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A randomized controlled trial of a mixed Kinesio taping–compression technique on venous symptoms, pain, peripheral venous flow, clinical severity and overall health status in postmenopausal women with chronic venous insufficiency

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Abstract

Objectives: To investigate the effect of a mixed Kinesio taping treatment in women with chronic venous insufficiency.

Design: A double-blinded randomized clinical trial.

Setting: Clinical setting.

Participants: One hundred and twenty postmenopausal women with mild–moderate chronic venous insufficiency were randomly assigned to an experimental group receiving standardized Kinesio taping treatment for gastrocnemius muscle enhancement and ankle functional correction, or to a placebo control group for simulated Kinesio taping.

Main outcomes variables: Venous symptoms, pain, photoplethysmographic measurements, bioelectrical impedance, temperature, severity and overall health were recorded at baseline and after four weeks of treatment.

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Results: The 2 × 2 mixed model ANCOVA with repeated measurements showed statistically significant group * time interaction for heaviness ($F = 22.99$, $p = 0.002$), claudication ($F = 8.57$, $p = 0.004$), swelling ($F = 22.58$, $p = 0.001$), muscle cramps ($F = 7.14$, $p = 0.008$), venous refill time (right: $F = 9.45$, $p = 0.023$; left: $F = 14.86$, $p = 0.001$), venous pump function (right: $F = 35.55$, $p = 0.004$; left: $F = 17.39$ $p = 0.001$), extracellular water (right: $F = 35.55$, $p = 0.004$; left: $F = 23.84$, $p = 0.001$), severity ($F = 18.47$, $p = 0.001$), physical function ($F = 9.15$, $p = 0.003$) and body pain ($F = 3.36$, $p = 0.043$). Both groups reported significant reduction in pain.

Conclusion: Mixed Kinesio taping-compression therapy improves symptoms, peripheral venous flow and severity and slightly increases overall health status in females with mild chronic venous insufficiency. Kinesio taping may have a placebo effect on pain.

Keywords
Kinesio taping, oedema, health status, pain, venous insufficiency in the leg

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Introduction

Postmenopausal women comprise a community with a high prevalence of chronic venous insufficiency due to a combination of various risk factors, including higher age, larger number of pregnancies, sedentary lifestyle and weight gain.[1] Venous insufficiency is characterized by persistent lower limb venous hypertension as a consequence of venous reflux and/or obstruction, a calf muscle pump function failure and ankle motion restriction.[2,3] Prolonged venous hypertension can increase calf muscle impairment and produce pain, perception of heaviness, nocturnal cramps, "restless leg" syndrome, pruritus pain, oedema and, in more advanced phases, venous eczema, skin hyperpigmentation, white atrophy and venous ulcers.[4] Hence, given the elevated incidence of chronic venous insufficiency[4] (17%) there is an urgent need to establish effective prevention and treatment protocols to meet the growing demand for the physiotherapy care of these patients.

Physical activity rehabilitation programmes and compression therapy are the main non-invasive methods used to treat venous insufficiency. Several studies have shown that walking, active kinesiotherapy, tiptoe exercises in the standing position and flexing and stretching of the feet in the sitting position can all effectively stimulate the calf muscle and improve venous haemodynamics.[5–8] Besides undertaking physical exercise, patients should also wear an appropriately prescribed compression garment to reduce the vein calibre and improve venous return.[9,10] However, a low adherence to these treatments has been observed.[6,11,12] Among the reasons for the poor compliance rates have been identified the presence of pain, leakage of exudates, skin irritation, aesthetic reasons, concerns about discomfort and difficulty in putting on the stockings.[6] Hence, novel approaches to bandaging and compression are required as adjuncts to conventional physiotherapy treatments.

Elastic kinesiology taping (Kinesio tape) is a new bandaging technique usually applied to normalize muscle function, increase lymphatic and vascular flow, diminish pain and/or aid the correction of joint misalignment.[13,14] The tape, which is attached to the skin, is thinner and more elastic than conventional tape and can be stretched to 120–140% of its original length. Although the precise action mechanism has yet to be fully understood, recent studies have indicated that Kinesio taping may have positive short-term effects on muscle activation and range of motion.[15–18] We have not been able to trace any previous studies on the application of Kinesio taping in venous disease and its musculoskeletal alterations.

With this background, the aim of our study was to analyse the effects of a mixed Kinesio

taping–compression model on venous symptoms, pain, peripheral venous flow, clinical severity and overall health status in postmenopausal women with mild or moderate venous insufficiency at one month in comparison to a placebo control group. Our study hypothesis was that the muscle and joint changes induced by Kinesio taping alongside the compression effect could have positive effects on symptoms and venous parameters in postmenopausal women with chronic mild–moderate venous insufficiency.

Methods

A double-blinded randomized clinical trial with parallel design was conducted in postmenopausal women from a community centre in Granada province (southern Spain), who were referred to the clinical laboratory of the Physiotherapy Department of the University of Granada, and who were studied between September 2008 and March 2012.

A screening phase was carried out by a single experienced vascular therapist who collected data on age, body mass index, aetiology, time since chronic venous insufficiency onset, disability, predisposing factors and pretreatment disease status. The same therapist then conducted an exploratory clinical examination to identify subjects with stages C1, C2 or C3 (C1: telangiectasies or reticular veins, C2: varicose veins, C3: oedema) following the criteria proposed by the American Venous Forum committee.[19] The examination was performed in two phases (sitting and standing), with examination of both lower limbs to assess clinical signs of chronic venous insufficiency and measure leg volume and peripheral pulse (by palpation). Study inclusion eligibility criteria were age between 50 and 75 years and presence of mild or moderate chronic venous insufficiency (grades C1, C2 and C3 on the Clinical, Etiologic, Anatomic, Pathophysiologic [CEAP] scale).[19] Exclusion criteria were: severe venous insufficiency (≥ grade C3), arterial disorders, plethysmographic signs of venous thrombotic obstruction, cardiorespiratory disease and contraindications for Kinesio taping technique,[13] including thrombosis, wounds, severe trauma, generalized oedema secondary to cardiac or renal problems, carcinomas, intolerability of/allergy to surgical tape and pregnancy.

Out of the 130 patients recruited from the accessible population, 120 met the above selection criteria and were randomly assigned to an experimental group (n =60), for Kinesio taping application or to a placebo-control group (n =60) for treatment with a sham protocol. During the randomization process, patients were blinded to treatment allocation. They were allocated (ratio 1 : 1) to the treatment or placebo group according to randomized codes. The vascular therapist who examined the patients (CM-L) for eligibility criteria and collected all baseline demographic and self-report variables was not involved in the rest of the study and prepared the randomization code by using computer software. Treatment allocation was concealed, and patients and study personnel were blinded to treatment assignment until after database lock (AMC-S). The three physical therapists, whose were blinded to group allocation, collected all outcome measures during the trial. All treatment interventions were carried out by a Kinesio taping instructor with wide clinical experience who was blinded to the outcome measures and baseline examination findings but not to the treatment allocation, although she did not reveal group membership to the physical therapists who gathered outcome measures.

Participants were previously informed that the study objective was to determine whether a mixed Kinesio taping–compression model could have positive effects on symptoms and venous parameters in postmenopausal women with chronic moderate venous insufficiency. Then written informed consent was obtained from all participants in the study, which was approved by the bioethics committee of the University of Granada (Spain) and complied with the 2008 modification of the Helsinki Declaration and with current Spanish legislation for clinical trials (number registration UGR-00012-409, University of Granada, Spain).The final results of the study were reported to the patients in both groups.

Data were gathered on venous symptoms, pain, peripheral venous flow, severity of venous disease and overall health status at two time points: baseline

(before the treatment) and at one month when the treatment was finished and the last application of taping was removed.

Participants were interviewed to obtain data on venous symptoms as primary outcome, including heaviness perception, sensation of swelling, muscle cramps and pruritus. Symptoms intensity was quantified using a 4-point scale (0 = absent, 1 = mild, 2 = significant, 3 = severe).

Peripheral venous flow was evaluated by assessing functional venous parameters: photoplethysmographic measurements, bioelectrical impedance and temperature. A photoplethysmograph (Vasoquant VQ4000/A-PPG; ELCAT, Germany)[3] was used to evaluate the degree of peripheral reflux, recording venous refill time (seconds) and venous pump power (V_0, %) in both lower limbs. These measures represent a numerical quantification of venous function, which is significantly influenced by the pumping capacity of the calf muscle. A venous refill time ≤20 seconds is commonly reported to be abnormal and to indicate incomplete emptying of the veins.[20,21] Venous pump power values >4% are considered normal.[3] Range of ankle motion and forced vital capacity were recorded before and after the treatment (data not shown), because changes in ankle mobility or breathing pattern may affect plethysmographic results.[20] Peripheral oedema was assessed in both lower limbs by using a Bioelectrical impedance meter (Bodycell 1E07004, Carin, Barcelona, Spain)[8] with Skintact RT-34 adhesive electrodes and four connectors. Cell mass, intracellular and extracellular water and fat mass were recorded.[22] An increase in extracellular water has been described during the initial formation of leg venous oedema.[23] A thermographic scanner of 0–100°C (Oregon Scientific–Mod. Naw-880 EXL, Guipuzcoa, Spain) was used to record the skin temperature at three levels of the lower limb: popliteal fossa, external calf muscle and foot dorsum.

The McGill Pain Questionnaire was used to assess pain levels.[24] It is based on a multidimensional perception of pain (sensory, affective and evaluative) that includes a visual analogue scale ranging from 0 = no pain to 10 = worst imaginable pain. Venous Clinical Severity Score,[25] which includes ten hallmarks of venous disease evaluated on a severity scale from 0 to 3 (absent, mild, moderate or severe), with a maximum total score of 30 points. SF-36 scores range from 0 to 100% and indicate the self-perceived health-related quality of life.[26]

Kinesio taping procedure

The experimental group received taping with three strips (5 cm × 5 m Kinesio Tex Gold) according to recommendations by Kase.[13,14] The initial procedure to enhance gastrocnemius muscle activation applied one Y-shaped strip (black) on the medial gastrocnemius and another on the lateral gastrocnemius. Patients were in prone position and the tape direction was from origin to insertion at tensions ranging from 15% to 50%. The taping was performed following the muscle anatomy with the appropriate tension and leaving the ends of the strips tension-free. In order to stimulate dorsal flexion, the patient was placed in supine position for Kinesio taping functional correction of the ankle, measuring and cutting an I-strip (blue) at maximum dorsiflexion and applied with 50% tension. Next, two tapes (blue and black) were placed with 50% tension at malleolar level in order to exert peripheral venous compression. The treatment was performed three times a week during a four-week period. Detailed instructions are available in the Appendix (online).

Placebo procedure

This group received an identical number of strips of the same material. The Y-strips for medial and lateral gastrocnemius and the I-strip for ankle movement were applied in the positions reported above but without tension. Moreover, the anatomical localizations were not correct according to Kinesio taping guidelines. The peripheral tape was placed without tension in a semi-circle on the anterior part of the subtalar joint and exerted no type of compression. The placebo was applied three times a week during a four-week period. Detailed instructions are available in the Appendix (online).

Despite these differences in their placement, the tape applications in the experimental and placebo

groups had a very similar appearance. The patients did not wear stockings during the experimental phase.

Based on published findings, a minimum clinically important improvement of 1.8 point in swelling, heaviness and cramps on the 4-point scale[27] (primary outcome) was used to calculate the sample size for the experimental versus placebo group, using the NCSS-PASS programme (www.ncss.com). A sample size of 30 participants per arm was estimated to provide a 95% confidence interval with a power of 80%, assuming a standard deviation (SD) of 6.74 for this difference and a significance level (alpha) of 0.05. The sample size was increased to a total of 60 in order to allow for a loss to follow-up of up to 50%.

SPSS for Windows version 20.0 (SPSS Inc., Chicago, IL, USA) was used for the statistical analyses. Key baseline demographic variables and self-report measures were compared between groups using independent *t*-tests for continuous data and chi-square tests for categorical data. Separate 2 × 2 mixed model ANCOVA with repeated measurements need to be conducted in order to test the effect of the treatment on venous symptoms as primary outcome and pain, peripheral venous flow, clinical severity and overall health status as secondary outcomes with time (baseline and four-week follow-up) as within-subject variable and group (experimental or placebo) as between-subjects variable. All analyses followed the intention-to-treat principle and groups were analysed as randomized. Changes in variable scores within and between groups were measured by means (95% confidential interval (CI)) of *t*-tests for paired or independent samples as appropriate. The effect size was calculated according to Cohen's *d* statistic. An effect size <0.2 reflects a negligible difference, between ≥0.2 and ≤0.5 a small difference, between ≥0.5 and ≤0.8 a moderate difference, and ≥0.8 a large difference. $P < 0.05$ was considered significant in all tests.

Results

The flow diagram in Figure 1 shows that 120 patients were recruited, and Table 1 shows the baseline characteristics and that there were no major differences between the two groups.

Venous symptoms and pain

The group * time interaction for the 2 × 2 mixed ANCOVA showed significantly lower score in the experimental *versus* placebo group in heaviness ($F = 22.99$; $p = 0.001$), venous claudication ($F = 8.57$; $p = 0.004$), swelling ($F = 22.58$; $p = 0.001$), muscle cramps ($F = 7.14$; $p = 0.008$), McGill sensory ($F = 35.50$; $p = 0.001$), evaluative ($F = 5.85$; $p = 0.032$), pain rating index ($F = 10.46$; $p = 0.009$ and visual analogue scale ($F = 23.94$; $p = 0.001$) scores. A large effect size was observed in experimental group for pain and venous symptoms with the exception of pruritus. Table 2 shows baseline, post-intervention, effect size, within-group and between-group differences with associated 95% CI for venous symptoms and pain.

Pair-wise comparisons with baseline values demonstrated significant differences in all pain variables at four weeks post treatment in the experimental group ($p = 0.001$) but only in McGill sensory ($p = 0.032$) and visual analogue scale ($p = 0.016$) outcomes in the control group. The improvement in pain scores (Table 2) between before and after treatment was significantly greater in the experimental group [McGill sensory 3.32 (1.88); visual analogue scale 3.12 (1.77)] than in the control group [McGill sensory 0.28 (0.76); visual analogue scale 0.37 (0.78)].

Peripheral venous flow

At the end of the four-week treatment period, the group * time interaction for the 2 × 2 mixed ANCOVA showed that the experimental group presented significantly less extracellular water (right: $F = 35.55$, $p = 0.004$; left: $F = 23.84$, $p = 0.001$) and higher venous refill time (right: $F = 9.45$, $p = 0.012$; left: $F = 14.86$, $p = 0.001$) and venous pump power (right: $F = 35.55$, $p = 0.004$; left: $F = 17.39$, $p = 0.001$) values than the placebo group for both lower limbs. The treatment showed a moderate–large effect for venous refill time and a large effect for venous pump function and extracellular water in the

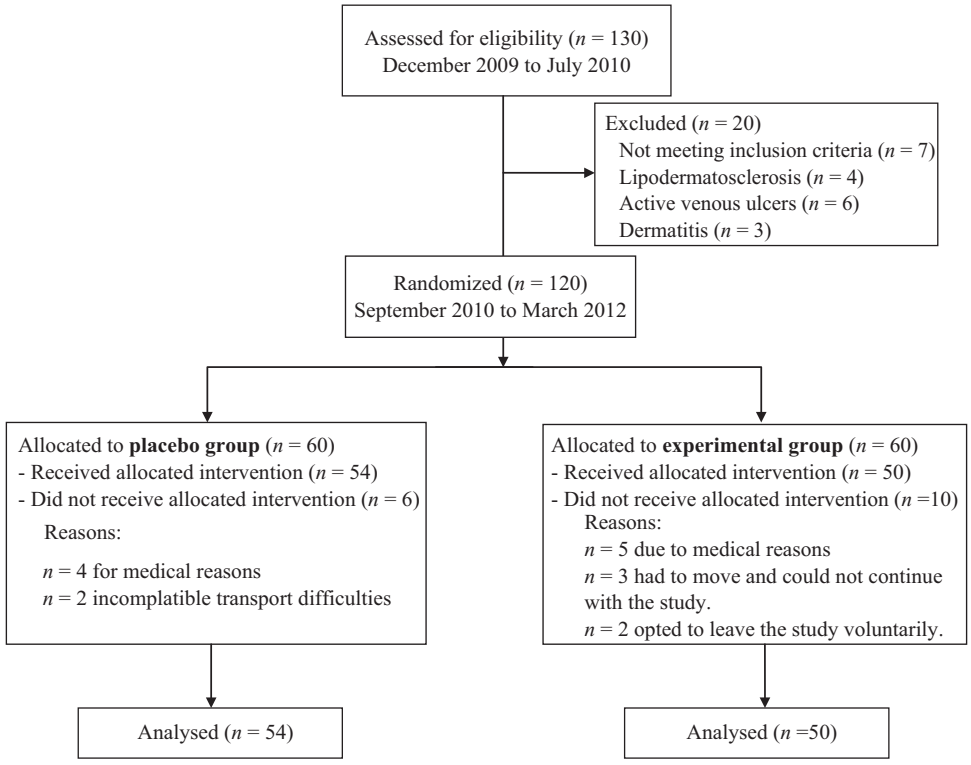

Figure 1. Flow of patients who participated in the study.

experimental group. The mixed Kinesio tape did not show any effect on intracellular water, cell mass, fat mass and temperature. Table 3 shows baseline, post-intervention, effect size, within and between-group changes scores (with 95% CI) for all venous functional parameters.

Severity of venous disease and overall health status

In comparison with the control group, the group * time interaction for the 2 × 2 mixed ANCOVA showed significantly higher scores in physical function ($F = 9.15$; $p = 0.003$) and body pain ($F = 3.36$; $p = 0.043$) and less severity ($F = 18.47$; $p = 0.001$) for the experimental group. The mixed Kinesio tape showed a large effect on severity, although its effect on physical function and body pain was small–moderate. Table 4 shows baseline, post-intervention, effect size within and between group changes in scores (with 95% CI) for severity and overall health status and its within-group significance level.

Discussion

At four weeks after application of a mixed Kinesio taping-compression model, chronic venous insufficiency patients showed a significantly reduced degree of reflux (venous refill time >20 seconds)[20,21] and oedema (less extracellular water) and a significant improvement in venous symptoms, pain intensity, severity, physical function and body pain in comparison to pretreatment values and to the outcomes of a placebo Kinesio taping application. The placebo group also experienced a post-treatment improvement in pain, though smaller, suggesting that this mixed bandaging model has a placebo effect on pain intensity.

Table 1. Characteristics of patients at baseline

	Experimental group $n = 50$		Control group $n = 54$		*P*-value
	Freq	%	Freq	%	
Age (years) (mean ± SD)	64.40 ± 13.1		66.48 ± 12.7		0.414
Body mass index (kg/m^2) (mean ± SD)	26.86 ± 4.8		27.69 ± 4.6		0.434
Time since CIV onset (years) (mean ± SD)	18.9 ± 11.2		17.51 ± 8.4		0.472
CIV aetiology					0.802
Congenital	0	0.0	0	0.0	
Primary	39	78.0	41	75.9	
Secondary	11	22.0	13	24.1	
VDS					0.659
Grade 0	0	0.0	0	0.0	
Grade 1	39	78.0	43	22.0	
Grade 2	11	22.0	11	20.4	
Grade 3	0	0.0	0	0.0	
Predisposing factors					
Family history	29	58.0	34	62.9	0.066
Orthostatism at work	37	74.0	39	72.2	0.596
Exposure to heat	1	2.0	2	3.7	0.960
Lower limb trauma	13	26.0	9	16.7	0.250
Sedentarism	20	40.0	22	40.7	0.085
Inadequate clothing and footwear	9	18.0	16	29.6	0.305
Pretreatment status					0.112
Major improvement	0	0.0	0	0.0	
Slight improvement	3	6.0	2	3.7	
Stabilization	14	28.0	19	35.1	
Worsening	32	64.0	33	61.1	
Major worsening	1	2.0	0	0.0	

Values are expressed as absolute and relative frequencies (n =104) for categorical variables and as means ± standard deviation for continuous variables.

CIV, chronic venous insufficiency; VDS, venous disability score. Grade 0: asymptomatic; Grade 1: symptomatic, works without external support; Grade 2: symptomatic, can only work with external support (8 hours/day); Grade 3: complete employment disability).

Compression (stroking or bandaging) is known to significantly decrease degree of reflux, oedema, venous symptoms and, therefore, diminish severity and improve quality of life in venous disease.[9,10,12] The application of external compression can help to diminish or reverse the skin and vascular changes described in these patients, by forcing fluid from the interstitial spaces back into the vascular and lymphatic compartments.[28] Multicomponent systems containing an elastic bandage, such as Kinesio taping, appear more effective than those composed mainly of inelastic constituents.[29] Despite the elasticity of Kinesio tape, movement restrictions imposed by mechanical taping could improve contractions of the gastrocnemius muscle, which is altered in chronic venous insufficiency patients.[30] In fact, an increase in electromyographic muscle activity has been reported after this type of Kinesio taping application (origin to insertion) in different pathologies.[15–17] Numerous studies[2,30,31] have suggested that periodic contractions of gastrocnemius significantly contribute to improving calf muscle pump function and decreasing venous stasis. Compression bandaging is therefore an important

Table 2. Baseline, post-treatment, pre–post-treatment differences and change scores in each group (95% confidence interval) for venous symptoms and pain

Outcome/group	Baseline	One month post-treatment	Cohen's *d*	Within-group score change	Between-group score change
Heaviness (0–3)					
Experimental	2.22 ± 0.65	1.24 ± 0.59	1.58	0.98 (0.80, 1.15)	–0.81 (–1.11, –0.52)*
Control	2.02 ± 0.73	2.11 ± 0.84	0.11	–0.09 (–0.28, 0.10)	
Venous claudication (0–3)					
Experimental	1.65 ± 0.75	0.98 ± 0.55	1.03	0.64 (0.47, 0.80)	–0.61 (–0.89, –0.33)*
Control	1.61 ± 0.79	1.59 ± 0.83	0.02	0.02 (–0.10, 0.14)	
Swelling (0–3)					
Experimental	2.06 ± 0.68	1.10 ± 0.64	1.45	0.96 (0.79, 1.12)	–0.90 (–1.17, –0.63)*
Control	1.98 ± 0.87	2.00 ± 0.80	0.02	–0.02 (–0.21, 0.18)	
Muscle cramps (0–3)					
Experimental	1.00 ± 0.86	0.30 ± 0.58	0.97	0.70 (0.52, 0.88)	–0.81 (–1.11, 0.52)*
Control	1.02 ± 0.87	1.11 ± 0.90	0.10	–0.09 (–0.23, 0.05)	
Pruritus (0–3)					
Experimental	0.26 ± 0.59	0.18 ± 0.48	0.15	0.08 (–0.05, 0.21)	–0.08 (–0.28, 0.13)
Control	0.29 ± 0.66	0.25 ± 0.59	0.06	0.03 (–0.01, 0.09)	
MPQ Sensory (1–53)					
Experimental	4.96 ± 1.75	1.94 ± 1.07	2.14	3.02 (2.50, 3.54)	–2.37 (–2.96, –1.79)*
Control	4.57 ± 1.94	4.31 ± 1.81	0.13	0.26 (0.06, 0.46)	
MPQ Affective (1–9)					
Experimental	2.62 ± 1.78	2.64 ± 1.65	0.01	0.08 (–0.27, 0.43)	–0.23 (–0.90, 0.43)
Control	2.73 ± 1.82	2.77 ± 1.75	0.02	–0.05 (–0.11, 0.19)	
MPQ Evaluative (1–4)					
Experimental	1.60 ± 0.64	1.06 ± 0.23	1.25	0.54 (0.36, 0.71)	–0.62 (–0.83, –0.41)*
Control	1.66 ± 0.58	1.68 ± 0.69	0.03	–0.01 (–0.18, 0.07)	
MPQ PRI (1–66)					
Experimental	9.18 ± 3.20	5.54 ± 2.25	1.33	3.64 (2.97, 4.30)	–3.24 (–4.45, –2.03)
Control	8.96 ± 3.99	8.77 ± 3.72	0.05	0.18 (–0.14, 0.51)	
MPQ PPI (1–5)					
Experimental	2.24 ± 1.01	1.26 ± 0.56	1.25	0.98 (0.70, 1.56)	–0.92 (–1.25, –0.60)*
Control	2.28 ± 1.03	2.18 ± 1.04	0.09	0.09 (–0.10, 0.28)	
VAS (0–10)					
Experimental	5.63 ± 2.07	2.51 ± 1.54	1.73	3.12 (2.61, 3.63)	–2.40 (–3.09, –1.70)*
Control	5.28 ± 2.36	4.91 ± 1.99	0.17	0.37 (0.16, 0.59)	

Values are expressed as means ± standard deviation for baseline and one month post-treatment and as mean (95% confidence interval) for within- and between-group change scores.
*Significant group * time interaction (ANCOVA, $P < 0.05$).
MPQ, McGill Pain Questionnaire; PPI, present pain intensity; PRI, pain rating index; VAS, visual analogue scale.

measure to treat peripheral stasis, to prevent venous thromboembolism and leg ulcers and should be taken into account in clinical management guidelines for physiotherapist practitioners.[32,33]

The results obtained have supported our working hypothesis: the Kinesio taping mixed model helps to improve venous pain in females with chronic venous insufficiency. Therefore, our estimate of the effect

Table 3. Baseline, post-treatment, pre–post-treatment differences and change scores in each group (95% confidence interval) for functional venous parameters

Outcome/group		Baseline	One month post treatment	Cohen's *d*	Within-group score changes	Between-group score changes
VRT (s)						
Experimental	Right	15.67 ± 6.53	21.36 ± 7.34	0.53	–5.68 (–7.37, – 3.99)	5.10 (2.39, 7.80)*
	Left	17.16 ± 7.19	25.54 ± 9.91	0.98	–8.38 (–10.77, –5.77)	9.36 (6.04, 12.69)*
Control	Right	16.38 ± 6.80	16.26 ± 7.01	0.02	0.12 (–0.29, 0.52)	
	Left	16.20 ± 7.03	16.17 ± 7.20	0.01	0.02 (–0.35, 0.40)	
VPP (%)						
Experimental	Right	2.28 ± 0.94	3.51 ± 1.16	1.17	–1.22 (–1.05, –0.94)	1.13 (0.73, 1.53)*
	Left	2.33 ± 0.98	3.66 ± 1.46	1.09	–1.32 (–1.68, –0.96)	1.27 (0.78, 1.76)*
Control	Right	2.30 ± 0.93	2.37 ± 0.90	0.07	–0.07 (–0.19, 0.03)	
	Left	2.31 ± 1.01	2.39 ± 1.20	0.07	–0.06 (–0.18, 0.04)	
Cell mass (kg)						
Experimental	Right	24.38 ± 4.13	24.81 ± 3.29	0.11	–0.43 (–1.2, –0.37)	–1.21 (–0.09, 2.5)
	Left	24.74 ± 4.05	25.09 ± 3.09	0.09	–0.35 (–0.98, 0.29)	–1.24 (–0.10, –2.6)
Control	Right	23.39 ± 3.79	23. 59 ± 3.43	0.08	–0.20 (–0.60, 0.21)	
	Left	23.72 ± 3.92	23.84 ± 3.77	0.03	–0.12 (–0.49, 0.24)	
Fat mass (kg)						
Experimental	Right	33.34 ± 10.96	33.27 ± 10.89	0.01	0.06 (–0.27, 0.41)	2.71 (–0.80,6.2)
	Left	33.23 ± 10.95	33.48 ± 10.80	0.02	–0.25 (–0.81, 0.31)	2.86 (–0.69, 6.4)
Control	Right	30.82 ± 7.11	30.56 ± 6.91	0.04	0.26 (–0.18, 0.71)	
	Left	31.04 ± 7.08	30.62 ± 7.25	0.06	0.41 (–0.13, 0.97)	
Intracellular water (L)						
Experimental	Right	22.45 ± 3.66	22.89 ± 3.30	0.12	–0.43 (–1.02, 0.15)	0.77 (–0.46, 2.01)
	Left	22.26 ± 3.37	22.21 ± 2.74	0.02	0.06 (–0.56, 0.67)	0.06 (–0.46, 2.03)
Control	Right	22.11 ± 3.39	22.12 ± 3.02	0.00	–0.01 (–0.38, 0.36)	
	Left	22.11 ± 3.39	22.15 ± 3.68	0.01	–0.04 (–1.21, 1.13)	
Extracellular water (L)						
Experimental	Right	5.93 ± 1.51	3.43 ± 1.44	1.70	2.51 (2.22, 2.79)	–2.11 (–2.67, –1.56)*
	Left	5.86 ± 1.61	3.29 ± 1.43	1.69	2.57 (2.28, 2.86)	–2.03 (–2.59, –1.45)*
Control	Right	5.64 ± 1.43	5.54 ± 1.42	0.07	0.10 (–0.08, 0.28)	
	Left	5.34 ± 1.39	5.32 ± 1.47	0.01	0.01 (–0.22, 0.25)	
Temperature PF (°C)						
Experimental	Right	32.95 ± 1.46	32.97 ± 1.40	0.01	–0.01 (–0.24, 0.21)	0.14 (–0.44, 0.73)
	Left	33.25 ± 1.50	33.11 ± 1.99	0.08	0.13 (–0.15, 0.40)	0.28 (–0.48, 1.04)
Control	Right	32.88 ± 2.16	32.83 ± 1.59	0.03	0.05 (–0.23, 0.33)	
	Left	32.93 ± 1.98	32.84 ± 1.91	0.05	0.10 (–0.15, 0.36)	
Temperature EC (°C)						
Experimental	Right	31.98 ± 1.48	32.04 ± 1.65	0.04	–0.05 (–0.34, 0.23)	0.20 (–0.49, 0.91)
	Left	32.24 ± 1.30	32.32 ± 1.74	0.05	0.02 (–0.29, 0.34)	–0.04 (–0.85, 0.77)
Control	Right	32.00 ± 2.62	31.83 ± 1.94	0.07	0.17 (–0.15, 0.49)	
	Left	32.24 ± 2.93	32.26 ± 2.37	0.01	–0.01 (–0.25, 0.23)	
Temperature DF (°C)						
Experimental	Right	30.89 ± 1.57	30.96 ± 1.82	0.04	–0.07 (–0.38, 0.23)	–0.09 (–0.92, 0.73)
	Left	30.85 ± 2.03	30.62 ± 2.77	0.09	0.23 (–0.12, 0.58)	0.07 (–0.78, 0.93)
Control	Right	30.77 ± 2.77	31.06 ± 2.35	0.11	–0.29 (–0.71, 0.12)	
	Left	30.59 ± 2.52	30.55 ± 2.36	0.01	0.04 (–0.23, 0.31)	

Values are expressed as means ± standard deviation for baseline and one month post treatment and as mean (95% confidence interval) for within- and between-group change scores.
*Significant group * time interaction (ANCOVA, $P < 0.05$).
DF, dorsal foot; EC, external calf muscle; PF, popliteal fossa; VPP, venous pump power; VRT, venous refill time.

Table 4. Baseline, post-treatment, pre–post-treatment differences and change scores in each group (95% confidence interval) for severity and overall health status

Outcome/group	Baseline	One month post treatment	Cohen's *d*	Within-group score change	Between-group score change
VCSS (0–30)					
Experimental	5.62 ± 1.06	3.28 ± 1.19	2.08	2.34 (2.03, 2.65)	–1.83 (–2.32, –1.33)*
Control SF-36	5.22 ± 1.16	5.11 ± 1.35	0.08	0.11 (–0.18, 0.40)	
Physical function (0–100)					
Experimental	75.92 ± 6.89	80.96 ± 6.99	0.72	–5.74 (–6.84, 4.63)	6.08 (3.38, 8.79)*
Control	75.01 ± 7.22	74.87 ± 6.93	0.02	0.14 (–0.72, 1.01)	
Physical role (0–100)					
Experimental	52.80 ± 8.72	51.98 ± 9.51	0.09	0.82 (–0.05, 0.69)	–0.68 (–4.38, 3.01)
Control	53.28 ± 8.93	52.66 ± 9.49	0.06	0.61 (–0.31, 1.53)	
Body pain (0–100)					
Experimental	49.26 ± 7.70	52.34 ± 8.62	0.37	–3.08 (–4.13, –2.03)	3.81 (0.58, 7.04)*
Control	48.94 ± 8.16	49.07 ± 8.10	0.01	–0.13 (–1.30, 1.04)	
General health (0–100)					
Experimental	57.56 ± 8.28	56.84 ± 7.44	0.09	0.72 (–0.46, 1.09)	1.13 (–1.9, 4.20)
Control	55.83 ± 8.08	55.70 ± 8.29	0.01	0.13 (–0.68, 0.93)	
Vitality (0–100)					
Experimental	51.88 ± 8.58	52.66 ± 9.39	0.08	–0.78 (–1.77, 0.21)	–1.32 (–4.68, 2.04)
Control	53.74 ± 10.3	54.15 ± 9.09	0.04	–0.40 (–1.26, 0.45)	
Social function (0–100)					
Experimental	75.34 ± 7.23	74.90 ± 7.47	0.06	0.44 (–0.89, 1.77)	1.51 (–1.61,4.60)
Control	72.42 ± 8.15	73.39 ± 8.51	0.12	–0.96 (–2.31, 0.39)	
Emotional role (0–100)					
Experimental	49.56 ± 7.84	48.58 ± 8.10	0.12	0.98 (–0.09, 2.05)	–0.97 (–4.20, 2.26)
Control	50.11 ± 7.86	49.55 ± 8.53	0.07	0.55 (–0.48, 1.59)	
Mental health (0–100)					
Experimental	56.12 ± 8.38	57.08 ± 8.29	0.11	–0.96 (–1.96, 0.04)	–2.53 (–6.01, 0.94)
Control	58.94 ± 9.25 9.25)	59.61 ± 9.47	0.07	–0.66 (–1.68, 0.34)	

Values are expressed as means ± standard deviation for baseline and one month post treatment and as mean (95% confidence interval) for within- and between-group change scores.
*Significant group * time interaction (ANCOVA, $P < 0.05$).
VCSS, venous clinical severity score.

(3.12 cm) was higher than 'worthwhile effect' for VAS pain (2.5 cm).[27] Numerous authors have reported a reduction of pain through the use of Kinesio taping,[16–18,34,35] but the exact mode of action remain unknown. The most frequently proposed hypothesis is that Kinesio taping generates a series of cutaneous afferents which interfere with the transmission of mechanical and painful stimuli. This causes a differential stimulation of rapid nerve fibres which, in turn, activate a descending pain inhibitory pathway (gate control theory).[13,14,17,36] In addition, peripheral compression may also have contributed to the pain relief

observed in the present study. Peripheral stasis can enhance a leukocyte–endothelial inflammatory reaction, which is considered as the main stimulator of nociceptors of the venous wall and paravasal tissue, thus giving rise to pain syndrome in chronic venous insufficiency patients.[37] Compression acts by reducing the calibre of the vein, which diminishes both stasis and nociceptive stimulation levels. Our estimate of the effect of the sham Kinesio taping on VAS is not clinically relevant but indicates a certain placebo effect of our technique on pain intensity. The perception of pain is subjective and involves both physical and psychological mechanisms. The input of visual (colours) and proprioceptive cutaneous afferents from Kinesio taping may have generated positive expectations of the therapeutic outcome, as well as improved perceptions of stability, confidence and reassurance.[38,39] In addition, placebo treatment was found to induce endogenous opiates via activation of different brain areas.[40] Hence, a placebo effect may have contributed somewhat to the effectiveness of our taping technique.

On the other hand, peripheral compression with muscle pump activation may also have beneficial effects on the cardiovascular and respiratory system and therefore on gait, which is altered in venous disease.[31,41,42] Compression combats blood stasis and reduces venous distensibility and peripheral flow resistance[12] and may therefore ameliorate the negative impact of chronic venous insufficiency on heart activity. Hence, further studies are required to elucidate the impact of this tape in the cardiorespiratory system. In addition, Kinesio taping possesses certain characteristics that can be expected to improve compliance with this therapy in comparison to other compression systems. It can be rapidly applied and is air-permeable and water-resistant, allowing its use in combination with aquatic therapy exercise programmes, unlike other peripheral compression techniques. Therefore, mixed Kinesio taping could be used in general clinical practice: to ameliorate venous flow and symptoms in patients with mild–moderate (C1–C3) venous disease and low or no adherence to conventional systems; and to improve venous return during aquatics exercises in hydrotherapy programmes.

This is the first study to contribute scientific evidence on the application of a system combining Kinesio taping and conventional compression principles in patients with chronic venous insufficiency. It is mainly limited by the short period of application, and research is warranted on the effects of multiple applications over a longer time period. Furthermore, the results of this study of an exclusively female group cannot be extrapolated to male populations. Cost-effectiveness of this therapy have not been studied, thus its clinical application may not add any additional benefits versus stockings or other conventional dressing. Although photoplethysmographic and bioelectrical impedance are frequently used in clinical research, the validity and reliability of these methods have not been well studied. In addition, long-term effects of mixed Kinesio taping on skin have not been researched and it could be a limitation of its clinical application. In fact, this is a bandage for mild venous insufficiency patients (C3 or less) without dermatology alterations. Finally, wider studies are needed on the utilization of this taping in combination with hydrotherapy and other conventional physical therapy programmes.

In conclusion a mixed Kinesio taping–compression procedure can improve venous symptoms, pain, peripheral venous flow and clinical severity and produce a slight increase in overall health status in patients with chronic venous insufficiency until at least four-weeks post treatment. This technique appears to exert a certain placebo effect on pain perception.

Clinical messages

- A short-term mixed Kinesio taping model improves the degree of venous reflux and peripheral oedema in postmenopausal females with mild chronic venous insufficiency (C3 or less).
- Its application three times per week reduces venous specific symptoms, pain and severity.
- Mixed Kinesio taping–compression therapy produces a slight improvement in overall health status and may have a placebo effect on venous pain.

Conflict of interest

The authors declare that there is no conflict of interest.

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References

1. Bromen K, Pannier F and Stang A. Should sex-specific differences in venous diseases be explained by pregnancies and hormonal intake? *Gesundheitswesen* 2004; 66: 170–174.
2. Labropoulos N, Giannoukas AD, Nicolaides AN, et al. The role of venous reflux and calf muscle pump function in nonthrombotic chronic venous insufficiency. Correlation with severity of signs and symptoms. *Arch Surg* 1996; 131: 403–406.
3. Dix FP, Brooke R and McCollum CN. Venous disease is associated with an impaired range of ankle movement. *Eur J Vasc Endovasc Surg* 2003; 25: 556–561.
4. Rabe E, Stücker M, Esperester A, et al. Efficacy and tolerability of a red-vine-leaf extract in patients suffering from chronic venous insufficiency – results of a double-blind placebo-controlled study. *Eur J Vasc Endovasc Surg* 2011; 41: 540–547.
5. Padberg Jr FT, Johnston MV and Sisto SA. Structured exercise improves calf muscle pump function in chronic venous insufficiency: a randomized trial. *J Vasc Surg* 2004; 39: 79–87.
6. Heinen MM, van der Vleuten C, de Rooij MJ, et al. Physical activity and adherence to compression therapy in patients with venous leg ulcers. *Arch Dermatol* 2007; 143: 1283–1288.
7. Long JB. Venous thromboembolism: pharmacological and nonpharmacological interventions. *J Cardiovasc Nurs* 2009; 24: 8–13.
8. Ramos-González E, Moreno Lorenzo C, Matarán Peñarrocha GA, et al. Comparative study on the effectiveness of myofascial release manual therapy and physical therapy for venous insufficiency in postmenopausal women. *Complement Ther Med* 2012; 20: 291–299.
9. Nicolaides AN, Allegra C, Bergan J, et al. Management of chronic venous disorders of the lower limbs: guidelines according to scientific evidence. *Int Angiol* 2008; 27: 1–59.
10. Partsch H, Flour M, Coleridge Smith P, et al. Consensus statement. Indications for compression therapy in venous and lymphatic disease. Consensus based on experimental data and scientific evidence. Under the auspices of the UIP. *Int Angiol* 2008; 27: 193–219.
11. Edwards LM. Why patients do not comply with compression bandaging. *Br J Nur* 2003; 12: 5–10.
12. Cataldo JL, De Godoy JM and De Barros N. The use of compression stockings for venous disorders in Brazil. *Phlebology* 2012; 27: 33–40.
13. Kase K, Tatyusuki H and Tomoki O. Development of Kinesio™ tape. In: Kase K, Tatyusuki H and Tomoki O. (eds) *Kinesio™ taping perfect manual*, second edition. Japan: Tokyo, 1996, pp. 117–118.
14. Kase K, Wallis J and Kase T. *Clinical therapeutic applications of the Kinesio taping method*, first edition. Japan: Tokyo, 2003.
15. Słupik A, Dwornik M, Białoszewski D, et al. Effect of Kinesio Taping on bioelectrical activity of vastus medialis muscle. Preliminary report. *Ortop Traumatol Rehabi*. 2007; 9: 644–651.
16. Hsu YH, Chen WY, Lin HC, et al. The effects of taping on scapular kinematics and muscle performance in baseball players with shoulder impingement syndrome. *J Electromyogr Kinesiol* 2009; 19: 1092–1099.
17. Paoloni M, Bernetti A, Fratocchi G, et al. Kinesio Taping applied to lumbar muscles influences clinical and electromyographic characteristics in chronic low back pain patients. *Eur J Phys Rehabil Med* 2011; 47: 237–243.
18. Yoshida A and Kahanov L. The effect of kinesio taping on lower trunk range of motions. *Res Sports Med* 2007; 15: 103–112.
19. Gloviczki P, Comerota AJ, Dalsing MC, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *J Vasc Surg* 2011; 53: 2–48.
20. Kelechi TJ and Bonham PA. Measuring venous insufficiency objectively in the clinical setting. *J Vasc Nurs* 2008; 26: 67–73.
21. Jünger M, Steins A, Hahn M, et al. Microcirculatory dysfunction in chronic venous insufficiency (CVI). *Microcirculation* 2000; 7: 3–12.
22. King RJ, Clamp JA, Hutchinson JW, et al. Bioelectrical impedance: a new method for measuring post-traumatic swelling. *J Orthop Trauma* 2007; 21: 462–470.
23. Mittermayr M, Fries D, Gruber H, et al. Leg edema formation and venous blood flow velocity during a simulated long-haul flight. *Thromb Res* 2007; 120: 497–504.
24. Masedo AI and Esteve R. Some empirical evidence regarding the validity of the Spanish version of the McGill Pain Questionnaire (MPQ-SV). *Pain* 2000; 85: 451–457.
25. Rutherford RB, Padberg FT, Comerota AJ, et al. Venous severity scoring: an adjunct to venous outcome assessment. *J Vasc Surg* 2000; 31: 1307–1312.
26. Vilagut G, Valderas JM, Ferrer M, et al. Interpretation of SF-36 and SF-12 questionnaires in Spain: physical and mental components. *Med Clin (Barc.)* 2008; 130: 726–735.
27. Launois R, Mansilha A and Jantet G. International psychometric validation of the Chronic venous disease quality of life questionnaire (CIVIQ-20). *Eur J Vasc Endovasc Surg* 2010; 40: 783–789.
28. Thomas S. Compression bandaging in the treatment of venous leg ulcers, 2001. http://www.worldwidewounds.com/1997/september/ThomasBandaging/bandage-paper.html (accessed 10 July 2012).

29. O'Meara S, Cullum NA and Nelson EA. Compression for venous leg ulcers. *Cochrane Database Syst Rev* 2009; 21: CD000265.
30. Qiao T, Liu C and Ran F. The impact of gastrocnemius muscle cell changes in chronic venous insufficiency. *Eur J Vasc Endovasc Surg* 2005; 30: 430–436.
31. Van Uden CJ, van der, Vleuten CJ, Kooloos JG, et al. Gait and calf muscle endurance in patients with chronic venous insufficiency. *Clin Rehabil* 2005; 19: 339–344.
32. Roaldsen KS, Biguet G and Elfving B. Physical activity in patients with venous leg ulcer–between engagement and avoidance. A patient perspective. *Clin Rehabil* 2011; 25: 275–286.
33. Nelson Worel J. Venous thromboembolism: what is preventing achievement of performance measures and consensus guidelines? *J Cardiovasc Nurs* 2009; 24: S14–S19.
34. Thelen MD, Dauber JA and Stoneman PD. The clinical efficacy of kinesio tape for shoulder pain: a randomized, double-blinded, clinical trial. *J Orthop Sports Phys Ther* 2008; 38: 389–395.
35. García-Muro F, Rodríguez-Fernández AL and Herrero-de-Lucas A. Treatment of myofascial pain in the shoulder with Kinesio taping. A case report. *Man Ther* 2010; 15: 292–295.
36. Castro-Sánchez AM, Lara-Palomo IC, Matarán-Peñarrocha GA, et al. Kinesio taping reduces disability and pain slightly in chronic non-specific low back pain: a randomised trial. *J Physiother* 2012; 58: 89–95.
37. Bogachev VIu and Shekoian AO. Pain and other symptoms of chronic venous diseases: pathophysiology and therapeutic principles. *Angiol Sosud Khir* 2009; 15: 79–85.
38. Sawkins K, Refshauge K, Kilbreath S, et al. The placebo effect of ankle taping in ankle instability. *Med Sci Sports Exerc* 2007; 39: 781–788.
39. Chen SM, Alexander R, Kai Lo S and Cook J. Effects of functional fascial taping on pain and function in patients with non-specific low back pain: a pilot randomized controlled trial. *Clin Rehabil* 2012; 26: 924–933.
40. Dobrila-Dintinjana R and Nacinović-Duletić A. Placebo in the treatment of pain. *Coll Antropol* 2011; 35: 319–323.
41. Faghri PD and Yount J. Electrically induced and voluntary activation of physiologic muscle pump: a comparison between spinal cord-injured and able-bodied individuals. *Clin Rehabil* 2002; 16: 878–885.
42. Pierce C and McLeod KJ. Feasibility of treatment of lower limb edema with calf muscle pump stimulation in chronic heart failure. *Eur J Cardiovasc Nurs* 2009; 8: 345–353.