



Original Article

Effect of Physical Therapy Treatment in Knee Osteoarthritis with and without Wedge Insole: A Randomized Controlled Trial

Syed Muhammad Shah¹, Khurram Sarfraz², Naveeda Ashraf¹, Danish Hassan² and Muhammad Waseem Akhtar³¹University Institute of Physical Therapy, The University of Lahore, Lahore, Pakistan²Riphah College of Rehabilitation & Allied Health Sciences, Riphah International University, Lahore, Pakistan³Akhtar Saeed College of Physical Therapy, Akhtar Saeed Medical College, Lahore, Pakistan

ARTICLE INFO

Key Words:

Foot Orthosis, Knee Osteoarthritis, Physical Therapy

How to Cite:

Mohammad Shah, S. ., Ashraf, N. ., Hassan, D., & Waseem Akhtar, M. . (2022). Effect of Physical Therapy Treatment in Knee Osteoarthritis with and without Wedge Insole: Randomized Controlled Trial: Physical Therapy Treatment in Knee Osteoarthritis With Wedge Insole. *Pakistan BioMedical Journal*, 5(3). <https://doi.org/10.54393/pbmj.v5i3.144>

*Corresponding Author:

Danish Hassan
 Riphah College of Rehabilitation & Allied Health Sciences, Riphah International University
danish.hassan009@gmail.com

ABSTRACT

Objective: To determine the effects of physical therapy treatment in knee osteoarthritis with and without wedge support **Methods:** This randomized controlled trial was conducted at Outpatient Department of Physical Therapy, Mayo Hospital, Lahore and Mid City Hospital, Lahore. Eighty patients with knee osteoarthritis were selected using a predefined inclusion and exclusion criteria and randomly allocated in two treatment groups; Group A (Routine physiotherapy treatment) and Group B (Routine physiotherapy with wedge insole). Outcome was recorded at the start and at the end of treatment at 3 weeks in terms of pain and disability as recorded on Numeric Pain Rating Scale (NPRS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) respectively. The collected data was entered and analyzed using SPSS v25 with p value < 0.05 as significant. **Results:** At the end of the third week, there was a statistically significant difference between the two treatment groups in terms of VAS (Mean Difference 1.55; p value 0.05) and WOMAC (Mean Difference 5.53; p value 0.0001). A statistically significant difference in before and after treatment VAS and WOMAC score was also noted within each group with p value < 0.0001. **Conclusions:** In comparison to conventional physical therapy alone, adding wedge insoles to the routine physical therapy treatment of Knee Osteoarthritis results in better pain relief and function improvement.

INTRODUCTION

Osteoarthritis (OA) is a debilitating disease that involves all structures of the joint being affected. It is one of the most common chronic health disorders in the western world; with a high prevalence among the aging population [1,2]. OA can cause severe pain, joint stiffness, localized swelling, instability of articulating bones and generalized muscular weakness, all of which can lead to decreased physical function which ultimately reduce quality of life particularly among elderly [3]. Accordingly, based on disease pathogenesis, treatments are based on conservative approaches that not only decrease severity of symptoms but also reduce joint loading which ultimately reduce progression of disease [4]. Non-pharmacological treatment strategies to improve symptoms are advocated and there are increasing evidences that physical therapy interventions can play a crucial role in the multidisciplinary

approaches or treatment and management of subjects with knee OA [3]. Physiotherapy incorporates a wide range of treatment options that are tailored to a patient's unique clinical presentation [5]. Wedge insoles or footwear are orthotic devices that put forward a great potential as effortless, economical treatment strategy for knee OA. During walking activities, the ground reaction force (GRF) directed towards the medial compartment of the knee joint thus generating an external knee adduction moment during the stance phase. Evidences suggests that all the features of the wedge including its length, the angle of inclination and the material used may alters the overall biomechanical aspects as well as the joint position at knee and ankle sites that provide benefits [6-8]. In subjects with knee OA, wedge insoles have been shown to decrease the peak knee adduction moment by more or less 12% on an

average which ultimately interact with this indirect biomechanical surrogate for knee loading [6-10]. Different biomechanical studies have reported use of lateral wedges helps in reducing the external knee adduction moment while walking by up to 13% in contrast with walking in barefoot or using simple shoes in the OA of the medial compartment of knee [7,10,11]. The prevalence of knee OA is very high in Pakistan as reported in previous studies [12,13]. Knee OA is mostly managed symptomatically using pharmacological intervention or physical therapy. Treatment of knee OA by the improving the altered biomechanics a result of which the load on the stressed compartment of knee is a neglected treatment option. Hence the main objective of this study was to determine the effect of physical therapy treatment in knee osteoarthritis with and without wedge insole.

METHODS

This study was a randomized control trial conducted at the Outpatient Department of Physical Therapy of Mayo Hospital Lahore, Mid City Hospital Lahore. The data was collected in a period of 06 months using the ethical guidelines of the Helsinki Declaration and Institutional Review Board (IRB) ethical approval form King Edward Medical University. Patients were included if aged above 45 years, both gender with an average knee pain on walking more than 4 on an 11 point scale, pain located over the medial knee compartment, evidence of osteophytes in the medial compartment or medial joint space narrowing on an X ray film [14]. All participants provided written informed consent. Patients were excluded for the study if they had features of advanced degenerated knee joint disease as induced on X ray [15], any history of intra articular steroid injection, any musculoskeletal condition affecting lower limb function, rheumatic disease, did not use appropriate footwear to accommodate foot insoles and were already using any assistive device while ambulating. A minimum sample of 80 knee OA patients was calculate based upon the mean change in NPRS across the two treatment groups based upon a previous study with confidence level 0.95 and power 80% using Open Epitool online software.

Outcome Measures

1. Western Ontario and McMaster Universities

Osteoarthritis Index(WOMAC): It is a self-administered 24 item questionnaire used to evaluate Hip and Knee osteoarthritis. There are three subscales of pain (5 items), stiffness (2 items) and physical activities (17 items) each scored on 0-4 point Likert scale. Higher scores on the WOMAC indicate worse pain, stiffness, and functional limitations.

2.Numeric Pain Rating Scale (NPRS): It is a self-reported 11 points Likert scale used to quantify level of pain. Zero on

Treatment Protocol: Detailed examination of knee joint was carried out after the initial eligibility of patients to participate in the study after which they were randomly allocated to two treatment groups (Group A or B) using random number generator. The allocation was carried out using sealed opaque envelope. Patients allocated to group A were treated with conventional physical therapy that included 10 minutes of moist heat application around the knee joint, Grade I and II oscillatory mobilization of tibio-femoral joint and strengthening exercises of knee flexors and extensors. Each session lasted for 30 minutes and every patient received 2 treatment session per week for a period of 3 weeks. Patients in this group B were treated by conventional physical therapy treatment along with wedge insole. Participants were provided with 5-degree lateral wedge made of high density ethyl vinyl acetate which they wore bilaterally for at least 6 hours per day for 3 weeks. NPRS and WOMAC score were recorded at the start and at end treatment at 3 weeks

Data Analysis: The data was analyzed using SPSS version 25. Normality of the data was assed using Shapiro-Wilk test. The data was normally distributed for pain and disability. Independent sample t test and repeated measure ANOVA were used to analyses across and within the group difference for VAS and WOMAC. P value <0.05 was considered to be significant.

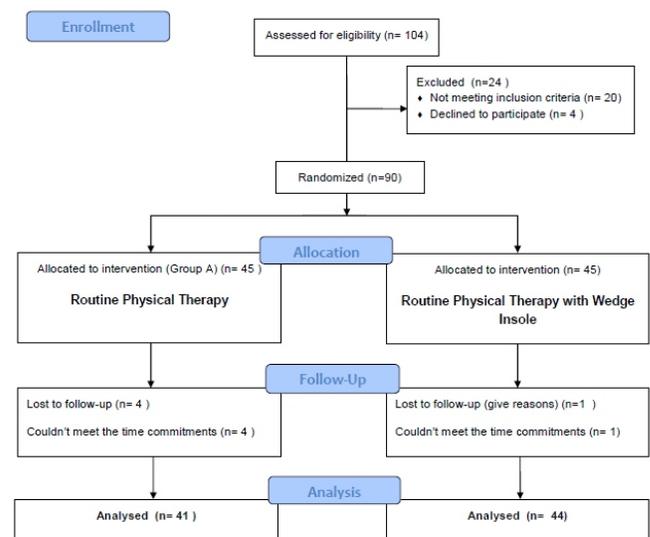


Figure 1: CONSORT Flow Sheet Diagram of the Research Process

RESULTS

Out of 90 patients randomized to two treatment groups, 5 patients dropped out making the follow up in the study 94.0% (Figure 1). The basic demographic of the two treatment groups is listed in Table 1 which show the treatment groups were similar at baseline. There was statistical significant difference between the two

treatment group at the end of 3rd week in terms of VAS (Mean Difference 1.55; p value < 0.05) and WOMAC (Mean Difference 5.53; p value < 0.0001). Statistical significant difference was also reported with in each group in pre and post treatment VAS and WOMAC score (Table 2).

Variables	Routine Physical Therapy N= 41	Routine Physical Therapy + Wedge Support N= 44	P value
Age (Years) (Mean ±SD)	53.56 ± 11.45	56.01 ± 9.39	0.09 ^a
Body Mass Index (BMI) kg/m ² (Mean ±SD)	28.03 ± 3.11	25.86 ± 4.88	0.13 ^a
Gender - Female % (n)	66.67(54)	71.42(60)	0.08 ^b
Duration of Symptoms(Days) (Mean ±SD)	24.86 ± 5.36	21.47 ± 3.01	0.16 ^a

Table 1: Comparison of demographic details across two groups

[a] Independent sample T-test, [b] Chi- Square test of Independence

Outcome Measure	Treatment Groups		Mean Difference ^a	P value
	Routine Physical Therapy (Mean ± SD)	Routine Physical Therapy + Wedge Support (Mean ± SD)		
Baseline NPRS	7.90 ± 0.84	8.23 ± 0.86	0.33 ± 0.23	0.09
Post Treatment NPRS	2.93 ± 1.02	1.38 ± 0.70	1.55 ± 0.59	<0.05
Mean Difference ^d	4.97 ± 1.25	6.85 ± 0.89		
P value	<0.0001	<0.0001		
Baseline WOMAC	52.14 ± 7.69	53.77 ± 6.93	1.63 ± 1.45	0.68
Post Treatment WOMAC	36.45 ± 6.34	30.92 ± 4.00	5.53 ± 2.28	<0.0001
Mean Difference ^b	15.68 ± 3.26	22.85 ± 5.71		
P value	<0.0001	<0.0001		

Table 2: Across and Within the Group Comparison for NPRS and WOMAC

[a] Across the group difference - Independent sample T-test, [d] Within the Group difference - Paired Sample T test, NPRS (Numeric Pain Rating Scale), WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index)

DISCUSSION

The main objective of this study was to determine the effective of addition on wedge insole with routine physical therapy on pain and daily functional activities in Knee OA patients. Pain and difficulty in performing the activities of the daily living are the chief complaints reported by every Knee OA patient. In a previous study, the effectiveness of different management approaches on knee pain, assessed using VAS and WOMAC scale demonstrated the positive effects of conventional physical therapy management on knee pain in OA population [16]. There results were also in concordance with our study that also reported decreases

in pain and disability in group treated with routine physical therapy. The use of lateral wedge insoles was studied in a randomized control experiment comprising of 26 patients. According to the research, both knee discomfort and external knee adduction movement decreased quickly within three months using insoles in accordance with other physical therapy interventions [8]. Another study comprising 15 patients having osteoarthritis of the medial compartment of knee was conducted [6] and patients were advised to use lateral wedges for most of the part of the day. Significant difference in knee pain and knee adduction movement after the completion of the treatment. Another study on a small group of 13 knee OA patients was demonstrated that wedge insoles when were applied on bare feet, gradually decreased the mean knee adduction during the stance-phase of walking [17]. A longitudinal study on the use of wedge insoles confirmed that there has been a significant reduction in the external knee adduction movement during walking, which has a significant role in reducing the progression of medial knee osteoarthritis [18]. Another long term study on the use on insoles in osteoarthritis depicted that there had been a remarkable improvement in knee pain during walking and also in knee adduction movement if the wedge insoles are used in accordance with other physical therapy interventions including static stretching and PNF techniques. the effect of both these therapies are added up resulting in quick reduction in knee pain [19]. A randomized controlled trial on 32 patients demonstrated that a comparison between the use of wedge insoles and flat insoles. There had been a significant difference in improvement of symptoms as well as in the progression of disease. All the patients were of early fifties and late fifties [20]. Wedge insole with usual physical therapy interventions had found to be more significant as compared to usual physical therapy techniques which include, quadriceps strengthening, hot pack and ultrasound application, PNF stretching and mobilization techniques etc. Health care provider managing the Knee OA should also consider addition of wedge insole for their patients as important way of managing this disease non-pharmacologically.

CONCLUSION

Wedge insoles addition to the routine physical therapy treatment of Knee Osteoarthritis results in more beneficial outcomes in terms of reduction in pain and improvement in function as compared to routine physical therapy alone.

REFERENCES

- [1] Zhang Y, Jordan JM. Epidemiology of osteoarthritis. Clinics in geriatric medicine. 2010;26(3):355-69. doi:

- 10.1016/j.cger.2010.03.001.
- [2] Loeser RF. Age-related changes in the musculoskeletal system and the development of osteoarthritis. *Clinics in geriatric medicine*. 2010;26(3):371-86. doi: [10.1016/j.cger.2010.03.002](https://doi.org/10.1016/j.cger.2010.03.002)
- [3] Page CJ, Hinman RS, Bennell KL. Physiotherapy management of knee osteoarthritis. *International Journal of Rheumatic Diseases*. 2011;14(2):145-51. doi: [10.1111/j.1756-185X.2011.01612.x](https://doi.org/10.1111/j.1756-185X.2011.01612.x).
- [4] Andriacchi TP, Mündermann A. The role of ambulatory mechanics in the initiation and progression of knee osteoarthritis. *Current opinion in rheumatology*. 2006;18(5):514-8. doi: [10.1097/01.bor.0000240365.16842.4e](https://doi.org/10.1097/01.bor.0000240365.16842.4e).
- [5] David T. Felson H-GS. *Pain in Osteoarthritis*. New Jersey: Wiley-Blackwell A John Wiley & Sons inc. Publication; 2009.
- [6] 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. *Archives of physical medicine and rehabilitation*. 2002;83(7):889-93. doi: doi.org/10.1053/apmr.2002.33225
- [7] 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. *Journal of orthopaedic research*. 2007;25(9):1121-7. doi: [10.1002/jor.20423](https://doi.org/10.1002/jor.20423)
- [8] 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 Care & Research*. 2008;59(3):408-15. doi: [10.1002/art.23326](https://doi.org/10.1002/art.23326).
- [9] Hinman RS, Bowles KA, Payne C, Bennell KL. Effect of length on laterally-wedged insoles in knee osteoarthritis. *Arthritis Care & Research: Official Journal of the American College of Rheumatology*. 2008;59(1):144-7. doi: [10.1002/art.23326](https://doi.org/10.1002/art.23326)
- [10] Shimada S, Kobayashi S, Wada M, Uchida K, Sasaki S, Kawahara H, et al. Effects of disease severity on response to lateral wedged shoe insole for medial compartment knee osteoarthritis. *Archives of physical medicine and rehabilitation*. 2006;87(11):1436-41. doi: [10.1016/j.apmr.2006.08.018](https://doi.org/10.1016/j.apmr.2006.08.018).
- [11] Altman R, Asch E, Bloch D, Bole G, Borenstein D, Brandt K, et al. Development of criteria for the classification and reporting of osteoarthritis: classification of osteoarthritis of the knee. *Arthritis & Rheumatism*. 1986;29(8):1039-49. doi: [10.1002/art.1780290816](https://doi.org/10.1002/art.1780290816).
- [12] Saeed O, Arif U, Saqib MU, Sidiqqe A, Khalid H, Shahzad A. A descriptive study of prevalence of musculoskeletal illnesses among farmers in faisalabad, Pakistan. *Journal of Novel Physiotherapy and Physical Rehabilitation*. 2021;8(1):001-4.
- [13] Farooqi A, Gibson T. Prevalence of the major rheumatic disorders in the adult population of north Pakistan. *British journal of rheumatology*. 1998;37(5):491-5. doi: [10.1093/rheumatology/37.5.491](https://doi.org/10.1093/rheumatology/37.5.491).
- [14] Altman RD, Hochberg M, Murphy Jr W, Wolfe F, Lequesne M. Atlas of individual radiographic features in osteoarthritis. *Osteoarthritis and cartilage*. 1995;3:3-70. doi: [10.1016/j.joca.2006.11.009](https://doi.org/10.1016/j.joca.2006.11.009).
- [15] Smith R, Egger P, Coggon D, Cawley M, Cooper C. 9. Kellgren JH, Lawrence JS. Radiological assessment of Osteoarthritis of the hip joint and acetabular dysplasia in osteoarthritis. *Ann Rheum Dis*. 1957;16:494-502. doi: [10.3109/17453674.2012.665331](https://doi.org/10.3109/17453674.2012.665331)
- [16] Holla JF, van der Leeden M, Roorda LD, Bierma-Zeinstra S, Damen J, Dekker J, et al. Diagnostic accuracy of range of motion measurements in early symptomatic hip and/or knee osteoarthritis. *Arthritis care & research*. 2012;64(1):59-65. doi: [10.1002/acr.20645](https://doi.org/10.1002/acr.20645).
- [17] Kakihana W, Akai M, Nakazawa K, Takashima T, Naito K, Torii S. Effects of laterally wedged insoles on knee and subtalar joint moments. *Archives of physical medicine and rehabilitation*. 2005;86(7):1465-71. doi: [10.1016/j.apmr.2004.09.033](https://doi.org/10.1016/j.apmr.2004.09.033).
- [18] 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. *Annals of the Rheumatic Diseases*. 2002;61(7):617-22. doi: [10.1136/ard.61.7.617](https://doi.org/10.1136/ard.61.7.617).
- [19] Pham T, Maillefert J-F, 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. *Osteoarthritis and Cartilage*. 2004;12(1):46-55. doi: [10.1016/j.joca.2003.08.011](https://doi.org/10.1016/j.joca.2003.08.011).
- [20] Bennell KL, Bowles K-A, 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](https://doi.org/10.1136/bmj.d2912).