

# Effectiveness of Lateral Insoles in Improving Activity of Daily Living Among Patients of Knee Osteoarthritis

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## Author's Contribution

<sup>1,2</sup>Conception and design, Collection and assembly of data, <sup>3</sup>Drafting of article, Analysis and interpretation of the data, <sup>4-5</sup>Critical revision of the article for important intellectual content, <sup>4</sup>Statistical expertise <sup>3</sup>Final approval and guarantor of the article.

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## A B S T R A C T

**Objective:** To determine the effectiveness of lateral insoles in patients of Knee Osteoarthritis for improving activities of daily living among patients with Knee Osteoarthritis.

**Methodology:** This a single blinded, Randomized controlled clinical trial conducted on 40 subjects at Madinah Teaching Hospital, physiotherapy clinics from 25 Feb 2016 to 26 August 2016 after approval from Institutional Review Board. By using simple convenient method subjects were recruited and randomized using coin toss method into group A and B. The study was completed in 07 months. Subjects diagnosed with Osteoarthritis (OA) on the basis of clinical and radiological finding of medial compartment knee OA grade II and III were included. Subjects were included as per inclusion criteria of study and then divided in two groups with 20 subjects in each. Activity of daily living was assessed at baseline, 2nd, 4th and 6th week. Using SPSS V.20 repeated measures ANOVA was used for analysis of outcome of interest.

**Results:** The results showed that there was significant improvement in activities including bathing, standing, and sitting, getting in and out of car and ascending chairs. The experimental group treated with lateral Insoles, showed greater improvement comparing pre and post intervention as compared to control group ( $P < .05$ )

**Conclusion:** The results of the study show that the lateral insoles have significant role for improving the activity of daily living in patients having grade III knee Osteoarthritis.

**Key words:** ADLS, Knee Osteoarthritis, Lateral Insoles

## Introduction

Osteoarthritis (OA) the most prevalent of the chronic rheumatic disease. Most commonly, effecting women more than males, leading to disability. Overall it exists in 28.7% and female prevalence was 31.6%.<sup>1</sup> There are near to 13% of the females and males aged 60 years have 10% and older have symptomatic knee OA. The ratio of the population affected by OA with symptoms, the knee is most likely to be increased due to the age related of that population and their ratio of obesity or overweight in comparison to the general population<sup>2</sup> especially those of above 55 years, have more severe OA in the knee as compared to the other joints in their body. The prevalence of

OA in the knee joint is affected by postmenopausal factors and gender differences.<sup>3</sup> The prevalence was found to be high based on the findings from radiographic results of Knee arthritic changes. The incidence was more in females than that of the men<sup>4</sup> knee arthritic symptoms were mostly in the general young was less but mostly found in women of older age. In a study Greece community, knee OA symptoms were observed.<sup>5,1</sup> The incidence rate was much higher in the females than in males and ratio was increased significantly with respect to age. Symptoms of OA in knee were not common in urban compared to rural and suburban study population. Obesity and a lower level of education were linked

in the knee OA involved population.<sup>7</sup> There were Knee symptoms, radiographic changes in knee OA, knee OA with its symptoms, and severe radiographic knee OA were added in 3018 participants of study (33%) in population of African and Americans (38% men). The Diagnosis of OA and its severity disease is usually based on Kellgren -Lawrence radiographic grade above II, severe radiographic knee OA classified as 3 grades and 4 grades, and symptomatic knee OA as knee symptoms in a knee with radiographic OA.<sup>8</sup> The symptoms in knee were found in 43% of population. 28% of patients having symptoms had changes in their radiographs of knee, but less ratio with symptomatic knee OA were 16% only, and only 8% of them have high changes in radiographs of knee OA.

Incidence was found more in older adults and women, but prevalence was higher of end stage findings as per radiographic knee OA than that according to literature available in studies.<sup>9</sup> The symptoms leading to concerns of Knee arthritis were due to higher body mass index, less education, increase in morbidity, activity limitations and joint space tenderness. All these can lead to increase in pain and limited activities of daily living.<sup>10</sup> These symptoms need to be managed using different interventional strategies using isometrics, traction, gliding, failure of these conservative need surgical or knee replacement procedures.<sup>11</sup> In a local study, it was reported that 40% had effected 26-50% quality of life due Osteoarthritis, while 23.8% had severely affected their life activities due Knee OA.<sup>12</sup> The lateral wedge insoles, a specific design that can induce difference of stiffness that can lead to decrease in adduction of knee along with the ankle/subtalar eversion reduction.<sup>13</sup> Nature has created an organised and balanced pattern of movements, but any underlying cause changes it that need conservative or surgical methods based on evidence. The purpose of this study was to measure the effects of lateral insoles in patients with knee osteoarthritis, so that they can be given a new strategy to live an improved activity of daily livings with decrease in symptoms due to knee Osteoarthritis.

## Methodology

This single blind randomized controlled trial, was conducted after ethical permission from Isra University, Islamabad from 15 Feb 2016 to Aug 2016. In the first step participant were selected through non- purposive convenient sampling. 53 patients were enrolled, (<sup>14</sup>) but 40 patients were considered for the conduction of this study. Before the start of their participation in the study, all the participants were informed about the study and its purpose. After their signed consent they were allowed to participate in the study. Subjects having Knee osteoarthritis patients with medial joint space reduction, male

and female adults with osteoarthritis between 40-60 <sup>15</sup> years of age, clinically and radiological based diagnosed cases of knee OA grade II and III were included<sup>16</sup> All the subjects with rheumatoid Arthritis, physical deformity, trauma in last 6 months, fracture of knee, systemic disease leading to knee pain and age less than 40 or greater than 60 years were excluded. After initial assessment all the subjects were recruited in two groups by coin toss method to remove chance of allocation Bias.

In Experimental group (A) Lateral insoles (of thickness 7mm)<sup>17</sup> were given and instructed to wear the shoes during day time throughout the week. The insoles were placed in the shoes and adjusted and they were also given same routine treatment as in control group. The control group (B) received ,Short Wave Diathermy (SWD)( for 15 minutes),therapeutic ultrasound<sup>18</sup> and Knee isometric exercises (for 15 minutes), session was given for 35 minutes, for 5 times in a week for 6 weeks. The therapeutic ultrasound was given at 1.5 watts/cm<sup>2</sup> for 5 minutes at continues mode. All these protocols are already available in literature and proved to be an effective regimen. The data from subjects was collected after explaining them the purpose of study and signing informed consent. Their Knee functioning was assessed by using ADLs Questionnaire of knee survey that consists of items for daily living including getting out car, standing ,ascending and descending chairs.<sup>19</sup> The assessor was asked to measure their ADL; s for baseline evaluative data. The assessor was blinded and was not aware of the group. Data was taken before, mid and end i.e. 2nd, 4th and 6th weeks respectively. Demographic data i.e. age, gender and baseline data of subjects were taken at zero visits. The intervention was given for 6 weeks; the outcome was measured at baseline, 2nd, 4th and 6<sup>th</sup> week. Using SPSS V. 20, appropriate statistical tests were used according to data distribution. The Repeated measurement ANOVA used for group comparisons.

## Results

There were 82.5% males while 17.5% were female participants with mean age 54.18±5.90. The mean score of symptom of going up and down at baseline in experimental group was 3.55± .51 while in the control group 4.00± 0.00. The mean score was improved to 1.10 ± 0.57 experimental and 3.00± 0.000 of control group on 6<sup>th</sup> week of evaluation. In ascending stairs at baseline experimental group was 3.55± 0.510 while in control group was 4.00± 0.00 and reduced to 1.10 ± 0.57 in experimental and 3.00± 0.000 in control group at 6<sup>th</sup> week. The p value was <0.05 showing a statistical significant effect of intervention in both groups. (Table No I)

**Table I: Descriptive Statistics of Going-up/down and ascending stairs with pain experience**

Descriptive Statistics between the group				
ADL's	Time point	Groups	Mean Std. Deviation	P-value
Pain while going up/down	Baseline	Experimental	3.55 ± 0.51	0.00
		Control	4.00 ± 0.00	
	2 <sup>nd</sup> week	Experimental	2.70 ± 0.57	
		Control	3.45 ± 0.51	
	4 <sup>th</sup> week	Experimental	2.15 ± 0.67	
		Control	3.00 ± 0.00	
ADL's ascending stair	6 <sup>th</sup> week	Experimental	1.65 ± 0.98	0.00
		Control	3.25 ± 0.44	
	Baseline	Experimental	3.45 ± 0.94	
		Control	3.75 ± 0.44	
	2 <sup>nd</sup> week	Experimental	2.70 ± 0.73	
		Control	3.45 ± 0.51	
	4 <sup>th</sup> week	Experimental	2.25 ± 0.71	0.00
		Control	3.10 ± 0.30	
	6 <sup>th</sup> week	Experimental	1.70 ± 0.86	
		Control	2.75 ± 0.44	

**Table II: Descriptive Statistics of ADL's standing, bending and getting in/out of bath pain experience**

Descriptive Statistics between the group				
ADL's	Time point	Groups	Mean Std. + Deviation	P-value
ADL'S standing	Baseline	Experimental	3.50 ± 1.00	0.00
		Control	3.50 ± 0.88	
	2 <sup>nd</sup> week	Experimental	2.75 ± 0.63	
		Control	3.50 ± 0.51	
	4 <sup>th</sup> week	Experimental	2.10 ± 0.78	
		Control	3.25 ± 0.44	
ADL'S bending	6 <sup>th</sup> week	Experimental	1.50 ± 0.76	0.00
		Control	2.75 ± 0.44	
	Baseline	Experimental	3.45 ± 0.99	
		Control	3.50 ± 0.88	
	2 <sup>nd</sup> week	Experimental	2.85 ± 0.58	
		Control	3.60 ± 0.50	
ADL's getting in/out of bath	4 <sup>th</sup> week	Experimental	2.10 ± 0.78	0.00
		Control	3.25 ± 0.44	
	6 <sup>th</sup> week	Experimental	1.75 ± 0.71	
		Control	2.85 ± 0.58	
	Baseline	Experimental	3.45 ± 0.75	
		Control	3.50 ± 0.51	
	2 <sup>nd</sup> week	Experimental	2.45 ± 0.60	0.00
		Control	3.50 ± 0.51	
	4 <sup>th</sup> week	Experimental	1.80 ± 0.69	
		Control	3.40 ± 0.50	
	6 <sup>th</sup> week	Experimental	1.15 ± 0.74	
		Control	3.00 ± 0.72	

In standing at baseline in experimental group was 3.55± 0.510 while the score amongst the control group was 4.00± 0.00. On last evaluation at 6<sup>th</sup> week the mean was 1.10 ± 0.57 in

experimental and 3.00± 0.000 in control group. In getting in and out at baseline in experimental group was 3.55± 0.510 while control group mean was 4.00± 0.00. (Table No II)

The group comparison shows that experimental group receiving routine therapy with lateral insoles has statistically significant difference with p value < 0.05. (Table. No. III)

**Table III: Descriptive statistics for Sum of ADL's in each phase**

		Group A (Lateral Insoles)		Group B (Routine +Lateral Insoles)	
		Mean $\pm$ SD	p-value	Mean SD	p-value
Total ADLS	At Baseline	10.9 $\pm$ 10.2	0.00	11.40 $\pm$ 8.52	0.00
	2 <sup>nd</sup> Week	31.4 $\pm$ 10.17		13.05 $\pm$ 6.42	
	4 <sup>th</sup> Week	34.4 $\pm$ 11.21	0.00	13.05 $\pm$ 6.42	0.00
	6 <sup>th</sup> Week	47.8 $\pm$ 11.44		18.90 $\pm$ 4.25	

ADLS=Activity of Daily Livings, P value was significant at <0.05

## Discussion

The results of the study showed that there was significant improvement in activities including bathing ,standing, sitting, getting in and out of car, socks wearing as well as ascending chairs. This finding suggests that the subgroup may have compensated at the rear foot for the orthotic differently than the majority of the subjects. These subjects may have accounted for the lack of significance found in peak knee adduction.<sup>20</sup> Knee adduction excursion was significantly reduced even though the mean reduction was 0.7 degrees. However, 12 of 20 subjects exhibited at least a 10% reduction. The clinical relevance of such a small reduction in knee adduction excursion may be questioned. Gustavo et al <sup>21</sup> prospectively applied it at baseline and at weeks 2, 8 and 24. At weeks 8 and 24, both groups showed lower scores for WOMAC (P = 0.023 and P = 0.012 respectively). Pain was significantly reduced in both the group. Similarly according to our study mean age of all patients were 55.05 ± 6.7 years while sensation of pain at knee joint due to osteoarthritis was reduced. As in zero week within experimental group the total pain score mean was 79.9 ± 2.2 while on final session the total pain score mean was 91.4 ± 4.2 as discussed earlier that 100 shows perfect condition while 0 means worst condition further suggested by P value =0.01. In recent study, by M.T Khan comparative effects of insoles proved in this year to be the best for joint biomechanics modification. It has been proved that lateral insoles are effective management of knee OA.<sup>22</sup>

In one of the study on Quality of life improvement among patients of Knee Osteoarthritis, it was linked to biomechanical loading factors was modified and improvement was seen but that's was reduction of infra-pattaler pads.<sup>23,24</sup> Similarly our study was also focused on biomechanical factors and change in biomechanics of knee by using lateral insoles so that load can be decreased on the joint which can help to some extent in performing ADLs. In one of the study foot orthotics were compared with flat insoles .The study concluded that there was no significant difference between them but flat were quite comfortable as compared to that of the foot orthotics .The value of  $p > 0.05$  ( flat shoes or flat insoles).Pain was also reduced when they assessed shoes alone, foot orthotics ( $p = 0.002$ ) but flat insoles ( $p < 0.001$ ) there was reduced pain during step-downs; foot orthotics reduced pain during walking ( $p = 0.008$ ; 1and flat insoles reduced pain for ambulation during stairs ( $p = 0.001$ ). No significant differences between foot orthotics and flat insoles were observed for pain severity, ease of performance or knee stability. It concluded that immediate pain-relieving effects of prefabricated flat insoles were equal to foot orthotics.<sup>25</sup> Similarly in our experimental group was mean at pre session  $3.55 \pm 0.510$  compared to end session was  $2.15 \pm 0.67$ . This study was found to be in favor of our results. In contrast to another study , another study found that insoles can reduce pain but the reported effect size was less and considered less significant clinically<sup>26</sup> We have focused on biomechanical factor but resistance training can also play an effective role in reduction of stiffness as well as Activities of daily livings , but isotonic exercise are considered dominant on it. <sup>27</sup> The study was conducted on fewer samples. Such studies should be continued at larger samples, so that results can be generalized in other populations as well. Less data from the females can affect the generalization of result.

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## Conclusion

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The current study results concluded the lateral insoles are significant in improving the activity of daily living among patients with knee Osteoarthritis to a level that can improve their ADLs towards improvement.

Recommendations: There should be studies with larger samples in various populations and regions to rule out if there are others affect the outcomes.

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