Original Article

Comparison of the Effect of Custom-made Medial Arch Support Insole with and without Medial Sole Wedge on the Degree of Pain and Hallux Valgus by Digital Imaging Immediately and after Six Weeks of Use

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Abstract

Introduction: Hallux valgus is one of the most common foot deformities that causes pain, decreased foot function and difficulty wearing shoes. Although different foot orthoses and medical insoles are considered as a therapeutic intervention in this complication, their impact is challenging. The aim of the present study was to compare the effect of custom-made medial arch support insole with and without medial sole wedge on the degree of pain and hallux valgus by fast digital imaging and after six weeks of use. **Materials and Methods:** In this quasi-experimental study, 5 patients with moderate hallux valgus deformity participated in this study, and were randomly divided into two groups. Intervention groups were provided with medial arch support insole with and without sole wedge. The effect of the intervention on the degree of pain and angle of hallux valgus deformity was evaluated at the beginning and after 6 weeks of intervention using an imaging technique and the FAOS questionnaire. **Results:** Six-week use of custom-made insoles with medial longitudinal arch support in both cases - with and without sole wedge- significantly reduced pain in patients with moderate hallux valgus. With respect to hallux valgus angle, two types of intervention immediately showed an improvement in angle, but in long-term use of the above-mentioned insoles, no significant difference was observed in the improvement of hallux valgus angle. **Discussion & Conclusion:** Custom-made insoles with medial longitudinal arch support can significantly reduce pain in patients with hallux valgus. Addition of changes such as medial sole wedge can clinically control and prevent the exacerbation of hallux valgus angle. Therefore, the use of the above-mentioned orthosis can be considered as one of the effective treatments.

Keywords: Hallux valgus, Hallux deviation, Medical insole

Introduction

Hallux valgus deformity is one of the most common foot-related deformities [1]. Orthoses as one of the treatment options can improve foot structure and reduce pain by affecting the biomechanics of the foot, and they include a variety of finger separators, medical insoles with medial longitudinal arch support, and splints [2-4]. According to the study of Tang et al., orthoses can improve foot structure and modify the plantar pressure distribution pattern by affecting the biomechanics of the foot [5]. In the study of Farzadi, it has also been proved that the insoles can reduce the angle of deviation of the large toe (or hallux) or prevent increasing the angle, and the influence of orthoses depends on factors such as design and construction standards, time of use, and type of orthosis [6]. But on the other hand, the results of the Reina and Landzmann study showed that medical insoles could not have an effect on the degree of hallux deviation [7, 8].

In hallux valgus deformity, medial longitudinal arch drop causes the first metatarsal axis to shift from transverse lie to vertical lie, thus increasing the mobility of the first ray and deforming the hallux valgus. It is worth noting that in people with ligament laxity, fore foot pronation and pressure in the

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first metatarsal head increase, which in some cases, causes hallux valgus [9, 10]. Initial treatment in these patients should include a heel cup, a medical insole with medial longitudinal arch support to correct hallux valgus deformity, and pronation [11]. Applying the wedge to the medial sole edge of the medical insole is likely to reduce pronation and pressure transfer to the outer edge of the foot, leading to a decrease in the pressure under the hallux and first metatarsal head, and these changes is expected to prevent the progress of this complication [12]. However, studies to date have often focused on the effect of common insoles on the extent of pain and apparent symptoms and manifestations [6, 8, 13-15]. There is insufficient evidence for the effect of using a medical insole with medial sole wedge on the severity of hallux valgus deformity.

Given the increasing pain intensity and progression of deviation to surgery in people with moderate deviation [9], the aim of the present study was to evaluate the immediate and long-term impact of custom-made insoles with medial longitudinal arch support and medial sole wedge on the degree of hallux valgus and pain in patients with moderate flexible hallux valgus.

Method

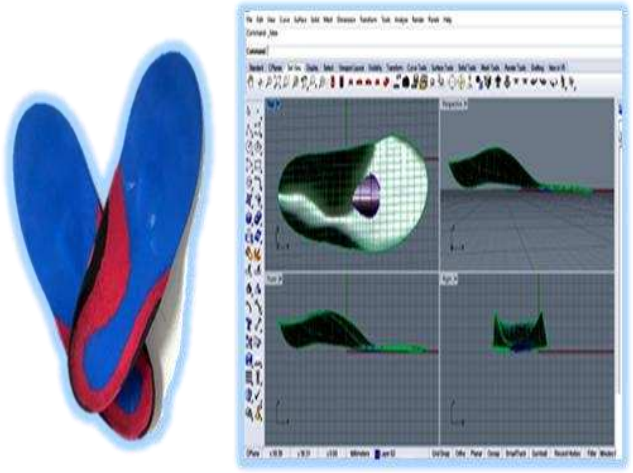
Participants

The present study was performed on 20 individuals with moderate flexible hallux valgus who were randomly divided into two groups of 10. Inclusion criteria were volunteers with 20-65 years of age, having moderate hallux valgus and fore foot pronation at the same time, and having ligament laxity. Exclusion criteria included having supination, any mobility limitation or arthritis in the hallux joints (hallux rigidus, hallux limmitus), a history of lower extremity fractures, a history of hallux valgus surgery, having diabetes, and having rheumatoid arthritis in foot joints. The study volunteers were selected from those who referred to the Bayat orthotics and prosthetics clinic from May to November 2018. The study protocol was approved by the Ethics Committee of the University of Social Welfare and Rehabilitation Sciences, and all volunteers read and signed the consent form.

Implementation method

To design and fabricate custom-made insole, volunteer's foot dimensions were first recorded by using Paya Fanavaran 3D scanner. The final medical insole structure was then designed by using the Rhinoceros software based on the information of the longitudinal and transverse dimensions, and evaluation of volunteer's medial longitudinal arch in the weight-bearing stat [11]. Then, by using Paya Fanavaran computer controlled device, EVA (ethylene vinyl acetate) insole was carved in 35 SHORE. The length of the medial longitudinal arch of the insoles was determined by the length of the foot, in addition, the minimum thickness of the heel cup was 6 mm and in the transverse arch was also 6 mm. In the insoles having medial sloe wedge, the wedge was considered to be 4 mm [12]. All participants involved in the research plan used sneakers with similar characteristics such as width of sole, heel-to-sole height ratio and heel counter, strap, and in-depth during the study.

All volunteers were provided with custom-made insoles. Eligible volunteers were placed into groups A and B though assigned random numbers. The medial arch support insole with medial sole wedge was prescribed to group A, and the medial arch support insole without medial sole wedge was prescribed to group B (Figures 1 and 2).



Figures 1 and 2: How to design and fabricate a medical insole

Data collection

Each patient was clinically examined and the severity of deformity was assessed using a Manchester test whose validity and reliability were confirmed. In the preparation phase of the volunteers, the 3 midpoints of the proximal hallux strap and the beginning and end of the first metatarsal bone were marked twice by the examiner by using an invisible ink marker based on the principles proposed by Reichert et al. [16]. After setting points twice, the repeatability of setting points was evaluated using UV light. If the points were identical on two settings, the point of interest was marked with a colored marker. To create a coordinate basis in Photoshop software calculations (for measuring hallux pronation) [17], it was necessary to have a vertical line in the image when shooting. For this purpose, a vertical swing was placed next to the hallux of the volunteers. The hallux valgus and hallux pronation angles were measured by using digital imaging and Knicks et al.'s method [18].

The gold standard for assessing the severity of hallux valgus involves measuring the angle between the first finger and the first metatarsal in weight-bearing state using radiographic (X-ray) imaging or methods such as evaluating using patient perception and using images showing different deformity intensities. Another clinical evaluation method is the use of goniometers, the validity of which has not been proven so far. The measurement of hallux valgus angle using digital imaging is one of the methods to evaluate this complication,

which has been proven to be valid in weight-bearing state as compared to radiographic (X-ray) imaging [3]. In digital imaging, the cell phone was positioned at a height of one meter and at an angle of 15 degrees to the vertical line. Mobile shooting (Apple, S6®) was performed twice at a resolution of 326 ppi [18, 19]. Each image was taken in two modes, including medical insoles and no medical insoles. For the evaluation of fore foot pronation, the degree of nail deviation relative to the horizontal line was taken into account, so a vertical line was drawn in the image by using a vertical swing to estimate this angle.

The first part of the FAOS questionnaire was used to measure the degree of patients' pain [20, 21]. All data were collected and evaluated in two steps: Immediately after the intervention and after six weeks of the intervention (Figures 3-5).

Figures 3, 4, and 5: How to take images and calculate the angles

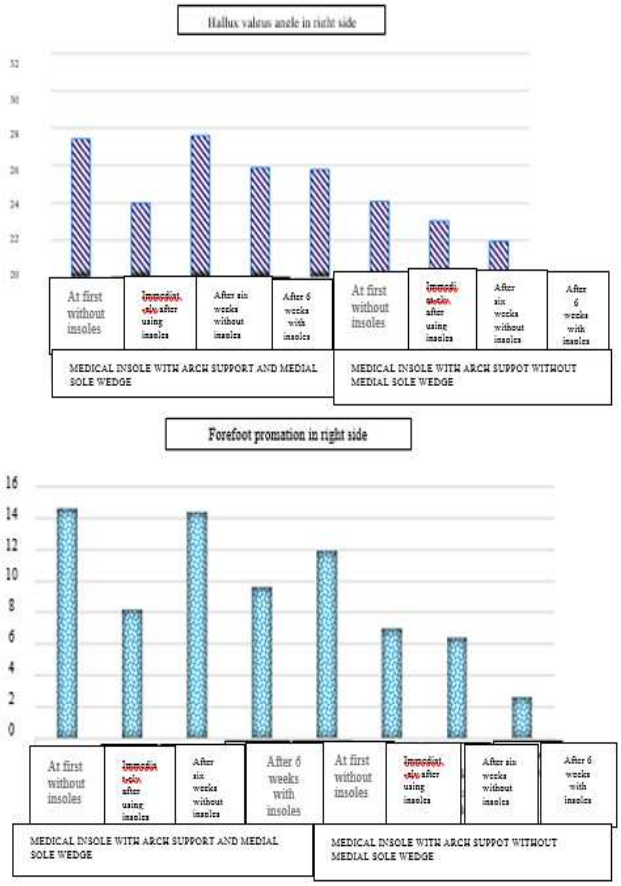
Results

There were 2 male volunteers and 5 female volunteers in the intervention group of the medial longitudinal arch with the medial sole wedge. In the other group, however, there were only one male and six other female volunteers. The demographic characteristics of the volunteers were described in Table 1.

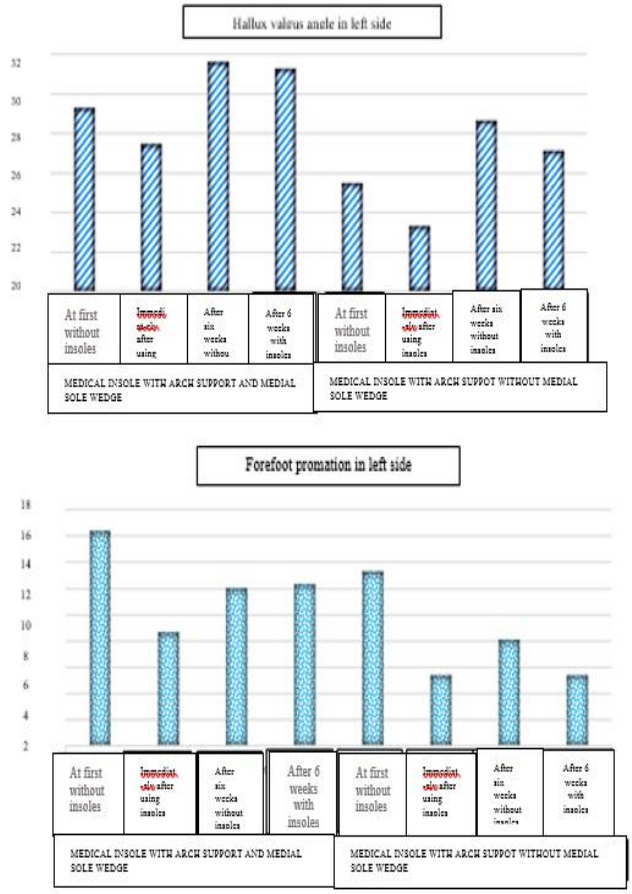
Table 1: Demographic information of the volunteers by intervention groups

	Variable	Type of intervention for the study groups		Mean	SD (standard deviation)	Minimum	Maximum
1	Age (years)	The medial longitudinal arch with the medial sole wedge		31	13/34	18	53
		The medial longitudinal arch without the medial sole wedge		27/11	13/10	18	47
2	Height (cm)	The medial longitudinal arch with the medial sole wedge		161	10/45	150	179
		The medial longitudinal arch without the medial sole wedge		161/78	8/53	152	175
3	Weight (kg)	The medial longitudinal arch with the medial sole wedge		63	15/96	51	93
		The medial longitudinal arch without the medial sole wedge		63/56	15/76	52	95
4	BMI (Body Mass Index)	The medial longitudinal arch with the medial sole wedge		24/27	5/78	21/45	29/33
		The medial longitudinal arch without the medial sole wedge		24/13	4/68	21/3	28/02
5	Foot length (cm)	The medial longitudinal arch with the medial sole wedge	Right side	24/97	1/53	23/09	27/62
			Left side	25/09	1/72	22/93	28/12
		The medial longitudinal arch without the medial sole wedge	Right side	24/88	1/31	22/49	26/63
			Left side	25/06	1/31	22/72	26/74

Using the One-Way Repeated Measure ANOVA to quantify the immediate impact of the aforementioned insoles and segmentation of the results for the right and left feet separately, the statistical results showed that although the reduction of the hallux valgus angle was only reported on the right side, this effect was not statistically significant ($p > 0.05$). Regarding the measurement of pronation and hallux valgus angles, the analysis showed that no insoles made any differences in these angles ($p = 0.056$) (Diagrams 1 and 2).



Diagrams 1 and 2: The degree of hallux valgus and hallux pronation angles in the right foot



Diagrams 3 and 4: The degree of hallux valgus and hallux pronation angles in the left foot

By performing the analysis of variance (ANOVA) between all steps to evaluate the long-term effect of the aforementioned insoles, the results obtained were as follows. After 4 weeks of using insoles with only the medial longitudinal arch, a statistically significant difference and improvement was found in the hallux pronation angle only in the right foot. On the other hand, there was no statistically significant difference in the hallux valgus angle.

The Kruskal-Wallis and Friedman tests were used for abnormal left foot data, with no statistically significant difference in the effect of both types of orthotic intervention on the hallux and pronation angles, both on immediate and long-term basis (Diagrams 3 and 4).

One-Way Repeated Measure ANOVA was used to evaluate the degree of pain reported by patients, and showed that the use of medical insoles with medial longitudinal arch support in both cases, with and without the medial sole wedge, caused a statistically significant improvement in pain ($p < 0.001$) (Diagram 5).

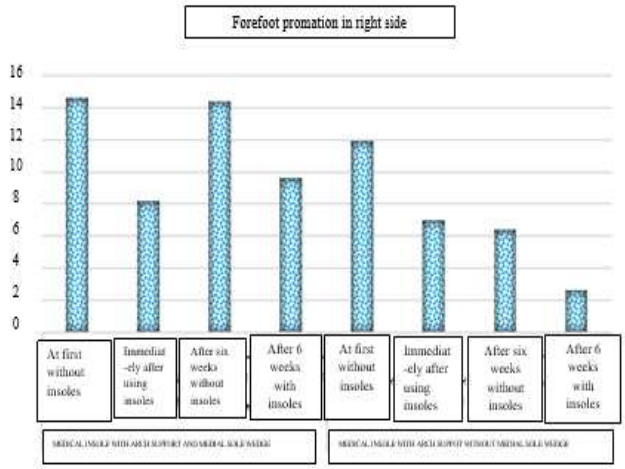


Diagram 5: The degree of pain reported by the volunteers

Discussion

Hallux valgus deformity causes pain, reduced function and difficulty in choosing shoes. The purpose of this study was to compare the immediate and long-term effect of using two types of custom-made insoles supporting the medial longitudinal arch with and without medial sole wedge on the degree of hallux valgus and pain in patients with moderate flexible hallux valgus.

The results of the present study, based on the scores obtained from the FAOS questionnaire, showed a significant reduction in pain reported by patients in both intervention groups. No significant difference was observed between the two groups. Also, according to the results of the Landzmann, Tong, and Tehrani Nasr's study [5, 15], using medical insole with medial longitudinal arch support and reduced pressure on the hallux significantly reduced the pain reported by the patients. In a study, Knicks et al. evaluated the association between the severity of hallux valgus deformity and pain in 60 healthy individuals with hallux valgus deformity with different severities. The results showed no association between the severity of hallux valgus deformity and the degree of pain reported by the patients [22]. In hallux valgus patients, pain symptoms at the site of protrusion of the first metatarsal-phalangeal joints (bunion) are due to sensitivity or internal-external superficial nerve injury or bursa wear on the shoe protrusion [8] .Therefore, it seems that the use of longitudinal arch insole can reduce the pressure under the hallux and, by raising the bunion part, reduce the friction generated, which can alleviate this challenge and reduce the patients' pain.

In response to the main study hypothesis stating that the effect of using medial arch support insoles with medial sole wedge on the degree of hallux valgus angle is statistically higher than that of using medial arch support insoles without medial sole wedge, it should be pointed out that the response to the intervention was different in the right foot and in the left foot. In the right foot, in the group of medical insoles with no wedge, the reduction in the hallux valgus angle was greater than the group of medical insoles with wedge, but on the left side, an opposite result was obtained. However, none of the differences were statistically significant ($p > 0.05$). Therefore, this hypothesis is rejected.

On the other hand, the effect of both types of aforementioned insoles on pain reduction was significant, but there was no significant difference between the two groups ($p = 0.07$).
In addition, in response to another hypothesis stating that the effect of using medical insoles with medial longitudinal arch support and medial sole wedge on the degree of hallux valgus and hallux pronation angles is statistically higher than using medial arch support insoles without medial sole wedge, it should be noted that analyzes performed [18] with radiographic (X-ray) imaging showed that there is a significant correlation between the first metatarsal pronation, hallux valgus, and longitudinal arch drop of the foot, and that hallux pronation occurs in the early stages of hallux valgus deformity. In this research, the immediate effect of using medical insole differed from its six-week effect. At the beginning of the study, the immediate effect of using both types of insoles was a significant decrease in the hallux pronation angle on the left side, but on the right side, the pronation was significantly reduced only in the case of medical insoles having wedge ($p < 0.001$). After six weeks, the use of medial wedge insoles was associated with an increase in mean pronation on the right side and a 2-degree decrease in mean on the left side, but the use of medial arch support insoles with no medial wedge was associated with a decrease in mean pronation on the both sides. However, separate analyses showed that the difference between the two groups was not statistically significant in terms of having effect on variable ($p = 0.056$). Therefore, this hypothesis is generally rejected.

Conclusion

In the present study, the effect of two types of intervention on the degree of hallux valgus, hallux pronation, and pain in patients with moderate flexible hallux valgus was evaluated. Following the both above-mentioned interventions, the severity of the deformity did not decrease significantly. But both interventions were able to alleviate first metatarsal pain in people with hallux valgus. Given that the mean hallux pronation angle on the right side had a greater reduction in the group with no wedge insoles, it seems that using medical insole with longitudinal arch support and no wedge would be a more appropriate treatment option than a medical insole with longitudinal arch support and medial sole wedge.

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