Original Article

# Gluteus Maximus-gastrocnemius versus Quadriceps Biofeedback Neuromuscular Training during Gait in Knee Osteoarthritis: Development and Feasibility of a Novel Concept with a Pilot Study

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## Abstract

**Background:** The neuromuscular training is a subgroup of functional exercises. The effectiveness of the neuromuscular training substantially improves in combination with electromyography (EMG) biofeedback. The present study aimed to investigate the effect of a new model of neuromuscular training in knee osteoarthritis (KOA). **Methods:** This pilot, parallel randomized-clinical-trial involved 10 participants with moderate KOA, who were randomly assigned into either neuromuscular training for the gluteus maximus and gastrocnemius (pro-group = 5) or the quadriceps (against-group = 5). Muscle activity in the feedback phase of gait (EMG), pain (Visual Analog Scale [VAS] and knee injury and osteoarthritis outcome score [KOOS]-pain score), and function (average walking speed and KOOS score) were assessed at baseline, immediately after the first treatment session (except KOOS), after 10 sessions of intervention, and after a 3-month of follow-up. **Results:** After the first treatment session, pain slightly (5.71%) increased in the against-group, whereas decreased by 6.45% in the Progroup; after the 10th session and 3 months, all variables in both groups improved, with a slight extra positive difference in the Pro-group. However, after 3 months, the percentage of changes in the Progroup was greater than that of the against-group. The pain intensity based on VAS (−96.8%), pain (+101.30%), and quality of life (+145.41%) scores of the KOOS questionnaire showed nearly 100% or even greater improvement in the pro-group. **Conclusion:** Retraining quadriceps and gastrocnemius and gluteus maximus using biofeedback during gait seems promising in KOA, although the Progroup apparently experienced considerably greater clinical improvement. The study provides preliminary evidence of the clinical feasibility of a novel neuromuscular training paradigm for KOA based on biofeedback during gait. **Trial Registration:** This study was registered under the International Randomized Controlled Trial Number registry on November 20, 2023.

**Keywords:** *Electromyography, electromyography-biofeedback, function, knee osteoarthritis, neuromuscular training, pain*

**Submitted:** 15-Dec-2025 **Revised:** 06-Jan-2026 **Accepted:** 03-Feb-2026 **Published:** 01-Jun-2026

## Introduction

Knee osteoarthritis (KOA) is the most common type of articular disease, especially in middle age;[1] That predominantly affects walking and climbing stairs.[2] Weakness, alterations in muscle tension during activity, and alterations of the joint biomechanics are noteworthy risk factors for KOA,[1,3,4] that may occur in compensation for the altered biomechanics of the knee joint.[5,6]

Various patterns of the alteration of tension and contractile activity of the peri-articular knee joint muscles are evident during different activities: for example, quadriceps activity during walking,[7,8] may be reduced because of artherogenic inhibition,[9] or could be increased for the sake of increasing joint stability;[6] in addition, longer duration of quadriceps activity,[6,8,10] and stronger co-contraction with other muscles, especially hamstrings are reported, that could also be a strategy for improving joint stability.[11,12] Besides, longer activity of the hamstrings,[10] their co-contraction with other knee muscles,[11,12] increased contractile activity of hip adductor muscles,[7] gastrocnemius,[8,10,13] and the gluteus maximus and medius[8] have been reported during the stance phase of walking. Biomechanical changes and



**How to cite this article:** Kalantari KK, Ganjeh S, Bijari K, Roostayi MM, Aslani H, Baghban AA, *et al.* Gluteus maximus-gastrocnemius versus quadriceps biofeedback neuromuscular training during gait in knee osteoarthritis: Development and feasibility of a novel concept with a pilot study. J Med Sign Sens 2026;16:15.

**Access this article online**

**Website:** www.jmssjournal.net

**DOI:** 10.4103/jmss.jmss_140_25

**Quick Response Code:**

compensatory patterns of muscle contraction occur mostly in moderate KOA (grade III in Kellgren-Lawrence (K-L) grading system).[12-15]

## The new concept in designing the therapeutic exercises for people with knee osteoarthritis

Quadriceps is the primary extensor of the knee, and one of the muscles that is inhibited with KOA progression as a result of the swelling, inflammation, and pain imposed by the disease;[16] in fact, quadriceps inhibition is a compensatory strategy for controlling the pain and knee joint loads during the static phase of walking.[5] However, quadriceps weakness conflicts with the muscle's role as a shock absorber and increases joint loading during weight bearing phase.[17,18] Progressive weakness of the quadriceps muscle would disturb the extensor mechanism of the knee during the static phase of walking. The muscle imbalance around the joint can subsequently lead to flexion contracture, which in turn creates a vicious cycle that exacerbates pain, increases knee joint loading, and disrupts both proximal and distal joints.[19]

Pathological changes related to KOA are stable and progressive.[20,21] Many of these changes patho-kinesiologically compensate for the biomechanical impairments to save performance and function.[5,6,22] Therefore, isometric strengthening of the knee extensors in nonfunctional positions for reaching back into the biomechanics and muscle strength of healthy peers does not seem to be adequate. Alterations of neuromuscular patterns during dynamic tasks like gait, are beyond simple muscle weakness and can be recovered through simple static exercises of solitary muscles. On the other hand, people with KOA usually suffer impairments in both executive function and motor control.[23]

With KOA progression, the concentric power of the knee extensors decreases; therefore, the hip extensors', specifically the Gluteus Maximus', eccentric power increases in the static phase of walking.[5] However, an increase in gastrocnemius activity is also reported during the static phase of walking.[8] These findings are biomechanically justifiable in people with weak quadriceps, where these two muscles help knee extension through increasing their activity in the closed-chain paradigm;[24] the theory proposes whether compensatory muscle activity can be harnessed to benefit individuals with KOA through aiding knee extension without increasing knee joint loads. Neuromuscular training of the muscles that indirectly contribute to knee extension may not only reduce the direct load on the knee but also provide support the inhibited quadriceps and help in prevention of the knee flexion contracture. Therefore, the first goal of the present study was to compare the effects of the therapeutic exercise for muscles in the opposite direction of altered biomechanics (against-group: quadriceps training) versus muscles in the same direction of altered biomechanics (ProGroup: gastrocnemius and gluteus maximus training) in term of change in pain, function and electromyography (EMG) activity amplitude.

Traditionally, the therapeutic exercise for KOA is practiced in nonfunctional, static positions. The exercises aim reversing the muscles weakness imposed by the disease for the sake of returning the muscle activity pattern to that of normal matches; the improvements following these exercises are interpreted as a sign of the recovery and the effectiveness of the therapeutic approach.[25-27] The clinical effect ranges from medium to low, decreasing over time responses[25] although, participant's functional performance shows minimal changes clinically; in fact, strengthening a muscle in a nonfunctional context does not necessarily lead to improvement of its collaboration in functional situations; therefore, it is possible that other factors are involved in the effectiveness of therapeutic exercise.[28] Maximizing therapeutic effectiveness requires determining how to apply therapeutic exercise based on the underlying pathogenesis, and identifying the key muscle groups to target.

When designing therapeutic exercises for individuals with KOA, it is crucial to consider the neuromuscular control of the lower limb to ensure effective engagement of the target muscle during the proposed functional activities.[28] The primary goal of strengthening exercises is to minimize the energy cost of the movement; thus, neuromuscular training is a justified therapeutic approach that prioritizes the quality (techniques, form, adaptation, and coordination) and efficiency of movement.[29,30]

The neuromuscular training basically targets improving sensory-motor control,[31] achieving compensatory functional stability,[30,31] and correcting muscle activation patterns. It also affects functional biomechanics and performance outcomes, such as faster times, greater distances, or improved accuracy.[31] Thus, neuromuscular training is supposed to enhance cognitive-motor integration and help symptoms relief during dynamic tasks like gait.

Neuromuscular training is extensively used as a gait retraining modality in people with KOA.[32-36] To optimize movement, neuromuscular training should be guided by objective metrics that clearly convey muscle activity to the participant. Biofeedback training is a neuromuscular rehabilitation approach that has been employed to facilitate normal movement patterns for more than five decades.[37]

Providing biofeedback during rehabilitation could have potential therapeutic effects; for example, it may enable users to gain control over physical processes previously considered to be automatic responses under the control of the autonomic nervous system; on the other hand, it leads to an increase in individual' compliance with exercise and motivates them.[38] Any activation of the neuromusculoskeletal system can be used to provide neuromuscular feedback. The neuromuscular feedback used

in rehabilitation includes electromyographic biofeedback and real-time feedback using ultrasound.[39]

The main functional limitation induced by KOA is the change in gait that consequently affects personal independence and social interaction.[40] Since people suffering from KOA are mostly elderly adults who are synchronously challenged by aging-induced neuromuscular impairments,[30,31] using biofeedback for improving KOA walking performance seems promising[41] for neuromuscular training.[30,32,42] Therefore, one objective of the present study was to evaluate the use of biofeedback as a tool to facilitate neuromuscular training during walking.

According to our search strategy, no study to date has compared the aforementioned exercise paradigms, combining neuromuscular training and EMG-biofeedback during walking for subjects with KOA. A preliminary pilot study has briefly explored a framework for biofeedback therapy in KOA during various tasks.[43] We believe that the neuromuscular training of muscles that indirectly help in knee joint extension may be helpful in improving knee joint pain and function for individuals with KOA who suffer from Quadriceps weakness.

This preliminary study provides a detailed summary of designing a clinical trial to evaluate the feasibility and effects of neuromuscular strengthening exercises using a biofeedback method during walking. The training plan focuses on the altered neuromuscular patterns of distinct muscle groups during walking and measures clinical outcomes in term of pain and function along with the muscle activity amplitude. If the feasibility of gait training through neuromuscular exercises using a biofeedback is confirmed, the efficiency of the proposed paradigm in improving pain, function, and EMG features should then be properly investigated during the gait as the most challenging task for people suffering from KOA.

## Methods

This study is a pilot, parallel-group, randomized single-blind (assessor) clinical trial in which participants with moderate KOA were randomly assigned into either the pro-group or the Against-group (1:1) using a block randomization approach. For those with bilateral KOA, the most painful knee (regardless the more severely affected side according to K-L grading) was chosen for the training. The primary outcomes included amplitude of muscle activity in EMG findings, pain intensity, and individual-reported functional improvements.

### Ethics, recruitment, and satisfaction process

Ethics approval was obtained from the institutional Research Ethics Committees on October 22nd, 2023; the protocol of the study was registered in the WHO-certified national registry on November 30, 2023. The participants were recruited from the orthopedic clinics of state centers affiliated by the University of Medical Sciences, in the period of December 1st, 2023 up–May 31st, 2024.

The eligibility screenings were conducted by SG, for volunteers of either gender who's the grade of KOA was approved by a blind orthopedic specialist. The inclusion criteria were grade of III KOA according to the K-L grading system, age between 40 and 75 years, pain score >3 based on the Visual Analog Scale (VAS), experience of pain on most days in the past month, ability to walk on a treadmill for at least 25 min without aid and to walk normally for at least 30 min. The volunteers were not included if they were athlete, had the history of hip or knee joint replacement surgery, body mass index (BMI) >35 kg/m², any neurological, muscular, or skeletal disorder that impairs independent walking or ability to participate in gait training (like cognitive disorders, Parkinson's, etc.) or any KOA treatments such as oral or injected corticosteroids, knee surgeries (e.g., osteotomy), or conservative treatments (e.g., physical therapy, manual therapy, acupuncture, exercise therapy) within the past 6 weeks prior to the study. Approved volunteers received a written formal consent and had 48 h to announce whether they are still interested in collaboration. Enrolled participants received detailed information about the treatment group they were assigned into.

The personal data of the participants were saved confidential and are only available to the research team. For each participant, a unique code was assigned for assuring confidentiality of their data during the analysis process. The written informed consent form participants were archived by the university for 2 years.

### Outcome measures and statistical analysis

Pain intensity (VAS score, knee injury and osteoarthritis outcome score [KOOS]), average walking speed (10-m fast-speed walking record, KOOS), and EMG data were collected at baseline (pretest), immediately after the first treatment session (except KOOS), after 10 sessions of predefined interventions and after 3 months of stopping either intervention paradigm (3-month follow-up). KOOS score assessed the assessments were conducted in the biomechanics laboratory.

### Demographics

Upon entering the study, the demographic information of the participants was recorded in a predesigned sheet using a questionnaire. The sheet include gender, age, BMI, and the affected leg.

#### *Assessment tools*

The KOOS[44-46] has shown strong validity and reliability for people with mild to moderate KOA.[47] We used the Persian version of the KOOS questionnaire to evaluate pain and function based on following manual calculations formulae:[45,46]

$$\text{PAIN } 100 - \frac{\text{Mean score (P1-P9)} \times 100}{4} = \text{KOOS pain}$$

$$\text{SYMPTOMS } 100 - \frac{\text{Mean score (S1-S7)} \times 100}{4} = \text{KOOS symptoms}$$

$$\text{ADL } 100 - \frac{\text{Mean score (A1-A17)} \times 100}{4} = \text{KOOS ADL}$$

$$\text{QOL } 100 - \frac{\text{Mean score (Q1-Q4)} \times 100}{4} = \text{KOOS QOL}$$

### Equation 2–5 knee injury and osteoarthritis outcome score scoring formulae

VAS, is well-established as a reliable and valid tool for measuring pain intensity in musculoskeletal disorders.[48] Because the KOOS questionnaire cannot capture pain intensity level immediately after the first treatment session, the VAS was included in all four assessment stages: pre-test, immediately after the first treatment session, posttest, and 3-month follow-up.

Ten meters Fast-speed Walking is a reliable measure for assessing walking speed and offers a moderate reflection of overall physical function.[49] Because the KOOS questionnaire does not assess the function immediately after the first treatment session, the 10-m fast-speed walking test was included at all four assessment stages.

Surface EMG has demonstrated sufficient reliability for assessing lower limb muscle activity within and between sessions.[50] The amplitude and duration of the quadriceps, Gluteus maximus, and gastrocnemius muscles during the stance phase of walking were reported using EMG, whereas feedback was provided synchronously.

The rectus femoris is the most commonly addressed section of the Quadriceps muscle in EMG studies of KOA gait.[6,51,52] Since discrete muscle groups were recorded for either study group, EMG parameters of the rectus femoris activity were reported in both groups to have reference evidence of the effect of proposed treatments on the EMG parameters.

The MegaWin eight-channel EMG device was employed, sampling at a frequency of 1000 Hz. Muscle activity signals were filtered using a high-pass filter at 10 Hz and a low-pass filter at 450 Hz to minimize signal noise. Before electrode placement, participants were instructed to shave and clean the skin thoroughly, with placement following the SENIAM protocol on vastus lateralis, rectus femoris, and vastus medialis in the against-group, and gluteus maximus, medial and lateral gastrocnemius in the pro-group. Each participant completed five walking trials in a gait laboratory at the desired speed, from which three trials were selected for analysis. EMG normalization was performed using maximum voluntary contraction tests for all three muscle groups. All the assessments were conducted by the assessor (KHB) who was blind to study groups.

Study outcomes were assessed quantitatively. A blinded assessor (KHB) entered all data into the statistical software, and a statistician (AAB) performed the analyses. Data on VAS, 10-m fast-speed walking, and EMG were collected at four assessment stages. KOOS scores were collected at pretest, posttest, and 3-month follow-up.

These data were analyzed using SPSS software (IBM Corp., Released 2018. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY, USA.). The magnitude of the change following the interventions was reported in the net term (Post–Pre) and in standard change percent (100× [Post–Pre]/Pre). Power analysis was performed using G * Power (G * Power 3.1.9.7 freeware, Released March 17, 2020, University of Düsseldorf, Düsseldorf, Germany) software.[53]

### Experimental setting and interventions

Treatment sessions were appointed in the physical therapy clinic of the University of Medical Sciences. All participants received standard treatments, including health-related education and routine physical therapy of conventional TENS, pulsed ultrasound, joint and soft tissue mobilization, and stretching exercises, for ten sessions.[54,55] In addition to the routine treatment, one group received neuromuscular training for the quadriceps muscle, whereas the other group received neuromuscular training for the gastrocnemius and gluteus maximus using EMG-biofeedback during walking at a convenient self-selected speed. All treatment procedures were administered by a single physical therapist (SG) with 5 years of experience in managing KOA subjects. The biofeedback exercise was thoroughly explained during the initial introduction and eligibility screening sessions. The therapist was present throughout the therapeutic sessions to ensure complete training was achieved.

We employed the physioparse biofeedback device [Figure 1], a micromodel manufactured in Iran by a knowledge-based company (Hormoz-Kian Company).

This device has been certified for medical equipment quality management (ISO13485), operates on a single channel, and offers a wireless range of up to 100 m without requiring a


**Figure 1: Physiopars biofeedback**

reference or ground electrode. To prepare participants for walking, each treatment session began with routine physical therapy, followed by neuromuscular training while walking with EMG-biofeedback based on the assigned group. This training was consisted of three phases:

1. Instruction by the therapist,
2. Solo practice with the device, and
3. Executing the learned method without monitoring the device's readout, under the therapist's supervision.

The biofeedback hub was attached to the participant's body with a belt, and the device was connected to a tablet via Wi-Fi. Participants were able to view their muscle activity as signals on a monitor or tablet screen while walking in the laboratory.

*Against-group (quadriceps muscles neuromuscular training)*

In this group, electrodes were placed on the rectus femoris muscle with 20 mm distance in between [Figure 2].

The therapist guided the participant through walking exercises, providing feedback to help improving their performance. Participants monitored their muscle activity on a screen, using their experience with the device and the therapist's instructions, they enhanced their performance over time. Each session involved setting a muscle activity threshold, typically ten to twenty percent higher than the individual's baseline activity [Figures 3 and 4], with adjustments as necessary. Participants performed this exercise during 15 min walking per session.

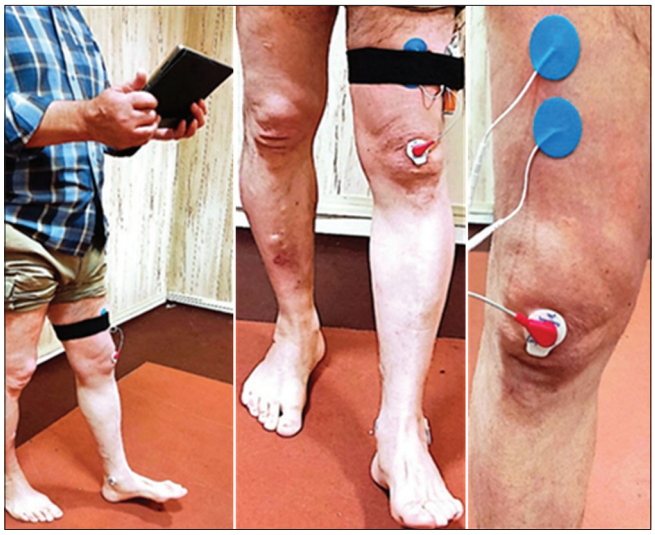

**Figure 2: Bio-feedback placement in against-group**

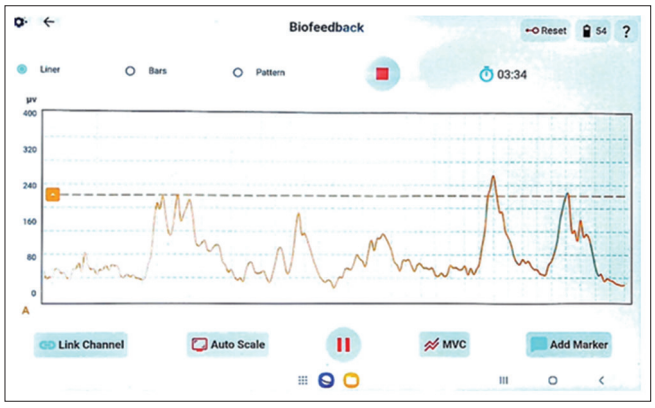


**Figure 4: Muscle activity with an addition of about 20% of the base activity**

*Pro-group (Gluteus maximus and gastrocnemius muscles neuromuscular training)*

In this group, electrodes were placed on both the Gluteus Maximus and the Gastrocnemius muscle bulk with 20 mm distance in between [Figure 5]. Each exercise was performed separately for 15 min, with a 10-min break between the two exercises. Due to the limitations of the single-channel biofeedback device, it was not possible to capture signals from both the medial and lateral gastrocnemius muscles simultaneously; therefore, electrodes were placed transversely on the gastrocnemius bulk. The remaining training procedures adhered to the same protocol as those used in the against-group.

## Safety and adverse events

The primary investigator (the PI: KHKH) and the other supervisor of the team (MMR) monitored the implementation process, the progress of the plan, data collection, and all safety, clinical, scientific, and executive

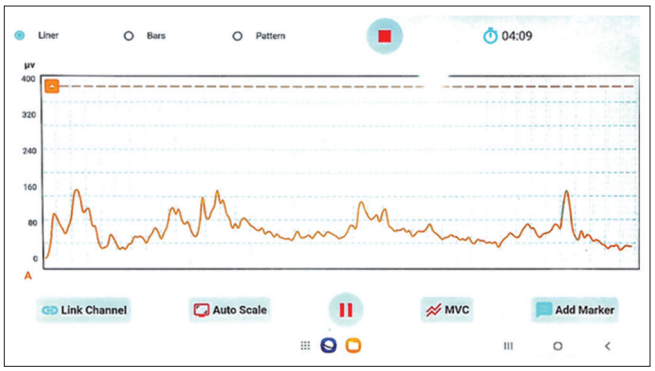


**Figure 3: Baseline muscle activity**

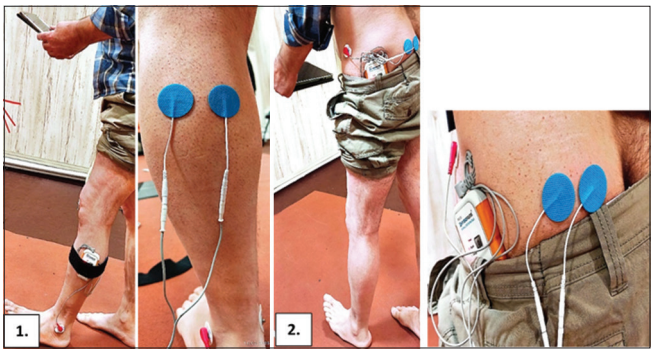


**Figure 5: Bio-feedback electrodes placement in pro-group (1. Gastrocnemius, 2. Gluteus Maximus)**

concerns related to the assessment and treatment of the participants.

The therapist (SG) was available to the participant from the beginning to the end of the interventions and follow-up periods and ensured their safety in all stages of treatment and assessment. The treatment environment and all the equipment related to the evaluation and treatment were safe and calibrated and were regularly checked by the Ethics supervisor and the gait laboratory technician. There was minimal risk of fatigue in the first treatment session, due to the assessment before and immediately after the session, for which the rest intervals were anticipated. The longer duration of the first session was informed to the participants in advance.

The treatment protocol was not anticipated to cause side effects, and no side effects were either observed by the supervisors or reported by the participants during the project.

### Withdrawal criteria

Participants were informed that they were free to leavethe study at any time, including before, during, and after data collection sessions. If a participant stopped collaboration, their data were imputed using the multiple imputation method and intention-to-treat (ITT) analysis was conducted.

The duration of the walking rehearsal in each session was less that of the average daily time of walking for each participant; however, if they reported discomfort and refused to walk as planned, they were excluded from the study upon their preference.

## Preliminary Clinical Results

Due to the lack of prior studies using the same method, this study was initially conducted as a pilot with five participants in two independent groups [Table 1].

Five participants in each group received 10 sessions routine physical therapy in addition to the neuromuscular EMG-biofeedback training during gait. Pain, function and EMG data at first treatment session are summarized in Table 2.

It seems that pain increased in the against-group immediately after the first treatment session (+5.71% change) while its value decreased in the pro-group (–6.45%). However, the average fast-walking speed decreased in both groups immediately after the first session. The increase in pain in the pro-group may be due to fatigue, and the decrease in fast-walking speed in both groups after the first session may be due to focusing on learning the instructions given during gait [Table 2]. Based on EMG-findings, it seems that at the end of the first session the activity of all muscles decreased, during stance phase of gait (feedback phase). The effects of ten-session interventional paradigms are presented in Table 3.

**Table 1: Demographic data of 5 participants in each group**

| Variable | Against-group | Pro-group |
|---|---|---|
| Sex | Male *n*=1, female *n*=4 | Male *n*=1, female *n*=4 |
| Age | 63.00±6.59, 54< age <71 | 65.60±7.50, 56< age <75 |
| BMI | 28.22±3.07, 24.83< BMI <31.62 | 26.82±3.13, 22.64< BMI <30.10 |
| Affected side | Left: *n*=4, right: *n*=1 | Left: *n*=1, right: *n*=4 |

BMI: Body mass index

After ten sessions, pain and function improved in both groups, although the changes were more prominent in the pro-group for all clinical variables, except for the KOOS quality of life (QoL) that showed somehow similar improvement in both groups. Based on EMG findings, the Rectus Femoris activity increased considerably (31.58%) in against-group while it moderately decreased (−11.76%) in pro-group after the tenth treatment session. The activity of the vastus lateralis (+10.90) and the medial and lateral heads of gastrocnemius increased in against- and pro-group, respectively, whereas the vastus medialis in the against-group and the gluteus maximus in the Pro-group showed lower activities [Table 3].

Table 4 summarizes the lasting impact of the proposed interventions in term of both clinical and EMG records.

The intensity pain, and function improved in both groups, although the improvement was significantly more prominent for all clinical variables in the pro-group. Interestingly, all patient-reported outcome measures (pain intensity and KOOS subclasses scores) continue to improve during the follow up period [Table 4]. Although the improvement was generally small (fairly < 4% on average), it was considerable for the pain intensity and the score of QoL subclass of KOOS in Pro-group (20% and 16%, respectively) [Table 5]. In contrast, average fast walking speed reduced by 9% in either group. These results suggest that the clinically perceived benefits of the proposed gait training paradigms may endure in the long term, but functionally they may not be as effective as initially anticipated.

Only in pro-group the rectus femoris activity continued to improve during follow up period. The activity of all muscles appeared to stabilized during follow-up in the against-group. In contrast, the Pro-groups demonstrated notable heterogenous changes: “while activity of gastrocnemius heads decreased by an average of 10%, Gluteus Maximus activity showed a significant improvement of 16%.”

During the sessions, subjects felt satisfied with the treatment they received; thus, they actively participated in their program. They specifically felt grateful because the therapist walked alongside them and explained muscle activity for them during gait training exercises.

At the end of the tenth session, they reported that they had learned the exercises well and will follow the instructions in their daily lives. Although some were over 60 years old, they did not find working with biofeedback difficult or challenging. Instead, they liked it as a joyful therapeutic exercise that entertained them like a game. None of the participants in either group left

**Table 2: The impact of one session intervention on the clinical, and electromyography -feedback records**

| Data type | Variable | Group | Baseline | After 1st session | Mean change (standard mean change %) |
|---|---|---|---|---|---|
| Clinical | Pain intensity (%) | Against-group | 70.00±18.70 | 74.00±18.20 | +4.00 (5.71) |
| | | Pro-group | 62.00±14.80 | 58.00±11.50 | −4.00 (6.45) |
| | Average fast walking speed (m/s) | Against-group | 1.05±0.30 | 0.87±0.28 | −0.18 (17.14) |
| | | Pro-group | 1.28±0.13 | 0.98±0.21 | −0.30 (23.44) |
| EMG amplitude | Rectus femoris | Against-group | 0.38±0.14 | 0.36±0.08 | −0.02 (5.26) |
| | | Pro-group | 0.34±0.05 | 0.23±0.05 | −0.11 (32.35) |
| | Vastus lateralis | Against-group | 0.55±0.09 | 0.44±0.11 | −0.11 (20.00) |
| | Vastus medialis | | 0.51±0.08 | 0.39±0.09 | −0.12 (23.53) |
| | Gluteus maximus | Pro-group | 0.49±0.17 | 0.37±0.14 | −0.12 (24.50) |
| | Gastrocnemius (medial head) | | 0.35±0.06 | 0.25±0.04 | −0.10 (28.57) |
| | Gastrocnemius (lateral head) | | 0.42±0.05 | 0.26±0.06 | −0.16 (38.09) |

EMG – Electromyography

**Table 3: The impact of ten-session intervention on the clinical, and electromyography feedback records**

| Data type | Variable | Group | Baseline | After 10th session | Mean change (standard mean change %) |
|---|---|---|---|---|---|
| Clinical | Pain intensity (%) | Against-group | 70.00±18.70 | 26.00±23.02 | −44.00 (62.86) |
| | | Pro-group | 62.00±14.80 | 22.00±8.37 | −40.00 (64.52) |
| | Average fast walking speed (m/s) | Against-group | 1.05±0.30 | 1.23±0.33 | +0.18 (17.14) |
| | | Pro-group | 1.28±0.10 | 1.55±0.14 | +0.27 (21.10) |
| | KOOS pain (%) | Against-group | 39.41±13.80 | 67.78±11.04 | +28.37 (72.00) |
| | | Pro-group | 41.10±6.30 | 74.42±5.34 | +33.32 (81.10) |
| | KOOS symptoms (%) | Against-group | 45.70±12 | 70.00±11.47 | +24.30 (53.17) |
| | | Pro-group | 50.00±8.00 | 82.80±6.77 | +32.80 (65.60) |
| | KOOS ADL (%) | Against-group | 48.20±14.61 | 71.16±8.11 | +22.96 (47.64) |
| | | Pro-group | 52.70±9.10 | 78.52±8.73 | +25.82 (49.00) |
| | KOOS QOL (%) | Against-group | 23.75±8.15 | 43.75±0.00 | +20.00 (84.21) |
| | | Pro-group | 24.97±10.85 | 45.00±10.27 | +20.03 (80.22) |
| EMG amplitude | Rectus femoris | Against-group | 0.38±0.14 | 0.50±0.09 | +0.12 (31.58) |
| | | Pro-group | 0.34±0.05 | 0.30±0.09 | −0.02 (5.88) |
| | Vastus lateralis | Against-group | 0.55±0.09 | 0.61±0.01 | +0.06 (10.90) |
| | Vastus medialis | | 0.51±0.08 | 0.44±0.11 | −0.07 (13.72) |
| | Gluteus maximus | Pro-group | 0.49±0.17 | 0.34±0.16 | −0.15 (30.61) |
| | Gastrocnemius (medial head) | | 0.35±0.06 | 0.47±0.12 | +0.12 (34.28) |
| | Gastrocnemius (lateral head) | | 0.42±0.05 | 0.53±0.06 | +0.11 (26.19) |

KOOS – Knee injury and osteoarthritis outcome score; ADL – Activity of daily living; QOL – Quality of life; EMG – Electromyography

the study because of increased pain or discomfort (attrition rate = 0%). Thus, the ITT analysis was not possible.

Finally, the importance of continuing the rehearsals at home was explained to all participants. They were assured that they could contact the therapist even after the 3-month follow-up if they had any questions and concerns.

### Sample size based on pilot study

The sample size for the main clinical trial was determined based on the clinical variables (VAS score for pain intensity, walking speed as measured by 10-meters fast walking test, KOOS Scores for the pain, symptoms, activities of daily living (ADL) function, QOL subclasses) and EMG-findings (rectus femoris activity in the feedback phase, in stance phase of gait). Other EMG data were not used for sample size estimation because they were reported for only on one group. Considering the age and the self-report level of physical activity of the eligible individuals, the sport activity subclass of the KOOS questionnaire was not considered in sample size estimation and in the target randomized controlled trial (RCT) outcomes. As a 3-month follow-up period was considered in the final RCT, to justify the durability of the clinical effects of the interventions, follow-up data for either group were used for calculating the sample size.

The formula for determining the sample size, considering the quantitative nature of the dependent variables in the study and the existence of two independent groups, was as follow (*Electromyographic data will be analyzed in each group in the final study):

$$n = \left[ \frac{\left( z_{1-\alpha/2} + z_{1-\beta} \right)^2 (\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2} \right]$$

**Table 4: The clinical, and electromyography -feedback records after 3-months follow up**

| Data type | Variable | Group | Baseline | After 3-month follow-up | Mean change (standard mean change %) |
|---|---|---|---|---|---|
| Clinical | Pain intensity (%) | Against-group | 70.00±18.70 | 20.00±20.00 | −50.00 (71.43) |
| | | Pro-group | 62.00±14.80 | 2.00±4.47 | −60.00 (96.80) |
| | Average fast walking speed (m/s) | Against-group | 1.05±0.30 | 1.11±0.30 | +0.06 (5.71) |
| | | Pro-group | 1.28±0.10 | 1.41±0.12 | +0.13 (10.16) |
| | KOOS pain (%) | Against-group | 39.41±13.80 | 72.20±10.36 | +32.79 (83.20) |
| | | Pro-group | 41.10±6.30 | 82.74±9.51 | +41.64 (101.30) |
| | KOOS symptoms (%) | Against-group | 45.70±12.00 | 67.86±13.34 | +22.16 (48.49) |
| | | Pro-group | 50.00±8.00 | 83.52±12.02 | +33.52 (67.04) |
| | KOOS ADL (%) | Against-group | 48.20±14.61 | 76.97±10.06 | +28.77 (59.69) |
| | | Pro-group | 52.70±9.10 | 86.63±6.42 | +33.93 (64.38) |
| | KOOS QOL (%) | Against-group | 23.75±8.15 | 45.00±2.80 | +21.25 (89.47) |
| | | Pro-group | 24.97±10.85 | 61.28±15.00 | +36.31 (145.41) |
| EMG amplitude | Rectus femoris | Against-group | 0.38±0.14 | 0.51±0.08 | +0.13 (34.21) |
| | | Pro-group | 0.34±0.05 | 0.35±0.05 | +0.01 (2.94) |
| | Vastus lateralis | Against-group | 0.55±0.09 | 0.58±0.11 | +0.03 (5.45) |
| | Vastus medialis | | 0.51±0.08 | 0.46±0.09 | −0.05 (9.80) |
| | Gluteus maximus | Pro-group | 0.49±0.17 | 0.50±0.16 | +0.01 (2.04) |
| | Gastrocnemius (medial head) | | 0.35±0.06 | 0.36±0.06 | +0.01 (2.86) |
| | Gastrocnemius (lateral head) | | 0.42±0.05 | 0.44±0.10 | +0.02 (4.76) |

KOOS – Knee injury and osteoarthritis outcome score; ADL – Activity of daily living; QOL – Quality of life; EMG – Electromyography

**Table 5: Comparing the records clinical, and electromyography -feedback parameters after 10 sessions and after 3-months follow up**

| Data type | Variable | Group | After $10^{th}$ session | After 3-month follow-up | Mean change (standard mean change %) |
|---|---|---|---|---|---|
| Clinical | Pain intensity (%) | Against-group | 26.00±23.02 | 20.00±20.00 | −6.00 (23.08) |
| | | Pro-group | 22.00±8.37 | 2.00±4.47 | −20.00 (90.91) |
| | Average fast walking speed (m/s) | Against-group | 1.23±0.33 | 1.11±0.30 | −0.12 (9.76) |
| | | Pro-group | 1.55±0.14 | 1.41±0.12 | −0.14 (9.03) |
| | KOOS pain (%) | Against-group | 67.78±11.04 | 72.20±10.36 | −4.42 (6.52) |
| | | Pro-group | 74.42±5.34 | 82.74±9.51 | +8.32 (11.18) |
| | KOOS symptoms (%) | Against-group | 70.00±11.47 | 67.86±13.34 | −2.14 (3.06) |
| | | Pro-group | 82.80±6.77 | 83.52±12.02 | +0.72 (0.87) |
| | KOOS ADL (%) | Against-group | 71.16±8.11 | 76.97±10.06 | +5.81 (8.16) |
| | | Pro-group | 78.52±8.73 | 86.63±6.42 | +8.11 (10.33) |
| | KOOS QOL (%) | Against-group | 43.75±0.00 | 45.00±2.80 | +1.25 (2.86) |
| | | Pro-group | 45.00±10.27 | 61.28±15.00 | +16.28 (36.18) |
| EMG amplitude | Rectus femoris | Against-group | 0.50±0.09 | 0.51±0.08 | +0.01 (2.00) |
| | | Pro-group | 0.30±0.09 | 0.35±0.05 | +0.05 (16.67) |
| | Vastus lateralis | Against-group | 0.61±0.01 | 0.58±0.11 | −0.03 (4.92) |
| | Vastus medialis | | 0.44±0.11 | 0.46±0.09 | +0.02 (4.55) |
| | Gluteus maximus | Pro-group | 0.34±0.16 | 0.50±0.16 | +0.16 (47.06) |
| | Gastrocnemius (medial head) | | 0.47±0.12 | 0.36±0.06 | −0.11 (23.40) |
| | Gastrocnemius (lateral head) | | 0.53±0.06 | 0.44±0.10 | −0.09 (16.98) |

KOOS – Knee injury and osteoarthritis outcome score; ADL – Activity of daily living; QOL – Quality of life; EMG – Electromyography

Equation 1: Sample size estimation formulae

Assuming a

- Type I error of $\alpha$ =0.05,
- Type II error of $\beta$ =0.2,
- $\mu_1$ = mean of Against-group,
- $\mu_2$ = mean of Pro-group
- $\sigma_1$ = standard deviation values for the pain and function variables of against-group
- $\sigma_2$ = standard deviation values for the pain and function variables of Pro-group

The actual power of the pilot study and the sample size estimated based on a two-tailed *t*-test with $\alpha$ =0.05, and $\beta$ =0.8 for each variable is summarized in Table 6:

*Estimated with $\beta$ =0.8

As the largest estimated sample size was 14 participants per group, the total sample size, for a study of reliable power, will be 30, with the probability of one dropout for either group.

## Discussion

This pilot study aimed to test the feasibility, adherence, retention rates, and acceptability of performing gait training with neuromuscular strengthening exercises using a biofeedback in people with KOA. We sought to examine the neuromuscular training during gait to correct the neuromuscular pattern. Neuromuscular training is widely used in therapeutic exercise for KOA.[30,32,42] We have taken advantage of the unique features of this approach and applied biofeedback for neuromuscular training. Finding approved the feasibility and clinical potential of the proposed paradigms to improve clinical, functional, and EMG records of the participants in the long term (3 months). EMG-Biofeedback-based neuromuscular training during gait, in particular, training the muscles that indirectly collaborate in knee extension, is one of the innovations of the present study.

### Clinical date

After one treatment session, pain in the against-group showed a slight increase, while it decreased in the pro-group. The increase in pain in the against-group could be due to inevitable increase in Quadriceps muscle activatiy; increased activity of the Quadriceps, which is weak and inhibited due to pain, may increase the load imposed to the joint and pain.[18,56] On the other hand, pre-test evaluation followed by an intervention session might caused fatigue, that gradually diminished over further sessions.[57] However, since both groups experienced practically similar conditions, the first explanation seems more plausible.

Meanwhile, the average walking speed decreased in both groups, with greater changes observed in the pro-group. Since KOA management essentially focuses on activating quadriceps,[25-27] the learning process for increasing quadriceps activity seems to be more comprehensible compared to that of gastrocnemius and gluteus maximusdevoting more energy during walking. Conversely, the increasing activity of the gastrocnemius and gluteus maximus was less perceptible to the participants. Besides the learning challenge, probably conscious utilizing gastrocnemius and Gluteus Maximus during walking posed an extra challenge, which contributed to a greater reduction in walking speed in the pro-group compared to the against-group.

Pain decreased in both groups after ten treatment sessions, with a slightly greater reduction in the pro-group. Although the baseline pain intensity was less intense in pro-group, still the more pronounce effect of pro-group biofeedback training in reducing pain is of clinical value.

Furthermore, the results showed positive changes in other variables in both groups; average walking speed, knee pain, symptoms, ADL, and QoL, as assessed by the KOOS questionnaire, improved in both groups, with the pro-group showing greater changes.

The improvement of symptoms in the against-group supports our hypothesis that proper quadriceps neuromuscular strengthening training help eliminating muscle inhibition. Management of quadriceps inhibition during challenging tasks, such as gait, can potentially modulate knee joint loads, reduce pain, and improve other symptoms over time. On the other hand, the changes reported in the pro-group provide valuable preliminary evidence supporting the positive clinical consequences of activation of the gastrocnemius and gluteus maximus over ten sessions. According to the reported changes and biomechanical principles,[24] these muscles indirectly assist the Quadriceps and contribute to modulating knee joint loads through their extensor roles.[8,22] However, this hypothesis requires further investigation with larger sample sizes and EMG analysis.

The long-term results of neuromuscular training after 3-month follow-up have critical value for clinical practice. The of changes remained positive as evidence of, the long-lasting improvement for all variables in both groups

**Table 6: Power analysis and sample size estimation**

| Variable | $\mu_1$ | $\mu_2$ | $SD_1$ | $SD_2$ | Actual power | Sample size* |
|---|---|---|---|---|---|---|
| Pain intensity (%) | 20.00 | 2.00 | 20.00 | 4.47 | 0.41 | 12 (total=24) |
| Average fast walking speed (m/s) | 1.12 | 1.41 | 0.30 | 0.12 | 0.45 | 11 (total=22) |
| KOOS pain (%) | 72.20 | 82.74 | 10.36 | 9.51 | 0.32 | 14 (total=28) |
| KOOS symptoms (%) | 67.86 | 83.52 | 13.34 | 12.02 | 0.32 | 12 (total=24) |
| KOOS ADL (%) | 76.97 | 86.63 | 10.06 | 6.42 | 0.36 | 14 (total=28) |
| KOOS QOL (%) | 45.00 | 61.28 | 2.80 | 15.00 | 0.55 | 14 (total=28) |
| Rectus femoris amplitude | 0.51 | 0.35 | 0.08 | 0.05 | 0.91 | 6 (total=12) |

*Estimated based on $\beta$=0.8. KOOS – Knee injury and osteoarthritis outcome score; ADL – Activity of daily living; QOL – Quality of life; SD – Standard deviation

after 3 months. The trend continued toward greater improvement for all variables except for the average walking speed, which, although increased compared to baseline, slightly decreased compared to "after ten sessions" record; the records for Pro-group were even almost 100% better than the baseline. Thus, although both biofeedback approaches appear to successfully improve clinical reports for individuals with KOA, the pro-group seems to experience greater changes.

According to our knowledge, this is the first study aimed at neuromuscular training with EMG-biofeedback during gait in people with KOA. For the first time ever, weinduced higher activity of muscles that are not directly involved in knee extension during gait. The emphasis of this study was on the participant's active collaboration during therapeutic exercise and momentary muscle activation during the dynamic gait task.

### Electromyography findings

Muscle activation during the stance phase of gait (feedback phase), decreased in all muscles in both groups, immediately after the first session. The finding suggests the possibility of fatigue induced by limited experience performing the requested tasks. Fatigue may be particularly relevant with aging, as middle-aged individuals often experience sarcopenia which is associated with weakness and loss of muscle mass;[58] the combination of pre- and post-treatment assessment sessions and a full treatment session of gait retraining exercises in between, could contribute to fatigue in participants leading to a reduction in the magnitude of muscle activity; given the fixed structure of the exercise therapy components, fatigue effects are likely to diminish over time as treatment sessions progress.[57]

After ten sessions, the against group showed a relative increase vastus lateralis activity and a relative more profound decrease in vastus medialis activity. This pattern favors load distribution toward the lateral aspect of the articular surface and reduces load on the medial side, which may partially mitigate cartilage degeneration on the joint's medial compartment.[12,15,59]

Considering the increased rectus femoris activity in the against-group, after ten sessions and 3 months follow up, neuromuscular training with biofeedback appears effective in improving neuromuscular pattern of the rectus femoris during gait; This training may help the quadriceps function as a shock absorber to modulate the loads on the knee joint.[18]

A significant increase in Gastrocnemius activity in the pro-group, accompanied by a decrease in Quadriceps activity after ten sessions, suggests that the study achieved its objectives of activating secondary knee extensor muscles,[24] without markedly engaging the primary extensors. However, Gluteus Maximus activity unexpectedly decreased after ten sessions. A plausible explanation is that the gluteus Maximus behaves as a phasic muscle, predisposed to inhibition and fatigue.[60] This fatigue could have been exacerbated by the walking component, which lasted twice longer in the pro-group than that in the against-group. To justify this finding, we recommend measuring the changes in gluteus maximus activity in a separate assessment session that isolates measurement from the exercise and treatment session.

According to the EMG results at the study after a 3-month follow-up, ten treatment sessions appear insufficient to retrain most muscles using neuromuscular training with biofeedback with the notable exception of the quadriceps. A continued follow up during the posttreatment period, potentially through tele-rehabilitation with regular, short weekly intervals, may be beneficial to sustain or enhance neuromuscular gains.

Our preliminary finding confirmed our basic hypothesis: apparently, in people with KOA who suffer from Quadriceps weakness, the neuromuscular training of muscles that indirectly help in knee joint extension may improve knee joint pain and function. The biofeedback-training sessions for correcting the neuromuscular pattern of participant' walking were set after the routine physical therapy sessions to implement dynamic neuromuscular training in this pilot study. One of the challenges of the present study was increasing the activity of the gastrocnemius and gluteus Maximus during gait, which is a dynamic and momentary activity and imposes considerable cognitive load because of the need for concentration. The clinical data indicate that the treatment had positive effects; however, the EMG evidences need to be also discussed and analyzed in more detail.

The feedback from participants in both groups was positive. The clinical findings supported the immediate and long-term clinical value of both neuromuscular training approaches with more satisfactory results for the gastrocnemius and gluteus maximus biofeedback training; However, based on the clinical findings, larger sample size and more detailed follow-up seem to be needed to examine the long-term effects. Thus, a statistically powerful study with at least 30 participants (15 in either group) is strongly recommended to get scientifically trustworthy results. Based on the results of that study, application of neuromuscular training during gait, the target muscle group with higher potential of reaching clinically impactful results and better understanding of implication approaches will be possible.

## Conclusion

In individuals with KOA, neuromuscular training based on EMG-biofeedback targeting the quadriceps, gastrocnemius, and gluteus maximus muscles is feasible during gait and yields clinically similar improvement of pain and function, with slightly greater changes toward improvement in the Pro-group. An accurate explanation of the differential effects and the mechanism by which training of Gastrocnemius and Gluteus Maximus may confer enhanced benefits will require a clinical trial an appropriately powered sample size.

## Ethical approval

The study is a preliminary report of a project ethically approved by the Student Research Committee of Shahid Beheshti University of Medical Sciences (IR.SBMU.RETECH.REC.1402.375, Approved in October 22, 2023); the protocol was prospectively registered under the Iranian registry for Randomized Controlled Trials on November 30, 2023 (IRCT20231024059846N1).

## Availability of data and materials

The data will be available upon formal request in the case of approval by the vice head of research, Shahid Beheshti University of Medical Sciences.

## Financial support and sponsorship

Nil.

## Conflicts of interest

There are no conflicts of interest.

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