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Original Article

The Immediate Effects of Conventional Physical Therapy on the Knee Joint Load in Subjects with Moderate Knee Osteoarthritis; A Preliminary Single Blinded Randomized Control Trial

Leila Fattahi[1], Zahra Sadat Rezaeian[2*]

[1]Musculoskeletal Research Center, Student Research Committee of Rehabilitation Students (Treata), Department of physiotherapy, Faculty of Rehabilitation sciences, Isfahan University of Medical Sciences, Isfahan, Iran
[2]Musculoskeletal Research Center, Department of physiotherapy, Faculty of Rehabilitation Sciences, Isfahan University of Medical Sciences, Isfahan, Iran

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ABSTRACT

Background: Subjects with knee osteoarthritis typically have higher knee adduction moment. Current research efforts are mainly focused on therapeutic procedures that potentially may modify disease progression. This preliminary study was designed as a single blind (examiner) randomized control trial to investigate the impact of conventional physical therapy on pain, and knee joint load in subjects with moderate knee osteoarthritis.
Methods: Twelve participants diagnosed with moderate knee OA were randomly assigned into control and intervention groups. Three-dimensional knee kinematic and kinetic data were recorded during the gait before and after 10 sessions of conventional physical therapy. In addition, pain intensity was evaluated by visual analog scale and pain subscale of KOOS questionnaire. The control group did not receive any intervention during the same period. Gait parameters were analyzed within and between groups using nonparametric tests.
Results: There was a significant difference between groups in baseline KOOS-pain Score and ML knee force (P=0.048 and P=0.01). Immediately after ten sessions of physical therapy the initial (first) peak of knee adduction moment was significantly (P=0.03) lower than that of the control group while the first and second peak of knee AP velocity were significantly (P=0.02, P=0.01 respectively) higher. In the intervention group, the second peaks of vertical and anteroposterior (AP) knee forces were strongly correlated with the pretest KOOS-pain Score (r=0.99 and r=0.98, P<0.001). Therefore a multivariate general linear model was adopted with adjustment to baseline KOOS-pain. By this adjustment, 51% alleviation of VAS pain score and 81% decrement of first peak of knee adduction moment in comparison to control group was statistically significant (P=0.02, P=0.03 respectively).
Conclusion: It seems that ten sessions of conventional physical therapy may modify knee joint load in subjects with moderate knee osteoarthritis. Further research is recommended.
Trial Registration Number: IRCT2016012120888N4

Introduction

Osteoarthritis (OA) is the most prevalent chronic age-related impairment causing pain and physical disability [1]. Several factors may influence knee OA (KOA) incidence & progression; among which mechanical factors [2,3] such as dynamic joint loading is a leading one [4]. Walking is the most common activity of daily living (ADL) associated with the largest overall cumulative load at the

Corresponding author:* Zahra Sadat Rezaeian, Assistant professor, Department of physiotherapy, Faculty of Rehabilitation sciences, Isfahan University of Medical Sciences, Isfahan, Iran. **Tel: +98-31-37925012
E-mail: zrezaeian@rehab.mui.ac.ir, zrezaeian@yahoo.com

knee joints [5]. Besides, gait analysis is a practical tool for quantitative description of the functional differences associated with KOA [6] through which biomechanical characteristics of the disease would be uncovered [4]. Unconscious modification in gait mechanics may affect subjects' quality of life and ADL [7].

In every step 70% of the knee joint load passes through the medial tibiofemoral compartment [2,8]. Knee adduction moment (KAM) is an important biomechanical parameter in tibiofemoral joint OA [9]. KAM can be modeled by using 3-dimensional (3-D) gait analysis [1-3,10]. Most often KAM is presented by its 2 peaks values in the stance phase of gait and by the area under the KAM-time curve known as impulse [1]. KAM is one of a few known modifiable risk factors for KOA progression [11]. It is being frequently used as an outcome measure in the KOA studies [12]. Subjects with KOA typically have higher KAM [10]. In fact the success of load-modifying interventions is typically evaluated by measuring KAM [1]. With regards to chronic, slow and progressive nature of the disease, extensive common adverse side effects of medications and limited number of surgical interventions available prior to end-stage disease [10], conservative interventions including physical therapy procedures are highly recommended [13,14]. Current research efforts are mainly focused on therapeutic procedures that potentially modify disease progression [8,15,16] including load-modifying interventions [10]. Many studies to date have focused on KAM modulation in KOA subjects following various rehabilitative protocols [13,14]. These studies provide evidences for improving the rehabilitation approach to KOA [13,17]. It has been documented that the chief complain in KOA is articular pain [18] and dependency in ADL [7] due of gait alterations [7]. Pain directly influences kinetic, kinematic and spatiotemporal features of gait [7] while physical therapy improves KOA pain [13]; However, it is not clear whether conventional physical therapy, as is practiced routinely by most clinicians in Iran, modifies knee joint loading in OA subjects. To answer this question we needed to first define the conventional physical therapy and then compare gait biomechanics following conventional physical therapy. The aim of the present study was to determine the immediate effects of conventional physical therapy on the knee joint loading in subjects with moderate KOA. Our main hypothesis was that in spite of its favorable effect on KOA pain, conventional physical therapy sessions may not immediately improve knee joint loading.

Methods

This interventional study was designed as a single blind (examiner) randomized clinical trial to explore the immediate effects of conventional physical therapy on the knee joint loading during gait in subjects with moderate KOA. This study was approved by The Ethics Committee of Isfahan University of Medical Sciences. The protocol has been registered in Iranian' registry for clinical trials (registration code: IRCT2016012120888N4).

KOA Subjects over 35 years of age [6,18] were recruited from state and private healthcare centers in Isfahan by advertising in specialists' offices, rehabilitation wards and rehabilitation centers and by using our research center data bank. Subjects were included only if they had been diagnosed with tibiofemoral KOA based on the criteria proposed by the American College of Rheumatology [13,17] i.e. pain for at least three months and a pain level higher than three on a visual numerical scale of zero (no pain) to ten (unbearable) during gait, crepitus on joint mobilization and morning stiffness lasting 30 min or less [13,17]. The conventional radiographic grading system developed for KOA by Kellgren and Lawrence [19-21] (KL) was used to specifically rule in subjects with moderate KOA. Subjects were included if they had primary osteoarthritis [8], independent walking without the use of an assistive device [7,8,17], and BMI<35 [7]. Subjects suffering from vestibular, musculoskeletal, neurological or cardiovascular problems that limited their ability to walk or caused any gait deviation or those with of any medical condition that precluded safe participation in an exercise or gait program were excluded [4,6,7,13,18,22]. Altered sensation or nerve damage over the anterior knee [4,7,17,18], lower body or trauma, injury, fracture or surgery within last six months [3,5,8,9,17], surgery or injury to the back in the past 2 years [7], dysfunction in back, hip or foot [3], inflammatory or systemic arthritic [2-7,9], chronic widespread pain [3], major loss of vision [22], intra-articular steroid or Hylan G-F20 injection within the previous 6 months [2,7-9], taking pain killers [17], intention to start/current participation or history of participation in physical therapy for KOA in the last 12 months [2,5,7,9,13], history of lower limb strengthening program [2], more than 5 degrees of valgus mal alignment on lower extremity full length radiograph [2,5,7] were considered as exclusion criteria.

Clinically, the severity of the disease is recorded according to the worst joint. That means in the case of one healthy knee with the other knee being moderately involved, the subject is considered as moderate KOA case [20,21]. In order to prevent between-subjects variations in 3D gait analysis, only moderate KOA subjects were included in the sample size. In asymmetrical cases, the worst side was considered as the target side for intervention and evaluation. In symmetrical cases the worst leg was the target side according to subject' complain. Subjects were informed about the testing procedures and instruments and signed the formal informed consent prior to the study.

Subjects were randomly assigned into the "intervention" and "control" groups using random numbers table. The control group continued their routine daily life as before with no change in their medications as prescribed by the physician. The intervention group participated in a conventional physical therapy program at physical therapy clinic at the faculty of rehabilitation sciences, Isfahan University of Medical Sciences, Isfahan, Iran. Thirty subjects volunteered for the study among which ten people were not included since they did not meet the inclusion criteria. Drop outs are depicted in figure 1.

Considering high attrition rate and because of long recruitment phase, the study terminated with data from

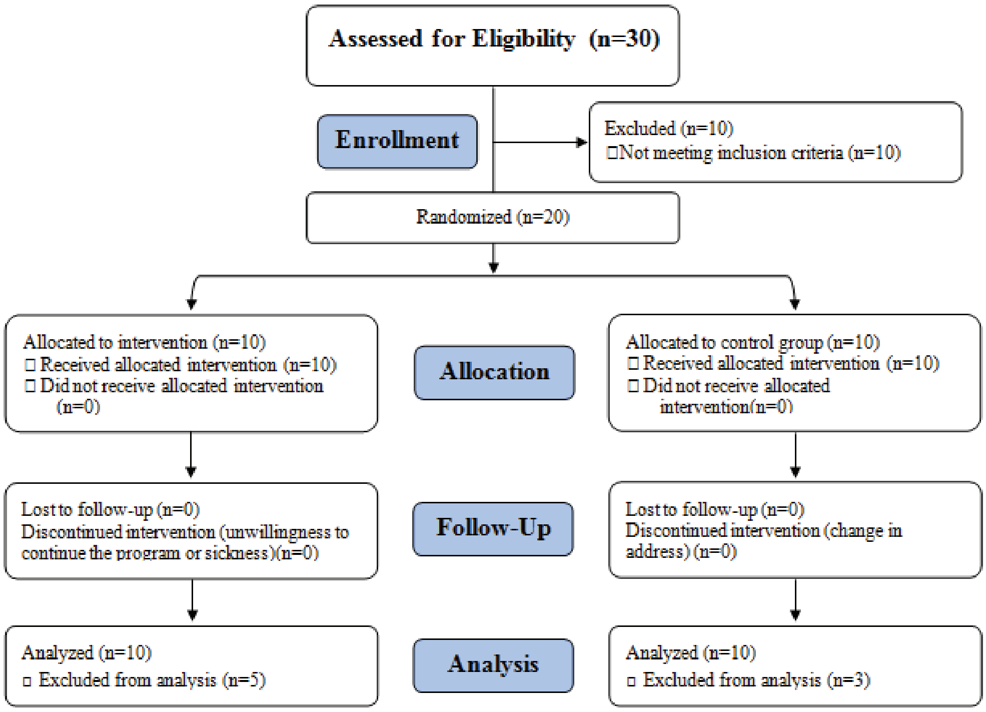

Figure 1: The CONSORT 2010 Diagram for subjects attrition in the study.

twelve subjects (5 in intervention and 7 in control group).

Among volunteers, those who properly fit the inclusion/exclusion criteria were evaluated clinically and biomechanically. At the beginning, subjects' demographic information i.e. age, gender, height, weight and body mass index (BMI) were collected.

Knee joint pain intensity was measured by the 100 mm version of the visual analogue scale (VAS) [13]. Higher VAS score indicates more severe pain. Beside, joint pain were assessed using valid and reliable Persian version of KOOS questionnaire [23]. Higher KOOS-pain score is a sign of better joint condition.

Kinematics and kinetic data were recorded using a three-dimensional motion measurement system (Qualysis motion analysis, Qualisys AB, Packhusgatan 6, 41113, Gothenburg, Sweden). Qualysis motion capture included seven infra-red high speed cameras that were synchronized with one set of eight-channel force-plate (Portable Kistler Force Plate 50×60 cm^2, 9260AA6, Kistler Instruments, Switzerland).

Twenty two Passive-reflective markers were placed bilaterally over the anterior and posterior superior iliac spines, top of the iliac crests, greater trochanters, lateral aspect of the thigh, lateral femoral epicondyle, medial femoral epicondyle, lateral aspect of the shank, lateral malleolus, medial malleolus, calcaneus, and on the foot at the base of the second and fifth metatarsal bones. Clusters of four reflective markers were attached to anterolateral aspect of tights and shanks. The marker placement was according to the manual by University of Strathclyde [24].

Prior to every evaluation session, static calibration trials were conducted through which participants were instructed to stand on a predetermined point on the force plate with feet apart at shoulder-width and equal weight on each foot. Then, they were asked to walk along an 8 meter-walkway at a self-selected comfortable speed. Every subject has permission for rehearsal trials with feedbacks from examiner until they felt comfortable in walking on the walkway. Three acceptable trials were collected from the target side. Acceptable trials were those encompassing a participant making full foot contact with the force plate for a complete single unilateral stance phase from heel strike to toe off (29). Data were filtered (Woltring filter, cut off frequency of 10 Hz) and delimited into gait cycle intervals using heel strike data. A 3D model of each trial for every subject was developed in Visual 3D (V3D) software (Visual 3D lite, version 4.96.10, C-Motion Inc., Germantown, MD, USA). Force and moment data were normalized per body weight. Kinematic and kinetic data were low pass filtered by Butterworth digital filter at cut off frequency of 6 and 15 Hz respectively. Knee joint force, moment and kinematics were recorded. KAM peaks in the stance phase of gait, knee joint angle and knee joint velocity were modeled for final analysis.

At first step physical therapy text books were reviewed to find proper scientific justification for rehabilitation of moderate KOA. Then according to the interview with clinical physical therapist from some randomly selected private and governmental rehabilitation centers in Isfahan, a practical KOA program was concluded. After that, the modalities that were prescribed by most clinicians were included in the final program.

A day after the first evaluation session, the intervention group attended physical therapy clinic in faculty of rehabilitation sciences, Isfahan, Iran three times a week, for ten sessions. The control group did not receive any therapeutic intervention and continued their routine daily activity as in the past within the same period. Both groups continued their medications as prescribed and their routine ADL during the study period. The conventional physical therapy treatment consisted of acupuncture TENS (low rate: 2-10 HZ, 200-300 microsecond, 25 minutes, four electrodes medial and lateral to the superior and inferior poles of the patella), Hot moist pack for 20 minute, Ultrasound (continuous 1 MHz, 1.5-2 Watt, 5 minutes, 1-2 minute per 10 cm^2 with circular motion covering medial, lateral and anterior aspects of the target knee joint), quadriceps setting, vastus mdeialis oblique(VMO) setting and an educational program (using an illustrated pamphlet).

Quadriceps setting was rehearsed by isometric contraction of quadriceps muscle in long sitting. The therapist educated the subjects to touch their quadriceps muscle, contract it slightly so that popliteal surface reached bed and hold this contraction for ten seconds [25]. VMO setting was practiced in straight leg raises combined with internal tibial rotation [25]. Each contraction was held for ten seconds. Individuals in intervention group received an illustrated pamphlet that simply explained KOA pathogenesis, risk factors, prognosis and treatments. In addition, aforementioned exercises were depicted and simply explained in the pamphlet.

The subjects were requested to repeat each exercise at home (2 set of 10 repetitions for the days through which they attended the physical therapy clinic and 3 sets of 10 repetitions every other day when they did not attend the clinic) just as was advised by the therapist. One day after the tenth session, all subjects were re-evaluated for pain intensity and gait parameters.

The subjects in both groups were asked to report participation in any exercise program, taking any therapeutic session, recent injury to lower extremities, beginning new medications or changing medication according to specialist' prescription or as a self-administration and any changes in their routine typical diet during the study.

Primary outcome measure was defined as pain (in VAS score and in KOOS-pain score) and the secondary outcome measures were aforementioned kinetic and kinematic parameters.

Statistical Analysis

Because of our small sample size, data were analyzed using nonparametric approach. Within- and between-group variations were addressed using "related sample Wilcoxon Signed Ranked test" and "independent sample Mann-Whitney U test" respectively. The correlation between clinical and biomechanical variables was analyzed using Spearman' rho coefficients. Using general linear models (GLMs), the effect of baseline variations was adjusted for more accurate judgment. Statistical analysis was performed by SPSS (version 16, SPSS Inc. Chicago, IL, USA) and statistical significance was set at 0.05.

Results

Twelve subjects (eleven women and one man) were compared in "intervention" (five subjects) and "control" groups. The study groups were perfectly similar according to demographic characteristics (table 1).

However, there was a significant difference between groups in baseline KOOS-pain Score (P=0.048) and normalized mediolateral (ML) force (P=0.01) (figure 2). Although, mediolateral knee force did not strongly correlated with VAS score (r=-0.20, P=0.75 and r=-0.05, P=0.91 respectively) or KOOS-pain score (r=0.050, 0.39 and r=-0.41, 0.36 respectively) in either groups.

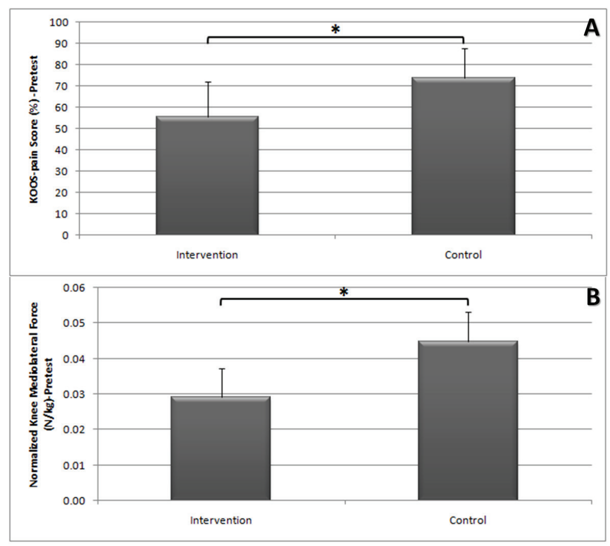

Figure 2: Baseline difference in KOOS-pain score (A) and normalized mediolateral knee force (B) between groups. Asterisk shows significant difference (α=0.05)

Following conventional physical therapy, pain improved in intervention group only in AS score (P=0.04) (figure 3).

Almost noun of gait parameters changed in intervention group after 10 session of conventional physical therapy (table 2).

The only exception was in the first peak of knee anteroposterior knee joint velocity that increased

Table 1: Demographic characteristics of the study groups

	Number of Subjects (Male)	Age (Years)	Weight (kg)	Height (m)	Body Mass Index (kg/m²)
Intervention	5(0)	46.80±4.60	73.48±16.78	1.64±0.05	27.19±5.43
Control	7(1)	44.57±4.83	73.18±10.74	1.60±0.08	28.46±3.95
t	-	0.80	0.04	-	-0.47
P value (between-group comparison)	0.38‡	0.44	0.97	0.43†	0.65

‡: P value from Pearson' Chi square; †: P value from Mann-Whitney U test

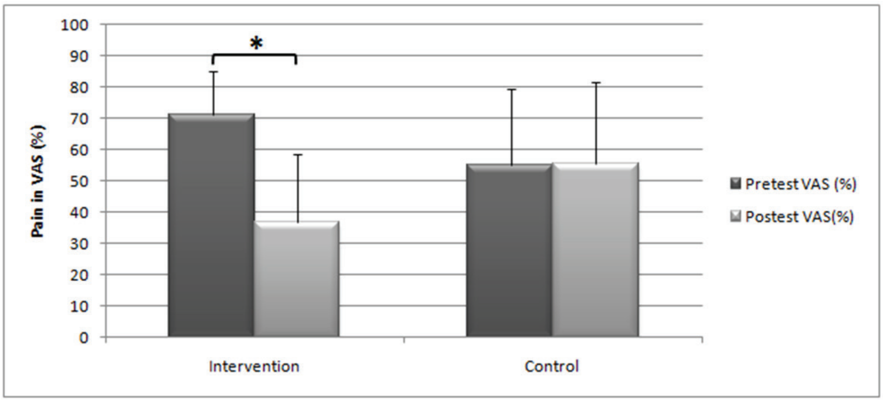

Figure 3: VAS score in study groups. Asterisk shows significant difference (α=0.05)

Table 2: Intra-group comparison of gait parameters

Parameter to be Compared	Intervention	P value	Change (%)	Control	P value	Change (%)
Pretest KAM First Peak	0.34±0.19	0.89	6	0.51±0.17	0.40	16
Posttest KAM First Peak	0.32±0.19			0.59±0.23		
Pretest KAM Second Peak	0.16±0.11	0.69	19	0.12±0.09	0.50	50
Posttest KAM Second Peak	0.13±0.09			0.18±0.16		
Pretest Velocity First Peak	81.41±25.72	0.04	27	86.70±21.61	0.02	17
Posttest Velocity First Peak	103.68±21.49			71.60±26.75		
Pretest Velocity Second Peak	53.68±18.53	0.69	6	30.59±19.73	0.04	39
Posttest Velocity Second Peak	56.84±18.47			18.64±18.08		
Pretest Angle First Peak	11.64±6.23	0.89	3	7.16±4.65	0.04	44
Posttest Angle First Peak	11.24±4.84			10.30±6.96		
Pretest Angle Second Peak	3.58±2.55	0.35	32	3.73±2.20	0.09	100
Posttest Angle Second Peak	5.10±3.59			7.60±4.66		
Pretest Normalized Vertical Force First Peak	0.98±0.06	0.69	4	0.99±0.16	0.87	1
Posttest Normalized Vertical Force First Peak	1.02±0.05			1.00±0.12		
Pretest Normalized Vertical Force Valley	0.86±0.05	0.35	3	0.88±0.11	0.50	1
Posttest Normalized Vertical Force Valley	0.89±0.06			0.89±0.12		
Pretest Normalized Vertical Force Second Peak	1.04±0.04	0.23	7	1.09±0.19	0.24	0.1
Posttest Normalized Vertical Force Second Peak	1.11±0.09			1.07±0.18		
Pretest Normalized Anteroposterior Force First Peak	0.11±0.05	0.89	9	0.11±0.02	0.50	1
Posttests Normalized Anteroposterior Force First Peak	0.12±0.03			0.12±0.05		
Pretest Normalized Anteroposterior Force Second Peak	0.16±0.04	0.08	12.5	0.14±0.03	0.61	7
Posttest Normalized Anteroposterior Force Second Peak	0.18±0.04			0.15±0.04		
Pretest Normalized Mediolateral Force	0.03±0.01	0.08	33	0.04±0.01	0.50	25
Posttest Normalized Mediolateral Force	0.04±0.01			0.05±0.02		

*Significant difference with control group (P<0.05).

significantly (P=0.04) while it decreased significantly in control group (P=0.02). Besides, significant reduction in second peak of knee AP velocity (P=0.04) and a statistically meaningful increase in first peak of AP knee angle (P=0.04) was detected in control group.

Between-group analysis showed that following conventional physiotherapy gait parameters in intervention group did not change significantly in comparison to control group (P>0.05, table 3) except for the first peak of KAM (P=0.03) and for the first and second peak of knee AP velocity (P=0.02 and P=0.01).

In the intervention group the spearman' rho coefficient confirmed strong correlation between baseline KOOS-pain score and some component of knee joint loads including first peak of KAM (r=0.9, P=0.04), second peak of vertical knee force (r=1.00, P<0.001) and second peak of anteroposterior

Table 3: Posttest comparison of the gait parameters in study groups

Parameter to be Compared	Group	Mean±SD	P value
VAS (%)	Intervention	37.00±21.68	0.34
	Control	55.71±25.89	
KOOS-pain Score (%)	Intervention	67.77±11.22	0.86
	Control	69.84±12.57	
KAM First Peak (Nm/kg)	Intervention	0.32±0.19	0.03
	Control	0.59±0.23	
KAM Second Peak(Nm/kg)	Intervention	0.13±0.09	0.76
	Control	0.18±0.16	
Velocity First Peak(°/s)	Intervention	103.68±21.49	0.02
	Control	71.60±26.75	
Velocity Second Peak(°/s)	Intervention	56.84±18.47	0.01
	Control	18.64±18.08	
Angle First Peak(°)	Intervention	11.24±4.84	1.00
	Control	10.30±6.96	
Angle Second Peak(°)	Intervention	5.10±3.59	0.27
	Control	7.60±4.66	
Normalized Vertical Force First Peak (N/kg)	Intervention	1.02±0.05	0.15
	Control	1.00±0.12	
Normalized Vertical Force Valley (N/kg)	Intervention	0.89±0.06	0.76
	Control	0.89±0.12	
Normalized Vertical Force Second Peak (N/kg)	Intervention	1.11±0.09	0.43
	Control	1.07±0.18	
Normalized Anteroposterior Force First Peak (N/kg)	Intervention	0.12±0.03	0.76
	Control	0.12±0.05	
Normalized Anteroposterior Force Second Peak (N/kg)	Intervention	0.18±0.04	0.34
	Control	0.15±0.04	
Normalized Mediolateral Force (N/kg)	Intervention	0.04±0.01	0.43
	Control	0.05±0.02	

Asterisk shows significant difference with control group (P<0.05)

knee force (r=0.9, P=0.04). Additionally, strong correlations were observed between post-intervention pain scores and these parameters (table 4).

Considering strong correlation between subjects' pain and some gait parameters along with significant baseline difference between groups in baseline pain and mediolateral knee force, we hypothesized that baseline KOOS-pain score or ML knee force and posttest VAS pain and KOOS-pain may modulate the proposed intervention on gait parameters. For correcting the discrepancies, univariate GLMs were adjusted for the aforementioned parameters (table 5).

The models showed that subject pre-, posttest pain is the most important factor to be controlled and adjusted when analyzing knee joint loading (KAM).

Discussion

In this study, load of knee joint was compared before and immediately after ten sessions of conventional physical therapy between subjects with moderate KOA and demographically matched control group. GLM with adjustment to baseline ML force showed that the intervention did not affect gait kinetic and kinematic parameters except for second peak of knee anteroposterior velocity. That means subjects in intervention group flexed knee more rapidly in moving toward swing phase.

Simple analysis of the data in the present study was confusing because of baseline difference in KOOS-pain and knee ML force. Any change in ground reaction force may change KAM and previous studies have shown that ML component of ground reaction force is more strongly correlated to KAM [3]. Developing GLMs with adjustment to subjects' pain scores before and after intervention period showed that the observed difference between groups may not be imposed by variation in pain scores. Because of our small sample size only univariate GLM were acceptable thus, we may not analysis the effect of synchronized adjustment to baseline KOOS-pain and ML force in present study. Further research is recommended to clarify the topic.

Baseline variation in KOOS-pain in present study with regard to insignificant difference in VAS score between groups may be related to the difference in VAS and KOOS-pain grading nature. VAS is a one-dimensional score to measure pain intensity while KOOS-pain score is calculated from subject' answer to nine questions concerning pain intensity and frequency and the pain they experienced in various activities [26].

An interesting finding was that after adjustment to knee ML force, the palliative effects of physical therapy, that was coincided with many other previous studies [3,13], disappeared. That means conventional physical therapy as proposed in present study may not even eliminate KOA pain although previous studies showed that physical therapy reduces KOA directly and indirectly as a result of physiological regulation in nutrition and neural stimulation [17] of peri-articular muscles [13] and connective tissues [13].

We cannot explain the baseline difference in knee joint ML force. An adjustment to baseline knee ML force significantly changed the results implying that the observed variation may not be a true difference between groups.

KAM is the key marker of deviated loading of the knee joint [9] and is strongly correlated with OA progression [2]. Although following physical therapy program KAM in intervention group was significantly lesser than that of control group, our findings primarily refused considerable modification of KAM immediately following short physical therapy because of GLM results with adjustment to baseline ML force. In fact, even without considering the model, synchronized 6% reduction in KAM in intervention group and 16% increase in KAM in control group puzzled between-group KAM difference.

It seems that some unknown factor(s) clearly worsened gait mechanics in control group (by more than even 20 percent in some parameters). In GLM, the mean value of the variable in one group is presented relative to the reference group. We set control group as reference in all GLMs since we though insignificant difference in raw data analyzed between groups may be imposed by alteration in control group status. Between group comparison with adjustment to baseline KOOS-pain showed that conventional physical therapy program successfully improves KAM, second peak of AP force in and knee flexion velocity during late stance. However this model lack the effect of significant difference in ML force at baseline.

The proposed protocol in present study was adopted from physical therapy text books [25,27,28] after adjustment to routine practice observed in private and state physical therapy centers in Isfahan (unpublished data). It seems that the program was not specific enough to modify knee kinetics and kinematics significantly. First peak of AP velocity of the knee joint represent flexion of the joint during initial contact [29].

Quadriceps strengthening is a commonly recommended in managing OA [2,3,8,9,17]. It improves walking speed and knee pain through better joint stabilization. Stronger quadriceps muscles are proposed to absorb shock [2,9] and attenuate ground reaction force during gait although they may not alter peak KAM in subjects suffering from KOA [2,9]. It seems that fast and powerful activation of muscles may not cause improvement in sub-maximal functions like walking. Previous studies claimed that high intensity quadriceps strengthening may not improve KAM in KOA subjects [2,8]. Therefore, the only exercises we prescribed for intervention group were quadriceps and VMO setting. VMO plays a critical role in anteromedial stability of the knee joint [25] especially through terminal extension [27]. Knee joint pain usually inhibits VMO leaving it weak and disused [25]. Considering the load, frequency and duration of muscle setting and overall duration of the intervention period, the exercise could not increase muscle strength significantly. Nonetheless, muscle settings are benign exercises to facilitate central neuromuscular pathways. We combined quadriceps and VMO settings with TENS since TENS effectively

Table 4: Correlation analysis between change in pain and change in gait parameters in control and intervention group

		KAM 1st Peak (N.m/Kg)	KAM 2nd Peak (N.m/Kg)	Velocity 1st Peak (°/s)	Velocity 2nd Peak(°/s)	Angle 1st Peak (°)	Angle 2nd Peak(°)	Normalize Vertical Force 1st Peak (N/Kg)	Normalized Vertical Valley Peak (N/Kg)	Normalized Vertical Force 2nd Peak (N/Kg)	Normalized Anteroposterior Force 1st Peak (N/Kg)	Normalized Anteroposterior Force 2nd Peak (N/Kg)	Normalized Mediolateral Force (N/Kg)
Intervention	Pretest VAS (%)	0.30	-0.50	-0.20	0.20	-0.70	-0.50	-0.10	-0.50	-0.60	-0.20	-0.80	0.20
		0.62	0.39	0.75	0.75	0.19	0.39	0.87	0.39	0.29	0.75	0.10	0.75
	Pretest KOOS-pain Score (%)	-0.900*	-0.30	-0.60	0.40	0.00	-0.30	0.70	-0.30	1.000**	0.50	.900*	0.60
		0.04	0.62	0.29	0.51	1.00	0.62	0.19	0.62	.	0.39	0.04	0.29
	Posttest VAS (%)	0.894*	0.22	0.45	-0.22	-0.11	0.22	-0.894*	0.22	-0.894*	-0.11	-0.78	-0.45
		0.04	0.72	0.45	0.72	0.86	0.72	0.04	0.72	0.04	0.86	0.12	0.45
	Posttest KOOS-pain Score (%)	-0.60	0.30	0.00	-0.10	0.60	0.30	0.50	0.30	0.80	0.10	.900*	0.00
		0.29	0.62	1.00	0.87	0.29	0.62	0.39	0.62	0.10	0.87	0.04	1.00
Control	Pretest VAS (%)	0.27	0.43	0.31	-0.40	0.02	0.02	-0.56	-0.09	-0.32	0.45	-0.29	-0.52
		0.56	0.33	0.50	0.38	0.97	0.97	0.19	0.85	0.48	0.31	0.53	0.23
	Pretest KOOS-pain Score (%)	-0.63	-0.775*	-0.32	0.14	-0.36	-0.31	0.25	0.11	0.49	-0.51	0.36	0.05
		0.13	0.04	0.48	0.76	0.43	0.50	0.59	0.82	0.27	0.25	0.43	0.91
	Posttest VAS (%)	0.28	0.36	0.60	-0.08	0.21	0.17	-0.54	-0.17	-0.30	0.37	-0.06	-0.34
		0.54	0.43	0.16	0.87	0.66	0.72	0.21	0.72	0.51	0.41	0.91	0.46
	Posttest KOOS-pain Score (%)	-0.27	-0.41	-0.05	0.41	0.07	0.07	0.07	-0.11	0.14	-0.36	0.07	0.31
		0.56	0.36	0.91	0.36	0.88	0.88	0.88	0.82	0.76	0.43	0.88	0.50

First row in each cell is Spearman' rho Coefficient and the second one is P value; VAS: Visual Analogue Scale; KAM: Knee Adduction Moment; **α=0.01 (2-tailed); * α=0.05 level (2-tailed).

Table 5: General linear models for the effect of physical therapy intervention on the gait parameters

	Adjusted to Baseline Mediolateral Force		Adjusted to Baseline KOOS-pain Score		Adjusted to Post test VAS-pain Score		Adjusted to Post test KOOS-pain Score	
Dependent Variable	**Coefficient[95% CI]**	**P value**	**Coefficient[95% CI]**	**P value**	**Coefficient[95% CI]**	**P value**	**Coefficient[95% CI]**	**P value**
VAS(%)	-21.55[-70.01,26.91]	0.34	-40.93[-67.99,-13.88]	0.01			-21.65[-45.75,2.44]	0.07
KOOS-pain Score (%)	0.53[-23.39,24.45]	0.96	8.50[-5.60,22.59]	0.21	-8.62[-21.51,4.26]	0.16		
KAM First Peak (Nm/kg)	-0.24[-0.67,0.19]	0.24	-0.44[-0.70,-0.17]	0.01	-0.15[-0.38,0.09]	0.19	-0.28[-0.55,-0.01]	0.04
KAM Second Peak(Nm/kg)	0.06[-0.18,0.30]	0.57	-0.15[-0.34,0.03]	0.10	-0.02[-0.21,0.17]	0.84	-0.06[-0.25,0.13]	0.52
Velocity First Peak(°/s)	13.76[-31.84,59.36]	0.51	28.65[-12.57,69.87]	0.15	40.13[6.16,74.11]	0.03	32.61[-1.87,67.08]	0.06
Velocity Second Peak(°/s)	40.64[4.27,77.00]	0.03	40.63[10.27,70.99]	0.01	37.41[9.87,64.95]	0.01	38.01[12.48,63.53]	0.01
Angle First Peak(°)	1.39[-11.00,13.77]	0.81	0.47[-9.89,10.83]	0.92	2.03[-7.10,11.16]	0.63	1.12[-7.46,9.69]	0.78
Angle Second Peak(°)	-1.14[-9.54,7.25]	0.77	-3.88[-10.76,3.00]	0.23	-1.83[-8.14,4.48]	0.53	-2.41[-8.33,3.52]	0.38
Normalized Vertical Force First Peak (N/kg)	-0.02[-0.21,0.16]	0.81	0.06[-0.09,0.21]	0.40	0.02[-0.13,0.16]	0.79	0.03[-0.11,0.16]	0.66
Normalized Vertical Force Valley (N/kg)	-0.06[-0.26,0.14]	0.53	-0.001[-0.17,0.17]	0.99	0.01[-0.14,0.17]	0.86	0[-0.15,0.14]	0.99
Normalized Vertical Force Second Peak (N/kg)	-0.03[-0.32,0.26]	0.84	0.12[-0.11,0.34]	0.27	0.02[-0.20,0.25]	0.82	0.04[-0.16,0.25]	0.65
Normalized Anteroposterior Force First Peak (N/kg)	0.04[-0.04,0.11]	0.33	-0.01[-0.08,0.06]	0.76	0.01[-0.06,0.07]	0.80	-0.004[-0.06,0.05]	0.88
Normalized Anteroposterior Force Second Peak (N/kg)	0.01[-0.07,0.09]	0.80	0.07[0.02,0.12]	0.01	0.02[-0.04,0.08]	0.54	0.03[-0.02,0.09]	0.18
Normalized Mediolateral Force (N/kg)	-0.01[-0.05,0.03]	0.56	-0.01[-0.04,0.03]	0.71	-0.01[-0.04,0.02]	0.40	-0.01[-0.04,0.02]	0.42

CI: Confidence Interval; All adjustment are in modeled with control group as reference; Asterisk shows significant interactions (P<0.05)

disinhibits quadriceps [17] and increases volitional activation of quadriceps and VMO [17]. The activated quadriceps properly controls sagittal plane motion [17]. Although, earlier studies disqualified TENS for kinetic modulation in KOA subjects [17], we suggest that this combination improved weight acceptance in the knee; VMO and quadriceps settings reduced reflex inhibition of knee musculature and TENS modulated pain and facilitated the muscles. The result of this combination was faster knee flexion in terminal stance [9]. It has been shown that physical therapy programs that focused on various types of exercises may change KAM in KOA subjects [13,30]. Precise discussion on mechanism by which combination of quadriceps and VMO setting with TENS may affect KAM requires further research.

Since we combined various intervention including electrical stimulus, exposure to ultrasonic energy, active muscular exercise and conceptual manipulation (using the pamphlet), we cannot determine which part of the program caused observed alterations in the gait. No part of the proposed physical therapy program in the present study was specifically included for manipulating knee joint load. However, the present study confirmed that conventional physical therapy as is practiced in private and state rehabilitation wards may be advantageous in reducing KAM and increasing joint velocity in sagittal plane. This study did not focused on any specific exercise paradigm.

There were some limitation for the present study that is worth mentioning. The main limitation of the present work was our small sample size. Power analysis suggested that we would need at least 60 subjects in each study group. Also, because of some technical limitations, we could not consider follow-up period. Future research is recommended to include a follow-up period.

Additionally, we included subjects with at most moderate OA in one knee joint. i. e. the contralateral knee might be healthy or deteriorated by mild or moderate OA. Asymmetrical involvement of the knee joints could affect KAM and joint forces in the target joint. We recommend bilateral comparison of joint loading in asymmetrical KOA. One more limitation to our study was restricting our analysis to the knee joint. The basic approach in analyzing joint load and forces is inverse dynamics. Simultaneous study of the kinetic and kinematic properties of other lower extremity joints may improve our understanding of how KOA may alter gait biomechanics. Finally, randomized assignment did not result in perfectly matched groups; larger sample size eliminates the risk of baseline mismatch. The difference between the groups was significant in KOOS-pain score and ML knee force thus we corrected our analysis accordingly. In the same way, because of strong correlations between pre- and post- pain scores and gait parameters, various univariate GLMs were developed. Using these models the pure effect of intervention on gait parameters was analyzed after adjustment for uncontrolled covariates. Because of our small sample size only univariate models were applicable [31]. The results confirmed that the intervention group has actually better gait kinetic and kinematic in some aspects. Whether longer intervention period and increasing number of physical therapy sessions may improve this effect is not clear yet. We recommend further research with more therapeutic sessions and follow up evaluations.

Conclusion

It seems that conventional physical therapy does not substantially improve KAM. This study opens up interesting avenues for future research in monitoring KOA subjects. The body of current research is an important initial step in the development of noninvasive and potentially structure- modifying treatment modalities for KOA. By providing more appropriate treatments, we not only improve the quality of life of these subjects but also hope to slow down the disease progression.

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