

Comparison of the Effectiveness of knee braces and lateral wedge insole in the Management of Medial Compartment knee osteoarthritis

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ABSTRACT

Aim: To compare the effect of non operative treatment of medial compartment knee osteoarthritis by off-loading knee braces and Lateral wedge insole (shoe modification).

Methods: We enrolled 120 consecutive patients with symptomatic medial compartmental knee OA, half of the patients were randomly given Valgus knee brace and half were given lateral wedge insoles. All patients were assessed at 6 months. 6 patients lost follow up. The primary outcome measure was pain severity as measured on a visual analog scale. Secondary outcome measures were knee function score using WOMAC.

Results: There were total 120 patients of which 52(43.3%) were male while 68(56.7%) were female. Pain severity and walking distance reduced significantly in both lateral wedge and un-loader bracing groups, while more pronounced reduction of the mean outcome assessments was observed in the un-loader brace group in the management of medial compartment knee osteoarthritis (P-value<0.05). Average resting pain of the knee bracing decreased from 6.14 to 4.2, while mean activity level was increases from 35 to 38 on a visual analog scoring scale

Conclusion: Both treatments are effective but three point valgus knee brace support had more significant effect on pain reduction, walking distance and pain killer as compared to lateral wedge insoles.

Keywords: Osteoarthritis, visual analog Scale, Western Ontario and McMaster Universities

INTRODUCTION

Knee OA is one of the most common joint disorders and causes considerable pain and immobility¹. It has prevalence between 6-12% in general population based on the age and sex². OA is a progressive disease that, at present, has no cure; as such, by 2020, the incidence of OA in US is predicted to reach 40 million and become the fourth-leading cause of disability³. Many patients present with predominant medial compartmental knee OA⁴. It is frequently associated with conditions of previous injury to the joint, excessive wear or obesity; and the relationship of exercise and work is probable but not clear^{5,6}. The initial treatment is non-operative and consists of patient education, weight reduction, physical therapy, and, if needed, medication. The overall risk for developing knee OA in one's lifetime has been reported to be 46% in the normal population, 57% when there is a history of knee injury, and 66% among obese individuals⁷.

According to the Osteoarthritis Research Society International's new guidelines for managing hip and knee OA, the strength of recommendations scored

76% (95% confidence interval, 69%-83%) in the ability of off-loader knee braces to reduce pain and improve stability⁸.

MATERIAL AND METHODS

This randomized controlled trial study was held in Orthotics Departments of HOPE Rehabilitation Center in Lahore, Pakistan. During study period from June 2012 to May 2013, 120 patients were enrolled between the age of 35-65 years having history of knee pain and genu varum deformity based on radiographic evidences and moderate to severe medial compartment DJD (grades II, III and IV of Kellgren and Lawrence grading system) were included in the study⁹. The degree of malalignment was measured on a whole leg x-ray in standing position. The degree was measured according to one line from the center of the femur head to the middle of the distance between the tibial spines and a second line from the center of the ankle to the center of the tibial spines. The degrees more than 180 were considered as varus deformity.

The exclusion criteria were history of any orthopedic lower limb surgery, both compartments DJD (based on radiologic findings), symptomatic patella femoral pain syndrome (radiographically

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confirmed), rheumatoid arthritis, any superimposed hip or ankle problems and body mass index greater than 30¹⁰. Patients were recommended randomly grouped by lottery method for local (custom made) 3 point versus correction knee braces (Group A) or grouped for laterally wedged insole (Group B). (The decision to put a specific type of procedure rests were randomized on the basis of alternate outdoor days (valgus brace on Monday, Tuesday and Wednesday while wedged insole on Thursday, Friday). All patients were examined and fitted with brace individually by doctor. The brace was adjusted if necessary during six month follow up period and patient were instructed to do it on and off every 3-4 hours for the first week and then put it on as long as possible during the day and take it off at nights. Patients were evaluated based on age, sex, severity of pain, severity of DJD and walking distance at base line and 6 months after interventions by an examiner. We used visual analog Scale to monitor the severity of pain and the second section of "Lequesne scale" to measure maximum walking distance. The second section of lequesne scale asked about the maximum walk distance in meters [graded from 0=unlimited to 6=less than 100m]¹¹. Complications i.e., (ipsilateral leg and foot swelling and uncomfortable feeling) of brace use were also noted.

Data was analyzed using SPSS version 20.0. All qualitative variables (like sex, age, and Osteoarthritis medial grade and Osteoarthritis lateral grade) were presented in the form of frequency, percentages and graph whereas quantitative variables i.e. (age, height, weight, BMI, pain, walking distance and pain killer) were presented as mean±standard deviation. The comparison of the qualitative variables were performed using chi-square test and for quantitative variables t-test was applied, 5% level of significance was used. All tests applied were two tailed.

RESULTS

The result shows that out of 120 patients; 4 patients in the insole group and 2 patients in the bracing group were lost to follow-up. Three patients in the insole group and 2 patients in the bracing group changed their initial treatment during the 6 months follow-up period because did not experience relief or felt that the brace was too cumbersome to use, Ipsilateral leg swelling was the main complication in the brace group (n=5). Out of 120 patients; 68(56.7%) were female while 52(43.3%) were male patients included in the study.

The mean age of the patients was 48.72±8.80. The mean age of presentation in valgus knee braces being 49.20 years, compared to the 48.23 years of the Lateral wedge insole. Mean height, weight and BMI of both procedural groups and their representation in the study appear to be slightly similar.

At baseline, the difference of the pain severity and walking distance in both groups was statistically insignificant (P-value >0.05), while after 6 months significant differences between the insole group and the bracing group were noted for VAS (3.97±1.67 vs. 4.53±1.41; P-value <0.05) and walking distance (1.93±0.80 vs 2.36±1.41; P-value <0.05).

After six month mean improvement of pain and activity level compared to the baseline scores between the insole and the brace groups were; respectively 6.14±1.53 vs.4.2±1.56, and 35±26vs. 38±24 additionally showed significant effect (p=0.001), such as improvements in pain and function subscales were more common observed in valgus knee braces group while less common initiated in lateral wedge insole group, hence the valgus brace shows more pain relief and better function however the lateral wedge insoles were more acceptable and easier to use by the patients.

Table-1: Demographical and clinical baseline characteristics of the interventional group.

		Valgus knee braces	Lateral wedge insole	P-value
Gender	Male	24(40%)	32(53.3%)	§0.143
	Female	36(60%)	28(46.7%)	
Height		65.43±3.32	64.50±2.86	0.102
Weight		80.53±12.92	74.97±10.28	0.010*
BMI		29.13±4.1	27.91±3.12	0.070
Age	35-40	14(17.5%)	11(18.0%)	§0.058
	41-46	32(40%)	18(30.0%)	
	47-52	18(22.5%)	15(25.0%)	
	53-58	5(6.2%)	4(6.7%)	
	59-64	7(8.8%)	9(15%)	
	65-70	4(5%)	3(5%)	
Osteoarthritis medial grade	2	20(33.3%)	13(21.7%)	§0.153
	3	35(58.3%)	36(60.0%)	
	4	5(8.3%)	11(18.3%)	
Pain		6.233±1.57	6.05±1.50	0.514
Walking distance		4.27±1.13	4.07±1.08	0.326

*significant as p-value <0.05, §: used for chi-square

Table-2: Comparison of the post operative (at 6 month follow up) outcome assessments (pain severity, walking distance) response with respect to un-loader bracing and lateral wedge insole:

Outcome	Valgus knee braces	Lateral wedge	p-value
Pain	3.97±1.67	4.53±1.41	†0.047*
Walking distance	1.93±0.80	2.36±1.41	†0.041*

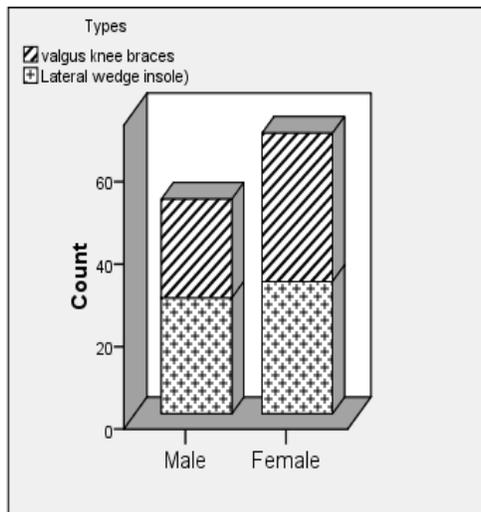
*significant as p-value <0.05, †: independent sample t test.

Table-3: Pre/ post operative pain and activity level of the knee bracing. Visual Analog Scores before and after Knee Bracing

Scale ^a	Before bracing	After bracing in normal mode	Significance
Pain (mm)	6.14 ±1.53	4.2±1.56	P = 0.001
Activity level (%)	35 ±26.0	38 ±24.0	P = 0.001

Pain was measured along a 100-mm line from no pain (0) to worst pain possible (100). Activity level was measured as percentage along the line, with 0% being complete limitation of activities of daily living and 100% as no limitation.

Fig.1: Frequency distribution of the interventional group with respect to the gender



DISCUSSION

Braces are recommended for the treatment of knee osteoarthritis. The different bracing modalities that are available must be adapted to the uni-compartmental symptomatic knee osteoarthritis, to decrease pain and improve function and thereby increase the quality of life of osteoarthritis patients. The structural effect of bracing has not yet been evaluated¹².

In this analysis we found detectable differences between patients treated with valgus knee and those treated by lateral wedge insoles in the rates of pain severity as measured on a visual analog scale and knee function score using WOMAC after the procedure. Present study reported an improvement of symptoms in patients with OA treated with both orthoses. Thus, management of medial compartment knee osteoarthritis with valgus knee appears to result in short-term outcomes at least as good as those with lateral wedge insoles; this appears to offer an

alternative strategy for treatment of selected medial compartment knee OA without lateral wedge insoles.

Our results suggest a un-loader brace can be an alternative conservative approach to lateral wedge insoles for treating symptoms of medial compartment knee OA. As previous reports indicated that both treatments reduce the outcome and increased walking speed but lateral wedge insoles appear to have a greater effect, due to the defective sampling frame (error of omission and duplication in the data) this study shows the diverse results from the present study¹³.

Another study mentioned by Wilson (2011) that a un-loader brace is effective in providing short-term pain relief and improved function; however, most patients subsequently opt for total knee replacement on the symptomatic knee, found statistically significant difference in osteoarthritis grades (3.47 vs. 2.0; $P \leq 0.05$) for patients who had undergone arthroplasty versus patients with unloader brace, we also demonstrate the similar result. All patients who underwent arthroplasty reported that brace use had been effective in temporarily relieving pain¹⁴. A further study by Tom et al (2010) examined no differences in pain scores between the wedged insoles or valgus braces as (5.7±3.0 vs. 5.6±2.2; P -value>0.05) and WOMAC score (46.5±18.9 vs. 46.8±18.2; P -value>0.05), although laterally wedged insole may be an alternative to valgus bracing for noninvasively treating symptoms of medial knee OA, also observed no differences between the insole group and the brace group for VAS pain scores and WOMAC function scores¹⁵.

Arazpour M et al (2013) initiated that laterally wedged insoles and unloader knee orthoses in the treatment of medial compartment knee osteoarthritis, improved all consequence. Conversely, no significant differences in pain ($p = 0.649$), adduction moment ($p=0.205$), speed of walking ($p=0.056$) were established between them. The knee range of motion ($p=0.000$) were significantly different between the two interventions¹⁶. Harilainen A found insignificant

differences either pre-operatively or 5 years post-operatively (80% of patients reviewed) between the groups in terms of the activity level (measured by Tegner scoring system)²⁰, owing to the regional difference, present study showed dissimilar results.

Sattari et al (2011) compared the effect of lateral wedge insoles and 3 point knee supports in treatment of medial compartment knee OA, results found that 17(85%) patients in the brace group reported significant pain relief as compare to the 14(70%) lateral wedge group as (3.1±1.4 4.3±1.2; P-value<0.020), whereas 14(70%) patients in lateral wedge group experienced significant pain relief after 9 months treatment ($p=0.045$). The mean walking distance was insignificantly longer only in brace group then lateral wedge groups (2.6± 0.33 then 2.1±0.52; $P\text{-value}=0.034$)¹⁷.

Varus knee alignment (bowleg) was reported as one of the best predictors of a high knee adduction moment during walking, and there is strong evidence that varus alignment or a high adduction moment predicts faster progression of knee osteoarthritis as compare to the lateral wedge insoles¹⁸, Schai PA et al initiated that activity levels (as described by Tegner and Lysholm scoring system) improved slightly from 2.3 points preoperatively to 2.7 points postoperatively with P-value 0.032²¹. Our study showed also analogous results as Sattari, Bierma and Schai.

Our study did not mention clearly the side effects of brace treatment as one study by Nicholas J et al mentioned within six months complications, found that two patients develop severe ipsilateral leg swelling, one of these two patients developed dyspnea and was found to have a pulmonary embolus¹⁹. We also do not know how much time in a day patient was using same shoes on which lateral wedge insole was being used. Study also does not tell whether some other factor like pain killers might have affected the outcome of results in lateral wedge insoles or the knee brace.

CONCLUSION

The treatment modalities have positive impact on health care cost, reduction of patient modality and improving quality of life with less pain and more activity. can also delay the need for knee arthroplasty in young patients with knee osteoarthritis.

Patients who have versus gonarthrosis may benefit significantly from use of a knee brace and lateral wedge insoles however more positive outcome seen with brace group. Few patients were taking off and on analgesics for the pain and our study could not find if analgesics might have changed the results of pain relief. This study could not figure out the end point of both these modalities.

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