
Additional Effects of Medial Wedge Insole Coupled with Conventional Therapy in Patients with Bilateral Lateral Compartmental Knee Osteoarthritis: A Clinical Trial Study

Fatema Campwala¹, Vinit Mody²

¹Student, Department of Physiotherapy, (MPT Musculoskeletal disorders & Sports), ²Associate Professor, (MPT Musculoskeletal conditions)

How to cite this article: Fatema Campwala, Vinit Mody. Additional Effects of Medial Wedge Insole Coupled with Conventional Therapy in Patients with Bilateral Lateral Compartmental Knee Osteoarthritis: A Clinical Trial Study. Indian Journal of Physiotherapy and Occupational Therapy 2023;17(3).

Abstract

Background: Osteoarthritis (OA) is the most prevalent disorder of the locomotor system, and involves the large weight bearing joints of the lower limb such as knee joint. The progression of OA knee is typically affected by mechanical stress created by varus and valgus malalignment, which in turn overloads the medial and lateral compartments, respectively. The rationale of wedged insoles is to transfer the load from the affected knee compartment to the joint contralateral compartment. So, the aim of the study was to compare the effectiveness of conventional therapy plus medial wedge insole in the footwear and conventional therapy alone on pain, physical function and alignment in lateral compartmental knee osteoarthritic patients.

Method: Study included 30 patients with bilateral lateral compartmental knee OA, aged 40-60 years and divided into 2 groups: Group A received conventional therapy plus medial wedge insole and Group B received conventional therapy alone for 6 weeks (3 sets of 10 repetitions daily). Inter-group analysis by unpaired t-test showed statistically significant improvement in Lequesne index score and tibiofemoral angle (P value ≤ 0.05).

Conclusion: In patients with lateral compartmental knee OA, conventional therapy plus medial wedge insole were more effective than conventional therapy alone in reducing pain, improving functional disability and tibiofemoral angle.

Key words: Medial wedge insole, Lateral compartmental knee OA

Introduction

Knee osteoarthritis (OA), also known as degenerative disorder of the knee joint, typically results from rupture and progressive loss of articular cartilage. It is a common joint disease with idiopathic causes.^{1,2} Still, aging, obesity, knee injuries, and abnormal mechanical loads are considered to be its risk factors.³

The etiology of OA is not entirely clear, but its incidence increases with age and in women.^{4,5} Obesity is a risk factor for the development and progression of OA knee.^{4,6,7} The biomechanical theory concluded that obesity leads to repetitive application of increased axial loading at the knee joint with consequent degeneration of articular cartilage and sclerosis of subchondral bone.⁸⁻¹⁰ The metabolic

Corresponding Author: Fatema Campwala, Student, MPT Musculoskeletal disorders & Sports, Pioneer Physiotherapy College, Sayajipura, Vadodara, Gujarat, India.

Email ID: fatemacampwala09@gmail.com

theory proposed that excess fat has a direct effect on cartilage over and above the effects of stress.¹¹

Based on the global statistics, over 100 million people are suffering from osteoarthritis worldwide.¹² In western population, OA of the knee joint is the third in prevalence of this condition, following spine and hip, because knee receives high loading while standing and walking.¹³ The prevalence rate of self-reported arthritis in the United States is projected to increase to 18.2% (59.4) million of the estimated population in 2020.¹⁴ The main concern is the disability associated with arthritis, which is projected to increase from 2.8% of the 1990 population to 3.6% of the 2020 population.¹⁵ In addition, arthritis limits daily activities in 11.6% of persons aged > 65 years. In India, prevalence of OA has been suggested to be 22 to 39%.¹⁶⁻¹⁸

In patients with lateral compartmental knee OA, joint space is lost in that compartment leading to knee valgus angulation. The angulation increases knee valgus torque which potentially leads to progressive joint space loss and angulation, then, becoming a vicious cycle. The wedge insole was postulated to be able to interrupt this vicious cycle and slow down the progression of this abnormality. It could also decrease knee valgus torque and knee pain.

Realignment of the femorotibial angle through corrective osteotomy for valgus malalignment and at the tibia for varus malalignment can slow down or retard progression of knee OA. However, the surgical approach has a number of difficulties and drawbacks, such as cost, insufficient correction, need for patient withdrawal from activities and complications in 15% of cases including conditions like thrombosis, thromboembolism and nerve injuries.^{19,20}

The use of wedge insole represents an alternative to surgical approach. The rationale for use of wedge insoles is to transfer the load from affected joint compartment to the knee contralateral compartment. In this regard, the evidence based literature states that lateral wedge insoles help reduce pain associated with varus knee OA. Additionally, medial wedge insoles seem to be effective in decreasing lateral thrust and reducing pain while walking, particularly in people with early disease.²¹

Materials and Method

Study Design: A Clinical trial study

Study Population: Patients with bilateral lateral compartmental OA knee

Study Setting: Various Physiotherapy OPDs in Vadodara

Sampling Design: Convenience sampling method

Sample size: 30 patients

Inclusion criteria:

- Age 40-60 years
- Bilateral valgus deformity $\geq 8^\circ$
- Grade ≥ 2 lateral compartment involvement on Kellgren Lawrence Scale

Exclusion criteria:

- Body mass index $\geq 40\text{kg}/\text{m}^2$
- Any history of trauma within one year to the knee joint
- Associated limb length discrepancy, congenital anomalies, neuromuscular disorders or any pathological conditions affecting knee joint.

Materials Used:

- Consent form
- Assessment form
- Lequesne Index Score for Osteoarthritis
- Examination table
- Medial wedge insole (8mm Height)
- Weight Cuffs, Sand bags and Pelvic strap
- Tracing Paper, Pencil, Scale
- Universal Goniometer
- Weighing machine
- Stadiometer
- Sony Cybershot 3x Zoom Digital Camera

Outcome Measures:

1) Lequesne Index:

It is a subjective scale used to measure pain/discomfort, maximum distance walked and activities of daily living in patients with osteoarthritis and

degenerative arthritis of the knee. It is a valid, reliable and disease specific measurement scale.²⁵ It consists of total 11 items covering pain/discomfort (5 items), maximum distance walked (2 items) and activities of daily living (4 items). The total score for Lequesne Index for osteoarthritis is 24, the score for Lequesne pain/ discomfort subscale is 8, the score for Lequesne maximum distance walked subscale is 8 and the score for Lequesne activities of daily living subscale is 8. The highest score indicates worst symptoms.²²⁻²⁴

2) Tibiofemoral angle (TFA):

It has been described as the angle defined by the mechanical axis of the femur intersecting the mechanical axis of the tibia. Radiological, photographic, and clinical methods have been used to assess the normal limits of the TFA. However, very few studies have reported the normal limits of the TFA from the beginning of walking age to the end of the adolescent period.

The anatomic (longitudinal) axis of the femur is oblique, directed inferiorly and medially from its proximal to distal end. The anatomic axis of the tibia is directed almost vertically. Hence, the femoral and tibial longitudinal axes normally form an angle medially at the knee joint of 180° to 187° i.e. the femur is angled up to 7° off vertical, creating a slight physiologic (normal) valgus angle at the knee. If the medial tibiofemoral angle is greater than 187° , an abnormal condition called genu valgum "knock knees" exists. If the medial tibiofemoral angle is 175° or less, the resulting abnormality is called genu varum "bow legs."

Patients were requested to continue normal activities and avoid any other forms of treatment for the duration of the study, apart from routine physical management. Participants other than designated protocol were not permitted to administer any other forms of electrotherapy or other techniques (steroids, acupuncture, or taping) during the intervention period of the trial.²⁶⁻²⁸

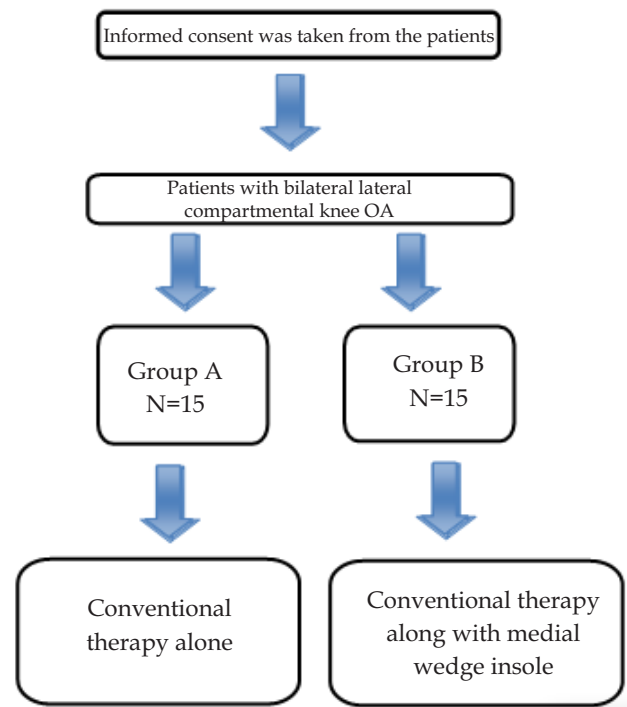


Figure 1: Consort Diagram

All the patients were informed in detail about the type and nature of the study. The subjects were divided into two groups; Group A and Group B; 15 participants in each group.

Group A: received only conventional therapy of knee osteoarthritis

Group B: received conventional therapy of knee osteoarthritis as well as medial wedge insole in the footwear.

Conventional therapy for both Group A and Group B:

Both Group A and Group B were educated about energy conservation and work simplification techniques and were given progressive muscular strengthening rehabilitation program, Frequency: 3 sets of 10 repetition daily for 6 weeks

- (A) Quadriceps Setting exercise
- (B) Short- Arc Terminal Knee Extension
- (C) Straight- Leg Raise
- (D) Hip Abductor strengthening in side lying
- (E) Hamstring Curls in prone lying position
- (F) Quadriceps Strengthening in high sitting position

- (G) Tensor Fascia Lata Stretch
- (H) Hamstring Muscle Stretch
- (I) Calf Muscle Stretch
- (J) Co-contraction of Quadriceps and Hamstring Muscles

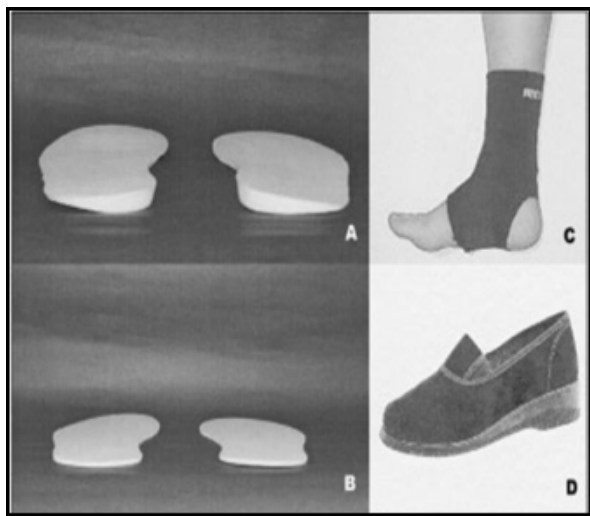


Figure 2: Medial wedge insole



Figure 3: Patient wearing medial wedge insole in the footwear

Results and Discussion

Data was analysed by SPSS software version 20.0 and Microsoft Excel 2010. Prior to the statistical test, data was screened for normal distribution by ShapiroWilk test. According to normal distribution, tests were applied for within group and between group analysis.

Table 1: Results of Unpaired t- test For Between Group Analysis (Between Group A & B)

Outcome Measures	Group A	Group B	P value	Remarks
Tibiofemoral Angle	2.066±0.7988	0.3333±0.4879	<0.001	Significant
Lequesne Index	4.333±1.0465	2.1333±1.1872	<0.001	Significant

Here, the difference of pre-intervention and post-intervention was taken and between group comparison of Tibiofemoral angle and Lequesne index showed statistically significant difference.

Hence, conventional therapy along with medial wedge insole were found to be more effective in reducing pain, improving functional disability and tibiofemoral angle in knee osteoarthritic patients.

In this study, additional effects of medial wedge insole along with conventional therapy in patients with bilateral lateral compartmental knee osteoarthritic patients were examined. Pain, physical function and alignment were assessed by Lequesne index and Tibiofemoral angle.

The first objective of the study was to find the effectiveness of conventional therapy on pain, physical function and alignment of knee osteoarthritic patients.

The second objective of the study was to find the effectiveness of conventional therapy plus medial wedge insole in the footwear on pain, physical function and alignment of knee osteoarthritic patients.

The third objective of the study was to compare the effectiveness of conventional therapy plus medial wedge insole in the footwear and conventional therapy alone on pain, physical function and alignment of knee osteoarthritic patients.

The results of this study showed statistically significant improvement in Lequesne index score and tibiofemoral angle with the use of conventional therapy along with medial wedge insole (within group comparison). However, in the inter-group comparison, conventional therapy along with medial wedge insole were found to be more effective than conventional therapy alone.

Thus, medial wedge insole along with conventional therapy can be further implemented in clinical practice for improving the pain, physical function and alignment in patients with bilateral lateral compartmental knee OA patients according to the availability of the clinical set up and the trained physiotherapists.

Conclusion

The results of this study support the alternative hypothesis and showed statistically significant improvement in Lequesne index score and tibiofemoral angle for pain, physical function and alignment with the use of conventional therapy along with medial wedge insole (within group comparison). However, in the inter-group comparison, conventional therapy along with medial wedge insole were found to be predominant than conventional therapy alone. All findings support the idea and concluded that conventional therapy plus medial wedge insole proved to be more effective than conventional therapy alone in patients with lateral compartmental knee OA.

Limitations

- The study consisted of only a small quantity of patients, which should be revised to a large number of patients and for longer duration of time.
- This was a short term study of 6 weeks and further follow up of patients were not carried out.
- The patients in this study were recruited without clinical diagnosis of OA knee, they were taken on the basis of radiological diagnosis of lateral compartmental OA knee.

Ethical clearance: Ethical clearance was obtained from The Institutional Review Board from Pioneer Physiotherapy College, Vadodara. Approval date: 17-09-2022, Reference/approval number- PPC/OW/4021A /2022.

Source of funding: Self

Conflict of interest: Nil

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