORMACIÓN

El Departamento de Educación Física y Deportiva de la Facultad de Ciencias de la Actividad Física y el Deporte, en colaboración con el Departamento de Fisiología de la Facultad de Medicina y Odontología y la Clínica Podológica de la Facultad de Enfermería y Podología de la Universidad de Valencia, están desarrollando una investigación en la que se analizan diversas variables biomecánicas relevantes durante la carrera.

El estudio está basado en una exploración previa del pie y una serie de tests realizados sobre cinta rodante.

Las pruebas se realizarán en el laboratorio de Biomecánica de la FCAFE (Universidad de Valencia), ubicada en la planta primera del Aulario V, c/ Gascó Oiliag, 3, de Valencia. El tiempo estimado de cada sesión de medida será de unos 60 minutos por persona (a excepción de la exploración del pie).

RIESGOS

La prueba no implica "*a priori*" ningún riesgo de lesión o daño para el participante.

CONFIDENCIALIDAD

Los datos personales que se le solicitan para participar en este proyecto, serán tratados siguiendo los principios de confidencialidad de acuerdo con la ley 15/1999 de Protección de Datos de Carácter Personal y complementada por la ley 41/2002 del 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica. En ninguno de los informes del estudio aparecerá su nombre, y su identidad no será revelada a persona alguna salvo para cumplir los fines del estudio y en el caso de urgencia médica o requerimiento legal. Los datos personales de los voluntarios serán recogidos en el estudio pero no serán publicados en ningún informe, memoria o artículo. Los datos serán confidenciales y estarán controlados exclusivamente por miembros del equipo de investigación.

CONTACTOS

Para cualquier consulta relacionada con el estudio, problemas en el test, cambio de cita, etc., pueden llamar al teléfono 646809833 y preguntar por D. Ángel Lucas (Doctorando responsable del proyecto).

PARTICIPACIÓN

Su participación en este estudio es voluntaria y, por tanto, puede comunicar su deseo de no continuar en cualquier momento.

CONSENTIMIENTO

Después de leer este documento, declaro que las condiciones expuestas son satisfactorias y declaro mi disposición a participar en este estudio.

Fdo.:____________________________ DNI___________________
Fecha_________________________

Nombre y Apellidos:_______________________________________

FOOT POSTURE INDEX

Foot Posture Index Datasheet

Patient name	***ID number***

	FACTOR	PLANE	SCORE 1 Date________ Comment______		SCORE 2 Date________ Comment______		SCORE 3 Date________ Comment______	
			Left -2 to +2	**Right** -2 to +2	**Left** -2 to +2	**Right** -2 to +2	**Left** -2 to +2	**Right** -2 to +2
Rearfoot	Talar head palpation	*Transverse*						
	Curves above and below the lateral malleolus	*Frontal/ transverse*						
	Inversion/eversion of the calcaneus	*Frontal*						
Forefoot	Prominence in the region of the TNJ	*Transverse*						
	Congruence of the medial longitudinal arch	*Sagittal*						
	Abd/adduction forefoot on rearfoot	*Transverse*						
	TOTAL							

Reference values
Normal = 0 to +5
Pronated = +6 to +9, Highly pronated 10+
Supinated = -1 to –4, Highly supinated –5 to -12