

Original Article

The Effects of Unloader Knee Orthosis and Lateral Wedge Insole in Patients with Mild and Moderate Knee Osteoarthritis (OA)

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Objective: Patients suffering from mild to moderate knee osteoarthritis may be treated with unloader knee orthoses or laterally wedged insoles. This study aimed to identify and compare the effects of two orthoses in these patients.

Methods: 56 patients with medial compartment knee OA were evaluated when wearing an unloader knee orthosis and insoles with a 6° lateral wedge which were randomly assigned. Testing was performed at baseline and after 6 months of use with the two types of orthoses. The KOOS score was used to assess outcomes in this study. A paired T test was used for comparing base line and the 6th month post interventions KOOS sub scale score. An independent T test was used for analyzing the efficacy between the two orthoses.

Results: Each of the interventions improved all the parameters comparing to the baseline condition (P=0.000). However, in comparing the effect between these orthoses, we did not find significant differences in activities of daily living (P=0.871), or sports and recreational activities (P=0.351). The pain and symptoms (P=0.000) were, however, significantly different between the two interventions.

Conclusion: The unloader knee orthoses were more effective than lateral wedge insoles in reducing pain and symptoms.

Keywords: knee osteoarthritis, conservative treatment, knee unloader orthoses, lateral wedges

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Introduction

Knee osteoarthritis (OA) is the most common type of arthritis, especially in the elderly population (1, 2). Pain and reduced activity in OA causes functional defects, disabilities and reduction in the quality of life (3, 4). Long term disabilities lead to decreased mobility and reduced independence of the individual, plus difficulty in both daily living activities and recreational and sports activities (3).

The prevalence of medial compartment osteoarthritis is 10% higher than that of lateral compartment osteoarthritis, because 62% of the weight line passes through the medial side (5). Initially there is a tendency to a varus deformity, followed by an increase in the adduction moment in the knee during gait and reduced joint space in the medial compartment (4, 6, 7). The incidence of this complication in the United States of America population was reported in 2003 to be approximately 20 million people and was predicted to reach 40

million in 2020 (8). The potential consequences of medial compartment knee OA is therefore a considerable burden for individuals and society; because of the costs of the related interventions and treatments (9).

The overall goals of conservative treatment in osteoarthritis are to reduce pain, improve function and reduce disease progression rates (10). Application of knee unloader orthoses and the use of lateral wedges to inlays are current conservative procedures used in the treatment of this complication (10). These approaches aim to create corrective forces to reduce the varus forces acting on the medial side of the knee (11).

Cross over studies have previously demonstrated that valgus braces improve confidence during walking and also aid in the ability to push off (11), and that custom made patient-adjustable knee braces improve function, stiffness, varus angulation and reduce medial compartment loading of knee (12).

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One cross-sectional study suggested that valgus braces immediately improved the function of the patient with unicompartamental osteoarthritis of the knee (13). A randomized clinical trial by Kirkley et al also showed that unloader knee orthoses were effective in improving quality of life and function in knee OA patients (7).

In comparison with another types of knee orthoses, knee unloader orthoses have been shown to provide a more successful effect (12, 14, 15). However, knee orthoses have many disadvantages, because using them requires upper limb strength, they are more expensive than insoles, they may cause skin sensitivity, and also reduce knee flexion and foot clearance during walking in patients with knee OA (7, 16).

Another alternative method in realignment of weight bearing load through the knee is the use of footwear modifications. The lateral wedge insole has been suggested for conservative treatment of mild knee OA. Kerrigan et al (17), in a cross over study, reported that lateral wedged insoles with 5° and 10° inclines were effective in reducing the varus torque at the knee during walking. A prospective quasi-experimental study for the effectiveness of lateral wedge insoles has also shown that this approach is effective in improving symptoms in medial compartment knee OA (18). Shimada et al (19), and Hinman et al both reported positive effects of lateral wedge insole use in reduction of the adduction moment in knee OA subjects. An added advantage of this type of orthotic intervention is that it is more economical than a sophisticated knee or thosis (18, 20).

However, few objective comparative studies exist which have compared knee or thoses to lateral wedged insoles by studying their effect on clinical parameters such as pain, daily living activities, recreational and sport functions and quality of life. One randomized controlled trial has shown that both orthoses decreased clinical parameters when compared to baseline, but did not report any differences between them in effecting pain, stiffness and function as measured by WOMAC (21). Due to their low cost and user-friendly design, laterally wedged insoles are thought to be a alternative option for the treatment of symptoms with medial compartment knee OA (18, 20). The aim of this study was therefore to identify and compare the effects of lateral wedge insoles to that of custom moulded unloader knee orthoses on the pain, daily living activities, recreational and sport function and quality of life in symptomatic individuals with medial compartment knee osteoarthritis.

Method

Subjects - Fifty six individuals (mean age 60.10 years, body mass index 27.74kg/m²) participated in this quasi-experimental study. Eighty three subjects were referred to the orthotics & prosthetics clinic of University of Social Welfare and Rehabilitation Sciences. The sample selection was based on non-probability judgment sampling. Referred subjects were assigned to participate in this study according to the following inclusion and exclusion criteria. Inclusion criteria included: pain in one or both knees, grade 1 or 2 of knee osteoarthritis according to the Kellgren/Lawrence Scale (range 0-4) (22). Subjects who had received knee arthroscopic surgery in the past 6 months, suffered from knee trauma or amputation of a lower limb, neurological disease, a symptomatic spine, hip, ankle or foot disease, any intra-articular steroid injections in the past 3 months, hyaluronic acid injection in the last 9 months, any previous tibial fractures, skin disease, peripheral vascular disease, blindness, any severe cardio vascular defect or an inability to apply a brace (e.g. due to arthritis in the hand or difficulty in bending) were excluded from study. Selected patients were assigned randomly to two groups of intervention (lateral wedge insoles or unloader knee orthoses). Subjects wore lateral wedge insoles or knee orthoses on the affected side. The subjects with bilateral knee pain wore lateral wedge insoles or knee orthoses bilaterally. Subject characteristics are reported in table 1. The Ethical committee of University of Social Welfare and Rehabilitation Sciences approved the performance of this study.

Description of insoles and knee unloader orthoses - Lateral wedge insoles were prepared from cork composite (Thermocork™) (Etrex Worldwide, Inc, Teaneck, New Jersey) with a density of 60 durometers which have high resistance to compressive deformation. The insoles were constructed with a medio-lateral elevation of 10 mm along the entire lateral length of the foot, which produced a 6° lateral wedge. A previous investigation has demonstrated that elevations greater than this are uncomfortable when worn (17). The lateral wedge insoles were cut to fit to subjects' shoes and were placed under the removable insert of the shoes. In subjects with unilateral knee osteoarthritis, a lateral wedge insole was used for affected side and a neutral -wedge insole with 0° medio-lateral incline was used on non-affected side. To control the effect of the lateral wedge insole and knee orthosis, subjects were fitted with a comfortable,

lightweight pair of shoes (Iran melli shoe) with a 1inch heel height.

The other group of subjects used knee unloader braces, which comprised of a bilateral side bar design. The knee unloader orthoses were custom moulded and individually constructed from a cast of each subject's lower extremity. All orthoses construction was performed by an experienced orthotist. This orthoses included thigh and calf polypropylene shells connected by orthotic knee joints to apply the three-point pressure principle for correction, and which extended proximally and distally to the knee so as to cover 2/3 of the femur and tibia length. This was done to provide suitably long lever arms for varus control within the orthoses in preference to off-the-shelf devices. At the beginning of the intervention, the brace adjustment was tailored for each subject according to his or her individual requirements. The valgus angle was set at a position which was both comfortable and acceptable for the patient (21,23). Patients subsequently attended on a monthly basis to adjust the orthosis fit.

Procedures - The baseline assessment included the KOOS, (Persian version (24)), which is a validated and disease-specific questionnaire that separately evaluates the severity of pain (9 questions), symptoms of the disease (7 questions), daily living activities (17 questions), sports and recreational activities (5questions), quality of life associated with knee problems (4 questions) plus assessment of joint pain and symptoms of the affected knee/s. Scores are

transformed to a 0-100 scale, with zero representing extreme knee problems and 100 representing no knee problems as commonly seen in orthopaedic scales and generic measures. Scores between 0 and 100 show the percentage of total possible score achieved. In assessing daily living activities, sports and recreational activities and quality of life, all subjects were asked to consider both knees. They also were asked to use orthosis while they were awake for activities that had been troublesome to them in the past. The assessment performed at the end of 6 month included use of the intervention and the KOOS assessment.

Data analysis - The differences between the 6 month post-intervention and the baseline KOOS sub-scale and total score were calculated. Changes were considered for subjects by calculating the means and SDs for each KOOS sub scale at baseline and at 6 months post- intervention. Due to the normality of data, a paired T test was used for comparing baseline and the 6th month post intervention KOOS sub scale scores. An Independent T test was used for analyzing the efficacy between two orthoses. SPSS statistical software was used for analysis of data. The level of significance was set at 0.05.

Results

There were no significant differences in mean of age, sex, BMI, and knee osteoarthritis grade between groups in baseline (table 1). All parameters were uniform among groups.

Table 1. Subject characteristics at baseline (N=56)

	Insole with lateral wedge Group	Unloader Knee brace Group	P-value
Number of subject	28	28	
Age	60.66+-2.8725	59.55+-3.0135	0.543
Sex (Female)	46.4%	57.1%	0.422
Body Mass Index (kg/m ²)	27.82+-3.0547	27.67+-3.409	0.621
	Index knee		0.369
Right	46.4%	35.7%	
Left	25.0%	42.9%	
Bilateral	28.6%	21.4%	
	Kellgren/Lawrence Grade (22)		0.342
1	39.3%	46.4%	
2	60.7%	53.6%	

When comparing the change between baseline and 6th months post intervention, we found the KOOS sub-scale score significantly improved (p=0.000) for both test conditions. When comparing knee orthoses and lateral wedge insoles in the sub-scales, there were no significant differences in the activity of daily living (P=0.871), or sports and recreational

activities (P=0.351) noted. However, in the pain, symptoms and quality of life sub-scales the differences were significant (p=0.000). The knee orthoses had a greater effect on the pain and symptoms sub- scales than the lateral wedges, but in the quality of life sub-scale the lateral wedge insoles were more effective than the knee orthosis (table 2).

Table 2: Mean (SD) of variables in OA patients in baseline and post intervention according to the Knee injury and osteoarthritis outcome score (KOOS)

	Insole with lateral wedge Group			Unloader Knee brace Group			P ₃
	Baseline	Post intervention	P ₁	Baseline	Post intervention	P ₂	
pain	39.66 (3.47970)	69.41 (3.09006)	0.000	47.41 (7.1962)	76.43 (4.99689)	0.000	0.000
Symptoms & Stiffness	29.44 (2.21290)	58.24 (6.06714)	0.000	45.00 (5.368)	66.47 (7.45446)	0.000	0.000
Daily living activities	59.49 (5.57685)	80.66 (4.54927)	0.000	39.95 (3.1580)	80.45 (5.1779)	0.000	0.871
sports and recreational activities	21.46 (2.365)	56.00 (5.670)	0.000	26.86 (3.493)	57.25 (4.169)	0.000	0.351
Quality of Life	58.21 (5.86292)	82.18 (4.16423)	0.000	56.90 (3.8693)	72.13 (5.94633)	0.000	0.000

P₁: comparison of the means between baseline and post intervention in the Insole with lateral wedge group;

P₂: comparison of the means between baseline and post intervention in the unloader Knee brace group;

P₃: comparison of the means between Insole with lateral wedge group and unloader Knee brace group.

Discussion

The question we asked was whether lateral wedged insoles, when compared to knee unloader orthoses, would have the same result in improvement of KOOS sub-scales. Lateral wedged insoles and knee unloader orthoses are both current conservative approaches in treating symptomatic medial compartment knee OA. The results of our study showed significant decreases in pain, and increases in daily living activities, recreational and sport function and quality of life as compared to baseline when using either intervention. However, the knee unloader orthoses were more effective than lateral wedge insoles in reducing pain levels. When considering symptoms and the value of the quality of life KOOS sub-scales, the lateral wedge insoles were more effective than the knee unloader orthoses. One other consideration is that patients with knee osteoarthritis have previously found knee brace treatment difficult to tolerate, because of skin irritation and poor orthosis fit (7, 12, 15, 16). Lateral wedge insoles are safe and more cost-effective than knee orthoses and also easier to use (18, 20). The results of this study therefore demonstrated that clinicians can chose with confidence between these two orthotic interventions when treating mild to moderate medial compartment knee OA.

Schmalz et al (23) and Harrington et al (25) observed that the adduction moment in individuals with medial compartment knee OA causes knee loading pattern changes during walking. Pollo et al (26) reported that a reduced adduction moment acting on the knee joint may be due to decreased pain. They reported that the adduction moment was reduced by 20% to 25% when subjects suffering from medial compartment knee OA used knee unloader orthoses. It therefore supposes that the knee orthoses used in this study applied a corrective

force to the knee joint. Enhanced proprioception that can occur when wearing a knee orthosis is another factor in the improvement of knee pain (27). Birmingham et al reported proprioception was significantly improved following application of a custom-fitted knee valgus brace on patients who had varus alignment and OA of the medial knee compartment (28). Ramsey et al (15) suggested that increasing the co-contraction of vastus medialis-medial hamstring and vastus lateralis which occurred when wearing knee unloader orthoses, could improve pain in the medial compartment knee OA. Kirkley et al (7) reported that when comparing use of knee unloader orthoses to a non-braced control group, the WOMAC pain sub-scale score improved with an unloader knee brace.

Barnes et al announced that the application of a knee orthosis reduced pain and an improvement in performing activities of daily living and quality of life (29). Lindenfeld and colleagues also demonstrated a reduction in pain scores, with functional scores during activities of daily living and sport activity increasing when patients wore a brace (30). Finger and Paulos reported that resting pain, night pain and pain during activities of daily living reduced after 3 months of brace use (31). In a crossover study, Draganich et al, reported subjects experienced improvement in function and a decrease in stiffness and pain when using a custom made adjustable knee brace (12). Conversely, Brouwer et al announced no significant differences in quality of life when patients used a knee brace (32). Richards et al (16) reported that reducing varus force using a knee unloader orthoses increased the knee joint space on the medial side and improved symptoms. Ramsey et al (15) suggested that knee orthoses increased knee joint stability and improved function.

Whilst we found significant differences between both interventions in pain, symptoms and quality of life KOOS sub-scales, Van raaij et al (21) conversely found no significant differences in pain and function WOMAC sub-scales between lateral wedged insoles and knee braces in patients with medial compartment knee OA. Backer et al (20) found no statistically significant and clinically important differences on WOMAC pain sub scale in 5 subjects who wore lateral wedged insoles in a cross-over trial. There is therefore variance in the literature.

The knee orthoses used in this study were custom made, and extended 2/3 of the length of the upper and lower leg; so giving an optimum fit and theoretically effective application of corrective forces using longer lever arms than most off-the-shelf devices. This paper therefore demonstrated that such orthoses are effective in providing symptom reduction as well as the other beneficial effects demonstrated in this paper, and similarly designed orthoses are therefore recommended for use by patients with medial compartment knee OA. The authors are not aware of previous evidence of comparing use of this design of custom orthosis to laterally-wedged insoles.

A limitation of this study was that the thickness of the lateral wedged insoles was not checked during the study period. However, the lateral wedge insoles used in this study were constructed from cork material with a density of 60 durometers that had

high resistance to compressive deformation, and such checking was not deemed necessary. Another limitation of this study was that the knee valgus angulation at baseline and after orthotic treatment was not measured. In addition, this study did not have a placebo control group and the patients acted as their own controls.

We intend to compare the effect of the two types of orthoses used in this study on knee valgus angulation angles, knee adduction moments and gait parameters during walking by patients with medial compartment knee osteoarthritis in a future study.

Conclusion

This study demonstrated that use of lateral wedge insoles and knee unloader orthoses improved pain ($P=0.000$), symptoms ($P=0.000$), daily living activities ($P=0.000$), recreational and sport function ($P=0.000$) and quality of life ($P=0.000$) in subjects as compared to baseline with symptomatic medial compartment knee OA. In comparing both interventions, we did not find significant differences in activity of daily living, sports and recreational activities between them. Reduction of pain and symptoms occurred when subjects wore knee unloader orthoses. However, in improving quality of life, lateral wedges showed that they were a suitable alternative to knee unloader orthoses for conservative treatment of the medial compartment knee osteoarthritis patients.

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