Comparison of Designed Slippers Splints with the Splints Available on the Market in the Treatment of Hallux Valgus

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Abstract- Hallux valgus or the lateral deviation of the great toe is a complex disease. If it is not treated, it will cause the deviation of other toes. Hallux valgus is three times more common in females and may cause uncomfortable deformity of the foot, problems in putting on unsuitable and narrow toe box shoes, and pain on the medial side of the first metatarsophalangeal joint; therefore, patients seek medical services. Untreated hallux valgus may cause the hammer toe deformity of the second toe. In this cohort study, 30 patients referring to the Orthopedic Clinic of Shohada Ashayer Hospital of Khorramabad, Iran, with a complaint of hallux valgus were randomly divided into two groups. The splints designed by the researches (slippers splints) were given to the case group, and the splints on the market including night splints and interdigital pads were given to the control group. The patients were followed every three months for a year and every time the weight bearing anteroposterior radiography of both feet were taken and hallux valgus and intermetatarsal angles were measured. The data was analyzed by the SPSS software using repeated measure tests. In the case group that used the designed splints regularly, hallux valgus angles decreased more dramatically than in the control group (P < 0.001). This study showed that, despite controversies over the nonoperative treatment of hallux valgus, if hallux valgus angle in patient is mild to moderate, the splint can be used as a nonoperative treatment.

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Introduction

Hallux valgus, the lateral deviation of the great toe, is not a unique disease but a complex disease that is seen in women more than in men.(1,2,3,4). In congenital hallux valgus, abnormal bone alignment is the cause of bunion formation (the increased space between the first and second metatarsals of a person is known as a twist of the foot towards inside). In acquired halllux valgus, bone alignment is common at the beginning of the disorder. Acquired halllux valgus is often caused by shoes with narrow toe boxes, and high heel shoes. Such shoes compress the great toe and the pressure is towards the second toe. This situation may cause additional bone formation and brushes on the pedestal of the great toe that can lead to inflammation, swelling, and pain (5). Heredity, arthritis, and trauma are among the other causes of the disease. Other signs of the disease include the enlarged or swollen metatarsophalangeal joint on the pedestal of the great toe, the external deviation of the great toe towards other toes, redness of joints, joint pain, persistent skin irritation, skin bunion, foot pain and dryness, and thickened skin on the bone appendix (6,7,8). The X-ray of radiography confirms the diagnosis that shows the internal deviation of the first and second metatarsals and the external deviation of the great toe. In the early nonoperative treatment of the acquired hallux valgus, using suitable shoes and foot care may suffice. Other useful measures for treatment include felt strip to protect foot bunion, foam tape or other devices to separate the first and second toes at night, and a supportive notebook and strengthening exercises for the

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metatarsal arch (9,10). Initial therapy in patients prone to foot problems, including people with rheumatic diseases, is necessary. If the disease results in severe deformity accompanied by debilitating, progressive pain, a surgery and removing a part of the bunion may be required (11,12). Currently hallux valgus has been treated by medical or surgical treatments (13,14). The medical treatment includes using the splints available on the market, shoe modification, daily exercise, and personal activities correction. Night splints and interphalangeal pads that are made of plastic are among the devices available for treating hallux valgus. However, their effectiveness is not definite and there is considerable disagreement over the nonoperative treatment.

Materials and Methods

Among the patients referring to the Orthopedic Clinic of Shohada Ashayer Hospital of Khorramabad, Iran, with complaints of hallux valgus, those with hallux valgus angles above 15 degrees and the first and second inter-metatarsal angles above 9 degrees in the weight bearing anteroposterior radiography of both their feet in the age range of 8-60 were included in the study. They were randomly divided into two groups of 30 patients and matched in terms of age and gender. Patients with family history, flat soles, and those with neuro-muscular disorders were excluded from the study. The remaining patients were divided into two groups of case, using the designed splints, and control, applying the splints available on the market. The patients had to use the prescribed splints for at least 8 hours a day and refer to the clinic every three months for a year. All the patients completed and signed the informed consent forms. Radiographies were taken from the patients every three months in a weight bearing posture. The angles of hallux valgus and the angle between the first and second metatarsals were measured. The patients were monitored

for one year and finally were given questionnaires to be completed. The collected data was analyzed using the SPSS software via repeated measure tests with a P value of 0.05. The results were also reported as mean \pm SD.

Results

After the data was analyzed, the following results were obtained. Table 1 and figure 1,2 show respectively the decrease rates in hallux valgus angles at different times for the two devices in terms of the left and right feet (for the designed splint in the left foot in the first 3 months, for example, the decrease in hallux valgus angle was was 0.16 ± 0.12 compared with the time before the treatment, and it was 0.21±0.12 for the second three months. Similarly, the decrease for the night splint was 0.02±0.03 in the fist three months compared with the time before the treatment, and 0.04±0.04 in the second three months, etc.). Comparing the decreases in the total angle deviation of the two splints in the left foot (0.25±0.03 in the designed splint and 0.05±0.09 in the night splint), and considering the P<0.001, a significant difference was found between the two devices so that the designed splint caused more decrease in angle deviation in comparison with the night splint. This difference was statistically significant and the significant difference between the two devices existed similarly for the right foot.

Comparison of the decrease in the deviation of hallux valgus angle at various times in the two devices in terms of the left and right feet (Table 1).

Similarly, night splint Table 2 and 3,4 respectively shows the decrease in the deviation between the first and second metatarsal bones at different times in the two devices in the left and right feet (for the designed splint in the left foot in the first 3 months, for example, the decrease in deviation was 0.09 ± 0.09 compared with the time before the treatment, and it was 0.11 ± 0.09 for the second three months, etc.).

Table 1. Comparison of the decrease in the deviation of hallux valgus angle at various times in the two devices in terms of the left and right feet.

	Device	First 3	Second 3	Third 3	Fourth 3	Total	РР
		Months	Months	Months	Months		
Left Foot	Designed splint	16±0.12	0.21±0.12	0.28±0.13	$0.34{\pm}0.14$	0.25±0.03	< 0.001
	Night splint	$0.02{\pm}0.03$	$0.04{\pm}0.04$	0.06 ± 0.05	0.09 ± 0.07	0.05 ± 0.09	
Right Foot	Designed splint	0.19±0.17	0.24±0.16	0.30±0.17	0.37±0.19	0.28 ± 0.14	< 0.001
	Night splint	0.05±0.12	0.07±0.12	0.09±0.12	0.12±0.12	0.08±0.14	

Table 2. Comparison of the decrease in the deviation of the angle between the first and second metatarsals at various times in the two devices in terms of the left and right feet.

	Device	First 3	Second 3	Third 3	Fourth 3	Total	Р
		Months	Months	Months	Months		
Left Foot	Designed Splint	09±0.09	0.11±0.09	0.17 ± 0.09	0.21±0.12	0.15±0.07	< 0.001
	Night Splint	0.01±0.03	0.03 ± 0.05	0.06 ± 0.05	0.07 ± 0.06	$0.04{\pm}0.07$	
Right Foot	Designed Splint	0.1±0.13	0.13±0.13	0.18±0.13	0.24±0.16	0.16 ± 0.09	< 0.001
	Night splint	0.02±0.03	0.03±0.03	0.06 ± 0.05	0.08 ± 0.05	0.05±0.09	

Table 3. Comparison between the mean comfort of the applied device in terms of type of splint.

Device	Frequency	Mean ± SD	Median	
Splint	30	98.6 ± 3	100	<i>P</i> <0.001
Night splint	30	62 ± 26	60	



Figure 1. Comparison of the improvement in hallux valgus angle in the left foot in various months in terms of type of splint. Error bar: Mean±Sd



Figure 2. Comparison of the improvement in halux valus angle in the right foot in various months in terms of type of splint. Error bar: Mean±Sd

On average, there was a 0.15 ± 0.07 decrease in the angle deviation and, if compared with the 0.04 ± 0.07 decrease in the night splint, it showed a significant difference between the means of the decreases in the metatarsal

angles by the two devices. In other words, the designed splint caused more decreases in angle deviation in comparison with the night splint and this decrease was statistically significant.

Designed slippers splints in treatment of hallux valgus

The rates of improvement in hallux valgus angles in the terms of the type of splint can be compared using the following graphs.

Table 3 shows the comparison between the mean comfort of the applied device in terms of type of splint. Considering the P<0.001, it shows a significant

difference between the two devices so that the slippers splint is much more comfortable.

The following graph, figure 5 indicates the mean of the frequency of using the splints in terms of the splint type.



Figure 3. comparison of the improvement in the deviation of the angle between the first and second metatarsals in the left foot in various months in terms of type of splint Error bar: Mean±Sd



Figure 4. Comparison of the improvement in the deviation of the angle between the first and second metatarsals in the right foot in various months in terms of type of splint. Error bar: Mean±Sd



Figure 5. Comparison of the means of the frequency of using the splints in terms of the splint type. Error bar: Mean±Sd

There is considerable disagreement over the nonoperative treatment of hallux valgus. Some recommend the use of splints and others consider splint using in the nonoperative treatment as ineffective (8,9,10). Some recommend exercising, changing in activities, and using proper shoes and avoiding unsuitable shoes with narrow toe boxes (10,14). No studies have been conducted to recommend the effectiveness of splints and this issue has caused challenges in the nonoperative treatment of these patients. Another problem for these patients concerning the splints available on the market is that using these splints is difficult for them, does not make sufficient comfort for them, and the splints cannot be used everywhere; as a result, they complicate the treatment. Therefore, a splint was designed in the form of shoes or slippers that can be worn everywhere (home, outside and ...), without attracting other people's attention, without causing any bother for patients, and without any drug and skin side effects. While the shoes with tight toe boxes intensify hallux valgus, our splints have two remarkable features: first, the toe box is completely loose; second, its great toe part improves hallux valgus. These simple and inexpensive, but effective slippers are designed to treat hallux valgus. Another advantage of the designed splint is that it can be used as a splint, a plaster, an interphalangeal pad, night and day splints, etc. at the same time. Using this splint does not obstruct patients' usual activities; in other words, it does not have the usual problems of plastering, interphalangeal pads, and other common methods, and it is light, comfortable, and cost-effective. The designed splints can be manufactured in shoe forms and to consumer's taste in various sizes. Persons from any age ranges, from 2-yearold children to adults, can use the designed slippers in different sizes.

The scientific and technical features of the designed splints include ease of use, cost-effectiveness, severe deformity correction strength, and beauty. It should be noted that the devices on the market in the treatment of hallux valgus are not very effective, bother and discomfort patients, and cannot be used everywhere. On the contrary, the designed slipper splints do not have such problems and cure halllux valgus considerably. This splint is made from a light metal and a wide and light sole and follows the necessary standards.

According to the results of this study, the decrease in hallux valgus angle in the left foot in the patients who used the designed splint was 0.25 ± 0.03 in a year, while

the decrease rate was 0.05 ± 0.09 in those who used the splints available on the market (night splint, interdigital pads). This difference was statistically significant (*P*<0.001). Moreover, the correction rates of the hallux valgus angles in the right foot were 0.28 ± 0.14 in the case group and 0.08 ± 0.14 in the control group (*P*<0.001).

In addition, a significant difference was found concerning the decrease in the angle between the first and second metatarsals in the left and right feet at the end of the study, so that using the designed splint caused considerable corrections in hallux valgus in the case group. Additionally, based on the statistical analyses, a statistically significant difference was found between the two groups in terms of comfort of using of the two splints (P<0.001), so that the patients in the case group were more satisfied with the designed splint. Consequently, due to the obtained results including a decrease in the deviation of angles in patients, comfort, patients' satisfaction, cost-effectiveness, and usability in different places, the designed splint can be used as a nonoperative treatment in patients with hallux valgus.

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