The Effects of Various Kinds of Lateral Wedge Insoles on Performance of Individuals with Knee Joint Osteoarthritis

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ABSTRACT

Background: Knee joint osteoarthritis (OA) is one of the most incapacitating diseases affecting older population, which is associated with pain and functional limitation. Various kinds of conservative treatment have been used to decrease knee pain and to improve the quality of life of the subjects suffering from this disease. There are discrepancies in the clinical effects reported for the use of lateral wedge insole in spite of being used as one of the first conservative mechanical treatments for patients with medial compartments of knee OA.

Methods: A total of 36 subjects with medial knee compartment OA were recruited in this research project. Subjects were randomized into two groups to receive 3- and 7-mm lateral wedge insoles based on the date of birth of the participants. Some parameters such as severity of knee pain, Tibiofemoral angle (TFA), severity of OA, and quality of life were selected in this research project.

Results: The use of both 3-mm and 7-mm lateral wedge insole improves the quality of life and decreases knee joint pain. However, the effect of 7 mm lateral wedge insole was more than that of 3 mm.

Conclusion: Using lateral wedge insole is a simple, inexpensive therapy for decreasing pain and improving quality of life; however, most research must be carried out to find the effects of lateral wedge on severity of knee joint OA and aligning TFA.

Key words: Knee, lateral wedge, osteoarthritis

INTRODUCTION

Osteoarthritis (OA) is a disease influencing the body joints. In this disease, the articular surfaces of the joint are damaged and the smooth motion of the joint is disturbed. It is the most common type of arthritis affecting nearly 16 millions of Americans. More than 13% of American, aged 55 to 64 years, and more than 17% with aged 65 to 74 years have knee OA associated with pain and functional limitation. By 2020, an estimated 18.2% (59.4 million) will be affected in the United states of America. OA is claimed to cause more damage to mobility in the elderly.
than any other disease. Patients with knee OA usually demonstrate major involvement of the medial compartment, approximately 10 times more frequently than the lateral compartment.[1] The most common types of alternations include decreased knee joint excursion, altered ground reaction force applied to the knee, and altered the pattern of key lower extremity muscles involving in gait.[3-5]

Increased force may be a contributing factor in development of the progression of knee OA. The force applied to the knee joint is not transmitted equally between the medial and lateral compartments during walking. The load applied to the medial compartment is 2.5 times more than the load applied to the lateral side. In healthy subjects, between 71% and 91% of total knee force is transmitted through the medial tibiofemoral compartment compared to 100% in OA.[3,5-7]

There are various treatments to manage varus knee deformity and to align the mechanical axis of the leg. Although tibial osteotomy, valgus realignment of femorotibial angle (FTA) by wedge osteotomy at the tibia, have been used for severe medial compartment of the knee OA with varus deformity, it associates with numerous severe complications which include malunion and nonunion of the tibia, intraoperative injury to the popliteal artery and tibial nerve, vein thrombosis, and Pin-track infections.[8,9]

As a result, most clinicians attempt to use conservative treatment instead. The two most common conservative treatment for patients with OA are using various kinds of knee brace and lateral wedge insoles, which have been used to reduce knee pain, to improve the alignment and to increase the knee joint range of motion (ROM) during walking.[2,4,6,8-14] Although using a knee brace offers some benefits for the patients such as reducing the knee joint varus moment, improving the configuration of the loads applied to the knee, and decreasing pain during walking, it has some problems which include prestressing the knee joint ligament which causes chronic ligamentous laxity. Moreover, the brace has the tendency to migrate distally, as a result of muscle contraction during walking.[4,6,9,15,16] Another most popular conservative treatment for patient with knee OA is an inserted lateral wedge insole which is made of sponge rubber materials inserted into ordinary shoes.

The use of this orthosis was firstly reported by Sasaki and Yasuda to alter the mechanical alignment of the lower limb, to reduce loading in the medial compartment of the knee, and to correct the valgus inclination at the calcaneus.[9] In the research undertook by Wolfe and Brueckmann, it was reported that 82% of their patients with knee OA had some lessening of pain with an inserted insole.[17] Moreover, 61% of patients participated in the research of Keating et al., which reported some pain reduction with lateral wedge insole.[18] It was shown that 5 and 10 degrees lateral wedge insoles significantly decreased the knee varus torque in the stance phase of gait cycle and effectively reduce the load at the medial compartment of the knee.[2]

However, from the results of double blind randomized cross over trial in 90 patients with knee OA, it was defined that the effect of using lateral wedge insole was neither statistically significant nor clinically important.[19] In another research study, it was shown that it does not influence the amount of pain, stiffness, and function. It was concluded by some investigators that the use of 5 degrees valgus heel wedge did not influence the static alignment and the alignment of the knee joint during walking.

There are discrepancies in the clinical effects reported for the use of lateral wedge insole in spite of being used as one of the first conservative mechanical treatments for patients with medial compartments of knee OA. Unfortunately, conflicting results in the literature have lead to criticism of most hypotheses on the health status remaining a matter of considerable debate. The aim of this research was to evaluate the effects of two types of lateral wedge insole on the alignment of legs reducing the knee pain and improving the quality of life of subjects suffering knee OA.

**METHODS**

A total of 36 subjects (28 females and 8 males) with medial compartment of knee OA were recruited in this research project. Subjects were randomized by date of birth into two groups, with even numbered dates of birth treated with the first design (3-mm lateral wedge insole) and those having odd number dates of birth treated with the second design (7-mm lateral wedge insole). Table 1 shows the characteristics of the subjects selected...
in this research study. Subjects were evaluated as having medial compartment knee OA according to the American College of Rheumatology criteria for a diagnosis of knee OA, medial knee pain, and radiographic osteophyte at the medial joint space of the knee. They were selected according to the following criteria:
• Age more than 50 years old
• Morning stiffness lasting more than 30 minutes
• Having crepitus on motion

Patients were excluded if they had a history of congenital foot problems, surgery on the knee, and also if they were unable to stand and walk.

Orthosis: Two types of insole were prepared in this research project: 1 - Urethane wedge with elevation of 3 mm of the lateral side and 2 - Urethane wedge with elevation of 7 mm. The insoles were manufactured for each participant based on the foot print data collected from the subject in a standing position.

Parameters: The following parameters were selected in this research project:
- Femorotibial angle (FTA)
- Severity of knee OA
- Severity of the knee pain
- Body Mass Index (BMI)

It should be mentioned that the project was approved by Isfahan University of Medical Sciences ethics committee and informed consent was provided by the participants.

Procedure: Participants were asked to stand in a comfortable position on both feet and to apply nearly 50% of body weight on each foot. They stood with full knee extension 1 m far from X-ray source with arms which were positioned at 20 degrees of shoulder flexion with hand gripping an adjustable height stabilizer bar. The X-ray bar was centered on the joint space and oriented parallel to the tibial plateau. The roentgenogram was taken when the participant’s posture was stabilized. The FTA was measured as the angle formed by the axes of femur and tibia according to Yasuda and Sasaki method.

The severity of knee OA was defined by use of the Kellgren and Lawrence grade (K-L grade) based on X-ray of the knee as was described in Atlas of standard radiography. The Western Ontario McMaster questioner (WOMAC) was employed to evaluate the severity of knee pain following OA. It is a validated instrument designed especially for the assessment of lower extremity pain and function in OA of the knee and hip joints. It evaluates 17 functional activities, five pain-related activities, and two stiffness categories. It has been well known and is amongst the most sensitive of all instruments used in the assessment of OA of the knee and is widely used in clinical trials. The other parameter selected in this research study was BMI which was defined as individual body weight divided by square of his or her height (kg/m²).

According to the aforementioned procedure, the severities of the knee OA, knee pain, and Tibiofemoral angle (TFA) were evaluated in the first session of participation. The insole was manufactured for each subject based on the size collected from the foot print of the subject in a standing position. After using the insole for 2 months, the subjects were evaluated by use of the same method. The differences between the mean values of the aforementioned parameters between and within groups were used for final analysis.

Statistical analysis
The normal distribution of the parameters was evaluated by use of Shapiro-Wilk test. As the parameters had normal distribution, some parametric tests were used for final analysis. The difference between the mean values of the above mentioned parameters before and after using the lateral wedge insole (in both groups) was analyzed by use of Paired t-test. The difference between the mean values of the parameters between the first and second groups was evaluated by use of Wilcoxon test. The significant level was chosen as 0.05. The SPSS software was used for statistics analysis.

RESULTS
The mean values of The FTA, pain severity,
severity of the knee OA, and quality of life of both groups are presented in Tables 2 and 3. As can be seen, the quality of life of the participants in the first group improved after two months of orthosis usage. However, the difference between the mean values of other parameters before and two months after orthosis intervention did not change significantly. In contrast, the use of 7-mm lateral wedge improved the life quality and decreased pain severity.

At the baseline assessment, there was no significant difference between two groups in age, BMI, the FTA, KL grade (severity of OA), and pain severity, before orthosis intervention. However, after two months of orthosis usage, the severity of knee pain of the participants in the second group decreased more in contrast to that in the first group [Figure 1].

DISCUSSION

It has been found from the results of this research study that the subjects experience a significant decrease in pain, joint stiffness, and functional impairment following the use of lateral wedge insole. It has been shown that putting a wedge under the feet will alter the angle of the limb with the supporting surface. Moreover, it influences the mediolateral moment applied to the limb during walking and standing.[2,7] Based on the research done by Kerrigan et al., a reduction in knee varus torque was noted following use of lateral wedge insole compared to no wedge in the early and late stance phase.[2] Moreover, the results of the research undertaken by Kakihana et al. showed that the use of 5 degrees lateral wedge decreased knee joint moment significantly and increased subtalar joint valgus moment.[23]

During walking, the normal force acting on the leg produces a varus torque. This torque directly associated with the compressive force transmitted through the knee. This torque is believed to be responsible for progression of knee OA.[24,25] This is no research regarding the effects of increasing loads on human knee in the literature; however, it has been shown that imposing a varus force on the animal limb directly induced an OA changes.[26] As

| Parameters            | Mean value after the intervention | Mean value before the intervention | Number of subjects | P value |
|-----------------------|----------------------------------|-----------------------------------|--------------------|---------|
| Quality of life       | 45.06 ± 21.64                    | 39.89 ± 19.87                     | 18                 | 0.006   |
| Severity of pain      | 54.67 ± 19.08                    | 52.9 ± 18.27                      | 18                 | 0.13    |
| TFA                   | 175.11 ± 1.27                    | 175.33 ± 1.08                     | 18                 | 0.6     |
| Severity of OA        | 3 ± 0.48                         | 2.83 ± 0.38                       | 18                 | 0.083   |

OA: Osteoarthritis, TFA: Tibiofemoral angle

| Parameters            | Mean value after the intervention | Mean value before the intervention | Number of subjects | P value |
|-----------------------|----------------------------------|-----------------------------------|--------------------|---------|
| Quality of life       | 57.4 ± 19.6                      | 41.19 ± 18.04                     | 18                 | \( P<0.0001 \) |
| Severity of pain      | 72.2 ± 20.05                     | 52.98 ± 19.86                     | 18                 | \( P<0.0001 \) |
| TFA                   | 175.11 ± 0.83                    | 175.71 ± 0.89                     | 18                 | 0.04    |
| Severity of OA        | 2.88 ± 0.47                      | 2.77 ± 0.42                       | 18                 | 0.163   |

OA: Osteoarthritis, TFA: Tibiofemoral angle
the mediolateral moment in the patients with knee OA increases in contrast to that in normal subjects, reduction in joint moment may be the main reason for improving the quality of life and decreasing the severity of pain.\cite{2,6,7} So, the decrease in pain following the use of lateral wedge insole is related to decrease of the mediolateral moment and applied force.

The effects of using 7-mm lateral wedge insole on pain relief and improving the quality of life in the patients was more than that following the use of 3-mm lateral wedge insole. Using lateral wedge insole shifts the location of applied loads lateral to subtalar joint axis in most patients and finally transfers the Centre of Pressure (COP) to the lateral part of the knee joint. It has been shown that shifting the body weight from one side of foot to other side by use of lateral wedge will reduce pain in the knee.\cite{9} As movement of talus may prevent calcaneus valgus correction and shifting the body weight, the effects of 3-mm lateral wedge is less than that of 7-mm one.\cite{27,28} Kerigan et al. first described the correlation between increased angulation of the insole and pain relief,\cite{3} but Fang et al. found that the use of simple 4 degrees lateral wedge also decreases the pain associated with knee OA and improves the performance of the subjects in daily activities.\cite{29} Although the use of 7-mm lateral wedge did not provide any significant problems for the users in this research study, increasing the thickness of the insole more than that may have a subsequent compliant for foot discomfort. Moreover, the subjects have to select a shoe which is one size longer than they commonly wear.\cite{28}

Although some research highlighted that the use of lateral wedge does not alter the lower limb significantly and not improve the quality of life,\cite{9,27} the results of this study approved that participants’ quality life improved following the use of both 3-mm and 7-mm lateral wedge insoles. It can be concluded that decreasing the pain associated with knee OA is the main reason for improving the quality of life.

TFA was the other parameter selected in this research study. Using 3-mm lateral wedge insole did not influence TFA angle significantly; however, the use of lateral wedge with 7-mm lateral thickness had a significant influence on this angle. According to the results of various research studies, using lateral wedge insole dose not affect the TFA significantly.\cite{27,28} It was concluded that the effects of the insole was diminished in the subtalar joint and increases the valgus angulations of this joint.

Several strategies have been employed in an attempt to delay the structural progression of OA, as characterized by narrowing of radiograph joint space width. It was shown in some research studies that the use of lateral wedge insole induces a significant delay in progression of OA severity by reducing the loads applied to the compartment during walking.\cite{30} However, the results of this research did not support this assumption. Although the difference between the severity of OA before and after orthotic intervention was not significant, the progression of OA in the second group (7-mm) was less than that in the first group. It is difficult to have a strong conclusion in this regard since there is no control group in this research. Difference in outcome measure results suggest a variety of factors which may interact with the use of lateral wedge insole in this population.

**CONCLUSION**

Using lateral wedge insole is a simple, inexpensive therapy for treatment of pain and improving the quality of life for the patients suffering from knee OA. Studies have produced inconsistent results regarding lateral wedge insole. While some studies have concluded that lateral wedge insole has no significant effects on OA pain and progression, the results of this research studies highlighted that the use of 3- and 7-mm lateral wedge insoles had a significant effect on severity of pain and improving the quality of life. However, most research must be carried out to find the effects of lateral wedge on severity of OA and TFA.

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