



Prospective Study on the Effect of Open Patellar Knee Orthosis on Knee Joint Loading and Physical Function in Primary Knee Osteoarthritis

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Abstract

Background

Osteoarthritis is a leading cause of disability in the US and worldwide. Increased knee joint loading is a significant risk factor for the progression of knee osteoarthritis. The external knee adduction moment (KAM) is usually accepted as a surrogate measure of the load in the medial compartment and, therefore, offers a potential target for treatment strategies to slow the disease progression. Open patellar knee orthosis is a type of knee sleeve with a patellar hole that is readily available, cheap, and lightweight. There is very little evidence to support the beneficial effects of knee sleeves on knee joint biomechanics.

Objective

To study the effect of Open Patellar knee orthosis on knee loading by 3-dimensional Kistler force platform and functional status using Western Ontario and McMaster Universities Osteoarthritis Index

(WOMAC) on patients with primary knee osteoarthritis (Kellgren-Lawrence grade I – III) in the age group of 35 to 70 years

Method

Study Area

Outpatient Department in National Institute for Locomotor Disabilities in Kolkata, 700090

Study Population

The patients enrolled in an outpatient setting in National Institute for Locomotor Disabilities with age group from 35 to 70 years with primary knee osteoarthritis in Kolkata.

Study Design & Sampling Strategy

This is a prospective observational study, done over two years after getting Institutional ethical committee clearance. A total of forty-four (44) knees with primary knee osteoarthritis, fulfilling the inclusion criteria were selected for the study. All the participants

were evaluated by the WOMAC questionnaire and force platform, after which they were advised to wear open patellar knee orthosis for six weeks. At the end of six weeks, the participants were again evaluated by the force platform and the WOMAC questionnaire. The patient's data was maintained on Microsoft excel. With the completion of data entry, it was analyzed with the help of SPSS, Microsoft excel, and epi-info. A test of proportion was used to find the Standard Normal Deviate (Z) to compare the different proportions, and Chi-square (χ^2) test was performed to find the associations. The t-test was used to compare two means. $p < 0.05$ was taken to be statistically significant.

Result

A total of 44 knees with primary knee osteoarthritis were analyzed. Significant ($p = 0.0022$) improvement of Knee adduction moment was observed after wearing the open patellar knee orthosis for six weeks. There was a significant ($p < 0.0001$) reduction of vertical load with the use of open patellar knee orthosis. The WOMAC score at the end of six weeks was significantly lower than that of at presentation ($p < 0.0001$). Thus significant improvement of the WOMAC score was observed. Additionally, significant ($p = 0.023$) improvement of walking speed was also observed after the orthotic intervention.

Conclusion

Our study provides evidence that wearing open patellar knee orthosis not only reduces the knee adduction moment and vertical ground reaction force but also improves the physical function of the patients suffering from primary knee osteoarthritis

Keywords

Primary knee osteoarthritis, knee loading, knee adduction moment, ground reaction force, physical function, WOMAC score, open patellar knee orthosis.

Introduction

Osteoarthritis (OA) is a degenerative joint disease. It is one of the leading causes of disability in the US and worldwide. ^[1] The prevalence of knee osteoarthritis increases with the increasing age. ^[2] The number of people suffering from symptomatic knee osteoarthritis is likely to increase because of the aging population and the obesity epidemic. ^[3] Knee OA affects the three compartments of the knee joint (medial, lateral, and patellofemoral joint). It usually develops slowly over several years, interfering with daily life activities. ^[4] It is postulated that knee OA is multifactorial in origin. Although both inflammatory and biomechanical processes play an essential role, it is also influenced by a combination of factors like family history, age, obesity, diabetes mellitus, synovitis, systemic inflammatory mediators, lower limb malalignment, joint dysplasia, trauma, and inflammation by metabolic syndromes. ^[5-12]

Knee osteoarthritis can be classified into two types - primary osteoarthritis and secondary osteoarthritis. Primary osteoarthritis is defined as articular degeneration without any underlying reason. Secondary osteoarthritis is the consequence of either an abnormal distribution of force across the joint as with post-traumatic causes or abnormal articular cartilage. The intensity of the clinical symptoms may vary from each patient of OA. However, they typically become more debilitating over time. The rate of progression varies for each individual. Common clinical symptoms of OA include knee pain that is gradual in onset and worsens with physical activity, knee stiffness and swelling, pain after prolonged sitting or resting, and pain that worsens over time. ^[13]

The American College of Rheumatology suggests that an accurate diagnosis of knee OA can be made without

radiologic investigation. X-rays may be used to assess the condition of the joint, to detect fractures, dislocations, and joint space narrowing (JSN). The most frequent radiographic grading system is described by Kellgren and Lawrence,^[14] where Grade 1 is described as doubtful JSN and possible osteophytic lipping; Grade 2, by definite osteophytes and possible JSN on an anteroposterior weight-bearing radiograph; Grade 3, by multiple osteophytes, definite JSN, sclerosis, and possible bony deformity; and Grade 4, by large osteophytes, marked JSN, severe sclerosis, and definite bony deformity.

Treatment designed for knee OA should aim to alleviate pain, improve physical function, and limit disabilities. Surgical interventions are generally needed to treat advanced stages of knee OA (Grade 4).^[15, 16] Non-operative treatments of knee OA are often useful for patients with Kellgren and Lawrence Grades 1 to 3 and which are "early" stages of OA. Non-invasive treatments with minimal side effects are encouraged as an early intervention for individuals with knee osteoarthritis.^[17] As demonstrated by several studies, increased knee joint loading is a significant risk factor for the progression of knee osteoarthritis.^[18] During walking, 60–80% of the total knee load passes through the medial compartment,^[19] causing the medial compartment of the knee to be affected approximately ten times more often than the lateral compartment.^[20] In the frontal plane, the load-bearing axis is represented by a line that runs from the center of the femoral head to the ankle joint center.^[21] In patients with varus malalignment, the ground reaction force (GRF) vector passes more medially to the center of the knee, thereby further increasing the force on the medial tibiofemoral compartment.^[22] The moments acting on the knee as a result of the orientation of the GRF vector are closely

related to the medial compartment contact force (MCF).

^[23] As it is not possible to directly measure contact forces in vivo without using invasive methods, the external knee adduction moment (KAM) is usually accepted as a surrogate measure of the load in the medial compartment and, therefore, offers a potential target for treatment strategies to slow the disease progression.^[24] Other kinetic variables such as ground reaction forces (GRF), vertical loading rate, impulses, and free moments are relevant to describe mechanical changes related to osteoarthritis. Valgus braces apply a valgus moment directly at the knee through a three-point bending mechanism, thus counteracting the KAM to lessen the medial compartment loading in medial knee osteoarthritis patients.^[25] Previous studies have shown that valgus braces effectively reduce the KAM^[25–27]; however, the magnitude of results varies significantly. Nevertheless, it has been suggested that poor patient compliance obstructs the treatment effect of bracing due to discomfort associated with brace use.^[28] Furthermore, the long-term effectiveness of unloader braces is affected by the loss of compliance over time.^[29] It has been demonstrated that both medial and vertical GRF increase in knee osteoarthritis patients.^[30] Furthermore, a higher vertical loading rate shortly after initial contact may contribute to the development and progression of knee osteoarthritis.^[31]

Unlike the unloaded braces, the knee sleeves are mostly elastic and provide lower mechanical stability than braces. There are two models of knee brace: the model with a patellar hole and the model without a patellar hole. The difference between them is that the patellar hole promotes patella stability within the knee's range of motion. They have been shown to improve function, quality of life, and relieve pain in patients with knee osteoarthritis.^[32–35] There are also

reports of improved proprioception^[36] and postural control in knee osteoarthritis patients wearing knee sleeves. Moreover, these are cheap, readily available, and lightweight than valgus brace.

There is very little evidence in the literature demonstrating the effects of knee sleeves on knee joint biomechanics. So, in this present study, we wanted to evaluate if open patella knee orthosis has any impact on knee joint loading and the physical function of the patients suffering from primary knee osteoarthritis.

Materials and Methods

This is a prospective observational study, conducted on 44 knees of the patients who had enrolled in an outpatient setting of a tertiary care centre with age group from 35 to 70 years with primary knee osteoarthritis. The aim of this study was to determine the effect of open patellar knee orthosis on knee joint loading and physical function in primary knee osteoarthritis. All patients who had fulfilled the inclusion and exclusion criteria were examined as per patient information sheet in the outpatient setting.

Inclusion Criteria

1. A person with primary knee osteoarthritis
2. A person in the age group of 35-70 years
3. A person fulfilling the American College of Rheumatology criteria for osteoarthritis
4. A person willing to participate in the study
5. A person with definite radiographic knee OA defined as KL grade I – III
6. A person with medial tibiofemoral compartment involvement greater than the lateral compartment
7. A person with intact cognitive function

Exclusion Criteria

1. A person with lateral tibiofemoral compartment involvement less than the medial compartment

2. A person who had undergone intra-articular corticosteroid injection to either knee within the past three months;
3. A person who had a systemic arthritic condition (e.g., rheumatoid arthritis)
4. A person who had any other muscular, joint or neurological condition influencing lower limb function;
5. A person who had reported current or previous (within six months) use of shoe inserts, knee/ankle braces, and/or customized shoes.
6. A person who was unable to walk unaided
7. A person who had reported ankle/foot pain/pathology.
8. Persons with a history of neurological impairment leading to impaired balance, orthopedic problems in the hips, ankles, or spine.
9. A person with a history of ligamentous injuries in the knee joint
10. A person with fractures around the knee
11. A person with infection in and around the knee
12. A person with myofascial pain
13. A person who was taking medicines like glucosamine, chondroitin sulfate, etc.
14. A person with knee flexion contracture.

The radiography of each patient was graded using the Kellgren-Lawrence scale. Each patient was then stratified on the WOMAC score; after that, they were asked to walk on a 3-dimensional force platform and their data was recorded on the computer. The patients were advised to wear open patellar knee orthosis on affected knees for 10-12 hr daily. Therapeutic exercise for the osteoarthritic knee was demonstrated to all the participants and also advised to practice the same twice a day. They were prescribed

Tab Paracetamol 1 gm and were asked to take it only when the pain would be unbearable. All the participants were instructed to visit the outpatient department of NILD after six weeks.

After six weeks, the patient's pain, stiffness, and physical function were again evaluated by the

WOMAC questionnaire and were documented. The gait parameters were evaluated by the Kistler force platform. The patient's data was maintained on Microsoft excel. With the completion of data entry, it was analyzed with the help of SPSS, Microsoft excel, and epi-info.



Fig 1: Patient Walks on Force Platform

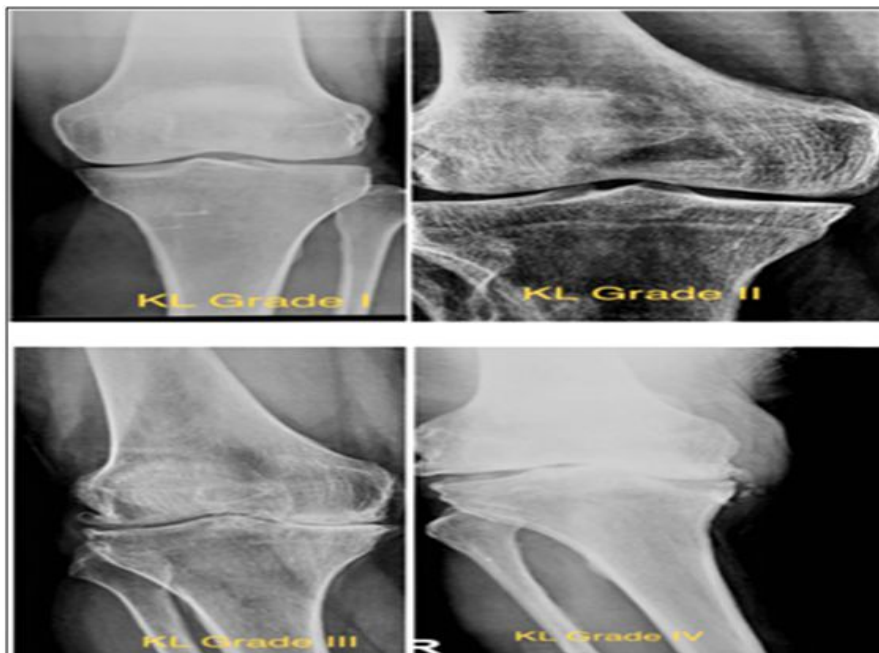


FIG 2: X-ray K-L GRADE

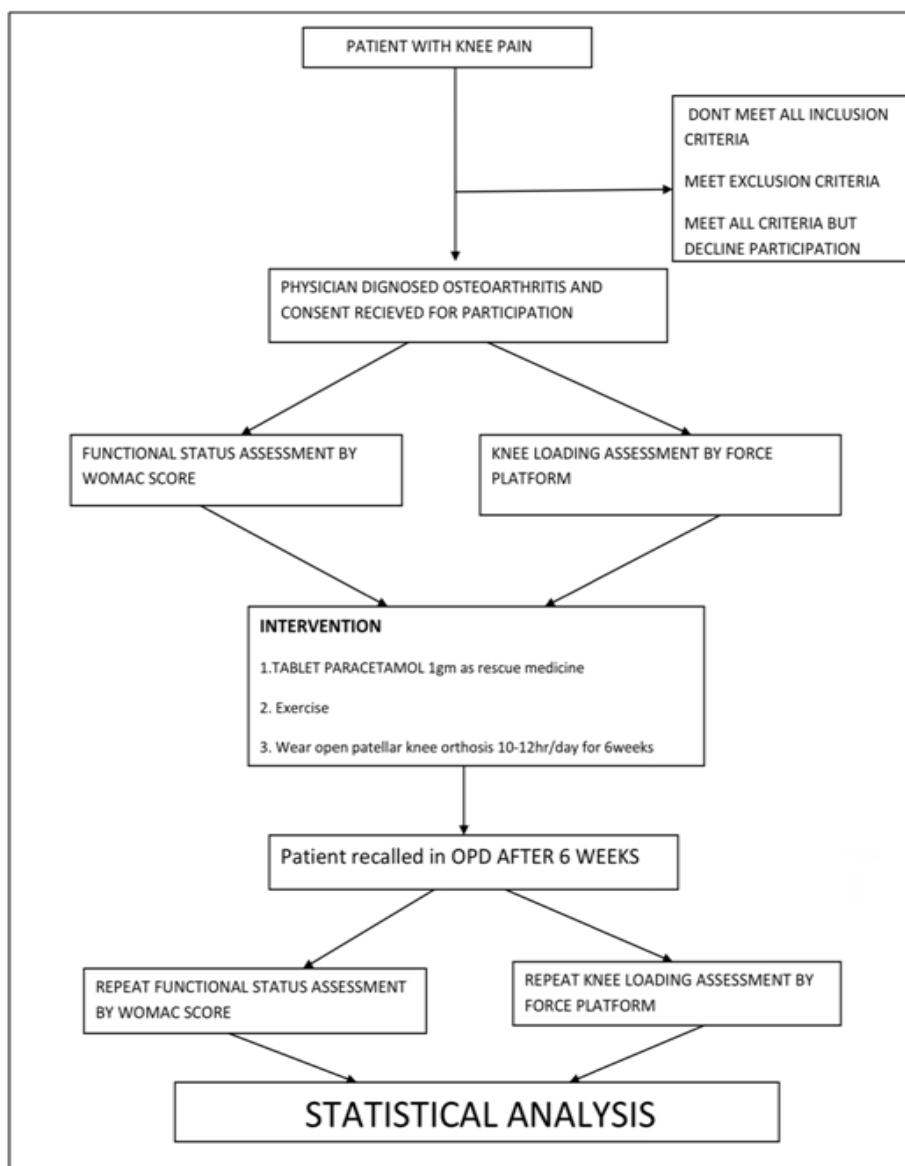


Fig 3: Study Technique

Statistical Methods

Statistical Analysis is performed with the help of Epi Info (TM) 7.2.2.2. EPI INFO is a trademark of the Centers for Disease Control and Prevention (CDC). Descriptive statistical analysis was performed to calculate the means with corresponding standard deviations (s.d.). A test of proportion was used to find the Standard Normal Deviate (Z) to compare the different proportions, and Chi-square (χ^2) test was

performed to find the associations. The t-test was used to compare two means. $p < 0.05$ was taken to be statistically significant. In this prospective study on the effect of open patellar knee orthosis on knee joint loading and physical function in primary knee osteoarthritis, there are 22 patients with bilateral primary knee osteoarthritis. Thus 44 knees were under this study.



Fig 4: Open Patellar Knee Orthosis

Results

Table1: Age of the Patients

Age Group (in years)	Number	%
40 - 54	7	31.8%
55 - 64	13	59.1%
≥65	2	9.1%
Total	22	100.0%
Mean ± s.d.	56.82±6.91	
Median	58.5	
Range	40 - 66	

Most of the patients (68.2%) were of age ≥ 55 years, which was significantly higher ($Z=3.34; p<0.0001$). Thus in this study, primary knee osteoarthritis was more prevalent among the patient's age ≥ 55 years.

Table 2: Gender of the patients

Gender	Number	%
Female	13	59.1%
Male	9	40.9%
Total	22	100.0%
Female: Male	1.4:1.0	

The ratio of female and male (Female: Male) was 1.4:1.0. The test of proportion showed that the proportion of females (59.1%) was significantly higher than that of males (40.9%) ($Z=3.67$; $p<0.001$).

Table3: X-ray KL-grade of the patients of the patients

X-ray KL-grade	Number	%
1	10	22.7%
2	26	59.1%
3	8	18.2%
Total	44	100.0%

Majority of the knee osteoarthritis cases were of KL-grade 2 (59.1%)

Table 4: Comparison of WOMAC score of the patients at presentation and 6th week after the intervention

WOMAC score	Time Interval		t-test (t _{ss})	p-value
	At presentation (n=44)	At 6 th week after the intervention (n=44)		
Mean ± s.d.	44.77±8.70	37.66±8.58	3.86	<0.0001 S
Median	46.5	38.5		
Range	29 - 61	23 - 53		

The mean WOMAC score in the 6th week was significantly lower than that of at presentation ($p<0.0001$). Thus significant improvement of the WOMAC score was observed after wearing the open patellar knee orthosis.

Table 5: Comparison of Knee adduction moment of both knees of the patients at presentation and 6th week after the intervention

Knee adduction moment	Time Interval		t-test (t ₉₈)	p-value
	At presentation (n=44)	At 6 th week after the intervention (n=44)		
Mean ± s.d.	217.94±45.66	187.46±43.13	3.14	0.0022 S
Median	211.75	182.45		
Range	130.30 - 322.30	102.50 - 283.00		

The mean Knee adduction moment in the 6th week was significantly lower than that of a presentation (p=0.0022). Thus significant improvement of Knee adduction moment was observed after the intervention.

Table 6: Comparison of vertical load (Fz) of both knees of the patients at presentation and 6th week after the intervention

Vertical load (Fz)	Time Interval		t-test (t ₉₈)	p-value
	At presentation (n=44)	At 6 th week after the intervention (n=44)		
Mean ± s.d.	645.24±115.66	556.55±113.82	3.62	<0.0001 S
Median	632.6	545.45		
Range	407.20 - 961.80	320.40 - 884.60		

The mean Vertical load (Fz) has reduced significantly (p<0.0001) at the end of 6th week. Thus significant improvement of Vertical load (Fz) was observed after the intervention

Discussion

The primary objective of our study was to know the effect of open patella knee brace on physical function and knee joint loading in patients with primary knee osteoarthritis. The patients were asked to wear the knee brace with a patellar hole for six weeks, and the effect on physical function and knee joint loading was evaluated.

In this study, we have found that the mean WOMAC score after six weeks of the intervention was

significantly (p < 0.0001) reduced than that of at presentation [TABLE-5], thus significant improvement of WOMAC score was observed after the orthotic intervention. In another study done by Gustavo-Jim Yamamoto et al. [37] They compared the effect of brace designed to stabilize the patella-femoral joint to that of the patella shaped neoprene sleeve with patella cut out in patients with patellofemoral OA. A total of 57 patients with femoral-patellar OA were allocated into

two groups: patients with a femoropatellar functional brace and a neoprene knee sleeve with a patellar orifice. The results showed that the WOMAC domains (pain, stiffness, and function) and the WOMAC total score reduced from inclusion to the other periods ($p < 0.05$). This result is in concordance with what we have found in our study regarding the reduction of the WOMAC score. A similar outcome in terms of improvement in physical function was seen in a gait analysis study that was done by Robert D.A Gaasbeek.^[38] In this study, the researchers wanted to evaluate the SofTecOA valgus brace on patients suffering from medial compartment OA of the knee with a clinical assessment and a gait analysis. The brace was worn seven days a week by all patients. After the six weeks of brace wear, statistically significant improvement was found for the WOMAC score ($p: 0.01$). Henry Ch Fu et al. did a prospective study on the effects of orthotic treatment for medial knee osteoarthritis in Chinese patients.^[39] All the patients were sequentially treated with a flat insole with subtalar strap, laterally wedged insole with arch support, valgus knee orthosis, and valgus knee brace with a laterally wedged insole with arch support for four weeks with no treatment break. The WOMAC total score was reduced, where a significant reduction in WOMAC pain score of 20.4% ($p = 0.02$) was documented. These results corroborate with our study, where significant improvement of the WOMAC score was found.

Our second objective of this study was to find out the effect of open patellar knee orthosis on knee joint loading in patients with primary knee osteoarthritis. The knee adduction moment is the surrogate marker for loading on the knee joint. In our study, a significant ($p = 0.0022$) reduction in knee adduction moment [TABLE-5] has been seen after

using the open patellar knee orthosis for six weeks. Henry ch Fu et al., in their prospective study, wanted to know the effects of orthotic treatment for Chinese patients who were suffering from medial knee osteoarthritis.^[39] The researchers have documented a significant reduction in the mean knee adduction moment and the peak knee adduction moment by 15.5% and 18.9%, respectively ($p < 0.05$). These results are similar to the results of our study, where a similar reduction of knee adduction moment was found too. Raphael Schween et al in their study had evaluated the immediate effects of an elastic knee sleeve on frontal plane gait biomechanics in people suffering from knee osteoarthritis.^[40] 18 subjects (8 women, 10 men) with medial tibiofemoral joint osteoarthritis walked over the ground with and without an elastic knee sleeve. The kinematic and forces were recorded, and joint moments were calculated using an inverse dynamics approach. They found that the first peak knee adduction moment was, on average, reduced by 0.74 ± 0.90 Nm/kg-1, which corresponds to 10.1% ($p = 0.012$), which was found to be statistically significant. These findings are in concordance with the results obtained by our study. The knee adduction moments are thought to be positively correlated with medial contact forces in the knee. Longitudinal studies have identified a higher knee adduction moment as a potential risk factor for disease progression in medial knee osteoarthritis. They have speculated that the decrease in knee adduction moments and impulse that they have found with the orthosis in their study may cause less disease progression over time. Arazpour et al did a pilot study to know the effects of a new design of knee unloader orthosis on specific gait parameters in patients with mild-to-moderate medial knee osteoarthritis.^[41] Gait analysis was done to know the alterations to the knee adduction

moment, speed of walking, step length, cadence, and knee sagittal plane range of motion during ambulation for the two test conditions. The gait of the patients was assessed in two situations: without an orthosis and when wearing an unloader knee orthosis. The external knee adduction moment was significantly reduced ($p = 0.001$) when wearing the orthosis. This finding is similar to the statistically significant reduction of knee adduction moments encountered in our study. A similar result was reported by Lamberg et al.^[42] The objective of their research was to know the effects of decompressive brace use in people with medial compartment knee osteoarthritis. A total of 15 subjects with medial knee osteoarthritis attended four sessions: baseline, fitting, two weeks after fitting (post), and 8 weeks after fitting (final). Gait analysis was done at baseline (without knee brace), post, and final. The second peak knee adduction moment was reduced significantly ($p < 0.05$) at post and final than baseline. Jones et al in their study had compared the biomechanical effects of valgus knee braces and laterally wedged insoles in patients with knee osteoarthritis.^[43] A cross over randomized design was used where each orthosis was worn by 28 patients for two weeks. Pre and post-intervention gait kinematic/kinetic data and clinical outcomes were collected to evaluate the biomechanical and clinical effects on the knee. The valgus knee brace significantly reduced the early stance EKAM ($p = 0.007$) by 7% compared to the baseline data. The results of this study are in concordance with the results we obtained in our study. Similar results were documented by Della et al in their research.^[44] A statistically significant reduction in net peak external knee adduction moment was found after using the knee brace.

The ground reaction forces (GRF), a kinetic variable is relevant to describe mechanical changes related to osteoarthritis. An increased Vertical ground reaction force has been demonstrated in knee osteoarthritis patients. In this study, we have analyzed 44 Knees with medial knee osteoarthritis and looked for the effect of open patellar knee orthosis on vertical ground reaction force (F_z) after six weeks of follow up. We have found that the vertical ground reaction force has reduced significantly ($p < 0.0001$) after six weeks of using open patellar knee orthosis [TABLE-6] Amir Ali Jafarnezhadgero et al in the year 2017 had done a study to determine the effects of the isolated and combined use of valgus knee brace and lateral wedge foot orthotic on peak forces and moments during gait in knee osteoarthritis patients.^[45] A total of twenty-four males with varus alignment, symptomatic medial compartment knee osteoarthritis participated in this study. Subjects walked overground at preferred speed in four conditions: (1) no assistive device (control); (2) using lateral wedges, (3) using knee braces, and (4) using both lateral wedges and knee braces. Ground reaction forces (GRF) and moments, as well as lower limb kinematics, were recorded. They found that the concurrent use of lateral wedge and knee brace significantly reduced the first peak vertical GRF (6%, $p = 0.002$). These findings are in concordance with our study, where a significant reduction in vertical ground reaction force has been seen.

In our study, the maximum number of patients was in the age group of more than 55 years (Table 1) and significantly less in the age of fewer than 55 years. This finding is corroborated by Chandra Prakash Pal^[46] et al. in 2016, who had done a community-based cross-sectional study in the Indian population and found that the prevalence of osteoarthritis knee is more in the age

group of above 60 years and lowest in the age group of 40-50 years.

Females were more commonly affected with knee OA than males in a ratio of 1.4:1 (Table 2). The result matches the prevalence study done by Bryan BD, Tosi L, et al in 2012, which found that females were more affected with the disease than males. ^[47] More of the patients (59.1%) presented with mild OA (Grade 2) (Table 3), and the same finding was supported by S. Murak et al who did a prevalence study on 2282 participants in 2009 and found to have 47% KL grade 2 OA alone. ^[48]

Conclusion

Very few studies have been reported in the literature where the effects of open patellar knee orthosis on knee joint biomechanics in primary knee osteoarthritis are evaluated. Our study provides new insights into the effectiveness of open patellar knee orthosis on knee joint loading, vertical ground reaction force, and physical function in medial knee osteoarthritis.

This study shows that open patellar knee orthosis significantly reduces knee joint loading and proves to be an effective, cheap, easily available method of treating patients with primary knee osteoarthritis. Moreover, the open patellar knee orthosis significantly improves the physical function of osteoarthritic patients and thus helps in improving the overall quality of life of the patients. A multicenter, double-blinded randomized control trial with a larger sample size to establish the exact effects of open patella knee orthosis on gait biomechanics and physical function in primary knee osteoarthritis patients is the need of the hour. Our study may act as a point of reference for designing such research in the future.

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