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Mechanical effectiveness of lateral foot wedging in medial knee osteoarthritis after one year of wear

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Abstract

Purpose—The use of lateral foot wedging in the management of medial knee osteoarthritis is under scrutiny. Interestingly, there have been minimal efforts to evaluate biomechanical effectiveness with long term use. Therefore, we aimed to evaluate dynamic knee loading (assessed using the knee adduction moment) and other secondary gait parameters in patients with medial knee osteoarthritis wearing lateral foot wedging at a baseline visit and after 1 year of wear.

Methods—3-dimensional gait data were captured in an intervention group of 19 patients with symptomatic medial knee osteoarthritis wearing their prescribed laterally wedged foot orthoses at 0 and 12 months. Wedge amounts were prescribed based on symptom response to a step-down test. A control group of 19 patients wearing prescribed neutral orthoses were also captured at 0 and 12 months. The gait of the intervention group wearing neutral orthoses was additionally captured. Walking speed and shoes were controlled. Analyses of variance were conducted to examine for group-by-time (between the groups in their prescribed orthoses) and condition-by-time (within the intervention group) interactions, main effects, and simple effects.

Results—We observed increased knee adduction moments and frontal plane motion over time in the control group but not the intervention group. Further, within the intervention group, the mechanical effectiveness of the lateral wedging did not decrease.

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Conclusions—In patients with medial knee osteoarthritis, the effects of lateral foot wedging on pathomechanics associated with medial knee osteoarthritis were favorable and sustained over time.

Introduction

Knee osteoarthritis (OA) is a progressive and disabling disease that is common in older adults. Approximately 12.1% of the general population in the United States aged over 45 years is diagnosed with knee OA[1]. The medial tibiofemoral compartment, which bears more than 60% of the medial-lateral load in a normal knee, is most commonly affected[2]. The knee external adduction moment (KEAM) is the most often used surrogate measure for medial-lateral loading at the knee. This moment has been correlated to *in vivo* medial knee loading in an instrumented knee[3], and has been found to be elevated in individuals with medial knee OA[4,5], as well as in asymptomatic varus knees[6]. Consistent with these cross-sectional findings, prospective studies have found that the KEAM may be a modifiable risk factor for the development and progression of medial knee OA [7-9].

A number of interventions are aimed at laterally redistributing tibiofemoral loads for those with medial knee OA. The most invasive of these interventions are osteotomies[10]. However, conservative management strategies are more appropriate for most individuals with medial knee OA. For example, use of knee braces has been recommended for individuals with varus gonarthrosis[11]. Unfortunately long-term compliance with bracing has been problematic[12]. Another approach is the use of laterally wedged foot orthoses[13-37]. These devices indirectly alter frontal plane knee mechanics by directly influencing foot, ankle and tibial mechanics[13,34].

The immediate effect of laterally wedged devices on the KEAM has been examined in both healthy and patient populations. In healthy subjects, Crenshaw and colleagues observed a 7% reduction in the KEAM when using a 5° full-length insole[19]. In contrast, a later study on 15 healthy subjects found no significant reductions using a 10° lateral wedge[22]. In patients, KEAM reductions between 5-12% have been noted with the use of full-length devices[20,24,30,32]. However, a 5° lateral heel wedge resulted in no significant decreases in peak KEAM[21]. Accordingly, a later comparative study found heel wedges to be less effective than full-length insoles[33].

Laterally wedged orthoses do not appear to discernibly alter knee kinematics. No reductions in peak knee adduction angle, a measure of dynamic knee alignment, have been reported with lateral wedging[19,22,24,30]. While an immediate reduction in knee adduction angle excursion from heel strike to peak knee adduction angle, sometimes termed varus thrust, has been observed, the implications of this reduction in frontal plane knee motion remain unclear[30].

To the best of our knowledge, only one biomechanical study to date has evaluated the effects of laterally wedged orthoses on the KEAM in a test-retest design. Hinman and colleagues found that a 5 degree laterally wedged insole significantly reduced the KEAM similarly at both baseline and at a one-month follow-up, suggesting that the mechanical

effects were not diminished after a month of wear [36]. These reductions were observed for both the first and second peaks of the moment waveform, as well as the knee adduction angular impulse (KAAI). However, their study lacked a longer-term follow-up, did not report kinematic results, and did not incorporate a control group.

Therefore, the primary aim of this study was to compare the knee mechanics of individuals with medial knee OA wearing laterally wedged orthoses (treatment group) to those of a control group wearing a neutral orthoses over the course of one year. We expected mean peak KEAM, KAAI, peak knee adduction angle, and knee adduction angle excursion to increase in both groups over time, but increase to a greater extent in the control group. As a secondary aim, we tested the effects of wearing laterally wedged orthoses within the treatment group at baseline and after one year to explore the potential for diminishing mechanical effectiveness.

Methods

Subjects

An *a priori* power assessment for a repeated measures analysis of variance design was conducted to detect differences in the peak KEAM, the primary variable of interest. Using a beta of 0.20, an alpha of 0.05, an effect size of 0.4, and variability from previous data[30], it was determined that 19 subjects per group would be needed[38]. Consecutive willing patients enrolled in a larger clinical trial were recruited[35]. To be included in the study, subjects were between the ages of 40-75 years, and diagnosed with medial compartment knee OA. A Kellgren-Lawrence (K-L) grade of OA disease severity was assigned by an experienced rheumatologist, based on a 30° flexed knee radiograph[39]. Inclusion in the study required subjects to have at least Grade II severity (definite osteophytes, possible joint space narrowing) at the medial tibiofemoral compartment. Subjects had to experience medial knee pain of at least 3/10 on a verbal analogue scale during level walking. These criteria were consistent with the American College of Rheumatology criteria for the classification and reporting of knee OA, based on either radiographic or clinical findings[40]. Exclusion criteria were also applied. Subjects were excluded if they reported the use of assistive devices. Subjects with a history of any neurological, cardiopulmonary, or musculoskeletal condition that could affect ambulation were excluded. Clinical presentations of symptomatic lateral tibiofemoral and/or patellofemoral OA, such as peripatellar or lateral joint line pain, were also cause for exclusion. Finally, subjects with foot conditions that could potentially be aggravated by a laterally wedged orthosis were excluded. Examples of these included hallux valgus, hallux rigidus, plantar fasciitis and bunion deformities.

Subjects that met all criteria and agreed to participate in the study provided written informed consent in accordance with institutional human subjects policies. The subjects were randomly assigned to one of two groups. The treatment group received the wedged orthoses and were part of both study aims. The control group wore neutral orthoses and their data served as a comparison to the treatment group to address the primary aim. The subjects were blinded from group assignment, and told that the study was assessing the long-term, differential effects of two types of foot orthoses in the treatment of medial knee OA. The

investigators were not blinded to group assignment. The lower extremity with the more symptomatic knee was chosen for analysis.

Shoes and orthoses

All subjects were fitted with a pair of walking shoes (New Balance Walking Shoes 810, Boston, MA) and a non-custom pair of neutral, contoured foot orthoses (KLM Cal-Pre, Valencia, CA). The orthoses were constructed of 70 durometer crepe and had a full-length micropuff covering. These served as the control foot orthoses.

The treatment group received the lateral wedging. The amount of wedging (Orthofeet, Northvale, NJ) was individually determined using a lateral step-down testing procedure as described by Butler and colleagues[30]. Different degrees of wedging were applied until the subject received the maximum knee pain relief with the least amount of wedging. Once the wedge amount was determined, the adhesive-backed wedges were adhered to the neutral orthoses. The wedges extended from the posterior heel to the metatarsal heads. A grinder was used to contour the wedging and bevel the front edge to improve comfort and fit. The more symptomatic limb received the wedged device, and the contralateral shoe used the neutral device. Finally, the orthoses were inserted into the walking shoes.

The subjects were given a two-week period to fully accommodate to the orthoses and shoes. They were instructed to use the foot orthoses only with the issued walking shoes. Individuals who experienced foot discomfort returned to the clinic for modification of the orthotic device. Most commonly, this involved thinning the material under the arch to provide pressure relief. Once the subjects were fully accommodated to the orthoses and shoes, they were encouraged to wear them as much as possible. Beyond this instruction, subjects were not prescribed or instructed to keep record of how often or how long to wear the shoes and orthoses. Replacement shoes were not provided during the follow-up period.

Data collection

After the accommodation period, all subjects returned for an instrumented gait analysis. Both groups were tested in the neutral orthoses and a laboratory shoe (Nike Air Pegasus, Beaverton, OR). The treatment group was also tested in their wedged orthoses placed in the laboratory shoe. Anatomical markers were placed over the following locations: the bilateral greater trochanters, medial and lateral femoral condyles, medial and lateral malleoli, heads of the first and fifth metatarsals and the distal aspect of the shoe. Tracking markers were placed at the L5-S1 interspinous space, the ipsilateral anterior superior iliac spine, and the ipsilateral iliac crest. In addition, shell-mounted clusters of four tracking markers were placed on the distal posterior thigh and the distal posterolateral shank. Finally, a cluster of three individual tracking markers were placed on the rearfoot. The rearfoot markers were placed directly over the calcaneus and projected through holes in the heel counters of the laboratory shoe. The use of these projecting markers did not allow for testing in the prescribed walking shoes, necessitating the use of the laboratory shoes in this study. Reliability of joint angle and moment data generated using this marker setup has been published elsewhere (ICC $(2,k) = 0.98$)[41].

After a standing calibration was collected to establish the pose of the pelvis, thigh, shank and foot, the anatomical markers were removed. Next, each subject's self-selected walking speed was determined using photocells as they traversed a 25-m walkway. Once determined, the speed for each trial was maintained within ±5% for all testing. The stance phases of eight usable trials were collected per orthotic condition. A six-camera motion analysis system sampling at 120 Hz captured the marker trajectories (VICON, Oxford Metrics, London, England). Kinetic data were captured using a floor-embedded force platform sampling at 1080 Hz (Bertec Corp., Worthington, OH).

All post-processing was performed using Visual 3D software (C-motion, Bethesda, MD). The marker trajectory data were low-pass filtered at 8 Hz using a fourth-order, zero-lag Butterworth filter. Joint angle data were derived using an XYZ Cardan rotation sequence. Kinetic data were low-pass filtered at 50 Hz using a fourth-order, zero-lag Butterworth filter. Moment data were expressed as external moments, and normalized to body mass and height. The stance-phase kinematic variables of interest were the peak knee adduction angle and knee adduction angle excursion. The kinetic variables of interest included the first peak of the KEAM and the KAAI. The variables of interest were extracted and averaged from five individual trials at each visit.

Subjects were monitored for one year. They were encouraged to wear the orthoses and shoes as much as possible, using only the prescribed shoes for their orthoses. All subjects were followed-up quarterly by phone by a blinded administrative assistant. During each phone call, compliance was encouraged, and questions or concerns were addressed. Any subjects with issues regarding the comfort of their orthoses returned to the lab for additional modification of the orthoses. Subjects were encouraged to continue wearing the shoes and orthoses as much as possible. Subjects then returned one year later for their repeat gait analysis.

Statistical analyses

Independent samples t-tests were used to compare the baseline group means for age and body mass index (BMI). A Chi-square test of independence was used to test group differences in K-L grade proportions between groups. Two-factor repeated measures analyses of variance (ANOVA) were used to address both aims of the study (Table 1). For the primary aim, the groups were compared over time in their prescribed devices. For the secondary aim, the wedged and non-wedged conditions were evaluated over time within the treatment group. In the case of statistical interactions, post-hoc simple effects were explored. In the absence of interactions, main effects were explored. Statistical significance was determined at an alpha level of 0.05, with a trend towards significance defined as $0.05<p<0.10$.

Results

A total of 38 subjects participated in the study. Nineteen subjects were assigned to each group (Table 2). The average degree of wedging in the treatment group was 8.7 ± 3.3°, and generally increased with disease severity. The baseline characteristics of the groups were not significantly different for age (p=0.608), BMI (p=0.190) and radiographic disease severity

(p=0.400) (Table 3). No differences in walking speed were observed between groups, conditions or visits (p>0.05).

For the first aim, we compared the control group (in their neutral orthoses) with the treatment group (in their wedged orthoses) at baseline and 1 year. Results revealed no baseline group differences. In addition no significant interactions or main effects were noted for knee adduction angle or KAAI. However, a group-by-time interaction was observed for knee adduction angle excursion (p=0.003), and nearly for first peak KEAM (p=0.052). Simple effect analysis revealed that the interactions were primarily a consequence of increases in knee adduction angle excursion (p=0.001) and peak KEAM (p=0.047) in the control group, and reductions in peak KEAM (p=0.039) in the treatment group.

For the secondary aim, within the treatment group only, we compared the wedged and neutral conditions at both visits. There were no significant interactions, so main effects were assessed. We found that first peak KEAM (p<0.001) and KAAI (p=0.009) were lower in the laterally wedged versus neutral condition when pooled across visits, suggesting mechanical effectiveness of the devices across the year.

Discussion

The purpose of this prospective biomechanical study was to evaluate frontal plane knee mechanics in individuals with medial knee OA who wore laterally wedged orthoses over a one-year period. Increasing magnitudes in these mechanics are thought to be deleterious. The results suggest that these mechanics remained largely stable in the group that received lateral wedging. However, these same mechanics demonstrated a tendency to increase over the course of the year in the control group wearing the neutral orthoses. Additionally, we found that the mechanical effectiveness of the wedged orthoses on knee mechanics in the treatment group were largely maintained across the year of wear.

The longitudinal results of this study were surprising. We expected both groups to show progressive degradation of mechanics, with the control group degrading more. However, the wedged group's data essentially remained the same, suggesting a mitigating effect of the wedged devices. They appeared to prevent the progression of faulty mechanics. However, the control group demonstrated increases (either significant or trending) in all four frontal plane knee variables tested. Most notably, these results suggest a degradation of knee mechanics as both peak dynamic load and frontal plane knee motion increased over the course of the year in the unwedged individuals. This is important as increased peak KEAM has been shown to be predictive of the presence and progression of knee OA[7,9].

The increase in knee adduction angle excursion at heel strike to the instance of maximum knee adduction angle in the control group may be related to ligamentous laxity or neuromuscular insufficiencies that have been noted in those with medial knee OA[42]. We should note that the method by which we calculated knee adduction angle excursion is similar to the method used to derive ‘varus thrust’ in another study[43]. Kuroyanagi and colleagues further describe ‘varus thrust’ as an abnormal lateral motion of the knee seen in

medial knee OA that is also a dynamic worsening of limb alignment that closely relates to progression of disease.

The mechanical effectiveness of the wedging appeared to remain consistent throughout the year-long intervention. Immediate improvements in frontal plane knee kinetics associated with lateral wedging from this trial have already been described by Butler and colleagues[30]. These authors noted a 9% reduction in first peak KEAM compared to the neutral condition at baseline. Our 1-year data revealed that this relative reduction was maintained (8%). These results are in line with the 1 month results reported by Hinman and colleagues[36], however they observed slightly lower KEAM reductions (between 4-6%) at both baseline and after 1 month. Peak knee adduction angle was not significantly altered in the wedged condition either acutely[30] or over the course of 1 year. These findings corroborate previous radiographic studies, where wedging had either a minimal or no measurable effect on knee alignment[13,17,21]. Thus, our results strengthen the increasingly accepted notion that measures of knee alignment, whether static or dynamic, are not strongly influenced by laterally wedged orthoses.

Overall, we did not find KAAI useful in providing additional information regarding frontal plane knee mechanics and lateral wedging in this study. While peak KEAM has been identified as a risk factor for the progression of medial knee OA[7,9], it represents a discrete instance during stance. In comparison, KAAI is a measure of loading over the entire stance period. Therefore, we felt the variable might provide additional insight into the effect of wedging on the quantity of overall knee loading. However, consistent with the results of Hinman et al.[36], we did not find this to be true. This null response may have been related to the fact that KAAI values are partly dependent on stance duration. Since we matched each subject's average walking speed at the 1 year collection to their walking speed at the baseline collection, stance time at the follow-up was similar to that at baseline. This matching procedure can constrain changes in KAAI magnitudes to some degree. Future studies might consider collecting a natural walking speed at follow-up in addition to a controlled speed, as natural walking speed may change over time. However, based on the available data, lateral wedging does not appear to influence KAAI.

Interestingly, the results of these longitudinal biomechanical data provide a contrast to the longitudinal clinical outcomes reported previously from this same trial[35]. The clinical outcome measures included the WOMAC index, a 6-minute walk test, and a stair negotiation task. Unlike the biomechanical measures that favored the wedged group, these functional outcome measures were similarly improved in both groups at 1 year. However, the degradation of knee mechanics over time in the control group suggests a disconnect between knee mechanics and function. Alternately, the neutral orthosis, with its arch support, may have somehow provided enough added support and shock absorption to improve function, but was not designed to affect improve frontal plane knee mechanics. In a well-executed randomized controlled trial, Bennell and colleagues also found no advantages to lateral foot wedging over neutral insoles in symptom or structure modification[37].

A possible limitation in longitudinal gait studies is the test-retest reliability of gait measurements. This study utilized a marker set with high between-day reliability for the

peak KEAM[41]. Other reliability studies have evaluated both healthy individuals and those with medial knee OA[44-46]. These four studies suggest that test-retest reliability for the KEAM is adequate for intervention studies. A second consideration is the small sample. As many of our p-values were borderline significant at the 0.05 level, we would have been able to make more definitive inferences with a larger sample. Third, as mentioned previously, follow-up assessment for disease progression could have been useful in interpreting the findings. Finally, we acknowledge that our study design did not incorporate a more traditional pre-treatment data point, rather allowing for accommodation to the orthotic prior to the baseline testing. Further information may have been revealed had we collected a third data point capturing the pre-accommodation data.

In summary, this study is among the first to present long-term knee mechanics data in a knee OA population[47], and is the first long-term study of the effects of lateral wedging on frontal plane knee mechanics. Our results suggest that lateral wedging may aid in maintaining baseline frontal plane knee mechanics over a 12 month time period in patients with medial knee OA as compared to neutral devices. Further, our data suggest individuals can expect long-term biomechanical effectiveness from lateral foot wedging. From a purely biomechanical perspective, these findings support the continued consideration of using lateral wedging in the management of medial knee OA.

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Table 1

Different conditions were analyzed in the two aims. Aim 1 was analyzed with a group-by-visit analysis of variance, comparing the groups in their prescribed orthoses over time. Aim 2 was analyzed with a condition-by-visit analysis of variance, comparing the effects of the devices within the treatment group over time.

Aim	**1**		**2**	
Visit	**Baseline**	**1 year**	**Baseline**	**1 year**
ANOVA	CN	CN	TN	TN
	TW	TW	TW	TW

C = control group, T = treatment group, N = neutral orthosis, W = laterally wedged orthosis

Table 2

Baseline characteristics of the 38 subjects

	Neutral Orthoses (Control)	Wedged Orthoses (Treatment)
Subjects (n)	19	19
Age (mean yrs ± SD)	61.2 ± 9.4	62.6 ± 7.4
BMI (mean kg/m^2 ± SD)	30.4 ± 7.1	33.6 ± 7.6
Kellgren-Lawrence grade		
II (# of subjects)	9	8
III (# of subjects)	8	6
IV (# of subjects)	2	5

Table 3

Mean and standard deviations for the four variables of interest at the knee (NW is the non-wedged condition, W is the wedged condition), and interaction and main effect p-values for the analyses of variance conducted

	Control Group				Treatment Group									
	Baseline		1 year		Baseline		1 year		Interaction p-values		Group (Aim 1) or Condition (Aim 2) main effect p-values		Visit main effect p-values	
	NW	W	NW	W	NW	W	NW	W	Aim 1	Aim 2	Aim 1	Aim 2	Aim 1	Aim 2
Peak KEAM Nm/(kg*m)	0.376 (0.118)	---	0.408 (0.108)	---	0.369 (0.142)	0.342 (0.131)	0.358 (0.127)	0.330 (0.115)	0.052	0.482	0.139	<0.001	0.379	0.474
KAAI (Nm*s)/(kg*m)	0.169 (0.068)	---	0.185 (0.059)	---	0.158 (0.078)	0.157 (0.078)	0.155 (0.076)	0.148 (0.066)	0.086	0.837	0.245	0.009	0.570	0.561
Peak adduction (degrees)	3.0 (3.7)	---	4.1 (4.2)	---	2.3 (5.5)	1.9 (4.8)	0.8 (5.3)	0.9 (5.7)	0.076	0.389	0.142	0.512	0.933	0.128
Adduction excursion (degrees)	5.2 (1.9)	---	6.9 (1.8)	---	7.0 (2.6)	6.5 (2.7)	6.2 (2.6)	6.1 (2.6)	0.003	0.309	0.729	0.286	0.082	0.177