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# Role of plain shoe insoles in the management of knee osteoarthritis

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#### Abstract

Knee osteoarthritis, which most commonly affects the medial compartment, is a chronic joint disorder that imposes a major healthcare burden. It imposes a significant economic burden and is associated with considerable pain, disability and loss of quality of life [1].

To date, most knee OA research has focused on tertiary management strategies, primarily drug therapies. Although effective, drug therapies have side effects and are expensive. As no cure exists, traditional management aims to reduce pain, improve function, and enhance quality of life while minimising the adverse effects of therapy [2].

There is a growing awareness of the importance of biomechanical factors in the pathogenesis and progression of knee osteoarthritis. However, there is controversial evidence regarding whether foot orthoses or knee braces improve pain and function or correct malalignment in selected patients with osteoarthritis (OA) of the medial knee compartment. The aim of our study was to evaluate the whether the insoles would result in reduction of pain and improvement in WOMAC function scores in patients with established osteoarthritis.

Keywords: Osteoarthritis, insole, pain, function

# Introduction

Osteoarthritis (OA), also sometimes called osteoarthrosis or degenerative joint disease, is not a single disease, but rather the clinical and pathological outcome of a range of disorders and conditions that lead to pain, disability and structural failure in synovial joints <sup>[3]</sup>. The knee is the most common lower limb site for OA. The medial tibiofemoral compartment is the most commonly affected (medial 67% versus lateral 16%) <sup>[4]</sup>

Osteoarthritis (OA) knee is a common, chronic, localised joint disease which is associated with pain and physical disability and imposes a significant personal, social, and economic burden <sup>[5]</sup>. Contemporary management aims to reduce pain and optimize physical function while minimizing adverse side effects of therapy. Since expensive surgical interventions (e.g. arthroplasty) are reserved for end-stage disease, conservative treatments are desirable. Although efficacious, drug therapies are associated with adverse effects. Accordingly non pharmacologic measures are considered the cornerstone of OA management <sup>[6]</sup>.

Shoe insoles are one such strategy recommended by health professionals for managing knee OA <sup>[7]</sup>. The remarkable lack of studies evaluating role of orthoses is a consequence of lucrative opportunities for the development of drug therapy. According to a recent meta-analysis, 60% of OA trials assess drug treatments, and 26% assess surgical procedures <sup>[8]</sup>.

Health practitioners frequently advise patients with knee OA regarding footwear choices and use of cane to unload the affected knee joint. A Cochrane review (2009) concluded there is some evidence that foot orthoses have additional beneficial effects in the treatment of symptomatic knee OA <sup>[9]</sup>. Foot orthoses are easy to apply, and good adherence to the intervention has been reported <sup>[10]</sup>. Treatment methodology using shoe insole was effective in significantly reducing pain and improving function <sup>[11]</sup>.

Wedged insoles were first proposed for knee osteoarthritis in the 1980s these have received attention but other types that potentially play a role in knee osteoarthritis are shock-absorbing insoles or textured insoles. Plain shoe insoles have a shock absorbing effect which leads to

decreased loading at the knee joint <sup>[12]</sup>. Patients suffering from OA knees have been managed by multiple modalities which were the subjects of research and study over the years. However there are very few studies conducted on usage of orthotics (shoe insoles) which is gaining acceptance worldwide. This prompted us to take up the present study to assess the role of shoe insoles in the management of knee osteoarthritis in reducing pain

# **Materials and Methods**

This prospective study was undertaken at Department of Orthopaedics, Christian Medical College & Hospital, and Ludhiana over a period of 1 year with follow up of 6 months minimum

All the patients diagnosed with knee osteoarthritis and who fulfilled the Inclusion Criteria and Exclusion Criteria mentioned below were enrolled in the study after explaining about the study and obtaining informed consent.

# **Inclusion Criteria**

- 1. Age 40 years and above
- 2. Knee pain since 1 month or more
- 3. Grade 1-3 of tibio femoral narrowing of knee joint space on standing anteroposterior radiographs (Kellgren Lawrence scale, 1957)
- 4. Pain on at least 2 of 5 items of pain aspect on modified Western Ontario and McMAster Universities osteoarthritis index (WOMAC pain scale, 1988)

# **Exclusion Criteria**

- Bed or chair ridden patients or patients using walking aids
- 2. Limited ability/refusal to wear shoes
- 3. Patients with lower limb amputations
- 4. Patients with foot sores or ulcers attributable to diabetes or other causes
- 5. Patients who have significant co-morbid condition that limits walking more than knee pain does
- 6. Patients who had received corticosteroid injection in the knee in the month before screening
- Patients who had bilateral total knee replacements or who are planned for total knee replacement surgery within the period of study
- 8. Grade 4 of tibiofemoral narrowing of knee joint space on standing anteroposterior radiographs (Kellgren Lawrence scale, 1957)

Informed consent was taken from the eligible patients included in the study. As submitted in the protocol, a semi-structured questionnaire was developed to record the history related to knee pain. Other medical comorbidities were also recorded in the protocol. Patient was examined.

The radiographs (both knees AP standing) were taken and the grade of osteoarthritis was noted according to Kellgren and Lawrence scale.

Patient was then assessed on the WOMAC scale.

After the patient was seen by a consultant, s/he was explained about the shoe insoles required and available and was asked to wear the same and note the duration. Shoe insoles used in this study were made of micro cellular rubber, 10 mm in thickness and trimmed according to footwear patient was using. S/he was followed up every 2, 4 and 6 months and the WOMAC scale value was calculated. The average duration for which the patient used the shoe insole was noted.

# **Statistical analysis**

Results were calculated by using SPSS software version 21 (Armonk, NY: IBM corp.). Continuous variables are represented by mean + / - SD. Mann Whitney U test was used for them. Categorical variables are represented by number and percentage. Chi square test was used for them. Friedmann test was used for comparing variables collected at different time periods. Kruskal wallis test was used for comparison between WOMAC score and KL scale.

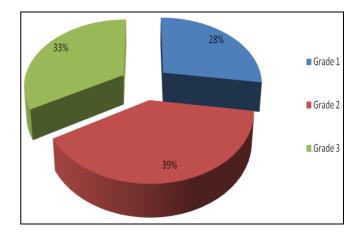
#### Results

Total of 44 patients with 84 affected knees completed minimum 6 months of follow up. Majority of the patients 21 (47.73%) were in age group 50-59 years followed by 14 (31.82%) in age group 40-49 years, 8 (18.18%) were in age group 60-69 years and 1 (2.27%) patient was of 76 years age. (Table 1).

Age (in years)	N	%age
40-49	14	31.82%
50-59	21	47.73%
60-69	8	18.18%
>,=70	1	2.27%
Total	44	100%

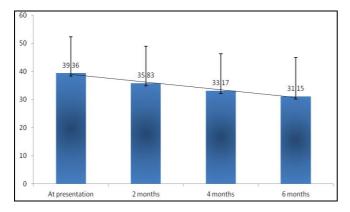
Most of these patients were females i.e. 30(68.2%). Most of the patients 40(91%) had bilateral knee involvement and only 4(9%) had unilateral knee involvement. Out of total 44 patients observed, 12(27.27%) were obese and 32(72.72%) were not obese.

Majority of the knees -33(39%) had grade 2 osteoarthritis on Kellgren Lawrence scale followed by grade 3 OA in 28(33%) and grade 1 OA in 23(28%) knees. Mean rank age (in years) for grade 1 OA was 38.89, grade 2 was 40.06 and for grade 3 was 48.34 (p=0.293). (Fig 1)



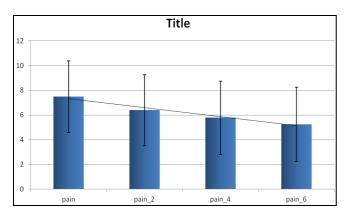
Majority of the patients 39(88.63%) used the shoe insoles for 4-6 hours/day followed by 5(11.4%) for 2-4 hours/day.

Amongst 84 knees studied, the mean value of WOMAC score was 39.36 at the time of presentation, 35.83 at 2 months follow up, 33.17 at 4 months follow up and 31.15 at 6 months follow up. The p value was <0.0001. It indicates that decrease in WOMAC scores was statistically significant after wearing shoe insoles. (Fig 2)



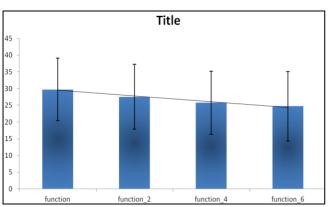
Mean rank value of WOMAC score was found to be greater in obese patients than non-obese patients at the time of presentation and during follow up of 2, 4, 6 months (p<0.0001) which was statistically significant. This indicated that level of pain, stiffness and difficulty in daily functions was more in obese patients than non-obese patients.

The mean score of pain subscale was 7.48 at the time of presentation, 6.39 at 2 months follow up, 5.78 at 4 months follow up and 5.26 at 6 months follow up. The p value was <0.0001. It indicates that pain measured on pain subscale decreased after intervention in subsequent follow ups and was statistically significant. (Fig 3)



The mean score of stiffness subscale was 2.40 at the time of presentation, 1.98 at 2 months follow up, 1.57 at 4 months follow up and 1.33 at 6 months follow up. The p value was <0.0001. It indicates that stiffness measured on stiffness subscale decreased after intervention in subsequent follow ups and was statistically significant.

The mean score of function subscale was 29.75 at the time of presentation, 27.56 at 2 months follow up, 25.75 at 4 months follow up and 24.74 at 6 months follow up. The p value was <0.0001. It indicates that difficulty in daily functions measured on function subscale decreased after intervention in subsequent follow ups and was statistically significant. (Fig 4)



#### Discussion

Knee osteoarthritis (OA) is a disabling disorder affecting approximately 13% of population [11]. Pain and disability associated with the disease lead to a loss of functional independence and a significant impairment in quality of life. The economic impact of knee OA is also a large and growing problem for health care systems. Given that there is currently no cure for knee OA and the only established treatment for end-stage OA is costly joint replacement, slowing of structural disease progression is essential to help reduce the personal and societal burden of knee OA [13].

Conflicting results are available from different studies conducted worldwide on use of shoe insoles for treatment of knee osteoarthritis. Various studies [14-15] reported an improvement of symptoms in patients with mild to moderate OA treated with laterally wedged insoles. A Cochrane review concluded there is some evidence that foot orthoses have additional beneficial effects in the treatment of symptomatic knee OA [9]. One crossover study showed no effect of wedged soles in an elderly population with advanced stages of OA [10]. In our study we observed statistically significant improvement in pain, stiffness and range of motion in subsequent follow ups. Function subscale score decreased after the usage of shoe insoles. In subsequent follow ups improvement was observed in activities of daily living.

WOMAC score decreased in all the 3 grades of OA after usage of shoe insoles in subsequent follow ups. It indicated relief in pain, improvement in range of motion, activities of daily living and quality of life.

Two third of patients who took analgesics prior to presentation and during treatment along with usage of shoe insoles reported relief in pain, improved range of motion and activities of daily living leading to better quality of life. This could be partially attributed to additional insole/s usage.

At initial presentation one third of patients had not been using analgesics. The subsequent pain reduction, improvement in range of motion and activities of daily living leading to better quality of life in them could be solely attributed to usage of shoe insoles.

# Conclusion

Osteoarthritis (OA) knee is an age related degenerative disorder most commonly seen in 5th and 6th decades. It was found more common in obese females. Management includes conservative and surgical treatment. Conservative management consists of life style modifications, drug therapies and non-pharmacologic measures like orthoses and braces, considered the cornerstone of OA management. Increased joint loading is amenable to change using orthoses (insoles or footwear) and braces. Accordingly, insoles and footwear offer great potential as simple, inexpensive treatment strategies for knee osteoarthritis as evident in our study by significant improvement in WOMAC scale, pain reduction and improvement in stiffness as well as daily function. Since shoe insoles are simple, safe and inexpensive, even a small improvement in pain translates into significant public health benefits.

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