The effectiveness of Kinesio Taping[®] for pain management in knee osteoarthritis: a randomized, double-blind, controlled clinical trial

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Abstract

Background: Kinesio Taping® method is a nonpharmacological alternative for pain management in musculoskeletal disorders. However, the existing evidence is insufficient to assess its full effectiveness for pain management in knee osteoarthritis (KO). Our aim was to evaluate the effectiveness of the Kinesio Taping method in reducing knee pain for KO patients. **Methods:** In this randomized, double blind, controlled trial, we recruited 187 patients with grade I-III KO who were allocated to either the Kinesio Taping or control group. The study was carried out in outpatient facility. Either Kinesio Taping or nonspecific taping was applied on the affected knee area for 4 weeks. Pain evaluation was performed at baseline, after 1 month of taping and after 1 further month without taping. The data on usage of painkillers were collected; Numeric Pain Rating Scale; an algometer, and Knee injury and Osteoarthritis Outcome Scores (KOOS) pain subscale were used to assess pain. Tolerance and subjective opinions toward the effectiveness of taping were evaluated. The chosen level of significance was p < 0.05, $\beta \le 0.2$.

Results: The majority (>70%) of both groups' patients indicated that tapes reduced the knee pain. The reported use of painkillers decreased, in addition to self-reported increase in the KOOS subscale, thereby indicating pain alleviation. All self-reported improvement remained at the 1-month follow up (p < 0.05). Significantly higher and clinically meaningful reduction of pain intensity was found in the Kinesio Taping group after the treatment month, in comparison with the control group (p < 0.05). More pain reduction was reported in the daytime for participants in the Kinesio Taping group at the follow up (p = 0.022). No changes in algometry results were observed.

Conclusions: Elastic taping can safely relieve knee pain and reduce the need for pharmacological management in KO. A specific Kinesio Taping technique is clinically more beneficial for knee-pain alleviation in comparison with nonspecific taping. [ClinicalTrials.gov identifier: NCT03076177.]

Keywords: elastic taping, Kinesio Taping, knee osteoarthritis, knee pain

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Knee pain in osteoarthritis is associated with a

poorer functional prognosis, fear of movement,

decreased mobility, and quality of life. It

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Introduction

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predisposes to higher levels of disability, with a

significant negative impact on various physical

and psychological components encountered in

daily life.1-5 Pharmacological treatment for knee

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© The Author(s), 2019. Article reuse guidelines: sagepub.com/journalspermissions pain is a popular management approach practiced daily in many clinical settings worldwide. However, in the context of an aging population and increasing prevalence of knee osteoarthritis (KO), the modest efficacy of currently used medication, and the health hazards caused by overuse of painkillers or polypharmacy, require identification of safe and effective nonpharmacological alternatives.^{1,2,6,7} The guidelines of the American College of Rheumatology, among other appropriate nonpharmacological treatment modalities for all individuals with KO, recommended nonelastic patellar taping as a beneficial therapeutic tool able to provide knee-pain relief.⁸

The Kinesio Taping® (KT) method is an alternative elastic taping technique, which was created by Dr Kenso Kase in the 1970s.9 This method stood out from the existing elastic and nonelastic taping techniques by the specially designed waterproof, hypoallergic, elastic tape, Kinesio[®] Tex Tape. The tape could be applied directly on the skin and left for several days with good adherence and low risk of skin irritation, providing the possibility for a large variety of therapeutic applications.9-12 Dr Kenso Kase suggested that, depending on the used application technique, KT can provide therapeutic effects, such as pain and edema reduction, mechanical correction or support, improvement of muscular activity, correction of joint misalignment, and functional, proprioceptive stimulation.¹²

The KT method has been studied and researched extensively by both clinicians and researchers as a possible tool in the field of medicine and rehabilitation.^{13–15} Nevertheless, despite the rapidly increasing scientific interest and the number of researchers investigating the effectiveness of KT for different pathologies in recent years, the available studies on the KT effectiveness for KO pain relief and functional improvement report conflicting results concerning its efficacy. Mostly, this is due to different methodological drawbacks and poor data quality.^{9,16–18}

The aim of our study was to evaluate the effectiveness of the KT method in reducing knee pain for KO patients after a month of taping. We were also assessing whether any beneficial effects lasted for a month after taping ended.

Methods

The study was a parallel-group, 1:1 allocation ratio, single-center, randomized, double-blind,

controlled trial, carried out at the Outpatient Rehabilitation Department, Medical Academy, Lithuanian University of Health Sciences, from October 2014 to August 2018. Volunteers, who responded to either the invitation by the coworking healthcare specialists or periodically published advertisements, were assessed for eligibility.

Inclusion criteria were: age > 18 years; radiologically verified grade I–III symptomatic KO (according to the Kellgren and Lawrence system);¹⁹ and willingness to participate in the research.

Exclusion criteria were: rheumatoid arthritis or other systemic rheumatoid disease (gout, scleroderma, etc.); fragile, very sensitive skin, or with lesions in the area where the tapes were to be applied; and inability to do the functional tests required by the study protocol. Other exclusion criteria were: diagnosed or suspected cancer in the area where the tapes were to be applied; less than 6 months after intra-articular injections; constant usage of analgesic medicaments for pain relief in other body parts (except for the knee); pregnancy; constant use of any orthotics; previous experience with the KT method; or unwillingness to follow the study's protocol requirements.

The study protocol was approved by the National Review Board and Ethics Committee Kaunas subdivision (approval No. BE-2-47, 08/10/2014). The study was carried out in accordance with the World Medical Association's Code of Ethics (Declaration of Helsinki, 1967). A written informed consent was obtained from all patients before participation in the study.

At the first visit (V0), the enrolled participant received his/her unique code in succession. Unique codes were randomly assigned to the KT or control group using a computer-generated list. Sequence randomization was obtained through: http://www.randomization.com (the seed for reproduction: 4514, created on 19 October 2014). The random sequence was concealed until the end of the trial. The group, to which the participants' unique code was ascribed, was revealed just to the certified KT practitioner (CKTP) responsible for the taping procedures.

Each participant was assessed by the same blinded researcher during three visits: at baseline (V0), at 4 weeks after the taping treatment (V1), and after the following 4 weeks without treatment (follow

up; V2). During the visits for reapplication of tapes, the tolerance of taping was evaluated through structured questioning and clinical examination by the CKTP [also a physical medicine and rehabilitation (PMR) physician]. These assessments were single blinded, as it was impossible to assure blindness of the CKTP responsible for taping applications and who had the required qualification to decide if taping could be continued safely, in case of any adverse effect.

For all participants, tapes were applied once a week for 4 weeks in succession. Tapes were left on the skin for 6 days; then, participants had to gently remove tapes by themselves and come for the next application (after 24h of a 'tapes-off' break). The Kinesio[®] Tex Gold FP was used for both groups. All possible colors of the tape were used randomly on participants without the difference between groups. In bilateral KO cases, both knees were taped.

In order to reduce the possible impact of other external factors on the results, the patients were asked not to start any new vigorous physical activities, refrain from any local ointments, plasters, knee massage, local physical agents (ice, heat pads and similar, available at home), as well as from starting a new treatment. Participants could continue using previously prescribed drugs but were asked to make detailed notes about the painkilling drug (the name, dose, and format each time they would take any analgesic medicament during the participation period) and at V1 and V2 assessments, provide this information by filling in the self-reported questionnaire.

Taping applications

Kinesio Taping group. Two Y-shaped and two I-shaped strips were used. Two Y strips ('paperoff' tension) were applied mainly for lymphatic correction in order to address possible chronic knee effusion, secondly seeking to improve anterior thigh-muscle function (here, the elements of lymphatic correction and muscle correction technique were combined). Two I strips (75–100% of available tension) were placed over the patella tendon and medial/lateral collateral ligaments to increase stimulation of mechanoreceptors over the area, and improve proprioception and knee stability. The Y strips were applied by being laid on the skin in a fully flexed knee position, with the participant lying supine. The first Y-shaped tape was applied from the mid third of the thigh over the rectus femoris, then its ends were directed toward the tibial tuberosity enwrapping the patella from lateral and medial sides. The second Y-shaped strip application started from slightly below tibial tuberosity, then, by its tails enwrapping the patella from the sides and directing the ends over the vastus medialis and vastus lateralis muscles. The first 5 cm of both Y tapes were laid with 0%; the middle part, with approximately 10–15% tension; and the last 2 cm, with 0% of available tension. Each application was ended with the adhesive activation according to the KT technique.

Afterwards, two I strips were applied over the patella tendon and lateral and medial collateral ligaments. The application of the first I strip started just below the inferior patellar border, over the patella tendon, in a fully flexed knee position when lying supine, using 100% of available tension, and the adhesive activation followed. Then, the knee position was changed to 20-30° of flexion, and taping was continued over the medial and lateral collateral ligaments, using approximately 75% of available tension with adhesive activation following. After that, the subject was asked to fully extend the knee, and the ends of the I strip (approximately 10 cm) were directed toward the posterolateral sides of the thigh (without overlapping one another at the back) with 0% tension and with adhesive activation following. The second I strip was applied identically to the first one, just laid lower, covering about one half of the previous one. The completed KT application view is presented in Figure 1.

Control group. For the nonspecific taping (NT) group, tapes were applied without using any specific KT technique, just having the purpose of imitating the KT technique for participants in order to assure their blinding. One I strip was applied over the anterolateromedial surface of the thigh, the second over the calf for the patient lying supine, with the knee fully extended, using 0% of available tension, approximately 10 cm above and 10 cm below the superior and inferior poles of the patella, perpendicular to the leg axis. Afterwards, two small pieces of tape, approximately 5×5 cm, were applied on the medial and lateral sides of the knee joint, using 0% tension. The adhesive activation followed each application to seek good adhesion. The view of the completed NT application is in Figure 2.



Figure 1. The Kinesio Taping application. The completed KT application view. Two Y-shaped strips (approximately 10–15% tension) were applied over the anterior knee joint surface and thigh muscles, and two I-shaped strips (approximately 75–100% tension) over the patellar tendon and medial/lateral collateral ligaments.

The possible neurophysiological effects on pain due to the irritation of skin receptors and sensory neurons evoked by the tapes attached to the skin at the affected knee site imply an NT technique to consider as competing treatment with the specific KT technique. However, as the irritation of skin receptors is very mild when the tape is attached without tension and only a small area of the knee joint was covered by the tape, the NT, in our opinion, should be regarded as a 'very close to placebo' intervention.

Participants in both groups were provided with the indifferent input from the research team toward the effectiveness of the KT method for KO. All researchers were instructed to indicate (in case of a participant's enquiry) that there is limited evidence for KT to be effective for KO, and that existing scientific data are insufficient to draw final conclusions. All participants were constantly encouraged to provide honest feedback about their experiences with taping.

Masking was fully assured: all subjects remained unaware of which taping technique was considered therapeutic. The assessors also remained blinded toward the participants' allocation until the end of the trial, as all participants were instructed not to discuss group allocation, nor how their tape applications looked, with the assessor at V1 and V2 visits, as well as being instructed to remove the tapes at home before V1 assessment. All participants fulfilled this request.

Outcomes

The primary outcome of this study was the change in knee-pain intensity from baseline at 4 weeks



Figure 2. The nonspecific taping application. Two I strips above and below the knee joint and two strips (approximately 5×5 cm) over the medial and lateral knee surface applied with 0% tension.

(V1 evaluation *versus* V0) evaluated by a Numeric Pain Rating Scale (NPRS; an 11-point scale from 0-10; '0' = no pain, '10' = the most intense pain imaginable). Subjects, through a self-reported questionnaire, were asked to evaluate pain intensity: generalized, during the day, during the night, while changing body position, during prolonged movements (e.g. walking, running, climbing stairs, etc.), and at rest during the last 4 weeks.

The secondary outcomes were: the change in kneepain intensity from baseline at 8 weeks (V2 evaluation versus V0) evaluated by NPRS; the change of pressure pain threshold (PPT; kg/cm²) at patellar tendon area 1 cm below inferior patellar pole (V1 versus V0 and V2 versus V0), measured by algometer (Wagner FPX[™] 25, Wagner Instruments, Greenwich, CT, USA). The rubber-tipped stylus was placed over the patellar tendon perpendicular to the skin surface. Then, steady and gentle pressure at a rate of approximately 1 kg/cm²/s was applied until the patient first felt the pain and responded by saying 'now'. The average of two such measurements with a 1-min break in between was recorded as a final value. For the assessments, a 1 cm² rubber tip was used. Also, the change in the Knee injury and Osteoarthritis Outcome Scores (KOOS) pain subscale (V1 versus V0 and V2 versus V0) was assessed through filling self-reported questionnaire: standardized answer options are given (five Likert-type boxes), and each question is assigned a score from 0 to 4, with the evaluation interval being 4 weeks. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) was calculated for the subscale. In cases of bilateral KO, patients filled in the questionnaires about pain (based on NPRS and KOOS) for the right and left knee separately.

During the V1 assessment, each participant was asked by the blinded researcher if tape alleviated

their knee pain (possible answers to choose from were 'yes', 'no', 'I don't know', or 'tapes increased my knee pain'). The data about the tolerance, side effects and participants' opinions toward effectiveness of taping were gathered during single-blinded evaluations by the CKTP.

Sample-size calculation

We performed power analysis for the sample-size estimation. The type I error was set at 0.05 and power of the test was selected 0.80. A change in pain of 1.74 cm on the NPRS has been recommended as the minimum clinically important difference in trials of KO.²⁰ With 80 participants, our study had 80% power to detect a change in pain of 1.74 cm between the KT and NT groups, assuming a standard deviation of 2.8 cm²¹ with a significance level of <0.05.

For secondary outcomes: the change in pain threshold by 1.77 kg/cm² is likely to exceed the magnitude of measurement error²² and meaningful change for KOOS pain subscale is suggested to be 10.²³ The change in pain threshold and in KOOS pain subscale with the power of 80% and 0.05 significance the sample size had to be 126 participants and 180 participants, if possible dropouts of 30% were taken into account. The allocation and recruitment of patients was stopped when we achieved 187 participants (we recruited 7 more participants than initially planned for their willingness to participate, meeting requirements of the studies protocol, our technical ability to include them, and mainly due to anticipating possible larger dropouts).

Statistical analysis

Statistical analysis was performed using software IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY). Data are presented as mean \pm standard deviation (SD) and 95% confidence interval (CI) for the mean for continuous variables and n (%) for categorical variables. For baseline characteristic comparisons between groups, also for primary and secondary outcomes, after testing for normality, parametric and nonparametric criteria, the Student's t test or repeated measures analysis of variance and Mann-Witney U or Friedman tests were used to compare quantitative samples and χ^2 test for categorical variables. Hedges' g effect sizes were calculated for intergroup comparison using the values of mean and SD. The significance level of 0.05 was chosen for testing statistical hypotheses.

Results

Between October 2014 and August 2018, 263 volunteers were screened for eligibility by the PMR physician enrolling to the study. A total of 187 were enrolled in the trial with 94 randomized to KT and 93 to the NT group. A detailed study flow chart is presented in Figure 3. Groups were comparable according baseline characteristics (see Table 1). There were no differences between the groups; neither in number, nor according to the reasons of dropouts (p > 0.05).

Effects on outcomes

After taping for a month, global improvement was found in all measured outcomes, except for algometry, within both groups; however, the KT group subjects indicated higher and more clinically significant knee-pain relief for generalized pain, pain in the daytime, pain at night, while changing body position, during prolonged movement (walking, running, climbing stairs etc.; p < 0.05). At rest, the pain relief was about the same for both groups' participants (p = 0.421).

In the KT group, all the measured outcomes, except for pain intensity at rest, remained significantly improved during follow-up assessment in comparison with baseline (p < 0.05), though the difference tended to decrease. The relief of pain intensity in the daytime (from baseline) remained statistically higher in comparison with the NT group (1.4 *versus* 0.6; p = 0.022), Figure 4.

In the NT group, at follow up, the statistically significant pain intensity improvement, though clinically of small value (<1 point),²⁰ remained in generalized knee pain and pain while changing body position categories; other values (in the daytime, pain at night, during prolonged movement, at rest) were found to be about the same as at baseline (p > 0.05).

KOOS pain subscale values remained significantly higher than baseline in both groups during follow up (p < 0.05). The summarized data about the changes in outcomes within groups are presented in Table 2.

The effect sizes for changes in outcomes are presented in Table 3. No differences were detected between groups according to KOOS and PPT (p > 0.05). The highest (moderate) effect size, 0.52 (CI 0.26–0.78), was found for pain reduction while changing body positions according to



Figure 3. Study flow chart.

NPRS in comparison with control group after the treatment month.

The subjective and objective tolerance (presented in Table 4) for both taping techniques was almost the same; no significant differences were found in skin irritation, intolerance, or participants' general opinion toward pain-alleviating effect of knee taping (p > 0.05). However, from the second week, a significantly higher pain relief and function improvement by taping was indicated by the KT group participants. No adverse effects, which would require discontinued taping or initiation of extra treatment, were observed.

Seventy-two participants (46%) indicated the usage of nonsteroidal anti-inflammatory drugs (NSAIDs) as painkillers for knee-pain management 4 weeks prior to the participation. Other possible analgesic medications were not used by participants; neither prior to the participation, nor during it. The significant reduction of NSAID
 Table 1. Comparison of baseline characteristics between groups.

Characteristic	KT group n = 81 subjects n = 123 knees	NT group n = 76 subjects n = 114 knees	p value
Age (mean \pm SD)	68.7±9.9	70.6±8.3	0.181
Sex: male/female	17 (21%)/64 (79%)	16 (21%)/60 (79%)	0.992
Number of concomitant diseases			0.134
None	7 (8.6%)	4 (5.3%)	
1	11 (13.6%)	15 (19.7%)	
2	22 (27.2%)	23 (30.3%)	
3	17 (21%)	23 (30,3%)	
≥4	24 (29.6%)	11 (14.5%)	
Body mass index	30.5 ± 5.3	30.7 ± 5.2	0.830
Uses painkillers ¹ for knee pain relief:			0.120
No	39 (48.1%)	46 (60.5%)	
Yes	42 (51.9%)	30 (39.5%)	
Diagnosis			0.576
Right knee osteoarthritis	22 (22.2%)	17 (22.4%)	
Left knee osteoarthritis	17 (21.1%)	21 (27.6%)	
Bilateral knee osteoarthritis	42 (51.9%)	38 (50.0%)	
Grade of the knee osteoarthritis ²			0.726
I	14 (11.4%)	12 (10.5%)	
I-II or II	43 (35%)	35 (30.7%)	
II–III or III	66 (53.7%)	67 (58.8%)	
Duration of the knee pain: ³			0.678
Acute	8 (6.5%)	9 (7.9%)	
Chronic	115 (93.5%)	105 (92.1%)	
Knee-pain intensity according to NPRS:4			
Generalized	5.9 ± 2.5	5.5 ± 2.3	0.237
In the daytime	5.5 ± 2.6	5.2 ± 2.4	0.355
At night	3.9±2.9	3.4 ± 2.9	0.362
While changing body position	6.1±2.8	5.6 ± 2.5	0.993
During prolonged movement	6.1±2.6	6.1 ± 2.5	0.140
At rest	3±2.7	2.8 ± 2.5	0.513

(Continued)

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Table 1. (Continued)

Characteristic	KT group n = 81 subjects n = 123 knees	NT group n = 76 subjects n = 114 knees	p value
Pressure pain threshold (kg/cm ²)	4.4±2.4	4.2±2.6	0.340
KOOS pain subscale ⁵	56.2 ± 15	52.9 ± 15	0.131

¹Nonsteroidal anti-inflammatory drugs were used by participants.

²Grades are according to the Kallgren and Lawrence system: the cases, where radiologist indicated grade I–II or II–III, were ascribed to the highergrade group.

³Acute pain: pain duration less than 3 months with active treatment or less than 6 months if the patient did not receive adequate treatment; chronic: >3 months with treatment or >6 months without adequate pain management.

⁴NPRS, Numeric Pain Rating Scale of 11 points from 0 to 10, where 0 = 'no pain at all', 10 = 'worst imaginable pain'.

⁵K00S pain subscale: Knee injury and Osteoarthritis Outcome Scores pain subscale. A normalized score: 100 indicating no symptoms and 0 indicating extreme symptoms.

KT, Kinesio Taping; NT, nonspecific taping (control); SD, standard deviation.

During the treatment (taping) month



During the follow-up month



Figure 4. The changes in the knee pain according to the NPRS.

The changes in the knee pain according to the NPRS (a) during the treatment month and (b) during the follow-up month. *The difference between groups is statistically significant (p < 0.05).

**The difference between groups is both statistically significant (p < 0.05) and clinically meaningful, that is, ≥ 1.7 points. NPRS, Numeric Pain Rating Scale (an 11-point scale from 0–10. '0' = no pain, '10' = the most intense pain imaginable).

	KT group			<i>p</i> values within the KT group	thin the KT	NT group			<i>p</i> values within the NT group	in the NT
	V0 mean ± SD	V1 mean ± SD	V2 mean ± SD	VO versus V1	V0 <i>versus</i> V2	V0 mean ± SD	V1 mean ± SD	V2 mean ± SD	VO versus V1	V0 versus V2
Knee-pain intensity according to NPRS¹:										
Generalized	5.9 ± 2.5	4.1 ± 2.3	4.4 ± 2.2	<0.001	<0.001	5.5 ± 2.3	4.7 ± 2.4	4.4 ± 2.1	<0.001	0.009
In the daytime	5.5 ± 2.6	3.7 ± 2.3	4.1±2.3	<0.001	<0.001	5.2 ± 2.4	4.4 ± 2.5	4.2 ± 2.3	0.001	0.405
At night	3.9 ± 2.9	2.6 ± 2.5	2.8 ± 2.4	<0.001	0.003	3.4 ± 2.9	2.8 ± 2.5	2.5 ± 2.4	0.012	0.123
While changing body position	6.1±2.8	4.1 ± 2.5	4.3±2.7	<0.001	<0.001	5.6 ± 2.5	4.7±2.6	4.0 ± 2.3	0.001	0.002
During prolonged movement	6.1±2.6	4.3 ± 2.5	5.1±2.6	<0.001	<0.001	6.1 <u>+</u> 2.5	5 ± 2.5	5 ± 2.4	<0.001	0.275
At rest	3 ± 2.7	2.1 ± 2.5	2.3 ± 2.1	0.001	0.07	2.8 ± 2.5	2.1 ± 2.3	1.9 ± 2.1	0.012	0.123
Pressure pain threshold (kg/ cm ²)	4.4 ± 2.4	4.7±2.2	4.7 ± 2.2	0.201	0.375	4.1±2.3	4.2 ± 2.5	4 .1 ± 2	0.698	0.351
KOOS pain subscale ²	56.2 ± 15	66.1 <u>±</u> 15	65.1 ± 15	<0.001	<0.001	52.9 ± 15	62.7 <u>±</u> 16	62.8 ± 15	<0.001	<0.001
Bolded numerals indicate statistically significant differences. ¹ NPRS, Numeric Pain Rating Scale (an 11-point scale from 0–10. '0' = no pain, '10' = the most intense pain imaginable). ² KOOS pain subscale, Knee injury and Osteoarthritis Outcome Scores pain subscale. A normalized score: 100 indicating no symptoms and 0 indicating extreme symptoms; V0, baseline assessment; V1, assessment after 4 weeks of taping; V2, follow-up assessment (8 weeks from baseline). KT, Kinesio Taping; NT, nonspecific taping (control); SD, standard deviation.	icate statistically Rating Scale [an , Knee injury and sssment after 4 w T, nonspecific tap	significant differe 11-point scale frr Osteoarthritis Out seks of taping; V2, ing (controll; SD,	nces. om 0–10. '0' = no come Scores pair follow-up assess standard deviatio	i pain, '10' = th subscale. A n sment (8 weeks n.	ne most intens. ormalized scor from baseline	e pain imaginable -e: 100 indicating . .).). no symptoms and	l 0 indicating extre	eme symptoms;	V0, baseline

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The improvement	KT group	NT group	p value	95% CI of the difference	Effect size (ES)	ES 95% confidence interval
The reduction of knee-pain inter	nsity according	NPRS ⁰ mean ±	± SD:			
Generalized pain						
Δ^1	$\textbf{1.74} \pm \textbf{2.1}^{*}$	$\textbf{0.84} \pm \textbf{2.2}$	0.016	0.33-1.46	0.42	0.15-0.68
Δ^2	1.4 ± 2.5	0.8 ± 2.5	0.134	-0.14 to 1.28	0.24	-0.04 to 0.52
Pain in the daytime						
Δ^1	$\textbf{1.7} \pm \textbf{2.3}^*$	$\textbf{0.8} \pm \textbf{2.3}$	0.004	0.31-0.47	0.39	0.13-0.65
Δ^2	$\textbf{1.38} \pm \textbf{2.6}$	$\textbf{0.59} \pm \textbf{2.5}$	0.022	0.07-1.5	0.32	0.04-0.59
At night						
Δ^1	$\textbf{1.27} \pm \textbf{2.5}$	$\textbf{0.64} \pm \textbf{2.4}$	0.019	0.01-1.26	0.26	0.00-0.51
Δ^2	1.03 ± 2.6	0.62 ± 2.5	0.611	-0.29 to 1.12	0.16	-0.12 to 0.44
While changing body position						
Δ^1	$\textbf{1.99} \pm \textbf{2.3}^{*}$	$\textbf{0.82} \pm \textbf{2.2}$	<0.001	0.59-1.74	0.52	0.26-0.78
Δ^2	1.63 ± 2.7	1.19 ± 2.6	0.173	-0.30 to 1.18	0.17	-0.11 to 0.44
During prolonged movement						
Δ^1	$\textbf{1.75} \pm \textbf{2.1}^*$	$\textbf{1.08} \pm \textbf{2.1}$	0.023	0.12-1.22	0.32	0.06-0.58
Δ^2	$\textbf{0.99} \pm \textbf{2.5}$	0.67 ± 2.7	0.375	-0.40 to 1.05	0.12	-0.15 to 0.4
At rest						
Δ^1	0.94 ± 2	0.67 ± 2.2	0.421	-0.28 to 1.18	0.13	-0.13 to 0.38
Δ^2	0.52 ± 2.2	0.62 ± 2.4	0.741	-0.74 to 0.55	-0.04	-0.32 to 0.23
The improvement in KOOS pain subscale						
Δ^1	$9.7 \pm 14.6^{\ast}$	$\textbf{9.8} \pm \textbf{12.5}^{*}$	0.511	-3.66 to 3.36	-0.01	-0.26 to 0.25
Δ^2	8.4±13.6	7.5 ± 14.8	0.505	-3.00 to 4.93	0.06	-0.21 to 0.34
The increase in pressure pain threshold (kg/cm²)						
Δ^1	0.33±1.78	0.13 ± 1.68	0.359	–0.25 to 0.65	0.11	-0.14 to 0.37
Δ^2	0.12 ± 1.88	0.05 ± 1.77	0.958	–0.45 to 0.58	0.05	-0.23 to 0.32

Table 3. Outcomes: the changes of pain during the taping month and follow up.

Bolded numerals marks statistically significant differences between groups and effect size.

^oNPRS, Numeric Pain Rating Scale (an 11-point scale from 0–10. '0' = no pain, '10' = the most intense pain imaginable).

 Δ^{1} : the change of absolute value from baseline during the taping month (V0–V2 in the NPRS case, and V1–V0 in the pressure pain threshold and K00S pain subscale cases).

 Δ^2 : the change of absolute value from baseline during follow up (V0–V2 in the NPRS case, and V2–V0 in the pressure pain threshold and KOOS pain subscale cases).

*Marks clinically meaningful change for chronic knee pain.

CI, confidence interval; KOOS, Knee injury and Osteoarthritis Outcome Scores pain subscale; KT, Kinesio Taping; NT, nonspecific taping; SD, standard deviation.

Table 4. The knee-taping tolerance data.

Characteristics	KT group	NT group	p value
Indicated intolerance	2 (2.1%)	2 (2.2%)	<i>p</i> =0.526
Expressed mild complains toward tapes during taping month*	13 (13.8%)	8 (8.6%)	
Good subjective tolerance**	79 (84%)	83 (89.2%)	
Verified mild skin reaction to tapes ^{\$}			
None	73 (77.7%)	68 (73.1%)	<i>p</i> =0.992
Present	8 (8.5%)	8 (8.6%)	
Unverified cases (dropouts during the first month)	13 (13.8%)	17 (18.3%)	
In your opinion, did tapes alleviate your knee pain?			
Yes	60 (74%)	55 (72%)	<i>p</i> =0.98
Νο	10 (12%)	9 (12%)	
l don't know	9 (11%)	10 (13%)	
Increased the knee pain	2 (2.5%)	2 (2.6%)	
In your opinion, how much did the knee taping relieve or aggravate your knee pain and function last week if: –100% means complete worsening; 0% is no change; 100% is complete alleviation? ^{\$\$}			
Improvement after first week of taping (mean \pm SD)	$28\pm28\%$	$28 \pm 31\%$	0.97
Improvement after second week of taping (mean \pm SD)	$\textbf{38} \pm \textbf{28\%}$	$25\pm\mathbf{34\%}$	0.005
Improvement after third week of taping (mean \pm SD)	46 ± 30%	$\textbf{34} \pm \textbf{35\%}$	0.01

Bolded numerals indicate statistically significant differences.

*Any indicated discomfort (like transient sense of unpleasant itching, wet or cold under the tapes, peeling off of edges of the tapes etc.).

**When the subject expressed only positive feedback throughout taping intervention, liked the applications, did not express any complaints toward the intervention.

^{\$}Any objectively observed skin irritation, rash, or redness and similar (no major skin reactions that would require extra treatment or discontinuation of taping were observed).

^{\$}Data from single-blinded assessments by certified Kinesio Taping practitioner.

KT, Kinesio Taping; NT, nonspecific taping; SD, standard deviation.

usage was detected within both groups during the taping month and follow up (p < 0.05). No differences according to these criteria were found between groups (p > 0.05). The data of changes in the pharmacological knee-pain management is presented in Figure 5.

Discussion

The aim of our study was to evaluate the effectiveness of the KT method in reducing knee pain for KO patients after a month of taping and whether the beneficial effect would last a month post taping. We found the specific KT technique to be clinically superior over the NT in knee-pain-intensity reduction, and the beneficial effects for this criterion lasted a month post taping. The greatest effect on pain intensity and superiority over NT was observed in pain during movement and while changing body positions. Anandkumar and colleagues also found KT taping for KO to produce an immediate effect on pain reduction during stair-climbing activity in the experimental group when compared with the sham taping.¹⁷ Cho and coworkers concluded KT, in comparison with sham taping, decreased the knee pain at rest and while walking, and the highest effect size was





The changes in the usage of the analgesic medicaments for those subjects, who were **non-users** of drugs for their knee pain relief **prior the study**





KT, Kinesio Taping; NT, nonspecific taping; V1, assessment after taping month; V2, follow-up assessment.

observed for changes in pain intensity during walking for patients with KO.¹⁸ Likewise, Mutlu and colleagues, who researched KT effectiveness in patients with KO for pain and functional improvement, reported significant differences in the improvement of pain during activities between the KT and sham-taping groups from the initial taping application to after the third, and until the 1-month follow up.⁹

The possible mechanism for a more significant effect of KT over the NT can be partially

explained by the higher mechanostimulation produced by the KT technique than the NT method. In the KT technique, the larger joint skin area was taped as well as higher proprioceptive stimulation acquired through higher tape tension used over the tendon and ligament areas. It has been proposed that taping over the skin can stimulate cutaneous mechanoreceptors and increase afferent feedback to the central nervous system resulting in decreased pain.^{24,25} Pamuk and Yucesoy, who used magnetic resonance imaging (MRI) analysis to visualize deformations within the

whole limb after the application of Kinesio tape over the skin along the tibialis anterior muscle and the dorsal aspect of the foot using approximately 50% of stretch, found that KT mechanically affects not only the targeted tissues, but also the deeper layers, and causes heterogeneous deformations within the whole limb.²⁶ Dynamic mechanoreceptors, such as Ruffini corpuscles and interstitial receptors, are localized in the border zones of the soft-tissue layers. Taping the skin with some stretch in a certain direction changes the shearing of the skin and fascial lavers and increases the afferent stimulation.²⁵ The more significant long-term pain-relieving effect in KO of KT applications with tension in comparison with those without tension applications was also reported by Castrogiovanni and colleagues.27

The more significant pain relief by KT during activities in comparison with the pain relief at rest or night, which was observed in our study and was reported by other researchers as well,^{9,18} can be partly explained by the fact that about 50% of interstitial dynamic mechanoreceptors have a high threshold and a sufficient amount of stretch is required to activate them. Therefore, tapes, when they are applied over the joints, by repeated movements stretch and activate the receptors, and rapid adaptation to tape is avoided.²⁵

It is impossible to assure placebo group as control with taping as any taping of the skin with whatever tape or method of application (sham/ nonspecific/'placebo') produces the afferent input at least from the skin in the somatic nervous system and can evoke neurophysiological effects.²⁵ Sadly, this fact is often ignored by researchers and reviewers of taping methods while interpreting the results. A recent pilot study by Callaghan and colleagues using functional MRI found nonspecific patellar taping (10-cm-wide strip of Hypafix [Smith & Nephew, Hull, UK] was used over the patella area) to modulate brain activity in several areas of the brain during a proprioception knee movement task.²⁸ Possible neurophysiological effects evoked by sham taping may explain our findings, which imply that even nonspecific knee taping is effective in pain management for patients with KO, as it reduced the need for analgesic medicaments not only during the taping month but also during follow up. Also, the lasting effect on subjectively perceived pain reduction was indicated through diminished KOOS pain scores; though the relief measured by NPRS did not reach the accepted meaningful change for chronic pain.21,29

Similar to our findings, the pain-relieving effect by sham taping for KO was also reported by Kocyigit and coworkers¹⁶ and Mutlu and colleagues.⁹ Interestingly, Kocyigit and coworkers¹⁶ used a large amount of Betafix surgical hypoallergenic flexible tape over the knee joint for the sham taping group, which might have caused the comparable-with-experimental-group effect on pain.

Wageck and colleagues concluded that 4-day application of KT techniques had no significant effect on pain in older people with KO.³⁰ The different findings of our study can be partly explained by the longer taping application course which might have been sufficient for beneficial effects to be induced in the chronic condition. Thus, our hypothesis is mainly supported by the subjective evaluations of KT effectiveness by participants, which demonstrated the indication of a higher percentage of improvement every subsequent week of taping. It is notable that the researchers interpreted only PPT changes and, due to no significant change found, concluded KT to have no significant effect on pain. Their findings with PPT are the same as ours. Nevertheless, in our opinion, it is not accurate to generalize the effect of any method on knee pain just by the changes in PPT.

PPT reflects perceived pain evoked by external pressure. Since it is reproducible over time and has been validated in studies with KO, it is a useful tool to provide insight into changes in knee pain.^{31,32} The higher PPT is associated with less pain in KO. The lower values of PPT in the knee area is associated with peripheral sensitization and, in remote sites, with central sensitization.³¹ The complex pathophysiology of sensitization can probably explain the limited effectiveness of taping to PPT. It has been reported that patients who had higher pain sensitization prior to surgery, even after knee joint replacement, remain sensitized and may develop chronic knee pain.³³ Algometry does not measure pain evoked by movement or at rest which can be caused by different pathophysiological and psychological mechanisms in KO than sensitization. PPT should not be used and interpreted as the only indicator for changes in pain.

All subjects in our study had never experienced KT: therefore, a placebo effect cannot be denied as a possible pain reduction mechanism.^{34,35} However, any treatment produces a placebo effect.

The placebo effect on pain in comparison with no treatment has been reported to be 0.65 cm if assessed by the visual analog scale (VAS).36 In a recent study, an excellent correlation (0.95) was reported between NPRS and VAS for KO, and minimal detectable change for NPRS to be 1.33.29 These values were exceeded in the majority of pain categories in the KT group. Due to the doubleblind study design and indifferent input toward the effectiveness of KT for KO provided by the researchers to the patients, the placebo effect was partially minimized and should not be considered as the main factor in inducing the observed changes in the outcomes. Beneficial psychological effects (other than placebo) of knee taping in KO, though little studied, are also possible mechanisms of pain reduction in both groups.37,38

The significant reduction of NSAID usage during the participation period in both groups, and the lasting reduction during a month without taping should not be underestimated and is an important clinical implication towards the beneficial effects of taping for knee-pain management, especially when dealing with polypharmacy cases or when there is a high risk of drug side effects, or they are contraindicated. Also, it is important that a patient with KO (or family members, other care givers) could be taught knee taping by a professional and then could continue the applications at home. Kinesio[®] tapes are relatively cheap, with low risk of dangerous adverse effects or health hazards.35 Considering these facts and our findings, we support the pro conclusions concerning the effectiveness of the KT method for KO pain management, expressed by other researchers in the field.9,17,18,24,27,34,39-41

Some researchers, who assessed the effectiveness of KT in a very short term and found no effect,³⁰ or found that the pain relief in the KT group was equal to the relief produced by sham taping,¹⁶ doubted the benefits of the KT effect for pain in KO. Some reviewers criticized the pain-relieving effect to be too small to be clinically worthwhile,⁴² or concluded KT to be just superior to minimal intervention for pain relief, yet not superior over other treatment approaches in reducing pain and disability.43 The different therapeutic applications, the amount of tension applied, and the duration of tape left in situ may influence the effect size for pain relief.43 However, the reduction of daily painkillers in KO with KT was also found in the study performed by Castrogiovanni and coworkers.27 The

most recent meta-analysis and review concluded KT as effective in relieving pain and improving joint function in patients with KO.^{34,44}

Based on our findings, we would agree that KT alone is not enough to completely solve the complex pain management problem in KO. Therefore, whenever possible, KT should be used as an adjunct to other rehabilitation interventions. Nevertheless, the reduction of analgesic medications usage is clinically a very important effect which, in some cases, when other more effective rehabilitative measures are unavailable, can justify the use of even NT for pain management in KO, at least in the short term.

No major side effects or intolerability of the method were reported in the studies conducted on the effectiveness of KT in KO. The 4-week-long knee taping was well tolerated by most of our KO patients as well. However, this should be viewed in light of the common limitation: only short-term knee taping and the follow up were analyzed, which might cause underestimation of complications.³⁴

Our results suggest that knee taping might not be tolerated by all KO patients, as a small number of participants (approximately 2%) discontinued participation in the research, indicating subjective intolerance. We did not manage to find a similar result in the reported studies on KO and KT. This can be partly explained either by the very short duration of taping or by poor data reporting in some studies, thus making it impossible to compare the findings. We also cannot exclude possible cultural aspects that may have caused some of our patients to subjectively not tolerate knee taping.

In our study, skin reactions/irritation did not demand any treatment or discontinuation of taping and was observed in approximately 9% of both groups' participants. The alertness toward possible skin reactions and irritations due to taping is clearly needed in clinical practice, especially for more vulnerable groups of patients like geriatric patients, patients with sensory disorders, lymphedema, etc.^{45–47} Medical staff, as well as patients, should be aware of the possible side effects of taping and how to manage them in order to avoid major skin lesions.

The strengths of our study are: the randomized, controlled, double-blind study design; minimization of possible external factors (local treatment, vigorous new physical activities, other rehabilitative interventions) that might directly affect knee pain and bring inaccuracies to the interpretation of findings; the monitoring of pharmacological pain treatment through the whole participation period and follow up; the sample-size assessment with a power of 80%; applications of the same-brand tape in treatment and control group, thereby assuring the blinding of participants toward which technique was considered therapeutic.

Limitations of this study may include the absence of a no-tape group, a relatively short taping course and follow up for a chronic condition. Also, our study's results and conclusions toward effectiveness of the KT technique, safety and tolerance of the method, should be interpreted with consideration that the brand of the tape used in the study might have had an important impact on the results for both groups' participants. This must not be underestimated due to high variety of commercially available brands of kinesiology tape, as other brands might produce a different effect and safety hazards in clinical practice.^{45,47,48}

Studies utilizing a longer period, comparing effects of different brands and taping techniques are warranted, to determine if there is a continued reduction in pain, and if taping remains effective and safe over time for pain management in KO.

Conclusions

Knee taping with Kinesio Tex Tape Gold FP can safely relieve knee pain and reduce the need for pharmacological pain management in KO, and the pain-relieving effect lasts at least 4 weeks post the taping month. A specific KT technique is clinically more beneficial for knee-pain alleviation in comparison with NT; therefore, it should be a preferred technique if a trained professional is available.

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Raimondas Kubilius contributed to the analysis and interpretation of data for the work; revised the work critically for important intellectual content; provided final approval of the version to be published; and provided agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Conflict of interest statement

The authors declare that there is no conflict of interest.

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