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Original Article

Physical Medicine and Rehabilitation Section

Immediate Effect of Valgus Knee Brace and Lateral Wedge Insole on Gait Parameters in Medial Compartment Osteoarthritis of Knee: A Cross-sectional Study

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ABSTRACT

Introduction: Orthoses have been reported to improve function and symptom reduction in knee Osteoarthritis (OA) of the medial compartment. Biomechanical changes introduced instantly in the gait with the use of orthoses can be evaluated to understand their effectiveness.

Aim: To determine and compare the immediate effect of valgus knee brace and Lateral Wedge Insole (LWI) on gait parameters in medial compartment OA knee patients.

Materials and Methods: This was a cross-sectional study conducted in the Department of Physical Medicine and Rehabilitation at a tertiary centre from August 2018 to July 2019. A 56 patients of knee OA (Kellgren-Lawrence system grades 2 or 3) were assessed by instrumented gait analysis before and just after orthotic fitment. Gait parameters related to External Knee Adduction Moment (EKAM) (e.g., maximum Ground Reaction Force (mGRF), vertical Ground Reaction Forces (vGRF), Varus Angle (VA) were assessed via motion capture during walking, in all four conditions: barefoot (B), LWI, valgus Knee brace (KB), Combined (C) i.e., (LW+KB). Statistical analysis was done using International Business Machines (IBM) Statistical Package for Social Sciences (SPSS) version 24.0. To find the significant difference in given parameters, repeated measure Analysis of Variance (ANOVA) was applied taking p-value <0.05.

Results: A total of 56 patients (13 men, 43 women) mean age of 58.04±5.8 years and a mean Body Mass Index (BMI) of 27.4±3.5 kg/m^2 were analysed. A 35 patients had OA grade 2 and 21 were classified as grade 3. No significant difference in mean vGRF and VA values was found among LW, KB and C (p=0.118) and (p=0.894) throughout the stance phase. The significant difference was in mean mGRF values during initial stance phase (0-20% of gait cycle) (p=0.036).

Conclusion: The orthoses may not swiftly provide beneficial biomechanical changes in gait parameters of medial OA knee patients.

Keywords: Gait cycle, Knee abduction, Motion capture, Orthoses

INTRODUCTION

The OA, also known as degenerative joint disease, wear and tear arthritis, or age-related arthritis, is a foremost cause of disability [1]. Knee OA more commonly affects the medial tibio-femoral joint compartment as compared with the lateral compartment of the knee. This discrepancy is due to the load carried by the medial compartment which is approximately 60-91% of the total knee load [2]. Although, the disease pathophysiology is still poorly understood, it is accepted that knee OA is multifactorial in origin. Risk factors related to the development of knee OA may be divided into non modifiable and modifiable. Modifiable risk factors can be targeted for treatment.

Nonoperative treatments of knee OA are often useful for patients with Kellgren and Lawrence Grades 1 to 3, which are "early" stages of OA [3]. Orthoses use in patients with varus medial knee OA is aimed at altering the biomechanics of the knee to reduce the medial load, reduce symptoms, and slow progression of medial knee OA in cases of malalignment. The functional improvement and symptom reduction have been reported in patients fitted with a valgus unloader knee brace or a laterally wedged insole [4].

It is difficult to measure tibio-femoral contact stress in vivo, the External Knee Adduction Moment (EKAM) is clinical surrogate measure of medial tibio-femoral joint loading [5]. In knee joints with varus malalignment, the ground reaction force vector runs medially and from the middle of the knee baseline. The moment arm is the perpendicular distance between the ground reaction force vector and the knee's centre of rotation. This moment arm produces an external adduction moment, also named varus moment [6]. The KAM has been identified as the mechanism primarily responsible for the increased compressive load on the medial compartment of varus knees. The magnitude of the KAM is most associated with the magnitude of the moment arm, which was inferred to be more dependent on knee adduction, followed by the magnitude of the frontal plane GRF [7].

The general purpose of unloading knee braces is to apply corrective forces by means of a three point pressure system, which distribute load away from the damaged compartment. The LWI is a wedge placed under the sole of the foot and angulated, so that it is thicker at the lateral part than the medial edge, transferring loading from the medial to the lateral knee joint during weight bearing. Reduction of EKAM ranging from 4-12% with an LWI of at least 5° [4]. Lateral wedges thus shift the center of pressure laterally, reducing the external KAM and knee adduction angular impulses, alleviating pain, and improving function in patients with knee OA [8,9].

Gait analysis being non invasive has become an important tool for quantifying normal and pathological gait patterns. There are literature comparing the changes in spatiotemporal, kinetic and kinematic parameters of gait after the orthotic fitment has been done and patients had got accustomed with those orthoses. Literature has also reported improvement in pain and functional aspect after long term use [8,9]. A thorough search of the best of author's knowledge, there is no study which has evaluated the changes in gait parameters just after orthotic fitment. The aim of this study was to determine and compare the immediate effect of valgus knee brace and LWI on gait parameters in medial compartment OA knee patients.

MATERIALS AND METHODS

This was a cross-sectional study conducted in the Department of Physical Medicine and Rehabilitation at King George's Medical University, Lucknow, Uttar Pradesh, India, over a period from August 2018 to July 2019. The ethical approval was obtained from the Institutional Ethics Committee (Ref code: 95th ECM II B- Thesis/ P1) and informed consent was signed by all the patients who participated in the study.

Sample size calculation: The reference paper by Duivenvoorden T et al., and Moyer RF et al., [4,10]. In order to compare the changes in gait parameters among orthoses (population variance=2.27), significant with 95% confidence interval and power of 80%, the minimum sample size required was 56 patients.

Inclusion criteria: Patients with age more than 50 years and confirmed diagnosis of OA knee as per American College of Rheumatology (ACR) criteria, with genu varus and medial compartment knee OA radiographic osteoarthritic signs according to the Kellgren-Lawrence system of Grade 2 and 3, ambulatory without the use of an assistive device, able to walk 11 meters repeatedly without the use of a walking aid were included in this study [11,12].

Exclusion criteria: Patients with a history of ligament deficiency or reconstruction, cardiovascular disease, diabetes, neurological impairment, impaired balance, total knee replacement in either knee, orthopaedic problems in the hips, ankles or spine, a Body Mass Index (BMI) ≥40.0 Kg/m^2, surgery of the lower extremities, congenital or developmental disease of lower limbs, paralysis of lower extremities, any disease or medication that might have worsened physical function of knee and patients not willing to participate in the study were excluded from the study.

Study Procedure

First the clinical and radiological assessment was done. Patients were provided with the bilateral, standardised, laterally wedged (5° inclination) insoles made of natural latex, wedged along the lateral edge of the full length of the foot, were trimmed to fit the shoes and off the shelf knee brace. Same patient was evaluated for changes in biomechanical gait parameters: (a) without orthosis i.e., barefoot; (b) LWI; (c) valgus knee brace; (d) combined valgus knee brace and LWI, immediately after orthotic fitment.

Kinematic and kinetic data were evaluated after motion capture using a 6 infrared camera system (BTS SMART-DX system) and two force plates (BTS P-6000) positioned on an 11 m walkway. Helen Hayes protocol provided with the BTS SMART- Clinic software was used which allowed the study of kinetics and kinematics of human locomotion [13].

Eighteen spherical retroreflective markers were attached to the skin over selected bony landmarks, defining trunk Cervical (C)7, bilateral acromion), pelvis (each Anterior End of Iliac Crest (ASIS), Sacral (S)2 vertebra), thigh (on lateral aspect of knee flexion- extension axis, bilateral at mid of thigh along the virtual line passing through hip joint center and knee joint center on lateral aspect), shank (lateral malleolus bilateral, at mid of shank along the virtual line passing through knee joint center and ankle joint center on lateral aspect bilateral), and foot (bilateral in the space between the heads of second and third metatarsals, bilateral heel).

Patients were asked to perform two different tasks i.e.,

(a) Standing task: the patient held an orthostatic position for at least 3-5 seconds, performed on the top of the force platform.

(b) Walking task: the patient walked normally in the straightest way possible across the working volume defined during the calibration phase of the optoelectronic system. The markers placed on the subject were clearly within the field of view of the cameras during the whole acquisition. A trial was valid if the subject stepped with the entire foot on one force platform, and all markers were recognised by the capture system. Patient walked: (1) barefoot; (2) with LWI; (3) with valgus knee brace; and (4) with combined LWI and KB.

The mean of six valid trials per condition was used for analysis. A gait cycle consists of two phases i.e., stance phase and swing phase [14]. Stance phase refers to the portion of gait cycle during which the reference limb is in contact with the ground. It constitutes about 60% of gait cycle at normal walking speed. It is further divided into five periods e.g., initial contact, loading response, midstance, terminal stance and pre swing. The first peak, valley and second peak of vGRF occurs at loading response, midstance and terminal stance in a normal gait cycle [15]. In this study, changes in gait parameters (vertical GRF, medial GRF, VA) were evaluated during 0-20%, 20-40%, 40-60% of the gait cycle which approximately corresponds to the periods of stance phase.

STATISTICAL ANALYSIS

Statistical analysis was done using IBM SPSS version 24.0 Statistics for Windows. To represent the continuous variable mean and standard deviation was used. To find the significant difference in given parameters, repeated measure ANOVA was applied taking p-value <0.05.

RESULTS

A total of 56 patients (13 men, 43 women) with mean age of 58.04±5.8 years and a mean BMI of 27.4±3.5 kg/m^2 were included. The 35 patients had OA grade 2 and 21 were classified as grade 3.

Analysis of changes in Kinetics and Kinematics variables: The variables which were evaluated are 1) vGRF (vertical ground reaction force); 2) mGRF were included in the study. (medial ground reaction force); 3) VA (varus angle) [Table/Fig-1].

The mean vGRF (0-60% of gait cycle i.e., entire stance phase) was minimum (87.64±10.74) in case of LW and maximum (90.97±8.98) in case of KB. However, no significant difference in mean vGRF values was found among LW, KB and C (p=0.118) throughout the stance phase.

On comparing the mGRF (medial GRF) values without and with orthoses, it can be concluded that at the 0-20% of gait cycle, the mean mGRF was minimum (6.88±5.28) in case of LW and maximum (9.03±5.84) in case of KB. The significant difference in mean mGRF values was found among LW, KB and C (p=0.036) [Table/Fig-2].

It is evident that mGRF in LW is showing significant difference when compared to KB and combined. Rest all comparisons did not show any statistically significant difference. So, the mean mGRF (0-60% of gait cycle i.e., entire stance phase) was minimum (7.63±4.52) in case of LW and maximum (8.88±5.38) in case of KB. However, no significant difference in mean mGRF values was found LW, KB and C (p=0.285) throughout the stance phase.

The mean VA (0-60% of gait cycle i.e., entire stance phase) was minimum (8.93±6.60) in case of C and maximum (9.36±6.60) in case of LW. However, no significant difference in mean VA values was found among LW, KB and C (p=0.894) throughout the stance phase.

vGRF	Barefoot B	With orthoses			Repeated measure ANOVA	
		LW	KB	C		
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	F-value	p-value
0-20% gait cycle	86.04±10.53	83.90±13.53	88.04±13.33	85.51±14	1.68	0.173
21-40% gait cycle	89.46±9.78	88.23±12.21	91.58±9.11	88.67±11.6	1.62	0.186
41-60% gait cycle	91.37±11.58	90.78±11.66	93.29±10.33	90.07±11.9	1.14	0.336
vGRF mean	88.96±9.27	87.64±10.74	90.97±8.98	88.08±11.3	1.99	0.118
Varus angle (VA°)						
0-20% gait cycle	8.95±7.04	9.58±6.87	9.45±6.94	9.15±6.76	0.51	0.675
21-40% gait cycle	9.29±7.02	9.52±6.95	9.19±7.21	8.96±6.84	0.29	0.830
41-60% gait cycle	9.20±6.51	8.97±6.24	8.58±6.95	8.67±6.43	0.49	0.688
VA mean	9.15±6.77	9.36±6.60	9.07±6.93	8.93±6.60	0.20	0.894
mGRF						
0-20% gait cycle	8.06±5.18	6.88±5.28	9.03±5.84	8.34±5.73	2.91	**0.036***
21-40% gait cycle	8.02±5.58	7.89±5	8.89±5.72	8.51±5.46	0.72	0.542
41-60% gait cycle	9.24±5.12	8.11±4.57	8.71±5.33	8.97±5.54	0.92	0.432
mGRF mean	8.44±4.90	7.63±4.52	8.88±5.38	8.61±5.39	1.27	0.285

[Table/Fig-1]: Comparison of vGRF, VA and mGRF values without and with orthoses.
*Significant; bold p-values are significant; LW: Lateral wedge; vGRF: Vertical ground reaction force; mGRF: Medial ground reaction force; C: Combined; KB: Knee brace; Anova: Analysis of variance

Pair name	Mean Diff	SD Diff	T statistic	p-value
mGRF 0-20 B - mGRF 0-20 LW	1.18182	6.35112	1.380	0.173
mGRF 0-20 B - mGRF 0-20 KB	-0.96364	6.61498	-1.080	0.285
mGRF 0-20 B - mGRF 0-20 C	-0.27273	5.34618	-0.378	0.707
mGRF 0-20 LW - mGRF 0-20 KB	-2.14545	3.98687	-3.991	0.000
mGRF 0-20 LW - mGRF 0-20 C	-1.45455	4.94720	-2.180	0.034
mGRF 0-20 KB - mGRF 0-20 C	0.69091	5.30155	0.966	0.338

[Table/Fig-2]: Paired t-tests result for mGRF in all four conditions for 0-20% of gait cycle.

DISCUSSION

With the advancement of 3D gait analysis mainly in the field of OA knee, changes in gait parameters are now well known. It has now become challenging to use this information for diagnostic purposes and decision making for different therapeutic approaches. Previous studies have reported that valgus knee brace and LWI decrease KAM [16-19]. The external KAM is a common indirect measure of the medial tibiofemoral contact force (F med). However, while there is indirect evidence that the EAM and the actual loads transferred through the medial tibiofemoral compartment are related, the quantitative relationship between EAM and Fmed is not well established [5,6].

In this study gait analysis of KL grade 2 and 3 OA knee patients was done before and just after the orthotic fitment. Patients did not receive any information about the different orthosis adjustments or what effect could be expected with the insoles and braces. It was hypothesised that just after orthotic fitment, there was no difference in the immediate effect of LWI and valgus knee brace on gait parameters.

The present study has evaluated changes in kinetic and kinematic gait parameters related to EKAM (e.g., vGRF, mGRF and VA) during 0-20%, 20-40%, 40-60% of gait cycle. Schmitz A and Noehren B concluded that the knee adduction angle and vertical magnitude of the GRF were significant predictors of the first peak KAM, explaining 58% and 20% of the variance, respectively [20]. A higher first peak KAM was associated with increased knee adduction angle and vertical magnitude of the GRF.

In this study, on comparing the mean VA (varus angle) values among all four conditions during 60% of gait cycle there was no significant difference. Overall, the mean VA was minimum in case of combined orthoses and maximum in case of LW. During 20-60% of the gait cycle, the varus angle was minimum in case of combined orthoses. Also, among LW and KB, VA was less with the use of knee brace throughout the stance phase although these changes were not significant. This may be due to analysis of gait parameters immediately after orthotic fitment and the adaptation with the orthosis was missing. Some previous studies failed to detect significant changes in peak knee varus angle with wedged insoles [21,22].

Since, the KAM is mostly determined by the frontal plane magnitude of the GRF and its moment arm about the knee joint center [7], a direct reduction in GRF would also result in a decreased KAM (e.g., canes or walking poles, weight loss). In this study, only those patients who could walk without using assistive devices were included, so changes in vGRF was not expected, this is consistent with what we have got through statistical analysis. During entire stance phase, there was no significant difference in mean vGRF in all four conditions. Overall, the mean vGRF was minimum in case of LW and maximum in case of KB. Also, vGRF was maximum during entire stance phase with the use of KB while it was minimum during 0-40% of gait cycle with LW. Although, these differences were not significant, it can be concluded that in case of LW due to load shifting on contralateral limb during initial stance phase may have resulted in decreased vGRF value. In case of KB, additional weight of knee braces has contributed to increase in vGRF throughout the gait cycle.

Nagura T et al., concluded that both medial and vertical GRF were increased in OA knees, however only medial GRF correlated with KAM [23]. They concluded that modification of gait pattern to reduce medial GRF by non surgical interventions (insoles, gait training, etc.,) may be effective to reduce KAM and medial compartment loads. In this study, on comparing the mGRF values among (knee brace and insole) no significant difference in mean mGRF values was found among LW, KB and C (p=0.432). During initial stance phase i.e., 0-20% of gait cycle there was significant difference in mean mGRF values among LW, KB and C (p=0.036). Also, the mean mGRF was minimum throughout the stance phase in case of LW. This signifies that LW was effectively decreasing KAM during initial stance phase.

Limitation(s)

Being a single center study, there was female preponderance in the study. Same patient was evaluated repeatedly with orthoses immediately after orthotic fitment for recording variations in gait parameters. This may have exhausted the patient and there may be possibility of some unwanted alterations in gait parameters. The patients were not adapted with the use of orthoses, it may be considered that the changes in gait parameters would have been significant. Also, there were several unidentifiable variables which could have played a role as confounders.

CONCLUSION(S)

It was found that immediate changes in the kinetic and kinematic gait parameters (VA, vGRF, mGRF,) which were affecting external KAM without and with orthoses (LW, KB and combined) were not significant. However, it was also found that during initial stance phase i.e., 0-20% of the gait cycle lateral wedge was effectively decreasing mGRF, which may have decreased KAM. The orthoses (insoles and braces) may have decreased KAM, but the changes were not being evaluated directly. Only those gait parameters which were affecting KAM were compared among orthoses. So, it can be concluded that the expected immediate beneficial biomechanical changes in gait parameters may not be possible with use of orthoses in medial OA knee patients.

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