

RESEARCH ARTICLE

EFFECTIVENESS OF LATERAL WEDGE INSOLE ON KNEE OSTEOARTHRITIS OUTCOMES IN PAKISTANI POPULATION

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ABSTRACT

Background: Osteoarthritis (OA) is a persistent joint disorder, which normally affects the weight bearing joints especially knee joint. Lateral wedge insole is one such approach suggested by professionals to manage the knee osteoarthritis. **Objective:** To determine the effectiveness of lateral wedge insoles on knee osteoarthritis outcomes in Pakistani population. **Methods:** A single-blinded, pretest-posttest comparison conducted at District Headquarter (DHQ) Hospital, Bahawalnagar and National Institute of Rehabilitation Medicine (NIRM), for a time period of one month. The patients with the age criteria of 40-70 years, and who had knee OA were included in the study: Participants were randomly divided in two groups; lateral wedge insoles (LWI) group (n=20), and conventional physical therapy (CPT) group (n=20). Pain, stiffness, activities of daily living, sports and recreational activities, and quality of life was assessed on Urdu version of Knee Injury and Osteoarthritis Outcome Score scale (KOOS) on every week till 4th week of intervention. Mixed ANOVA was used for interaction effect of between-subject factor (group) and within-subject factor (time) with-in group analysis and one way ANOVA for between group comparisons with their effect size (η^2). **Results:** Significant improvement with large effect size was observed in Symptoms and stiffness ($p<0.001$, $\eta^2=.329$), pain ($p<0.001$, $\eta^2=.559$), functional activities ($p<0.001$, $\eta^2=.394$), recreational activities ($p<0.001$, $\eta^2=.369$) and quality of life ($p<0.001$, $\eta^2=.280$). The CPT group showed more significant improvement ($p<0.001$) in all domains of KOOS as compared to LWI group. **Conclusion:** Lateral wedge insoles (LWI) and conventional physical therapy (CPT) both have positive impact on knee osteoarthritis outcomes. But conventional physical therapy was more effective in improving functional independence.

Keywords: Knee osteoarthritis, functional independence, geriatric population, musculoskeletal physiotherapy, orthotics, quality of life, rehabilitation.

INTRODUCTION

Osteoarthritis is a degenerative and progressive disorder of joints which gradually involves cartilage and leads to bony spurs in joint's margins¹. It usually affects the weight bearing joints such as knee, hip and back which varies from very mild to severe, therefore, middle age and older adults are more prone to OA². Abnormal load distribution due to shifting of the centre of pressure of the tibiofemoral force, resulting in locally increased stress on the articular cartilage that leads to degenerative changes^{3,4}. The most common cause of musculoskeletal pain, [3] and disability in the geriatric population is knee osteoarthritis. It occurs symptomatically in 6% and 11% of the population with the age criteria of 30 years and 65 years respectively⁴. Osteoarthritis is more prevalent in 54-61 years of age, and of which, 95% were affected from Knee OA².

One of the most common rheumatic disease in the Asia-Pacific region is non-specific knee osteoarthritis⁵. The prevalence of knee OA in India is 5.78% while Bangladesh reported 10.20%^{6,7}. A study conducted in Pakistan showed 25% rural and 28% urban population has been affected by knee OA⁸. According to the

previous literature, females are more prone to osteoarthritis in contrast to males,² due to menopause in women (66.7%), and obesity (42.4%)⁹. The American College of Rheumatology (ACR) and European League against Rheumatism (EULAR) recommended physiotherapy for knee OA, which is a non-surgical and non-pharmacological intervention^{10,11}. It includes exercises, knee tapping, manual techniques, and patient education and a study reported the clinically significant effectiveness of physiotherapy treatment for knee OA¹¹.

Moreover, lateral wedge insoles are also being used for the medial compartment knee OA, because of the less complexity, cost and side effects¹². The load on the tibiofemoral joint promotes varus deformity which increases the load on the medial compartment and leads to the damage of the compartment¹³. While, lateral wedge insoles reduce 4-12% of adduction movement, which decreases stress on the medial compartment. Also, previous literature supports the efficacy of lateral wedge insoles¹⁴.

The studies by Hinman RS et. al, Esfendiari E et. al, on the effectiveness of lateral wedge insole in Knee OA

reported contradictory results i.e. either no improvement or improvement with small effect size¹⁵⁻¹⁸. Lateral wedge insole was not currently an option as conservative management along with conventional physical therapy for osteoarthritis in Pakistan. It was hypothesized that lateral wedge insole (LWI) significantly improve pain, stiffness, activities of daily living, sports and recreational activities and Quality of life in knee osteoarthritic patients, along with conventional physical therapy (CPT).

METHODOLOGY

A single-blinded randomized control trial, pretest-posttest comparison group design (NCT03848130) was conducted at National Institute of Rehabilitation Medicine (NIRM) Islamabad and District Headquarter Hospital (DHQ), Bahawalnagar, Pakistan for a period of six months from June 2019 to December 2019. The study was initiated after taking ethical approval from the Medical Superintendent of DHQ Hospital Bahawalnagar and Executive Director NIRM Islamabad. Written informed consent was obtained from each participant before the intervention and assured them about the confidentiality of the data, according to Declaration of Helsinki.¹⁹ Patients with the age criteria of 40-70 years, and who had a history of knee OA were included in the study. However, patients had knee OA due to trauma or any pathology, multiple fractures, or had a medical condition due to which rehabilitation wasn't possible, and not willing to participate in the clinical trials were excluded from the study. A total of n=104 patients were recruited through the non-probability convenience sampling technique and were thus evaluated for the inclusion criteria. Of which, n=40 participants fulfilled the inclusion criteria. Participants were randomly divided through the sealed envelope method in two groups: lateral wedge insoles with home exercises group (n=20), and traditional physiotherapy with home exercises group (n=20). Each group received 1 month-long intervention as shown in Figure 1.

Conventional Physical Therapy (CPT) Group: Each participant received 40-45 minutes long session, started in lying position. The therapeutic low-intensity pulsed ultrasound (US) was used for 7 minutes with the frequency of 1 MHz, Spatial Average Intensity was 0.2 W/cm², pulsed duty cycle 20%, therapeutic dose was 112.5 J/cm² with fixed application on the medial side of the knee joint. The model of US was Unit Intellect Mobile, (Chattanooga Inc). After US therapy passive stretching of calf, hamstring, quadriceps, hip flexors, adductors &

abductor s was done, which was followed by the manual strengthening exercises and strengthening with quadriceps bench. The session was repeated thrice a week and 12 sessions per month.

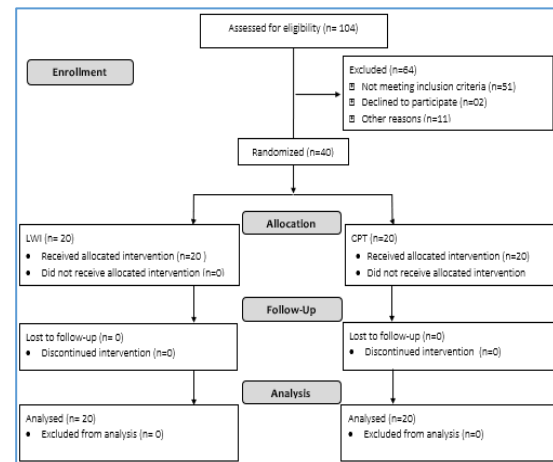


Figure 1: CONSORT diagram

The home program was guided in both groups including avoiding low sitting, cross leg sitting along with Isometrics of quadriceps at least 3 times a day, with 5-10 seconds hold of each contraction.

The data was collected through a general demographic questionnaire and Knee injury and Osteoarthritis Outcome Score (KOOS) in Urdu to determine the severity of pain, stiffness, functional activities, recreational activities and Quality of life to promote functional independence in osteoarthritic patients²³. The level of significance was set at $p < 0.05$. Statistical Package for the Social Sciences (SPSS) ver. 23 was used for data analysis.

The demographics of the participants were presented in the form of mean \pm SD and n(%). As the assumption of the parametric test was met, mixed ANOVA was used for the interaction effect of between-subject factor (group) and within-subject factor (time). As the sphericity was not assumed, the Greenhouse-Geisser values showed that there is significant interaction effect between interventions and time factor/assessment in all domains. Within group analysis and one way ANOVA was used for between-group comparisons to determine the effect size (η^2). The mean difference was also compared between the groups for functional activities while controlling baseline differences.

RESULTS

The mean age of study participants was 55.13 \pm 7.03 (R=43-70) years. The gender distribution of n=26 female and n=14 male. The mean BMI was

27.39±3.377 (R=21-35) showed that most of the population was overweight. (Figure 2)

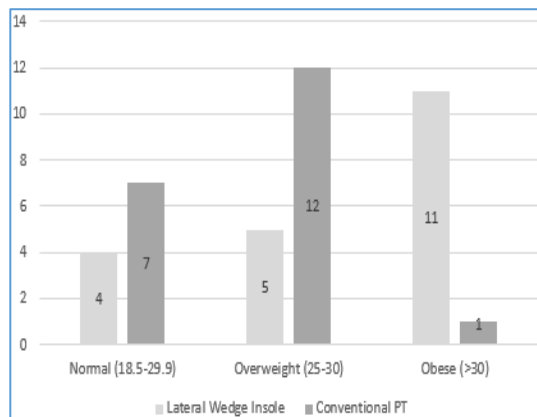


Figure 2: BMI distribution of study participants

As the sphericity was not assumed, the Greenhouse-Geisser values showed that there is significant interaction effect between interventions and time factor/assessment in all domains, Symptoms and stiffness, { $F=18.669(2.695, 102.423)$, $p<0.001$, $\eta^2=.329$ }, Pain { $F=48.156(2.742, 104.205)$, $p<0.001$, $\eta^2=.559$ }, functional activities { $F=24.659(2.741, 104.165)$, $p<0.001$, $\eta^2=.394$ } and recreational activities { $F=22.195(2.794, 106.170)$, $p<0.001$, $\eta^2=.369$ }.

With-in group analysis, all the domains showed significant improvement in the Convectional physical therapy (CPT) and lateral wedge insole (LWI) group with large effect size. The symptoms and stiffness related to osteoarthritis (OA) showed significant improvement in both LWI and CPT group throughout the treatment duration ($p<0.05$). In LWI it was observed that in the initial two weeks symptoms and stiffness were significantly improved ($p<0.05$) but at the end of the 3rd week and 4th week, no significant change ($p\geq 0.05$) in score was observed, whereas in the CPT group at the end of every week significant Improvement ($p<0.05$) was observed. The pain was also significantly improved in both groups throughout treatment duration except in LWI where no change was ($p=1$) observed in between the 3rd and 4th week, while in the CPT group significant improvement ($p<0.05$) was observed at the end of every week. While observing functional activities score, changes in both groups were significant ($p<0.05$) except in the LWI group where no significant changes were observed between the 3rd & 4th week ($p=0.053$).

Table 1: Within- group changes –KOOS subscale

		LWI						CPT					
		Mean	SD	<i>p-value</i> (Pairwise)	F(df)	<i>p-value</i> (Main Effects)	η^2	Mean	SD	<i>p-value</i>	F(df)	<i>p-value</i> (Main Effects)	η^2
Symptoms & Stiffness	0 week	16.75	13.757	0.001 ^{a***}	48.14(4,76)	<0.001	0.717	14.60	12.107	0.000 ^{a***}	244.74(4,76)	<0.001	.928
	week 1 st	25.95	12.955	0.000 ^{b***}				29.85	10.210	0.000 ^{b***}			
	week 2 nd	34.35	11.212	0.126 ^c				43.40	10.947	0.000 ^{c***}			
	week 3 rd	38.75	14.917	1.000 ^d				54.60	8.617	0.042 ^{d*}			
	week 4 th	41.30	15.944	0.000 ^{e***}				58.00	9.537	0.000 ^{e***}			
Pain	0 week	8.90	9.313	0.000 ^{a***}	68.336(4,76)	<0.001	0.782	6.70	9.056	0.000 ^{a***}	328.77(4, 76)	<0.001	.945
	week 1 st	18.80	8.205	0.010 ^{b*}				23.55	8.556	0.000 ^{b***}			
	week 2 nd	23.95	10.390	0.000 ^{c***}				37.35	11.403	0.000 ^{c***}			
	week 3 rd	32.05	10.531	1.00 ^d				53.40	12.059	0.037 ^{d*}			
	week 4 th	32.55	10.674	0.000 ^{e***}				58.80	9.099	0.000 ^{e***}			
Functional Activities	0 week	3.10	4.471	0.000 ^{a***}	91.150(4,76)	<0.001	0.828	7.10	7.055	0.000 ^{a***}	239.220(4,76)	<0.001	.926
	week 1 st	11.50	5.853	0.000 ^{b***}				20.60	6.676	0.000 ^{b***}			
	week 2 nd	20.75	4.865	0.005 ^{c**}				32.65	8.725	0.000 ^{c***}			
	week 3 rd	27.75	10.161	0.053 ^d				49.40	9.875	0.012 ^{d*}			
	week 4 th	31.10	9.591	0.000 ^{e***}				56.40	8.923	0.000 ^{e***}			
Recreational Activities	0 week	3.75	5.821	0.066 ^a	39.155(4,76)	<0.001	0.673	1.25	3.193	0.000 ^{a***}	166.224(4,76)	<0.001	.897
	week 1 st	10.00	9.597	0.003 ^{b***}				18.75	9.716	0.000 ^{b***}			
	week 2 nd	19.90	9.101	0.435 ^c				31.00	10.208	0.000 ^{c***}			
	week 3 rd	24.40	6.636	0.421 ^d				42.50	12.618	0.001 ^{d**}			
	week 4 th	25.40	6.451	0.000 ^{e***}				49.25	12.594	0.000 ^{e***}			
Quality of life	0 week	14.00	10.402	0.006 ^{a**}	40.28(2.22, 42.26)	<0.001	0.697	18.50	7.193	0.000 ^{a***}	241.28(3.003, 57.05)	<0.001	0.927
	week 1 st	24.40	8.917	0.161 ^b				37.55	8.236	0.000 ^{b***}			
	week 2 nd	30.30	6.959	0.000 ^{c***}				46.90	8.932	0.000 ^{c***}			
	week 3 rd	37.20	8.770	0.354 ^d				59.20	8.383	0.022 ^{d*}			
	week 4 th	39.60	9.185	0.000 ^{e***}				63.35	7.095	0.000 ^{e***}			

^a0 week vs. week 1st, ^bweek 1st vs. 2nd week, ^c2nd week vs. week 3rd, ^d3rd week vs. 4th week, ^e0 week vs. 4th week

Significance Level: $p<0.05^*$, $p<0.01^{**}$, $p<0.001^{***}$

Both groups showed significant improvement ($p<0.05$) in recreational activities after Four-week interventions, except in LWI group did not significantly improve between baseline and after 1st week ($p=0.066$) as well as between 2nd & 3rd week

($p=0.435$), but between 1st week and 2nd-week significant improvement ($p=0.003$) was observed.

The quality of life after 4 week intervention significant improvement was observed in both groups. While pairwise comparison in LWI showed no significant

improvement was observed between 1st week to 2nd week ($p=0.161$) and 3rd week to 4th week ($p=0.354$) but significant improvement was observed after 4th week ($p<0.05$). (Table 1)

While comparing both groups, no significant difference ($p\geq 0.05$) observed in symptoms & stiffness (SS) and pain after 1st week, but the conventional Physical Therapy (CPT) group showed more significant improvement ($p<0.05$) as compare to the LWI group at

the end of 2nd, 3rd and 4th week. The recreational activities and quality of life showed more significant improvement ($p<0.05$) in the CPT group than LWI group at the end of 1st week to 4th week with a large effect size in. (Table 2). Although there was baseline significant difference between LWI and CPT group, the one ANOVA on mean difference showed of overall treatment duration.

Table 2: Comparison between LWI & CPT

Variables	Outcome time	LWI		CPT		F(df)	p-value	ηp^2
		Mean	SD	Mean	SD			
Symptoms & Stiffness	0 week	16.75	13.75	14.60	12.10	.275(1,38)	.603	0.007
	1 st week	25.95	12.95	29.85	10.21	1.118(1,38)	.297	0.029
	2 nd week	34.35	11.21	43.40	10.94	6.671(1,38)	.014**	0.149
	3 rd week	38.75	14.91	54.60	8.61	16.931(1,38)	<0.001***	0.308
	4 th week	41.30	15.94	58.00	9.53	16.160(1,38)	<0.001***	0.298
Pain	0 week	8.90	9.31	6.70	9.05	.574(1,38)	.453	0.015
	1 st week	18.80	8.20	23.55	8.55	3.211(1,38)	.081	0.078
	2 nd week	23.95	10.39	37.35	11.40	15.091(1,38)	<0.001***	0.284
	3 rd week	32.05	10.53	53.40	12.05	35.569(1,38)	<0.001***	0.483
	4 th week	32.55	10.67	58.80	9.09	70.046(1,38)	<0.001***	0.648
Functional Activities	0 week	3.10	4.47	7.10	7.05	4.587(1,38)	.039*	0.108
	1 st week	11.50	5.85	20.60	6.67	21.009(1,38)	<0.001***	0.356
	2 nd week	20.75	4.86	32.65	8.72	28.377(1,38)	<0.001***	0.428
	3 rd week	27.75	10.16	49.40	9.87	46.693(1,38)	<0.001***	0.551
	4 th week	31.10	9.59	56.40	8.92	74.598(1,38)	<0.001***	0.663
Recreational Activities	0 week	3.75	5.82	1.25	3.19	2.836(1,38)	.100	0.069
	1 st week	10.00	9.59	18.75	9.71	8.210(1,38)	.007**	0.178
	2 nd week	19.90	9.10	31.00	10.20	13.175(1,38)	.001**	0.257
	3 rd week	24.40	6.63	42.50	12.61	32.237(1,38)	<0.001***	0.459
	4 th week	25.40	6.45	49.25	12.59	56.814(1,38)	<0.001***	0.599
Quality of Life	0 week	14.00	10.40	18.50	7.19	2.53(1,38)	0.120	0.62
	1 st week	24.40	8.91	37.55	8.23	23.47(1,38)	<0.001***	0.382
	2 nd week	30.30	6.95	46.90	8.93	42.98(1,38)	<0.001***	0.531
	3 rd week	37.20	8.77	59.20	8.38	42.98(1,38)	<0.001***	0.634
	4 th week	39.60	9.18	63.35	7.09	83.74(1,38)	<0.001***	0.688

Significance Level: $p<0.05$ *, $p<0.01$ **, $p<0.001$ ***

DISCUSSION

The hypothesis of the study was the lateral wedge insoles are more effective; however, according to the results of the study conventional physical therapy was more effective for knee osteoarthritis. Hence, the null hypothesis was accepted.

Within-group analysis showed that the stiffness, pain, activities of daily living, sports and recreational activities, and quality of life measured on the KOOS scale was significantly improved in both groups but conventional physical therapy showed more clinically significant improvement throughout the intervention. While between groups comparison didn't show a significant difference in lateral wedge insoles group but significant difference was observed in the group of conventional physical therapy.

The findings of this study also supported a previous study in which after using lateral wedge insoles significant improvement was observed in KOOS subscales i.e. pain, symptoms, sports-recreational and functional activities and quality of life²⁴. The medial knee osteoarthritis is more prevalent as compared to lateral knee osteoarthritis,²⁵ because during walking

load on medial condyles is 2.5 times more than the lateral compartment¹⁴. The possible reasons for significant improvement could be decreased mechanical load on the medial compartment which may reduce pain and hence leads to improved quality of life²⁰. Moreover, wedge under the feet changes the angle of the limb and affect the mediolateral moment which is applied on the limb during standing and walking. Also, lateral wedge insoles are responsible for the reduction in knee varus torque, and it is assumed that increased Varus torque is responsible for knee osteoarthritis progression¹⁴. The literature mentioned above also supported the findings of current study.

Similar to the results of the current study, it has been discussed in previous study that 7mm insoles relieve pain and improves the quality of life because of the shifting of applied load to the lateral part of the subtalar joint and centre of position to the lateral side of the knee. Thus, pain is reduced by shifting the body weight from one side of the foot to the other. However, increasing the thickness of 7mm lateral wedge insoles more than normal may cause foot discomfort¹⁴. Also, pronation and ankle invertor

moment may increase due to the lateral wedge insoles and increased invertor moment cause fatigue of those muscles, after prolonged use. Therefore, arches in lateral wedge insoles reduce the ankle invertor moment and eversion of the ankle²¹. These studies emphasized on the thickness of 7mm lateral wedge insoles which also supported current study in the same way that lateral wedges of full length and thickness of 7mm are effective in reducing pain and improving the quality of life of medial compartment knee OA patients.

In some previous studies, it has been concluded that lateral wedge insoles reduces the moment arm by shifting the ground reaction force on lateral foot during walking. Therefore, the load on knee is redistributed, which reduces the medial knee adduction moment, so that load on the medial knee is reduced^{22,24,26}. However, in recent literature, it has been discussed that lateral wedge insoles are effective for only 20% of osteoarthritic patients because of very small reductions in knee adduction angular impulse and medial knee adduction moment, thus, is not significantly affected for medial knee osteoarthritis²⁷. Similar to the results of this study, literature also has discussed that type of insole and the degree of the wedge are the possible reasons for less significant improvement. The same degree of wedge insoles for all the participants has been used in different studies i.e. 5 or 6 degrees²⁸. the problem of lack of customization of insoles, similar to the current study may contribute to less significant improvement²⁹.

Traditional physical therapy including ultrasound modality and stretching followed by strengthening may contribute in improving pain and stiffness supported by previous literature³⁰. Also, a previous study discussed the multiple exercises i.e. stretching and strengthening with a home exercise plan improves the pain symptoms and dysfunction by reducing the load on the medial knee joint³¹. Thermal and non-thermal effects of therapeutic ultrasound-induced analgesic effect and reduce soft tissue pain by increasing tissue metabolism, capillary permeability and fibrous tissue extensibility through the thermal mechanism. However, the non-thermal mechanism also relief pain by promoting tissue regeneration, increasing intracellular calcium in the nervous system and changing the permeability of the cell membrane³². Therefore, therapeutic ultrasound may also block pain transmission receptors³⁰.

Furthermore, similar to the results of this study, ultrasound,³³ and strengthening exercises improves KOOS score in domains of pain, stiffness, activities of daily living, sports and recreational activities and quality of life. The possible reasons of improved

symptoms and stiffness maybe the healing and thermal effects of US on periarticular structures. The flexibility of tendons, ligaments and joint capsule can be improved through ultrasound, heating, and strengthening exercises³⁴. Whereas, non-thermal effects regulate collagen synthesis, fibroblast production, cell diffusion, breakdown adhesions, alter extracellular matrix arrangement and all these factors promote healing^{33, 34}.

Moreover, in previous literature, it has been found that ultrasound with supervised exercise protocol not only reduces pain but also improves function and thus the quality of life in chronic osteoarthritic patients³⁵. The patients with OA has decrease muscle strength, joint instability and pain which also limits the functional capacity, therefore, isometrics and strengthening of quadriceps is highly recommended for OA patients³⁶. A study conducted by Fatih Tok et al, supports the findings of the current study that continuous motion either active or passive, conventional physical therapy and modality strengthen the muscles which improve balance and coordination, thus, leads to decreased pain, improved functional capacity and quality of life without deteriorating the disease.³⁷

The limitation in the study is the variation in BMI category in relation to distribution in treatment groups may also have confounding effects on the results.

CONCLUSION

Lateral wedge insoles (LWI) and conventional physical therapy (CPT) both have positive impact on knee osteoarthritis outcomes. But conventional physical therapy was more effective in improving the functional independence of osteoarthritic patient. It is recommended that future study should be conducted to evaluate the combined effects of both interventions as some degrees of biomechanical adjustment of LWI may augment the effects of conventional Physical Therapy.

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