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Effect of lateral wedged insole shoe in knee osteoarthritis: A 12 month randomized controlled trial

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Abstract

Introduction: Knee osteoarthritis (OA) is a chronic degenerative musculoskeletal condition that imposes a major healthcare burden due to considerable pain, disability and loss of quality of life especially among the older adults. Most knee OA researchers have focused on tertiary management strategies i.e pain relief with effective drug therapies (Non steroidal anti inflammatory drugs, chondroitin supplements etc). However, long-term use of NSAIDS have significant side effects and are expensive. With the exception of knee joint arthroplasty, typically reserved for end-stage disease, there is no definitive cure for osteoarthritis. Accordingly, there is an urgent need for conservative treatment modalities, that not only alleviate painful symptoms of OA, but also reduce the progression of the degenerative pathology over time. Patients with knee OA usually show major involvement in only one compartment; medial tibiofemoral compartment being more common than the lateral compartment. The lateral wedge shoe insole is an orthotic device, which is hypothesized to reduce the moment arm of the ground reaction force vector relative to the knee joint center during walking. They are an inexpensive and feasible treatment modality, that has shown to reduce medial knee load.

Materials and Methods: 80 patients with bilateral medial compartment osteoarthritis of knee were included in the present study. They were randomly divided into two groups ; Group A (n = 40) included patients who were given lateral wedged insole shoes and Group B (n = 40) included those who were given normal flat soled shoes. All patients who fulfilled the inclusion and exclusion criteria were recruited for the study. The present study was carried between January 2020 to January 2021 in Krishna Institute Of Medical Sciences, "Deemed to be University" Karad. Severity of pain using WOMAC score, FTA using plain knee radiograph in AP view and frequency of intake of NSAIDS were calculated at the start of study, thereafter at each follow up every 2 months up to 12 months.

Results: At the initial 2nd month follow up group A patients showed significant reduction in severity pain scale (66.74+/-19.44) as compared to group B (72.78+/-17.04), but neither of group A or group B showed any significant change in remaining variable characters ($p>0.005$). At the end of 12 months follow up assessment, Group A patients showed a marked reduction in severity of pain (average 46.8+/-16.24) as compared to Group B (mean 59.26+/-18.74). Patients in Group A showed significant decrease in the frequency of intake of NSAIDS for pain relief as compared to patients in Group B ($p<0.05$).

Conclusion: Our findings show that use of lateral wedged insole shoes as the primary treatment option in knee OA had marked effect in reduction of severity of pain and frequency of intake of NSAIDS to relieve pain. However, our study has reported insignificant reduction in the FTA and no changes in radiological progression of the disease of knee OA.

Keywords: osteoarthritis, Kellegren and lawrence, WOMAC, NSAIDS, lateral wedged insoles, femorotibial angle

Introduction

With the increase in life-expectancy of the population, prevalence of patients with knee pain is on the rise among the elderly. Knee osteoarthritis (OA) is a chronic degenerative musculoskeletal condition that imposes a major healthcare burden due to considerable pain, disability and loss of quality of life especially among the older adults [1]. Demographic predictions indicate that people aged over 65 years will comprise more than 20% of the population by 2040 [2]. Management strategies for knee OA are generally grouped as primary prevention (aims at reduction of risk factors to reduce the incidence of the condition); secondary prevention (aim to slow down the progression to a detrimental state of disease) and;

tertiary prevention (aims to reduce pain and disability) [3]. Most knee OA researchers have focused on tertiary management strategies i.e pain relief with effective drug therapies (Non steroidal anti inflammatory drugs, chondroitin supplements etc). However, long-term use of non-steroidal anti inflammatory drugs (NSAIDs) have significant side effects and are expensive [4]. With the exception of knee joint arthroplasty, typically reserved for end-stage disease, there is no definitive cure for osteoarthritis. Adding to this, the high cost of the surgery has added to the burden, and made it difficult in preferring it as a primary mode of treatment in most developing countries.

Accordingly, there is an urgent need for conservative treatment modalities, that not only alleviate painful symptoms of OA, but also reduce the progression of the degenerative pathology over time [5]. Available modalities for non-surgical management of osteoarthritis include: (a) pharmacological therapy with NSAIDs, oral steroids, chondroitin sulfate supplements etc. (b) use of mobility aids (c) intra-articular injection of corticosteroids or visco-supplements (d) Cold fomentation and splinting. These interventions mainly aim at alleviating pain, improving joint function and ultimately enhancing the quality of life by reducing disability. However, given that a substantial proportion of patients with knee OA experience progression of the structural disease [6], our management should also aim at reducing structural deterioration over time.

Patients with knee OA usually show major involvement in only one compartment; medial tibiofemoral compartment being more common than the lateral compartment (medial 67%, lateral 16%) [7]. The external knee adduction moment determines the load distribution across the medial and lateral tibial plateaus. Forces exerted across the medial compartment are almost 2.5 times that across the lateral [8]. This explains greater prevalence of involvement of the medial tibiofemoral compartment as compared to the lateral compartment. Cross-sectional studies have shown that patients with knee OA have a higher knee adduction moment while walking as compared to healthy age-matched controls [9, 10]. Recent research has demonstrated that a higher external knee adduction moment is associated with greater severity of knee pain [11]. Thus, interventions which alter this biomechanical factor, and reduce medial load on the knee are helpful in symptomatic pain relief, as well as reducing disease progression over time [12]. The lateral wedge shoe insole is an orthotic device, which is hypothesised to reduce the moment arm of the ground reaction force vector relative to the knee joint centre during walking [13]. They are an inexpensive and feasible treatment modality, that has shown to reduce medial knee load by approximately 5-10% [13-16]. The wedge is placed under the sole of the foot and angulated so that it is thicker over the lateral than the medial border of the foot, thereby transferring greater load during weight bearing from medial to lateral knee compartment. In the present study, we aim to assess the efficacy of lateral wedge insole shoes in providing symptomatic pain relief and reducing disease progression in patients with osteoarthritis of knee.

Materials and Methods

80 patients with bilateral medial compartment osteoarthritis of knee were included in the present study. They were randomly divided into two groups; Group A (n = 40) included patients who were given lateral wedged insole shoes and Group B (n = 40) included those who were given normal flat soled shoes.

The inclusion criteria were (a) age above 50 years, of any sex (b) patients having pain and tenderness over medial aspect of knee (c) Patients with radiographic evidence of Grade I/II osteoarthritis of knee (according to Kellegren Lawrence grading of OA).

The exclusion criteria were (1) Patients diagnosed with pathological conditions like rheumatoid arthritis, pseudogout etc. (2) Patients having knee flexion contracture greater than 20 degrees (3) Lateral tibiofemoral joint space narrowing greater than the medial compartment, as evident on plain knee x-ray (4) Patients with BMI $>= 36$ kg/m² (5) Patients with valgus knee alignment $>185^\circ$ on a standardised standing knee x-ray (6) Patients with history of ipsilateral hip/knee arthroplasty surgery in the past (7) Patients using gait-aids while walking (8) Patients who have been administered intra-articular corticosteroid injections within 6 months of the study.

All patients who fulfilled the inclusion and exclusion criteria were recruited for the study. The present study was carried between January 2020 to January 2021 in Krishna Institute Of Medical Sciences, "Deemed to be University" Karad. All the participants had signed the written and informed consent before enrolling in the study. This randomized controlled trial was approved by the Institutional Ethical Committee.

Following baseline data of the patients were recorded at 0 weeks, and thereafter at each follow up (1) Standing knee radiograph in antero-posterior view (for calculating femorotibial angle i.e FTA and grading the severity of OA knee using Kellegren and Lawrence Score (2) Severity of pain using the WOMAC scale [24], Frequency of NSAID uptake of the patients every month.

Femorotibial angle (FTA) in the frontal plane, is the angle formed by the intersection of the anatomical axis of the femur and tibia (174.6 \pm 1.7 degrees). The severity of OA was evaluated by radiographs using the Kellegren and Lawrence [23] grading system in which Grade 0 is normal; Grade 1 is osteophytic lipping; Grade 2 is definite osteophytes and possible joint space narrowing; Grade 3 is moderate and/or multiple osteophytes, definite joint space narrowing with some sclerosis and Grade 4 is large osteophytes, marked joint space narrowing, severe sclerosis and definite bony attrition [figure 1]



Fig 1: Kellegren Lawrence Grading A. Grade 1 B. Grade 2 C. Grade 3 D. Grade 4

The Western Ontario Mc Master questionnaire (WOMAC) was utilized to evaluate the severity of knee pain(7). The patients were enquired about the number of days they had to consume NSAIDs per month, in the last three months, due to intolerable pain. The baseline parameters of patient were assessed by a blinded examiner and were randomly divided into two groups. Group A included patients who were given

lateral wedged insole shoes and Group B included those who were given normal flat soled shoes. The demographic parameter of both groups were similar.

The insoles were manufactured for each patient based on the print data collected from subject in a standing position. A 10 mm lateral elevation wedge was prepared along the lateral edge of the entire length of the foot for the patients in Group A [Figure 2]. A normal flat insole was prepared for those in Group B. Urethane material was used for preparing the

insoles. The patients were encouraged to wear the shoes with insoles for at least 10 hours each day and were asked to note down the number of times they consumed NSAIDs for relieving pain. The patients were followed up every 2 months for 12 months and on each follow up the variable parameters were noted.

All data was entered in Microsoft excel spreadsheet. Data analysis was done using SPSS software.



Fig 2: lateral wedged insoles

Results

The present study had 32 males and 48 female patients. The mean age in Group A was 64.88 \pm 7.74 and in Group B was 62.94 \pm 8.04. The mean BMI in patients in Group A was 29.33 \pm 10.1 and that in Group B was 27.32 \pm 1.77. The average FTA in patients in Group A was 175.11 \pm 1.06 and

that in Group B was 175.24 \pm 1.08. Average number of days when the patient had to consume NSAIDs due to intolerable pain was 18.36 \pm 2.44 in Group A and 16.88 \pm 2.08 in Group B. Table 1 depicts the demographic data and baseline readings in both groups.

Table 1: Demographic parameters and initial base line values

Sl.no.	Parameter	Group A (N= 40)	Group B (N=40)
1	Age (mean)	64.88 \pm 7.74	62.94 \pm 8.04
2	Gender (M/F)	14/26	18/22
3	BMI	29.33 \pm 10.1	27.32 \pm 1.77
4	Severity of pain	74.6 \pm 18.64	71.26 \pm 19.24
5	FTA	175.11 \pm 1.06	175.24 \pm 1.08
6	Frequency of NSAIDS intake(days per month)	18.36 \pm 2.44	16.88 \pm 2.08

BMI: body mass index kg/m² ; FTA: femorotibial angle

The mean values of the FTA, pain severity (according to WOMAC score), severity of knee OA (according to Kellegren and Lawrence grading) and frequency of NSAIDS taken per month of both groups, at the 2 months follow up, are depicted in Table number 2. At the initial 2nd month follow up group A

patients showed significant reduction in severity pain scale (66.74 \pm 19.44) as compared to group B (72.78 \pm 17.04), but neither of group A or group B showed any significant change in remaining variable characters. ($P>0.005$)

Table 2: Values at 2 month follow up

Sl.no.	Parameters	Group A	Group B
1	Severity of pain	66.74 \pm 19.44	72.78 \pm 17.04
2	FTA	175.11 \pm 1.06	175.24 \pm 1.08
3	Frequency of NSAIDS intake (days per month)	14.96 \pm 2.64	15.22 \pm 3.04

FTA: femorotibial angle

At the 6 month follow up, Group A patients showed significant reduction in the pain (mean 58.34 \pm 17.89) as compared to patients in Group B (mean 77.26 \pm 18.62) ($p<0.005$). There was no significant change in the FTA in patients belonging to either of the groups (as examined on

plain radiographs of the knee in antero-posterior view). The patients in Group A also showed significant decrease in the frequency of consumption of NSAIDS for pain relief as compared to patients in Group B ($p<0.005$). The values are depicted in Table no.3.

Table 3: Values at 6 month follow up

Sl.no.	Parameters	Group A	Group B
1	Severity of pain	58.34 \pm 17.89	77.26 \pm 18.62
2	FTA	175.11 \pm 1.06	175.24 \pm 1.08
3	Frequency of NSAIDS intake (days per month)	10.76 \pm 1.65	16.56 \pm 2.29

FTA: femorotibial angle

At the end of 12 months follow up assessment, Group A patients showed a marked reduction in severity of pain (average 46.8+/-16.24) as compared to Group B (mean 59.26+/-18.74). Patients in Group A showed significant decrease in the frequency of intake of NSAIDS for pain relief

as compared to patients in Group B ($p<0.05$). Radiographic assessment of the knee in antero-posterior view (standing) at the end of 12 months, showed insignificant changes in both the groups. The values of the variables at 12 month follow up are depicted in table no. 4.

Table 4: Values at 12 months follow up

Sl.no.	Parameters	Group A	Group B
1	Severity of pain	46.8+/-16.24	59.26+/-18.74
2	FTA	175.11+/-1.06	175.24+/-1.08
3	Frequency of NSAIDS intake (days per month)	5.88+/-1.94	18.22+/-2.34

Discussion

The results of our study has shown that the patients experience significant decrease in pain, joint stiffness and function impairment following use of lateral wedge insole shoes. Andriacchi *et al.* [17, 18] stated that patients osteoarthritis of knee with varus deformity, have a high adduction moment at the knee. An increase in the adduction moment during walking is proportional to the increase in medial compartment loading at the knee joint. Using lateral wedged insole shoes, by changing the mechanical axis of lower limb, there is reduction of adduction momentum, shifting the applied loads lateral to the sub-talar joint axis in most patients and thereby transfers the center of pressure to the lateral part of the knee joint.

Kuroyanagi *et al.* [19] reported that the adduction moment in patients with varus deformity knee OA while walking barefoot, was significantly reduced after wearing the lateral wedged insole with subtalar strapping as compared with the use of the neutral insole, during the dynamic phase of gait. Their results suggested that the insole with subtalar strapping may have a therapeutic effect by decreasing the medial compartment loading at the knee joint not only during the static, but also during the dynamic phase.

In the present study, there was significant reduction in the pain over medial aspect of the knee (as judged by the mean WOMAC score) by the end of 12 months in patients in Group A as compared to those in Group B ($p<0.005$).

Femorotibial angle was the other parameter assessed in this research. Using lateral wedged insole shoes had very less influence on the FTA, as in our study, there were insignificant changes in FTA in patients belonging to either groups. This goes in accordance with the findings of the study conducted by Bennel *et al.* (2011) [20] who concluded that there was no relation between the use of lateral wedged insoles and FTA in patients with knee OA. Few earlier studies, having follow up period of minimum 2 years have shown significant change in radiological progression, suggesting that time duration for such changes need more time and extended patient follow up time must be considered.

Coming to the frequency of intake of NSAIDS ; patients using lateral wedged insole shoes had a significant reduction in NSAIDS usage compared to controls ($p<0.005$). The decreased frequency of NSAIDS intake implies reduced adverse drug reactions like gastritis, nausea etc, which has ultimately works towards enhancing the quality of life in patients with osteoarthritis of the the knee. In a study by Pham T *et al.*, it was found that customised lateral heel wedge insoles, worn for a period of two years, were associated with a reduction in the frequency of intake of non-steroidal anti-inflammatory drugs, but did not alter stiffness, function, or joint space narrowing as evident on radiography [21, 22].

We are aware of the limitations of our study. The current study did not clarify the duration of the insole usage each day. The patients were instructed to use the insole shoes for at least 10 hours per day. Non compliance of the patients could be inferred by observing the condition of the material wear at the time of subsequent follow ups. A longer follow up period and a larger sample size was needed to comment definitively upon the effect of using lateral wedged insoles on radiological findings of joint space narrowing and FTA alteration.

Conclusion

In summary, our findings show that use of lateral wedged insole shoes as the primary treatment option in knee OA had marked effect in reduction of severity of pain and frequency of intake of NSAIDS to relieve pain. However, our study has

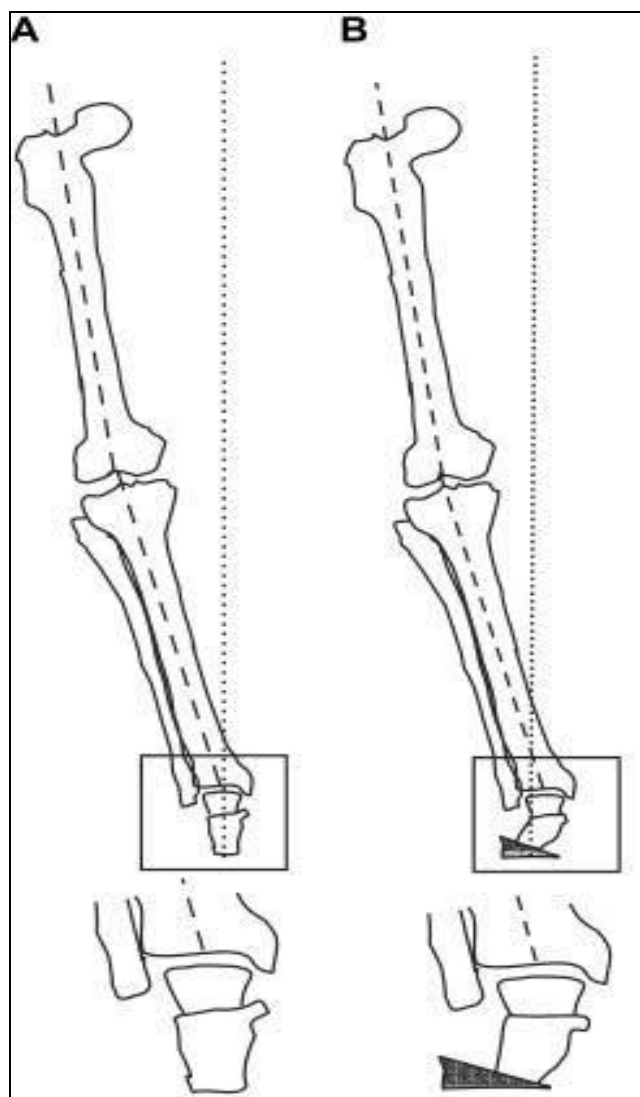


Fig 3: Showing effect of lateral wedged insoles on the mechanical axis of lower limb

reported insignificant reduction in the FTA and no changes in radiological progression of the disease of knee OA. A longer study period and a larger sample size if hypothesized to be necessary to comment definitively on structural and radiological changes. We thus support the clinical recommendation of the using lateral wedged insoles for patients with Grade I/II knee osteoarthritis.

References

- Felson DT, Naimark A, Anderson J, Kazis L, Castelli W, Meenan RF: The prevalence of knee osteoarthritis in the elderly. The Framingham Osteoarthritis Study. *Arthritis and Rheumatism* 1987;30:914-918.
- Hamerman D. Clinical implications of osteoarthritis and aging. *Annals of the Rheumatic Diseases* 1995;54:82-85.
- Dieppe P, Brandt KD. What is important in treating osteoarthritis? Whom should we treat and how should we treat them? *Rheum Dis Clin N Am* 2003;29(4):687-716.
- Dieppe PA, Ebrahim S, Martin RM, Juni P. Lessons from the withdrawal of rofecoxib. *Bmj* 2004;329(7471):867-868.
- Zhang W, Moskowitz RW, Nuki G, Abramson S, Altman RD, Arden N *et al.* OARSI recommendations for the management of hip and knee osteoarthritis, part II: OARSI evidence-based, expert consensus guidelines. *Osteo & Cart* 2008;16:137.
- Lachance L, Sowers MF, Jamadar D, Hochberg M. The natural history of emergent osteoarthritis of the knee in women.
- Ledingham J, Regan M, Jones A, Doherty M. Radiographic patterns and associations of osteoarthritis of the knee in patients referred to hospital. *Ann Rheum Dis* 1993;52:520-6.
- Schipplein OD, Andriacchi TP. Interaction between active and passive knee stabilizers during level walking. *Journal of Orthopaedic Research* 1991;9:113-119.
- Bailunas AJ, Hurwitz DE, Ryals AB, Karrar A, Case JP, Block JA, Andriacchi TP. Increased knee joint loads during walking are present in subjects with knee osteoarthritis. *Osteoarthritis & Cartilage* 2002;10:573-579.
- Hurwitz DE, Ryals AB, Case JP, Block JA, Andriacchi TP. The knee adduction moment during gait in subjects with knee osteoarthritis is more closely correlated with static alignment than radiographic disease severity, toe out angle and pain. *J Orthop Res* 2002;20:101-108.
- Miyazaki T, Wada M, Kawahara H, Sato M, Baba H, Shimada S. Dynamic load at baseline can predict radiographic disease progression in medial compartment knee osteoarthritis. *Ann Rheum Dis* 2002;61:617-622.
- Bennell K, Bowles KA, Payne C *et al.* Effects of laterally wedged insoles on symptoms and disease progression in medial knee osteoarthritis: a protocol for a randomised, double-blind, placebo controlled trial. *BMC Musculoskelet Disord* 2007;8:96
<https://doi.org/10.1186/1471-2474-8-96>
- Kakihana W, Akai M, Nakazawa K, Takashima T, Naito K, Torii S. Effects of laterally wedged insoles on knee and subtalar joint moments. *Arch Phys Med Rehabil* 2005;86:1465-71.
- Kerrigan DC, Lelas JL, Goggins J, Merriman GJ, Kaplan RJ, Felson DT. Effectiveness of a lateral-wedge insole on knee varus torque in patients with knee osteoarthritis. *Arch Phys Med Rehabil* 2002;83:889-93.
- Butler RJ, Marchesi S, Royer T, Davis IS. The effect of a subject-specific amount of lateral wedge on knee mechanics in patients with medial knee osteoarthritis. *J Orthop Res* 2007;25:1121-7.
- Hinman RS, Payne C, Metcalf BR, Wrigley TV, Bennell KL: Lateral wedges in knee osteoarthritis: what are their immediate clinical and biomechanical effects and can these predict a three-month clinical outcome? *Arthritis Rheum (Arthritis Care Res)* 2008;59:408-15.
- Schipplein OD, Andriacchi TP. Interaction between active and passive stabilizers during level walking 1991;9:113-9.
- Andriacchi TP. Dynamics of knee malalignment 1991;25:395-403.
- Kuroyanagi Y, Nagura T *et al.* effect of lateral wedged insole on the joint load of knees and ankles – with special reference to the effect on insoles with elastic bandage 2004;18:16-4.
- Bennell KL, Bowles KA, Payne C, Cicuttini F, Williamson E, Forbes A *et al.* Lateral wedge insoles for medial knee osteoarthritis: 12 month randomised controlled trial. *BMJ* 2011;342:d2912. doi: 10.1136/bmj.d2912. PMID: 21593096; PMCID: PMC3100910.
- Pham T, Maillefert JF, Hudry C, Kieffert P, Bourgeois P, Lechevalier D *et al.* Laterally elevated wedged insoles in the treatment of medial knee osteoarthritis. A two-year prospective randomized controlled study. *Osteo & Cart* 2004;12:46-55.
- Maillefert JF, Hudry C, Baron G, Kieffert P, Bourgeois P, Lechevalier D *et al.* Laterally elevated wedged insoles in the treatment of medial knee osteoarthritis: a prospective randomized controlled study. *Osteo & Cart* 2001;9:738-45.
- Kellgren JH, Lawrence JS. Radiological assessment of osteoarthritis 1957;16:494-501.
- Ebrahimzadeh MH, Makhmalbaf H, Birjandinejad A, Keshtan FG, Hoseini HA, Mazlumi SM. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) in Persian Speaking Patients with Knee Osteoarthritis. *Arch Bone Jt Surg* 2014;2(1):57-62.