

**Original article:**

**Feasibility of Lateral Wedge Insole v/s Neutral Insole in combination with Neuromuscular Training on Pain and Function in patients with Medial Compartment Osteoarthritis of Knee - a Pilot Double Blinded Randomized Control Trial**

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**ABSTRACT**

**BACKGROUND:** Medial compartment in Knee osteoarthritis is the highly affected compartment and more common amongst the elderly population . It leads to knee pain, reduced knee ROM, lower knee muscle as well hip muscle strength, decreased balance and thus lower performance level. Hence this Pilot study was conducted to check feasibility of a treatment protocol, which is a cheap and effective way for reducing pain and improving function .

**MATERIAL AND METHODOLOGY:** In this Pilot Double-blinded, Randomized Controlled trial, participants were screened and included meeting eligibility criteria.They were randomly divided 10 in each, receiving Neuromuscular training combined with Lateral wedge insole(NMT +LWI -experimental group )and Neuromuscular training combined with Neutral insole(NMT NI -control )group. They were assessed for pain and function using VAS, TUG, ROM and WOMAC scale, at baseline, post 4 weeks and after 2 weeks follow up i.e., at 6<sup>th</sup> week.

**RESULT:** After 4 weeks of treatment and 2 weeks follow up,NMT+LWI group was significantly effective( $p < 0.01$ ) than NMT NI group in reducing Medial Knee Pain, improving function. Except for ROM and WOMAC Stiffness and physical function Subscale which showed no statistically significant improvement.

**CONCLUSION:** Thus combination of Neuromuscular training and Lateral wedge insole is an effective way in reducing pain and improving function, thus should be considered as a treatment option while treating patients with Medial compartment OA knee.

**KEYWORDS:** Medial Compartment OA knee, Neuromuscular training, Lateral wedge insole, Neutral insole, Pain, Function.

**Introduction**

Osteoarthritis(OA) is one the major leading musculoskeletal disorder leading to functional disability. It has been found that every year atleast 1 crore Indians undergo Total knee arthroplasty (TKA ) due to severe pain and disability.<sup>1</sup>Majority of the individuals who undergo TKA on Xray are found to be affected with Medial tibiofemoral compartment OA.Medial compartment OA as compared to the others types is commonest.Factors such as Knee adduction moment passing medially to the knee joint axis during weight-bearing activities in standing and during walking and during functional activities such squatting and cross leg sitting and Varus deformity.<sup>2,3</sup>

Treatment option available consists of electrotherapeutic modalities( TENS,IFT ,LASER Ultrasound therapy )etc.<sup>4</sup>, strengthening exercises mainly concentrating on the Quadriceps,Hip abductors muscles.<sup>5</sup> Manual therapy approaches which comprises of joint Mobilization<sup>6,7,8</sup> viz Maitland,Kalterborn ,Mulligan Mobilization,Muscle energy Technique and Mckenzie approach. .Soft tissue mobilization technique<sup>9,10,11</sup>. such as Cyriax,Myofascial release Technique and Trigger point release technique. Adjunt method involves Taping,knee bracing and Footwear modification. Majority of the these treatment are addressing pain reduction.Among these technique only few interventions focus on the functional aspect along with pain reduction and halting of the disease progression.

Many treatment strategies have been administered to decrease the medial joint loading.Among these, the most studied ones are the neuromuscular training and lateral wedge insole. Neuromuscular exercise (NEXA) is performed in functional weight-bearing positions and focuses on the quality of movement and alignment of the trunk and lower limb.<sup>12</sup> 11 Neuromuscular techniques is proven to benefit in patients with ACL injury and ACL Reconstruction,<sup>13</sup> PFS.<sup>14</sup> Various studies done shows that NEXA can improve pain and function in patients with knee OA.<sup>15,16,17,18</sup> In these studies they found out that NEXA could affect knee joint load through appropriate alignment of the limb and trunk , thus this intervention may be beneficial for patients with varus malalignment. As a compensatory mechanism the foot which is a distal joint to the knee goes into pronation for decrease in knee adduction moment at joint.Evidences suggest that lateral wedge insole the centre of pressure shifts laterally ,thereby reducing the Knee Adduction Moment .The amount of reduction on Knee adduction Moment is directly proportional to the degree of wedging achieved.<sup>19</sup> On reviewing the existing literature there is lack studies done in which the effect of combination therapy that is lateral insoles in combination with neuromuscular training have been done. The purpose of this pilot randomized control trial was to find the feasibility of lateral wedge in combination with neuromuscular training on pain and functions in patients with medial compartment OA knee.

## **Methodology**

### **Study design**

This study was a pilot double blinded randomized control trial designed to compare the effects of two different protocols( lateral wedge insole in combination with neuromuscular training v/s neutral wedge insole in combination with neuromuscular training ) on pain and functions in patients with medial compartment OA knee.Ethical approval was granted by Institutional Ethical Committee.DVVPF, COPT,Ahmednagar.

### **Recruitment and participants**

A convenient sampling was used to recruit participants who visited Physiotherapy OPD. Participants in the age 45 – 70 years ,with Bilateral medial compartment OA knee ( Kellegran and Lawrence grading 2 and 3) and ability to walk independently on a flat surface without any ambulatory assistive device. Participants with History of the knee surgery,Inflammatory arthritis ,Bone Fractures of the lower limb,use of previously prescribed Orthosis for same problem,Neurological problem affecting Lower Limb.Severe co-existing Medical morbidity,Back condition that hampers the ability to do the exercises were excluded.43 participants were screened and 20 participants who were eligible were then randomly allocated into 2 groups using computer generated random number tables and concealed using the SNOSE method.Fig 1 shows the CONSORT Flow chart of the study.

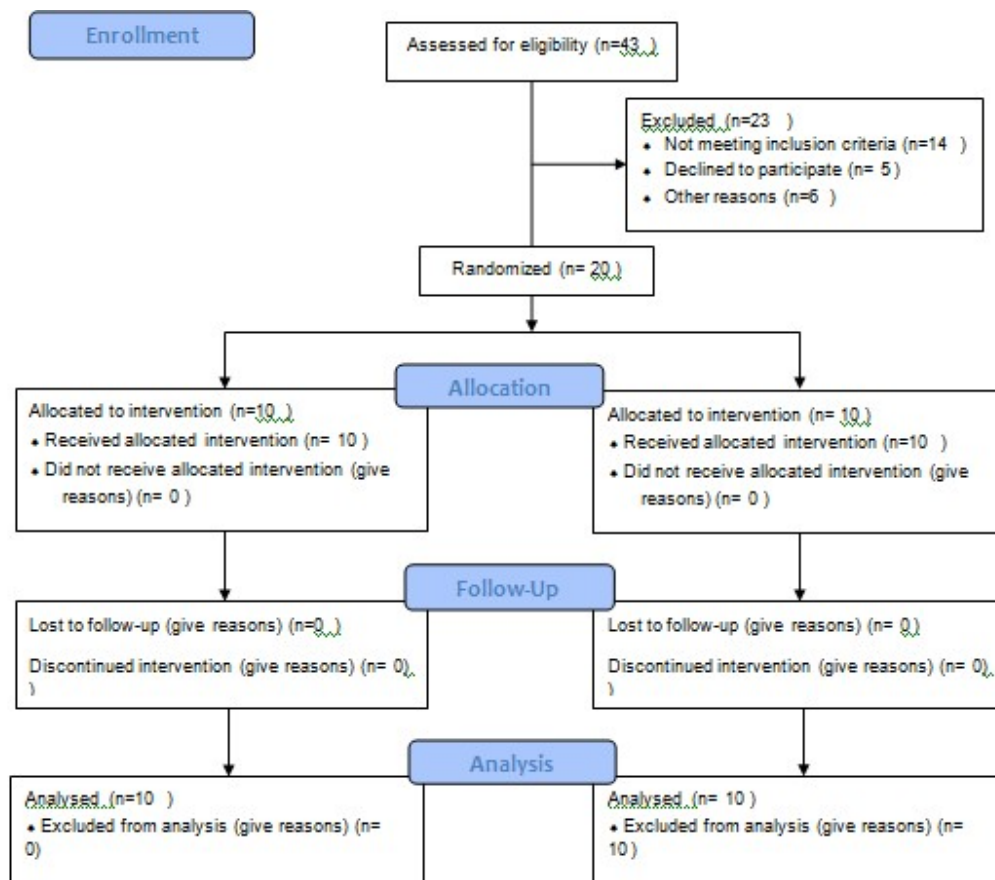


Fig 1. Consort Flow Chart

### Outcome measure

**Pain** was measured using VAS( $r=0.97$ ).<sup>20</sup> Functions were measured using Timed up and Go test(TUG) knee ROM, and WOMAC questionnaire. TUG is an easy functional measure with interrater and test-retest reliability is 0.87 and 0.75.<sup>21</sup> **Knee ROM** –Active Knee ROM were assessed with the use of universal goniometer with the participants in prone position for flexion and sitting position for extension ROM.<sup>22</sup> **WOMAC questionnaire** consisting of pain, stiffness and physical function( 5,2,17 items in each subscale, score ranging from 0- 100) is a reliable and valid subjective tool , but amongst the subscale , pain subscale was highly related to physical function.<sup>23</sup>

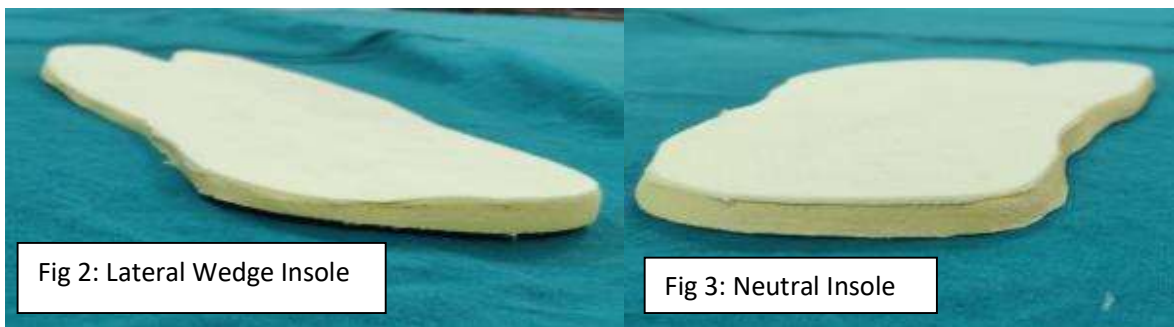
They were measured pre-treatment, post treatment i.e at 4<sup>th</sup> week and after 2 weeks follow up i.e at 6<sup>th</sup> week. The assessor who was blinded to treatment allocation of the participants took the assessment at all the three points

### Intervention

Prior to beginning the treatment protocol the participants were sent to the Orthosis and Prosthetic department for fitting of insoles. After the insoles were inserted in their footwear ,they were given two days for reporting any

discomfort regarding the use of insole. The participants in the experimental had to wear the pair of footwear modified with lateral wedge insole with 8 mm of wedging, made of ethaplex material (Fig 2). Whereas those in the control group wore neutral insole (Fig 3) with the same material without wedging for a period of 6 weeks.

Both the experimental and the control group received neuromuscular training, 4 sessions /week for a period of 4 weeks. Each session the participants had a warm up session for 5-10 mins and at the end of exercises cool down session 5-10 minutes consisting of simple mobility exercises for lower limb such as stationary bicycling and AROM's. The neuromuscular training exercises are described in detail in a previous study done.<sup>16</sup> They were instructed to maintain the knee over foot alignment for the exercises in front of the mirror and after each exercise they were given a 2 minutes rest break (Fig 3,4). At the 2 weeks follow up i.e. at the 5<sup>th</sup> and 6<sup>th</sup> week the participants were given a home exercise diary. In this diary the exercise that they had to perform at home were given in their local language with illustrated picture and the procedure of the exercise. And the participant had to tick the day and time they performed the exercise. Through-out the 6 weeks they were advised to wear the footwear during all the activities which required standing and walking.



**Statistical analysis**

SPSS version 20.0 was used. Sample size was calculated according to criteria given by Kieser et al.<sup>24</sup> Normality of the data was analysed using Shapiro Wilk test. Analysis of between the two groups at different point of time was done using unpaired t test for data which passed normality test. Whereas for the data which didn't pass normality between group analysis was done using Mann Whitney U test.

**Results.**

All the 20 participants completed the study. There were no adverse affects reported by the participants. The baseline characteristics data of the study participants were homogenous at the baseline (Table 1). On between group comparison of the studied outcome measure there was no significant difference at the baseline. At 4<sup>th</sup> week and 6<sup>th</sup> week the VAS, TUG and the WOMAC pain subscale showed significant difference. (Table 2). Figure 6 to 12 shows the graphical representation of the between group analysis at baseline, 4<sup>th</sup> week and 6<sup>th</sup> week.

**Table 1 : Baseline characteristics of the study participants**

Components	Mean ± SD (NMT +LWI )	Mean ± SD (NMT + NI )	p value
Age	58.3 ± 6.81	57.6 ± 8.44	0.8407
BMI	23.34 ± 2.44	23.19 ± 2.54	0.6547
FPI Right foot	7.2 ± 1.39	7.3 ± 1.56	0.9696
FPI Left Foot	7.1 ± 1.37	7.9 ± 1.7	0.3052
MMT Hip Right Flexor	3.4 ± 0.51	3.4 ± 0.57	0.9691
MMT Hip Left Flexor	3.3 ± 0.48	3.4 ± 0.51	0.7269
MMT Hip Right Extensor	3.6 ± 0.51	3.7 ± 0.48	0.7264
MMT Hip Left Extensor	3.5 ± 0.52	3.7 ± 0.43	0.4616
MMT Right Hip Abductor	3.4 ± 0.51	3.7 ± 0.48	0.2626
MMT Hip Left Abductor	3.6 ± 0.51	3.7 ± 0.48	0.7264
MMT Knee Right Extensor	3.4 ± 0.51	3.5 ± 0.52	0.7279
MMT Left Knee Extensor	3.5 ± 0.52	3.6 ± 0.51	0.7272
MMT Right knee flexor	3.4 ± 0.51	3.5 ± 0.52	0.7790
MMT Left knee flexor	3.3 ± 0.48	3.7 ± 0.67	0.2185

(NMT + LWI = Neuromuscular training + lateral wedge insole group , NMT +NI = Neuromuscular training + neutral insole group p<0.005 considered significant, Normality test used = Shapiro Wilk test)

**Table 2: Between the group comparison for outcome measure**

Outcome measures	At baseline			At 4 <sup>th</sup> week			At 6 <sup>th</sup> week		
	Mean ± SD (NMT +LWI )	Mean ± SD (NMT + NI)	P value	Mean ± SD (NMT +LWI )	Mean ± SD (NMT + NI)	P value	Mean ± SD (NMT +LWI )	Mean ± SD (NMT + NI)	P value
Right VAS	4.81± 1.68	5 ± 0.47	0.9999	1.7 ± 0.94	3.7±0.82	0.001*	1.1 ± 0.87	2 ± 0.47	0.015 *
Left VAS	4.5 ± 1.26	3.9 ± 1.37	0.3232	1.7 ± 0.82	2.7 ± 1.05	0.0480*	1.1 ± 0.31	2.1 ± 1.10	0.042 *
TUG	13.79 ± 1.26	13.38 ± 1.65	0.4461	9.52 ± 0.85	12.08 ± 1.21	0.0001**	7.92 ± 0.59	10.55 ± 1.01	0.000 1*
Right ROM	125.6 ± 7.60	125.8 ± 7.06	0.9523	128.1 ± 8.47	129.1 ± 6.12	0.6345	129 ± 8.15	130.70 ± 6.0	0.999 9
Left ROM	125.3 ± 6.23	127.3± 6.9	0.5067	128.40 ± 7.12	130.10 ± 6.40	0.5815	129.80 ± 6.46	131.0 ± 6.21	0.677 2
WOMAC pain subscale	9.5 ± 2.06	10.3 ± 1.33	0.2094	5.2 ± 1.22	7.70 ± 1.48	0.0028**	3.60 ± 0.84	6.1 ± 1.28	0.001 3**
WOMAC Stiffness subscale	3.4 ± 0.51	3.2 ± 0.63	0.2094	2.40 ± 0.51	2.20 ± 0.42	0.4579	2.1 ± 0.31	1.7 ± 0.67	0.177 1
WOMAC Physical function subscale	38.2 ± 8.87	33.70 ± 3.12	0.1480	26.8 ± 8.57	30.50 ± 3.10	0.2156	24.50 ± 8.27	27.50 ± 4.22	0.320 8

(NMT + LWI = Neuromuscular training + lateral wedge insole group , NMT +NI = Neuromuscular training + neutral insole group , Manwhitney U test statistics for nonparametric data, Unpaired t test statistics for parametric data, p<0.005 considered significant, \*)

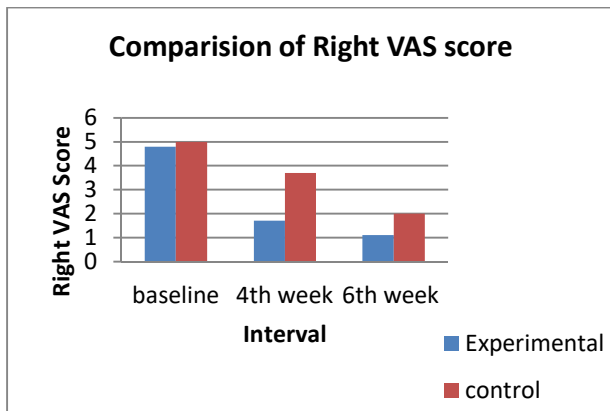


Fig 6 : Comparison between group comparison of left VAS Score

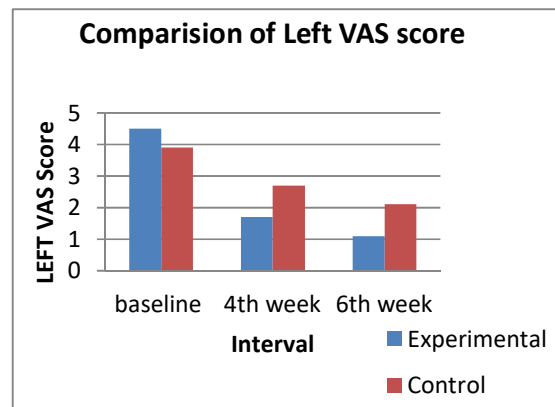


Fig 7 : Comparison between group comparison of Right VAS Score

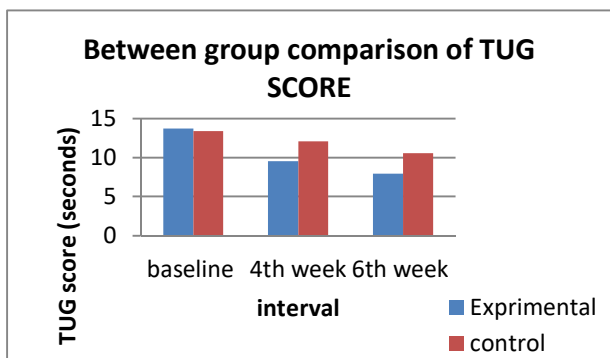


Fig 8 : Comparison between group comparison of TUG Score

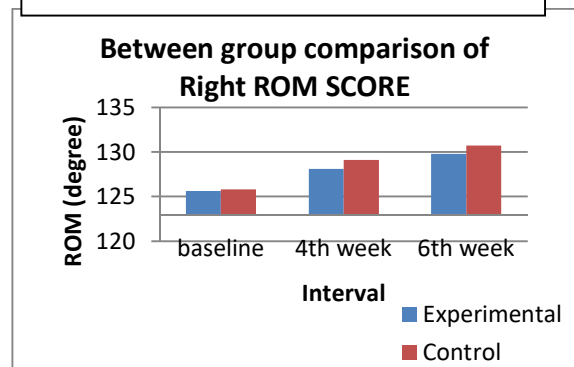


Fig 9 : Between group comparison of Right ROM SCORE

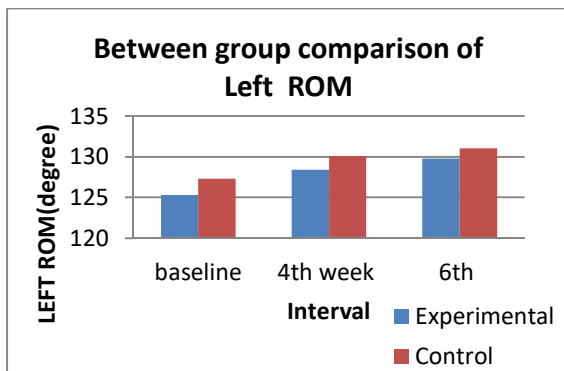


Fig 10 : Between Group Comparison of Left ROM

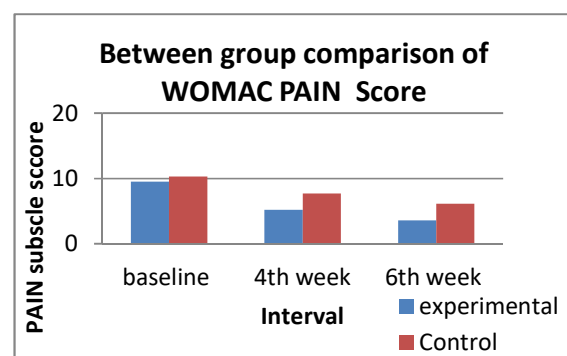


Fig 11 : Between group comparison of WOMAC PAIN Score

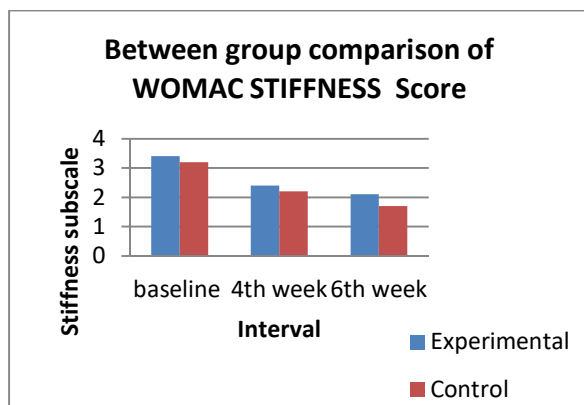


Fig 12: Between group comparison of WOMAC STIFFNESS Score

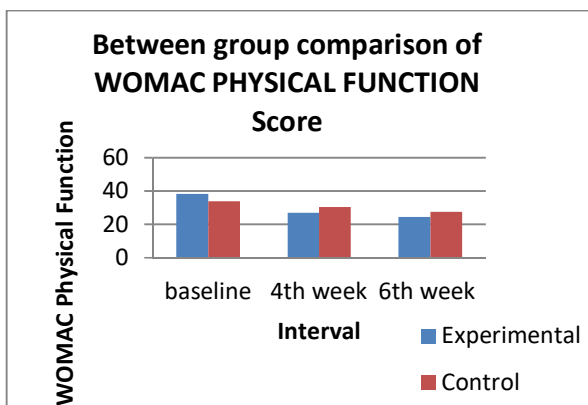


Fig 13: Between group comparison of WOMAC PHYSICAL FUNCTION Score

## DISCUSSION

Our study aimed at finding the effectiveness of lateral wedge insole v/s neutral insole in combination with neuromuscular training on pain and function in patients with medial compartment OA Knee. Pain and function were assessed using VAS, TUG, ROM and WOMAC scale. Ours is the first study to evaluate the effects of combined Neuromuscular training and Lateral wedge insole on pain and function in medial compartment knee OA patients. In the current study, we found that the Neuromuscular training in combination with Lateral wedge insole (NMT+NI) proved to be more effective for reducing pain and improving function as compared to the control group i.e Neuromuscular training and Neutral insole group (NMT + NI). Except for ROM, Stiffness and physical function subscale of WOMAC scale which showed no significant statistical difference.

### Pain Reduction

We found significant pain reduction in NMT +LWI group. VAS score at 4th-week post-intervention (Right knee  $p=0.01$ , Left knee  $p=0.04$ ), and 6th week (Right knee  $p=0.01$ , Left knee  $p=0.04$ ) reduced significantly. There was a decrease in pain associated with function which was measured using the WOMAC pain subscale. Our study's finding is in line with the recent study done by David et al in their randomized trial, patient with medial OA knee were given lateral wedge and neutral insole for a period of 8 weeks and 8 week washout lateral wedge insole showed a greater reduction in knee pain symptoms than neutral insoles with a mean difference of 0.7 on 0–10 scale ( $P=0.02$ ).<sup>25</sup> The significant effect in our study may be because of the addition of neuromuscular training with lateral wedge insole. Lateral wedge insoles reduce the peak knee external adduction moment in patients with medial Knee OA by shifting the center of pressure laterally. This reduces the frontal plane ground reaction force and lever arm resulting in a decrease in load, thereby causing a reduction in pain.<sup>26</sup> This must have led to the minimization of nociceptors activation and the effects of hysteresis and tissue cavitation.<sup>27</sup> In addition to the pain relief due to the use of LWI, there was analgesia induced due to the neuromuscular exercise which stimulated the proprioceptors at knee joints. According to the pain gate theory, these interneurons depend on the competition



between noxious and proprioceptive stimuli. Since the proprioceptive stimuli are faster, its arrival in the dorsal horn activates interneurons and helps in the release of opioid substances and GABA, thus leads to pain reduction.<sup>28</sup>

### **Improvement in physical function**

The participant in the LWI + NMT group showed marked improvement in function and this can be inferred, primarily by a decrease in the time taken to complete the TUG both at the 4th week (  $p = 0.0001$ ) and 6th week i.e 2 weeks follow up (  $p = 0.0001$ ) These findings are consistent with the study done by Casey et al<sup>29</sup> where they found LWI led to a significant reduction in the knee varus torque during walking when it was compared with walking with no insole and walking with nonwedged 3.175-mm and 6.35-mm control insoles. Though their study didn't find any change in walking speed in a 10-meter gait laboratory record using a video-based motion analysis system. The results of their study cannot be generalized due to small sample size and only the immediate effects of the insole were recorded. If there is pain associated with OA knee, it may interfere with the ability to perform activities of daily living.<sup>30</sup> Therefore decrease in pain might also have contributed to the increase in function as compared to the control group. Studies have found ,Lateral wedge insole also alters the step width, progression angle, and valgus angle at the subtalar joint, enabling the users to walk more naturally.<sup>31</sup> This might be the reason for a decrease in the time taken to walk which is reflected in the decrease in TUG score to as compared to( NMT + neutral insole) group. The improvement in function was also maintained in the follow-up period after 2 weeks i.e at the 6th week. It is primarily due to the carry-over effect of the well-supervised 4-week exercise session and home exercise program dairy.

In the current study, there was no statistical improvement in ROM and WOMAC stiffness and physical function subscale when it was compared between the group at intervals .This might be due to the participant's baseline ROM being close to normal. In a study by Seung et al they compared ROM and stiffness in individuals awaiting for Total Knee Arthroplasty. They measured the ROM preoperatively as well as postoperatively. They found participants with mild stiffness and less restricted ROM preoperatively didn't improve significantly after intervention, as compared to those who had severe stiffness and more restriction.<sup>32</sup> This can also be explained by the nature of the baseline characteristics of the participants in our study i.e BMI, the severity of the disease, age of the participants. All these characteristics were similar for both groups. These factors are directly related to the ROM and thus the stiffness level.<sup>33</sup>

Our study's participants in both the groups had a BMI in normal range and participants with mild to moderate OA on the KL grading scale (grades 2 and 3) were included. There was no significant changes in WOMAC physical Function Subscale. It can be due to subjective nature of the items of the scale which was dependent on the participants response. It is contrast with the finding of TUG score which significantly decreased. TUG test is an objective measure, thus is a more reliable method in terms of measuring physical function.

### Conclusion

A combination of Lateral wedge insole and neuromuscular training is an effective way to decrease pain and improve function. Thus can be included in the current treatment strategies in patients with Medial compartment OA knee.

### Limitation and Future Scope.

Though the adherence to set protocol was good as there were no drop outs. Further studies considering the outcome measure for quantification of adherence during follow up period shall be included. This was a pilot study, thus a Large scale studies should be undertaken. Only a follow up period of 2 weeks was studied. Thus to study long term effectiveness, a longer follow up period should be considered. The difficulty level of the exercise were low to medium, higher difficulty level in performing the exercises should be considered.

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