

Effect of long-term use of kinesiotape on hallux valgus angle: A double-blinded randomized controlled trial

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ABSTRACT

Hallux valgus (HV) has an impact on quality of life since it alters the mechanics of the foot and causes pain. Kinesiotape (KT) has been demonstrated to be challengeable, cost-effective tool for restoring muscle function and strength, improving range of motion, reducing discomfort, and increasing lymphatic drainage. The aim of this study was to investigate the influence of 8 weeks KT on the degree HV angle (HVA) and subsequently on pain intensity. In this double-blinded randomized controlled trial, 30 subjects with HV deformity (mean age 29.07±6.3 years) were randomly allocated to study group (A) and control group (B). Group A received KT for HV, which was replaced every 5 days for 8 weeks, along with a home regular exercise program for HV, while Group B received placebo KT replaced every 5 days and the same exercise program for HV. HVA was measured using x-ray, pain intensity was measured using visual analogue scale (VAS). Outcomes were measured before and after 8 weeks of intervention. HVA showed a significant reduction in group A ($p = 0.001$) for both feet in comparison to group B ($p = 0.11$ for right foot, $p = 0.09$ for left foot, while pain showed significant improvement in both groups for both feet ($p = 0.001$). The results revealed that KT in mobile HV is effective on improving the metatarsophalangeal joint angle, decreasing pain, and hence may has positive functional impact on subjects with HV.

KEYWORDS

Hallux Valgus; Pain Severity; Foot Deformities; Kinesiotape; Mechanical Correction

1. INTRODUCTION

The most common metatarsophalangeal (MTP) problem is hallux valgus (HV), which is characterized by progressive subluxation of MTP joint of the big toe and increased valgus angle combined with proximal phalanx pronation (Akaras et al., 2020).

The incidence rate of HV in adults reached to 23%, more in females than males and increase with age to 35.7% in people exceeding 65 years. HV severity increases with using shoes with narrow tips, and high heels (Akaras et al., 2020). Till now the main cause of HV is not clear enough, while many researchers were searching for that as this deformity has negative effects on balance, gait, and even kinematics of the gait, which affect human function and quality of life (Formosa et al., 2017).

Assessment of HV using x-ray depends on measuring one of the following angles, hallux valgus angle (HVA) or intermetatarsal angle (IMA) angle (Iliou et al., 2016). Too many protocols were used for management of HV, aiming to stop the progression of the case, case accommodation with rigid deformities, and pressure distribution on the area of deformity instead of pressure concentration during weight bearing (Hwang et al., 2018). Many types of taping, exercise therapy, orthotics, modification of footwear, mobilization, chiropractic, and different modalities of physical therapy are widely being used conservatively to control HV in mild to moderate cases (Taheri et al., 2021). While surgical intervention alternatively may be used with severe cases (Reina et al., 2013).

A Cochrane review about conservative measures for HV control and reduction was conducted by Ferrari et al. 2004, suggested that foot orthoses, and night splints had no effect (Ferrari et al., 2004; Reina et al., 2013).

Nowadays, usage of different taping techniques as a conservative control and management of HV becomes a trend (S.-M. Lee & Lee, 2016b). One of the safe, practical, and comfortable options of taping techniques with good clinical impact is Kinesiotape (KT). Kenzo Kaze firstly developed and used KT in clinical settings to decrease edema, control pain, and improve the motor functionality, he mostly used KT for musculoskeletal problems and in some types of injuries (Oktas & Vergili, 2018).

Although there have been many studies on taping protocols for knee, and ankle problems, on the other hand studies concerning taping for HV are limited or short-term use and the available studies had contradicted results (Ferrari et al., 2004).

So, the main purpose of this study is to evaluate the long-term use (8 weeks) of KT on mobile hallux valgus deformity, and to determine the taping long-term use on pain of the first metatarsophalangeal joint with HV.

2. METHODS

2.1. Participants

This study was a double-blinded randomized controlled trial (RCT) with two parallel groups, where patients, outcome assessors, and data analysts were blinded to group allocation. All subjects were selected from Physical Therapy department of Jazan University hospital within Jazan city, Jazan, Saudi Arabia. The study was performed according to CONSORT guidelines. Ethical approval was obtained from the ethics committee of scientific research of Jazan University and each patient signed an informed consent form authorizing his/her participation. All steps of evaluation and treatment of this study was performed between August 2020 till January 2021. The study was registered retrospectively at ClinicalTrials.gov under identifier NCT05165134. The procedures followed were in accordance with the Declaration of Helsinki.

The inclusion criteria included 30 volunteers, comprising 18 females and 12 males, with ages ranging from 18 to 40 years old, as this range is considered productive age. Their BMI ranged from 20 kg/m² to 25 kg/m². All subjects had mobile HV bilaterally, meaning that the hallux could be repositioned manually without significant resistance. Nearly all the volunteers experienced discomfort in the metatarsophalangeal (MTP) joint of the big toe. Exclusion criteria included patients with lower extremity malalignment (e.g., genu valgum, genu varum) and limitation in the abduction motion of the big toe (rigid HV). Additionally, patients with rheumatoid arthritis, a history of previous foot surgery, previous use of orthotics, especially for the foot, or any precautions for exposure to X-ray were excluded.

2.2. Procedures

The patients were allocated randomly into two groups using the block randomization method. All subjects were informed about the procedures and gave their written informed consent form. Group A (study) received KT for realignment of HVA (Metatarsophalangeal angle MPA) changed every 5 days for 8 weeks (Kaya et al., 2014). Plus, exercise program for 8 weeks, subjects informed to do 10 repetitions three times a day. Group B (control) received placebo taping on Metatarsophalangeal joint with the same exercises for group A (Figure 1) (Radwan et al., 2017).

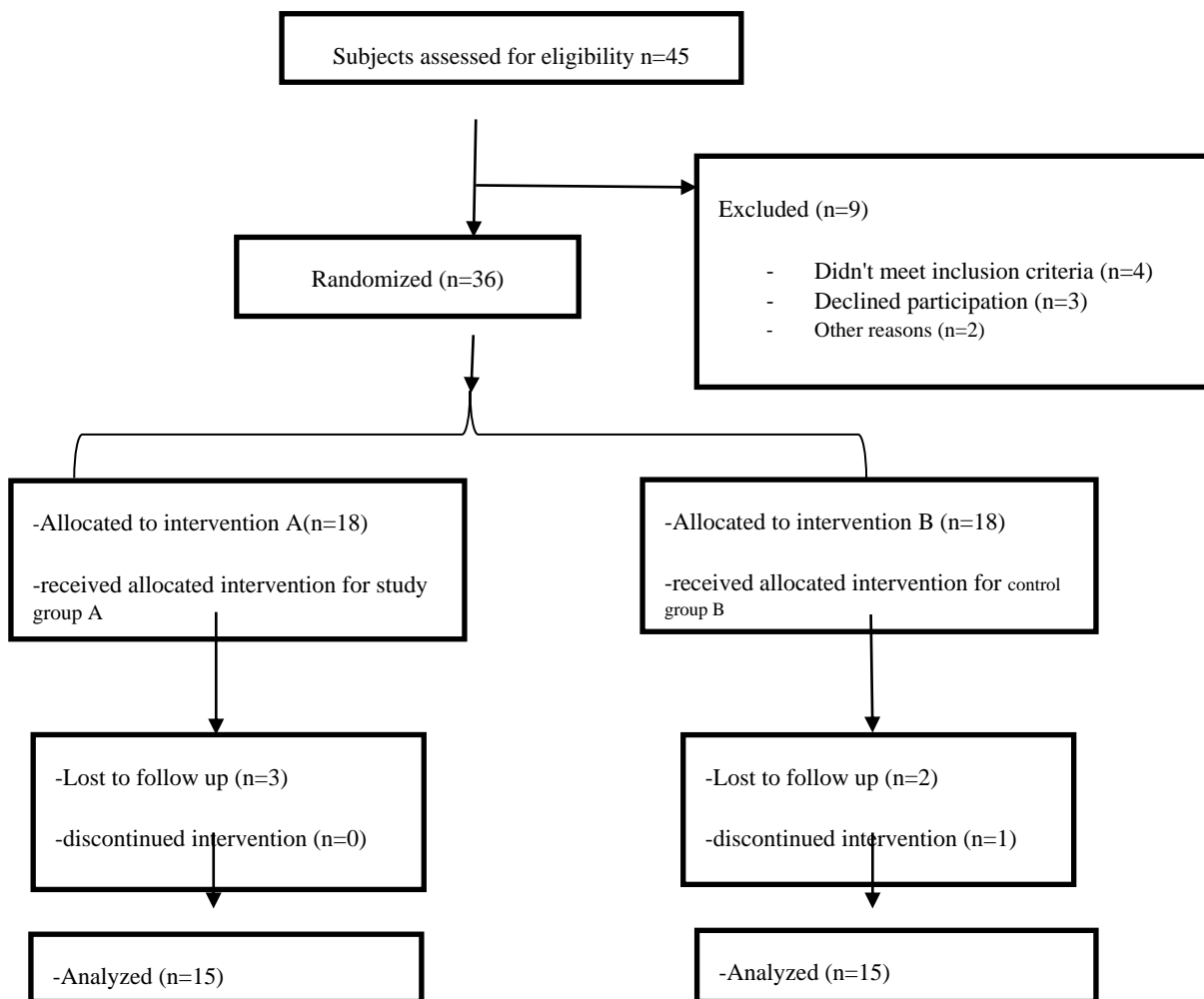


Figure 1. Consort flow chart of the participants with randomization

The appropriate minimum sample size for this study was 45 subjects were assigned to be assessed for eligibility to share in the study, 9 were excluded because they didn't meet criteria (4), declined participation (3), (2) for other reasons. Finally, 36 Patients were assigned randomly with 1:1 ratio into either to study (A) or control (B) group. 15 participants only complete the study in each group due to lost to follow up and exclusion due to loss of data.

A Universal Weight and Height Scale was utilized for measuring the patients' BMI. The Visual Analogue Scale (VAS) employed a single dimension pain intensity measure (McCormack et al., 1988), consisting of a straight horizontal line with a constant length of 100 mm (10 cm), where 0 indicated no pain and 10 represented the utmost agony experienced by the patient (Scott & Huskisson, 1976). Digital mobile x-ray machine (AGFA DX-D100 model, India). KT (made in Korea 2020) was used for both groups A and B. Cotton is the main constituent of the tape, it has an

anti-allergic, evaporating, and quick drying adhesive layer. These properties make it resistant and wearable for extended period, in general, three to five days per once; it is even water resistant. The tape's flexibility reached about 140 percent, which is comparable to human skin (Ramírez & Cruz, 2017).

2.3. Outcome Measures

Pain assessment: Patients in both groups were instructed to mark their own pain intensity perception on a 10 cm horizontal line (VAS), in which 0 states painless and 10 states maximum pain that the patient feels. Pain assessment procedure was done pre and post treatment.

Radiographic assessment: For both groups, a weight bearing dorsoplantar X-ray was taken for both feet together including the HVA. HVA is the angle formed by the longitudinal axis of first metatarsal and longitudinal axis of proximal phalanx of big toe, its normal value is $<15^\circ$. Also, the Intermetatarsal angle (IMA) angle formed by the longitudinal axes of metatarsal bones of big and second toes, its normal value is $<9^\circ$, variety of methods for measuring these angles have been documented. our study employed the approach specified by the American Orthopedic Foot and Ankle Society's (Srivastava et al., 2010; Zhou et al., 2013). The bared feet were in a standing erect position the tube was 100 cm away from feet, and the voltage and ampere of current were 55 KVP and 1.7 mAS, respectively (Figure 2), After that, the CorelDraw software was used to examine the image (Version 12.0, Corel Corporation, Ottawa, Canada) (Figure 3). The radiologic evaluation was completed by radiologists who were kept in the dark about the study's purpose and group allocation to avoid bias, the angles measured pre and post treatment (Wülker & Mittag, 2012).



Figure 2. Standing erect with bared feet during radiographic evaluation

Using the Digital mobile x-ray machine, AGFA DX-D100 model, manufactured in 25-07-2017 by India Mart. The patient stands with both feet on the cassette. The cassette is positioned to include all the metatarsals and phalanges. The weight of the patient's body is distributed equally. The vertical ray 15 degree for feet is centered midway between the feet at the level of the first metatarsophalangeal joint.



Figure 3. Measurement of HVA on X-ray film

The angle between the lines of the first metatarsal's central longitudinal axis and the axis of the hallux connecting to the first MTP joint measured using the CorelDraw software.

2.4. Interventions

Group A (Study group): 18 subjects with HV received The KT method, invented by Kenzo Kase, was applied to tape the subjects (Kase et al., 2003). Two Y-shaped strips of elastic tape were employed, with the base end of the Y-shaped strip put on the hallux's base. After the big toe was adjusted to its estimated normal position, the tape was put through the first ray (big toe was manually abducted by the practitioner) with a light to moderate stretch (Figure 4). This adjustment was made only once during the tape's installation and took less than 10 seconds. There wasn't any traction used, performing a mechanical correction technique on hallux, the second tape piece was placed over metatarsophalangeal joints (Karabicak et al., 2015). KT was applied on both right and left sides and was being replaced every 5 days for the period of 8 weeks which is the period of study (Radwan et al., 2017).

Group B (control group): 18 subjects with HV received KT for placebo taping. The tape had been cut in I shape and applied to the foot's medial surface just above the 1st MTP joint without any stretch force (Akaras et al., 2020). All subjects of both groups were made aware of the significance of

using appropriate shoes for their deformities and advised to wear wide toe box footwear with pliable upper material to alleviate pressure on the hallux, well fitted and contained flat foot insole inside (Menz et al., 2022). Also, they were given an exercise program for deformity of HV to perform during the period of study for 8 weeks. Strengthening and mobilization activities were included in the workout. The patient was effectively abducting the hallux during the strengthening exercise, which was done in a sitting position (moving hallux medially while fixing the second toe).

Patients were taught to count 5-10 repetitions for this activity. In a sitting position, the patient applied traction to his/her own hallux in a longitudinal direction, then aligned the hallux for 30 seconds without releasing the traction. This practice was completed five times. The physiotherapist demonstrated each exercise, and Patients were instructed to do them twice a day for 8 weeks (Glasoe, 2016).



Figure 4. KT for hallux valgus

Two Y-shaped strips of elastic tape were employed, with the base end of the Y-shaped strip put on the hallux's base. The tape was put through the first ray with a light to moderate stretch. The second tape piece was placed over metatarsophalangeal joints.

2.5. Sample size calculation

Using G*Power software (Universität Mannheim, Mannheim, Germany), and assuming effect size 0.3 of the main outcome variable obtained from a previous similar study (Radwan et al., 2017), and prior sample size analysis with 90% power (Type II error rate, 0.10) and alpha-level 0.05 (Type I

error rate) predicted that we would totally require 32 participants, For the case of dropout, the sample size is increased by a 15% rate, and so the appropriate minimum sample size for this study was 45 subjects were assigned to be assessed for eligibility to share in the study, finally 36 Patients were assigned randomly with 1:1 ratio into either to study (A) or control (B) group. Finally, thirty subjects completed the study due to some causes listed in the consort flow chart

2.6. Statistical analysis

Unpaired t-test was conducted for comparison of subject characteristics between groups. Normal distribution of data was checked using the Shapiro-Wilk test. Levene's test for homogeneity of variances was conducted to ensure the homogeneity between groups. Mixed design MANOVA was performed to compare within and between groups effects on HVA and pain. Post-hoc tests using the Bonferroni correction were carried out for subsequent multiple comparison. The level of significance for all statistical tests was set at $p < 0.05$. All statistical analysis was conducted through the statistical package for social studies (SPSS) version 25 for windows (IBM SPSS, Chicago, IL, USA).

3. RESULTS

Thirty participants were part of the study. Table 1 illustrates the comparison of subject characteristics within the study group (A) and control group (B). There was no significant difference between groups in age, weight, height, and BMI ($p > 0.05$).

Table 1. Comparison of subject characteristics between study and control groups

	Mean \pm SD		p-value
	Study group	Control group	
Age (years)	29.86 \pm 7.08	28.26 \pm 5.41	0.49
Weight (kg)	61.4 \pm 6.44	61.86 \pm 6.35	0.84
Height (cm)	164.4 \pm 5.74	163.13 \pm 6.44	0.57
BMI (kg/m²)	22.65 \pm 1.22	23.18 \pm 0.89	0.19

Note: SD, Standard deviation; p-value, level of significance

HVA and VAS results, measured pre- and post-treatment for both groups, are shown in Table 2. HVA and pain perception (VAS) showed great improvement in study group with non-significant changes of HVA in control group with significant improvement of pain perception (VAS). HVA

improved in study group, but both groups had significant improvement in pain perception (VAS) $p \leq 0.001$.

Table 2. Mean HVA and pain pre and post treatment of study and control groups

	Study group	Control group	MD (95% CI)	P value
	Mean \pm SD	Mean \pm SD		
Right HVA				
Pretreatment	29.53 \pm 4.1	29.13 \pm 3.73	0.4 (-2.53: 3.33)	0.78
Post treatment	24.33 \pm 2.89	28.53 \pm 4.01	-4.2 (-6.81: -1.58)	0.003
MD (95% CI)	5.2 (4.45: 5.94)	0.6 (-0.14: 1.34)		
% Of change	17.61	2.06		
	<i>p = 0.001</i>	<i>p = 0.11</i>		
Left HVA				
Pretreatment	26.53 \pm 2.89	27 \pm 2.75	-0.47 (-2.58: 1.64)	0.65
Post treatment	23.26 \pm 2.63	26.33 \pm 2.32	-3.07 (-4.92: -1.21)	0.002
MD (95% CI)	3.27 (2.46: 4.06)	0.67 (-0.13: 1.46)		
% Of change	12.32	2.48		
	<i>p = 0.001</i>	<i>p = 0.09</i>		
VAS of right side				
Pretreatment	5.6 \pm 1.68	5.73 \pm 1.94	-0.13 (-1.49: 1.22)	0.84
Post treatment	2.2 \pm 1.93	2.53 \pm 1.59	-0.33 (-1.66: 0.99)	0.61
MD (95% CI)	3.4 (2.64: 4.16)	3.2 (2.43: 3.96)		
% Of change	60.71	55.84		
	<i>p = 0.001</i>	<i>p = 0.001</i>		
VAS of left side				
Pretreatment	3.53 \pm 1.88	3.66 \pm 1.91	-0.13 (-1.55: 1.28)	0.84
Post treatment	1.66 \pm 1.23	2.13 \pm 1.45	-0.47 (-1.47: 0.54)	0.35
MD (95% CI)	1.87 (1.25: 2.47)	1.53 (0.92: 0.14)		
% of change	52.97	41.8		
	<i>p = 0.001</i>	<i>p = 0.001</i>		

3.1. Effect of treatment on HVA and pain

There was a significant interaction of treatment and time ($F_{(4,25)} = 21.63$, $p = 0.001$, $\eta^2 = 0.77$). There was a significant main effect of time ($F_{(4,25)} = 80.79$, $p = 0.001$, $\eta^2 = 0.92$). There was no significant main effect of treatment ($F_{(4,25)} = 1.21$, $p = 0.32$, $\eta^2 = 0.16$).

3.2. Within group comparison

There was a significant decrease in right and left HVA of the study group post treatment compared with that pretreatment ($p < 0.001$), while there was no significant difference in right and left HVA of the control group between pre and post treatment ($p > 0.05$). The percent of change of right and left HVA of study group was 17.61 and 12.32% respectively and that of control group was 2.06 and 2.48% respectively (Fig. 5). There was a significant decrease in VAS of right and left sides of both groups post treatment compared with pretreatment ($p < 0.001$). The percent of change of VAS of right and left sides of study group was 60.71 and 52.97% respectively and that of control group was 55.84 and 41.8% respectively (Fig. 6) (Table 2).

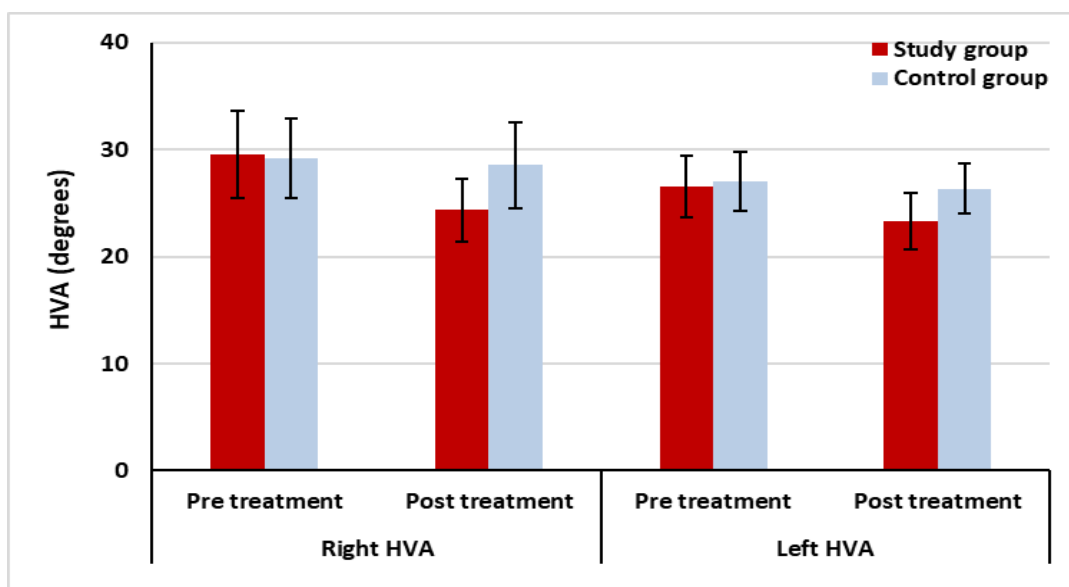


Figure 5. Mean HVA pre and post treatment of study and control groups

The figure above showed a significant decrease in right and left HVA of the study group post treatment compared with that pretreatment ($p > 0.001$), while there was no significant difference in right and left HVA of the control group between pre and post treatment ($p > 0.05$).

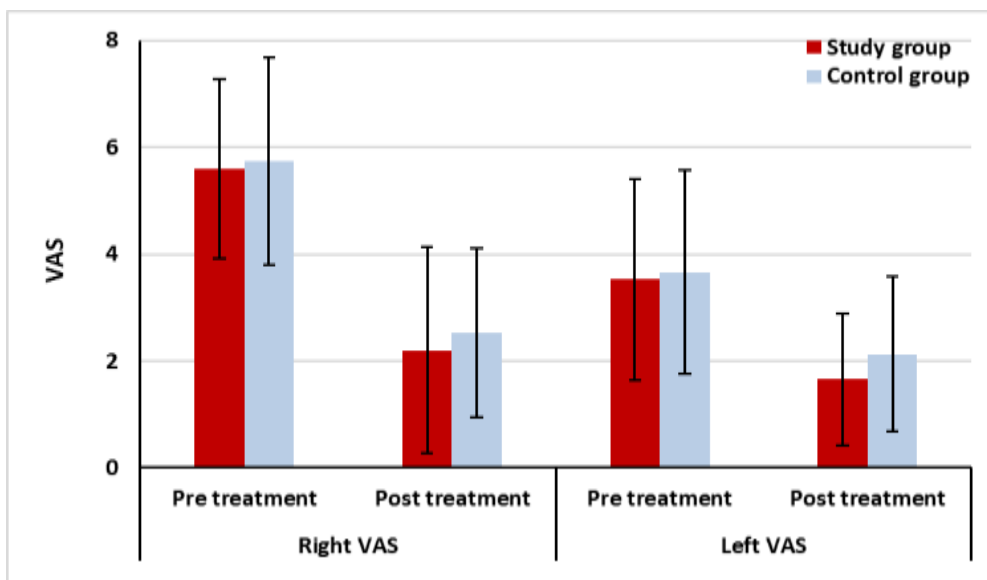


Figure 6. Mean VAS pre and post treatment of study and control groups

Figure 6 showed a significant decrease in VAS of right and left sides of the study and control groups post treatment compared with that pretreatment ($p < 0.001$).

3.3. Between groups comparison

There was no significant difference between groups pre-treatment ($p > 0.05$). There was a significant decrease in right and left HVA of study group compared with that of control group post treatment ($p < 0.01$). However, there was no significant difference in VAS of right and left sides between groups post treatment ($p > 0.05$) (Table 2).

4. DISCUSSION

The results of our study revealed that HVA and pain perception showed great improvement in study group with non-significant change of HVA and significant improvement of pain perception (VAS) in control group.

In this study (KT) was used which is well known as therapeutic elastic tape that have an effect on mechanical correction of malalignment and malorientation of pelvis (Lee & Yoo, 2012b), shoulder (Hwang-Bo et al., 2013), it may also share in injury prevention (Williams et al., 2012), has great role in pain alleviation (Hwang-Bo & Lee, 2011; Lee & Yoo, 2012a; Lee & Lee, 2015, 2016a), and improvement of lymphatic system function (Shim et al., 2003).

Our current study was differed than previous studies in the method and duration of tape application. The most common toes, and feet deformities is HV specially between females. Medial arch, sole of the feet, and other toes than big toe are the most common feet sites that suffer from symptoms related to HV in which there is involvement of adductor and abductor muscles of big toe mainly. The underlying HV etiology is still not have detailed definition, but there is a common explanation between researchers talking about foot deformities due to ill-fitting shoes. Females are the most who run after fashion trends which in common lead to wear high heel shoes with narrow toe boxes that leads to crowd toes due to forefoot shift towards toe box (Radwan et al., 2017).

The significant improvement of HVA in study group after using KT was reported in previous studies. Their authors reported that the better information integration occurs in consistent use of KT on skin due to increased sensory signals to the central nervous system (CNS) which occurred in response to cutaneous mechanoreceptors stimulation (Choi, 2017). That may lead to normalization of proprioceptive sense and improve the position of HVA in study group.

Also, there may be a possibility of creating axial mobilization similar action by correcting the alignment position of the big toe MTP joint using KT in study group. This come in agree with the opinion of Karabicak et al, 2015 they stated that KT in HV leads to mechanical correction that greatly help fascia, muscle, joint realignment and positioning, therefore lead to stimulus adaptation of the body to normalize the positioning (Karabicak et al., 2015).

Brantingham et al. (2005) also reported that light mobilization exercises may have a great impact on pain sensation, which is obtained in this study due to the correction method that looks like light mobilization exercises. That lead to significant decrease of pain occurred in the study group. KT is considered a dynamic elastic orthotics that generally maintains a position of functional correction without suffering of the complications of usage of rigid orthotics with HV, as this rigid orthotics may lead to lose of active Range of Motion (ROM) and/or circulation inhibition, beside the effect of manipulative correction due to continuity of application. So, KT produces the same axial mobilization exercise which shared previously in normalization of joint alignment also share in pain inhibition in study group (Brantingham et al., 2005).

On the other hand, continuous cutaneous stimulation through the KT may reduce the threshold of motor neurons which increase recruitment of more motor units that will enhance muscle contraction of big toe abductors and therefore their strength in study group. These findings agree with Kim et al, 2016 who stated that, improvement of contraction of inactive muscles may be achieved with enhancement of sensory feedback occurred within the skin area under KT in response to the combined previous mentioned mechanisms (Kim & Kim, 2016). Also, muscle strengthening which

is performed in both groups as routine exercise for the whole period of the study and combined with KT in study group may lead to improvement of HVA due to abductor hallucis strength improvement, this finding come in agree with Glasoe (2016) who reported that in patients with HV, in spite the effect of strengthening of big toe muscles is totally unexamined but, a program of exercise in combination with taping may decrease pain and, gradually lead to patient's walking ability improvement due to HVA correction.

The improvement of pain sensation with KT occurred in our study in both groups. For the study group many causes of improving pain sensation mentioned before and another explanation combined with placebo KT in control group may occurred for both groups due to the slight stretch occurred to the skin under the KT whether in study or control groups, this slight stretch will open the superficial lymphatic channels due to the skin recoil occurred after stretch and improve blood circulation hence relief pain. That agreed with Radwan et al. (2017) who reported that the area under KT is very rich in circulation after opening of the superficial lymphatic channels.

Hence, the lactic acid that induce pain with the waste products efficiently removed with the fluid through the superficial lymphatic channels and leave the superficial pain receptors under KT free of pressure (Radwan et al., 2017). That previous mechanism reflected on the results of pain relief in the study and control groups. According to Easley & Trnka (2007), pain reduction may occur due to correction of the big toe, and foot mechanics produced by KT. The results of this study reported that functional improvement obviously noticed but more studies will be needed to measure this functional improvement with KT objectively, this is one of our limitations in this study. Other limitations are lack of long term follow up for our results after stopping use KT, also using more objective methods to assess muscle strength and endurance of foot muscles and correction of other foot deformities after correction of HV. We hope to conduct larger, more objective studies in the future to overcome these limitations.

5. CONCLUSIONS

This study concluded that KT in mobile hallux valgus for 8 weeks is effective in improving the metatarsophalangeal joint angle and decreasing pain, and hence may has positive functional impact on patients with hallux valgus.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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