## Role Of Lateral Sole Raise In The Management Of Primary Osteoarthritis Of Knee -A Clinical Study

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Abstract: Background: Primary osteoarthritis of knee joint is a frequent disorder usually affecting the patients after 5th decade. Medial compartment of knee is most commonly affected leading to physical impairment in the form of knee pain, stiffness, swelling and alteration of gait in the advanced disease. Aim of this study was to study the role of Lateral sole raise as a conservative treatment modality for patients with degenerative OA of knee. Material And Methods: Study included 60 patients with stage I and II O. A. (Kellgren & Lawrance Radiological classification of Osteoarthirits) knee over 60 yrs. of age, randomly distributed in two groups. Control group has received conventional treatment in the form of physiotherapy with NSAID's while Study group received lateral sole raise in footwear of 2 cm in addition to Physiotherapy. Two group evaluated by Lysholm Knee rating scale & Tibiofemoral angle at initial presentation (T0), after six months (T1) and after one year (T2) respectively. Result: It shows that mean of difference in Lysholm Knee rating scale between T<sub>0</sub>- T<sub>1</sub>& T<sub>0</sub>- T<sub>2</sub> of control group & study group is significant while mean of difference in Tibiofemoral angle between  $T_0$ -  $T_1$  &  $T_0$ -  $T_2$  of study group is significant except  $T_0$ -  $T_1$  in study group is insignificant. Conclusion: Significant results were obtained in lateral sole raise group. Outer sole raise creates a favourable environment for healing of medial knee compartment articular cartilage due to improved biomechanics thereby leading to improvements in pain, gait and also in knee scoring. It seems that the wedged insole exerts no effect in patients with advanced degenerative changes therefore advanced osteoarthritis is not an indication for this method of treatment. These results led to the conclusion that treatment with a wedged insole was effective in patients with mild to moderate osteoarthritis of the knee. Out of all the modalities lateral sole raise seems to be the convenient, cost effective, non invasive and well suited to Indian population. [Khan A Natl J Integr Res Med, 2020; 11(4):22-261

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**Introduction:** Primary osteoarthritis of knee joint is a frequent disorder usually affecting the patients after 5<sup>th</sup> decade. Medial compartment of knee is most commonly affected leading to physical impairment in the form of knee pain, stiffness, swelling, Genu Varum deformity & alteration of gait in the advanced cases<sup>1</sup>.

This is a age related degenerative disorder where articular cartilage in the medial compartment of the knee is eroded gradually, leading to decreased medial joint space which manifests clinically as Genu varum or medial deviation of leg at knee<sup>2</sup>.

This leads to biomechanical disadvantage at knee causing knee pain and awkward gait<sup>3</sup>. Varus deformity further aggravates the situation leading to vicious cycle of deformity, instability and pain<sup>4</sup>. Osteoarthritis knee can be treated by non operative and operative means depending upon the stage of disease.

Conservative treatment is useful for mild to moderate degree of Osteoarthritis, which includes life style modification, weight reduction, physical therapy, NSAIDS, lateral sole raise and intraarticular injections. Operative treatment is useful for moderate to severe cases where a conservative treatment fails. Arthroscopic levage, chondro-plasty, high tibial osteotomy, unicondylar arthro-plasty and total knee arthroplasty are the mainstay of operative treatment wherever indicated. Out of the entire conservative modalities lateral sole raise seems to be the convenient, cost effective, noninvasive and well suited to Indian population<sup>5</sup>.

Outer offloads the sole rise medial compartment of knee and tends to correct the disturbed biomechanics of varus knee. Offloading of the medial knee compartment redistributes the forces in the both compartments leading to better environment for healing of articular cartilage and thus eases the symptoms of osteoarthiritis<sup>6,7</sup>. Aim of this study is to study the role of Lateral sole raise as a conservative treatment modality for patients with degenerative OA of knee.

Material & Methods: This study was conducted on 60 patients presenting to the out-patient

section of department of Orthopaedic Surgery, J.N.Medical College, AMU, Aligarh. Patients of >60 years with primary stage I/II Osteoarthiritis of knee<sup>8</sup> (Kellgren & Lawrance Radiological classification of Osteoarthirits knee<sup>11</sup>) involving the medial compartment as evident by clinical & radiological examination, were included in this study.

Patients with limb length discrepancies, previous knee surgeries, coexisting Hip & Ankle pathologies and recent trauma or injuries to the knee were excluded. The patients were randomly allocated into two groups of 30 patients each.

Group A was control and Group B was study group. Control group received conventional treatment in the form of physiotherapy with NSAID's and local pain killer gel, while Study group received lateral sole raise of 2 cm in footwear, in addition to Physiotherapy.

Two groups were evaluated by Lysholm Knee rating scale<sup>9</sup> at initial presentation ( $T_0$ ), at 6 months ( $T_1$ ) and at 12 months ( $T_2$ ). X-Rays of all the patients with antero-posterior view of both the knees in standing position including hip and ankle at the initial presentation ( $T_0$ ), at 6 months ( $T_1$ ) and at 12 months ( $T_2$ ) was done in both groups.

Femoral head centre, knee centre and centre of ankle was marked on the X-ray and Tibio-femoral angle was calculated. The control and study group was compared by using t-test and data was analyzed to know whether the difference between two groups is statistically significant based on the p-value.

**Results:** This study involved 60 patients including 36 males and 24 females. Age of the patients ranged from 62 – 74 years, mean age being 67 years. They were randomly allocated in two groups by computer generated randomization method. Group A was control group receiving pain killers and group B was study group receiving sole raise.

Associated co-morbidities like Diabetes, Hypertension and Obesity etc were equally distributed in both the group with no significant difference. Patients' bodyweight and height were also uniformly distributed with no statistically significant difference in two groups. Table 1, shows that mean of difference in Lysholm Knee Rating Scale between TO-  $T_1 \& T_0$ -  $T_2$  of control group & study group is significant.

This results also depicts the effect of lateral sole raise in footwear is more beneficial in study group than effect of physiotherapy with NSAIDs in control group. This conservative treatment, lateral foot raise in footwear helps the patient gradually from start of treatment to follow up T  $_1$ & T<sub>2</sub>while physiotherapy with NSAIDs start its effect initially after 6 month T<sub>1</sub>& then gradually decline after follow up T<sub>2</sub>.

At the same time, Tibiofemoral angle (degree) in Table 1 shows non-significant changes in control group except statistically significant changes is seen in study group while comparing with control group. Graph 1 shows the comparison of Lysholm knee rating scale changes at two presentation time between control & study group which depict beneficial effect of lateral sole raise in footwear.

Graph 2 shows the comparison of Tibiofemoral angle changes at two presentation time between control & study group which also show the same result as in graph 1, i.e., Lateral sole raise in footwear gradually helping the study population (Table-1 & Graph-1,2).

Lysholm Knee Rating Scale mean of difference is 11.73 in control group, while it is 51.2 in study group. A comparison of total scores of the Group A and B, suggests that subjects in both groups showed nearly similar recovery in "Initial-First" phase.

But in the next "First/ Second" and "Initial-Second" periods Group B have statistically much better results than Group A. These findings support the idea that indeed, exercises strengthening programs are beneficial for early medial OA knee subjects but additional modified footwear undoubtedly increases the relief score.

Tibiofemoral angle mean of difference is 1.37 in control group and 4.38 in study group. The results for 2-dimensional X-ray analysis indicate no change in the tibiofemoral angle with or without the lateral raise.

The orientation of mechanical axis of lower extremity with the vertical ( $\alpha$ ), however significantly shifted medially with the usage of footwear.

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Evaluation	Control Group					Study Group				
Time/ Parameters	To	T <sub>1</sub>	T <sub>2</sub>	Mean Of Difference (P-Value)	Mean Of Difference (P-Value)	To	T <sub>1</sub>	T <sub>2</sub>	Mean Of Difference (P-Value)	Mean Of Difference (P-Value)
				(T <sub>0</sub> - T <sub>1</sub> )	(T <sub>0</sub> - T <sub>2</sub> )				$(T_0 - T_1)$	$(T_0 - T_2)$
Lysholm Knee Rating Scale	37.0	91.2	48.73	54.2 (0.00001)	11.73 (0.00001)	43.66	74.33	94.86	30.67 (0.00001)	51.2 (0.00001)
Tibiofemoral Angle(Degree)	89.88	89.88	91.25	0(NS)	1.37 (0.0011)	88	87.5	83.62	1.5 (0.6831)	4.38 (0.0013 )

Table 1: Mean Difference In Lysholm Knee Rating Scale Between T0- T<sub>1</sub> & T<sub>0</sub>- T<sub>2</sub> Of Control Group & Study Groun

P value < 0.05 is significant

10

0

T0-T1







T0-T2



**Discussion:** Osteoarthritis alters the inclination of the Knee and therefore leads to abnormal standing and walking conditions. A 2 cm outer sole raise can be used to serve as a corrective maneuver to patients with osteoarthritis of the knee. The wedged insole causes favourable

change in the spatial position of the knee joint due to redistribution of forces at knee. When the patient attempts to adapt to the new standing biomechanics, changes occur in the balance of standing through muscle activity, producing a new standing and walking condition. These changes jointly cause the extended mechanical axis of the lower limb to approach a more upright position. In the new scenario, there is a decrease in loading on the medial aspect of the knee joint. The activated muscle also helps reduce lateral instability.

It reduces tension of the lateral collateral ligament, the iliotibial tract, and the lateral capsule, resulting in pain relief. A satisfactory angle for the wedged insole is higher than a angle and does stimulant not demand hypermobility of the spine to maintain balance; in other words, the angle is applicable to the area below the pelvis. An angle of 5° is suitable for the wedge.

In the management of osteoarthritis knee, conservative treatment still continues to be important. In this conventional regime, analgesics viz. NSAIDs have been the most in use. However, Schmitzer, Popovich<sup>8</sup> in 1993 studied the effects of piroxicam on OA knees and found that although symptomatic pain relieved, loading of the knee increased.

This concept was supported in 1993 by Hurwitz, Sharma, and Andriachi<sup>3</sup>. They analyzed that such pain relieving methods result in loss of protective mechanism associated with pain and subject the joint to more rapid disease progression. Analgesics therefore may not be beneficial in the long run; rather they will aggravate the condition. The wedged insole is noninvasive and easily applied option in this regard. While the

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treatment is known through experience to be effective and is gradually increasing in popularity, objective evaluation of its effect and elucidation of its mechanism of action has not been much discussed. An orthosis is meaningless unless it is rapidly applicable for routine use.

Few patients were not satisfied with wedged insole, the reasons for their dissatisfaction with the wedged insole have been investigated. Patient complaints regarding the insole included in effectiveness, foot perspiration, and inability to wash the insole.

We thought that the improvement of materials of the insole was necessary. An example of the improvement is the use of polypropylene mesh in a shoe-type insole. It is washable, durable and cheaper than that of leather and the insole lasts for more than two years.

The complaints mentioned above about the wedged insole were less frequent in the patients using a shoe-type insole. As has been suggested by Pottenger, Philips and Draganich<sup>10</sup> in their study in 1990, the marginal osteophytes around the knee appear to stabilize the knee in the initial stages of OA, although they can later cause deformity.

A similar study in July 1994 by Brage, Pottenger and Draganichre affirmed that OA knees tend to have less laxity than normal knees. Based on these suggestions, the domain of instability was eliminated from the rating scale for the purpose of the study. The remaining scale with 7 items was analyzed for its reliability on Equal Length Spearman Brown Test and found to be very reliable.

**Conclusion:** Comparing the two groups consisting of Stage I and Stage II, Group B, treated by a combination of a wedged insole and NSAIDS, showed a significantly greater improvement in the rating scores than Group A, and treated with NSAIDS alone.

As for the therapeutic effect according to the radiographic stage, the wedged insole was effective in Stages I and II, but was ineffective in Stage III and IV. It seems that the wedged insole exerts no effect in patients with advanced degenerative changes. It is our opinion that advanced osteoarthritis is not an indication for this method of treatment.

These results lead to the conclusion that treatment with a wedged insole is effective in patients with mild osteoarthritis of the knee.

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