

EFFECTS OF LATERAL WEDGE HEEL RAISE WITH SUBTALAR STRAPPING ON JOINT LOADING, PAIN, STIFFNESS AND FUNCTION IN PATIENTS WITH OSTEOARTHRITIS OF MEDIAL TIBIOFEMORAL COMPARTMENT

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ABSTRACT

BACKGROUND

Osteoarthritis is the most common form of arthritis and a leading cause of pain and disability in older adults. Knee osteoarthritis has the greatest impact on disability. There are several treatments to manage varus knee deformity. For moderate or severe varus OA, surgical treatment, such as high tibial osteotomy and total knee arthroplasty (TKA) have been performed. Alternatives to surgical treatment are required to lighten the patient's burden and the medical costs.

The objective of the study is to evaluate the effects of lateral wedge heel raise with subtalar strapping on joint loading, pain and stiffness in osteoarthritis of medial tibiofemoral compartment.

MATERIALS AND METHODS

A cohort study over a period of one year in 29 patients with medial tibiofemoral osteoarthritis who were prescribed with lateral wedge heel raise and subtalar strapping are studied for changes in the Knee Adduction Moment by 3-dimensional gait analysis. Also, the changes in WOMAC score and VAS score are studied.

RESULTS

Lateral wedge heel raise and subtalar strapping is an effective biomechanical intervention in the management of osteoarthritis of medial tibiofemoral compartment. It showed a significant decrease in the Knee Adduction Moment, which is a valid indicator of medial compartment joint loading. The use of lateral wedge heel raise and subtalar strapping also showed significant decrease in WOMAC and VAS score. So, a symptomatic improvement in patients with medial knee osteoarthritis can be ensured with the use of this simple and cheap orthotic intervention.

CONCLUSION

The lateral wedge heel raise and subtalar strapping is a very effective orthotic intervention in patients with medial tibio femoral osteo arthritis.

KEYWORDS

Osteoarthritis, Gait Analysis, Foot Wear Modification.

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BACKGROUND

Osteoarthritis (OA) is a chronic, progressive disease involving the degeneration of articular cartilage and joint tissues, resulting in pain, stiffness and disability.¹ It is the most common form of arthritis and a leading cause of pain and disability in older adults. The knees, hips and hands are most commonly affected, with knee OA having the greatest impact on disability.

In India, the overall prevalence of osteoarthritis in the elderly is 56.6%;² OA is more common in females as compared to males (70.1% vs. 41.6%).³ It is thought to cause more damage to mobility in the elderly than any other disease. The worldwide prevalence estimate for symptomatic OA is 9.6% among men and 18% among women.⁴

The pathophysiological mechanisms of OA are under debate, but there is general agreement that biomechanics and increased dynamic loading of the joint are involved. Osteoarthritis patients usually have major involvement in one compartment, either medial or lateral. The lateral compartment is less involved than medial.⁵ Nearly 2.5 times mechanical load is transferred through the medial compartment than the lateral compartment during normal walking.⁶ The high joint load in the medial compartment causes cartilage damage and pain.⁷ Therefore to improve the

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disease or relieve pain joint load in medial compartment should be reduced.

Western Ontario and Mc Master Universities (WOMAC) OA Index is a disease specific, self-administered questionnaire for assessing health status and health outcomes in OA knee. The WOMAC includes a total of 24 questions divided into three sections: pain (5 questions), stiffness (2 questions), and functions (17 questions). All the symptoms are answered by 5-point Likert scale. This scale includes none, slight, moderate, severe and extreme and is scored 0 to 4 respectively. Results are reported as total WOMAC score which is obtained by summing 3 sub-scores that is pain, stiffness and physical function 79.

High WOMAC scores reflects greater severity.

The Visual Analogue Scale for pain is a subjective measure of pain intensity. It has been widely used in diverse adult populations, including those with rheumatic diseases. Several treatment options are there to manage varus knee deformity with the primary goal to correct the mechanical axis of the limb for moderate to severe OA, high tibial osteotomy and total knee arthroplasty (TKA) is the surgical management. The surgeries are proven to be successful, but it is very expensive and also requires prolonged hospital stay.^{8,9}

To lighten the patient's burden and medical cost alternative non-surgical methods are required. One such option is lateral wedge heel raise for medial knee OA.¹⁰ This orthosis was firstly reported by Sasaki and Yasuda.^{11,12} It works by reducing load on the medial compartment of knee by causing valgus inclination at the calcaneus. There are studies showing the effectiveness of lateral wedged insole in reducing the medial compartment load.

The lateral wedged heel raise with elastic strapping of the subtalar and ankle joints (strapping insole) showed more clinical effects when compared to heel raise alone.¹³⁻¹⁶

The knee adduction moment (KAM) has been demonstrated to be a very good indicator for joint loading on medial compartment.¹⁷ KAM is the product of ground reaction force and moment arm with respect to center of knee joint. An increase in KAM result in adduction of medial tibiofemoral joint. This causes increased compressive load on the medial compartment. This eventually leads to destruction of cartilage and contributes to development and progression of OA. The knee adduction moment can be easily calculated by a 3D gait analysis.

In this study, conducted in our department, an attempt has been made to explore the changes in the knee adduction moment using 3D gait analysis following the use of lateral wedge heel raise with subtalar strapping in patients with medial compartment OA and also, we studied the changes in knee joint pain, stiffness and function using WOMAC & VAS.

Objective of the Study

- To study the effects of lateral wedge heel raise with subtalar strapping on knee joint loading by measuring the External Knee Adduction Moment in gait analysis lab.

- To study the effects of lateral wedge heel raise with subtalar strapping on knee pain by using WOMAC & VAS.

MATERIALS AND METHODS

Study Design: Cohort study.

Study Period: A period of one year (March 2016 – February 2017)

Study Settings: The study was conducted at the Department of Physical Medicine and Rehabilitation, Government Medical College, Kozhikode, a tertiary care center in Kerala.

Study Group: Patients attending Department of Physical Medicine & Rehabilitation with Unilateral and bilateral Medial Knee Osteoarthritis. This study was done in 29 such Patients attended our department over a period of one year. After history and clinical Examination, those who satisfied the following criteria were studied.

Inclusion Criteria

- Predominant medial compartment osteoarthritis of the knee according to the American College of Rheumatology criteria.
- Unilateral and/or bilateral knee involvement.
- Male/female gender.
- Age between 50 and 70 years.

Exclusion Criteria:

- Patients already using footwear modification.
- Rheumatoid arthritis, gouty arthritis.
- Central nervous system diseases.
- Any surgery on knee.
- Persons not able to walk without walking aids.
- Predominant lateral compartment osteoarthritis of knee.
- Cognitive dysfunction
- Significant visual impairment.
- Patients with peripheral neuropathy

Patients who satisfy the inclusion and exclusion criteria will be enrolled consecutively into the study during study period. Initially a detailed history and clinical examination will be made. The grade of radiographic progression of knee OA was evaluated according to the Kellgren and Lawrence system (K-L grading) for classification of osteoarthritis of knee.

Description of the insole A Microcellular Rubber (MCR) 6 mm lateral wedge is fixed to the footwear of the patient. The lateral wedge has 6 mm lateral elevation. A neoprene ankle binder was used for subtalar strapping, designed to fit around the ankle and subtalar joints. Foot wear preferably used was those with back strap. Gait analysis (primary outcome measure).

All subjects performed the trials, 6-meter level walking at a comfortable walking speed in a gait laboratory. They walked under three different conditions; footwear without lateral wedge, footwear with lateral wedge heel raise and footwear with lateral wedge heel raise and subtalar strapping on both sides. Five trials were conducted with each of these and average is taken.

Retro – reflective markers were placed over anterior superior iliac spine, posterior superior iliac spine, mid-thigh, lateral femoral condyles, mid-calf, lateral malleolus, heel and head of 2nd metatarsal.

The three-dimensional positions of the markers were captured using a four-camera system fixed in the gait laboratory (250 frames/s, VICON). During the gait, ground reaction force was also measured using a force plate fixed on the floor in the gait laboratory (sample frequency 1000 Hz; AMTI). The three – dimensional knee kinetics were assessed by an inverse dynamic method and the peak knee adduction moment was calculated as the maximum moment during stance phase. Average moment of each five trial were taken. Moments were normalized to bodyweight and height (% BW x HT) to allow for comparison between subjects. So that value become unit less. Patients were asked to wear the footwear with lateral wedge heel raise and subtalar strapping about six hours a day for three months. The trials were repeated in the same manner after three months of use. The usage was assessed by looking the wear out in the lateral wedge and replaced with new heel wedges once severely worn out. The patients were asked to continue conservative management along with this. The conservative management will consist of appropriate exercises, medications including analgesics and NSAIDs given for two weeks and then as a SOS (si opus sit) basis. Symptomatic outcome measure (secondary outcome measure). At the baseline and 3-month visits, each patient was asked to complete a written WOMAC index questionnaire about the affected knee. The WOMAC scale quantifies pain, stiffness, and physical function associated with knee osteoarthritis during the past 48 hours. Also, patient asked to mark the severity of pain in a visual analogue scale (VAS), which consists of a horizontal line of 10 cm (100 mm).



Figure 1. Marker Placements Over the Body



Figure 2. Gait Analysis Lab

Statistical Analysis

All the data was entered in Microsoft excel sheet, rechecked and analysed using Statistical package for social sciences (SPSS 18.0) software. Comparison of means was done by paired sample t test. p values of less than 0.05 were considered statistically significant.

Ethical Aspect

The study protocol was submitted to the scientific research committee as well as the institutional ethics committee of Government Medical College, Kozhikode and clearance was obtained for conducting the study.

- Informed consent was obtained from all patients.
- All the information collected was kept confidential.
- No procedure was carried out which directly or indirectly produce risk to the subjects.

RESULTS

A cohort study was conducted to find out the changes in the knee joint loading, pain, stiffness and physical function in patients with osteoarthritis of medial tibiofemoral compartment following the use of lateral wedge heel raise and subtalar strapping as foot wear modification. During a period of 1 year, a total of 33 patients with unilateral / bilateral medial tibiofemoral osteoarthritis were presented to our department. 4 patients lost follow up and were excluded from the study. So, a total of 29 patients were studied in detail. Out of these 18 patients had unilateral and 11 patients had bilateral osteoarthritis. So in this study a total of 40 knees were given foot wear modification. The results obtained from the study are presented here.

The patients had a mean age of 58.75 ± 6.41 years, mean BMI of 25.30 ± 0.98 kg/m².

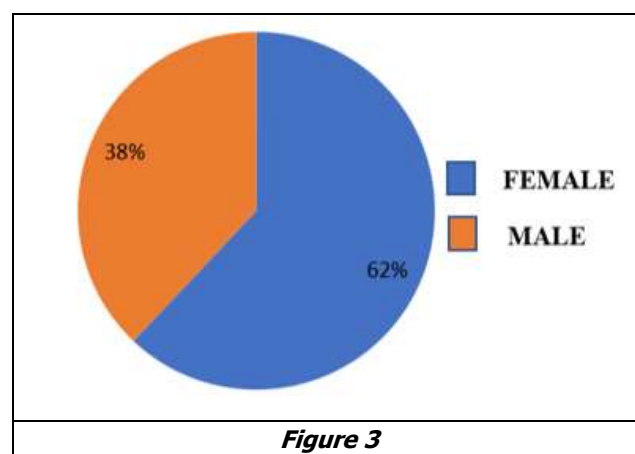
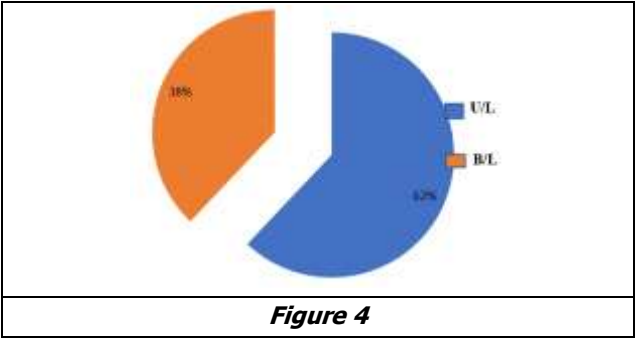


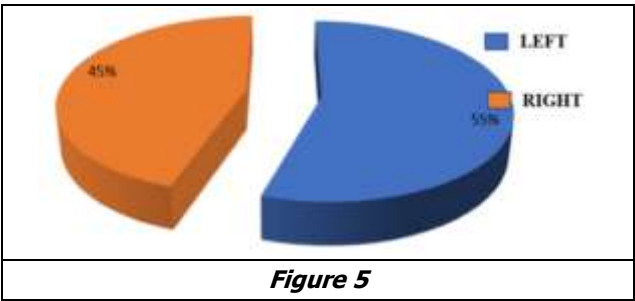
Figure 3

Out of 29 patients studied, 18 (62%) were females and 11 (38%) were males.

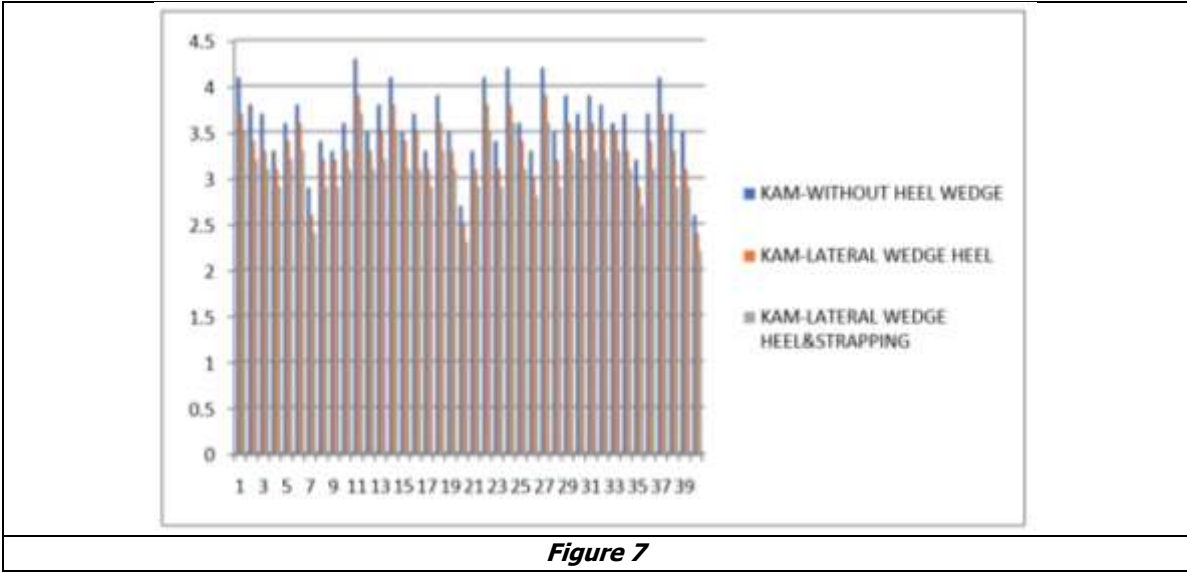
Unilateral OA vs. Bilateral OA



Out of 29 patients studied 18 (62%) patients had unilateral osteoarthritis And 11(38%) had bilateral osteoarthritis.



Knee Adduction Moment Without Heel Wedge vs Lateral Wedge Heel vs Lateral Wedge Heel & Strapping (Baseline)



Mean Knee Adduction Moment (baseline) (n=40)*

Knee Adduction Moment (% BWT *HT)	
Without Heel Wedge	3.62 ± 0.38
With Lateral Wedge Heel	3.34 ± 0.35
With Lateral Wedge Heel & Strapping	3.09 ± 0.33

*Mean ± standard deviation.

There was 7.73% reduction in the knee adduction moment immediately following the use of laterally wedge insole and 14.4% reduction following the use of lateral wedge heel and subtalar strapping.

Knee Adduction Movement Without Heel Wedge vs Lateral Wedge Heel vs Lateral Wedge Heel & Strapping at 3 Months

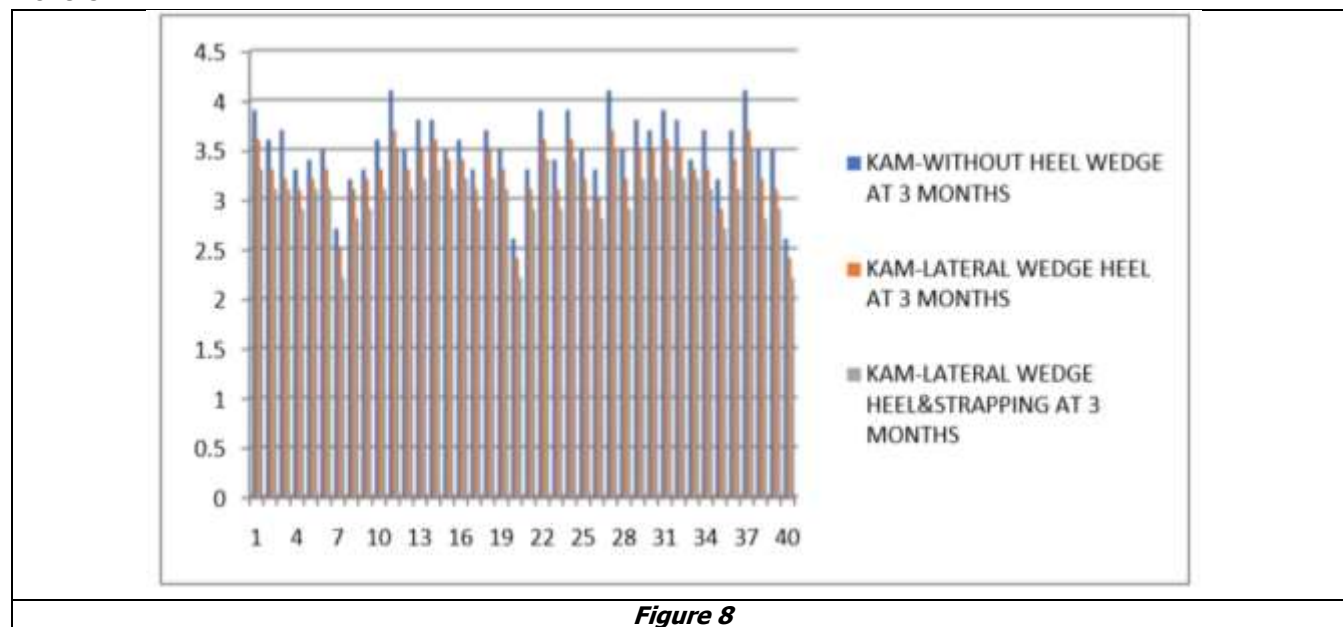


Figure 8

Mean Knee Adduction Moment (3 months) (n=40)*

Knee Adduction Moment (% BWT *HT)	
Without Heel Wedge	3.52 ± 0.34
With Lateral Wedge Heel	3.26 ± 0.31
With Lateral Wedge Heel & Strapping	3.05 ± 0.33

Table 2

*Mean ± standard deviation.

The changes in the knee adduction moment following 3 months of using subtalar strapping insole found 7.38% reduction with the lateral wedge. Also the subtalar strapping showed a 13.35% reduction.

Womac-Pain

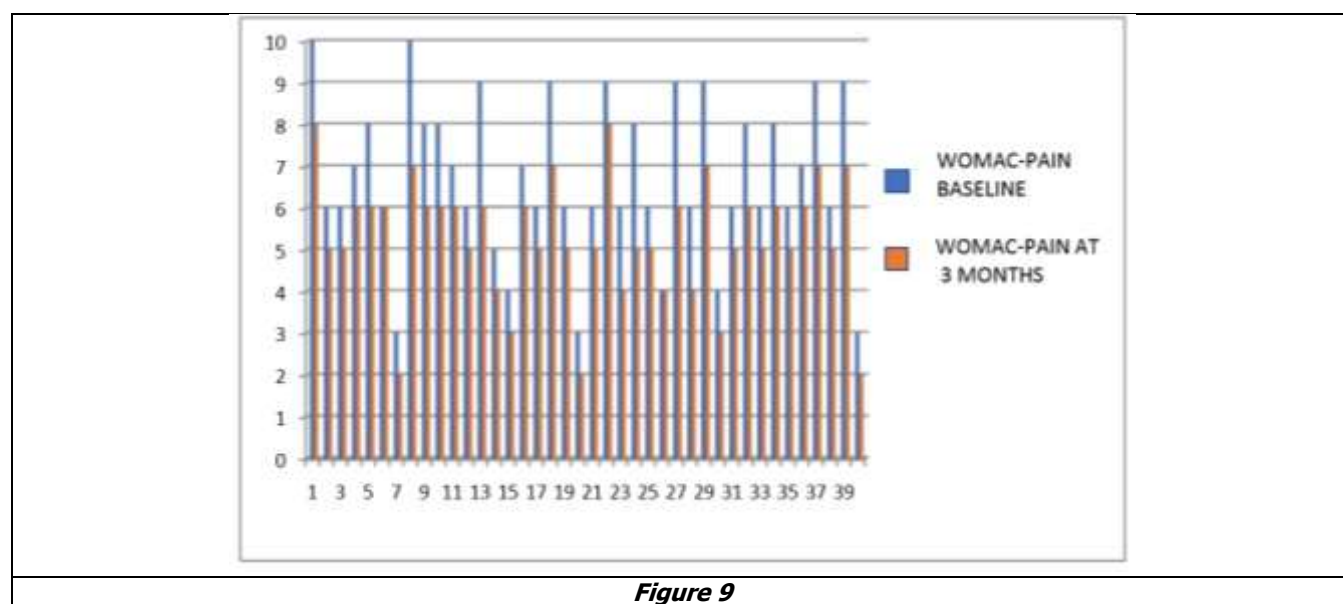


Figure 9

The patients had a mean WOMAC pain score of 6.73 ± 1.91 at baseline and 5.28 ± 1.48 at 3 months. There was 21.5% reduction in the score following the orthotic intervention.

Womac-Stiffness

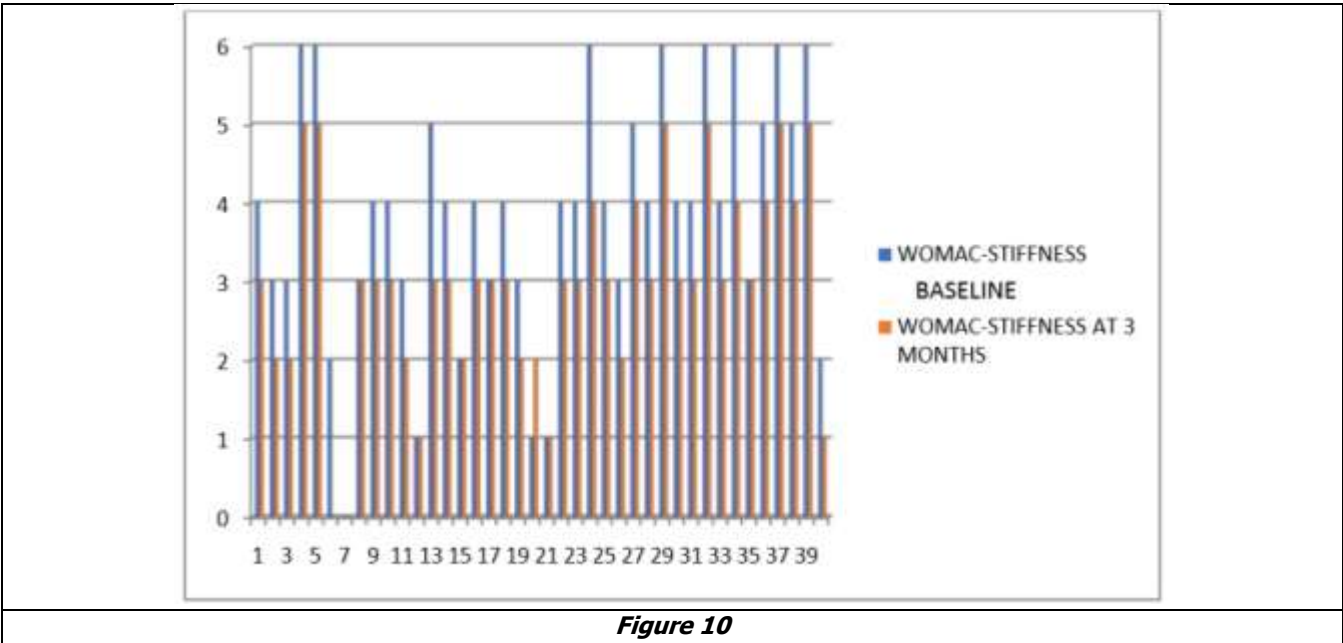


Figure 10

The patients had a mean WOMAC stiffness score of 3.83 ± 1.58 at baseline and 2.95 ± 1.30 at 3 months. 23% reduction of the score for stiffness found following the use of the subtalar strapping insole.

Womac Physical Function

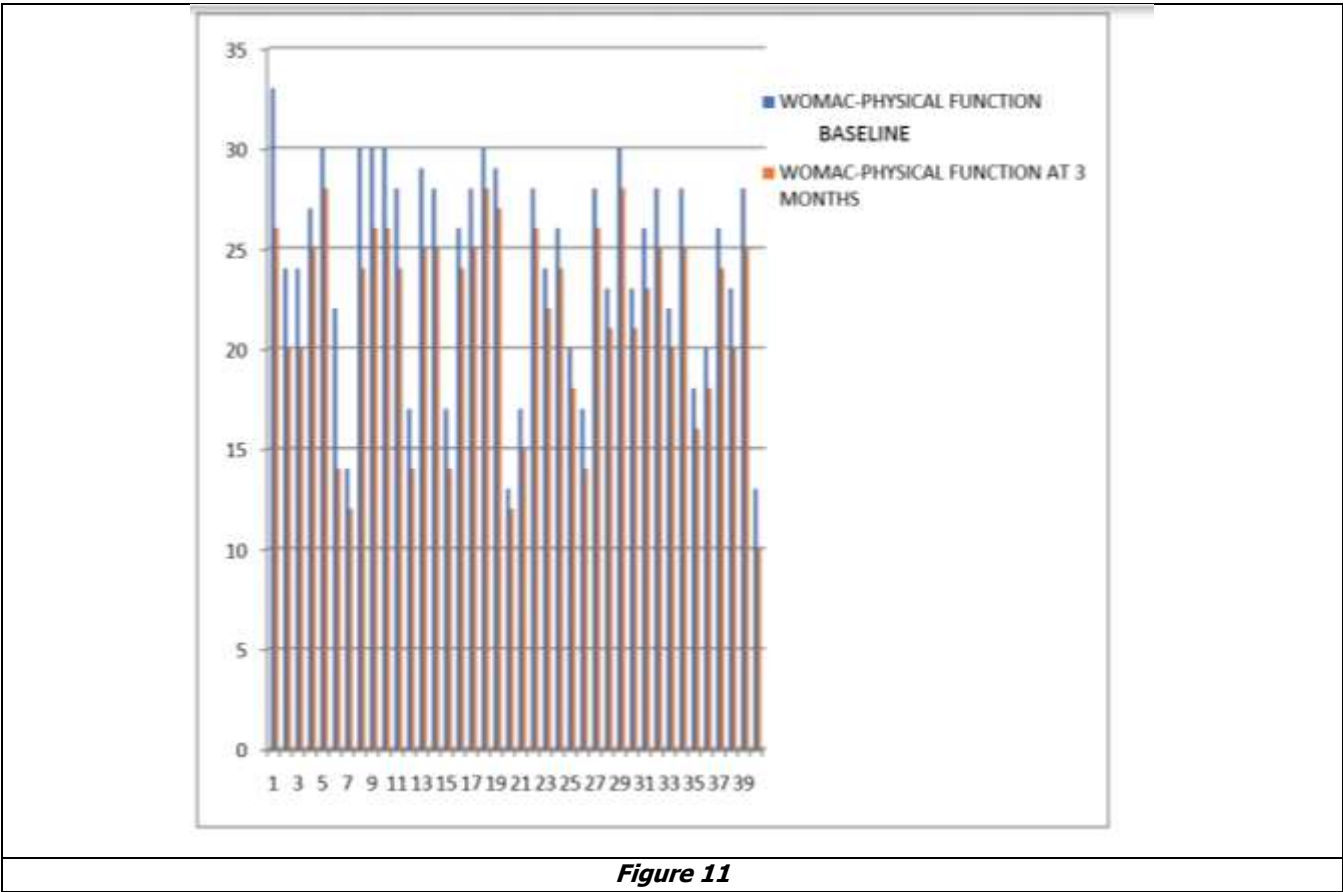


Figure 11

The patients had a mean WOMAC physical function score of 24.43 ± 5.33 at baseline and 21.50 ± 5.11 at 3 months. Physical function score showed 12% reduction with the use of strapping insole.

Visual Analog Scale

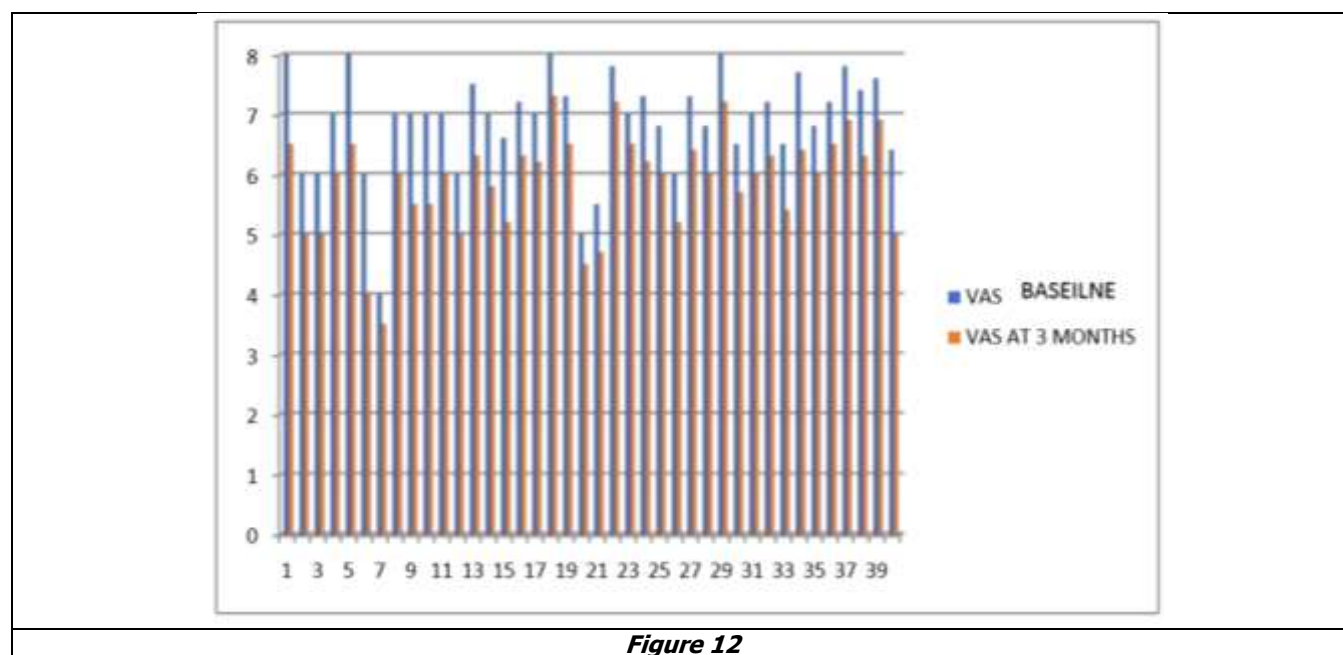


Figure 12

The patients had a mean VAS score of 6.88 ± 0.84 at baseline and 5.88 ± 0.84 at 3 months. VAS score had a 14.5% reduction from the baseline score.

Baseline and 3rd Month WOMAC Score

	Mean	Standard Deviation	P Value
Womac-Pain			
Baseline- 3rd Month	1.45	0.75	0.000
Womac-Stiffness			
Baseline – 3rd Month	0.87	0.61	0.000
Womac-Physical Function			
Baseline – 3rd Month	2.95	1.42	0.000

Table 3

WOMAC score assessed after 3 months of giving lateral wedge heel and subtalar strapping found significant decrease in all sub-scores namely pain, stiffness and physical function. Paired t test was done and found it is statistically significant (p value <0.001).

Baseline and 3rd Month VAS

	Mean	Standard Deviation	P Value
VAS Baseline – VAS at 3 rd Month	0.99	0.32	0.000

Table 4

The VAS assessed after 3 months of giving the lateral wedge heel and subtalar strapping found significant decrease from baseline. Paired t test was done and found that it is statistically significant (p value <0.001).

DISCUSSION

Osteoarthritis is the most common form of arthritis. Knee osteoarthritis is having the greatest impact on disability. Various Orthotic interventions including insoles in the footwear are used for symptomatic relief. Laterally wedged insoles are advocated for the management of medial tibiofemoral knee OA.^{18,19} Studies on biomechanical changes following the use of laterally wedged insoles have shown that such an intervention can immediately reduce the knee adduction moment by 5-10% on average.²⁰⁻²² In this study the immediate change following the use of laterally wedged insole was 7.73% which is comparable to the previous studies. The studies using lateral wedged heel raise with elastic strapping of the subtalar and ankle joints (strapping insole) showed more clinical effects when compared to heel raise alone.¹³⁻¹⁶ In a study by Y. Kuroyanagi M.D et al,²³ the strapping insole showed 13% reduction in the KAM compared to barefoot. In our study the strapping insole decreased the KAM by 14% compared to foot wear without heel wedge which is consistent with the Y. Kuroyanagi M.D et al study. The small change may be because of the differences in the design of wedges and the footwear utilised. In the study by Y. Kuroyanagi M.D et al, used silicon rubber 10 mm lateral wedge and it was attached to bare foot. In our study we used 6 mm Micro cellular rubber to make the lateral heel wedge and it was fixed to the foot wear of the patient. It is difficult for the patients to wear a 10 mm lateral wedge, so we used 6 mm lateral wedge. Also, we fixed this to the foot wear as it will be easier for the patient to use.

Various studies found that the laterally wedged heel raise decrease the WOMAC score.²⁴⁻²⁶ In a study by Hinman RS et al,²³ found a 22% reduction in pain score and 20%

reduction physical function score from baseline. In another study by Barrios JA et al²⁶ demonstrated that laterally wedged insole improved the WOMAC subscales for pain ($p<0.001$), stiffness ($p<0.001$), and physical function ($p<0.001$) at 1 month and 1 year follow up. In our study the WOMAC sub-scores showed a statistically significant ($p<0.001$), change at 3 months of the use of strapping insole. Sub-scores namely pain, stiffness and physical function showed 21.5%, 23% and 12% reduction respectively from the baseline. The changes are comparable with previous studies.

The study by Hinman RS et al,²² showed that the load reducing effects of laterally wedged insoles on the adduction moment do not appear to decline after one month. In our study a follow-up after 3 months of use of the strapping insole was done and was found that the changes persisted, and it was statistically significant. In a study by Toda Y, Tsukimura N¹⁶ the strapped insole group showed a significantly ($p<0.001$) decreased VAS score at 3 months. In our study the VAS score showed a statistically significant ($p<0.001$) decrease following the use of strapping insole.

The lateral wedge heel raises are an effective, easy to use, cheap and easily available orthotic intervention in osteoarthritis of medial tibiofemoral compartment. In our study its usage demonstrated a decrease in the knee joint loading which was measured by KAM. By adding a subtalar strapping showed much more decrease in the KAM. The varus deformity of the knee will not be changed by the conventional insole because the lateral wedge effect is thought to be cancelled in the subtalar joint. On the other hand, the elastic strap would fix the subtalar and ankle joints, and cause valgus angulation both in talus and tibia.²¹ The orthotic intervention in our study also showed a significant decrease in the symptoms also. So, this orthotic intervention can be used as an effective treatment option both for preventing disease progression and also for symptomatic improvement.

CONCLUSION

29 patients (40 knees) with medial tibiofemoral OA were studied. 11 Males and 18 Females were assessed. Mean of age of the patients was 58.75 ± 6.41 years. Mean BMI was 25.30 ± 0.98 kg/m². The lateral wedge heel raise and subtalar strapping is simple and cheap orthotic intervention that can be used in patient with osteoarthritis of medial tibiofemoral compartment.

The study showed that the use of this insole significantly reduced medial joint load and the symptoms of osteoarthritis.

Further research is required to assess the long-term effects of the insole on the joint load and symptoms.

Limitation

In this study, it was not able to restrict conservative management which consists of appropriate exercises, medications including analgesics and NSAIDs. So future studies should include a control group.

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