TESIS DOCTORAL INTERNACIONAL

UCAM
UNIVERSIDAD CATÓLICA DE MURCIA

ESCUELA INTERNACIONAL DE DOCTORADO

Programa de Doctorado en Ciencias de la Salud

Crecimiento y desarrollo del pie infantil. Análisis de las manifestaciones clínicas y los factores de riesgo en la población pediátrica

Autora:

Dña. Cristina Molina García

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DECLARACIÓN JURADA DE ORIGINALIDAD DEL TRABAJO

Yo, Cristina Molina García con DNI/Pasaporte 45923899K alumna inscrita en la Escuela Internacional de Doctorado, perteneciente a la Universidad Católica San Antonio de Murcia,

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En Murcia, a 4 de septiembre de 2023

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PARA SU PRESENTACIÓN

La Dra. Dña. Laura Ramos Petersen, el Dr. D. Andrés López del Amo Lorente y el Dr. D. Manuel Pardo Ríos como Directores de la Tesis Doctoral titulada "Crecimiento y desarrollo del pie infantil. Análisis de las manifestaciones clínicas y los factores de riesgo en la población pediátrica" realizada por Dña. Cristina Molina García en el Programa de Doctorado de Ciencias de la Salud, **autorización su presentación a trámite** dado que reúne las condiciones necesarias para su defensa. Dicha tesis está realizada bajo la normativa de Compendio de Publicaciones y con la Mención «Doctorado Internacional».

Lo que firmo, para dar cumplimiento al Real Decreto 99/2011 de 28 de enero, en Murcia a 4 de septiembre de 2023.

Fdo. Dra. Dña. Laura Ramos Petersen	Fdo. Dr. D. Andrés López del Amo Lorente	Fdo. Dr. D. Manuel Pardo Ríos

PRESENTACIÓN DE LOS ESTUDIOS

TESIS POR COMPEDIO DE ARTÍCULOS

Esta tesis doctoral se ha elaborado mediante un compendio de artículos, los cuales han sido publicados durante este último año durante el desarrollo del Programa de Doctorado en Ciencias de la Salud en la Universidad Católica San Antonio de Murcia.

Todos los artículos que están publicados pertenecen a revistas indexadas en el Journal Citation Reports (JCR) de la Web of Knowledge (WoS), cuyo factor de impacto, cuartil y área de conocimiento (año 2022/23) se muestra a continuación.

Artículo

Molina-García, C.; Banwell, G.; Rodríguez-Blanque, R.; Sánchez-García, J.C.; Reinoso-Cobo, A.; Cortés-Martín, J.; Ramos-Petersen, L. Efficacy of Plantar Orthoses in Paediatric Flexible Flatfoot: A Five-Year Systematic Review. Children 2023, 10, 371. https://doi.org/10.3390/children10020371

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Categoría		PEDIATRICS	
Factor de impacto	Ranking	Cuartil	Percentil del Factor de impacto
2,4	58/130	Q2	55,8

Artículo

Molina-García, C.; Jiménez-García, J.D.; Velázquez-Díaz, D.; Ramos-Petersen, L.; López-del-Amo-Lorente, A.; Martínez-Sebastián, C.; Álvarez-Salvago, F. Overweight and Obesity: Its Impact on Foot Type, Flexibility, Foot Strength, Plantar Pressure and Stability in Children from 5 to 10 Years of Age: Descriptive Observational Study. Children 2023, 10, 696. https://doi.org/10.3390/children10040696

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Molina-García, C.; Reinoso-Cobo, A.; Cortés-Martín, J.; Lopezosa-Reca, E.; Marchena-Rodriguez, A.; Banwell, G.; Ramos-Petersen, L. Efficacy of Personalized Foot Orthoses in Children with Flexible Flat Foot: Protocol for a Randomized Controlled Trial. J. Pers. Med. 2023, 13, 1269. https://doi.org/10.3390/jpm13081269

Revista: Journal of Personalized Medicine

ISSN: 2075-4426; **DOI**: https://doi.org/10.3390/jpm13081269

Categoría		HEALTH CARE SCIENCES & SERVICES	
Factor de impacto	Ranking by Journal Impact Factor	Cuartil	Percentil del Factor de impacto
3,4	42/109	Q2	61,93
Categoría		MEDICINE, GENERAL & INTERNAL	
Factor de impacto	Ranking by Journal Citation Indicator	Cuartil	Percentil del Factor de impacto
3,4	57/329	Q1	82,83

RESUMEN

ANTECEDENTES: Investigar y ampliar el conocimiento sobre el pie infantil es de gran importancia debido a numerosos motivos que afectan tanto a la salud individual como a la salud pública en general. Tener conocimiento sobre cómo se desarrolla el pie en esta etapa y todos los factores que pueden afectar a su desarrollo puede ayudar a identificar posibles anomalías y condiciones tempranas que podrían afectar a la calidad de vida y la funcionalidad de los niños a medida que estos evolucionan y crecen. En la actualidad hay muchas investigaciones que abordan el pie del adulto, pero en la población infantil estas investigaciones son escasas. Factores como el pie plano infantil flexible (PPIF), el sobrepeso o la obesidad (SP/OB) infantil, la pérdida de fuerza, el exceso de presiones plantares o la falta de control neuromuscular pueden presentar desafíos en este proceso, afectando potencialmente la calidad de vida y la funcionalidad de esta población tan especial. **OBJETIVOS**: En primer lugar, se propuso investigar las características descriptivas y analizar las asociaciones entre la obesidad infantil en relación con variables baropodométricas, de laxitud, fuerza muscular y nivel de actividad física en niños de 5 a 10 años. Además de llevar a cabo dos revisiones sistemáticas y síntesis de la literatura para analizar la eficacia de las órtesis plantares (OP)y la reeducación funcional (RF) como tratamiento en el PPIF y realizar un protocolo de estudio sobre la eficacia de las órtesis plantares en PPIF. **RESULTADOS PRINCIPALES**: El SP/OB infantil afecta a las presiones plantares, la laxitud y la fuerza del pie en niños de 5 a 10 años. Las OP y la RF son eficaces para la mejora de signos y síntomas del PPIF. **CONCLUSIÓN GENERAL**: La presente Tesis Doctoral supone un importante avance en el conocimiento del SP/OB infantil, el PPIF y las variables que pueden afectar al desarrollo del pie en la población pediátrica desde una perspectiva biomecánica y sus implicaciones en la salud musculoesquelética.

PALABRAS CLAVE: “niños”; “presiones plantares”; “pie plano infantil”; “obesidad infantil”; “reeducación funcional”; “órtesis plantares”; “tipo de pie”

ABSTRACT

BACKGROUND: Investigating and expanding knowledge about the pediatric foot is of great importance due to numerous reasons that affect both individual health and public health in general. Understanding how the foot develops during this stage and all the factors that can impact its development can help identify possible anomalies and early conditions that could affect the quality of life and functionality of children as they evolve and grow. Currently, there is significant research addressing the adult foot, but such research in the pediatric population is scarce. Factors such as paediatric flexible flatfoot (PFF), pediatric overweight or obesity (OW/OB), loss of strength, excessive plantar pressures, or lack of neuromuscular control can present challenges in this process, potentially affecting the quality of life and functionality of this special population. **OBJECTIVES**: Firstly, the aim was to investigate the descriptive characteristics and analyze the associations between childhood obesity in relation to baropodometric variables, laxity, muscle strength, and level of physical activity in children aged 5 to 10 years of age. In addition to conducting two systematic reviews and literature syntheses to analyze the effectiveness of foot orthoses (FO) and functional re-education (FR) as treatments in PFF, a study protocol was also carried out to assess the efficacy of plantar orthoses in PPIF. **MAIN RESULTS**: Pediatric OW/OB and foot type affect plantar pressures, laxity, and foot strength in children aged 5 to 10 years. FO and FR are effective in improving signs and symptoms of PFF. **GENERAL CONCLUSION**: This Doctoral Thesis represents a significant advancement in the understanding of childhood overweight, obesity, PFF, and foot types in the pediatric population from a biomechanical perspective and their implications on musculoskeletal health."

KEY WORDS: “pediatric obesity”; “children”; “plantar pressure”; “static stability”; “flatfoot”; “paediatrics”; “foot orthoses”; “foot posture index”; “Gait”; “Stance Phases”; “functional reeducation”; “exercises”

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"Ten fe ciega en el éxito y sé inasequible al desaliento"

"Grande es aquel que, para brillar, no necesita apagar la luz de los demás".

Anónimo.

ÍNDICE GENERAL

SIGLAS Y ABREVIATURAS

ABBREVIATIONS AND ACRONYMS

ABD, Abducción

ADD, Aducción

ALI, Arco Longitudinal Interno

ASA, Articulación subastragalina

BADL, Basic Activities of Daily Living

BAQA, Before-After Quality Assessment Tool

BMI, Body Mass Index

CT, Controlled Trials

CCTs, Controlled Clinical Trials

CG, Control Group

cm, centímetros/ centimetre

CSI, Chippaux–Smirak index

EVA, Ethylene-Vinyl Acetate

F, Female

FF, Flat feet

FO, Foot Orthoses

FPI, Foot Posture Index

HRT, Heel Rise Test

ICC, Intraclass Correlation Coefficient

IG, Intervention Group

IMC, Índice de Masa Corporal

Kg, Kilogramos/ kilogram

JH, Joint Hypermobility

LLAS, The Lower Limb Assessment Score

N/A, not applicable

NIH, National Institute of Health

NW, Normoweight

M, Male

MLA, Medial Longitudinal Arch

mm, milímetros/ millimetre

OMS, Organización Mundial de la Salud

OP, Órtesis Plantar

OW/OB, Overweight/Obesity

PNCA, Posición Neutra de Calcáneo en apoyo

PP, Pie Plano

PPI, Pie Plano Infantil

PPIF, Pie Plano Infantil Flexible

PRCA, Posición Relajada de Calcáneo en Apoyo

PRISMA, Preferred reported items of systematic reviews and meta-analysis

RCSP, The Relaxed Calcaneal Stance Position

RCTs, Randomised Controlled Trials

RF, Reeducación Funcional

SD, Standard Deviation

SIGN, Scottish Intercollegiate Guidelines Network

SP/OB, Sobrepeso/Obesidad

STROBE, Strengthening Reporting of Observational Studies in Epidemiology

WHO, World Health Organization

ÍNDICE DE FIGURAS, DE TABLAS Y DE ANEXOS

ÍNDICE DE FIGURAS

ÍNDICE DE TABLAS

ÍNDICE DE ANEXOS

I – INTRODUCCIÓN

I - INTRODUCCIÓN

El pie representa un objeto de estudio que requiere un análisis minucioso y exhaustivo, dada su función como fundamento anatómico de nuestro organismo y su papel fundamental como el único punto de contacto directo con la superficie de apoyo. En virtud de su compleja estructura y su interacción constante con el entorno, la exploración detallada del pie no solo es esencial para comprender la biomecánica y funcionalidad de este sistema, sino también para desentrañar las posibles implicaciones en la salud y el bienestar humano en general.

El pie infantil es un componente fundamental en el desarrollo y crecimiento de los niños, desempeñando un papel crucial en su movilidad y bienestar. A medida que los niños atraviesan diversas etapas de su desarrollo musculoesquelético, el pie experimenta una serie de transformaciones anatómicas y funcionales que son esenciales para su capacidad de moverse, explorar su entorno y participar en actividades físicas. La atención a la salud y el desarrollo del pie en la infancia es de suma importancia, ya que las características y condiciones que se presentan en esta etapa pueden tener repercusiones significativas en la salud a lo largo de la vida. Desde las primeras fases de gateo y los primeros pasos hasta la consolidación de la marcha independiente, el pie infantil enfrenta desafíos únicos y está expuesto a diversas patologías que pueden afectar su forma, función y desarrollo.

1.1. EVOLUCIÓN ANATÓMICA DEL PIE

Conocer el desarrollo del pie del niño es de gran importancia para todos los profesionales de la salud (podólogos, fisioterapeutas, pediatras, traumatólogos, etc.), los cuales tengan que evaluar, diagnosticar y tratar cualquier alteración del pie infantil. Además, también es de suma importancia para los padres o tutores legales a los cuales les preocupan el desarrollo del pie del niño y sus posibles alteraciones (1). Los pies de los niños no son una escala a menor de los pies de los adultos, los pies infantiles aún no han madurado ni en tamaño ni en forma y están en continua evolución. El desarrollo de los miembros inferiores y los pies inicia en el período embrionario y experimenta cambios fisiológicos a lo largo del

crecimiento hasta la finalización de la adolescencia. Estos cambios naturales pueden verse influenciados por diversos factores como la laxitud, la obesidad, irregularidades rotacionales en el fémur o la tibia, tibia vara patológica, equino, la presencia del "os tibiale externum" o la existencia de coaliciones tarsales, entre otros (2). El desarrollo del pie ocurre rápidamente entre los 2 y los 6 años de edad, con una velocidad mayor en las niñas (3).

1.2.1. Evolución del pie durante el periodo fetal

La ontogenia de la extremidad inferior o morfogénesis del pie evoluciona de manera veloz y en una secuencia ordenada, con transformaciones morfológicas permanentes que ocurren cada 2 días; Streeter (4) categoriza el período embrionario en 23 fases distintas.

Es en la etapa 17 (5º semana de desarrollo embrionario) donde podemos apreciar una forma redondeada que sugiere la presencia de un pie incipiente. La superficie de esta estructura se encuentra en el plano transversal, mientras que la superficie ventral, que dará lugar a la planta del pie en el futuro, se orienta hacia la cabeza. Los dedos no se aprecian aún, aunque en embriones más avanzados de este grupo, se puede notar un atisbo de un primer dedo en el borde tibial. En la etapa 21 los dedos de los pies se encuentran claramente definidos y separados. La superficie del pie se conecta de manera continua con la superficie de la pierna (no hay una inclinación dorsal del pie en relación a la pierna). Además, toda la extremidad inferior muestra una pronunciada rotación externa. Durante la etapa fetal, se desarrollan transformaciones cruciales de rotación que impactan la relación entre la pierna y el pie. Inicialmente, los pies, con sus plantas frente a frente, están en una posición de equino. Es decir, se produce un giro interno gradual del muslo-pierna, llevando al pie a adoptar una posición de equino, supinación y rotación externa respecto a la pierna. En una fase posterior, el pie experimenta dorsiflexión y pronación, acercándose a la postura neutral propia del adulto, con los dedos sin divergencia (5–7).

En cuanto al desarrollo esquelético intrauterino se desarrolla durante 3 fases o etapas, la etapa mesenquimatosa, la etapa cartilaginosa y la etapa ósea. La etapa mesenquimatosa durante la etapa 17 y 18 el pie ya está presente. El tejido mesenquimal axial se compacta y da origen al contorno inicial del pie. Las falanges

inicialmente exhiben una estructura densa interconectada entre los dedos durante un breve período. Con el tiempo, los metatarsianos comienzan a diferenciarse y a alejarse, aunque su acercamiento ocurre gradualmente. Posteriormente, se inicia la diferenciación del tarso. El procartílago emerge en las áreas donde el tejido se compacta. La etapa cartilaginosa (proceso de condrogénesis) empieza gradualmente y es donde se empiezan a diferenciar los huesos. La condrificación del mesénquima no ocurre de manera simultánea en su totalidad, por ejemplo en calcáneo condrifica en la etapa 18 la zona central y en la etapa 23 lo hace el sustentaculum tali. Por último, en la etapa ósea, la osificación del antepié es anterior a la del retropié. Cabe señalar que el astrágalo, su núcleo de osificación no está siempre presente en el momento del nacimiento. En recién nacidos con un peso inferior a 2 kg, el astrágalo no está osificado al momento de nacer. En cuanto al cuboides, es la última estructura del tarso que puede experimentar osificación antes del nacimiento (5–7).

En cuanto al crecimiento intrauterino del pie, la medición del mismo es posible desde la etapa 21, cuando el embrión llega a 24 mm de longitud. Durante el desarrollo fetal temprano (30 a 60 mm), el pie crece más despacio que el cuerpo. Luego, pasados los 70 mm hasta el nacimiento, el crecimiento corporal se desacelera mientras el pie mantiene su ritmo y hasta acelera su crecimiento relativo. A partir de la semana 14, el incremento promedio semanal es de alrededor de 3 mm. Hacia el final del tercer mes, el pie mide en promedio 0.8 cm, y al nacer, su longitud media es de 7.6 cm. Las medidas se toman en línea recta desde el talón hasta la punta del primer dedo extendido. A medida que crece, el pie fetal se estrecha gradualmente y permanece más largo que el pie adulto en relación con la longitud de la tibia (5–7).

1.2.2. Evolución del pie durante la infancia

El sistema musculoesquelético experimenta cambios significativos en las estructuras musculares y óseas a lo largo de toda la infancia, un proceso de gran relevancia.

Cuando un niño alcanza la edad de un año, su pie mide la mitad de lo que será en la adultez, proporción que se observa al año y medio en niñas. El incremento anual promedio de longitud es de 0,9 cm entre los 5 y 12 años en niñas

y hasta los 14 años en niños. La longitud definitiva del pie se logra a los 14 años en niñas y a los 16 años en niños. Hasta los 12 años, tanto en niños como en niñas, la longitud promedio es de 23,5 cm. Luego, el pie crece pausadamente, aumentando en promedio 0,8 cm durante 2 años en niñas y 2,2 cm durante 4 años en niños. El crecimiento del pie está sincronizado con el cuerpo, no con la extremidad inferior, alcanzando su longitud adulta antes que los huesos largos y la estatura total del individuo (8,9).

En cuanto a los centros de osificación primarios, secundarios y a los cierres epifisiarios, el primer núcleo de osificación primario en el tarso en manifestarse es el del cuneiforme lateral, seguido por el núcleo de osificación secundario en el extremo distal del peroné. La secuencia de osificación continúa con el cuneiforme medial, seguido del cuneiforme intermedio y el navicular. En la región del antepié, el primer núcleo de osificación aparece en la epífisis de la falange distal del primer dedo, seguido por la osificación de las epífisis en la base de las falanges proximales del segundo, tercer y cuarto dedo. La osificación epifisaria sigue una dirección de distal a proximal. Los núcleos de osificación epifisaria de las falanges distales de los dedos menores del pie surgen alrededor de los 3-4 años. En el primer dedo del pie, los núcleos de osificación secundaria surgen de manera progresiva de distal a proximal. A nivel de las cabezas de los metatarsianos, los núcleos de osificación epifisaria emergen de manera secuencial de medial a lateral (8,9). El último hueso en osificarse completamente en el pie es el hueso navicular o escafoides, el cual, generalmente se completa en la adolescencia (entre los 12 y 15 años). Como el último hueso en completar su osificación en el pie, el navicular juega un papel importante en la estabilidad y la función del pie durante la marcha y las actividades cotidianas, por ejemplo, es clave para el manejo del pie plano (PP) (10).

También encontramos cambios estructurales que se producen en el niño después del nacimiento; estos cambios en la morfología y posición de los diferentes huesos son parte del proceso de desarrollo y maduración del pie a medida que el individuo crece y se desarrolla. En relación con la tibia, los recién nacidos no muestran torsión tibial. La torsión externa del extremo distal de la tibia se desarrolla gradualmente, alcanzando los niveles de normalidad que se dan en el adulto alrededor de los 5 años. Durante los primeros tres meses después del nacimiento, se produce un aumento rápido de la torsión hacia afuera, llegando a un promedio de alrededor de 10 grados, que se mantiene constante durante el

segundo y tercer año de vida. Entre los 3 años y medio y los 4 años, se observa otro aumento súbito en la torsión tibial externa, llegando a un promedio de 20 grados. A los 4-5 años, la torsión alcanza alrededor de 23 grados, que es el promedio de torsión tibial externa en adultos (11).

En relación con el astrágalo, el ángulo de declinación entre el eje de la tróclea y el cuello del astrágalo es aproximadamente de 29 grados al momento del nacimiento, y esta cifra disminuye hasta alcanzar un valor promedio de alrededor de 22 grados en la edad adulta. A lo largo del período, desde el nacimiento hasta la adultez, el astrágalo experimenta un crecimiento más rápido en términos de anchura y altura que en longitud. Además, la rotación externa de la cabeza del astrágalo continúa durante este período. Esta rotación progresa desde aproximadamente 23 grados en el nacimiento hasta llegar a alrededor de 37 grados en la edad adulta. Con relación al calcáneo, su posición en varo (inclinación hacia el interior) disminuye tras el nacimiento y continúa hasta que finaliza el crecimiento óseo. Durante este proceso, el segmento posterior del cuerpo calcáneo muestra una tasa de crecimiento mayor en comparación con el segmento anterior. El ángulo que se forma entre el calcáneo y el cuello del astrágalo es de 30 grados en el momento del nacimiento, y esta medida disminuye a alrededor de 23.6 grados en la etapa adulta. En relación a los metatarsianos, el ángulo que existente entre el primer y segundo metatarsiano es de alrededor de 9 grados en el recién nacido, y esta medida disminuye a aproximadamente 6 grados en el pie adulto (6,9).

La formación del arco longitudinal interno (ALI) sigue una progresión natural. Hasta los 5-6 años de edad, los niños tienen una acumulación de tejido adiposo en el ALI, que combinado con la laxitud inherente y la falta de control neuromuscular, resulta en una apariencia de PP (12). La formación del ALI comienza a partir del segundo o tercer año de vida, lo que conlleva a una redistribución de la grasa en la planta del pie. Durante la fase de apoyo del pie en el suelo, en el niño se observa un desplazamiento medial y plantar del astrágalo, mientras que el ligamento calcaneonavicular plantar (ligamento de Spring) no logra mantener la cabeza del astrágalo sostenida, lo que resulta en una evidente distensión debido a la laxitud ligamentosa. Además, el retropié experimenta una eversión debido a la distensión del ligamento interóseo astrágalo-calcáneo. En el antepié, se produce un movimiento de supinación y aducción como mecanismo

compensatorio. A medida que el niño madura, este patrón mecánico tiende a revertirse (13).

La osificación total de los pies se lleva a cabo durante los primeros diez años de vida. Los centros de osificación de las epífisis y apófisis también se desarrollan hacia el final de la primera década. El cierre de estos centros ocurre mediante la osificación de las placas epifisarias al final del período de crecimiento, que suele abarcar entre los 15 y 21 años de edad (14).

1.2.3. Pie convencional o dentro de la neutralidad

Una vez que el pie ya está formado, las características que determinan que un pie está dentro de la neutralidad o es convencional, son las que se ilustran en la figura 1 (15).

Figura 1. Características de un pie convencionall

Aun así, Root (16) sugiere que estos criterios de normalidad deben considerarse únicamente como un punto de partida para el análisis clínico, y que posteriormente es necesario evaluar si las variaciones observadas en relación a estos criterios son lo suficientemente significativos como para ser consideradas como anormales o patológicas.

1.2. EVOLUCIÓN BIOMECÁNICA DE LA MARCHA

El comienzo de los movimientos coordinados genera fuerzas de compresión y tensión que contribuyen al desarrollo apropiado de huesos y músculos para futuras cargas. Esto promueve la adquisición de la capacidad de ponerse de pie y caminar en posición vertical. El conseguir estos logros a su vez influye en el desarrollo de las estructuras del pie, lo que a su vez promueve el desarrollo del resto del sistema musculoesquelético; "la forma facilita la función y la función sigue a la forma" (17).

La marcha puede describirse como una secuencia de pasos, siendo un paso el conjunto de acciones y movimientos que ocurren desde el impacto del talón de un pie hasta el impacto del talón del pie opuesto. Además, también podemos definirla como la modalidad de desplazamiento en posición vertical característica del ser humano, en la que se alternan los apoyos unipodales y bipodales. La marcha implica un proceso de automatización y desarrollo. En los seres humanos, este desarrollo sigue una dirección céfalo-caudal, lo que se traduce en que la marcha independiente generalmente comienza después del primer año de vida (18).

La marcha se puede entender como algo innato o como un proceso que se aprende, es decir, la capacidad para caminar se adquiriría a través de la imitación y el aprendizaje, utilizando el sistema de prueba y error. Cada individuo exhibe en su proceso de desarrollo rasgos particulares que están influenciados por diversos factores, como el entorno y las variaciones en la longitud y masa de cada uno de los segmentos del cuerpo (18,19).

Un 10% de los niños presentan un inicio tardío de la marcha, en su mayoría debido a problemas de sobrepeso infantil. Además, los niños con deficiencias sensoriales pueden también empezar a caminar más tarde. En algunos casos, la sobreprotección por parte de sus familiares u otros cuidadores puede ser un factor que retarda el inicio de la marcha, ya que temen posibles caídas o lesiones. En

presencia de patologías como trastornos neurológicos, problemas en el sistema locomotor o retrasos en el desarrollo psicomotor, la adquisición de la marcha puede producirse en etapas más avanzadas o con características anómalas (18–20).

Los primeros pasos en los seres humanos son tardíos en comparación con otros animales; el ser humano requiere un período más prolongado para lograr la posición bípeda y la capacidad de caminar de manera independiente (21).

1.2.1. Adquisición de la marcha

En la figura 2 se puede observar la evolución de la adquisición de la marcha de los niños. El niño recién nacido presenta automatismos de la marcha, estos aparecen cuando se coloca en posición bípeda con sujeción y los pies están en contacto con alguna superficie, el recién nacido hará gestos de la marcha con movimientos de basculación. Cuando el pie entra en contacto con la superficie, se desencadena el reflejo de triple retirada en forma de flexión, lo que se asemeja a la fase de oscilación o balanceo durante la marcha. Este reflejo se conoce como marcha automática (20,22).

A los siete meses de edad, los niños comienzan a desplazarse mediante movimientos de rastreo o reptación, y a los ocho meses logran mantenerse de pie momentáneamente con el apoyo de ambas manos. A los diez meses, comienzan a gatear con el abdomen cerca del suelo y pueden ponerse de pie si tienen algo a lo que agarrarse. Entre los 11 y 12 meses, muchos niños gatean utilizando manos y pies, y dan sus primeros pasos cuando se les sostienen ambas manos. Solo alrededor del 3% de los niños logran dar diez pasos sin apoyo de manos a los 9.6 meses, mientras que alrededor del 97% logra este hito a los 18 meses y medio, es decir, conseguir una marcha independiente (18,20,23–25).

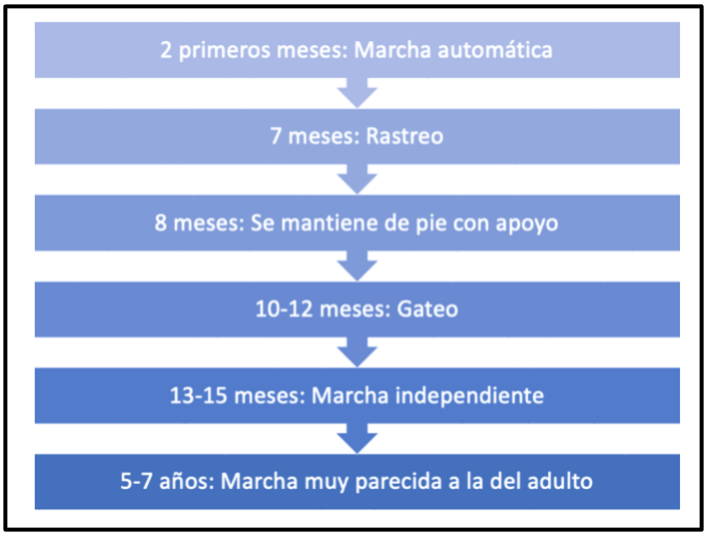

Figura 2. Evolución de la adquisición de la marcha

La adquisición de la marcha puede verse influenciada por factores como estímulos externos o la maduración del sistema nervioso. En niños prematuros, la marcha puede retrasarse hasta los 14-18 meses en comparación con los 12-15 meses en niños a término. Los primeros pasos suelen ser inseguros, irregulares y tambaleantes, con una separación de los pies y las extremidades superiores del cuerpo para lograr un mayor equilibrio y sustentación. En esos primeros pasos la longitud del paso va a ser irregular, la pelvis no va a hacer ningún movimiento de rotación o inclinaciones laterales. El aumento de la base de apoyo junto con una pronación de los pies hará que mantengan un mejor equilibrio. Toda la planta del pie va a estar en contacto con el suelo y en la fase de oscilación habrá una gran flexión de cadera y de rodilla. Además, el apoyo monopodal será de menor duración (20,26,27).

1.2.2. Evolución de la marcha

En cuanto a las características de la marcha, entre los 2 y 3 años, se evidencian signos de maduración en la marcha, incluyendo aumento en la velocidad y duración del apoyo con un solo pie, así como rotaciones opuestas de las cinturas pélvica y escapular, aumento del equilibrio y de los ángulos de flexión y extensión de tobillo. Entre los 5 y 7 años, los niños desarrollan un patrón de marcha similar al de los adultos (bipedestación estable, carga en el talón del 60-65% y sobre 35% en la zona del antepié). A los 6-7 años, las características cinéticas y cinemáticas y electromiográficas son casi como las del adulto. El patrón de marcha infantil se asemeja más al del adulto hacia los 7-9 años, como resultado de una maduración del sistema neuromuscular y una mayor coordinación; después de ajustar los movimientos en las distintas partes del cuerpo (24–26).

Durante la infancia temprana, la longitud del paso aumenta significativamente, se duplica en los primeros años, triplica a los ocho y cuadriplica a los diez años. Este crecimiento se debe al desarrollo de las extremidades, a un incremento en las angulaciones articulares y al alargamiento de la fase de oscilación en la marcha. Paralelamente, la velocidad de la marcha se multiplica: se duplica a los cuatro años, triplica a los siete y quintuplica a los diez. Este incremento en longitud de paso y velocidad no solo resulta de la adaptación funcional de las extremidades, sino también de una mayor coordinación, equilibrio y precisión en los movimientos. La cadencia, medida en ciclos por minuto, disminuye desde alrededor de 85-90 en el primer año de vida hasta 50-55 en la etapa adulta (24,27,28).

En los niños, la marcha se caracteriza por inseguridad y falta de equilibrio, lo que acorta la fase de apoyo monopodal, que es la menos estable. Conforme los niños crecen, el período de oscilación en la marcha aumenta, aproximándose al de los adultos, ya que mejoran su equilibrio en ambos tipos de apoyo. Además, se aprecia una evolución en los aspectos cinéticos de la marcha, tanto en fuerzas verticales como anteroposteriores y mediolaterales. La gráfica de las fuerzas verticales demuestra que el segundo pico, correspondiente al despegue del antepié (impulso), es de menor magnitud hasta los 4 años, las fuerzas anteroposteriores reflejan valores bajos en la fase de impulso hasta los 2 años, y las fuerzas mediolaterales se asemejan a las del adulto hacia los dos años (24,26,28).

1.3. PATOLOGÍAS MÚSCULOESQUELÉTICAS MÁS COMUNES EN LOS PIES DE LOS NIÑOS

El entendimiento de la gama completa de cambios fisiológicos en la extremidad inferior a lo largo del proceso de crecimiento facilita la detección temprana de posibles afecciones o patologías. Esto, a su vez, posibilita la implementación oportuna de intervenciones en caso de requerirlas (17).

La salud y el desarrollo de los pies en los niños suscitan una inquietud significativa entre padres o cuidadores y profesionales de la salud. Conforme los niños experimentan un proceso de crecimiento y maduración del sistema musculoesquelético, se encuentran susceptibles a una diversidad de afecciones que pueden influir en la estructura y funcionalidad de sus pies. Estas condiciones abarcan un amplio espectro en términos de su naturaleza y gravedad, abarcando desde trastornos de carácter transitorio que tienden a resolverse con el tiempo hasta problemas más persistentes que demandan atención médica y tratamiento especializado. La complejidad de estas patologías radica en su variedad, desde deformidades congénitas hasta problemas adquiridos a lo largo del tiempo (29).

Durante la etapa escolar, muchas de las irregularidades musculoesqueléticas son corregibles, y es más efectivo iniciar el tratamiento lo más temprano posible, dado que el contenido de cartílago es más predominante. Hasta los 6 años, las deformidades del pie pueden ser tratadas con un grado considerable de éxito; sin embargo, alrededor de los 12 años, la mayoría de los huesos cortos del pie (tarso) ya han finalizado su proceso de osificación. El dolor en el pie es una experiencia común y diversa en los escolares. Durante los primeros diez años de vida, el dolor generalmente está relacionado con lesiones traumáticas e inflamatorias. Sin embargo, en la segunda década de vida, el dolor en el pie con frecuencia está asociado con deformidades anatómicas (30–32).

Hay una gran variedad de patologías musculoesqueléticas que pueden darse en el niño, aunque las más frecuentes son: marcha en puntillas ("*Toe Walker*"), marcha en abducción (ABD) o aducción (ADD), sintomatología dolorosa relacionada con el crecimiento (osteocondrosis-osteonecrosis-"*growing pains*"), deformidades en los dedos, disimetrías y pie plano infantil (PPI) (33). En pacientes pediátricos, el crecimiento y desarrollo físico son procesos continuos. La edad del paciente y su etapa de desarrollo son elementos fundamentales al evaluar posibles irregularidades ortopédicas (29,31,34).

1.2.1. Marcha en puntillas (“*Toe Walker*”)

La marcha en puntillas o “*Toe Walker”* puede ser consecuencia de algún trastarnos neurológico o puede ser ideopática. La marcha en puntillas idiopática o la “*idiopathic toe walking*” es una condición en la que un niño camina principalmente apoyándose en las puntas de los dedos de los pies en lugar de hacerlo con toda la planta del pie. Esta condición se considera "idiopática" porque no tiene una causa clara o específica, es decir, no se debe a una afección médica subyacente identificable. En muchos casos, los niños pequeños pueden caminar de puntillas ocasionalmente mientras están explorando el movimiento de sus cuerpos. Sin embargo, si esta forma de caminar persiste más allá de los primeros años de vida y se vuelve una forma predominante de desplazamiento, puede indicar la presencia de la condición de "*idiopathic toe walking*". En muchos niños, el “*idiopathic toe walking*” mejora con el tiempo sin necesidad de tratamiento. Sin embargo, en casos en los que persiste o puede causar problemas en el desarrollo normal del pie y la marcha, se ha de considerar su tratamiento para corregir la forma de caminar y prevenir complicaciones futuras (35,36). La marcha de puntillas generalmente es idiopática y se resuelve por sí sola, pero puede ser un rasgo inicial de enfermedades neuromusculares, artritis y problemas ortopédicos (37).

1.2.2. Marcha en ABD o ADD

"*In-toeing”* es un término que se refiere a un pie que se gira hacia interno, de manera que los dedos apuntan hacia adentro. “*Out-toeing”*, por otro lado, se refiere a un giro en la dirección opuesta, alejándose del otro pie. El giro real, o torsión, puede estar en cualquier nivel de la pierna, desde la cadera (anteversión femoral) hasta la tibia (torsión tibial) o el propio pie (metatarso aducto). La marcha en aducción y abducción generalmente es simétrica, sin dolor y permite una movilidad normal (37).

La marcha en adución o “*In-toeing gait*” se da en el 30% de los niños de 4 años, pero esta condición persiste solo en un 4% de los adultos. Cuando el niño tiene marcha en ADD, la extremidad inferior puede compensar en varios niveles como en la articulación de la cadera, rodilla, en la tibia o en el ASA. Por lo general, la corrección de la aducción en la marcha ocurre espontáneamente entre los 4 y los 11 años de edad, a menos que exista una anomalía estructural en el pie o la pierna. La

gran mayoría de las variaciones rotacionales se encuentran dentro del amplio rango de normalidad y no requieren tratamiento (38,39).

La marcha en abducción o "*Out-toeing gait*" es menos común que la marcha en aducción y tiende a manifestarse en niños más jóvenes. Por lo general, se origina por una contractura externa de la cadera, torsión externa de la tibia y torsión externa del fémur. Esta tendencia suele mejorar con el tiempo de la misma manera que ocurre con la marcha en aducción (37).

1.2.3. Sintomatología dolorosa relacionada con el crecimiento

Dentro de las patologías que abarcan la sintomatología dolorosa relacionada con el crecimiento encontramos la osteocondrosis y osteonecrosis (las más comunes son la enfermedad de "*Perthes"*, enfermedad de "*Freiberg"*, enfermedad de "*Iselin"*, enfermedad de "*Sever"*, enfermedades "*Renander* y *Kohle"r*) y "*growing pains"*.

La osteocondrosis describe una serie de trastornos en los cuales se produce una alteración en el proceso normal de formación del tejido óseo y cartilaginoso en áreas específicas de crecimiento. Estas áreas de crecimiento, llamadas "placas de crecimiento" u "osificación epifisaria", son puntos en los huesos donde el tejido óseo nuevo se está formando a medida que el esqueleto crece. En la osteocondrosis, hay una interrupción en la irrigación sanguínea de estas zonas, lo que puede llevar a una degeneración del tejido óseo y cartilaginoso en esa área. Esto puede resultar en dolor, inflamación y, en algunos casos, la formación de pequeñas fracturas o fragmentos de hueso y cartílago, por lo que también puede ocasionar limitación funcional (29,40).

La osteonecrosis o necrosis avascular, es una condición en la que el suministro de sangre se ve comprometido, lo que resulta en la muerte de las células óseas en esa región. Esto puede llevar a la degeneración del tejido óseo y a la deformidad ósea. Como resultado, el hueso puede volverse más débil y deformarse, lo que puede llevar a problemas de movilidad, dolor y cojera. Es importante abordar la osteonecrosis en niños de manera temprana, ya que un diagnóstico y tratamiento adecuados pueden ayudar a minimizar la deformidad y prevenir complicaciones a largo plazo (41).

Entre las osteocondrosis y osteonecrosis más comunes nos encontramos con la enfermedad de "*Perthes"*, también conocida como enfermedad de "*Legg-Calvé-*

Perthes", es una afección de la cadera en la que la cabeza femoral experimenta una interrupción del flujo sanguíneo, lo que lleva a la degeneración y colapso del hueso en crecimiento. Esto puede resultar en deformidades y limitaciones en el movimiento de la cadera. La enfermedad de "*Freiberg"* afecta los metatarsianos, en particular el segundo metatarsiano. Provoca la necrosis avascular y el colapso del hueso en esa área, lo que puede resultar en dolor y dificultad para caminar. La enfermedad de "*Iselin2* se caracteriza por la inflamación y el dolor en la apófisis estiloides del quinto metatarsiano. Principalmente se da en niños que están muy involucrados en deportes que implican movimientos repetitivos del pie. La enfermedad de *Sever*, también llamada apofisitis calcánea, es una inflamación del cartílago de crecimiento en el calcáneo. La enfermedad de "*Renander"* afecta al escafoides, resulta en necrosis avascular y puede causar dolor y problemas en el movimiento. Por último, la enfermedad de "*Köhler"* es una afección que afecta el hueso navicular. Se caracteriza por la necrosis avascular del hueso, lo que puede causar dolor, inflamación y dificultad para caminar (42).

El término "dolores de crecimiento" o "*growing pains*" se utiliza para describir un tipo de síndrome de dolor no inflamatorio que es una de las causas más comunes de dolor musculoesquelético en niños. Su prevalencia varía entre el 3% y el 37% en la población infantil. Este síndrome presenta características clínicas distintivas, siendo predominantemente de naturaleza no articular. Suele manifestarse de manera bilateral. El dolor típicamente surge en horas tardías del día o durante la noche, llegando a despertar al niño en algunos casos. La duración de los episodios puede variar desde minutos hasta horas, y la intensidad del dolor puede oscilar desde leve hasta intensa. Por lo general, los síntomas desaparecen en la mañana siguiente. A pesar de la molestia que ocasiona, no se presentan signos objetivos de inflamación durante el examen físico. Los episodios de dolor tienden a ser episódicos, con períodos intermitentes de días a meses en los que el niño no presenta dolor. En algunos casos más graves, el dolor puede ser más frecuente y recurrente, llegando a manifestarse diariamente. Aunque la etiología exacta de los "dolores de crecimiento" sigue siendo desconocida, se reconoce que la evolución de esta afección es benigna en la mayoría de los casos. La gran mayoría de los episodios dolorosos tienden a disminuir o desaparecer en la adolescencia. Sin embargo, aún no está del todo claro si algunos de los niños que experimentan este

síndrome podrían desarrollar síntomas de otros trastornos de dolor no inflamatorios en etapas posteriores de su vida (43,44).

1.2.4. Deformidades en los dedos

Se pueden presentan diversas desviaciones en la posición de los dedos, tales como polidactilias (dedos supernumerarios), microdactilias (dedos pequeños), sindactilias (fusión de dedos), dedos rotados (quintos varos o hallux abductus valgus), dedos supraductus o infraductus y dedos en garra. Estas anomalías suelen derivar de malformaciones congénitas, alteraciones neuromusculares, en especial aquellas que afectan la musculatura intrínseca del pie, procesos inflamatorios como la artritis o lesiones. A su vez, es importante considerar que el tipo de calzado también puede tener un papel influyente en la manifestación de estas desviaciones digitales (45,46).

1.2.5. Disimetrías

La disimetría se refiere a la discrepancia en longitud de las extremidades inferiores, mientras que la dismetría, también conocida como heterometría, implica una diferencia tanto en longitud como en grosor de una extremidad en comparación con la otra. Identificar este problema de manera temprana y tomar medidas adecuadas en sus etapas iniciales permitirá corregir esta alteración en el tiempo y la forma más apropiada, evitando posibles consecuencias en la edad adulta. Las disimetrías pueden inducir diversas compensaciones en el sistema musculoesquelético en su totalidad. Cualquier variación en la longitud de las extremidades inferiores repercutirá en el conjunto del aparato locomotor, ya que funcionan como una unidad integral, generando un problema podológico que también puede influir en la columna vertebral (31).

1.2.6. Pie plano infantil

El pie plano infantil flexible (PPIF) es una de las condiciones ortopédicas más comunes en el campo de la pediatría y que se observa con mayor frecuencia en la clínica (47). El 90% de las consultas médicas relacionadas con problemas en los pies están asociadas al diagnóstico de pie PP, además de que es una inquietud común

entre los padres y un tema ampliamente debatido por los profesionales de la salud (48).

A lo largo de décadas, y hasta el día de hoy, el PP ha sido un asunto polémico en el que se cuestiona la definición de lo normal o convencional y lo patológico, cómo realizar el diagnóstico, cuándo es necesario intervenir y cuándo se debe permitir la evolución fisiológica, cuál es el enfoque óptimo de tratamiento conservador o cuándo es apropiado considerar intervenciones quirúrgicas. Además, no hay un consenso universal ni una definición precisa para esta condición. Varios autores han propuesto distintas definiciones en base a diversas clasificaciones (30,49,50).

Desde una perspectiva clínica, el PP se caracteriza por la reducción del ALI cuando el individuo se encuentra en posición de bipedestación o carga. Esta característica general se asocia con una posición en valgo del calcáneo o retropié que excede los 6 grados (desviación en equino y valgo del calcáneo). Se observa la prominencia medial del astrágalo, la huella del pie muestra un aspecto plano, y la ASA tiende a estar medializada. Además, se presenta una ABD del antepié en relación al retropié, y se puede identificar una rotación interna de la tibia. Todas estas características contribuyen a darle al pie una apariencia aplanada. El PP es una deformidad que involucra tres planos de movimiento, y se origina debido a una insuficiente formación del ALI durante los primeros años de vida (12,49,51,52).

En el caso del PPIF, el término "flexible" hace referencia a la capacidad de las articulaciones para corregir la deformidad cuando el pie está en carga, permitiendo que el arco se reconfigure temporalmente (49,52–54). La clasificación de los diferentes grados o etapas del PPI no está claramente definida. Generalmente, se categoriza en PP rígido o flexible. Cuando se trata de un PPI rígido (aplanamiento del ALI tanto en carga como en descarga), la mayoría de los profesionales de la salud están de acuerdo en que debe recibir tratamiento, ya sea conservador o quirúrgico. Sin embargo, la controversia entre los diferentes profesionales surge cuando se trata de un PPIF. Esta controversia se origina porque algunos profesionales consideran que el PPIF es una variante normal del desarrollo del pie en los niños, argumentando que se corregirá de forma espontánea a medida que el niño crezca (55).

También hay una gran controversia en cuanto a las manifestaciones clínicas, ya que la mayoría de los PPIF son asintomáticos. No todos los PPIF causan dolor o

discapacidad durante la infancia o niñez. En aquellos casos en los que se presenta sintomatología, los síntomas más comunes podrían incluir dolor después de actividades intensas o caminatas largas, fatiga, calambres nocturnos, dificultades de equilibrio o caídas al correr (56–58). Independientemente de la presencia de síntomas, en el caso del PPI existen alteraciones biomecánicas. Estas alteraciones biomecánicas pueden ser observadas tanto en la postura estática como en el movimiento dinámico del pie. Cuando evaluamos a estos pacientes en movimiento, podemos observar que durante el segundo período de apoyo (segundo rocker) hay una reducción en la flexión dorsal del tobillo y un aumento en la eversión del retropié, acompañado de un aumento en la ABD y supinación del antepié. En la fase propulsiva, se podría notar una deficiencia en la inversión del retropié, un aumento en la flexión plantar del antepié y una disminución en la ADD del antepié (59–61).

La etiología del PPIF es un tema que aún plantea interrogantes y diversas teorías. Múltiples estudios han examinado factores asociados, aunque no se ha identificado una causa definitiva. Se ha observado una fuerte relación con la genética, la laxitud de los tejidos, el sobrepeso u obesidad (SP/OB), el género masculino o estatura más baja. Además, se ha notado que patrones torsionales anómalos y la presencia de un PP en niños están vinculados con el PPIF. La actividad física también puede influir, ya que se ha observado que los niños con PPI tienden a tener menor actividad física (62,63).

El acortamiento del tendón de Aquiles es otro factor relevante, ya que alrededor del 25% de los casos de PPIF presentan contractura en este tendón, lo que puede causar dolor e inestabilidad. Existe una teoría que sugiere que la debilidad de la musculatura podría contribuir a la falta de soporte del arco longitudinal interno. Otra perspectiva se enfoca en que el complejo músculo-ligamentario desempeña un papel en el descenso del arco. Además, algunos autores plantean que la almohadilla grasa, la presencia de un navicular accesorio, coalición tarsal, astrágalo vertical o una disfunción del músculo tibial posterior podrían ser causantes del PPIF (57,64–66).

Se ha considerado que el uso de calzado antes de los 6 años puede ser un factor predisponente para el PPIF. Estudios han demostrado que el uso de calzado podría tener una incidencia más alta (8.6%) en comparación con aquellos que no lo usan (2.8%), en relación con la predisposición al PPIF (67,68). Sin embargo, es

importante señalar que la etiología del PPIF sigue siendo objeto de investigación y debate en la comunidad médica, y no se ha llegado a un consenso definitivo sobre sus causas exactas.

La epidemiología del PPIF es un tema que presenta desafíos debido a la variabilidad en la metodología de los estudios, las definiciones subjetivas y la falta de consenso en el diagnóstico. Por lo tanto, la prevalencia real de esta condición aún no está claramente establecida. Diversos estudios ofrecen diferentes cifras, y se estima que la prevalencia del PPIF podría oscilar entre el 20% y el 78% en niños de 3 a 15 años de edad (49,69).

Es importante destacar que la dificultad para determinar con precisión la incidencia del PP radica en la presencia de casos asintomáticos que no buscan atención médica. En diferentes países y regiones, se han reportado distintos rangos de prevalencia. Por ejemplo, en Europa, las cifras varían del 11% al 44%. En España, los estudios han arrojado prevalencias entre el 2,7% y el 18,16% (70,71). A lo largo del tiempo, se ha observado que el PPIF fisiológico puede persistir en un porcentaje significativo de adultos, como señala el estudio de Harris et al. (55), donde se menciona que el 23% de los adultos mantienen este tipo de pie. Otra investigación realizada por Staheli et al. (72) revela que el 4% de los casos fisiológicos continúan después de los 10 años. Investigaciones más recientes, como la de Bordin et al. (73), indican que alrededor del 16.4% de los niños de 10 años presentan PPIF, aunque es probable que existan más casos no diagnosticados debido a la falta de síntomas evidentes.

El autor Fabry G (48) sostiene que los PP y desalineados eventualmente pueden dar lugar a otras patologías en el pie, tobillo y estructuras adyacentes, ya sea en el futuro cercano o lejano. Diversos estudios han revelado que los adolescentes y adultos con PP tienen el doble de probabilidad de experimentar dolor en las rodillas y la espalda en comparación con aquellos sin esta condición. Además, se ha observado una asociación entre el PP y afecciones como la fasciopatía plantar, tendinopatía aquílea y del tibial posterior, hallux límitus y rígidus, condromalacia rotuliana y síndrome de dolor patelofemoral (56,74). Otros investigaciones también han vinculado el PP con problemas en la cadera, un mayor riesgo de esguinces de tobillo e incluso fracturas de estrés en los metatarsianos (75).

En el contexto de los adultos, existe evidencia que sugiere que los PP en adultos pueden experimentar un deterioro progresivo con el tiempo, lo que implica

que los PP asintomáticos en la infancia eventualmente podrían desarrollarse en PP sintomáticos en la edad adulta (76,77).

En relación al diagnóstico, existen una variedad de técnicas utilizadas (pruebas clínicas, análisis de fotopodogramas y radiografías) para evaluar el pie PP. Entre las pruebas clínicas más comunes se encuentran la Posición Relajada de Calcáneo en Apoyo (PRCA), la Posición Neutra de Calcáneo en Apoyo (PNCA), pruebas como Navicular Drop, Navicular Drift, Navicular Height, Índice de Postura del Pie (FPI), Test de Jack, Single/Doble Heel Rise Test (HRT), test de pronación máxima, test de resistencia a la supinación, ángulo de pronación, posición del antepié y el "Too Many Toes". También se emplean herramientas como el pedígrafo para estudiar la huella plantar, plataformas de presión, fotopodogramas (para medir el índice de altura del arco) y el podoscopio. Sin embargo, las mediciones radiográficas suelen proporcionar una mayor objetividad en el diagnóstico (12,56,78).

Además de estas pruebas, también se utilizan pruebas clínicas para evaluar posibles factores etiológicos previamente mencionados, como la genu valgo, la disimetría, torsiones tibiales, metatarso aducto y la flexibilidad, que puede evaluarse mediante la escala de Beighton, entre otros métodos (42,46,61,78).

Las cuestiones y dudas planteadas anteriormente resaltan la considerable incertidumbre sobre si el PPI es una variante más del desarrollo normal del pie o si constituye un indicio patológico que necesita tratamiento (55,78). Es fundamental considerar la amplia gama de factores que pueden influir en la evolución del pie y correlacionar meticulosamente los datos recopilados mediante las diferentes pruebas aplicadas a cada paciente. La combinación de todos los datos objetivos obtenidos desempeñará un papel crucial en la toma de decisiones con respecto a la necesidad o no de intervención.

El PPI no debe ser pasado por alto ni minimizarse en términos de tratamiento, ya que intervenir con un tratamiento efectivo en las primeras etapas puede prevenir daños posteriores en otras áreas del cuerpo (77). Además, los autores enfatizan la importancia de optar por enfoques de tratamiento conservadores antes de considerar opciones más invasivas (53,56,78).

1.2.7. Factores etiológicos y de riesgo en la población infantil

Tanto la marcha como el desarrollo músculo-esquelético, así como el desarrollo psicomotor de los niños son procesos que están determinados por numerosos factores del entorno y genéticos (25,27). A diferencia de los pies completamente desarrollados de los adultos, los pies de los niños todavía están en proceso de crecimiento en términos de tamaño y forma. Debido a esta fase de maduración, los pies infantiles son más susceptibles a influencias externas desfavorables (1).

El crecimiento y la formación adecuada de los pies en los niños, así como, su correcto funcionamiento pueden verse influenciados por una serie de factores. Es importante brindar un entorno adecuado, incluyendo el uso de calzado apropiado, fomentar la actividad física y estar atento a cualquier señal de alteraciones en el desarrollo del pie para abordar tempranamente cualquier problema potencial. La infancia es un período crítico en el desarrollo musculoesquelético, coincidiendo con la adquisición de una postura erguida y habilidades básicas de movimiento. Por lo tanto, los niños son particularmente susceptibles a los factores externos que influyen en su postura corporal (79,80).

En cuanto a los factores de riesgo que pueden condicionar que el niño desarrolle patologías o tengan alteraciones en su desarrollo, en primer lugar, encontramos la genética. La predisposición genética puede influir en la forma y estructura del pie del niño y en la biomecánica, incluyendo la tendencia a desarrollar ciertas condiciones, problemas o deformidades. Los factores de crecimiento y los desbalances musculares también influyen, puesto que, durante el período de crecimiento, el rápido desarrollo óseo y muscular puede contribuir a desequilibrios musculares o alteraciones en la alineación de las articulaciones incluso la biomecánica de la marcha. Esto sumado a malos hábitos posturales, es decir, la adopción de posturas incorrectas al caminar, estar de pie o sentarse puede afectar el desarrollo normal del pie y causar deformidades (17,51,79,81,82).

Además, el niño puede presentar enfermedades subyacentes o condiciones médicas como trastornos neuromusculares o endocrinos que pueden interferir con el crecimiento normal del pie. También pueden sufrir traumas o lesiones en los pies que pueden afectar el crecimiento y desarrollo adecuado de los huesos y articulaciones. Así como condiciones médicas congénitas presentes desde el

nacimiento que pueden afectar el desarrollo normal del pie. El crecimiento ocurre en etapas y ritmos específicos, y las alteraciones en el crecimiento de los huesos pueden afectar la formación del pie (1,83).

Los factores ambientales también se pueden considerar un factor de riesgo, por ejemplo, la exposición a superficies irregulares o terrenos difíciles puede influir en el desarrollo del equilibrio y la musculatura del pie. Por el contrario, el uso de calzado que no se ajuste correctamente a los pies en crecimiento o el uso de calzado antes de que el pie esté completamente formado puede alterar la forma natural del pie en crecimiento (84,85).

Por último, la falta de actividad física y movimiento unido al exceso de peso puede afectar el desarrollo muscular y la formación adecuada del pie (86,87).

1.2.7.1. ***Obesidad infantil***

La obesidad infantil es considerada uno de los desafíos más serios para la salud pública en el siglo XXI (88). Datos recientes de la Federación Mundial de Obesidad revelan que más de 340 millones de niños y adolescentes alrededor del mundo están experimentando sobrepeso u obesidad (89). Para comprender el dramático aumento en las últimas décadas, en 1975 solamente el 4% de la población infantil global padecía SP/OB, mientras que esta cifra ha aumentado al 18% o más en 2016 (90). Europa no ha sido inmune a este incremento, y España, entre los países europeos, se encuentra en los cinco primeros con un 30-35% de niños con SP/OB (91).

La Organización Mundial de la Salud (OMS) destaca cuatro consecuencias principales de la obesidad infantil en la salud a largo plazo (92): 1) enfermedades cardiovasculares (como enfermedades cardíacas y accidentes cerebrovasculares), 2) diabetes (principalmente diabetes tipo II), 3) trastornos musculoesqueléticos (sobre todo la osteoartritis) y 4) ciertos tipos de cáncer (incluyendo endometrio, mama y colon).

La obesidad infantil constituye un problema de gran relevancia en la sociedad contemporánea. Los niños con exceso de peso u obesidad exhiben una postura y adoptan un estilo de movimiento distintos desde el punto de vista biomecánico, lo que conlleva consecuencias significativas para el desarrollo de afecciones musculoesqueléticas y limitaciones físicas en su vida cotidiana. No

obstante, aún persiste un desconocimiento acerca de cuáles son exactamente estas alteraciones biomecánicas y cuál es su impacto en la salud musculoesquelética de los niños (93,94).

Los niños con sobrepeso y obesidad presentan una prevalencia aproximadamente un 26% mayor de dolor musculoesquelético en comparación con aquellos con peso normal. Además, esta población infantil enfrenta un mayor riesgo de sufrir lesiones en las extremidades inferiores durante la práctica de actividades físicas (95). Se ha argumentado que los estilos de vida sedentarios, la salud psicológica deficiente y los procesos inflamatorios relacionados con el sobrepeso y la obesidad podrían contribuir a esta mayor prevalencia de trastornos musculoesqueléticos (93). Sin embargo, desde una perspectiva biomecánica, también se ha sugerido que las alteraciones estructurales en el sistema musculoesquelético, así como las desalineaciones articulares durante la realización de tareas locomotoras, podrían estar contribuyendo a estas condiciones (87).

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II – JUSTIFICACIÓN

II - JUSTIFICACIÓN

Investigar y ampliar el conocimiento sobre el pie infantil es de gran importancia debido a numerosos motivos que afectan tanto a la salud individual como a la salud pública en general.

Si pensamos en el desarrollo y la calidad de vida, el pie es una estructura fundamental para el desarrollo motor en la infancia. Tener conocimiento sobre cómo se desarrolla el pie en esta etapa y todos los factores que pueden afectar a su desarrollo puede ayudar a identificar posibles anomalías y condiciones tempranas que podrían afectar a la calidad de vida y la funcionalidad de los niños a medida que estos evolucionan y crecen. Un pie saludable es esencial para la movilidad y el equilibrio en todas las etapas de la vida. Investigar sobre el pie infantil puede ayudar a desarrollar estrategias para mejorar la función y la movilidad, permitiendo a los niños participar plenamente en actividades físicas y deportivas.

Hablando desde una perspectiva de prevención y tratamiento temprano, el pie en desarrollo es susceptible a ciertas condiciones como por ejemplo una entidad tan frecuente como es el pie plano infantil. Detectar y saber cómo tratar estas condiciones de manera temprana puede prevenir problemas musculoesqueléticos a largo plazo y mejorar la calidad de vida de los niños y por lo tanto también la vida del adulto. Además de detectar y saber cómo tratar esta entidad tan frecuente como es el pie plano, se debe de conocer qué tratamientos son más efectivos y cómo han de ser cada uno de ellos, basándonos en la evidencia científica. También es de gran importancia poder establecer un protocolo de investigación debido a las características propias del pie plano infantil.

Las condiciones del pie en la infancia pueden tener un impacto a largo plazo en la salud musculoesquelética y la postura en la edad adulta. La investigación en esta área puede proporcionar información valiosa sobre cómo prevenir problemas futuros al intervenir en la infancia.

Conociendo mejor el pie del niño, su desarrollo y los factores que pueden afectar al mismo (como es la obesidad infantil o el tipo de pie que presente cada niño), también estamos contribuyendo a la Salud Pública. El estudio del pie infantil puede tener un impacto en la salud pública al reducir la carga de enfermedades y

discapacidades relacionadas con el pie en la población adulta. Esto podría llevar a una mejora general en la calidad de vida y una disminución de los costos de atención médica.

En resumen, investigar sobre el pie infantil es esencial para comprender su desarrollo, prevenir problemas futuros, mejorar la función y la calidad de vida, y contribuir al bienestar general de la población.

En la actualidad hay muchas investigaciones que abordan el pie del adolescente y el adulto, pero en la población infantil estas investigaciones son escasas. La salud y el desarrollo adecuado del pie en la infancia son elementos esenciales para el bienestar general y la calidad de vida a lo largo del ciclo vital. El pie infantil, en su compleja interacción con el entorno y el crecimiento, desempeña un papel crucial en la función locomotora, el equilibrio postural y la participación en actividades cotidianas. Además, la configuración y el desarrollo del pie en la niñez tienen implicaciones a largo plazo en la estructura y función del sistema musculoesquelético en la edad adulta.

El estudio del pie infantil es de particular importancia debido a su capacidad de adaptación y cambio durante las diversas etapas del desarrollo. El proceso de formación del arco longitudinal, la alineación del sistema esquelético y el establecimiento de la función biomecánica adecuada son aspectos cruciales que definen la base para una marcha y un movimiento eficientes. Sin embargo, factores como el pie plano, la pronación excesiva, la obesidad infantil, la pérdida de fuerza, el exceso de presiones plantares o la falta de control neuromuscular pueden presentar desafíos en este proceso, afectando potencialmente la calidad de vida y la funcionalidad de esta población tan especial.

Dado el limitado conocimiento y la escasa información disponible acerca del pie infantil en la literatura, consideramos crucial continuar investigando en esta área. Esta investigación contribuirá a enriquecer nuestra comprensión sobre su desarrollo, prevenir problemas futuros, mejorar la función y la calidad de vida, y contribuir al bienestar general.

III – OBJETIVOS

III - OBJETIVOS

1) Investigar las características descriptivas y analizar las asociaciones entre la obesidad infantil y las variables baropodométricas, variables de laxitud y fuerza muscular en niños de 5 a 10 años. (ESTUDIOS I y II)

2) Llevar a cabo dos revisiones sistemáticas y síntesis de la literatura para analizar la eficacia de las órtesis plantares y la reeducación funcional como tratamiento en el PPIF. (ESTUDIOS III y IV)

3) Realizar un protocolo de estudio sobre la eficacia de las órtesis plantares en el PPIF. (ESTUDIO V)

IV – ESTUDIO I

IV -ESTUDIO I

OVERWEIGHT AND OBESITY: ITS IMPACT ON FOOT TYPE, FLEXIBILITY, FOOT STRENGTH, PLANTAR PRESSURE AND STABILITY IN CHILDREN FROM 5 TO 10 YEARS OF AGE: DESCRIPTIVE OBSERVATIONAL STUDY

Abstract:

Background: Overweight (OW) and childhood obesity (OB) may cause foot problems and affect one's ability to perform physical activities. The study aimed to analyze the differences in descriptive characteristics, foot type, laxity, foot strength, and baropodometric variables by body mass status and age groups in children and, secondly, to analyze the associations of the BMI with different physical variables by age groups in children. **Methods**: A descriptive observational study involving 196 children aged 5–10 years was conducted. The variables used were: type of foot, flexibility, foot strength and baropodometric analysis of plantar pressures, and stability by pressure platform. **Results**: Most of the foot strength variables showed significant differences between the normal weight (NW), OW and OB groups in children aged between 5 and 8. The OW and OB groups showed the highest level of foot strength. In addition, the linear regression analyses showed, in children aged 5 to 8 years, a positive association between BMI and foot strength (the higher the BMI, the greater the strength) and negative association between BMI and stability (lower BMI, greater instability). **Conclusions**: Children from 5 to 8 years of age with OW and OB show greater levels of foot strength, and OW and OB children from 7 to 8 years are more stable in terms of static stabilometrics. Furthermore, between 5 and 8 years, having OW and OB implies having more strength and static stability.

Keywords:

Pediatric obesity; children; plantar pressure; static stability

4.1. INTRODUCTION

The World Health Organization (WHO) defines overweight (OW) and obesity (OB) as an abnormal accumulation of fat that represents a health risk [1]. It is also considered as "one of the most serious public health challenges of the 21st century" due to the fact that childhood OB continues to rise and more frequently occurs at younger ages with more serious health consequences associated with the early onset of OB [2,3]. According to the WHO, the prevalence of OW and OB in children and adolescents aged between 5 and 19 increased during the past years, rising from 4% of that population in 1975 to 18% in 2016 [4]. The World Obesity Federation has already stated that in 2030, 254 million children and adolescents will suffer from OB [5]. Interestingly, the vast majority of OW or obese children live in developing countries, where the rate of increase has been more than 30% higher than in developed countries in 2022 [1].

Considering previous literature, some studies have already highlighted how children who have OW and OB are more likely to suffer from several clinical comorbidities such as diabetes or metabolic syndrome [6], while others have already remarked how there is an association between increased risk of injury and childhood OB and gait, plantar pressures and stability [7–9], these being the main factors related to pain in the feet and lower limbs in children [10]. Notwithstanding, there is still controversy about the level of association between OW and OB and gait disturbance in children. In this sense, some studies have reported that children with OW and OB have weaker stability, a flatter foot pattern and a larger axis of the foot than normal weight (NW) children, which seems to impact plantar pressures [10–13], provoke pain and affect their quality of life [14,15]. Other studies, on the contrary, described no relationship between the OW and OB and foot pronation [16,17]. Therefore, and bearing in mind the lack of consensus and evidence, more studies are still needed to shed more light on this subject, which could be very useful for the clinical management of these young patients.

At the clinical level, the impact of gait is of great importance due to the fact that there is a large inverse correlation between physical activity level and plantar pressure [18]. This is mainly because deformities of the musculoskeletal system can be caused by an increase in pressure as a result of an increase in body mass index (BMI) [10]. Thus, by increasing plantar pressure, pain would increase and,

consequently, the ability to perform physical activity would be limited, which could result in an impairment of children's quality of life [14,15]. In fact, it is known that suffering from alterations of this type limits the motivation of children to perform physical activities, which would further aggravate the problem of inactivity and suffering from OW and OB [19]. Considering all of the above, as the main clinical implication, all risk factors related to the onset of pain must be recognized. Signs such as excessive pressure or altered stability, should be recognized to prevent pain and complications in the short and long term, that is, to work from early prevention.

Therefore, this study aims to analyze the differences in descriptive characteristics, foot type, laxity, foot strength and baropodometric variables by body mass status and age groups in children and, secondly, to analyze the associations of BMI with variables foot type, laxity, foot strength and baropodometric variables by age groups in children.

4.2. MATERIALS AND METHODS

4.2.1. Participants

One hundred and ninety-six children (78 males and 118 females) aged between 5 and 10 years were recruited for this descriptive observational study. This age range was chosen because it is the age at which the Foot Posture Index (FPI) is validated [20]. The study was approved by the Ethics Committee of the Catholic University of San Antonio de Murcia (Spain) (Code: CE022205). For the realization of the study, the Strengthening Reporting of Observational Studies in Epidemiology (STROBE) guidelines have been followed [21]. This study was performed in line with the principles of the Declaration of Helsinki [22].

The selection criteria of the sample were children aged 5–10 years, who do not have foot pain and who had the consent of the parents/guardians. Parents/guardians were previously informed about the study, completed a questionnaire and signed their consent to confirm their children's participation. Children who had any of the following condi- tions were excluded from the study: recent damage to lower limbs; congenital structural alterations affecting distal areas of the ankle joint, as well as those cases with pathological flatfoot caused by

cerebral palsy; surgical treatments in the foot or lower extremity; or genetic and neurological or muscular pathology.

All children were evaluated between February and June 2022 in a primary school in the region of Murcia (Spain). For 5 months, all participating children completed all the assessments in one morning on the same schedule. Demographic and anthropometric data were collected from all children prior to the investigation. Children were assigned a specific number to maintain confidentiality. To examine them, they were asked to be barefoot and in light clothing (t-shirts and shorts) and were individually evaluated by two expert clinicians at the same time. If these two clinicians disagreed during measurements of the same child, a third clinician decided which of the two values was more accurate. Similarly, another clinician who was not involved in the assessments was in charge of analyzing the data.

Before starting the test, each test was demonstrated and explained to every child. In this sense, each item of each test had to be performed three times, and the measurements obtained were averaged. Children received standard verbal encouragement and support throughout the whole testing procedure. When a child made a procedural error, the instructions and demonstrations were repeated and the child was allowed to try again; each child was allowed to fail a maximum of 5 times. All children completed all the measurements correctly.

4.2.2. Measurement of the Variables

4.2.2.1. Anthropometric Measures

Height was measured with a calibrated portable SECO 7710 m, with a bubble level fixed to the arm for greater accuracy, while weight was measured with Digital Pegasus Scales, with a margin of error of 0.05 kg and keeping subjects with as little clothing as possible (shirt and shorts).

To establish cut-off points for specific BMI by sex and age, cut-off points established in previous bibliography were considered [23,24], children were categorized as normal weight “NW”, overweight “OW” or obese “OB”.

4.2.2.2. ***Type of Foot, Laxity and Foot Strenght***

To find out what type of foot each child had, the evaluation of each foot was carried out by measuring the Foot Posture Index (FPI-6) with the subjects standing barefoot, in a relaxed position, on a 50 cm bench to facilitate visual and manual inspection. The FPI-6 rates 6 aspects of foot anatomy in the 3 planes of the foot. The FPI-6 takes into account the posture of the hindfoot, midfoot and forefoot. The FPI-6 provides a total value from −12 points (highly supinated) to +12 points (highly pronated). Interobserver reliability for FPI-6 in the pediatric population has reached a consistent weighted Kappa value (Kw = 0.86) in a sample of children aged 5 to 16 years of age [25].

To recognize whether the children had joint hypermobility (JH) or hyperlaxity, two scales and one test were also used: the Beighton Scale [26], the Lower Limb Assessment Score (LLAS) [27], and the Ankle Lunge Test [28]. For both scales, goniometry was used, which is a valid instrument to measure generalized joint mobility in school-age children [29].

The Beighton scale is used to observe if the child presents JH at a general level, that is, in the wrist, the metacarpophalangeal joint of the fifth metacarpal, in the elbow, in the knee (all bilateral and without weight bearing) and in the lumbosacral spine. The Beighton scale has a score of 9 points, so the usual arbitrary cutoff of 5/9 or higher indicates that the child has JH. This scale has shown to be reliable, with a Kw 0.81 [26].

The LLAS measures JH, but of the lower extremity. The hip, knee, ankle, subtalar joint, midtarsal joint and metatarsophalangeal joint were assessed. On the LLAS scale, each limb produces a final score of 12 points, so a score of 7/12 or higher indicates JH. The LLAS has shown to be reliable, with an intraclass correlation coefficient (ICC) of 0.84 [27].

The Ankle Lunge Test assesses the range of weight-bearing ankle dorsiflexion with the knee flexed. To quantify the Ankle Lunge Test, a digital inclinometer (Smart ToolTM) was used, which was applied to the anterior surface of the tibia to measure ankle dorsiflexion. This test has shown to be reliable, with an intra-assessed ICC of 0.98 and an inter-assessed ICC of 0.97 [28].

Isometric muscle strength was quantified using the Lafayette Instrument Company Hand Dynamometer, Model 01160, Lafayette, Indiana, U.S.A. The device

was calibrated at the factory, according to the manufacturer's data, at a sensitivity of 0.1 kg and a range of 0.0 to 199.9 kg. Each child was placed in a long sitting position (hips flexed and knees extended) on an examination table with a backrest. Isometric foot inversion and eversion muscle strength, and ankle plantarflexion and dorsiflexion was measured according to a standardized procedure [30]. This measurement has shown good intra-rater (ICC = 0.92–0.97) and inter-rater (ICC = 0.80–0.95) reliability [31].

4.2.3. Baropodometry

The baropodometric analysis was performed with the RSscan Footscan® 9 platform, with dimensions of 578 mm × 418 mm × 12 mm. The platform contains 4096 sensors (arranged in a 64 × 64 matrix), the dimensions of the sensors are 7.62 mm × 5.08 mm and the active area is 488 mm × 325 mm. The precision range is 1–127 N/cm2 and the data acquisition frequency is 500 Hz with a 10-bit resolution.

Following the manufacturer's manual, the platform was calibrated before each session. Three baropodometric measurements in an orthostatic position and three stabilometric measurements in an orthostatic position with eyes open for 60 s were taken for each child; a minute of rest was left between each measurement. Children were asked to stand on the platform, with their own Fick angle, arms along the body, feet at the same height and facing forward towards a fixed point that was placed at eye level at a distance of 3.8 m. Before data collection, children were allowed to familiarize themselves with the platform until they were confidently able to perform it.

The parameters considered were the % of pressure distribution in left and right leg, forefoot and rearfoot, left (C1) and right (C2) forefoot and left (C3) and right (C4) rearfoot for both static and stabilometry. In addition, in the stabilometric measurement, the following parameters were measured:

- Position (minimum–maximum x-y axis): the current, minimum and maximum position in millimeter for the x- and y-coordinate.
- Range (interval–average x-y): the spread between the minimum and maximum position in millimeters for the x- and y-coordinate.
- Travelled distance: the length of the center of pressure line in millimeters.

• Ellipse area: the area of the calculated center of pressure ellipse in square millimeters.

• Principal–second axis ellipse: Length of the major–minor axis of the ellipse of the center of pressure of the left and right foot, measured in millimeters.

The reliability of the Footscan® system (RSscan International, Olen, Belgium) has been demonstrated by different investigations with ICC values from good to excellent for the intra- and inter-evaluator scores (ICC 0.81–0.86 and ICC 0.87–0.95, respectively) on plantar pressure variables [32].

4.2.4. Statistical Analysis

All variables were checked for normality using both graphical and statistical procedures. Differences in descriptive characteristics, type of foot, laxity, foot strength and baropodometric characteristics of the overall sample by age and body mass status were examined applying the t-test. For that, three age groups were created: (1) 5–6 years; (2) 7–8 years; and (3) 9–10 years. Moreover, two BMI groups were also created: (1) children with NW and (2) children with OW and OB.

Then, linear regression analyses were performed to analyze the association of BMI with type of foot, laxity, foot strength and baropodometric variables across all three age groups. Previously, sex interaction was analyzed by including the interaction terms in the code of regression analyses. Since there was no sex interaction, the sample was segmented by age and BMI. In addition, the collinearity of the regression models was calculated using command .vif, which did not show independent variables with a coefficient > 10. Finally, for each regression model, the normality analyses were recalculated for the residuals for the models.

All analyses were performed using the STATA software for Windows version 13.0. The level of significance was set at $p < 0.05$.

4.3. RESULTS

4.3.1. Descriptive Characteristics, Type of Foot, Laxity, Foot Strength and Baropodometric Characteristics of the Sample by Age and BMI in Children

The characteristics of the sample by age and body mass status are shown in Table 1. In terms of descriptive characteristics, there were no significant differences between the NW group and the OW and OB groups for the three age groups with respect to age and height (all $p > 0.005$). However, there were significant differences between the NW group and the OW and OB groups in all three age groups for weight and BMI (all < 0.005).

Then, type of foot and laxity were analyzed; however, there were no significant differences between NW groups and OW and OB groups in all three age groups for any of the variables (all $p > 0.05$). In relation to foot strength variables, most variables of eversion, inversion and plantar flexion and dorsiflexion strength showed significant differences between the NW group and the OW and OB groups in the 5–6 and 7–8 years groups ($p < 0.005$). However, there were no significant differences between the NW group and the OW and OB group in the 9 to 10 years group for foot strength variables ($p > 0.005$).

As for static variables, there were no significant differences between the NW group and the OW and OB groups in all three age groups for any of the variables (all $p > 0.05$). This same trend was observed with the analysis of the stabilometric variables, where there were no significant differences between the NW group and the OW and OB groups in all three age groups for none of the variables (all $p > 0.05$), except for the interval and distance traveled in the 7–8 years group (both $p < 0.05$).

Tabla 1. Descriptive, type of foot, laxity, foot strength and baropodometric characteristics of the sample by age and body mass status in children.

	5 to 6 years				7 to 8 years				9 to 10 years			
Variables	Total n=79 M/F	NW n=55 M/F	OW and OB n=24 M/F	p^a	Total n=67 M/F	NW n=45 M/F	OW and OB n=22 M/F	p^a	Total n=50 M/F	NW n=29 M/F	OW and OB n=21 M/F	p^a
Physical characteristics												
Age (years)	6.14±0.48	6.13±0.48	6.17±0.46	0.742	7.98±0.62	7.92±0.58	8.11±0.67	0.221	9.51±0.29	9.52±0.29	9.51±0.40	0.944
Weight (kg)	23.10±4.47	21.22±2.72	27.42±4.75	**<0.001**	29.48±7.18	25.62±3.08	37.38±6.68	**<0.001**	37.30±7.36	33.25±4.04	42.89±7.96	**<0.001**
Height (cm)	1.17±0.05	1.17±0.05	1.18±0.05	0.309	1.28±0.07	1.27±0.06	1.30±0.06	0.160	1.39±0.07	1.39±0.06	1.38±0.07	0.512
BMI ($kg \cdot m^{-2}$)	16.77±2.27	15.54±1.02	19.60±2.28	**<0.001**	17.88±3.48	15.95±1.07	21.83±3.39	**<0.001**	19.30±3.53	17.06±1.26	22.38±3.53	**<0.001**
Gender, *n* (%)	39(49)/ 40(51)	30 (55)/ 25(45)	9(38)/ 15(62)	**0.857[b]**	24(36)/ 43(64)	16 (36)/ 29(64)	8(36)/ 14(64)	**0.232[b]**	15(30)/ 35(70)	8(28)/ 21(72)	7(33)/ 14(67)	**0.178[b]**
Type of foot, laxity and foot strength												
FPI total (Score)	7.76±5.56	7.42±5.31	8.54±5.98	0.407	7.39±5.58	7.53±5.89	7.09±4.99	0.763	8.34±5.24	9.00±0.97	7.42±5.70	0.318
Lungue test (º)	106.7±10.5	108.2±10.4	103.4±10.3	0.065	97.62±13.12	99.00±13.62	94.81±11.85	0.223	95.40±12.24	95.14±13.26	95.76±10.97	0.860
Beighton (Score)	3.49±2.98	3.71±3.14	3.00±2.59	0.334	3.10±3.07	2.67±3.02	4.00±3.05	0.095	2.34±2.73	2.79±2.82	1.71±2.53	0.170
R LLAS (Score)	6.64±3.49	7.05±3.56	5.71±3.21	0.116	5.43±3.54	5.20±3.62	5.91±3.39	0.445	4.30±3.18	4.86±3.40	3.52±2.77	0.145
L LLAS (Score)	6.51±3.55	6.85±3.61	5.71±3.35	0.189	5.42±3.48	5.20±3.58	5.86±3.31	0.468	4.30±3.33	4.83±3.50	3.57±3.01	0.190
R eversion (N)	6.62±2.90	6.39±3.37	7.14±1.21	0.294	7.52±1.88	7.10±1.89	8.37±2.03	**0.013**	11.84±2.37	12.02±2.34	11.59±2.43	0.536
L eversion (N)	6.00±1.44	5.70±1.32	6.67±1.48	**0.005**	7.22±2.47	6.99±2.68	7.68±1.95	0.290	11.28±2.09	11.33±1.73	11.22±2.56	0.877
R inversion (N)	7.38±1.34	7.10±1.16	8.05±1.51	**0.003**	8.67±1.58	8.34±1.56	9.33±1.44	**0.014**	12.33±2.02	12.42±2.07	12.20±1.99	0.717
L inversion (N)	6.67±1.37	6.47±1.29	7.12±1.46	0.054	7.75±1.83	7.42±1.75	8.39±1.88	**0.041**	11.66±1.79	11.70±1.65	11.60±2.01	0.841
R. plantarflexion (N)	10.59±2.62	10.04±2.03	2.63±3.37	**0.004**	14.28±3.88	13.85±3.68	15.15±4.20	0.199	26.06±5.77	25.89±5.50	26.30±6.27	0.810
L plantarflexion (N)	10.21±2.73	9.78±2.22	11.19±3.50	**0.034**	14.52±5.84	13.56±4.19	16.46±8.03	0.055	25.17±5.66	24.78±5.17	25.70±6.36	0.574
R dorsiflexion (N)	6.67±1.18	6.45±1.02	7.18±1.38	**0.010**	7.53±1.59	7.25±1.46	8.11±1.70	**0.036**	10.45±1.39	10.55±1.21	10.33±1.63	0.590
L dorsiflexion (N)	6.71±2.16	6.62±2.38	6.94±1.56	0.544	7.21±1.71	6.89±1.50	7.87±1.94	**0.025**	10.17±1.56	10.22±1.16	10.09±1.83	0.755

Static variables (%)												
R-L difference static	7.78±6.32	7.77±6.68	7.80±5.55	0.981	7.55±5.63	7.22±5.63	8.23±5.71	0.497	7.32±6.49	6.80±4.22	8.05±6.49	0.415
Forefoot static	41.40±8.47	41.40±8.96	38.76±6.65	0.067	42.27±8.26	42.93±9.03	40.91±6.36	0.351	43.86±7.80	44.16±8.50	43.44±6.90	0.749
Rearfoot static	58.56±8.46	57.39±8.95	61.23±6.66	0.063	57.72±8.25	57.05±9.02	59.08±6.36	0.346	56.14±7.80	55.83±8.50	56.56±6.90	0.749
C1 static	22.01±7.03	22.76±7.67	20.30±4.98	0.152	21.74±4.91	22.32±5.35	20.56±3.70	0.171	22.52±5.00	22.92±5.45	21.96±4.36	0.508
C2 static	19.84±4.03	20.33±4.13	18.72±4.57	0.126	20.55±4.84	20.65±4.88	20.34±4.87	0.811	21.35±4.45	21.24±4.76	21.49±4.09	0.845
C3 static	30.27±6.17	29.58±6.66	31.86±4.60	0.131	29.86±5.35	30.05±5.82	29.46±4.35	0.675	29.02±5.16	29.04±4.52	29.00±6.05	0.977
C4 static	28.33±5.58	27.87±5.89	29.38±4.73	0.274	27.85±5.99	26.99±6.26	29.62±5.06	0.092	27.12±6.79	26.78±7.24	27.57±6.27	0.689
Stabilometric variables (static) (%)												
R-L difference stabilometric	9.25±7.18	9.30±7.57	9.14±6.33	0.929	7.30±5.92	7.38±5.52	7.13±5.93	0.872	9.00±8.12	9.28±6.29	8.60±10.28	0.773
Forefoot stabilometric	39.07±6.44	39.84±7.21	37.30±3.73	0.107	40.93±7.74	40.82±8.92	41.13±4.61	0.880	42.91±8.12	44.04±8.27	41.35±5.28	0.198
Rearfoot stabilometric	60.82±6.49	60.16±7.21	62.35±4.16	0.169	59.07±7.73	59.17±8.92	58.86±7.74	0.880	57.09±7.24	55.96±8.27	58.64±5.31	0.199
C1 stabilometric	20.49±3.47	20.93±5.14	19.48±3.47	0.208	21.14±4.40	21.19±4.89	21.05±3.26	0.912	22.01±4.38	22.72±4.72	21.01±3.74	0.175
C2 stabilometric	18.62±3.61	18.91±3.79	17.96±3.12	0.286	19.77±4.84	19.62±5.41	20.08±3.51	0.724	20.92±4.31	21.33±4.81	20.36±3.55	0.438
C3 stabilometric	19.84±4.13	20.33±4.13	18.72±4.57	0.126	20.55±4.84	20.64±4.88	20.34±4.88	0.811	21.35±4.45	21.24±4.76	21.49±4.09	0.845
C4 stabilometric	32.47±5.11	32.13±5.77	33.22±3.11	0.386	30.40±5.37	30.77±5.84	29.63±4.27	0.568	27.28±6.06	26.87±6.70	27.83±5.16	0.583
Stabilometric variables (gravity center) (mm)												
Minimum x-axis	-0.72±5.64	-1.05±6.27	0.04±3.86	0.431	-0.40±4.18	-0.40±4.36	-0.41±3.88	0.993	1.16±2.96	0.97±3.04	1.43±2.89	0.590
Minimum y-axis	-7.82.4.60	-8.16±4.97	-7.04±3.59	0.322	-6.52±3.54	-6.77±3.83	-6.00±2.89	0.403	-7.42±4.49	-7.93±4.49	-6.71±4.20	0.337
Maximum x-axis	7.13±4.01	7.36±4.01	6.58±4.04	0.429	6.87±4.43	7.49±4.78	5.59±3.33	0.099	7.64±4.02	7.69±3.92	7.57±4.25	0.919
Maximum y-axis	1.58±4.40	1.65±4.76	1.42±3.51	0.826	1.57±3.56	2.04±3.80	0.59±2.82	0.116	1.00±4.44	0.21±4.49	2.10±5.40	0.140
Interval x	7.78±5.45	8.35±5.91	6.50±4.00	0.167	7.33±4.28	7.98±4.74	6.00±2.76	0.075	6.66±3.29	7.07±3.60	6.09±2.79	0.306
Interval y	9.49±4.93	9.85±5.45	8.67±3.42	0.327	8.09±4.28	8.82±4.13	6.59±2.75	**0.036**	8.48±3.89	8.21±3.93	8.86±3.90	0.565
Average x	3.76±5.02	3.80±5.53	3.67±3.66	0.914	3.32±4.03	3.64±4.21	2.68±3.63	0.362	4.50±3.51	4.38±3.58	4.66±3.50	0.778
Average y	-2.94±3.53	-3.07±3.75	-2.67±3.03	0.641	-2.42±2.86	-2.24±3.25	-2.77±2.86	0.519	-3.14±4.06	-3.82±3.84	-2.19±4.25	0.161
Distance traveled foot	50.19±29.34	54.11±31.87	41.21±20.35	0.072	42.65±29.33	47.71±33.30	32.32±14.66	**0.042**	40.14±18.45	42.79±19.27	36.47±17.02	0.236
Ellipse area (mm^2)	14.71±20.33	16.27±23.27	11.13±10.55	0.304	10.43±11.79	12.20±13.64	6.82±5.09	0.079	8.84±6.70	8.66±6.32	9.10±7.35	0.821

Principal axis ellipse	5.73±2.9	5.89±3.17	5.37±2.44	0.480	4.54±2.36	4.87±2.61	3.86±1.58	0.102	4.78±1.96	4.72±2.34	4.86±1.96	0.833
Second axis ellipse	2.65±1.6	2.82±1.73	2.25±1.07	0.142	2.37±1.34	2.58±1.47	1.95±0.89	0.072	2.18±0.90	2.17±0.80	2.19±1.03	0.944

Values are presented as mean ± standard deviation or percentages. T-test square statistics was applied. Statically significant between body mass status group for each age group are highlighted in bold. C1: left forefoot load; C2: right forefoot load; C3: left hindfoot load; C4: right hindfoot load; F: female; FPI: Foot Posture Index; L: left; LLAS: Lower Limb Assessment Score; M: male; NW: Normal Weight; Ob: Obesity; OW: Overweight; R: Right. [a]p shows differences for all variables between groups of body mass status, except [b]for gender which shows differences in body mass index between sexes.

4.3.2. Associations of BMI with Type of Foot, Laxity, Foot Strength and Baropodometric Variables by Age Groups in Children

The regression analyses of the BMI with type of foot, laxity, foot strength and baropodo- metric characteristics by age group are shown in Table 2. Regarding type of foot and laxity, there were no significant associations of BMI with the variables analyzed (all $p > 0.05$), except for the Beighton Scale in children 7–8 years ($p < 0.049$). In relation to foot strength variables, all variables showed positive significant associations of BMI with eversion, inver- sion and plantar flexion and dorsiflexion strength (all $p < 0.05$), except for right eversion and left dorsiflexion in children 5–6 years. In children 7–8 years, BMI was positively associated with left and right inversion strength (all $p < 0.05$). However, there were no significant associations of BMI with foot strength variables in children 9 to 10 years (all $p > 0.05$).

As for the associations of BMI with static variables, there were no significant associa- tions of BMI with any of the static variables in all three age groups (all $p > 0.05$), except for C4 static in children 7–8 years ($p = 0.043$). Then, the associations of BMI with stabilometric variables were performed. There were no significant associations of BMI with any of the stabilometric variables in all three age groups (all $p > 0.05$), except for left–right difference in children 9 to 10 years ($p = 0.032$). In relation to gravity center, BMI was negatively associated with interval x, distance traveled, and secondary axis ellipse in children 5–6 years (all $p < 0.05$). Finally, BMI was negatively associated with interval x and y, maximum y-axis and principal axis ellipse in children 7–8 years (all $p < 0.05$). However, there were no significant associations of BMI with any of the gravity center variables in children 9–10 years (all $p > 0.05$)

Tabla 2. Associations of BMI with type of foot, laxity, foot strength and baropodometric variables by age groups

	5 to 6 years			7 to 8 years			9 to 10 years		
Variables	R^2	β	*p* value	R^2	β	*p* value	R^2	β	*p* value
Type of foot, laxity and foot strength									
FPI total (Score)	0.02	0.131	0.247	0.01	0.082	0.505	0.01	-0.050	0.729
Lungue test (º)	0.04	-0.210	0.062	0.05	-0.212	0.085	0.02	-0.129	0.371
Beighton Scale (Score)	0.01	-0.072	0.527	0.06	0.241	**0.049**	0.02	-0.145	0.313
Right LLAS (Score))	0.04	-0.193	0.088	0.00	0.017	0.887	0.02	-0.131	0.364
Left LLAS (Score)	0.03	-0.169	0.137	0.00	0.006	0.963	0.02	-0.127	0.377
Right eversion (N)	0.03	0.160	0.158	0.04	0.206	0.094	0.00	0.016	0.911
Left eversion (N)	0.21	0.460	**<0.001**	0.01	0.083	0.504	0.02	0.126	0.381
Right inversion (N)	0.20	0.450	**<0.001**	0.09	0.298	**0.014**	0.00	0.018	0.904
Left inversion (N)	0.10	0.312	**0.005**	0.06	0.242	**0.048**	0.00	0.050	0.731
Right plantarflexion(N)	0.02	0.396	**<0.001**	0.05	0.218	0.076	0.00	0.012	0.931
Left plantarflexion (N)	0.11	0.329	**0.003**	0.06	0.238	0.052	0.00	0.064	0.656
Right dorsiflexion (N)	0.10	0.313	**0.005**	0.02	0.144	0.244	0.00	-0.008	0.954
Left dorsiflexion (N)	0.02	0.136	0.230	0.01	0.117	0.343	0.00	-0.051	0.725
Static variables									

Left-right difference (%)	0.00	0.054	0.638	0.01	0.114	0.360	0.07	0.058	0.058
Forefoot static (%)	0.03	-0.159	0.161	0.02	-0.124	0.317	0.00	-0.045	0.754
Rearfoot static (%)	0.03	0.163	0.150	0.02	0.124	0.317	0.00	0.045	0.754
C1 static (%)	0.01	-0.121	0.289	0.04	-0.197	0.110	0.00	-0.026	0.857
C2 static (%)	0.03	-0.170	0.134	0.00	-0.013	0.916	0.00	-0.047	0.741
C3 static (%)	0.02	0.145	0.203	0.01	-0.085	0.489	0.01	0.075	0.603
C4 static (%)	0.01	0.081	0.478	0.06	0.248	**0.043**	0.00	-0.004	0.976
Stabilometric variables (static)									
Left-right difference (%)	0.00	0.002	0.986	0.01	0.100	0.418	0.09	0.303	**0.032**
Front stabilometric (%)	0.02	-0.147	0.194	0.00	0.026	0.832	0.05	-0.213	0.137
Rear stabilometric (%)	0.02	0.129	0.256	0.00	-0.026	0.832	0.05	0.213	0.137
C1 stabilometric (%)	0.01	-0.100	0.378	0.00	-0.053	0.668	0.02	-0.157	0.275
C2 stabilometric (%)	0.02	-0.123	0.280	0.01	0.092	0.454	0.04	-0.199	0.166
C3 stabilometric (%)	0.00	0.046	0.688	0.02	-0.125	0.312	0.04	0.189	0.187
C4 stabilometric (%)	0.02	0.127	0.265	0.01	0.083	0.500	0.00	0.026	0.856
Stabilometric variables (gravity center)									

Minimum x-axis (mm)	0.02	0.138	0.224	0.00	0.062	0.619	0.01	0.091	0.529
Minimum y-axis (mm)	0.02	0.139	0.223	0.01	0.082	0.507	0.00	0.044	0.756
Maximum x-axis (mm)	0.01	-0.121	0.287	0.03	-0.165	0.181	0.00	-0.001	0.997
Maximum y-axis (mm)	0.00	-0.057	0.618	0.07	-0.263	**0.031**	0.03	0.177	0.218
Interval x (mm)	0.05	-0.233	**0.039**	0.06	-0.240	**0.050**	0.01	-0.113	0.434
Interval y (mm)	0.03	-0.163	0.151	0.09	-0.296	**0.015**	0.02	0.149	0.301
Average x (mm)	0.00	0.037	0.749	0.01	-0.077	0.537	0.01	0.070	0.631
Average y (mm)	0.00	0.049	0.669	0.02	-0.133	0.281	0.02	0.142	0.324
Distance traveled foot (mm)	0.06	-0.243	**0.030**	0.05	-0.232	0.059	0.03	-0.176	0.221
Ellipse area (1DS) (mm^2)	0.04	-0.195	0.084	0.06	-0.236	0.054	0.00	0.010	0.947
Principal axis ellipse (mm)	0.04	-0.188	0.096	0.09	-0.291	**0.017**	0.01	0.088	0.541
Secondary axis ellipse (mm)	0.05	-0.231	**0.040**	0.04	-0.198	0.108	0.00	-0.055	0.702

Statically significant are highlighted in bold. C1: left forefoot load; C2: right forefoot load; C3: left hindfoot load; C4: right hindfoot load; FPI: Foot Posture Index; L: left; LLAS: Lower Limb Assessment Score; R: Right.

4.4. DISCUSSION

The purpose of this study was to analyze the differences in descriptive characteristics, foot type, laxity, foot strength and baropodometric variables by body mass status and age groups in children and, secondly, to analyze the associations of BMI with foot type, laxity, foot strength and baropodometric variables by age groups in children.

The main findings of the present work revealed that most foot strength variables showed significant differences between the NW groups and the OW and OB groups in children 5–6 and 7–8 years, OW and OB children having a higher level. Moreover, some stabilometric variables showed significant differences between the NW group and the OW and OB group in children 7–8 years. Then, linear regression analyses showed positive associations of BMI with most of the foot strength variables in children 5–6 and 7–8 years, as well as negative associations with the gravity center variables.

Considering our results, it can be observed that OW and OB children between 5 and 8 years have significantly higher levels of foot strength compared to NW children and that NW children between 7 and 8 years show worse stabilometric values compared to children with OW and OB. On the one hand, and despite the limited evidence, only a few articles have shown to date how the foot type, strength and flexibility can influence foot structure, pressure distribution and other possible musculoskeletal disorders [10,13,14]. In this regard, our results reflect how children with OW and OB had more foot isometric strength. No previous studies have shown a relationship between OW and OB and isometric strength of the foot. However, a previous study showed a relationship between OW and OB and isometric strength of the hands [33]. Thus, in our humble opinion, we believe this is the first study to assess the impact of isometric foot strength in children with OW and OB. On the other hand, and although the evidence so far supports the fact that children with OW and OB are less stable when walking [7], it is possible that this dissimilarity was caused by the same fact mentioned by Kjölhede et al. (2014), in which they concluded that children with NW tend to be more restless than children with OW and OB [34]. Therefore, considering that, in our study, we analyzed the pressures in static/stabilometry and not in dynamic motion could explain why NW children showed worse stabilometry.

This study also explored in the regression analysis the association between OW and OB on the other dependent variables. Firstly, it is important to remark that there is no significant association between type of foot (FPI-6) and OW and OB. In this sense, these results are in contrast and in line with those shown by previous literature, as some authors have concluded that there was a correlation between flatter feet and children with OW and OB [35,36], while others have stated that there is no relationship between increased BMI in children and having “flatter” feet

[37–39]. In this sense, we believe that the controversy among these studies investigating the relationship between BMI and OW and OB could be the method of grading the foot. Therefore, future studies should unify the method of evaluating flatfoot to facilitate the comparison of results and to be able to draw more accurate and precise conclusions.

When it comes to JH, previous evidence showed discrepancies because some studies have shown that children with OW and OB have a stronger relationship with JH [40], while others confirm that JH is more prevalent in underweight children [41]. In this sense, our results suggest that having a higher BMI is associated with having more JH overall from 7 to 8 years of age. Hence, more studies are needed to corroborate this association, since JH is a risk factor for musculoskeletal pain during adolescence [40].

As far as we know at present, there are no studies that relate BMI to ankle muscle strength and its possible involvement with excess plantar pressures, gait biomechanics and musculoskeletal alterations in the lower limbs in children. This issue has only been addressed in the adult population, where it has been observed that OW and OB decrease ankle muscle strength and quality of life [42,43]. In our study, we have observed how an increase in BMI is directly related to a greater isometric strength of ankle movements (inversion, eversion, dorsiflexion and plantar flexion) mainly in younger children (5–6 years of age). At this point, even if OB children show more strength, it is still of clinical alarm since this can translate into joint overload and having more strength does not mean that they execute movements more correctly, a fact that has already been mentioned in previous research [33,44–46].

Hereinafter, the results of the present study are consistent with previous research, where it was reported that an increase in BMI is related to alterations in static plantar pressures and stabilometry in children [7,8,47,48]. In this way, our regression analyses showed in children 7–8 years of age that the pressure in the right heel is significantly higher. In this sense, studies such as Bittar et al. [49] and Feka et al. [48] showed that BMI is associated with greater pressure in the hindfoot. Additionally, and regarding the difference in pressure between the left and right leg, we also found that the BMI mainly influences children of the age of 9–10 years, who tend to receive more pressure in the right foot. In this sense, this result is in line and in contrast with previous research, since some studies mention that there

is more support in the right foot [48,50,51], while Bittar el al. [49] mention that there is more support in the left foot. Therefore, more studies are still needed to clarify this fact in children because an asymmetrical distribution of loads could lead to asymmetrical growth of the limbs or overloads, leading to postural deformities.

Finally, we could also observe a relationship between having a higher BMI and pre- senting better static stability in children from 5 to 8 years of age; that is, they had fewer oscillations. However, it is important to remark that this better static stability due to higher BMI values could also be translated into a worse capacity to compensate for the overload that their feet receive due to excess weight. This clinical reasoning is built on the results of previous studies that have already highlighted the impact of OW and OB on stability [7,11,52], remarking how an excessive BMI leads to mechanical overexertion which cannot be compensated for by the musculoskeletal system [53]. The basis of most movements is due to balance control [7], so if this control is affected, it would also affect the daily living activities of children with OW and OB. Hence, these findings seem to confirm that OW and OB negatively impact the normal musculoskeletal development of children's feet compared to children with NW. In this way, we also dare to speculate that, in turn, this could have a negative impact on their quality of life and global health status.

Although there are a wide variety of plantar pressure measurement systems [54–56], such as the use of instrumented insoles, the pressure platform was used because in children the size of the foot varies greatly from one child to another, even more in an age range as wide as 5 to 10 years of age. Perhaps if the instrument templates had been used instead of the pressure platform, the data would have been more accurate.

This study has several limitations that deserve attention. First, the values used as cut-off points to divide children as normal weight "NW", overweight "OW" or obese "OB" has been previously used and accepted [23,24], although other cut-off values could have modified our results. Secondly, although the RSscan Footscan® 9 pressure platform has demonstrated good intra-rater and inter-rater reliability [32], it only measures forces perpendicular to the ground, not taking into account forces on other planes. Thirdly, it should take into account that the age range of our study was from 5– to 10 years of age, so

direct comparisons with other studies could be difficult due to other possible age ranges. Finally, the data collected through the pressure platform are static;

hence, we cannot just infer that static positioning will directly impact dynamic movements.

Despite these cited limitations, this study has several strengths. First, it comprised a wide age range of children. Secondly, is the first study to assess foot type, strength and flexibility in the same sample of obese children. Thirdly, the measuring instruments implemented in our study are widely used in both clinical practice and research, which, together with the data obtained and taking into account the increasing rate of childhood OB [1–3], our findings may have important clinical and public health implications.

The clinical implications of the findings presented in this study imply that signs such as excessive pressure, impaired stability or increased foot strength must be recognized to prevent future pain and possible short- and long-term complications. OW and OB prophylaxis, which is becoming more frequent every day, as well as early diagnosis of musculoskeletal deformities, will have long-term effects on the general health status of children. An alteration in the feet and all that this implies (strength, flexibility, pressure, stability) can have consequences such as decreased physical activity, aggravating the OW and OB problem. Children with OW and OB should be managed by a multidisciplinary team, which should be made up of psychologists, nutritionists, pediatricians, rehabilitators, podiatrists and physiotherapists.

4.5. CONCLUSIONS

Children from 5–8 years of age with OW and OB show greater levels of foot strength and also how OW and OB children from 7–8 years are more stable in static stabilometrics. Furthermore, the linear regression analyses showed how, between 5 and 8 years, having OW and OB implies having more strength and static stability. This should not be translated as a positive aspect for health in this population. Considering the scarcity of studies, that OB rates continue to grow and that having greater strength and that stability as a consequence of a higher BMI is not beneficial to health, more studies are still needed in this regard in order to provide a more adequate management of the consequences of OB in children.

4.6. REFERENCES

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V – ESTUDIO II

V - ESTUDIO II

EVALUATION OF THE CHARACTERISTICS OF GAIT STANCE PHASES IN CHILDREN WITH NORMOWEIGHT, OVERWEIGHT AND OBESITY. A CROSS-SECTIONAL STUDY

Abstract:

Objectives: The purpose of the study was to examine the differences in foot type, laxity, and dynamic characteristics of the gait, as well as stance phase of gait characteristic between body mass index (BMI) and age groups in children. Secondly, to analyze the associations between BMI and these variables across these age groups in children. **Methods**: A cross-sectional study involving 196 children aged 5-10 years. The variables used were BMI, type of foot, laxity, dynamic variables, and stance phase of gait characteristics. **Results**: Type of foot, laxity, some dynamic variables and stance phase of gait characteristics showed significant differences between normoweight (NW) groups, and overweight/obesity (OW/OB) groups in children 5 to 10 years of age (P ranged between 0,019-0,050). Moreover, BMI was also positively associated with initial forefoot contact, heel off, total duration of the step, and forefoot contact phase in children 7 to 10 years of age (P ranged between <0,010-0,040). **Conclusions**: Children with OW/OB have alterations at different stages of gait. Having OW/OB is related to alterations of the phases of gait mainly from 7 to 10 years of age, spending more time in each of the phases of walking. This fact could indicate that children with OW/OB, in addition to walking slower, overload the musculoskeletal system subjecting their joints and muscles to greater stress.

Keywords:

Gait; Stance Phases, Pediatric Obesity; Children

5.1. INTRODUCTION

For diagnostic assessment and therapy, the utilization of lower limb testing or gait analysis systems in the pediatric population is crucial. Overweight (OW) and obesity (OB) in children are becoming more of a global problem for health services because its incidence rate has tripled between 1975 and 2016, from 4% to 18% according to the World Health Organization (WHO) (1). Thus, this increasing incidence rate is accompanied by not only a significant long- and short-term influence on socioeconomic levels (2), but also by great medical consequences such as diabetes, cardiovascular diseases and many other comorbidities (1). Therefore, the significance of providing children with OW and OB with the best and most effective healthcare interventions is a matter of vital importance nowadays.

Due to their excess body mass index (BMI), children who become OW or OB may experience changes to their musculoskeletal system, posture and gait (3,4). We can avoid problems in the future by being aware of the major gait biomechanical alterations in this population. In this sense, children with OW and OB put more load on their musculoskeletal systems, which can have an impact on their posture, biomechanical axis, mobility, physical activity, and ability to carry out daily tasks (5,6). The most common physical exercise that is done on a daily basis is walking, increasing children's daily step counts has gained significant attention in the fight against the obesity epidemic (7,8). Preventing and managing obesity, maintaining good musculoskeletal health, and reducing orthopedic comorbidity and functional impairment all depend on physical exercise (9). If this population presents biomechanical problems derived from OW and OB, such as musculoskeletal pain or increased joint loads (4), this will directly influence a reduction in mobility or less physical activity, which will aggravate the problem of childhood OW and OB (10). In particular, and when it comes to plantar pressures, there is previous literature that has corroborated in adult populations how excessive plantar loading or pressure causes pain and discomfort in the foot (11,12). This could be reflecting how stress and pressure are two fundamental aspects of foot biomechanics. However, these conclusions are not entirely clear in child populations due to the scarce information that exists in this regard.

Despite the scarce information, it is true that there has been a growing interest in the last few years about the biomechanical changes in the gait of children with

OW and OB. In this sense, this previous studies have stated how there are changes in the intersegmental angular movement of the body during walking (13), that they may present an increased risk of osteoarthritis in adulthood (14), that they need to produce more energy in the joints of the lower limbs (14) or that there is a progression of deformities angles in valgus/varus of the knee (15), among others. However, these previous studies have omitted an assessment of plantar pressure, although they do assess other aspects related to gait. At this point, and when it comes to the assessment of plantar pressure in children with OW and OB, two systematic reviews have mentioned how plantar pressures are altered but do not take into account the characteristics of the stance phase of gait (16,17). Therefore, to test optimal loading and gait stance phases, health-related professionals should be particularly interested in adding plantar pressure variables in health surveillance systems. As Montagnani et al. (18) noted in his recent review, further research in the area of plantar pressure is required to create an ideal methodological framework that would enable a deeper comprehension of the aspects of foot function and development throughout infancy and childhood.

Thus, the main objective of this study was to analyze the differences in foot type, laxity, and dynamic characteristics of the gait, as well as stance phase of gait characteristic between BMI and age groups in children from 5 to 10 years of age. Secondly, to analyze the associations between BMI and the characteristics of gait stance phases across these age groups in children.

5.2. MATERIALS AND METHODS

5.2.1. Participants

In this cross-sectional study, 156 kids (78 boys and 118 girls) between the ages of 5 and 10 were included. The application of the EPIDAT program decided the sample size. The study aimed to detect changes greater than 0.8 (high effect size), maintaining a type I error rate of 0.05 and a type II error rate of 0.2.This age range was selected because it falls within the window of validity for the Foot Posture Index (FPI) (19). The Catholic University of San Antonio de Murcia Ethics Committee approved the study (Code: CE022205). Strengthening Reporting of Observational Studies in Epidemiology (STROBE) principles were adhered to in

order to complete the study (20). The Declaration of Helsinki's guiding principles were followed when conducting this study (21).

Children between the ages of 5 and 10 who do not experience foot pain and who have their parents' or guardians' permission made up the sample. In order to confirm their children's involvement in the study, parents and guardians were beforehand notified about it, asked to fill out a questionnaire, and sign a consent form. Children with recent lower limb damage, congenital structural alterations affecting the distal areas of the ankle joint, as well as those cases with pathological flatfoot caused by cerebral palsy, surgical treatments in the foot or lower extremity, genetic pathology, and neurological or muscular pathology were all disqualified from the study.

Children were examined between February and June 2022 in a primary school in the region of Murcia (Spain). Throughout the course of five months, each kid completed each evaluation in one morning according to the same schedule. All children had their demographic and anthropometric information gathered before the exploration. To protect privacy, a certain number was given to each child. They were requested to remove their shoes and wear casual attire (t-shirts and shorts) for the examination, which was conducted simultaneously by two experienced clinicians. If necessary, a third physician judged which of the two values was more accurate when the two main clinicians differed while measuring the same youngster. Analyzing the data was handled by a different clinician who was not involved in the examinations.

Each test was demonstrated and explained to every child before it was administered. In this way, each test item had to be completed three times, and the average of the results was used. Youngsters received the usual verbal support and encouragement during the whole assessment process. Each child was given a maximum of five opportunities to fail when they made a procedural error, after which the instructions and demonstrations were repeated again before the new chance.

5.2.2. Measurement of the variables

5.2.2.1 Anthropometric evaluations

Weight was measured using Digital Pegasus Scales with a margin of error of 0.05 kg, while height was measured using a calibrated portable SECO 7710 meter with a bubble level fixed to the arm for enhanced accuracy (shirt and shorts).

Children were divided into two weight categories: normal weight ("NW") and overweight or obesity ("OW/OB") in order to determine cut-off points for specific BMI by sex and age (22–24).

5.2.2.2. Type of foot and laxity

In order to know the type of foot and the laxity or joint hypermobility (JH) that each child presented, four tests were measured; these tests were: The Foot Posture Index (FPI-6), The Ankle Lunge Test, The Relaxed Calcaneal Stance Position (RCSP) and The Lower Limb Assessment Score (LLAS). A visual inspection, goniometry, (which is a reliable tool for assessing generalized joint mobility in children of school age) (25), digital inclinometer (Smart ToolTM) were also used.

The FPI-6 was used to assess each foot while the subjects were standing barefoot and at ease on a 50 cm bench to enable visual and manual inspection. The FPI-6 rates 6 aspects of foot anatomy in the 3 plans of the foot; 1) talar head palpation, 2) supra and infra lateral malleolar curvature, 3) calcaneal frontal plane position, 4) prominence in the region of the talonavicular joint, 5) congruence of the medial longitudinal arch, and 6) abduction/ adduction of the forefoot on the rearfoot. The FPI-6 considers the position of the forefoot, midfoot, and hindfoot. The FPI-6 delivers a total value from -12 points (very supinated) to +12 points (highly pronated). The following are the reference values: normal = 0 to +5, pronated = +6 to +9, severely pronated = 10+, supinated = -1 to -4, and highly supinated = -5 to -12 . A sample of kids between the ages of 5 and 16 showed consistent weighted Kappa reliability for the FPI-6 in the pediatric population (Kw=0.86) (26).

Based on the process outlined by Root et al., RCSP was evaluated. Participants were instructed to lay face down on a bed that was parallel to the ground with their feet hanging over the edge. In order to create a bisection line independent of the amount of fat surrounding the calcaneus, the investigator

manually checked the subjects' foot and placed three dots on the upper, middle, and lower portions of the bone. Individuals were measured while standing with their feet separated by a fist's width. A measurement was made of the angle formed by the bisector of the calcaneus and the perpendicular line to the ground (27). When either of the feet exhibited an RCSP angle greater than four degrees valgus, flat foot was considered to exist (28).

The lower extremity is measured for JH by the LLAS. Evaluations were performed on the hip, knee, ankle, subtalar joint, midtarsal joint, and metatarsophalangeal joint. A cut of 7/12 or above suggests JH on the LLAS scale, which assigns a total score of 12 points on each of the four limbs. With an intraclass correlation coefficient (ICC) of 0.84, the LLAS has demonstrated its dependability (29).

With the knee flexed, the Ankle Lunge Test measures the range of weight-bearing ankle dorsiflexion. The digital inclinometer was placed on the anterior surface of the tibia to measure ankle dorsiflexion in order to quantify the Ankle Lunge Test. With an intra-rate ICC of 0.98 and an inter-rate ICC of 0.97 (30), this test has been demonstrated to be reliable.

5.2.3. Baropodometry

The RSscan Footscan® 9 platform, dimensions 578mm x 418mm x 12mm, was used to measure the baropodometric gait variables. The platform has 4096 sensors (organized in a 64x64 matrix), each measuring 7.62mm x 5.08mm, with a 488mm x 325mm active area. The 10-bit resolution and 500Hz data capture frequency correspond to an accuracy range of 1-127 N/Cm2. This platform measures plantar pressure using an X-Y matrix of resistive pressure sensitive sensors that are sequentially scanned. While the subject moves across the platform, the system logs dynamic pressure data and footfall patterns. The data is subsequently processed by the software. The result is an image of the foot pressure with all its numerical data.

The weight calibration was completed before beginning the data collection to ensure an accurate reading. This uses a measurement of a subject with a known weight to scale the pressure data appropriately. Children were permitted to become comfortable with the platform before data collection until they were capable and confident to conduct it.

Diverse studies on plantar pressure variations have shown the dependability of the Footscan® system (RSscam), with ICC values ranging from good to excellent for the intra- and inter-evaluators (ICC 0.81-0.86 and ICC 0.87-0.95, respectively) (31).

The pressure platform was in the center of a 10 m-long corridor that participants were instructed to walk ten times barefoot along. Trials of familiarization were conducted to make sure that subjects walked comfortably and naturally. In order to ensure that a constant velocity had been achieved prior to first impact, participants struck the platform no earlier than their fourth step (32). The measurements were determined by adding up all of the trials for each foot. For each patient, between 8 and 10 valid footprints were included. When the participant did not become unbalanced during gait [1], when they were not distracted (such as by looking around or conversing) while walking [2], and when the entire plantar area was captured [3], the researchers regarded the footprints as valid. The first two evaluation criteria were controlled during scan, and the third was later visually examined by the same assessor. The usage of a minimum of eight footprints per child complies with the advice of McPoil et al. (33), who claimed that when 5-7 trials were averaged, a reliability plateau was attained. Plantar pressure results from the left and right foot were averaged into a single observation to prevent issues caused by paired data (34).

5. 2.3.1. Dynamic 2D

The dynamic 2D analysis replays the roll-offs of the foot. Information about subtalar joint angles and flexibility of the right and left feet is provided by the Clinical Scientific Package and is presented in degrees:

- Subtalar joint angle (Fick Angle): provides for an indication of the amount of frontal plane rearfoot motion in relation to the ground during the initial contact phase. A higher value for the subtalar joint angle suggests a more pronated rearfoot.

- The minimum and maximum values indicate the maximal supination and maximal pronation position of the rearfoot in relationship to the ground for the initial contact phase.

- Subtalar joint flexibility (pronation excursion): the range between the minimum and maximum subtalar joint angle.

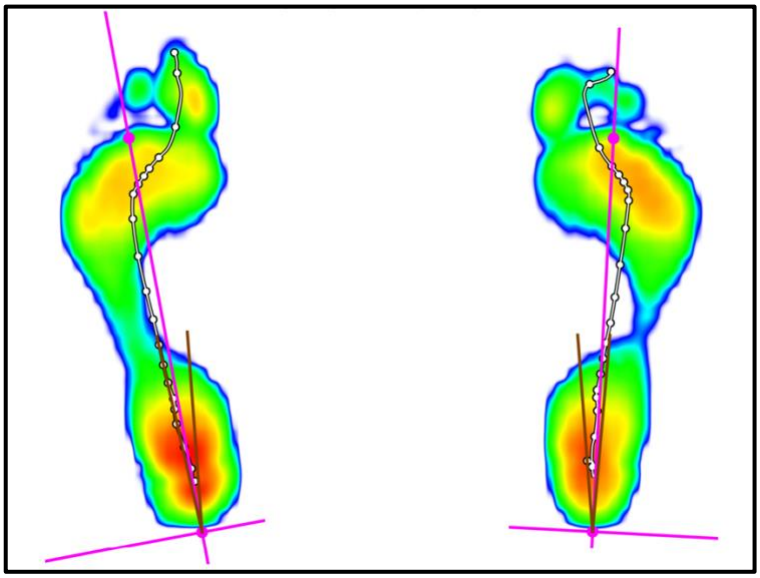

Figura 3. Dynamic 2D

5.2.3.2. During Stance Phase of Gait

The foot timing analysis shows the different events and phases during a foot displacement (foot roll-off) for the left and right foot. For each event and phase, the time or duration is displayed both in milliseconds and as a percentage. The percentages are relative to the total roll-off time. The following events and phases are shown of the right and left feet:

- Initial Forefoot Contact (ms and %): the time when the first pressure is registered.
- Heel Off (ms and %): the time when there is no pressure under the heel.
- Total duration of the step (ms).
- Initial Contact Phase (ms and %): the duration between the Initial Foot Contact event and the Initial Metatarsal Contact event.
- Forefoot Contact Phase (ms and %): the duration between the Initial Metatarsal Contact event and the Initial Forefoot Contact event.

• Foot Flat Phase (ms and %): the duration between the Initial Forefoot Contact event and the Heel Off event.

• Forefoot Push Off Phase (ms and %): the duration between the Heel Off event and the Last Foot Contact event.

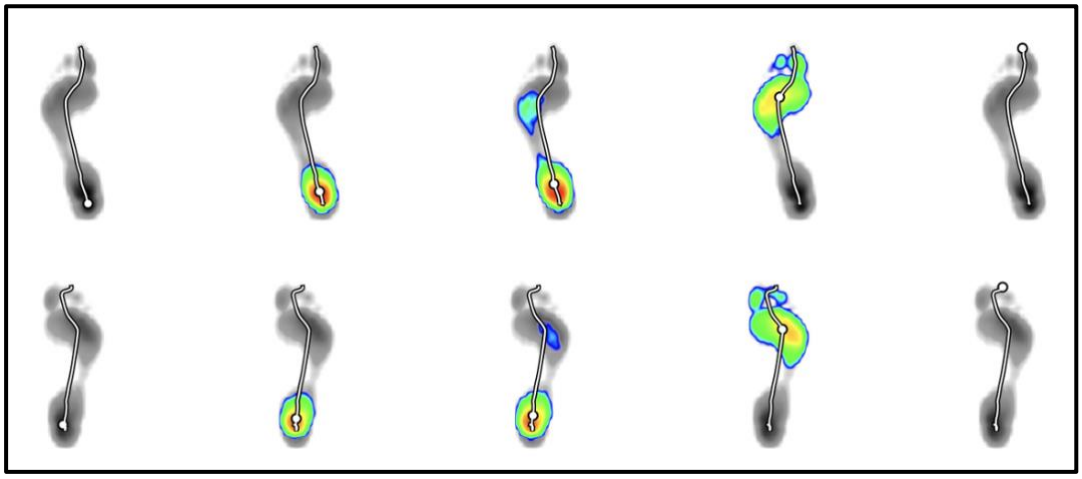

Figura 4. During Stance Phase of Gait

5.2.4. Statistical Analyses

All variables were checked for normality using both graphical (histogram) and statistical (Kolmogorov-Smirnov test) methods. Additionally, the variables that were not normally distributed were transformed. The differences in physical, type of foot, laxity, dynamic, and stance phase of gait characteristics of the overall sample by age and body mass status were examined applying the t-test. For that, three age groups were created: (i), 5 to 6 years; (ii), 7 to 8 years; and (iii), 9 to 10 years. These 3 groups were created to take into account those children who did not yet have a mature gait pattern and those who had not completed the maturation process, those who were, on the contrary, in the process of finishing (from 7 to 8 years old), and those who already had a mature gait pattern (9 to 10 years old). Moreover, two BMI groups were also created: (i) including normal weight, and (ii) OW/OB children.

After that, linear regression analyses were performed to analyze the association of BMI with dynamic and phase of gait variables by all three age groups. Previously, sex interaction was analyzed by including the interaction terms in the code of regression analyses. Therefore, the sample was segmented by age, since there was no sex interaction. In addition, the collinearity of the regression models was calculated using command .vif, which did not show independent variables with a coefficient > 10. Finally, for each regression model, the normality analyses were recalculated for the residuals for the models. In all regression analyzes, BMI was used as an independent variable, and dynamic and phase of gait variables were used as dependent variables. Normality analyzes were re-evaluated for the residuals of each regression model using normality analyzes and histogram and p graphs. No residues were found and only one participant was eliminated for not completing all the evaluation tests.

All analyses were performed using the STATA software for Windows version 13.0. The level of significance was set at $p < 0.050$.

5.3. RESULTS

5.3.1. Study sample

During the study period, 156 out of 176 eligible patients were enrolled. (Figure 5)

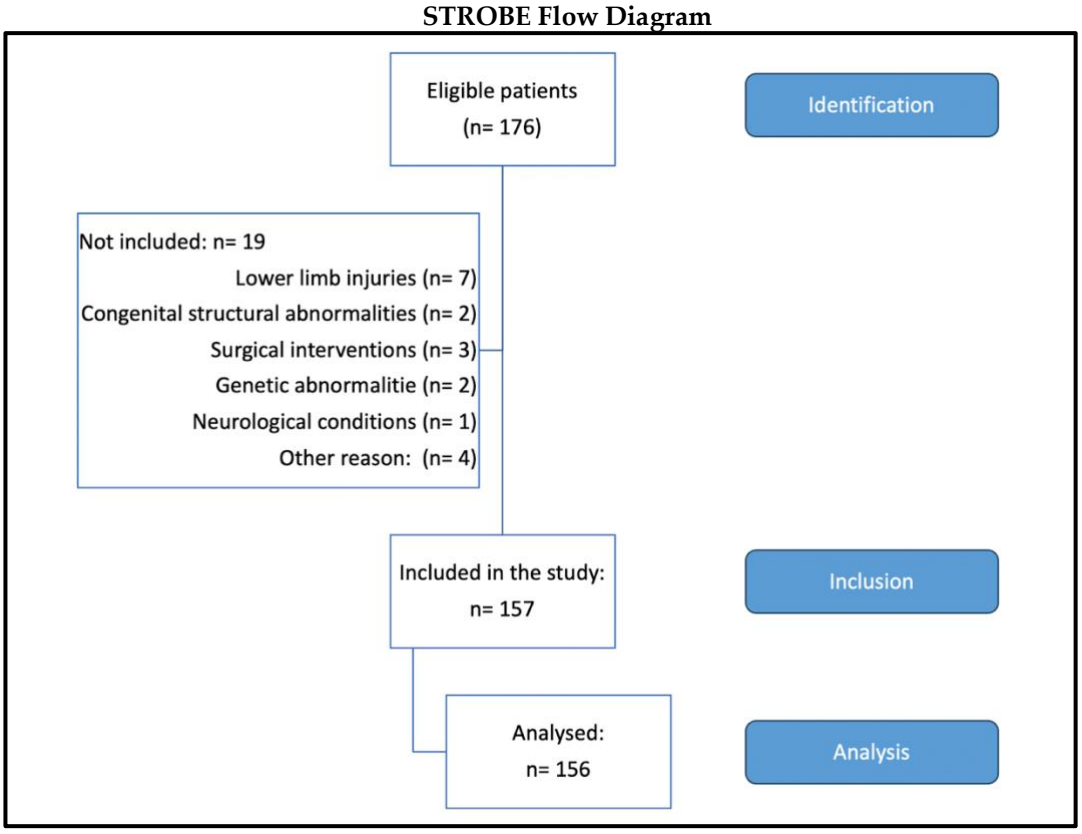

Figure 5. STROBE Flow Diagram. Study enrollment flow chart. STROBE, Strengthening the Reporting of Observational Studies in Epidemiology

5.3.2. Foot type, laxity, dynamic, and stance phase of gait characteristics of the sample by age and BMI in children

The characteristics of the sample by age and body mass status are shown in Table 3. According to physical characteristics, there were no significant differences between NW groups, and OW/OB groups in all three age groups for age and height

(all $p>0.005$). However, there were significant differences between NW groups, and OW/OB groups in all three age groups for weight and BMI (all<0.005).

Then, type of foot and laxity variables were analyzed, however, there were only significant differences between NW groups, and OW/OB groups in the 5 to 6 years group for right lunge test, and in the 9 to 10 years group for left relaxed calcaneal stance position (both $p<0.05$). In relation to type of foot and laxity variables, there were only significant differences between NW groups, and OW/OB groups in the 5 to 6 years group for left pronation excursion, and in the 7 to 8 years group for left maximal pronation calcaneal stance position (both $p<0.050$). Finally, regarding to phase of gait variables there were significant differences between NW group, and OW/OB group in the 7 to 8 years group for left and right total duration of the step (both $p<0.005$), and in the 9 to 10 years group for left forefoot contact phase ($p=0.019$).

Tabla 3. Physical, foot, laxity, dynamic, and stance phase of gait characteristics of the sample by age and body mass status in children.

	5 to 6 years				7 to 8 years				9 to 10 years			
Variables	Total n=79 M/F	NW n=55 M/F	OW / OB n=24 M/F	p^a	Total n=67 M/F	NW n=45 M/F	OW / OB n=22 M/F	p^a	Total n=50 M/F	NW n=29 M/F	OW / OB n=21 M/F	p^a
Physical characteristics												
Age (years)	6.14±0.48	6.13±0.48	6.17±0.46	0.742	7.98±0.62	7.92±0.58	8.11±0.67	0.221	9.51±0.29	9.52±0.29	9.51±0.40	0.944
Weight (kg)	23.10±4.47	21.22±2.72	27.42±4.75	**<0.001**	29.48±7.18	25.62±3.08	37.38±6.68	**<0.001**	37.30±7.36	33.25±4.04	42.89±7.96	**<0.001**
Height (cm)	1.17±0.05	1.17±0.05	1.18±0.05	0.309	1.28±0.07	1.27±0.06	1.30±0.06	0.160	1.39±0.07	1.39±0.06	1.38±0.07	0.512
BMI (kg·m^{-2})	16.77±2.27	15.54±1.02	19.60±2.28	**<0.001**	17.88±3.48	15.95±1.07	21.83±3.39	**<0.001**	19.30±3.53	17.06±1.26	22.38±3.53	**<0.001**
Gender, *n* (%)	39(49)/ 40(51)	30 (55)/ 25(45)	9(38)/ 15(62)	0.857 [b]	24(36)/ 43(64)	16 (36)/ 29(64)	8(36)/ 14(64)	0.232 [b]	15(30)/ 35(70)	8(28)/ 21(72)	7(33)/ 14(67)	0.178 [b]
Type of foot and laxity												
L FPI total (Score)	3.93±2.92	3.69±2.70	4.50±3.36	0.259	3.81±2.88	3.96±3.12	3.50±2.89	0.548	4.28±2.80	4.55±2.54	3.90±3.14	0.426
R FPI total (Score)	3.82±2.73	3.73±2.72	4.04±2.79	0.640	3.58±2.83	3.58±2.95	3.59±2.65	0.986	4.06±2.80	4.45±2.77	3.52±2.80	0.253
L Lunge test (º)	53.47±5.17	54.07±4.96	52.08±5.46	0.116	48.83±6.50	49.38±6.86	47.73±5.67	0.333	47.66±6.61	47.59±7.04	47.76±6.12	0.927
R Lunge test (º)	53.24±5.65	54.07±5.76	51.33±4.98	**0.047**	48.79±6.85	49.62±6.97	47.09±6.41	0.157	47.74±5.94	47.55±6.60	48.00±5.03	0.795
L RCSP (º)	4.49±2.68	4.32±2.65	4.88±2.76	0.407	4.04±2.45	3.84±2.51	4.45±2.30	0.342	4.68±2.42	5.45±2.21	3.62±2.33	**0.007**
R RCSP (º)	4.46±2.63	4.13±2.36	5.21±3.08	0.093	4.10±2.43	4.02±2.67	4.27±1.88	0.695	4.78±2.55	5.24±2.12	4.14±2.99	0.134

L LLAS (Score)	6.64±3.49	7.05±3.56	5.71±3.21	0.116	5.43±3.54	5.20±3.62	5.91±3.39	0.445	4.30±3.18	4.86±3.40	3.52±2.77	0.145
R LLAS (Score)	6.51±3.55	6.85±3.61	5.71±3.35	0.189	5.42±3.48	5.20±3.58	5.86±3.31	0.468	4.30±3.33	4.83±3.50	3.57±3.01	0.190
Dynamic 2D (º)												
L Fick Angle	3.15±5.56	3.25±5.13	2.90±6.54	0.800	4.97±6.13	5.15±6.23	4.61±6.04	0.741	4.47±5.26	5.02±5.39	3.71±5.10	0.392
R Fick Angle	4.16±5.18	4.53±5.30	3.31±4.87	0.337	5.67±6.34	5.84±6.68	5.32±6.68	0.755	5.74±4.76	5.51±4.39	6.06±5.32	0.688
L max pronation	-2.84±4.66	-3.47±4.90	-1.42±3.77	0.071	-3.20±4.61	-2.44±4.39	-4.77±4.76	**0.050**	-3.50±5.28	-3.24±3.41	-3.86±7.20	0.688
R max supination	-3.73±5.14	-3.90±5.50	-3.33±4.30	0.650	-5.16±5.37	-5.33±5.50	-4.82±5.21	0.715	-3.58±5.49	-3.48±4.37	-3.71±6.84	0.885
L max pronation	10.52±4.42	11.22±4.45	8.91±3.99	0.032	10.49±6.25	11.31±6.40	8.82±5.71	0.126	11.64±4.58	12.09±4.57	11.02±4.58	0.422
R max supination	9.76±4.56	10.15±4.56	8.88±4.51	0.257	9.42±4.90	9.51±4.93	9.23±4.95	0.826	10.98±12.70	10.21±6.28	12.05±18.39	0.618
L pronation excursion	13.35±6.13	14.67±5.99	10.33±5.43	**0.003**	13.54±6.23	13.51±6.35	13.59±6.12	0.961	15.52±5.38	15.41±5.10	15.67±5.86	0.872
R pronation excursion	13.51±6.06	14.07±6.23	12.21±5.56	0.211	14.63±8.18	15.02±8.89	13.82±6.59	0.575	14.06±6.75	14.28±6.26	13.76±7.53	0.793
During Stance Phase of Gait												
L Initial Forefoot Contact (ms)	54.00±31.26	51.53±30.67	59.67±32.53	0.290	62.01±44.80	57.47±26.11	71.32±68.87	0.237	71.40±33.91	69.31±37.15	74.29±29.48	0.614

R Initial Forefoot Contact (ms)	60.82±43.17	60.82±30.68	59.67±43.17	0.694	59.51±31.61	56.80±32.20	65.04±30.31	0.320	72.30±38.31	72.52±32.61	72.00±45.90	0.963
L Initial Forefoot Contact (%)	9.06±4.99	8.69±4.75	9.92±5.53	0.319	9.81±5.84	9.42±3.84	10.59±8.69	0.446	10.68±4.57	10.21±4.88	11.33±4.13	0.395
R Initial Forefoot Contact (%)	9.90±6.07	10.05±6.62	9.54±4.68	0.732	9.52±4.54	9.29±4.65	10.00±4.35	0.551	10.76±5.06	11.03±4.55	10.38±5.38	0.657
L Heel Off (ms)	328.9±110.2	318.4±122.0	353.1±73.34	0.200	350.0±110.8	336.9±102.3	376.9±124.6	0.168	392.7±102.8	394.7±91.05	389.8±119.5	0.869
R Heel Off (ms)	329.1±90.7	322.2±87.7	345.0±97.41	0.308	332.5±119.1	318.6±118.7	361.1±117.2	0.171	359.4±112.0	344.9±110.3	379.5±113.8	0.286
L Heel Off (%)	55.17±16.13	53.82±10.03	58.29±10.23	0.259	56.22±15.12	55.11±13.84	58.50±17.58	0.393	59.19±12.86	58.69±10.31	59.86±16.00	0.755
R Heel Off (%)	55.70±13.74	54.49±13.08	58.45±15.09	0.241	53.55±17.14	52.33±17.68	56.04±16.10	0.409	54.80±14.93	53.17±14.35	57.05±15.78	0.371
L Total duration of the step (ms)	595.7±81.42	591.0±86.7	606.6±68.23	0.437	624.1±82.43	609.2±83.40	654.6±73.10	**0.033**	662.7±85.77	672.9±99.50	648.5±61.54	0.326
R Total duration of the step (ms)	584.9±87.42	580.3±93.6	595.8±71.64	0.470	619.0±71.58	607.4±73.11	642.6±63.53	**0.050**	662.2±77.12	659.5±79.51	666.0±75.46	0.771
L Initial Contact Phase (ms)	38.91±25.22	36.7±26.2	43.9±22.64	0.239	51.67±21.03	20.26±19.46	44.55±24.15	0.438	44.84±26.37	46.07±29.09	43.14±22.67	0.703
R Initial Contact Phase ms	37.59±22.30	36.71±21.78	39.62±24.04	0.596	39.49±24.24	37.73±22.56	43.09±27.56	0.400	46.08±26.26	50.03±27.50	40.62±24.03	0.214

L Initial Contact Phase (%)	6.34±3.82	5.95±3.80	7.25±3.80	0.164	6.58±3.01	6.51±2.85	6.73±3.38	0.785	6.66±3.71	6.72±4.11	6.57±3.15	0.887
R Initial Contact Phase (%)	6.35±3.46	6.18±3.23	6.75±4.00	0.506	6.34±3.56	6.22±3.44	6.59±3.87	0.694	6.96±3.82	7.62±3.95	6.05±3.49	0.152
L Forefoot Contact Phase (ms)	15.10±12.76	14.85±12.44	15.67±13.72	0.796	20.27±33.68	17.09±13.75	26.77±55.71	0.272	26.70±16.74	23.48±16.56	31.14±16.34	0.111
R Forefoot Contact Phase (ms)	22.67±32.42	25.13±37.81	17.04±12.66	0.311	20.06±14.88	19.00±15.43	22.23±13.78	0.409	26.22±23.55	22.48±15.24	31.38±31.40	0.190
L Forefoot Contact Phase (%)	2.64±2.25	2.58±2.24	2.79±2.32	0.706	3.21±4.43	2.89±2.22	3.86±7.12	0.402	3.98±2.40	3.31±2.19	4.90±2.43	**0.019**
R Forefoot Contact Phase (%)	6.18±22.24	7.56±26.57	3.04±2.37	0.409	3.20±2.20	3.11±2.22	3.41±2.20	0.606	3.90±2.98	3.48±2.15	4.48±3.83	0.248
L Foot Flat Phase (ms)	274.9±94.55	266.8±98.2	293.5±64.50	0.249	287.9±98.66	279.3±92.62	305.6±110.1	0.310	321.2±91.37	325.4±79.73	315.5±107.2	0.710
R Foot Flat Phase (ms)	267.5±86.02	258.4±84.6	288.4±87.34	0.155	272.0±106.5	261.7±107.5	296.1±103.3	0.218	290.3±92.00	279.2±90.52	305.6±94.03	0.322
L Foot Flat Phase (%)	46.03±14.06	44.95±15.76	48.50±8.87	0.305	46.16±13.99	45.69±13.10	47.14±15.93	0.694	48.44±12.21	48.44±10.17	48.43±14.85	0.995
R Foot Flat Phase (%)	50.97±46.16	51.89±54.74	48.88±13.59	0.791	44.01±15.90	42.96±16.50	46.18±14.71	0.440	44.00±13.08	42.17±12.12	46.52±14.21	0.250
L Forefoot Push Off Phase (ms)	267.0±105.4	272.7±117.7	253.9±69.83	0.469	272.5±99.01	272.2±86.76	273.0±122.6	0.977	271.9±90.24	281.6±80.54	258.7±102.7	0.380

R Forefoot Push Off Phase (ms)	257.6±92.01	260.3±78.2	251.4±119.4	0.693	286.4±114.6	288.9±115.5	281.3±115.1	0.803	298.8±101.0	307.7±97.91	286.5±106.2	0.469
L Forefoot Push Off Phase (%)	44.78±16.16	46.16±18.05	41.63±10.26	0.254	44.04±14.69	44.84±13.77	42.41±16.63	0.528	40.82±12.86	41.31±10.31	40.14±16.00	0.755
R Forefoot Push Off Phase (%)	43.61±14.12	44.51±13.72	41.54±15.09	0.394	46.42±17.12	47.67±17.68	43.86±15.99	0.397	45.20±14.93	46.83±14.35	42.95±15.78	0.370

Values are presented as mean ± standard deviation or percentages. T-test was applied. Statically significant between body mass status group for each age group are highlighted in bold.

Abbreviatures: BMI, body mass index; F, females; FPI, foot posture index; L, left; LLAS, Lower Limb Assessment Score; M, males; NW, Normalweight; OB2, Obesity; OW, Overweight; RCSP, relaxed calcaneal stance position.

5.3.3. Associations of body mass index with dynamic and stance phase of gait variables by age groups in children.

The regression analyses of the BMI with dynamic and stance phase of gait variables by age groups are shown in Table 4. Regarding dynamic variables, there were no significant associations of BMI with none of the variables in all three age groups (all p>0.050). In relation to stance phase of gait variables, there were positive significant associations of BMI with left initial forefoot contact, heel off, total duration of the step, and forefoot contact phase in children 7 to 8 years (all p<0.050). Moreover, there were positive significant associations of BMI with left and right forefoot contact phase in children 9 to 10 years (all p<0.050).

Tabla 4. Associations of BMI with dynamic and phase of gait variables by age groups in children.

		5 to 6 years			7 to 8 years			9 to 10 years		
Variables		R^2	β	*p* value	R^2	β	*p* value	R^2	β	*p* value
Dynamic 2D (º)										
Fick Angle	*Left*	0.01	0.074	0.514	0.00	-0.002	0.985	0.00	-0.051	0727
	Right	0.00	-0.030	0.787	0.00	-0.022	0.861	0.02	0.150	0.295
Max pronation	*Left*	0.01	0.073	0.521	0.02	-0.127	0.307	0.02	-0.198	0.166
	Right	0.01	0.074	0.516	0.01	0.083	0.503	0.06	-0.250	0.080
Max supination	*Left*	0.01	-0.074	0.516	0.03	-0.172	0.162	0.01	-0.111	0.441
	Right	0.00	-0.030	0.788	0.01	0.120	0.331	0.01	0.076	0.602
Pronation excursion	*Left*	0.01	-0.109	0.336	0.00	-0.059	0.634	0.01	0.090	0.534
	Right	0.01	-0.093	0.415	0.00	0.001	0.999	0.01	0.086	0.553
During Stance Phase of Gait										
Initial Forefoot Contact (ms)	*Left*	0.01	0.110	0.334	0.16	0.401	**<0.001**	0.02	0.150	0.296
	Right	0.00	0.00	0.997	0.04	0.197	0.110	0.04	0.195	0.173
Initial Forefoot Contact (%)	*Left*	0.01	0.099	0.386	0.12	0.341	**0.005**	0.01	0.105	0.465
	Right	0.00	-0.011	0.918	0.03	0.182	0.140	0.01	0.112	0.435

Heel Off (ms)	*Left*	0.03	0.171	0.133	0.06	0.251	**0.040**	0.01	0.119	0.412
	Right	0.03	0.186	0.100	0.02	0.146	0.237	0.04	0.210	0.143
Heel Off (%)	*Left*	0.02	0.152	0.182	0.04	0.187	0.129	0.00	0.041	0.779
	Right	0.02	0.157	0.167	0.01	0.113	0.360	0.01	0.105	0.466
Total duration of the step (ms)	*Left*	0.02	0.124	0.275	0.08	0.274	**0.024**	0.02	0.148	0.312
	Right	0.03	0.161	0.157	0.03	0.176	0.153	0.08	0.275	0.053
Initial Contact Phase (ms)	*Left*	0.01	0.112	0.326	0.03	0.178	0.150	0.00	-0.035	0.805
	Right	0.01	0.076	0.505	0.04	0.210	0.088	0.01	-0.099	0.491
Initial Contact Phase (%)	*Left*	0.01	0.099	0.382	0.01	0.108	0.383	0.00	-0.070	0.628
	Right	0.00	0.066	0.562	0.03	0.182	0.139	0.02	-0.144	0.318
Forefoot Contact Phase (ms)	*Left*	0.00	0.047	0.681	0.18	0.426	**<0.001**	0.13	0.355	**0.011**
	Right	0.00	-0.053	0.639	0.01	0.085	0.492	0.18	0.428	**0.002**
Forefoot Contact Phase (%)	*Left*	0.00	0.064	0.569	0.14	0.380	**0.002**	0.13	0.357	**0.011**
	Right	0.00	-0.022	0.845	0.00	0.058	0.642	0.16	0.398	**0.004**
Foot Flat Phase (ms)	*Left*	0.03	0.164	0.248	0.01	0.100	0.419	0.01	0.077	0.593
	Right	0.04	0.200	0.079	0.01	0.106	0.394	0.02	0.150	0.298
Foot Flat Phase (%)	*Left*	0.02	0.138	0.225	0.00	0.038	0.757	0.00	-0.001	0.995
	Right	0.00	0.038	0.741	0.01	0.073	0.553	0.00	0.070	0.630
Forefoot Push Off Phase (ms)	*Left*	0.01	-0.080	0.481	0.00	-0.061	0.619	0.00	-0.009	0.946
	Right	0.01	-0.084	0.458	0.00	-0.043	0.730	0.00	-0.005	0.974
Forefoot Push Off Phase (%)	*Left*	0.02	-0.150	0.185	0.03	-0.168	0.173	0.00	-0.040	0.779
	Right	0.02	-0.148	0.192	0.01	-0.113	0.359	0.01	-0.105	0.466

Statically significant are highlighted in bold. BMI, Body mass index. In all regression analyzes, BMI was used as an independent variable, and dynamic and phase of gait variables were used as dependent variables.

5.4. DISCUSSION

The purpose of this study was to investigate how pediatric OW/OB affect the typical patterns of plantar pressure produced during walking. Along with measuring the length of the gait phases using the pressure platform. Findings of the present work provided that some variables of type of foot, laxity, some dynamic

variables and stance phase of gait characteristics showed significant differences between NW groups, and OW/OB groups in children 5 to 10 years of age (P ranged between 0,019-0,050). Moreover, BMI was also positively associated with initial forefoot contact, heel off, total duration of the step, and forefoot contact phase in children 7 to 10 years of age (P ranged between <0,010-0,040).

In relation to our first objective, which was to analyze the differences in foot type, laxity, and dynamic characteristics of the gait, as well as stance phase of gait characteristic between BMI and age groups in children from 5 to 10 years of age, it can be observed that children with OW/OB between 5 and 6 years of age present less dorsiflexion of the right ankle (Lunge Test of 51º compared to the average 54º of children with NW). In this respect, reduced ankle dorsiflexion can result in an altered gait pattern because of ineffective tibial anterior rotation on the supporting foot during the stance phase, so this is another factor to consider when examining gait stance (excellent ankle mobility permits the tibia to rotate anteriorly with espect to the foot during the mid-stance phase of locomotion, helping the body move forward) (35). In this sense, and in addition to the possible consequences above mentioned, we believe that our results could be due to what has already been mentioned in previous research. In this study, the authors mentioned that children with OW/OB present greater activation of the triceps surae compared to children with NW, this greater activation implying a greater limitation of dorsal ankle flexion (36).

We also observed that the RCSP presents fewer degrees in children with OW/OB (3.62º of RCSP in children with OW/OB compared to 5.45º in children with NW). The RCSP is one of the main tests that are evaluated to diagnose flat feet (FF) (37). This result questions the association between presenting OW/OB and having a higher prevalence of PP (38,39) and adds to the findings of recent studies, which reflect that PP should not be associated with OW/OB (40,41). In this regard, we think that the method of evaluating the foot may be the source of disagreement in these studies examining the association between PP and OW/OB (38,39) (40,41). Therefore, to make it easier to compare the data and to be able to draw more clear and accurate conclusions, future research should standardize the approach of evaluating flatfoot. We believe that looking only at the footprint can lead to confusion because children with OW/OB have more fat in their internal longitudinal arch (42).

Regarding the dynamic variables, it is also observed that children between 5 and 6 years of age with OB present fewer degrees of pronation excursion (10º) compared to children with NW of the same age who present 14º (P=0.003). This indicates that the movement in the frontal plane is greater for children with NW, a finding that can be explained by the RCSP that these children present. Considering our results, the variable of maximum pronation, it was also found that children from 7 to 8 years of age present more pronation than children with NW (P=0.050). This excess of pronation could be a risk factor for multiple conditions such as "growing pains" (43). These results are in contrast to those of Yan et al. (44); in this study, children with OW/OB have more pronation than children with NW, arguing that the excess of pronation in children with OW/OB is due to the fact that children with these characteristics present less stability, so that this excess of pronation it is an adaptation to instability, that is, it is a balance reflex of the foot. Therefore, our results seem to reflect that younger children with NW have a greater excursion of pronation, a finding that may be justified by their eversion position of the calcaneus. However, as children with OW/OB grow older and their foot becomes more similar to the one they will have in adulthood, we observed that they have a greater maximum pronation, a finding that is related to the probability of suffering more growing pains (43) and is an adaptation to the instability that these children present (44).

When it comes to the variables of the gait phases, it is observed that children from 7 to 8 years of age have altered the total duration of the step of both feet, spending children with OW/OB more time in this phase. The difference is greater in the left foot than in the right foot; on the left foot they spend 45 ms more than children with NW and on the right foot they spend 35 ms more than children with NW. In children from 9 to 10 years of age, it can be seen how the percentage of the forefoot contact phase of the left foot of children with OW/OB is 4.90%; much higher than in children with NW, which is 3.31%. These data reflect that children with OW/OB spend more time in the stance phase, which means that they are putting even more stress on their joints. In this sense, our results are in concordance with the results mentioned by Although Montes-Alguacil et al. (45). Despite the fact they used another device to assess gait stance phases, they mentioned that phases last significantly longer for children with OW/OB, a fact also observed in our results. Thus, our results seem to support the belief remarked by previous

literature, showing how gait disturbances observed in children with OW/OB could have detrimental implications for their musculoskeletal system (5,16,17,46). Therefore, and considering all of the aforementioned, it seems to be evident that children with OW/OB present alterations in their gait and foot characteristics. Therefore, it would be important for all health professionals to evaluate the dynamics of children and work on prevention in order to avoid long-term problems in this population.

Answering the second objective, which was to analyze the associations between BMI and the characteristics of gait stance phases across these age groups in children, it is necessary to remark that the findings of this present study are difficult to compare because more attention has been previously paid to the timing of the foot, rather than to the forces received in the different anatomical regions of the foot. Firstly, it can be seen that the greatest influence of the OW/OB in children is in the age range of 7 to 8 years of age. OW/OB is related to alterations in initial forefoot, heel off, total duration of the step and forefoot contact phase. Interestingly, all of these positive associations occur on the left foot. On the other hand, we also expected to find that the foot flat phase would be most associated during the dynamics for children with OW/OB, but to our surprise, no association has emerged. This idea is due to the fact that the foot flat phase, which transitions the body's weight from the double supporting phase to the single stance phase, that is to say, the dynamic performance of the foot, is represented by the variation in pressure during the foot flat phase (47). A possible explanation for this fact in our results could be, as reported by a previous study, that children with OW/OB had more strength in their tibialis posterior muscle (48), and this slowed down the movement.

Last but not least, we could see a connection between having a higher BMI and presenting for the age range from 9 to 10 years of age, it can be observed how the OW/OB is related to a greater forefoot contact phase, both for the right foot and the left foot, the association being greater for the right foot ($P<0.002$). This should alarm us since from the age of 8 the support time is similar to that of older children (49); which may mean that this alteration can be maintained and extrapolated to adult life. The fact of spending more time in the forefoot contact phase translates into greater pressure in that area. The increase in pressure in the forefoot in children older than 7 years of age, may be indicating a change in the more normal turning

pattern of the foot, mainly in the push phase (50). In adults, the normal thing is that the forefoot is loaded more, that is, that it supports greater forces since the forefoot is prepared to absorb greater mechanical stress (50). Therefore, we humbly believe that our results could be attributed to the fact that the foot of these children is already maturing and is increasingly resembling the foot that they will have in adult life, or even, we could attribute it to the excess weight due to presenting OW/OB it makes that area load more and is giving it more stress. Hence, more studies are needed to clarify and corroborate these possible theories, which would permit establishing normal values for gait characteristics and to observe whether these changes in children with OW/OB continue into adulthood or whether they disappear with growth, facilitating therefore, a more accurate approach to these patients.

There are a number of limitations to this study that warrant discussion. First off, although various cut-off values might have altered our results, the values utilized as cut-off points to categorize children as normal weight "NW," overweight "OW," or obese "OB" have been previously used and accepted (22–24). Furthermore, despite the RSscan Footscan® 9 pressure platform's strong intra- and inter-rater reliability (31), it only measures forces perpendicular to the ground and ignores forces on other planes, even so, the measurement of plantar pressure during dynamics has been shown to be a reliable method of evaluating foot form and function. Thirdly, direct comparisons with other research may be challenging due to multiple possible age ranges because the age range of our study ranged from 5- to 10-years-old. The fact that the children were being observed while walking may have caused them to change their habitual gait pattern. Finally, the results must be taken with caution because in the analysis there were children with a mature gait pattern and others who did not complete the maturation process, so it would be necessary to take into account the process in which each child is in order to extrapolate the results.

Despite the limitation's shortcomings, this study has a number of strengths. The children that make up the study are within a large age range (from 5 to 10 years of age). Second, this is the first study that relates the childhood OW/OB with so many variables gait (dynamic during stance phase of gait, Fick angle, the maximal supination and pronation and pronation excursion). Thirdly, given the prevalence of the measuring tools utilized in our investigation in both clinical practice and

research, along with the data collected and the rising incidence of OW/OB in children (1,2), our findings may have significant clinical and public health ramifications.

The clinical implications of the results of this study suggest that in order to prevent future pain and potential short- and long-term problems, symptoms like for example too high or too low angular values or too extreme foot timings such as long total contact time or too short forefoot contact phase must be detected. The prevalence of OW/OB prophylaxis as well as the early detection of musculoskeletal abnormalities will have a long-term impact on children's overall health. Reduced physical activity can result from a change in the feet and everything that this entails (changes in normal gait values), which can exacerbate the OW/OB problem. A multidisciplinary team composed of nutritionists, psychologists, rehabilitators, pediatricians, physiotherapists, and podiatrists should handle children with OW/OB. We highlight the importance of knowing and analyzing the footprint in children, since often the problems in children's feet and the gait patterns established in childhood persist later in adulthood.

5.5. CONCLUSIONS

Children with OW/OB have alterations at different stages of gait. Having OW/OB is related to alterations of the phases of gait mainly from 7 to 10 years of age, spending more time in each of the phases of walking. This fact could indicate that children with OW/OB, in addition to walking slower, overload the musculoskeletal system subjecting their joints and muscles to greater stress. In addition to the clinical examination, determining the early changes in foot structure and function in children with OW/OB should take into account the assessment of plantar pressure. Therefore, more research in the area of plantar pressures is required to create an ideal methodological framework that will enable us to better understand the characteristics of foot function and how it develops in childhood and the influence of OW/OB.

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VI – ESTUDIO III

VI -ESTUDIO III

EFFICACY OF PLANTAR ORTHOSES IN PAEDIATRIC FLEXIBLE FLATFOOT: A FIVE-YEAR SYSTEMATIC REVIEW

Abstract:

Paediatric flexible flatfoot (PFF) is a very common condition and a common concern among parents and various healthcare professionals. There is a multitude of conservative and surgical treatments, with foot orthoses (FO) being the first line of treatment due to their lack of contraindications and because the active participation of the child is not required, although the evidence supporting them is weak. It is not clear what the effect of FO is, nor when it is advisable to recommend them. PFF, if left untreated or uncorrected, could eventually cause problems in the foot itself or adjacent structures. It was necessary to update the existing information on the efficacy of FO as a conservative treatment for the reduction in signs and symptoms in patients with PFF, to know the best type of FO and the minimum time of use and to identify the diagnostic techniques most commonly used for PFF and the definition of PFF. A systematic review was carried out in the databases PubMed, EBSCO, Web of Science, Cochrane, SCOPUS and PEDro using the following strategy: randomised controlled trials (RCTs) and controlled clinical trials (CCTs) on child patients with PFF, compared to those treated with FO or not being treated, assessing the improvement of signs and symptoms of PFF. Studies in which subjects had neurological or systemic disease or had undergone surgery were excluded. Two of the authors independently assessed study quality. PRISMA guidelines were followed, and the systematic review was registered in PROSPERO: CRD42021240163. Of the 237 initial studies considered, 7 RCTs and CCTs published between 2017 and 2022 met the inclusion criteria, representing 679 participants with PFF aged 3–14 years. The interventions of the included studies differed in diagnostic criteria, types of FO and duration of treatment, among others. All articles conclude that FO are beneficial, although the results must be taken with caution due to the risk of bias of the included articles. There is evidence for the

efficacy of FO as a treatment for PFF signs and symptoms. There is no treatment algorithm. There is no clear definition for PFF. There is no ideal type of FO, although all have in common the incorporation of a large internal longitudinal arch.

Keywords:

Flatfoot; paediatrics; child; foot orthoses

6.1. INTRODUCTION

Paediatric flexible flatfoot (PFF) is a common condition in children [1,2]. Ninety percent of appointments in foot clinics are related to flat feet (FF) [3]. Epidemiological studies indicate that 4% of 10-year-old children suffer from PFF and 10% of them are under treatment to prevent secondary pathologies during adulthood [4]. In addition, PFF is a common concern for parents and a highly debated topic by all healthcare professionals [5–7].

For decades, up to the present, PFF has been a highly controversial issue, being difficult to differentiate what is normal or pathological. There are also questions about how to diagnose it, when it should be treated, when the physiological evolution should be allowed to continue, what is the best conservative treatment and when surgical treatment is necessary [8–10].

There is no universally accepted or precise definition for FF. Clinically, FF is understood as a flattening of the medial longitudinal arch when the subject is in a standing position [11]. FF is a triplanar presentation of the foot [12], accompanied by a valgus position of the calcaneus, medial prominence of the talus, flattened footprint, abduction of the forefoot with respect to the hindfoot and internal rotation of the tibia [5,13]. In the PFF, it is possible to correct the deformity when the person is not in a standing position, where the arch is present [14]. Therefore, there is controversy among different professionals regarding its treatment. Some professionals indicate that it is a physiological variant of foot development and that it will correct itself in time [15]. Other professionals indicate that PFF will slowly lead to pathologies in the foot, ankle or proximal structures, such as plantar fasciopathy, Achilles and posterior tibial tendinopathy, hallux limitus and rigidus, chondromalacia patellae and patellofemoral pain syndrome [5,16–20].

The most common symptoms are functional disability and general foot and leg pain, although the majority of PFF cases are asymptomatic [21]. Regardless of

symptomatology, there are biomechanical abnormalities, including decreased ankle dorsiflexion, increased hindfoot eversion and forefoot supination [5,13,22].

The diagnosis is based on clinical tests, analysis of the footprint or radiology. The most widely used clinical tests are relaxed calcaneus position in standing, neutral calcaneal position in standing position, navicular drop, navicular drift, navicular height, foot posture index (FPI), Jack's test, double/single heel rise test (HRT), maximum pronation test, supina- tion resistance test, pronation angle and too many toes test. Furthermore, assessments and evaluations such as genu valgus, asymmetry, tibial torsions, metatarsus adductus, flexibility assessment (most commonly assessed by Beighton scale or the Wynne-Davies criteria [23]), etc.) are used. In terms of the analysis of the footprint, it can be conducted by pedigraph, pressure platform, photopodogram and podoscope. Finally, radiographic measurements are the most objective ones, including assessment from two load projections. The most common radiology assessments are lateral and dorsoplantar talocalcaneal angle, angle of inclination of the calcaneus, talus and first metatarsal, medial and lateral Costa-Bartani angle, talus–first metatarsal angle, calcaneus–fifth metatarsal, tibial talus, line of Cyma and Schade [5,8,24–28].

There is a wide range of treatments for PFF. Evidence is lacking or very limited for most conservative treatments. Since there are no established criteria to differentiate a pathological PFF from a physiological one, the decision to treat PFF depends on each clinician [13]. The factors that are considered when establishing a treatment are age, flexibility, severity of the deformity, equinus position, adequate footwear and the presented symptoms [29]. Surgery, including procedures such as subtalar arthroereisis [30], is reserved for feet that have severe deformity, rigid FF or FF with persistent symptoms that do not improve with conservative treatment. The most used conservative treatments are foot orthoses (FO), corrective shoes, physical exercises, physiotherapy with joint manipulations and the Mulligan method [5,7,13,16,19,31–34]. The most frequent conservative intervention is the use of FO [25,35].

The short-term purpose of treatment with FO is to decrease pronator movement, hence decreasing the tensile forces on ligaments, tendons and the plantar fascia. The long-term goal would be to reduce the pathological position of the foot and slow down the progression [22,29,36,37]. FO treatment has been modified and has evolved over time, including thermoplastic, polypropylene FO

and postings which aim to achieve a neutral hindfoot position [38]. The current evidence of FO treatments is very limited as system- atic reviews have demonstrated; some of them concluded that FO present efficacy and some of them did not [13,14,21,29,31,35,39,40]. Recent studies continue to show ambi- guity, although the evidence on the efficacy of FO is increasing, especially when FO are customised [4,19,21,41–48].

Recent studies conclude that PFF should not be ignored, and their treatment should not be downplayed, considering that the sooner that effective treatment is prescribed, the less damage will occur to other parts of the body. They also add that a conservative corrective treatment should be carried out, rather than an invasive treatment [19,20].

Therefore, since untreated PFF could cause problems in the foot itself or in other structures, it is necessary to demonstrate the efficacy of FO as a conservative treatment to reduce signs and symptoms in patients with PFF. It is also important to know the best type of FO and the minimum time of use as well as to identify which are the most used diagnostic techniques for PFF and how it is defined.

6.2. MATERIALS AND METHODS

This protocol was registered on the International Prospective Register of Systematic Reviews PROSPERO: CRD42021240163. In order to respond to the objectives set out in this present study, a systematic review was carried out following the regulations "Preferred reported items of systematic reviews and meta-analysis" (PRISMA) and in accordance with the recommendations of the Cochrane Collaboration [49].

6.2.1. Selection Criteria

6.2.1.1. Types of Studies

Randomised controlled trials (RCTs) and controlled clinical trials (CCTs) published in the last five years were included. All other types of studies, such as systematic reviews, were excluded.

6.2.1.2. Participants

Studies included in this review had to include children diagnosed with PFF. Patients who had surgery in the lower limbs, or who presented some systemic or infectious neuro- logical disease were excluded.

6.2.1.3. Type of Intervention

Interventions which were considered included FO as treatments for at least 2 months, both customised or prefabricated, and/or with modifications.

6.2.1.4. Comparison

Studies that compared the intervention with another type of FO or placebo.

6.2.1.5. Outcome Measure

The outcomes considered were those used to evaluate the improvement of signs and symptoms of the PFF.

6.2.2. Search Strategy

The search was carried out by two researchers independently in the following databases: PubMed, EBSCO, Web of Science, Cochrane, SCOPUS and PEDro. The following medical subject headings (MeSH) were used: flatfoot, paediatrics, child, foot orthoses, according to the characteristics of each database, accompanied by the Boolean operators "AND" and "OR".

The following search strategy was used: (("Flatfoot"[Mesh] AND ("Paediatrics"[Mesh] OR "Child"[Mesh] OR "Child, Preschool"[Mesh]) AND "Foot Orthoses"[Mesh]) OR (("Flex- ible Flatf**t"[tw] OR "Flat F**t"[tw] OR "Pes Planus"[tw] OR Flatf**t[tw] OR Splayfoot[tw] OR "F**t, Flat" [tw] OR "Flatf**t,

Flexible"[tw]) AND (Paediatrics[tw] OR "Preschool Child*"[tw] OR Child*[tw] OR "Child*, Preschool"[tw]) AND ("Foot Orthosis"[tw] OR "Or- thotic Insole*"[tw] OR "Orthos*s, Foot"[tw] OR "Foot Orthotic Device*"[tw] OR "Device*, Foot Orthotic"[tw] OR "Orthotic Device*, Foot"[tw] OR "Arch Support*, Foot"[tw] OR

"Foot Arch Support*"[tw] OR "Support*, Foot Arch"[tw] OR "Orthotic Shoe Inserts"[tw] OR "Insole*, Orthotic"[tw] OR "Orthotic Insole*"[tw])))

In addition, the papers bibliographies were reviewed.

6.2.3. Study Selection

The selection of the studies was carried out by two researchers. After the selection of the papers from the databases, the duplicates were eliminated. After the elimination, a screening of the titles and abstracts was carried out, based on the inclusion and exclusion criteria. The selected studies were then fully read to assess compliance with the eligibility criteria. Any disagreements between reviewers in any phase of study selection were resolved by consulting another reviewer.

6.2.4. Data Extraction and Management

In order to respond to the proposed objectives, data were extracted from the studies, including characteristics of the publication (author, country, year and journal of publication, study design, objectives, keywords), characteristics of the sample (sample size, age, sex, height, weight, body mass index (BMI), whether the PFF was symptomatic or not, previ- ous treatments and diagnosis), characteristics of the diagnosis and characteristics of the intervention (FO type and material, FO use, what health education/recommendations each participant received and the duration of the treatment) and the results together with the final conclusions of each study.

6.2.5. Risk of Bias and Quality Assessment

To estimate the methodological quality/risk of bias of each of the included studies, two different types of scales were used for the two study types (i.e., RCT or CCT).

To evaluate the RCTs, the tool recommended by the Cochrane manual was used to assess the risk of bias. It is a domain-based assessment that evaluates each domain with three possibilities: 'low risk of bias', 'high risk of bias' or 'unclear risk' [50]. To assess the CCTs, the "Before-After Quality Assessment Tool (BAQA)" developed by the National Institute of Health (NIH) in collaboration with the Cochrane team, among others, was used. It is a tool that answers 12 very specific questions to assess key concepts of the internal validity of the studies [51].

In addition, the Scottish Intercollegiate Guidelines Network (SIGN) scale was used to reflect the level of evidence and degree of recommendation [52].

6.2.6. Data Synthesis

Data have been presented in tables and narrative forms to describe the characteristics of the included studies. As the studies were not sufficiently homogeneous, it was impossible to perform a meta-analysis.

6.3. RESULTS

Using the search strategy outlined above, we identified a total of 237 studies in the databases, as well as 4 additional records identified through other sources, which was via the reference lists of the initial papers that were retrieved. Of these 241 items, 181 were duplicated records. The remaining 60 studies were evaluated by title and abstract by 2 independent reviewers. Of these, 19 were excluded due to differences in inclusion criteria as they were observational studies, clinical trials without control group or the participants were not children. After that, 41 full texts were assessed for eligibility and 34 were excluded because participants had previously undergone surgery in the lower limbs, or the FO they were prescribed had been used for less than 2 months, among other reasons. Thus, only seven papers fully met the inclusion criteria. Figure 6 shows the PRISMA flow diagram for the studies included in this review.

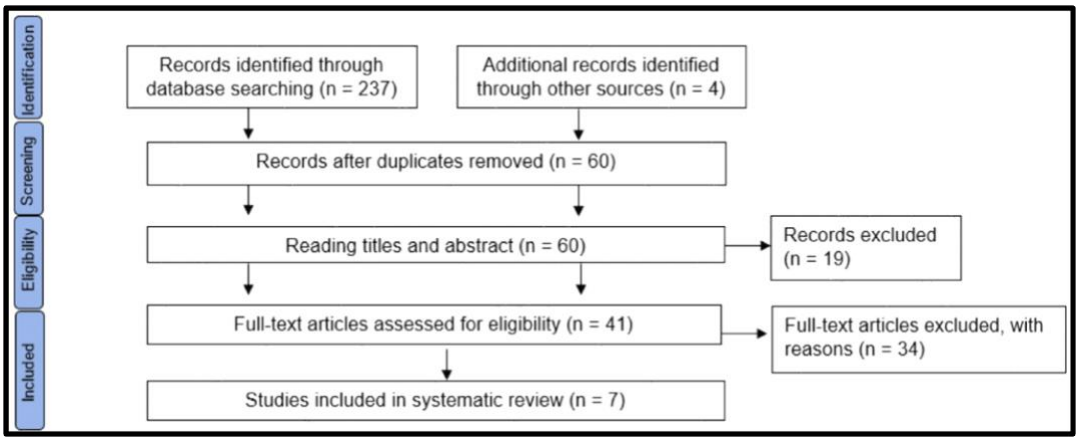

Figure 6. Article selection flowchart. Adapted from Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).

6.3.1. General Characteristics of the Studies Assessed

The included studies were published in the last 5 years and all of them were developed on the Asian continent, except for Rusu et al. [53]. Regarding the levels of evidence assessed by the SIGN grading system, the included studies presented levels II+A and II+B.

Of the 679 included participants, 412 were boys and 267 were girls, between 3 and 14 years of age. The study with the largest sample size was carried out by Chen et al. [42], with a total of 466 subjects, being more than two thirds of the total population included in this review.

In terms of the characteristics of the participants, their BMI was from 16.04 [42] to 20.1 [4,54]. Some of the studies did not provide BMI data. All the participants, to be selected, presented with PFF. Furthermore, in some of the included studies the participants presented pain [42,43,55]. None of the participants received previous treatment (Table 5).

Tabla 5. Study characteristics and publication characteristics

Evidence level BY SIGN	Author, country (year of publication); study desing	Sample size	Year of age (Mean/ SD); Gender (M/F)	Weight in Kg (SD); height in cm (SD)	BMI Kg/m2 (SD)	Previous treatment	Diagnoses, symptoms
II+A	**Rusu et al, Romania (2022) [53]; RCT**	**CG**: 15 **IG**:15	9.37 (1.42); (17/13)	41.8 (12.72); 148.7 (10.96)	18.84 (5.32)	N/A	Bilateral PFF level II, asymptomatic
II+A	**Jafarnezhadgero et al, Iran (2020) [4]; RCT (single blind)**	**CG**: 15 **IG**:15	**CG**: 10.4 (1.5); (15/0) **IG**: 10.5 (1.4); (15/0)	**CG**: 48.2 (5.4); 141.2 (6.1) **IG**: 48.1 (9.1); 142.4 (5.7)	**CG**: 20.1 (4.2) **IG**:20.0 (4.0)	N/A	PFF
II+A	**Chen et al, Taiwan (2019) [42]; CT**	**CG**: 343 **IG**: 123	**CG**: 4.4 (7.9) meses; (187/156) **IG**: 4.3 (11.2); (77/46)	**CG**:18.0 (3.4); 104.5 (6.7) **IG**:18.2 (4.0); 105 (7.6)	**CG**:16.4 (2) **IG**:16.4 (2.1)	No	PFF, symptomatic
II+B		**IG**:18	**IG**:10.22 (0.43); (10/8)	N/A	N/A	N/A	PFF, symptomatic

	Choi et al, South Korea (2019) [43]; CT	**CG**:13	**CG**:10.15 (0.38); (9/4)				
II+B	**Hsieh et al, Taiwan (2018) [55]; RCT (single blind)**	**IG**: 26	**IG**: 6.9 (0.6); (14/12)	N/A	N/A	N/A	PFF, symptomatic
		CG:26	**CG**: 6.2 (0.4); (14/12)				
II+A	**Jafarnezhadgero et al, Iran (2018) [54]; RCT (single blind)**	**CG**: 15	**CG**: 10.4 (1.5); (15/0)	**GC**: 48.2 (5.4); 141.2 (6.1)	**CG**: 20.1 (4.2)	N/A	PFF, N/A
		IG:15	**IG**: 10.5 (1.4); (15/0)	**GE**: 48.1 (9.1); 142.4 (5.7)	**IG**:20 (4)		
I+B	**Ahn et al, South Korea (2017) [56]; CT**	**IG**: 20	**CG**: 10.4 (4.99); (12/8)	**GC**:35.13 (16.93); 138.23 (10.17)	**CG**:18.37 (4.67)	N/A	PFF, N/A
		CG:20	**IG**: 9.59 (4.24); (12/8)	**GE**:37.41 (11.33); (139.28 ±12.78)	**IG**:19.18 (2.39)		

SD: standard deviation; M: male; F: female; Kg: kilogram; Cm: centimetre; BMI: body mass index; RCT: randomised controlled trial; CT: controlled trial; CG: control group; IG: intervention group; SIGN: Scottish Intercollegiate Guidelines Network; N/A: not applicable; PFF: paediatric flexible flatfoot.

Participants were excluded if they had some type of foot or lower limb surgery, neurological, neuromuscular or hereditary disease, or if they had a developmental or coordination/mobility disorder.

Each author defined PFF with different characteristics. To do this, all authors used clinical diagnostic tests, even Rusu et al. [53] who did not specify the diagnoses but indicated that participants were evaluated using static and dynamic assessment. In addition, only three of the included studies, Choi et al. [43], Hsieh et al. [55] and Ahn et al. [56], also used radiographic examination for diagnosis.

All the studies that performed a radiographic diagnosis evaluated the lateral and anteroposterior projections of the feet in loadbearing. In addition, Choi et al. [43] evaluated the posterior projection, which was introduced by Saltzman and el-Khoury. The angles measured in the different projections were highly variable; only three authors agreed on the same angle: the angle of inclination of the calcaneus in the lateral projection. For Hsieh et al. [55], patients were diagnosed with PFF when two of the three angles they measured were not within normal values. For Ahn et al. [56], patients were diagnosed with PFF when a radiological finding in any of the four angles that were evaluated were not within normal values. Choi et al. [43] did not specify when patients were diagnosed with PFF.

Regarding diagnostic clinical tests, eight different tests were identified: (1) navicu- lar drop, (2) RCPS, (3) arch height index, (4) pedigraphy Chippaux–Smirak index (CSI), (5) Beighton scale, (6) Jack's test, (7) double/single heel rise test and (8) FPI. Each author used different tests in their studies. If tests were positive, it meant that they presented PFF. For this, the navicular drop had to be greater than 10 mm for Jafarnezhadgero et al. [4,54] and greater or equal to 6 mm for Hsieh et al. [55]. Additionally, PRCA had to be greater than 4◦ of eversion, the arch height index less than 0.31, the CSI greater than 62.7%, the Beighton scale greater than 4 and finally the FPI had to be greater than 6 in the total score (Table 6).

Tabla 6. Sample selection and diagnoses

Sample selection			**Diagnoses**
Authors	**Inclusion criteria**	**Exclusion criteria**	**PFF definition and assessment**
Rusu et al (2022) [53]	PFF after static and dynamic analysis	Surgery of foot or ankle; lower limbs pain; overweight; neuromuscular or neurological disorders.	• **STATIC AND DYNAMIC ANALYSIS:** Clinical examination in standing and walking. Arch height index and subtalar flexibility, which was assessed by a force platform
Jafarnezhadgero et al (2020) [4]	Navicular Drop > 10mm, RCPS >4º eversion, Navicular Height < 0.31	Surgery or fracture of foot or ankle; neuromuscular problems, asymmetry of > 5mm.	• **STATIC AND DYNAMIC ANALYSIS**: collapsed LMA while standing position and recovered when offloading. • **NAVICULAR DROP** > 10mm. • **RCPS:** >4º de eversión. • **NAVICULAR HEIGHT:** < 0.31.
Chen et al (2019) [42]	PFF symptoms	Musculoskeletal injury, neurological disorder, previous FO	• **ANAMNESIS, BEIGHTON SCALE, STATIC AND DYNAMIC ANALYSIS:** foot pain, fatigue and instability during walking, and changes in the normal morphology of the foot.

			• **PEDIGRAPHY**: + (CSI > 62.7 %)
Choi et al (2019) [43]	PFF	Systematic inflammatory disease, lower limb trauma or surgery affecting their alignment.	• **ANAMNESIS:** Characteristic signs and symptoms of PFF. • **DOUBLE/SINGLE HEEL RISE TEST**: + • **TEST DE WINDLAS**: + • **X-ray:** loadbearing, anteroposterior and lateral projections of the rearfoot (Saltzman and el-Khoury).
Hsieh et al (2018) [55]	Symptomatic PFF (foot or calf pain, fatigue when walking or gait disturbances)	Surgery of foot or ankle; lower limb abnormalities, neuromuscular or neurological disorders.	• **BEIGHTON SCALE**: >4 • **NAVICULAR DROP:** ≥ 6 mm • **FPI**: >6 • **X-ray:** loadbearing, anteroposterior and lateral projections
Jafarnezhadgero et al (2018) [54]	Boys from 8 to 12 years. Navicular Drop > 10mm, RCPS >4º eversion,	Surgery or fracture of foot or ankle; neuromuscular problems, asymmetry of > 10mm.	• **STATIC AND DYNAMIC ANALYSIS**: collapsed LMA while standing position and recovered when offloading. • **NAVICULAR DROP** > 10mm.

	Navicular Height < 0.31		• **RCPS:** >4º de eversión. • **NAVICULAR HEIGHT:** < 0.31.
Ahn et al (2017) [56]	PFF	Rigid FF, hereditary or neuromuscular diseases, fixed foot deformity or surgery of foot or ankle	• **RCPS:** >4º de eversión. • **X-ray:** loadbearing, anteroposterior and lateral projections

mm: millimetre; RCPS: relaxed calcaneus position in standing; PFF: paediatric flexible flatfoot; FO: foot orthoses; CSI: Chippaux–Smirak index; FPI: foot posture index; FF: flat foot; MLA: medial longitudinal arch.

Risk of Bias Assessment

All the included studies presented a high risk of bias in at least one field. For Ahn et al. [56] most of the items presented unclear risk of bias and the study by Rusu et al. [53] did not report whether or not the investigators were blinded or not (Figure 7).

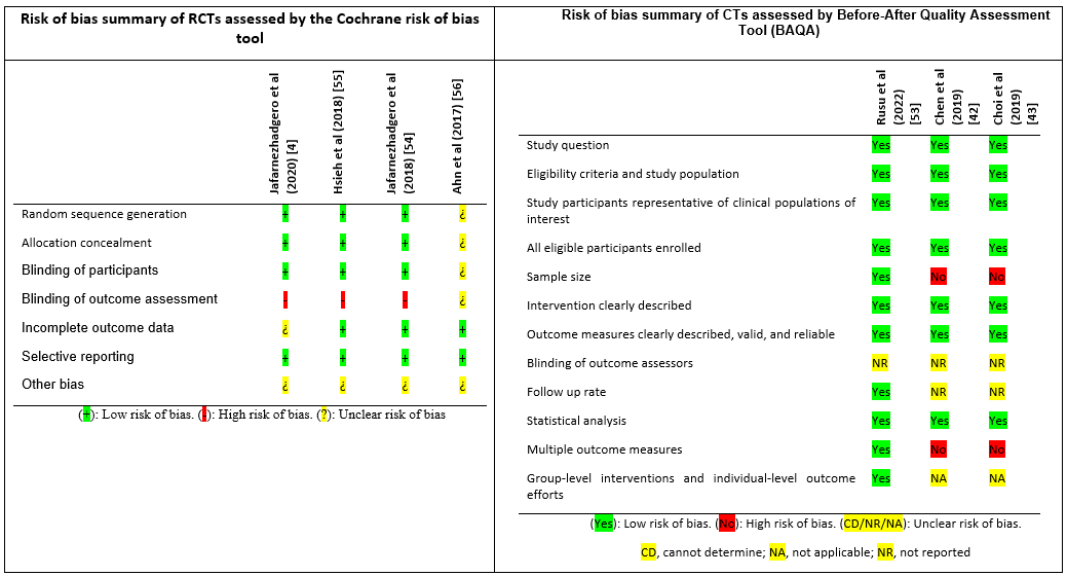

Figure 7. Risk of bias of the included studies. RCT: randomised controlled trial; CCT: controlled clinical trial; BAQA: Before-After Quality Assessment Tool.

6.3.2. Results by Outcome Measures

As required by one of our inclusion criteria, all the studies divided the sample into two different groups, an intervention group (IG) and a control group (CG). It should be added that all the authors, except Ahn et al. [56], provided FO treatment to the IG and the CG received a placebo treatment.

All the authors casted the patients' feet, apart from Hsieh et al. [55] who provided a FO with a direct adaptation technique, and Chen et al. [42] who provided off-the-shelf FO. Choi et al. [43] used a phenolic foam, Jafarnezhadgero

et al. [4,54] used plaster with the foot in a neutral position and Rusu et al. [53] used a 3D scanner.

Some authors included information about the casting of the foot and more detailed information about the FO. Rusu et al. (2022) [53] included personalised semi-rigid FO, with increased medial longitudinal arch support and heel cup, which were manufactured by the company Ortoprotesica. The design of the FO was computerised using a CAD-CAM system. In the studies of Jafarnezhadgero et al. (2020) [4] and Jafarnezhadgero et al. (2018) [54] the FO was made from ethylene-vinyl acetate (EVA) and microcellular rubber, and the negative cast was made in a subtalar joint neutral position. Chen et al. (2019) [42] included prefabricated FO, which were adapted by an orthotist. Choi et al. (2019) [43] used phenolic foam to cast the foot in a weight-bearing position. The FO were personalised with an increased medial longitudinal arch support. In the study of Hsieh et al. (2018) [55] the FO were directly adapted to participants' feet, in an offloading and neutral position. The FO were personalised with a medial longitudinal arch support. Finally, in the study of Ahn et al. (2017) [56], the neutral position of weightbearing plaster cast technique was used to capture foot shape, and the FO manufactured were BlakeÀs inverted orthoses.

All the FO from the IG of the included studies had a marked medial longitudinal arch and EVA was used for some parts of the FO. However, all the FO were different. Rusu et al. [53] made semi-rigid custom FO, using a thermoplastic heel cup which extended to the base of the metatarsals and had an EVA top cover and a metatarsal dome. For the IG Jafarnezhadgero et al. [4,54] provided a resin FO with a maximum of 25 mm medial longi- tudinal arch, and the CG received a flat polyester resin FO. The following papers provided an intervention for the IG, but nothing for the CG. Chen et al. [42] provided polypropylene and EVA off-the-shelf FO. Choi et al. [43], provided personalised FO, including materials with different hardness, such as EVA, plastazote, poron, evazote or ucolite. Hsieh et al. [55] provided customised FO made of thermoplastic, a medial longitudinal arch made of EVA and hindfoot posting. Finally, Ahn et al. [56], provided a Blake inverted FO together with a medial longitudinal arch for the IG and a Blake inverted FO without a medial longitudinal arch for the CG.

All the authors recommended a daily use of the FO during the daily activities of life, from 3 months to 6 years. Regarding the follow-up of the participants, all

the studies carried out an initial assessment (pre-treatment) and then a final assessment (post-treatment). Only Choi et al. [43], carried out an assessment every 6 months until the end of the treatment.

Different outcome measurements were evaluated in the included studies even though the objective in all the studies was the same, which was to determine the efficacy of the FO. Some of the studies evaluated radiographic changes, others evaluated kinetic-kinematics changes and others evaluated changes in the plantar footprint. Some authors highlighted functional changes and others evaluated morphological changes after FO use.

The authors used different devices and tests to quantify the results: the VICON system, pressure platform, pedigraph (CSI), radiographs, International Classification of Functionality, RCPS and static and dynamic changes (Table 7).

Tabla 7. Intervention characteristics

Authors	Intervention	FO material	FO use	Education	Treatment duration
Rusu et al (2022) [53]	**CG** (n=15): workout **IG** (n=15): Personalised FO with LMA, heel cup and metatarsal dome + workout	Semirigid thermoplastic	Daily	FO use and normal BADL	3 months
Jafarnezhadgero et al (2020) [4]	**CG** (n=15): placebo FO **IG** (n=15): FO with LMA	**GC**: Polyester resin **GE**: EVA	Daily	Progressive FO use. Footwear New Balance 749, USA	4 months
Chen et al (2019) [42]	**CG** (n=343): none **IG** (n=123): FO with LMA	Polipropilene and EVA	Daily	N/A	Mean of 11,3 months
Choi et al (2019) [43]	**IG** (n=18): FO with LMA **CG** (n=13): none	EVA, plastazote, poron, evazote or ucolite.	Daily	FO use and replace FO every 6 months	3-6 years

Hsieh et al (2018) [55]	**IG** (n=26): FO with LMA **CG** (n=26): none	Thermoplastic and EVA	Daily, minimum 5 hours	FO use and comfortable footwear	3 months
Jafarnezhadgero et al (2018) [54]	**IG** (n=15): FO with LMA **CG** (n=15): placebo FO	**GC**: Polyester resin **GE**: EVA	Daily	Progressive FO use. Footwear New Balance 749, USA	4 months
Ahn et al (2017) [56]	**IG** (n=20): inverted Blake´s FO with LMA **CG** (n=20): inverted Blake´s FO	N/A	Daily, minimum 8 hours	FO use	12 months

CG: control group; IG: intervention group; FO: foot orthoses; LMA: longitudinal medial arch; BADL: Basic Activities of Daily Living, mm: millimetre; EVA: ethylene-vinyl acetate; N/A: not applicable

All authors conclude that FO are an effective treatment, although more evidence is needed to fully confirm this statement. Choi et al. [43] concluded that FO may make structural changes, and that FO improve functionality and pain. Rusu et al. [53] concluded that exercise is beneficial, particularly when combined with FO treatment. They also reported that a decrease in subtalar joint flexibility could lead to an increase in the plantar arch index. Jafarnezhadgero et al. [4,54] assessed the changes in kinetics and kinematics measured by the VICON system and pressure platform in two papers. They noted a difference in the kinetics and kinematics, concluding that the long-term use of FO with medial longitudinal arch support help to improve the alignment of the lower limbs and gait in PFF. Chen et al. [42] concluded that although PFF may resolve with age, the use of FO may reduce the characteristic signs, especially in 5-year-olds (more than in 3-year-olds). Hsieh et al. [55] concluded that FO provided a reduction in pain and an increase in comfort. Finally, the authors Ahn et al. [56] observed clinical and radiological improvements in both groups in their study, but that the IG obtained greater changes. Therefore, they concluded that a Blake inverted FO together with a medial longitudinal arch was more effective than a Blake inverted FO without a medial longitudinal arch.

6.4. DISCUSSION

The aim of this review was to demonstrate the efficacy of FO as a conservative treat- ment to reduce signs and symptoms in patients with PFF. In addition, it was important to determine the best type of FO and the minimum time of use and finally, to identify which are the most used diagnostic techniques for PFF and how it is defined.

To answer the main objective, in five of the included studies [4,42,43,54,55] the CG received no treatment or placebo. This makes the point that no therapy was applied, meaning that all the outcome measures that were improved in the IC were because of the FO, not because of the natural evolution of the PFF.

This study shows that FO were an effective treatment for PFF. Recently, more studies have been published supporting the efficacy of FO, showing their positive impact on a wide variety of PFF outcomes such as pain, foot posture, gait, foot

function, etc. [35]. This review shows a different perspective from previously published research where a positive impact from the FO was not shown.

However, no ideal type of FO has been agreed in the literature. Each author used a different FO, including different types and materials, though always rigid or semirigid materials. However, all the FO had something in common, which was a high longitudinal medial arch support. A recent study has shown that the use of custom FO for PFF is more effective than prefabricated FO, providing better pressure distribution and conform better to the foot [44]. Su et al. [57] concluded that there is a relationship between hardness of the FO and effectiveness of treatment, however the increase in hardness was also linked to soft tissue damage.

In terms of FO use, all included studies specified that FO should be worn every day, the period of which varied from 3 months to 6 years. Reviewing the literature, there is no consensus on how long children with PFF should wear their FO, with differing periods from 3 months to 2 years. However, some authors consider 3 months an insufficient amount of time [21,38]. Radwan et al. [45] concluded that FO can modify children's feet with immediate effect, but it is after 12 months when more changes and improvements are shown. Jafarnezhadgero et al. [4,54] concluded that long-term FO use was effective to improve alignment and coordination of the lower limbs, as well as gait kinetics and kinematics. Those results agree with previous studies [45,58]. Chen et al. [42] and Hsieh et al. [55] also concluded that FO were effective, reducing the characteristic signs and symptoms of PFF and improving quality of life, which agrees with previous studies [54,59–63]. However, none of the included studies indicated negative effects from the use of FO; previous studies indicated localised irritation of the skin, increased pain, problems with shoe fit, intolerance or discomfort after FO use in some of the participants [46].

Previous studies concluded that the use of footwear is part of the treatment in order to ensure the effectiveness of the FO [25,38]. However, only Jafarnezhadgero et al. [4,54] recommended a specific type of footwear for the participants.

Age may be the characteristic that most influenced the results and the evolution of the treatment [25,64]. The mean age of most of the included participants was 10 (except for the studies by Chen et al. [42] and Hsieh et al. [55]). Depending on the study, the ideal age to treat PFF varies. Some studies concluded

that the ideal age is before six and other studies conclude after six [65,66]. For example, the study published by Lee et al. [60] concluded that FO should be provided to children younger than six. In their study 66 children from 1 to 12 years of age, showed that the greatest changes in the RPCS were for preschool-age children (under 7), and that children older than 7 presented a minimal correction. It could be concluded that the younger the patient is, the greater the possibility to correct the PFF. However, it should also be noted that natural foot development occurs before 6–7 years of age [11,24,67]. Moreover, it is not yet known whether gender is an etiological factor. Some papers indicate that gender influences the prevalence of PFF, showing a higher incidence in male children [25,31,68,69], which agrees with the present study as most of the included participants were male (60.7% boys).

Another of the etiological factors related to PFF is a low level of physical activity [11,17,70,71]. We planned to collect information about participants physical activity, but those data were not provided by any author. Regarding pain levels, only three of the included studies data related to this [42,43,55], where an improvement of pain after FO use was shown [35,46].

Previous studies showed great confusion in what to call the present pathology (i.e., flat foot valgus, pes planus, etc.) [13,71]. However, that was not an issue in the present study as the final diagnosis of all the authors was PFF, differentiating between asymptomatic or symptomatic patients.

The Beighton scale, navicular drop and RPCS tests, and X-rays were the most widely used tests by the included authors to assess PFF. Other tests, such as the arch height index, pedigraphy, JackÀs test, double/single heel rise test or FPI, were also used but not unanimously. Only the FPI has been validated for children under 6 years old. However, they show great specificity and sensitivity in adults [25,27,72–74]. The use of radiographs for the diagnosis of PFF is considered the "gold standard". However, due to all the ethical problems caused by radiation, and the fact that an accurate diagnosis can be reached with clinical tests, radiographs are not used daily for the diagnosis of PFF.

Some of the tests have highlighted great controversy because the same values were not used by the different authors. For example, for Jafarnezhadgero et al. [4,54] the nav- icular drop was considered positive when the result was greater than 10 mm; however, Hsieh et al. [55] considered a positive result when it was greater

than or equal to 6 mm. Given this ambiguity, it is not surprising that treatments such as FO do not have scientific evidence. After previous reviews and meta-analyses, it is difficult to obtain clear results. Morrison et al. [46] surveyed podiatrists, orthotists and physiotherapists in the United King- dom about PFF diagnoses and came to the conclusion that what podiatrists used the most was the heel rise test, FPI and joint mobility to diagnose PFF. Recently, Zukauskas et al. [75] indicated that the navicular drop, FPI and CSI should be used for children between 5–8 years of age.

This systematic review presents some strengths; for example, the included studies presented a high level of evidence and a large number of scientific databases were reviewed. The main limitation of the present study is the small number of the included studies and participants, which could reduce the external validity of these results. Even though numerous studies related to FO and PFF are available in the literature, we have only found seven studies that were published in the last five years with a good methodological quality. Another limitation was the diversity of the outcome measures used and the heterogeneity of the interventions. Most of the studies were carried out on the Asian continent. The ethnic characteristics of each population are different, and these could have influenced the development and results of the treatment.

Future research should be undertaken with standardised diagnostic protocols with validated tests. These studies should be performed with a larger sample size and a longer- term follow-up (more than 3 months). In addition, studies should be separated between those who include children younger than 6 years old and those who include participants older than 6 years old. Finally, studies which assess the whole participant, including general painful symptoms and quality of life should be conducted. Then, the evidence for the effectiveness of FO treatment would be more concrete.

6.5. CONCLUSIONS

Conclusions from this review should be viewed with caution due to the low number of the included studies. The best type of FO and the optimal time of use cannot be concluded due to the heterogeneity between studies. There is no algorithm for PFF diagnosis, and there is a great diversity of clinical tests,

characteristic signs and symptoms and radiographic measurements for PFF diagnosis. There is no universally accepted definition for PFF, although all authors of the included studies define it when there are more than two characteristic signs and symptoms or positive tests. The use of FO with high medial longitudinal arch may improve the signs and symptoms in some patients with PFF.

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VIII – ESTUDIO IV

VII - ESTUDIO IV

VIII - EFICACIA DE LA REEDUCACIÓN FUNCIONAL COMO TRATAMIENTO PARA EL PIE PLANO INFANTIL FLEXIBLE. REVISIÓN SISTEMÁTICA

Resumen:

Introducción: El pie plano infantil flexible (PPIF) es una entidad muy frecuente y se trata de un tema de debate entre varios profesionales de la salud. Existen una multitud de tratamientos conservadores y quirúrgicos, siendo el fortalecimiento de la musculatura uno de los menos usados, pero a priori ofrece grandes beneficios. La principal característica anatómica del PPIF es el descenso del arco longitudinal interno, este arco es sustentado por la musculatura. No se sabe con exactitud el efecto que tienen los ejercicios de fortalecimiento en el desarrollo muscular ni durante cuánto tiempo son necesarios para obtener mejoras en el PPIF. En la actualidad no existe ninguna revisión sobre el tema que se propone. **Objetivos**: identificar la eficacia del fortalecimiento muscular como tratamiento en el PPIF. Además, determinar qué ejercicios son más efectivos para identificar un protocolo y compararlos con otros tratamientos conservadores para el PPIF. **Metodología**: Se llevó a cabo una revisión sistemática en las bases de datos PubMed, EBSCO, Web of Science, Cochrane, SCOPUS y PEDro, utilizando la siguiente estrategia: ensayos clínicos aleatorizados (ECA) sobre pacientes niños con PPIF, con ejercicios de fortalecimiento de la musculatura en comparación a otros ejercicios o tratamientos conservadores, para evaluar la mejora de signos y síntomas del PPIF. Se excluyeron los estudios en los cuales los sujetos presentaban enfermedades neurológicas, o sistémicas o si habían estado sometidos a alguna operación. Dos de los autores evaluaron de forma independiente la calidad de los estudios. **Resultados**: De los 327 estudios iniciales considerados, 9 ECAs cumplieron los criterios de inclusión, representando 381 participantes con PPIF con edades comprendidas entre 6 y 14

años. Las intervenciones de los estudios incluidos diferían en tipos de ejercicios y duración del tratamiento. Aun así, todos los artículos concluyen que el fortalecimiento de la musculatura es beneficioso en pacientes con PPIF. **Conclusiones**: Hay evidencia sobre la eficacia de los ejercicios como tratamiento para disminuir los signos y síntomas del PPIF, aunque no se puede establecer un protocolo debido a la heterogeneidad de los estudios. Los ejercicios de la musculatura intrínseca se consideran uno de los tratamientos más efectivos para el desarrollo de la musculatura del pie y el periodo de duración para ver cambios es de mínimo 4 semanas.

Palabras Clave: "Pie Plano Flexible", "Pediatría", "Niños", "Ejercicios", "Reeducación funcional" "Estiramiento" "Fortalecimiento" "Ejercicios correctivos"

Abstract:

Introduction: Paediatric flat foot (PFF) is currently a topic of common concern and debate among various health professionals. There is no established definition or clear diagnostic method. There are a multitude of conservative and surgical treatments, muscle strengthening being one of the least used, however it offers great benefits. It is not known exactly the effect of muscle development or for how long it is necessary to obtain improvements in the PFF. There is currently no review on the proposed topic. **Objectives**: to analyse the efficacy of muscular strengthening as a conservative treatment of children with PFF. In addition, an attempt will be made to analyse which exercises are most effective to identify a protocol. Methodology: A systematic review was carried out in 6 databases (PubMed, EBSCO, Web of Science, Cochrane, SCOPUS and PEDro) using the following PICOS strategy: randomised controlled trials (RCTs) focused on children with PFF, which included muscular strengthening compared to other conservative treatments, to assess the PFF progression. Studies in which the subjects had neurological or systemic diseases or if they had undergone an operation were excluded. Two authors assessed the risk of bias of the studies. **Methodology**: A systematic review was carried out in 6 databases (PubMed, EBSCO, Web of Science, Cochrane, SCOPUS and PEDro) using the following PICOS strategy: randomised controlled trials (RCTs) focused on children

with PFF, which included muscular strengthening compared to other conservative treatments, to assess the PFF progression. Studies in which the subjects had neurological or systemic diseases or if they had undergone an operation were excluded. Two authors assessed the risk of bias of the studies. **Results**: Of the initial 327 studies considered, 9 RCTs met the inclusion criteria, representing 381 participants with PFF aged between 6 and 14 years. The included studies presented differences in diagnostic criteria, types of exercises and duration of treatment. Even so, all the articles conclude that muscle strengthening is beneficial in patients with PFF. Conclusions: There is evidence on the efficacy of exercises as a treatment to reduce the signs and symptoms of PFF, although a protocol cannot be established due to the heterogeneity of the studies. The intrinsic musculature exercises are considered one of the most effective treatments for the development of the foot musculature and the period of time to see changes is a minimum of 4 weeks.

Key words: "Flexible Flatfoot", "Pediatrics", "Children", "Exercises", "Functional reeducation" "Stretching" "Strengthening" "Corrective exercises"

7.1 INTRODUCCIÓN

El noventa por ciento de las visitas a la clínica por problemas de pie en niños se atribuyen a pies planos (PP) (1). La prevalencia de PP en la población adulta es de entre el 2 % y el 23 % (2). De los adultos con PP el 77% tienen dolor de espalda o de las extremidades inferiores (3). Es por este motivo por el cual el pie plano infantil (PPI) no se debe dejar pasar por alto y se le debe dar la importancia que se merece, puesto que si evitamos que el niño crezca con PP estaremos evitando problemas a la larga. Además, algunos pacientes con PPI son sintomáticos, reduciendo su calidad de vida y presentando dolor, fatiga o torpeza (4).

No existe una definición universalmente aceptada de PPI, aunque los autores la definen cuando hay más de dos signos y síntomas característicos o pruebas positivas (5). Clínicamente, el PPI se presenta como un pie con una reducción o aplanamiento del arco longitudinal interno (ALI), si además esta situación se puede corregir cuando el niño está en descarga o con ciertas maniobras el PPI se cataloga como flexible (6). Puesto que se trata de una deformación triplanar el PP también

se puede acompañar de abducción del antepié con respecto al retropié, de una posición en valgo del calcáneo, de la prominencia medial del astrágalo más sobresalida y la tibia puede estar rotada internamente (7,8). Existen una gran variedad de pruebas que se pueden utilizar para el diagnóstico del PP, aunque los más utilizados son el Heel Rise Test, Jack's test, Navicular Drop Test (NDT), Navicular Height, Resting Calcaneal Stance Position (RCPS), el Foot Posture Index (FPI-6) o el Arch Index (5,7–9).

El sistema de soporte activo para el arco del pie incluye los músculos extrínsecos e intrínsecos del pie (10). Los músculos extrínsecos son los principales motores del pie, mientras que los músculos intrínsecos ayudan a estabilizar el ALI. Los músculos extrínsecos brindan soporte dinámico al arco durante la marcha, mientras que los músculos intrínsecos ayudan a regular la rigidez del MLA en situaciones estáticas y dinámicas (11,12). El tibial posterior (TP) es un músculo extrínseco clave que soporta el ALI. Durante la fase de apoyo de la marcha, el TP se contrae excéntricamente para controlar el aplanamiento del arco. También ayuda a adducir, supinar y flexionar el pie (13). El subsistema neural del complejo tobillo-pie incluye los receptores sensoriales dentro de la fascia, las cápsulas y los ligamentos. Estos receptores proporcionan información al cerebro sobre la posición y el movimiento del pie. Esta retroalimentación ayuda a coordinar la actividad de los músculos para mantener el ALI (10,14). Puesto que los músculos sustentas el ALI, pensamos que la reeducación funcional (RF) de los mismos es clave para la mejora de signos y síntomas del PPI.

Uno de los factores que contribuyen al aplanamiento del ALI en posición de soporte de peso es la existencia de una fuerza inadecuada en los músculos del pie. (15). Se ha demostrado que los niños que hacen menos ejercicio tienen muchas más probabilidades de tener PP (15). Los niveles inadecuados de actividad física pueden conducir a una fuerza muscular retrasada o desigual, lo que resulta en un ALI debilitado. El ejercicio se asocia estrechamente con el desarrollo físico, el control del peso y un estilo de vida saludable (16).

Existen multitud de tratamiento conservadores para el pie plano infantil flexible (PPIF). Las órtesis plantares (OP) es uno de los tratamientos conservadores más usados pero tienen el problema de las crecientes quejas de los niños y sus padres durante el tratamiento con OP (ansiedad sobre el tratamiento, restricciones en el calzado, estigma social, incomodidad inicial o el costo de las mismas) (17).

Dentro de todos los tratamientos para el PPIF el ejercicio forma parte, ya sea caminando descalzo o con actividades de fortalecimiento o estiramiento de los diferentes músculos que pueden afectar a la deformidad del PP (17). El enfoque principal del programa de ejercicios se centra en alargar las estructuras tensas, fortalecer las áreas de debilidad y mejorar tanto la propiocepción como el equilibrio postural (9). Encontramos en la literatura afirmaciones como que "el desarrollo normal y el fortalecimiento del pie pueden ser todo el tratamiento indicado" (18), pero desafortunadamente aún no hay suficiente evidencia que respalde tal afirmación.

En la actualidad hay una tendencia a optar por los tratamientos más naturales, como son los ejercicios o RF, cuyo beneficio se ha estudiado para el tratamiento de diversas patologías como la fasciopatía plantar, la disfunción del TP o la tendinopatía aquílea, entre otras (19,20) incluyendo revisiones sistemáticas centradas en el FF (21–24), demostrando nulos efectos adversos, accesibilidad, baratos y beneficiosos. Sin embargo, ninguna de esas revisiones sistemáticas incluía población infantil. Por lo tanto, puesto que el PPIF si no se trata o se corrige a la larga podría dar problemas y que los ejercicios son unos de los tratamientos más recomendados para el PP (25) consideramos necesario llevar a cabo esta revisión para así poder resumir y llegar a una conclusión sobre la eficacia del ejercicio para el tratamiento del PPI tipo flexible.

Es por ello por lo que se planteó realizar esta revisión sistemática donde se propuso como objetivo principal identificar la eficacia de la reeducación funcional (ejercicios de fortalecimiento, estiramientos o ejercicios del pie y miembros inferiores) como tratamiento en el PPI tipo flexible. Además, se planteó determinar qué ejercicios son más efectivos para identificar un protocolo y compararlos con otros tratamientos conservadores para el PPI tipo flexible.

7.2. MATERIAL Y MÉTODOS

Este protocolo fue registrado en el Registro Prospectivo Internacional de Revisiones Sistemáticas PROSPERO: CRD42023391030. Para dar respuesta a los objetivos planteados en el presente estudio, se llevó a cabo una revisión sistemática siguiendo la normativa "Preferred reported items ofsystem reviews and meta-analysis" (PRISMA) y de acuerdo con las recomendaciones de la Colaboración Cochrane (26).

7.2.1. Criterios de selección

7.2.1.1. Tipos de estudios

Se incluyeron ensayos clínicos controlados aleatorios (ECCA). Se excluyeron todos los demás tipos de estudios, como las revisiones sistemáticas.

No se utilizaron filtro de año de publicación o idioma para así no acotar la búsqueda.

7.2.1.2. Participantes

Los estudios incluidos en esta revisión debían incluir niños diagnosticados con PPIF; la edad de los niños debía de ser menor o igual a 14 años. Se excluyeron los pacientes que se sometieron a cirugía en miembros inferiores o que presentaron alguna enfermedad neurológica sistémica o infecciosa.

7.2.1.3. Tipo de intervención

Se incluyeron todas aquellas intervenciones de tratamiento que eran consideradas como RF (fortalecimiento, estiramiento, ejercicios para los pies o miembros inferiores).

7.2.1.4 Comparación

Estudios que compararon la intervención con otro tipo de tratamiento conservador, como otros tipos de ejercicios o placebo.

7.2.1.5. Medidas de resultado

Los resultados considerados fueron los utilizados para evaluar la mejoría de los signos y síntomas de la PFF.

7.2.2. Estrategia de búsqueda

La búsqueda fue realizada por dos investigadores de forma independiente en las siguientes bases de datos: PubMed, EBSCO, Web Of Science, Cochrane, SCOPUS y PEDro. Además, se revisaron las bibliografías de los artículos. La última búsqueda se realizó en agosto de 2023.

Se utilizaron los siguientes términos del tesauro Medical Subject Headings (MeSH): pie plano, pediatría, niño y ejercicio, según las características de cada base de datos, acompañados de los operadores booleanos "AND" y "OR".

Se utilizó la siguiente estrategia de búsqueda: (("Flatfoot"[Mesh] AND ("Pediatrics"[Mesh] OR "Child"[Mesh] OR "Child, Preschool"[Mesh] OR "Infant"[Mesh])) AND ("Exercise Therapy"[Mesh] OR "Exercise"[Mesh]))

También se usó la siguiente estrategia de búsqueda para incluir los términos libres y sinónimos de los tesauros: ((("Flatfoot"[Mesh] AND ("Pediatrics"[Mesh] OR "Child"[Mesh] OR "Child, Preschool"[Mesh] OR "Infant"[Mesh])) AND ("Exercise Therapy"[Mesh] OR "Exercise"[Mesh])) OR ((("Flexible Flatf**t"[tw] OR "Flat F**t"[tw] OR "Pes Planus"[tw] OR Flatf**t[tw] OR Splayfoot[tw] OR "F**t, Flat" [tw] OR "Flatf**t, Flexible"[tw]) AND ("Pediatrics"[tw] OR "Child"[tw] OR "Infant"[tw] OR "Preschool Child*"[tw] OR "Child*, Preschool"[tw])) AND ("Exercise Therapy"[tw] OR "Exercise"[tw] OR “muscle strenght"[tw] OR “stretching”[tw]) OR “strengthening”[tw] OR “functional reeducation”[tw] OR “rehabilitation”[tw]))

7.2.3. Selección de estudios

La selección de los estudios fue realizada por dos investigadores. Después de la selección de los artículos de las bases de datos, los duplicados fueron eliminados. Después de la eliminación, se realizó un cribado de los títulos y resúmenes, basado en los criterios de inclusión y exclusión. Los estudios seleccionados se leyeron completamente para evaluar el cumplimiento de los criterios de elegibilidad. Cualquier desacuerdo entre los revisores en cualquier fase de la selección del estudio se resolvió consultando a otro revisor.

7.2.4. Extracción y gestión de datos

Para responder a los objetivos propuestos, se extrajeron datos de los estudios, incluyendo características de la publicación (autor, país, año y, diseño del estudio), características de la muestra (tamaño de la muestra, edad, año, sexo, altura, peso, índice de masa corporal, tratamiento previo, diagnóstico y síntomas), características del diagnóstico, características de la intervención (tipo de ejercicio, protocolo de ejercicio, frecuencia y duración del tratamiento, supervisión y medida de resultado para evaluar la intervención) y los resultados junto con las conclusiones finales de cada estudio.

7.2.5. Evaluación de la calidad y el riesgo de sesgo

Para calcular la calidad metodológica/riesgo de sesgo de cada uno de los estudios incluidos, se utilizaron escalas para los tipos de estudio ECCA.

Para evaluar los ECCA, se utilizó la herramienta recomendada por el manual Cochrane para evaluar el riesgo de sesgo. Es una evaluación basada en dominios que evalúa cada dominio con tres posibilidades: "bajo riesgo de sesgo", "alto riesgo de sesgo" o "riesgo incierto" (27).

Además, se utilizó la escala Scottish Intercollegiate Guidelines Network (SIGN) para reflejar el nivel de evidencia y el grado de recomendación (28).

7.2.6. Síntesis de datos

Los datos se han presentado en tablas y formas narrativas para describir las características de los estudios incluidos. Debido a que los estudios no fueron suficientemente homogéneos, fue imposible realizar un metanálisis.

7.3. RESULTADOS

Mediante la estrategia de búsqueda descrita anteriormente, se identificó un total de 325 estudios en las bases de datos, así como 2 registros adicionales identificados a través de otras fuentes, que fue a través de las listas de referencias de los artículos iniciales que se recuperaron. De estos 327 artículos, 251 eran

registros duplicados. Los 76 estudios restantes fueron evaluados por título y resumen por 2 revisores independientes. De estos, 54 fueron excluidos debido a diferencias en los criterios de inclusión ya que eran estudios observacionales, ensayos clínicos sin grupo control o los participantes no eran niños. Después de eso, se evaluaron 22 textos completos para determinar su elegibilidad y 12 se excluyeron porque los participantes se habían sometido previamente a cirugía en los miembros inferiores, o no se especificaron los ejercicios que se realizaron, entre otras razones. Por lo tanto, sólo 9 ECA cumplieron plenamente los criterios de inclusión. La figura 8 muestra el diagrama de flujo de PRISMA para los estudios incluidos en esta revisión

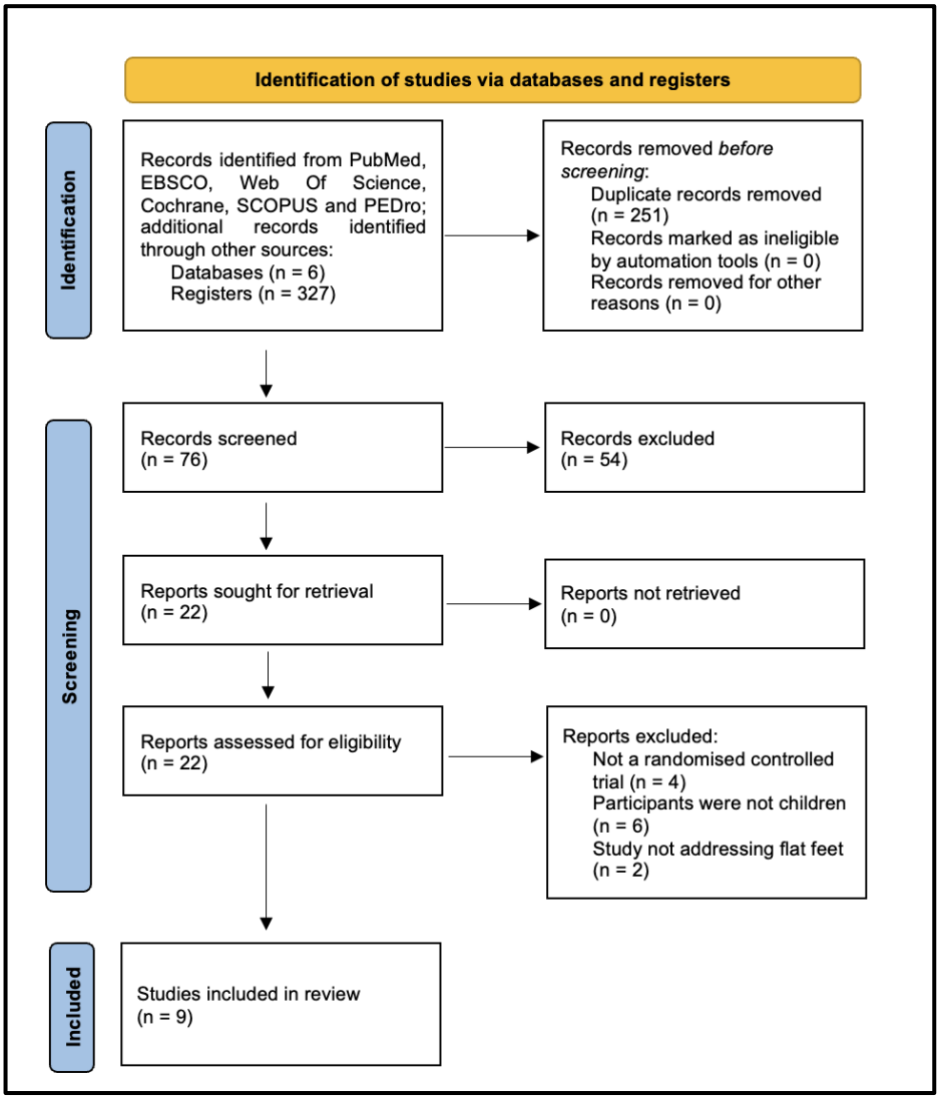

Figura 8. Article selection flowchart. Adapted from Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).

7.3.1. Características generales de los estudios evaluados

El estudio incluido más antiguo fue el de Khamooshi et al. (29) en el año 2016. Al realizar la búsqueda no se aplicaron filtros de año de publicación por lo que este es el estudio más antiguo publicado que cumple nuestros criterios de inclusión. Todos los artículos excepto el de Rusu et al. (30) se desarrollan en el continente asiático (si contamos a Egipto como país asiático). En relación a los niveles de evidencia evaluados mediante el sistema de calificación SIGN, los estudios incluidos presentaron niveles II+A y II+B.

De los 381 participantes incluidos, 137 eran niñas y 134 niños. De los 110 sujetos restantes no se conoce el género, puesto los autores no lo facilitan. La edad varía de los 6 a los 14 años, aunque la edad media es de 9-10 años. El autor Priyanka et al. (31) no nos facilita la edad de los sujetos, pero nos dice que los Children were in 8th and 9th standard in the school por lo que suponemos que tengan entre 13 and 14 year olds. El autor con el mayor tamaño muestral es Abd-Elmonem et al. (32), con 72 sujetos.

En cuanto a las características de los participantes, el IMC medio fue de 22,19. Algunos de los estudios no proporcionaron datos del IMC (29,31,33). Todos los participantes incluidos tenían que tener pie plano, aunque a la hora de nombrar el diagnóstico cada autor lo nombre de una manera diferente, por ejemplo, Allam et al. (34) lo nombra como "Mobile flat foot" y Rusu et al. (30) que es el autor que lo nombra a la entidad de forma más completa lo hace como "bilateral flexible flatfoot level II, asymptomatic". Solamente 2 autores (29,35) nos informan de que los participantes no habían recibido tratamiento anteriormente. Respecto a la sintomatología los autores Abd-Elmonem et al. (32) y Rusu et al. (30) son los únicos que nos indican que el pie plano era asintomático (Table 8).

Tabla 8. Study characteristics and publication characteristics

Author, Country (Year of Publication); Evidence Level by Sign; Age	Sample Size	Year of Age (Mean/SD); Gender (M/F)	Weight in kg (SD); Height in cm (SD)	BMI kg/m^2 (SD)	Diagnosis, Symptoms; Previous Treatment
Gheitasi et al,. Iran (2022) (35); II+A; 12–14 years	**CG**: 12	13.3 (0,33); N/A	CG: 49.3 (2.8); 151(2.67)	CG**:** 21.25 (0.86)	Flat Feet; No
	IG 1: 12	13.3 (0.42); N/A	IG 1: 51.4 (2.7); 159.7(1.39)	IG 1: 20.24 (1.12)	
	IG 2: 12	12.8 (0.61); N/A	IG 2: 52.7 (3.72); 1.57(3.83)	IG 2: **:**21.05 (0.93)	
Karthika et al,. India (2022) (36); II+A; 7 to 14 years of age	**CG**: 12	11.64 (1.38); (6/6)	N/A	28 (1)	Flexible flat foot; N/A
	IG: 12	I11.52 (0.89); (7/5)		27.6 (1.9)	
Rusu et al., Romania (2022) (30); II+A; 7-11 years	**CG**: 15	9.37 (1.42); (17/13)	41.8 (12.72); 148.7 (10.96)	18.84 (5.32)	Bilateral PFF level II, asymptomatic; N/A
	IG:15				
Abd-Elmonem et al,. Egypt (2021) (32); II+A; 7 to 12 years old	**CG**: 36	9.45 (0.76); 17/19	CG: 39.27 (6.45); 147.91 (7.69)	CG: 17.82 (1.59)	Flexible flatfoot, asymptomatic; N/A
	IG: 36	9.55(1,02); 16/20	IG: 37.9 (8.22); 148 (7,85)	IG: 17.12 (2.25)	
Allam et al,. Saudi Arabia (2021) (34); II+A; 7 to 11 years	**CG**: 15	9.07 (1.22); 15/0	CG: 42.04 (8.55); 125 (0.12)	CG: 22.01 (2.05)	Mobile flat foot; N/A
	IG 1: 16	9.48 (1.12); 16/0	IG 1: 45.37 (8.14); 137 (0.17)	IG 1: 23.71 (2.06)	
	IG 2: 16	9.74 (0.95); 16/0	IG 2: 41.44 (6.02); 135 (0.14)	IG 2: 22.71 (3.06)	
Priyanka et al,. India (2020) (31); I-B; Children were in 8th and 9th standard in the	**CG**: 22	N/A; N/A	N/A; N/A	N/A	Flat foot; N/A

school (probably 13 and 14 year olds)	**IG**: 22				
Sativani et al,. Indonesia (2020) (37); I-B; Children 6-10 Years Old	**CG**: 15	6 años (2 niños), 7 años (12 niños), 8 años (2 niños), 9 años (10 niños), 10 años (4 niños); 18/12	N/A; N/A	23 (1,9)	Flexible Flatfoot; N/A
	IG: 15				
Sharath Hullumani et al,. India (2020) (33); II+B; aged 6 – 14 years	**CG**: 19	9.79 (2.07); 11/8	N/A; N/A	N/A	Flat foot; N/A
	IG: 19	9.42 (2.31); 13/6			
Khamooshi et al,. Iran (2016) (29); II-B; 9 to 13 year old	**CG**: 20	11.5 (0.9); 0/20	37.9 (2.5); 142.4 (5)	N/A	Flexible flat feet ; No
	IG 1: 20	11.2 (0.8); 0/20	38.1 (3.4); 142.9 (5)		
	IG 2: 20	11.18 (0.8); 0/20	36.7 (3.4); 143.4 (5)		

SD: standard deviation; M: male; F: female; Kg: kilogram; Cm: centimetre; BMI: body mass index; RCT: randomised controlled trial; CT: controlled trial; CG: control group; IG: intervention group; SIGN: Scottish Intercollegiate Guidelines Network; N/A: not applicable; PFF: paediatric flexible flatfoot.

Para la inclusión de los participantes los niños debían tener pie plano, además algunos autores se fijaron en características como el peso (34–36) o en la sintomatología (32,36). Los sujetos fueron excluidos de los estudios si tenían cirugías en los miembros inferiores o el pie, enfermedades neuromusculares, neurológicas o hereditarias o fracturas o lesiones 3-6 meses antes de dar comienzo el estudio. También algunos autores excluyeron específicamente a sujetos si tenían falta de voluntad para realizar el estudio o los ejercicios (35), dolor en el pie o pie plano rígido (36) o si realizaban algún tipo de actividad física (34).

Cada autor utilizó características diferentes para diagnosticar el pie plano infantil. El NDT fue la prueba más usada, utilizada en 5 (29,32,34–36) de los 9 artículos incluidos, aun así, cada autor utilizó valores diferentes para catalogarla como positiva o negativa. Priyanka et al. (31) usó la variante de Navicular Height y Khamooshi et al. (29) el navicular collapse test. El Arch height index fue la segunda prueba más usada (29,30,33,37). Ninguno de los autores usó el examen radiográfico para el diagnóstico. Además, se identificaron las siguientes pruebas en los diferentes artículos incluidos: FPI-6, Too May Toes, RCPS y Staheli index. Solamente Gheitasi et al. (35) tuvo en cuenta la función del pie y la disfunción de las articulaciones adyascentes como tobillo o rodilla y solamente Rusu et al. (30) utilizó una plataforma de fuerzas para la valoración y diagnóstico del pie plano infantil (Table 9).

Tabla 9. Sample selection and diagnoses

Sample Selection			Diagnoses
Authors	**Inclusion Criteria**	**Exclusion Criteria**	**PFF Definition and Assessment**
Gheitasi et al. (2022) (35)	- Subjects with Flat Feet - Peso saludable -No haber recibido tratamiento.	-History of neurological, orthopedic and cardiovascular diseases. -BMI out of normal. -Qx trauma, standing fx in the last 6 months -Lack of will.	• Fatigue earlier than usual • Deficit in foot function • Risk of pain • Dysfunction in the ankle, knee and hip joints • NDT >10 mm
Karthika et al. (2022) (36)	-PFF level II, asymptomatic .-Subjects with flexible flat foot - BMI between 25 to 30 - Grade 2 and 3 in foot structure assessment.	-Foot pain -History of lower limb injury (during the previous 6 month). -Congenital foot or leg abnormalities. -Unequal lower limb -Rigid pes planus	• NDT • FPI-6
Rusu et al. (2022) (30)	- PFF after static and dynamic analysis	- Surgery of foot or ankle - Lower limbs pain - Overweight -Neuromuscular or neurological disorders.	• Clinical examination in standing and walking. • Arch height index and subtalar flexibility, which was assessed by a force platform
Abd-Elmonem et al. (2021) (32)	-Diagnosed asymptomatic flexible flatfoot -Grade III flatfoot grade	-Congenital deformities of the lower extremities -Scar/ osseous anomalies	• Diagnosed by an orthopedist • NDT > 9 mm
Allam et al. (2021) (34)	- BMI > 95th percentile . -Not involved in strength, balance training, or competitive sports aiming to enhance muscular strength or balance. -Had balance impairments and a mobile flat foot .	-Previous injury to the lower limb. -Engaged in obesity treatment programs 3 months prior to the study.	• NDT was ranged from 16 to 19 mm
Priyanka et al. (2020) (31)	-Children with flat feet	-Previous trauma or fracture of lower limb -History of previous surgeries of the lower limb during last 3 months	• "Too many toes" sign • RCPS >10º • Navicular height (Less than 1 cm).

		-Hypersensitive skin, and any allergy to tape	
Sativani et al. (2020) (37)	-PPF with a footprint of 1 o 2º	-Fx or ankle dislocation -Taking painkillers	• NDT > 10 mm • MLA reduced or absent
Sharath Hullumani et al. (2020) (33)	- Flat foot	-Having musculoskeletal injuries from the last 6 months -Mental disorders -Limb length discrepancy	• Arch Index was used to check the distance of the ankle axis
Khamooshi et al. (2016) (29)	- Flexible flat feet -Ranges of age from 9 to 13 years -Female -Good health status	-Prior history of lower extremities surgery or lesion -Severe orthopedic problems and a prior history of medical pads.	• Staheli index (Pedoscope and foot arch rate) • The navicular collapse test: to stand in an erect position bearing the whole weight of the body and the other time to stand on the tip of their toes. If in the weight bearing state, there was no observable interior feet arch but observable while standing on the tip of the toes: was diagnosed with the flexible flat feet

BMI, body mass index; mm: millimetre; fx, fracture; RCPS: relaxed calcaneus position in standing; PFF: paediatric flexible flatfoot; FPI: foot posture index; FF: flat foot; NDT, Navicular Drop Test, MLA: medial longitudinal arch; Qx, surgery.

7.3.1.1. Evaluación del riesgo de sesgo

Ninguno de los estudios incluidos presentó un alto riesgo de sesgo en ninguno de los campos. El estudio de Khamooshi et al. (29) presentó todos los ítems con un riesgo de sesgo poco claro. Los estudios de Rusu et al. (30) y de Sativani et al. (2020) (37) presentaban la mayoría de sus ítems con sesgo poco claro. El resto de artículos incluidos por lo general presentaban bajo riesgo de sesgo (Figura 9).

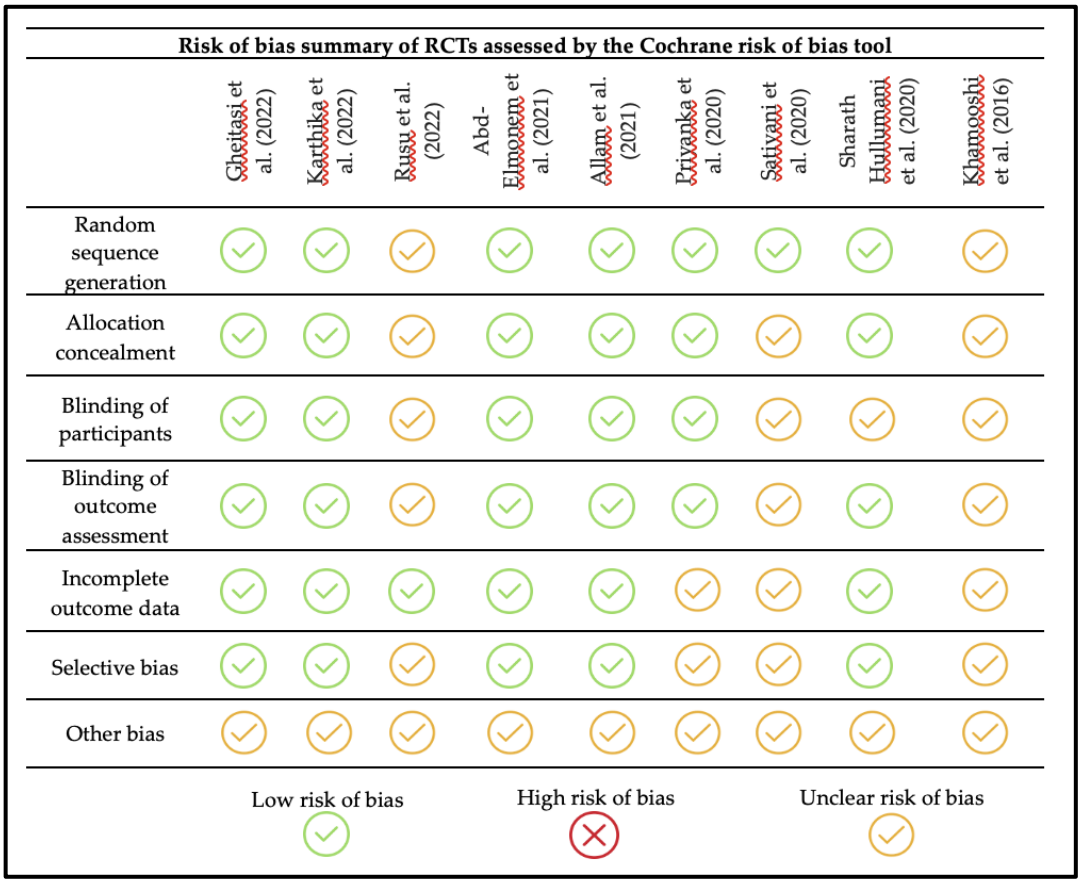

Figura 9. Risk of bias of the included studies. RCT: randomised controlled trial

7.3.2. Resultados de las medidas de resultados

Como exigían nuestros criterios de inclusión debía de haber mínimo dos grupos para así poder comparar el efecto de los ejercicios o la RF. Además, uno de los grupos debía de ser de solamente RF (fortalecimiento, estiramiento, ejercicios del pie o de los miembros inferiores) para así poder comprobar de forma más adecuada el efecto de los mismos. De los 9 artículos incluidos, 4 de ellos (29,34,35,37) incluían un grupo control placebo, el resto aplicaba tratamiento a todos los grupos.

En cuanto al tipo de RF o. ejercicios aplicados a cada uno de los grupos encontramos una gran variedad de ejercicios, prácticamente cada autor implementa unos ejercicios diferentes en cada grupo (estiramientos, fortalecimiento de la musculatura intrínseca, fortalecimiento de la musculatura extrínseca, fortalecimiento del TP, pliométricos, caminar descalzo, estiramientos, ejercicios junto con neuromuscular electrical stimulation (NMES), ejercicios pliométricos, ejercicios correctivos como curl de dedos, o levantamiento de talones o ejercicios de estabilidad) (29–37).

Solamente Khamooshi et al. (29) y Allam et al. (34) hicieron 5 minutos calentamiento antes de los ejercicios, y solamente Allam et al. (34) fue el que hizo relajación después de los ejercicios. Encontramos dos autores que combinan los ejercicios con electroterapia. Abd-Elmonem et al. (32) a uno de los grupos de ejercicios los complementa con 30 minutos de NMES para reforzar el fortalecimiento de la musculatura intrínseca y Priyanka et al. (31) complementa los ejercicios con faradic foot bath that was given for 30 minutes per day.

Solamente encontramos un autor, Allam et al. (34) que realiza ejercicios pliométricos, en los cuales desarrolla diferentes saltos encima de una colchoneta, haciendo hincapié en que cuando bajen del salto tienen que hacerlo de puntillas y que cuando cargasen peso lo hiciesen controlando la pronación de manera activa.

Todas las características y la descripción de cada uno de los ejercicios realizados en los estudios se encuentra de manera detallada en la tabla 3.

En cuanto a la duración y la frecuencia de los ejercicios esta varía en los diferentes estudios, desde 2 días a la semana en el estudio de Allam et al. (34) hasta 5 días a la semana (33,36); la media es de realizar los ejercicios 3 días a la semana.

En cuanto a la frecuencia encontramos gran heterogeneidad debido a la gran variabilidad de los ejercicios, según el ejercicio la frecuencia cambia, la media es de 3 series de 20 repeticiones de cada ejercicio de fortalecimiento. El tiempo de los estiramientos varía desde 5 segundos de mantenimiento hasta 15 segundos. La duración de la reeducación funcional también varía de 30 minutos a 60 minutos por sesión.

Todos los ejercicios son supervisados (por fisioterapeutas o investigadores), excepto el artículo de Sativani et al. (37), en el cual esta información no se facilita. La duración del tratamiento va desde 4 semanas en los artículos de Sativani et al. (37) y Priyanka et al. (31) hasta 16 semanas en el artículo de Abd-Elmonem et al. (32). En cuanto al seguimiento de los sujetos, todos los estudios realizaron dos mediciones (pre y post tratamiento). Solamente Priyanka et al. (31) hace más de dos mediciones (las mediciones se tomaron el primer día antes del tratamiento y al final de la 1ª, 2ª, 3ª y 4ª semana del tratamiento) (Tabla 10).

Tabla 10. Intervention characteristics

Authors	Interventions	Exercise protocol	Supervision/ Treatment Duration (measurements)
Gheitasi et al. (2022) (35)	CG: None IG 1: Intrinsic muscle exercise (IEG) IG 2: Extrinsic muscle exercise (EEG)	3 days per week for 8 weeks (each session 45–60 min) Intensity/duration: Varies from 10–30 repetitions x 3 **IG 1**: Initial phase (1-4 week): (Feet Rolling, Toe flexion (curls), Big toe extension, Lift objects (marble pick-up), Short foot (sitting), Towel gathering (curls)) Improvement phase (5-8 week): (Toe flexion (curls), Big toe extension with resistance, Lift smaller objects, Short foot (standing), Towel gathering with weights, Toe spread, Tennis ball exercise) **IG 2:** Initial phase: (Calf muscle stretch, Plantar flexion, Hip external rotation-sidelying, Hip abduction, Foot adduction, Foot supination-sitting). Improvement phase: (Calf muscle stretch, Plantar flexion with resistance, Hip abduction with resistance, Hip external rotation-prone, Hip extension-prone, Foot supination-standing)	Supervised in the rehabilitation center / 8 weeks (pre and post treatment)
Karthika et al. (2022) (36)	CG: obesity reduction program IG: obesity reduction program + tibialis posterior strengthening	**Obesity reduction program**: 30 minutes moderate intensity aerobic training exercise program five days in a week for 6 weeks and provided with home-based program sheet/booklet. **Tibialis posterior strengthening exercise program**: five days in a week for 6 weeks, each session for 30 minutes. 1- Closed chain resisted foot adduction 2- Unilateral heel raise (heel raise) 3- Open chain resisted (foot supination)	Supervised in College of Physiotherapy / 6 weeks (pre y post tratamiento)
Rusu et al. (2022) (30)	CG: Physiotherapy program IG: Physiotherapy program + foot orthoses	**Physiotherapy program** (A posture was maintained for 10 s followed by 5 s of relaxing; this process was repeated for a total of 30 min per session, with three sessions per week for a total of 12 weeks): Single leg stance on a fixed surface, Forward lean on a fixed Surface, Standing on one leg on an unstable Surface, Forward lean on an unstable Surface, Throwing a ball with different	Supervised in Sports Medicine Department / 12 weeks (pre y post tratamiento)

		directions on fixed surface, Throwing a ball in different directions on an unstable surface , Squat on a fixed surface, Jump on a fixed Surface, Squat on an unstable surface and Jump on an unstable surface	
Abd-Elmonem et al. (2021) (32)	CG: Corrective exercises IG: Corrective exercises + NMES	**-Corrective exercises** (3 times a week, Both groups performed five designed strengthening exercises for 60 min with each exercise performed for 30 repetitions holding each repetition for 5 s : Short-foot exercise, Toes-spread-out exercise, Toes–extension exercise; Toe-curls exercise and Selected tibialis posterior muscle strengthening **-Neuromuscular electrical stimulation**: received NMES for 30 min aiming to rein- force the planter intrinsic foot muscles:	Supervised in Out-patient Physical Therapy Clinic of Faculty of Physical Therapy/ 16 weeks (pre y post tto.)
Allam et al. (2021) (34)	CG: None IG 1: Plyometric exercise program IG 2: Corrective exercises	Two sessions per week with three days of rest. The session started with 5 minutes warming up and ended with 5 minutes cooling down in the form of gentle stretching of the lower limb muscles. **Plyometric exercise program** (It was done on a spongy mat for shock absorption. We emphasized that all participants should get down from jumping on tiptoes and the weight-bearing activities should be done with foot prona- tion control. The jumps were divided into five sets and two- minute rests were given in between each set and the other): Jump jacks, Skipping, Jump side to side, Jump front and back, Vertical jump, Hopping forwards and backwards on the right foot, Hopping forwards and backwards on the left foot, Short jump forwards and backwards. **Corrective exercises:** Flexibility (Passive range of motion exercises and global movement of the ankle and all foot joints; stretching of the calf and peroneus brevis muscles) and Strengthening, proprioception, and balance (Anterior and posterior tibialis muscles and the flexor hallucis longus (to neutralize valgus), intrinsic, interosseus plantaris muscles, and the abductor hallucis (to prevent anterior arch flattening); global activation/movement of the muscles involved in maintaining the medial longitudinal arch and the varus; single-leg weight bearing (with pronation control); toe and heel walking; descending an inclined surface)	The supervisor emphasized the correct application of the exercises / 10 weeks (pre y post tto.)

Priyanka et al. (2020) (31)	CG: Reeducación Funcional IG: anti-pronation taping + Reeducación Funcional	Strengthening exercise, stretching, and faradic foot bath that was given for 30 minutes per day **Strengthening Exercises** -Exercises against resistance: Inversion, eversion, and dorsiflexion exercise were performed. Movements were performed with a controlled eccentric return without rotation the leg. We started with 3 sets of 10 repetitions and gradually increased the number of sets and repetitions until 10 sets of 20 repetitions can be performed. -Double Leg Heel Rises: The uninvolved leg should take 75-85% of the body weight. Participants started at 4 sets of 5 repetitions and progressed to 10 sets of 20 repetitions. **Stretching Exercises:** - 1. Participants sat to the floor, and legs were straight to touch the floor. Participants lifted one leg feet (normal leg) and touched the last toe finger of the opposite feet (pronated leg). This foot exercise was an effective stretching to build an arch. - 2. Participants sat on the floor with knees bend and the both hands in the back for support. Then they separated the foot from the floor whilst keeping the heel on the floor, cramped the toes and were asked to hold it for 15 seconds.	Physiotherapy / 4-week (The measurements were taken very first day prior to the treatment and at the end of the 1st, 2nd, 3rd and 4th week of the treatment)
Sativani et al. (2020) (37)	CG: None IG: Ejercicios correctivos	Corrective exercises (3 times a week): 1. Heel lift (10 repetitions in 3 sets) 2. Finger curl (5 repetitions with resistance for 15 seconds)	N/A / 4-week (pre and post treatment)
Sharath Hullumani et al. (2020) (33)	CG: had performed barefoot walking IG: had received foot-specific exercises + barefoot walking	- Barefoot walking: for 45 minutes a day bare feet every day, five times a week - Foot-specific exercises children have to be barefoot while doing exercises, as follows: 1.Towel gathering exercise for 15 minutes 2.Heel cord stretching (holding for 30 seconds and then relax for 30 seconds; repeat once) 3.Toe spread (5 seconds, than 2 second relax) 4.Posterior tibialis exercises (3 sets, 10 repetitions)]	Physiotherapist / 8 weeks (Pre and post treatment)
Khamooshi et al. (2016) (29)	CG: None IG 1: stretching and strength exercises IG 2: stretching and strength exercises + exercises related to	**Stretching and strength exercises**: F**irst and second** week of the training was to focus on the stretching of the Achilles tendon; the long, short, and lateral fibular muscles; the lateral exterior ligaments such as sole fibula and the talocalcaneal ligament.	Yes / 8 weeks (pre y post)

	central stability training	**Week three and four** was to strengthen the plantar muscles, internal rotators that are the anterior and posterior tibia, gastrocnemius, soleus, and long flexors of the toes. **Week five to eight** of the training program, a combination of the stretching and strengthening movements were carried out. **Exercises related to central stability training,** the exercises related to the central body stability along with the stretching and strengthening exercises. The central stability- related exercises were carried out in three levels: **Level one** was included static contraction exercises which were conducted in a stable status of the body, **Level two** incorporated static contraction exercises in an environment lacking stability, and **Level three** involved dynamic movements in an unstable environment which were carried out by making use of Swiss ball At the beginning of every training session, the testees were asked to perform warm-up activities for five minutes, and then they followed the corrective training exercises. The aforesaid exercises took about 25 minutes during the first sessions, and they gradually were increased to 45 minutes during the final sessions. three times a week, in the form of three turns with 20 repetitions.

Abbreviatures: CG, Control Group; IG, Intervention Group

Se evaluaron diferentes medidas de resultado, aunque los objetivos en todos era comprobar la eficacia del tratamiento aplicado para la mejora de signos y síntomas del PFF. Algunos autores se centraron en los cambios a nivel morfológico, es decir, cambios en el FPI-6 (36), en el NDT (32,34,35), Foot Print Index (32), Staheli índices (29,32) o en el índice del arco (33). Por el contrario, otros autores evaluaron la funcionalidad del pie con Stability Test (34), Plataforma de fuerza y presión RSScan (flexibilidad subastragalina e índice del arco) (30), La movilidad funcional se evaluó mediante the timed up and go (TUG) (34), Star excursion balance test (SEBT) (31), Vertical jump height (VJH) (31), Illinois agility test (IAT) (31), One Leg Stand Test o el Unterberger Test (37). Otros autores se interesaron más en medir la calidad de vida, midiendo el dolor o pasando diferentes escalas como The Oxford Ankle Foot Questionnaire for Children (OxAFQ-C) time point (33,37) o CPA-Questionnaire (36). Solamente un autor miró los cambios radiográficos, este fue Abd-Elmonem et al. (32), que midió diferentes índices radiográficos (mediante radiografía anteroposterior y mediolateral).

Todos los autores concluyen que la RF es efectiva para la mejora de signos y síntomas del PPIF. Además, los autores que lo conbinan con otras terapias como un programa para disminuir de peso con 30 minutos de ejercicio aeróbico durante 30 min 5 días a la semana (36), caminar descalzo durante 30 minutos al día (33) o junto a NMES (32) refieren que las mejorías son mayores. Solamente Priyanka et al. (31) refiere que tiene las mismas mejorías la reeducación funcional (fortalecimiento, estiramiento y aplicación de corrientes farádicas) solo que la reeducación funcional combinada con vendaje (anti-pronation taping). Gheitasi et al. (35) concluye que las intervenciones de ejercicio centradas en los músculos intrínsecos y extrínsecos del pie eran factibles, pero que la intervención con ejercicios para fortalecer el músculo intrínseco del pie sería más efectiva que la extrínseca para mejorar el pie plano. Karthika et al. (36) demuestra que el fortalecimiento del TP junto con la reducción de peso no solo mejora el PPIF sino que también mejora el ALI y el nivel de actividad física entre los escolares obesos con PPIF. Allam et al. (34) concluyen que tanto los ejercicios pliométricos como los ejercicios de corrección del pie tuvieron un efecto positivo sobre la postura del pie, el equilibrio y la movilidad funcional en niños obesos con pie plano.

7.4. DISCUSIÓN

El objetivo de esta revisión fue demostrar la eficacia de la reeducación funcional (ejercicios de fortalecimiento, estiramientos o ejercicios del pie y miembros inferiores) como tratamiento en el PPI tipo flexible. Además, se planteó determinar qué ejercicios son más efectivos para identificar un protocolo y compararlos con otros tratamientos conservadores para el PPI tipo flexible.

Para responder al objetivo principal, se analizaron estudios donde se compararan los ejercicios con ningún tratamiento (placebo) o con la combinación de cualquier ejercicio de reeducación funcional y otra terapia u otros tipos de ejercicios. Esto se traduce a que las mejoras encontradas en los artículos donde el grupo comparación era placebo (no se aplicaron ninguna terapia) (29,34,35,37) se debiese a la instauración de la RF y no a la evolución natural del pie. Y en aquellos artículos donde la comparación era con otras terapias u otros tipos de ejercicios era por efecto de los ejercicios implantados (30–33,36).

Esta revisión muestra que la RF (ya sea en forma de ejercicios de fortalecimiento, estiramiento, ejercicios correctivos, pliométricos o caminar descalzo) es un tratamiento eficaz para el PPIF. Estos resultados coinciden con muchos más artículos publicados recientemente, los cuales no se han incluido por no cumplir los criterios de inclusión, que respaldan el uso de la RF como principal tratamiento para el PPIF (20,38–45).

Actualmente no existe ninguna revisión sistemática sobre la eficacia de la RF o los ejercicios como tratamiento para el PFF, por lo que es la primera revisión sobre el tema que se aborda. Por el contrario, si encontramos revisiones que abordan este tema en el PP del adulto (21–24,46), todos concluyen que la RF o los ejercicios son eficaces para la mejora de signos y síntomas del PP. Además, las conclusiones específicas a las que llegan los diferentes autores son que ejercicio de pie corto, es decir, el de la musculatura intrínseca es más eficaz que los ejercicios de la musculatura intrínseca (46,47), que los ejercicios son más eficaces que las órtesis plantares para reducir el dolor en el PP (21), que los ejercicios pueden mejorar el ALI (22) o la caída del navicular (24). Además, el reciente meta-análisis de Huang et al. (23) concluye que el ejercicio de pie corto normaliza significativamente la alineación del pie en comparación con otras intervenciones a pesar de que no se

observe tal diferencia en la hipertrofia muscular. Otra de las revisiones publicadas recientemente sobre la eficacia de los ejercicios en PP adulto concluye que el fortalecimiento de la musculatura intrínseca plantar mejora principalmente la cinética y cinemática de la marcha, actúa sobre la alineación del pie y, además, se disminuye la pronación, el dolor y la discapacidad (47).

En cuanto a los objetivos secundarios de determinar qué ejercicios son más efectivos para identificar un protocolo, resulta muy difícil llegar a un consenso debido a la gran variedad de ejercicios, protocolos, tiempos y frecuencias de los mismos en los 9 artículos incluidos en esta revisión sistemática (29–37). Encontramos que la musculatura intrínseca casi siempre está presente en todos los ejercicios de fortalecimiento de la musculatura o de ejercicios correctivos (29–34,37). La musculatura intrínseca constituye una de las principales estructuras que mantienen el ALI. Las características anatómicas de la musculatura intrínseca, junto con las modificaciones en sus propiedades mecánicas, pueden desempeñar un papel significativo en la aparición del PP y la disminución de la altura de la ALI (48). También observamos que el fortalecimiento del TP, como músculo extrínseco y el estiramiento del tríceps sural o del tendón de Aquiles también están muy presentes en los diferentes ejercicios de los artículos incluidos (29,31–37). La disfunción del tibial posterior se origina principalmente debido a un déficit en la función del ligamento navicular calcáneo plantar, también conocido como ligamento resorte, que desempeña un papel fundamental en la estabilidad del ALI. Esta insuficiencia en el ligamento resultaría en un mayor estrés ejercido sobre el tendón tibial posterior, que ya de por sí es insuficiente, llevando gradualmente a su fatiga (49). Otro aspecto que también encontramos que tienen varios autores en común es trabajar la estabilidad de los niños para que a la misma que se fortalece la musculatura mejora el equilibrio (29,34). Estos hallazgos los podemos encontrar en diversa bibliografía, pero en la literatura no se acordado ningún ejercicio o protocolo ideal para el manejo el PPIF (38,41,46).

En lo que se refiere al otro objetivo de comparar los ejercicios con otros tratamientos conservadores para el PPI tipo flexible, nos encontramos que en nuestra revisión solamente podemos hacer comparación con el uso de órtesis plantares junto con ejercicios (30), el uso de vendaje junto con ejercicios (31), la disminución de peso junto con ejercicio (36), el caminar descalzo junto con ejercicios (33) y la combinación de NMES junto con ejercicio (32) en comparación

con solo ejercicio. En todos los estudios las mejoras son más significativas que en el grupo donde solamente se aplicaba ejercicio, excepto en el uso de vendaje junto ejercicio en el cual el resultado es el mismo, es decir, el vendaje no aporta beneficios al PPIF (31), conclusión que comparte con otros autores (50,51). Podemos llegar a la conclusión de que un tratamiento donde se combine cualquier tipo de ejercicio más otro tratamiento conservador va a ser más eficaz para el tratamiento del PPIF que solamente ejercicio. En cuanto al uso de vendajes en el PPIF, aunque en el artículo incluido en nuestra revisión no consiguió mejoras, sí que encontramos artículos donde el vendaje es eficaz como tratamiento conservador para el PPIF (52,53).

Investigaciones previas han revelado una considerable ambigüedad en la terminología utilizada para describir PPIF (por ejemplo, pie plano valgo, pie plano, entre otros) (9,54). Nos encontramos que a día de hoy este problema sigue existiendo, puesto que, aunque la gran mayoría lo denomina como PP, para una descripción más completa, algunos autores lo denominan sintomático o asintomático, otros usa terminología como mobile flat feet o flexible flatfoot, e incluso otros autores lo clasifican según diferentes escalas, lo que refleja que aún hay un consenso para denominar a esta entidad.

Si bien las radiografías se consideran el "gold standar" para diagnosticar el FF (55), se ha cuestionado su uso debido a las preocupaciones éticas relacionadas con la exposición a la radiación. Dado que es posible obtener un diagnóstico preciso utilizando pruebas clínicas y considerando los problemas éticos asociados con la radiación, las radiografías no se emplean de manera rutinaria para el diagnóstico de la PPIF. Aunque el FPI-6 es la única prueba validad en niños mayores de 6 años (56), encontramos que no es la más usada. Por el contrario, la prueba que más usan para diagnosticar el PPIF en el NDT, aunque encontramos el gran problema de que cada autor usa valores diferentes para catalogarla como positiva o negativa. Dada esta ambigüedad, no nos sorprende que haya tanta confusión respecto al PPIF, su tratamiento y su diagnóstico.

Esta revisión sistemática presenta grandes fortalezas que han de ser mencionadas, la primera de todas es que es la primera revisión sobre el uso de la RF o ejercicios en el PPIF. No se aplican filtros de ningún tipo (solamente se aplicaron los criterios de inclusión una vez habíamos recuperado todos los artículos) en la selección de estudios para así no sesgar los resultados, además de

la gran cantidad de bases de datos consultadas. El nivel de riesgo de sesgo no es alto. Se hace una recopilación de todos los ejercicios que se pueden implantar en el PPIF.

La principal limitación del estudio es que 5 de los artículos incluidos no tenían un grupo placebo al que no se le aplicara ningún tratamiento, para así poder decir con más certeza que los ejercicios son eficaces respecto a no hacer nada o dejar la evolución natural del pie. Además, la edad media de los sujetos es de 9 años, pensamos que edad muy tardía para encontrar mejores resultados de los ejercicios. Otra limitación involucró la variedad de medidas de resultado empleadas y la heterogeneidad observada en las intervenciones, puesto que prácticamente cada autor empleaba una RF diferente. La mayoría de los estudios se realizaron en Asia. Los distintos rasgos étnicos de cada población podrían haber influido en la configuración del progreso y los resultados del tratamiento.

Los esfuerzos de investigaciones futuras deben centrarse en la implementación de protocolos de diagnóstico estandarizados que incorporen pruebas validadas. Además, se recomienda separar los estudios en grupos que incluyan niños menores de 6 años y aquellos que incluyan participantes de 6 años o más. Además, se debería hacer un periodo de seguimiento para observar si estas mejoras se mantienen en el tiempo. Otro aspecto de gran importancia es que todos los autores deberían diagnosticar de la misma manera al PPIF y usar las mismas variables de resultado, solo de esta forma se podría llegar a una evidencia más concreta.

7.5. CONCLUSIONES

Los ejercicios de RF (fortalecimiento, estiramiento, ejercicios correctivos, pliométricos o caminar descalzo) son eficaces para la mejora de signos y síntomas del PPIF. Si además a esos ejercicios le sumas cualquier otra terapia conservadora para el PPIF como ejercicio aeróbico para bajar de peso, electroterapia u órtesis plantares, los beneficios de los ejercicios se incrementan. Actualmente con la bibliografía publicada no se puede llegar a un protocolo debido a la gran variedad de ejercicios y formas de aplicación (frecuencia e intensidad), aunque el mínimo de tratamiento para obtener resultados sería de 1 mes de tratamiento con RF mínimo dos veces por semana y que la duración de esta RF fuese de mínimo 30 min de trabajo.

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VIII – ESTUDIO V

XIII- ESTUDIO V

EFFICACY OF PERSONALIZED FOOT ORTHOSES IN CHILDREN WITH FLEXIBLE FLAT FOOT: PROTOCOL FOR A RANDOMIZED CONTROLLED TRIAL

Abstract:

Pediatric flat foot (PFF) is a very frequent entity and a common concern for parents and health professionals. There is no established definition, diagnostic method, or clear treatment approach. There are multiple conservative and surgical treatments, the implantation of foot orthoses (FO) being the most used treatment. The evidence supporting FOs is very thin. It is not clearly known what the effect of these is, nor when it is convenient to recommend them. The main objective of this protocol is to design a randomized controlled trial to determine if personalized FOs, together with a specific exercise regimen, produce the same or better results regarding the signs and symptoms of PFF, compared to only specific exercises. In order to respond to the stated objectives, we have proposed a randomized controlled clinical trial, in which we intend to evaluate the efficacy of FOs, together with strengthening exercises, compared to a control group in which placebos will be implanted as FO treatment along with the same exercises as experimental group. For this, 4 measurements will be made during 18 months (pre-treatment, two during treatment and finally another post-treatment measurement). The combination of FO plus exercise is expected to improve the signs and symptoms (if present) of PFF compared to exercise alone and placebo FO group. In addition, it is expected that in both conditions the biomechanics of the foot will improve compared to the initial measurements.

Keywords:

"Flexible Flatfoot", "Pediatrics", "Children", "Foot Orthosis", "Strengthening Exercises"

8.1. INTRODUCTION

Pediatric flat foot (PFF) is a very frequent syndrome in Primary Care consultations, and it is also a shared concern among parents and professionals. Currently there is no clear definition for the diagnosis of PFF, no treatment protocol, nor solid scientific evidence on the wide range of treatments [1,2].

PFF is characterized by a talocalcaneal misalignment, which is reflected as a collapse of the medial longitudinal arch (MLA) in a standing position [3]. Consequently, there is excessive pronation, accompanied by a drooping of the navicular. Some feet are also accompanied by calcaneal valgus [4]. All these alterations in the morphology of the foot force the rest of the structures, such as soft tissues or joints, to compensate for the excessive forces that act on the MLA [5]. These compensations cause an inefficient gait and symptoms such as pain, fatigue, stumbling when walking, problems in the proximal joints and reduced quality of life [6,7].

Diagnosis is based on clinical findings, including a variety of clinical tests and ra-diographic signs, these being considered the "gold standard" [6,8,9].

Regarding treatment, there are both conservative and surgical options, surgical being the last treatment option [10]. The most common conservative treatment is the use of foot orthoses (FO), where previous studies have concluded that they improve the results of some clinical tests, radiographic angles and symptomatology [11–17]. The purpose of the FOs is to modify the position of the axis of the subtalar joint, decrease the speed of pronation, support the MLA and distribute loads more effectively [18, 19]. Previous systematic reviews indicate that FOs are beneficial and create positive changes in the development of the child's foot [8,20,21], these changes being greater in the earlier age of the treatment [22]. The exact age to start treatment is not clear, although it is recommended to start at preschool age (under 7 years old) so that the possibility of correcting the PFF is greater [23,24]. It has also been seen that the combination of FO with exercises is much more beneficial [25]. However, other studies indicate that the modifications that occur are those resulting from the natural development of the foot [26,27]. The evidence regarding the use of FOs still does not present a consensus [20, 28,29].

Therefore, there is a discrepancy between treating and not treating PFF. There are authors who conclude that it is not necessary, since the natural evolution of the

foot is that the MLA begins to form at 3-4 years of age and ends at 10 years of age [26,27]. A recent meta-analysis [30] concludes that, due to the normal development of the foot, treatments should be ruled out, unless there are symptoms such as pain, limited function or reduced quality of life. However, other authors recommend early treatment, based on the fact that flat feet persist in 23% of adults and may be associated with Achilles tendinopathy, plantar fasciopathy, tibial posterior tendinopathy, hallux rigidus, chondromalacia patellae or patello-femoral pain syndrome [1,2,7,13,20]. Based on these latest data, it would be un-ethical to leave these types of feet untreated. Additionally, a recent systematic review [24] demonstrated that FOs are beneficial, with evidence regarding efficacy in treating signs and symptoms.

Therefore, since PFF is a very common syndrome, which, if left untreated, could cause problems in the long term, and there is no consensus on the treatment protocol, it is necessary to investigate the effectiveness of FOs, in terms of improvement of the signs and symptoms, including the prevention of pathologies or injuries and the improvement of the quality of life. Sagat, P et al. have shown that children with flat feet exhibited lower performance in certain physical tasks, in contrast to their counterparts with normal feet [31]. In addition, since it is a subject of great interest for researchers, health professionals and parents, it is necessary to carry out an investigation to assess the effectiveness of FOs, with a standardized diagnostic protocol with validated tests in a larger sample size than previously published studies and with longer-term follow-up. As the authors Zhang J. et al. early identification and intervention play a crucial role in enhancing the outlook. Furthermore, there is an absence of consistent quantitative standards for diagnosing flexible flatfoot [32].

Therefore, the objective of the current study is to design a protocol for a randomized controlled trial (RCT) to determine whether personalized FOs together with a specific exercise regimen produce the same or better results regarding the signs and symptoms of PFF, compared to only specific exercises. In addition, as specific objectives, to detect whether the possible bias that has prevented previous studies from demonstrating the efficacy of FOs is due to the fact that these FOs were not personalized; to define the PFF and to evaluate if there is a correlation between the clinical methods and the diagnosis and severity of the PFF.

8.2. MATERIALS AND METHODS

8.2.1. Study design and setting

The design is a randomized controlled two-arm trial.

Patients will be recruited from the university clinic from Universidad Católica San Antonio de Murcia, University of Malaga and schools nearby, in Spain. They will be randomized to one of the two groups, each receiving a different intervention. The schedule to follow while carrying out this RCT can be found in Annex 1. The total period intended to be allocated to this study is from September 2023 to February 2025.

To randomize the sample, a Microsoft Excel spreadsheet will be used where a random assignment sequence will be generated. Each patient will be given a consecutive number in order of arrival and allocation concealed in envelopes.

8.2.2. Elegibility criteria

Subjects aged 3 to 12 years diagnosed with PFF. For the diagnosis of the PFF, the following criteria must be met:

- Foot Posture Index (FPI) >6 [33].
- Navicular Drop > 10mm [34].
- Relaxed calcaneal stance position (RCSP) 6º a 12º valgus [35].
- Pronation angle >10º [36].
- Arch index > a 1.35 [37].
- Double/Single Heel Rise Test negative [38].
- Windlass test negative [39].

In addition, the signature of the parents or legal guardians with consent to participate in the study will be necessary (Annex 2).

Participants will be excluded if they have undergone any surgery in the lower limbs, have previously received treatment for PFF, present osteoarticular injury, foot fractures or in the lower limbs in the last 6 months, ankle sprain, asymmetry, systemic diseases with osteoarticular involvement that present symptoms in the lower limb with gait disturbance (for example, Perthes disease) or biomechanical

alteration of the lower limb with re-percussions on the foot and ankle. Children suffering from any type of neurological or systemic disability (cerebral palsy, Down Syndrome, clubfoot or equino-varus, ...) will also be excluded.

8.2.3. Interventions

At the first visit, parents will be informed of their child's current problem, treatments, and the existence of this study. In the case of accepting to participate in the study, the process will begin: all the variables will be carefully collected, the treatment will be established, and an appointment will be made for follow-up at 6 months.

First, all the affiliation data will be collected and the PFF will be diagnosed.

8.2.3.1. ***Group 1***

For custom insoles, a mold will be taken using phenolic foam. To do this, the child will be asked to sit in a chair (to take the mold in semi-load baring). The mold will be taken in a corrected position, that is, limiting the internal rotation of the tibia with one hand and the Windlass mechanism will be performed to increase the MLA. The mold must remain neutral, so in the event that a varus or valgus print has emerged, this process will be repeated. Once we have the mold filled with plaster, two modifications will be made: a moderate Medial Heel Skive (5 mm and an angulation of 15º) in the hindfoot and a slight inversion balance of 4º in the forefoot. Once the mold is prepared, the FO will be thermoformed, for this we will use a 3 mm polypropylene, 25 Shore-A EVA as lining and 65 Shore-A EVA to stabilize the hindfoot.

In addition, the exercises to be performed will be explained to them and they will be given all the recommendations regarding the performance of exercises, the use of FOs and shoe therapy. These explanations will be provided in an additional report (Annex 3) that will be given to all subjects together with a calendar so that they write down all the days they perform the exercises with an X.

The exercises will first be explained by the podiatrist and to the child and the parent/legal guardian. In addition, a standard video will be created so that the child can see it, in which the exercises will be explained through drawings in order to

capture the attention of the child. The parent/legal guardian needs to confirm that the child is doing it correctly.

Once the FOs have been provided, after assessing that it adapts well to the foot and does not cause discomfort, the patient will be requested to come at 6 months. In the event that there is any discomfort or irritation to the child's skin, an appointment will be made to readjust or modify the FO (in this visit the variables will not be evaluated, only the FO will be fixed; and if there are no problems this visit will not be carried out).

8.2.3.2. ***Group 2***

The participants will have the same intervention described for group 1, with the dif-ference that they will use placebo FO. This will be constructed using flat 1mm 65 shore Ethylene-vinyl acetate (EVA), which will be cut to the foot size of the child and covered with the same top cover as the FO Group 1 to visually prevent them from being dis-tinguished.

The instruments necessary for the development of this study and the budget necessary to carry out this clinical trial are included in Annex 4.

8.2.4. Outcomes measures

The document present in Annex 3 will be used for data collection. It contains all the data to be collected in the anamnesis and all the variables to be studied, including all the clinical tests that would be carried out.

8.2.4.1. ***2.4.1. Qualitative or categorical variables:***

- Gender: masculine or feminine.
- Pain: symptomatic or asymptomatic.
- Level of physical activity: High-Low-Nil.
- Double/Simple Heel Rise Test: Standing on toes with two legs/one leg for 25 repetitions. It will be considered positive if the participant is incapable due to fatigue or if when raising the calcaneus does not present a varus position [38].
- Supination Resistance Test: High-Moderate-Low. The patient is instructed to stand relaxed without any attempt to move the foot or lift the arch. The

examiner's fingertips are then placed plantar to the medial half of the navicular, and the examiner exerts a significant lifting force on the navicular. A normal foot will demonstrate subtalar joint supination with minimal lifting force. A pes valgus deformity will need extreme amounts of lifting force in order to produce little, if any, subtalar joint supination motion [40].

• Subtalar joint axis: Lateralized-Neutral-Medialyzed. The center of the neck of the talus should be located and marked to see if the lateralized or medialized point, or if, on the contrary, it stops at the 2nd finger, which would indicate that it is neutral [36].

• Shoe wear at heel level: Medial-Center-Lateral.

• Maximum Pronation Test: Positive or negative. The patient is asked to try pronate as much as possible; It is considered positive when performing the maneuver, the calcaneus cannot pronate more than 2º [41].

• Forefoot: adduction – neutral – abduction position [36].

• Foot posture index (FPI): Normal= 0 to +5; Pronated = +6 to +9; Highly Pronated = +10 to +12; Supinated = -1 to -4 and Highly Supinated = -5 to -12. The six clinical criteria assessed: 1. Palpation of the talus head; 2. Lateral supra and inframalleolar curvature; 3. Position of the calcaneus in the frontal plane; 4. Prominence of the talonavicular region; 5. Con-gruence of the internal longitudinal arch and 6. Abduction \ adduction of the forefoot with respect to the rearfoot. As we observe them, the following score is given: Neutral = 0; clear signs of supination = -2; clear signs of pronation = + 2 [33].

• Test of Windlass: Positive or negative. It will be considered positive when performing dorsiflexion of the hallux there is not supination of the foot, plantarflexion of the 1st ray, increase of the MLA and internal rotation of the tibia [39].

• Beighton scale: Hypermobility or normal. Subjects are rated on a 9-point scale, con-sidering 1 point for each hypermobile site. These 9 points are: 1-Hyperextension of the elbows (more than 10º), 2-Passively touch the forearm with the thumb, having the wrist in flexion, 3-Passive extension of the index finger to more than 90°, with the palm of the hand resting on the bed, 4-Hyperextension of the knees (10° or more), patient in supine position and 5-Flexion of the trunk forward touching the ground with the palms of the hands by bending without

bending your knees. To be considered as hypermobile it is required to have 4 points or more of the total of 9 [42].

- Podoscope: pronated-supinated-neutral [36].
- Pressure platform: maximum pressure zone, location of the centre of gravity, gait progression line [43].

*8.2.4.2. **Quantitative or numerical variables***

- Age: in months.
- Weight: in Kg.
- Height: in meters.
- Body Mass Index (BMI): Will be calculated with the formula weight (Kg) divided by height squared (meters^2). The classification of each child in low weight, normal weight, overweight or obesity will depend on the child's sex, height, weight and age [44].

- Pain: visual analog scale (from 1 to 10, 1 being minimum pain and 10 maximum pain).
- FPI: The six clinical criteria used in PFI are: 1. Palpation of the talus head; 2. Curvature supra and lateral inframaleolar region; 3. Position of the calcaneus in the frontal plane; 4. Prominence of the talonavicular region; 5. Congruence of the internal longitudinal arch and 6. Abduction \ adduction of the forefoot with respect to the rearfoot. (Score: Neutral = 0; clear signs of supination = -2; clear signs of pronation = + 2) [33].
- RCSP: degrees of calcaneal eversion. The valgus degrees of the calcaneus are measured in bipedal support [35].
- Navicular Drop: in millimeters. It measures the difference between the navicular po-sition when the patient's foot is in a neutral position and when the patient's foot is in its normal position. It measures how many millimeters the medial tuberosity of the scaphoid has descended [34].
- Pronation angle: in degrees. To calculate the bisection of the distal third of the tibia with respect to the bisection of the calcaneus [36].

• Chippaux-Smirak index: in cm. On the footprint of the subject taken from a pedi-graphy, the narrowest distance from the medial part of the foot (B) with the widest distance from the forefoot (A) must be measured. It is divided B/A [45].

• Pressure platform: Percentage of load/weight on each foot and distribution of the same (anterior load, posterior load, load of the left and right foot) [43].

• Arch index: numerical scale. The patient's footprint is taken with a pedigraphy, the toe area is excluded and a longitudinal line is drawn that goes from the center of the heel to the 2nd toe. A line is then drawn perpendicular to the 1st. Two lines are drawn per-pendicular to this axis to see the anterior extent of the forefoot area. The axis of the foot is divided into 3 equal parts and here 3 zones are defined: A: forefoot, B: midfoot and C: rearfoot. The arch index is calculated: B/(A+B+C) [37].

• Foot size: in cm.

• Silfverskiold test: in degrees. The degrees of dorsiflexion of the ankle (starting from a position of 90º) with extended knee and bent knee [46] will be measured.

• Navicular height: in millimeters. Measure the height of the scaphoid to the ground with the subject sitting [47].

8.2.5. Blinding and monitoring

Participants and their parent/guardians will be blinded as to which group they are al-located to and will not see the other group.

An initial assessment will be made, these same measurements will be repeated 3 times throughout the duration of the study. In total we will obtain 4 measurements for statistical analysis.

The second measurement will be a month of treatment, in addition, in this visit, we will assess the state of the FO and verify that the exercises are going well. We will ask about the FOs, if any pain has appeared that was not there before, any blisters or reddened areas. In the event that the adaptation to the FO has not been good, we will make the necessary adjustments to the FO, such as lowering the MLA. If any subject needs their FO to be modified, they will be called by telephone

after 2 weeks to see the evolution; in the event that it has not improved, it will be cited to re-evaluate the FO.

To corroborate that the execution of the exercises is good, we will ask the participant to repeat them, and in case there is an exercise that is not being performed correctly we will explain it again.

The third assessment will be in the middle of the treatment/study period, that is, at 6 months. At this stage all the initial measurements/assessments will be done again, as well as in the last one that will be at 12 months.

The estimated time for the measurement assessments is one hour for the 1st visit and 30 minutes for the rest of the visits.

8.2.6. Sample size

The calculation of the sample size has been carried out with the data analysis program EPIDAT (https://www. sergas. es/ Saude- publica/EPIDAT? language= es) program. For the calculation, a clinical variation of 2 and a standard deviation of 1 have been consid-ered. A statistical power of 80% and a significance level of $p<0.05$; 95% confidence level. The minimum size would be a sample of 128 subjects (64 in each group randomly dis-tributed). Considering that the loss rate could be 30%, the final size of should be 84 subjects in each group. The total sample size should be 168 subjects.

8.2.7. Statistical analysis

The description of data will be calculated using the percentages and frequencies of the qualitative variables and for the quantitative variables the standard deviation and the mean. In addition, in case of presenting high deviations, the measures of central tendency would be calculated, as is the case of the mean, median or mode. All this will be carried out in frequency distribution tables of different categories, using SPSS (IBM SPSS Statistics: V.28, USA).

It is intended to compare the dependent variables with the independent ones. The Kolgorov-Smirnof test (the adjustment to the normal of the distribution) will be used to check the normality of the quantitative variables, in the event that they follow a normal distribution, the following techniques would be used: linear

regression or Pearson cor-relation for the comparison of quantitative variables, Chi-square (X^2) to compare quali-tative variables and Student's t or ANOVA to compare qualitative with quantitative variables. In the event that they do not conform to the normal, it will be calculated ac-cording to the case; the Wilcoxon test, the Kruskal-Wallis test, and the Mann-Whitney test.

To determine that the supposed differences between control group and experimental group are not due to a random error, but to a real difference, in the bivariate analysis a hypothesis test will be carried out. The significance level of p shall be 0.05.

8.2.8. Ethics and dissemination

The study has been awarded ethical approval from the committee of the Universidad Católica San Antonia de Murcia (CE032213).

8.3. EXPECTED RESULTS

Personalized FOs along with a specific exercise regimen are expected to produce better results for signs and symptoms of PFF compared to specific exercises alone. In addition, it will be detected if the possible bias that has made the previous studies not demonstrate the efficacy of FOs is that these FOs were not personalized.

After the completion of this study, in which a large number of tests will be analyzed, the research will provide a definition of the PFF, according to the common findings presented by the sample, a definition that nowadays is non-existent. Finally, we can evaluate if there is a correlation between clinical methods and the diagnosis and severity of PFF, in order to make an accurate diagnosis.

It is anticipated that the study will provide valuable evidence for the improvement of the treatment of PFF, as well as for the diagnosis and management of this entity.

8.3.1.Limitations

The main limitation that can be found in this RCT is the involvement and adherence to the study by parents or legal guardians and children. Another limitation that should be mentioned is not having a control group that does not

undergo any treatment, as PFF can lead to problems in the biomechanics of gait and in the development of future pathologies. Also, we cannot claim that all patients will be using their orthoses the whole period of our study. This is because the study will be undertaken in Spain, where there are very high temperatures in summer. This may make it difficult for the patients to wear close-toed shoes, thus limiting the orthoses use and interfering with the adherence to the treatment. The use of FO will be monitored by phone, but we cannot be sure that they use them every day.

8.3.2.Strengths

This research will have several strengths; such as, the random assignment to the treatment and the blinding of the evaluators, the direct applicability of the results ob-tained and the absence of quality information in this field. This research will clarify many aspects that are still unclear regarding PFF and its treatment. This section may be divided by subheadings. It should provide a concise and precise description of the experimental results, their interpretation, as well as the experimental conclusions that can be drawn.

8.4. APPENDIX 1. PLANNED SCHEDULE FOR THE STUDY.

	2023					2024			2025	
Time/Activities	August	September	October	November	December	Full year	January	February	March	April
Project development and patient recruitment	X									
Data collection and initiation of processing		X								
Prospective follow-up			X	X	X	X	X	X		
Data analysis									X	
Results and conclusions									X	X
Preparation of the document										X

8.5. APPENDIX 2. INFORMED CONSENT AND PATIENT INFORMATION MODEL

Project Title: "EFFECTIVENESS OF PERSONALIZED PLANTAR ORTHOSES IN CHILDREN WITH FLEXIBLE FLAT FEET. A RANDOMIZED CONTROLLED TRIAL"

I, _____

-I have read the Information Sheet that has been given to me.

-I have asked all the questions I considered necessary about the study.

-I have received satisfactory answers to all my questions.

-I have received enough information about the study.

-I will not receive any financial compensation.

-The decision to allow the analysis of my data is completely voluntary.

-If I decide freely and voluntarily to allow the evaluation of my data and those of my child, I will have the right not to be informed of the results of the investigation.

-The evaluation of all data (clinical, demographic and background) will never pose an additional danger to my child's health.

-The information about my personal and health data will be incorporated and processed in a computerized database complying with the guarantees established by the General Data Protection Regulation, as well as Organic Law 3/2018, of December 5, Protection of Personal Data and guarantee of digital rights.

I understand that my child's participation is voluntary.

I understand that all of my child's data will be treated confidentially.

I understand that I can withdraw my child from the study:

-Whenever.

-Without having to give any kind of explanation.

-Without this decision having any impact.

With all of the above, I agree for my child to participate in this study.

Remarks:_____
_____

In Murcia, ____ of ____ of 2020

ID of the parent/legal guardian: _____

Child's ID: _____

Date:_____

Signature of parent/legal guardian: _____

Signature of Investigator: ____

PATIENT INFORMATION

STUDY TITLE

"EFFICACY OF PERSONALIZED PLANTAR ORTHOSES IN CHILDREN WITH FLEXIBLE FLAT FEET. A RANDOMIZED CONTROLLED TRIAL"

STUDY PROMOTER

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It is important that you understand before deciding whether or not to participate in this study, why this research is necessary, everything that may involve your child's participation, what will be done with the information and also the possible benefits, inconveniences or risks that may entail. Without further ado, take the time

you need to do a comprehensive reading and read all the information provided below.

REASON FOR STUDY

The main reason is to know if personalized plantar orthoses together with a regimen of specific exercises produce equal or better results regarding the signs and symptoms of PFF, compared to only specific exercises.

VOLUNTARY PARTICIPATION

You should know that your child's participation in this study is completely voluntary, so you can decide not to participate, change your decision at any time, without this having any impact on you or your child.

WITHDRAWAL FROM THE STUDY

In the event that you decide to leave the study, you may do so by allowing the data obtained up to the time of withdrawal from the study to be used, or by deleting all the data obtained from your child.

PARTICIPANTS

The study is designed so that all children from 3 to 12 years old, who have flexible infant flatfoot and also do not have any neurological disease or have undergone any surgery on the lower limbs, can participate.

DESCRIPTION OF THE INTERVENTION AND THE FOLLOW-UP

The clinical trial consists of the diagnosis of flexible flatfoot and the establishment of one of the two available treatment options at random. Your child may be treated with one type or another of plantar orthoses (some specific for flatfoot and others for all types of feet) in addition to a series of specific exercises. A review would be made at one month of treatment and another at 6 months and finally, the final review of the study, 12 months after the start of treatment.

All data related to flatfoot (type of flatfoot, valgus degrees, joint mobility, if there is pain, etc.) and its evolution will be collected.

POSSIBLE BENEFITS

We find several benefits, first of all is the diagnosis of this alteration of the foot, since there are many people who do not know that they suffer from it and that it can bring problems in the long run, so preventing these future ailments would be the first and most important benefit. In addition, your child will have 3 complete and thorough biomechanical studies, so other alterations that could be missed

could be detected. All interventions are completely harmless and will provide you with information about the health of your child's feet.

The cost of treatment and biomechanical studies is zero, with the possibility, once the study period is over, to continue seeing evolution or establishment of a "more correct" treatment.

Universally, the results and conclusions of the study will be beneficial in the future for all children who have flexible flat feet. If we get results that show which treatment is more effective, health professionals will not have so many uncertainties for the treatment of flat feet. This way all flexible flat feet will be treated properly, and money would be saved or unnecessary surgeries.

POSSIBLE RISKS OR DISCOMFORT

According to the current literature there is no risk when treating flatfoot with plantar orthoses and exercises. In addition, the purpose of this study is to know if plantar orthoses are really necessary for the treatment of flatfoot, so the treatment group with plantar orthoses for all types of feet would not trigger any risk either.

The discomfort could come from the adaptation to the plantar orthosis or the exercises. Some type of dermatology alterations derived from chafing or allergy to the materials of the plantar orthoses have been described, although these are not frequent.

ACCESS AND PROTECTION OF PERSONAL DATA

All data are of a personal nature and will comply with the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights. According to what is established in this legislation, you could exercise all your rights (access, modification, opposition and cancellation of data). The way to exercise this right would be to address any staff working in the clinic.

All the data handled in the study will be identified through a code, which means that only the study promoter and the collaborators will be able to relate that code with the data of their child. Therefore, your identity and that of your child will not be disclosed to any person, except for exceptions such as a medical emergency or a legal requirement.

CONTACT IN CASE OF DOUBTS

If at any time you have any questions or require more information you can contact Cristina Molina García as responsible for the study at the telephone number 968 280 023 or through the email ucampodologia@ucam.edu.

Annex 3. Model for revocation of informed consent.

SECTION FOR THE REVOCATION OF CONSENT

I, D./Dª__ with DNI ____ representative of the participant D./Dª__

I revoke the consent to participate in the study, signed above. Dated _____

Signature parent/legal guardian ____

Investigator's signature _____

8.6. APPENDIX 3. PATIENT MEDICAL HISTORY AND REPORT

ANAMNESIS		
Name:		**Identification Code:**
Name and ID father/mother/legal guardian:		
Address:		**Phone**:
DNI:	**Email**:	
Date of birth:		**Age**:
Weight:	**Height**:	**BMI**:
Allergies:	**Background**:	
Standing number:	**Gender**: Male/Female	
Level of physical activity:		High/Medium/Low

EXPLORATION-ASSESSMENT		
IPF	Punctuation:	Pronated/Normal/Supinate
NAVICULAR DROP		(mm)
DOUBLE HEEL RISE TEST		Positive/Negative
SINGLE HEEL RISE TEST		Positive/Negative
PAIN (VAS SCALE)	Symptomatic/Asymptomatic	Punctuation:
PRCA		(degrees)
WINDLASS TEST		Positive/Negative
ARC HEIGHT INDEX		Punctuation:

MAXIMUM PRONATION TEST	Positive/Negative	
ASA AXIS	Lateralized/Neutral/Medialized	
SUPINATION RESISTANCE TEST	High/Moderate/Low	
CHIPPAUX-SMIRAK INDEX		(cm)
BEIGHTON SCALE	Punctuation:	Hyperlax/Normal
TYPE OF FOREFOOT	Abduccido/Neutral/Adducido	
FOOTWEAR	Heel level: Medial/Center/Lateral	
PODOSCOPE	Pronate/Supine/Neutral	
PRONATION ANGLE		(degrees)
SILFVERSKIOLD TEST		(degrees)
NAVICULAR HEIGHT		(mm)

PRESSURE PLATFORM

Maximum pressure zone:		
Center of gravity		
Gait progression line		
	Left	Right
Load/weight percentage	Ant: Post:	Ant: Post:
	Left:	Dx:

REPORT EXERCISES AND RECOMMENDATIONS

Exercises to be performed:

1- Tiptoe for 1 minute.
2- Walk with the outer lateral edge of the foot for 1 minute.
3- Stand on tiptoe, hold on for 2 seconds and go down 15 times.
4- Hold a tennis ball with your heels and stand on tiptoe without the ball falling, hold 2 seconds and go down. Perform 15 repetitions.
5- Take marbles or pens with your toes and try to put them in a bucket or change them for 1 minute.
6- Stand on a towel or paper and crumple it with your toes, make this gesture for a minute.
7- Standing try to increase the arch of the foot making the greatest possible effort, do 15 repetitions.
8- To finish, standing with a ball under the sole of the foot make pressures at different points of the foot and perform stretching of the triceps sural with extended knee and bent knee.

All exercises will be repeated twice each.

All these exercises will not structure the deformity and do not develop compensations in other body segments. With them we are working all the intrinsic and extrinsic muscles of the foot involved in children's flatfoot. The rebalancing of this musculature will cause the stabilizing function of the foot to develop, in addition to improving its correct activation during dynamics.

Using the template:

1- During the first week, the plantar orthoses should be implanted progressively, that is, on the 1st day for two hours, on the 2nd day for 4 hours and so on.
2- Plantar orthoses are for daily use whenever the child is standing or walking, that is, they must be worn every day for as many hours as possible.
3- They can be washed with soap and cold water.
4- Do not put them near a heat source, such as on top of a radiator.
5- If they cause discomfort or signs of inflammation, redness or blisters appear on their skin, remove their child's plantar orthoses and contact the clinic.

Footwear:

The use of correct footwear is of great importance and is considered as one more part of the treatment of flatfoot, it is also considered as a trigger of flatfoot.

Avoid wearing shoes without any type of support type flip-flops or footwear that is totally flat, without any sole.

An ideal footwear for children should have a rigid buttress, should not be small or too large (should fit the index finger between the heel and the shoe), should also have a thick sole (never heels) and should not be very rigid. Children's shoes should carry any method of adjustment such as laces or Velcro and care must be taken that they are not made of synthetic material to allow perspiration.

8.7. APPENDIX 4 NECESSARY MATERIAL AND BUDGET

MATERIALS	COST
Pressure platform, computer, stretcher, goniometer, scissors, vacum, polisher, podoscope, printer, SPSS package, pedigraph	€0
Consumables: folios, pens, stretcher sheets, printer ink, gloves, masks, pedigraph ink	100 €
Elaboration 168 plantar orthoses: phenolic foams, plaster, polypropylene, EVA linings, glue	1680 €
Publication of the article in open access	2000 €
Presentation at congresses	700 €
TOTAL BUDGET	**4480 €**

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IX – SÍNTESIS DE LA TESIS

IX - SÍNTESIS DE LA TESIS

En esta tesis se han desarrollado una secuencia de estudios para dar respuesta a los objetivos planteados. Además, termina con un protocolo de ensayo clínico controlado aleatorizado el cual pone fin a esta etapa investigadora predoctoral y a la misma vez da pie al inicio de otra etapa investigadora postdoctoral (Figura 10).

La realización de estos estudios se ha llevado a cabo ante la necesidad de ampliar el conocimiento acerca del pie infantil, su evolución y los factores predisponentes a anomalías como es el pie plano infantil. Tras esta tesis doctoral es posible obtener una mayor comprensión sobre el desarrollo del pie del niño, todo lo que involucra a este y en qué punto estamos a nivel científico en cuanto al tema del pie plano infantil y sus tratamientos conservadores más utilizados en la práctica clínica.

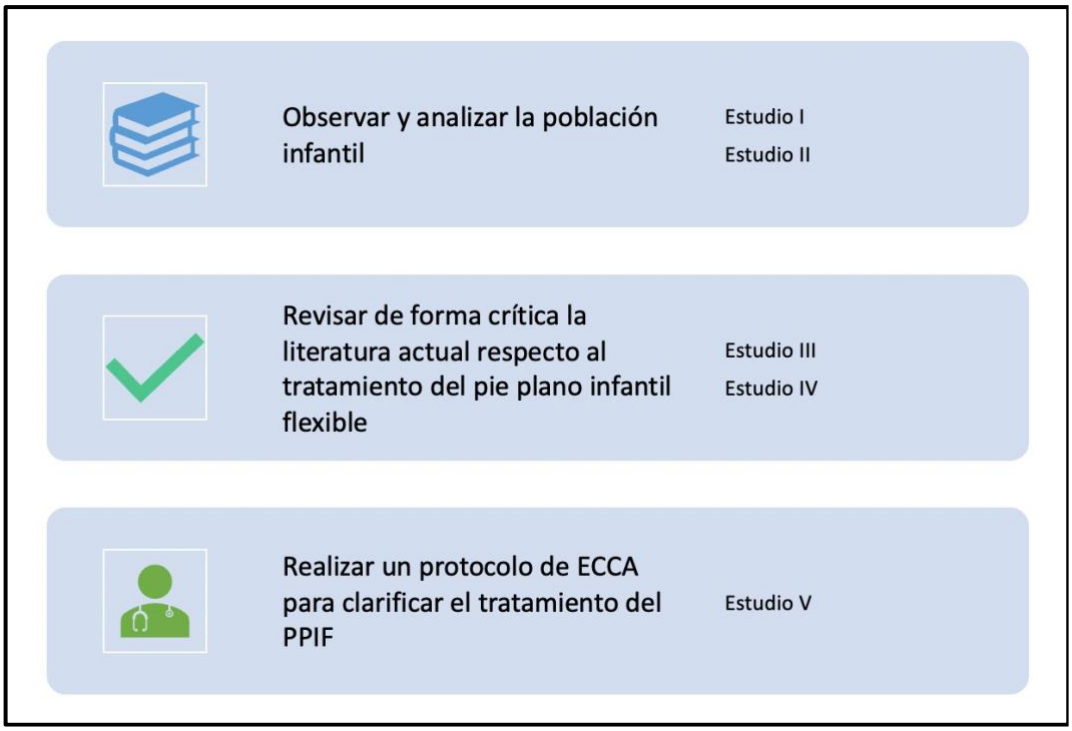

Figura10. Diagrama de la metodología empleada.

El Comité de Ética de la Universidad Católica San Antonio de Murcia, institución a la que pertenece esta tesis, dio su aprobación a todos los estudios llevados a cabo en el marco de este trabajo de investigación.

- Código CE032213
- Código CE022205

9.1. OBSERVAR Y ANALIZAR LA POBLACIÓN INFANTIL.

INVESTIGACIÓN OBSERVACIONAL DESCRIPTIVA TRANSVERSAL

A la hora de diagnosticar cualquier anomalía en el pie del niño nos encontramos con escasos métodos de evaluación. Estos se basan principalmente en las características estructurales del pie, los cuales asocian estas características con características funcionales, y estas a su vez pueden estar asociadas con patomecánica del pie o de toda la extremidad inferior. Sin embargo, nos encontramos con investigaciones que cuestionan la utilidad de estas mediciones clínicas como posibles predictores de las lesiones de la extremidad inferior.

La baropodometría se trata de una herramienta clínica que, cada vez más, se usa para la evaluación del pie en adulto. Sin embargo, en el ámbito infantil se trata de una herramienta muy poco usada. En el sector infantil supondría conocer y de definir un patrón de marcha, para poder hacer un diagnóstico precoz y objetivo. Este chequeo mediante la baropodometría permitiría un diagnóstico asistido y automatizado con la finalidad de prevenir lesiones, deformidades o alteraciones funcionales en el pie, principalmente en las formas iniciales. La combinación de la baropodometría junto con los diferentes test nos llevaría a hacer un tratamiento adecuado para el niño de las disfunciones de los pies en las primeras etapas. Esto podría prevenir diferentes tipos de dolor y problemas asociados con los pies, la rodilla, la cadera y la columna vertebral o la espalda, que podrían estar causando dolor, fatiga, frustración e incapacidad para moverse correctamente.

Poder correlacionar las variables tipo de pie, laxitud, nivel de actividad física y estudio baropodométrico nos daría un algoritmo para así detectar posibles cambios biomecánicos que puedan desencadenar futuras lesiones. En este estudio se pretendía conseguir una buena medida de resultado para así evaluar el progreso y efectividad del tratamiento en patologías infantiles.

Mientras evaluábamos a niños de 5 a 10 años, midiendo diferentes variables, para poder después sacar conclusiones estadísticamente significativas sobre la relación entre las variables baropodmétricas y el resto de test, observamos una gran prevalencia de obesidad y sobrepeso (SP/OB) infantil. Hecho que nos alentó, y nos hizo plantearnos estudiar cómo podía afectar ese exceso de peso al pie y todo lo que envuelve a este. Esto dio lugar a los dos primeros estudios de la presente tesis doctoral.

Tabla 11. Investigación Observacional Descriptiva Transversal

ESTUDIO I **Sobrepeso y obesidad: su impacto en el tipo de pie, flexibilidad, fuerza del pie, presión plantar y estabilidad en niños de 5 a 10 años: estudio observacional descriptivo**
ESTUDIO II **La obesidad infantil y su impacto en las características de las fases de la marcha. Un estudio transversal**

9.2. REVISAR DE FORMA CRÍTICA LA LITERATURA ACTUAL.

REVISIONES SISTEMÁTICAS

Mientras se llevaba a cabo la revisón de los niños para el estudio observacional; y tras analizar gran cantidad de bibliografía sobre el pie infantil, se detectó una falta de información y una gran demanda sobre información acerca del PPI. Evidenciamos como no hay un consenso sobre cómo diagnosticar, definir y manejar esta entidad.

Además, dos de los tratamientos más usados eran las OP y la RF o ejercicios de fortalecimiento, pero la evidencia que las abalaba era muy pobre.

Es por ello por lo que se decidió llevar a cabo estas dos revisiones, para así, de este modo, dar un poco de claridad a esta patología y sus opciones de tratamiento conservador más utilizados.

Tabla 12. Revisiones Sistemáticas

ESTUDIO III **Eficacia de las órtesis plantares en el pie plano infantil flexible: una revisión sistemática de los últimos cinco años**
ESTUDIO IV **Eficacia de la reeducación funcional como tratamiento para el pie plano infantil flexible. Revisión sistemática**

9.3. REALIZAR UN PROTOCOLO PARA UN ECCA

Ante la clara demanda de estudiar si verdaderamente las OP son beneficiosas para el PPIF y la inexistencia de un adecuado protocolo de estudio, el cual abarcase todas las áreas del pie (y no solamente fijarse en la formación del ALI), se desarrolló un protocolo para un ECCA. Este ECCA aborda todas las dimensiones del pie (estructura, funcionalidad, biomecánica y calidad de vida) y pretende no solamente demostrar la eficacia de las OP, sino que también se podrá investigar si el sesgo potencial que ha obstaculizado la demostración de la efectividad de las OP en estudios anteriores se debió a la falta de personalización de las mismas. Además, se podrá establecer una definición precisa del PPIF y analizar si existe una relación entre los métodos clínicos utilizados y el diagnóstico y la gravedad del PPIF. Por último, de forma indirecta; puesto que al grupo control se le aplicarán los mismos ejercicios de fortalecimiento-reeducación funcional, podremos valorar la influencia de estos en el PPIF.

Tabla 13. Protocolo para un ECCA

ESTUDIO V

Eficacia de las ortesis de pie personalizadas en niños con pie plano flexible: protocolo para un ensayo clínico controlado aleatorizado

9.4. APLICACIONES PRÁCTICAS

Las implicaciones clínicas de los hallazgos presentados en esta tesis implican que se deben reconocer signos como presión excesiva, estabilidad deteriorada o aumento de la fuerza del pie para prevenir dolor futuro y posibles complicaciones a corto y largo plazo. Además, para prevenir dolores futuros y posibles problemas a corto y largo plazo, síntomas como, por ejemplo, valores angulares demasiado altos o demasiado bajos o fases de la marcha con duraciones inusuales, como un tiempo total de contacto prolongado o se debe detectar una fase de contacto demasiado corta del antepié. La profilaxis del SP/OB infantil, cada día más frecuente, así como el diagnóstico precoz de las deformidades musculoesqueléticas, tendrán efectos a largo plazo en el estado de salud general de los niños. Una alteración en los pies y todo lo que ello implica (fuerza, flexibilidad, presión, estabilidad) puede tener consecuencias como disminución de la actividad física, agravando el problema del SP/OB. Los niños con SP/OB deben ser manejados por un equipo multidisciplinario, el cual debe estar conformado por psicólogos, nutricionistas, pediatras, rehabilitadores, podólogos y fisioterapeutas

Se destaca la importancia de conocer y analizar la pisada en los niños, ya que muchas veces los problemas en los pies de los niños y los patrones de marcha establecidos en la infancia persisten más tarde en la edad adulta.

En cuanto las órtesis plantares (OP) se destacan como una de las principales herramientas terapéuticas en el tratamiento conservador del pie plano infantil flexible (PPIF). La efectividad de las OP ha quedado demostrada en la revisión sistemática, aunque aún quedan áreas por investigar. Como se ha observado, el PPIF tiene una alta prevalencia en la población pediátrica y tanto el diagnóstico

como el enfoque terapéutico no están claros. Estudios recientes sugieren que las OP personalizadas son más efectivas y pueden influir en la progresión de los ángulos radiográficos, siendo los cambios más notables cuando el tratamiento se inicia a una edad temprana.

También se ha comprobado que otros tratamientos, como los ejercicios físicos, son efectivos para mejorar los signos y síntomas del PPIF. Estos ejercicios podrían usarse en conjunto con la implementación de las OP.

En resumen, las OP son una opción de tratamiento segura, con escasos efectos adversos y no invasiva, que mejora varios aspectos del desarrollo del PPIF. No existen pruebas que sugieran que el uso de OP dificulte el desarrollo normal del pie o empeore la condición inicial. La única desventaja en comparación con las técnicas invasivas es el prolongado período de tratamiento asociado con las OP. No existe una definición universalmente aceptada de PPIF, aunque todos los autores de los estudios incluidos la definen cuando hay más de dos signos y síntomas característicos o pruebas positivas. El uso de OP con arco longitudinal medial alto puede mejorar los signos y síntomas en algunos pacientes con PPIF.

Por otro lado, los ejercicios de RF (fortalecimiento, estiramiento, ejercicios correctivos, pliométricos o caminar descalzo) son eficaces para la mejora de signos y síntomas del PFF. Si además a esos ejercicios le sumas cualquier otra terapia conservadora para el PFF como ejercicio aeróbico para bajar de peso, electroterapia u órtesis plantares, los beneficios de los ejercicios se incrementan. El mínimo de tratamiento para obtener resultados sería de 1 mes de tratamiento con RF mínimo dos veces por semana y que la duración de esta RF fuese de mínimo 30 min de trabajo.

X – CONCLUSIONES

X - CONCLUSIONES

1- Los niños de 5 a 8 años con sobrepeso/obesidad (SP/OB) muestran mayores niveles de fuerza en los pies y los niños con SP/OB de 7 a 8 años son más estables en estabilometría estática. Además, los análisis de regresión lineal muestran cómo entre 5 y 8 años tener SP/OB implica tener más fuerza y estabilidad estática. Esto no debe traducirse como un aspecto positivo para la salud de esta población.

2- Los niños con SP/OB presentan alteraciones en diferentes etapas de la marcha. Tener SP/OB se relaciona con alteraciones de las fases de la marcha principalmente desde los 7 a 10 años, pasando más tiempo en cada una de las fases de la marcha. Este hecho podría indicar que los niños con SP/OB, además de caminar más lento, sobrecargan el sistema musculoesquelético sometiendo sus articulaciones y músculos a un mayor estrés.

3- Las órtesis plantares (OP) son eficaces para la mejora de signos y síntomas en los niños con PPIF. No se puede concluir cuál es el mejor tipo de OP ni cual es el momento óptimo de uso debido a la heterogeneidad entre los estudios. No existe un algoritmo para el diagnóstico de pie plano infantil flexible (PPIF) y existe una gran diversidad de pruebas clínicas, signos y síntomas característicos y mediciones radiográficas para el diagnóstico del PPIF. No existe una definición universalmente aceptada para el PPIF, aunque todos los autores de los estudios incluidos la definen cuando hay más de dos signos y síntomas característicos o pruebas positivas. El uso de OP con arco longitudinal medial alto puede mejorar los signos y síntomas en algunos pacientes con PPIF.

4- Los ejercicios de reeducación funcional (RF) (fortalecimiento, estiramiento, ejercicios correctivos, pliométricos o caminar descalzo) son eficaces para la mejora de signos y síntomas del PPIF. Si además a esos ejercicios le sumas cualquier otra terapia conservadora para el PPIF como ejercicio aeróbico para bajar de peso, electroterapia u órtesis plantares, los beneficios de la RF se incrementan. Actualmente con la bibliografía

publicada no se puede llegar a un protocolo debido a la gran variedad de ejercicios y formas de aplicación (frecuencia e intensidad), aunque el mínimo de tratamiento para obtener resultados sería de 1 mes de tratamiento con RF mínimo dos veces por semana y que la duración de esta RF fuese de mínimo 30 min de trabajo.

5- El protocolo que se ha diseñado para el ECA determinará si las OP personalizadas junto con un régimen de ejercicio específico o RF produce los mismos o mejores resultados con respecto a los signos y síntomas de PPIF, en comparación con sólo específicos ejercicios o RF. Además, se podrá detectar si el posible sesgo que ha impedido que estudios previos demuestren la eficacia de las OP se debe a que las OP no fueron personalizadas; podremos definir el PPIF y evaluar si existe correlación entre los métodos clínicos, el diagnóstico y gravedad del PPIF.

XI - LIMITACIONES Y FUTURAS LÍNEAS DE INVESTIGACIÓN

XI - LIMITACIONES Y FUTURAS LÍNEAS DE INVESTIGACIÓN

Esta tesis doctoral tiene varias limitaciones que merecen atención.

En primer lugar, los valores utilizados como puntos de corte para dividir a los niños como peso normal "NW", sobrepeso "OW" u obesidad "OB" se han utilizado y aceptado previamente, aunque otros valores de corte podrían haber modificado. nuestros resultados.

En segundo lugar, aunque la plataforma de presión RSscan Footscan ® 9 ha demostrado una buena confiabilidad intraevaluador e interevaluador, solo mide fuerzas perpendiculares al suelo, sin tener en cuenta fuerzas en otros planos, aun así, se ha demostrado que la medición de la presión plantar durante la dinámica es un método confiable para evaluar la forma y función del pie, aspecto que no comparte con la medición en estática.

En tercer lugar, hay que tener en cuenta que el rango de edad de nuestro estudio fue de 5 a 10 años, por lo que las comparaciones directas con otros estudios podrían resultar difíciles debido a otros posibles rangos de edad. Asimismo, se tiene que tener en cuenta que el patrón de marcha se desarrolla hasta el sexto, a veces hasta el séptimo año de edad, en los grupos analizados hubo niños con patrón de marcha maduro y aquellos que no finalizaron el proceso de maduración. También hay que tener en cuenta que la estructura del pie cambia no sólo debido al aumento (anormal) del peso corporal, sino también en el proceso fisiológico de maduración.

De igual forma, se ha de mencionar que el hecho de que se observara a los niños mientras caminaban puede haberles provocado un cambio en su patrón de marcha habitual.

Para permitir conclusiones más claras y precisas, la investigación futura debe estandarizar el enfoque para evaluar el pie del niño. Además, se requiere más investigación en el área de las presiones plantares para crear un marco metodológico ideal que nos permita comprender mejor las características de la función del pie y cómo se desarrolla en la infancia y la influencia de SP/OB en la población infantil.

En cuanto a las revisiones sistemáticas, la principal limitación de la revisión sistemática acerca de la eficacia de las OP es el pequeño número de estudios incluidos y participantes, lo que podría reducir la validez externa de estos resultados. Si bien en la literatura se encuentran disponibles numerosos estudios relacionados con las OP y el PPIF, solo hemos encontrado siete estudios publicados en los últimos cinco años con buena calidad metodológica.

En lo que refiere a la revisión sistemática sobre la eficacia de la RF, la principal limitación es que 5 de los artículos incluidos no tenían un grupo placebo al que no se le aplicara ningún tratamiento, para así poder decir con más certeza que los ejercicios son eficaces respecto a no hacer nada o dejar la evolución natural del pie. Además, la edad media de los sujetos es de 9 años, pensamos que edad muy tardía para encontrar mejores resultados de los ejercicios o RF.

A su vez, ambas revisiones comparten ciertas limitaciones como la variedad de medidas de resultado empleadas y la heterogeneidad observada en las intervenciones, puesto que prácticamente cada autor empleaba una RF o unas OP diferentes.

La mayoría de los estudios se llevaron a cabo en el continente asiático. Las características étnicas de cada población son diferentes, y estas podrían haber influido en el desarrollo y resultados del tratamiento.

Otro aspecto de gran importancia es que todos los autores deberían diagnosticar de la misma manera al PPIF y usar las mismas variables de resultado, solo de esta forma se podría llegar a una evidencia más concreta. Por ejemplo, confiar únicamente en las huellas puede ser engañoso puesto que los niños con SP/OB tienen más tejido adiposo en su ALI.

Además, en investigaciones futuras, los estudios deberían separarse entre aquellos que incluyen niños menores de 6 años y aquellos que incluyen participantes mayores de 6 años. Finalmente, se deben realizar estudios que evalúen al participante en su totalidad, incluidos los síntomas dolorosos generales y la calidad de vida. Entonces, la evidencia de la efectividad del tratamiento con RF o OP sería más concreta.

En cuanto a la investigación acerca de las OP, estos estudios deben realizarse con un tamaño de muestra mayor y un seguimiento a más largo plazo (más de 3 meses). Y en lo que refiere a la investigación RF se debería hacer un periodo de seguimiento para observar si estas mejoras se mantienen en el tiempo.

XII – ANEXOS

XII - ANEXOS

ANEXO 1. Compendio de publicaciones y estancias

Esta tesis adopta un formato de estudios independientes, presentados como artículos que reflejan distintas secciones de la investigación.

Los estudios I, III y V están publicados en revistas científicas con un factor de impacto JCR (2022) de Q2 y Q1 (según la categoría), los restantes estudios II y IV se encuentran en revisión en la revista EUROPEAN JOURNAL OF PEDIATRICS con factor de impacto JCR de Q1. El artículo II se encuentra en periodo de adaptación con los cambios pedidos por el editor y los revisores.

Tabla 14. Compendio de publicaciones

Estudios	*Cita*	*Revista*	*Información*	*Estado*
Estudio 1	*Molina-García, C., Jiménez-García, J. D., Velázquez-Díaz, D., Ramos-Petersen, L., López-del-Amo-Lorente, A., Martínez-Sebastián, C., & Álvarez-Salvago, F. (2023). Overweight and Obesity: Its Impact on Foot Type, Flexibility, Foot Strength, Plantar Pressure and Stability in Children from 5 to 10 Years of Age: Descriptive Observational Study. Children, 10(4), 696.*	*Children Basel*	*EISSN: 2227-9067* *2022 JOURNAL IMPACT FACTOR: 2.4* *Journal Citation Indicator (JCI): 0.93* *CATEGORY: PEDIATRICS; JIF RANK: 58/130* *JIF QUARTILE: Q2* *JIF PERCENTILE: 55,8*	*Publicado*

Estudio 2	*Childhood obesity and its impact on the characteristics of gait stance phases. A Cross-sectional study*	*EUROPEAN JOURNAL OF PEDIATRICS*	*ISSN: 0340-6199* *EISSN: 1432-1076* *2022 JOURNAL IMPACT FACTOR: 3.6* *Journal Citation Indicator (JCI):1.38* *CATEGORY: PEDIATRICS; JIF RANK: 23/130* *JIF QUARTILE:Q1* *JIF PERCENTILE: 82,7*	*En revisión*
Estudio 3	*Molina-García, C., Banwell, G., Rodríguez-Blanque, R., Sánchez-García, J. C., Reinoso-Cobo, A., Cortés-Martín, J., & Ramos-Petersen, L. (2023). Efficacy of Plantar Orthoses in Paediatric Flexible Flatfoot: A Five-Year Systematic Review. Children, 10(2), 371.*	*Children Basel*	*EISSN: 2227-9067* *2022 JOURNAL IMPACT FACTOR: 2.4* *Journal Citation Indicator (JCI): 0.93* *CATEGORY: PEDIATRICS; JIF RANK: 58/130* *JIF QUARTILE:Q2* *JIF PERCENTILE: 55,8*	*Publicado*

Estudio 4	*Efficacy of functional re-education as a treatment for Paediatric Flexible Flatfoot. Systematic review*	*EUROPEAN JOURNAL OF PEDIATRICS*	*ISSN: 0340-6199* *EISSN: 1432-1076* *2022 JOURNAL IMPACT FACTOR: 3.6* *Journal Citation Indicator (JCI):1.38* *CATEGORY: PEDIATRICS; JIF RANK: 23/130* *JIF QUARTILE:Q1* *JIF PERCENTILE: 82,7*	*En revisión*
Estudio 5	*Molina-García, C., Reinoso-Cobo, A., Cortés-Martín, J., Lopezosa-Reca, E., Marchena-Rodriguez, A., Banwell, G., & Ramos-Petersen, L. (2023). Efficacy of Personalized Foot Orthoses in Children with Flexible Flat Foot: Protocol for a Randomized Controlled Trial. Journal of Personalized Medicine, 13(8), 1269.*	*Children Basel*	*EISSN: 2227-9067* *2022 JOURNAL IMPACT FACTOR: 2.4* *Journal Citation Indicator (JCI): 0.93* *CATEGORY: PEDIATRICS; JIF RANK: 58/130* *JIF QUARTILE: Q2* *JIF PERCENTILE: 55,8*	*Publicado*

A este compendio de publicaciones se añaden dos estancias predoctorales (con una duración de 3 meses cada una), una internacional en la Universidad del Gran Rosario (UGR) en Argentina y otra estancia nacional en la Universidad de Málaga (UMA) en Málaga. Además de asistencia a congresos y presentación de póster y comunicaciones orales, tanto a nivel nacional como a nivel internacional.

UNIVERSIDAD DE MÁLAGA

Vicerrectorado de Investigación y Transferencia

COMUNICACIÓN DE FINALIZACIÓN DE ESTANCIA DE INVESTIGADORES EXTERNOS

Datos investigador externo

Apellidos: Molina García	Nombre: Cristina
Pasaporte/Documento Nacional de Identidad: 45923799K	
Universidad: Universidad Católica San Antonio de Murcia	
Facultad: Ciencias de la Salud	Departamento: Podología

Datos sobre la estancia en la Universidad de Málaga

Actividades realizadas durante la estancia: Creación de líneas de investigación entre el departamento de Podología de la Universidad Católica San Antonio de Murcia (UCAM) y el departamento de Enfermedía y Podología de la Universidad de Málaga (UMA). Se ha realizado un artículo pendiente de publicación, de tipo cualitativo, explorando la experiencia de diferentes deportistas tras el uso de soportes plantares.	
Profesor que avala la estancia: Laura Ramos Petersen	Teléfonos de contacto: 686583936 /
Fecha inicio de la estancia: 10/04/2023	
Fecha finalización de la estancia: 10/07/2023	

Lo que comunica a los efectos oportunos,

Fecha

Firmado por RAMOS PETERSEN LAURA - ***0332** el día 21/07/2023 con un certificado emitido por AC FNMT Usuarios

Firmado por MORALES GIL ISABEL MARIA - ***5092** el día 21/07/2023 con un certificado emitido por AC FNMT Usuarios

Firma investigador de acogida

Firma Director/Secretario Departamento

Secretaría de Relaciones
Institucionales e Internacionalización
UNIVERSIDAD DEL GRAN ROSARIO

CERTIFICADO DE ESTANCIA ACADÉMICA INTERNACIONAL

Por medio de la presente, certifico que la **Mg. Cristina Molina García**, Nº de Pasaporte PAN736702, docente-investigadora del Grado en Podología de la Universidad Católica San Antonio de Murcia (UCAM), España, ha realizado una estancia de investigación en la Universidad del Gran Rosario entre el 27 de junio y el 30 de septiembre de 2022.

Cabe aclarar que dicha estancia se enmarcó en el cursado del Doctorado en Ciencias de la Salud que la docente lleva adelante en la UCAM.

Rosario, 19 de septiembre de 2022.

Lic. MARIA EUGENIA NORIEGA
SECRETARIA DE RELACIONES
INSTITUCIONALES e INTERNACIONALIZACIÓN
UNIVERSIDAD DEL GRAN ROSARIO

ANEXO 2. Publicación Estudio I

children

MDPI

Article

Overweight and Obesity: Its Impact on Foot Type, Flexibility, Foot Strength, Plantar Pressure and Stability in Children from 5 to 10 Years of Age: Descriptive Observational Study

Cristina Molina-García [1], José Daniel Jiménez-García [2,*], Daniel Velázquez-Díaz [3,4], Laura Ramos-Petersen [5], Andrés López-del-Amo-Lorente [1], Carlos Martínez-Sebastián [5] and Francisco Álvarez-Salvago [2,6]

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Abstract: Background: Overweight (OW) and childhood obesity (OB) may cause foot problems and affect one's ability to perform physical activities. The study aimed to analyze the differences in descriptive characteristics, foot type, laxity, foot strength, and baropodometric variables by body mass status and age groups in children and, secondly, to analyze the associations of the BMI with different physical variables by age groups in children. Methods: A descriptive observational study involving 196 children aged 5–10 years was conducted. The variables used were: type of foot, flexibility, foot strength and baropodometric analysis of plantar pressures, and stability by pressure platform. Results: Most of the foot strength variables showed significant differences between the normal weight (NW), OW and OB groups in children aged between 5 and 8. The OW and OB groups showed the highest level of foot strength. In addition, the linear regression analyses showed, in children aged 5 to 8 years, a positive association between BMI and foot strength (the higher the BMI, the greater the strength) and negative association between BMI and stability (lower BMI, greater instability). Conclusions: Children from 5 to 8 years of age with OW and OB show greater levels of foot strength, and OW and OB children from 7 to 8 years are more stable in terms of static stabilometrics. Furthermore, between 5 and 8 years, having OW and OB implies having more strength and static stability.

Keywords: pediatric obesity; children; plantar pressure; static stability

Citation: Molina-García, C.; Jiménez-García, J.D.; Velázquez-Díaz, D.; Ramos-Petersen, L.; López-del-Amo-Lorente, A.; Martínez-Sebastián, C.; Álvarez-Salvago, F. Overweight and Obesity: Its Impact on Foot Type, Flexibility, Foot Strength, Plantar Pressure and Stability in Children from 5 to 10 Years of Age: Descriptive Observational Study. *Children* **2023**, *10*, 696. https://doi.org/10.3390/children10040696

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1. Introduction

The World Health Organization (WHO) defines overweight (OW) and obesity (OB) as an abnormal accumulation of fat that represents a health risk [1]. It is also considered as "one of the most serious public health challenges of the 21st century" due to the fact that childhood OB continues to rise and more frequently occurs at younger ages with more serious health consequences associated with the early onset of OB [2,3]. According to the WHO, the prevalence of OW and OB in children and adolescents aged between 5 and 19 increased during the past years, rising from 4% of that population in 1975 to 18% in 2016 [4]. The World Obesity Federation has already stated that in 2030, 254 million children and adolescents will suffer from OB [5]. Interestingly, the vast majority of OW or obese children live in developing countries, where the rate of increase has been more than 30% higher than in developed countries in 2022 [1].

Considering previous literature, some studies have already highlighted how children who have OW and OB are more likely to suffer from several clinical comorbidities such as diabetes or metabolic syndrome [6], while others have already remarked how there is an association between increased risk of injury and childhood OB and gait, plantar pressures and stability [7–9], these being the main factors related to pain in the feet and lower limbs in children [10]. Notwithstanding, there is still controversy about the level of association between OW and OB and gait disturbance in children. In this sense, some studies have reported that children with OW and OB have weaker stability, a flatter foot pattern and a larger axis of the foot than normal weight (NW) children, which seems to impact plantar pressures [10–13], provoke pain and affect their quality of life [14,15]. Other studies, on the contrary, described no relationship between the OW and OB and foot pronation [16,17]. Therefore, and bearing in mind the lack of consensus and evidence, more studies are still needed to shed more light on this subject, which could be very useful for the clinical management of these young patients.

At the clinical level, the impact of gait is of great importance due to the fact that there is a large inverse correlation between physical activity level and plantar pressure [18]. This is mainly because deformities of the musculoskeletal system can be caused by an increase in pressure as a result of an increase in body mass index (BMI) [10]. Thus, by increasing plantar pressure, pain would increase and, consequently, the ability to perform physical activity would be limited, which could result in an impairment of children's quality of life [14,15]. In fact, it is known that suffering from alterations of this type limits the motivation of children to perform physical activities, which would further aggravate the problem of inactivity and suffering from OW and OB [19]. Considering all of the above, as the main clinical implication, all risk factors related to the onset of pain must be recognized. Signs such as excessive pressure or altered stability, should be recognized to prevent pain and complications in the short and long term, that is, to work from early prevention.

Therefore, this study aims to analyze the differences in descriptive characteristics, foot type, laxity, foot strength and baropodometric variables by body mass status and age groups in children and, secondly, to analyze the associations of BMI with variables foot type, laxity, foot strength and baropodometric variables by age groups in children.

2. Materials and Methods

2.1. Participants

One hundred and ninety-six children (78 males and 118 females) aged between 5 and 10 years were recruited for this descriptive observational study. This age range was chosen because it is the age at which the Foot Posture Index (FPI) is validated [20]. The study was approved by the Ethics Committee of the Catholic University of San Antonio de Murcia (Spain) (Code: CE022205). For the realization of the study, the Strengthening Reporting of Observational Studies in Epidemiology (STROBE) guidelines have been followed [21]. This study was performed in line with the principles of the Declaration of Helsinki [22].

The selection criteria of the sample were children aged 5–10 years, who do not have foot pain and who had the consent of the parents/guardians. Parents/guardians were previously informed about the study, completed a questionnaire and signed their consent to confirm their children's participation. Children who had any of the following conditions were excluded from the study: recent damage to lower limbs; congenital structural alterations affecting distal areas of the ankle joint, as well as those cases with pathological flatfoot caused by cerebral palsy; surgical treatments in the foot or lower extremity; or genetic and neurological or muscular pathology.

All children were evaluated between February and June 2022 in a primary school in the region of Murcia (Spain). For 5 months, all participating children completed all the assessments in one morning on the same schedule. Demographic and anthropometric data were collected from all children prior to the investigation. Children were assigned a specific number to maintain confidentiality. To examine them, they were asked to be barefoot and in light clothing (t-shirts and shorts) and were individually evaluated by two expert clinicians

at the same time. If these two clinicians disagreed during measurements of the same child, a third clinician decided which of the two values was more accurate. Similarly, another clinician who was not involved in the assessments was in charge of analyzing the data.

Before starting the test, each test was demonstrated and explained to every child. In this sense, each item of each test had to be performed three times, and the measurements obtained were averaged. Children received standard verbal encouragement and support throughout the whole testing procedure. When a child made a procedural error, the instructions and demonstrations were repeated and the child was allowed to try again; each child was allowed to fail a maximum of 5 times. All children completed all the measurements correctly.

2.2. Measurement of the Variables

2.2.1. Anthropometric Measures

Height was measured with a calibrated portable SECO 7710 m, with a bubble level fixed to the arm for greater accuracy, while weight was measured with Digital Pegasus Scales, with a margin of error of 0.05 kg and keeping subjects with as little clothing as possible (shirt and shorts).

To establish cut-off points for specific BMI by sex and age, cut-off points established in previous bibliography were considered [23,24], children were categorized as normal weight "NW", overweight "OW" or obese "OB".

2.2.2. Type of Foot, Laxity and Foot Strength

To find out what type of foot each child had, the evaluation of each foot was carried out by measuring the Foot Posture Index (FPI-6) with the subjects standing barefoot, in a relaxed position, on a 50 cm bench to facilitate visual and manual inspection. The FPI-6 rates 6 aspects of foot anatomy in the 3 planes of the foot. The FPI-6 takes into account the posture of the hindfoot, midfoot and forefoot. The FPI-6 provides a total value from −12 points (highly supinated) to +12 points (highly pronated). Interobserver reliability for FPI-6 in the pediatric population has reached a consistent weighted Kappa value (Kw = 0.86) in a sample of children aged 5 to 16 years of age [25].

To recognize whether the children had joint hypermobility (JH) or hyperlaxity, two scales and one test were also used: the Beighton Scale [26], the Lower Limb Assessment Score (LLAS) [27], and the Ankle Lunge Test [28]. For both scales, goniometry was used, which is a valid instrument to measure generalized joint mobility in school-age children [29].

The Beighton scale is used to observe if the child presents JH at a general level, that is, in the wrist, the metacarpophalangeal joint of the fifth metacarpal, in the elbow, in the knee (all bilateral and without weight bearing) and in the lumbosacral spine. The Beighton scale has a score of 9 points, so the usual arbitrary cutoff of 5/9 or higher indicates that the child has JH. This scale has shown to be reliable, with a Kw 0.81 [26].

The LLAS measures JH, but of the lower extremity. The hip, knee, ankle, subtalar joint, midtarsal joint and metatarsophalangeal joint were assessed. On the LLAS scale, each limb produces a final score of 12 points, so a score of 7/12 or higher indicates JH. The LLAS has shown to be reliable, with an intraclass correlation coefficient (ICC) of 0.84 [27].

The Ankle Lunge Test assesses the range of weight-bearing ankle dorsiflexion with the knee flexed. To quantify the Ankle Lunge Test, a digital inclinometer (Smart Tool™) was used, which was applied to the anterior surface of the tibia to measure ankle dorsiflexion. This test has shown to be reliable, with an intra-assessed ICC of 0.98 and an inter-assessed ICC of 0.97 [28].

Isometric muscle strength was quantified using the Lafayette Instrument Company Hand Dynamometer, Model 01160, Lafayette, Indiana, U.S.A. The device was calibrated at the factory, according to the manufacturer's data, at a sensitivity of 0.1 kg and a range of 0.0 to 199.9 kg. Each child was placed in a long sitting position (hips flexed and knees extended) on an examination table with a backrest. Isometric foot inversion and eversion muscle strength, and ankle plantarflexion and dorsiflexion was measured according to a standard-

ized procedure [30]. This measurement has shown good intra-rater (ICC = 0.92–0.97) and inter-rater (ICC = 0.80–0.95) reliability [31].

2.3. Baropodometry

The baropodometric analysis was performed with the RSscan Footscan® 9 platform, with dimensions of 578 mm × 418 mm × 12 mm. The platform contains 4096 sensors (arranged in a 64 × 64 matrix), the dimensions of the sensors are 7.62 mm × 5.08 mm and the active area is 488 mm × 325 mm. The precision range is 1–127 N/cm^2 and the data acquisition frequency is 500 Hz with a 10-bit resolution.

Following the manufacturer's manual, the platform was calibrated before each session. Three baropodometric measurements in an orthostatic position and three stabilometric measurements in an orthostatic position with eyes open for 60 s were taken for each child; a minute of rest was left between each measurement. Children were asked to stand on the platform, with their own Fick angle, arms along the body, feet at the same height and facing forward towards a fixed point that was placed at eye level at a distance of 3.8 m. Before data collection, children were allowed to familiarize themselves with the platform until they were confidently able to perform it.

The parameters considered were the % of pressure distribution in left and right leg, forefoot and rearfoot, left (C1) and right (C2) forefoot and left (C3) and right (C4) rearfoot for both static and stabilometry. In addition, in the stabilometric measurement, the following parameters were measured:

- Position (minimum–maximum *x*-*y* axis): the current, minimum and maximum position in millimeter for the x- and y-coordinate;
- Range (interval–average x-y): the spread between the minimum and maximum position in millimeters for the x- and y-coordinate;
- Travelled distance: the length of the center of pressure line in millimeters;
- Ellipse area: the area of the calculated center of pressure ellipse in square millimeters;
- Principal–second axis ellipse: Length of the major–minor axis of the ellipse of the center of pressure of the left and right foot, measured in millimeters.

The reliability of the Footscan® system (RSscan International, Olen, Belgium) has been demonstrated by different investigations with ICC values from good to excellent for the intra- and inter-evaluator scores (ICC 0.81–0.86 and ICC 0.87–0.95, respectively) on plantar pressure variables [32].

2.4. Statistical Analysis

All variables were checked for normality using both graphical and statistical procedures. Differences in descriptive characteristics, type of foot, laxity, foot strength and baropodometric characteristics of the overall sample by age and body mass status were examined applying the t-test. For that, three age groups were created: (1) 5–6 years; (2) 7–8 years; and (3) 9–10 years. Moreover, two BMI groups were also created: (1) children with NW and (2) children with OW and OB.

Then, linear regression analyses were performed to analyze the association of BMI with type of foot, laxity, foot strength and baropodometric variables across all three age groups. Previously, sex interaction was analyzed by including the interaction terms in the code of regression analyses. Since there was no sex interaction, the sample was segmented by age and BMI. In addition, the collinearity of the regression models was calculated using command .vif, which did not show independent variables with a coefficient > 10. Finally, for each regression model, the normality analyses were recalculated for the residuals for the models.

All analyses were performed using the STATA software for Windows version 13.0. The level of significance was set at $p < 0.05$.

3. Results

3.1. Descriptive Characteristics, Type of Foot, Laxity, Foot Strength and Baropodometric Characteristics of the Sample by Age and BMI in Children

The characteristics of the sample by age and body mass status are shown in Table 1. In terms of descriptive characteristics, there were no significant differences between the NW group and the OW and OB groups for the three age groups with respect to age and height (all $p > 0.005$). However, there were significant differences between the NW group and the OW and OB groups in all three age groups for weight and BMI (all < 0.005).

Table 1. Descriptive characteristics, type of foot, laxity, foot strength and baropodometric characteristics of the sample by age and body mass status in children.

	5 to 6 Years				7 to 8 Years				9 to 10 Years			
Variables	**Total n = 79 M/F**	**NW n = 55 M/F**	**OW and OB n = 24 M/F**	***p*** [a]	**Total n = 67 M/F**	**NW n = 45 M/F**	**OW and OB n = 22 M/F**	***p*** [a]	**Total n = 50 M/F**	**NW n = 29 M/F**	**OW and OB n = 21 M/F**	***p*** [a]
Physical characteristics												
Age (years)	6.14 ± 0.48	6.13 ± 0.48	6.17 ± 0.46	0.742	7.98 ± 0.62	7.92 ± 0.58	8.11 ± 0.67	0.221	9.51 ± 0.29	9.52 ± 0.29	9.51 ± 0.40	0.944
Weight (kg)	23.10 ± 4.47	21.22 ± 2.72	27.42 ± 4.75	**<0.001**	29.48 ± 7.18	25.62 ± 3.08	37.38 ± 6.68	**<0.001**	37.30 ± 7.36	33.25 ± 4.04	42.89 ± 7.96	**<0.001**
Height (cm)	1.17 ± 0.05	1.17 ± 0.05	1.18 ± 0.05	0.309	1.28 ± 0.07	1.27 ± 0.06	1.30 ± 0.06	0.160	1.39 ± 0.07	1.39 ± 0.06	1.38 ± 0.07	0.512
BMI ($kg \cdot m^{-2}$)	16.77 ± 2.27	15.54 ± 1.02	19.60 ± 2.28	**<0.001**	17.88 ± 3.48	15.95 ± 1.07	21.83 ± 3.39	**<0.001**	19.30 ± 3.53	17.06 ± 1.26	22.38 ± 3.53	**<0.001**
Gender, *n* (%)	39(49)/ 40(51)	30 (55)/ 25(45)	9(38)/ 15(62)	**0.857** [b]	24(36)/ 43(64)	16 (36)/ 29(64)	8(36)/ 14(64)	**0.232** [b]	15(30)/ 35(70)	8(28)/ 21(72)	7(33)/ 14(67)	**0.178** [b]
Type of foot, laxity and foot strength												
FPI total (Score)	7.76 ± 5.56	7.42 ± 5.31	8.54 ± 5.98	0.407	7.39 ± 5.58	7.53 ± 5.89	7.09 ± 4.99	0.763	8.34 ± 5.24	9.00 ± 0.97	7.42 ± 5.70	0.318
Lunge test (°)	106.7 ± 10.5	108.2 ± 10.4	103.4 ± 10.3	0.065	97.62 ± 13.12	99.00 ± 13.62	94.81 ± 11.85	0.223	95.40 ± 12.24	95.14 ± 13.26	95.76 ± 10.97	0.860
Beighton (Score)	3.49 ± 2.98	3.71 ± 3.14	3.00 ± 2.59	0.334	3.10 ± 3.07	2.67 ± 3.02	4.00 ± 3.05	0.095	2.34 ± 2.73	2.79 ± 2.82	1.71 ± 2.53	0.170
R LLAS (Score)	6.64 ± 3.49	7.05 ± 3.56	5.71 ± 3.21	0.116	5.43 ± 3.54	5.20 ± 3.62	5.91 ± 3.39	0.445	4.30 ± 3.18	4.86 ± 3.40	3.52 ± 2.77	0.145
L LLAS (Score)	6.51 ± 3.55	6.85 ± 3.61	5.71 ± 3.35	0.189	5.42 ± 3.48	5.20 ± 3.58	5.86 ± 3.31	0.468	4.30 ± 3.33	4.83 ± 3.50	3.57 ± 3.01	0.190
R eversion (N)	6.62 ± 2.90	6.39 ± 3.37	7.14 ± 1.21	0.294	7.52 ± 1.88	7.10 ± 1.89	8.37 ± 2.03	**0.013**	11.84 ± 2.37	12.02 ± 2.34	11.59 ± 2.43	0.536
L eversion (N)	6.00 ± 1.44	5.70 ± 1.32	6.67 ± 1.48	**0.005**	7.22 ± 2.47	6.99 ± 2.68	7.68 ± 1.95	0.290	11.28 ± 2.09	11.33 ± 1.73	11.22 ± 2.56	0.877
R inversion (N)	7.38 ± 1.34	7.10 ± 1.16	8.05 ± 1.51	**0.003**	8.67 ± 1.58	8.34 ± 1.56	9.33 ± 1.44	**0.014**	12.33 ± 2.02	12.42 ± 2.07	12.20 ± 1.99	0.717
L inversion (N)	6.67 ± 1.37	6.47 ± 1.29	7.12 ± 1.46	0.054	7.75 ± 1.83	7.42 ± 1.75	8.39 ± 1.88	**0.041**	11.66 ± 1.79	11.70 ± 1.65	11.60 ± 2.01	0.841
R. plantarflexion (N)	10.59 ± 2.62	10.04 ± 2.03	2.63 ± 3.37	**0.004**	14.28 ± 3.88	13.85 ± 3.68	15.15 ± 4.20	0.199	26.06 ± 5.77	25.89 ± 5.50	26.30 ± 6.27	0.810
L plantarflexion (N)	10.21 ± 2.73	9.78 ± 2.22	11.19 ± 3.50	**0.034**	14.52 ± 5.84	13.56 ± 4.19	16.46 ± 8.03	0.055	25.17 ± 5.66	24.78 ± 5.17	25.70 ± 6.36	0.574
R dorsiflexion (N)	6.67 ± 1.18	6.45 ± 1.02	7.18 ± 1.38	**0.010**	7.53 ± 1.59	7.25 ± 1.46	8.11 ± 1.70	**0.036**	10.45 ± 1.39	10.55 ± 1.21	10.33 ± 1.63	0.590
L dorsiflexion (N)	6.71 ± 2.16	6.62 ± 2.38	6.94 ± 1.56	0.544	7.21 ± 1.71	6.89 ± 1.50	7.87 ± 1.94	**0.025**	10.17 ± 1.56	10.22 ± 1.16	10.09 ± 1.83	0.755

Table 1. *Cont.*

Variables	5 to 6 Years				7 to 8 Years				9 to 10 Years			
	Total n = 79 M/F	NW n = 55 M/F	OW and OB n = 24 M/F	*p* [a]	Total n = 67 M/F	NW n = 45 M/F	OW and OB n = 22 M/F	*p* [a]	Total n = 50 M/F	NW n = 29 M/F	OW and OB n = 21 M/F	*p* [a]
Static variables (%)												
R-L difference static	7.78 ± 6.32	7.77 ± 6.68	7.80 ± 5.55	0.981	7.55 ± 5.63	7.22 ± 5.63	8.23 ± 5.71	0.497	7.32 ± 6.49	6.80 ± 4.22	8.05 ± 6.49	0.415
Forefoot static	41.40 ± 8.47	41.40 ± 8.96	38.76 ± 6.65	0.067	42.27 ± 8.26	42.93 ± 9.03	40.91 ± 6.36	0.351	43.86 ± 7.80	44.16 ± 8.50	43.44 ± 6.90	0.749
Rearfoot static	58.56 ± 8.46	57.39 ± 8.95	61.23 ± 6.66	0.063	57.72 ± 8.25	57.05 ± 9.02	59.08 ± 6.36	0.346	56.14 ± 7.80	55.83 ± 8.50	56.56 ± 6.90	0.749
C1 static	22.01 ± 7.03	22.76 ± 7.67	20.30 ± 4.98	0.152	21.74 ± 4.91	22.32 ± 5.35	20.56 ± 3.70	0.171	22.52 ± 5.00	22.92 ± 5.45	21.96 ± 4.36	0.508
C2 static	19.84 ± 4.03	20.33 ± 4.13	18.72 ± 4.57	0.126	20.55 ± 4.84	20.65 ± 4.88	20.34 ± 4.87	0.811	21.35 ± 4.45	21.24 ± 4.76	21.49 ± 4.09	0.845
C3 static	30.27 ± 6.17	29.58 ± 6.66	31.86 ± 4.60	0.131	29.86 ± 5.35	30.05 ± 5.82	29.46 ± 4.35	0.675	29.02 ± 5.16	29.04 ± 4.52	29.00 ± 6.05	0.977
C4 static	28.33 ± 5.58	27.87 ± 5.89	29.38 ± 4.73	0.274	27.85 ± 5.99	26.99 ± 6.26	29.62 ± 5.06	0.092	27.12 ± 6.79	26.78 ± 7.24	27.57 ± 6.27	0.689
Stabilometric variables (static) (%)												
R-L difference stabilometric	9.25 ± 7.18	9.30 ± 7.57	9.14 ± 6.33	0.929	7.30 ± 5.92	7.38 ± 5.52	7.13 ± 5.93	0.872	9.00 ± 8.12	9.28 ± 6.29	8.60 ± 10.28	0.773
Forefoot stabilometric	39.07 ± 6.44	39.84 ± 7.21	37.30 ± 3.73	0.107	40.93 ± 7.74	40.82 ± 8.92	41.13 ± 4.61	0.880	42.91 ± 8.12	44.04 ± 8.27	41.35 ± 5.28	0.198
Rearfoot stabilometric	60.82 ± 6.49	60.16 ± 7.21	62.35 ± 4.16	0.169	59.07 ± 7.73	59.17 ± 8.92	58.86 ± 7.74	0.880	57.09 ± 7.24	55.96 ± 8.27	58.64 ± 5.31	0.199
C1 stabilometric	20.49 ± 3.47	20.93 ± 5.14	19.48 ± 3.47	0.208	21.14 ± 4.40	21.19 ± 4.89	21.05 ± 3.26	0.912	22.01 ± 4.38	22.72 ± 4.72	21.01 ± 3.74	0.175
C2 stabilometric	18.62 ± 3.61	18.91 ± 3.79	17.96 ± 3.12	0.286	19.77 ± 4.84	19.62 ± 5.41	20.08 ± 3.51	0.724	20.92 ± 4.31	21.33 ± 4.81	20.36 ± 3.55	0.438
C3 stabilometric	19.84 ± 4.13	20.33 ± 4.13	18.72 ± 4.57	0.126	20.55 ± 4.84	20.64 ± 4.88	20.34 ± 4.88	0.811	21.35 ± 4.45	21.24 ± 4.76	21.49 ± 4.09	0.845
C4 stabilometric	32.47 ± 5.11	32.13 ± 5.77	33.22 ± 3.11	0.386	30.40 ± 5.37	30.77 ± 5.84	29.63 ± 4.27	0.568	27.28 ± 6.06	26.87 ± 6.70	27.83 ± 5.16	0.583
Stabilometric variables (gravity center) (mm)												
Minimum *x*-axis	−0.72 ± 5.64	−1.05 ± 6.27	0.04 ± 3.86	0.431	−0.40 ± 4.18	−0.40 ± 4.36	−0.41 ± 3.88	0.993	1.16 ± 2.96	0.97 ± 3.04	1.43 ± 2.89	0.590
Minimum *y*-axis	−7.82 ± 4.60	−8.16 ± 4.97	−7.04 ± 3.59	0.322	−6.52 ± 3.54	−6.77 ± 3.83	−6.00 ± 2.89	0.403	−7.42 ± 4.49	−7.93 ± 4.49	−6.71 ± 4.20	0.337
Maximum *x*-axis	7.13 ± 4.01	7.36 ± 4.01	6.58 ± 4.04	0.429	6.87 ± 4.43	7.49 ± 4.78	5.59 ± 3.33	0.099	7.64 ± 4.02	7.69 ± 3.92	7.57 ± 4.25	0.919
Maximum *y*-axis	1.58 ± 4.40	1.65 ± 4.76	1.42 ± 3.51	0.826	1.57 ± 3.56	2.04 ± 3.80	0.59 ± 2.82	0.116	1.00 ± 4.44	0.21 ± 4.49	2.10 ± 5.40	0.140
Interval x	7.78 ± 5.45	8.35 ± 5.91	6.50 ± 4.00	0.167	7.33 ± 4.28	7.98 ± 4.74	6.00 ± 2.76	0.075	6.66 ± 3.29	7.07 ± 3.60	6.09 ± 2.79	0.306
Interval y	9.49 ± 4.93	9.85 ± 5.45	8.67 ± 3.42	0.327	8.09 ± 4.28	8.82 ± 4.13	6.59 ± 2.75	**0.036**	8.48 ± 3.89	8.21 ± 3.93	8.86 ± 3.90	0.565
Average x	3.76 ± 5.02	3.80 ± 5.53	3.67 ± 3.66	0.914	3.32 ± 4.03	3.64 ± 4.21	2.68 ± 3.63	0.362	4.50 ± 3.51	4.38 ± 3.58	4.66 ± 3.50	0.778

Table 1. *Cont.*

Variables	5 to 6 Years				7 to 8 Years				9 to 10 Years			
	Total n = 79 M/F	**NW n = 55 M/F**	**OW and OB n = 24 M/F**	***p*** [a]	**Total n = 67 M/F**	**NW n = 45 M/F**	**OW and OB n = 22 M/F**	***p*** [a]	**Total n = 50 M/F**	**NW n = 29 M/F**	**OW and OB n = 21 M/F**	***p*** [a]
Average y	−2.94 ± 3.53	−3.07 ± 3.75	−2.67 ± 3.03	0.641	−2.42 ± 2.86	−2.24 ± 3.25	−2.77 ± 2.86	0.519	−3.14 ± 4.06	−3.82 ± 3.84	−2.19 ± 4.25	0.161
Distance traveled	50.19 ± 29.34	54.11 ± 31.87	41.21 ± 20.35	0.072	42.65 ± 29.33	47.71 ± 33.30	32.32 ± 14.66	**0.042**	40.14 ± 18.45	42.79 ± 19.27	36.47 ± 17.02	0.236
Ellipse area (mm^2)	14.71 ± 20.33	16.27 ± 23.27	11.13 ± 10.55	0.304	10.43 ± 11.79	12.20 ± 13.64	6.82 ± 5.09	0.079	8.84 ± 6.70	8.66 ± 6.32	9.10 ± 7.35	0.821
Principal axis ellipse	5.73 ± 2.9	5.89 ± 3.17	5.37 ± 2.44	0.480	4.54 ± 2.36	4.87 ± 2.61	3.86 ± 1.58	0.102	4.78 ± 1.96	4.72 ± 2.34	4.86 ± 1.96	0.833
Second axis ellipse	2.65 ± 1.6	2.82 ± 1.73	2.25 ± 1.07	0.142	2.37 ± 1.34	2.58 ± 1.47	1.95 ± 0.89	0.072	2.18 ± 0.90	2.17 ± 0.80	2.19 ± 1.03	0.944

Values are presented as mean ± standard deviation or percentages. *t*-test square statistics was applied. Statically significant between body mass status group for each age group are highlighted in bold. C1: left forefoot load; C2: right forefoot load; C3: left hindfoot load; C4: right hindfoot load; F: female; FPI: Foot Posture Index; L: left; LLAS: Lower Limb Assessment Score; M: male; NW: Normal Weight; Ob: Obesity; OW: Overweight; R: Right. [a] *p* shows differences for all variables between groups of body mass status, except [b] for gender which shows differences in body mass index between sexes.

Then, type of foot and laxity were analyzed; however, there were no significant differences between NW groups and OW and OB groups in all three age groups for any of the variables (all $p > 0.05$). In relation to foot strength variables, most variables of eversion, inversion and plantar flexion and dorsiflexion strength showed significant differences between the NW group and the OW and OB groups in the 5–6 and 7–8 years groups ($p < 0.005$). However, there were no significant differences between the NW group and the OW and OB group in the 9 to 10 years group for foot strength variables ($p > 0.005$).

As for static variables, there were no significant differences between the NW group and the OW and OB groups in all three age groups for any of the variables (all $p > 0.05$). This same trend was observed with the analysis of the stabilometric variables, where there were no significant differences between the NW group and the OW and OB groups in all three age groups for none of the variables (all $p > 0.05$), except for the interval and distance traveled in the 7–8 years group (both $p < 0.05$).

3.2. Associations of BMI with Type of Foot, Laxity, Foot Strength and Baropodometric Variables by Age Groups in Children

The regression analyses of the BMI with type of foot, laxity, foot strength and baropodometric characteristics by age group are shown in Table 2. Regarding type of foot and laxity, there were no significant associations of BMI with the variables analyzed (all $p > 0.05$), except for the Beighton Scale in children 7–8 years ($p < 0.049$). In relation to foot strength variables, all variables showed positive significant associations of BMI with eversion, inversion and plantar flexion and dorsiflexion strength (all $p < 0.05$), except for right eversion and left dorsiflexion in children 5–6 years. In children 7–8 years, BMI was positively associated with left and right inversion strength (all $p < 0.05$). However, there were no significant associations of BMI with foot strength variables in children 9 to 10 years (all $p > 0.05$).

As for the associations of BMI with static variables, there were no significant associations of BMI with any of the static variables in all three age groups (all $p > 0.05$), except for C4 static in children 7–8 years ($p = 0.043$). Then, the associations of BMI with stabilometric variables were performed. There were no significant associations of BMI with any of the stabilometric variables in all three age groups (all $p > 0.05$), except for left–right difference in children 9 to 10 years ($p = 0.032$). In relation to gravity center, BMI was negatively associated with interval x, distance traveled, and secondary axis ellipse in children 5–6 years (all $p < 0.05$). Finally, BMI was negatively associated with interval x and y, maximum

y-axis and principal axis ellipse in children 7–8 years (all $p < 0.05$). However, there were no significant associations of BMI with any of the gravity center variables in children 9–10 years (all $p > 0.05$).

Table 2. Associations of BMI with type of foot, laxity, foot strength and baropodometric variables by age groups in children.

	5 to 6 Years			7 to 8 Years			9 to 10 Years		
Variables	**R^2**	**β**	***p* Value**	**R^2**	**β**	***p* Value**	**R^2**	**β**	***p* Value**
Type of foot, laxity and foot strength									
FPI total (Score)	0.02	0.131	0.247	0.01	0.082	0.505	0.01	−0.050	0.729
Lunge test (°)	0.04	−0.210	0.062	0.05	−0.212	0.085	0.02	−0.129	0.371
Beighton Scale (Score)	0.01	−0.072	0.527	0.06	0.241	**0.049**	0.02	−0.145	0.313
Right LLAS (Score))	0.04	−0.193	0.088	0.00	0.017	0.887	0.02	−0.131	0.364
Left LLAS (Score)	0.03	−0.169	0.137	0.00	0.006	0.963	0.02	−0.127	0.377
Right eversion (N)	0.03	0.160	0.158	0.04	0.206	0.094	0.00	0.016	0.911
Left eversion (N)	0.21	0.460	**<0.001**	0.01	0.083	0.504	0.02	0.126	0.381
Right inversion (N)	0.20	0.450	**<0.001**	0.09	0.298	**0.014**	0.00	0.018	0.904
Left inversion (N)	0.10	0.312	**0.005**	0.06	0.242	**0.048**	0.00	0.050	0.731
Right plantarflexion(N)	0.02	0.396	**<0.001**	0.05	0.218	0.076	0.00	0.012	0.931
Left plantarflexion (N)	0.11	0.329	**0.003**	0.06	0.238	0.052	0.00	0.064	0.656
Right dorsiflexion (N)	0.10	0.313	**0.005**	0.02	0.144	0.244	0.00	−0.008	0.954
Left dorsiflexion (N)	0.02	0.136	0.230	0.01	0.117	0.343	0.00	−0.051	0.725
Static variables									
Left–right difference (%)	0.00	0.054	0.638	0.01	0.114	0.360	0.07	0.058	0.058
Forefoot static (%)	0.03	−0.159	0.161	0.02	−0.124	0.317	0.00	−0.045	0.754
Rearfoot static (%)	0.03	0.163	0.150	0.02	0.124	0.317	0.00	0.045	0.754
C1 static (%)	0.01	−0.121	0.289	0.04	−0.197	0.110	0.00	−0.026	0.857
C2 static (%)	0.03	−0.170	0.134	0.00	−0.013	0.916	0.00	−0.047	0.741
C3 static (%)	0.02	0.145	0.203	0.01	−0.085	0.489	0.01	0.075	0.603
C4 static (%)	0.01	0.081	0.478	0.06	0.248	**0.043**	0.00	−0.004	0.976
Stabilometric variables (static)									
Left-right difference (%)	0.00	0.002	0.986	0.01	0.100	0.418	0.09	0.303	**0.032**
Front stabilometric (%)	0.02	−0.147	0.194	0.00	0.026	0.832	0.05	−0.213	0.137
Rear stabilometric (%)	0.02	0.129	0.256	0.00	−0.026	0.832	0.05	0.213	0.137
C1 stabilometric (%)	0.01	−0.100	0.378	0.00	−0.053	0.668	0.02	−0.157	0.275
C2 stabilometric (%)	0.02	−0.123	0.280	0.01	0.092	0.454	0.04	−0.199	0.166
C3 stabilometric (%)	0.00	0.046	0.688	0.02	−0.125	0.312	0.04	0.189	0.187
C4 stabilometric (%)	0.02	0.127	0.265	0.01	0.083	0.500	0.00	0.026	0.856
Stabilometric variables (gravity center)									
Minimum *x*-axis (mm)	0.02	0.138	0.224	0.00	0.062	0.619	0.01	0.091	0.529
Minimum *y*-axis (mm)	0.02	0.139	0.223	0.01	0.082	0.507	0.00	0.044	0.756
Maximum *x*-axis (mm)	0.01	−0.121	0.287	0.03	−0.165	0.181	0.00	−0.001	0.997
Maximum *y*-axis (mm)	0.00	−0.057	0.618	0.07	−0.263	**0.031**	0.03	0.177	0.218
Interval x (mm)	0.05	−0.233	**0.039**	0.06	−0.240	**0.050**	0.01	−0.113	0.434
Interval y (mm)	0.03	−0.163	0.151	0.09	−0.296	**0.015**	0.02	0.149	0.301
Average x (mm)	0.00	0.037	0.749	0.01	−0.077	0.537	0.01	0.070	0.631
Average y (mm)	0.00	0.049	0.669	0.02	−0.133	0.281	0.02	0.142	0.324
Distance traveled (mm)	0.06	−0.243	**0.030**	0.05	−0.232	0.059	0.03	−0.176	0.221
Ellipse area (1DS) (mm^2)	0.04	−0.195	0.084	0.06	−0.236	0.054	0.00	0.010	0.947
Principal axis ellipse (mm)	0.04	−0.188	0.096	0.09	−0.291	**0.017**	0.01	0.088	0.541
Secondary axis ellipse (mm)	0.05	−0.231	**0.040**	0.04	−0.198	0.108	0.00	−0.055	0.702

Statically significant are highlighted in bold. C1: left forefoot load; C2: right forefoot load; C3: left hindfoot load; C4: right hindfoot load; FPI: Foot Posture Index; L: left; LLAS: Lower Limb Assessment Score; R: Right.

4. Discussion

The purpose of this study was to analyze the differences in descriptive characteristics, foot type, laxity, foot strength and baropodometric variables by body mass status and age

groups in children and, secondly, to analyze the associations of BMI with foot type, laxity, foot strength and baropodometric variables by age groups in children.

The main findings of the present work revealed that most foot strength variables showed significant differences between the NW groups and the OW and OB groups in children 5–6 and 7–8 years, OW and OB children having a higher level. Moreover, some stabilometric variables showed significant differences between the NW group and the OW and OB group in children 7–8 years. Then, linear regression analyses showed positive associations of BMI with most of the foot strength variables in children 5–6 and 7–8 years, as well as negative associations with the gravity center variables.

Considering our results, it can be observed that OW and OB children between 5 and 8 years have significantly higher levels of foot strength compared to NW children and that NW children between 7 and 8 years show worse stabilometric values compared to children with OW and OB. On the one hand, and despite the limited evidence, only a few articles have shown to date how the foot type, strength and flexibility can influence foot structure, pressure distribution and other possible musculoskeletal disorders [10,13,14]. In this regard, our results reflect how children with OW and OB had more foot isometric strength. No previous studies have shown a relationship between OW and OB and isometric strength of the foot. However, a previous study showed a relationship between OW and OB and isometric strength of the hands [33]. Thus, in our humble opinion, we believe this is the first study to assess the impact of isometric foot strength in children with OW and OB. On the other hand, and although the evidence so far supports the fact that children with OW and OB are less stable when walking [7], it is possible that this dissimilarity was caused by the same fact mentioned by Kjölhede et al. (2014), in which they concluded that children with NW tend to be more restless than children with OW and OB [34]. Therefore, considering that, in our study, we analyzed the pressures in static/stabilometry and not in dynamic motion could explain why NW children showed worse stabilometry.

This study also explored in the regression analysis the association between OW and OB on the other dependent variables. Firstly, it is important to remark that there is no significant association between type of foot (FPI-6) and OW and OB. In this sense, these results are in contrast and in line with those shown by previous literature, as some authors have concluded that there was a correlation between flatter feet and children with OW and OB [35,36], while others have stated that there is no relationship between increased BMI in children and having "flatter" feet [37–39]. In this sense, we believe that the controversy among these studies investigating the relationship between BMI and OW and OB could be the method of grading the foot. Therefore, future studies should unify the method of evaluating flatfoot to facilitate the comparison of results and to be able to draw more accurate and precise conclusions.

When it comes to JH, previous evidence showed discrepancies because some studies have shown that children with OW and OB have a stronger relationship with JH [40], while others confirm that JH is more prevalent in underweight children [41]. In this sense, our results suggest that having a higher BMI is associated with having more JH overall from 7 to 8 years of age. Hence, more studies are needed to corroborate this association, since JH is a risk factor for musculoskeletal pain during adolescence [40].

As far as we know at present, there are no studies that relate BMI to ankle muscle strength and its possible involvement with excess plantar pressures, gait biomechanics and musculoskeletal alterations in the lower limbs in children. This issue has only been addressed in the adult population, where it has been observed that OW and OB decrease ankle muscle strength and quality of life [42,43]. In our study, we have observed how an increase in BMI is directly related to a greater isometric strength of ankle movements (inversion, eversion, dorsiflexion and plantar flexion) mainly in younger children (5–6 years of age). At this point, even if OB children show more strength, it is still of clinical alarm since this can translate into joint overload and having more strength does not mean that they execute movements more correctly, a fact that has already been mentioned in previous research [33,44–46].

Hereinafter, the results of the present study are consistent with previous research, where it was reported that an increase in BMI is related to alterations in static plantar pressures and stabilometry in children [7,8,47,48]. In this way, our regression analyses showed in children 7–8 years of age that the pressure in the right heel is significantly higher. In this sense, studies such as Bittar et al. [49] and Feka et al. [48] showed that BMI is associated with greater pressure in the hindfoot. Additionally, and regarding the difference in pressure between the left and right leg, we also found that the BMI mainly influences children of the age of 9–10 years, who tend to receive more pressure in the right foot. In this sense, this result is in line and in contrast with previous research, since some studies mention that there is more support in the right foot [48,50,51], while Bittar el al. [49] mention that there is more support in the left foot. Therefore, more studies are still needed to clarify this fact in children because an asymmetrical distribution of loads could lead to asymmetrical growth of the limbs or overloads, leading to postural deformities.

Finally, we could also observe a relationship between having a higher BMI and presenting better static stability in children from 5 to 8 years of age; that is, they had fewer oscillations. However, it is important to remark that this better static stability due to higher BMI values could also be translated into a worse capacity to compensate for the overload that their feet receive due to excess weight. This clinical reasoning is built on the results of previous studies that have already highlighted the impact of OW and OB on stability [7,11,52], remarking how an excessive BMI leads to mechanical overexertion which cannot be compensated for by the musculoskeletal system [53]. The basis of most movements is due to balance control [7], so if this control is affected, it would also affect the daily living activities of children with OW and OB. Hence, these findings seem to confirm that OW and OB negatively impact the normal musculoskeletal development of children's feet compared to children with NW. In this way, we also dare to speculate that, in turn, this could have a negative impact on their quality of life and global health status.

Although there are a wide variety of plantar pressure measurement systems [54–56], such as the use of instrumented insoles, the pressure platform was used because in children the size of the foot varies greatly from one child to another, even more in an age range as wide as 5 to 10 years of age. Perhaps if the instrument templates had been used instead of the pressure platform, the data would have been more accurate.

This study has several limitations that deserve attention. First, the values used as cut-off points to divide children as normal weight "NW", overweight "OW" or obese "OB" has been previously used and accepted [23,24], although other cut-off values could have modified our results. Secondly, although the RSscan Footscan® 9 pressure platform has demonstrated good intra-rater and inter-rater reliability [32], it only measures forces perpendicular to the ground, not taking into account forces on other planes. Thirdly, it should take into account that the age range of our study was from 5– to 10 years of age, so direct comparisons with other studies could be difficult due to other possible age ranges. Finally, the data collected through the pressure platform are static; hence, we cannot just infer that static positioning will directly impact dynamic movements.

Despite these cited limitations, this study has several strengths. First, it comprised a wide age range of children. Secondly, is the first study to assess foot type, strength and flexibility in the same sample of obese children. Thirdly, the measuring instruments implemented in our study are widely used in both clinical practice and research, which, together with the data obtained and taking into account the increasing rate of childhood OB [1–3], our findings may have important clinical and public health implications.

The clinical implications of the findings presented in this study imply that signs such as excessive pressure, impaired stability or increased foot strength must be recognized to prevent future pain and possible short- and long-term complications. OW and OB prophylaxis, which is becoming more frequent every day, as well as early diagnosis of musculoskeletal deformities, will have long-term effects on the general health status of children. An alteration in the feet and all that this implies (strength, flexibility, pressure, stability) can have consequences such as decreased physical activity, aggravating the OW

and OB problem. Children with OW and OB should be managed by a multidisciplinary team, which should be made up of psychologists, nutritionists, pediatricians, rehabilitators, podiatrists and physiotherapists.

5. Conclusions

Children from 5–8 years of age with OW and OB show greater levels of foot strength and also how OW and OB children from 7–8 years are more stable in static stabilometrics. Furthermore, the linear regression analyses showed how, between 5 and 8 years, having OW and OB implies having more strength and static stability. This should not be translated as a positive aspect for health in this population. Considering the scarcity of studies, that OB rates continue to grow and that having greater strength and that stability as a consequence of a higher BMI is not beneficial to health, more studies are still needed in this regard in order to provide a more adequate management of the consequences of OB in children.

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ANEXO 3. Publicación Estudio IV

children

MDPI

Systematic Review

Efficacy of Plantar Orthoses in Paediatric Flexible Flatfoot: A Five-Year Systematic Review

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Abstract: Paediatric flexible flatfoot (PFF) is a very common condition and a common concern among parents and various healthcare professionals. There is a multitude of conservative and surgical treatments, with foot orthoses (FO) being the first line of treatment due to their lack of contraindications and because the active participation of the child is not required, although the evidence supporting them is weak. It is not clear what the effect of FO is, nor when it is advisable to recommend them. PFF, if left untreated or uncorrected, could eventually cause problems in the foot itself or adjacent structures. It was necessary to update the existing information on the efficacy of FO as a conservative treatment for the reduction in signs and symptoms in patients with PFF, to know the best type of FO and the minimum time of use and to identify the diagnostic techniques most commonly used for PFF and the definition of PFF. A systematic review was carried out in the databases PubMed, EBSCO, Web of Science, Cochrane, SCOPUS and PEDro using the following strategy: randomised controlled trials (RCTs) and controlled clinical trials (CCTs) on child patients with PFF, compared to those treated with FO or not being treated, assessing the improvement of signs and symptoms of PFF. Studies in which subjects had neurological or systemic disease or had undergone surgery were excluded. Two of the authors independently assessed study quality. PRISMA guidelines were followed, and the systematic review was registered in PROSPERO: CRD42021240163. Of the 237 initial studies considered, 7 RCTs and CCTs published between 2017 and 2022 met the inclusion criteria, representing 679 participants with PFF aged 3–14 years. The interventions of the included studies differed in diagnostic criteria, types of FO and duration of treatment, among others. All articles conclude that FO are beneficial, although the results must be taken with caution due to the risk of bias of the included articles. There is evidence for the efficacy of FO as a treatment for PFF signs and symptoms. There is no treatment algorithm. There is no clear definition for PFF. There is no ideal type of FO, although all have in common the incorporation of a large internal longitudinal arch.

Keywords: flatfoot; paediatrics; child; foot orthoses

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1. Introduction

Paediatric flexible flatfoot (PFF) is a common condition in children [1,2]. Ninety percent of appointments in foot clinics are related to flat feet (FF) [3]. Epidemiological studies indicate that 4% of 10-year-old children suffer from PFF and 10% of them are under treatment to prevent secondary pathologies during adulthood [4]. In addition, PFF is a common concern for parents and a highly debated topic by all healthcare professionals [5–7].

For decades, up to the present, PFF has been a highly controversial issue, being difficult to differentiate what is normal or pathological. There are also questions about

how to diagnose it, when it should be treated, when the physiological evolution should be allowed to continue, what is the best conservative treatment and when surgical treatment is necessary [8–10].

There is no universally accepted or precise definition for FF. Clinically, FF is understood as a flattening of the medial longitudinal arch when the subject is in a standing position [11]. FF is a triplanar presentation of the foot [12], accompanied by a valgus position of the calcaneus, medial prominence of the talus, flattened footprint, abduction of the forefoot with respect to the hindfoot and internal rotation of the tibia [5,13]. In the PFF, it is possible to correct the deformity when the person is not in a standing position, where the arch is present [14]. Therefore, there is controversy among different professionals regarding its treatment. Some professionals indicate that it is a physiological variant of foot development and that it will correct itself in time [15]. Other professionals indicate that PFF will slowly lead to pathologies in the foot, ankle or proximal structures, such as plantar fasciopathy, Achilles and posterior tibial tendinopathy, hallux limitus and rigidus, chondromalacia patellae and patellofemoral pain syndrome [5,16–20].

The most common symptoms are functional disability and general foot and leg pain, although the majority of PFF cases are asymptomatic [21]. Regardless of symptomatology, there are biomechanical abnormalities, including decreased ankle dorsiflexion, increased hindfoot eversion and forefoot supination [5,13,22].

The diagnosis is based on clinical tests, analysis of the footprint or radiology. The most widely used clinical tests are relaxed calcaneus position in standing, neutral calcaneal position in standing position, navicular drop, navicular drift, navicular height, foot posture index (FPI), Jack's test, double/single heel rise test (HRT), maximum pronation test, supination resistance test, pronation angle and too many toes test. Furthermore, assessments and evaluations such as genu valgus, asymmetry, tibial torsions, metatarsus adductus, flexibility assessment (most commonly assessed by Beighton scale or the Wynne-Davies criteria [23]), etc.) are used. In terms of the analysis of the footprint, it can be conducted by pedigraph, pressure platform, photopodogram and podoscope. Finally, radiographic measurements are the most objective ones, including assessment from two load projections. The most common radiology assessments are lateral and dorsoplantar talocalcaneal angle, angle of inclination of the calcaneus, talus and first metatarsal, medial and lateral Costa-Bartani angle, talus–first metatarsal angle, calcaneus–fifth metatarsal, tibial talus, line of Cyma and Schade [5,8,24–28].

There is a wide range of treatments for PFF. Evidence is lacking or very limited for most conservative treatments. Since there are no established criteria to differentiate a pathological PFF from a physiological one, the decision to treat PFF depends on each clinician [13]. The factors that are considered when establishing a treatment are age, flexibility, severity of the deformity, equinus position, adequate footwear and the presented symptoms [29]. Surgery, including procedures such as subtalar arthroereisis [30], is reserved for feet that have severe deformity, rigid FF or FF with persistent symptoms that do not improve with conservative treatment. The most used conservative treatments are foot orthoses (FO), corrective shoes, physical exercises, physiotherapy with joint manipulations and the Mulligan method [5,7,13,16,19,31–34]. The most frequent conservative intervention is the use of FO [25,35].

The short-term purpose of treatment with FO is to decrease pronator movement, hence decreasing the tensile forces on ligaments, tendons and the plantar fascia. The long-term goal would be to reduce the pathological position of the foot and slow down the progression [22,29,36,37]. FO treatment has been modified and has evolved over time, including thermoplastic, polypropylene FO and postings which aim to achieve a neutral hindfoot position [38]. The current evidence of FO treatments is very limited as systematic reviews have demonstrated; some of them concluded that FO present efficacy and some of them did not [13,14,21,29,31,35,39,40]. Recent studies continue to show ambiguity, although the evidence on the efficacy of FO is increasing, especially when FO are customised [4,19,21,41–48].

Recent studies conclude that PFF should not be ignored, and their treatment should not be downplayed, considering that the sooner that effective treatment is prescribed, the less damage will occur to other parts of the body. They also add that a conservative corrective treatment should be carried out, rather than an invasive treatment [19,20].

Therefore, since untreated PFF could cause problems in the foot itself or in other structures, it is necessary to demonstrate the efficacy of FO as a conservative treatment to reduce signs and symptoms in patients with PFF. It is also important to know the best type of FO and the minimum time of use as well as to identify which are the most used diagnostic techniques for PFF and how it is defined.

2. Materials and Methods

This protocol was registered on the International Prospective Register of Systematic Reviews PROSPERO: CRD42021240163. In order to respond to the objectives set out in this present study, a systematic review was carried out following the regulations "Preferred reported items of systematic reviews and meta-analysis" (PRISMA) and in accordance with the recommendations of the Cochrane Collaboration [49].

2.1. Selection Criteria

2.1.1. Types of Studies

Randomised controlled trials (RCTs) and controlled clinical trials (CCTs) published in the last five years were included. All other types of studies, such as systematic reviews, were excluded.

2.1.2. Participants

Studies included in this review had to include children diagnosed with PFF. Patients who had surgery in the lower limbs, or who presented some systemic or infectious neurological disease were excluded.

2.1.3. Type of Intervention

Interventions which were considered included FO as treatments for at least 2 months, both customised or prefabricated, and/or with modifications.

2.1.4. Comparison

Studies that compared the intervention with another type of FO or placebo.

2.1.5. Outcome Measure

The outcomes considered were those used to evaluate the improvement of signs and symptoms of the PFF.

2.2. Search Strategy

The search was carried out by two researchers independently in the following databases: PubMed, EBSCO, Web of Science, Cochrane, SCOPUS and PEDro. The following medical subject headings (MeSH) were used: flatfoot, paediatrics, child, foot orthoses, according to the characteristics of each database, accompanied by the Boolean operators "AND" and "OR".

The following search strategy was used: (("Flatfoot"[Mesh] AND ("Paediatrics"[Mesh] OR "Child"[Mesh] OR "Child, Preschool"[Mesh]) AND "Foot Orthoses"[Mesh]) OR (("Flexible Flatf**t"[tw] OR "Flat F**t"[tw] OR "Pes Planus"[tw] OR Flatf**t[tw] OR Splayfoot[tw] OR "F**t, Flat" [tw] OR "Flatf**t, Flexible"[tw]) AND (Paediatrics[tw] OR "Preschool Child*"[tw] OR Child*[tw] OR "Child*, Preschool"[tw]) AND ("Foot Orthosis"[tw] OR "Orthotic Insole*"[tw] OR "Orthos*s, Foot"[tw] OR "Foot Orthotic Device*"[tw] OR "Device*, Foot Orthotic"[tw] OR "Orthotic Device*, Foot"[tw] OR "Arch Support*, Foot"[tw] OR "Foot Arch Support*"[tw] OR "Support*, Foot Arch"[tw] OR "Orthotic Shoe Inserts"[tw] OR "Insole*, Orthotic"[tw] OR "Orthotic Insole*"[tw])))

In addition, the papers bibliographies were reviewed.

2.3. Study Selection

The selection of the studies was carried out by two researchers. After the selection of the papers from the databases, the duplicates were eliminated. After the elimination, a screening of the titles and abstracts was carried out, based on the inclusion and exclusion criteria. The selected studies were then fully read to assess compliance with the eligibility criteria. Any disagreements between reviewers in any phase of study selection were resolved by consulting another reviewer.

2.4. Data Extraction and Management

In order to respond to the proposed objectives, data were extracted from the studies, including characteristics of the publication (author, country, year and journal of publication, study design, objectives, keywords), characteristics of the sample (sample size, age, sex, height, weight, body mass index (BMI), whether the PFF was symptomatic or not, previous treatments and diagnosis), characteristics of the diagnosis and characteristics of the intervention (FO type and material, FO use, what health education/recommendations each participant received and the duration of the treatment) and the results together with the final conclusions of each study.

2.5. Risk of Bias and Quality Assessment

To estimate the methodological quality/risk of bias of each of the included studies, two different types of scales were used for the two study types (i.e., RCT or CCT).

To evaluate the RCTs, the tool recommended by the Cochrane manual was used to assess the risk of bias. It is a domain-based assessment that evaluates each domain with three possibilities: 'low risk of bias', 'high risk of bias' or 'unclear risk' [50]. To assess the CCTs, the "Before-After Quality Assessment Tool (BAQA)" developed by the National Institute of Health (NIH) in collaboration with the Cochrane team, among others, was used. It is a tool that answers 12 very specific questions to assess key concepts of the internal validity of the studies [51].

In addition, the Scottish Intercollegiate Guidelines Network (SIGN) scale was used to reflect the level of evidence and degree of recommendation [52].

2.6. Data Synthesis

Data have been presented in tables and narrative forms to describe the characteristics of the included studies. As the studies were not sufficiently homogeneous, it was impossible to perform a meta-analysis.

3. Results

Using the search strategy outlined above, we identified a total of 237 studies in the databases, as well as 4 additional records identified through other sources, which was via the reference lists of the initial papers that were retrieved. Of these 241 items, 181 were duplicated records. The remaining 60 studies were evaluated by title and abstract by 2 independent reviewers. Of these, 19 were excluded due to differences in inclusion criteria as they were observational studies, clinical trials without control group or the participants were not children. After that, 41 full texts were assessed for eligibility and 34 were excluded because participants had previously undergone surgery in the lower limbs, or the FO they were prescribed had been used for less than 2 months, among other reasons. Thus, only seven papers fully met the inclusion criteria. Figure 1 shows the PRISMA flow diagram for the studies included in this review.

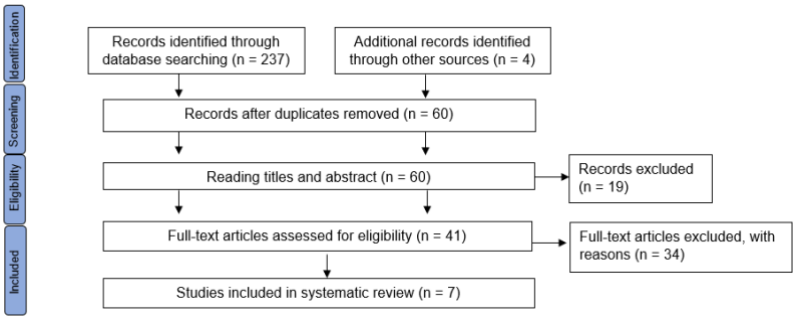

Figure 1. Article selection flowchart. Adapted from Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).

3.1. General Characteristics of the Studies Assessed

The included studies were published in the last 5 years and all of them were developed on the Asian continent, except for Rusu et al. [53]. Regarding the levels of evidence assessed by the SIGN grading system, the included studies presented levels II+A and II+B.

Of the 679 included participants, 412 were boys and 267 were girls, between 3 and 14 years of age. The study with the largest sample size was carried out by Chen et al. [42], with a total of 466 subjects, being more than two thirds of the total population included in this review.

In terms of the characteristics of the participants, their BMI was from 16.04 [42] to 20.1 [4,54]. Some of the studies did not provide BMI data. All the participants, to be selected, presented with PFF. Furthermore, in some of the included studies the participants presented pain [42,43,55]. None of the participants received previous treatment (Table 1).

Table 1. Study characteristics and publication characteristics.

Evidence Level by Sign	Author, Country (Year of Publication); Study Design	Sample Size	Year of Age (Mean/SD); Gender (M/F)	Weight in kg (SD); Height in cm (SD)	BMI kg/m^2 (SD)	Previous Treatment	Diagnosis, Symptoms
II+A	Rusu et al., Romania (2022) [53]; RCT	CG: 15 IG:15	9.37 (1.42); (17/13)	41.8 (12.72); 148.7 (10.96)	18.84 (5.32)	N/A	Bilateral PFF level II, asymptomatic
II+A	Jafarnezhadgero et al., Iran (2020) [4]; RCT (single blind)	CG: 15 IG:15	CG: 10.4 (1.5); (15/0) IG: 10.5 (1.4); (15/0)	CG: 48.2 (5.4); 141.2 (6.1) IG: 48.1 (9.1); 142.4 (5.7)	CG: 20.1 (4.2) IG:20.0 (4.0)	N/A	PFF
II+A	Chen et al., Taiwan (2019) [42]; CT	CG: 343 IG: 123	CG: 4.4 (7.9) meses; (187/156) IG: 4.3 (11.2); (77/46)	CG:18.0 (3.4); 104.5 (6.7) IG:18.2 (4.0); 105 (7.6)	CG:16.4 (2) IG:16.4 (2.1)	No	PFF, symptomatic
II+B	Choi et al., South Korea (2019) [43]; CT	IG:18 CG:13	IG:10.22 (0.43); (10/8) CG:10.15 (0.38); (9/4)	N/A	N/A	N/A	PFF, symptomatic
II+B	Hsieh et al., Taiwan (2018) [55]; RCT (single blind)	IG: 26 CG:26	IG: 6.9 (0.6); (14/12) CG: 6.2 (0.4); (14/12)	N/A	N/A	N/A	PFF, symptomatic
II+A	Jafarnezhadgero et al., Iran (2018) [54]; RCT (single blind)	CG: 15 IG:15	CG: 10.4 (1.5); (15/0) IG: 10.5 (1.4); (15/0)	GC: 48.2 (5.4); 141.2 (6.1) GE: 48.1 (9.1); 142.4 (5.7)	CG: 20.1 (4.2) IG:20 (4)	N/A	PFF, N/A

Table 1. *Cont.*

Evidence Level by Sign	Author, Country (Year of Publication); Study Design	Sample Size	Year of Age (Mean/SD); Gender (M/F)	Weight in kg (SD); Height in cm (SD)	BMI kg/m^2 (SD)	Previous Treatment	Diagnosis, Symptoms
I+B	Ahn et al., South Korea (2017) [56]; CT	IG: 20	CG: 10.4 (4.99); (12/8)	GC:35.13 (16.93); 138.23 (10.17)	CG:18.37 (4.67)	N/A	PFF, N/A
		CG:20	IG: 9.59 (4.24); (12/8)	GE:37.41 (11.33); (139.28 ±12.78)	IG:19.18 (2.39)		

SD: standard deviation; M: male; F: female; Kg: kilogram; Cm: centimetre; BMI: body mass index; RCT: randomised controlled trial; CT: controlled trial; CG: control group; IG: intervention group; SIGN: Scottish Intercollegiate Guidelines Network; N/A: not applicable; PFF: paediatric flexible flatfoot.

Participants were excluded if they had some type of foot or lower limb surgery, neurological, neuromuscular or hereditary disease, or if they had a developmental or coordination/mobility disorder.

Each author defined PFF with different characteristics. To do this, all authors used clinical diagnostic tests, even Rusu et al. [53] who did not specify the diagnoses but indicated that participants were evaluated using static and dynamic assessment. In addition, only three of the included studies, Choi et al. [43], Hsieh et al. [55] and Ahn et al. [56], also used radiographic examination for diagnosis.

All the studies that performed a radiographic diagnosis evaluated the lateral and anteroposterior projections of the feet in loadbearing. In addition, Choi et al. [43] evaluated the posterior projection, which was introduced by Saltzman and el-Khoury. The angles measured in the different projections were highly variable; only three authors agreed on the same angle: the angle of inclination of the calcaneus in the lateral projection. For Hsieh et al. [55], patients were diagnosed with PFF when two of the three angles they measured were not within normal values. For Ahn et al. [56], patients were diagnosed with PFF when a radiological finding in any of the four angles that were evaluated were not within normal values. Choi et al. [43] did not specify when patients were diagnosed with PFF.

Regarding diagnostic clinical tests, eight different tests were identified: (1) navicular drop, (2) RCPS, (3) arch height index, (4) pedigraphy Chippaux–Smirak index (CSI), (5) Beighton scale, (6) Jack's test, (7) double/single heel rise test and (8) FPI. Each author used different tests in their studies. If tests were positive, it meant that they presented PFF. For this, the navicular drop had to be greater than 10 mm for Jafarnezhadgero et al. [4,54] and greater or equal to 6 mm for Hsieh et al. [55]. Additionally, PRCA had to be greater than 4° of eversion, the arch height index less than 0.31, the CSI greater than 62.7%, the Beighton scale greater than 4 and finally the FPI had to be greater than 6 in the total score (Table 2).

Table 2. Sample selection and diagnoses.

Sample Selection			Diagnoses
Authors	**Inclusion Criteria**	**Exclusion Criteria**	**PFF Definition and Assessment**
Rusu et al. (2022) [53]	PFF after static and dynamic analysis	Surgery of foot or ankle; lower limbs pain; overweight; neuromuscular or neurological disorders.	• Static and dynamic analysis: Clinical examination in standing and walking. Arch height index and subtalar flexibility, which was assessed by a force platform
Jafarnezhadgero et al. (2020) [4]	Navicular Drop > 10mm, RCPS > 4° eversion, Navicular Height < 0.31	Surgery or fracture of foot or ankle; neuromuscular problems, asymmetry of > 5mm.	• Static and dynamic analysis: collapsed LMA while standing position and recovered when offloading. • Navicular drop> 10mm. • RCPS: >4° de eversión. • Navicular height: <0.31.
Chen et al. (2019) [42]	PFF symptoms	Musculoskeletal injury, neurological disorder, previous FO	• Anamnesis, Beighton scale, static and dynamic analysis: foot pain, fatigue and instability during walking, and changes in the normal morphology of the foot. • Pedigraphy: + (CSI > 62.7 %)

Table 2. *Cont.*

Sample Selection			Diagnoses
Authors	**Inclusion Criteria**	**Exclusion Criteria**	**PFF Definition and Assessment**
Choi et al. (2019) [43]	PFF	Systematic inflammatory disease, lower limb trauma or surgery affecting their alignment.	• Anamnesis: Characteristic signs and symptoms of PFF. • Double/Single Heel Rise Test: + • Test de Windlas: + • X-Ray: loadbearing, anteroposterior and lateral projections of the rearfoot (Saltzman and el-Khoury).
Hsieh et al. (2018) [55]	Symptomatic PFF (foot or calf pain, fatigue when walking or gait disturbances)	Surgery of foot or ankle; lower limb abnormalities, neuromuscular or neurological disorders.	• Beighton scale: >4 • Navicular drop: ≥ 6 mm • FPI: >6 • X-Ray: loadbearing, anteroposterior and lateral projections
Jafarnezhadgero et al. (2018) [54]	Boys from 8 to 12 years. Navicular Drop > 10mm, RCPS > 4° eversion, Navicular Height < 0.31	Surgery or fracture of foot or ankle; neuromuscular problems, asymmetry of > 10mm.	• Static and dynamic analysis: collapsed LMA while standing position and recovered when offloading. • Navicular drop > 10mm. • RCPS: >4° de eversión. • Navicular height: <0.31.
Ahn et al. (2017) [56]	PFF	Rigid FF, hereditary or neuromuscular diseases, fixed foot deformity or surgery of foot or ankle	• RCPS: >4° de eversión. • X-ray: loadbearing, anteroposterior and lateral projections

mm: millimetre; RCPS: relaxed calcaneus position in standing; PFF: paediatric flexible flatfoot; FO: foot orthoses; CSI: Chippaux–Smirak index; FPI: foot posture index; FF: flat foot; MLA: medial longitudinal arch.

Risk of Bias Assessment

All the included studies presented a high risk of bias in at least one field. For Ahn et al. [56] most of the items presented unclear risk of bias and the study by Rusu et al. [53] did not report whether or not the investigators were blinded or not (Figure 2).

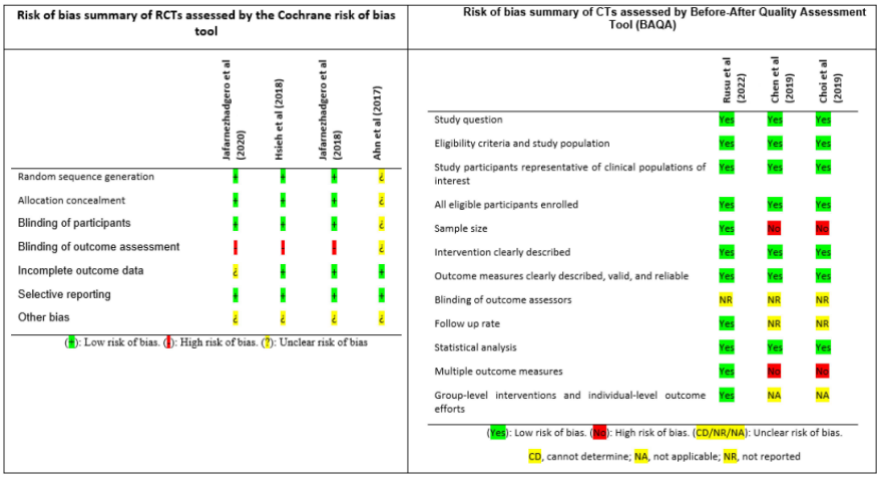

Figure 2. Risk of bias of the included studies. RCT: randomised controlled trial; CCT: controlled clinical trial; BAQA: Before-After Quality Assessment Tool [4,42,43,53–56].

3.2. Results by Outcome Measures

As required by one of our inclusion criteria, all the studies divided the sample into two different groups, an intervention group (IG) and a control group (CG). It should be

added that all the authors, except Ahn et al. [56], provided FO treatment to the IG and the CG received a placebo treatment.

All the authors casted the patients' feet, apart from Hsieh et al. [55] who provided a FO with a direct adaptation technique, and Chen et al. [42] who provided off-the-shelf FO. Choi et al. [43] used a phenolic foam, Jafarnezhadgero et al. [4,54] used plaster with the foot in a neutral position and Rusu et al. [53] used a 3D scanner.

Some authors included information about the casting of the foot and more detailed information about the FO. Rusu et al. (2022) [53] included personalised semi-rigid FO, with increased medial longitudinal arch support and heel cup, which were manufactured by the company Ortoprotesica. The design of the FO was computerised using a CAD-CAM system. In the studies of Jafarnezhadgero et al. (2020) [4] and Jafarnezhadgero et al. (2018) [54] the FO was made from ethylene-vinyl acetate (EVA) and microcellular rubber, and the negative cast was made in a subtalar joint neutral position. Chen et al. (2019) [42] included prefabricated FO, which were adapted by an orthotist. Choi et al. (2019) [43] used phenolic foam to cast the foot in a weight-bearing position. The FO were personalised with an increased medial longitudinal arch support. In the study of Hsieh et al. (2018) [55] the FO were directly adapted to participants' feet, in an offloading and neutral position. The FO were personalised with a medial longitudinal arch support. Finally, in the study of Ahn et al. (2017) [56], the neutral position of weightbearing plaster cast technique was used to capture foot shape, and the FO manufactured were Blake´s inverted orthoses.

All the FO from the IG of the included studies had a marked medial longitudinal arch and EVA was used for some parts of the FO. However, all the FO were different. Rusu et al. [53] made semi-rigid custom FO, using a thermoplastic heel cup which extended to the base of the metatarsals and had an EVA top cover and a metatarsal dome. For the IG Jafarnezhadgero et al. [4,54] provided a resin FO with a maximum of 25 mm medial longitudinal arch, and the CG received a flat polyester resin FO. The following papers provided an intervention for the IG, but nothing for the CG. Chen et al. [42] provided polypropylene and EVA off-the-shelf FO. Choi et al. [43], provided personalised FO, including materials with different hardness, such as EVA, plastazote, poron, evazote or ucolite. Hsieh et al. [55] provided customised FO made of thermoplastic, a medial longitudinal arch made of EVA and hindfoot posting. Finally, Ahn et al. [56], provided a Blake inverted FO together with a medial longitudinal arch for the IG and a Blake inverted FO without a medial longitudinal arch for the CG.

All the authors recommended a daily use of the FO during the daily activities of life, from 3 months to 6 years. Regarding the follow-up of the participants, all the studies carried out an initial assessment (pre-treatment) and then a final assessment (post-treatment). Only Choi et al. [43], carried out an assessment every 6 months until the end of the treatment.

Different outcome measurements were evaluated in the included studies even though the objective in all the studies was the same, which was to determine the efficacy of the FO. Some of the studies evaluated radiographic changes, others evaluated kinetic-kinematics changes and others evaluated changes in the plantar footprint. Some authors highlighted functional changes and others evaluated morphological changes after FO use.

The authors used different devices and tests to quantify the results: the VICON system, pressure platform, pedigraph (CSI), radiographs, International Classification of Functionality, RCPS and static and dynamic changes (Table 3).

All authors conclude that FO are an effective treatment, although more evidence is needed to fully confirm this statement. Choi et al. [43] concluded that FO may make structural changes, and that FO improve functionality and pain. Rusu et al. [53] concluded that exercise is beneficial, particularly when combined with FO treatment. They also reported that a decrease in subtalar joint flexibility could lead to an increase in the plantar arch index. Jafarnezhadgero et al. [4,54] assessed the changes in kinetics and kinematics measured by the VICON system and pressure platform in two papers. They noted a difference in the kinetics and kinematics, concluding that the long-term use of FO with medial longitudinal arch support help to improve the alignment of the lower limbs and

gait in PFF. Chen et al. [42] concluded that although PFF may resolve with age, the use of FO may reduce the characteristic signs, especially in 5-year-olds (more than in 3-year-olds). Hsieh et al. [55] concluded that FO provided a reduction in pain and an increase in comfort. Finally, the authors Ahn et al. [56] observed clinical and radiological improvements in both groups in their study, but that the IG obtained greater changes. Therefore, they concluded that a Blake inverted FO together with a medial longitudinal arch was more effective than a Blake inverted FO without a medial longitudinal arch.

Table 3. Intervention characteristics.

Authors	Intervention	FO Material	FO Use	Education	Treatment Duration
Rusu et al. (2022) [53]	CG (n = 15): workout IG (n = 15): Personalised FO with LMA, heel cup and metatarsal dome + workout	Semirigid thermoplastic	Daily	FO use and normal BADL	3 months
Jafarnezhadgero et al. (2020) [4]	CG (n = 15): placebo FO IG (n = 15): FO with LMA	GC: Polyester resin GE: EVA	Daily	Progressive FO use. Footwear New Balance 749, USA	4 months
Chen et al. (2019) [42]	CG (n = 343): none IG (n = 123): FO with LMA	Polipropilene and EVA	Daily	N/A	Mean of 11, 3 months
Choi et al. (2019) [43]	IG (n = 18): FO with LMA CG (n = 13): none	EVA, plastazote, poron, evazote or ucolite.	Daily	FO use and replace FO every 6 months	3–6 years
Hsieh et al. (2018) [55]	IG (n = 26): FO with LMA CG (n = 26): none	Thermoplastic and EVA	Daily, minimum 5 h	FO use and comfortable footwear	3 months
Jafarnezhadgero et al. (2018) [54]	IG (n = 15): FO with LMA CG (n = 15): placebo FO	GC: Polyester resin GE: EVA	Daily	Progressive FO use. Footwear New Balance 749, USA	4 months
Ahn et al. (2017) [56]	IG (n = 20): inverted Blake's FO with LMA CG (n = 20): inverted Blake's FO	N/A	Daily, minimum 8 h	FO use	12 months

CG: control group; IG: intervention group; FO: foot orthoses; LMA: longitudinal medial arch; BADL: Basic Activities of Daily Living, mm: millimetre; EVA: ethylene-vinyl acetate; N/A: not applicable.

4. Discussion

The aim of this review was to demonstrate the efficacy of FO as a conservative treatment to reduce signs and symptoms in patients with PFF. In addition, it was important to determine the best type of FO and the minimum time of use and finally, to identify which are the most used diagnostic techniques for PFF and how it is defined.

To answer the main objective, in five of the included studies [4,42,43,54,55] the CG received no treatment or placebo. This makes the point that no therapy was applied, meaning that all the outcome measures that were improved in the IC were because of the FO, not because of the natural evolution of the PFF.

This study shows that FO were an effective treatment for PFF. Recently, more studies have been published supporting the efficacy of FO, showing their positive impact on a wide variety of PFF outcomes such as pain, foot posture, gait, foot function, etc. [35]. This review shows a different perspective from previously published research where a positive impact from the FO was not shown.

However, no ideal type of FO has been agreed in the literature. Each author used a different FO, including different types and materials, though always rigid or semirigid materials. However, all the FO had something in common, which was a high longitudinal medial arch support. A recent study has shown that the use of custom FO for PFF is more effective than prefabricated FO, providing better pressure distribution and conform better to the foot [44]. Su et al. [57] concluded that there is a relationship between hardness of the FO and effectiveness of treatment, however the increase in hardness was also linked to soft tissue damage.

In terms of FO use, all included studies specified that FO should be worn every day, the period of which varied from 3 months to 6 years. Reviewing the literature, there is no

consensus on how long children with PFF should wear their FO, with differing periods from 3 months to 2 years. However, some authors consider 3 months an insufficient amount of time [21,38]. Radwan et al. [45] concluded that FO can modify children's feet with immediate effect, but it is after 12 months when more changes and improvements are shown. Jafarnezhadgero et al. [4,54] concluded that long-term FO use was effective to improve alignment and coordination of the lower limbs, as well as gait kinetics and kinematics. Those results agree with previous studies [45,58]. Chen et al. [42] and Hsieh et al. [55] also concluded that FO were effective, reducing the characteristic signs and symptoms of PFF and improving quality of life, which agrees with previous studies [54,59–63]. However, none of the included studies indicated negative effects from the use of FO; previous studies indicated localised irritation of the skin, increased pain, problems with shoe fit, intolerance or discomfort after FO use in some of the participants [46].

Previous studies concluded that the use of footwear is part of the treatment in order to ensure the effectiveness of the FO [25,38]. However, only Jafarnezhadgero et al. [4,54] recommended a specific type of footwear for the participants.

Age may be the characteristic that most influenced the results and the evolution of the treatment [25,64]. The mean age of most of the included participants was 10 (except for the studies by Chen et al. [42] and Hsieh et al. [55]). Depending on the study, the ideal age to treat PFF varies. Some studies concluded that the ideal age is before six and other studies conclude after six [65,66]. For example, the study published by Lee et al. [60] concluded that FO should be provided to children younger than six. In their study 66 children from 1 to 12 years of age, showed that the greatest changes in the RPCS were for preschool-age children (under 7), and that children older than 7 presented a minimal correction. It could be concluded that the younger the patient is, the greater the possibility to correct the PFF. However, it should also be noted that natural foot development occurs before 6–7 years of age [11,24,67]. Moreover, it is not yet known whether gender is an etiological factor. Some papers indicate that gender influences the prevalence of PFF, showing a higher incidence in male children [25,31,68,69], which agrees with the present study as most of the included participants were male (60.7% boys).

Another of the etiological factors related to PFF is a low level of physical activity [11,17,70,71]. We planned to collect information about participants physical activity, but those data were not provided by any author. Regarding pain levels, only three of the included studies data related to this [42,43,55], where an improvement of pain after FO use was shown [35,46].

Previous studies showed great confusion in what to call the present pathology (i.e., flat foot valgus, pes planus, etc.) [13,71]. However, that was not an issue in the present study as the final diagnosis of all the authors was PFF, differentiating between asymptomatic or symptomatic patients.

The Beighton scale, navicular drop and RPCS tests, and X-rays were the most widely used tests by the included authors to assess PFF. Other tests, such as the arch height index, pedigraphy, Jack´s test, double/single heel rise test or FPI, were also used but not unanimously. Only the FPI has been validated for children under 6 years old. However, they show great specificity and sensitivity in adults [25,27,72–74]. The use of radiographs for the diagnosis of PFF is considered the "gold standard". However, due to all the ethical problems caused by radiation, and the fact that an accurate diagnosis can be reached with clinical tests, radiographs are not used daily for the diagnosis of PFF.

Some of the tests have highlighted great controversy because the same values were not used by the different authors. For example, for Jafarnezhadgero et al. [4,54] the navicular drop was considered positive when the result was greater than 10 mm; however, Hsieh et al. [55] considered a positive result when it was greater than or equal to 6 mm. Given this ambiguity, it is not surprising that treatments such as FO do not have scientific evidence. After previous reviews and meta-analyses, it is difficult to obtain clear results. Morrison et al. [46] surveyed podiatrists, orthotists and physiotherapists in the United Kingdom about PFF diagnoses and came to the conclusion that what podiatrists used the most

was the heel rise test, FPI and joint mobility to diagnose PFF. Recently, Zukauskas et al. [75] indicated that the navicular drop, FPI and CSI should be used for children between 5–8 years of age.

This systematic review presents some strengths; for example, the included studies presented a high level of evidence and a large number of scientific databases were reviewed. The main limitation of the present study is the small number of the included studies and participants, which could reduce the external validity of these results. Even though numerous studies related to FO and PFF are available in the literature, we have only found seven studies that were published in the last five years with a good methodological quality. Another limitation was the diversity of the outcome measures used and the heterogeneity of the interventions. Most of the studies were carried out on the Asian continent. The ethnic characteristics of each population are different, and these could have influenced the development and results of the treatment.

Future research should be undertaken with standardised diagnostic protocols with validated tests. These studies should be performed with a larger sample size and a longer-term follow-up (more than 3 months). In addition, studies should be separated between those who include children younger than 6 years old and those who include participants older than 6 years old. Finally, studies which assess the whole participant, including general painful symptoms and quality of life should be conducted. Then, the evidence for the effectiveness of FO treatment would be more concrete.

5. Conclusions

Conclusions from this review should be viewed with caution due to the low number of the included studies. The best type of FO and the optimal time of use cannot be concluded due to the heterogeneity between studies. There is no algorithm for PFF diagnosis, and there is a great diversity of clinical tests, characteristic signs and symptoms and radiographic measurements for PFF diagnosis. There is no universally accepted definition for PFF, although all authors of the included studies define it when there are more than two characteristic signs and symptoms or positive tests. The use of FO with high medial longitudinal arch may improve the signs and symptoms in some patients with PFF.

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ANEXO 4. Publicación Estudio IV

Journal of *Personalized Medicine*

MDPI

Protocol

Efficacy of Personalized Foot Orthoses in Children with Flexible Flat Foot: Protocol for a Randomized Controlled Trial

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Abstract: Pediatric flat foot (PFF) is a very frequent entity and a common concern for parents and health professionals. There is no established definition, diagnostic method, or clear treatment approach. There are multiple conservative and surgical treatments, the implantation of foot orthoses (FO) being the most used treatment. The evidence supporting FO is very thin. It is not clearly known what the effect of these is, nor when it is convenient to recommend them. The main objective of this protocol is to design a randomized controlled trial to determine if personalized FO, together with a specific exercise regimen, produce the same or better results regarding the signs and symptoms of PFF, compared to only specific exercises. In order to respond to the stated objectives, we have proposed a randomized controlled clinical trial, in which we intend to evaluate the efficacy of FO together with strengthening exercises, compared to a control group in which placebos will be implanted as FO treatment along with the same exercises as the experimental group. For this, four measurements will be taken throughout 18 months (pre-treatment, two during treatment and finally another post-treatment measurement). The combination of FO plus exercise is expected to improve the signs and symptoms (if present) of PFF compared to exercise alone and the placebo FO group. In addition, it is expected that in both conditions the biomechanics of the foot will improve compared to the initial measurements.

Keywords: flexible flatfoot; pediatrics; children; foot orthosis; strengthening exercises

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1. Introduction

Pediatric flat foot (PFF) is a very frequent syndrome in primary care consultations, and it is also a shared concern among parents and professionals. Currently, there is no clear definition for the diagnosis of PFF, no treatment protocol, nor solid scientific evidence on the wide range of treatments [1,2].

PFF is characterized by a talocalcaneal misalignment, which is reflected as a collapse of the medial longitudinal arch (MLA) in a standing position [3]. Consequently, there is excessive pronation, accompanied by a drooping of the navicular. Some feet are also accompanied by calcaneal valgus [4]. All these alterations in the morphology of the foot force the rest of the structures, such as soft tissues or joints, to compensate for the excessive forces that act on the MLA [5]. These compensations cause an inefficient gait and symptoms such as pain, fatigue, stumbling when walking, problems in the proximal joints and reduced quality of life [6,7].

Diagnosis is based on clinical findings, including a variety of clinical tests and radiographic signs, these being considered the "gold standard" [6,8,9].

Regarding treatment, there are both conservative and surgical options, surgical being the last treatment option [10]. The most common conservative treatment is the use of foot orthoses (FO), where previous studies have concluded that they improve the results of some clinical tests, radiographic angles and symptomatology [11–17]. The purpose of the FO is to modify the position of the axis of the subtalar joint, decrease the speed of pronation, support the MLA and distribute loads more effectively [18,19]. Previous systematic reviews indicate that FO are beneficial and create positive changes in the development of the child's foot [8,20,21]; these changes being greater in earlier ages of the treatment [22]. The exact age to start treatment is not clear, although it is recommended to start at preschool age (under 7 years old) so that the possibility of correcting the PFF is greater [23,24]. It has also been seen that the combination of FO with exercises is much more beneficial [25]. However, other studies indicate that the modifications that occur are those resulting from the natural development of the foot [26,27]. The evidence regarding the use of FO still does not present a consensus [20,28,29].

Therefore, there is a discrepancy between treating and not treating PFF. There are authors who conclude that it is not necessary, since the natural evolution of the foot is that the MLA begins to form at 3–4 years of age and ends at 10 years of age [26,27]. A recent meta-analysis [30] concludes that, due to the normal development of the foot, treatments should be ruled out unless there are symptoms such as pain, limited function or reduced quality of life. However, other authors recommend early treatment, based on the fact that flat feet persist in 23% of adults and may be associated with Achilles tendinopathy, plantar fasciopathy, tibial posterior tendinopathy, hallux rigidus, chondromalacia patellae or patello-femoral pain syndrome [1,2,7,13,20]. Based on these latest data, it would be unethical to leave these types of feet untreated. Additionally, a recent systematic review [24] demonstrated that FO are beneficial, with evidence regarding efficacy in treating signs and symptoms.

Therefore, since PFF is a very common syndrome which, if left untreated, could cause problems in the long term and there is no consensus on the treatment protocol, it is necessary to investigate the effectiveness of FO in terms of improvement of the signs and symptoms, including the prevention of pathologies or injuries and the improvement of the quality of life. Sagat, P et al. have shown that children with flat feet presented poor performance in certain physical tasks, in contrast to a control group with neutral feet [31]. In addition, since it is a subject of great interest for researchers, health professionals and parents, it is necessary to carry out an investigation to assess the effectiveness of FO, with a standardized diagnostic protocol with validated tests in a larger sample size than previously published studies and with a longer-term follow-up. Furthermore, as the authors Zhang J. et al. pointed out, early identification of PFF is necessary; thus an intervention plays a crucial role in enhancing the outlook. Also, there is an absence of consistent quantitative standards for diagnosing flexible flatfoot [32].

Therefore, the objective of the current study is to design a protocol for a randomized controlled trial (RCT) to determine whether personalized FO together with a specific exercise regimen produce the same or better results regarding the signs and symptoms of PFF, compared to only specific exercises. In addition, as specific objectives, to detect whether the possible bias that has prevented previous studies from demonstrating the efficacy of FO is due to the fact that these FO were not personalized; to define the PFF and to evaluate if there is a correlation between the clinical methods and the diagnosis and severity of the PFF.

2. Materials and Methods

2.1. Study Design and Setting

The design is a randomized controlled two-arm trial.

Patients will be recruited from the university clinic from Universidad Católica San Antonio de Murcia, University of Malaga and schools nearby in Spain. They will be randomized to one of the two groups, each receiving a different intervention. The schedule

to follow while carrying out this RCT can be found in Appendix A. The total period intended to be allocated to this study is from September 2023 to February 2025.

To randomize the sample, a Microsoft Excel spreadsheet will be used where a random assignment sequence will be generated. Each patient will be given a consecutive number in order of arrival and allocation concealed in envelopes.

2.2. Eligibility Criteria

Subjects aged 3 to 12 years diagnosed with PFF. For the diagnosis of the PFF, the following criteria must be met:

- Foot Posture Index (FPI) > 6 [33].
- Navicular drop > 10 mm [34].
- Relaxed calcaneal stance position (RCSP) 6° to 12° valgus [35].
- Pronation angle > 10° [36].
- Arch index > a 1.35 [37].
- Double/single heel rise test negative [38].
- Windlass test negative [39].

In addition, the signature of the parents or legal guardians with consent to participate in the study will be necessary (Appendix B).

Participants will be excluded if they have undergone any surgery in the lower limbs, have previously received treatment for PFF, present osteoarticular injury, foot fractures or in the lower limbs in the last 6 months, ankle sprain, asymmetry, systemic diseases with osteoarticular involvement that present symptoms in the lower limb with gait disturbance (for example, Perthes disease) or biomechanical alteration of the lower limb with repercussions on the foot and ankle. Children suffering from any type of neurological or systemic disability (cerebral palsy, Down Syndrome, clubfoot or equino-varus, . . .) will also be excluded.

2.3. Interventions

At the first visit, parents will be informed of their child's current problem, treatments, and the existence of this study. In the case of accepting to participate in the study, the process will begin: all the variables will be carefully collected, the treatment will be established and an appointment will be made for follow-up at 6 months.

First, all the affiliation data will be collected and the PFF will be diagnosed.

2.3.1. Group 1

For custom insoles, a mold will be taken using phenolic foam. To do this, the child will be asked to sit in a chair (to take the mold semi-load baring). The mold will be taken in a corrected position, that is, limiting the internal rotation of the tibia with one hand and the windlass mechanism will be performed to increase the MLA. The mold must remain neutral, so in the event that a varus or valgus print has emerged, this process will be repeated. Once we have the mold filled with plaster, two modifications will be made: a moderate medial heel skive (5 mm and an angulation of 15°) in the hindfoot and a slight inversion balance of 4° in the forefoot. Once the mold is prepared, the FO will be thermoformed; for this, we will use a 3 mm polypropylene, 25 Shore-A EVA as lining and 65 Shore-A EVA to stabilize the hindfoot.

In addition, the exercises to be performed will be explained to them and they will be given all the recommendations regarding the performance of exercises, the use of FOs and shoe therapy. These explanations will be provided in an additional report (Appendix C) that will be given to all subjects together with a calendar so that they write down all the days they perform the exercises with an X.

The exercises will first be explained by the podiatrist to the child and the parent/legal guardian. In addition, a standard video will be created so that the child can see it, in which the exercises will be explained through drawings in order to capture the attention of the child. The parent/legal guardian needs to confirm that the child is doing it correctly.

Once the FO have been provided, after assessing that it adapts well to the foot and does not cause discomfort, the patient will be requested to come in at 6 months. In the event that there is any discomfort or irritation to the child's skin, an appointment will be made to readjust or modify the FO (in this visit the variables will not be evaluated, only the FO will be fixed; if there are no problems, this visit will not be carried out).

2.3.2. Group 2

The participants will have the same intervention described for group 1, with the difference that they will use a placebo FO. This will be constructed using flat 1 mm 65 shore Ethylene-vinyl acetate (EVA), which will be cut to the foot size of the child and covered with the same top cover as the FO Group 1 to visually prevent them from being distinguished.

The instruments necessary for the development of this study and the budget necessary to carry out this clinical trial are included in Appendix D.

2.4. Outcomes Measures

The document presented in Appendix C will be used for data collection. It contains all the data to be collected in the anamnesis and all the variables to be studied, including all the clinical tests that would be carried out.

2.4.1. Qualitative or Categorical Variables:

- Gender: masculine or feminine.
- Pain: symptomatic or asymptomatic.
- Level of physical activity: high-low-nil.
- Double/simple heel rise test: Standing on toes with two legs/one leg for 25 repetitions. It will be considered positive if the participant is incapable due to fatigue or if when raising the calcaneus does not present a varus position [38].
- Supination resistance test: high-moderate-low. The patient is instructed to stand relaxed without any attempt to move the foot or lift the arch. The examiner's fingertips are then placed plantar to the medial half of the navicular, and the examiner exerts a significant lifting force on the navicular. A normal foot will demonstrate subtalar joint supination with minimal lifting force. A pes valgus deformity will need extreme amounts of lifting force in order to produce little, if any, subtalar joint supination motion [40].
- Subtalar joint axis: Lateralized-neutral-medialized. The center of the neck of the talus should be located and marked to see the lateralized or medialized point, or if, on the contrary, it stops at the 2nd finger, which would indicate that it is neutral [36].
- Shoe wear at heel level: medial-center-lateral.
- Maximum pronation test: Positive or negative. The patient is asked to try pronate as much as possible; it is considered positive when performing the maneuver, the calcaneus cannot pronate more than 2° [41].
- Forefoot: adduction-neutral-abduction position [36].
- Foot posture index (FPI): Normal = 0 to +5; pronated = +6 to +9; highly Pronated = +10 to +12; supinated = −1 to −4 and highly supinated = −5 to −12. The six clinical criteria assessed: 1. palpation of the talus head; 2. lateral supra and inframalleolar curvature; 3. position of the calcaneus in the frontal plane; 4. prominence of the talonavicular region; 5. congruence of the internal longitudinal arch and 6. abduction/adduction of the forefoot with respect to the rearfoot. As we observe them, the following score is given: neutral = 0; clear signs of supination = −2; clear signs of pronation = +2 [33].
- Test of windlass: Positive or negative. It will be considered positive if, when performing dorsiflexion of the hallux, there is not supination of the foot, plantarflexion of the 1st ray, increase in the MLA and internal rotation of the tibia [39].
- Beighton scale: Hypermobility or normal. Subjects are rated on a 9-point scale, considering 1 point for each hypermobile site. These 9 points are: 1-hyperextension of the elbows (more than 10°), 2-passively touch the forearm with the thumb, having

the wrist in flexion, 3-passive extension of the index finger to more than 90°, with the palm of the hand resting on the bed, 4-hyperextension of the knees (10° or more), patient in supine position and 5-flexion of the trunk forward touching the ground with the palms of the hands by bending without bending your knees. To be considered as hypermobile, it is required to have 4 points or more of the total of 9 [42].
- Podoscope: pronated-supinated-neutral [36].
- Pressure platform: maximum pressure zone, location of the center of gravity, gait progression line [43].

2.4.2. Quantitative or Numerical Variables

- Age: in months.
- Weight: in Kg.
- Height: in meters.
- Body Mass Index (BMI): Will be calculated with the formula weight (Kg) divided by height squared (meters^2). The classification of each child in low weight, normal weight, overweight or obesity will depend on the child's sex, height, weight and age [44].
- Pain: visual analog scale (from 1 to 10, 1 being minimum pain and 10 maximum pain).
- FPI: The six clinical criteria used in PFI are: 1. palpation of the talus head; 2. curvature supra and lateral inframaleolar region; 3. position of the calcaneus in the frontal plane; 4. prominence of the talonavicular region; 5. congruence of the internal longitudinal arch and 6. abduction/adduction of the forefoot with respect to the rearfoot. (Score: neutral = 0; clear signs of supination = −2; clear signs of pronation = +2) [33].
- RCSP: degrees of calcaneal eversion. The valgus degrees of the calcaneus are measured in bipedal support [35].
- Navicular drop: in millimeters. It measures the difference between the navicular position when the patient's foot is in a neutral position and when the patient's foot is in its normal position. It measures how many millimeters the medial tuberosity of the scaphoid has descended [34].
- Pronation angle: in degrees. To calculate the bisection of the distal third of the tibia with respect to the bisection of the calcaneus [36].
- Chippaux-Smirak index: in cm. On the footprint of the subject taken from a pedigraphy, the narrowest distance from the medial part of the foot (B) with the widest distance from the forefoot (A) must be measured. It is divided B/A [45].
- Pressure platform: percentage of load/weight on each foot and distribution of the same (anterior load, posterior load, load of the left and right foot) [43].
- Arch index: numerical scale. The patient's footprint is taken with a pedigraphy, the toe area is excluded and a longitudinal line is drawn that goes from the center of the heel to the 2nd toe. A line is then drawn perpendicular to the 1st. Two lines are drawn perpendicular to this axis to see the anterior extent of the forefoot area. The axis of the foot is divided into 3 equal parts and here 3 zones are defined: A: forefoot, B: midfoot and C: rearfoot. The arch index is calculated: B/(A + B + C) [37].
- Foot size: in cm.
- Silfverskiold test: in degrees. The degrees of dorsiflexion of the ankle (starting from a position of 90°) with extended knee and bent knee [46] will be measured.
- Navicular height: in millimeters. Measure the height of the scaphoid to the ground with the subject sitting [47].

2.5. Blinding and Monitoring

Participants and their parents/guardians will be blinded as to which group they are allocated to and will not see the other group.

An initial assessment will be made, these same measurements will be repeated 3 times throughout the duration of the study. In total we will obtain 4 measurements for statistical analysis.

The second measurement will be a month of treatment; in addition, in this visit we will assess the state of the FO and verify that the exercises are going well. We will ask about the FO, if any pain has appeared that was not there before, any blisters or reddened areas. In the event that the adaptation to the FO has not been good, we will make the necessary adjustments to the FO, such as lowering the MLA. If any subject needs their FO to be modified, they will be called by telephone after 2 weeks to see the evolution; in the event that it has not improved, it will be cited to re-evaluate the FO.

To corroborate that the execution of the exercises is good, we will ask the participant to repeat them, and in case there is an exercise that is not being performed correctly, we will explain it again.

The third assessment will be in the middle of the treatment/study period, that is, at 6 months. At this stage, all the initial measurements/assessments will be conducted again, as well as the last one at 12 months.

The estimated time for the measurement assessments is one hour for the 1st visit and 30 min for the rest of the visits.

2.6. Sample Size

The calculation of the sample size has been carried out with the data analysis program EPIDAT https://www.sergas.es/Saude-publica/EPIDAT?language=es (accessed on 4 August 2023). For the calculation, a clinical variation of 2 and a standard deviation of 1 have been considered. A statistical power of 80% and a significance level of $p < 0.05$; 95% confidence level. The minimum size would be a sample of 128 subjects (64 in each group randomly distributed). Considering that the loss rate could be 30%, the final size should be 84 subjects in each group. The total sample size should be 168 subjects.

2.7. Statistical Analysis

The description of data will be calculated using the percentages and frequencies of the qualitative variables and for the quantitative variables, the standard deviation and the mean. In addition, in case of presenting high deviations, the measures of central tendency would be calculated, as is the case of the mean, median or mode. All this will be carried out in frequency distribution tables of different categories, using SPSS (IBM SPSS Statistics: V.28, USA).

It is intended to compare the dependent variables with the independent ones. The Kolgorov–Smirnof test (the adjustment to the normal of the distribution) will be used to check the normality of the quantitative variables; in the event that they follow a normal distribution, the following techniques would be used: linear regression or Pearson correlation for the comparison of quantitative variables, chi-square (X^2) to compare qualitative variables and Student's *t* or ANOVA to compare qualitative with quantitative variables. In the event that they do not conform to the normal, it will be calculated according to the case; the Wilcoxon test, the Kruskal–Wallis test, and the Mann–Whitney test.

To determine that the supposed differences between control group and experimental group are not due to a random error, but to a real difference, in the bivariate analysis a hypothesis test will be carried out. The significance level of p shall be 0.05.

2.8. Ethics and Dissemination

The study has been awarded ethical approval from the committee of the Universidad Católica San Antonia de Murcia (CE032213).

3. Expected Results

Personalized FO along with a specific exercise regimen are expected to produce better results for signs and symptoms of PFF compared to specific exercises alone. In addition, it will be detected if the possible bias that has made the previous studies not demonstrate the efficacy of FO is that these FO were not personalized.

After the completion of this study, in which a large number of tests will be analyzed, the research will provide a definition of the PFF according to the common findings presented by the sample, a definition that nowadays is non-existent. Finally, we can evaluate if there is a correlation between clinical methods and the diagnosis and severity of PFF, in order to make an accurate diagnosis.

It is anticipated that the study will provide valuable evidence for improvement of the treatment of PFF, as well as for the diagnosis and management of this entity.

The main future research which is required after this protocol study is to carry out the detailed RCT described in the present manuscript. Also, qualitative research to understand the experience of patients with PFF wearing an FO is required.

3.1. Limitations

The main limitation that can be found in this RCT is the involvement and adherence to the study by parents or legal guardians and children. Another limitation that should be mentioned is not having a control group that does not undergo any treatment, as PFF can lead to problems in the biomechanics of gait and in the development of future pathologies. Also, we cannot claim that all patients will be using their orthoses the whole period of our study. This is because the study will be undertaken in Spain, where there are very high temperatures in summer. This may make it difficult for the patients to wear close-toed shoes, thus limiting the orthoses use and interfering with the adherence to the treatment. The use of FO will be monitored by phone, but we cannot be sure that they use them every day.

3.2. Strengths

This research will have several strengths, such as the random assignment to the treatment and the blinding of the evaluators, the direct applicability of the results obtained and the absence of quality information in this field. This research will clarify many aspects that are still unclear regarding PFF and its treatment. This section may be divided by subheadings. It should provide a concise and precise description of the experimental results, their interpretation, as well as the experimental conclusions that can be drawn.

Author Contributions: Conceptualization, C.M.-G., G.B. and L.R.-P.; methodology, C.M.-G., A.R.-C., J.C.-M., E.L.-R., A.M.-R., G.B. and L.R.-P.; writing—original draft preparation, C.M.-G., G.B. and L.R.-P.; writing—review and editing, C.M.-G., A.R.-C., J.C.-M., E.L.-R., A.M.-R., G.B. and L.R.-P. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: The study has been awarded ethical approval from the committee of the Universidad Católica San Antonia de Murcia (CE032213).

Informed Consent Statement: Not applicable.

Data Availability Statement: No more data is available.

Conflicts of Interest: The authors declare no conflict of interest.

Appendix A. Planned Schedule for the Study

Table A1. Planned Schedule for the Study.

	2023					2024			2025	
Time/Activities	August	September	October	November	December	Full year	January	February	March	April
Project development and patient recruitment	X									
Data collection and initiation of processing		X								
Prospective follow-up			X	X	X	X	X	X		
Data analysis									X	
Results and conclusions									X	X
Preparation of the document										X

Appendix B. Informed Consent and Patient Information Model

Project Title: "EFFECTIVENESS OF PERSONALIZED PLANTAR ORTHOSES IN CHILDREN WITH FLEXIBLE FLAT FEET. A RANDOMIZED CONTROLLED TRIAL"

- I have read the Information Sheet that has been given to me.
- I have asked all the questions I considered necessary about the study.
- I have received satisfactory answers to all my questions.
- I have received enough information about the study.
- I will not receive any financial compensation.
- The decision to allow the analysis of my data is completely voluntary.
- If I decide freely and voluntarily to allow the evaluation of my data and those of my child, I will have the right not to be informed of the results of the investigation.
- The evaluation of all data (clinical, demographic and background) will never pose an additional danger to my child's health.
- The information about my personal and health data will be incorporated and processed in a computerized database complying with the guarantees established by the General Data Protection Regulation, as well as Organic Law 3/2018, of December 5, Protection of Personal Data and guarantee of digital rights.
- I understand that my child's participation is voluntary.
- I understand that all of my child's data will be treated confidentially.
- I understand that I can withdraw my child from the study:

  Whenever.
  Without having to give any kind of explanation.
  Without this decision having any impact.

With all of the above, I agree for my child to participate in this study.
Signature:
In Murcia, of of 202
ID of the parent/legal guardian:
Child's ID:
Signature of parent/legal guardian:
Signature of Investigator:

PATIENT INFORMATION

STUDY TITLE
"EFFICACY OF PERSONALIZED PLANTAR ORTHOSES IN CHILDREN WITH FLEXIBLE FLAT FEET. A RANDOMIZED CONTROLLED TRIAL"

STUDY PROMOTER
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It is important that you understand before deciding whether or not to participate in this study, why this research is necessary, everything that may involve your child's participation, what will be done with the information and also the possible benefits, inconveniences or risks that may entail. Without further ado, take the time you need to do a comprehensive reading and read all the information provided below.
REASON FOR STUDY
The main reason is to know if personalized plantar orthoses together with a regimen of specific exercises produce equal or better results regarding the signs and symptoms of PFF, compared to only specific exercises.
VOLUNTARY PARTICIPATION
You should know that your child's participation in this study is completely voluntary, so you can decide not to participate, change your decision at any time, without this having any impact on you or your child.
WITHDRAWAL FROM THE STUDY
In the event that you decide to leave the study, you may do so by allowing the data obtained up to the time of withdrawal from the study to be used, or by deleting all the data obtained from your child.
PARTICIPANTS
The study is designed so that all children from 3 to 12 years old, who have flexible infant flatfoot and also do not have any neurological disease or have undergone any surgery on the lower limbs, can participate.
DESCRIPTION OF THE INTERVENTION AND THE FOLLOW-UP
The clinical trial consists of the diagnosis of flexible flatfoot and the establishment of one of the two available treatment options at random. Your child may be treated with one type or another of plantar orthoses (some specific for flatfoot and others for all types of feet) in addition to a series of specific exercises. A review would be made at one month of treatment and another at 6 months and finally, the final review of the study, 12 months after the start of treatment.
All data related to flatfoot (type of flatfoot, valgus degrees, joint mobility, if there is pain, etc.) and its evolution will be collected.
POSSIBLE BENEFITS
We find several benefits, first of all is the diagnosis of this alteration of the foot, since there are many people who do not know that they suffer from it and that it can bring problems in the long run, so preventing these future ailments would be the first and most important benefit. In addition, your child will have 3 complete and thorough biomechanical studies, so other alterations that could be missed could be detected. All interventions are completely harmless and will provide you with information about the health of your child's feet.
The cost of treatment and biomechanical studies is zero, with the possibility, once the study period is over, to continue seeing evolution or establishment of a "more correct" treatment. Universally, the results and conclusions of the study will be beneficial in the future for all children who have flexible flat feet. If we get results that show which treatment is more effective, health professionals will not have so many uncertainties for the treatment of flat feet. This way all flexible flat feet will be treated properly, and money would be saved or unnecessary surgeries.
POSSIBLE RISKS OR DISCOMFORT
According to the current literature there is no risk when treating flatfoot with plantar orthoses and exercises. In addition, the purpose of this study is to know if plantar orthoses

are really necessary for the treatment of flatfoot, so the treatment group with plantar orthoses for all types of feet would not trigger any risk either.
The discomfort could come from the adaptation to the plantar orthosis or the exercises. Some type of dermatology alterations derived from chafing or allergy to the materials of the plantar orthoses have been described, although these are not frequent.
ACCESS AND PROTECTION OF PERSONAL DATA
All data are of a personal nature and will comply with the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights. According to what is established in this legislation, you could exercise all your rights (access, modification, opposition and cancellation of data). The way to exercise this right would be to address any staff working in the clinic.
All the data handled in the study will be identified through a code, which means that only the study promoter and the collaborators will be able to relate that code with the data of their child. Therefore, your identity and that of your child will not be disclosed to any person, except for exceptions such as a medical emergency or a legal requirement.
CONTACT IN CASE OF DOUBTS
If at any time you have any questions or require more information you can contact Cristina Molina García as responsible for the study at the telephone number 968 280 023 or through the email ucampodologia@ucam.edu.
Model for revocation of informed consent:
SECTION FOR THE REVOCATION OF CONSENT
I, D./D^{a} with DNI representative of the participant D./D^{a}__
I revoke the consent to participate in the study, signed above. Dated
Signature parent/legal guardian
Investigator's signature

Appendix C. Patient Medical History and Report

Table A2. Patient Medical History and Report.

ANAMNESIS.			
Name:		Identification Code:	
Name and ID father/mother/legal guardian:			
Address:		Phone:	
DNI:	Email:		
Date of birth:		Age:	
Weight:	Height:	BMI:	
Allergies:	Background:		
Standing number:	Gender: Male/Female		
Level of physical activity:	High/Medium/Low		
EXPLORATION-ASSESSMENT			
IPF	Punctuation:	Pronated/Normal/Supinate	
NAVICULAR DROP			(mm)
DOUBLE HEEL RISE TEST	Positive/Negative		
SINGLE HEEL RISE TEST	Positive/Negative		
PAIN (VAS SCALE)	Symptomatic/Asymptomatic	Punctuation:	
PRCA			(degrees)

Table A2. *Cont.*

WINDLASS TEST	Positive/Negative		
ARC HEIGHT INDEX	Punctuation:		
MAXIMUM PRONATION TEST	Positive/Negative		
ASA AXIS	Lateralized/Neutral/Medialized		
SUPINATION RESISTANCE TEST	High/Moderate/Low		
CHIPPAUX-SMIRAK INDEX			(cm)
BEIGHTON SCALE	Punctuation:	Hyperlax/Normal	
TYPE OF FOREFOOT	Abduccido/Neutral/Adducido		
FOOTWEAR	Heel level: Medial/Center/Lateral		
PODOSCOPE	Pronate/Supine/Neutral		
PRONATION ANGLE			(degrees)
SILFVERSKIOLD TEST			(degrees)
NAVICULAR HEIGHT			(mm)
PRESSURE PLATFORM			
Maximum pressure zone:			
Center of gravity			
Gait progression line			
Load/weight percentage	Left	Right	
	Ant: Post:	Ant: Post:	
	Left:	Dx:	

REPORT EXERCISES AND RECOMMENDATIONS

Exercises to be performed:

1. Tiptoe for 1 min.
2. Walk with the outer lateral edge of the foot for 1 min.
3. Stand on tiptoe, hold on for 2 s and go down 15 times.
4. Hold a tennis ball with your heels and stand on tiptoe without the ball falling, hold 2 s and go down. Perform 15 repetitions.
5. Take marbles or pens with your toes and try to put them in a bucket or change them for 1 min.
6. Stand on a towel or paper and crumple it with your toes, make this gesture for a minute.
7. Standing try to increase the arch of the foot making the greatest possible effort, do 15 repetitions.
8. To finish, standing with a ball under the sole of the foot make pressures at different points of the foot and perform stretching of the triceps sural with extended knee and bent knee.

All exercises will be repeated twice each.
All these exercises will not structure the deformity and do not develop compensations in other body segments. With them we are working all the intrinsic and extrinsic muscles of the foot involved in children's flatfoot. The rebalancing of this musculature will cause the stabilizing function of the foot to develop, in addition to improving its correct activation during dynamics.
Using the template:

1. During the first week, the plantar orthoses should be implanted progressively, that is, on the 1st day for two hours, on the 2nd day for 4 h and so on.

2. Plantar orthoses are for daily use whenever the child is standing or walking, that is, they must be worn every day for as many hours as possible.
3. They can be washed with soap and cold water.
4. Do not put them near a heat source, such as on top of a radiator.
5. If they cause discomfort or signs of inflammation, redness or blisters appear on their skin, remove their child's plantar orthoses and contact the clinic.

Footwear:

The use of correct footwear is of great importance and is considered as one more part of the treatment of flatfoot, it is also considered as a trigger of flatfoot.

Avoid wearing shoes without any type of support type flip-flops or footwear that is totally flat, without any sole.

An ideal footwear for children should have a rigid buttress, should not be small or too large (should fit the index finger between the heel and the shoe), should also have a thick sole (never heels) and should not be very rigid. Children's shoes should carry any method of adjustment such as laces or Velcro and care must be taken that they are not made of synthetic material to allow perspiration.

Appendix D. Necessary Material and Budget

MATERIALS	COST
Pressure platform, computer, stretcher, goniometer, scissors, vacuum, polisher, podoscope, printer, SPSS package, pedigraph	€0
Consumables: folios, pens, stretcher sheets, printer ink, gloves, masks, pedigraph ink	100 €
Elaboration 168 plantar orthoses: phenolic foams, plaster, polypropylene, EVA linings, glue	1680 €
Publication of the article in open access	2000 €
Presentation at congresses	700 €
TOTAL BUDGET	4480 €

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