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APLICACIÓN DE CUESTIONARIOS DE AUTOVALORACIÓN EN PACIENTES CON HALLUX VALGUS

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"**APLICACIÓN DE CUESTIONARIOS DE AUTOVALORACIÓN EN PACIENTES CON HALLUX VALGUS**",

presentada por la doctoranda Dña. Luci Motta da Rocha y dirigida por el Doctor D. Gerardo Luis Garcés Martín.

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Que ha valorado la Tesis Doctoral presentada por **Dña. Luci Motta da Rocha** titulada "**APLICACIÓN DE CUESTIONARIOS DE AUTOVALORACIÓN EN PACIENTES CON HALLUX VALGUS**", realizada en la modalidad de Compendio de publicaciones, y que surge tras la publicación de tres artículos en revistas de impacto en JCR. Considera que la Tesis reúne los requisitos de calidad, rigor científico y exposición para ser defendida públicamente por su autora a fin de conseguir el grado de doctor por la Universidad de Las Palmas de Gran Canaria.

Las Palmas de Gran Canaria, a 10 de noviembre de 2023

José Manuel García Castellano

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RESUMEN

Antecedentes: El hallux valgus es una deformidad del primer dedo del pie que afecta fundamentalmente a mujeres, con una prevalencia entre el 28 y 36%, que se incrementa con la edad. La tendencia actual de su tratamiento es la realización de técnicas percutáneas y mínimamente invasivas para corregir las deformidades y aumentar la calidad de vida de los pacientes. Para valorar los resultados del tratamiento se efectúan fundamentalmente estudios radiológicos, aplicación de pruebas funcionales y objetivas sobre el pie y, de forma especial, se aplican cuestionarios auto-cumplimentados por los pacientes que permiten conocer la satisfacción de éstos con el resultado obtenido. Todas estas pruebas se llevan a cabo antes de la intervención y posteriormente un tiempo tras la misma, bien secuencialmente o en un momento determinado.

Metodología: Este trabajo constituye una memoria de tesis doctoral por compendio de tres publicaciones en revistas internacionales con factor de impacto en JCR. En el primero de ellos se comparan los resultados radiológicos previos a la intervención, los resultados funcionales aplicando la escala de la American Orthopaedic Foot and Ankle Society (AOFAS) y los resultados basados en la percepción de los pacientes aplicando el cuestionario de Manchester Oxford Foot Questionnaire (MOXFQ) en 73 mujeres operadas percutáneamente de hallux valgus, con los observados 6 años después de la operación. En el segundo trabajo se efectúa un estudio secuencial de los valores del MOXFQ en 63 mujeres operadas percutáeamente de hallux valgus, desde el preoperatorio hasta seis años después, en tres ocasiones. La característica especial es que las pacientes no sufrieron complicaciones postoperatorias. En el tercer trabajo se efectúa una traducción, adaptación transcultural y validación de un cuestionario de valoración de patología del pie auto-aplicable por el paciente, el Self-administered Foot and Ankle Questionnaire (SAFE-Q), desde el original en inglés al español.

Resultados: En el primer artículo se aprecia una mejora significativa de los resultados entre el preoperatorio y el postoperatorio, tanto en los parámetros radiológicos como en los funcionales y de auto-valoración. Sin embargo, no se apreció correlación significativa entre las diferencias radiológicas pre-postoperatorias con las diferencias pre-postoperatorias de los valores de AOFAS y MOXFQ, salvo entre los valores de AOFAS con la posición del sesamoideo medial y la traslación de la primera cabeza metatarsal. En el segundo artículo, se apreció una mejora significativa de los valores de MOXFQ entre el preoperatorio y el primer año tras la cirugía, manteniéndose los valores en cifras similares durante los otros cinco años estudiados. En el tercer artículo se aporta la versión en español del SAFE-Q apreciándose una correlación significativa entre las diferentes subescalas del cuestionario, con una correlación máxima de 0.768 ($p<0.001$) y un valor alfa de Chronback de 0.894 (95% IC, 0.858-0.924), que varió entre 0.863 y 0.889 cuando se suprimió una de las subescalas, indicando la alta consistencia interna.

Conclusiones: Estos estudios muestran que no hay correlación significativa entre las diferencias radiológicas y las diferencias de los parámetros clínicos entre los valores preoperatorios y los observados seis años después de la cirugía percutánea de hallux valgus. Los valores del cuestionario de autovaloración mejoran significativamente tras el primer año, pero se mantienen sin cambios posteriormente en pacientes que no presentan complicaciones. La versión en español del cuestionario SAFE-Q puede ser usada con seguridad por pacientes y terapeutas hispanoparlantes, al mostrar alta consistencia con el cuestionario original en inglés.

Palabras clave: Hallux valgus; Cirugía percutánea; AOFAS; MOXFQ; SAFE-Q

SUMMARY

Background: Hallux valgus is a deformity of the first toe that mainly affects women, with a prevalence between 28 and 36%, which increases with age. The current trend in its treatment is using percutaneous and minimally invasive techniques to correct deformities and improve patients' quality of life. Radiological studies and functional and objective tests were applied to assess the treatment results. In particular, questionnaires self-completed by the patients are used to determine their satisfaction with the result obtained. All these tests are carried out before the intervention and later, sometime after it, either sequentially or at a specific time. **Methodology**: This work constitutes a doctoral thesis report by a compendium of three publications in international journals with an impact factor in JCR. In the first one, the radiological results before the intervention are compared, the functional results applying the American Orthopedic Foot and Ankle Society (AOFAS) scale and the effects based on the patient's perception using the Manchester Oxford Foot Questionnaire. (MOXFQ) in 73 women undergoing percutaneous surgery for hallux valgus, with those observed six years after the operation. In the second work, a sequential study of the MOXFQ values is carried out in 63 women who underwent percutaneous surgery for hallux valgus from preoperative to six years, then on four occasions. The special feature is that the patients did not suffer postoperative complications. In the third work, a translation, cross-cultural adaptation, and validation of a self-administered foot pathology assessment questionnaire by the patient, the Self-administered Foot and Ankle Questionnaire (SAFE-Q), is carried out. **Results**: In the first article, a significant improvement in the results between preoperative and postoperative periods is seen, both in the radiological, functional, and self-assessment parameters. However, no significant correlation was observed between the pre-postoperative radiological differences with the pre-postoperative differences in the AOFAS and

MOXFQ values, except between the AOFAS values with the position of the medial sesamoid and the translation of the first metatarsal head. In the second article, a significant improvement in MOXFQ values was observed between preoperative and the first year after surgery, with values remaining at similar figures during the other five years studied. The third article provides the Spanish version of the SAFE-Q, showing a significant correlation between the different subscales of the questionnaire, with a maximum correlation of 0.768 ($p<0.001$) and a Chronback alpha value of 0.894 (95% CI, 0.858 - 0.924), which varied between 0.863 and 0.889 when one of the subscales was deleted, indicating high internal consistency. **Conclusions**: These studies show no significant correlation between radiological differences and differences in clinical parameters between preoperative values and those observed six years after percutaneous hallux valgus surgery. The values of the self-assessment questionnaire improve significantly after the first year but remain unchanged later in patients without complications. The Spanish version of the SAFE-Q questionnaire can be used safely by Spanish-speaking patients and therapists, as it shows high consistency with the original questionnaire in English.

Keywords: Hallux valgus; Percutaneous surgery; AOFAS; MOXFQ; SAFE-Q

ABREVIATURAS

AOFAS: American Orthopaedic Foot and Ankle Society

DFS: distancia entre el eje del segundo metatarsiano y el borde lateral del sesamoideo externo

FSP: posición del sesamoideo lateral

HVA: ángulo de hallux valgus

IMA: ángulo intermetatarsal entre primer y segundo radio

MOXFQ: Manchester-Oxford Foot Questionnaire

MIS: cirugía mínimamente invasiva

PROMs: patient reported outcomes measures

SAFE-Q: Self-administered Foot Evaluation Questionnaire

TMH: traslación de la primera cabeza metatarsal

TSP: posición del sesamoideo medial con respecto al eje del primer metatarsiano

INTRODUCCIÓN

El hallux valgus es una deformidad del primer dedo del pie que consiste en desviación hacia fuera del dedo con traslación interna de la cabeza del primer metatarsiano. Este desplazamiento puede producir una protrusión en la piel y crear un bultoma que puede ser doloroso y es conocido popularmente como "juanete". Afecta fundamentalmente a mujeres y existen factores predisponentes para su aparición, entre los que se encuentran el sexo, la edad, el uso de calzado inadecuado y una historia familiar positiva para esta deformidad. Aunque su nivel de prevalencia es muy elevado, su importancia principal radica en la disminución de la calidad de vida que provoca en las pacientes que la padecen (Zhu et al. 2021, Lewis et al. 2022).

El tratamiento conservador del hallux valgus incluye modificaciones en el estilo de vida, en el tipo de calzado a usar, el empleo de ortesis correctoras y en modificar algunas actividades de la vida diaria. Cuando estas medidas no son efectivas para evitar el progreso de la deformidad y el dolor que puede presentarse se recurre al tratamiento quirúrgico. En líneas generales se considera que los objetivos de este tipo de tratamiento persiguen mejorar el estado estético del pie, aliviar el dolor, mejorar la estabilidad de la primera articulación metatarso-falángica y mejorar la calidad de vida de los pacientes (Ray et al. 2019).

Se han descrito más de 120 técnicas quirúrgicas para corregir el hallux valgus y sus deformidades asociadas. Clásicamente estas técnicas se llevaban a cabo mediante cirugía abierta, apoyada en el uso de elementos de fijación de los fragmentos óseos desplazados para la corrección. Sin embargo, en las últimas décadas se ha ido imponiendo el uso de técnicas percutáneas y mínimamente invasivas para efectuar las correcciones. Sus teóricas ventajas incluyen que las incisiones son más pequeñas, el dolor post-operatorio es menor, el uso de rehabilitación menos prolongado, y la reincorporación a las actividades de los pacientes mucho más precoz (Biz et al. 2016, Guo et al. 2021, Trnka 2021, Nair et al. 2022). No obstante, también pueden ser considerables sus desventajas, entre las que hay que incluir el incremento del tiempo operatorio, el uso de fluoroscopia para las intervenciones, el mayor número de complicaciones cutáneas postquirúrgicas, y el mayor coste de las intervenciones (Guo et al. 2021, Nair et al. 2022, Castellini et al. 2022).

Estado actual de la cirugía mínimamente invasiva en el tratamiento del hallux valgus

Es importante tener en cuenta que suele haber una gran confusión a la hora de discernir entre cirugía percutánea y cirugía mínimamente invasiva (MIS). Siguiendo a Trnka (2021), debe considerarse cirugía percutánea en aquellos casos en los que la intervención se lleva a cabo mediante pequeñas incisiones en la piel y la corrección de las osteotomías se efectúa manualmente. Sin embargo, el término mínimamente invasiva debería ser aplicado a aquellos casos en los que se requiere una apertura mayor, aunque no tanto como en la cirugía abierta, y se usan materiales a través de esas incisiones, generalmente para osteosíntesis.

Las técnicas mínimamente invasivas comenzaron tras la propuesta de Isham (1991), el cual producía una incisión oblicua incompleta a nivel de la metáfisis del primer metatarsiano. Al ser incompleta la osteotomía, el cirujano junta los dos fragmentos a través del hueco de la osteotomía y permite corregir buena parte de la deformidad. Este tipo de técnicas forman parte de la denominada primera generación de MIS, en las que no se usan elementos externos para mantener unidos los fragmentos óseos, salvo vendajes.

En la segunda generación de MIS, el fundamento de la ostetomía de cuello del primer metatarsiano es el mismo, añadiéndole un desplazamiento lateral de la cabeza para cerrar el ángulo intermetatarsal y además una aguja de Kirshner intramedular, colocada percutáneamente, que ayuda a mantener el desplazamiento logrado en la cabeza (Bosh et al. 1990).

La tercera generación de MIS mantiene la osteotomía percutánea, realizada mediante broca cilíndrica dentada, lo que permite cerrar el ángulo intermetatarsal y también el ángulo de hallux valgus. En estas técnicas se añade algún tipo de tornillo (el tipo Herbert es el más usado) colocado percutáneamente para ayudar a fijar la cabeza metatarsal en el sitio deseado (Del Vechio et al. 2020, Trnka 2021). Finalmente, en la cuarta generación de MIS se mantienen los mismos fundamentos, pero el desplazamiento de la cabeza metatarsal se efectúa a nivel tridimensional, corrigiendo no sólo el ángulo intermetatarsal y hallux valgus, sino también las deformidades giratorias. Ello implica la colocación de tornillos largos tipo Herbert colocados proximalmente hacia la cabeza metatarsal bajo visión fluoroscópica, permitiéndose incluso el apoyo inmediato tras la cirugía (Lewis et al. 2022).

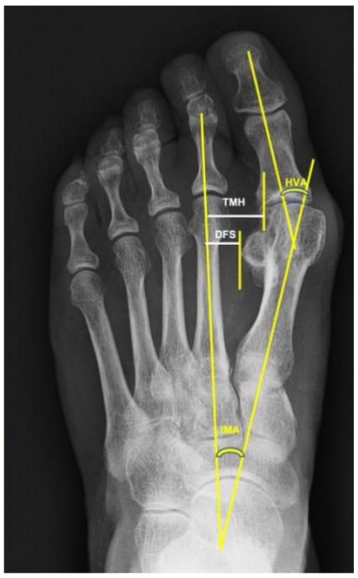
Métodos de valoración de resultados en cirugía del hallux valgus

La valoración de resultados en el tratamiento de hallux valgus está basada en tres bloques. En uno de ellos se estudian las modificaciones radiológicas pre y postoperatoriamente de las deformidades presentes; en otro se valoran los resultados objetivamente bajo el punto de vista del observador, casi siempre el terapeuta implicado; y en el tercero se estudian los resultados basados en la opinión de los pacientes, los cuales son casi siempre los que cumplimentan el cuestionario que se les presenta para dicha autovaloración.

Valoración radiológica

Se efectúa a partir de radiografías de ambos pies, tomadas en bipedestación o apoyo monopodal, en proyección dorso-plantar y lateral. Los parámetros más usados para la valoración son el ángulo de hallux valgus (HVA), el ángulo intermetatarsal entre primer y segundo radio (IMA), y la posición de los sesamoideos (Zambelli et al. 2020). El HVA está formado por la prolongación del eje del primer metatarsiano con el eje de la primera falange. Su valor normal es de 15º o menos. Cuanto mayor sea el ángulo, mayor la severidad del hallux valgus. El IMA se mide entre las prolongaciones de los ejes diafisarios del primer y segundo metatarsianos. En condiciones normales debe ser de 9º o menos, siendo su aumento también un índice de severidad de la deformidad. La posición de los sesamoideos indica cual es la relación de la cabeza del primer metatarsiano con respecto a los mismos, especialmente el sesamoideo lateral. Aunque hay muchas formas de medirlas, generalmente las más usadas son la distancia entre el eje del segundo metatarsiano y el borde lateral del sesamoideo externo (DFS), y la posición del sesamoideo medial con respecto al eje del primer metatarsiano (TSP).

(Figura 1)



Métodos objetivos de valoración del hallux valgus

Los métodos objetivos de valoración están basados en la observación por parte de un explorador externo, casi siempre el terapeuta que ha efectuado el tratamiento. El método más usado y sencillo es la simple observación, diferenciando entre el aspecto pre y postoperatorio, incluso con el uso de fotografías. Obviamente este método tiene muchos problemas de reproducibilidad por lo que se tiende a una valoración más objetiva y que pueda servir de comparación medible entre los momentos que se realiza. Aunque hay muchas escalas, la más usada es la publicada por la American Orthopaedic Foot and Ankle Society (AOFAS), una escala con un rango entre 0 y 100 puntos que incluye estudio de movilidad, dolor y actividades de la vida diaria. A pesar de haber sido publicados resultados controvertidos con su uso, continúa siendo el cuestionario de valoración objetiva más usado (Adames et al. 2022, Alimy et al. 2023, Hernández-Castillejo et al. 2022).

Métodos de auto-valoración de resultados quirúrgicos del hallux valgus

Los métodos de autovaloración de resultados o *patient reported outcomes measures (PROMs)* son los más usados en la actualidad porque proporcionan información obtenida directamente desde el paciente, sin intervención de la perspectiva del terapeuta, lo que minimiza las interpretaciones del equipo quirúrgico. En líneas generales miden calidad de vida, dolor y aspectos específicos del problema a tratar.

Entre los más usados para valorar la calidad de vida en pacientes con hallux valgus se encuentran el cuestionario SF-36 y el Euroquol-5, siendo casi unánime el uso de la escala analógica visual para valorar el dolor (Schrier et al. 2015, Adames et al. 2022, Hernández-Castillejo et al. 2022). Aunque existen varias escalas de valoración como PROMs, sin duda la de Manchester-Oxford Foot Questionnaire (MOXFQ) es la más usada en patología del pie (Schrier et al. 2015, Adames et al. 2022, Hernández-Castillejo et al. 2022). Consiste en una escala de 16 preguntas separadas en 3 subescalas que pueden alcanzar un valor máximo de 100, aportando un interesante abordaje evaluador desde cada una de las subescalas. Su reproducibilidad, validez y aplicabilidad han sido ampliamente demostradas (Dawson et al. 2021, Adames et al. 2022).

JUSTIFICACIÓN

El hallux valgus es una deformidad que afecta fundamentalmente a mujeres, con una prevalencia de alrededor del 28% en edades entre los 18 y 65 años, ascendiendo hasta el 36% por encima de los 65 años (Trnka 2022). Debido a la disminución de la calidad de vida que provoca en las personas que lo padecen (Lewis 2021, Hernández-Castillejo 2022), se recomienda un tratamiento quirúrgico para solucionar las deformidades que entraña. Aunque clásicamente el tratamiento quirúrgico ha consistido en la realización de técnicas de cirugía abierta tradicional, en las últimas décadas hay una clara tendencia a la realización de técnicas mínimamente invasivas y percutáneas para corregir las deformidades, debido a las ventajas demostradas sobre la cirugía clásica.

Para valorar si las técnicas efectuadas han sido efectivas, se aplican unos cuestionarios y escalas que permitan comparar los resultados en distintos periodos de tiempo, especialmente entre el preoperatorio y etapas postoperatorias. Como se ha señalado anteriormente, la escala de AOFAS y el cuestionario de MOXFQ son los más usados para valorar funcional y subjetivamente los resultados de la cirugía del hallux valgus. Diversos estudios demuestran que los pacientes mejoran los resultados al comparar valores pre con postoperatorios, aunque con seguimientos relativamente cortos de alrededor de dos años (Holme et al. 2020, McMurrich et al. 2020, Lewis et al. 2021, Lewis et al. 2022). Algunos autores han estudiado los resultados con seguimientos de al menos 5 años (Lewis et al. 2023). Sin embargo no está claro cuál es la evolución en el tiempo de los resultados.

Actualmente se prioriza la satisfacción de los pacientes en la valoración de resultados tras un procedimiento terapéutico. Se ha comprobado que hasta un 10% de pacientes sometidos a cirugía de hallux valgus quedan insatisfechos, independientemente de la técnica usada (Klein et al, 2022). Sin duda, la aparición de complicaciones como

infecciones, no-unión de la osteotomía, problemas relacionados con el material de osteosíntesis y tromboflebitis, son factores que influyen negativamente en los resultados quirúrgicos. En este sentido, es fundamental que el cirujano advierta a sus pacientes de esta posibilidad y como puede influir en el resultado final. El conocimiento de la evolución en el tiempo de los resultados es de gran importancia para aportar esa información. La mayoría de cirujanos condicionan la información aportada a los pacientes a la aparición de complicaciones. Sin embargo, es de gran valor comunicarles lo que deben esperar con el paso del tiempo y como se modifican los resultados si no sobrevienen complicaciones a las que achacar la negatividad de los mismos. Uno de los artículos que constituyen esta tesis doctoral tuvo como objetivo estudiar las modificaciones observadas a lo largo del tiempo en los resultados, cuando no se producen complicaciones.

Las modificaciones en los parámetros radiológicos entre el pre y el postoperatorio constituyen uno de los más importantes criterios de valoración de resultados tras la corrección quirúrgica del hallux valgus. Los dos parámetros más usados son el HVA y el IMA (Zambelli et al. 2020). Sin embargo, actualmente se considera que la subluxación de los sesamoideos con respecto a la primera cabeza metatarsal es uno de los criterios fundamentales para valorar el hallux valgus. Durante la progresión de la deformidad la cabeza es la que va desplazándose hacia dentro, mientras que los sesamoideos retienen su posición con respecto a la segunda cabeza metatarsal (Agraval et al. 2011). Por ello se han establecido diversas clasificaciones basadas en la posición de los sesamoideos, especialmente la del sesamoideo medial con respecto al primer metatarsiano. Entre estos métodos de valoración se encuentran la clasificación de Hardy y Clapman (1951), que considera siete posibles posiciones del sesamoideo medial, y la más reciente y sencilla de la American Orthopaedic Foot and Ankle Society (Smith et al. 1986), que etiqueta sólo cuatro posiciones y es más reproducible.

Varios autores han señalado la importancia de la posición de los sesamoideos sobre la recurrencia de la deformidad (Choi et al. 2018, Ezzatvar et al. 2021). Sin embargo, hay una gran controversia acerca de la relación de la posición de los sesamoideos con los resultados clínicos (Wilson et al. 2009, Chen et al. 2016, Zitouna et al. 2019, Mathews et al. 2019). Dado que el principal objetivo de la corrección quirúrgica del hallux valgus es mejorar la alineación del dedo y mejorar los resultados de los parámetros clínicos preoperatorios, es importante conocer si la corrección alcanzada radiológicamente se correlaciona con la obtenida clínicamente. Partiendo de la hipótesis de que deberían estar significativamente correlacionados, se llevó a cabo un trabajo para estudiar si las diferencias observadas radiológicamente entre los valores pre y postoperatorios se correlacionaban con las diferencias pre-postoperatorias de los valores funcionales y los basados en la observación de los pacientes.

Como se ha señalado previamente, hay varios tipos de cuestionarios que deben ser auto-cumplimentados por los pacientes para valorar los resultados de la corrección del hallux valgus (Schrier et al. 2015). En todos ellos se echa en falta una valoración más exhaustiva de la importancia del calzado en los resultados obtenidos. La publicación por parte de la Sociedad Japonesa de Cirugía Ortopédica del SAFE-Q (Self-administered Foot Evaluation Questionnaire) (Niki et al. 2013) supuso un importante avance en este sentido. Fue originariamente publicado en inglés y posteriormente validado, mostrando unas adecuadas propiedades psicométricas (Niki et al. 2017).

El SAFE-Q es un cuestionario de fácil auto-cumplimentación de 34 puntos divididos en 5 subescalas que cubren casi todos los aspectos relacionados con la patología del pie y su relación con el calzado. Adicionalmente cuenta con otros 9 puntos dedicados especialmente a aspectos deportivos. El uso de un PROM en una lengua diferente a la publicación original requiere de una traducción exacta y de una adaptación cultural al

nuevo idioma para mantener la validez y las propiedades psicométricas del cuestionario original (Gijón-Nogueron et al. 2014, Garcés et al. 2016). Teniendo en cuenta que el español es la lengua madre de más de 400 millones de personas en el mundo, se consideró como tercera aportación a esta tesis por compendio de publicaciones efectuar una traducción y adaptación transcultural del SAFE-Q al español, para ser usado por los hispanoparlantes de forma válida y reproducible.

OBJETIVOS

General

El objetivo general de este trabajo fue valorar las modificaciones que se producen en los resultados funcionales y subjetivos, bajo el punto de vista de los pacientes, tras corrección percutánea de las deformidades en pacientes afectos de hallux valgus.

Específicos

Como objetivos específicos del estudio se establecieron:

- Valorar si las deformidades radiológicas en pacientes con hallux valgus se correlacionan con los resultados funcionales y subjetivos de cuestionarios aplicados a este tipo de pacientes antes de la corrección quirúrgica, y cómo se modifica esta correlación tras la cirugía.
- Valorar la evolución en el tiempo de los resultados de los cuestionarios más usados en el estudio de la patología del hallux valgus, centrado en pacientes que no refirieron complicaciones postquirúrgicas.
- Validar un cuestionario internacional contestado por pacientes con patología de antepié, publicado y validado en inglés, para ser usado fácilmente y de forma reproducible por pacientes hispanoparlantes.

ESTUDIOS REALIZADOS

Los estudios efectuados fueron sometidos previamente a aprobación por el Comité Ético de la Universidad de Las Palmas de Gran Canaria (Ref. CEIH-2018-02) (Anexo 1) y por el del hospital Dr Negrín, responsable de esta función en la provincia de Las Palmas (Ref. CEIm-LP-2021-418-1) (Anexo 2). Los pacientes recibieron una explicación oral y escrita y firmaron un consentimiento informado para participar en el estudio (Anexo 3). Los estudios se realizaron de acuerdo con los principios de la Declaración de Helsinki de 1964 de protección a los pacientes.

La metodología y resultados con el aplicativo estadístico se presenta en cada uno de los trabajos publicados. A modo de orientación se resumen a continuación los tipos de estudios realizados, los cuales dieron lugar a los trabajos publicados posteriormente.

Estudio de la correlación de resultados clínicos y radiológicos entre el preoperatorio y seis años tras la corrección quirúrgica de hallux valgus.

El principal objetivo de la corrección quirúrgica del hallux valgus es corregir la alineación del primer dedo del pie, mejorando los resultados funcionales y reportados por el paciente. Aparte de las aparentes modificaciones clínicas, los cambios radiológicos son el medio para determinar el resultado de la corrección quirúrgica. Sin embargo, existe una gran controversia en la literatura acerca de la importancia real que pueda tener la corrección desde el punto de vista radiológico con respecto a los resultados clínicos. El objetivo principal de este trabajo fue estudiar la correlación de la diferencias entre los valores pre y postoperatorios de los parámetros radiológicos, principalmente la posición sesamoidea,

con las diferencias entre los resultados clínicos del preoperatorio y los del seguimiento postoperatorio.

Los objetivos específicos de este trabajo fueron los siguientes:

1. Comparar los valores de los parámetros radiológicos y los resultados clínicos medidos en el preoperatorio versus postoperatorio tras la corrección del HV.
2. Estudiar la correlación de los valores radiológicos pre y postoperatorios con los valores pre y posoperatorios de las puntuaciones de resultados funcionales y reportadas por el paciente.

Nuestra hipótesis fue que la mejora de los parámetros radiológicos tras la operación debería estar significativamente relacionado con la mejora en los resultados de la puntuación clínica.

El estudio se llevó a cabo con 73 mujeres mayores de 18 años, intervenidas de hallux valgus unilateral de forma percutánea mediante la técnica de Inshall-Reverdin modificada. Desde el punto de vista clínico la valoración se efectuó a través de los cuestionarios de AOFAS y del MOXFQ. Radiológicamente las pacientes fueron valoradas mediante radiografía en apoyo monopodal para medir el HVA, el ángulo intermetatarsal I-II, la posición del sesamoideo medial (TSP), la traslación de la primera cabeza metatarsal (TMH) y la posición del sesamoideo lateral (FSP). Todas las medidas y valoraciones fueron llevadas a cabo por dos observadores 24 horas antes de la intervención y alrededor de 6 años después de la misma. El análisis estadístico se efectuó aplicando una T-Student para muestras pareadas al comparar valores de los mismos pacientes y un test de regresión multiple para predecir las variables numéricas.

Los resultados mostraron una mejoría significativa entre el preoperatorio y el postoperatorio, tanto en los parámetros clínicos como radiológicos. Los parámetros radiológicos no se correlacionaron significativamente ni con los valores de AOFAS ni con los de MOXFQ, tanto en el preoperatorio como en el postoperatorio. Sin embargo se apreció una correlación moderada entre la diferencia pre-postoperatoria de los valores de AOFAS con la diferencia pre-postoperatoria de los valores de TSM y TMH. La correlación de la diferencia pre-postoperatoria de los valores de MOXFQ no fue significativa con las diferencias pre-postoperatoria de ninguno de los parámetros radiológicos.

En el trabajo se concluye que aunque los parámetros radiológicos y los test funcionales y subjetivos mostraron una mejoría significativa entre el pre y el postoperatorio, la correlación de las diferencias de los resultados pre-postoperatorio radiológicos solo fue discretamente significativa con respecto a algunos parámetros de las posiciones sesamoideas. Este hallazgo debería informarse a los pacientes para que no consideren que mejoría clínica y mejoría radiológica están significativamente relacionadas.

Modificaciones en el tiempo de los valores funcionales y subjetivos de pacientes sometidos a cirugía percutánea de hallux valgus que no presentan complicaciones

La cirugía mínimamente invasiva del hallux valgus se ha ido popularizando cada vez más, hasta el punto de ser la más usada en la actualidad. Sin embargo, aunque la técnica sea efectuada por cirujanos expertos, hay un gran potencial para complicaciones postoperatorias, lo que condiciona en gran medida los resultados funcionales y

satisfacción de los pacientes, a pesar de la consecución de correcciones radiológicas evidentes.

Aunque se usan muchas escalas y cuestionarios para valorar los resultados funcionales tras la cirugía, la escala AOFAS (American Orthopaedic Foot and Ankle Society) es la más empleada, a pesar de que su valoración incluye parámetros que presentan cierta controversia en su reproducibilidad y aplicabilidad. Esta escala es obtenida a partir de observaciones del terapeuta, lo que permite incluir algún tipo de subjetividad en su aplicación. Actualmente se da más importancia a los resultados obtenidos desde el punto de vista de la valoración del paciente. Ello implica que aunque los resultados funcionales y radiológicos "sean buenos", si el paciente no está satisfecho, el resultado sea cuestionable. Entre los distintos cuestionarios basados en la valoración del paciente o PROMs, el más usado en el tratamiento del hallux valgus es el de Manchester-Oxford Foot Questionnaire (MOXFQ).

Los cirujanos están obligados a informar a sus pacientes acerca del tipo de intervención al que van a ser sometidos, las posibles complicaciones y la durabilidad de los resultados obtenidos. Estos vienen condicionados en gran medida por las posibles complicaciones que se presenten, lo cual es imposible de determinar con certeza antes de la cirugía. No obstante, el paciente debe saber lo que puede esperar si todo va "bien" y no hay complicaciones, aspecto que no se ha estudiado hasta ahora.

Los objetivos de este trabajo fueron valorar las modificaciones en los resultados funcionales y subjetivos a lo largo del tiempo, en mujeres intervenidas de hallux valgus mediante cirugía minimamente invasiva, cuando no se producen complicaciones. Nuestra hipótesis fue que cuando no se presentan complicaciones los resultados no varían con el

tiempo, y ello debe informarse al paciente como un aspecto importante sobre las expectativas de su intervención.

El trabajo fue un estudio observacional longitudinal retrospectivo que incluyó a 63 mujeres intervenidas por MIS de hallux valgus mediante una técnica modificada de Inshall-Reverdin. La edad media fue de 57 años y solo se incluyó en el estudio a mayores de 18 años con hallux valgus unilateral mayor de 20º y cuya causa de intervención fue dolor o limitación en actividades de la vida diaria. Se excluyeron las pacientes intervenidas de los dedos menores o con dolor bilateral. Todas las pacientes fueron valoradas mediante la escala de AOFAS y el cuestionario de MOXFQ dentro de los cinco días previos a la intervención, y posteriormente al cabo de 1, 4.7 y 6.5 años tras la operación. Los valores fueron comparados mediante un modelo lineal de medidas repetidas considerando el tiempo (desde el preoperatorio hasta el tercer control postoperatorio) como factor de referencia.

Los resultados demuestran que, si bien hubo una mejora significativa de los valores de ambos cuestionarios entre el estadio preoperatorio y los otros tres periodos, las diferencias entre los tres periodos postoperatorios con ambas escalas fueron mínimas y en ningún caso estadísticamente significativas. Estas diferencias fueron similares cuando se consideró individualmente a las tres subescalas del MOXFQ (Walking-Standing, Pain y Social Interaction). Aunque se reconoce que el número de pacientes para obtener una mayor implicación clínica es escaso, este trabajo confirma la hipótesis de que cuando no hay complicaciones, los resultados funcionales y subjetivos observados el primer año tras la intervención se mantendrán con mínimos cambios al menos seis años después.

Adaptación transcultural al español del Self-Administered Foot Evaluation Questionnaire (SAFE-Q)

La medición de resultados basada en la percepción de los pacientes (PROMs) ha ido adquiriendo cada vez más importancia para comparar y valorar situaciones clínicas y aspectos terapéuticos, muchas veces incluso por encima de valoraciones efectuadas por los terapeutas. El cuestionario basado en la opinión de los pacientes más usado para valorar el hallux valgus es el MOXFQ, que ha sido validado en varios idiomas, entre ellos el español (Garcés et al. 2016). Sin embargo, a pesar de la importancia que tiene el calzado sobre los resultados del tratamiento del hallux valgus, se le ha dado poco resalte a este aspecto en los cuestionarios publicados.

La Sociedad Japonesa para la Cirugía del Pie desarrolló en 2013 un cuestionario específico para ser auto-cumplimentado por pacientes afectos de patología de tobillo y pie (Niki et al. 2013). El cuestionario, denominado Self-Administered Foot Evaluation Questionnaire (SAFE-Q), consiste en 34 preguntas de fácil respuesta agrupadas en 5 subescalas: Dolor y dolor-relacionado con determinadas actividades (PP), Funcionalidad y actividades de la vida diaria (PF), Funcionalidad social (SF), Aspectos relacionados con el calzado (SH) y Situación de Salud y Bienestar (GH). Además, cuenta con nueve preguntas relacionadas con la actividad deportiva y el pie. El cuestionario fue publicado en inglés y ha sido validado para su uso en ese idioma (Niki et al. 2017).

Dado que el español es hablado por más de cuatrocientos millones de personas en el mundo como idioma materno, el objetivo de este trabajo fue realizar una adaptación transcultural del SAFE-Q al español y valorar su aplicación en un grupo de pacientes para determinar su validez y correspondencia con el cuestionario original.

La adaptación transcultural siguió las directrices marcadas por la International Society for Pharmaco Economics and Outcomes Research (ISPOR) para la traducción y validación de cuestionarios de autovaloración. En la primera fase el cuestionario en inglés fue traducido al español por dos expertos bilingües. Posteriormente, tras conciliación de interpretaciones, el cuestionario resultante en español fue traducido nuevamente al inglés por dos expertos bilingües diferentes a los anteriores y conciliadas las posibles discrepancias. El documento final en español fue valorado por 2 enfermeros, 2 fisioterapeutas y 4 cirujanos ortopédicos con experiencia en patología del pie (Anexo 4). Para validar el cuestionario en español se efectuó un estudio piloto con 10 pacientes, y posteriormente un estudio más completo con 100 pacientes afectos de patología unilateral del pie.

Los resultados mostraron un tiempo medio invertido por los pacientes en rellenar el cuestionario inferior a 10 minutos. El grado de correlación entre las distintas subescalas fue altamente significativo. El alfa de Chonbach fue de 0.894, con mínimas diferencias aunque se suprimiese alguna subescala, evidenciando un alto grado de consistencia interna y de consistencia con el cuestionario original en inglés, permitiendo su recomendación para ser usado por pacientes hispanoparlantes.

ARTÍCULOS PUBLICADOS

1. Motta LM, Manchado I, Blanco G, García-Flemate F, González J, Garcés GL. Pre- and Post-Operative Relationship between Radiological Measures and Clinical Outcomes in Women with Hallux Valgus. J Clin Med. 2022 Jun 23;11(13):3626. doi: 10.3390/jcm11133626. PMID: 35806910; PMCID: PMC9267403.

Datos de la revista: **Journal of Clinical Medicine (J Clin Med)**. El **Journal of Clinical Medicine** se enfoca en la publicación de investigaciones originales, revisiones sistemáticas, estudios clínicos, ensayos clínicos y otros tipos de estudios relacionados con la medicina clínica y la atención médica. Cubre una amplia variedad de disciplinas médicas y subespecialidades, lo que la convierte en una revista interdisciplinaria. Su proceso de selección de artículos está basado en el de revisión por pares, mediante expertos en cada tema de los sometidos a publicación.

La revista utiliza un proceso de revisión por pares, lo que significa que los manuscritos enviados son evaluados de manera crítica por expertos en el campo antes de su publicación. Esto ayuda a garantizar la calidad y la integridad de los artículos publicados. Ofrece acceso abierto a sus artículos, lo que significa que los artículos publicados están disponibles de forma gratuita para cualquier persona que desee leerlos. Su frecuencia de publicación puede variar, pero suele tener varias ediciones al año.

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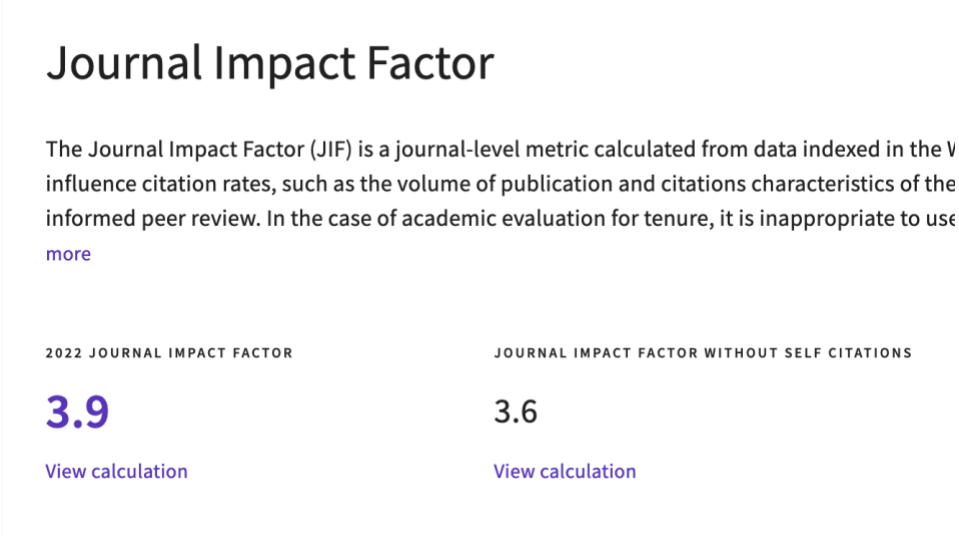

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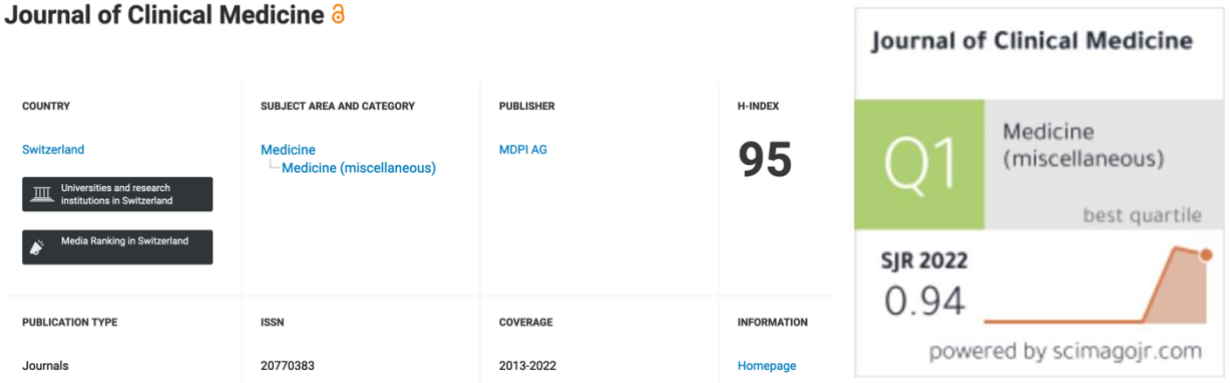
2018	27/304	Q1	91.28
2017	31/298	Q1	89.77



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Pre- and Post-Operative Relationship between Radiological Measures and Clinical Outcomes in Women with Hallux Valgus

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Abstract: The surgical correction of a hallux valgus (HV) deformity improves radiological parameters and clinical outcomes. However, it is not known how these improvements are related between themselves. In this retrospective study, 73 women were assessed preoperatively and 60 months after HV surgical correction. Several radiological parameters were measured: the hallux valgus angle (HVA), I–II intermetatarsal angle (IMA) and sesamoid position. The functional outcomes were assessed using the American Orthopaedic Foot and Ankle Society (AOFAS) Hallux Metatarsophalangeal-Interphalangeal (HMI) scale, and patient-reported outcomes (PROMs) were recorded with the Manchester–Oxford Foot Questionnaire (MOXFQ). A pre–post-surgery comparison of radiological and clinical values was performed, the correlation among them was studied and the differences pre–post-surgery in the radiological measurements compared with those for the clinical outcomes were studied. The results show that all the radiological parameters, functional outcomes and PROMs improved significantly from their pre-operative values to the follow-up values. Multivariate regression analysis showed a significant relationship ($p < 0.001$) between the differential pre–post-surgery AOFAS scoring only with two sesamoid position differential pre–post-surgery measures: position of medial sesamoid (PMS) and translation of the first metatarsal head (TMH). However, no significant association was observed between the pre–post-surgery radiological differences and the pre–post-surgery MOXFQ scoring.

Keywords: hallux valgus; surgical correction; radiological measurements; clinical outcomes

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1. Introduction

There are many surgical techniques for correcting hallux valgus deformities. The preoperative assessment includes an exhaustive clinical examination of both feet of the patient and a weight-bearing anteroposterior (AP) and lateral radiograph. This allows the assessment of the type and grade of the deformities to be corrected and the results to be compared to postoperative radiographies. The parameters most used for the radiological evaluation are the hallux valgus angle (HVA), the first-to-second intermetatarsal angle (IMA) and the position of the sesamoids [1].

Sesamoid subluxation off the head of the first metatarsal is indicative of an HV deformity. Currently, it is considered that during the progression of an HV deformity, the head of the first metatarsal bone drifts medially away from the sesamoids, whereas the sesamoids retain their anatomical relationship to the second metatarsus [2]. The sesamoid position is assessed through several radiological parameters [3,4]. The classifications most frequently used to assess the tibial sesamoid position (TSP), which represents the position of the medial sesamoid with respect to the axis of the first metatarsal bone, are the method of Hardy and Clapham [5], which classifies seven grades, and the American Orthopaedic

Foot Ankle Society classification [6], with only four possible positions. The distance of the fibular sesamoid (DFS) between the axis of the second metatarsus and the lateral sesamoid is obtained [3]. The translation of the first metatarsal head (TMH) between the axis of the second metatarsal bone and the head of the first metatarsus is measured [3].

In addition to the HVA and IMA, many surgeons aim to correct the sesamoid position when surgically treating an HV deformity. Chen et al. [7] found that the TSP improved from Grade VII preoperatively to Grade IV postoperatively (Hardy and Clapham classification [5]), two years after surgery. However, some authors have shown that first metatarsal osteotomies can improve head-to-sesamoid congruency, but the sesamoids' position remains unchanged with respect to the second metatarsal bone [3,8–11].

Several authors have outlined the importance of the sesamoid position for the recurrence of the deformity [3,12]. The assessment of the lateral sesamoid position (LSP) in relation to the flare of the first metatarsal head on a weight-bearing AP radiograph should help clinicians to grade the severity of the HV deformity [2]. Okuda et al. [13] concluded that the incomplete reduction of the sesamoids following corrective surgery resulted in a higher recurrence of hallux valgus 41 months after the surgery. Hagio et al. [14] found that a Grade ≥ 2 sesamoid position was significantly associated with the recurrence of the deformity. Ezzatvar et al. [12], in a systematic review, observed that a post-operative TSP ≥ 4 was strongly correlated with the recurrence of the deformity. However, there is some controversy about the influence of the pre-operative sesamoid position on the hallux valgus deformity. Machado et al. [4] observed that neither the absolute nor the relative distance of the lateral sesamoid bone to the second metatarsus was different between a hallux valgus group (HVA > 15°) and a control group of patients (HVA < 15°). Kaufman et al. [15] found no significant correlation between the pre-operative sesamoid position and the recurrence of an HV deformity after surgical correction. On the other hand, some authors have reported that the pre-operative sesamoid position significantly affected recurrence years after the surgical correction of an HV [16,17].

The influence of the sesamoid position on the clinical outcome of an HV deformity is another source of controversy. Wilson et al. [18] reviewed 46 patients who underwent scarf osteotomy and concluded that, although patient satisfaction was dependent on the HVA and IMA, there was little correlation between the change in sesamoid position and patient satisfaction. Zitouna et al. [19] observed a significant increase in AOFAS score from before to one year after the operation. However, there was no relationship between the post-operative sesamoid position and clinical outcome. Contrarily, Chen et al. [7] found that subjective and functional scores were significantly better in patients with "normal" TSP in comparison with "outliers". Mathews et al. [20] observed that no radiographic variable showed even a moderate correlation with any of the Foot and Ankle Outcome Score (FAOS) subscales, with the exception of TSP in patients aged 56 years and older.

The main objective of the surgical correction of HV is to correct the hallux alignment, improving the functional and patient-reported outcomes. Since the relationship among them is not clear, the main purpose of this work was to study the correlation of the differences between the pre- and post-operation values of the radiological parameters, mainly the sesamoid position, with the differences between the preoperative vs. at follow-up results of the clinical outcome scores.

The specific objectives were as follows:

1. To compare the preoperative vs. post-operative follow-up values of the radiological parameters and clinical outcomes related to HV deformities.
2. To study the correlation of the pre- and post-operative radiological values with the pre- and post-operative values of functional and patient-reported outcome scores.

Our hypothesis was that the improvement in radiological parameters after the operation should be significantly related to the improvement in clinical score results.

2. Materials and Methods

This was a retrospective study of 73 female patients who underwent an operation to correct unilateral hallux valgus deformities (angle > 20°) undertaken by the same surgical team between 2013 and 2014. Their median age was 57 (IQR: 46–63; range: 22–77). Informed consent was obtained from the patients to participate in the study. This work was approved by the Ethic Local Committees (Ref CEIH-2018-02 and CEIm-LP-2021-418-1) and carried out according to the principles of the Helsinki Declaration.

Patients were included in the study if they were women older than 18 years with a unilateral hallux valgus angle (HVA) >20° that caused some kind of discomfort or pain during activities of daily living and who agreed to participate in the study. The exclusion criteria were bilateral symptomatic hallux valgus; a previous operation or fracture on the affected foot; hallux rigidus; general or local inflammatory, neurological or vascular disease; and lesser toe deformities on the same foot subsidiaries of surgical correction. An asymptomatic contralateral hallux valgus was not an exclusion criterion.

2.1. Type of Operation

The operations were executed using a minimally invasive technique modified from the Isham–Reverdin procedure [21]. This technique has been exhaustively described by Biz et al. [22]. In summary, under local anesthesia and sedation, using fluoroscopy vision, 3 percutaneous incisions of 3–4 mm were made. The first one was at the level of the first metatarsal neck, to allow a bunionectomy and a transverse osteotomy of the metatarsal bone, just proximal to the sesamoid level, to be performed. Contrarily to Biz et al.'s technique [22], we pushed out the metatarsal head to translate it laterally approximately one-fourth of the osteotomy line length, closing the inter-metatarsal space (Figure 1). Through a second dorsal incision, immediately lateral to the metatarsophalangeal joint, the lateral soft tissues and the transverse head of the abductor hallucis were released to allow the translation of the first metatarsal head. In some cases, through a third incision, an incomplete medial transverse osteotomy of the proximal phalange (Akin osteotomy) was made 1 cm distal to the articular line to improve the hallux valgus angle. No internal fixation was carried out. The correction was kept with a dressing around the hallux, under fluoroscopic vision. Immediate weight bearing was allowed postoperatively, using a shoe with a flat, stiff sole, and the dressing was changed every two weeks over 8 weeks after the operation.

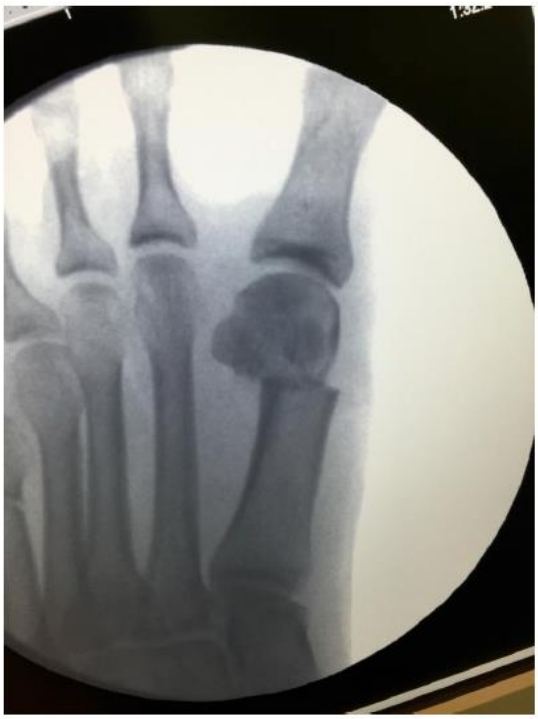

Figure 1. Fluoroscopic view of metatarsal metaphyseal osteotomy with lateral head displacement.

2.2. Assessment Method

Scores on the American Orthopaedic Foot and Ankle Society (AOFAS) Hallux Metatarsophalangeal-Interphalangeal (HMI) scale [23,24] and the Manchester–Oxford Foot Questionnaire (MOXFQ) [25] and radiographies were obtained from the patients 4–5 days pre-operation and at follow-up, after a median of 60 months (IQR: 51–82).

2.3. Radiographic Measurements

Weight-bearing antero-posterior and lateral radiographies of both feet were obtained preoperatively and at follow-up. All the radiographs were obtained using a picture-archiving and communications system (PACS; General Electronic, Chicago, IL, USA). The distances and angles were computed automatically using the Centricity Foot Print Universal viewer, version 6.0.SP 10.2.1 (GE Healthcare, Chicago, IL, USA), following Choi et al.'s [3] criteria (Figure 2). The hallux valgus angle (HVA) between the line connecting the center of the first metatarsal base and the center of the metatarsal head with the line connecting the centers of the proximal and distal articular surfaces of the proximal phalanx was measured. The translation of the first metatarsal head (TMH) was the distance between the second metatarsal axis and the lateral line of the first metatarsal head. The distance of the fibular sesamoid (DFS) was assessed by measuring the distance between the perpendicular line of the second metatarsal axis and the lateral margin of the fibular sesamoid. Measurements were taken twice by two researchers, and the mean was used for statistical analysis (the intra- and interobserver differences were less than 10%). The tibial sesamoid position (TSP) was determined using the 4 classification grades of the American Orthopaedic Foot Society [6]. On this scale, the medial sesamoid position is graduated according to its location with respect to the longitudinal axis of the first metatarsal bone. Grade 0 indicates

that the tibial sesamoid is medial to this line; Grade 1 indicates that < 50% of its transversal diameter is overlapping the line; an overlap > 50% of its diameter is Grade 2; a lateral displacement of the complete sesamoid beyond that line is classified as Grade 3.

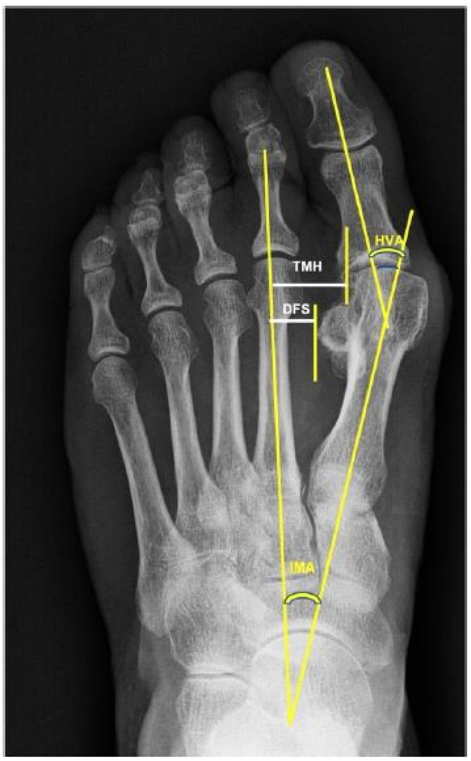

Figure 2. Radiological measures. **DFS:** Distance of the fibular sesamoid bone to the second metatarsal axis. **TMH:** Translation of the first distal metatarsal head. **HVA:** Hallux valgus angle. **IMA:** I–II intermetatarsal angle.

2.4. Statistical Analysis

The Shapiro–Wilk test was used to check the normality. The median (25–75% IQR) and mean (95% CI) values were used as the quantitative variables. Student's t-test for paired samples was used to compare the differences between the mean results prior to the operation and at the final follow-up. Multiple linear regression was used to predict numerical variables. Due to the sample size, the linear regression coefficients were also calculated using the Bootstrapping technique, with 2000 repetitions. To check the multicollinearity of the predictive variables, the statistical variance inflation factor (VIF) was used. In all cases, its value was less than 5. Furthermore, p-values < 0.05 were considered significant. The data were analyzed with the R Core Team 2021 program, version 4.1.2 (R Foundation for Statistical Computing, Vienna, Austria).

3. Results

Thirty-five operations were on left feet, and 38 were on right ones. A few complications were encountered. Five patients had transfer metatarsalgia, with four of them being treated conservatively. One patient had postoperative hallux varus. Two patients were reoperated

due to valgus recurrence; one more, for exostosis of the first metatarsus; and another one, for mallet finger. Two patients complained of persistent pain in the forefoot.

Table 1 shows the preoperative and final follow-up values of the quantitative variables. The results of all these variables were significantly improved at follow-up in comparison with the preoperative results ($p < 0.001$ for all cases). The median HVA decreased from 29.8° preoperatively to 10.3° at follow-up. The median IMA decreased from 13.3° preoperation to 8.6° at follow-up. The median DFS and TMH decreased from 11.99 and 18.17 mm preoperatively to 10.35 and 15.5 mm at follow-up, respectively. The median AOFAS score improved from 35 preoperatively to 90 at follow-up, while the median MOXFQ score improved from 29 before the operation to 18 at follow-up.

Table 1. Preoperative and postoperative values of quantitative variables ($n = 73$). **Pre:** Preoperative values. **Post:** Values at follow-up. **DFS:** Distance of the fibular sesamoid bone to the second metatarsal axis. **TMH:** Translation of the first distal metatarsal head. **HVA:** Hallux valgus angle. **IMA:** I–II intermetatarsal angle. AOFAS: American Orthopaedic Foot and Ankle Society Questionnaire. **MOXFQ:** Manchester–Oxford Foot Questionnaire. Pre and Post data are medians (25–75% IQR). Mean Correction is the difference between the Pre and Post mean values (95% CI). Student's *t*-test for paired samples was used.

	Pre	Post	Mean Correction (95% CI)	*p*-Value
DFS	11.99 (10.6–13.01)	10.35 (9.09–11.88)	1.29 (0.75–1.83)	**<0.001**
TMH	18.17 (16.69–20.46)	15.5 (13.78–17.46)	3.03 (2.32–3.75)	**<0.001**
HVA	29.8 (26–34)	10.3 (7.7–13.2)	20.23 (18.52–21.94)	**<0.001**
IMA	13.3 (12–15)	8.6 (7.8–9.6)	4.62 (4.06–5.17)	**<0.001**
AOFAS	35 (19–44)	90 (83–95)	54.4 (57.93–50.87)	**<0.001**
MOXFQ	29 (26–42)	18 (16–26)	11.22 (8.82–13.62)	**<0.001**

Table 2 shows the distribution of cases for each grade of TSP. No cases of Grade 0 were observed preoperatively, and 18 cases were present at follow-up. Grade 1 was observed in 16 cases preoperatively and in 40 cases at follow-up, Grade 2 in 30 cases preoperatively and in 15 cases at follow-up and Grade 3 in 27 cases preoperatively and no cases at follow-up. Individually, considering Grade 0 as the best situation, 1 case improved by three levels (from Grade 3 preoperatively to Grade 0 at follow-up), 22 cases improved by two levels, 41 cases improved by one level, 8 cases showed no change and 1 case was classified with a worse level.

Table 2. Contingency table with number of cases and percentages of TSP classification, preoperatively (PRE) and at follow-up (POST). $p < 0.001$ in McNemar test. TSP: Tibial sesamoid position.

		TSP POST			
		Grade 0	**Grade 1**	**Grade 2**	**Total**
TSP PRE	Grade 1	9 56.2%	6 37.5%	1 6.2%	16 21.9%
	Grade 2	8 26.7%	20 66.7%	2 6.7%	30 41.1%
	Grade 3	1 3.7%	14 51.9%	12 44.4%	27 37.0%
	Total	18	40	15	73

The relationship of the preoperative AOFAS values (AOFAS Pre) with the radiological measures was not significant (Table 3).

Table 3. Multivariate regression of preoperative AOFAS values with the preoperative radiological measures. **Pre:** Preoperative values. **DFS:** Distance of the fibular sesamoid bone to the second metatarsal axis. **TMH:** Translation of the first distal metatarsal head. **HVA:** Hallux valgus angle. **IMA:** I–II intermetatarsal angle. **TSP**: Tibial Sesamoid Position. AOFAS: American Orthopaedic Foot and Ankle Society Questionnaire.

Variables	Multivariate Regression					AM Bootstrapping	
	b	SE	B	IC (95%)	*p*	b	IC (95%)
Intercept	30.01	15.57	-	−1.08–61.1	0.058	29.24	−0.98–60.32
TSP_pre: Type 1	-	-	-	-	-	-	-
TSP_pre: Type 2	−1.15	4.15	−0.04	−9.44–7.14	0.782	−1.47	−9.99–7.19
TSP_pre: Type 3	−1.45	4.36	−0.06	−10.16–7.26	0.741	−1.73	−9.8–7.37
HVA_pre	−0.44	0.31	−0.19	−1.05–0.17	0.158	−0.45	−1.06–0.18
IMA_pre	0.72	0.74	0.12	−0.76–2.21	0.333	0.75	−0.67–2.19
DFS_pre	−0.14	0.69	−0.03	−1.53–1.24	0.838	−0.16	−1.5–1.41
TMH_pr	0.44	0.5	0.12	−0.56–1.44	0.38	0.48	−0.55–1.28
Adjusted R^2			−0.04				

b: Regression coefficient. SE: Standart error. B: Standart coefficient. *p*: *p*-value.

Similarly, the relationship of the postoperative AOFAS values (AOFAS Post) with the radiological measures was also not significant (Table 4), although the IMA was nearly significant ($p < 0.075$), with a negative association (b = −2.28).

Table 4. Multivariate regression analysis of postoperative AOFAS values with the postoperative radiological measures. **Pre:** Preoperative values. **DFS:** Distance of the fibular sesamoid bone to the second metatarsal axis. **TMH:** Translation of the first distal metatarsal head. **HVA:** Hallux valgus angle. **IMA:** I–II intermetatarsal angle. **TSP**: Tibial Sesamoid Position. AOFAS: American Orthopaedic Foot and Ankle Society Questionnaire.

Variables	Multivariate Regression					AM Bootstrapping	
	b	SE	B	IC (95%)	*p*	b	IC (95%)
Intercept	105.18	11.43	-	82.35–128.01	<000.1	105.59	82.23–131.61
TSP_post: Type 0	-	-	-	-	-	-	-
TSP_post: Type 1	0.76	3.5	0.03	−6.24–7.76	0.829	0.89	−4.6–7.91
TSP_post: Type 2	−0.88	5.08	−0.03	−11.03–9.27	0.863	−1.2	−11–8.32
HVA_post	−0.34	0.28	−0.16	−0.89–0.22	0.228	−0.31	−1.04–0.6
IMA_ post	−2.28	1.26	−0.24	−4.79–0.23	0.075	−2.44	−5.42–0.12
DFS_ post	−0.17	0.87	−0.03	−1.92–1.57	0.843	−0.31	−2.35–1.87
TMH_ post	0.36	0.71	0.09	−1.05–1.78	0.61	0.5	−1.01–2.17
Adjusted R^2			−0.04				

b: Regression coefficient. SE: Standart error. B: Standart coefficient. *p*: *p*-value.

Differential pre-postoperative AOFAS scoring was significantly related to differential pre-postoperative values of PSM (negatively, b: −8.65) and THM (positively, b: 2.12)

($p < 0.001$ in both cases). However, the relationship with the rest of the radiological variables was not significant (Table 5).

Table 5. Multivariate regression of pre-postoperative AOFAS difference values with the pre-postoperative differences of radiological measures. **Pre:** Preoperative values. **DFS:** Distance of the fibular sesamoid bone to the second metatarsal axis. **TMH:** Translation of the first distal metatarsal head. **HVA:** Hallux valgus angle. **IMA:** I–II intermetatarsal angle. **TSP**: Tibial Sesamoid Position. AOFAS: American Orthopaedic Foot and Ankle Society Questionnaire. b: Regression coefficient. SE: Standart error. B: Standart coefficient. *p*: *p*-value.

Variables	Multivariate Regression					AM Bootstrapping	
	b	SE	B	IC (95%)	*p*	b	IC (95%)
Intercept	51.48	5.53	-	40.44–62.52	<000.1	51.38	38.82–62.43
TSP_dif	−8.65	2.45	−0.4	−13.55–−3.76	<000.1	−8.72	−13.3–−3.18
HVA_d	−0.02	0.23	−0.01	−0.48–0.44	0.928	−0.01	−0.69–0.47
IMA_dif	0.17	0.7	0.03	−1.23–1.58	0.808	0.08	−1.41–1.52
DFS_dif	0.46	0.7	0.07	−0.94–1.86	0.511	0.38	−0.9–2.24
TMH_dif	2.12	0.56	0.43	1.01–3.23	<000.1	2.19	1.08–3.2
Adjusted R^2			0.20				

The association of the MOXFQ preoperative values with the radiological measure values was non-significant (Table 6).

Table 6. Multivariate regression of preoperative MOXFQ values with the preoperative radiological measures. **Pre:** Preoperative values. **DFS:** Distance of the fibular sesamoid bone to the second metatarsal axis. **TMH:** Translation of the first distal metatarsal head. **HVA:** Hallux valgus angle. **IMA:** I–II intermetatarsal angle. **TSP**: Tibial Sesamoid Position. MOXFQ: Manchester-Oxford Foot Questionnaire. b: Regression coefficient. SE: Standart error. B: Standart coefficient. *p*: *p*-value.

Variables	Multivariate Regression					AM Bootstrapping	
	b	SE	B	IC (95%)	*p*	b	IC (95%)
Intercept	21.24	12.31	-	−3.33–45.81	0.089	19.21	−9–43.59
TSP_pre: Type 1	-	-	-	-	-	-	-
TSP_pre: Type 2	4.26	3.28	0.2	−2.29–10.81	0.199	4.13	−2.43–10.07
TSP_pre: Type 3	−4.08	3.45	−0.19	−10.96–2.8	0.241	−4.33	−11.25–2.08
HVA_pre	−0.13	0.24	−0.07	−0.61–0.35	0.594	−0.14	−0.67–0.41
IMA_pre	0.3	0.59	0.06	−0.87–1.48	0.609	0.32	−0.76–1.37
DFS_pre	0.57	0.55	0.13	−0.53–1.66	0.305	0.65	−0.59–1.91
TMH_pre	0.27	0.39	0.09	−0.52–1.05	0.503	0.26	−0.5–1.17
Adjusted R^2			0.04				

Similarly, the relationship between the post-operative values of the MOXFQ score and the post-operative values of the radiological parameters was non-significant (Table 7), as it was non-significant the association between the differential pre-postoperative values of the MOXFQ scores with the differential pre-postoperative values of the radiological measures (Table 8).

Table 7. Multivariate regression analysis of postoperative MOXFQ values with the postoperative radiological measures. **Post:** Postoperative values. **DFS:** Distance of the fibular sesamoid bone to the second metatarsal axis. **TMH:** Translation of the first distal metatarsal head. **HVA:** Hallux valgus angle. **IMA:** I–II intermetatarsal angle. **TSP**: Tibial Sesamoid Position. MOXFQ: Manchester-Oxford Foot Questionnaire. b: Regression coefficient. SE: Standart error. B: Standart coefficient. *p*: *p*-value.

Variables	Multivariate Regression					AM Bootstrapping	
	b	SE	B	IC (95%)	*p*	b	IC (95%)
Intercept	16.39	9.05	-	−1.67–34.45	0.075	16.14	−4.82–34.53
TSP_post: Type 0	-	-	-	-	-	-	-
TSP_post: Type 1	−3.03	2.77	−0.17	−8.57–2.51	0.278	−3.12	−7.95–1.43
TSP_post: Type 2	−3.81	4.02	−0.17	−11.84–4.22	0.347	−3.9	−10.59–1.71
HVA_post	0.35	0.22	0.21	−0.09–0.79	0.119	0.36	−0.17–1.09
IMA_ post	0.47	1	0.07	−1.51–2.46	0.636	0.39	−2.33–2.3
DFS_ post	0.02	0.69	0	−1.36–1.4	0.978	0.05	−1.52–1.66
TMH_ post	0.02	0.56	0.01	−1.1–1.14	0.973	0.03	−1.11–1.6
Adjusted R^2			−0.02				

Table 8. Multivariate regression analysis of pre-postoperative MOXFQ values with the pre-postoperative radiological measures. **Dif:** Differential values. **DFS:** Distance of the fibular sesamoid bone to the second metatarsal axis. **TMH:** Translation of the first distal metatarsal head. **HVA:** Hallux valgus angle. **IMA:** I–II intermetatarsal angle. **TSP**: Tibial Sesamoid Position. MOXFQ: Manchester-Oxford Foot Questionnaire. b: Regression coefficient. SE: Standart error. B: Standart coefficient. *p*: *p*-value.

Variables	Multivariate Regression					AM Bootstrapping	
	b	SE	B	IC (95%)	*p*	b	IC (95%)
Intercept	−7.85	4.22	-	−16.27–0.58	0.067	−7.82	−17.04–1.06
TSP_dif	2.52	1.87	0.17	−1.21–6.25	0.182	2.51	−1.16–5.99
HVA_dif	0.04	0.18	0.03	−0.31–0.39	0.832	0.03	−0.29–0.35
IMA_dif	0.35	0.54	0.08	−0.72–1.42	0.513	0.37	−0.81–1.27
DFS_dif	−0.1	0.53	−0.02	−1.17–0.96	0.846	−0.09	−1.14–0.94
TMH_dif	−0.62	0.42	−0.18	−1.47–0.23	0.15	−0.65	−1.26–0.05
Adjusted R^2			−0.02				

4. Discussion

Two findings should be outlined in our work. First, the radiological and clinical parameters improved significantly from preoperative values to follow-up. Second, the improvement of AOFAS scoring was only significantly associated with improvement in some parameters of the sesamoid position. However, the relationship between the improvement in MOXFQ scoring and the change in radiological measures was not significant.

There is evidence that females younger than 65 years with HV had a statistically significantly worse quality of life than females of the same age group in the general population [26], and that HV surgery resulted in decreased body pain and improved physical function and patient quality of life [27]. More than 100 different procedures for treating hallux valgus have been described [28]; they include combinations of soft

tissue balancing, bone osteotomies and joint fusion. The aim of most operations is to obtain a hallux metatarsophalangeal angle of less than 15° and an I–II IMA of less than 10°. However, the importance of the sesamoid position in HV deformities is a subject of controversy. Some authors outlined that the lateral sesamoid position was not different between patients with hallux valgus (HVA > 15°) and a control group (HVA < 15°) [4].

The first point to be highlighted in this work is the fact that the HVA and IMA values, the variables most frequently used to quantify HV deformities, significantly improved from before the operation to the follow-up. This has also been frequently reported with the use of different surgical techniques [3,7,15,19,22,29–31]. In our work, two of the parameters used to assess the sesamoid position, namely, the DFS and TMH, also significatively improved from the pre- to the postoperative assessment. The preoperative vs. postoperative differential DFS of 1.3 mm is like that observed by others [3]. It is likely that this very small difference and the different methods used for measurement are the reasons for the lack of agreement regarding the role of the DFS in this condition. While some authors [2] consider there to be a strong relationship between the angular deformities and the lateral sesamoid position, others point out that the lateral sesamoid retains its relationship with the second metatarsal in the transverse plane and that the surgical correction of HV does not result in a medial shift or reduction in the sesamoid position [3,7,8,11]. The TMH in our patients improved by a mean of 3 mm from preoperation to the follow-up, which is smaller than the improvement observed by Choi et al. [3].

The radiological parameter most frequently used to assess the sesamoid position is the TSP. Most authors [7,10,29,32] have used the seven-grade Hardy and Clapham classification [5], while others [3,22] have used the simpler four-grade AOFS classification [6]. When comparing changes in TSP, all authors use the mean ± SD of the grade of all the patients preoperatively vs. at follow-up. However, since the TSP is an ordinal variable, we preferred to differentiate the pre–postoperative changes individually. Our findings show that the TSP improved by at least one grade at follow-up in 64 out of 73 cases, with 8 remaining unchanged and 1 getting worse. Improvements in TSP after surgery have also been reported by several authors, using different surgical techniques [3,7–10,15,29].

Our results show that the functional score, using the AOFAS-HMI scale, significantly improved from the preoperative assessment to the follow-up. This scale, with a 0–100 score, is the most frequently used functional outcome tool [27]. Other authors have also reported significant improvements in AOFAS scores after HV surgery using different techniques [3, 11,19,22,29–31,33]. Our patients also showed a significant improvement in PROMs from the preoperative period to the follow-up, assessed through the MOXFQ. This is one of the best available tools for evaluating HV surgery outcomes and the most used [34]. It consists of 16 questions with a score out of 100 for three separate domains, although the three domain scores can be summarized into a single index score [35]. Similarly to our results, other authors have also reported significant improvements in MOXFQ scores after HV surgery [30].

Radiological parameters are the gold standard for assessing HV deformities pre- and postoperatively. Functional and patient-reported results provide complementary data for assessing the clinical situation and post-treatment outcomes. However, there is little information about the correlation between radiological results and clinical results in patients with HV. Some authors have reported a strong negative correlation of the HVA and IMA with the AOFAS score in non-operated patients [36]. Others found no correlation between these preoperative angles and AOFAS results [37]. Similarly, several authors have found that quality of life is decreased in patients with HV in comparison with a "normal" population, but the MOXFQ score showed no correlation with the radiological parameters [26,38]. Others have also observed that there is no correlation between radiological results and MOXFQ score after surgery [30]. Our results show that there is no significant relationship between the AOFAS and MOXFQ scoring with the HVA and IMA values both pre and postoperatively.

Many authors consider that the position of the sesamoids is very important in HV deformities, the ideal situation being both sesamoids being centered under the metatarsal head. As most authors focus their studies on the relationship of the sesamoid position with several radiological parameters, little attention has been paid to the clinical consequences of the changes in the sesamoid position after surgery. Chen et al. [7] found significantly better results for the AOFAS score when the TSP was <4 than when it was >5 (Hardy–Clapham classification). Zitouna et al. [19] observed that there was no relationship between the postoperative sesamoid position and the clinical outcome (AOFAS), regardless of the radiological classification used. Our results show that there was no significant association between the AOFAS or MOXFQ scores in the preoperative or the postoperative period with any of the radiological values of the sesamoid position in the same period. However, the differential pre to postoperative AOFAS values are significantly related to the PSM and TMH differential pre to postoperative values. We have not found references about the correlation between PROMs and the sesamoid position.

The main objective of our work was to study whether pre–post-surgery improvements in radiological parameters correlated with pre–post-surgery AOFAS and MOXFQ scores. Our results lead us to partially reject this hypothesis. To the best of our knowledge, this has not been studied previously. Despite advancements in operative techniques and the extraordinary number of procedures described for correcting hallux valgus (HV), there is still uncertainty as to why some patients thrive postoperatively whereas others do not. As others have also reported, our work shows a significant improvement in radiological and clinical outcomes after surgery. However, our findings lead us to assume that the correction achieved will not correlate to the clinical outcomes. Although the clinical importance of this lack of correlation cannot be determined from our work, we think that patients should be informed about it.

This work also has several limitations. Our population comprised only females, and we do not know if the results with men would have been different, although Choi et al. [3] observed no differences between the sexes regarding the clinical outcomes after chevron osteotomy. Our results are based only on one functional score and one PROM. However, the AOFAS and the MOXFQ are the most used questionnaires for assessing clinical results after HV surgery [27,34]. Our findings were observed after using a minimally invasive technique, and different results could be obtained with open surgical techniques. Nevertheless, currently, there is sufficient evidence for the reproducibility of the results and good clinical outcomes after the percutaneous correction of HV [22,26,28,29,31], and some authors have reported no differences in clinical results with open and mini-invasive techniques [39]. Another limitation of our study is that we did not consider how it was the relationship of radiological measures with specific important factors, such as the first ray mobility, which must be considered in routine clinical practice, before and post HV surgery [40,41].

5. Conclusions

All the radiological parameters, functional outcomes and PROMs improved significantly from their preoperative values to the follow-up values. However, apart from some sesamoid position values, no significant relationship between the pre–post-surgery radiological differences and the pre–post-surgery clinical outcome differences were found. Our findings allow us to assume that the correction achieved after surgery will not be correlated with the clinical outcomes, and this should be made known to the patients.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

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Temporal Changes in Clinical Outcomes after Minimally Invasive Surgery for Hallux Valgus Correction in Women without Postoperative Complications

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Abstract: Minimally invasive surgery (MIS) is currently used to correct hallux valgus deformities. Most studies reporting on MIS techniques to correct hallux valgus deformities included patients with postoperative complications. These reported complications, with an average rate of 23%, had significant negative effects on the clinical outcomes in this patient population. In the present study, a cohort of 63 women who underwent MIS hallux valgus correction was assessed preoperatively and at a mean follow-up of 1.0, 4.7, and 6.5 years using the American Orthopaedic Foot and Ankle Society (AOFAS) scale and the Manchester Oxford Foot Questionnaire (MOXFQ). The main criterion for inclusion in this cohort was a lack of complications during the entire follow-up period. The results showed significant improvements in both AOFAS and MOXFQ scores between the preoperative and 1-year follow-up assessments. By contrast, clinically small and nonsignificant changes were observed among postoperative follow-up values. The number of enrolled patients needs to be increased in future studies, with different surgeons and techniques included. Nevertheless, our study findings will inform patients about the outcomes they can expect over the years if no complications occur.

Keywords: AOFAS score; clinical outcomes; hallux valgus; MIS correction; MOXFQ

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1. Introduction

Hallux valgus (HV), a common condition that results from a complex positional deformity of the first ray, can lead to considerable pain and altered joint mechanics. Predisposing factors include female sex, age, inadequate footwear, and family history of HV. Women younger than 65 years with HV have a significantly worse quality of life than age-matched women in the general population [1,2]. Nonsurgical treatments include shoe modifications, pads, orthotic devices, and activity modifications. Surgery is considered when nonsurgical treatments fail or for cosmetic reasons. The goals of surgical treatment are pain relief, correction of the deformity, improved first-ray stability, and improved quality of life [3].

More than 100 surgical procedures are available for correcting HV deformities. Most procedures are performed using open techniques, but in the last two decades, percutaneous and minimally invasive surgery (MIS) approaches tended to be used. Their theoretical advantages include smaller scars, less postoperative pain, rapid recovery, reduced rehabilitation time, and decreased risk of infection [4–8]. Concerns regarding MIS use include a difficult learning curve, imprecise results, the necessity of fluoroscopy, higher economic costs, and an increased frequency of cutaneous complications [6,8,9]. Several changes have

been implemented from the first-generation to the current third-generation MIS techniques. Inshall [10] initially described a percutaneous osteotomy without internal fixation. Due to the difficulties in keeping the reduction after the correction, there is a tendency to fix the osteotomy with percutaneous screws [11,12] or with a more sophisticated minimally invasive intramedullary nail device (MIIND) [13]. Despite initial concerns regarding the reproducibility of surgical outcomes, current MIS and open techniques offer similar clinical and radiological results [7,14–19].

In the past, authors have reported HV surgery results considering the radiological correction of deformities. However, sufficient evidence now suggests that radiological improvement is unrelated to patient satisfaction or clinical outcomes [1,16,20,21]. Distal linear metatarsal osteotomy improves foot-related quality of life in patients with HV deformity despite a high rate of postoperative radiographic complications, especially hallux varus [22]. Even when surgery is performed by an experienced surgeon, the potentials for patient dissatisfaction and unfavourable outcomes remain despite adequate radiological correction of the deformities [23].

Functional and subjective assessments are essential for measuring clinical results. Several questionnaires and scales have been used to measure functional clinical outcomes after HV surgery. The American Orthopaedic Foot and Ankle Society (AOFAS) scale, ranging from 0 to 100, is most frequently used [16,24,25]. Its disadvantages include the incorporation of physical examination parameters that have shown poor inter- and intra-observer reliability, the lack of self-administration thereby increasing the risk of bias, and the use of a single question regarding pain [25]. However, several authors reported significant improvements in AOFAS scores after MIS for HV correction [4,9,20,26–28].

Patient-reported outcome measures (PROMs) are preferred because they directly provide information, are independent of the surgeon's perspective, and aid in minimizing bias of the surgical team [25]. Several PROM questionnaires are available, and the Manchester Oxford Foot Questionnaire (MOXFQ) is the most commonly used [29,30]. It consists of 16 questions with a score of 100 for three separate domains, although the three domain scores can be summarized as a single index score [31]. The MOXFQ properties have been validated in different studies concerning HV pathology and have shown good reliability, validity, and responsiveness [25,32].

Studies examining MOXFQ scores after MIS for HV correction demonstrated that all patients reported significant improvements between preoperative and final follow-up states. Most authors followed their patients for 2 years or less [18,33–36], but some followed them for at least 5 years [20,37]. All these studies compare the preoperative values with those of the final follow-up. However, it is unclear whether the results would differ if they were analysed at different time points. Lewis et al. [38] studied changes over time in MOXFQ scores of 202 feet operated using MIS techniques and found that the majority of improvements occurred within the first 6 months. A subgroup of 17 feet (8.4%) had worse MOXFQ index scores 6 months following minimally invasive chevron and Akin osteotomy (MICA); of these, 14 feet (82.4%) showed a significant improvement in the MOXFQ index score 2 years after the operation compared to their preoperative score.

Worldwide, healthcare delivery has been increasingly prioritizing patient satisfaction. Up to 10% of patients are dissatisfied with the results of HV surgery [39]. Therefore, it is necessary to broaden the search for predictors of patient-reported outcomes after HV correction. Several psychological, clinical, and social factors influence these outcomes. Complications such as infections, nonunion of osteotomies, hardware-related problems, and thrombophlebitis have considerable negative effects on correction outcomes [36,40]. These complications are infrequent but should be explained to patients. Most patients are informed of the expected outcomes if no major complications occur. However, little is known about the outcomes in cohorts of patients without complications.

Understanding how functional and PROM scores change over time following MIS HV surgery and whether this change is clinically meaningful will help surgeons counsel patients, reassure surgeons, and predict the likelihood of improvement at a certain time

point [38]. Patients should be advised about possible surgery complications; however, informing them about the expected results if no complication occurs could be of great utility. The aim of this study was to investigate changes over time in functional (AOFAS) and PROM (MOXFQ) scores in a cohort of women who underwent MIS to correct HV deformities and had no operation-related complications during follow-up. Our hypothesis was that no significant changes should be expected in clinical outcomes later than 1 year after the operation if no complications occurred.

2. Materials and Methods

2.1. Study Design

This retrospective study comprised 73 female patients who underwent MIS to correct unilateral HV deformities performed by the same surgical team between 2013 and 2014. Laterality and morphological type of the operated foot were considered as variables. The median patient age was 57 (interquartile range [IQR]: 46–63; range: 22–77) years.

Patients were initially included in the study if they were women older than 18 years with a unilateral radiological HV angle > 20° that caused discomfort or pain during activities of daily living. Exclusion criteria were bilateral symptomatic HV, a previous operation or fracture on the affected foot, hallux rigidus, general or local inflammatory, neurological, or vascular disease, and lesser toe deformities on the same foot subsidiaries of surgical correction. Patients with asymptomatic contralateral HV were also excluded.

2.2. Type of Operation

The operations were performed using a modified MIS technique based on the Isham–Reverdin procedure [10]. This technique was described in detail by Biz et al. [4]. In summary, a peri-malleolar tibialis and peroneal nerves block was made under local anaesthesia (15–20 cc of 50% bupivacaine-mepivacaine solution) and sedation, and three percutaneous incisions of 3–4 mm were made under fluoroscopic vision. The first was at the level of the first metatarsal neck to allow bunionectomy and transverse osteotomy of the metatarsal bone just proximal to the sesamoid level. Contrary to the technique of Biz et al. [4], we pushed out the metatarsal head to translate it laterally, approximately one-fourth of the osteotomy line length, thus closing the intermetatarsal space. The sesamoid position was not checked after the metatarsal head displacement. Through a second dorsal incision, the lateral soft tissue and transverse head of the abductor hallucis were released immediately, lateral to the metatarsophalangeal joint. In some cases, through a third incision, an incomplete medial transverse osteotomy of the proximal phalange (Akin osteotomy) was performed 1 cm distal to the articular line to improve the HV angle. Internal fixation was not performed. The correction was retained with a dressing around the hallux under fluoroscopic vision. Immediate weight bearing was allowed postoperatively using a shoe with a flat, stiff sole, and the dressing was changed every 2 weeks for 8 weeks after the operation.

2.3. Assessment Method

To assess functional outcome and pain the AOFAS score was used. To assess patient reported outcome after corrective surgery the MOXFQ was used. Using the AOFAS Hallux Metatarsophalangeal–Interphalangeal scale [41,42] and the MOXFQ [43], with specific values of the three subscales of this questionnaire—Walking–Standing (W-S), Pain, and Social Interaction (S-I)—patient scores were obtained at 4–5 days preoperatively and at a mean of 1.0, 4.7, and 6.5 years postoperatively (Table 1). Values were differentiated regarding the laterality and the morphological type of the affected foot. Standard weight-bearing dorsoplantar and lateral views were acquired to verify the bone union at the osteotomy site 2 months after the operation or during follow-up in cases of persistent pain or recurrence of the deformity.

Table 1. Time points at which the patients were assessed.

Time of Clinical Assessment	Mean (SD)	Min–Max
Preoperative evaluation, days	2.7 (1.1)	1–9
First postoperative evaluation (1.0 years), months	12.6 (1.21)	10–15
Second postoperative evaluation (4.7 years), months	56.8 (5.9)	41–65
Third postoperative evaluation (6.5 years), months	77.1 (8.4)	55–88

Max, maximum; Min, minimum; SD, standard deviation.

2.4. Statistical Analysis

Statistical analyses were performed using SPSS Statistics v27.0 for Windows (IBM Corp., Armonk, NY, USA). Categorical variables were summarized using absolute frequencies and percentages. The chi-square test was used to analyse the association between two categorical variables. The numerical variables were summarized using the mean, standard deviation, minimum, and maximum. The Shapiro–Wilk test was used to check for normality. To compare the preoperative status of the patients according to the laterality of the foot, Student's *t*-test for two independent samples or the nonparametric Mann–Whitney U test was used, depending on whether the condition of normality of the data was met. Furthermore, to assess whether the preoperative baseline measurements were independent of the three-foot types, ANOVA or the nonparametric Kruskal–Wallis test was used, depending on whether the normality of the samples was confirmed. The non-parametric Wilcoxon test was used to compare the pre-operative and post-operative (at 6.5 years) scores according to the laterality and morphological type of the affected foot. General linear-model repeated measures were used to analyse whether the evolution of the patients according to the numerical data varied from the preoperative assessment to the third postoperative control, considering time as an intra-subject factor (four levels). Results were considered statistically significant if p-values were <0.05.

3. Results

From the initial 73 operated patients, 2 were excluded due to deep infection of the operative site, one due to thrombophlebitis of the operated limb, 1 due to death of the patient unrelated to HV surgery, 1 due to nonunion of the osteotomy, 2 who needed reoperation due to transfer metatarsalgia, 1 due to insufficient correction, and 2 who were lost to follow-up. The final patient population consisted of 63 women between 28 and 73 (mean age 50.3 ± 12.8) years, who presented no complications during the observation period. Table 2 summarizes the morphological characteristics of the affected feet. No significant association was found between foot type and laterality ($p = 0.964$).

Table 2. Morphological type of the affected foot of the study population.

Foot Type	Foot Laterality		Total
	Right	Left	
Egyptian	6 (23.1%)	9 (24.3%)	15
Square	10 (38.5%)	13 (35.1%)	23
Greek	10 (38.5%)	15 (40.5%)	25
Total	26	37	63

The preoperative MOXFQ and AOFAS scores of the patients showed no significant differences regarding the laterality (Table 3) or the morphological type of the affected foot (Table 4).

Table 3. Preoperative AOFAS and MOXFQ scores according to the laterality of the affected foot.

Scales	Foot Laterality	Mean (SD)	Min–Max	*p*
MOXFQ_pre	Right (n = 26)	43.23 (10.69)	24–63	0.594
	Left (n = 37)	41.84 (9.76)	23–60	
AOFAS_pre	Right (n = 26)	36.04 (13.34)	10–52	0.480
	Left (n = 37)	34.59 (10.77)	14–52	

AOFAS, American Orthopaedic Foot and Ankle Society; Max, maximum; Min, minimum; MOXFQ; Manchester Oxford Foot Questionnaire; SD, standard deviation.

Table 4. Preoperative AOFAS and MOXFQ scores according to the morphological type of the affected foot.

Scales	Foot Type	Mean (SD)	Min–Max	*p*
MOXFQ_pre	Egyptian (n = 15)	42.00 (9.82)	30–56	0.968
	Square (n = 23)	42.83 (6.62)	32–56	
	Greek (n = 25)	42.28 (12.89)	23–63	
AOFAS_pre	Egyptian (n = 15)	35.80 (12.58)	10–52	0.975
	Square (n = 23)	35.13 (11.74)	18–52	
	Greek (n = 25)	34.88 (11.92)	14–50	

AOFAS, American Orthopaedic Foot and Ankle Society; Max, maximum; Min, minimum; MOXFQ; Manchester Oxford Foot Questionnaire; SD, standard deviation.

Similarly, the preoperative W-S, Pain, and S-I scores showed no significant differences regarding the laterality (Table 5) or the morphological type of the affected foot (Table 6).

Table 5. Preoperative scores of the W-S, Pain, and S-I subscales according to the laterality of the affected foot.

Items	Foot Laterality	Mean (SD)	Min–Max	*p*
W-S_pre	Right (n = 26)	17.08 (5.20)	7–27	0.739
	Left (n = 37)	16.65 (4.87)	8–27	
Pain_pre	Right (n = 26)	15.88 (3.81)	8–21	0.989
	Left (n = 37)	15.95 (3.67)	8–22	
S-I_pre	Right (n = 26)	10.27 (2.93)	6–16	0.132
	Left (n = 37)	9.24 (2.39)	6–15	

Max, maximum; Min, minimum; SD, standard deviation; S-I, Social Interaction; W-S, Walking–Standing.

Table 7 summarizes and compares the pre- and postoperative AOFAS and MOXFQ scores. The AOFAS score increased by nearly 50 points from the preoperative level at all postoperative time points ($p < 0.001$); F = 223.1; df = 3; eta partial squared= 0.918; observed power = 1 (Multivariate test). The three postoperative scores differed by less than 2 points, although the values were significantly different between postoperative years 4.7 and 6.5 ($p = 0.002$). The MOXFQ score decreased by nearly 20 points from the preoperative level at all postoperative time points ($p < 0.001$); F = 61.8; df = 3; eta partial squared = 0.756; observed power = 1 (Multivariate test). Differences in MOXFQ scores among the three postoperative values did not exceed 1 point, although the values were again significantly different between postoperative years 4.7 and 6.5 ($p = 0.048$). The 95% confidence intervals (CIs) are shown in Figure 1. Time had a significant effect on the scores of both scales ($p < 0.001$). Mauchly's sphericity test indicated that the assumption of sphericity was violated ($p < 0.001$), and the Greenhouse–Geisser correction was used in both cases. The eta partial squared value was 0.732 (Observed power = 1) for the MOXFQ scale and 0.893 (Observed power = 1) for the AOFAS scale, which implies a large effect size for each scale.

Table 6. Preoperative scores of the W-S, Pain, and S-I subscales according to the morphological type of the affected foot.

Items	Foot Type	Mean (SD)	Min–Max	*p*
W-S_pre	Egyptian (n = 15)	16.73 (4.30)	9–23	0.997
	Square (n = 23)	16.87 (3.65)	12–27	
	Greek (n = 25)	16.84 (6.39)	7–27	
Pain_pre	Egyptian (n = 15)	15.73 (3.75)	10–20	0.935
	Square (n = 23)	16.39 (2.82)	10–20	
	Greek (n = 25)	15.60 (4.41)	8–22	
S-I_pre	Egyptian (n = 15)	9.53 (2.80)	6–15	0.953
	Square (n = 23)	9.57 (2.13)	7–14	
	Greek (n = 25)	9.84 (3.06)	6–16	

Max, maximum; Min, minimum; SD, standard deviation; S-I, Social Interaction; W-S, Walking–Standing.

Table 7. Scores of the MOXFQ and AOFAS scales at the four examined time points.

Scale	Mean (SD)	Min–Max	Scale	Mean (SD)	Min–Max
MOXFQ_pre *a	42.41 (10.09)	23–63	AOFAS_pre *c	35.19 (11.82)	10–52
MOXFQ_1y *a,*b	22.95 (10.21)	16–63	AOFAS_1y *c	85.03 (12.12)	49–95
MOXFQ_4.7y *a	23.35 (10.51)	16–62	AOFAS_4.7y *c,*d	85.94 (12.67)	45–95
MOXFQ_6.5y *b	23.43 (10.42)	16–61	AOFAS_6.5y *c,*d	84.05 (13.14)	45–95

*a MOXFQ_pre > MOXFQ_i (i = 1y, 4.7y, and 6.5y; $p < 0.001$). *b MOXFQ_1y < MOXFQ_6.5y ($p = 0.048$). *c AOFAS_pre < AOFAS_i (i = 1y, 4.7y, and 6.5y; $p < 0.001$). *d AOFAS_4.7y > AOFAS_6.5y ($p = 0.002$). AOFAS, American Orthopaedic Foot and Ankle Society; Max, maximum; Min, minimum; MOXFQ; Manchester Oxford Foot Questionnaire; SD, standard deviation; y, years.

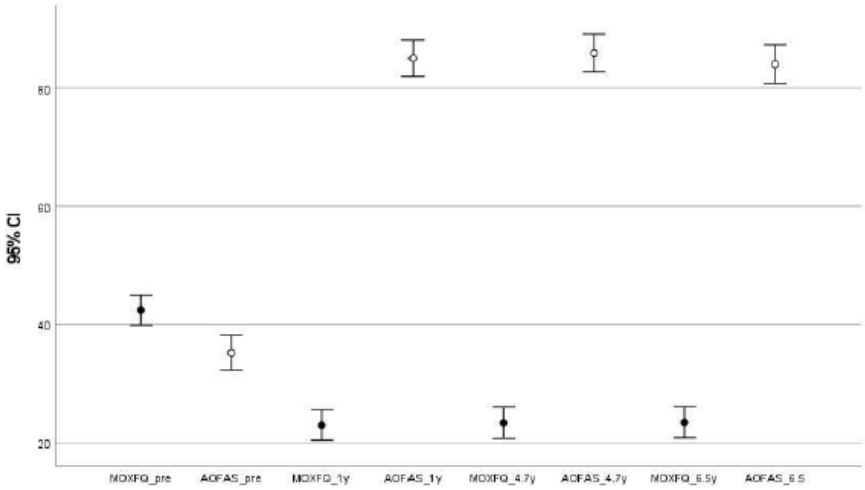

Figure 1. AOFAS and MOXFQ scores with their 95% CIs at pre- and postoperative time points. AOFAS, American Orthopaedic Foot and Ankle Society; CI, confidence interval; MOXFQ; Manchester Oxford Foot Questionnaire; y, years.

Table 8 shows the scores of the three MOXFQ subscales at pre- and postoperative time points. According to the multivariate test there was a significant effect of time for Walking–Standing (F = 31.79; df = 3; eta partial squared = 0.614; observed power = 1), for Pain (F = 90.26; df = 3; eta partial squared = 0.819; observed power = 1) and for the Social Interact values (F = 34.54; df = 3; eta partial squared = 0.633; observed power = 1).

The difference between the preoperative W-S score and all postoperative W-S scores was about 6 points ($p < 0.001$), whereas the postoperative W-S scores differed by 0.2 points or less (not significant). Likewise, the difference between the preoperative Pain score and all postoperative Pain scores was 6 points ($p < 0.001$); there were no differences among the postoperative pain scores. The differences between the preoperative S-I score and all postoperative S-I scores ranged between 3.6 and 3.8 ($p < 0.001$). The maximum difference among postoperative S-I scores was 0.2 points (not significant). The 95% CIs are shown in Figure 2. Mauchly's sphericity test indicated that the assumption of sphericity was violated ($p < 0.001$), and the Greenhouse–Geisser correction was used for each of the three variables. The eta partial squared value was 0.593 (Observed power = 1) for the W-S item, 0.804 (Observed power = 1) for the Pain item, and 0.581 (Observed power = 1) for the S-I item. In all cases, a large effect size was confirmed.

Table 8. Scores of the W-S, Pain, and S-I subscales of the MOXFQ at the four examined time points.

Item	Mean (SD)	Min–Max	Item	Mean (SD)	Min–Max	Item	Mean (SD)	Min–Max
W-S_pre *a	16.8 (4.9)	7–27	Pain_pre *b	15.9 (3.7)	8–22	S-I_pre *c	9.6 (2.6)	6–16
W-S_1y *a	10.2 (4.4)	7–27	Pain_1y *b	6.9 (3.6)	5–20	S-I_1y *c	5.8 (2.6)	4–16
W-S_4.7y *a	10.4 (4.5)	7–27	Pain_4.7y *b	6.9 (3.5)	5–20	S-I_4.7y *c	6.0 (2.8)	4–17
W-S_6.5y *a	10.4 (4.5)	7–26	Pain_6.5y *b	6.9 (3.4)	5–19	S-I_6.5y *c	6.0 (2.7)	4–16

*a W-S_pre > W-S_i (i = 1y, 4.7y, and 6.5y; $p < 0.001$). *b Pain_pre > Pain_i (i = 1y, 4.7y, and 6.5y; $p < 0.001$). *c S-I_pre > S-I_i (i = 1y, 4.7y, and 6.5y; $p < 0.001$). Max, maximum; Min, minimum; MOXFQ; Manchester Oxford Foot Questionnaire; SD, standard deviation; S-I, Social Interaction; W-S, Walking–Standing; y, years.

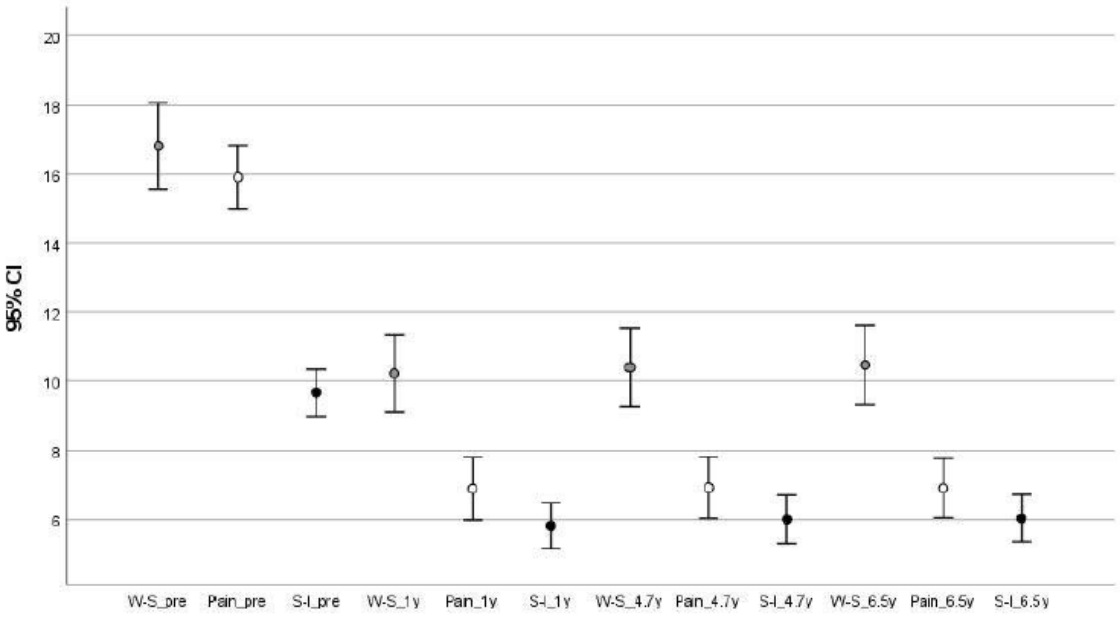

Figure 2. Scores of the three MOXFQ subscales with their 95% CIs at pre- and postoperative time points. CI, confidence interval; MOXFQ; Manchester Oxford Foot Questionnaire; S-I, Social Interaction; W-S, Walking–Standing; y, years.

Differences in pre- vs. post-operative (6.5 years) AOFAS and MOXFQ scores regarding the laterality of the affected foot (Table 9) and the morphological type of the affected foot (Table 10) were highly significant.

Table 9. AOFAS and MOXFQ scores at preoperative and postoperative (6.5 years) according to the laterality of the affected foot.

Foot Laterality	MOXFQ_Pre	MOXFQ_6.5y	*p*
Right (n = 26)	43.23 (10.69)	23.85 (11.8)	<0.001
Left (n = 37)	41.84 (9.76)	23.14 (9.50)	<0.001
Foot Laterality	**AOFAS_Pre**	**AOFAS_6.5y**	***p***
Right (n = 26)	36.04 (13.34)	83.46 (13.28)	<0.001
Left (n = 37)	34.59 (10.77)	84.46 (13.22)	<0.001

AOFAS, American Orthopaedic Foot and Ankle Society; MOXFQ; Manchester Oxford Foot Questionnaire; SD, standard deviation; y, years.

Table 10. AOFAS and MOXFQ scores at preoperative and postoperative (6.5 years) according to the morphological type of the affected foot.

Foot Type	MOXFQ_Pre	MOXFQ_6.5y	*p*
Egyptian (n= 15)	42.00 (9.82)	24.33 (12.26)	0.001
Square (n = 23)	42.83 (6.62)	24.87 (10.29)	<0.001
Greek (n = 25)	42.28 (12.89)	21.56 (9.46)	<0.001
Foot Type	**AOFAS_Pre**	**AOFAS_6.5y**	***p***
Egyptian (n= 15)	35.80 (12.58)	82.73 (16.11)	0.001
Square (n = 23)	35.13 (11.74)	82.83 (11.51)	<0.001
Greek (n = 25)	34.88 (11.92)	85.96 (12.93)	<0.001

AOFAS, American Orthopaedic Foot and Ankle Society; MOXFQ; Manchester Oxford Foot Questionnaire; SD, standard deviation; y, years.

Differences in pre- vs. post-operative (6.5 years) subscales of the MOXFQ scores regarding the laterality of the affected foot (Table 11) and the morphological type of the affected foot (Table 12) were highly significant.

Some examples of pre- to post-operative radiological and clinical changes are shown in Figures 3 and 4.

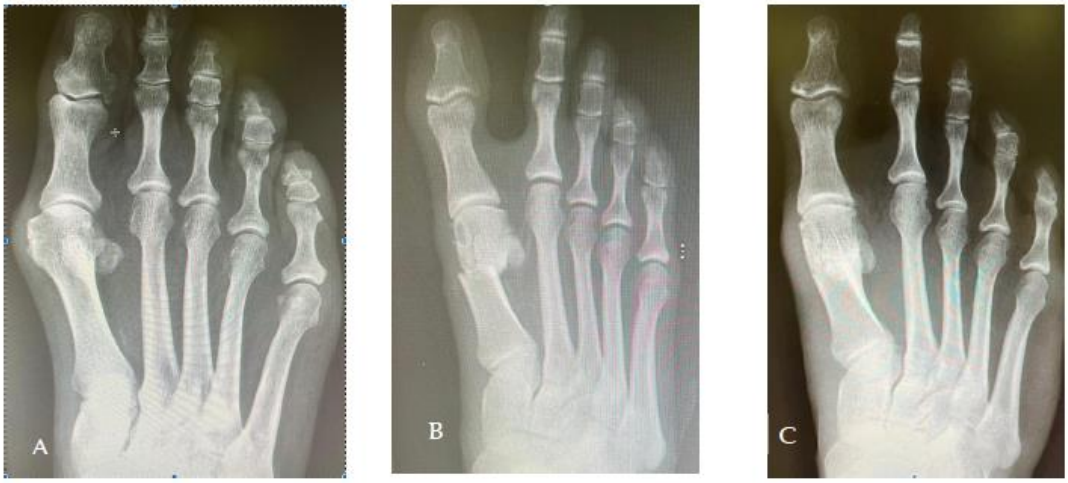

Figure 3. Radiological views of one case. (**A**): Preoperative; (**B**): Two weeks after the operation; (**C**): Two years after the operation.

Table 11. Walking–Standing (W-S). Pain and Social Interact (S-I) scores at preoperative and postoperative (6.5 years) according to the laterality of the affected foot.

Foot Laterality	**W-S_Pre**	**W-S_6.5y**	***p***
Right (n = 26)	17.08 (5.20)	10.5 (4.97)	<0.001
Left (n = 37)	16.65 (4.87)	10.43 (4.36)	<0.001
Foot Laterality	**Pain_Pre**	**Pain_6.5y**	***p***
Right (n = 26)	15.88 (3.81)	7.00 (3.83)	<0.001
Left (n = 37)	15.95 (3.67)	6.86 (3.20)	<0.001
Foot Laterality	**S-I_Pre**	**S-I_6.5y**	***p***
Right (n = 26)	10.27 (2.93)	6.35 (3.22)	<0.001
Left (n = 37)	9.24 (2.39)	5.84 (2.34)	<0.001

W-S, Walking–Standing; S-I, Social Interact; pre, preoperative; y, years.

Table 12. Walking–Standing (W-S). Pain and Social Interact (S-I) scores at preoperative and postoperative (6.5 years) according to the morphological type of the affected foot.

Foot Type	**W-S_Pre**	**W-S_6.5y**	***p***
Egyptian (n = 15)	16.73 (4.30)	10.40 (5.21)	0.003
Square (n = 23)	16.87 (3.65)	11.57 (4.67)	0.001
Greek (n = 25)	16.84 (6.39)	9.48 (4.03)	0.014
Foot Type	**Pain_Pre**	**Pain_6.5y**	***p***
Egyptian (n= 15)	15.73 (3.75)	7.67 (4.19)	<0.001
Square (n = 23)	16.39 (2.82)	7.00 (3.25)	<0.001
Greek (n = 25)	15.60 (4.41)	6.40 (3.18)	<0.001
Foot Type	**S-I_Pre**	**S-I_6.5y**	***p***
Egyptian (n= 15)	9.53 (2.80)	6.27 (3.17)	<0.001
Square (n = 23)	9.57 (2.13)	6.30 (2.69)	<0.001
Greek (n = 25)	9.84 (3.06)	5.68 (2.54)	<0.001

W-S, Walking–Standing; S-I, Social Interact; pre, preoperative; y, years.

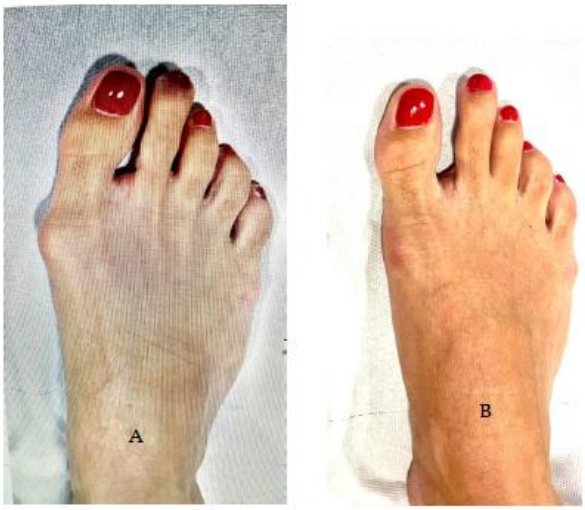

Figure 4. Clinical views of the same case of Figure 3. (**A**): Preoperative; (**B**): Two years after the operation.

4. Discussion

The main finding of this work is that both AOFAS and MOXFQ scores significantly improved 1 year after MIS correction of HV and that this correction was maintained without significant changes 4.7 and 6.5 years later. Moreover, the scores of the three MOXFQ subscales also significantly improved 1 year after the operation and remained at this level without significant changes during follow-ups until 6.5 years postoperatively.

Our results showed a significant difference in the AOFAS score from the preoperative to the final follow-up value at 6.5 years (35.1 vs. 84.0 points, respectively). This difference was similar to that observed by other authors after MIS correction. Biz et al. [4] reported a score of 87.15 points 48 months after surgery representing an increase of 33 points. With the use of a MIIND, Biz et al. [13] found an improvement in AOFAS score from 57.9 preoperatively to 90.5 after a mean of 96 months postoperatively. Motta et al. [20] found a pre-to-post difference of 54 points 6 years after the operation (from 35 to 90 points). Castellini et al. [9] reported pre- to postoperative changes in AOFAS scores from 47.3 to 87.0 points, respectively, 2 years after surgery. Xu et al. [19] found that the AOFAS score increased from preoperative 44.0 points to postoperative 90.2 points. Del Vecchio et al. [44] observed a pre-to-post change from 52.1 to 92.1 points. For a systematic review, Miranda et al. [40] selected 16 publications including 1246 patients with MIS for HV correction. The mean AOFAS scores improved from pre- to postoperative values ranging from 51.0 to 89.3 points. In a recent meta-analysis, Alimy et al. [14] selected seven studies (395 feet) including six randomized controlled studies and one prospective comparative study. They reported a final AOFAS score of 88 $\pm$ 7 points. Caravelli et al. ([8] reported four studies (464 cases) with a mean final AOFAS score of 90.2.

In our study, the MOXFQ scores improved from 42.4 points preoperatively to 23.4 points 6 years later. This difference was smaller than that reported by other studies on MIS HV correction. Del Vecchio et al. [44] observed a preoperative score of 40 points, which changed to 5.3 points at follow-up 18 months later. Patnaik et al. [18] found a pre-to-post change in MOXFQ score of 64.6 vs. 11.6 points 2 years later. Likewise, Lewis et al. [38] reported a score of 40.6 points in the preoperative control and 6.7 points 2 years later, and Lewis et al. [37] observed a MOXFQ index score of 2.3 points 5 years after the operation.

Our results showed a differential development from preoperative to final follow-up scores among the three MOXFQ domains, i.e., 16.8 vs. 10.4 points for W-S, 15.9 vs. 6.9 points for Pain, and 9.6 vs. 6.0 points for S-I. These results differ from those of Lewis et al. [38], who observed at a minimum 2-year follow-up that the MOXFQ scores had significantly improved in each domain, i.e., they decreased from 44.5 points preoperatively to 9.4 points postoperatively for Pain, from 38.7 to 6.5 points for W-S, and from 48.0 to 6.6 points for S-I. In addition, Lewis et al. [36] reported that 2 years after surgery, the MOXFQ scores significantly improved in the Pain, W-S, and S-I domains from 39.2 to 7.5 points, 38.2 to 5.9 points, and 48.6 to 5.5 points, respectively.

Few authors have reported results at multiple time points in the same cohort of patients after MIS correction of HV [4,45,46]. Apart from Lewis et al. [38], little attention has been paid to changes over time. The majority of PROM improvements following MIS correction are achieved by 6 months postoperatively, but a further small significant improvement can be seen up to 2 years [36]. Other authors have reported similar findings but without reaching statistical significance [47]. Biz et al. [4] observed at different follow-up time points that the mean total AOFAS score of MIS-treated patients improved progressively and significantly: 54.1 points before surgery, 72.2 points at 3-month follow-up, 78.6 points at 12-month follow-up, and 87.2 points at the final 48 months-follow-up. Using a MIINF, Biz et al. [13] observed a progression of the AOFAS score from 26.2 at pre-operation to 69.6 at 6 months, 81.4 at 12 months, and 87.6 at a mean of 96 months post-operatively.

We found only one report that studied the changes in MOXFQ scores over time in a cohort of patients after MIS correction for HV [38]. These authors evaluated 202 feet with complete PROM data. They found a statistically significant improvement in the MOXFQ index score at each time point following MICA surgery for up to 2 years of follow-up.

However, the differences after 6 months may not be clinically significant. Our study also showed significant differences in MOXFQ scores between pre- and postoperative time points, but the differences among the three postoperative values were less than 1 point and not significant. Our patients also showed significant differences in AOFAS scores between the preoperative and follow-up time points. Although a significant difference of nearly 2 points in the AOFAS score between the 4.7-year and 6.5-year follow-ups was found, this difference is probably not clinically relevant. Chan et al. [48] observed 2 years after HV correction that the mean AOFAS score difference between good vs. fair satisfaction was 7.9 (83.9 vs. 78.1) points and that the mean preoperative vs. postoperative change was 30.2 vs. 22.3 points, respectively.

Complication rates after MIS correction vary. A recent systematic review of 1246 patients reported that the overall complication rate of percutaneous HV surgery ranged from 0% to 80%, with a weighted mean of 22.99% [40]. The most common complication was joint stiffness (18.47%), followed by HV recurrence and shortening of the M1 (both 15.2%), material intolerance (10.1%), osteoarthritic changes (9.1%), infection (7.6%), and transfer metatarsalgia (5.4%) [40]. A revision of 317 cases of Inshall–Reverdain distal osteotomy reported 21 cases (6.3%) with different types of complications [8]. Patients who experience a complication are significantly more likely to have a worse MOXFQ index score at 6 months than those who have a normal postoperative recovery [36].

Female patients presenting with HV deformities have a significantly reduced quality of life compared to the general population [1]. Surgical correction of this deformity significantly improves patient quality of life [16]. However, physical and psychological factors of patients may influence the outcomes and recovery from surgery. Even when surgery is performed by an experienced surgeon, a potential remains for patients to experience dissatisfaction and unfavourable outcomes [23].

We used only one functional questionnaire and one PROM questionnaire to assess the patients in this study. However, both MOXFQ and AOFAS have been shown to be highly responsive to clinical changes in the context of HV surgery [32]. These questionnaires are most commonly used to assess clinical results after HV correction [7,14,18,49,50]. Moreover, unlike the AOFAS and MOXFQ, other widely used tools, such as the Short Form 36 questionnaire, have proven to be neither reliable nor responsive enough to detect real changes after forefoot surgery [25].

We did not radiologically assess at any time point possible changes. However, we aimed to study only clinical score changes, and several publications have shown no significant correlation between radiological and clinical findings in patients with HV [16,20,21,36]. Moreover, some authors have reported that predictors of patient satisfaction include subjective outcomes, such as those assessed by the AOFAS score and the Short Form 36 composite quality of life scale, rather than objective radiological outcomes [21].

We only enrolled patients with isolated HV correction, and we do not know whether the results would be different if minor toe corrections were included. However, Lewis et al. [36] reported no significant differences in the scores of the three MOXFQ subscales 2 years after HV correction whether MICA had been performed alone or in association with other procedures. Nevertheless, Miranda et al. [40] pointed out that associated procedures of the lesser toes may affect surgery outcomes, as lateral ray osteotomies may prevent one of the most-feared complications, namely transfer metatarsalgia.

Limitations

Our study has several limitations. Although large effect sizes were observed in our study, the total number of included patients was relatively small. However, the inclusion criteria restricted the size of the study population. We do not know how the inclusion of patients with complications after surgery may have influenced the results or whether the inclusion of men in the study population may have altered the results. We did not consider demographic/social data (Body mass index, smoking, alcohol habits, etc.) and do not know how these factors might influence our results. We used only one MIS technique; however,

there is sufficient recent evidence that the type of operation has no significant influence on the clinical results after HV surgery [15–18,21]. Moreover, Miranda et al. [40] found in a systematic review that none of the percutaneous techniques were superior. We did not report the follow-up results between the immediate postoperative period and 1 year after the operation, although these data might provide important information. Evidence suggests that most of the clinically important improvements are reached as soon as 3 months after surgery [36]. Over 90% of patients showed an improvement in clinical PROMs 6 months after MICA. Nevertheless, postoperative complications have a negative impact on PROMs 6 months after surgery, although patients can improve over time despite complications [38]. Finally, although our patients did not complain of the operated hallux valgus-related pain, we did not study specific tools such as the visual analogic scale to measure this point.

5. Conclusions

We studied a cohort of patients without any complications after MIS for HV correction. Surgeons must inform their patients about possible complications of the operation and how these can influence the outcomes. However, it is also important to inform patients of the expected outcomes when no complications occur. To our knowledge, this is the first study to report this perspective. Although the number of cases needs to be increased and different surgeons and techniques should be included in future studies, this study will help inform patients about the outcomes they can expect over the years if no complications occur. According to our results, the outcomes reported 1 year after MIS correction with the Isham–Reverdin technique in patients without postoperative complications will last without substantial changes for at least 6 years.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Institutional Human Research Ethics Committee of Las Palmas de Gran Canaria University (protocol number CEIH-2018-02) and Las Palmas Province (Ref CEIm-LP-2021-418-1) in accordance with the 1964 Helsinki Declaration.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data that support the findings of this study are available from the corresponding author, G.L.G., upon reasonable request.

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

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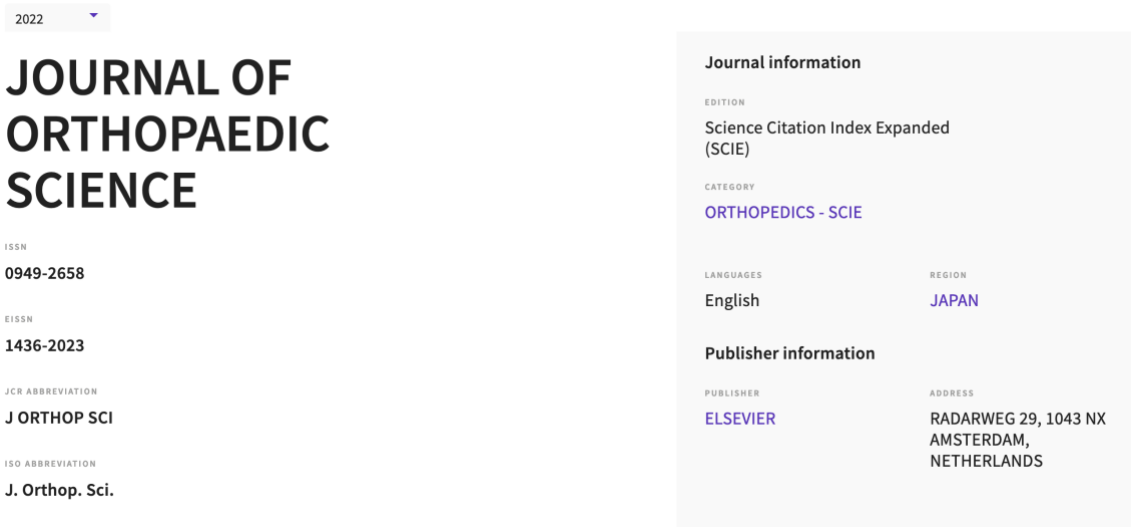

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Original Article

Cross-cultural adaptation and validation of a Spanish version of the self-administered foot evaluation questionnaire (SAFE-Q)☆

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ABSTRACT

Background: The self-administered foot evaluation questionnaire is a comprehensive measure for assessing the perception of patients regarding their foot-related problems. However, it is currently only available in English and Japanese. Therefore, this study aimed to cross-culturally adapt the questionnaire to Spanish and assess its psychometric properties.

Methods: The methodology recommended by the International Society for Pharmaco Economics and Outcomes Research for translating and validating patient-reported outcome measures was followed for the Spanish translation. After a pilot study with 10 patients and 10 controls, an observational study was carried out between March and December 2021. The Spanish version of the questionnaire was filled by 100 patients with unilateral foot disorders, and the time spent to complete each questionnaire was recorded. Cronbach's alpha was calculated to analyze the internal consistency of the scale and Pearson's correlation coefficients for the degree of inter-subscale associations.

Results: The maximum correlation coefficient for the Physical Functioning, Daily Living, and Social Functioning subscales was 0.768. The inter-subscale correlation coefficients were significant ($p < 0.001$). Additionally, the value of Cronbach's alpha for the whole scale was 0.894 (95% confidence interval, 0.858–0.924). The values of Cronbach's alpha varied between 0.863 and 0.889 when the value of one of the five subscales was suppressed, which can be considered a measure of good internal consistency.

Conclusion: The Spanish version of the questionnaire is valid and reliable. The method followed for its transcultural adaptation ensured its conceptual equivalence with the original questionnaire. Health practitioners can use the self-administered foot evaluation questionnaire as a complementary method to assess the interventions performed for ankle and foot disorders among native Spanish speakers; however, further research is necessary to assess its consistency for use by populations from other Spanish-speaking countries.

1. Introduction

Orthopedic foot and ankle pathologies are quite common [1–3], and their impact on daily life can be assessed using several methods. Treatment outcomes can be assessed with a clinician- or patient-reported questionnaires. The American Orthopaedic Foot and Ankle Society (AOFAS) Clinical Rating Systems are the most widely used by clinicians [4,5]. However, they include physical exam parameters that have shown poor inter-observer and intra-observer reliability, and the inability to self-administration by patients increases the risk of bias [6]. Self-reported questionnaires are commonly used [1,7,8], of which patient-reported outcome measures (PROMs) are used to assess health status changes over time from the perspective of the patient [9,10]. There are four basic types of patient-based outcome instruments: generic, disease-specific, region-specific, and patient-specific. A region-specific instrument is used for diseases that affect a particular site [9]. The Manchester-Oxford foot questionnaire (MOXFQ) is a PROM for health-related quality of life assessment in patients undergoing foot or ankle

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surgery [2]. The MOXFQ exhibits good psychometric qualities [11] and is validated for use in Spanish [2]. However, it does not comprise a section regarding shoe usage despite its association with pain and foot disorders [12,13].

The Japanese Society for Surgery of the Foot developed a region-specific PROM for individuals with foot and ankle-related pathologies in 2013: the self-administered foot evaluation questionnaire (SAFE-Q), published in English [9]. The SAFE-Q consists of 34 items among the following five subscales: pain and pain-related (PP), physical functioning and daily living (PF), social functioning (SF), shoe-related (SH), and general health and well-being (GH). In addition, the instrument has nine optional items to derive a sports ability score [14].

The use of a PROM in a language other than English requires accurate translation along with cultural adaptation to preserve content validity and psychometric properties [2,15]. "Cross-cultural adaptation" ensures consistency in content and validity between the original and translated versions of the questionnaire [15], thereby allowing data comparisons among regions with different spoken languages and cultural roots [1,2,15].

Spanish is the mother tongue of more than 450 million people globally. However, a Spanish version of the SAFE-Q has not been created yet. The creation of a Spanish version of a valid and reliable SAFE-Q is clinically significant. Health practitioners can use the SAFE-Q as a complementary method to assess the interventions performed for ankle and foot disorders among native Spanish speakers. This may improve the treatment outcomes through an improved assessment by removing any possible language barriers. Therefore, this study aimed to develop a Spanish translation of the questionnaire with cross-cultural adaptation and content validation.

2. Methods

This cross-sectional observational study was approved by the Local Human Research Ethics Committee and performed in accordance with the 1975 Helsinki Declaration. Written informed consent was obtained from all participants prior to their participation in the study.

The translation and validation of the PROM followed the methodology recommended by the International Society for Pharmaco Economics and Outcomes Research [16]. Transcultural adaptation comprises two phases: cross-cultural adaptation and validation [15,17,18].

Initially, written permission through email was obtained from the creators of the SAFE-Q for its Spanish translation, which was then carried out by two bilingual (English and Spanish) researchers. The next step was the reconciliation of the two forwarded translations into a single document after discussions with the project manager. Subsequently, a reverse translation from Spanish to English was performed by two bilingual native English-speaking translators. These translations were also coalesced into a final document with the inputs of the project manager. Cognitive equivalence was checked for by an expert committee comprising two physiotherapists, two orthopedic nurses, and four orthopedic surgeons specializing in ankle and foot diseases.

The resulting Spanish version of the SAFE-Q was individually filled by 10 patients with foot disorders and 10 healthy individuals to analyze the comprehension of the translation among the general and patient populations. Two orthopedic nurses clarified any doubts that arose among the patients and controls. Following this pilot study, a definitive version was launched and tested in 100 patients with unilateral foot pain or deformity. These participants were chosen from a subset of patients complaining of unilateral foot pain or deformity and treated at the same hospital by the same medical team between March and December 2021. The inclusion criteria for the patients were: age $\geq$18 years, unilateral non-traumatic foot pain lasting $\geq$2 weeks, foot deformity that compelled the patient to seek medical attention, ability to fill out a questionnaire without aid, mobility, and capability of walking the household distance unaided, and native Spanish usage. The exclusion criteria considered were: inability to comprehend the questionnaire or follow instructions regarding study participation, history of psychiatric or cognitive disorders, and refusal to participate in the study or sign the informed consent form. Patients were asked to fill out the Spanish version of the SAFE-Q, and the time required to do so was documented. They were questioned regarding any difficulty they faced in comprehending the questions and asked to indicate the unanswered ones. Subsequently, cross-cultural validation was performed to evaluate reliability and validity.

2.1. Statistical analysis

Categorical and continuous variables are presented as absolute frequencies and percentages and means±standard deviations (SDs), medians, and interquartile ranges (IQRs), respectively. The Kolmogorov–Smirnov test was used to analyze sample normality, and the non-parametric Mann–Whitney *U* test was used to compare the means of two independent samples. Cronbach's alpha was calculated to analyze the internal consistency of the scale and Pearson's correlation coefficients to evaluate the level of association among the subscales. Statistical significance was set at $p < 0.05$. Statistical analysis was performed with the Statistical Package for the Social Sciences (SPSS) software, version 27.0 (IBM Corp., Armonk, NY, USA).

3. Results

Of the 100 patients included in this study, 14 were men and 86 women with ages of 54.7 ± 12.7 and 52.8 ± 11, respectively (Table 1). All study participants indicated that they were able to understand all questions from the Spanish translation of the SAFE-Q. The response time was 9.57 ± 3 min (Table 2).

The means±SDs and medians for the five subscales were as follows: PP: 44.87 ± 16.49, 44.44; PF: 66.97 ± 18.08, 70.45; SF: 69.54 ± 23.86, 75; SH: 36.91 ± 21.43, 33.33; and GH: 75.25 ± 24.21, 75 (Table 3). The distributions of the subscale scores are illustrated in Fig. 1.

Correlation coefficients are summarized in Table 4. Subscale correlations measure the degree of association between scores on one subscale and those on all other subscales within the completed scale. The maximum coefficient for the correlation between the PF and SF subscales was 0.768. Additionally, inter-subscale correlation coefficients were significant ($p < 0.001$). Fig. 2 shows the linear associations between each subscale pair and indicates which pair had a greater correlation, according to the analysis of the scales derived from the translated questionnaire.

For the five subscales of the Spanish SAFE-Q, the value of Cronbach's alpha, which is a measure of scale reliability, was 0.894 (95% confidence interval, 0.858–0.924); this can be considered a measure of good internal consistency. Table 5 shows the mean, variance, and Cronbach's alpha values with the suppression of each subscale. The global Cronbach's alpha value (0.894) remained the highest even after item suppression.

4. Discussion

Following the recommended international guidelines [15–18], the Spanish version of the SAFE-Q is a PROM validated for use in

Table 1
Demographic data of the participants.

Gender		Age[a] (years)	
		Mean (SD)	P50 (IQR)
Male	14%	54.7 (12.7)	56.5 (26)
Female	86%	52.8 (11)	53 (19)

SD: standard deviation; P50: Median; IQR: interquartile range.
[a] No significant differences were detected in age-stratified by gender (p-value = 0.51).

Table 2
Time taken to complete the SAFE-Q.

	Mean (SD)	P25	P50	P75	Min–Max
Total time taken to answer the Spanish SAFE-Q (min)	9.57 (3.01)	8	10	10	2–30[a]

SAFE-Q: Self-administered foot evaluation questionnaire; SD: standard deviation; P25: 25th percentile; P50: median; P75: 75th percentile; Min–Max: minimum–maximum values.
[a] Most response times ranged from 2 to 15 min; however, one patient took 30 min.

Table 3
Evaluation of the five subscales of the SAFE-Q (n = 100).

Subscales	Mean score (SD)	Median score (IQR)
Pain and pain-related	44.87 (16.49)	44.44 (22.67)
Physical functioning and daily living	66.97 (18.08)	70.45 (27.27)
Social functioning	69.54 (23.86)	75 (36.46)
Shoe-related	36.91 (21.43)	33.33 (33.34)
General health and well-being	72.25 (24.21)	75 (38.75)

SAFE-Q: Self-administered foot evaluation questionnaire; SD: standard deviation; IQR: interquartile range.

Spain for patients with foot and ankle diseases. The questionnaire was easily self-filled by 100 patients complaining of unilateral foot pain for 9 months in 2021. The methods followed for the transcultural adaptation of the SAFE-Q translation in our study ensured its conceptual equivalence with the original questionnaire.

Reliability can be assessed using internal consistency, which is a measure of (sub)scale homogeneity and indicates the degree of correlation between the items of the (sub)scale, thereby measuring the same construct of a health problem [11,19,20]. Items that measure the same construct should show a high correlation [19]. Internal consistency ensures that multiple items (subscales) of a score (scale) that measure different aspects of a particular characteristic produce consistent scores. It can be evaluated using Cronbach's alpha, and a value of >0.80 indicates good internal consistency. However, a score >0.95 might indicate item redundancy [21]. Therefore, the Spanish SAFE-Q has proven to be reliable with good internal consistency (Cronbach's alpha = 0.894). The value of Cronbach's alpha after subscale suppression was lower than the global value (Table 5). This indicated the relevance and necessity of all subscales and that there were no redundant items because Cronbach's alpha was always <0.9.

Validity is the degree to which a score actually measures its intended target [20,22]. Content validity is an important criterion of PROM; it is the extent to which a set of items comprehensively address the various health components to be measured and evaluates whether the range of these components is adequately covered [20,23]. There is no absolute criterion to assess content

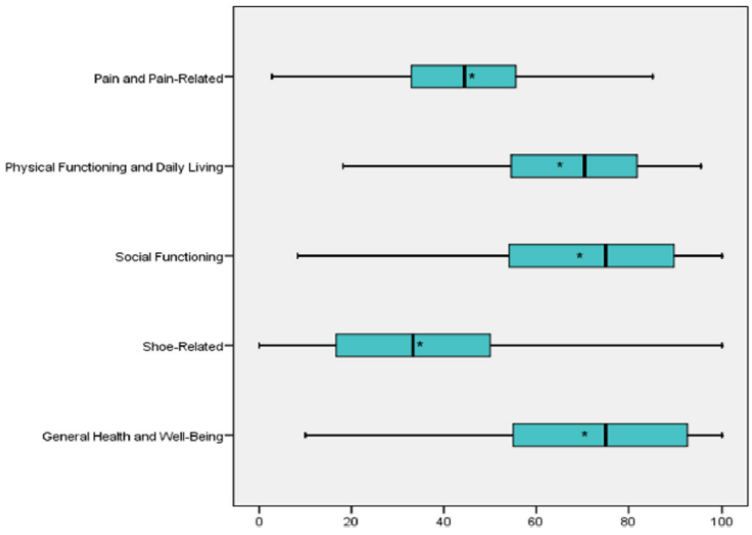

Fig. 1. Subscale-score distribution in box plots.
The left and right rectangle edges indicate the 25th and 75th percentiles, respectively. Vertical lines, bullet marks, and the left and right end of the horizontal lines within/passing through the rectangles show the medians, means, and 5th and 95th percentiles, respectively.

Table 4
Pearson's linear correlation coefficients between the five subscales.

	Pain and pain-related	Physical functioning and daily living	Social functioning	Shoe-related	General health and well-being
Pain and pain-related		0.697*	0.537*	0.531*	0.582*
Physical functioning and daily living			0.768*	0.550*	0.675*
Social functioning				0.609*	0.728*
Shoe-related					0.720*

* p-value < 0.001 (bilateral); n = 100.

validity [19]. Additionally, face validity indicates whether the items in each domain are sensible, appropriate, and relevant for those, including patients and healthcare practitioners, who use the measure on a daily basis [23]. In this study, there were no difficulties in translating and adapting the SAFE-Q to Spanish, and only minor corrections were necessary, which were resolved at the harmonization meeting. None of the patients had difficulties in completing the translated questionnaire, and additionally, they considered it comprehensive, with all subscales being necessary. Altogether, the Spanish translation of the SAFE-Q is acceptable for use by patients and health practitioners with face and content validity. Moreover, the mean time taken for questionnaire completion was less than 10 min. Therefore, the Spanish version of the SAFE-Q appears to be a quick and simple tool for use in clinical practice and research.

All correlation coefficients between different subscales were less than 0.9 (Table 4). The correlation between the GH and SH subscales (0.720) is particularly important. In general, women have a higher incidence of foot pain [24]. Women aged 25–45 years have reported high pain scores in previous studies [25,26]. This may be due to increased functional demands, such as sports or fitness participation. Additionally, younger women may choose to wear narrower shoes or those with higher heels [25], which may increase pain when worn [12,13]. The relationship between the shoes worn and pain and foot disorders have been established [12,13]; therefore, a strength of the SAFE-Q is its inclusion of an SH subscale, which evaluates this relationship. To the best of our knowledge, the SAFE-Q is the only PROM that includes this shoe-related section, making it a necessary tool for the global assessment of patients with foot and ankle pathologies.

Our study had some limitations, mostly owing to its cross-sectional design. First, we could not assess the test-retest or inter-observer reliability with a single measurement. Second, we did not compare the SAFE-Q to any "gold standard" method; therefore, we did not have criterion validity. Third, different dialects of Spanish with linguistic variations are spoken in different countries, including the United States, Mexico, Peru, and Argentina. However, our research group included members from Spain, Mexico, Venezuela, and Argentina. Therefore, further research is required to generalize its use in all Spanish-speaking countries.

In conclusion, the Spanish version of the SAFE-Q is valid and reliable. The methods followed for its transcultural adaptation ensured its conceptual equivalence with the original questionnaire.

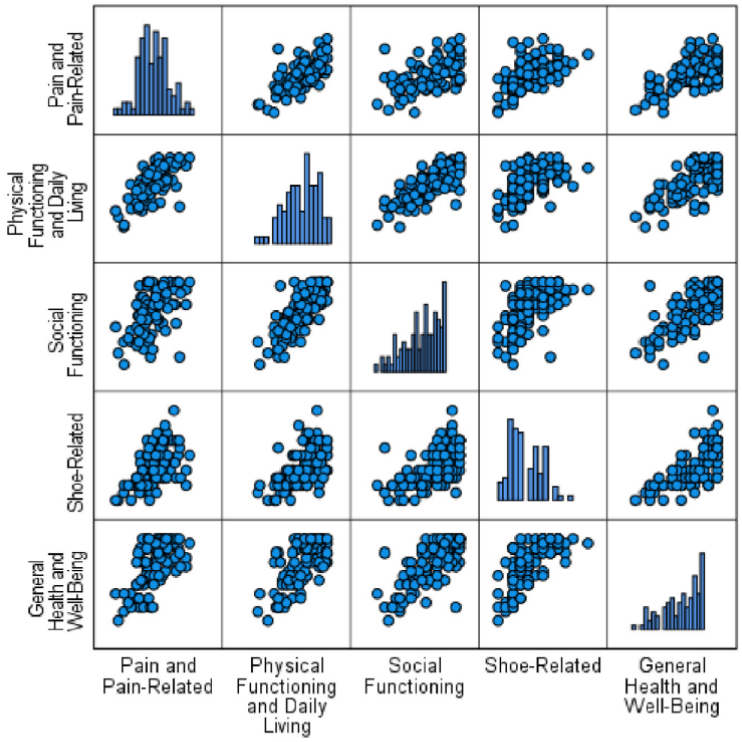

Fig. 2. Scatter plots for the five subscales. Scatter plots show the positive correlation between the two items. The diagonal contains the histograms of the items.

Table 5
Subscale statistics after item suppression and internal consistency measurement.

	Mean of the scale if the item is suppressed	Variance of the scale if the item is suppressed	Total item correlation corrected	Squared multiple correlation	Cronbach's alpha if the item is suppressed
Pain and pain-related	245.66	5830.99	0.666	0.529	0.889[a]
Physical functioning and daily living	223.57	5359.41	0.791	0.708	0.864[a]
Social functioning	220.99	4662.88	0.782	0.681	0.863[a]
Shoe-related	253.63	5150.95	0.706	0.548	0.879[a]
General health and well-being	218.29	4551.97	0.809	0.672	0.857[a]

[a] Cronbach's alpha, if an item is suppressed, has a value lower than the global Cronbach's alpha (0.894), for which all subscales are considered.

Health practitioners can use the SAFE-Q as a complementary method to assess the interventions performed for ankle and foot disorders among native Spanish speakers. Further research is necessary to generalize its use in all Spanish-speaking countries and evaluate their response to the questionnaire.

Ethical disclaimer

The study was approved by the Local Institutional Human Research Ethics Committee (protocol numbers CEIH-2018-02 and CEIm-LP-2021-418-1) and conducted in accordance with the 1975 Helsinki Declaration. Written informed consent was obtained from all study participants prior to their inclusion.

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Declaration of competing interest

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jos.2023.02.010.

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CONCLUSIONES

1. Los parámetros radiológicos, resultados funcionales y PROMs mejoran significativamente al comparar los valores preoperatorios con los postoperatorios en pacientes afectos de hallux valgus. Sin embargo, no hay correlación significativa entre las diferencias de los valores radiológicos preoperatorios v.s. postoperatorios, ni entre las diferencias de los valores clínicos preoperatorios v.s. postoperatorios.

2. El estudio de regresión multivariable demuestra que la diferencia pre-post-cirugía únicamente se correlacionó significativamente entre los valores de AOFAS y los de la posición del sesamoideo medial (TSP) y la traslación de la primera cabeza metatarsal (TMH).

1

3. Los resultados clínicos reportados un año tras la cirugía percutánea de hallux valgus se mantienen sin cambios seis años después cuando no se producen complicaciones. Es importante informar a los pacientes que sus expectativas tras cirugía mínimamente invasiva de hallux valgus pueden estar condicionadas por la ausencia de complicaciones en los primeros meses tras la intervención.

4. La adaptación transcultural al español del SAFE-Q ha demostrado ser fiable, reproducible y con alta equivalencia a la versión original en inglés. Constituye un método complementario al uso de cuestionarios auto-cumplimentados para ser usado por pacientes hispano hablantes afectos de patología del tobillo y pie.

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ANEXOS

Anexo 1

UNIVERSIDAD DE LAS PALMAS DE GRAN CANARIA
Vicerrectorado de Investigación, Innovación
Y Transferencia

Comité Ético de Investigación Humana de la ULPGC

REFERENCIA: CEIH-2018-02

José Pablo Suárez Rivero, Vicerrector de Investigación, Innovación y Transferencia y Presidente del Comité Ético de Investigación Humana de la Universidad de Las Palmas de Gran Canaria,

INFORMA

Que el Proyecto de Investigación titulado **"Resultados objetivos y subjetivos de la cirugía percutánea del hallux valgus"** cuyo Investigador Principal es **Don Gerardo Garcés Martín,** ha obtenido la consideración de ***FAVORABLE*** por los miembros vocales del Comité Ético de Investigación de la ULPGC reunidos a tal efecto.

Y para que surta los efectos oportunos, firmo el presente documento en Las Palmas de Gran Canaria a seis de marzo de dos mil dieciocho.

Vicerrectorado de Investigación, Innovación y Transferencia C/Juan de Quesada, nº 30 35001 – Las Palmas de Gran Canaria	**teléfonos** +34 928 451 030 **fax** +34 928 457 477	**Web:** www.ulpgc.es/investigación_inicio **Correo electrónico:** vitt@ulpgc.es svitt@ulpgc.es

Anexo 2

Servicio Canario de la Salud
CEI/CEIm de Las Palmas

Gobierno de Canarias
Consejería de Sanidad

DICTAMEN DEL COMITÉ DE ÉTICA DE LA INVESTIGACIÓN/COMITÉ DE ÉTICA DE LA INVESTIGACIÓN CON MEDICAMENTOS

Dña Maria Dolores Fiuza Pérez, Secretaria Técnica del Comité de Ética de la Investigación/Comité de Ética de la Investigación con Medicamentos (CEI/CEIm) de Las Palmas.

C E R T I F I C A:

Que este Comité, según consta en el Acta 11/2021 de fecha 26/11/2021, ha evaluado la propuesta del promotor GARCÉS MARTÍN GERARDO LUIS para que se realice el ESTUDIO OBSERVACIONAL titulado:

"RESULTADOS OBJETIVOS Y SUBJETIVOS DE LA CIRUGIA PERCUTANEA DEL HALLUX VALGUS ".

Promotor: GARCÉS MARTÍN GERARDO LUIS
Código CEIm de Las Palmas: 2021-418-1
Código Protocolo: CEIH-2018-02
Docs. con versiones:

Tipo documento	*Fecha*
CEIH ULPGC	***6-03-2018***

CEIC de Referencia: COMITE ETICA INVESTIGACION HUMANA ULPGC.
Datos del Investigador Principal:

Nombre	Centro	Servicio
GERARDO LUIS GARCÉS MARTÍN	Universidad de Las Palmas de Gran Canaria	Ciencias Médicas y Quirúrgicas

Y considera que:

Se cumplen los requisitos necesarios de idoneidad del protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles para el sujeto.

La capacidad del investigador y los medios disponibles son apropiados para llevar a cabo el ESTUDIO OBSERVACIONAL .

Es adecuado el procedimiento para obtener el consentimiento informado y el modo de reclutamiento.

El investigador y su equipo se comprometen a cumplir las recomendaciones y directrices de Buena Práctica Clínica aplicables a este tipo de estudios y la Declaración de Helsinki actualizada.

El alcance de las compensaciones económicas previstas no interfiere con el respeto a los postulados éticos.

Por tanto este COMITÉ resuelve que se adhiere a al informe favorable y el estudio queda **APROBADO** con fecha de hoy.

Que este Comité, tanto en su composición como en los PNTs, cumple con las normas de BPC (CPMP/ICH/135/95).

Con la elevación de este Dictamen a la Dirección Gerencia de este Centro para valoración de su Conformidad, terminan las acciones competencia de este CEI/CEIm sobre su estudio.

Que en dicha reunión se cumplió el quórum preceptivo legalmente.

Que, en el caso de que se evalúe algún proyecto del que un miembro sea investigador/colaborador, dicho miembro no participa en la evaluación ni el dictamen del propio protocolo.

Lo que firmo en Las Palmas de Gran Canaria

La Secretaria Técnica

Fdo.: Dra Dña Maria Dolores Fiuza Pérez

ANEXO I:

La Composición actual del Comité es la siguiente:

Presidente:
- ANTONIO GARCÍA QUINTANA - FEA-Cardiología HUGCDN

Vicepresidente:
- VICENTE OLMO QUINTANA - FEA- Farmacia AP

Secretario:
- Mª DOLORES FIUZA PEREZ - FEA-Epidemióloga Clínica HUGCDN

Vocales:
- DAVID AGUIAR BUJANDA - FEA- Oncología Médica HUGCDN
- JESUS MARÍA GONZALEZ MARTIN - Estadistico U. Investigación HUGCDN
- FRANCISCO JOSÉ NAVARRO VÁZQUEZ. - FEA-Técnico Salud Pública AP
- JORGE ARENCIBIA BORREGO - FEA-Medicina Interna HUGCDN
- JUANA TERESA RODRIGUEZ SOSA - FEA-Psiquiatría HUGCDN
- RITA GUTIERREZ GIL - Ldo. en Derecho
- MARÍA DOLORES JARILLO LOPEZ-MORA - DUE HUGCDN
- MIREYA AMAT LOPEZ - FEA-Farmacia HUGCDN
- ATTENYA ÁLAMO MEDINA - FEA-Farmacia CHUIMI
- JOSÉ LUIS ALONSO BILBAO - FEA-Medicina Preventiva A.P
- MAURO BORONAT CORTÉS - FEA-Endocrinología CHUIMI
- ELISABETH CHENEAU - DUE Docencia Salud Mental CHUIMI
- FÉLIX LÓPEZ BLANCO - Profesor Farmacología ULPGC
- JOSÉ JUAN MORALES CASTRO - DUE CHUIMI
- OCTAVIO RAMÍREZ GARCÍA - FEA-Ginecología y Obstetricia CHUIMI
- JULIO ÁNGEL DE SANTIAGO ANGULO - Ldo. en Derecho
- ANTONIO TUGORES CESTER - FEA-Unidad de Investigación CHUIMI
- BLANCA VALENCIANO FUENTE - FEA-Pediatría CHUIMI
- JORGE SOLÉ VIOLAN - FEA-Medicina Intensiva HUGCDN
- ELISABET GUERRA HERNÁNDEZ - FEA- Anestesiología y Reanimación HUGCD
- ASUNCIÓN ACOSTA MÉRIDA - FEA-Cirugía General y Disgestiva HUGCDN
- DANIEL LOPEZ FERNANDEZ - Fisioterapeuta Rehabilitación HUGCDN
- EMILIO JOSÉ SANZ ÁLVAREZ - FEA-Farmacología HUC
- BERNARDINO CLAVO VARAS - FEA-Unidad de Invesatigación HUGCDN
- CARMEN GONZÁLEZ VECINO - Miembro no lego
- CASIMIRA DOMÍNGUEZ CABRERA - FEA-Analisis Clínico HUGCDN
- MARGARITA MEDINA CASTELLANO - FEA-Ginecología y Obstetricia CHUIMI
- DULCE MARÍA PRINZ DÍAZ - Lda. en Derecho Asesoría Jurídica CHUIMI

ANEXO II:

Centros colaboradores:

Investigadores:

GERARDO LUIS GARCÉS MARTÍN	**Universidad de Las Palmas de Gran Canaria**	**Ciencias Médicas y Quirúrgicas**

Anexo 3

Este Formulario de Consentimiento Informado se dirige a pacientes que van a ser intervenidos de cirugía percutánea para corregir hallux valgus, a los que se les invita a participar en la investigación que lleva por título:

"Resultados objetivos y subjetivos de la cirugía percutánea del hallux valgus"

Nombre del Investigador Principal: Prof. Dr. Gerardo Garcés Martín, Catedrático de Traumatología de la Universidad de Las Palmas Gran Canaria (ULPGC)
Nombre de la Organización: ULPGC y Hospital Perpetuo Socorro
Nombre del Patrocinador: Traumaquir SL

Este Documento de Consentimiento Informado tiene dos partes:

• **Hoja de Información al Paciente** (proporciona información sobre el estudio)
• **Formulario de Consentimiento** (para firmar por parte del paciente si está de acuerdo en participar)

Se le dará una copia del Documento completo de Consentimiento Informado

PARTE I: Hoja de Información al Paciente

Introducción

El hallux valgus (también conocido como juanete) generalmente se describe como una protuberancia a un lado del primer dedo del pie. Esta protuberancia refleja cambios en el marco óseo de la parte frontal del pie.

El juanete es un padecimiento progresivo. Se inicia con la inclinación del dedo gordo que, a través de los años, modifica gradualmente el ángulo de los huesos y produce paulatinamente la protuberancia característica, la cual se vuelve cada vez más prominente. Se produce una alineación incorrecta de los huesos del pie y consecuentemente un mal apoyo y dolor.

El procedimiento quirúrgico por lo general se realiza de forma percutánea (a través de unas pequeñas incisiones en la piel) utilizando unos dispositivos para eliminar la protuberancia y recuperar la alineación ósea y rayos X.

Propósito

La realización de este tipo de estudio permitirá definir indicaciones y factores que influyen sobre la satisfacción de los pacientes con los resultados obtenidos tras el tratamiento de esta afección.

Procedimientos y Protocolo

Si usted forma parte de este estudio, se le realizará lo siguiente:

- Historia clínica completa sobre las características de su dolencia
- Estudio radiológico pre y postoperatorio

- Valoración de dolor por Escala Visual Analógica (cuestionario rellenado por usted).
- Cuestionarios de valoración sobre la percepción del procedimiento, tanto pre como postoperatoriamente

Para rellenar los cuestionarios de valoración contará con enfermeros cualificados que le orientarán acerca del proceso a seguir.

Duración

La investigación durará 5 años en total. Durante ese tiempo, será necesario que venga al hospital durante unos 30 minutos aproximadamente en cada visita.
En total, se le pedirá que venga 3 veces al hospital durante el primer año tras la cirugía y luego una vez al año. Al finalizar los 5 años, se finalizará la investigación.

Riesgos

Este estudio se clasifica en la categoría de riesgo mínimo. Esto significa que los riesgos asociados en este estudio son los mismos que usted enfrenta diariamente. No existen riesgos adicionales para aquellos que participan en este estudio.

Molestias

La participación de los pacientes en el estudio no implica la realización de ninguna prueba o procedimiento que no estuviera indicado en su caso según la práctica clínica habitual, y con independencia de la participación en el estudio. Este estudio no representará ningún coste adicional para los pacientes, los cuales estarán cubiertos por el seguro de responsabilidad civil correspondiente por parte de la institución y equipo sanitario que lo trate.

Beneficios

Si usted participa en esta investigación habrá beneficio para la sociedad entera atendiendo a los principios éticos de justicia (disminuyendo el costo de la atención sanitaria) y beneficencia (obteniendo evidencia de una mejor atención sanitaria desde la excelencia).

Incentivos

Los participantes no recibirán compensación económica por formar parte en este estudio.

Confidencialidad

Este estudio cumplirá de manera estricta la Ley Orgánica de Protección de Datos de Carácter Personal vigente (15/1999), comprometiendo a cualquier persona involucrada en el estudio a su cumplimiento. Cualquier dato que permita la identificación personal de los pacientes incluidos será disociado, es decir, la identidad de los pacientes será codificada en los documentos del estudio y sólo el personal debidamente autorizado tendrá acceso a dichos datos.

Participación Voluntaria/ Retiro

Su participación en esta investigación es voluntaria. Usted no tiene porque tomar parte en esta investigación si no desea hacerlo. Si decide participar, podrá abandonar libremente la investigación en cualquier momento sin tener que dar explicaciones. Es su elección y todos sus derechos serán respetados.

Si en cualquier momento tiene alguna pregunta, no dude en preguntar a la persona que le está hablando sobre este estudio. Si decide participar se le facilitará este documento informativo para que lo lea, lo entienda y lo conserve para su referencia. Asimismo, se le pedirá que firme un formulario de consentimiento.

Tanto si decide abandonar el estudio, como si decide no participar, ello no afectará al nivel de atención y cuidados que se le proporcionarán.

A Quién Contactar

Si tiene cualquier pregunta puede hacerlas ahora o más tarde, incluso después de haberse iniciado el estudio. Si desea hacer preguntas más tarde, puede contactar con cualquiera de las siguientes personas en el Hospital Perpetuo Socorro (Tfn. 928499900)

Ignacio Manchado Herrera, Enfermero del Hospital Perpetuo Socorro
Luci Motta da Rocha, Enfermera del Hospital Perpetuo Socorro
Dr Gerardo Garcés Martín, Traumatólogo del Hospital Perpetuo Socorro e investigador principal del proyecto

T

PARTE II: Formulario de Consentimiento

CONSENTIMIENTO INFORMADO

Nº de identificación del paciente en el estudio: _____

CONSENTIMIENTO INFORMADO DEL PACIENTE
Título del estudio: **"Resultados objetivos y subjetivos de la cirugía percutánea del hallux valgus"**

He leído la información proporcionada o me ha sido leída. He tenido la oportunidad de preguntar sobre ella y se me ha contestado satisfactoriamente las preguntas que he realizado.

Se me ha proporcionado una copia de este Formulario de Consentimiento Informado firmado y fechado junto con la Hoja de Información del Paciente para que lo conserve.

Doy mi conformidad para que mis datos clínicos sean revisados por personal ajeno a su asistencia sanitaria, para los fines del estudio, y siendo consciente de que este consentimiento es revocable.

Soy consciente de que mis datos personales serán procesados y codificados con el fin de salvaguardar la confidencialidad y si los resultados del estudio se publicaran o se utilizaran en los informes del estudio o para presentaciones científicas, mis datos personales seguirán siendo confidenciales. Según lo requerido por la legislación sobre protección de datos, he recibido información sobre el objetivo de la recogida y el procesamiento de estos datos y sobre quién tendrá acceso a ellos, así como mis derechos de acceso y modificación.

Al firmar este formulario autorizo expresamente la recopilación, uso y transferencia de mi información de acuerdo con este formulario de consentimiento.

Consiento voluntariamente participar en esta investigación como participante y entiendo que tengo el derecho de retirarme de la investigación en cualquier momento sin que me afecte en ninguna manera mi cuidado médico.

Nombre del participante o representante Fecha y Firma

Confirmo que he explicado la naturaleza, los objetivos y los efectos previsibles del estudio al paciente o representante del paciente cuyo nombre aparece más arriba.

Nombre del investigador Fecha y Firma

Anexo 4

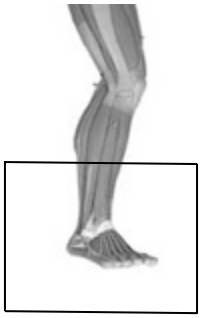
Versión en español del Self-Administered Foot Evaluation Questionnaire (SAFE-Q)

El siguiente cuestionario está hecho con la intención de preguntar sobre la condición de sus pies, y que le causa dificultades y problemas en su vida cotidiana. El cuestionario no sólo contiene preguntas sobre dolor y función física, también contiene preguntas del Estado emocional. También pregunta como su calidad de vida puede verse afectada por una lesión y/o enfermedad de su pie.

Creemos que su opinión sincera beneficiará los futuros tratamientos y cuidados de los pies.

Nosotros agradeceríamos que se tomara el tiempo suficiente en responder este cuestionario.

Cuando usemos la palabra pie nos referiremos a la imagen enmarcada en un rectángulo de la ilustración que aparece debajo, desde la pierna hasta los dedos sin incluir la rodilla.



Precauciones al llenar este cuestionario

1 Por favor piense acerca de la última semana o del último mes cuando conteste las preguntas.

2 Cada pregunta también le da la explicación de como contestarla, por favor léala cuidadosamente antes de contestar la pregunta. Le llevará cerca de 10 minutos contestar el cuestionario, aunque este tiempo puede variar de persona a persona.

Hay 2 maneras de responder este cuestionario

Ponga una marca en la casilla adecuada

Ponga una x en la línea

- 1) ¿Ha notado Ud dolor en su pie / pies en la última semana ?

Seleccione la que casilla que aplique con una x

( ) Nunca ( ) Rara vez ( ) Algunas veces ( ) Frecuentemente ( ) Siempre

- 2) ¿Ha tenido dificultad para dormir por dolor en su pie en la última semana ?

Seleccione la que casilla que aplique con una x

( ) Nunca ( ) Rara vez ( ) Algunas veces ( ) Frecuentemente ( ) Siempre

- 3)¿Qué intensidad ha tenido el dolor más severo que ha experimentado en sus pies en la última semana ?

Coloque una x en el punto de la línea que considere a su caso. 0 indica que no hay dolor y 10 indica el peor dolor imaginable.

0_____10

- 4) ¿Qué intensidad ha tenido el dolor que ha experimentado en su pie mientras caminaba en terreno plano la semana pasada?

Seleccione la que casilla que aplique con una x

( ) Sin dolor ( ) Leve ( ) Moderado ( ) Severo ( ) Extremo

-5) ¿Ha tenido dolor en el pie en la última semana?

Seleccione la que casilla que aplique con una x

( ) Nunca ( ) Rara vez ( ) Algunas veces ( ) Frecuentemente ( ) Siempre

- 6) ¿Qué intensidad ha tenido el dolor que ha experimentado al despertarse en la mañana durante la última semana?

Seleccione la que casilla que aplique con una x

( ) Sin dolor ( ) Leve ( ) Moderado ( ) Severo ( ) Extremo

-7) ¿Qué intensidad ha tenido el dolor en el pie al final de cada día durante la última semana ?

Seleccione la que casilla que aplique con una x

( ) Sin dolor ( ) Leve ( ) Moderado ( ) Severo ( ) Extremo

-8) ¿Ha sido difícil ponerse sus zapatos habituales debido al dolor en el pie en la última semana?

Seleccione la que casilla que aplique con una x

( ) Nunca ( ) Rara vez ( ) Algunas veces ( ) Frecuentemente ( ) Siempre

- 9) ¿Le es difícil encontrar zapatos que le queden cómodos debido a sus síntomas del pie?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

10) ¿Qué intensidad ha tenido el dolor en el pie al caminar descalzo en la última semana?

Seleccione la que casilla que aplique con una x

( ) Sin dolor	( ) Leve	( ) Moderado	( ) Severo	( ) Extremo

- 11) ¿Qué intensidad ha tenido el dolor en el pie al caminar con zapatos en la última semana?

Seleccione la que casilla que aplique con una x

( ) Sin dolor	( ) Leve	( ) Moderado	( ) Severo	( ) Extremo

-12)¿Ha encontrado difícil subir escaleras debido a los síntomas de su pie en la ultima semana?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-13)¿Ha encontrado difícil bajar escaleras debido a los síntomas en su pie en la última semana?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-14)¿Ha encontrado difícil agacharse debido a los síntomas de su pie en la última semana ?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-15)¿Ha encontrado difícil ponerse los calcetines debido a los síntomas de su pie en la última semana?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

- 16)¿Cuánto ha podido ser capaz de caminar en un terreno llano con zapatos, sin descansar en la última semana?

Seleccione la que casilla que aplique con una x

( ) Más de 30min, ( ) Cerca de 15min, ( ) Cerca de 5min , ( ) Cerca de 1min, ( ) Menos de 1min

-17)¿Ha encontrado difícil subir una cuesta debido a los síntomas de su pie en la última semana?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-18)¿Ha encontrado difícil <u>bajar una pendiente</u> debido a los síntomas de su pie en la última semana?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-19) ¿Ha encontrado difícil caminar en <u>terreno irregular</u> como senderos o caminos de tierra debido a los síntomas de su pie en la última semana?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-20)¿Ha encontrado difícil ponerse de puntillas debido a los síntomas de su pie en la ultima semana?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-21) ¿Ha tenido que usar bastón o barandilla para caminar <u>dentro de casa</u> debido a los síntomas de su pie en la última semana?

Seleccione la que casilla que aplique con una x

( ) Nunca	( ) Rara vez	( ) Algunas veces	( ) Frecuentemente	( ) Siempre

- 22) ¿Ha tenido que usar bastón para caminar <u>fuera de casa</u> debido a los síntomas de su pie en la última semana?

Seleccione la que casilla que aplique con una x

( ) Nunca	( ) Rara vez	( ) Algunas veces	( ) Frecuentemente	( ) Siempre

- 23) ¿Le ha sido difícil ir a alguna cita o ir a comprar debido a los síntomas de su pie en el último mes<u>?</u>

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

- 24) ¿Ha encontrado difícil hacer actividades rutinarias como asistir a clases , salir con amigos o hacer trabajo voluntario debido a los síntomas de su pie en el último mes ?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-25) ¿Ha tenido dificultad para ir al trabajo, escuela, de compras en los alrededores debido a lo síntomas del pie en el mes pasado?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-26) ¿Ha tenido dificultad en hacer un viaje de negocios o placer, debido a los síntomas de su pie en el mes pasado?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-27) ¿Ha tenido dificultad en disfrutar de sus aficiones o actividades de ocio, debido a los síntomas de su pie en el mes pasado?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

- 28) ¿Ha tenido dificultad en trabajar, realizar actividades escolares o tareas del hogar , debido a los síntomas de su pie en el mes pasado?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

- 29) ¿Se ha sentido ansioso debido a los síntomas de su pie en la ultima semana?

Seleccione la que casilla que aplique con una x

( ) Nunca	( ) Rara vez	( ) Algunas veces	( ) Frecuentemente	( ) Siempre

-30) ¿Se ha sentido deprimido debido a los síntomas de su pie en la última semana?

Seleccione la que casilla que aplique con una x

( ) Nunca ( ) Rara vez ( ) Algunas veces ( ) Frecuentemente ( ) Siempre

-31) ¿Se ha sentido frustrado debido a los síntomas de su pie en la ultima semana?

Seleccione la que casilla que aplique con una x

( ) Nunca ( ) Rara vez ( ) Algunas veces ( ) Frecuentemente ( ) Siempre

-32) ¿Ha sentido que estaba molestando a la gente a su alrededor debido a los síntomas de su pie en la última semana?

( ) Nunca ( ) Rara vez ( ) Algunas veces ( ) Frecuentemente ( ) Siempre

-33) ¿Se ha sentido como un minusválido debido a los síntomas de su pie en la última semana?

Seleccione la que casilla que aplique con una x

( ) Nunca ( ) Rara vez ( ) Algunas veces ( ) Frecuentemente ( ) Siempre

-34) ¿Ha tenido dificultad en ponerse zapatos de moda o de tipo formal, en el último mes?

Seleccione la que casilla que aplique con una x

( ) Nunca ( ) Rara vez ( ) Algunas veces ( ) Frecuentemente ( ) Siempre

Las siguientes preguntas son para aquellos que practican deportes de forma rutinaria

Aquellos que no practiquen deporte NO deben contestar las preguntas de la 35 a la 43

Por favor marque una de las siguientes casillas, indicando si practica deportes o no

( ) No practico deportes

( ) Sí practico deportes

Si usted practica uno o varios tipos de deportes, por favor indíquenos la actividad deportiva que usted considera mas importante:

-35) ¿Ha encontrado dificultad en <u>correr</u> en terreno llano o <u>regular</u> debido a los síntomas de su pie en el mes pasado?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-36) ¿Ha encontrado dificultad en <u>correr</u> en terreno <u>irregular</u> debido a los síntomas de su pie en el mes pasado?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-37 ¿Ha tenido dificultad en realizar cambios de dirección súbitos mientras corre a gran velocidad, debido a los síntomas de su pie en el mes pasado?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-38) ¿Ha tenido problemas en saltar sobre un pie debido a los síntomas de su pie en el mes pasado?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-39) ¿Ha tenido problemas para hacer sentadillas debido a los síntomas de su pie en el mes pasado?

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

- 40) ¿Ha encontrado dificultad en saltar debido a los síntomas de su pie en el mes pasado?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-41) ¿ Ha tenido dificultad para realizar actividades de pivoteo (girar su cuerpo alrededor del eje de un pie) debido a los síntomas de su pie en el pasado mes?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-42) ¿Ha tenido dificultad en correr <u>a máxima velocidad</u> debido a los síntomas de su pie en el pasado mes?

Seleccione la que casilla que aplique con una x

( ) De ningún modo	( ) Ligeramente	( ) Moderada-mente	( ) Considerable-mente	( ) Extremada-mente

-43) ¿Cuál es su nivel de actividad deportiva actualmente?

Coloque una "x" en el punto apropiado de la línea, en el que el 10 indica "un estado comparable antes de la aparición del problema en el pie" y el 0 "indica un estado en el que no se pueden realizar actividades deportivas"

0_____10

0= No puedo realizar actividades relacionadas con el deporte

10= Tengo el mismo nivel deportivo previo a la aparición de problemas del pie