

Alterations in Sagittal Plane Knee Kinetics in Knee Osteoarthritis Using a Biomechanical Therapy Device

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Abstract—Knee frontal (adduction/abduction) and sagittal (flexion/extension) moments have been implicated in the pathomechanics of knee osteoarthritis (OA). The aim of this study was to evaluate the change in the knee sagittal moment in a cohort of patients with knee OA undergoing a biomechanical training program. Twenty-five female patients with symptomatic medial compartment knee OA were enrolled in a customized biomechanical intervention program. All patients underwent consecutive gait analyses prior to treatment initiation, and after 3 months and 9 months of therapy. Self-evaluative questionnaires, spatio-temporal gait parameters, peak knee sagittal moments, knee sagittal impulses, and duration of knee moments were compared throughout the duration of therapy. Differences between baseline and follow-up values were examined using nonparametric tests. Peak knee flexion moment (KFM) at loading response decreased significantly with therapy ($p = 0.001$). Duration of KFM and impulse of knee flexion also decreased significantly ($p = 0.024$ and $p = 0.029$, respectively). These changes were accompanied by increased walking velocity, significant pain reduction, and increased functional activity. Post-training kinetic evaluation demonstrated profound alterations of knee sagittal moments at the loading response KFM. We speculate that knee sagittal moments can potentially be improved in patients with knee OA over time with a biomechanical training program.

Keywords—Kinetics, Moment, Flexion, Extension, Gait, Pain, Stiffness, Function.

INTRODUCTION

The role of biomechanics in the pathogenesis of knee osteoarthritis (OA) has been examined exten-

sively.^{1,19} Multiple studies have suggested that abnormal gait patterns may contribute to the disease progression.^{1,19} Knee OA patients walk with a slower velocity, greater double-limb support, reduced stride length, and decreased range of motion in all the lower limb joints.^{1,2,11} Bejek *et al.*⁴ analyzed the effect of gait speed on gait parameters in patients with OA and set a standard walking speed for gait analysis. They reported that 15 gait parameters (cadence, step length, walking base, time of swing phase and double support phase, motion of hip joint, motion of pelvis rotation, motion range of pelvis obliquity, maximal value and motion range of pelvis flexion) were significantly influenced by walking speed in patients with knee OA, and that the gait speed of 2.00 km/h was the highest gait speed suitable for all patients without pain and loss of coordination. In addition, they compared the gait patterns of patients with OA to healthy individuals. In comparison to healthy individuals, lower limb joint OA was compensated for in part by the pelvis and other joints in the lower limb.^{4,5}

With the advent of complex gait motion-analysis systems, researchers also examined the kinematic and kinetic gait changes in knee OA. Locomotion is generated through a balance of internal and external forces and moments acting on the lower limbs. Internal forces are comprised of both structural elements (bones, ligaments, cartilage, and more) and of muscles and tendons that are attached to the structural elements. The external forces result mostly from the ground reaction force (GRF). These internal and external forces create moments acting on the joint. Each magnitude of each moment is determined by the magnitude of the force and its sagittal distance from the center of rotation of the knee joint.³¹ The external moments are generated by the displacement of the

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GRF from the joint center, due to the location of the body's center of mass compared to location of the center of pressure (COP) of the foot.

During the stance phase of gait, the GRF creates moments acting on the knee joint in all three planes in space (coronal, sagittal and transverse). This force, as well as the generated moment, can be measured with a three-dimensional gait analysis with force plates. When there is no movement, the net forces and moments (internal and external) must add up to zero. In order for movement and gait to occur, the net value of one moment must be larger than the counteractive moment that balances it. Often counteractive muscle pairs create internal moments which, combined with the external moments, act in synchronous to allow for slow and coordinated movements of the joint. This critical imbalance is what enables controlled human locomotion.

In the Gait Lab, only the GRF vector is measured using force plates in synchronous with a three-dimensional reconstruction of the joints of the lower limb in space and time. Through a process of inverse dynamic analysis, the external moments acting on the knee are calculated. It is assumed that each data point represents a quasi-static state in which the magnitude of internal and external moments acting on the knee joint are equal and the net moment is zero. This methodology, however, is only an approximation of the true moments acting on the knee. In reality, there are several forces and moments acting on the knee that also contribute to gait which are not measured accurately, such as gravitational forces on the different parts of the lower limb, inertial contributions and passive moments. Nevertheless, in analyzing human gait in the lab, we act on the assumption that external moments of the GRF are a close enough approximation to the true external moment acting on the knee. The assumption is widely used in the field of gait analysis and in many studies employing these techniques.

The external moment acting on the knee in the coronal plane, the knee adduction moment (KAM), was shown to be abnormally elevated in medial compartment knee OA^{23,28} and an excellent marker for disease severity.^{17,28} In addition to KAM, there are external moments, knee flexion moments (KFM) and knee extension moments (KEM), acting on the knee in the sagittal plane. The knee sagittal moment, created by the net moment of the GRF in the sagittal plane, is balanced by the moments created by the muscles acting on the knee joint in the sagittal plane.

During the loading response phase of gait, the GRF creates a flexion moment due to its upward-posterior direction relative to the knee. This is balanced by the quadriceps muscle, which creates an extension moment acting to extend the knee. Normally, the quadriceps

moment is lower than the flexion moment created by the GRF and the quadriceps contacts eccentrically, thus the knee undergoes flexion in a gradual manner in order to brace for the impact of the foot on the ground. As the gait cycle progresses into the midstance phase, the quadriceps moment predominates and contracts concentrically, thus extending the knee.^{26,31}

From the midstance to terminal stance phases of gait, the GRF creates an extension moment due to its upward-anterior direction. This is balanced by the knee ligaments, as well as the gastrocnemius and hamstrings muscles in faster walking, which create a flexion moment attempting to flex the knee. The sum of these moments usually results in a KEM which allows the leg to remain straight and stable during the second rocker of rotation at the ankle joint, when the body's center of mass shifts forward, and during the push-off action of the triceps surae. The KEM is eventually reduced by a posterior shift in the GRF vector relative to the knee joint and the contraction of the triceps surae in push-off. While the total GRF vector is advanced forward, the gastrocnemius helps flex the knee and bring the GRF vector posterior to the knee. This changes the KEM to a second KFM as the leg leaves the ground, eventually balanced and reversed in the swing phase of gait by the quadriceps.^{26,31} The direction of the GRF vector during the gait cycle is illustrated in Fig. 1.

Studies have shown that individuals with knee OA have a greater KFM at loading response and a reduced KEM at terminal stance.^{1,27} This may be due to elevated co-contractions of knee muscles,¹⁶ due to joint instability⁹ or excessive frontal plane "pseudo-laxity".^{22,29} In these cases, the knee joint remains in flexion during most of the gait cycle and the direction of the GRF is further posterior from the joint center of rotation, increasing and lengthening the KFM and reducing or eliminating the KEM. The quadriceps muscle may be weak or functioning poorly and thus compensates poorly for the shift in GRF.¹ A weak quadriceps will have difficulty sustaining prolonged walking with higher flexion moments and is one of the reasons patients with knee OA become easily fatigued. By adapting a gait pattern of greater external KFM, patients may be able to increase the compressive forces on the knee in order to avoid lateral instability and opening of the knee joint.²⁷ Nevertheless, without accurate measures of the true forces across the joint, it is difficult to confirm the true pathological effects of higher KFM.

Several biomechanical interventions (i.e., wedged-insoles) developed for knee OA have been shown to be beneficial in reducing KAM *via* COP manipulations at the foot.^{7,30,32,33} We systematically examined one biomechanical device used in a therapy program that

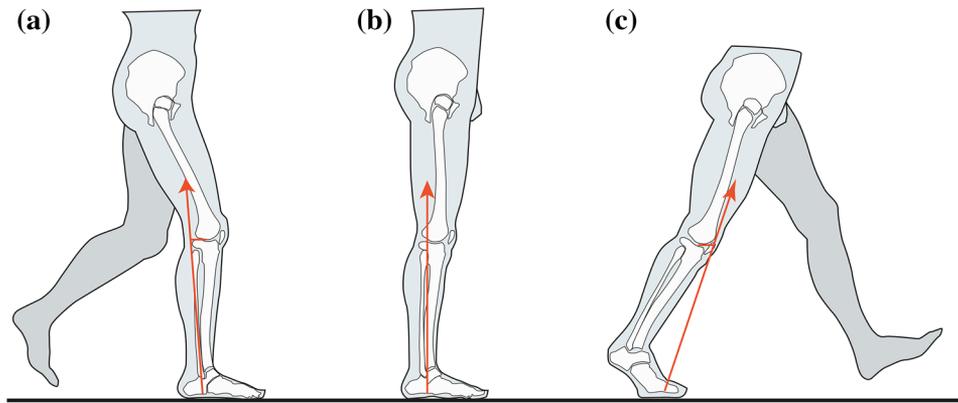


FIGURE 1. Ground reaction force acting on lower limb in the sagittal plane during gait. (a) Loading response phase of the gait cycle. (b) Midstance phase of the gait cycle. (c) Terminal stance phase of the gait cycle.

allows for patient-specific calibration of the COP. We documented and modeled the changes in foot COP and GRF in both the coronal and sagittal planes, and showed that the device can directly affect knee coronal moments (i.e., KAM) as well as sagittal moments (i.e., KFM and KEM) in healthy individuals.^{13,14} We also reported muscle activation changes that complemented these findings.¹²

Furthermore, we modeled the effects of the device when used as therapy in knee OA patients. In a recent prospective study, we tested the 1-year outcome of this biomechanical intervention in a group of 25 knee OA patients and reported that patients showed significant improvements over time in KAM when not wearing the device.¹⁵ This suggested imprinting of the changes to KAM in healthy individuals. In the present study, we focused on and analyzed the alterations in knee sagittal moments in these individuals. We hypothesized that, in addition to the reduction in the coronal moment, these patients would also show changes in the parameters of the sagittal moment over time.

METHODS

Participants

The study cohort was comprised of 25 female patients with symptomatic bilateral medial compartment knee OA. Participants' mean age was 62 ± 7 years; height was 1590 ± 56.54 mm; weight was 77.27 ± 9.99 kg; KL grade was 3 ± 0.9 ; WOMAC score was 4.09 ± 2.29 cm; and coronal knee alignment was 1.52 ± 5.28 (positive values corresponded to varus knee alignment).

Patients were allocated to the study by a senior orthopedic surgeon. Inclusion criteria included physician-diagnosed medial knee OA for at least 6 months and fulfillment of the American College of Rheuma-

tology criteria for OA of the knee. Exclusion criteria included any other orthopedic musculoskeletal or neurological pathology, prior knee surgery (excluding arthroscopy), significant co-morbidities affecting the back, hip or foot, other major systemic diseases, and the need for walking aids to assist in ambulation. The study was limited to one gender in order to limit biases in the study group. Females were chosen over males because of the higher prevalence of knee OA in females as compared to males.

The purpose and methods of the study were explained to the subjects. All subjects gave informed consent prior to entering the study. Subjects were asked to refrain from using any analgesic medication for a 5-day washout period prior to the first examination and prior to each follow-up. Additionally, patients were prohibited from participating in any other treatment programs throughout the study period. The study received IRB approval and was registered in the NIH clinical trial registry (No. NCT00724139).

Biomechanical Intervention

The biomechanical device consists of two convex-shaped rubber biomechanical elements attached to each foot using a foot-worn platform (Fig. 2).^{12,15} The elements can be shifted along the plane of the sole in any direction. By shifting the biomechanical elements, the device can be individually calibrated for each patient. The device is calibrated to shift the trajectory of the foot's COP and, thereby, the direction of the GRF vector. The convex form of the biomechanical elements generates perturbations applied throughout the stance phase of the gait cycle, enabling dynamic, functional, and repetitive training intended to improve neuromuscular control.⁸ During the study, the device was applied to each foot so that two separate devices were used in total, one on each foot, during walking.

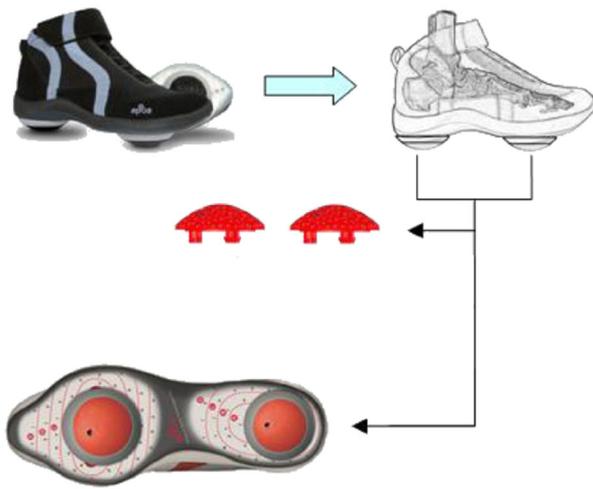


FIGURE 2. Biomechanical system used for motor re-education therapy. The biomechanical device (AposTherapy System) is a foot-worn platform with a specially designed sole to which two rubber convex elements are attached. The elements can be moved in all directions along the plane of the sole. The convex form of the biomechanical elements generates perturbations applied throughout the stance phase of the gait cycle enabling dynamic, functional and repetitive training intended to reeducate the neuromuscular system.

Experimental Protocol

Following enrollment to the study, patients completed a full barefoot gait analysis. In addition, participants completed the Western Ontario and McMaster Osteoarthritis Index (WOMAC)²⁵ and the SF-36 health survey.²⁰ Patients then met with a physiotherapist trained in applying the biomechanical intervention. The device was calibrated to each patient by a single trained physiotherapist. Calibration was carried out in accordance with our previous findings.^{13,14} First, the position of the elements in the “functional neutral sagittal axis” was determined and recorded. The functional neutral axis was defined as the configuration in which the apparatus caused the least valgus or varus torque at the ankle of the individual being examined. This was described in previous studies by our group and others.^{3,13,14} It was determined by a set of trials in which the patient walked with the device. The axis was taken as the configuration in which the patient reported feeling no torques to either side of her ankle. This was confirmed visually by the physiotherapist. Next, the posterior (hindfoot) biomechanical element was shifted laterally and the anterior (forefoot) element was shifted medially. The magnitude of the parasagittal offset was determined by patient feedback on pain reduction and stability.

After calibration, patients were given a treatment protocol based on walking during activities of daily living, starting with 10 min of indoor walking each day during the first week, gradually increasing to 30 min of

daily outdoor walking at the fourth week and for the rest of the treatment period. Follow-up appointments were scheduled after 3 months and 9 months of therapy. On arrival, a barefoot gait analysis was carried out and the questionnaires were completed. Once completed, patients met again with the trained physiotherapist who examined the device and recalibrated it, where necessary. Recalibration is sometimes necessary after walking with the device over time. Patients completed a treatment log to ensure compliance with the training protocol.

Data Acquisition, Processing and Analysis

Acquisition, processing, graphing and interpretation of the data were carried out in accordance with several previous studies that analyzed the sagittal plane kinetics in gait in this specific patient population.^{1,14,19,21} Three-dimensional analysis was performed using an eight-camera Vicon motion analysis system (Oxford Metrics Ltd., Oxford UK) for kinematic data capture. GRF was recorded by two three-dimensional AMTI OR6-7-1000 force plates. Kinematic and kinetic data were collected simultaneously while the subjects walked over a 10 m walkway. Passive reflective markers were fixed with adhesive tape to anatomical landmarks identified by an experienced physician. A standard marker set was used to define joint centers and axes of rotation.¹⁸ A knee alignment device (KAD; Motion Lab Systems Inc, Baton Rouge LA) was utilized to estimate the three-dimensional alignment of the knee flexion axis during the static trial. The KAD is meant to differentiate and isolate the parameters from all three planes of the knee joint. Cross-talk between the values in each plane is a well-known fundamental limitation of gait analysis.

Knee joint moments in the sagittal plane were calculated using inverse dynamic analyses from the kinematic data and force platform measurements using the ‘PlugInGait’ model (Oxford Metrics, Oxford UK). All analyses were performed for the more symptomatic leg, as designated by the patient at the commencement of the study. Joint moments were normalized for body mass and reported in SI units (Newton meters per kg). Data were recorded by a computer running the Vicon Nexus program.

Six barefoot trials were collected per subject and each analysis. Data were exported to MATLAB. The knee sagittal moment was graphed for the stance phase of gait, which was further segmented into phases as in previous studies.^{1,19} A program was purposely written in MATLAB software to examine the following outcome measures: spatiotemporal gait parameters, peak KEM at initial contact, peak KFM at loading response, peak KEM at terminal stance, duration of

KFM at loading response, duration of KEM at terminal stance, impulse of KFM at loading response and impulse of KEM at terminal stance.

All statistical analyses were carried out by an independent biostatistician. Mean values and standard deviation were presented for all continuous measurements. Normality of the distributions were examined at each exam using Kolmogorov-Smirnov tests showing that the distributions of the parameters were not normal. Therefore, the outcomes were compared across baseline and 3 months and 9 months of training using non-parametric Friedman tests. All analyses were performed using SPSS v.17. A probability of 0.05 or less was considered as statistically significant.

RESULTS

All twenty-five patients enrolled in the study completed the training program with satisfactory compliance with the treatment protocol. Satisfactory compliance was defined as adherence of >75% to the proposed treatment protocol, which was determined by a patient log and follow-up telephone calls. Two study participants had brief breaks in therapy; one had a 4-week intermission due to plantar fasciitis and another had a 3-week intermission due to trochanteric bursitis. Both conditions resolved spontaneously. Due to their short breach in protocol and their satisfactory compliance during the relatively long duration of the study, these participants were still included in the analysis of the results.

There were significant improvements in the WOMAC pain and function scores, as well as in most

of the SF-36 subscales over time ($p < 0.001$) (Table 1). The SF-36 subscale of limitations due to emotional problems and emotional well-being did not show significant changes.

By the 3-month follow-up, all patients showed a small but significant increase in walking velocity of 0.07 m/s (from 1.00 ± 0.13 to 1.07 ± 0.14 m/s, $p = 0.017$). The cadence increased by 5 steps/min (from 105.54 ± 9.54 to 110.08 ± 7.59 step/min) but was not significant ($p = 0.058$). Changes in knee sagittal moments are presented in Table 2. Peak KFM at loading response decreased significantly with therapy ($p = 0.001$). The knee flexion impulse and duration of the KFM decreased significantly as well ($p = 0.024$ and $p = 0.029$, respectively). Figures 3a–3c illustrate these reductions over time for the entire study cohort. Figure 4 illustrates the changes in the knee sagittal moments over time for the entire study cohort.

DISCUSSION

The present study aimed to examine changes in knee sagittal kinetics in a cohort of patients with knee OA undergoing a biomechanical therapy program. An analysis of the knee coronal moments (i.e., KAM) has been published previously and should be viewed in the context of these findings.¹⁵ We previously found that patients undergoing the biomechanical therapy program had, on average, a 13% reduction in KAM impulse ($p < 0.0001$), an 8.4% reduction in KAM at loading response ($p = 0.002$), and a 12.7% reduction in KAM at terminal stance ($p < 0.001$).¹⁵ The external KFM during loading response changed most

TABLE 1. Clinical outcomes *via* self-reported subjective questionnaires.

	Baseline	3 months	9 months	Significance p value
WOMAC				
Pain	4.1 \pm 2.3	1.7 \pm 1.3	1.6 \pm 1.5	<0.001
Stiffness	5.2 \pm 3.2	2.5 \pm 2.1	1.6 \pm 1.5	<0.001
Function	4.6 \pm 2.2	2.1 \pm 1.6	1.7 \pm 1.2	<0.001
SF-36				
Physical functioning	48.1 \pm 22.2	67.9 \pm 18.8	68.1 \pm 15	<0.001
Limitation due to physical health	41.7 \pm 42.1	72.9 \pm 31.2	70.8 \pm 35.9	0.005
Limitation due to emotional problem	55.6 \pm 45.7	69.4 \pm 36.7	80.6 \pm 30.9	0.09
Energy/fatigue	54.4 \pm 17.9	62.9 \pm 17.4	68.3 \pm 15	0.004
Emotional well-being	67.2 \pm 13.5	76.5 \pm 8.5	74.5 \pm 8.3	0.25
Social functioning	64.1 \pm 28.6	87.0 \pm 17.1	93.2 \pm 11.6	<0.001
Pain	39.7 \pm 17.2	67.4 \pm 20.9	63.65 \pm 18.3	<0.001
General health	62.5 \pm 15.2	66.7 \pm 13.5	72.6 \pm 12	0.001

Notes The WOMAC questionnaire includes 24 questions in a VAS format (0–10 scale), where each value represents the average score for the pain/stiffness/function sub-categories. The SF-36 Health Survey was a 0–100 scale.

Mean values are presented as mean \pm SD.

The p value represents the group differences at the three examination points.

TABLE 2. Change in knee sagittal moments with motor re-education therapy.

	Baseline	3 months	9 months	Significance p value
Peak knee extension moment at initial contact	0.36 ± 0.11	0.43 ± 0.22	0.43 ± 0.18	0.494
Peak knee flexion moment at loading response	0.55 ± 0.17	0.43 ± 0.26	0.33 ± 0.21	0.001*
Peak knee extension moment at terminal stance	0.18 ± 0.17	0.19 ± 0.16	0.27 ± 0.20	0.172
Knee flexion impulse at loading response	19.2 ± 10.8	13.2 ± 12.8	9.78 ± 9.7	0.024*
Knee extension impulse at terminal stance	4.8 ± 5.7	6.0 ± 6.4	7.7 ± 6.8	0.137
Duration of knee flexion moment at loading response	55.8 ± 19.7	45.1 ± 25.2	33.4 ± 22.0	0.029*
Duration of knee extension moment at terminal stance	32.5 ± 27.3	41.1 ± 26.5	47.0 ± 29.9	0.292

Notes Values are presented as Moments = Nm/Kg; Impulse = Nm/Kg * seconds; Duration = percent of gait cycle. The significance threshold was set at 0.05.

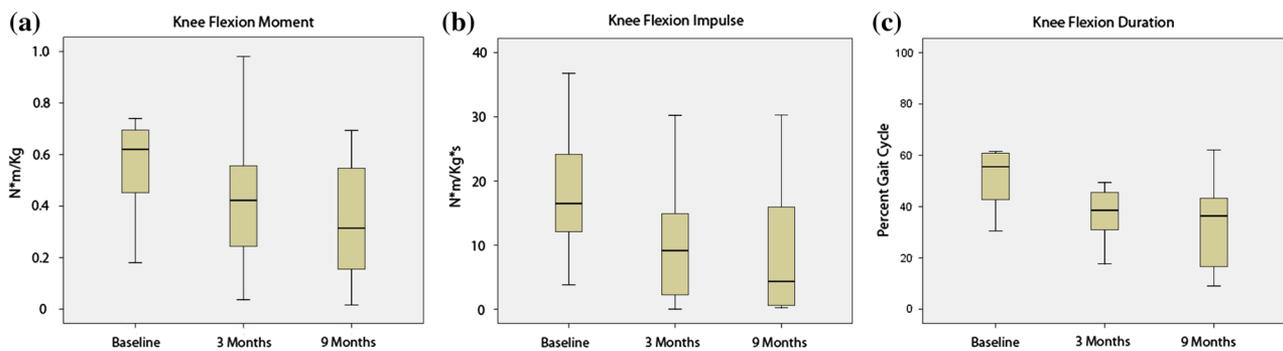


FIGURE 3. Changes in the external knee flexion moment at loading response with motor re-education therapy from baseline to the 3 months and 9 months follow-up points. The differences between baseline and follow-ups were significant for all three parameters. (a) This figure illustrates the decrease in peak knee flexion moment from baseline to 3 months to 9 months. (b) This figure illustrates the decrease in knee flexion impulse from baseline to 3 months to 9 months. (c) This figure illustrates the decrease in duration of knee flexion moment from baseline to 3 months to 9 months.

significantly with the biomechanical intervention. Peak KFM, as well as the impulse and duration of KFM, decreased significantly with therapy at loading response. These reductions were already evident at 3 months. Furthermore, the external peak KEM at terminal stance increased from baseline to 9 months. A similar trend was observed for the external KEM at initial contact. Due to the methodology of the study, the analysis may not have been sensitive enough to detect the full changes in external KEM at terminal stance. Knee OA patients are notorious for having a low, and often non-existent, external KEM. Instead, many patients display a high external KFM at loading response.^{1,6,27} As the external KFM at loading response decreased during the therapy period in the study, the external KEM during terminal stance increased. Initial values for the external KEM at terminal stance, however, could not be quantified in many cases because they were above the value of zero and had no peak at terminal stance. There was no data available for the peak, impulse and duration of these external KEMs and, therefore, changes with time were difficult to determine. For these reasons, it is possible that the external KEM at terminal stance changed as

much, or even more so, than the external KFM at loading response.

In previous studies we have shown that, when worn by healthy individuals, the device used in the present study directly shifts the GRF vector acting at the knee. When calibrated appropriately, the device reduces external KAM, reduces external KFM and increases external KEM.¹⁴ This has been shown in other biomechanical devices based on these principles.¹⁰ In a recently published report,¹⁵ we showed that, when the device is worn for 30 min a day over several months, knee OA patients appear to acquire gait modifications in the coronal plane because they demonstrated lower external KAM values even when walking without the device. In the present study it appears that these individuals also acquired changes in the sagittal plane because they demonstrated lower external KFMs and higher external KEMs when not wearing the device.

External knee moments are directly related to the magnitude of the GRF. Therefore, reductions in these moments, such as the reduction in KFM noted in the present study, can also be due to a reduction in gait velocity. At lower velocities, there is less impact at loading response and thus a smaller GRF and smaller

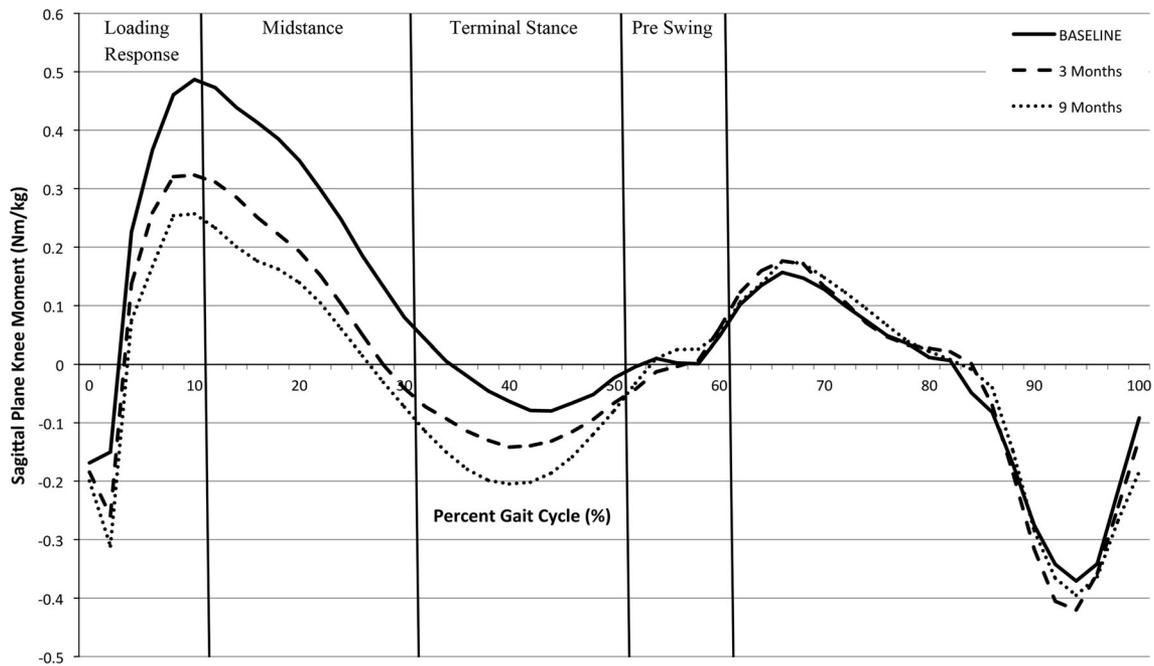


FIGURE 4. Changes in the knee sagittal moments over time with motor re-education therapy.

moment. Of course, this is based on the assumption that the lever arm of the GRF in relation to the knee does not change. In the present study, however, velocity increased over time, which suggests that the reductions in external KFM and KAM are due to a change in biomechanics rather than a slower gait.

The results of the self-evaluative questionnaires support the biomechanical findings of the present study. By reducing the magnitude and duration of the KFM, we assume that we also decrease the force of quadriceps muscle on the knee joint and the magnitude and duration of knee joint loading. Ideally, this means that quadriceps muscle activity was strengthened, walking coordination and efficiency were improved, and the joint pathology was reduced. These goals of the study are supported by the self-evaluative questionnaires that showed significant improvements in pain, stiffness, function and quality-of-life measures. The magnitude of improvement in the level of pain and function corresponded with the clinical response to treatment, according to the OARSI-OMERACT criteria.²⁴ Nevertheless, the true changes at the knee due to lower external KFM can also not be determined by the present study, as this would require an ability to determine the real-time changes at the joint during gait.

There are several limitations to the present study. Firstly, the results of the study are based on the assumption that patients with OA of the knee have higher KFMs and lower KEMs, which have been illustrated by several previous studies. However, the

study's evaluation of the present therapy as a clinical tool for knee OA is limited by the fact that there was no control group. It would be interesting to compare the results of the study to changes in knee sagittal moments in patients with knee OA treated with just simple walking exercises only. This would allow researchers to determine if the improvements observed in our study resulted directly from the biomechanical therapy, and, if so, whether these improvements are clinically significant. Nevertheless, considering that past studies have shown that there are relatively minor changes in the gait patterns of knee OA patients over just 9 months without any intervention, we believe that the sizeable change in variables (i.e., a 40% change in KFM) seen after 9 months of intervention are of clinical significance. This is further supported by the major improvements in patients' subjective outcome scores. Secondly, since the study group was limited to females, the interpretation of the results is limited to this gender only. Females and males with knee OA have some differences in gait patterns and the effect of the therapy in male patients with knee OA should be determined in future studies. Additionally, the true changes in the magnitude of the external KFM cannot be determined in the present study design. Due to the nature of the biomechanical analysis, there could be cross-talk between the various moments about the knee, specifically between the coronal and sagittal moments. Thus, while we witnessed a reduction in both in this cohort, it is difficult to tell which had a greater

reduction. This is a known fundamental limitation of three-dimensional gait analysis.

The present study illustrates for researchers and clinicians that the knee sagittal moments in knee OA may be able to be adjusted *via* biomechanical motor therapies. This should be considered when treating and developing new tools for improving the function of knee OA patients. The study also demonstrates the potential of biomechanical interventions that combine pain reduction with motor training. Future studies should examine these therapies in other contexts and in other patient populations with pathological gait patterns, such as patients after total knee arthroplasty.

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CONFLICT OF INTEREST

No author has any conflict of interest to declare.

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