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**EFICACIA DE DIFERENTES DISEÑOS DE ORTESIS
PLANTARES EN LA BIOMECÁNICA
MULTISEGMENTARIA DEL PIE EN PACIENTES CON
HALLUX LIMITUS**

**EFFICACY OF DIFFERENT FOOT ORTHOSES
DESIGNS ON MULTI-SEGMENT FOOT
BIOMECHANICS IN PATIENTS WITH HALLUX
LIMITUS**

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DOCTORAL TRAINING IN BIOMEDICAL SCIENCES

Movement and Rehabilitation Sciences

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LIMITUS**

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Realizada bajo la tutorización del **Prof.Dr. Gabriel Gijón Noguero**n de la universidad de Málaga y el **Prof.Dr. Kevin Deschamps** de la universidad de Lovaina y la dirección de la **Prof.Dra. Ana Belén Ortega Ávila**.

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ACRONYMS AND ABBREVIATIONS

- **HL** = Hallux Limitus
- **FHL** = Functional hallux limitus
- **SHL** = Structural Hallux limitus
- **AFSE** = Anterior Forefoot Stabilizer element
- **CFO** = Custom foot orthoses
- **MTPJ** = Metatarso phalangeal joint
- **SJ** = Subtalar Joint
- **EVA** = Ethylene vinyl acetate
- **MHS** = Medial heel skive
- **CM** = Cuneo-metatarsal
- **HV** = Hallux valgus
- **HVA** = Hallux valgus angle
- **IMA** = Intermetatarsal angle
- **DMAA** = Distal metatarsal articular angle
- **PPAA** = Proximal phalangeal articular angle
- **DPAA** = Distal articular angle of the proximal phalanx
- **HVIP** = Interphalangeal hallux valgus angle
- **TMA** = Tarsal metatarsal angle
- **WM** = Windlass mechanism
- **ROI** = Region of interest
- **COP** = Center of pressure
- **FO** = Foot orthosis
- **FOs** = Foot orthoses
- **FPW** = Frontal plane wedge
- **SATM** = Semi-automatic mapping
- **FPI** = Foot posture index
- **MT** = Midfoot joint
- **DF** = Dorsiflexion
- **PF** = Plantarflexion
- **AB** = Abduction
- **AD** = Adduction
- **IN** = Inversion
- **EV** = Eversion
- **1ª AMTF** = 1ª articulación metatarso falángica
- **HLF** = Hallux limitus funcional
- **HLE** = Hallux limitus estructurado
- **ASA** = Articulación subastragalina
- **EEA** = Elemento estabilizado anterior
- **TAD** = Técnica de adaptación en directo
- **ALI** = Arco longitudinal interno



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ABSTRACT.

Introduction.

The first metatarsophalangeal joint (1st MTPJ) is fundamental in human gait. Its limited mobility, as in the case of hallux limitus (HL), significantly affects foot functionality and quality of life. HL, characterized by dorsiflexion of less than 65°, is a common cause of foot osteoarthritis, especially in older adults. Despite the importance of this condition and the availability of various foot orthoses (FOs) designs for its treatment, the literature on the effects of these treatments in improving joint functionality is scarce, and there is no consensus on the most effective Foot orthosis (FO) design. The objective of this doctoral thesis was to evaluate the effect of two different types of custom-made foot orthoses (CFO) : Cut-out CFO and AFSE CFO) on foot kinetic, kinematics, and plantar pressure distribution in patients with structured HL (SHL).

Methods.

This thesis comprises four research articles. The first is a systematic review on the effect of frontal plane wedges on plantar pressure distribution, providing a framework for the objective of the doctoral thesis. The following three articles are quasi-experimental repeated-measures studies, sharing methodology, protocol, and measurement tools, but with different objectives:

1. To study the effect of cut-out CFO and AFSE CFO on center of pressure (COP) displacement and plantar pressure distribution.
2. To evaluate the effect of cut-out CFO and AFSE CFO on foot kinetics and kinematics.
3. To investigate the relationship between cut-out CFO and AFSE CFO and joint stiffness.

The studies were conducted with a common population: patients with SHL (dorsiflexion range <65°), over 18 years old, with positive Jack and Lunge tests, and a Foot posture index (FPI) > 6. Following measurement tools were used: a pressure platform to measure COP displacement and plantar loading, and an optometric motion analysis system with 8 infrared cameras (Vero, Vicon® Motion Systems Ltd., Oxford, UK) for three-dimensional motion analysis.

Results.

The systematic review showed that frontal plane wedges alter plantar pressure distribution and COP displacement. Lateral wedges increased pressure on the lateral heel and cause a lateral shift of the gait line, while medial wedges produced the opposite effect.

The three experimental studies revealed that both CFO designs alter plantar pressure distribution and loading. Cut-out CFO shifted the COP medially and anteriorly by decreasing pressure on the lateral foot and hallux, together with a load transfer to the first metatarsal head. Similarly, AFSE CFO shifted the COP medially and anteriorly, increasing load on the first metatarsal head.

Additionally, changes in foot kinematics and kinetics were observed. Regarding the ankle joint, AFSE CFO reduced ankle plantarflexion during propulsion compared to barefoot, and both CFO showed a less plantarflexed position at initial contact/loading response compared to barefoot as well. In the frontal plane, barefoot conditions were associated with a greater degree of ankle inversion during the propulsion phase.

In the midfoot, both cut-out CFO and AFSE CFO reduced plantarflexion and adduction of the midtarsal joint compared to barefoot. Additionally, cut-out CFO showed a higher degree of eversion compared to both barefoot and AFSE CFO.

Regarding the 1st MTPJ, significant differences were observed in all three planes. Both cut-out CFO and AFSE CFO showed lower 1st MTPJ dorsiflexion, eversion, and abduction.

In terms of foot joint kinetics, a higher external dorsiflexion moment during midstance was observed with both CFO compared to the barefoot condition in the ankle joint. Furthermore, in the frontal plane, the barefoot condition was characterized by a higher external inversion moment. In the midfoot, cut-out CFO significantly reduced the external eversion moment. Significant differences were also found in the 1st MTPJ in the sagittal plane, particularly during the propulsion phase, with a greater dorsiflexion moment observed with AFSE CFO compared to cut-out CFO and barefoot.

Finally, the third study demonstrated that AFSE CFO significantly increased 1st MTPJ stiffness compared to barefoot, with no significant differences observed with cut-out CFO.

Conclusion.

The results demonstrated that CFO induced changes in plantar pressure distribution, foot kinematics, and kinetics in patients with SHL. The conducted studies revealed unexpected results, as anticipated functional enhancements were not always observed. However, alterations in joint rigidity were noted, particularly in relation to AFSE CFO.

Cut-out CFOs were more effective in redistributing plantar pressure and may be particularly useful for enhancing foot stability and reducing pain. AFSE CFO improved the propulsion phase and foot stability, increasing the patient's energy efficiency. The choice of FO should consider the specific needs of each patient, balancing stiffness and mobility. This work provides a solid foundation for future research and clinical applications, emphasizing the importance of a personalized approach in the treatment of HL.

RESUMEN.

In accordance with the University of Malaga, and following the guidelines established by the same, since the thesis is written in English, it is required the presence of a “summary” section in Spanish more extensive than usual.

Introducción.

La primera articulación metatarsofalángica (1ª AMTF) está constituida por el primer metatarsiano, la falange proximal del primer dedo y los dos huesos sesamoideos. Esta articulación está sostenida por un complejo cápsulo-ligamentoso y un conjunto de músculos que permiten su correcta funcionalidad.

Presenta dos ejes de movimiento: uno vertical y otro transversal, que pasan por el cuello del metatarsiano. En el plano frontal, realiza movimientos de abducción y aducción, los cuales, debido a su pequeña amplitud, carecen de importancia funcional significativa. En el plano sagital, se producen movimientos de flexión dorsal y flexión plantar, esenciales para la marcha humana.

Los rangos normales de movimiento para la 1ª AMTF son aproximadamente 45° para la flexión plantar y entre 70° y 90° para la dorsiflexión. Sin embargo, no existe un consenso claro entre los autores sobre el rango exacto de dorsiflexión, con valores reportados entre 50° y 90°. Se estima que al menos 60°-65° de dorsiflexión son necesarios para una correcta propulsión durante la fase final del ciclo de la marcha.

Diversas patologías pueden afectar a la 1ª AMTF, como afecciones de los sesamoideos (fracturas, sesamoiditis), "turf toe", hallux valgus y hallux limitus/rigidus. Esta última se caracteriza por una disminución de la capacidad de flexión dorsal de la 1ª AMTF y es el objeto de estudio de esta tesis doctoral.

El HL se define como una dorsiflexión de la 1ª AMTF inferior a 65° y afecta a 1 de cada 40 personas mayores de 50 años. Es la principal causa de artrosis en el pie y su incidencia aumenta en poblaciones mayores. Es la segunda patología más común del primer radio, después del hallux valgus. Cuando la limitación es menor de 10°, se conoce como hallux rigidus. La dorsiflexión de esta articulación es necesaria para estabilizar el pie durante la

fase de propulsión de la marcha y activar el mecanismo de Windlass; por tanto, una disminución en esta capacidad provoca una disfunción del pie.

Existen dos tipos de hallux limitus: hallux limitus funcional (HLF) y hallux limitus estructurado (HLE). El HLF se caracteriza por la incapacidad de la 1ª AMTF de realizar una dorsiflexión en carga, aunque puede alcanzar los 65°-70° en descarga (cadena cinética abierta). Por otro lado, en el HLE, la articulación presenta una disminución de la movilidad tanto en carga como en descarga, no alcanzando los 65° de movimiento.

La etiología del HL es multifactorial, incluyendo factores traumáticos, anatómicos/estructurales, metabólicos, biomecánicos, neuromusculares o postquirúrgicos. Una de las clasificaciones destacadas del HL es la de Regnaud, que describe tres grados de HL según sus síntomas, capacidad de movimiento y deterioro articular.

La 1ª AMTF desempeña un papel fundamental durante la marcha humana, especialmente en la propulsión y el despegue del antepié. Durante la fase de contacto de talón, el primer dedo se encuentra en dorsiflexión para evitar que el antepié contacte con el suelo, frenando el momento plantarflexor que ocurre en esta fase, esencial para absorber el impacto del pie contra el suelo. En la fase de medio apoyo, se distinguen dos momentos importantes para entender el funcionamiento del primer radio: al inicio de la fase, cuando el antepié está en contacto total con el suelo, el primer dedo continúa en dorsiflexión debido a las fuerzas de reacción del suelo, lo que evita el aumento de cargas en la cabeza del primer metatarsiano y permite la adaptación al terreno. Al finalizar la fase de medio apoyo, cuando cesan las fuerzas de reacción sobre el retropié, se produce un movimiento de supinación en la articulación subastragalina (ASA), convirtiendo el pie en una palanca rígida y preparándolo para la propulsión. En este momento, se produce una plantarflexión del primer radio, facilitada por el músculo peroneo lateral largo, anclando el primer dedo al suelo y potenciando la propulsión. Durante la fase de propulsión, la elevación progresiva del talón provoca el despegue secuencial de los metatarsianos desde el exterior hacia el interior, finalizando en el primer metatarsiano y la cabeza del primer dedo, que transfieren las cargas hacia la falange proximal, permitiendo el avance del cuerpo hacia adelante y contribuyendo a la estabilización del pie a través de la activación del mecanismo de Windlass. En esta fase, se requieren los máximos grados de dorsiflexión de la 1ª AMTF.

En resumen, el primer radio cumple principalmente dos funciones durante la marcha: la absorción del impacto en la fase de contacto de talón y la estabilización durante la propulsión, donde el primer radio permanece estacionario en el suelo mientras el resto del cuerpo se mueve hacia adelante. Por tanto, un bloqueo o restricción de la movilidad de la 1ª AMTF puede interferir con el avance normal del cuerpo y alterar los mecanismos donde este primer radio está involucrado, como el mecanismo de Windlass.

Se ha demostrado que la falta de dorsiflexión de la 1ª AMTF puede afectar la cinemática del tobillo, la cadera y la rodilla en el plano sagital. En la fase de medio apoyo, se observa un aumento de la dorsiflexión del tobillo para permitir que el cuerpo continúe avanzando, así como una reducción de la plantarflexión durante la fase de propulsión, acompañada de una disminución de la fuerza propulsiva y una alteración de la musculatura posterior de la pierna. También se observa un aumento de la flexión de la rodilla, posiblemente debido al incremento de tensión en los músculos gastrocnemios por el aumento de dorsiflexión, y una disminución de la extensión de la cadera. Dananberg sostiene que la limitación de la movilidad de esta articulación durante la fase propulsiva, repetida miles de veces al día, no solo altera la biomecánica del pie, sino que también puede causar alteraciones posturales crónicas, como rectificaciones lumbares, características en pacientes con HL. Además de las alteraciones posturales, se observan también cambios en la distribución de las presiones plantares y en las transferencias de carga.

Por tanto, mejorar la eficiencia del paso en pacientes con HL puede mejorar significativamente su calidad de vida, tanto a corto plazo, aliviando sus síntomas, como a largo plazo, previniendo problemas futuros.

El tratamiento para esta patología dependerá del grado o etapa en la que se encuentre. En los estadios iniciales, se prefiere el tratamiento conservador, que incluye antiinflamatorios, terapia física, infiltraciones con corticoesteroides peri e intraarticulares, modificaciones en el calzado y ortesis plantares. Si estos tratamientos no logran reducir el dolor e incrementar la funcionalidad del primer dedo, el tratamiento quirúrgico puede ser necesario. Las ortesis plantares pueden ser efectivas en las etapas iniciales de la enfermedad, y los resultados son casi inmediatos cuando se prescriben correctamente. Aunque el diseño de las ortesis depende de la etiología y el estadio de la enfermedad, las ortesis con elementos en la zona del antepié pueden ayudar a incrementar los grados de dorsiflexión en los estadios iniciales o bien limitar la movilidad de la articulación en los más avanzados. En las ortesis plantares se pueden utilizar varios

elementos, como cuñas dinámicas, extensiones de Morton, descargas o fenestraciones en la cabeza del primer metatarsiano, o control de la pronación en el caso de HLF.

Entre estos elementos, el más estudiado es el uso de ortesis plantares con fenestración en la cabeza del primer metatarsiano (conocidas como ortesis cut-out). El diseño de estas ortesis varía; algunos autores utilizan únicamente la fenestración a nivel de la cabeza del primer metatarsiano, mientras que otros añaden una extensión a nivel del hallux (cuña extensora dinámica) para colocar la falange proximal en una posición más dorsiflexionada respecto al primer metatarsiano.

Aunque la bibliografía es limitada y no existe un consenso claro entre los autores, algunos sugieren que el uso de este tipo de ortesis aumenta el ángulo de declinación del primer metatarsiano, así como una aducción en el plano transversal, manteniendo el contacto del primer dedo con el suelo, descomprimiendo la articulación y reduciendo el dolor. Esto favorecería la propulsión, haciendo esta fase más eficiente. Por otro lado, se han observado alteraciones en las presiones plantares con este tipo de ortesis, aunque con discrepancias entre los autores.

Además de este diseño de ortesis plantar, existen otros que incluyen la aplicación de un elemento balancín colocado en la zona anterior del antepié, conocido como elemento estabilizador anterior (EEA). Este elemento tiene como objetivo facilitar la amplitud de movimiento de la 1ª AMTF, reduciendo las presiones articulares y, por lo tanto, optimizando la transferencia de carga entre la 1ª AMTF y el hallux. Sin embargo, la eficacia de este tipo de ortesis plantares sigue sin estudiarse.

A pesar de la importancia de una correcta movilidad de esta articulación y las compensaciones que conlleva, tanto a corto como a largo plazo, provocando una disminución considerable de la calidad de vida de los pacientes, la bibliografía sobre el tratamiento mediante ortesis plantares es escasa, y no existe consenso sobre el diseño de las ortesis ni sobre su efectividad en mejorar la funcionalidad de esta articulación.

Basado en las incógnitas aún presentes en la literatura, la presente tesis doctoral provee las siguientes contribuciones al conocimiento actual:

1. Una revisión sistemática de la efectividad de las cuñas frontales tanto dentro del zapato como con el paciente descalzo en la carga plantar.

2. Estudiar el efecto de las ortesis cut-out y las ortesis con elemento estabilizador anterior (EEA) en la distribución de las presiones plantares y el desplazamiento del centro de presiones (CDP).
3. Evaluar el efecto de las ortesis cut-out y ortesis con EEA en la cinemática y cinética del pie.
4. Investigar la relación entre las ortesis cut-out y las ortesis con EEA en la rigidez articular.

Esta tesis comprende cuatro artículos científicos: una revisión sistemática y tres estudios cuasiexperimentales de medidas repetidas, con los cuales se dará respuesta a los objetivos planteados previamente.

Revisión sistemática.

El primer estudio que compone esta tesis es una revisión sistemática titulada "*Impacto de las cuñas frontales colocadas en el zapato y con el paciente descalzo sobre la carga plantar*". Esta revisión está registrada en el registro prospectivo internacional de revisiones sistemáticas (PROSPERO CDR 42020210082) y publicada en la revista "Gait and posture".

El objetivo principal de esta revisión fue analizar el efecto de diferentes tipos de cuñas colocadas tanto en el zapato como con el paciente descalzo en la distribución de la carga plantar en el pie humano. El propósito era determinar si la adición de elementos externos al pie provoca un cambio o redistribución de las presiones plantares.

Hipótesis.

- La hipótesis principal de esta revisión fue que las cuñas colocadas medialmente provocan un desplazamiento medial de la línea de marcha y un aumento de la fuerza vertical en las regiones de interés situadas medialmente.
- La segunda hipótesis fue que la fuerza máxima de impacto se ve alterada tras la utilización de cuñas en el plano frontal.

Se realizó una búsqueda en las siguientes bases de datos: PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Scopus y Prospero. Todos los artículos incluidos fueron estudios observacionales (cross-over), ensayos clínicos aleatorizados (ECA) y estudios cuasiexperimentales. Se aplicó una estrategia de búsqueda sistemática

basada en los criterios PRISMA desde la fecha de la primera publicación hasta mayo de 2020. Los estudios fueron seleccionados de acuerdo con la siguiente pregunta PICO:

- **Participantes:** Todos los participantes eran adultos (mayores de 18 años), con o sin patologías. Se excluyeron aquellos estudios que incluyeran participantes que habían sido sometidos a cirugía. No hubo ninguna restricción en cuanto al género o etnia de los participantes.
- **Intervención:** Se incluyeron todos los tipos de cuñas posibles, fabricadas a mano o no, con ortesis que incluían arco longitudinal interno o sin él, y con o sin otros elementos en la ortesis plantar, como bandas metatarsales. Esto incluía cuñas en varo o valgo, cuñas laterales o mediales, de antepié o retropié, independientemente del material utilizado o del método de producción. Únicamente se excluyeron los artículos que estudiaban cuñas integradas en el exterior de la suela del zapato.
- **Comparación:** Se incluyeron estudios que analizaran el denominado "análisis dosis-respuesta" (por ejemplo, estudios que incluyeran diferentes grados de cuñas) o los que compararan las condiciones con cuñas con una plantilla plana o sin plantilla. Los artículos que estudiaban cuñas junto con otros elementos, como una rodillera, solo se incluyeron si los resultados relativos a las condiciones con cuña podían extraerse de forma independiente.
- **Herramienta de medida:** Se incluyeron estudios que utilizaran herramientas de medida como plataformas de presión, plataformas de fuerza o sistemas de análisis de plantillas instrumentalizadas dentro del calzado, siempre que estudiaran alguna de las siguientes variables: Centro de presiones (línea de marcha) y/o fuerza vertical (pico de fuerza, fuerza media, integral fuerza-tiempo) y/o datos de presiones (presión media, pico de presión, integral presión-tiempo) y/o datos de área (área de contacto) y/o superficie y/o variables relacionadas con el tiempo (contacto inicial, contacto final, duración del contacto, tiempo transcurrido hasta alcanzar el punto de máxima presión) en una región de interés específica.

Tras el proceso de búsqueda, se siguió un protocolo para la selección de los artículos de interés. En primer lugar, un autor revisó las citas y resúmenes obtenidos para identificar los artículos elegibles. A continuación, dos investigadores analizaron cada artículo en su totalidad para comprobar si cumplía con los criterios de inclusión. Debido a la

heterogeneidad de las poblaciones, el seguimiento de los pacientes y los resultados incluidos en estos estudios no fue posible realizar un metaanálisis.

De la búsqueda inicial, se seleccionaron 11 artículos, de los cuales se extrajeron los siguiente datos para su análisis: autor, año, país, tipo de estudio, población, resultado, herramienta de medida, intervención, seguimiento y subdivisión del pie. Además, se realizó una evaluación de la calidad de los artículos utilizando la escala Newcastle-Ottawa para estudios observacionales, la herramienta Cochrane para ensayos clínicos aleatorizados y la escala TREND para estudios cuasiexperimentales.

Resultados.

De los once estudios seleccionados, tres fueron ensayos clínicos aleatorizados, cuatro fueron estudios observacionales y cuatro fueron estudios cuasiexperimentales. Se analizó una población total de 320 participantes, con una edad media que oscilaba entre 20 y 62 años, predominando los hombres (63,44%).

En cuanto al riesgo de sesgo, la mayoría de los artículos mostraron una calidad metodológica aceptable, aunque presentaron puntos débiles comunes, como el marco temporal considerado y las medidas adoptadas para optimizar el cumplimiento o la adherencia. Otros resultados deficientes se observaron en el análisis de los resultados, en áreas como la descripción de la desviación del protocolo original del estudio, el reclutamiento y los acontecimientos adversos. Ninguno de los estudios cumplió plenamente con estos requisitos. Además, la discusión y las implicaciones de los resultados también fueron inadecuadas.

Conclusión.

Tras un exhaustivo análisis de los resultados obtenidos, se concluyó que existen numerosas pruebas que sugieren que las cuñas en el plano frontal provocan una redistribución de la presión plantar.

Las cuñas laterales produjeron un aumento de la presión lateral del talón, y las cuñas mediales produjeron un aumento de la presión medial del talón. Además, las cuñas laterales o en valgo causaron un desplazamiento lateral del centro de presiones o línea de marcha, mientras que las cuñas mediales o en varo provocaron un desplazamiento medial de esta característica biomecánica.

Estas cuñas en el plano frontal pueden inducir aumentos de fuerza y presión en diferentes zonas del pie. Los estudios futuros deberán considerar cómo cambia el centro de presión en función de la distribución de la presión en el pie. En relación con la fuerza máxima de impacto (fuerza vertical de reacción al suelo), los resultados publicados fueron contradictorios y no se pudieron extraer conclusiones claras.

Este primer artículo sirve como introducción para comprender que los elementos externos en las ortesis plantares permiten desplazar el centro de presiones y alterar la distribución de las presiones plantares. Esto refuerza y justifica la realización de los estudios posteriores.

Estudios cuasiexperimentales de medidas repetidas.

Los tres artículos restantes fueron estudios cuasiexperimentales de medidas repetidas, que permitieron abordar los objetivos planteados previamente. Los artículos fueron:

1. El efecto directo de diferentes diseños de ortesis plantares en la carga plantar de pacientes con HLE: Un estudio cuasiexperimental.
 - Publicado en la revista “Applied Science”.
 - **Objetivo:** Investigar el efecto de las ortesis cut-out y ortesis con EEA en la distribución de presiones plantares en paciente con HLE.

2. Efecto de las ortesis plantares personalizadas en la cinemática y cinética del pie en pacientes con HLE.
 - Publicado en la revista “Sensor”
 - **Objetivo:** Analizar la función de las ortesis cut-out y ortesis con EEA en la mejora de la funcionalidad de la 1 AMTF.

3. El efecto de diferentes ortesis plantares personalizadas en la rigidez articular en pacientes con HLE: Un estudio cuasiexperimental.
 - Pendiente de publicación en la revista “Clinical Biomechanics”
 - **Objetivo:** Investigar la relación entre las ortesis cut-out y las ortesis con EEA en la rigidez articular.

En todos ellos se utilizó una metodología uniforme:

La población de estudio consistió en 24 pacientes con HLE. Los pacientes fueron reclutados en la Universidad de San Jorge (Zaragoza, Spain), en una clínica privada y en un centro de deportes en Zaragoza, desde octubre de 2021 hasta diciembre de 2022.

Criterios de inclusión.

- Pacientes entre 18 y 65 años.
- HLE ($< 60^\circ$ medido en descarga con un goniómetro).
- Test de Jack positivo.
- Test de Lunge positivo.
- FPI > 6 .

Criterios de exclusión.

- Pacientes con enfermedades neurológicas, sistémicas o alguna condición ortopédica.
- Pacientes que hubieran sufrido algún trauma en el pie o en la extremidad inferior antes del estudio.
- Incapacidad para caminar sin ayuda.

Intervención.

Se estudiaron dos tipos diferentes de ortesis plantares y se usó un calzado común para todos los participantes del estudio:

1. **Ortesis con EEA:** Hecha a medida mediante una técnica de adaptación en directo (TAD), utilizando cojines de vacío e incluyendo en su diseño un elemento estabilizador de antepié (EEA). Este elemento forma la parte anterior de la ortesis plantar, tiene forma de balancín y se extiende desde la zona metatarsal hasta los dedos.

Para la fabricación de esta ortesis se utilizó resina de poliéster con una combinación de podiaflex de 1,2 mm y podiaflux de 1,2 mm (Podiatech) para el retropié y el mediopié, y podiaflex de 0,8 mm para el EEA. Como cubierta, se utilizó un EVA (polietileno-vinílico) de 30 Shore A y 148 kg/m^3 de densidad.

2. **Ortesis cut-out:** Realizada en 3D utilizando la impresión de fusión multijet de HP. La huella plantar tomada para la elaboración de la ortesis anterior se digitalizó

usando Structure Sensor. El diseño incluía un arco longitudinal interno (al igual que la ortesis anterior) y una fenestración en la cabeza del primer metatarsiano, así como una extensión de EVA de 1 mm bajo el hallux. La ortesis se fabricó utilizando diversos materiales: poliamida 12 (PA 12) para la estructura principal y una combinación de EVA de 30 Shore A y 148 kg/m³ de densidad para la cubierta superior y el elemento colocado en la zona anterior de la ortesis.

3. **Calzado:** Calzado minimalista (calzado de neopreno SAGURO®) el cual permite el ajuste de las diferentes ortesis plantares y tiene un menor impacto mecánico en la función del pie.

Herramientas de Medida.

Para el análisis de la desviación del centro de presiones y la distribución de presiones plantares, se utilizó una plataforma de presiones (Podoprint® [Namrol Group, Barcelona, España] con 1600 sensores, un tamaño de 10x10 mm y un rango de presión por sensor de 0,4 N/m² a 100 N/m²).

Para el análisis de la cinemática y la cinética, se empleó un sistema de análisis de movimiento con 8 cámaras infrarrojas (VICON®) que funcionaba con una frecuencia de muestreo de 100 Hz.

Procedimiento.

Para el análisis de la cinética y cinemática se escogió un modelo multisegmento del pie, el modelo de Bruening, (Bruening et al., 2012) el cual divide el pie en tres segmentos: retropié, antepié y hallux y utiliza 20 marcas reflectivas colocadas en puntos anatómicos de referencia. (Rodilla lateral, rodilla medial, 4 marcas fijas a nivel de la tibia (marcas de seguimiento), maléolo medial, maléolo lateral, 2 marcas posteriores a nivel del calcáneo, calcáneo medial, calcáneo lateral, cuboides, escafoides, base primer metatarsiano, base de quinto metatarsiano, cabeza primer metatarsiano, cabeza 2º metatarsiano y 2 marcas a nivel del hallux (medial y dorsal).

Para la obtención de datos se siguió un protocolo preestablecido:

- En primer lugar, cada participante firmó un consentimiento informado.
- A continuación, se midieron las características antropométricas del pie del participante.

- Posteriormente, se colocaron todas las marcas reflectantes en las posiciones anatómicas de referencia siguiendo el modelo multisegmento del pie de Bruening. Las marcas se colocaron directamente sobre la piel del paciente.
- Se le pidió al participante caminar durante un periodo de tiempo de 5-10 min a velocidad normal, con el objetivo de que se familiarizase con las marcas y el calzado.
- Se colocó la plataforma de presiones en el centro de la sala, donde la imagen fuese mejor captada por las 8 cámara infrarrojas, las cuales estaban situadas en la zona superior de la sala, formando un círculo alrededor de la plataforma de presiones, para poder medir al participante desde todos los ángulos posibles. La plataforma se colocó en una posición y dirección concreta, siguiendo el protocolo descrito por Sanchís-Sales et al. (Sanchis-Sales et al., 2016).
- Para obtener los datos se siguió el protocolo de los tres pasos: Se colocó al participante a una distancia de la plataforma de presiones tal, que su tercer paso contactara con la plataforma. De esta forma, se intentó adoptar una velocidad similar en todos los sujetos de estudio.
- La trayectoria de las marcas se siguió usando un sistema optoelectrónico de 8 cámaras VICON Vero 2.2 y un software nexus para captar el movimiento (VICON®). En primer lugar, se llevó a cabo una sincronización de todas las cámaras y se estableció un eje de coordenadas común. Este proceso se repitió antes de cada una de las condiciones de estudio, para asegurar la sincronización constante. Se tomó antes de cada condición, una primera medida en estática y 10 medidas representativas en dinámica con cada una de las condiciones. Los datos cinéticos, cinemáticos y de presiones plantares se tomaron al mismo tiempo, sincronizando la grabación con las cámaras y la captación de las presiones a través de la plataforma de presiones.

Cada sujeto fue medido con 3 condiciones diferentes:

- Descalzo.
- Con el calzado minimalista y la ortesis cut-out.
- Con el calzado minimalista y la ortesis con EEA.

Se realizaron fenestraciones en el calzado, en las áreas anatómicas descritas por el modelo de Bruening. De esta forma, se evitaron dos posibles errores: por un lado, permitió colocar las marcas directamente sobre la piel del paciente, evitando el movimiento de las mismas

provocado por el propio movimiento de la tela del zapato. Por otro lado, permitió cambiar de condición sin tener que quitar y volver a poner cada una de las marcas, evitando, por tanto, que se colocaran en un lugar diferente al colocar una condición nueva.

El orden de colocación de las ortesis se realizó de forma aleatorio. Se tomaron tantas muestras como fueron necesarias hasta obtener 10 representativas (se consideró una muestra representativa cuando la imagen tenía una visualización óptima en la plataforma de presiones. En cuanto a la trayectoria de las marcas, se consideró válidas aquellas en las que no había pérdidas de ninguna de las marcas (Gaps), durante todo un ciclo de la marcha completo.

Procesamiento de datos y análisis.

1. **Para cumplir con los objetivos del primer artículo** “El efecto directo de diferentes diseños de ortesis plantares en la carga plantar de pacientes con HLE: Un estudio cuasiexperimental” se estudiaron una serie de variables:
 - **Presión máxima (g/cm²).**
 - **Radios de la presión máxima (Datos 0-D).**
 - **Desplazamiento del centro de presiones (anteroposterior y Mediolateral).**

Para el procesamiento de la presión máxima y los radios se realizó un mapeo semiautomático (SATM) de los campos pedobarográficos obtenidos utilizando el software Podoprint Namrol El SATM consistió en determinar ocho regiones de interés (ROI): hallux (T1), segundo dedo (T2), dedos menores (T3-T5), cabezas del primer y segundo metatarsiano (M1, M2), metatarsianos menores (M3-M5), mediopié (MF) y talón (H). Para llevar a cabo el SATM, se realizó una circunscripción manual de las ROI utilizando las herramientas gráficas del software. El procedimiento para la circunscripción manual incluyó los siguientes pasos: primero, se aisló la región correspondiente a la cabeza del primer metatarsiano (M1), luego la del segundo metatarsiano (M2) y los metatarsianos menores (M3-M5). A continuación, se aisló la región del hallux (T1), seguida de la del segundo dedo (T2) y los dedos menores (T3-T5). Finalmente, se aislaron las áreas correspondientes al mediopié (MF) y al talón (H). Se midió la presión máxima (g/cm²) asociada a cada una de estas ocho regiones de interés y se calcularon los radios de presión máxima entre el hallux y la cabeza del primer

metatarsiano, entre el primer y el segundo metatarsiano, y entre el primer metatarsiano y los metatarsianos menores.

Para los datos 0- dimensionales asociados a las 8 regiones de interés, se utilizó un análisis de varianza (ANOVA) unidireccional de medidas repetidas para evaluar las posibles diferencias entre las 3 condiciones. Para evaluar las posibles diferencias entre grupos en el caso de una prueba ANOVA significativa, se realizó un análisis post-hoc.

La segunda parte del procesamiento de datos consistió en exportar los datos del Centro de Presiones (CDP) de todas las pruebas pedobarográficas recogidas. Primero, se alinearon automáticamente todas las imágenes de cada muestra utilizando el software Podoprint Namrol. Posteriormente, los datos sobre las desviaciones (mediolaterales y anteroposteriores) de cada participante se exportaron manualmente e insertaron en una hoja de cálculo de Excel. Se estableció un sistema de coordenadas común para todos los participantes tomando una primera muestra como referencia. El punto más bajo en la primera fase del ciclo de marcha (fase de contacto con el talón) se consideró el origen del sistema de coordenadas. Este punto inicial no se tomó en cuenta debido a posibles influencias de otros factores como la grasa del talón y la capacidad de compresión de los tejidos. Se asumió que en este momento el talón está en contacto completo con el suelo, marcando el inicio de la fase de apoyo. Todos los datos de CDP restantes se ajustaron para que comenzaran en el mismo punto común, lo que permitió la comparación entre ellos y la definición adecuada del sistema de coordenadas. Este punto inicial también se utilizó como referencia para las desviaciones anteroposteriores. El proceso se repitió con cada participante y todos los datos se normalizaron en tiempo real (fase de apoyo al 100%) utilizando MATLAB 2021 (The Mathworks, US).

Las diferencias potenciales entre los perfiles de CDP asociados a las tres condiciones diferentes se evaluaron aplicando el ANOVA de medidas repetidas 1D SMP sobre las series temporales normalizadas. Si existían diferencias estadísticas, se utilizaron pruebas t post-hoc (SPM (t)) para determinar las diferencias entre condiciones.

2. **Para cumplir con el objetivo del segundo de los artículos** “Efecto de las ortesis plantares personalizadas en la cinemática y cinética del pie en pacientes con HLE” se estudiaron principalmente 2 variables:

- **Rotaciones articulares de tobillo, mediopié y 1º AMTF.**
- **Momentos articulares de tobillo, mediopié y 1º AMTF.**

Las coordenadas 3D de los marcadores se utilizaron para determinar la posición y orientación de los segmentos del pie en cada instante. A partir de la postura de referencia estática erguida del participante, se calcularon los ángulos articulares en una posición relajada. Esta postura se registró al inicio del experimento. Los ángulos articulares se derivaron usando una secuencia de rotación de ángulos de Cardan, abarcando dorsiflexión/plantarflexión, abducción/aducción e inversión/eversión. Para asegurar la precisión, los datos cinemáticos se filtraron con un filtro Butterworth de cuarto orden a 10 Hz.

La plataforma de presión se sincronizó con un sistema de cámaras infrarrojas para medir la distribución de la presión a 100 Hz. Los datos de presión se segmentaron para asignar la presión de cada sensor al segmento correspondiente del pie. Se calcularon los componentes normales de las fuerzas de reacción del suelo y los centros de presión para cada fotograma, y los momentos articulares tridimensionales se calcularon a partir del producto cruzado de las fuerzas de reacción y las distancias entre los centros de presión y los centros de rotación de las articulaciones, siguiendo el método de Bruening et al. El efecto del peso del pie, junto con la velocidad angular y las aceleraciones, se descartó en el cálculo de los momentos articulares. Los momentos de flexión articular se expresaron como porcentaje de la fase de apoyo del ciclo de marcha y se normalizaron en relación con el peso corporal. Los datos cinéticos se filtraron con un filtro Butterworth de cuarto orden a 50 Hz.

Las rotaciones articulares 3D medias y los momentos articulares a lo largo de la fase de apoyo de la marcha se compararon entre condiciones utilizando ANOVA de mapeo paramétrico estadístico unidimensional (SPM(F)), seguido de pruebas t post-hoc (SPM(t)). En los casos en que los clústeres de SPM(F) superaron el umbral crítico, se emplearon pruebas t emparejadas (SPM(t)) para comparar las condiciones. Todos los análisis SPM1D se realizaron utilizando el código SPM1D de código abierto (v.M0.1, www.spm1d.org) en MATLAB (R2021a, 8.3.0.532, The MathWorks Inc., Natick, MA).

1. **Para cumplir con el objetivo del tercer artículo** “El efecto de diferentes ortesis plantares hechas a medida en la rigidez articular en pacientes con HLE: Un estudio cuasiexperimental” se estudiaron varias variables:
 - **Rotaciones 3D de la articulaciones.**
 - **Momentos de las articulaciones.**
 - **Rigidez dinámica de la articulación.**

Se compararon las rotaciones tridimensionales medias de las articulaciones y los momentos articulares a lo largo de la fase de apoyo de la marcha utilizando un ANOVA paramétrico estadístico unidimensional.

Resultados.

- **Presión máxima.**

Tras el análisis de la distribución de las presiones máximas se observó que con las ortesis con EEA se produjo un aumento de la presión en el segundo dedo, las cabezas de los metatarsianos menores, mediopié y retropié en comparación con el paciente descalzo.

Las ortesis cut-out provocaron una disminución de la presión en el segundo metatarsiano y dedos menores, así como un incremento de la presión en mediopié y talón comparado con el paciente descalzo.

- **Radios de la presión máxima.**

Se encontraron diferencias significativas en los radios entre las 3 condiciones. Tanto las ortesis con EEA como las ortesis cut-out se caracterizaron por un menor radio entre el hallux y la cabeza del primer metatarsiano en comparación con el paciente descalzo. Además, se observó una disminución del radio con las ortesis cut-out en comparación con las ortesis con EEA. Por otro lado, se observó un aumento del radio entre la primera y la segunda cabeza metatarsiana, así como entre la cabeza del primer metatarsiano y los dedos menores con las ortesis cut-out en comparación con las ortesis con EEA y el paciente descalzo.

- **Centro de presiones.**

Con respecto al centro de presiones, el análisis mostró que tanto la ortesis cut-out como la ortesis con EEA provocaron un desplazamiento medial del centro de presiones durante la fase de medioapoyo en comparación con el paciente descalzo.

En el caso del desplazamiento anteroposterior del CDP, el análisis mostró que las ortesis cut-out estaban asociadas a un mayor desplazamiento anterior del centro de presiones durante la fase de medioapoyo y la fase de pre-oscilación mientras que las ortesis con EEA presentaron un mayor desplazamiento anterior del centro de presiones únicamente en la fase de medioapoyo en comparación con el paciente descalzo.

La comparación entre condiciones mostró que las ortesis con EEA presentaban un mayor desplazamiento anterior del centro de presiones durante la fase de respuesta a la carga y medioapoyo en comparación con las ortesis cut-out.

- **Cinemática (Rotaciones articulares).**

- **Tobillo.**

Se observó una mayor plantarflexión del tobillo en la fase de propulsión y la fase de contacto inicial con el paciente descalzo en comparación con la ortesis cut-out y la ortesis con EEA.

Además, se constató una diferencia significativa también en el plano frontal. Tanto la ortesis con EEA como la ortesis cut-out provocaron una disminución de la inversión del tobillo en comparación con el paciente descalzo.

- **Mediopié.**

El análisis estadístico reveló un mayor grado de plantarflexión del mediopié durante la propulsión con el paciente descalzo en comparación con las ortesis cut-out y las ortesis con EEA.

En el plano frontal, las ortesis cut-out mostraron una mayor eversión durante la fase de medioapoyo. En el plano transversal, se encontraron diferencias significativas entre el paciente descalzo y ambas condiciones de estudio. El paciente descalzo se caracterizó por un mayor grado de aducción.

- **1ª AMTF.**

En primer lugar, en el plano sagital, el paciente descalzo presentaba un mayor grado de dorsiflexión en comparación con ambas condiciones, especialmente en la fase de propulsión. Las ortesis cut-out mostraban una dorsiflexión más temprana en comparación con las ortesis con EEA durante la última fase del ciclo de la marcha.

Esta articulación presentaba una mayor eversión en las fases de respuesta a la carga y la fase de propulsión con el paciente descalzo en comparación con ambas condiciones de estudio.

En el plano transverso la articulación mostró un mayor grado de abducción con el paciente descalzo en comparación con las ortesis cut-out y ortesis con EEA.

- **Cinética (Momentos articulares).**

- **Tobillo.**

En el plano sagital, las ortesis cut-out y la ortesis con EEA mostraron un mayor momento dorsiflexor durante la fase de medioapoyo y la fase terminal del ciclo de la marcha en comparación con el paciente descalzo.

En el plano frontal, el paciente descalzo se caracterizó por un mayor momento de inversión en comparación con la ortesis cut-out y ortesis con EEA.

- **Mediopié.**

En el plano frontal, el análisis mostró una diferencia significativa entre las ortesis cut-out y el paciente descalzo y las ortesis con EEA. Las ortesis cut-out mostraron una reducción significativa del momento eversor en el mediopié.

- **1ª AMTF.**

A nivel de la primera articulación metatarsofalángica se observaron diferencias en el plano sagital, donde se evidenciaba un mayor momento dorsiflexor del hallux con las ortesis con EEA y las ortesis cut-out.

- **Rigidez.**

El análisis demostró que tanto las plantillas con EEA como las plantillas cut-out provocaron un aumento de la rigidez articular.

Discusión.

El propósito principal de este estudio fue examinar el impacto de dos tipos de ortesis plantares en la cinética y cinemática del pie, así como en la distribución de las presiones plantares y el desplazamiento del CDP en pacientes con HLE.

A pesar de la relevancia de esta patología, que provoca compensaciones no solo en el pie sino en todo el cuerpo, sigue siendo un área poco investigada. La literatura sobre el efecto

de los diferentes tratamientos es limitada y no hay consenso sobre el tratamiento conservador más efectivo para evitar estas compensaciones y mejorar la calidad de vida de los pacientes. Aunque abundan los estudios que abordan el desarrollo y las consecuencias del HL, pocos autores han investigado de manera conjunta el efecto de los tratamientos en la distribución de las presiones plantares y en la cinética y cinemática del pie, dejando así un amplio campo de estudio sin explorar.

Con esta tesis doctoral se pretende abordar estas cuestiones mediante una revisión sistemática y tres estudios cuasiexperimentales.

La revisión sistemática fue clave para establecer las bases de la investigación. Antes de estudiar el efecto de varios elementos en las presiones plantares, era necesario comprobar si cualquier elemento externo, como la colocación de cuñas o posteados, alteraba dichas presiones. Los resultados de esta revisión fueron claros: Las cuñas laterales provocan un desplazamiento lateral del CDP acompañado de un aumento de las presiones en esta misma zona y las cuñas mediales provocan un desplazamiento medial del CDP acompañado de un aumento de presiones en la zona medial. Siendo el CDP una representación espacial de la distribución de las presiones a lo largo del tiempo es lógico que un desplazamiento lateral o medial se traduzca en un aumento de presión en dichas áreas.

Este hallazgo guio la selección del tratamiento para los estudios de investigación posteriores, permitiendo controlar la influencia de elemento externos. De esta forma, se decidió emplear ortesis sin correcciones en el retropié para asegurar que los efectos observados fueran debidos únicamente a los elementos de estudio. Además, la heterogeneidad en la elección del calzado observada en los estudios revisados llevó a optar por un calzado minimalista común para todos los sujetos, reduciendo así su influencia en las variables analizadas. Finalmente, la realización de esta revisión nos sirvió como guía para conocer la metodología de otros autores y poder así seguir un protocolo similar.

El primer estudio investigó el efecto de dos tipos de ortesis plantares en la redistribución de las presiones plantares en pacientes con HLE. La novedad de este artículo radica en que no solo se midió el desplazamiento del CDP, sino que además se aportó una explicación objetiva. Los resultados mostraron que ambas ortesis provocan un desplazamiento medial y anterior del CDP en comparación con el paciente descalzo.

Con las ortesis cut-out se observó un desplazamiento lateral y anterior del centro de presiones, explicado por una disminución de las presiones en los dedos menores y hallux y un aumento de cargas en la cabeza del primer metatarsiano. Solo un estudio en la literatura mostró resultados similares en cuanto a la distribución de las presiones plantares, el resto de literatura encontrada difiere con nuestros resultados, sin embargo, la metodología usada, así como el diseño de la ortesis plantares varía ligeramente con respecto a nuestro diseño (añadiendo elementos externos como cuñas de corrección de retropié, elementos amortiguadores a nivel de la cabeza del primer metatarsiano, o utilizando como población de estudio pacientes con dolor), motivos que explicarían la diferencia en los resultados. Las ortesis con EEA mostraron un mayor enfoque en el desplazamiento anterior del centro de presiones, lo que sugiere una mejora en la propulsión del paciente, aspecto beneficioso en pacientes que presentan esta patología, donde esta fase de la marcha se ve comprometida, ayudando a disminuir las compensaciones provocadas por la misma. Estudios previos, han demostrado que las ortesis cut-out producen un aumento de la velocidad del desplazamiento anterior del CDP.

Estos hallazgos sugieren que las ortesis plantares son realmente efectivas en la distribución de las presiones plantares, y podrían ayudar a disminuir el dolor en pacientes sintomáticos, ya que provocan una disminución de la presión máxima en aquellas zonas donde el HL las aumentas, y las cuales suelen ser zonas de dolor o conflictivas en pacientes que presentan esta patología.

No obstante, queda por determinar si este cambio en las presiones se debe a una mejora en la funcionalidad de la 1ª AMTF o simplemente a la presencia de materiales blando en las ortesis que amortiguan y redistribuyen las carga.

A partir de estos resultados, se desarrolló el segundo estudio de investigación, cuyo objetivo principal es examinar el impacto de estas dos ortesis plantares en la cinética y cinemática del pie en pacientes con HLS. Este estudio aporta información novedosa no solo sobre 1ª AMTF durante la marcha, sino también sobre la interacción con otras articulaciones del pie, proporcionando una visión más completa del comportamiento del retropié, mediopié y la 1ª AMTF en las distintas fases del ciclo de la marcha y en los tres planos del espacio.

Los resultados obtenidos fueron sorprendentes, mostrando una disminución de la inversión del tobillo y mediopié, así como en la plantarflexión del tobillo tanto con las

ortesis cut-out como con la ortesis con EEA. Además, en relación con la 1ªAMTF, se observó un aumento de la dorsiflexión de la misma con el paciente descalzo, lo que sugiere que las ortesis plantares provocan una disminución en movilidad de las articulaciones estudiadas. Esto contrasta con nuestra hipótesis inicial y también difiere de la literatura encontrada, en la que se observa que las ortesis cut-out provocan un aumento del ángulo de declinación del primer metatarsiano, aumentando la dorsiflexión de la primera articulación metatarsofalángica. Sin embargo, el estudio está realizado en pacientes con HLF y no con HLE, lo que podría ser el factor que haga que los resultados difieran.

La disminución de la dorsiflexión en la 1ª AMTF podría explicar la reducción en la inversión del retropié y el mediopié, dado que esta articulación juega un papel crucial en la fase de propulsión de la marcha al activar el mecanismo de Windlass. Si la dorsiflexión no ocurre adecuadamente, el mecanismo de Windlass no se activa correctamente, lo que resulta en una menor inversión de dichas articulaciones. Por lo tanto, no podemos asegurar que las ortesis estudiadas aumenten la funcionalidad del primer radio, ni que el cambio en la distribución de las presiones plantares observados en nuestro primer estudio se deba a una mayor dorsiflexión de la 1ª AMTF, tal y como se planteó al principio de esta tesis doctoral.

Existen dos posibles HLE, lo que implica que la patología ya involucra un proceso artrósico a diferencia del HLF. Estos pacientes podrían beneficiarse más de elementos que favorezcan la propulsión, sin centrarnos tanto en aumentar la funcionalidad del dedo. En segundo lugar, el calzado minimalista empleado podría haber interferido en la correcta adaptación de las ortesis al pie, afectando a los resultados.

El tercer estudio se centró en evaluar la rigidez articular con el uso de ortesis, dado que los estudios anteriores indicaban una menor movilidad de las articulaciones con ambas condiciones, pero un mayor momento articular.

Este estudio mostró que, efectivamente, ambas ortesis provocaban un aumento de la rigidez de retropié, mediopié y 1ª AMTF. Este aumento de la rigidez puede interpretarse como un signo de mejora de la eficiencia energética. Autores anteriores han demostrado que los pacientes con pies pronados presentan una menor rigidez articular, provocando, a nivel biomecánico, una disminución de la eficiencia energética. Esto refuerza aún más la hipótesis planteada anteriormente, donde se destacaba que las ortesis estudiadas

provocaban un aumento de la propulsión, ahora demostrado además de por ese aumento de la velocidad y desplazamiento anterior del centro de presiones, por un aumento de la rigidez de la articulación y por tanto una mejora de eficiencia energética del paciente en esta última fase de la marcha. Además, este aumento de rigidez podría proporcionar una mayor estabilidad a los pacientes.

En conclusión, las ortesis con EEA mejoran la propulsión y la eficiencia energética en pacientes con HLE, mientras que las ortesis cut-out son más efectivas para redistribuir las presiones plantares. Sin embargo, no se ha podido demostrar una mejora en la funcionalidad de la 1ª AMTF. Esto subraya la importancia de individualizar el tratamiento según las necesidades del paciente, considerando si se busca mejorar la estabilidad, la propulsión o la redistribución de las presiones plantares.

Limitaciones y prospectiva.

A pesar de los importantes hallazgos encontrados durante todo el desarrollo de esta tesis doctoral, estos estudios presentan varias limitaciones. En primer lugar, la falta de bibliografía encontrada, especialmente en relación con el EEA, ha dificultado la comparativa entre estudios. Por otra parte, la muestra utilizada en cada uno de los estudios es relativamente pequeña, lo que impide generalizar los resultados. Y, por último, la falta de seguimiento a largo plazo para evaluar los efectos sostenidos de las plantillas.

Entre las fortalezas cabe destacar que es la primera tesis doctoral que compara el efecto de dos tipos diferentes de ortesis plantares en pacientes con HLE, estudiando el efecto tanto a nivel de desplazamiento del CDP y distribución de las presiones plantares como a nivel de cinemática y cinética del pie en varias articulaciones del mismo, en los tres planos del espacio en cada una de las fases del ciclo de la marcha, permitiendo una visión global del comportamiento del pie, abarcando todas las áreas de estudio y estudiando su funcionalidad.

Futuras investigaciones deberían estudiar el efecto a largo plazo, usando un calzado diferente al utilizado en este estudio, el cual tenga otra forma o material que permita un correcto acople de las ortesis al pie. Además, sería interesante profundizar más en el efecto observado en las ortesis en cuanto a la rigidez de las articulaciones, ya que no existen artículos previos que aborden este tema en esta patología en concreto. Y, además, realizar más estudios de investigación con este nuevo elemento, el EEA, ya que ha demostrado su efectividad en pacientes con HLE.



INTRODUCTION.

1. ANATOMY.

1.1 Anatomy of the first ray.

Some authors argue that the first metatarsal and the medial cuneiform constitute the osseous components of the first ray (W M Glasoe, 1999) while other assert that the first ray encompasses the anatomical joints between the first metatarsal, the medial and intermediate cuneiforms (Hild & McKee, 2011) and the navicular bone.

In comparison with the other metatarsals, the first metatarsal has a unique configuration (Elsaid A, 2006). It is characterized by its greater thickness, being the thickest and shortest of the metatarsal (W M Glasoe, 1999). Additionally, the diaphysis has an almost cylindrical shape, with the same perimeter as the epiphyses, providing it with greater mechanical resistance (Antonio Viladot Voegeli, 2011).

The head of the first metatarsal has two different articular surfaces: The upper surface, (which articulates with the proximal phalanx forming the metatarsophalangeal joint) is convex and wide, extending to the dorsal aspect of the metaphysis (Nery et al., 2020). The lower surface, which is larger than the upper surface, is divided into two separate joints by an anterior-to-posterior-directed crest where the sesamoids are located. This surface is generally found at the junction of the lateral third and the two medial thirds of the articular surface (Lucas & Hunt, 2015) (Figure 1).



Figure 1. First metatarsal head (Image created by the author).

The first ray contributes to a great extent to the normal mechanics of the foot, and structural or functional alterations of the first ray may be an etiologic factor in various foot disorders (W M Glasoe, 1999).

1.2 First metatarsophalangeal joint.

The first metatarsophalangeal joint (1st MTPJ) comprises four bony segments, including the first metatarsal, proximal phalanx, and the tibial and lateral sesamoid, all enclosed within a synovial capsule (Hild & McKee, 2011). There are two sesamoids located in this capsuloligamentous complex. They are elliptical in shape and approximately the size of a sesame seed. The medial sesamoid, or tibial sesamoid, is generally longer and more ovoid, while the lateral sesamoid is smaller, rounder, and located more proximally (Lucas & Hunt, 2015). Each is within a fibrocartilaginous structure-the glenosesamoid pad-strongly adhered to the base of the proximal phalanx of the hallux. The sesamoids in this joint are intracapsular and slide anteriorly and posteriorly (Rosenbaum De Britto, 1982).

This joint is of the arthrodial and hinge type, with the hinge movement occurring during the first 20/30° of dorsiflexion and the arthrodial or sliding movement occurring during the rest of the propulsion. Described as a hammock, this joint cradle and rolls the head of the first metatarsal (Hild & McKee, 2011).

The 1st MTPJ is intrinsically unstable, relying on its soft tissue complex to maintain stability. Only a small part of this instability is attributed to the joint's shape, with the shallow cavity of the proximal phalanx articulating with the convex surface of the first metatarsal (Waldrop, 2021). This complex supports between 40-60% of the body weight during the gait cycle.

Perhaps the most crucial structure providing stability to the first metatarsophalangeal joint is the plantar plate (De Maeseneer et al., 2018).

The plantar plate can be divided into four portions: (the central portion of the plantar plate and the intersesamoid, sesamoid-phalangeal, and metatarsosesamoid ligaments) (Wang et al., 2021). The fibrocartilaginous pad of the 1st MTPJ is inseparable from the plantar capsule and all the previously mentioned structures, forming what is known as the capsuloligamentous complex of the plantar plate (Hallinan et al., 2020).

Among the musculature of the 1st MTPJ we find: The extensor hallucis longus, (Hild & McKee, 2011), (Iriarte Posse I, 2020), (Armen S. Kelikian, 2011), (Gilroy Anne M.M, 2007) the extensor digitorum brevis (Armen S. Kelikian, 2011), the abductor of the hallux (Bayer et al., 2014), the adductor hallucis (Gilroy Anne M.M, 2007.), the flexor hallucis brevis, the flexor hallucis longus (Armen S. Kelikian, 2011), the long lateral peroneus and tibialis anterior (De Maeseneer et al., 2018), (Gilroy Anne M.M, 2007.).

Table 1 and Figure 2 show a summary of the ligaments and muscles comprising the plantar plate complex.

Table 1. Summary of the ligaments and muscles comprising the plantar plate complex (Table created by the author).

Anatomical structure	Characteristics
Plantar plate	Fibrous Band extending from the metatarsal head to the proximal phalanx.
Sesamoids	Small Ossifications inserted in the metatarsal head.
Intersesamoid ligament	Transverse ligament that runs between the tibial and peroneal sesamoids.
Metatarso-sesamoids ligaments (medial and lateral)	Thickened portions of the plantar capsule that can sometimes be difficult to distinguish from it. It originates proximally on the plantar surface of the neck of the first metatarsal along with the capsule and distally on the undersurface and edges of the sesamoids.
Phalangeal-sesamoid ligaments (medial and lateral)	It extends from the distal area of the sesamoid to the base of the proximal phalanx.
Principal collateral ligament (medial and lateral)	It originates from the medial/lateral area of the metatarsal head and inserts into the medial/lateral area of the proximal phalanx.
Accessory collateral ligaments (medial and lateral)	They originate from the same area as the main ligaments, extending to the periphery of the sesamoid bones.
Medial head of the short flexor tendon	From the medial plantar tubercle to the base of the proximal phalanx of the hallux.
Lateral head of the short flexor tendon	From the lateral plantar tubercle to the base of the proximal phalanx of the hallux.
First ray abductor	From the medial plantar tubercle to the base of the proximal phalanx of the hallux (along with the flexor).
First ray adductor	From the medial plantar tubercle to the base of the proximal phalanx of the hallux (together with the flexor).

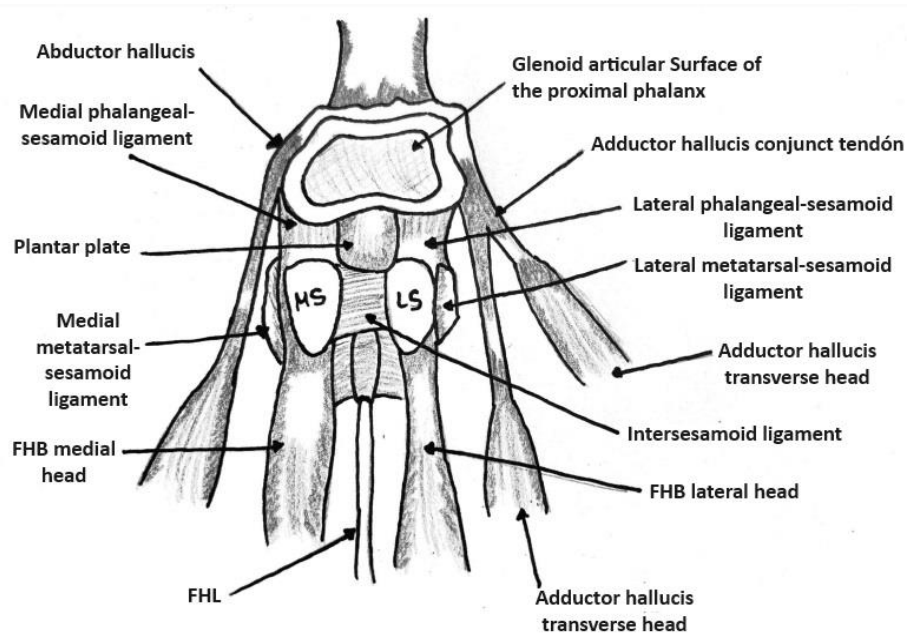


Figure 2. Plantar plate complex. Adaptated of (Nery et al., 2020). (Image created by the author).

1.3 Plantar fascia.

It is a thick band of connective tissue that originates from the calcaneus and insert into the metatarsal bones (Figure 3). In anatomical dissections, the plantar fascia appears as a shiny, pearly white layer of fibrous bundles a few millimetres thick, tapering in a proximal-distal direction, with an elastic and viscous consistency to the touch (Stecco et al., 2013). It is formed by a network of compacted collagen fibers, most of which appear oriented longitudinally, although some appear transversely (Campo Soage, 2020). The plantar fascia is 2-6 cm thick at its proximal and distal ends and 12 cm long from the medial tubercle to the metatarsophalangeal joint.

The fascia contributes to the receptive and propulsive behaviour of the foot joints and has an essential role in the (re)positioning of the foot joints. It has the capacity for elastic stretching with return to its initial length, therefore, it contributes to creating a “hydraulic” damping effect and a “spring” propulsion effect (Damiano, 2017). The biomechanics of the plantar fascia has been widely studied, since it plays a fundamental role during the gait cycle, helping, together with the first ray, the propulsion of the foot and advancement of the body, enhancing what is known as the Windlass mechanism (Hicks, 1954).

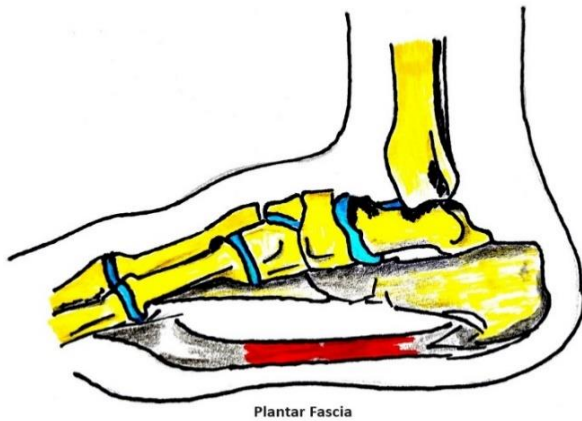


Figure 3. Plantar fascia (Image created by the author).

2. KINEMATICS OF THE FIRST RAY.

2.1 Axis of movement of the first ray.

From a functional point of view, the first ray presents movement based on two joints: Cuneo- metatarsal (CM) and metatarsophalangeal (MTP) (Antonio Viladot Voegeli, 2011).

Hicks, (Hicks JH, 1954) was the first to describe a single axis of motion, which ran across the dorsum of the foot over the base of the third metatarsal to the navicular tuberosity. This was supported and later described by Root, who describe an axis of movement that passes from the proximal dorsal medial aspect of the talo-navicular joint to the distal plantar lateral aspect of the cuneiform joint of the third metatarsal, forming an angle of approximately 45° in the sagittal and frontal planes and an angle of just 5° in the transverse plane (Hild & McKee, 2011; Prats Climent Baldiri & Vergés Salas Carles, 1998) (Figure 4).

This leaves the first ray a very small range of motion through the CM joint in its transverse plane, and although it presents a triplane movement, it performs its movement mainly in the sagittal and frontal plane. The orientation of this axis causes an arc-shaped rotary movement to occur, meaning that when the first metatarsal moves in dorsiflexion it simultaneously performs a supination movement and when it moves in plantar flexion it performs pronation (Glasoe et al., 1999). The amplitude of these two movements is equivalent, establishing approximately 6 mm. They are important especially during walking, to absorb the ground reaction forces during the full support phase (dorsiflexion),

and to keep the entire forefoot under load when the foot performs an inversion movement (plantar flexion) (Blasco García Carlos et al., 2010.).

The 1st MTPJ, for its part, has two axes of movement, one vertical and the other transverse, passing through the neck of the metatarsal. In the transverse plane this joint performs abduction and adduction movements which, because it is very small, has no functional significance. While in the sagittal plane it presents wide flexion and extension movements, essential for walking (Antonio Viladot Voegeli, n.d.; Uroz Alonso, 2008).

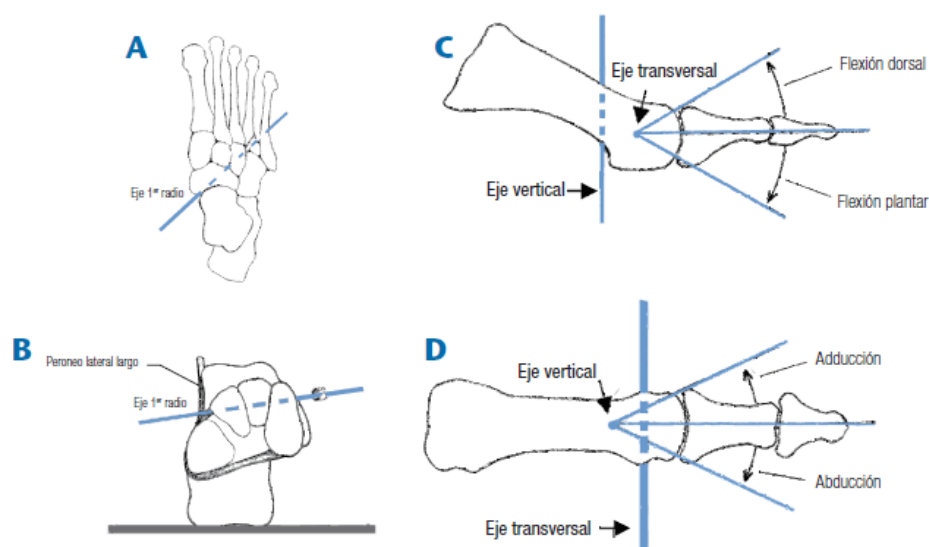


Figure 4. Axes of movement of the first ray.

Source: Antonio Viladot Voegeli. (n.d.).” Bases anatómicas y funcionales del primer radio” Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License.

2.2 Range of motion of the 1st ray and 1st MTPJ.

Because of the number of joints that participate in the mobility of the 1st ray, it is sometimes difficult to quantify its mobility, and there is no clear consensus among authors (Távora-Vidalón et al., 2017).

In a clinical context, the range of motion of the 1st ray is typically quantified in mm and not in degrees, since the proximal segments of this functional unit are small (Teresa Angulo Carrere Ana Álvarez Méndez, 2009). Some authors show a lack of agreement regarding the mobility of the 1st ray and how to measure it (López del Amo Lorente et al., 2013). Different methods have been used for this, with manual examination being the

test most used by podiatrists (Távora Vidalón, Lafuente Sotillos, Manfredi Márquez, et al., 2021).

Root, (Leveau, 1979) describes a manual exploration manoeuvre to determine maximum dorsiflexion and plantarflexion, which is what is currently used. With one hand, and in the form of a clamp, the clinician holds the heads of the second to fifth metatarsals, and with the other hand, he holds the head of the first metatarsal. Starting from the neutral position (defined as those in which all the metatarsal head are at the same height), the head of the first metatarsal is moved upwards to its maximum range of dorsiflexion and downwards, to its maximum range of plantarflexion (Figure 5).

Some authors have determined that the movement of this first ray in the sagittal plane is 5.91 ± 0.33 mm of dorsiflexion and 4.92 ± 0.36 mm of plantarflexion with a total range of movement of 10.84 ± 0.54 mm. In the frontal plane, the movement is 2.67 ± 0.52 degrees of inversion during dorsiflexion and 2.97 ± 0.36 degrees of eversion during plantarflexion with a total range of 5.63 ± 0.54 degrees of movement in the frontal plane (Távora Vidalón, Lafuente Sotillos, Manfredi Márquez, et al., 2021).



Figure 5. First ray manoeuvre (Image created by the author).

Due to the subjectivity of this manoeuvre, and the little consensus regarding the range of motion, numerous authors have developed tools to accurately measure the mobility of this joint complex (Glasoe & Michaud, 2019; Klaue et al., 1994; Munuera-Martínez et al., 2020).

The device designed by Klaue (Klaue et al., 1994) consists of a modification of an ankle-FO, which consist of an aluminium plate at the heel level and two parallel metal plates,

to which a clinical measuring device (micrometre) is accommodated at the level of the head of the first metatarsal to be able to measure this movement.

In the case of Glasoe (Glasoe & Michaud, 2019), the device consists of a metal box in which the rearfoot and leg are fixed with a boot on its front part. It is made up of a part that fixes the second to fifth toe and another that mobilized the 1st metatarsal only in dorsiflexion, measuring it using an electrical position sensor.

These devices had problems such as being too large and difficult to use, not measuring plantarflexion, or not taking into account this combination of inversion/eversion movements when plantarflexion/dorsiflexion occurs. As a consequence of this, Munuera-Martinez and co-workers designed an instrument that overcomes a majority of the previously mentioned deficiencies, with which it allows us to quantify the amount of movements, taking into account the two planes of movements and that is also small and easy to use (Munuera-Martínez et al., 2020).

The device consists of two parts joined in the central part, thus allowing movement between them. It has a lower, horizontal part that is placed on the head of the 1st metatarsal and in its upper part, vertically, a millimeter ruler (Figure 6) (Távora Vidalón, Lafuente Sotillos, & Munuera-Martínez, 2021). These authors show a good validity of this device, demonstrating good agreement with radiographic measurements. In addition to good to excellent intra- and inter-pair reliability (Munuera-Martínez et al., 2020).

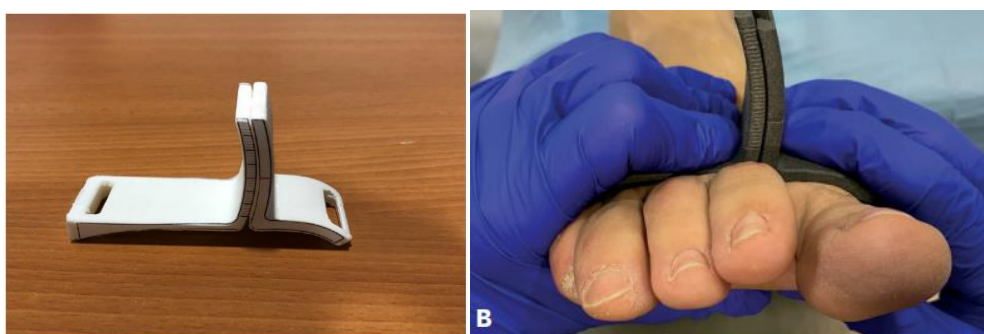


Figure 6. New device for 1st ray measurement.

Source: Pedro V. Munuera-Martínez 1, * Priscila Távora-Vidalón 1, Manuel A. Monge-Vera 2, Antonia Sáez-Díaz 3 and Guillermo Lafuente-Sotillos 1, “The Validity and Reliability of a New Simple Instrument for the Measurement of First Ray Mobility,” *Sensors*, 20(8), 2020. Distributed under the Creative Commons Attribution (CC BY) license.

In the case of the 1st MTPJ, we can assess its mobility both in weightbearing and non-weightbearing conditions.

For its non-weightbearing assessment, a two-branch goniometer is used (measuring instrument formed by two mobile branches, which join at a centre of rotation) (Toboadela, 2007). With the patient in a non-weightbearing position, and with the foot in a relaxed position, the centre of the goniometer is placed right in the centre of the head of the 1st metatarsal. One of the branches (which will act as a fixed branch) is placed on the bisector of the 1st metatarsal, fixing it with one hand. The other branch (which act as a mobile branch) is placed on the bisector of the proximal phalanx. From this position, the mobile branch of the goniometer, together with the finger, will be brought to its maximum extension, thus measuring the mobility of this segment (Figure 7) (Halstead et al., 2005; López del Amo Lorente et al., 2013; Távara Vidalón, Lafuente Sotillos, & Munuera-Martínez, 2021; Vicente de la Puente, 2014). It is important to note that the branch will be placed on the bisector of the proximal phalanx, and not on the bisector of the entire finger.



Figure 7. Assessment of the 1st MTPJ in a non-weightbearing position (image created by the author).

The normal values for flexion and extension of this 1st MTPJ are 45° of plantarflexion and 70-90° of dorsiflexion (Toboadela, 2007; Vicente de la Puente, 2014).

However, there is no clear consensus among the authors regarding the degrees of normality of the extension of the 1st MTPJ, causing a disparity in results (López del Amo Lorente et al., 2013) (Table 2).

Table 2. Measurement in Degrees of the 1st MTPJ.

Source: López del Amo Lorente, Andrés; Cintado Reyes, Raquel; Munuera Martínez, Pedro Vicente; González Úbeda, Rafael; Salcini Macías, José Luis, “¿Cuál es el protocolo de exploración más adecuado a la hora de valorar la primera articulación metatarsofalángica?”, *Revista española de podología*, 24 (1), 25-29. Licencia CC BY-NC-ND 4.0 Internacional.

PREVIOUS STUDIES	DORSIFLEXION OBTAINED
Burell, Green, and Risser (1989)	82°
Bojsen-Moller, Lamoreux (1979)	50°-60°
Gerbert (1989)	60°-65°
Joseph (1954)	75°
Mann and Hagy (1979)	70°-90°
Root, Orien, and Weed (1977)	65°-75°
Sgarlato (1971)	50°-60°
Buell (1988)	77°

On the other hand, it is estimated that at least 60-65° of dorsiflexion is necessary for correct propulsion in the final phase of walking (Leveau, 1979; Lopez del Amo Lorente, 2011).

In addition to a non-weightbearing assessment, the mobility of the 1st MTPJ can be done statically, with the patient in a weight-bearing and standing position (Lopez del Amo Lorente, 2011; López del Amo Lorente et al., 2013).

For static measurements, the protocol described by Munteanu is used (Munteanu & Bassed, 2006). To do this, the patient will be placed in a weight-bearing position, and a two-branches goniometer will be used, as in the previous case, to assess its passive movement. One of the branches (which will act as a fixed branch) will be placed on the bisector of the metatarsal, and the other (mobile branch), next to the bisector of the phalanx. A dorsiflexion movement will then be performed through the proximal phalanx. (López del Amo Lorente et al., 2013; Munteanu & Bassed, 2006).

3. BIOMECHANICS OF THE FIRST RAY AND 1ST MTPJ IN HUMAN GAIT.

The human gait is defined as the form of movement in bipedal position in which bipodal and monopodal supports follow occur. (Dankloff C. et al., 1993.).

Each gait cycle is divided into two periods: Stance phase (which occupies 62% of the gait cycle) and swing phase (which occupies 38% of the gait cycle). It begins when the foot contacts the ground and ends with the next contact with the ground of the same foot (Henry Osorio José & Hernando Valencia Mauricio, 2013) (Figure 8).

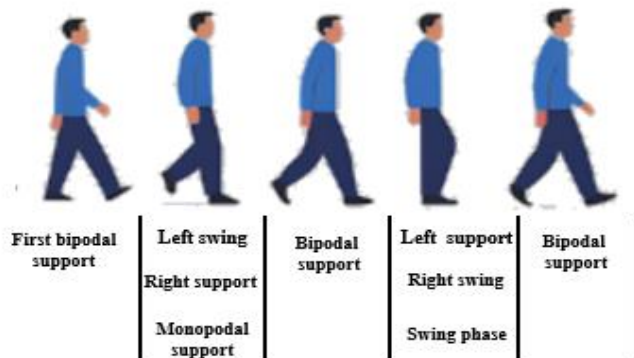


Figure 8. The gait cycle. (Image created by the author).

The 1st MTPJ and the first ray play a fundamental role during the gait cycle, being especially important during the propulsion and take-off phase (Antonio Viladot Voegeli, 2011).

During initial contact and loading responses, due to the everted position (abduction and dorsiflexion) of the midtarsal joint, the first ray is in a dorsiflexed position, thanks to the eccentric contraction of the tibialis anterior and extensor of hallux, which allows to control the external plantar flexion moment at the ankle that occurs in this phase. This is also essential for absorbing the shock of the forefoot with the ground, softening the trauma that the plantar soft tissue may suffer (Bellón Sande, 2022) (Perry Jacquelin & M. Burnfield Judith, 2015).

In Midstance, two moments must be distinguished to understand the functioning of the first ray in this phase. At the beginning of midstance, when the forefoot is in complete contact with the ground due to pronation of the subtalar joint (SJ) the first ray remains dorsiflexed, due to ground reaction forces, causing the medial longitudinal arch to flatten and all metatarsal heads bear loads. This is a passive movement, that is mainly driven by the ground reaction force and discretely controlled under eccentric action of the peroneus longus muscle. This is crucial during this phase because, without it, pronation of the SJ would increase the load on the hallux, causing its head to be repeatedly subjected to trauma from ground contact. In addition, it is essential for adaptation to the ground surface (Pumares Núñez, 2019).

However, when these reaction forces stop acting on the rearfoot, towards the end of this phase, the SJ undergoes a supination movement to go from being a mobile adapter to being a rigid element that serves as a lever for propulsion. As this SJ supinates, two movements must occur in the midfoot to guarantee its support throughout the phase. Firstly, the pronation of the midfoot joint, however, as the inversion of the SJ increases, the forefoot also tends to invert, therefore plantarflexion of the first ray is crucial to keep the metatarsal in contact with the ground. This occurs thanks to the action of the peroneus longus muscle. In addition to this plantarflexion, a calcaneocuboid block is necessary, which provides rigidity and stability to the foot for the last phase of the stance phase, the propulsion phase (Hild & McKee, 2011).

During propulsion, the progressive elevation of the heel causes a progressive take-off of the metatarsals, which lose contact with the ground first at the fifth metatarsal head and subsequently the other metatarsals. The offloading of the forefoot tends at the first metatarsal and the hallux. Being the widest and strongest, it plays a primary role in take-off. Therefore, the first ray increases its plantar flexion, making the function of the peroneus longus essential. As this propulsion advances, the metatarsal head rotates and moves over the gleno-sesamoid apparatus. The hallux must remain firm on the ground, and loads are transferred to the base of the proximal phalanx to accomplish this objective. Then the proximal phalanx begins to slide over the head of the first metatarsal, contributing to the stabilization of the foot through the activation of the Windlass mechanism. In this phase, the maximum degree of dorsiflexion of the metatarsophalangeal joint is required (López iglesias, 2013).

During the swing phase, the first ray is mainly hold in a dorsiflexed position because of the concentric action of the tibialis anterior that starts at the end of the propulsive phase and is maintained throughout the swing phase. (Leal et al., 2012.; Lopez del Amo Lorente, 2011).

3.1 The Windlass mechanism.

The windlass mechanism was described for the first time by Hicks (Hicks, 1954). Originally, this author described the foot and its ligaments as a triangular arch-shaped structure. This arch would be formed by a long arm (the plantar fascia) and two shorter arms (the midtarsal joint and the first metatarsal) (Bolgia & Malone, 2004).

Hicks observed that, during passive extension of the first ray, the plantar fascia wrapped around the head of the first metatarsal, increasing its tension and causing an increase in the height of the internal longitudinal arch, shortening the distance between its origin and its insertion. This would also cause supination of the rearfoot and external rotation of the tibia (Kappel-Bargas et al., 1998).

The first ray contribute to a considerable extend to this mechanism, since it is facilitating the passive extension of the 1st MTPJ, together with the plantar fascia, which are the two most important structures for the development of the mechanism (Aquino & Payne, 2001).

The extension movement of the 1st MTPJ causes a plantarflexion movement of the first ray during propulsion. This will cause an elevation of the internal longitudinal arch, as a consequence of the shortening of the plantar fascia when rolling over the head of the first metatarsal and the increase in its tension, changing the relationship of all the joints, generating, in turn, a supination movement of the SJ. At the same time, the talus dorsiflexes, this is important to help the stability of the foot, externally rotating the leg. Finally, supination of the midtarsal joint occurs, with the aim of keeping the foot in contact with the ground (Manfredi Márquez, 2022).

Therefore, for the Windlass mechanism to take place correctly, when performing a dorsiflexion of the 1st MTPJ, mainly 3 movements must occur: Increase in the height of the internal longitudinal arch, supination of the rearfoot and external rotation of the tibia.

The first ray, therefore, plays a crucial role for the correct functioning of the windlass mechanism. If it presents any alteration, such as a decrease in mobility, this mechanism cannot be carried out efficiently, therefore affecting the biomechanics of the individual giving rise to a series of pathologies.

4. HUMAN GAIT MEASUREMENT METHODS.

The analysis and study of human gait is an important tool for the diagnosis of neuro-musculoskeletal pathology (Villa Moreno et al., 2008). For its evaluation, the most used strategies are dynamometry, accelerometry, ultrasound, digital goniometry and 2D and 3D analysis systems. Currently, the most used are those that combine dynamometric platforms (pressure and force platform) for the evaluation of kinetics, with videogrammetry techniques for the evaluation of kinematics (Ordóñez Mora LT & Sánchez DP, 2020).

Decision making in the clinical treatment of patients with gait dysfunction requires the ability to measure spatiotemporal variables of gait in a valid and reliable manner (Barker et al., 2006).

Three-dimensional (3D) stereophotogrammetric analysis is the probably the most commonly used method for the analysis of joint kinematics in humans, (Deschamps et al., 2011; Lynn Martori, 2013). Data acquisition using these systems is carried out using an optoelectronic system of infrared cameras, which allow three-dimensional trajectories to be reconstructed following reflective spherical markers placed at anatomical reference points on the individual.

The number of infrared cameras in these set-ups ranges between 6 and 12, they are mounted on the ceiling of the laboratory, they have rounded infrared LED arrays that emit pulsed light. The only light that these cameras capture is that reflected by the spherical markers, highlighting them in the image (Figure 9).

Reflective markers are usually spherical or hemispherical covered with reflective paint to be detected by cameras. Its size differs depending on its function.

When the analysis is carried out with these systems, it is necessary to take into account a series of considerations such as the equipment to be used depending on the objective to be achieved, the calibration of the system, the dimensions of the track or corridor where the patient will walk and the position of the markers (Villa Moreno et al., 2008) (Figure 9).

The positioning of the markers is one of the critical points in the evaluation of gait using 3D systems. The ideal way to achieve maximum precision in the movement of the bone structures would be to place the markers directly on them; however, the invasive nature of the technique and the pain it would entail for the patient limit the use of this method of placing markers (Deschamps et al., 2011; Villa Moreno et al., 2008). Alternatively, skin-mounted markers, marking arrays, or a combination of both are used. The main problem with these models is what is known as “the soft tissue artifact.” Measurements are affected by skin movement and the difference between marker placement on the skin and the actual bony anatomy of the underlying bony segment (Leardini et al., 2019).



Figure 9. Infrared camera and reflective markers (Image created by the author).

During the last decade so-called multi-segment 3D models of the foot have been developed, which divide the foot in small segments that facilitate motion capture and subsequent data analysis (Deschamps et al., 2011). There are a large number of models (>40 models) defined by various authors, which are differentiated by anatomical references, definition of segments, types of markers or joint rotation (Deschamps et al., 2011; Leardini et al., 2019; Rankine et al., 2008). The biggest difference between the models is the number and selection of segments. Among the most used and well-known models is Oxford foot model and Rizzoli foot model (Carson et al., 2001; Leardini et al., 2007). In this thesis the model published by Bruening was used (Bruening et al., 2012).

4.1 Bruening Model

This model consists of a Shank (Tibia and fibula) and three-foot segments (Table 3) (Figure 10):

- Hindfoot (calcaneus and talus).
- Forefoot (navicular, cuboid, cuneiforms, and metatarsal).
- Hallux (Proximal and distal phalanges).
- 1 and 2 are separated by a mid-tarsal joint, with center defined as the midpoint between markers placed over the navicular and cuboid bones.
- 2 and 3 are separated by the 1st MTPJ joint, whose center is defined by a projection from a marker placed over the superior aspect of the first metatarsal head.

Table 3 . Markers in Bruening model (Table created by the author).

Conv.	Yam	Description
THE	Side ankle	Apex of lateral malleolus
M.A.	Medial ankle	Apex of medial malleolus
C1	Calcaneus 1	Apex of calcaneal tuberosity
C2	Calcaneus 2	Superior apex of calcaneus (Achilles' tendon insertion)
L.C.	Lateral Calcaneus	Lateral calcaneus (peroneal tubercle)
MC	medial calcaneus	Medial calcaneus (sustentaculum tali)
N.V.	Navicular	Medial prominence of navicular bone
C.U.	Cuboid	Lateral centroid of cuboid bone
B1	Base 1	Medial aspect of 1 st metatarsal base
B5	Base 5	Lateral aspect of 5th metatarsal base
H2	Head 2	Midway between 2 nd and 3 rd metatarsal heads.
HX	Hallux	Centroid of hallux nail
H1	Head 1	Superior aspect of 1 st metatarsal head.



Figure 10. Bruening model (Image created by the author).

In addition to this, other methods are currently used to study foot function, such as the study of plantar pressures.

4.2 Plantar pressure

In recent decades, plantar foot pressure measurement technology has gained popularity due to its low cost compared to other diagnostic methods. The study of plantar pressures of the foot through an electronic recording platform is known as baropodometry (Hurtado Padilla, 2006). Pressure (P) (also called “stress” or tension) is defined as the force (F) per unit surface (area) (A).

$$P = \frac{F}{A}$$

When studying plantar pressure, a sensor or an array of multiple sensors is used to measure the vertical force acting on each sensor while the foot is in contact with the supporting surface. The magnitude of the pressure is determined by dividing the force by the known area of the sensor or sensors while the foot was in contact with the ground. The unit of pressure is the Pascal (PA) (Orlin & McPoil, 2000). There are mainly two quantitative methods for the study of plantar pressures: i) pressure platform, ii) in-shoe system (instrumented insoles) (Martínez Nova, 2009).

Instrumented insoles.

It is a flexible device in the form of insoles that feature a number of built-in sensors. The device is placed between the foot and the shoe (like an orthopaedic insole) and is connected to cuffs that are fixed to the patient's leg, capturing information about the vertical force exerted by the foot each time each of the sensors is activated and sending it to a computer, which collects, processes and displays the data using software associated with the device (Gómez Echeverry et al., 2017; Jones et al., 2021; Martínez Nova, 2009; Orlin & McPoil, 2000; Zulkifli & Loh, 2020).

Pressure platform.

It is a platform-shaped device equipped with an array of sensors. When subjected to pressure, it generates a measurable potential difference, which is detected by the sensors and transmitted to a computer system that converts the input into a digital output. This

conversion results in a dynamic footprint with a range of colours according to the relative isopressure captured (Figure 11). The main disadvantage is that it requires a period of adaptation on the part of the patient, since it requires a centred step in a specific direction (Cobos-Moreno et al., 2022; Gómez Echeverry et al., 2017; Hurtado Padilla, 2006; Martínez Nova, 2009; Zulkifli & Loh, 2020).



Figure 11. Pressure platform (Image created by the author).

There are a series of advantages and disadvantages between these two devices, which are detailed below (Zulkifli & Loh, 2020) (Table 4).

Table 4. Advantages and disadvantages of pressure platform and in-shoe system. (Table created by the author).

System	Advantages	Disadvantages
Pressure platform	<ul style="list-style-type: none"> - Sturdy platform. - Smooth surface. - Larger area relative to the sensor (Higher resolution). - Pressure sensors are aligned parallel to the support surface. 	<ul style="list-style-type: none"> -Limited length. -Requires many steps for data collection. -Normal gait may be disrupted as the user must center their support on the platform surface. - A natural walking pattern is not ensured.
In-shoe system	<ul style="list-style-type: none"> -Flexible and fits inside footwear. -Can be used with various types of shoes and heels. 	<ul style="list-style-type: none"> -Sensor sensitivity might decrease when placed inside the shoe. - the effect of temperature and humidity on sensor output.

	<ul style="list-style-type: none"> - Does not need to centre or adapt the patient's step to any surface. - Data can be obtained with shoes on. 	<ul style="list-style-type: none"> - Sensor space is confined to the insole size.
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The analysis of plantar pressures, using both pressure platforms and insoles, produces two-dimensional images of the plantar footprint. To extract information and enable clinical interpretation, various methods are employed, such as partial sampling, division by regions of interest, the total mapping technique, the local mapping technique, or other so-called total pedobarographic mapping techniques (K. Deschamps et al., 2015).

The measurement of the plantar pressures of the foot provides us with information about the function of the foot and ankle during walking and other dynamic activities (Orlin & McPoil, 2000). It has been shown that structural changes and pathologies of the foot alter the distribution of plantar pressures.

The big amount of sensors that are typically integrated in these pedobarographic systems result in a situation where multiple type of data-extraction can be performed (from 0-dimensional to 3D perspectives)/ The most commonly studied variables of interest are (K. Deschamps et al., 2015; Orlin & McPoil, 2000):

The maximum pressure is defined as the maximum pressure recorded in each of the sensors during the gait cycle (K. Deschamps et al., 2015).

The average pressure refers to the total sum of all the pressures divided by the number of sensors at each moment of the gait cycle (K. Deschamps et al., 2015).

Contact duration quantifies the time that the total area of the foot is in contact with the ground and is expressed in milliseconds. It is used to analyze different gait parameters such as symmetry or deviation, as well as to analyze postural control (K. Deschamps et al., 2015).

The contact area is calculated by adding all the active sensors due to the foot resting on the platform at a given moment or during the entire stance phase (K. Deschamps et al., 2015; Orlin & McPoil, 2000; Zulkifli & Loh, 2020).

The Centre of pressures (COP), also known as the gait line, is known as the centroid of the total number of active sensors for each data sample collected and represents the spatial

distribution of pressure over time (Menz et al., 2018). As a global measure of pressure distribution, it has been suggested that the centre of pressure provides a greater understanding of the dynamic function of the foot compared to measures that are limited to specific regions, such as maximum pressure and maximum force (Buldt et al., 2018).

A “typical” centre of pressure trajectory has been described in healthy patients (Chagollán Rodríguez, 2020), based on the different movements made by the foot during a complete stance phase (Figure 12). However, numerous authors have shown that alterations in the structure or biomechanics of the foot can produce a change in the trajectory of the centre of pressure (Buldt et al., 2018; Lugade & Kaufman, 2014; Menz et al., 2018).

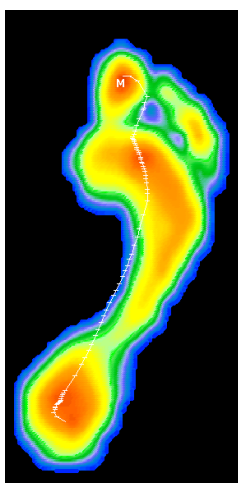


Figure 12. Typical trajectory of the COP (white line) (Image created by the author).

5. PATHOLOGIES OF THE FIRST RAY.

There are numerous pathologies that can affect the first ray and 1st MTPJ, including sesamoid pathologies, turf toe, hallux valgus (HV), and hallux limitus, with the latter being one of the most common conditions affecting the first ray.

5.1 Hallux limitus/Rigidus.

HL is a pathology characterized by a decreased dorsiflexion motion at the 1st MTPJ (below 65° in a non-weightbearing condition). It affects 1 in 40 people aged around 50 years and is the main cause of arthritis in the foot, with an increasing incidence in the older population (Fung et al., 2020). It is the second most common cause of involvement of the 1st ray (after HV). When the limitation of the range of motion of the 1st MTPJ is less than 10°, it is known as hallux rigidus.

It is important to differentiate two types of HL, since they present with different symptoms and progression patterns: structural HL (SHL) and functional hallux limitus (FHL) (Padilla Urrea et al., 2011).

5.1.1 Structural HL.

It is a limitation of dorsiflexion that occurs when the range of motion falls below 65° in both weightbearing and non-weightbearing conditions, and is caused, in most cases, by progressive osteoarthritis of the joint (Fung et al., 2020). To diagnose this pathology, it would be enough to measure the mobility of the 1st ray in non-weightbearing condition as described in the previous sections.

- **Etiology.**

The Etiology of HL is multifactorial, with multiple factors that can cause a reduction in the range of motion of this 1st MTPJ (Saxena, 1995).

The factors influencing the development of HL can be traumatic, anatomical/structural, metabolic, biomechanical, neuromuscular or postsurgical. A summary of these is set out in the following Table 5 (Blázquez et al., 2010; Blázquez Viudas, 2011; Grady et al., 2002; P. V. Munuera Martínez, 2006).

Table 5. Etiology of HL (Table created by the author).

Anatomical	Metabolic	Traumatic	Neuromuscular	Biomechanical	Surgical
-Elevated first metatarsal	-Rheumatoid arthritis	-Acute trauma	-Shortened fascial band	-Straight forefoot with abnormal rearfoot pronation	-Iatrogenesis derived from surgery
- Long first metatarsal or proximal phalanx	-Drop	-Repeated microtrauma	-Peroneus longus insufficiency	-Hypermobility of the first ray	-Excessive fibrosis
- Square Metatarsal Head	-Psoriasis arthritis		-Narrowing of the flexor hallucis brevis	-Increased pronation in the mid-stance and take-off phase	-Bad alignment of the 1st AMTF
- Tarsal coalition	-Reiter's syndrome			-First ray dorsiflexed	-Prolonged immobilization of the 1st AMTF
	-Spondylitis				

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Recent studies have shown that, of a sample of 330 patients (in 43%), more than one etiology was present in the development of HL. In addition, the main causes were trauma, elevated first metatarsal, long first metatarsal, excessive pronation, gout, Reiter's syndrome, ankylosing spondylitis and rheumatoid arthritis (Grady et al., 2002).

- **Classification.**

There are a wide variety of classification system for SHL, from its initial stage to its most advanced phases (Hallux rigidus). Here we will mainly show 2 of them: The Regnauld classification, which is based on both its symptoms and its radiographic signs (Table 6) and the Hanft et al radiographic classification (Table 7) (Grady et al., 2002; Hanft et al, 1993; Regnauld, 1986; Vanore et al., 2003).

Table 6. Regnauld classification for hallux limitus/rigidus (Table created by the author).

Regnauld classification for Hallux limitus/Rigidus	
First grade	<ul style="list-style-type: none"> - Acute/subacute pain. - Less than 40° dorsiflexion and 20° plantarflexion. - Joint enlargement/mild dorsal spur. - Mild joint space narrowing. - Sesamoids regular, but slightly enlarged.
Second grade	<ul style="list-style-type: none"> - Intermittent pain and tingling at rest. - Limitation of movement of the metatarsophalangeal joint. - Narrowing of the joint space. - Flattening of the first metatarsal and phalanx. - Lengthening and elevation of the first metatarsal. - Sesamoid hypertrophy and irregularity.
Third grade	<ul style="list-style-type: none"> - Dorsal, medial and lateral spur of the joint. - Flexor digitorum longus contracture. - Severe loss of joint space. - Hypertrophy of the metatarsus, phalanx and sesamoids.

	<ul style="list-style-type: none"> - Osteophytes in the metatarso-sesamoid joint. - Joint mice. - Ankylosis.
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Table 7. Radiographic classification of HL (Table created by the author).

Radiographic classification of HL by Hanft et al	
Grade I	<ul style="list-style-type: none"> - Metarsus primus elevatus. - Mild spur with dorsal hypertrophy of the head of the first metatarsal and base of the phalanx. - Sclerosis of the junction surrounding the first metatarsophalangeal joint.
Grade II	<p>Grade I elements plus:</p> <ul style="list-style-type: none"> - Widening or flattening of the head of the first metatarsal and proximal phalanx. - Decreased joint space. - Sesamoid hypertrophy.
Grade IIB	<p>Grade II elements plus:</p> <ul style="list-style-type: none"> - Evidence of osteochondral defects. - Formation of subchondral cysts. - Loose bodies.
Grade III	<p>Grade II elements plus:</p> <ul style="list-style-type: none"> - More severe flattening of the head of the first metatarsal and phalanx. - Minimum metatarsophalangeal joint space. - Severe dorsal and lateral spurs and osteophyte formation. - Extensive sesamoid hypertrophy.
Grade IIIB	<p>Grade III elements plus:</p> <ul style="list-style-type: none"> - Large osteochondral defects. - Loose bodies. - Formation of subchondral cysts.

Therefore, the symptoms of HL will depend on the stage or degree in which it is found (Grady et al., 2002).

The most common symptom is pain in the 1st MTPJ, which is usually deep, and worsen when the patient walks. As the joint hypertrophies, irritation of the joint caused by the footwear is observed, which can cause secondary pain or skin irritation. The patient sometimes experiences burning pain, with irritation of the dorsal digital branch of the medial dorsal cutaneous nerve, and this can lead to distal paraesthesia. At the skin level, a tyloma can occur just below the interphalangeal joint (at the plantar level) or in the medial plantar area of the hallux (pinch callous). All of these symptoms are aggravated by walking barefoot, wearing heels, or very flexible sports shoes (Camasta, 1996).

5.1.2 Functional Hallux limitus.

This is the initial stage of structured hallux limitus, characterized by the inability of the 1st MTPJ to perform a dorsiflexion movement when the patient is in a weightbearing condition. The joint is not capable of reaching 20° of dorsiflexion in a closed kinetic chain, while, in an open kinetic chain, it is capable of reaching 65°-70° of movement (Alfaro Santafé et al., 2017). The main difference with SHL is the absence of degenerative changes in the 1st MTPJ and the presence of a full range of motion when the patient is in a non-weightbearing condition (Jacquez Valloton et al., 2010).

One of the first authors describing FHL was Dananberg (Payne et al., 2002). FHL is a temporary restriction of mobility that can sometimes go unnoticed. This blockage of the joint in the sagittal plane occurs in the propulsion phase of the gait cycle, where this movement acquires the most importance. If this mechanism fails, important biomechanical and dynamic consequences may occur (Jacquez Valloton et al., 2010), producing compensatory mechanisms that affect not only the foot, but other joints such as the hip and back, such as premature heel take-off or excessive pronation in the tarsal joint which can give rise to pathological symptoms (Clough James G., 2005).

Dananberg points out that for correct function of the foot, the existence of self-support mechanisms and pivot points is necessary, which ensure correct movement in the sagittal plane. Self-support mechanisms that has been described include the calcaneal cuboidal block, the Windlass mechanism and the intercuneal block (Dananberg Howard J., 1986). The pivot points include the heel's circumference, the postero-anterior displacement of the tibia on the talus during the stance phase, and the dorsiflexion of the 1st MTPJ during

the propulsion phase. Dananberg argues that the onset of this pathology is caused by a movement block at one of these three pivot points, leading to mechanical compensations (Padilla Urrea et al., 2011).

More modern theories highlight the role played by the plantar fascia and the Windlass mechanism in limiting the range of motion of this 1st MTPJ during walking. During the midstance phase of the gait cycle, tension in the plantar fascia is generated to prevent the collapse of the medial longitudinal arch. This tension increases the plantarflexor moment and creates a retrograde compressive force. Under normal conditions, when the metatarsal is angled at approximately 20°, this compressive force acts as a couple, facilitating the plantarflexion (a rotational movement) of the first metatarsal during the propulsion phase of the gait cycle. However, when the metatarsal angle is reduced due to various pathologies such as forefoot equinus or foot pronation, the torque is insufficient to produce this plantarflexion. As a result, dorsiflexion is diminished, and compressive force within the joint increase, leading to joint degeneration and the development of pathological condition (Bueno Feroso, 2011; Padilla Urrea et al., 2011).

For diagnosis in a non-weightbearing position, the FHL test, as described by Dananberg, is used (Dananberg, 2000; Payne et al., 2002). To perform this, the patient is positioned sitting or supine, with both the subtalar and tibiotalar joints in a neutral position. A force is then applied under the first metatarsal head with one hand, simulating the ground reaction force. With the other hand, a dorsiflexion movement of the 1st MTPJ will be performed, at the level of the proximal phalanx. The test will be positive if before exceeding 20° of mobility we notice plantarflexion of the head of the first metatarsal.

In addition to this non-weightbearing test, a weightbearing test, known as the Hubscher maneuver or Jack test, can also be used to diagnose FHL (Durrant & Chockalingam, 2009). With the patient standing in a relaxed position, dorsiflexion of the 1st MTPJ is performed. In a normal test, the hallux dorsiflexes freely and subsequently increases the tension throughout the plantar fascia, which causes an inversion of the calcaneus (called Windlass mechanism). The test will be positive when the examiner is unable to dorsiflex the toe without applying a lot of force and also when the foot does not perform the Windlass mechanism efficiently (Gatt et al., 2014).

6. PATHOMECHANICS OF HALLUX LIMITUS.

As previously mentioned, during walking, the first ray primarily serves two functions: dissipating impact during the forefoot contact phase and providing stabilization during propulsion, where it becomes a rigid lever through dorsiflexion of the 1st MTPJ, activating the Windlass mechanism (Castro-Méndez et al., 2023).

During walking, the body is designed to propel the center of mass forward using a single pivot point, which is the first metatarsophalangeal joint. During propulsion, the first ray remains stationary, resting on the ground while the rest of the body moves on it to move forward. Therefore, any motion restriction of the 1st MTPJ can alter the normal forward progress of the body (Canseco et al., 2008) (Figure 13).

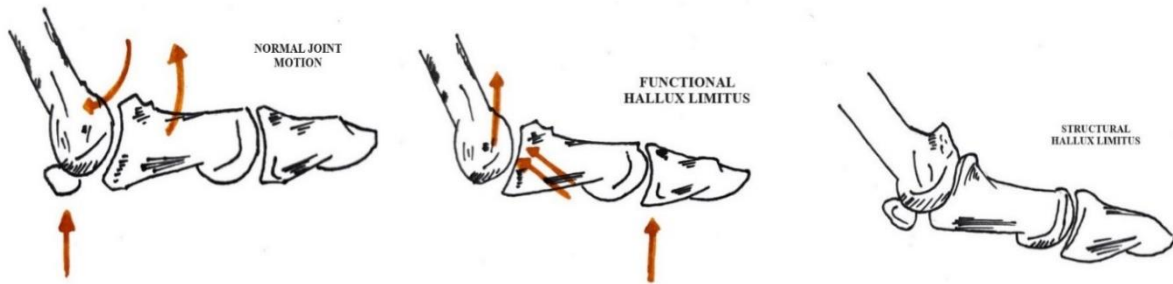


Figure 13. Normal, functional and structural hallux limitus. Image adapted from (Vanore et al., 2003).
Order licenses ID Link(s): 1510189-1.

It has been found that the lack of dorsiflexion of the 1st MTPJ can affect the kinematics of the ankle, hip and knee in the sagittal plane (Allan et al., 2020; Hall & Nester, 2004). A first compensation mechanism encompasses an increase in ankle dorsiflexion during midstance. Here, the ankle recreates the degrees of dorsiflexion that the first metatarsophalangeal joint is unable to recreate. At the ankle level, a reduction in ankle plantarflexion during propulsion is also observed. This is likely accompanied by a reduction in the propulsive force generated and alterations in the posterior leg musculature (Marcha, 2020). On the other hand, there is an increase in knee flexion, which may be due to compensation for the increased tension in the gastrocnemius muscles as a result of increased ankle dorsiflexion. Finally, a decrease in hip extension may also be observed, potentially resulting from reduced femur extension due to increased knee flexion. Although it is not clear whether these compensations in the knee and hip are as a

consequence of a limitation in the mobility of the first ray or due to increased dorsiflexion of the ankle (Hall & Nester, 2004).

Dananberg, in his study (Dananberg H J, 1993), states that hypomobility of the first ray in the propulsive phase of gait, when repeated thousands of times, not only alters the biomechanics of the foot, but also creates chronic postural alterations such as case of lumbar lordosis rectification, leading to pain in this area, a common symptom in patients with HL. Moreover, this create other compensations at the level of the upper joints of the body and cervical spine (Dananberg H J, 1993; Marcha, 2020). The gait alterations caused by HL are not limited to changes in lower limb kinematics; alterations in spatiotemporal parameters can also be observed.

Canseco, in his study, demonstrated that in patients who present HL there is an increase in the duration of the support phase (Taranto et al., 2007). Other authors also show a longer stance phase, with a notable reduction in gait and stride speed (Castro-Méndez et al., 2023; Marcha, 2020), as well as other alterations such as a decrease in the internal rotator pattern of the tibialis, and an increase in the gait angle (Canseco et al., 2008; Távara-Vidalón et al., 2017).

Therefore, gait efficiency in patients with HL can significantly improve their quality of life, both in the short term, relieving their symptoms, and in the long term, avoiding future problems.

In addition to the aforementioned alterations, there is also an alteration in the distribution of the plantar pressure in patients with HL.

6.1 Distribution of plantar pressure in patients with hallux limitus.

Numerous studies have indicated an altered plantar pressure distribution in patients with HL (Bryant et al., 1999; Clough James G., 2005; Cuevas-Martínez, Becerro-de-Bengoa-Vallejo, Losa-Iglesias, Casado-Hernández, Navarro-Flores, et al., 2023; Cuevas-Martínez, Becerro-de-Bengoa-Vallejo, Losa-Iglesias, Casado-Hernández, Turné-Cárceles, et al., 2023; Hernandez Gombau, 2020; Lopez del Amo Lorente, 2011; Van Gheluwe et al., 2006; Zammit et al., 2008).

Some authors (Bryant et al., 1999; Van Gheluwe et al., 2006; Zammit et al., 2008) demonstrated that patients who present a limitation in the range of motion of the 1st MTPJ show a significant increase in force and maximum pressure under the hallux and lesser

toes, as well as a decrease in pressure under the first metatarsal head. This is explained using the concept of high and low speed thrust described by Bojson-Moller (Bojsen-Møller, 1979). This model explains that the propulsion of the foot occurs through two metatarsal axes, one transverse that connects the first and second metatarsal heads and another oblique, which connects the heads of the second to fifth metatarsals. Under normal conditions, that is, when there is at least 65° of dorsiflexion at the 1st MTPJ, propulsion occurs through the transverse axis, which gives rise to an effective transfer of body weight. Conversely, when dorsiflexion of the 1st MTPJ is limited, a low-speed thrust is generated along the oblique axis, which places greater load on the lesser metatarsal heads. One of the metatarsals most affected by this overload is the second metatarsal head, which can sometimes lead to pathologies such as plantar plate rupture (Clough James G., 2005).

Dananberg, (Van Gheluwe et al., 2006) highlights in his study that one of the key factors in analysing plantar pressure distribution in individuals with HL is the ratio of pressure between the hallux and the first metatarsal head. His findings show an increase in the loading rate on the hallux. This can be explained by the fact that, during the propulsion phase, a rigid 1st MTPJ leads to reduced loading on the first metatarsal head, shifting the load toward the hallux. Additionally, he demonstrates that this variable is a highly effective tool for clinical diagnosis.

Therefore, in summary, HL is characterized by an increase in maximum pressure both at the hallux and the central metatarsals (especially the 2nd and 3rd metatarsal). An increase in the loading rate under the hallux is also observed, as well as an increase in the maximum force under the hallux and the lesser metatarsal heads (Figure 14).

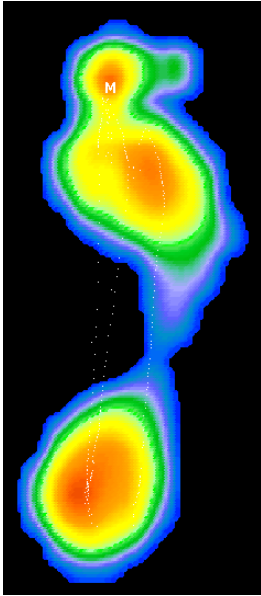


Figure 14. Characteristic pattern of plantar pressure in patients with HL (Image created by the author).

Previous research has shown that areas with higher pressures may lead to dermatological conditions such as the development of plantar callus or hyperkeratosis (Zammit et al., 2008). Therefore, HL also presents a characteristic pattern of hyperkeratosis, which is observed especially in the interphalangeal joint and the lesser metatarsal heads (Lopez del Amo Lorente, 2011).

7. TREATMENT.

The treatment of HL will depend on the stage, and the symptoms of the patient (Vanore et al., 2003).

To treat this pathology, surgical intervention is typically reserved for more advanced stages of the disease (Grady et al., 2002), such as a hallux rigidus, when conservatives' treatments have not succeeded in alleviating pain or improving functionality in the first ray (Hamid & Parekh, 2015; Herrera-Pérez et al., 2014; Vanore et al., 2003; Viladot-Pericé et al., 2006). Surgical options vary depending on the severity of the joint involvement and include both joint preservation procedures, such as interposition arthroplasties, and joint removal techniques. In case of mild degeneration, a cheilectomy may be performed to remove excess osteophytes and prevent dorsal impingement, with or without phalangeal osteotomy, improving joint mobility (Colò et al., 2020).

When the pathology is in its early stages, however, conservative treatments are the first line of treatment. These treatments typically include anti-inflammatories, physical therapy, peri-and intra-articular corticosteroid infiltrations, footwear modifications, and FOs (Fung et al., 2020; Grady et al., 2002; Vanore et al., 2003). Corticosteroid infiltrations

can offer short-term relief, although their long-term efficacy remains uncertain (Hamid & Parekh, 2015).

Among conservative treatments, FOs play a key role. Kirby argues that the main objective in treating HL is to reduce the ground reaction forces on the 1st MTPJ and to improve its range of motion (Rodríguez Sanjorge, 2015).

7.1 Plantar orthoses for the treatment of hallux limitus.

The International Standard Organization (ISO) defines FOs as “an externally applied device used to modify the structural or functional characteristics of the neuromusculoskeletal system” (Pratt, 1995). These devices have been used for many years with the intention of relieving symptoms, prevent deformities and improve performance. However, they often lack scientific evidence (Karl B. Landorf & Anne-Maree Keenan, 2000).

In the case of HL, using FOs can be effective in the initial stages of the disease and the results are seen almost immediately when the FOs prescription is carried out correctly. Although its design will depend on both the etiology of the pathology and the stage in which it is found, the main function of the orthosis is to reduce ground reaction forces (making the first ray as stable as possible) avoiding moments of pronation (in the case of FHL), and increasing the degrees of dorsiflexion (therefore increasing its functionality) with forefoot modifying elements in initial stages (Ferreiro Villamizar, 2017; Rodríguez Sanjorge, 2015; Rosenbloom, 2011) or limiting the mobility of the first MTPJ in the case of more advanced stages (Munuera Martínez, 2008).

Different FOs designs for the treatment of HL are described in the literature.

7.1.1 Kinetic Wedge

The term “Kinetic wedge” was first described by Dananberg in 1988 (H J Dananberg, 1988).

This geometric feature is nothing more than a pronating forefoot wedge. Originally, the geometric feature used a combination of materials of two different densities: a medium-density EVA (40-45 Shore A), for the 2nd to 5th metatarsal, and Poron (cushioning material), under the head of the first metatarsal. It is a dynamic wedge that raises the heads of the metatarsals from 2nd to 5th. Generally, the thickness is greatest at the level of the fifth metatarsal and decreases to 0 mm as it reaches the 2nd metatarsal, creating a

wedge and allowing the plantarflexion of the first metatarsal (Ferreiro Villamisar, 2017; H J Dananberg, 1988).

The main objective of this element focuses on promoting an increase in the range of motion of the 1st MTPJ in midstance and propulsion phase, improving the plantarflexion of the first metatarsal, thus favouring the dorsiflexion of the joint and helping to avoid the aforementioned compensations and reduce the level of plantar pressures in the forefoot (Hernandez Gombau, 2020).

7.1.2 Morton Extension.

The main objective of this geometric features, unlike the kinetic wedge, is to limit the range of motion of the 1st MTPJ, (Hamid & Parekh, 2015; Sammarco & Nichols, 2005) and is used in advanced stages of the disease. It is a made of a semi-rigid material (of different thicknesses) that is placed under the entire first ray (Sanchez-gomez et al., 2021). This piece extends from the head of the first metatarsal to the proximal phalanx of the hallux (Palomo-Toucedo et al., 2023) (Figure 15).



Figure 15. Morton Extension (Image created by the author).

7.1.3 FOs with pronation control.

Pronation of the SJ is an important factor in the appearance of both FHL and SHL. Some authors have demonstrated that controlling rearfoot pronation using specific orthoses elements can increase the range of motion of the 1st MTPJ in patients with FHL over the long term, with an increase of up to 8° in dorsiflexion observed after five months of treatment. Other studies using a 4 mm medial heel skive have shown that all subjects experienced an increase in dorsiflexion of the 1st MTPJ when standing, along with a reduction in pressure under the first toe. Additionally, some research, although not specifically focused on HL, demonstrated that varus and valgus wedges significantly affect the peak dorsiflexion of the 1st MTPJ, with valgus wedges reducing dorsiflexion by at least 6° and varus wedges by 8°. However, in cases of SHL, controlling pronation alone does not seem sufficient to restore functionality to the 1st MTPJ. (Munuera et al., 2006; Rodriguez Sanjorge, 2015; Scherer et al., 2006; Smith et al., 2004).

7.1.4 Cut-out FOs.

One of the most used geometric features for the treatment of HL is the use of a FOs with a cut-out on the head of the first metatarsal head (De Bengoa Vallejo et al., 2016; Grady et al., 2002; Kerry K. Rambarran, 2003; Menz et al., 2014; Rosenbloom, 2011; Welsh et al., 2010) (Figure 16). The design varies in two different ways, some authors perform only a fenestration of the head of the first metatarsal head, while others, in addition to this fenestration, add an extension at the level of the hallux (known as dynamic wedge extension) to place the proximal phalanx in an even more dorsiflexed position with respect to the first metatarsal.

Biomechanically, it has been shown that the use of this type of FO cause statistically significant changes. Cut-out FOs produces an increase in the angle of declination of the first metatarsal, with a minimal detectable change (MDC) 95% of 0.73° as well as a decrease in adduction displacement in its transverse plane with a MDC 95% of 0.45° (De Bengoa Vallejo et al., 2016). This elevates the medial longitudinal arch and places the metatarsal in a plantarflexed position due to traction from the peroneus longus muscle. This increases the angle of declination while keeping the hallux in contact with the ground under load, which in turn enhances dorsiflexion of the first metatarsophalangeal joint, decompresses the joint, and reduces pain. All of this favour's propulsion, allowing the proximal phalanx to rotate on the head of the first metatarsal, achieving sufficient

dorsiflexion of the metatarsophalangeal joint and making this last phase of the gait cycle more efficient (Kerry K. Rambarran, 2003; Menz et al., 2014).



Figure 16. Cut-out FO (image created by the author).

7.1.5 AFSE FOs.

The AFSE CFO represents an innovation in biomechanical research, as no prior descriptions of this specific device exist in the literature. This FO features a distinctive rocker-shaped design in the anterior portion, extending from the metatarsal region to the toes, which facilitates increased mobility in the first metatarsophalangeal joint (1st MTPJ). This design helps reduce joint pressure and optimizes load transfer between the 1st MTPJ and the hallux. In terms of materials, the AFSE CFO is primarily constructed from polyester resin, combined with 1.2 mm *Podiaflex* and 1.2 mm *Podiaflux* (Podiatech) in the rearfoot and midfoot areas, and 0.8 mm *Podiaflex* in the forefoot. The orthotic shell utilizes polyethylene-ethylene-vinyl-alcohol (PE-EVA) with a Shore A hardness of 30 and a density of 148 kg/m³. This specific choice of PE-EVA is particularly relevant in cases of hallux limitus (HL), as it provides the essential balance between flexibility and resistance, adapting effectively to the demands of this condition.

SUMMARY OF KNOWLEDGE GAPS AND CONTRIBUTION OF THIS DOCTORAL THESIS.

HL, characterized by a decrease in the range of motion of 1st MTPJ (below 65°), is a condition that affects one in every 40 people around the age of 50 and is the primary cause of arthritis in the foot, with an increasing incidence in older populations. Additionally, it is the second most common pathology of the first ray, after hallux valgus.

The onset of this condition directly impacts the gait cycle, where the first ray and the 1st MTPJ play a crucial role. This is particularly significant during the propulsion phase, where the activation of the Windlass mechanism through dorsiflexion of this joint is required for efficient propulsion.

Limited mobility in this joint leads to both kinetic and kinematic alterations, causing compensations not only in the foot but also in the rest of the body. This can result in pain in specific areas of the foot due to a redistribution of plantar pressures and even lumbar rectification.

Despite the significance of this condition and the loss of gait efficiency it causes, the literature on its biomechanical efficacy or effectiveness is scarce. The most commonly used non-invasive treatment is the use of FOs; however, there is no clear consensus on the most effective design. Furthermore, we have not found literature that examines the effects of these treatments on the kinetics and kinematics of the foot, as well as on plantar pressure distribution, which is essential for a comprehensive understanding of how these treatments can help manage this condition.

Identifying the most effective treatment and understanding its mechanism of action is particularly important for podiatric professionals. This would enhance clinical practice, allowing for the prescription of the most appropriate treatment based on the specific needs of each patient, always grounded in scientific evidence. The goal is to achieve efficient gait in patients with HL, significantly improving their quality of life both in the short term by alleviating symptoms and in the long term by preventing future problems.

OBJETIVES

Based on these literature gaps, the present doctoral thesis provides the following contributions to the current knowledge:

1. To review the effectiveness of in shoe and barefoot placed frontal wedges on plantar loading.
2. To investigate the effect of two types of FOs: Cut-out CFO and AFSE CFO on the distribution of plantar pressures in patients with structured hallux limitus, studying the displacement of the center of pressures.
3. To analyze the function of cut-out CFO and AFSE CFO in improving the functionality of this joint, investigating whether they increase the range of motion of the 1st AMTF.
4. To compare cut-out CFO and AFSE CFO, identifying which one is more effective for the treatment of this pathology.

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THESIS BY PUBLISHED WORKS.

1. **Impact of in shoe and barefoot placed frontal wedges on plantar loading: a systematic review.**

- Martinez-Rico, M., Deschamps, K., Gijon-Nogueron, G., & Ortega-Avila, A. B. (2022). Impact of in shoe and barefoot placed frontal wedges on plantar loading: A systematic review. *Gait & Posture*, *97*, 62–72. <https://doi.org/10.1016/j.gaitpost.2022.07.233>

- Purpose: The main aim of this review is to report the effect of different types of in-shoe and barefoot wedges on the distribution of the plantar loading of the human foot. We hypothesise that frontal plane wedges modify this parameter. Methods: A systematic review was performed, using the PubMed, CINAHL, Prospero and Scopus databases, consulted from their date of first publication to May 2020. Only observational (cross-over studies), randomised controlled trials (RCTs) and quasi-experimental studies addressing the effects of in-shoe and barefoot frontal plane wedges on plantar loading were included. All articles were subjected to quality assessment, using the Newcastle-Ottawa scale for the observational (cross-over) studies, TREND for quasi-experimental studies and the Cochrane Collaboration's tool for the RCTs. Results: Eleven papers were included in the final review. Four were cross-over studies, other four were quasi experimental studies and three were RCTs. These eleven studies included 320 patients, with ages ranging from 20 to 60 years. Regarding the risk of bias, most of the observational studies and RCTs had a moderate level of quality. Conclusions: The results suggest that lateral wedges are more effective, producing a lateral shift of the centre of pressure and increasing the pressure. Regarding the impact on the peak impact force there seems to be less consensus among the published data.

2. **The direct impact effect of different foot orthotic designs on the plantar loading of patients with structural hallux limitus: a quasi-experimental study.**

- Martinez-Rico M, Gijon-Nogueron G, Ortega-Avila AB, Roche-Seruendo LE, Climent-Pedrosa A, Sanchis-Sales E, Deschamps K. The Direct Impact Effect of Different Foot Orthotic Designs on the Plantar Loading of Patients with Structural Hallux Limitus: A Quasi-Experimental Study. *Applied Sciences*. 2024; 14(20):9510. <https://doi.org/10.3390/app14209510>
- Background: This study examines the effect of two types of CFO in patients with SHL. Methods: In this quasi-experimental, repeated measures study, 24 participants with SHL were sampled. Two CFOs—cut-out CFO and anterior stabilizer element (AFSE) CFO— were compared using minimalist SAGURO neoprene shoes: no foot orthoses (FO), cut out CFO, and AFSE CFO. Plantar pressures and center of pressure (CoP) displacement were measured using a Podoprint® platform. Results: : Both CFOs shifted the CoP medially during midstance ($p < 0.001$ with AFSE CFO and $p = 0.0036$ with cu-out CFO). The AFSE CFO showed a more anterior Cop in midstance, while the cut-out CFO affected anterior Cop in midstance and pre-swing. The AFSE CFO significantly increased pressure in the second toe, lesser metatarsal heads (MTH), midfoot, and rearfoot. In contrast, the cut-out CFO decreased pressure in the 2nd MTH and lesser toes regions, increasing pressure in the midfoot and heel. Both CFOs lowered the Hallux/1st MTH ratio compared to shod without CFO. Conclusions: The cut-out CFO led to medial and anterior Cop displacement, reducing lateral foot and hallux pressure while transferring loads to the 1st MTH. The AFSE CFO caused a similar shift by increasing loads on the 1st MTH.

3. Effect of custom-made foot orthotics on multi segment foot kinematics and kinetics in individuals with structural hallux limitus.

- Martinez-Rico M, Gijon-Nogueron G, Ortega-Avila AB, Roche-Seruendo LE, Climent-Pedrosa A, Sanchis-Sales E, Deschamps K. Effect of Custom-Made Foot Orthotics on Multi-Segment Foot Kinematics and Kinetics in Individuals with Structural Hallux Limitus. *Sensors*. <https://doi.org/10.3390/s24196430> 2024; 24(19):6430.
- Abstract: The first metatarsophalangeal joint (MTPJ) and the first ray are crucial in walking, particularly during propulsion. Limitation in this joint's sagittal plane motion, known as hallux limitus, can cause compensatory movements in other

joints. Some studies assessed the impact of various FOs designs on the foot biomechanics; however, a comprehensive understanding is lacking. This study compared the effects of two custom made foot orthoses (CFOs) on the foot joint kinematics and kinetics in patients with SHL. In this quasi-experimental study, 24 patients with HL were assessed in three conditions: (i) barefoot, (ii) shod with a cut-out custom foot orthosis (cut-out CFO), and (iii) shod with an anterior forefoot-stabilized element custom foot orthosis (AFSE CFO), fitted into a minimalist neoprene shoe. Multi-segment foot kinematics and kinetics were assessed during the stance phase of the gait. A decrease in ankle and midfoot inversion, as well as in ankle plantarflexion, was found in both orthotic conditions. Regarding the first MTPJ, a greater dorsiflexion was observed with the patient being barefoot compared to both of the conditions under study. From the current finding, it should be concluded that neither of the CFOs produced the predefined functional effects.

4. Effect of different custom-made foot orthotics on foot joint stiffness in individuals with structural hallux limitus: a quasi-experimental study.

- Martinez-Rico M, Gijon-Nogueron G, Ortega-Avila AB, Roche-Seruendo LE, Climent-Pedrosa A, Sanchis-Sales E, Deschamps K. Submitted to the journal *Clinical Biomechanics* (JCR Q3 in Orthopaedics, IF 1.4)
- Background Normal dorsiflexion of the first metatarsophalangeal joint (1st MTPJ) during dynamic activities plays a critical role for effective propulsion. Therapeutic intervention is the application of foot orthotics (FO) since it is hypothesized that these medical devices may address the (mal)adaptive pathomechanical loading and foot joint kinematics that this population is facing. this study aims to bridge this existing knowledge gap by evaluating the dynamic stiffness properties of the 1st MTPJ among other foot segments in patients with HL and assess the effects of varying effects of varying FO designs on the kinematics and kinetics of the foot in patients with structural Hallux Limitus. Methods This quasi-experimental study used a repeated-measures design with a single cohort 24 participants with SHL were sampled. Two custom-made FOs (CFO)– a cut-out CFO and an anterior stabilizer element (AFSE) CFO – were compared under three conditions using minimalist SAGURO neoprene shoes: no

FO, cut-out CFO, and AFSE CFO. Kinematic data were captured using a modified Bruening model, which divides the lower limb into three segments: rearfoot, forefoot, and hallux and the calculation of stiffness were performed following the protocol described by Sanchis-Sales. Findings: Significant differences were found only between AFSE and barefoot during the propulsion phase at the metatarsophalangeal joint. No significant differences were observed for dynamic stiffness in any other phase of the stance period across all conditions. Interpretation: The AFSE insole, in particular, significantly increases the stiffness of the 1st MTP joint compared to walking barefoot.

GENERAL DISCUSSION.

The main objective of our study was to investigate the effects of two different CFO designs on foot kinetics and kinematics, as well as plantar pressure distribution and the displacement of the center of pressure (COP) in patients with SHL.

As observed in the literature, a restriction in the mobility of the 1st MTPJ leads to compensatory mechanisms in other joints, not only within the foot but also in other joints, potentially resulting in chronic postural alterations (Dananberg, 2000). However, despite the relevance of this condition, it remains an under-researched field. During this doctoral project, we identified a lack of comprehensive literature regarding how treatments for HL influence plantar pressures and foot biomechanics. Furthermore, there is no consensus on the most effective treatment to address potential (mal)adaptive movement strategies and improve the quality of life for affected patients.

Our literature review revealed that few studies address our research question. While there is abundant research on the development and consequences of the pathology, only a limited number of articles have explored the effects of treatments on plantar pressure distribution, foot kinetics, and kinematics (De Bengoa Vallejo et al., 2016; Hernández Gombau, 2020; Menz et al., 2014; Rambarran Kerry, 2003). None of these studies, however, examined these aspects in an interconnected manner, highlighting a significant research gap.

This gap led us to our research question, addressed through four scientific articles: one systematic review and three quasi-experimental repeated measures studies, focusing on SHL patients and comparing two specific types of CFO. The first, a cut-out design (cut-out CFO), is commonly used to treat this condition (De Bengoa Vallejo et al., 2016; Hernández Gombau, 2020; Menz et al., 2014, 2016; Rambarran Kerry, 2003). The second is a novel self-designed orthosis featuring an anterior forefoot stabilizer element (AFSE) in the shape of a rocker. There is no prior literature on this specific element, making one of the aims of this dissertation the promotion of its study as a potential treatment for various pathologies.

Initially, we conducted a systematic review to assess the impact of frontal wedges placed in shoes or barefoot on plantar pressure distribution, COP displacement, vertical ground reaction forces, and plantar load (Martínez-Rico et al., 2022). This review was essential

for laying the foundation for our research. Before analysing the effects of different FO elements on plantar pressure, it was necessary to determine whether external factors, such as wedge placement, affect these pressures. The conclusion was clear: lateral and medial wedges alter plantar pressure distribution and shift the COP accordingly. Lateral wedges cause a lateral COP shift with increased lateral pressure, while medial wedges result in a medial shift with increased pressure in the medial area. This aligns with the understanding that COP reflects the spatial representation of pressure distribution over time.

The importance of this review lies in guiding treatment selection for our research. Some studies on the effect of cut-out CFO in HL patients used medial wedges to correct foot valgus or pronation (Hernández Gombau, 2020; Rambarran Kerry, 2003). Our review contributed in highlighting how these elements can influence results, making it difficult to isolate the effects of the main FO element. This observation has driven our research design, and we have chosen to exclude rearfoot corrections in our study, ensuring that observed effects were derived solely from the study elements.

One of the main challenges encountered during the review was the variability in study methodologies, especially regarding footwear. Some studies were conducted barefoot (Kakihana, Akai, et al., 2005; Kakihana et al., 2004), while others used socks (Jin et al., 2019; Telfer et al., 2013) or the shoes of the participants (Telfer et al., 2013), which likely affected the results. For our study, we standardized footwear by using minimalist shoes, ensuring minimal interference with plantar pressure measurements, and enabling us to isolate the intrinsic effects of the FOs.

Our first research article focused on understanding how the two CFO types (cut-out CFO and AFSE CFO) affected plantar pressure redistribution in patients with SHL. The novelty of this study lay in not only examining COP displacement but also providing an objective explanation for these displacements. To better understand why these shifts occurred, we used a subsampling of pedobarographic data, dividing the foot into anatomical regions to gain insight into how pressure was distributed throughout the gait cycle (Van Gheluwe et al., 2006). This methodology provided a clearer understanding of why and how COP changes occur under different study conditions.

Our findings indicated that both CFO conditions led to a medial and anterior displacement of the COP compared to barefoot patients. Given that lateral COP displacement is

typically seen in HL patients due to 1st MTPJ dorsiflexion limitation (Bus et al., 2004), these results suggest that the orthoses were effective in reversing the pattern associated with the pathology. Additionally, other studies demonstrated increased anterior COP displacement speed with cut-out FO (Rambarran Kerry, 2003), supporting our findings that both conditions improved propulsion.

Regarding the plantar pressure distribution, the cut-out CFO led to decreased pressure in the hallux and lesser toes, while increasing pressure in the heel and midfoot, with a notable load increase in the first metatarsal head. These results differ from some studies, but methodological differences, such as the use of rearfoot-correcting wedges (Harradine & Bevan, 2000) or shock-absorbing elements (Menz et al., 2014; Tong & Ng, 2010), likely explain these discrepancies. Only one study presented results similar to ours (Rambarran Kerry, 2003). This study provided clear conclusions: both FO conditions significantly affected COP displacement and plantar pressure distribution. The cut-out CFO induced a medial and anterior COP shift, likely due to reduced pressure in the lesser toes and hallux and increased load on the first metatarsal head. Meanwhile, the AFSE CFO focused more on anterior COP displacement, suggesting it may enhance propulsion in SHL patients and reduce compensatory mechanisms associated with the condition.

Although the conclusions were clear, it was necessary to investigate whether these changes in pressure were due to increased 1st MTPJ functionality or merely the result of cushioning from soft insole materials. To address this, a third study examined the effects of FOs on the kinetics and kinematics of SHL patients using a multi-segment foot model (Bruening et al., 2012) and a 3D motion capture system (VICON).

Surprisingly, our results showed a decrease in ankle and midfoot inversion, as well as reduced ankle plantarflexion in both CFO conditions. Additionally, 1st MTPJ dorsiflexion was greater in barefoot patients, suggesting less joint mobility with CFOs. This contrasts with our initial hypothesis and previous literature (De Bengoa Vallejo et al., 2016), where cut-out FO increased 1st MTPJ dorsiflexion in patients with FHL, likely due to differences between FHL and SHL.

This reduced dorsiflexion may explain the decreased midfoot and rearfoot inversion, as the 1st MTPJ plays a critical role in propulsion by activating the Windlass mechanism. Without adequate dorsiflexion, this mechanism may be compromised, leading to reduced inversion. Thus, we cannot confirm that FOs increase the functionality of the first ray, nor

can we assert that changes in plantar pressure distribution were due to increased 1st MTPJ dorsiflexion.

However, two potential explanations emerge: First, our population comprised SHL patients, meaning the pathology involved an osteoarthritic process. These patients may benefit more from elements that enhance propulsion rather than those that aim to increase 1st MTPJ functionality. In this sense, both FOs, especially the AFSE CFO, could be advantageous by improving propulsion during the final phase of the gait cycle. Second, the minimalist footwear used may have interfered with the function of the orthoses, affecting the results.

Lastly, we conducted a study to explore joint stiffness, as our previous results indicated increased joint moments and decreased joint range of motion, suggesting increased stiffness. This study confirmed that FOs led to increased midfoot and 1st MTPJ stiffness, which could improve energy efficiency. Patients with pronated feet often exhibit lower joint stiffness, resulting in decreased energy efficiency (Sanchis-Sales et al., 2016). Therefore, using treatments that increase 1st MTPJ stiffness in pronated feet could be biomechanically beneficial. This supports our previous findings of improved propulsion and energy efficiency with FOs, particularly the AFSE CFO, with which we also observed an increase in velocity and a greater anterior displacement of the COP. Moreover, increasing joint stiffness could be beneficial in patients who present instability or excess joint mobility (hypermobility), thus demonstrating that these orthoses could help reduce instability.

In conclusion, both FOs, particularly the AFSE CFO, improved propulsion and energy efficiency in SHL patients, while the cut-out CFO proved more effective in redistributing plantar pressures. However, we could not demonstrate that either treatment improved 1st MTPJ functionality.

A comparison of the results from these studies reveals both consistencies and discrepancies. On one hand, all studies agree that CFOs significantly impact plantar pressure distribution and foot biomechanics. However, discrepancies, particularly concerning foot joint mobility, suggest that treatment decisions must consider each patient's specific condition. It is essential to determine whether the goal of the patient is to increase mobility or enhance stability before prescribing a treatment. Each case should

be approached individually, avoiding generalized treatment, as the research shows that each type of FO operates through distinct mechanisms.

For instance, cut-out CFOs have been shown to significantly redistribute plantar pressure, making them especially useful for patients presenting with pain. Additionally, their ability to increase joint stiffness contributes to improved stability. Conversely, with AFSE CFOs, the focus shifts toward optimizing the propulsion phase, while still enhancing foot stability and boosting the patient's overall energy efficiency.

LIMITATIONS AND FUTURE DIRECTIONS.

Despite the notable findings of the current observed in the current doctoral project, several limitations exist. Firstly, the scarcity of literature on AFSE CFO limited comparisons with previous studies. Additionally, the small sample size prevented broader generalization of the results, and the lack of long-term follow-up hindered the assessment of sustained FO effects. FO adaptation periods are crucial, and treatment effects are not always immediately apparent.

Among the strengths of this study **was** its comprehensive analysis, being the first to compare two different FO types in SHL patients. It examined both COP displacement and plantar pressure distribution, contributing valuable knowledge to the field. Nonetheless, further studies with larger sample sizes and longer follow-ups are essential to validate the findings and explore the long-term impact of different CFOs in patients with SHL. Expanding the study population to include patients with other forms of HL (such as FHL) would also allow a broader understanding of CFO efficacy in various conditions. Ultimately, future research should aim to develop more personalized FO treatments for SHL patients, considering both individual patient characteristics and specific gait abnormalities.

CONCLUSION.

First objective.

To review the effectiveness of in shoe and barefoot placed frontal wedges on plantar loading.

- Frontal plane wedges cause a redistribution of the plantar pressure.
- Lateral wedges produce an increase in lateral heel pressure and medial wedge an increase in medial heel pressure.
- Lateral or valgus wedges produce a lateral shift of the gait line and varus or medial wedges produce a medial shift on this biomechanical feature.

Second objective.

To investigate the effect of two types of FOs: Cut-out CFO and AFSE CFO on the distribution of plantar pressures in patients with structured hallux limitus, studying the displacement of the center of pressures.

- Both study conditions significantly affect the displacement of the COP and the distribution of plantar pressures.
- Cut-out CFOs cause a medial and anterior displacement of the COP, which can be explained by a decrease in pressure on the lesser toes and hallux, along with an increase in load on the first metatarsal head.
- AFSE CFOs place greater emphasis on anterior displacement of the COP, resulting in a more pronounced effect on patient propulsion.

Third objective.

To analyze the function of cut-out CFO and AFSE CFO in improving the functionality of this joint, investigating whether they increase the range of motion of the 1st MTPJ.

- It cannot be concluded that FOs improve the functionality of the 1st MTPJ, so it is not possible to affirm that changes in plantar pressure distribution are due to increased dorsiflexion of the 1st MTPJ.

- Both FOs reduce ankle and midfoot inversion, as well as ankle plantarflexion. An increase in dorsiflexion was observed when the patient was barefoot.
- FOs increase the stiffness of the 1st MTPJ and midfoot, leading to less mobility but with a greater joint moment.

Fourth objective.

To compare cut-out CFO and AFSE CFO, identifying which one is more effective for the treatment of this pathology.

- It cannot be determined which of the two orthoses is more effective in treating this condition. The specific circumstances of each patient should be considered before prescribing one treatment over the other. Each case should be approached individually, as each orthosis operates through a different mechanism of action.
- The cut-out CFO has a greater impact on the distribution of plantar pressures, making it particularly beneficial for patients with pain, as it alleviates pressure in problematic areas while also increasing joint stiffness, thereby improving stability. The AFSE CFO is more focused on enhancing the propulsion phase and, like the cut-out CFO, increases stability, leading to improved energy efficiency for the patient.