

Short-term effectiveness of epidermis dermis fascia kinesiotopeing technique in myofascial pain syndrome on upper trapezius: A multi-center, double-blind, randomized clinical study

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ABSTRACT

Objectives: This study aims to investigate the efficacy of epidermis dermis fascia (EDF) kinesiotopeing (KT) technique on pain intensity, number of active trigger points (TrPs), cervical range of motion (ROM) angles, and disability levels in patients with myofascial pain syndrome (MPS) on upper trapezius (UT) muscle.

Patients and methods: Between January 2019 and January 2020, a total of 180 patients (21 males, 159 females; mean age: 35.9±9.0 years; range, 18 to 56 years) with MPS were included. The patients were randomized into either KT with EDF technique (Group 1) or sham KT (Group 2). Outcome measures were Visual Analog Scale (VAS) pain score, number of active TrPs, cervical ROM angles, and Neck Pain Disability Scale (NPDS).

Results: Both groups improved in terms of all outcome parameters except for cervical flexion and extension angles in Group 2. The VAS pain scores significantly decreased in Group 1 ($p<0.05$), compared to Group 2. The number of active TrPs ($p=0.001$) and NPDS scores ($p=0.016$) of Group 1 significantly improved than Group 2. Cervical flexion ($p=0.001$), extension ($p=0.001$), and left and right lateral flexion angles ($p<0.0001$) significantly improved in Group 1. Cervical left ($p=0.001$) and right ($p<0.0001$) lateral flexion angles significantly improved in Group 2. There was no significant difference between the groups regarding cervical ROM angles.

Conclusion: Our study results suggest that KT with the EDF technique is an effective method in reducing pain and number of active TrPs, improving disability and cervical ROM angles.

Keywords: Kinesiotopeing, myofascial pain syndrome, trigger point.

Myofascial pain syndrome (MPS) is a common musculoskeletal disorder characterized by regional pain originating from hyperirritable spots located within taut bands of skeletal muscle, known as myofascial trigger points (TrPs).^[1] Patients typically

suffer from local and/or referred pain, limited range of motion (ROM), muscle spasm, and tenderness.

Medication, local injections, physical therapy modalities, cold spray and stretching, dry needling, acupuncture and exercise programs are some of

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the treatment choices.^[2] Kinesiotaping (KT) is an application of a form of elastic tape and became popular in the treatment of musculoskeletal conditions and sports injuries to decrease pain and edema, to increase the ROM and strength, to correct the postural alignment.^[3,4] The exact mechanism of KT has not been well understood. It is thought that KT exerts its effect by providing proprioceptive and sensorimotor stimulation to the skin, muscle and fascia and providing appropriate afferent input to the central nervous system.^[5] There are different KT techniques such as facilitation, inhibition, fascia correction, space correction, functional correction, and mechanic correction. According to the aim, practitioners may choose different application techniques.^[6]

Many studies investigating the effect of KT on MPS have applied inhibition technique or space correction technique.^[7-13] Inhibition technique has a tonus decreasing effect. The application is affixed from muscle insertion to muscle origin. The KT exerts tension in the direction of insertion to the origin and likewise displaces the skin in the same direction. This application causes a reduction in muscle contraction.^[14] Space correction technique is applied to the painful area with 10 to 35% tension to create more space directly above the area of pain, inflammation, swelling or edema. The increased space is believed to reduce pressure by lifting the skin.^[6]

However, there is no study examining the efficacy of epidermis dermis fascia (EDF) technique on MPS. The EDF is a new course about applying a new KT product to the microlayers at the surface of the epidermis. The EDF taping was designed to stimulate more lift in the epidermis layers and to elevate more space. Considering both the direction of application and the cutting technique, the EDF technique seems to show the effect of both inhibition and space correction techniques.^[15]

In the present study, we hypothesized that an application of KT with EDF technique can reduce pain and number of active trigger points since this technique can lift and elevate the space between the tissue layers in the epidermis, by spreading out the application over overlapping layers. We, therefore, aimed to investigate the efficacy of EDF technique on pain intensity, number of active TrPs, cervical ROM angles, and disability levels in patients with MPS on upper trapezius (UT) muscle.

PATIENTS AND METHODS

This multi-center, double-blind, prospective randomized, sham-controlled study was conducted at Physical Medicine and Rehabilitation Department of six centers between January 2019 and January 2020. A total of 196 patients with cervical MPS of UT muscle who were admitted to outpatient clinics of six centers were screened. The diagnosis of MPS was based on the diagnostic criteria described by Travell and Simon.^[16] Inclusion criteria were as follows: presence of an at least one active TrP and palpable taut band in the UT muscle, pain duration less than three months, Visual Analog Scale (VAS) pain score ≥ 4 , and age between 18 and 50 years. Exclusion criteria were as follows: having a diagnosis of neuromuscular, rheumatic, inflammatory diseases, malignancy or uncontrolled systemic conditions, infections, trauma, neck surgery, pregnancy or obesity (body mass index [BMI] ≥ 30 kg/m²). Finally, a total of 180 patients (21 males, 159 females; mean age: 35.9 \pm 9.0 years; range, 18 to 56 years) who met the inclusion criteria were recruited.

Sample size and randomization

To determine the sample size, power analysis was performed using the G*Power version 3.1.9.7 software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). An effect size of 1.32 was set up for the VAS pain score changes in treatment group as per the previous study.^[8] For power calculations, a confidence level (α) of 0.05 and a power level of 0.95 were assumed.

Fifteen patients per group in each center was required. All patients were randomized into two groups in each center by numbered envelopes method. The Group 1 and Group 2 notes were put into to the closed envelopes separately, and each patient randomly chose an envelope and gave it to a physician who was not the researcher. One researcher evaluated the patient and then collected the data, and the second researcher who was certified as KT practitioner applied the KT. Both patients and the researcher who recorded the data were blinded to treatment allocation. The study flowchart is shown in Figure 1.

Demographic data including age, BMI, sex, smoking habit, symptom duration, education level, symptom side were recorded.

Applications

The Kinesio Tex Gold FP (Kinesio Tex Tape, Kinesio Holding Corp., NM, USA) was used in

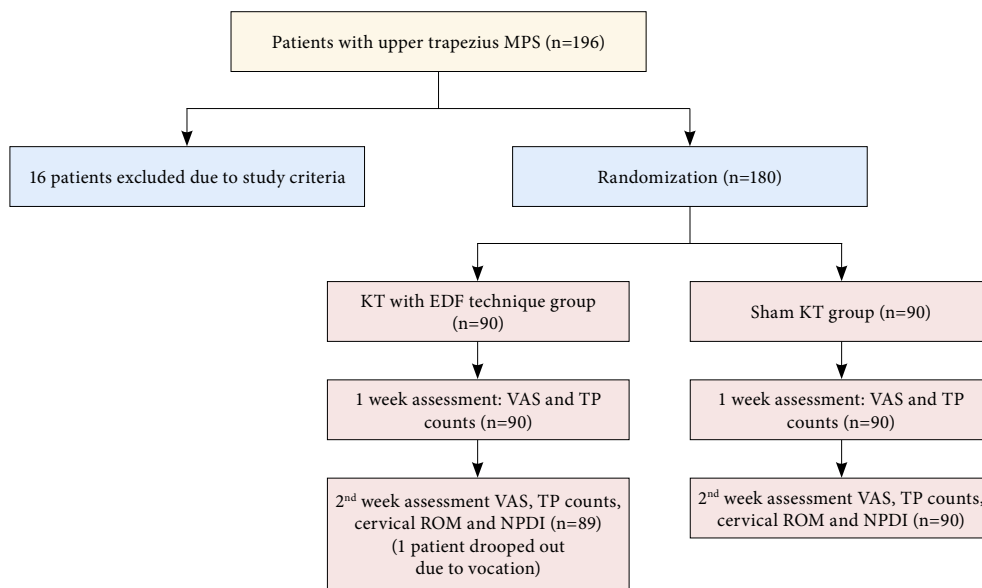


Figure 1. Study flowchart.

MPS: Myofascial pain syndrome; KT: Kinesiotaping; EDF: Epidermis dermis fascia; VAS: Visual Analog Scale; TP: Trigger point; ROM: Range of motion; NPDI: Neck Pain Disability Index.

this study, since this type of KT is suitable and offered by Dr. Kase for EDF taping applications, as it can be cut thinly so the application is lighter and can stimulate the surface of the skin. It is waterproof, porous and adhesive, has a width of 5 cm and a thickness of 0.5 mm. The same brand of tape was used in both groups. Before applying the applications, participants underwent testing for potential allergies to the band. This involved

attaching a small piece of tape to the inner surface of the forearm without stretching it for 15 min. Those exhibiting allergic symptoms or dermographism were excluded from the study.

The KT with EDF technique group (Group 1)

Prior to application, the patients were seated and asked to flex their neck laterally to the contralateral side and to rotate their head to the same side while

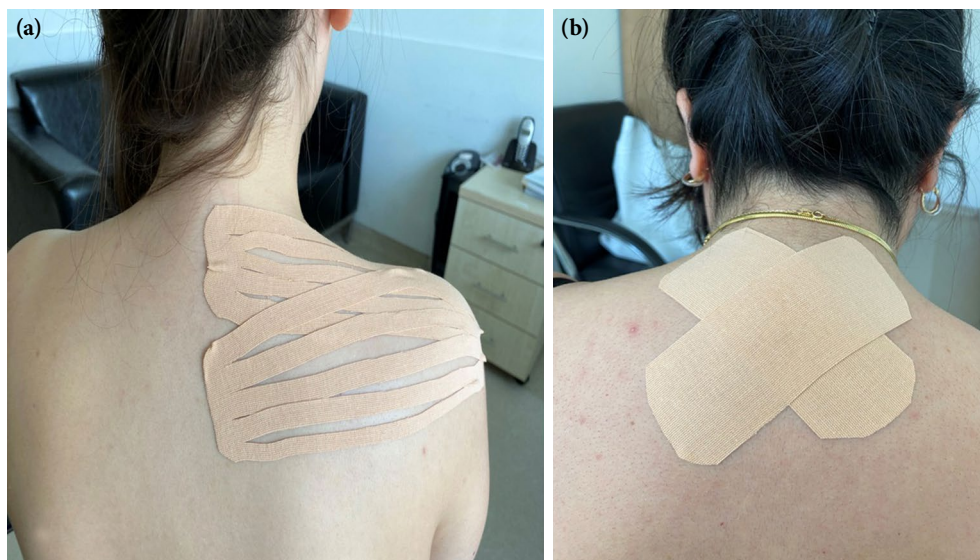


Figure 2. (a) Epidermis dermis fascia kinesiotaping. (b) Sham kinesiotaping.

the shoulder was adducted. I band was first fold in half and then divided into five lines without cutting the ends to form a web shape. Two pieces of web shaped 20 to 25 cm length KT were used. The end of the KT was applied to the acromion, and the spinal process of C7 vertebra without stretching, but the web on the muscle had 10 to 15% tension. The second webshaped band was applied using the same technique between acromion and thoracic vertebral insertion of the middle trapezius muscle (Figure 2a).

The KT with sham application group (Group 2)

The sham group received improper KT application consisting two I strips (same material as the real application) applied with no tension on C7 spinal process as cross sign. For sham taping, the cervical spine of the participants was placed in a neutral position (Figure 2b).

Kinesiotaping was planned to stay on for five days; it was applied twice, with two days of rest between applications in both groups. Trapezius stretching exercises were given to patients in both groups as home-based exercise program.

Outcome measures

Pain intensity: The VAS (0-10 cm) was used to record each patient's current level of neck pain, with 0 indicating no pain and 10 indicating the worst pain that the patient experienced. Patients filled out pain VAS scores on a ruler marked scale in centimeters at rest, during activity and at night at baseline (Time point 1 (T1)), 7th (Time point 2 (T2)) and 14th days (Time point 3 (T3)) of the study.

Number of active TrPs: Number of painful TrPs with palpation in UT muscle were recorded at baseline (T1), Day 7 (T2) and Day 14 (T3) of the study.

Cervical ROM angles: The active cervical ROM (flexion, extension, right-left flexion) was measured using a goniometer, when the patient was in sitting position at baseline (T1), and at the end of the study (Day 14) (T3).

Disability level

Neck Pain Disability Scale (NPDS): The questionnaire consists of 20 items and measures neck movements, pain intensity, effect of neck pain on emotion factors, and interference with daily life activities. Each section is scored on a 0 to 5 rating scale and total score ranges from 0 to 100. The Turkish version of this scale has been shown to be valid and reliable.^[17]

The NPDS was evaluated at baseline (T1), and at the end of the study (Day 14) (T3).

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 25.0 software (IBM Corp., Armonk, NY, USA). Continuous data were expressed in mean \pm standard deviation (SD) or median (min-max), while categorical data were expressed in number and frequency. The normal distribution of variables was assessed using the Kolmogorov-Smirnov test. For normally distributed variables, group comparisons were conducted using the Student t-test, whereas non-normally distributed variables were compared using the Mann-Whitney U test. Proportions of groups were compared using the chi-square and Fisher exact test, while appropriate Friedman test was employed to investigate changes in non-normally distributed data over time. The significance of pairwise differences was assessed using the Wilcoxon signed-rank test with Bonferroni correction for multiple comparisons. A 5% type 1 error level was adopted to determine statistical significance, with a level of significance set at p value of <0.05 (two-tailed) for this study.

RESULTS

There was no significant difference between the groups regarding the demographic characteristics ($p>0.05$) (Table 1).

Pain intensity-VAS scores

There was no significant difference between the groups in terms of VAS pain scores at rest, night and during activity at T1 and T2. The VAS pain scores at rest ($p=0.001$), night ($p=0.015$) and during activity ($p=0.006$) significantly decreased in Group 1 compared to those of Group 2 at T3.

Within-group analysis of VAS pain scores at rest, at night and during activity demonstrated significant reduction in both groups ($p<0.05$) (Table 2). In Group 1, post-hoc analysis for VAS night and VAS rest scores showed that difference is between T1 and T3, and between T1 and T2. Post-hoc analysis for VAS activity scores showed that difference was also between T2 and T3. In Group 2, post-hoc analysis for VAS night, VAS rest, and VAS activity scores showed that difference was between T1 and T3, and between T1 and T2 (Table 2).

Number of active TrPs

There was no significant difference regarding number of TrPs between the groups at T1. The number

TABLE 1
Demographic properties of the groups

	Group 1 (n=89)					Group 2 (n=90)					p
	n	%	Mean±SD	Median	Min-Max	n	%	Mean±SD	Median	Min-Max	
Age (year)			34.4±8.9					37.4±9.2			0.058 ^a
BMI (kg/m ²)				23.59	17.30-37.11				25.00	14.0-120.0	0.056 ^b
Pain duration (day)				30	1-650				30	1-545	0.408 ^b
Smoking (year)				0	0-20				0	0-20	0.985 ^b
Sex											0.453 ^c
Female	77	86.5				81	90				
Male	12	13.5				9	10				
Education (year)											0.397 ^c
<5	18	24.0				20	27.0				
<8	5	6.7				5	6.8				
<11	16	21.3				23	31.1				
>11	36	48.0				26	35.1				
Pain side											0.298 ^c
Right		54.9					47.2				
Left		45.1					52.8				

SD: Standard deviation; BMI: Body mass index; a Two independent samples t-test p value; b: Mann-Whitney U test; c Chi-square test.

of active TrPs of Group 1 was statistically lower than that of Group 2 at T2 and T3 (Table 2). The number of active TrPs significantly decreased in both groups ($p < 0.0001$). In Group 1, post-hoc analysis showed that difference was between all timepoints ($T3 < T2 < T1$). In Group 2, post-hoc analysis showed that difference was between T1 and T3 (Table 2).

Cervical ROM angles

There was no significant difference in terms of all ROM angles between groups at baseline (T1) and at the end of the study (T3). Cervical flexion ($p = 0.001$), extension ($p = 0.001$), left and right lateral flexion angles ($p < 0.0001$) significantly improved in Group 1. While cervical left ($p = 0.001$) and right ($p < 0.0001$) lateral flexion ROM angles significantly improved in Group 2, cervical flexion ($p = 0.061$) and extension ROM angles ($p = 0.155$) did not significantly improved (Table 2).

Disability level-NPDS scores

The NPDS scores were not significantly different between the groups at baseline, but significantly different at the end of the treatment ($p = 0.016$) in favor of Group 1. Within-group analysis of the NPDS scores demonstrated a reduction in both groups ($p < 0.001$) (Table 2).

DISCUSSION

The study demonstrated that application of KT with EDF technique to the UT muscle provided

a significant improvement in pain level, disability, number of active TrPs and cervical ROM angles and found superior to sham application.

Since myofascial TrPs are most commonly found in the UT muscle^[18] and UT muscle is also the most sensitive to myofascial TrPs,^[19] it has been most preferred muscle in recent studies, which investigated the efficacy of KT on MPS. Pain has been assessed by VAS scores and/or pain pressure threshold (PPT), disability has been assessed by NPDS in those recent studies. Dilek et al.^[9] investigated efficacy of the KT application with inhibition technique on UT muscle with TrPs by comparing sham application and found that both groups improved in terms of VAS pain scores, PPT scores, and NPDS scores and none of the groups were superior to each other. Similarly, Ay et al.^[8] investigated the KT application with inhibition technique on UT muscle by comparing to sham application. They found that both groups improved in terms of VAS pain, PPT, NDPS scores and ROM angles; improvement in outcome parameters was superior in KT group than those of sham group, except for NPDS scores. Similar to the results of Ay et al.'s study,^[8] we found significant improvements in VAS pain scores, number of TrPs and NPDS scores in both groups; the difference between the groups at the end of the treatment was significant in favor of KT group. Both groups received home-based exercise program in these studies and in our study. According to the ethical rules, adding exercise to the sham group

TABLE 2
Comparison of outcome parameters between and within groups

	Group 1 (n=89)		Group2 (n=90)		<i>p</i> **
	Median	Min-max	Median	Min-max	
VAS-night (cm)					
T1	5	0-10	5	0-10	0.762 ^b
T2	3	0-9	3	0-9	0.255 ^b
T3	2	0-8	3	0-10	0.015^b
<i>p</i> *	<0.0001^a T2<T1, T3<T1 ^d		<0.0001^a T2<T1, T3<T1 ^d		
VAS-rest (cm)					
T1	6	0-10	5	1-10	0.426 ^b
T2	4	0-10	4	0-10	0.063 ^b
T3	2	0-9	4	0-10	0.001^b
<i>p</i> *	<0.0001^a T2<T1, T3<T1 ^d		<0.0001^a T2<T1, T3<T1 ^d		
VAS-activity (cm)					
T1	7	0-10	7	0-10	0.202 ^b
T2	5	0-10	6	0-10	0.104 ^b
T3	3	0-10	5	0-10	0.006^b
<i>p</i> *	<0.0001^a T3<T2<T1 ^d		<0.0001^a T2<T1, T3<T1 ^d		
Number of trigger points (n)					
T1	2	1-10	2	1-6	<0.889 ^b
T2	2	0-9	2	1-6	0.008^b
T3	1	0-8	2	0-6	0.001^b
<i>p</i> *	<0.0001^a T3<T2<T1 ^d		<0.0001^a T3<T1 ^d		
Cervical flexion ROM angles (°)					
T1	45	20-80	45	30-65	0.917 ^b
T3	45	20-80	45	30-80	0.366 ^b
<i>p</i> *	0.001^c		0.061 ^c		
Cervical extension ROM angles (°)					
T1	45	20-80	45	25-80	0.507 ^b
T3	45	20-85	45	15-70	0.107 ^b
<i>p</i> *	0.001^c		0.155 ^c		
Cervical lateral flexion ROM angles (°) right					
T1	35	10-70	40	20-70	0.346 ^b
T3	40	15-60	40	20-60	0.080 ^b
<i>p</i> *	<0.0001^c		<0.0001^c		
Cervical lateral flexion ROM angles (°) left					
T1	35	10-60	35	15-60	0.412 ^b
T3	40	15-60	40	15-55	0.082 ^b
<i>p</i> *	<0.0001^c		0.001^c		
NPDS scores					
T1	54	24-89	49	9-92	0.452 ^b
T3	29	0-85	39	0-949	0.016^b
<i>p</i> *	<0.0001^c		<0.0001^c		

VAS: Visual Analog Scale; ROM: Range of motion; NPDS: Neck pain disability scale; T1: Baseline (Time point 1); T2: 7th days of the study (Time point 2); T3: 14th days of the study (Time point 3); * Within groups; ** Between groups; a Freidman test; b Mann-Whitney U test; c Wilcoxon test; d Wilcoxon test with Benferroni correction.

was also preferred in other studies like ours, in order not to leave the patients without treatment. We gave a home-based exercise program to both groups to ensure group equality. If there was another group that was given only the exercise program, a clearer inference could be made from the results. Although we cannot ignore the therapeutic effect of exercise, there are several studies which did not give exercise but found an effect on sham group even then.

In a study by Öztürk et al.,^[7] KT application with inhibition technique was compared to sham application without giving exercise to both groups. Although they did not give exercise to the sham and KT group, similar to our results, they found that both groups improved in terms of pain VAS, PPT and disability scores, but KT group was found superior to those of sham group. Noguera-Iturbe et al.^[13] compared the KT application with space correction technique (with 25% stretching) with sham application on active TrPs of UT muscle and found no significant difference between improved PPT scores of the groups at the end of the study. In a similar study, Kalichman et al.^[12] compared KT application with space correction technique (with 30% stretching) with sham application on active TrPs of UT muscle and found increased PPT scores immediately after application and superior to sham group. Halski et al.^[11] compared the effects of space correction technique (with 50% stretching) with sham application on latent TrPs of UT muscle. They found no significant difference between the groups in terms of VAS pain scores, resting bioelectrical activity of UT muscle as assessed by surface electromyography (sEMG) immediately after intervention and after 24-h follow-up. In the present study, we evaluated number of active TrPs instead of PPT scores. Since our study has a multi-center design, algometer device would not be same in different centers. Therefore, we decided to evaluate whether the number of active TrPs would decrease with KT application. We found that active TrPs decreased greater in KT group compared to that of sham group from the first week (T2).

There are two systematic reviews and meta-analyses about the effect of KT in reducing MPS in the literature.^[20,21] Alotaibi et al.^[20] analyzed six randomized-controlled trials (RCT) which investigated the efficacy of KT on myofascial pain in the UT muscle and showed that KT was significantly effective in treating myofascial pain on the UT muscle with or without other therapeutic protocols. Zhang et al.^[21] showed that KT was more effective than other treatments in reducing pain intensity and

increasing ROM at post-intervention. Kinesiotaping was also superior to other non-invasive techniques in relieving pain intensity at follow-up in their analysis. However, comparison of the results of recent studies is difficult, since there is a heterogeneity among the groups. The application techniques (space correction, inhibition), the amount of stretching in the same application type, inclusion criteria (active/latent TrPs), different products or the brands of applied KT, assessment time points, presence or absence of an additional exercise program in study protocols vary among the studies. Despite these heterogeneities, the common result of those studies is the efficacy of sham application. The sham application was done in several improper ways, but on the muscle in all studies. The reduction of subcutaneous nociceptor pressure by KT itself (independently of the application technique) is a possible mechanism for these results. Another hypothesis is that KT itself facilitates pain-relieving mechanisms and activates the gate control mechanism by providing afferent stimuli to soft tissue structures.^[22] Presumably, KT reduces mechanical irritation of soft tissues by providing appropriate sensory feedback during cervical spine movements.^[23] Sensory feedback provided by KT may increase patient awareness and attention to ergonomic principles and posture.^[22,24] Therefore, we considered to apply sham application not on the muscle, on the C7 process. However, origin of the UT muscle involves the C7 process and may have an effect. Applying to a very unrelated area may affect the blindness. Thus, we considered that instead of KT, a plaster with same color and shape should be used in further studies for sham application. On the other hand, placebo effect independent from the tape, is thought to be a biopsychological response and its benefits should not be overlooked. Analgesic neurotransmitters are released as a result of placebo effect.^[25,26] Due to the possible therapeutic effects of sham KT, as mentioned above, Akpınar et al.,^[10] compared two different techniques; space correction and inhibition technique with the control group. They gave a home-based exercise program to all groups. They found that all groups improved in terms of pain and disability parameters. Both KT techniques were found to be superior to the exercise group. However, both application techniques were not superior to each other.

It is claimed that applying KT from the muscle's insertion point to its origin can effectively inhibit muscle spasms and promote muscle relaxation.^[27] The space correction technique alleviates pain by

lifting the skin, fascia, and soft tissue just above the painful region through the elastic nature of KT. This process aims to decrease pressure on chemical receptors and nociceptors beneath the applied area. Additionally, it is advocated to enhance lymphatic drainage, improve blood circulation, and facilitate the removal of exudates.^[6,27]

Different from recent studies, we investigated the efficacy of EDF taping in the current study. This is the first study to evaluate the effect of EDF taping. The EDF taping was designed to stimulate the epidermis and elevate more space. An application of EDF can lift and elevate the space between the tissue layers in the epidermis, by spreading out the application over overlapping layers. We found that pain intensity and number of active TrPs improved better compared to those of sham group. However, sham group received the same KT to the origin of the UT muscle and had improved pain intensity, active TrPs and disability levels. As a limitation of our study, we should prefer another brand of KT or another product to show whether there is a difference between the Kinesio Tex Gold FP and the others.

In our study, a significant increase was obtained in ROM angles of all directions in the KT group in two weeks, whereas only flexion and extension angles improved in sham group. However, we could not find KT superior to sham in terms of ROM angles. We should conclude that this result is compatible with the results of the recent studies. Enhanced ROM is expected to result from an augmented proprioceptive feedback mechanism and improved muscle facilitation.^[3,4,28,29] Cervical ROM limitations commonly arise from muscle spasms in MPS. The observed increase in cervical ROM is likely attributable to a decrease in muscle spasms among patients or the implementation of exercise programs designed for them. Longitudinal strips of the KT in EDF technique, which was applied overlapped and spread out, may optimize the length of the muscle fibers and produce a decrease in the afferent Ia discharge from the neuromuscular spindle. Applying EDF technique from insertion to origin without stretching should decrease the muscle tone by producing an excentric pull on fascia.^[29-31] Mobility of cervical spine should be facilitated by positive neural feedback provided by KT.^[32]

Since the disability level is associated with pain intensity and ROM, it is not surprising that the results of the studies showed improved disability levels, as we observed.^[8,9,12,13] Recent studies have utilized the

NPDS for disability assessment. Items of the NPDS involve pain intensity, daily living activities, reading, and lifting. These items are associated with pain and motion. Therefore, long period is not needed to observe an improvement in the NPDS scores. This may be the reason why improvement has been observed immediately after applications in recent studies,^[8,13] as well as in our study.

A systematic review and meta-analysis was conducted, focusing on six studies that investigated the effectiveness of KT on MPS in the UT muscle. The results of the meta-analysis indicate that when combined with other therapeutic protocols, KT appears to be beneficial in treating MPS, leading to improvements in cervical ROM and functional activities.^[11] Another meta-analysis, which included 20 randomized RCTs with 959 participants, demonstrated that KT was superior to other treatments in reducing pain intensity and enhancing ROM at the post-intervention stage.^[14] Our results support the results of these systematic reviews. The main strength of our study is that this study is the first which evaluated a new technique and tape type in MPS of UT. Another strength of our study is the large sample size (n=180). As mentioned before, a lack of exercise group alone is the main limitation.

In conclusion, our study results suggest that KT with EDF technique is effective in reducing pain and improving disability and ROM angles and should be preferred. Further studies are warranted to assess the efficacy of the EDF technique in other diseases and to compare the effect of EDF technique with other techniques.

Ethics Committee Approval: The study protocol was approved by the Haydarpaşa Numune Training and Research Hospital Clinical Research Ethics Committee (date: 09.10.2017, no: HNEAH-KAEK2017/K.K/109). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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