



## Original Article

# Effects of Physical Therapy Treatment With and Without Wedge Insole in Patients with Knee Osteoarthritis; A Randomized Controlled Trial

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### ABSTRACT

**Background:** Osteoarthritis has been known as the most incapacitating disease. All the structures present in a joint have equal chances of developing this disease. It has been recognized as the most common chronic health disorder in the Western world. **Objective:** The purpose of this study was to see the effect of physical therapy treatment in knee osteoarthritis with and without wedge support. **Methods:** This randomized controlled trial was conducted at the OPD physiotherapy department, Mayo Hospital, Lahore and Mid-City Hospital, Lahore. Patients aged 45-65 years of both genders who have osteoarthritic changes were included in the study. Patients who were contraindicated for physiotherapy like patients suffering from various knee joint pathologies like tumors, fractures, and inflammatory pathologies. Patients having other major musculoskeletal problems and having red flag signs e.g. rheumatoid arthritis, osteoporosis and Paget's disease are excluded. In this study, 80 patients were randomly selected in two groups. Group 1 patients were treated with conventional physiotherapy treatment. While group 2 patients were treated with conventional physiotherapy and wedge insole. Performa was filled and Informed consent was taken from each patient. Patients were followed for 3 weeks. The pre-tested questionnaire is used as a data collection tool. The questionnaires used for data collection were WOMAC and Visual Analogue Scale. Baseline characteristics including mean and standard deviations were described. **Results:** Patients in Group 2 showed marked improvement as compared to group 1. The p-value (0.000) less than 0.05 is considered significant. The mean age of patients for groups 1 and 2 was 45 ±1.2 and 65±1.5 respectively. **Conclusion:** It was concluded from the study that the use of wedge insole by conventional physiotherapy is a significant treatment outcome on WOMAC and Visual Analogue Scale. When treated with conventional physiotherapy and wedge insole, the patients with knee osteoarthritis showed a significant treatment outcome when analyzed on the WOMAC and Visual Analogue Scale. When both groups were compared, it was seen that group 2 showed more significant results on the WOMAC and pain scale.

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## INTRODUCTION

Of all the diseases affecting the articulating surfaces of the joint, osteoarthritis (OA) is the most debilitating disease. Structures around joints have an equal probability of developing this disease. It is the most chronic disorder in the West, with an increased prevalence among the aged population.<sup>1,2</sup> The National Arthritis Data Workshop reported a rise in OA occurrence with a projected 27 million US adults in 2005 having clinical OA of hand, hip or knee joint.<sup>3</sup> The incidence of OA was also seen to rise hand in hand in obese people. Knee OA is four times more prevalent in obese women, subsequently the risk is one degree more in obese men.<sup>4</sup>

The obesity has been considered as a major risk factor in the progression of OA. Other factors include race, gender, genetics, diet, smoking, and injury.<sup>1,5</sup> The relative significance of certain risk factors may differ from joint to joint, for early versus end-stage OA, for development as opposed to progression of disease and for radiographic versus symptomatic disease. Physical therapy is a non-pharmacological treatment for knee OA according to the American College of Rheumatology and the European League Against Rheumatism.<sup>6,7</sup> Physiotherapy treatment is the systematic, planned performance of movements, postures, or functional activities intended to provide a patient/client with the means to prevent impairments, improve body function or reduce risk factors and optimize overall health status, fitness, or sense of well-being. Wedge Insoles or footwear put forward great potential as an effortless, economical treatment strategy for knee osteoarthritis. For the treatment of OA do the medial compartment of the knee Lateral wedge insoles are advised and medial wedge insoles in case of the involvement of the lateral compartment. because of the increased incidences of medial knee OA, massive research has been done on Lateral Wedge

Insoles.<sup>8</sup> Depending upon the biomechanical Studies, the use of lateral wedge insoles helps in reducing the External Knee adduction moment while walking by up to 13% in comparison to walking barefoot or using simple shoes in the OA of the medial compartment of the knee.<sup>9-11</sup> As a result the load on the medial compartment is reduced.<sup>12</sup>

Evidence suggests that all the features of the wedge including its length, the angle of inclination and the material used may alter the overall biomechanical aspects as well as the joint position at knee and ankle sites that provide benefits.<sup>9,13,14</sup> The literature especially considering the Pakistani population lacks studies conducted on this topic. Countries like Pakistan need studies like these to cover the domain of knee osteoarthritis to find new, cheaper, and economical ways of treating patients with knee osteoarthritis. Our current study would add a randomized control trial to the literature focusing on Pakistani patients with knee osteoarthritis.

## METHODS

The current study design was a randomized controlled trial. Data was collected from Mansoor Hospital and University of Lahore Teaching Hospital Lahore. The study was completed 6 months after the approval of the synopsis. A lottery method was used to collect the data. A total number of 80 patients were included in the study 40 in each group. Patients aged 45-65 years of both genders who have osteoarthritic changes were included in the study. Patients who were contraindicated for physiotherapy like patients suffering from various knee joint pathologies like tumors, fractures, and inflammatory pathologies. Patients having other major musculoskeletal problems and having red flag signs e.g. rheumatoid arthritis, osteoporosis and Paget's disease are excluded. Data was collected after getting approval from the committee providing the information to the patients in

obtaining the informed consent from them. Patients were assessed on following these steps and findings would be noted on the performa. A detailed history from the patients was obtained to rule out any active pathology and other causes of included systemic illness. All the subjects were observed from front, back and lateral views to see the change in the alignment of the knee joint, leg and ankle joint to see contour changes. Palpated soft tissue structures around the knee joint to see the tenderness and have seen the temperature difference around this area. The distribution of dermatomes and myotomes to find any nerve root involvement was also evaluated. Further examination of movements and follow-up active and passive movements, strength measurement by using Western Ontario and McMaster University Arthritis Index and Visual Analogue Scale (VAS) was done. The patients were treated with four sessions for three weeks according to their requirements. **Group 1:** Patients in this group are treated with conventional physical therapy and reassessed after every 1 week as post-treatment reading. Decreased pain intensity was recorded after 1 week along with conventional physical therapy treatment i.e. heating, ultrasonography and quadriceps strengthening. **Group 2:** Patients in this group were treated by conventional physical therapy treatment with applying wedge insole. 10min x 3 times = 1 session and reassessed after one week as post-treatment reading, decreased

pain and disability were recorded after one week. **Follow-up:** Patients were followed for 3 weeks. The pre-tested questionnaire is used as a data collection tool. Standardized WOMAC scale and VAS is used to collect relevant information from subjects. Baseline characteristics including mean and standard deviations were described.

## RESULTS

Most of the patients in the study were in the age group 51 to 55 years. Table 1 shows the mean VAS value of patients with and without wedge insole. The mean VAS was less in patients using wedge insole. Table 3 represents the mean difference in WOMAC value.

## DISCUSSION

The purpose of this study was to see the effects of physical therapy treatment with and without wedge insoles in knee osteoarthritis so that functional status of the knee can be improved. Based on the results, it was shown that group 2 had more pronounced effects of treatment as compared to group 1. While group 2 showed a significant result with a p-value of 0.021 then Group 1 of a significant value of 0.498 on the VAS scale. The 2-tailed value of 0.000 of both groups showed significant results. The significant value of 0.000 of the paired sample test on the WOMAC scale showed a significant result and also the 2-tailed value of 0.000 showed

**Table 1: Mean VAS Score of Patients With and Without Wedge Insole**

Study Group		Mean	n	Std. Deviation	Std. Error means
Routine Physical Therapy	VAS Pre-treatment Score	7.90	40	.84	0.13
	VAS Post-treatment Score	2.93	40	1.02	0.16
Routine Physical Therapy + Wedge Support	VAS Pre-treatment Score	8.23	40	.86	0.14
	VAS Post-treatment Score	1.38	40	.70	0.11

Table 2: Paired Sample Correlations in VAS

Study Group		n	Correlation	Sig.	Paired Differences	
					Mean	Std. Deviation
Routine Physical Therapy	VAS Pre-treatment Score & VAS Post-treatment Score	40	.110	.498	4.97	1.25
Routine Physical Therapy + Wedge Support	VAS Pre-treatment Score & VAS Post-treatment Score	40	.364	.021	6.85	0.89

Table 3: Mean Difference in WOMAC Scores

Paired Samples Statistics					
Study Group		Mean	n	Std. Deviation	Std. Error Mean
Routine Physical Therapy	WOMAC Pre-Treatment Score	52.14	40	7.69	1.22
	WOMAC Post-Treatment Score	36.46	40	6.35	1.00
Routine Physical Therapy + Wedge Support	WOMAC Pre-Treatment Score	53.78	40	6.93	1.09
	WOMAC Post-Treatment Score	30.92	40	4.00	.63

the same significance of the result. If the mean standard deviation is compared of both groups, then Group 2 with pre-mean value  $53.77 \pm 6.93$  to post-mean  $30.92 \pm 4.00$  than Group 1 as compared to pre-mean  $52.14 \pm 7.69$  to post-mean  $36.45 \pm 6.34$  showed that Group 2 outcome is more significant. Independent tests showed 2-tailed value of 0.000 on the WOMAC scale are significant outcome.

Leven's test with the value of 0.005 also showed the significance of the results. An overabundance of studies has examined numerous traits associated with muscle action and their respective function which include the strength of underlying muscle,<sup>15</sup> its aerobic capacity<sup>16</sup> as well as various numerous clinical features which are pain,<sup>17</sup> toughness, range of

motion and WOMAC score<sup>18</sup> in patients with knee osteoarthritis. Regardless of these important developments in research as we as knowledge, limited studies have considered the effects of different forms of nonpharmacological management on the efficient exercise capability of patients having knee OA. Among the most common complaints reported by patients of knee osteoarthritis Pain is the foremost most common disabling sign in OA patients. In a randomized study, the effectiveness of different management approaches on knee pain was assessed using VAS and the pain measurement of the WOMAC scale. Another study on the effectiveness of physical therapy treatment depicted that pain in both knees was reduced in all the groups under consideration.

**Table 4: Paired Samples Correlations in WOMAC scale**

Study Group		n	Correlation	Sig.	Paired Differences	
					Mean	Std. Deviation
Routine Physical Therapy	WOMAC Pre-treatment Score & WOMAC Post-treatment Score	40	.910		15.68	3.26
Routine Physical Therapy + Wedge Support	WOMAC Pre-treatment Score & WOMAC Post-treatment Score	40	.566	.000	22.86	5.72

**Table 5: Paired Sample Test**

Study Group		Paired Differences	t	Df	Sig. (2-tailed)
		95% Confidence Interval of the Difference			
Routine Physical Therapy	WOMAC Pre-Post Treatment Score	16.73	30.38	39	.000
Routine Physical Therapy + Wedge Insole	WOMAC Pre-Post Treatment Score	24.68	25.29	39	

This is not the first study to demonstrate the positive effects of conventional physical therapy management on knee pain in OA population.<sup>18</sup>

A randomized controlled trial on the use of lateral wedge insoles. 26 patients were included in the study. The study stated that there was a quick decrease in knee pain as well as the external knee adduction movement. These changes were seen after a treatment of three months using insoles following other physical therapy interventions. the basic aim of the study was to decrease the disease severity reduction in knee pain during walking and also reduction in knee adduction movement.<sup>14</sup> Another study comprising 15

patients having osteoarthritis of the medial compartment of the knee was done.<sup>13</sup> Patients were advised to use lateral wedges for most of the part of the day. There had been a clear difference in knee pain and knee adduction movement after the completion of the treatment. Another study on a small group of 13 patients was done that demonstrated the use of wedge insoles that when they are applied on bare feet, gradually decreased the mean standard deviation knee adduction during the stance phase of walking.<sup>19</sup> Most evidence related to arthritis and predominantly osteoarthritis has mainly considered mediations and physical therapy interventions which comprise exercise plans. Very little emphasis has been employed on other manual



therapy methodologies. A lot of studies have inspected the effectiveness of manual therapy for OA of the knee.<sup>20</sup> Using procedures that are contained within other procedures of rehabilitation procedures in a multi-modal methodology. Few precise studies intervene one manual therapy strategies for effective and marked decrease in pain in the osteoarthritic knee population. An important contemplation stated that the post-treatment opinion poll was the issue of pain and distress produced by manual therapy management. There are huge concerns about the use of manual therapy techniques in the elderly, or in patients having progressive degenerative conditions, it is unstated that there is an assortment of chiropractic approaches suitable for several patients and specific circumstances<sup>21</sup> there is evidence that the manual therapy approach may produce a very little amount and in some cases no pain to the patients. Such conclusions are appreciated as participants' ages fluctuated from 47 to 70 years. Whilst medical practitioner preventive measures are advised in commerce with the patient's current presenting conditions concerned bone feebleness, ligamentous laxity, malformation and tumor, much can be accessible to the patient that has strong bony, muscular and ligamentous integrity that is also to affected from osteoarthritis of the knee.<sup>22</sup> 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.<sup>23</sup>

Another long-term study on the use of 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 following other physical therapy interventions including static stretching and PNF techniques. the effect of both these therapies is added up resulting in a

quick reduction in knee pain.<sup>24</sup> A randomized controlled trial on 32 patients demonstrated a comparison between the use of wedge insoles and flat insoles. There had been a clear difference in the improvement of symptoms as well as in the progression of the disease. All the patients were in early fifties and late fifties. The study duration was of 12 months. patients wearing wedge insoles had clear alleviation of the symptoms of osteoarthritis.<sup>25</sup> So, it is concluded that the use of wedge insoles following conventional physical therapy has significant effects on knee osteoarthritis and range of motion around the knee joint. Two techniques are used to achieve the effects for improvement. Wedge insole with usual physical therapy interventions was 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. This study concluded that use of wedge insoles with conventional physical therapy had more profound effects than only conventional physical therapy techniques. The patients in Group 2 showed significant results as compared to the patients in group 1.

## CONCLUSION

It is concluded from the study that the use of wedge insoles following conventional physical therapy is a significant treatment outcome for WOMAC and VAS. The patients with knee osteoarthritis, when treated by conventional physical therapy having edge placed in their soles showed a significant treatment outcome when analyzed on WOMAC and VAS. When both groups were compared, it was seen that group 2 showed more significant results than group 1 on WOMAC.

## DECLARATIONS

**Consent to participate:** Written consent had been taken from patients. All methods were

performed following the relevant guidelines and regulations.

**Availability of data and materials:** Data will be available on request. The corresponding author will submit all dataset files.

**Competing interests:** None

**Funding:** No funding source is involved.

**Authors' contributions:** All authors read and approved the final manuscript.

**CONSORT Guidelines:** All methods were performed following the relevant guidelines and regulations.

## REFERENCES

- Zhang Y, Jordan JM. Epidemiology of osteoarthritis. *Clinics in geriatric medicine* 2010; 26(3): 355-69. <https://doi.org/10.1016/j.cger.2010.03.001>
- Loeser RF. Age-related changes in the musculoskeletal system and the development of osteoarthritis. *Clinics in geriatric medicine* 2010; 26(3): 371-86. <https://doi.org/10.1016/j.cger.2010.03.002>
- Lawrence RC, Felson DT, Helmick CG, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States: Part II. *Arthritis & Rheumatism* 2008; 58(1): 26-35. <https://doi.org/10.1002/art.23176>
- Anderson JJ, Felson DT. Factors associated with osteoarthritis of the knee in the first national Health and Nutrition Examination Survey (HANES I) evidence for an association with overweight, race, and physical demands of work. *American journal of epidemiology* 1988; 128(1): 179-89. <https://doi.org/10.1093/oxfordjournals.aje.a114939>
- Felson DT, Lawrence RC, Dieppe PA, et al. Osteoarthritis: new insights. Part 1: the disease and its risk factors. *Annals of internal medicine* 2000; 133(8): 635-46. <https://doi.org/10.7326/0003-4819-133-8-200010170-00016>
- Jordan K, Arden N, Doherty M, et al. EULAR Recommendations 2003: an evidence based approach to the management of knee osteoarthritis: Report of a Task Force of the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT). *Annals of the Rheumatic Diseases* 2003; 62(12): 1145-55. <http://dx.doi.org/10.1136/ard.2003.011742>
- hip Rftmmoot, update k. American College of Rheumatology Subcommittee on Osteoarthritis Guidelines. *Arthritis Rheum* 2000; 43: 1905-15. [https://doi.org/10.1002/1529-0131\(200110\)44:10<2451::aid-art416>3.0.co;2-f](https://doi.org/10.1002/1529-0131(200110)44:10<2451::aid-art416>3.0.co;2-f)
- Ledingham J, Regan M, Jones A, Doherty M. Radiographic patterns and associations of osteoarthritis of the knee in patients referred to hospital. *Annals of the Rheumatic Diseases* 1993; 52(7): 520-6. <http://dx.doi.org/10.1136/ard.52.7.520>
- 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. <https://doi.org/10.1002/jor.20423>
- Altman R, Asch E, Bloch D, 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. <https://doi.org/10.1002/art.1780290816>
- Shimada S, Kobayashi S, Wada M, 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. <https://doi.org/10.1016/j.apmr.2006.08.018>
- Shelburne KB, Torry MR, Steadman JR, Pandy MG. Effects of foot orthoses and valgus bracing on the knee adduction moment and medial joint load during gait. *Clinical Biomechanics* 2008; 23(6): 814-21. <https://doi.org/10.1016/j.clinbiomech.2008.02.005>

13. 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. <https://doi.org/10.1053/apmr.2002.33225>
14. 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. <https://doi.org/10.1002/art.23326>
15. Thorlund JB, Aagaard P, Roos EM. Muscle strength and functional performance in patients at high risk of knee osteoarthritis: a follow-up study. *Knee Surgery, Sports Traumatology, Arthroscopy* 2012; 20(6): 1110-7. <https://doi.org/10.1007/s00167-011-1719-2>
16. Escalante Y, García-Hermoso A, Saavedra J. Effects of exercise on functional aerobic capacity in lower limb osteoarthritis: a systematic review. *Journal of Science and Medicine in Sport* 2011; 14(3): 190-8. <https://doi.org/10.1016/j.jsams.2010.10.004>
17. Roseff MG, Schneeberger EE, Citera G, et al. Effects of functional electrostimulation on pain, muscular strength, and functional capacity in patients with osteoarthritis of the knee. *JCR: Journal of Clinical Rheumatology* 2004; 10(5): 246-9. DOI: 10.1097/01.rhu.0000141831.40350.91
18. Holla JF, van der Leeden M, Roorda LD, 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. <https://doi.org/10.1002/acr.20645>
19. 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. <https://doi.org/10.1016/j.apmr.2004.09.033>
20. Deyle GD, Henderson NE, Matekel RL, Ryder MG, Garber MB, Allison SC. Effectiveness of manual physical therapy and exercise in osteoarthritis of the knee: a randomized, controlled trial. *Annals of internal medicine* 2000; 132(3): 173-81. <https://doi.org/10.7326/0003-4819-132-3-200002010-00002>
21. Pollard H, Ward G, Hoskins W, Hardy K. The effect of a manual therapy knee protocol on osteoarthritic knee pain: a randomised controlled trial. *The Journal of the Canadian Chiropractic Association* 2008; 52(4): 229. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2597887/>
22. Killinger L. Chiropractic adjusting and the "aging" patient. *J Amer Chiropr Assoc* 2003; 40(11): 26-8. <https://doi.org/10.1016/j.cger.2004.02.008>
23. 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. <http://dx.doi.org/10.1136/ard.61.7.61>
24. Pham T, Maillefert J-F, Hudry C, 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. <https://doi.org/10.1016/j.joca.2003.08.011>
25. Bennell KL, Bowles K-A, Payne C, et al. Lateral wedge insoles for medial knee osteoarthritis: 12 month randomised controlled trial. *Bmj* 2011; 342: d2912. <https://doi.org/10.1136/bmj.d2912>