Effect of Hinged Ankle-Foot-Orthosis with or without Lateral Wedge on Pain, Function in Medial Compartment Knee Osteoarthritis

Abstract

Background: Knee osteoarthritis often causes disability due to the pain it causes and affects a person's quality of life. The purpose of this study is to investigate the effect of ankle-foot-orthosis with and without lateral wedge on pain, function and displacement of the center of pressure in patients with the medial compartment knee osteoarthritis.

Methods: The research method was quasi-experimental with a pre-test and post-test design. This study was conducted on 13 patients with medial compartment knee osteoarthritis in the age range of 40 to 75 years as available sampling. Demographic information and WOMAC questionnaire were completed and the displacement of the center of pressure in the internal-external plane was recorded by the Kistler force plate device, in three situations: bare feet, ankle-foot orthosis with lateral wedge and ankle-foot orthosis without lateral wedge. The obtained data were analyzed using SPSS software. Shapiro-Wilk test was used to check the conformity of distribution of quantitative variables with normal distribution. According to the normality ($p>0.05$), variance analysis tests, multiple comparisons and generalized linear models were used for data analysis.

Results: 13 patients participating in this study were examined in three situations, and the pain of the patients in the state of using the orthosis with the lateral wedge was significantly reduced ($p=0.006$), the function of the patients was better in the state of using the orthosis with the lateral wedge. ($p=0.003$), but the displacement of the center of pressure in the case of using the orthosis without wedge had a significant decrease ($p=0.03$).

Conclusion: The results of the study showed that the use of an orthosis with an lateral wedge was effective in improving pain and function, but the use of an orthosis without an wedge led to a reduction in the displacement of the center of pressure in the internal-external plane. Therefore, it will probably reduce the knee adduction moment.

Keywords: Pain, Knee osteoarthritis, Orthotic devices, Orthotic insoles

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Introduction

Knee osteoarthritis is the most common type of osteoarthritis that starts with any abnormality of the joint or tissue around the joint and manifests as destruction and erosion of articular cartilage [(1)]. About 16% of adults over the age of 45 years suffer from osteoarthritis [(2)]. In Iran, 16.9% of Iranians were suffering from joint destruction diseases in 2016. Among them, 15.5% of people were suffering from knee osteoarthritis [(3)]. The amount of force applied and the possibility of osteoarthritis is in medial compartment is higher than lateral compartment of knee since the line of gravity of the body passes through the medial of the knee [(4)]. In osteoarthritis of the knee, the knee adduction moment is higher, and the development and progression of the disease leads to a greater increase in the lateral

knee adduction moment during standing on one foot [5]. The increase in fluctuations of the center of pressure in the knee joint in the medial-lateral plane in patients with knee osteoarthritis causes an increase in the abduction/adduction of the knee joint, which is directly associated with the destructive force of the adduction moment on the knee [6]. Increasing the stability of the ankle joint by using an ankle-foot orthosis is one way to reduce the knee adduction moment as it reduces the lateral rotation of the tibia bone in the frontal plane and thus leads to the reduction of knee varus deformity. This correction in the position of the tibia will lead the center of the knee inward and reduce the lever arm in the frontal plane, so it will reduce the adduction moment of the knee [7].

Based on previous articles, it seems that the insole with the lateral wedge is accepted by the patients, but it alone cannot correct the alignment of the knee and reduce the amount of knee adduction moment, and probably the corrective force is absorbed in the ankle joint. Thus, it is necessary to combine it with an ankle stabilizer [8, 9]. Thus, it is assumed that the use of ankle-foot orthosis prevents the absorption of corrective force in the subtalar joint. It is used as a suitable alternative to orthopedic shoes and insoles at home. It reduces pain, improves performance, and reduces displacement in the center of pressure. Thus, this study seeks to evaluate the effect of an articulated ankle-foot orthosis with and without a lateral wedge in reducing pain, improving performance, and displacement in the center of pressure.

The study hypothesizes that pain, performance, and displacement of the center of pressure will be different in ankle-foot orthosis with and without a lateral wedge. The present study is quasi-experimental.

Methods

The number of research samples was 13 patients with medial knee osteoarthritis with grades 2 and 3 according to the Kellgren and Lawrence methods. Convenience sampling was used. Our priority in patient selection was a specific age range and grade of osteoarthritis. Due to the higher cooperation of females and lower cooperation of males in the research, the number of female samples was more than males (11 females and 2 males). The inclusion criteria of the study included age between 40 and 75 years [10], at least 2 out of 5 cases of WOMAC's test about pain [9], patients with osteoarthritis of the medial compartment of the knee grade 2 and 3 according to Kellgren and Lawrence criteria, diagnosed by a physician using radiographs [11], unilateral osteoarthritis of the inside of the knee, no orthotic treatment (shoes), and previous surgery to treat knee osteoarthritis [12]. The orthosis used in the present study was an articulated ankle-foot orthosis with an 8 mm lateral wedge and no wedge. To make the orthosis, a 5 mm polypropylene sheet was used. To move the ankle-foot orthosis in the sagittal plane of the subtalar joint, the sheet was used. In the ankle-foot orthosis with a lateral wedge, 8 mm of hard foam (ethylene vinyl acetate) with high density was used to apply the lateral wedge, and a 3 mm thick rubber sole layer was used to prevent the patient from slipping and easy to use at home (Figure 1). In the orthosis without a lateral wedge, only one layer of rubber sole with a thickness of 3 mm was applied (Figure 2).

The Western Ontario and McMaster Universities Arthritis (WOMAC) Index was used to evaluate patients' pain and function. Kistler's force plate device was also used to measure the displacement of the center of pressure and other variables related to static balance. The patients with the mentioned characteristics referring to Javad Movafakian Analysis Laboratory completed the consent form and demographic information form after receiving the ethics code number IR.USWR.REC.1401.118 from the University of Rehabilitation Sciences and Social Health. To investigate the relationship between body mass index, foot length, and width, and the effect of orthosis, the height, weight, and foot dimensions of the patients were also recorded. To adapt the patients to the orthosis, we asked them to use the orthosis at home for 2 hours the day before the test. The necessary training was given to the patients in

this regard. On the test day, before using the orthosis, each person completed the WOMAC questionnaire and stood barefoot on the force plate in two positions (once both feet were placed on the same plane to record the mean of the two feet and each foot was again placed on a separate plane to record each foot separately. Then, each person was given one of two orthosis models randomly (ankle-foot orthosis with lateral wedge or ankle-foot orthosis without lateral wedge).

Each patient used their orthosis for at least 20 minutes and then completed the WOMAC questionnaire. To avoid errors and equalize the length of the two limbs, we once considered the healthy foot barefoot and then we covered the healthy foot with a sandal that had the same height as the orthosis and took the test. Thus, the test was taken in 4 situations (1- Orthosis for the suffered foot and healthy foot in the barefoot position, both feet on one force plate,

2- Orthosis for the suffered foot and sandals for the healthy foot, both feet on one force plate, 3- Orthosis for the suffered foot and the healthy foot in the barefoot position, each foot on a force plate, and 4- orthosis for the suffered foot and the sandal for the healthy foot, each foot on a force plate). Then, the therapist took the orthosis from the patients, separated their soles, and added a lateral wedge to the orthosis of the patients who initially received an orthosis without a lateral wedge. Also, she removed the lateral wedge from the orthosis of the patients who initially received an orthosis with a lateral wedge and installed only the treaded sole. In other words, the patients received both orthoses.

Patients rested for at least 30 minutes so the impact of the orthosis was removed. Then, they used their new orthosis again for at least 20 minutes and completed the WOMAC questionnaire. Four stages of the test were repeated to examine the displacement of the center of pressure and other static balance variables on the Kistler force plate. Due to the impossibility of measuring some items of the WOMAC questionnaire in the laboratory environment, which include pain at night in bed, performance when getting in and out of the car, shopping, getting up and lying down in bed, taking bath, and performing light and heavy works, they were removed with the opinion of professors.

Figure 1: Articulated ankle-foot orthosis with 8 mm lateral wedge

Figure 2: Articulated ankle-foot orthosis without lateral wedge

Results

SPSS results on 13 patients with medial knee osteoarthritis, including 11 females and 2 males, are shown in the following tables. The mean and standard deviation of the body mass index of the patients are 28.31 and 4.63, respectively. The mean age of the patients is 58.85, as presented in Table 1. Regarding disease severity (grade 2 and grade 3), 8 people had grades 2, and 5 people had grade 3. To evaluate the normality of the data, the Shapiro-Wilk test was used and all were normal. Paired t-test was used to analyze the pain and performance data. Also, multiple comparisons and generalized linear models were used to analyze the displacement of the center of pressure and other variables of static balance. The data were analyzed in SPSS-23 software and the significance level was considered to be 0.05.

The results of Table 2 indicated that the pain in the condition of comparing barefoot and the use of orthosis with the lateral wedge (t=-3.29 and p<0.006) and the performance of the patients in the condition of barefoot and the use of the ankle-foot orthosis with the lateral wedge (t=-3.69 and p<0.003) have a significant difference. In other words, the use of ankle-foot orthosis with a lateral wedge is effective in reducing pain and improving the performance of patients with medial knee osteoarthritis.

Table 3 shows the means of both feet when they are placed on the same force plate. Based on the table, the use of ankle-foot orthosis with and without lateral wedge did not have a significant impact on reducing the displacement of the center of pressure in the medial-lateral plane and other variables of static balance.

Table 4 presents the data of the feet in a position in which each foot was placed on one plate. The displacement of the center of pressure in the medial-lateral plate when using an orthosis without a wedge has been significantly reduced compared to barefoot (p=0.031). Additionally, foot length and width showed a significant relationship with the use of orthoses (p=0.026) (p=0.038) so in patients with longer foot length (B=0.70) and less foot width (B=-1.82), the center of pressure decreases in the medial-lateral plate. The displacement of the center of pressure in the medial-lateral plate was reduced when using an orthosis with a lateral wedge and sandals compared to barefoot. However, this reduction was not significant.

The displacement distance of the center of pressure in the medial-lateral plate when using an orthosis with a lateral wedge and sandals was significantly reduced (p=0.037). Also, body mass index, length, and width of the foot were associated with using the orthosis (p=0.000) (p=0.000) (p=0.001) so the patients who had a larger body mass index (B=3.68) and larger foot width (B=16.49) and smaller foot length (B=-7.33) will probably show a further decrease in the displacement distance of the center of pressure in the medial-lateral plane.

The displacement velocity of the center of pressure in the medial-lateral plate when using an orthosis with a lateral wedge and a sandal was significantly reduced (p=0.037) compared to barefoot. Also, body mass index, foot length, and width were associated with the use of orthoses (p=0.000) (p=0.000) (p=0.001). Thus, patients with a lower body mass index (B=-0.18), smaller foot length (B=-0.36), and larger foot width (B=0.82) will probably show more reduction in the displacement velocity of the center of pressure in the medial-lateral plane. In other words, orthosis will be more effective in these patients.

Table 1: Mean and standard deviation of demographic characteristics according to body mass index and age of patients with medial knee osteoarthritis

variable	Min	Max	Mean	SD
BMI	20.89	34.78	28.31	4.63
Age	45	71	58.85	8.49

Table 2: Mean, standard deviation, and test of comparing the mean pain and function in three conditions					
Variable		Mean	SD	Paired t-test	Probability value
Pain	Barefoot Ankle-foot orthosis with lateral wedge	54.05 63.94	23.27 25.91	-3.29	0.006
	Barefoot Ankle-foot orthosis without lateral wedge	54.05 56.25	23.27 21.65	1.08	0.301
	Ankle-foot-orthosis with lateral wedge and ankle -foot -orthosis without lateral wedge	63.94 56.25	25.91 21.65	2.21	0.047
Function	Ankle-foot orthosis without lateral Wedge	59.61 65.76	20.15 21.89	-3.69	0.003
	Barefoot	59.61 61.15	20.15 20.11	-1.17	0.264
	ankle-foot-orthosis with lateral wedge and ankle -foot -orthosis without lateral wedge	65.76 61.15	21.89 20.11	2.65	0.021

Discussion

The results revealed that the use of ankle-foot orthosis with lateral wedges and sandals reduced the displacement of the center of pressure, but it was not significant (p=0.06). The ankle-foot orthosis without lateral wedge significantly reduced the displacement of the center of pressure (p=0.031). Given the direct relationship between the displacement of the center of pressure and the knee adduction moment, the ankle-foot orthosis can reduce the amount of knee adduction moment, and reduce the pressure applied on the inside of the knee. No study was found to examine the effect of ankle-foot orthosis on reducing the displacement of the center of pressure, and we only discussed the studies that investigated the effect of ankle-foot orthosis on knee adduction moment. A study reported that ankle-foot orthosis in all three positions (lateral load at 5 degrees of varus, normal, and 5 degrees of valgus) led to a decrease in knee adduction torque, knee lever arm, and correction of alignment in the frontal plane. However, no change was observed in the sole state with the lateral wedge [13]. Based on previous studies, if the amount of displacement of central of pressure is reduced, it can be stated that the knee adduction moment will probably decrease [6, 14, 15]. Another study reported that ankle-foot orthosis with a bilateral joint had a greater reduction in knee adduction moment compared to insoles with a lateral wedge, but this difference was not significant (16).

In other words, the ankle-foot orthosis leads to the transfer of force to the knee by controlling the movement of the ankle in the subtalar joint, so it works better than the insole with a lateral wedge. Additionally, given the biomechanical nature of osteoarthritis of the medial compartment of the knee, it can be assumed that if treatment corrects the abnormal forces on the knee, it can slow down or stop the disease process. Ankle-foot orthosis shortens the knee adduction moment arm by transferring the weight line of patients with knee osteoarthritis to the outside and reducing the displacement of the center of pressure. In other words, it can lead to the correction of the angle of the femur and tibia and is effective in improving knee osteoarthritis symptoms. In the position where the suffered foot was recorded separately, only the orthosis without lateral wedge led to a significant reduction in the displacement of the center of pressure in the medial-lateral plate (p=0.031) and the orthosis with lateral wedge and sandals reduced the displacement of the center of pressure in the medial-lateral plane. However, it was not significant (p=0.06). Also, orthosis with lateral wedges and sandals led to a significant decrease in velocity and distance in the medial-lateral plane (p=0.03 and p=0.03).

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Table 3: Balance parameters when both feet are placed on the same force plane

Variable*		Orthosis without lateral wedge and with sandals	Orthosis with lateral wedge and with sandals	Orthosis without lateral wedge	Orthosis with lateral wedge	BMI	Foot length	Foot width
The standard deviation of the displacement of the center of pressure in the anterior-posterior plane (mm)	**Probability value (p)**	0.98	0.56	0.39	0.95	0.10	0.87	0.56
	Estimated (B)	-0.01	0.38	-0.43	0.03	-0.06	-0.07	0.59
Standard deviation of the displacement of the center of pressure in the medial-lateral plane (mm)	**Probability value (p)**	0.522	0.641	0.564	0.144	0.306	0.100	0.080
	Estimated (B)	0.24	0.17	0.25	0.67	0.04	0.44	-1.33
The total displacement velocity of the center of pressure	**Probability value (p)**	0.987	0.978	0.971	0.230	0.666	0.002	0.000
	Estimated (B)	0.006	-0.01	0.01	0.58	-0.01	-0.84	3.20
The displacement velocity of the center of pressure in the anterior-posterior plane (mm/s)	**Probability value (p)**	0.726	0.910	0.900	0.329	0.457	0.002	0.000
	Estimated (B)	0.15	0.05	0.06	0.53	0.02	-0.93	3.42
The displacement velocity of the center of pressure in the medial-lateral plane (mm/s)	**Probability value (p)**	0.813	0.944	0.989	0.420	0.052	0.920	0.715
	Estimated (B)	-0.06	0.02	0.005	0.27	-0.06	-0.02	0.20
The total displacement distance of the center of pressure (mm)	**Probability value (p)**	0.987	0.978	0.971	0.230	0.666	0.002	0.000
	Estimated (B)	0.13	-0.24	0.36	11.78	-0.33	-16.97	64.02
The displacement distance of the center of pressure in the anterior-posterior plane (mm)	**Probability value (p)**	0.726	0.910	0.900	0.329	0.457	0.002	0.000
	Estimated (B)	3.16	1.16	1.22	10.74	0.54	-18.68	68.47
The displacement distance of the center of pressure in the medial-lateral plane (mm)	**Probability value (p)**	0.813	0.944	0.989	0.420	0.052	0.920	0.715
	Estimated (B)	-1.38	0.42	0.10	5.45	-1.29	-0.40	4.07
Displacement of the center of pressure in the anterior-posterior plane (mm)	**Probability value (p)**	0.817	0.501	0.684	0.549	0.171	0.349	0.161
	Estimated (B)	0.44	1.42	-0.81	1.31	-0.24	-1.37	4.87
Displacement of the center of pressure in the medial-lateral plane (mm)	**Probability value (p)**	0.700	0.794	0.706	0.160	0.467	0.184	0.148
	Estimated (B)	0.62	0.38	0.76	2.83	0.12	1.57	-4.85

***Barefoot was considered as the reference category for the groups

Table 4: Balance parameters when each foot is placed on a force plane.

Variable*		Orthosis without lateral wedge and with sandals	Orthosis with lateral wedge and with	Orthosis without lateral wedge	Orthosis with lateral wedge	BMI	Foot length	Foot width
Displacement of the center of pressure in the medial-lateral plane (mm)	**Estimated (B)**	-1.23	-1.44	-1.55	-0.99	-0.02	0.70	-1.82
	Probability value (p)	0.109	0.064	0.031	0.223	0.662	0.026	0.038
Displacement of the center of pressure in the anterior-posterior plane (mm)	**Estimated (B)**	0.18	-0.40	-1.54	-2.49	0.24	0.15	0.72
	Probability value (p)	0.943	0.835	0.482	0.306	0.306	0.902	0.854
The displacement distance of the center of pressure in the medial-lateral plane (mm)	**Estimated (B)**	-5.71	-7.76	-1.31	-6.93	3.68	-7.33	16.49
	Probability value (p)	0.175	0.037	0.727	0.081	0.000	0.000	0.001
The displacement distance of the center of pressure in the anterior-posterior plane (mm)	**Estimated (B)**	6.78	8.78	3.95	-0.21	0.06	-26.63	99.80
	Probability value (p)	0.690	0.666	0.820	0.990	0.964	0.001	0.000
The total displacement distance of the center of pressure (mm)	**Estimated (B)**	3.83	5.33	4.23	-3.24	-2.01	29.25	102.14
	Probability value (p)	0.827	0.791	0.805	0.855	0.186	0.000	0.000
The displacement velocity of the center of pressure in the medial-lateral plane (mm/s)	**Estimated (B)**	-0.28	-0.38	-0.06	-0.34	-0.18	-0.36	0.82
	Probability value (p)	0.175	0.037	0.727	0.081	0.000	0.000	0.001
The displacement velocity velocity of the center of pressure in the anterior-posterior plane (mm/s)	**Estimated (B)**	0.33	0.43	0.19	-0.01	0.003	-1.33	4.99
	Probability value (p)	0.690	0.666	0.820	0.990	0.964	0.001	0.000
The total displacement of the center of pressure (mm/s)	**Estimated (B)**	0.192	0.26	0.21	-0.16	-0.10	-1.46	5.10
	Probability value (p)	0.827	0.791	0.805	0.855	0.186	0.000	0.000
Standard deviation of the displacement of the center of pressure in the medial-lateral plane (mm)	**Estimated (B)**	-0.20	-0.22	-0.24	-0.14	0.004	0.16	-0.44
	Probability value (p)	0.185	0.173	0.091	0.371	0.757	0.022	0.019
The standard deviation of the displacement of the center of pressure in the anterior-posterior plane (mm)	**Estimated (B)**	0.326	0.22	0.01	-0.30	0.05	-0.03	0.06
	Probability value (p)	0.575	0.625	0.982	0.594	0.306	0.890	0.942

*Barefoot was considered as the reference category for the groups

Knee osteoarthritis is one of the factors of loss of balance and the risk of falling in affected people [17]. Patients with knee osteoarthritis have higher postural fluctuations compared to healthy people [18]. Therefore, the static balance was improved by reducing the amount of displacement, velocity, and displacement distance of the center of pressure. A study by Esfandiarpour revealed that the use of insoles with a lateral wedge had a 20-30% improvement in the velocity and standard deviation of the displacement of the center of pressure in the medial-lateral and anterior-posterior plates [4]. Another study reported a significant improvement in balance after one month of using insoles with lateral wedges. According to this study, it can be stated that if the patients in the present study had used the orthosis for a longer period of time, a greater improvement in their balance would probably have been observed [19].

Another study reported that shoes with lateral wedges compared to insoles with lateral wedges and simple insoles have a greater impact on improving the static balance of patients with knee osteoarthritis. In other words, the use of shoes similar to the subtalar strap restricts the movement of the subtalar joint. Also, due to further correction of the femur and tibia angle, the patients' static balance improves [20].

Based on this study, the reason for improving static balance in patients using ankle-foot orthosis with the lateral wedge is the restricted ankle movement.

Due to the association of orthoses with body mass index, and foot length and width, orthoses were generally more effective on patients with lower body mass index, and greater foot length or width, since they lead to an increase in the base of support. The mean pain was 54.05 in the WOMAC questionnaire in the barefoot condition and 63.94 in the case of using an orthosis with a lateral wedge. In other words, a higher number indicates greater improvement. Thus, with a probability value of p=0.006, the pain of the patients decreased significantly. Many researchers have reported pain reduction using the Agilium ankle-foot orthosis on patients with medial knee osteoarthritis. Barati reported a reduction in pain after using bilateral ankle foot orthosis two weeks [16]. Petersen compared Agilium ankle-foot orthosis and weight-bearing knee brace and evaluated pain at three time points, zero time, after 8 weeks, and after 6 months. He found that pain was significantly reduced in both orthoses [21]. A study reported that the patient's pain by using Agilium decreased even at the zero time and after 3, 6, 9, and 12 months [22]. After 6 weeks of patients using the orthosis, Slafen found that the patient's pain decreased [23]. Two studies reported that patients' pain decreased when using Agilium ankle-foot orthosis and insoles with lateral edges, but there was no significant difference between them [12, 24]. We hypothesized that the presence of the lateral wedge and the ankle-foot orthosis would reduce pain, and it was confirmed. The lateral wedge reduces the applied load to the medial compartment of the knee and transfers the reaction force to the outside of the knee joint in the frontal plane. The presence of an ankle-foot orthosis prevents absorbing corrective forces in the subtalar joint of the ankle, and the possibility of transfer to the knee is provided. We assume that the force applied to the patient's leg from the outside of the leg led to a reduction in pain. Based on the results obtained from the WOMAC questionnaire, the mean function was 59.61 in the barefoot state and it was 65.76 when the ankle-foot orthosis with lateral wedge was used. As stated before, the higher the number indicates the more improvement. Hence, the performance with a probability value of p=0.003 improved significantly. Many studies such as Barati and Petersen reported the significant impact of ankle-foot orthosis on the performance of patients with osteoarthritis in the medial compartment of the knee [16, 21]. Manjar stated that by using ankle foot orthosis the function of patients improved significantly in daily life and their pain decreased. However, the patients were not willing to continue using the ankle-foot orthosis [22]. In another study, a functional test was used to evaluate the daily performance of patients when using an ankle-foot orthosis. However, after 6 weeks of using

the orthosis, no effect was observed in increasing the level of activity and This study was not in line with the present study. In other words, patients were able to perform more activities due to the pleasant feeling and reduction of pain caused by the use of the ankle-foot orthosis with a lateral wedge in the orthosis.

Conclusion

There are still doubts about the function of this type of orthosis in the treatment of knee osteoarthritis. However, it seems that ankle-foot orthosis can be a suitable alternative to medical shoes at home to control the symptoms caused by osteoarthritis of the medial compartment of the knee.

The ankle-foot orthosis without lateral wedge significantly reduces the displacement of the center of pressure. The ankle-foot orthosis may reduce the amount of adduction moment of the knee and reduce the pressure on the inside of the knee. Pain and performance of patients improved significantly when ankle-foot orthosis with lateral wedge was used. The use of ankle-foot orthosis with lateral wedge and sandals improved the static balance of the patients.

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