

The Effects of Challenging Walking Conditions on Kinematic Synergy and Stability of Gait in People with Knee Osteoarthritis: A Study Protocol

Abstract

Background: Knee osteoarthritis (KOA) may considerably change the gait parameters, including the gait variability patterns. Uncontrolled manifold (UCM) analysis has been used to evaluate the relationship between motor control and gait variability as a useful index for assessing the multi-segmental movements' coordination during walking. To our knowledge, no research has evaluated the alterations in the gait kinematic parameters during normal and narrow path walking in individuals with KOA as compared to asymptomatic people. **Materials and Methods:** In this cross-sectional study, individuals diagnosed with mild to moderate medial KOA and asymptomatic people will walk at their comfortable preferred speed on a treadmill. A motion capture system will be used to record at least 50 successful gait cycles. The kinematic variability of joints during gait will be analyzed using UCM, with the center of mass (COM) displacement considered as the performance variable. The primary outcome measure will be the lower limb synergy index. Variability of the COM displacement and changes in angles and angular velocities of lower extremity joints will be assessed as the secondary outcomes. **Results:** The results of this protocol study provide information on the lower limb kinematic synergy during gait on normal and narrow paths for individuals with KOA and asymptomatic controls. **Conclusion:** This information will help the researchers and clinicians understand KOA patients' gait variability characteristics more deeply. Moreover, it may lead to an enhanced evidence-based approach for clinical decision-making concerning improving gait stability and decreasing the falling risk in these people.

Keywords: Center of mass, gait, kinematic synergy, knee osteoarthritis, uncontrolled manifold

Introduction

Knee osteoarthritis (KOA) is one of the most common musculoskeletal disorders, which results in pain, abnormal joint loading, instability, and impaired gait pattern.^[1-3] Gait is stable by appropriate control of the position of the body's center of mass (COM) relative to the support surface that does not lead to falling.^[4,5] Any perturbation to the COM that affects the mechanical state of the stance limb can disturb the gait stability maintenance.^[6,7] In general, walking in the frontal plane is mechanically less stable than the sagittal plane, causing the mediolateral (ML) instability to be more dominant than anteroposterior.^[5,8] ML instability has a critical role in gait performance and is considered a major risk factor for falls in the elderly. Given the fact that the narrow base walking increases demand on frontal plane balance, it is usually used to evaluate ML stability.^[9,10]

Change in gait stability is often evaluated in terms of variability. Although some variability in walking is normal, the patterns of gait variability observed in people with KOA are different,^[11] because many neuromuscular factors that help to control the COM and foot placement are degenerated by aging.^[6] Alteration of variability compared to normal indicates that the central nervous system (CNS) contributes to variable gait to maintain a stable COM.^[11] The uncontrolled manifold (UCM) analysis is a useful index for assessing the coordination of multi-segmental movements during the gait, which has recently been used to evaluate the relationship between motor control and gait variability.^[11-14] This analysis evaluates all combinations of motor elements (elemental variables [EV]) produced by the motor system that leads to performance variables (PV).^[3] Based on the UCM, variability is divided into two variance components. One component

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is good variance, implying the variances within the UCM (V_{UCM}), which does not affect the PV. The other component, i.e., bad variance, represents the variances orthogonal to the UCM (V_{ORT}) that deteriorate the PV. If the value of V_{UCM} is identified to be more than V_{ORT} , it is concluded that the performance variable is stabilized by synergy.^[14,15]

The presence of a kinematic synergy in the frontal and sagittal planes has previously been investigated in individuals with end stages of KOA.^[11] It has been shown that KOA, which mainly affects the elderly, causes problems especially ML instability and an increased risk of falling.^[10] Therefore, analysis of synergies can provide a better understanding of motor coordination and its relationship with rehabilitation approaches of these individuals.^[12] Considering the changes in the walking step width in KOA people and the effect of COM displacement on the ML stability of gait, comparing the kinematic changes during normal and narrow path walking may clarify how motor variability controls the COM displacement. Previously, narrow gait has been shown to reduce the first peak of external knee adduction moment only on the nondominant limb in healthy adults. Although narrow gait might be useful in reducing medial compartment loading, the consequence of this strategy on the balance and fall risk, as well as its effectiveness in improving the gait pattern of people suffering from KOA is not well understood.^[16] To the best of our knowledge, the previous studies have often investigated the kinematics of the elderly on narrow pathway walking, and no study has addressed this issue in individuals with KOA.

Moreover, the previous findings indicate increased compensatory mechanisms, following worsening severity of KOA, due to the increased pain and disability, decreased neuromuscular control, as well as changes in the biomechanical alignment.^[17] However, such behaviors have not been studied in those with mild-to-moderate KOA, which is the main focus of the rehabilitation and gait retraining programs to prevent surgery. On the other hand, it is not clear whether the changes in motor variances will lead to changes in these people's synergy index due to alteration of the control of the COM displacement while walking on a narrow path compared to a normal path. Walking on the narrow path needs tight COM control, leading to changes in COM variability and metabolic costs.^[18,19] The effectiveness of this walking for KOA patients is unknown and should be examined. Unlike traditional measures, the UCM method can explain the origin of gait variability and help understand the functional roles of gait variability in various task conditions. Since the UCM method examines the available degrees of freedom to perform a task, it can help detect and characterize the changes of the kinematic synergy in individuals with KOA during walking on normal and narrow paths. Increasing knowledge about the

relationship between gait variability and control of COM displacement in KOA patients may enable us to explore the possibility of using the UCM method as a biomarker for gait stability. The current study protocol describes the rationale, the design, and the methods of the UCM and the test procedures for individuals with mild to moderate KOA and asymptomatic participants.

Study aims and hypothesis

The primary objective is to determine and compare the lower limb synergy index during walking on normal and narrow pathways between individuals with KOA and asymptomatic controls. The secondary objectives are to determine and compare the COM displacement variability, angles, and angular velocities of the lower extremity joints during walking in two conditions between the two groups of participants. We hypothesized that (1) the synergy index is significantly different in KOA and asymptomatic people during normal and narrow path walking, (2) the variability of the COM displacement, as well as that of the lower extremity joints angles, and angular velocities are significantly different in KOA and asymptomatic people during walking on normal and narrow paths.

Materials and Methods

Study design

A between- and within-subject cross-sectional analytical study is designed to evaluate and compare the synergy index and the variability of the kinematic parameters of lower extremities and COM displacement during gait on normal and narrow paths on the treadmill in individuals with KOA and asymptomatic controls.

Study setting

The study will be conducted in the Musculoskeletal Research Center at Isfahan University of Medical Sciences.

Approval of study protocol

The study protocol was approved by the Ethics Committee at Iran University of Medical Sciences (Reference number: IR.IUMS.REC.1399.440).

Informed consent

All eligible participants will be informed about the study procedure and sign a consent form prior to participation.

Trial status

At the time of submitting this study protocol, data collection is ongoing.

Participants

As medial KOA is more common than lateral KOA and considering the differences of kinematics and momentum between medial and lateral KOA,^[20,21] individuals diagnosed with bilateral medial knee OA and asymptomatic

people aged 40–65 years will be recruited for this study. The KOA group whose symptoms are consistent with the criteria of the American College of Rheumatology (knee pain in the last 3 months, joint crepitation, and morning stiffness lasting less than 30 min) will be selected for this study.^[22] In addition, recent radiographic evidence of the tibiofemoral KOA, according to the atlas of the Osteoarthritis Research Society International, will be used as diagnostic criteria (osteophyte and narrowing of joint space in the medial side of the knee joint) based on the Kellgren-Lawrence (K-L) scale.^[23] Asymptomatic people who do not have radiological and clinical symptoms of KOA will participate in this study as a control group.

The inclusion criteria for the KOA group are:

- People with radiological signs of medial KOA according to K-L scale for mild to moderate severities/pain and tenderness in the medial side of the knee joint (minimum intensity of 3 based on the Visual Analog Scale [VAS]), while being able to stand and walk at least 200 meters without the use of assistive devices.

The inclusion criteria for the control group are:

- Absence of radiological and clinical signs and symptoms for osteoarthritis.

The exclusion criteria for both groups are:

Obesity with body mass index (BMI) >30 kg/m², the most knee varus based on the Moreland method in radiographic images ($\geq 6^\circ$ varus), previous knee injury or surgery over the last 6 months/prior arthroplasty in any joints of lower extremity/fracture of the spine and either lower extremity joints in the last 6 months/any inflammatory arthritis/congenital or acquired musculoskeletal disorders in the low back and lower extremities (i.e., lateral tibiofemoral OA, patellofemoral OA, ligamentous and meniscal injuries, etc.), self-reported joint instability (giving way, shifting, etc.), intraarticular steroid injection within the last 6 months/any neurological disorder (i.e. stroke, Parkinson, and Guillain – Barre syndrome, etc.)/cardiovascular disease as uncontrolled hypertension that can affect patient's gait, especially on the treadmill/visual and vestibular disorders/use of assistive devices. People who are unable to complete treadmill-walking tests (dizziness, cardiovascular disorders, limping, etc.) will also be excluded.

Sample size

Participants will be recruited in the study by the nonprobability convenient sampling. Fisher's z-transformation was used to calculate the sample size using G-Power software (G*power 3.1.2; Franz Faul, University of Kiel, Kiel, Germany).^[24] Based on the F test and considering the effect size of 0.325 from the pilot test, $\alpha = 0.05$ and power $(1-\beta) = 0.80$, a minimum of 22 participants are needed. Accounting for 10% drop-out, the total number of participants required is 24 (12 participants in each group).

Procedures

An expert examiner, skilled in evaluating and determining the severity of OA, will carefully screen participants. All participants in the knee OA group will have bilateral radiological signs and clinical symptoms. In this case, the more severe limb will be considered, and if the severity of the sign and symptoms is similar, the dominant limb of the participants will be the criterion.

Asymptomatic individuals will be matched in terms of age, gender, BMI, and physical activity with the KOA group. All participants will complete a demographic form at the baseline assessment. The participants' pain intensity on the day of the test and the average in the last week will be examined using a Visual Analog Scale. To determine the level of physical activity of the participants in both groups, the Persian version of the International Physical Activity Questionnaire (IPAQ) will be used.^[25]

During tests, the 3D kinematic data will be recorded using a motion analysis system with an array of seven high-speed infrared cameras (Qualisys Motion Capture System, Gothenburg, Sweden). Twenty passive reflective markers of 14 mm diameter will be attached to the body according to the preferred method of marker fixation described by the Bioengineering Unit of Strathclyde University [Figure 1].^[26] The data will be sampled at a frequency of 100 Hz.^[6] The parameters obtained from gait analysis are used to answer the objectives raised in this study protocol.

Before the main tests, each participant will walk for at least 1 min on the treadmill (Kettler, Ense-Parsit, Germany) to be familiarized with the test procedure. The examiner uses the same trial to identify the preferred walking speed of the participant. Participants will be asked to walk at a natural pace along the walkway over the ground to determine the preferred speed. The speed will be calculated by dividing the distance walked by the averaged durations of three trials. The calculated speed in m/s will then be converted to units of km/h to be used for treadmill walking.^[27]

The narrow path will be outlined by retroreflective tape on the treadmill belt, and participants will be instructed to walk within the taped path. The narrow path width will be limited to 50% of the distance between the participant's anterior superior iliac spines.^[9,28] Participants are then asked to walk barefoot 3 times at their comfortable preferred speed for each of the two conditions of walking on normal and narrow paths in the calibrated space on the treadmill, and the results are reported as averages. Only the correct narrow conditions to be confirmed by visual inspection, where participants remain within the taped boundaries, will be used for analysis.^[16] According to previous studies, at least 16 and 50 steps are required to obtain a reasonable and appropriate approximation of the synergistic index and variance components, respectively.^[29] Therefore, the participants will walk for 2 min along the walking path to collect at least

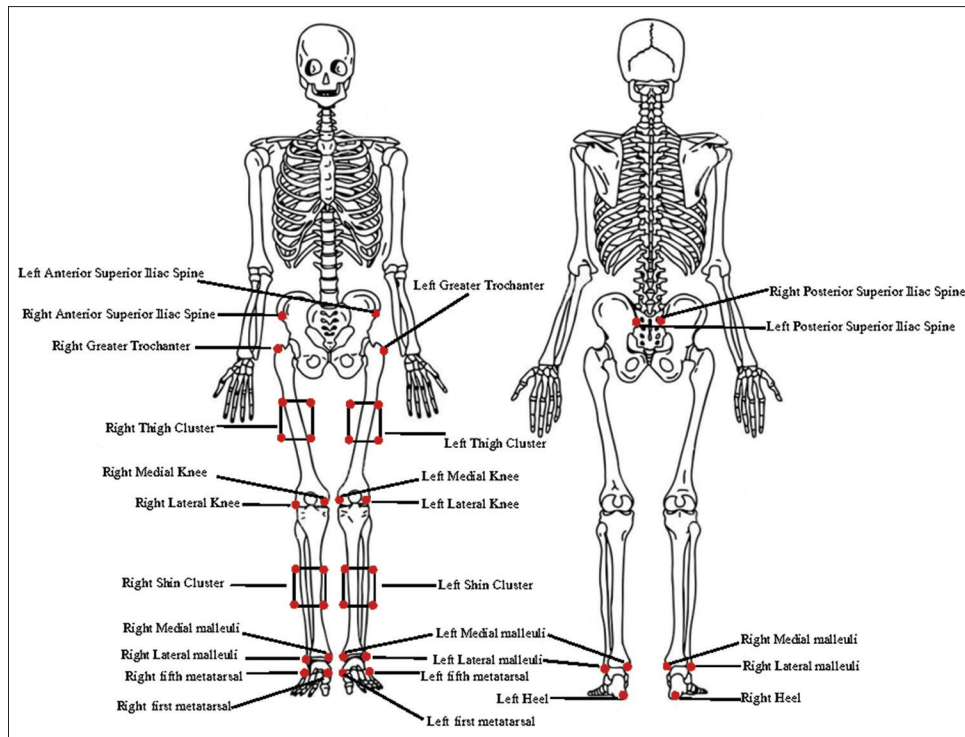


Figure 1: The location of the markers will be used in this study

50 successful consecutive walking cycles in each trial. To minimize the learning effect, the conditions will be presented in random order, and a 2-min rest will be considered between the trials to minimize the fatigue effects.^[11]

Outcome measures

The data obtained from the markers' position will be used to calculate the outcome measures of the present study, namely the kinematic and synergy parameters. Kinematic variables include angular velocity and angles (range of motion) of each lower extremity joint, whereas kinematic synergy includes the synergy index and the COM displacement variability. All calculations will be done by the codes written in a custom-written MATLAB software (Version R2017b, MathWorks, Natick, MA, USA). Pain intensity and physical activity will also be examined in this study using the VAS and IPAQ questionnaire, respectively. VAS includes a 100- mm horizontal line, where 0 mm indicates the absence of pain and 100 mm indicates the maximum pain the patient can imagine.^[30] For monitoring and determining the physical activity level, the IPAQ questionnaire will be used.^[25] A summary of all data acquired in this study is provided in Table 1.

Kinematic synergy evaluation using uncontrolled manifold analysis

In the present study, the COM displacement will be considered as the performance variable and the joint angles in the frontal and sagittal planes as the EV. Moreover, UCM analysis will be conducted for the sagittal and frontal

planes. Initially, a geometric model of the performance variable comprised of the lower limb segments, i.e., the thighs, legs, feet, and pelvis, will be created. Then, a linear approximation of the geometric model of the performance variable will be obtained in the mean segmental configuration for each of the sagittal and frontal planes. This approximation is calculated using the Jacobian (J) matrix during gait cycles. The null space of the J matrix defines a linear UCM. The null space has n-d vectors, where $n = 4$ in the sagittal plane and $n = 8$ in the frontal plane is the number of dimensions in the segmental configuration space and $d = 2$ represents the number of dimensions of the performance variable. Good variance ($\parallel UCM = V_{UCM}$) and bad variance ($\perp UCM = V_{ORT}$) will be calculated using the following formulas.^[3,13,14]

$$\parallel \Theta = \sum_{i=1}^{n-d} (e_i^T (\theta - \bar{\theta})) e_i$$

$$\parallel \Theta = (\theta - \bar{\theta}) - \parallel \Theta$$

$$\parallel UCM = \sqrt{(n-d)^{-1} N^{-1} \sum (\parallel \Theta)^2}$$

$$\perp UCM = \sqrt{d^{-1} N^{-1} \sum (\perp \Theta)^2}$$

Where N is the number of repetitions, and $\theta - \bar{\theta}$ is the deviation of the segmental angles from the mean segmental configuration per repetition. The synergy strength will be calculated using the following formula based on the synergy index:^[3,13,31,32]

$$\Delta V = \frac{V_{UCM} - V_{ORT}}{V_{TOT}}$$

Table 1: Schedule of assessment and outcome measures

Variable	Study aim/outcome	Assessment
Pain	Outcome	VAS
Physical activity level	Outcome	IPAQ Questionnaire
Synergy index	Primary aim/outcome	Gait analysis/UCM method
COM displacement variability	Secondary aim/outcome	Gait analysis/UCM method
Angular velocity	Secondary aim/outcome	Gait analysis
Joint angles	Secondary aim/outcome	Gait analysis

COM: Center of mass, VAS: Visual Analog Scale, IPAQ: International Physical Activity Questionnaire, UCM: Uncontrolled manifold

The more positive ΔV indicates a stronger synergy, while Non-positive values suggest the absence of synergy. For statistical analysis, we will be modified ΔV using Fisher's z-transformation (ΔVz):^[33]

$$\Delta Vz = \frac{1}{2} \log \left[\frac{(n+d) + \Delta V}{\frac{n+d}{n-d} - \Delta V} \right]$$

Statistical analysis

The data will be analyzed using SPSS software (SPSS 20, IBM Corp., Armonk, NY, USA) at a statistical significance level of 0.05. The Shapiro-Wilk test will determine the normal distribution of data. If the data distribution would be normally distributed, the parametric tests will be used for within-group and between-group analysis. To test the existence of kinematic synergy during both conditions, a separate 2×2 analysis of variance (ANOVA) with variance components (VUCM and VORT) as the within-subjects factors and the group as the between-subjects factor will be performed. The same ANOVA analysis will be used to test the effects of group \times condition for each of the variance components (VUCM and VORT) in both sagittal and frontal planes.

Results

The demographic characteristics of participants in the study groups will be provided. According to the outcomes, this study's results will be reported and illustrated in related tables and figures. Figure 2 shows the process followed in this study, as indicated by the consort flow diagram.

Discussion

This study will analyze and compare the gait kinematic synergy during normal and narrow path walking in knee osteoarthritic and asymptomatic individuals. The results of this study would be helpful for researchers and clinicians in choosing the appropriate treatment method in patients with KOA.

Controlling COM movements through stance leg will lead to gait stability.^[5] COM stability is related to the EV' ability to maintain a stable mean COM position during multiple trials, despite the variability between trials. If

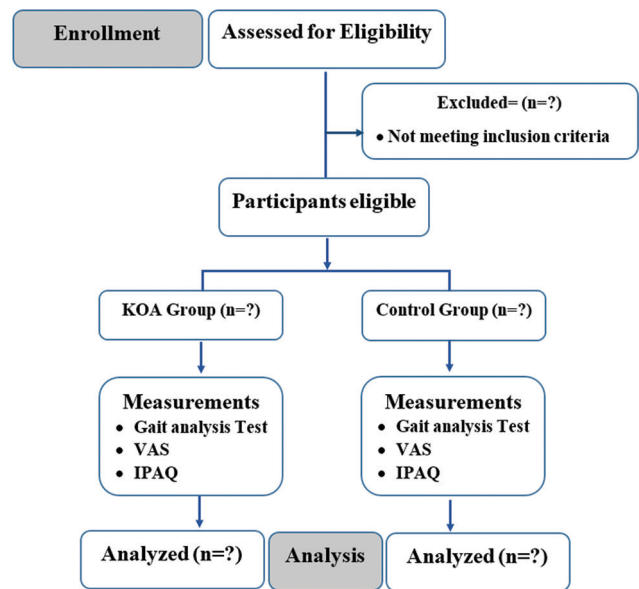


Figure 2: Consort flow diagram. KOA: Knee osteoarthritis, VAS: Visual Analog Scale, IPAQ: International Physical Activity Questionnaire

changes in the EV cause the COM to deviate from its mean position, the COM's stability is compromised.^[11] Therefore, it is important to understand how the CNS organizes the joint angles as EV to establish smooth movements in the COM as the performance variable in order to provide safe and secure locomotion. Investigating COM variability using UCM analysis can be a useful index for assessing the multi-segmental movements' coordination while walking.^[14] A few studies have analyzed the gait kinematic synergy in healthy or people with musculoskeletal disorders using the UCM approach. They have provided evidence for maintaining kinematic synergy during lateral trunk lean gait or in people with end-stage KOA during normal gait, using the UCM approach.^[3,11] Therefore, this method might be a capable clinical approach for effective evaluation and gait retraining in KOA patients. While utilizing good variability may affect the control of the COM displacement and improve the stability of gait patterns.^[3] However, the effects of mild to moderate KOA on the COM variability and the synergy index remain unknown. This study investigates these parameters by comparing the gait variability patterns of mild to moderate KOA individuals and healthy control populations while walking on normal and narrow paths.

Studying the gait pattern changes is of great importance for understanding musculoskeletal disorders and improving the quality of treatment. Analyzing the lower extremity's kinematic synergy can help identify impaired gait pattern components and determine the synergy indices. Based on the UCM approach, variability in the movement patterns is necessary to perform daily functional tasks in various environmental contexts. However, the variability pattern contains valuable information for understanding the postural control mechanisms during walking and assessing the rehabilitation intervention.^[12]

Conclusion

In particular, the UCM results can help characterize the effects of rehabilitation treatments, which is of great importance in designing cohort or interventional studies for KOA individuals; any increase in the good variance indicates a promising improvement in the stability of gait patterns and reduction of the falling risk.

Strength and limitations of this study

There are some limitations in this study that need to be considered. First, previous studies have shown differences in some biomechanical parameters between gait over ground and treadmill.^[11] However, our proposed protocol measures the gait kinematics in treadmill walking, considering a large amount of space required to record 50 consecutive gait cycles to analyze the gait variability. Second, although all human body segments contribute to the walking task, we have not considered the effects of the trunk and upper limbs in our study. The main strength of our protocol, on the other hand, is that it performs the UCM analysis while walking on normal and narrow paths in both the sagittal and frontal planes. As a result, the findings are expected to understand the nature of the gait variability better. Moreover, in our study, the people in both the test and control groups will walk at their self-selected speeds. Given that motor variability is a part of the nature of biological systems, the walking pattern remains natural, and the UCM method can provide a good representation of the body's functional system.

Clinical relevance

- COM displacement variability may be different in KOA people
- Kinematic synergy results may help to clarify the gait variability characteristics
- UCM analysis may help to determine the effects of treatments.

Dissemination

Results of this protocol will be disseminated through the publication at research conferences and in peer-reviewed journals and will be included in a doctoral thesis. Participants and relevant research staff in the field will be informed about the study results.

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Conflicts of interest

There are no conflict of interest.

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