Effect of Lateral-Wedge Shoe Insoles on Pain and Function in Patients with Knee Osteoarthritis

Diz Osteoartriti Olan Hastalarda Lateral Kamalı Tabanlık Kullanımının Ağrı ve Fonksiyon Üzerine Etkisi

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Summary

Objective: We aimed to assess the effect of 6 mm lateral-wedge insole on both pain and function in women with clinically and radiologically documented knee osteoarthritis (OA) compared to patients using no insole.
Materials and Methods: Thirty seven women with unilateral knee pain, who were diagnosed with knee OA grade II and III according to the radiographic criteria of Kellegren Lawrence grading system, were included in the study. The patients randomized into either treated with exercise and analgesic plus 6 mm wedge insole (19 patients) or only with analgesics and exercise (18 patients). Pain while walking, standing and at rest was recorded on a 100 mm Visual Analogue Scale (VAS), pain with passive motion was evaluated by Doyle's Ritchie Index, and functional status was evaluated by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at baseline, 1st month and 3rd month visits.
Results: At the 3rd month visit, the ratio of patients with improvement according to the Ritchie Index score was higher in the group using 6 mm wedge insole compared to group using no insole (p=0.008). The patients using 6 mm wedge insole had significant improvement in WOMAC pain subscale (p=0.003) and total WOMAC (p=0.01) scores at the 1st month visit and VAS at rest (p=0.03), standing (p=0.02), walking (p=0.01), total WOMAC (p=0.001), and all subscales of WOMAC (except WOMAC stiffness score) at the 3rd month visit compared to group using no insole.
Conclusion: 6 mm lateral wedge insole significantly reduces pain while walking, standing, at rest and with passive movement of the knee in patients with grade II and III knee osteoarthritis. At the end of the 3rd month, besides pain reduction, significant improvement in function was observed in patients using wedge insole compared to patients treated only with analgesics and exercises. *Turk J Phys Med Rehab 2009;55:158-62.*
Key Words: Knee osteoarthritis, lateral-wedge insole

Özet

Amaç: Klinik ve radyolojik olarak diz osteoartriti tanısı olan kadın hastalarda lateral topuk kaması kullanımının ağrı ve fonksiyon üzerine etkilerini araştırmayı amaçladık.
Gereç ve Yöntem: Unilateral diz ağrısı olan ve Kellegren Lawrence radyolojik evrelemesine göre evre II ve III diz osteoartriti olan olan 37 kadın hasta çalışmaya dahil edildi. Hastalar egzersiz ve analjezik ile beraber 6 mm topuk kaması kullananlar (19 hasta) ve sadece egzersiz ve analjezik kullananlar (18 hasta) şeklinde iki gruba randomize edildi. Yürürken, ayakda dururken ve dinlenirken oluşan ağrı şiddeti Visual Analog Skala (VAS) ile belirlendi. Pasif hareket ile oluşan ağrı şiddeti Doyle'un Ritche indeksi ile ve fonksiyonel durum Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) ile değerlendirildi. Değerlendirmeler başlangıçta, 1. ay ve 3. ay visitlerinde gerçekleştirildi.
Bulgular: Ritche indeksi skorunda düzelme gösteren hastaların oranı 6 mm topuk kaması kullanan hastalarda kullanmayanlara göre 3. ayın sonunda anlamlı olarak daha fazlaydı (p=0,008). WOMAC ağrı (p=0,003) ve total WOMAC skorları (p=0,01) 1. ayın sonunda; istirahatte (p=0,03), ayakda durma (p=0,02) ve yürürken (p=0,01) VAS, total WOMAC (p=0,001) ve tüm eklem sertliği dışında tüm WOMAC alt parametreleri 3. ayın sonunda diğer gruba kıyasla 6 mm kama kullanan hastalarda anlamlı olarak düzelme gösterdi (p<0,05).
Sonuç: Evre II ve III gonartrozu olan kadın hastalarda 6 mm lateral topuk kaması kullanımı yürürken, ayakda dururken, dinlenirken ve pasif hareket sırasında olan ağrıyı anlamlı olarak azaltır. Ağrı azalmasının yanısıra 3. ayın sonunda, kama kullananlarda sadece egzersiz ve analjezik kullananlara göre anlamlı fonksiyonel düzelme gözlenir. *Türk Fiz Tıp Rehab Derg 2009;55:158-62.*
Anahtar Kelimeler: Diz osteoartriti, lateral kamalı tabanlık

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Introduction

Osteoarthritis (OA) of the knee is a common medical problem which is a potentially disabilling disease. OA typically affects the knee joint in a nonuniform manner; the medial compartment of the knee is the most frequently affected (1). The involvement of medial compartment is 10 times more frequent than that of the lateral (2). The predominance of varus moments and high medial compartment forces are thought to be responsible for the greater incidence of OA in this compartment during-weight bearing activities (3,4). Conservative treatments include braces unloading the weight from the medial compartment and wedged insoles, used for relieving pain and improving function in OA (5).

Sasaki and Yasuda (6) first reported significant pain relief in patients with knee OA using laterally wedged insoles. They also attempted to determine the mechanism of wedged insoles in reducing pain and concluded that the improved knee joint alligment with a 50 lateral-wedge insole reduces the load on the medial compartment (7).

Wolfe and Brueckmann (8), as well as also Tohyama (9) also reported pain reduction in patients treated with lateral-wedge insole+analgesics compared to those treated with analgesics alone.

We aimed to assess the effect of 6 mm lateral-wedge insoles on both pain and function in patients with clinically and radiologically documented knee OA compared to patients using no insole.

Materials and Methods

Thirty seven women with 37 painful knees who attended the physical medicine and rehabilitation (PMR) clinic were admitted to the study. The patients were diagnosed with knee OA according to ACR criteria (10) and classified as grade II and III according to the Kellgren Lawrence radiologic grading. Exclusion criteria were: presence of knee flexion contracture, instability, hip and ankle pathologhy, involvement of the lateral compartment of the knee, history of knee surgery, signs of meniscopathy at physical examination, infective or inflammatory pathologies of knee, presence of trauma, intraarticular injection within 6 months and physical therapy within 1 year. The study was approved by the appropriate ethics committee related to our hospital in which it was performed and the all subjects gave written informed consent.

Laboratory analysis of serum erythrocyte sedimentation rate, C-reactive protein, rheumatoid factor and other routine biochemical analysis were performed. Kellgren Lawrence radiologic grading was done according to the anteroposterior and lateral radiographies of the patients in standing position (11).

Demographic and clinical data were obtained from the patients who attended the study. The patients sequentially randomized into 2 therapy groups. No insole group, consisted of 18 knees, was treated with parecetamol 1500 mg/day and quadriceps strengthening exercises for 3 months. Second group, consisted of 19 knees, used 6 mm wedge insole all day long in addition to the therapy prescribed for the no insole group. The outside height of the insole was 6 mm, so the sagittal axis of the posterior part of the calcaneus was tilted laterally at 5^{o} to the floor. Primary outcome measures were pain while walking and standing and at rest during the previous 24 hour, recorded on a 100 mm Visual Analogue Scale (VAS) and pain or tenderness, produced under firm digital pressure and with movement of the affected knee, scored according to Doyle's Ritchie Index on a 4-point scale (0=no tenderness, 1=patient complained of pain, 2=patient complained of pain and winced, 3=pain, wincing leading to withdrawal) (12,13).

The patients completed the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (14) for pain and functional evaluation at baseline, 1st month and 3rd month visits.

Wilcoxon Signed Rank Test is used to compare outcome parameters within groups. Ratio of patients who improved in Ritchie Index was compared by chi-square test. Improvement in pain and WOMAC scores of groups were compared by Mann-Whitney U test.

Results

Thirty-seven women admitted to the study had a mean age of 55.11±10.34 years. 21.6% of patients were classified as grade II and 78.4% as grade III according to the Kellgren Lawrence radiologic grading. Mean age, weight and body mass index and affected side of the groups were compared and no statistically significant difference was found between the groups. In addition, baseline Ritchie index, VAS score at rest, walking and at standing position, and total WOMAC scores of the patients were not statistically different between the groups (Table 1).

The mean Ritchie index scores of the groups were not improved at the 1st month visit, but statistically significant improvement was found at the 3rd month visit in the group using 6 mm wedge insole compared to the baseline values (p=0.011) (Table 3 and 4). The ratio of patients with improvement in the Ritchie Index scores at the 3rd month visit was higher in the group using 6 mm wedge insole to no insole group (p=0.008) (Table 2).

At the end of 1st month, the patients using 6 mm wedge insole improved in VAS at rest and standing, WOMAC pain and function subcales and total WOMAC score, while the patients in no insole group had no improvement in all outcome parameters compared to the baseline values. When the two groups were compared, the patients using 6 mm wedge insole had statistically significant improvement in WOMAC pain subscale (p=0.003) and total WOMAC (p=0.01) scores compared to the patients in no insole group (Table 3).

At the end of 3rd month the patients using 6mm wedge insole improved in VAS at rest, walking and standing position and total WOMAC and all subscales of WOMAC, except stiffness scores, compared to the baseline values ($p<0.05$), while the patients in no insole group had no improvement in all outcome parameters ($p<0.05$). The patients using 6 mm wedge insole had statistically significant improvement in VAS at rest (p=0.03), standing (p=0.02), walking (p=0.01), total WOMAC (p=0.001) and all subscales of WOMAC (except WOMAC stiffness score) when compared to no insole group (Table 4).

Discussion

This is a randomised controlled trial, comparing the effect of 6 mm wedge insole on pain and function, used as a conservative therapy for unicompartmental OA of the knee. The study was constructed on the hipothesis that use of a lateral-wedge insole

can reduce the high forces on medial compartment, which can provide relief of pain and subsequently improvement of function. The wedges with different heights was compared by Kerrigan et al. (1) and showed that both 5° and 10° (slightly greater) wedged insole reduced the knee varus torques during walking to a greater extend than the control insole and no in sole group, however, the smaller wedge found to be more confortable in patients with medial knee OA. So, we decided to investigate the effect of 5° (6 mm) lateral-wedge insole on pain and function in medial knee OA.

In this study, pain at daily activities, at rest and especially with passive movement of the knee was reduced significantly in patients using 6 mm lateral-wedge insole. At the end of the 3rd month, WOMAC scores were also improved in patients using 6 mm wedged insole compared to the control group.

Some other studies also suggested the clinical success of wedge insoles in the management of unicompartmental OA of the knee. If the calcaneus was tilted 5°-10° laterally by a wedged insole, a significant relief of pain was observed in the patients using wedged insole (6-10).

Some of these studies were long-term follow-up studies, such as Tohyama (9), who reported that 62 patients treated with analgesics and wedged insole tilted 5°–10° laterally showed significantly greater improvement in pain and walking scores than those treated with analgesics alone in a follow-up study for 7 years and 5 months to 12 years.

In an uncontrolled study, Wolfe and Brueckman (8) showed that 45% of the patients had their moderate pain reduced to no pain at all; and 37% had severe pain, which was reduced to mild pain or no pain at all by using heel wedges for 1 week. Most (80%) of the patients continued using their wedges due to pain relief and inceased ability, but still continued medication, while 20% discontinued medication still experienced pain relief. Sixty-nine percent of them defined increase in pain and decrease in ability when they stopped wearing the wedges.

Sasaki (6) reported that wedged insoles were effective in the management of the knee OA, thus half of the patients who used 5° customized orthotic wedges had a decrease in pain and increased walking ability. In this study 64.7% of the patients discontinued orthotic wedges use as a result of pain relief in one-third of the cases.

Brington (15) aimed to find out the effect of lateral heel wedges of 6.35 mm and lateral sole elevation of 4.76 cm in 85 patients with medial knee OA of the knee. They showed improvement in the average pain scores of the patients evaluated by the Hospital for Special Surgery knee scoring system; fifty percent of patients improved to a score coresponding to a good and 38% of them improved to an excellent arthroplasty result at the end of a follow up period ranged 4 to 24 months. Absence of the control group, role of competing interventions was the limitation of the study.

Özgül et al. (16) reported that usage of 6 mm of heel wedges for 3 months resulted in statistically significant improvement of VAS values (mean: 2.36) and increase in the medial joint space obtained from stress X-rays in patients with knee OA.

Table 1. Baseline evaluation of both groups.

	NSAID+exercise+6 mm wedge insole group	NSAID+exercises	P value
Age (year)	55.36+11.50	54.83+9.27	0.893
Effected side (L/R)	11/8	9/9	0.630
Stage 2/3	4/15	4/14	0.621
Height (cm)	161.4+4,40	157.5+4.54	0.009*
Weight (kg)	76.68+12.25	77.50+6.93	0.343
BMI (kg/cm^2)	31.33+3.44	29.64+4.79	0.110
Mean Rich İndex score	1.68+0.67	1.72+0.66	0.869
Pain at rest (VAS)	3.57+2.50	4.00+2.84	0.578
Pain at standing (VAS)	4.47+2.58	4.88+2.02	0.707
Pain at walking (VAS)	6.57+2.03	7.00+1.71	0.443
Womac pain score	16.36+3.91	17.50+4.21	0.313
Womac function score	52.68+14.56	60.27+13.52	0.118
Womac stiffness score	4.84+2.03	5.72+2.37	0.221
Total Womac score	59.89+25.25	80.55+24.70	0.134

Table 2. The number of patients classified according to Ritchie index scores in groups at baseline, 1st month and 3rd month visits.

	Number of patients in NSAII+exercise group / 6 mm wedge group		
Ritchie index score	Baseline	1st month	3rd month
(0) no tenderness	0/0	0/2	0/2
(1) pain without wincing	7/8	8/7	7/10
(2) pain with wincing	9/9	8/7	9/7
(3) pain leading to withdrawal	2/2	2/3	2/0
Ritche index (higher or not changed/lower)	- -	(17/1)/(15/4) P=0.128	(17/1)/(10/9) P=0.008*

Maillefert et al. (17) also reported that no clinical differences were evident among the patients using laterally wedged insoles and neutrally wedged insoles evaluated by WOMAC subscales at 6 months, and that the medication consumption was lower and compliance was higher in patients with the laterally wedged insoles. In addition, in this study, the patern of osteoarthritic damage at the knees was not consistent between the groups, where twice as many subjects in the active intervention had grade IV lesions compared the control group. In a more recent study which examined the effect of laterally wedged insole on pain compared to neutral insole, no statistically significant difference was observed between the groups (18).

In studies of Toda (19,20) the effect of a lateral-wedge insole with subtalar stapping on VAS scores, femorotibial angle and Lequesne Index scores was significantly better compared to inshoe lateral-wedge insole in patients with varus deformity OA of the knee. These differences in these parameters were not seen in the participants wearing a traditional lateral-wedge insole or the sock-type orthesis with lateral heel wedge insert, which implicates that the subtalar strapping causes the joint realignment and reduces the pain (21,22).

Although our study assessed the effect of wedged insole in small number of patients and within a relatively short period of time, we found significant improvement in pain and function in grade II and III knee OA patients using 6 mm wedged insole. Our results were consistant with the literature suggesting the effectiveness of lateral-wedge insole usage on pain and function as a conservative method in medial knee OA patients, especially in early and moderate disease.

Table 3. Comparition of improvement within and between groups in pain and WOMAC scores at 1st month visit.

	NSAID+exercise (baseline/1st month)	**NSAID+exercise+6 mm wedge insole(baseline/1st month)**	**P values**
Mean Ritche index score	1.72+0.66/1.66+0.685 P=0.317	1.68+0.67/1.57+0.90 P=0.480	0.599
VAS at rest	4.11+3.03/4.00+2.84 P=0.157	3.57+2.50/2.78+2.29 P=0.010*	0.092
VAS at walking	7.00+1.71/6.77+1.80 P=0.46	6.57+2.03/6.15+2.47 P=0.172	0.663
VAS at standing	4.88+2.02/4.88+1.84 P=1.00	4.47+2.59/3.95+2.24 P=0.008*	0.046
WOMAC pain score	17.50+4.21/17.61+4.27 P=0.593	16.36+3.91/14.47+4.47 P=0.005*	0.003*
WOMAC stiffness score	5.72+2.37/5.77+2.26 P=0.705	4.84+2.03/4.36+2.06 P=0.086	0.408
WOMAC function score	60.27+13.52/58.11+14.82 P=0.240	52.68+14.56/48.05+15.02 P=0.006*	0.086
Total WOMAC score	80.55+24.71/82.05+20.76 P=0.814	59.89+25.25/66.89+20.36 P=0.001*	0.011*

Table 4. Comparition of improvement within and between groups in pain and WOMAC scores at 3rd month visit.

	NSAID+exercise (baseline/3rd month)	**NSAID+exercise+6 mm wedge insole (baseline/3rd month)**	**P values**
Mean Ritche index scores	1.72+0.66/1.72+0.67 P=1.00	1.68+0.67/1.26+0.65 P=0.011	0.039*
VAS at rest	4.11+3.03/4.06+2.81 P=0.564	3.57+2.50/2.78+1.93 P=0.037*	0.030*
VAS at walking	7.00+1.71/6.83+1.91 P=0.257	6.57+2.03/5.15+2.65 P=0.006*	0.010*
VAS at standing	4.88+2.02/5.00+2.03 P=0.527	4.47+2.59/3.84+2.29 P=0.024*	0.017*
WOMAC pain score	17.50+4.21/17.33+4.15 P=0.521	16.36+3.91/13.31+4.44 P=0.003*	0.002*
WOMAC stiffness score	5.72+2.37/5.72+2.29 P=0.903	4.84+2.03/3.84+1.89 P=0.031	0.061
WOMAC function score	60.27+13.52/57.94+13.98 P=0.146	52.68+14.56/46.16+15.18 P=0.001*	0.004*
Total WOMAC score	83.50+19.11/81.00+19.60 P=0.241	73.89+19.69/63.32+19.77 P=0.001*	0.012*

However, in 2005 Cochrane database analysis only three controlled trials included had conflicting results. It was also noted that there was a silver level of evidence for the effectiveness of a foot/ankle orthosis for medial compartment OA. Maillefert (17) described a significant decrease of NSAID intake and a higher degree of compliance with a wedged insole compared to neutral insole, but the WOMAC pain was more decreased in the neutral group at 6 months and at 2 years of follow up. Moreover, Toda reported no significant VAS pain reduction with a traditional wedged insole (19).

The controversy between studies thought to be as a result of different methodologies and patient selection criteria. It was shown that when the effect of the wedged insole was considered according to the radiologic stage, a significant improvement in pain as well as walking ability was observed for those patients in radiographic disease stages I-III, but not for those in stage IV (6).

Conclusion

These results supported the hypothesis that a 6 mm lateral wedge insole significantly reduces pain while walking, standing, at rest and with passive movement of the knee in patients with grade II and III knee osteoarthritis. At the end of the 3rd month, besides the pain reduction, significant improvement in function was also observed in patients using wedge insole compared to patients treated only with analgesics and exercises.

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