

**Effect of custom-made foot orthoses in female hallux valgus after one year
followup**

ABSTRACT

STUDY DESIGN: Prospective trial, using a repeated-measures design.

BACKGROUND: Subtalar joint hyperpronation plays a fundamental role in the development of hallux valgus; then treating this condition with foot orthotics should prevent progress of the deformity.

OBJECTIVES: The aim of this study was to determine whether the use of custom-made foot orthoses for 12 months prevented the advance of hallux valgus in women.

MATERIAL AND METHODS: Fifty-four women with mild to moderate hallux valgus were divided into two groups: the experimental group used custom-made foot orthoses, and the control group used no treatment. First Intermetatarsal (IMA) and hallux abductus

(HAA) angles were measured at the beginning of the study and after 12 months followup.

Inter-group comparisons were made of these angles at both times of measurement, and intra-group comparisons between the two times of measurement.

RESULTS: The initial HAA was similar in both groups (19.92 ± 4.25 degrees for the control group, 20.55 ± 5.10 degrees for the experimental group; $p = 0.392$), and also the

IMA (10.56 ± 2.45 degrees for the control group, 10.86 ± 2.33 for the experimental group; $p = 0.618$) There were no significant differences in the followup values of these

angles ($p = 0.395$ and $p = 0.288$, respectively). There were no significant intra-group differences in the comparisons of the initial and followup angles.

CONCLUSIONS: Hallux valgus did not have a significantly slower evolution in participants of the experimental group comparing with controls, so the custom made orthotics seems to have no effect in the evolution of mild and moderate hallux valgus.

Word count of the abstract: 257 words.

CLINICAL RELEVANCE

If subtalar joint hyperpronation plays a fundamental role in the development of hallux valgus, then controlling the abnormal mobility of this joint by means of foot orthotics should prevent or control progress of the condition. This paper could help solve this controversy.

Word count of the clinical relevance statement: 42 words.

BACKGROUND

In hallux valgus (HV) the great toe is deviated laterally and the first metatarsal medially, resulting in a medial bony prominence at the first metatarsophalangeal joint (MPJ).^{1,2}

The exact aetiology of the development of HV is not entirely clear. According to many authors, the development of HV is multi-factorial, including both intrinsic and extrinsic factors.³⁻¹¹ The commonest cause of adult HV is a combination of environmental factors (e.g., mechanical abnormalities caused by badly fitting footwear) and a genetic predisposition to constitutional anatomical factors, with some authors describing the latter to be involved in 70% of cases.^{4,12} However, in most cases there is a clear biomechanical base aetiology. Excessive pronation of the subtalar joint during the stance phase of gait is responsible for instability of the foot, causing dysfunction of the first ray and the first MPJ, leading to deformities as HV.^{1,6,8,13-15}

If subtalar joint hyperpronation plays a fundamental role in the development of HV, then controlling the abnormal mobility of this joint by means of foot orthotics should prevent or control progress of the condition. But even though there have been various studies of the effectiveness of such conservative treatments, they have led to a situation of some controversy. Some longitudinal studies have reported that foot orthoses are effective in preventing HV while others have refuted this claim. The present work was aimed at responding to the question of whether treatment with custom-made foot orthotics can reduce or slow down the progress of HV in women with mild to moderate HV (according to the classification of Kelikian¹⁶), after a 12-month followup period. The null hypothesis is that foot orthoses have no effect in controlling the advance of

HV, i.e., that the study participants using foot orthoses for 12 months would have the same increase in HV as participants who did not use them.

METHODS

Subjects

A prospective trial, using a repeated-measures study was carried out with 54 women of mean age 30.63 ± 11.87 years with mild to moderate HV (97 affected feet). Each foot was counted as a separate case, since for a given participant only one foot may be affected. The participants were volunteers from three sources: students of Podiatry at the XXXXXXXXXXXX XX XXXXXXXX (30 women); patients attending the Podiatry Clinic Area at the XXXXXXXXXXXX XX XXXXXXXX who met the inclusion criteria and agreed to participate voluntarily in the study (11 women); and staff of this centre who, when they heard of the study, decided to volunteer (13 women). Patients were divided into two groups – an experimental group corresponding to participants to whom the use of foot orthotics was applied, and a control group corresponding to participants to whom no treatment was applied. Data for the study were collected between January 2008 and November 2011, at the Podiatry Clinic Area of the XXXXXXXXXXXX XX XXXXXXXX (XXXXXX). The study was approved by the Experimentation Ethics Committee of the XXXXXXXXXXXX XX XXXXXXXX.

Allocation to either the control or the experimental group was as follows (see flow diagram in figure 1). All the women who met the inclusion criteria and had attended the Podiatry Clinic Area at the XXXXXXXXXXXX XX XXXXXXXX seeking treatment with orthotics and had agreed to participate in the study were assigned to the experimental group (11 participants). For ethical reasons, and to maintain the quality of care provided by this centre, the authors believed that when patients had presented seeking treatment they

could not be assigned to the control group because this would have meant 12 months without treatment. To prevent this producing heterogeneity between the groups, it was used the technique of matching on grounds of age and severity of the HV to choose the first 11 participants to include in the control group. The remaining participants (32 people) voluntarily asked to participate in the study, and they were randomly assigned to the groups (coin toss). Originally, the control group consisted of 48 feet of 26 women, mean age 30.31 ± 9.27 years, and the experimental group of 49 feet of 28 women, mean age 30.94 ± 14.05 years.

In the control group, three women did not attend the 12-month followup study for the following reasons: one of them because of change of residence and two did not attend on the day set for the followup (unknown reasons). In the experimental group, five women did not attend the 12-month followup study for the following reasons: one of them for pregnancy, another one because she had lost the foot orthoses, and three did not attend on the day set for the followup (unknown reasons). The final sample consisted of 46 women (83 feet), aged 30.63 ± 11.87 years. Control group consisted of 23 women (42 feet) aged 30.94 ± 14.06 years, and experimental group consisted of 23 women (41 feet) aged 30.31 ± 9.27 years.

Insert figure 1.

Inclusion criteria

One selection criterion was that the growth physes of the participant's bones should be

closed for there to be no possibility of variation in any of the parameters measured due to growth. Other inclusion criteria were: having an inclination angle of the calcaneus to the ground greater than five degrees, and presenting an HV angle greater than 15 degrees and lower than 40 degrees. Exclusion criteria were: having undergone osteoarticular surgery on the foot; having suffered serious injury to the foot that could have altered its bone morphology; having received orthopædic treatment; suffering from degenerative bone and joint diseases or neuromuscular imbalances; obvious deformities other than HV in the forefoot that might affect the results of the study; pregnancy; women who experienced poor acceptance of the treatment, or who refused the X-ray of the feet.

Variables

The independent variable was the use of foot orthoses. The dependent variables were the intermetatarsal angle between the first and second metatarsals (first IMA) and the hallux abductus angle (HAA) (Figure 2). These variables were measured at the beginning of the study (initial) and after one year (followup) so that comparisons could be made. The HAA is a measure of the deviation of the proximal phalanx of the hallux with respect to the longitudinal axis of the first metatarsal. It is considered to be the principal parameter with which to quantify the HV deformity.¹⁵ The first IMA is considered to be the best measure of the medial deviation of the first metatarsal in the transverse plane – one of the components of the HV deformity.¹⁷

Insert figure 2.

Procedure

Each participant was given an informative document which explained the nature of the research, its objectives, and its potential risks. If, after reading it and having any doubts clarified, she agreed to participate, she was asked to provide her written consent. For each participant, a data sheet was prepared with her parentage data and an anamnesis. Articular explorations were made with the participant on the examination table, standing, and walking, following the protocol used in the Podiatry Clinic Area of the University of Seville. The data from this exploration were used to establish that there existed rearfoot hyperpronation and mild to moderate HV according to the classification of Kelikian.¹⁶

For all the participants, a weightbearing dorsoplantar X-ray was taken of both feet together, with the X-ray tube at one metre from the feet and inclined at 15 degrees from the vertical.^{18, 19} The apparatus used was a Sedecal SPS HF-4.0[®] portable X-ray unit with a collimator. Kodak[®] Point of Care CR Cassette[®] chassis were used, equipped with a flexible GP phosphor screen of 24×30 cm. The operating parameters were 45 kV and four mA/sec, as recommended by the manufacturer. Each subject wore a lead apron to shield the rest of the body from radiation. A Kodak Point of Care 140[®] digital radiology device with Kodak Acquisition Software[®] was used for the acquisition and transmission of DICOM data, elements, and images. With this set-up, it is obtained a digital radiographic image which can subsequently be exported to the AutoCAD[®] computer program (AutoCAD 2006; Autodesk Inc, San Rafael, California) to perform

the measurements. X-ray measurements using this procedure have been described in previous works.^{18,20} Measurements were made by a single observer (MR) in order to reduce the error due to variability in the measurements.²¹

Fabrication of the foot orthoses

For each participant in the experimental group, a mold of the foot was obtained with phenolic foam with the subtalar joint placed in neutral position. The patient's foot was manipulated before being introduced into the phenolic foam to place the subtalar joint in the neutral position and the forefoot plantar plane parallel to the floor. The negative molds of phenolic foam were filled with liquid plaster to obtain a positive mold of the foot on which to make the foot orthosis. Foot orthoses were made with polypropylene of three-mm thickness from the heel to just behind the metatarsal heads, and three-mm thick polyethylene foam posting of 45 shore A hardness on the distal part (Figure 3).

The positive plaster cast was placed into a vacuum with the plantar surface upwards. A 3-mm thick polypropylene sheet was heated up to 180 degrees, until it became transparent (3-4 minutes), for vacuum press forming the orthosis. The 3-mm thick polyethylene foam sheet was heated and placed to the upper surface of the positive cast just before the polypropylene, so that both materials got adhered by heat and pressure. Some marks were painted on the orthosis in order to remove the spare material. These marks were the following: a calcaneal line parallel to the dorsal surface of the positive cast and 10-15 millimeters above the support surface level; one point just below the navicular tuberosity, representing the maximum height of the orthosis on the medial side; and a distal line joining the points just proximal to the metatarsal heads and ending at the proximal edges of the first and fifth metatarsal heads. The spare material was

removed by means of a polishing machine.

Insert figure 3.

When the orthoses were finally handed over to the patient, their definitive adjustment to the foot was made, and the participant then tried out the treatment in her footwear, being asked to walk for five minutes so as to report any discomfort or incidence. Only when she stated that she felt comfortable was the orthosis taken as being completed. She was recommended to use the foot orthoses for at least seven hours a day, five days a week.

Telephone followup was conducted every two months to check the correct use of the treatment. After 12 months of followup, a new radiological control was performed for the participants in both groups following the same protocol as at the beginning of the study.

Data analysis

The study was designed to detect changes with an effect size greater than 0.8 (large effect size) for a contrast of difference between two independent means, assuming type I and type II errors of 0.05 and 0.1, respectively. With these design values, the GPower 3.1.0 software package (Franz Faul, Universität Kiel, Germany) was used to calculate the minimum sample size, which was found to be 36 cases per group. We assumed 15% loss during followup, so it was required a minimum of 48 cases per group.

The data were analyzed with the SPSS statistical software package (SPSS Science, Chicago, Illinois). The Shapiro-Wilk test was used to check for normality of the

variables. The initial and followup first IMA and the age were found to be normally distributed, but the corresponding sets of HAA were not.

A preliminary exploratory analysis was made to check for homogeneity between the groups in age and side (right or left foot), using Mann Whitney's *U*-test for independent samples in the former case, and the chi-squared test in the latter.

Then an inter-group comparison was made of the initial and followup angles using Mann-Whitney's *U*-test, and of the initial and followup first IMA using Student's *t*-test for independent samples.

For the evolution of the condition over the 12 months, an intra-group comparison was made for each group between the initial and followup HAA using the non-parametric Wilcoxon test, and between the initial and followup first IMA using Student's *t*-test for paired samples.

Differences were considered to be statistically significant if $p < 0.05$.

Cohen's *d* was calculated to estimate the effect size in the dependent variables, using the formula: $(\text{Mean 1} - \text{Mean 2}) / ([\text{SD1} + \text{SD2}] / 2)$, where the value of *d* is positive if the difference between the means is in the predicted sense. This parameter classifies the effect size into small if $d = 0.20$, medium if $d = 0.50$, and large if *d* is greater than or equal to 0.80.

RESULTS

The groups were homogeneous (no significant difference) with respect both to age ($p = 0.530$; Mann Whitney's *U*-test for independent samples) and side (i.e., left or right foot: $p = 0.920$; chi-squared test), with the total sample comprising 49.5% left feet and 50.5%

right feet, the control group 50% and 50%, respectively, and the experimental group 49% and 51%, respectively.

The initial values of the dependent variables no presented statistically significant differences between the two groups. The initial HAA was homogeneous (19.92 ± 4.25 degrees for the control group, 20.55 ± 5.10 degrees for the experimental group; $p = 0.392$; Mann Whitney's *U*-test for independent samples). The same was the case for the initial values of the first IMA (10.56 ± 2.45 degrees for the control group, 10.86 ± 2.33 for the experimental group; $p = 0.618$; Mann Whitney's *U*-test for independent samples). The groups were therefore homogeneous with respect to the values of the dependent variables.

The inter-group comparison of the followup values of these dependent variables revealed that there was no significant difference after the followup period (HAA: 20.36 ± 4.54 degrees for the control group, 21.02 ± 5.14 degrees for the experimental group, $p = 0.395$; and IMA: 10.52 ± 1.85 degrees for the control group, for the experimental group, $p = 0.288$).

The intra-group comparisons showed there to be no significant changes for either group in the values of the dependent variables from the beginning of the study to the followup at 12 months. In addition, size effect was small for both comparisons. Table 1 summarizes the initial and followup values of the HV and first IMA for the two groups, and P-values and size effect for comparisons.

DISCUSSION

The main objective of the present study was to test whether the type of custom-made

foot orthoses employed controlled the advance of the HV deformity. According to the results observed, the null hypothesis cannot be rejected. The progression of the HV deformity was similar in both, the control group and the experimental group, after a 12-month followup period.

This study has certain limitations. Firstly, the followup period was relatively short; if the progress of this deformity had been observed over a longer time period, the results might have been more conclusive. Nevertheless, many studies on this subject have used similar, or even shorter followup periods, obtaining significant results in three or four months.^{8, 22-26} Another limitation may be that the sample consisted entirely of women. The main reason is that hallux valgus is far more common in women than in men,²⁷⁻²⁹ and various studies of this type have been conducted with samples entirely, or in a large proportion, consisting of women.^{25, 26, 30, 31} Finally, although in most cases the origin of HV is biomechanical due to excessive pronation of subtalar joint during gait,^{1, 6, 13, 14} the progress of HV is multi-factorial,^{3, 7, 10, 11} and those remaining factors were not controlled.

Several studies have been carried out in order to test the effectiveness of different conservative treatments to reduce or control HV. Although many have concluded that foot orthoses at least prevent advance of the deformity, others have reported unfavourable results. Kilmartin et al.³⁰ studied the effectiveness of foot orthoses in adolescents with HV. After 3 years of treatment, the deformity was assessed by means of the HAA and the first IMA. The difference in the degree of advance of the deformity between the two groups was not significant. Tehraninasr et al.²⁵ studied the effect of semi-rigid foot orthoses incorporating a toe-separator compared with night splints in female patients with painful HV. A followup conducted at three months showed both treatments to have reduced the HAA, but not significantly. The authors concluded that

these treatments could not serve to correct HV, but did prevent its progress. Also in 2008, Ferrari et al.³² published a Cochrane review on interventions in the treatment of HV. This review included 3 trials that evaluated conservative treatments versus no treatment,^{23, 30, 31} finding no evidence for differences in outcome between treatment and no treatment. The evidence from these trials suggests that neither foot orthoses nor night splints appear to be more beneficial than no treatment at all.

On the other hand, a positive effect of foot orthotics in reducing or preventing the HV deformity has also been reported. Budiman-Mak et al.³³ studied the prevention of HV by means of foot orthoses in patients with active rheumatoid arthritis. After three years, the HV had advanced more in the control group than in the group using the orthotics. Tang et al.⁸ studied the application of a new plantar orthosis to control foot pronation, with an incorporated toe-separator. They found that, after three months of use, the HV angle had decreased significantly. In 2009, Landsman et al.²⁴ published a study designed to determine the effect on foot position of medial longitudinal arch support with over-the-counter foot orthoses. After the use of these orthotics for a period of 2 to 4 weeks, X-ray evaluations showed a significant decline in the first IMA and a non-significant decline in the HAA. According to those authors, their results indicated that there was a reduction of the HV deformity, and hence that this type of treatment is effective.

As it can be observed, the results of studies on the effectiveness of foot orthoses in preventing or reducing HV have been very varied. Excessive pronation of the subtalar joint favours the first metatarsal acquiring a position of dorsiflexion in the push-off phase of gait.³⁴ In this position of the first ray, the hallux is destabilized instead of lying flat along the ground to favour propulsion. Treatment to prevent excessive pronation of the subtalar joint in the stance phase of gait would, in theory, prevent this abnormal

position of the first metatarsal, and would favour a normal push-off phase.³⁴ Although in clinical practice foot orthoses are often recommended to reduce the progress of HV, further studies are clearly required before one can rigorously assert that this treatment reduces the HV deformity or halts its advance.

CONCLUSION

At the beginning of the study there were not significant differences in the dependent variables, the HAA and the first IMA, between the control group and the experimental group. After 12 months of followup, these differences were not significant. Comparison of the values at the beginning of the study with those at the 12-month followup within each group showed no significant differences at a significance level of $p < 0.05$.

According to these results, there was no difference between having used the foot orthoses applied in this study, and not having used them. **So custom-made foot orthotics**

had no effect in the evolution of mild and moderate hallux valgus in the women who took part in this study.

Word count: 3,231 words.

DECLARATION OF CONFLICTING INTERESTS

The Authors declare that there is no conflict of interest.

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LEGENDS

FIGURE 1. Flow diagram explaining the inclusion process.

FIGURE 2. Radiographic measurements: hallux abductus angle (HAA) (top) and the first intermetatarsal angle (between the first and second metatarsals, first IMA) (bottom).

FIGURE 3. The custom-made foot orthoses used in the study.