Comparison the Effectiveness of Lateral Wedge Insole with and without Longitudinal Arch Support on Ankles' Function and Pain in People with Medial Knee Osteoarthritis

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Abstract

Introduction: Lateral wedge insole (LWI) is one of the therapeutic interventions in the management of medial compartment knee osteoarthritis. The aim of this study was to investigate the effect of the LWI with and without a medial arch on the pain and the ankle function in patients with medial compartment knee osteoarthritis. **Methods and Materials:** Twenty-six people with medial knee osteoarthritis were assigned. All participants were asked to complete the questionnaires of the Foot and Ankle Outcome Survey (FAOS) and the Visual Analog Scale (VAS) in the first session. Then, participants were divided into two groups. The first group was given a LWI and the second group a LWI with the medial arch support. After a 6-weeks use of the insoles, participants were asked to complete the questionnaires again. **Result:** The use of LWI and arch support did not alter all items of the FAOS including the stiffness, pain, activity level, sports restriction, and quality of life restrictions and the VAS score after six weeks compared with the first session ($P>0.05$), but the using only LWI increased all subscales of FAOS and VAS score after six weeks wearing the insole ($P<0.05$) and there was no significant change just in the stiffness subscale ($P=0.6$). Also, the difference between the two groups was significant by increase of all outcomes using only the LWI compared with the LWI along with an arch support ($P<0.05$). **Conclusion:** Using a LWI in isolation can result in pain and discomforting in the ankle joint. However, LWI combined with arch support could prevent joint stiffness, pain and discomforting in the ankle joint of patients with medial knee osteoarthritis.

Keywords: Ankle; Arch support; Function; Lateral wedge Insole; Medial Knee Osteoarthritis; Pain

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Introduction

Knee osteoarthritis (KOA) which occurs symptomatically in approximately 27% of adults younger than 70 years and in 44% of adults older than 80 years, causes knee pain and disability(1, 2). Treatments used in knee osteoarthritis divided into three general categories: surgery, medication, and conservative treatments(3). Conservative treatments include physiotherapy, exercise, orthoses, assistive devices, hydrotherapy, lifestyle changes, and weight loss, which are usually the first treatment choices because they have the least side effects(4). Lateral wedge insole (LWI) is a common prescribed orthosis in patients with KOA(5). Studies have shown that using a LWI can be effective in reducing the knee osteoarthritis pain(6). Based on the amount of wedge insole angulation, LWI moves the center of pressure to the lateral side of knee joint which can reduce the adduction moment, a parameter which is strongly associated with the progression of KOA (5, 7, 8).

One of the most common problems in people with medial compartment KOA is pain and pressure in the ankle usually caused by biomechanical changes in the knee and its effect on the ankle (9). Since human body is a closed chain and also the

Figure 1. Left side: lateral wedge insole; right side: lateral wedge insole with arch support

knee joint progresses to the varus alignment in KOA, these changes of knee alignment should be compensated by the hip and ankle joints. In this regard, the ankle goes to valgus to be adapted with the knee varus alignment (10, 11). Changing the ankle joint alignment from neutral to valgus position can increase the pressure on the inside of the ankle joint (7). LWIs led to locating the patient's foot in the pronation. In this position, the ankle is locked and its movements are limited; hence, the foot's ability to shock absorbing while walking is reduced. In addition, the use of LWI moves the weight line out of the ankle and increases the local pressure on it, which can make patient's discomfort (10). In some studies, the use of a LWI with a longitudinal arch support has been reported to be more effective than without a longitudinal arch support (12, 13). However, one study showed no significant difference between the two conditions (15). Thus, the results of researches on the need of adding longitudinal arch support on a LWI or not are inconsistent, and further research in this area is needed.

Due to the fact that the first and most important effect of the LWI is on the ankle joint created by the varus in the knee joint as a compensatory mechanism, the valgus moment increases on the ankle joint and the lateral wedge may aggravate it. Thus, this joint can be exposed to damage. Therefore, it is necessary to investigate the clinical effect of LWI use on ankle pain and function in people with medial compartment KOA. Awareness of the side effects of lateral wedge on the ankle joint can help to the efficiency of orthosis prescription in these patients as well as minimizing the side effects of treatment. Most studies have focused on the type and characteristics of LWI and its effect only on the knee joint (7, 10, 11). However, to our best knowledge, there is no study which examines the effect of LWI on ankles' function and pain with and without the longitudinal arch support. Therefore, the aim of this study was to evaluate the effect of LWI with and without longitudinal arch support on ankles' function and pain in people with medial KOA.

Methods and Materials

Participants

Twenty-six patients with medial compartment knee OA were recruited from Red Crescent Center. The participants were prescribed an insole by their physician. The eligibility criteria for participations in the study were as follow: age 40-60 years, medial knee OA with grade 2 or 3 based on Kellgren Lawrence, have a daily activity of at least 6-8 hours, and did not use another foot orthosis (14-16). The exclusion criteria were: other diseases influencing walking ability, foot injury, a history of cardiovascular disease, intra-articular injection, patients with ligament problems and meniscus tear of the knee, and acute joint effusion (1).

Signed consent forms were obtained from all participants. This study was approved by the ethical committee at the University of Social Welfare and Rehabilitation Science.

Interventions

Two types Full length custom-made LWIs with and without arch support were made from cork with a density of 60 durometers. The insoles were constructed with a 5-mm lateral wedge (17). An arch support was added to the LWI for one of the groups. The arch support length was 33% of the insole length and width 45% of the insole width. the height of the arch was 1 cm (excluding the rubber foam height) (Figure 1) (18).

Data collection

This was a quasi-experimental study. Patients divided into two groups. The first group received only a LWI and the second group received a LWI with the arch support. The intervention was adjusted and fitted by an expert orthotist in patients' shoe.

In the first session, after the initial evaluations, participants were asked to complete the ankle pain questionnaire by Visual analog scale (VAS) and ankle function questionnaire by Foot and Ankle Outcome Score (FAOS). Then, each of the orthotic treatments was employed for a 6-week continuous usage monitored and confirmed by the lead researcher via telephone. People were told that they would be excluded from the study if they used other treatments including physiotherapy, intra-articular injections, and other treatments during six weeks. After 6 weeks, the participants again referred to the Red Crescent Center for the completion of the questionnaires. During the intervention period, if patients had any complaint and dissatisfaction with the continuation of the study, they were allowed to leave the study.

Table 1. Demographic characteristics of the participants

Index	Group 1 (LWI) (n=13)	Group 2 (LWI+ arch support) (n=13)	*P*-value
Age	58.2 (8.07)	57.4 (7.48)	0.808
Weight	81.4 (11.04)	82.14 (10.87)	0.747
Height	162.7 (8.92)	154.6 (9.19)	0.270
Gender (female)	57%	71%	0.848
Kellgren Lawrence (grade 2)	43%	39%	0.60

LWI: lateral wedge insole

Table 2. The results of intra-group comparison of the before and after six weeks wearing the insole with the FAOS and VAS questionnaires in each group

Variable (n=13)		Group 1 (LWI)		Group 2 (LWI+arch support)	
		Mean (SD)	*P*-value	Mean (SD)	*P*-value
Stiffness0.42	**Before**	49.83 (1.2)	0.6	46.70 (1.4)	0.4
	After	50.25 (0.5)		40.83 (0.3)	
Pain	**Before**	30.74 (0.5)	0.000**	41.79 (3.5)	0.1
	After	63.23 (0.35)		28.81 (0.25)	
Daily activity	**Before**	39.47 (2.5)	0.02*	47.53 (4.1)	0.2
	After	50.39 (1.3)		30.28(1. 5)	
Sport activity	**Before**	52.77 (1.7)	0.01*	50.92 (3.8)	0.3
	After	65.15 (2.1)		33.84 (2.0)	
Quality of life	**Before**	30.14 (1.7)	0.02*	35.12 (4.8)	0.1
	After	44.06 (3.2)		23.44 (2.8)	
Pain (VAS)	**Before**	30.1(2)	0.000**	40 (2.2)	0.4
	After	50.8 (1.8)		20.8 (1.2)	

*LWI: lateral wedge insole, * P<0.05, ** P<0.001*

Table3. The results of the FAOS and VAS questionnaires between two groups

Variable	Mean differences [(LWI+ arch support)– (LWI)]	Significance level
Stiffness	-6.29	0.21
Pain	-45.47	0.033*
Daily activity	-28.17	0.01*
Sport activity	-29.46	0.02*
Quality of life	-25.6	0.01*
Pain (VAS)	-39.9	0.01*

Outcome measurement tools

Visual analog scale (VAS)

For pain intensity, the VAS scale which is most commonly anchored by "no pain" (score of 0) and "pain as bad as it could be" or "worst imaginable pain" (score of 100 [100-mm scale]) was used (19).

Foot and Ankle Outcome Score (FAOS) questionnaire

A commonly used instrument to assess functional limitations and symptoms related to a variety of foot and ankle symptoms is the Foot and Ankle Outcome Score (FAOS)(20) . This tool was developed for patients to comment on a variety of foot and ankle problems. The questionnaire is currently used in patients with ankle instability, Achilles tendonitis, and plantar fasciitis. FAOS content is based on knee injury and the outcome of osteoarthritis. This questionnaire includes 5 subsets including pain, stiffness, functional tests in daily activity, functional tests in sports and recreation, and quality of life (QoL). This questionnaire is user-friendly and takes about 10 minutes to be completed. FAOS is a self-explanatory tool and can be filled in the waiting room or completed as a survey, such as by email (21). The highest score in the FAOS indicates the lowest ankle function and the lowest score indicates the highest ankle function. The Persian version of FAOS has been translated and validated by Negahban *et al.* (22).

Statistical Analysis

The normality distribution of data was confirmed using the Shapiro-Wilk test. Wilcoxon signed rank test and Mann-Whitney U test were used to compare intra group (before and after 6-week using the intervention in each group) and between two groups (LWI and LWI+arch support) respectively. The significance level of P=0.05 was used for all analyses.

Results

Twenty-six patients with medial KOA were analyzed. Patients were divided into two groups with 13 participants. Table 1 shows demographic characteristics of the individuals in each group.

The results of the FAOS and VAS questionnaires for comparison of Intra-group

Table 2 demonstrates the intra-group results. The findings indicated that in the LWI group with arch support, all of the FAOS subscales and pain (by VAS) were decreased to some extent after 6-week use of the intervention in comparison of the before its use; however those did not reach a statistically significant (P>0.05). In the only LWI group without a longitudinal arch support, the subscales of the FAOS questionnaire, except joint stiffness (P=0.6), and pain score (by VAS) were significantly increased after six weeks of the insole use (Pain: 32.49%, daily activity: 10.92%, sport activity: 12.38 %, quality of life: 13.92%, pain (VAS): 20.7%; P<0.05). So, the LWI with an arch support did not result in the pain or discomfort in the ankle.

The results of the FAOS and VAS questionnaires for comparing two groups:

The findings shows that all parameters of FAOS between the two groups, except of joint stiffness, were significantly different (p<0.05) and the LWI with a longitudinal arch support had no adverse effect on ankle function. The findings of the statistical test also demonstrated that the ankles' pain measured by VAS was significantly increased using a LWI compared with the LWI with an arch support (p <0.005).

Discussion

The main goal in the treatment of medial KOA is to reduce pain by correcting the knee alignment and reducing the forces applied to the medial joint surface (23). One of the most common and non-invasive treatments is the use of orthoses. LWI is one of the most common types of orthosis treatments(24). Despite the positive effect of LWI on the pain reduction of the knee joint, it could result in the pain increase of the ankle joint (7, 11, 25). Due to the fact that clinical effect of LWI on the ankle joint of patients with medial knee OA is not completely clear, therefore, the present study compared the effect of LWI use with and without longitudinal arch support on the pain and the function parameters of the ankle joint in patients with medial KOA after a 6-week use on the insoles. We recruited two treatment groups, and in order to reduce bias, patients were not aware of the differences between the two types of insoles.

In the intragroup comparison, the ankle pain parameter in the first group (only LWI) was significantly increased after six weeks compared with the first day. This result indicated the negative effect of LWI on the ankle joint. But in the second group, adding a longitudinal arch support to the LWI did not result in a significant increase of pain in the ankle joint. Therefore, the results of the present study demonstrated that LWI significantly increase pain in the ankle joint, while LWI with longitudinal arch support do not cause significant pain in the ankle joint.

The results of the present study are in consistent with the studies of Kakihana et al.(7) and Fukucci et al. (26) which reported the negative effect of LWI on the pain , symptoms, and functional limitations of ankle joint. Because the LWI alone can have a detrimental effect on the compensatory position of the joints, especially the subtalar joints' pronation which is common in people with medial KOA, adding a longitudinal arch support to the LWI can decrease the negative effect of lateral wedge on the ankle joint. So, It can help to keep the subtalar joint in a neutral position, thereby resulting in no pain in the ankle joint (24). In other words, due to the varus alignment of the knee and the closed chain of the human body, the ankle pronation occurs as a compensatory mechanism in the ankle joint(27). The use of the lateral wedge, despite the positive effect on the knee and reducing the force on the joint, can aggravate the ankle pronation condition which leads to pain in the ankle joint. in other words, the use of the LWI may make damage to the ankle joint by creating a severe eversion moment in the ankle (7). Based on the results of Hunt's study (27) and the present study, adding an arch support to the LWI can prevent ankle joint pain.

For functional parameter, the four subscales of the FAOS questionnaire namely joint stiffness, daily activity, exercise activity, and QoL were evaluated. In the intragroup comparison, all four parameters in the second group (LWI with arch support) did not significantly change, which show the positive effect of arch support on the LWI. In the first group (LWI), all three parameters of daily activity, sports activity, and QoL after six weeks of the intervention use compared to the first day were significantly increased which indicate the negative effectiveness of this intervention.

According to a study by Esco *et al.*, adding an arch support to the lateral wedge and wearing it in shoes on average 7.75

months improved pain, knee joint function, and QoL in individuals with medial KOA and patients expressed 40% more in the symptoms improvement of KOA than the LWI in isolation(28). Also, the same results were mentioned in Jones' study (29).

Because of the pain improvement which is a factor affecting on the level of QoL and function(30), It can be said that according to the results of previous studies (24, 31) and the present study, improving pain by using LWI combined with longitudinal arch support is one of the main and effective reasons for improving a person's function. However, the pain reduction did not reach a significant difference in the present study. Moreover, the effectiveness of LWI in isolation did not significantly make the ankle joint stiffness worse. Summarizing the results of the present study, it can be stated that LWI combined with a longitudinal arch support can apply a positive effect on both the ankle and knee joints of people with medial KOA.

This work was performed with a few sample sizes and just 6 weeks of follow-up. Also, the comparison of different types of insoles including different amount of wedge insole angulation and various materials was not performed and it should be investigated in a future study.

Conclusion

A LWI can improve function and pain in knee joint based on the literature, but it may have a negative effect on ankle joint in patients who experienced pain and function limitation in this joint. Since adding a longitudinal arch support to the lateral wedge caused a pressure reduction on the ankle, patients report no pain or function limitations on the ankle by using LWI combined with an arch support. Therefore, it seems the simultaneous use of the arch support and the lateral wedge is a proper type of insole for individuals with medial knee OA.

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