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Kinesio Taping™ effects with different directions and tensions on the muscle activity of the rectus femoris of young adults with a muscle imbalance promoted by mechanical vibration: a randomized controlled trial

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Abstract

Background Therapeutic strategies such as improvement muscle activation are fundamental for clinical practice, especially for the quadriceps muscle. It is not yet clear in the literature whether Kinesio Taping (KT) can modify muscle activation. This study sought to evaluate the effect of Kinesio Taping™ (KT) with different directions and tensions on the muscle activity of the rectus femoris in young adults with a muscle imbalance promoted by mechanical vibration. Thirty-two subjects were allocated into two groups: group A, used taping origin to insertion and group B, used taping insertion to origin. In both groups the dominant limb received the taping while the non-dominant limb was used as a control. A continuous vibration (60 Hz) was conducted on the patella tendon for 20 min before the electromyography (EMG) evaluation. Mean and maximum EMG values of the rectus femoris were collected during three maximal isometric voluntary contractions performed in 5 s. Muscle activity was evaluated three times: prior to KT application, immediately after KT placement, and 24 h later. These evaluations were done with 0% (no tension), with 10% (paper off), and with 75–100% (total tension) on both groups. Significance level of $p < 0.05$ was used.

Results Compared with no intervention, on group A, there were differences for mean and maximum EMG values 24-h post-application with 0%, 10%, and 75% of tension ($p < 0.05$). On group B, there were differences for maximum EMG values immediately and 24 h post-application with 0% and 75% of tension ($p < 0.05$). There were no differences between both groups ($p > 0.05$).

Conclusions Kinesio Taping applied with different directions and tensions increased the muscle activity immediately and 24 h post-application of the rectus femoris of healthy individuals. The inhibition technique cannot decrease the muscle activity.

Keywords Kinesio tape, Electromyography, Rectus femoris

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Background

In order to improve or enhance muscle function, various techniques can be used, such as electrical stimulation, stretching and heating. Another type of external stimulus that has been used is the taping application [1].

Kinesio Taping™ (KT) is a kinesthetic method of therapeutic taping that has been introduced to help a variety of physical dysfunctions. One of its purposes is to enhance somatosensory inputs and improve muscle function through the stimulation of the mechanoreceptors [2, 3]. The KT has elastic properties similar to the skin and can be stretched from 40 to 60% of its original length, and this elasticity allows a full range of motion during the functional activities [4].

KT can modulate muscle function through the stimulation of the mechanoreceptors, and some hypotheses raised to explain this effect are the cutaneous stimulation and communication with the deeper tissues provided by the tape and the modulation of afferent input to the central nervous system. The improvement in muscle function can manifest as an increase or decrease in muscle activity, an increase in muscle strength, and better proprioception, although this has not yet been fully elucidated in the literature [5–8].

According to the inventors, to promote an increase in the muscle activity (facilitation) is advised to use an application from origin to insertion with a tension of 10–35%, while to promote a decrease in the muscle activity (inhibition) is advised to use an application from insertion to origin with a tension of 10–25% [9].

Few studies have evaluated the hypothesis of increase (facilitation) and decrease (inhibition) in the muscle activity according to the direction of application, and there are also few studies that evaluated the effects of KT according to the different tensions. Two studies showed that the different directions or tensions of the KT application do not increase the strength of quadriceps, and one study found that the different directions do not increase the muscle activity of the wrist extensor muscles [10–12].

The purpose of this study is to evaluate the effects of Kinesio Taping™ with different directions and tensions on the muscle activity of the rectus femoris in individuals who have a muscle imbalance due to exposure to continuous vibration prior to the taping application. Based on the theories proposed by the method, it is expected that the application from origin to insertion with 10% of tension will generate an increase in the muscle activity of the rectus femoris, while the application from insertion to origin with 10% of tension will generate the opposite effect.

Methods

This is a randomized controlled trial, in which the principal investigator who assessed the outcomes was blinded to the allocation of intervention. The study was conducted in according to the Resolution of the Ministry of Health 466/12, and the participants gave informed consent. This trial was prospectively registered at ClinicalTrials.gov and followed the CONSORT (Consolidated Standards of Reporting Trials) recommendations [13].

The inclusion criteria were (I) participants of both genders, (II) age between 18 and 40 years old, (III) no musculoskeletal disorders in the lower limbs (i.e., knee osteoarthritis, patellofemoral pain, patellar tendinopathy, knee ligament injuries, iliotibial band syndrome, and Achilles tendinopathy), and (IV) no history of injury in the last 6 months in the lower limbs. The exclusion criteria were (I) participants with body mass index greater than 24.99; (II) competing in elite level; (III) presence of cardiovascular, neurological, or rheumatic disease; (IV) pregnancy; (V) history of tape allergy or skin sensitivity; and (VI) previous knowledge about the KT.

The participants recruited were ignorant about KT, and they were informed about the possibility to be allocated in a placebo group in order to minimize the placebo effect. As described in previous studies, potential placebo effects are eliminated by deception [12, 14, 15].

The sample of this study was determined based on a sample size calculation carried out in a pilot study to this research. The G-power software was used, and a sample size was calculated based on an electromyographic score of 6 individuals divided into 2 groups. Calculations were made using a difference between two independent means, $\alpha=0.05$, $\beta=0.20$, allocation ratio N2/N1 = 1, effect size $(d)=1.13$, and 80% of statistical power. Based on these criteria, at least 14 individuals per group were required in each group. Therefore, a sample of 32 individuals completed the study: group A ($n=16$) and group B ($n=16$).

The participants were randomly allocated into two groups: group A, KT application from the muscle origin to its insertion and group B, KT application from insertion to origin as shown in the diagram (Fig. 1). The dominant limb received the KT application, and the non-dominant limb was the control of the study on both groups. The leg dominance was determined according to the following definition "the leg used to kick a ball." Participant selection and randomization were conducted by a person who was not involved with the interventions. The randomization schedule was generated by http://www.randomization.org. The participants and the investigator who assessed the outcomes of the study were blinded to the treatment allocation.

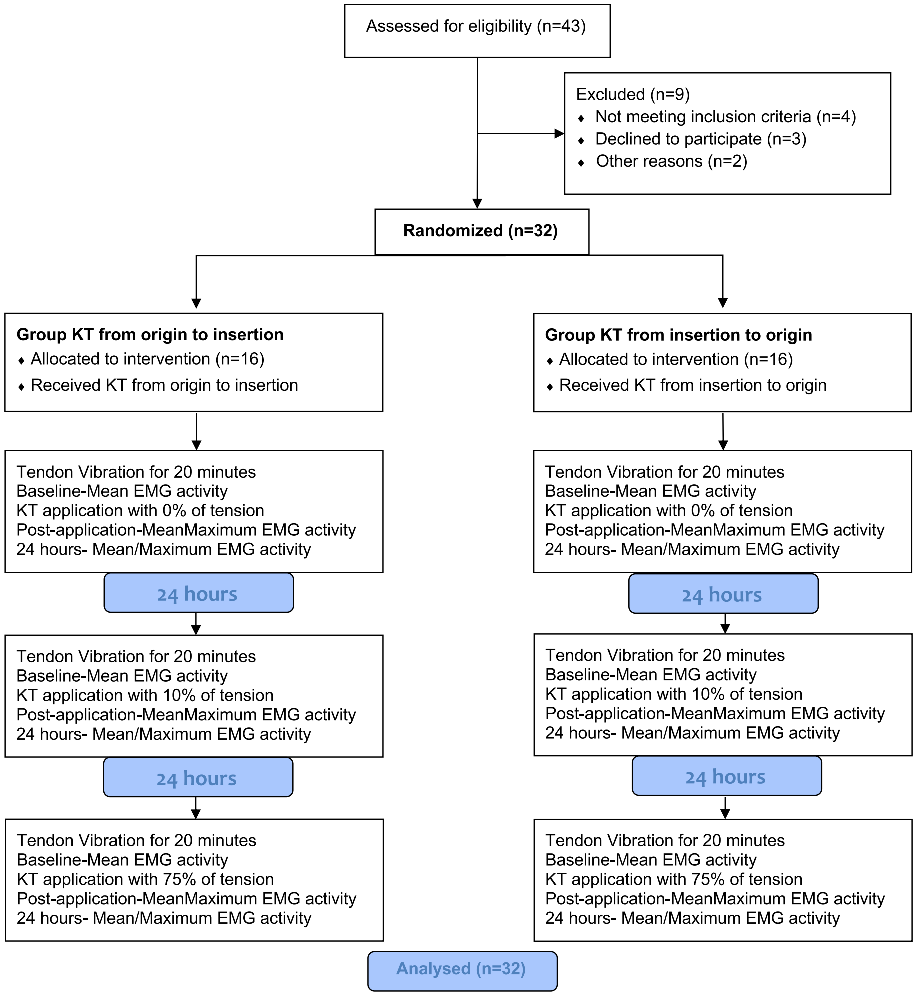

Fig. 1 Diagram of the study

The primary outcomes were mean and maximum EMG values. The activity of the rectus femoris muscle was evaluated using the EMG 400 MyoTrace with two channels from Noraxon System (Sistema de EMG MyoTrace 400, 2013). Two capture electrodes were placed on the belly muscle in the direction of the muscle fibers. The participants were seated in a back-supported extensor chair while performing a full extension of the knee (Fig. 2). The electrodes were placed at a 50% imaginary line between the anterior–superior iliac spine and the superior edge of the patella. A measuring tape was used to ensure consistency of the positioning of the electrodes in the taping for all participants. The surface electrodes were a differential active-type, with a gain of 20-fold and with a length of 10 mm and a width of 2 mm. In all evaluations, the reference electrode was kept on the patella. To capture the EMG signal with the KT over the muscle, the electrodes remained on the skin underneath the taping. A scissor was used to make the hole around the metal part. The diameter of the hole was the same as the metal part of the electrode to not influence the possible effects of the tape and the assessment.

The participants performed three maximal isometric voluntary contractions during 5 s and with an interval of 30 s between them. Muscle activity was evaluated three times: prior to KT application, immediately after KT placement, and 24 h later. These evaluations were done with 0% of tension, with 10% (paper off tension), and with 75–100% (total tension) on both groups.

The continuous vibration (professional massager gun by Hypervolt) was conducted using 60 Hz on the patella tendon for 20 min before the EMG evaluation. The effects of the MV stimulation are similar to a voluntary contraction, causing intrafusal muscle thixotropy, resulting in cross-bridge detachment from actin and myosin [16]. In addition, prolonged vibration (20 min) in the patellar tendon of health subjects can decreased the normalized reflex torque (≅20%), rate of torque

Fig. 2 KT application with the EMG

development (≅25%), and rectus femoris/vastus lateralis surface electromyography amplitude (≅30–40%). Also, increased total reflex latency and premotor reflex latency of both muscles. These findings suggest that muscle spindle reflex arc function is decreased following prolonged vibration [17]. So the vibration was performed to cause a neuromuscular disorder in the rectus femoris promoting changes in the muscle balance [18].

After the vibration, the first intervention was performed with the KT without tension (0%) on the rectus femoris on the dominant limb (experimental) with the participant lying in a supine position with the knee off the table in elongated position for the rectus femoris muscle. The participants were blinded to the allocation since they were unable to watch the KT application. Also, they did not have knowledge about the origin or insertion of the rectus femoris. The same procedure was performed on the second and third day with the specific tension.

For the EMG assessment, the position of the electrodes did follow the procedures recommended by SENIAM (surface EMG for non-invasive assessment of muscles), and the electrode reference was placed on the patella [19].

Data were analyzed in SPSS (Statistical Package for Social Science), version 22.0, and was considered $p<0.05$. The Shapiro–Wilk test was used to verify the normality of the data. Results were expressed as mean, standard deviation, and 95% confidence intervals (CI). To compare the mean and maximum EMG values, the *t* test for independent samples was used to between-group comparisons (KT x without KT; group A, KT application from the origin to insertion x group B, KT application from the insertion to origin) and the analysis of variance (ANOVA) for repeated measures with post hoc Bonferroni was used to within-group comparisons (0% × 10% × 75%; pre-application x post-application × 24 h).

Results

Forty-three participants were assessed for eligibility, 34 women and 9 men, with a mean age of 20.5 (SD = 4.6) years and body mass index average of 18.7 (SD = 2.34) kg/m^2. Forty-one participated in weekly exercises such as weight training and jogging. Of these 43 participants, 4 individuals had previous knowledge about the KT, 3 declined to participate, and 2 failed to complete the study. In this context, the assessment of muscle activity was made on 32 participants (group A application from the origin to insertion—$n=16$; group B application from the insertion to origin—$n=16$). The gender distribution in group A consisted of 12 females (75%) and 4 males (25%), while in group B, there were 13 females (81.3%) and 3 males (18.8%). The chi-square test resulted a *p* value of 0.66, indicating no significant difference in gender distribution between the two groups.

Within-group differences in mean EMG values were found in group A, experimental limb, with 0% of tension on pre- and 24 h ($p=0.00$) and post- and 24 h ($p=0.02$), with 10% on pre- and 24 h ($p=0.02$) and post- and 24 h ($p=0.00$), and with 75% on pre- and 24 h ($p=0.02$) and post- and 24 h ($p=0.00$). For the maximum EMG values, significant differences were found with 0% of tension on post- and 24 h ($p=0.00$), with 10% on post- and 24 h ($p=0.00$), and with 75% of tension on post- and 24 h ($p=0.00$). Within-group differences in mean EMG values were also found in group B, experimental limb, with 0% of tension on pre- and 24 h ($p=0.02$). For the maximum EMG values, significant differences were found with 10% of tension on post- and 24 h ($p=0.04$) and with 75% of tension on post- and 24 h ($p=0.00$).

Between-member differences were found in group A for mean EMG values 24 h post-application with 0%

and 75% of tension ($p=0.00$, $p=0.00$) and for maximum EMG values 24 h post-application with 0%, 10%, and 75% ($p=0.01$, $p=0.00$, $p=0.00$). In group B, there were between-member differences for maximum EMG values immediately post-application with 0% ($p=0.00$) and 24 h post-application with 0% ($p=0.01$) and 75% of tension ($p=0.00$). There were between-group differences only for maximum EMG values 24 h post-application with 10% of tension ($p=0.00$), with group A presenting high values (Tables 1 and 2).

Discussion

Compared with no intervention, Kinesio Taping™ applied from origin to insertion increased the mean and maximum EMG values 24 h post-application with 0%, 10%, and 75% of tension, while the Kinesio Taping™ applied from insertion to origin increased the maximum EMG values immediately post-application with 0% of tension and 24 h post-application with 0% and 75% of tension. In addition, Kinesio Taping applied from origin to insertion was superior to Kinesio Taping™ applied from insertion to origin in the maximum EMG values 24 h post-application with 10% of tension.

Some studies on the effect of Kinesio Taping on muscle electromyographic activity have shown effects [3, 20, 21], while others have not [8, 22, 23].

There are some similarities between the findings of Watanabe's study [20] and those of this study, such as the verification of a modification in quadricep electromyographic activation after application. However, in Watanabe's study, this modification was a reduction in electromyographic activity, whereas in our study, the opposite was observed.

Other studies have also shown some modification of electromyographic activity after the application of the bandage on leg muscles of individuals with chronic ankle instability [21], on arm muscles (biceps brachii) of healthy individuals [3], and on hip muscles (gluteus medius) [24].

On the other hand, there is still disagreement in the literature and some authors have not observed changes in electromyographic activity in their research. For instance, Dolphin et al. [22] also studied the application of KT in the quadriceps muscle and did not find any differences between the groups in their clinical trial. However, the groups formed were both with KT application to verify if there was any difference between applying from muscle origin to insertion versus insertion to origin. Thus, their findings partially agree with ours, as we also did not find relevant differences in the direction of KT application.

Other studies with control groups do not agree with our results. Both studies evaluated quadriceps muscle activation in healthy individuals and did not find relevant changes in muscle activity [8, 23].

Indeed, there is still disagreement in the literature regarding the effect of Kinesio Taping on electromyographic activity in healthy individuals [3, 8, 20–23]. However, there are more consistent findings regarding the effect on individuals with some neuromuscular impairment [21, 25], whether it is pathological or induced, as was the case in our study.

Based on our findings and those of Dolphin et al. [22], it appears that the direction of application is not related with the changes on muscle activity, as there was no significant difference observed between applying the tape from origin to insertion versus from insertion to origin. Additionally, the tension of application does not affect the changes in muscle activity, as there were no significant differences observed between tensions of 0%, 10%, and 75%, which is consistent with the findings of Watanabe's study [20].

Clinicians should not use Kinesio Taping™ in order to promote an inhibition effect. Also, clinicians should be aware that the possible effects generated on the muscle activity with the KT are independent of the direction and tension of application. For researchers, KT applied with 0% of tension generated an increase on muscle activity, which means that this tension should not be used in clinical trials as a placebo application.

The strongest point of the study was the choice of deceptive placebo, because our understanding is that any study that is conducted with different kind of tapes or even the elastic tape placed with no tension, it cannot be called placebo because it is also causing sensorial activity like the KT. So the subjects were informed during the explanation of the procedures of research that was a presence of a placebo group, in which they could be allocated. Also the subjects were asked whether they knew the group that they were allocated with the intention of testing the blinding of the study. These were done with the intention of minimizing the placebo effect.

This study involved participants who were induced with temporary neuromuscular deficits through 20 min of tendon vibration, which caused proprioceptive deficits during and after the application of vibratory stimulation [16, 18, 26]. The purpose of this was to simulate a non-healthy condition or a muscle imbalance. The same protocol was used in another study and the authors found a decrease in the normalized reflex torque (≅20%), rate of torque development (≅25%), and Rectus femoris/Vastus lateralis surface electromyography amplitude (≅30–40%). Also, increased total reflex latency and premotor reflex latency of both muscles. These findings suggest that muscle spindle reflex arc function is decreased following prolonged vibration [17].

Table 1 Within-group and between-member comparison, mean (SD) and mean difference, and 95% CIs for the outcomes of the study ($n = 32$)

Outcomes	Mean (SD)		Mean differences (95% CI)	*p*
	KTT	Without KTT		
Group A				
Mean 0%				
Baseline	49.99 (5.83)	51.72 (5.78)	− 1.72 (− 5.91 to 2.46)	
Post-application	53.52 (9.36)	52.78 (7.55)	0.73 (− 5.69 to 7.15)	0.81
24 h	71.89 (22.46)[a,b]	49.22 (14)	22.66 (8.41 to 36.90)	0.00[§]
Mean 10%				
Baseline	52.13 (4.81)	53.83 (5.87)	− 1.70 (− 5.57 to 2.17)	
Post-application	53.80 (12.45)	51.03 (7.33)	2.76 (− 5.02 to 10.55)	0.47
24 h	63.14 (13.30)[a,b]	67.33 (27.91)	− 4.19 (− 20.43 to 12.04)	0.61
Mean 75–100%				
Baseline	52.46 (5.04)	52.66 (2.81)	− 0.20 (− 3.20 to 2.79)	
Post-application	54.28 (9.50)	50.56 (7.62)	3.73 (− 2.57 to 10.04)	0.24
24 h	63.73 (12.56)[a,b]	45.66 (4.61)	18.06 (10.90 to 25.21)	0.00[§]
Maximum 0%				
Post-application	105.28 (19.47)	103.67 (20.05)	1.60 (− 12.66 to 15.87)	0.82
24 h	142.80 (52.71)[b]	99.93 (28.36)	42.87 (11.46 to 74.27)	0.01[§]
Maximum 10%				
Post-application	100.38 (22.56)	93.86 (8.74)	6.52 (− 6.77 to 19.81)	0.31
24 h	158.82 (55.28)[b]	106.60 (31.61)	52.21 (16.75 to 87.68)	0.00[§]
Maximum 75–100%				
Post-application	105.04 (16.78)	93.33 (16.28)	11.70 (− 0.44 to 23.85)	0.05
24 h	132.81 (26.80)[b]	88.30 (15.15)[b]	44.51 (26.75 to 62.26)	0.00[§]
Group B				
Mean 0%				
Baseline	51.44 (7.43)	51.55 (4.84)	− 0.11 (− 4.64 to 4.41)	
Post-application	57.64 (10.99)	79.30 (46.31)	− 21.64 (− 46.78 to 3.49)	0.08
24 h	73.22 (22.30)[a]	69.62 (36.32)	3.59 (− 18.38 to 25.57)	0.74
Mean 10%				
Baseline	51.54 (5.94)	52.50 (4.53)	− 0.95 (− 4.77 to 2.85)	
Post-application	58.11 (8.00)	63.70 (34.01)	− 5.60 (− 25.52 to 14.32)	0.55
24 h	63.11 (14.72)	63.47 (41.70)	− 0.36 (− 24.40 to 23.68)	0.97
Mean 75–100%				
Baseline	51.45 (3.48)	50.92 (5.47)	0.53 (− 2.99 to 4.05)	
Post-application	49.90 (29.23)	52.33 (8.90)	− 2.43 (− 19.73 to 14.87)	0.76
24 h	56 (31.45)	44.50 (18.94)	11.54 (− 7.58 to 30.68)	0.22
Maximum 0%				
Post-application	117.29 (18.39)	98.68 (15.29)	18.60 (6.13 to 31.07)	0.00[§]
24 h	144.66 (40.72)	110.32 (32.42)	34.34 (7.76 to 60.92)	0.01[§]
Maximum 10%				
Post-application	104.36 (7.54)	104.68 (11.07)	− 0.32 (− 8.34 to 7.70)	0.94
24 h	124.80 (30.02)[b]	103.74 (31.04)	21.05 (− 1.40 to 43.41)	0.06
Maximum 75–100%				
Post-application	101.27 (14.95)	107.55 (15.84)	− 6.27 (− 17.40 to 4.84)	0.25
24 h	119.87 (22.66)[b]	79.51 (21.37)[b]	40.36 (23.88 to 56.84)	0.00[§]

KTT Kinesio Taping Technique, *Group A* origin to insertion, *Group B* insertion to origin

[a] Indicates a statistically significant difference within-group (pre- and 24 h)

[b] Indicates a statistically significant difference within-group (post- and 24 h)

[§] Indicates a statistically significant difference between-member

Table 2 Between-group comparison, mean (SD) and mean difference, and 95% CIs for the outcomes of the study ($n = 32$)

Outcomes	Mean (SD)		Mean differences (95% CI)	*p*
	Group A	Group B		
Mean 0%				
Baseline	49.99 (5.83)	51.44 (7.43)	− 1.44 (− 6.27 to 3.37)	
Post-application	53.52 (9.36)	57.64 (10.99)	− 4.11 (− 11.49 to 3.25)	0.26
24 h	71.89 (22.46)	73.22 (22.30)	− 1.33 (− 17.49 to 14.82)	0.86
Mean 10%				
Baseline	52.13 (4.81)	51.54 (5.94)	0.58 (− 3.31 to 4.48)	
Post-application	53.80 (12.45)	58.11 (8.00)	− 4.30 (− 11.85 to 3.25)	0.25
24 h	63.14 (13.30)	63.11 (14.72)	− 0.02 (− 10.70 to 10.74)	0.99
Mean 75–100%				
Baseline	52.46 (5.04)	51.45 (3.48)	1 (− 2.28 to 4.29)	
Post-application	54.28 (9.50)	49.90 (29.23)	4.38 (− 13.01 to 21.79)	0.60
24 h	63.73 (12.56)	56 (31.45)	7.73 (− 11.24 to 26.69)	0.40
Maximum 0%				
Post-application	105.28 (19.47)	117.29 (18.39)	− 12.00 (− 25.68 to 1.66)	0.08
24 h	142.80 (52.71)	144.66 (40.72)	− 1.86 (− 35.87 to 32.14)	0.91
Maximum 10%				
Post-application	100.38 (22.56)	104.36 (7.54)	− 3.97 (− 17.05 to 9.10)	0.53
24 h	158.82 (55.28)	124.80 (30.02)	34.02 (1.27 to 66.77)	0.04⅃
Maximum 75–100%				
Post-application	105.04 (16.78)	101.27 (14.95)	3.77 (− 7.89 to 15.43)	0.51
24 h	132.81 (26.80)	119.87 (22.66)	12.94 (− 5.35 to 31.24)	0.15

Group A origin to insertion, *Group B* insertion to origin

⅃ Indicates a statistically significant difference between-group

These results question the theory created by the method that KT applied from insertion to origin generates an inhibitory effect and that a specific amount of tension should be used to obtain the proposed effects. Another hypothesis for the directions has been proposed with the fascia specific direction [27, 28], and another is the fact that cutaneous and muscle afferents show common general movement-encoding characteristics that may facilitate the central co-processing of the feedback information subserving kinaesthesia [29]. These hypotheses must be elucidated in future studies.

Limitations and strengthens

Limitations are as follows: (I) the level of muscle activation before mechanical vibration was not measured, which would have made it possible to verify the effect that mechanical vibration had on each individual; (II) the order of application was unified and not randomized; and (III) there was not a wash-out period between applications. A 24-h period may have a significant carry-over effect; (IV) the study sample is composed of both sexes, which may decrease the precision of the results since there is evidence in the literature of differences in efficiency and neuromuscular control variables between genders [30]; (V) having applied the technique on the dominant side, we suggest that future studies should randomize the side of application; and (VI) our results cannot be generalized to symptomatic patients, we understand our study as providing preliminary information for the future application of the technique in patients with pathological neuromuscular control deficits.

Strengths are as follows: (I) this paper demonstrates interesting findings regarding the effects of Kinesio Taping on muscle activity, considering different directions and tensions of application. While most studies in this field have focused on healthy subjects, we deliberately induced muscle imbalance in all our participants through continuous vibration; (II) previous studies have examined the application of the tape from insertion to origin or from origin to insertion. However, no prior study has investigated the electromyographic activity in relation to different tensions of the tape, such as 0%, 10%, and 75–100% tension levels; (III) the placebo effect was minimized by excluding participants who had prior knowledge or experience with Kinesio Taping from the study;

and (IV) therefore, this study is of great interest to a wide readership, including those involved in sport physical therapy, musculoskeletal dysfunctions, and the utilization of the widely adopted Kinesio Taping method, which has shown a lack of consensus between evidence and practice.

Conclusions

Based on the results from this study, KT applied from origin to insertion with 0%, 10%, and 75% of tension increased the mean and maximum EMG values of the rectus femoris in individuals with a muscle imbalance promoted by mechanical vibration at 24 h post-application. In addition, KT applied from insertion to origin increased the maximum EMG values immediately post-application with 0% of tension and 24 h post-application with 75% of tension. KT applied with the inhibition technique can not promote inhibition of the muscle activity as described by the manufacturers. There is not a specific amount of tension that should be used to obtain an increase on the muscle activity, another fact that differs from what was proposed by the manufacturers. Other explanations for this effect must be considered. Future studies are recommended with different kind of injuries, imbalances, and conditions.

Abbreviations

KT	Kinesio Taping
EMG	Electromyography
CONSORT	Consolidated Standards of Reporting Trials
MV	Mechanical vibration
SENIAM	Surface EMG for non-invasive assessment of muscles
SPSS	Statistical Package for Social Science
SD	Standard deviation
GTO	Golgi Tendon Organs

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Authors' contributions

TVL and JPCM: concept development (provided idea for the research), design (planned the methods to generate the results), and supervision (provided oversight, responsible for organization and implementation, writing of the manuscript). TVL, MGRS, MMNR, and LGCS: data collection/processing (responsible for experiments, patient management, organization, or reporting data). TVL, JRSJ, and MGRS: analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results) and writing (responsible for writing a substantive part of the manuscript). TVL and JPCM: critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking). The authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This research as approved by the Ethics Committee of the Universidade Salgado Oliveira (UNIVERSO), with the number 561.500, according to the Resolution of the Ministry of Health 466/12, and the participants gave informed consent. This trial was prospectively registered at ClinicalTrials.gov (NCT02501915) and followed the CONSORT.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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