Is Kinesio Taping Effective for Knee Osteoarthritis? Randomised, Controlled, Double-blind Study

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ABSTRACT

Objective: To determine the effects of Kinesio taping on pain, functional performance, range of motion, and postural stability in patients with knee osteoarthritis.

Study Design: Randomised double-blind controlled trial.

Place and Duration of Study: Department of Physical Medicine and Rehabilitation, University of Health Sciences, Izmir Bozyaka Training and Research Hospital, Turkey, from November 2019 to October 2021.

Methodology: Fifty-seven patients with knee osteoarthritis (grade II or higher) according to the Kellgren-Lawrence classification received Kinesio tape or sham-Kinesio tape on the rectus femoris muscle three times a week. Patients were evaluated using the visual analogue scale (VAS), Western ontario and McMaster Universities Osteoarthritis Index (WOMAC), 50-meter walk time, range of motion (ROM), and postural stability index at baseline, 1st hour, 3rd week, 7th week. A mixed model analysis of repeated measures was used to test the effect of KT on outcome measures. Calculations were based on an intention-to-treat analysis.

Results: The only significant difference between groups was in the dynamic medio-lateral stability index [F (2.6,144.1)=3.83, p=0.015], indicating the inferiority of KT at week 3. There were differences within groups in 50-meter walking time and VAS at rest, which showed improvements over time in both groups. No significant difference was found between or within groups for other outcomes.

Conclusion: The KT intervention for three consecutive weeks showed no superiority over sham-KT in terms of pain intensity, knee-related health status, knee ROM, functional performance, and postural stability.

Key Words: *Kinesio taping, Knee osteoarthritis, Pain, Gait, Functions.*

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INTRODUCTION

Osteoarthritis (OA) is one of the most common musculoskeletal disorders. Kinesiotape (KT) has been considered a supplementary intervention for patients with knee OA. However, KT is only conditionally recommended for knee OA in the 2019 American College of Rheumatology (ACR) treatment recommendations because the quality of evidence is limited.[1]

KT is a conservative therapeutic intervention for the treatment of musculoskeletal disorders. However, studies on the effectiveness of KT show conflicting results, and only a small number of randomised controlled trials (RCTs) have been included in meta analyses.[2-7]

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In addition, the results were evaluated immediately after taping or within a short period of time.[4,5,8] The inconsistency of the study data further suggests that the efficacy of KT for knee OA should be investigated in further RCTs. Therefore, studies examining both short- and long-term outcomes are warranted.

Patients with knee OA have poorer postural stability than healthy controls.[9] It is an important challenge to improve postural stability in knee OA. To the authors' knowledge, there is only one study that addresses the effects of KT on postural control in patients with knee OA, using objective assessment methods and comparing it to a sham group.[4] One of the questions to be answered is the outcome of repeated KT interventions, including dynamic parameters of postural control.

The aim of this study was to investigate the immediate, short--term, and long-term effects of a single and repeated application of KT compared to sham-KT on pain, range of motion (ROM), postural stability and walking performance in patients with knee OA. It was aimed to evaluate the effect of KT on the static and dynamic components of postural stability and compare it with the sham group.

METHODOLOGY

A double-blind, sham-controlled study RCT was conducted at the University of Health Sciences Izmir Bozyaka Training and Research Hospital in Turkey, Department of Physical Medicine and Rehabilitation. Consecutive 57 female patients with knee OA were enrolled between November 2019 and October 2021.

The study was approved by the National Review Board and the Ethics Committee of the University of Health Sciences, Izmir Bozyaka Training and Research Hospital (Approval No. 2019/06; date 11/09/2019) and in accordance with the Declaration of Helsinki. All patients provided written informed consent. The identifier in ClinicalTrials.gov is NCT05351996.

In the pilot study consisting of 10 patients (5 patients in each group), the effect size of the group*time interaction for rest pain was 0.20 (partial eta squared). G*Power® (version 3.1.9.6) programme, ANOVA, repeated measures, within-between interaction test, were used to calculate the sample size. To detect a difference of this magnitude with a mixed analysis of variance with a power of 95% and a significance level of 0.05%, the total number of samples required was calculated as 56. Taking into account the loss of follow-up rate of 15%, the total sample size was set at 65.

An experienced specialist in physical medicine and rehabilitation performed the clinical examination and assessed the radiographs. To be eligible, subjects had to meet the clinical criteria for a diagnosis of knee OA according to the ACR diagnostic criteria and radiologically knee osteoarthritis (grade II or higher) according to the Kellgren-Lawrence classification.[10] The study included patients between 40 and 65 years of age who had been suffering from knee pain for at least three months, whose pain intensity within the last week was at least 3 on the visual analogue scale (VAS) at the symptomatic knee, and who were able to perform the Biodex Balance System tests (BBS). For cases with bilateral knee OA, only the most severely affected knee was evaluated and included in the intervention procedure. Skin disease or irritation, lesions in the area where the tapes were to be applied, intervention for knee pain within the past 6 months, inflammatory arthritis, pregnancy, previous knee or hip replacement surgery on the affected joint, patients with advanced degenerative radiographic changes (stage IV), and patients with diseases that could lead to balance disorders, loss of muscle strength in the lower extremities were excluded because of possible confounding effects disorders that could cause and previous experience with any KT method.

One of the investigators, who had no contact with the subjects, prepared the randomisation sequence with an allocation ratio of 1:1 and a block size of 6 and placed it in sealed opaque envelopes. Patients enrolled in the study received the next envelope and were referred to the interventionist. During the study, the physician who enrolled the patients, the patients, and the outcome assessor were blinded. The interventionist was aware of the study arms. During the 1st hour assessment, the assessor was blinded to the ROM examination because the patient was wearing loose clothing that did not interfere with joint motion. Both the KT group and the sham-KT group received three applications. The outcomes of all patients were assessed before (baseline - without tape) and in the first hour after the first KT session (1st hour - with tape), 1 week after the last taping session (3rd week - without tape), and 4 weeks after the last session (7th week - without tape) for a total of 4 times. CONSORT flowchart of the study procedure including the number of subjects is shown in Figure 1. Patients were instructed not to take any analgesics nonsteroidal anti-inflammatory agents during the study period.

Kinesio tape (Kinesio-Tex Tape) with a width of 5 cm and a thickness of 0.5 mm was used in both groups. KT was applied to the rectus femoris muscle using a Y-shaped facilitation technique.[11] The patient was placed in the supine with the hip flexed at 30° and the knee at 60°. The skin was cleansed with alcohol before the application of KT or sham-KT. Y-strip tape was used. The first 5 cm of the tape head was applied to the inferior iliac spine without stretching. It was taped to the superior patellar line with 25-50% tension. The Y-shaped strips were adhered to the tibial tuberosity, wrapping the medial and lateral edges of the patella with 25% tension, and the last 5 cm has adhered to the tibial tuberosity without stretching.[12] The view of the applied KT is shown in Figure 2a. In the Sham group, the KT was adhered to the rectus femoris without stretching, with the patient in the supine position but the knee extended. The view of the applied Sham-KT is shown in Figure 2b. The tapes were left in place for 6 consecutive days. Patients were instructed to remove the tapes 24 hours before the next session at home. Sham-KT was applied with the same frequency as in the KT group.

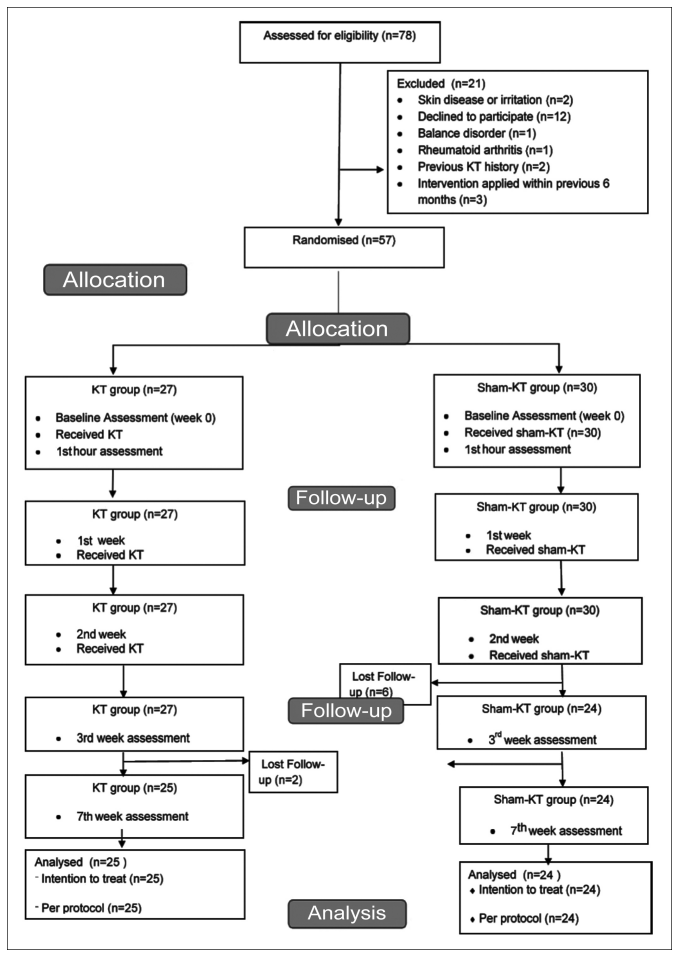

Figure 1: Flowchart of the study.

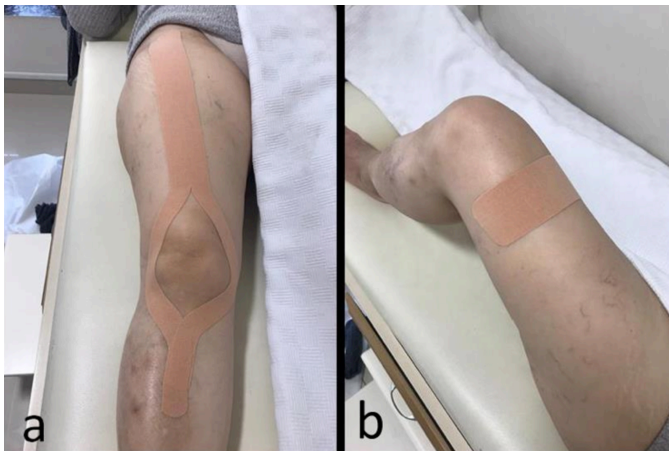

Figure 2: Kinesio tape applications. (a) Kinesio tape application. (b) Sham-kinesio tape application

All cases were taught an exercise program with individual exercises, and they were asked to perform it at home three days per week in three sets of 15 repetitions. The program was based on exercises to strengthen the quadriceps, knee flexors, and knee joint ROM. To increase adherence, patients were motivated during each KT intervention session and contacted by telephone once a week after completion of the KT program. The exercise program continued throughout the study.

All patients were assessed at each assessment time point in the following order: Pain intensity at rest, knee-related health status, pain-free knee joint ROM, postural stability, functional assessment, and pain intensity with activity while performing the functional assessment test.

Primary outcome measures included VAS_rest and VAS_activity during 50-meter walk. Secondary outcome measures included Western Ontario and McMaster Universities (WOMAC) OA index, pain-free knee joint ROM, 50-meter walk time, and Postural Stability Index (PSI) parameters.

Pain intensity was assessed using the VAS. Each patient was asked to indicate their pain at rest at each assessment time point (on a numerical pain rating scale of 0-10 points, with higher scores indicating severe pain).[13] Pain intensity during 50-meter walking was queried using VAS_activity.

To determine the baseline and degree of change in knee-related health status, the WOMAC scale was used. The scale consists of 24 items and is divided into three dimensions; pain, stiffness, and functionality. It is scored using a Likert scale of 0-4 points. Higher scores indicate worse pain, stiffness, and functionality.[14]

Active, pain-free knee range of motion (AROM) testing was performed as described by Clarkson *et al*. with a 360° double-arm universal goniometer.[15] For AROM-E, the assessor recorded the angle at which the patient extended the knee as far as possible. If the initial position of 0 degrees could not be achieved, the angle was assigned a negative value reflecting the lack of angle to full extension. Three assessments were performed, and the mean value was recorded as the active flexion and extension angle.

Patients' mobility was assessed by the 50-meter walk time. Subjects walked 2.5 round trips between two cones placed 10 m apart on a walking track. The patients stood next to the cone. They were instructed to walk to the other cone at a signal from the assessor, walk around it, and walk back as fast as possible. The time required for the task was recorded for scoring using the same chronometer.[16,17]

Quantitative measurement of patients' balance and postural stability was performed using BBS. The validity of BBS for assessing postural stability and its reliability in assessing changes in postural control have been reported previously.[18]

During the dynamic balance test, the platform moved simultaneously in the anteroposterior (AP) or mediolateral (ML) direction in 12 different stability levels (level 1 is the least stable, level and 12 is the most stable level within a 20-degree inclination range). The dynamic PSI (dPSI) represents the variance of displacement of the foot platform in degrees from the plane for all movements during the test. The static PSI (sPSI), on the other hand, reflected the angular displacement of the patient's centre of gravity when the platform is stationary. The dynamic balance test was performed for the duration of 20 seconds, stability level of 12, and stance position of two legs. For the static balance test, the platform was in the locked position.

For both the static and dynamic balance tests, three assessments were performed in each measurement session and an average of the three trials was calculated. The instrument provides three postural stability indices (PSI) obtained by calculating the standard deviations of the degrees of inclination for the zero point: overall static postural stability index (sPSI_O), static anteroposterior postural stability index (sPSI_AP), and static mediolateral postural stability index (sPSI_ML); overall dynamic postural stability index (dPSI_O), dynamic anteroposterior postural stability index (dPSI_AP), and dynamic mediolateral postural stability index (dPSI_ML). A higher value indicates greater postural variability and poorer stability when balancing on the platform than lower values.

IBM SPSS 26.0 Version (IBM Corp., Armonk, NY, USA) and RStudio (2021.09.2 Build 382 © 2009-2022 RStudio, PBC) were used for data analysis. Descriptive statistics of the study were reported as means (standard deviation) for continuous data and frequencies (percentages) for categorical variables. A mixed type three repeated-measures model (ANOVA) was used to test the effect of KT on primary and secondary outcomes at each time interval (1st hour, 3rd week, and 7th week follow-up). In cases where assumptions could not be met because of an abnormal distribution, the nonparametric Analysis of Longitudinal Data in Factorial Experiments (nparLD) package was used.[19] When the sphericity was violated the degrees of freedom were corrected using Greenhouse and Geisser estimates of sphericity.[20] When a significant effect was detected, post hoc tests were performed for pairwise comparisons. Because the study had two primary outcomes, the Bonferroni correction was applied, taking into account multi-

plicity. As a result, a p-value of 0.025 or less for the primary outcomes and 0.05 or less for the remaining outcomes was set as the threshold for statistical significance.

Table I: Demographic characteristics of the participants.

	Kinesiotape (n=27)	Sham-Kinesiotape (n=30)	p-value
Mean (SD) age (years)	56.9 (6.9)	55.7 (6.9)	0.32[a]
Education (%)			
0-5 years	22 (73.3)	22 (81.5)	0.74[b]
6-11 years	2 (6,7)	1 (3.7)	
≥12 years	6 (20)	4 (14.8)	
Employment status (%)			
Working	2 (7.4)	25 (83.3)	0.28[b]
Not working	25 (92.6)	5 (16.7)	
Mean (SD) duration of symptoms (months)	51.6 (38.0)	41.7 (37.3)	0.32[a]
Mean (SD) height, cm	161.1 (5.0)	160.8 (4.3)	0.76[c]
Mean (SD) weight, kg	85.3 (16.8)	79.7 (13.6)	0.16[a]
Mean (SD), BMI Kg/m^2	32.8 (5.8)	30.8 (5.4)	0.19[a]

[a] Independent -samples t-test. [b] Chi-square test. [c] Mann-Whitney U-test.

All calculations were based on intention-to-treat analysis. To replace missing data, values calculated using the expectation maximisation method with regression analysis were used. All outcome variables were included in the model.

RESULTS

Fifty-seven of 78 female volunteers participated in the study. The loss of follow-up rate was 8.9% of all subjects, as two patients from the KT group and six patients from the sham-KT group could not be followed up because of COVID-19 infection. No adverse effects due to the intervention were reported in either the KT group or the sham-KT group. The patient demographic characteristics are shown in Table I. The groups were similar in age, education, symptom duration, body mass index, and employment status. The primary and secondary outcome parameters of the groups during the study were detailed in Table II. Baseline data VAS_rest, VAS_activity, WOMAC, PSI parameters, 50-m walking time, and ROM measurements did not differ between groups.

Analysis of variance revealed significant interactions only for dPSI_ML, [F (2.6,144.1)=3.83, p=0.015], and 50-meter walking time, [F (1.96,108.29) =4,087, p=0.02], and a near significant interaction for VAS_rest, [F (2,115) =2.93, p=0.055]. Pairwise comparisons revealed that the KT group had significantly higher dPSI_ML values than the sham KT group at week three. There were no differences between groups, but there were differences within groups at the 50-meter walking time and at VAS_rest. For 50-meter walking time, all scores were better than the baseline and the 3rd and 7th-week scores were better than the 1st-hour scores in the KT group. Sham-KT group displayed significant improvement only in 1st hour and 3rd week compared to the baseline (Table II).

Table II: Primary and secondary mean outcome scores.

	Baseline (SD)	First hour (SD)	3rd week (SD)	7th week (SD)
Kinesiotape				
50-m walking test (sc)	44.2 (7.4)	42.0 (6.4)	40.3 (5.2)	39.2 (6.3)
WOMAC				
Total	46.1 (10.4)	40.3 (10.1)	32.5 (11.3)	32.7 (14.6)
Pain	10.2 (2.4)	8.4 (2.6)	6.7 (2.6)	6.7 (2.4)
Function	32.3 (7.9)	28.8 (7.7)	23.7 (7.9)	23.6 (9.1)
Stiffness	3.6 (1.4)	3.1 (1.1)	2.3 (1.3)	2.4 (1.3)
VAS- rest	5.2 (1.4)	4.4 (1.5)	4.1 (1.6)	3.8 (1.6)
VAS- at 50 m walking	6.9 (1.1)	5.6 (1.5)	5.2 (1.8)	5.0 (2.0)
dPSI_OA	0.99 (0.26)	0.95 (0.27)	1.08 (0.27)	0.99 (0.28)
dPSI_AP	0.68 (0.22)	0.67 (0.21)	0.73 (0.22)	0.68 (0.24)
dPSI_ML	0.58 (0.19)	0.57 (0.18)	0.64 (0.16)	0.57 (0.18)
sPSI_OA	0.57 (023)	0.60 (0.29)	0.60 (0.25)	0.58 (0.29)
sPSI_AP	0.44 (0.16)	0.44 (0.20)	0.42 (0.19)	0.41 (0.20)
sPSI_ML	0.25 (0.18)	0.29 (0.21)	0.31 (0.20)	0.29 (0.23)
Flexion ROM, degrees	108 (10)	110 (9)	111 (9)	112 (9)
Extention ROM, degrees	-5.8 (5.8)	-5.3 (5,5)	-4.0 (4.1)	-3.3 (4.0)
Sham-Kinesiotape				
50-m walking test	41.9 (6.8)	40.5 (6.3)	39.5 (6.1)	39.9 (6.8)
WOMAC				
Total	45.7 (9.1)	40.3 (10.1)	39.8 (11.8)	33.6 (13.4)
Pain	10.1 (2.1)	8.2 (1.8)	7.9 (2.3)	7.3 (2.8)
Function	32.2 (6.4)	29.5 (6.0)	28.7 (6.0)	24.0 (7.6)
Stiffness	3.4 (1.4)	3.4 (1.2)	3.2 (1.3)	2.3 (1.4)
VAS- rest	5.1 (1.0)	4.4 (1.0)	4.6 (1.4)	4.5 (1.7)
VAS- at 50 m walking	6.9 (0.9)	6.0 (1.2)	5.6 (1.2)	5.3 (1.7)
dPSI_OA	1.01 (0.25)	0.93 (0.25)	0.84 (0.40)	0.92 (0.32)
dPSI_AP	0.67 (0.21)	0.64 (0.22)	0.61 (0.32)	0.66 (0.26)
dPSI_ML	0.62 (0.19)	0.55 (0.19)	0.47 (0.23)	0.52 (0.20)
sPSI_OA	0.63 (0.23)	0.60 (0.28)	0.53 (0.28)	0.55 (027)
sPSI_AP	0.47 (0.17)	0.43 (0.23)	0.41 (0.23)	0.40 (0.18)
sPSI_ML	0.30 (0.17)	0.30 (0.21)	0.25 (0.17)	0.28 (0.20)
Flexion ROM, degrees	109 (9)	110 (7)	112 (6)	112 (7)
Extention ROM, degrees	-6,1 (6.8)	-5.1 (6.2)	-4.0 (5.2)	-3.7 (5.3)

SD, standard deviation; sc, seconds; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; VAS, visual analogue scale; dPSI, dynamic postural stability index; sPSI, static postural stability index; OA, overall; AP, anteroposterior; ML, mediolateral; ROM, range of motion.

For VAS_rest only a significant difference was found between baseline and 1st-hour scores in the sham-KT group, while all scores in the KT group were better than baseline in the KT group.

There was a significant time main effect for VAS_activity, [F (2.07, 114.24) = 42.513, p<0.01], WOMAC_pain [F (2.26, 124.77) = 34.749, p<0.01], WOMAC_stiffness [F (2.65, 146.09) = 34.831, p<0.01], WOMAC_function [F (2.24, 123.63) = 34.831, p<0.01], AROM_F, [F (1.61, 88.98) = 20.119, p<0.01] and for AROM_E, [F (1.97, 108.83) = 22.691, p<0.01] indicating an improvement for the whole sample but not differing at the group level.

No main effect of group was found in any of the outcome measures and no significant group, time, or interaction effects were detected in any of the dPSI_OA, dPSI_AP, and static postural stability indices.

DISCUSSION

The results of this study show that the use of KT for three consecutive weeks was well tolerated but did not significantly improve pain intensity, knee-related health status, physical function, pain-free ROM, and postural stability compared with sham-KT.

Pain is the most commonly investigated outcome measure in studies examining KT in knee OA, and KT has been reported to significantly reduce pain.[2-4] Administration of KT would have to differ between groups over time to explain the true treatment effect, but the analgesic effect of KT (both during activity and at rest) did not differ from that of sham-KT, in this study. In fact, the improvement in pain intensity at rest and the improvement may not coincide in all circumstances.[5] It is important to capture not only pain responses at rest and during activity, but also long-term outcomes in addition to immediate effects to eliminate the rationale for the previous study that blamed the short-term intervention for the negative outcomes of KT.[3] In this study, pain intensity at rest improved immediately in both groups. However, in the KT group, improvement was observed at every assessment interval, whereas the sham-KT group showed improvement from baseline only in the first hour. On the other hand, there are an increasing number of studies reporting that KT does not improve pain and function compared to sham-KT. [3,21-24] Another point to consider is the standardization of the activity pain queried. Some of these studies had not specified what activity was queried, some of the specified VAS_activity while walking or climbing stairs.[2,5,8,21]

Evaluating the efficacy of KT in patients with knee OA using performance tests that are sensitive to assess mobility parameters is a reasonable method.[2] Although several performance tests exist to assess mobility, gait speed has often been preferred in studies.[2,4,8,22] Donec *et al.* reported that KT showed no superiority to sham treatment, but there was improvement in pain, functionality, mobility, and ROM in both groups.[22] However, with convincing data, it is necessary that the KT group predominates over the sham group. There was no difference between groups in 50-meter walk time, so the results do not support the ameliorative effect on performance tests, even if there is a significant time*-group interaction.[6,17]

Pain and joint-related processes are associated with decreased ROM in patients with knee OA. Some of the studies reported improvement in knee ROM after using KT in the knee, but the results are inconsistent.[2,4,5,17,22,25] The absence of differences between groups in our study rules out the palliative effect of KT on pain-free ROM.

It was concluded that the intervention KT had no effect on postural stability. In addition, the KT group had significantly worse dPSI_ML scores at the third week than the sham-KT group. The fact that the groups had similar results for overall PSI. The overall PSI is considered the most reliable indicator of postural stability. The only study that investigated the effects of using KT on postural stability in knee OA using objective parameters concluded that KT did not significantly improve postural stability compared to the control group.[4] The lack of a significant effect of using KT on postural stability in patients with knee OA is consistent with existing study.[4]

In the present study, no treatment effect was found in terms of WOMAC subgroup scores between groups, which is consistent with the results of meta-analysis.[24] The lack of improvement in knee-related health status seems to be a consequence of the unfavourable results for the other outcome parameters.[3] The time effect in WOMAC, VAS_activity, and knee ROM in the whole study group might be related to the home exercise program used in the patients in this study. Although an increasing number of studies investigated the superiority of KT over sham treatment KT, an improvement in outcome scores was observed in all groups.[3,21,22] In general, the results of studies from KT are relatively inconsistent and do not support the evidence-based benefits of KT for knee OA.[24] Methodological reasons for inconsistency include: the lack of treatment rationale, number of taping sessions, duration of taping, follow-up intervals, and differences in whether assessments were performed with or without tape. The present study differs from RCTs in that assessments were conducted with or without tape.[8,24] Another point that needs to be standardized is the technique of sham- KT. The sham- KT was not applied directly to the knee region. If the study showed the superiority of KT over sham- KT, the authors would criticise the lack of proprioceptive reinforcement in the knee region in the sham group KT.[4,17] The participants in our study were patients with grade II-III knee OA, and the possible ceiling effect in advanced OA should not be ignored. Detection of small

improvements in pain, mobility, postural control, and ROM in participants with advanced knee OA may be insufficient to expose the intervention effect.[22] Therefore, investigating the clinical effectiveness of KT in knee OA may require follow-up of participants at the same stage of OA and may be more logical in selecting the patient population in which the intervention is effective.

The study had some limitations. The assessments in the first hour were done with tape and the others without tape, which could be an inconsistency, but there is a need to evaluate the immediate and long-term effects of using KT in the same study. Patients were asked not to take pain medication during the study period; however, it was not followed up to determine whether they took pain medication. Although all patients received a home-based exercise program and were motivated during intervention sessions and weekly telephone calls, and their compliance was not checked.

CONCLUSION

The present study concludes that the use of KT for three consecutive weeks does not show significant superiority over sham treatment in terms of pain, knee-related health status, functional performance, pain-free ROM and postural stability. However, the presence of a time effect on WOMAC, ROM, and VAS_activity should be considered with caution when interpreting the results. Future RCTs examining the effect of KT alone or in addition to therapeutic approaches are needed.

ETHICAL APPROVAL

The study was approved by the National Review Board and Ethics Committee University of Health Sciences, Izmir Bozyaka Training and Research Hospital (Approval No. 2019/06; date 11/09/2019). Clinical Trials.gov Identifier: NCT05351996

PATIENTS' CONSENT:

Written informed consent were obtained from all the patients participating in the study.

COMPETING INTEREST:

The authors declared no competing interest.

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AUTHORS' CONTRIBUTION:

ND: Investigation, methodology, and conceptualisation.

HY: Investigation, and methodology.

BI: Analysis, validation, interpretation of data for the work, and writing-review/editing.

SA: Supervision, writing original draft, and review.

All the authors have approved the final version of the manuscript to be published.

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