

# The treatment of venous leg ulcers with a specifically designed compression stocking kit

## Comparison with bandaging

F. Mariani,<sup>1,2</sup> V. Mattaliano,<sup>2,3</sup> G. Mosti,<sup>2,3</sup> V. Gasbarro,<sup>2,4</sup> M. Bucalossi,<sup>1,2</sup> W. Blättler,<sup>5</sup> F. Amsler,<sup>5,6</sup> St. Mancini<sup>1,2</sup>

<sup>1</sup>Department of General Surgery, University of Siena, <sup>2</sup>The Compression Therapy Study Group (CTG), Colle di Val d'Elsa, Siena, <sup>3</sup>Department of Angiology and Phlebological Surgery, Clinic M. D.

Barbantini, Lucca, <sup>4</sup>Department of Vascular Surgery, University of Ferrara, Italy,

<sup>5</sup>Sigvaris Research Center, Winterthur, <sup>6</sup>Amsler Consulting, Biel-Benken, Switzerland

### Keywords

Chronic venous insufficiency, venous leg ulcers, medical compression stockings, bandages

### Summary

Traditionally, venous leg ulcers are treated with firm non-elastic bandages. Medical compression stockings are not the first choice although comparative studies found them equally effective or superior to bandages. **Patients, methods:** We report on a multi-center randomized trial with 60 patients treated with either short stretch multi-layer bandages or a two-stocking system (Sigvaris® Ulcer X® kit). Three patients have been excluded because their ankle movement was restricted to the extent that they could not put on the stockings and 1 patient withdrew consent. Patient characteristics and ulcer features were evenly distributed. The proportion of ulcers healed within 4 months and the time to completion of healing were recorded. Subjective appraisal was assessed with a validated questionnaire. **Results:** Complete wound closure was achieved in 70.0% (21 of 30) with bandages and in 96.2% (25 of 26) with the ulcer X kit ( $p = 0.011$ ). Ulcers with a diameter of up to about 4 cm healed twice as rapidly, the larger ones as fast with the stocking kit as with bandages. The sum of problems encountered with bandages was significantly greater than that observed with the stocking kit ( $p < 0.0001$ ). Pain at night and in the morning was absent with stockings but reported by 40% and 20% in the bandage group, respectively. The cardinal features associated with delayed or absent healing were ulcer size and pain. **Conclusions:** Common venous ulcers can readily be treated with the ulcer X compression kit provided the ankle movement allow its painless donning. Bandages, even when applied by the most experienced staff are less effective and cause more problems.

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### Schlüsselwörter

Chronisch-venöse Insuffizienz, venöse Beingeschwüre, medizinische Kompressionsstrümpfe, Verbände

### Zusammenfassung

Traditionell werden venöse Beingeschwüre mit straffen, nicht elastischen Verbänden behandelt. Medizinische Kompressionsstrümpfe sind nicht erste Wahl obwohl einige vergleichende Studien eine gleiche oder höhere Effektivität gezeigt haben. **Patienten und Methoden:** Offene, multizentrische, randomisierte Studie. 60 Patienten mit venösen Ulzera. Symmetrische Verteilung der Risikofaktoren: mittlerer Durchmesser 3 cm, Dauer 3,4 Monate, 39% PTS. Therapie mit Verbänden oder einem System mit 2 Strümpfen (Sigvaris® Ulcer X® kit). Ausschlüsse: 3 Patienten wegen Unfähigkeit den Überziehstrumpf anzuziehen bei stark eingeschränkter Sprunggelenkbeweglichkeit; 1 Patient wegen Widerruf des Einverständnisses. Kontrolle des Heilungsverlaufes über 4 Monate, der subjektiven Einschätzung bei Abheilung oder am Ende der Beobachtung mittels validiertem Fragebogen. **Ergebnisse:** Vollständige Wundheilung in 70,0% (21 von 30) mit Verbänden, in 96,2% (25 von 26) mit dem Ulcer X kit ( $p = 0,011$ ). Ulzera mit einem Durchmesser von bis etwa 4 cm heilten doppelt so schnell mit dem Ulcer X kit, größere gleich schnell wie mit Verbänden. Die Summe der subjektiven Probleme war viel größer mit Verbänden als mit dem Strümpfsystem ( $p < 0,0001$ ). Schmerzen in der Nacht und am Morgen fehlten gänzlich in der Strümpfgruppe, während sie in 40% respektive 20% in der Gruppe mit Verbänden angegeben wurden. Die wichtigsten prädiktiven Faktoren für verzögerte Heilung waren Ulkusgröße und Schmerz. **Schlussfolgerung:** Gewöhnliche venöse Ulzera können mit dem Ulcer X kit einfach und sicher behandelt werden, vorausgesetzt die Sprunggelenkbeweglichkeit erlaubt ein schmerzfreies Anlegen. Verbände, auch wenn sie von erfahrenen Ärzten angelegt werden, sind weniger effektiv und verursachen mehr Probleme.

Behandlung venöser Beingeschwüre mit einem speziell entworfenen Kompressionsstrumpf-Kit

Vergleich mit Verbänden

### Mots clés

Insuffisance veineuse chronique, ulcères variqueux, bas à compression élastique, bandages rigides

### Résumé

Traditionnellement les ulcères de jambes sont traités avec des bandages rigides, non élastiques. Les bas de contention élastique ne sont pas le premier choix malgré les études comparatives les jugeant égaux ou supérieurs aux bandages rigides. **Patients et méthode:** 60 patients font l'objet d'une étude randomisée multicentrique par traitement comparé d'une part avec bandages rigides courts multi-couches, d'autre part avec un système de contention double (Sigvaris® Ulcer X® kit). Trois patients ont été exclus en raison d'une diminution de mobilité de cheville ne leur permettant pas de mettre les bas élastiques et un patient en raison d'un refus. Les caractéristiques de chaque patient et les types d'ulcères ont été également répartis dans les 2 groupes. La proportion de guérison d'ulcère après 4 mois et le temps complémentaire de guérison ont été notés. Une évaluation subjective a été établie par un questionnaire homologué. **Résultat:** Une guérison complète a été obtenue dans 70% des cas (21 patients sur 30) avec des bandages rigides et dans 96,2% (25 patients sur 26) avec le kit „ulcer X“ ( $p = 0,011$ ). Des ulcères dont le diamètre atteignait 4 cm ont guéri deux fois plus vite, les grands ulcères aussi rapidement avec les bas qu'avec les bandages rigides. Les complications rencontrées par les bandages rigides ont été significativement plus grandes que celles observées avec les bas élastiques ( $p < 0,0001$ ). Les douleurs nocturnes et matinales étaient absentes avec les bas élastiques mais présentes dans 40% et respectivement 20% dans le groupe de bandages rigides. Les caractéristiques principales associées à un retard ou une absence de guérison ont été la taille de l'ulcère et la douleur. **Conclusion:** Les ulcères veineux habituels peuvent être traités par un kit de compression „ulcer X“ permettant le mouvement de la cheville et supprimant la douleur. Les bandages rigides, même posés par les équipes les plus expérimentées ont été moins efficaces et ont créé plus de problèmes.

Traitement des ulcères variqueux avec un kit spécifique de contention élastique

Comparaison avec les bandages rigides

Compression is the therapeutic strong-hold for patients with venous leg ulcers (1–5). It is used on the basis of experience rather than scientific evidence and particular modalities reflect a long tradition (6, 7). Elaborate bandaging systems yielded marginally better results than relatively simple techniques and medical compression stockings (MCS) are not first choice although comparative studies found them equally effective or superior to bandages (8–14). Conceptually, compression stockings have inherent advantages as compared with bandages but they are difficult to put on if they have to exert an ankle pressure of about 40 mmHg. A stocking-based system was designed (Sigvaris® Ulcer X® kit) with the intention to implement the advantages while minimizing eventual problems. The kit consists of an under-stocking which exerts a moderate pressure, fixing the dressing to the wound, and left on the leg day and night. A second and stronger stocking is donned over the under-stocking for day time use. We report on a randomised multi-center trial which compared this medical compression system with the patient-tailored bandages in use at the participating centers.

## Patients, methods

### Study design

The study is a prospective, randomised, open-label, parallel-group clinical trial, sponsored by the investigators and performed in three centres specialized in ulcer care in Italy.

It compares the effectiveness and acceptance of the new stocking system with traditional bandages. No stratification is done, neither for the size of the ulcer nor its presumed cause. Randomization is done in two blocks of 10 patients for each center.

### Patient evaluation and endpoint assessment

Patient work-up followed standard clinical procedures. The quantitative evaluation of

the ulcer features was performed by the principal investigator at each center. The differentiation between chronic venous insufficiency due to superficial venous disease (CVI) and the post-thrombotic syndrome (PTS) was based on the clinical aspect and a duplex ultrasound investigation of all leg veins. Information on the time of the presence of the actual ulcer and recurrence was obtained from the patient. The ulcer size was determined with a tape: The largest diameter was recorded. A validated score system was used to assess subjective patient information.

### Inclusion criteria

- Presence of a leg ulcer caused by venous disease, with maximum diameter of 8 cm, present for at least one month,
- no effective compression treatment performed before study entrance,
- ability and willingness of the patient to follow the protocol.

### Exclusion criteria

- Effective compression therapy started before presentation,
- arterial insufficiency (foot pulse not palpable and ankle-brachial-index < 0.8),
- neuropathy of diabetic or other origin,
- surgery on the ulcer (débridement, skin graft, etc.) or varicose vein ablation within three months before entry into the study,
- acute deep venous thrombosis (DVT) or varico-thrombosis requiring anticoagulant therapy,
- ulcer of dermatologic cause (pyoderma gangraenosum, vasculitis, infection, neoplasia, etc.),
- primary lymphoedema,
- pregnancy,
- life expectancy < 90 days.

### Study treatment

The study treatment was either the usual compression therapy provided at the participating centres or the ulcer X kit. No bandaging was allowed before using the kit. All interventions were performed during the

study visits which were set to take place once a week. The intervals were shortened or prolonged according to the patients' needs.

### Bandaging

Bandages were applied by an expert study physician. They were tailored to the individual patients situation and the condition of the ulcer. Short-stretch bandages were applied in two or more layers with spiral turns or turns in eight. The bandages were worn day and night for all the time between the visits.

### Ulcer X kit

The kit consists of an under-stocking whose inner layer is cotton and the outer layer knitted of a smooth garment that allows an easy donning of a second stocking over it. The under-stocking firmly fixes the dressing and protects the vulnerable leg area. The second stocking is the Sigvaris® Traditional®, earlier called 503®. The under-stocking exerts a mean pressure at rest of 16.5 mmHg (n = 6; range 13–21) at the ankle. The ankle pressure acting with both stockings in place is 39.0 mmHg (n = 6; range 37–41). With both stockings in place, the amplitude of pressure change observed during leg movements is 8.7 mmHg on average (range 8 and 10 mmHg). Donning of the second stocking increases the pressure amplitude, as compared with the under-stocking alone, by an average of 3.3 mmHg (range 1–5). In an in vitro test, the force required to put on and remove the under-stocking is 50–60N. Putting-on and taking off the Sigvaris Traditional over the under-stocking requires again a force of 50–60N. Donning of the Sigvaris Traditional (503) directly over the skin would require a force of 80–90N. The size of the stockings was determined with the dressing on the leg. All patients used one kit (2 under-stockings and 2 Sigvaris Traditional stockings) with the exception of one case in which the under-stocking was replaced. The kit was washed every two days on the average.

## Concomitant therapy

The local therapy was left to the judgement of the treating physician. Wound dressings with standard materials were applied and changed at the centre only. Surgery was not allowed.

### Primary study endpoints:

- Subjective appraisal: Prevalence and intensity of pain, discomfort and hindrance of activities as assessed by a validated questionnaire (Chapter 8 of the Venous Leg Ulcer Questionnaire; 15). The questionnaire was applied at the last visit, which was either when the ulcer was healed or at the end of the survey, 4 months after randomisation. Each of the 10 questions proposed 5 grades in a Likert format to quantify the subjective estimation. The percentage of patients with more than 1 point on the Likert scale, the mean of each item and scores of 3 factors (daytime discomfort & pain; Cronbach- $\alpha$ =0.39; inhibition of activities, Cronbach- $\alpha$ =0.59; pain at donning & removal, Cronbach- $\alpha$ =0.41) and total number of problems were used to adequately present the findings.
- Objective outcome: Ulcer healing, i.e. complete skin closure, within 4 months after randomisation, time to healing, number of visits until healing, and intervals between visits.

**Secondary endpoints:** Associations of various clinical factors between each other, with healing or non-healing and time to healing

## Statistical analysis

Data were analyzed using SPSS for Windows 13.0 (SPSS Inc., Chicago, IL, USA). All statistical tests were two-tailed, and a p-value <0.05 was considered significant. Student's t-test for independent samples was used for comparisons of means in normally distributed data of continuous variables; Chi-square analysis was used to test categorical data. Pearson correlations were calculated to test the influence of patient characteristics on healing and time to healing. Linear regression analysis was per-

**Tab. 1** Characteristics of patients and features of ulcers

characteristics		Ulcer X kit		bandage		total		difference	
		n	%	n	%	n	%	chi <sup>2</sup>	p-value
sex	male	13	50.0	10	33.3	23	41.1	1.60	0.206
	female	13	50.0	20	66.7	33	58.9		
cause of ulcer	CVI	16	61.5	18	60.0	34	60.7	0.01	0.906
	PTS	10	38.5	12	40.0	22	39.3		
recurrence	no	22	84.6	24	80.0	46	82.1	0.20	0.653
	yes	4	15.4	6	20.0	10	17.9		
ulcer ground	granulation	1	3.8	2	6.7	3	5.4	3.52	0.061
	cleaned	1	3.8	8	26.7	9	16.1		
	fibrinous	21	80.8	18	60.0	39	69.6		
	necrotic	3	11.5	2	6.7	5	8.9		
exudation	absent	0	0.0	2	6.7	2	3.6	1.76	0.185
	poor	15	57.7	10	33.3	25	44.6		
	moderate	11	42.3	14	46.7	25	44.6		
	abundant	0	0.0	4	13.3	4	7.1		
pain	absent	2	7.7	0	0.0	2	3.6	0.06	0.437
	weak	10	38.5	15	50.0	25	44.6		
	moderate	12	46.2	9	30.0	21	37.5		
	strong	2	7.7	6	20.0	8	14.3		
skin aspects	normal	9	34.6	7	23.3	16	28.6	0.90	0.343
	dry	11	42.3	11	36.7	22	39.3		
	moist	0	0.0	5	16.7	5	8.9		
	eczema	6	23.1	7	23.3	13	23.2		
		mean	SD	mean	SD	mean	SD	t-value	p-value
patient age [years]		62.38	14.00	65.20	15.33	63.89	14.66	0.71	0.479
diameter [cm]		3.38	2.73	2.76	2.37	3.05	2.54	0.90	0.370
presence of ulcer [mos]		3.2	2.96	3.60	4.01	3.43	3.54	0.39	0.701

formed to test the influence of diameter and treatment group on time to healing. Cronbach- $\alpha$  was used to test the internal consistency of the used subjective scales.

## Patients

Sixty patients were entered into the study, 20 at each center, located at Siena, Lucca, and Ferrara, Italy. Four patients were excluded within the first week after randomisation, all in the stocking group. One patient refused to continue with any kind of compression therapy. Three patients were unwilling to continue as donning of the second stocking was

too difficult for them. They had severe restriction of ankle movement not recognized at study entrance. After exclusion of the four patients ankle restriction was still present in one patient in the stocking and four in the bandage group. The characteristics of the remaining 56 patients (33 women, 23 men; mean age 63.9 years, range 36–89) who all finished the study and the features of their ulcers are depicted in Table 1. All variables were evenly distributed with one possible exception: The ulcer ground appeared worse in the stocking group as compared with the bandage group. Neither for patient characteristics nor for outcome variables was a center effect detected (data not shown).

individual items		Ulcer X kit		bandage		difference	
		n	%	n	%	chi <sup>2</sup>	p-value
pain when	applied	0.00	0.00	0.23	0.43	2.76	0.008
	removed	0.00	0.00	0.20	0.41	2.50	0.015
	walking	0.15	0.37	0.43	0.50	2.34	0.023
	wearing shoes	0.08	0.27	0.27	0.45	1.87	0.066
discomfort	when asleep	0.00	0.00	0.57	0.77	3.73	0.000
	in the morning	0.00	0.00	0.30	0.65	2.35	0.023
	in the afternoon	0.62	1.06	0.63	0.72	0.07	0.941
hindrance of	normal activities	0.58	0.76	1.23	1.14	2.50	0.015
	climbing stairs	0.23	0.43	0.30	0.47	0.57	0.568
	visiting friends	0.12	0.33	0.23	0.43	1.14	0.258
scores	daytime discomfort, pain	0.26	0.39	0.46	0.45	1.75	0.086
	inhibition of activities	0.35	0.49	0.73	0.73	2.30	0.025
	pain at donning & removal	0.00	0.00	0.22	0.31	3.52	0.001
	number of problems	1.31	1.16	3.40	1.65	5.40	0.000

**Tab. 2**  
Comparison of subjective outcome measures (mean Likert scales) between treatment groups

the morning was absent with the ulcer X kit, which was not the case with bandages. The amount of discomfort in the afternoon did not differ significantly. Hindrance of normal activities was more pronounced with bandages. Pain and daytime discomfort was associated with older age ( $r = 0.27$ ;  $p = 0.04$ ) while younger age was strongly correlated with inhibition of activities ( $r = -0.68$ ;  $p < 0.0001$ ).

## Objective endpoints

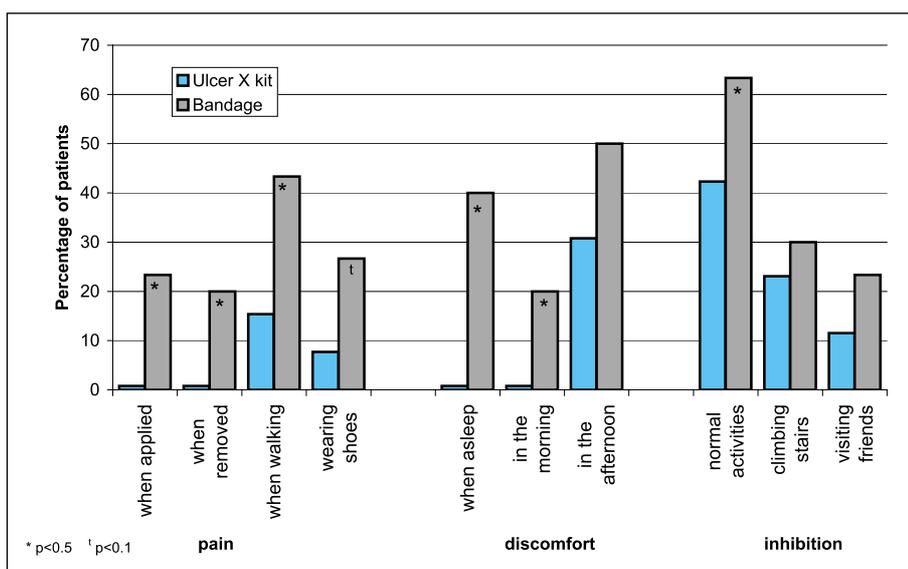
Complete skin closure within the preset study period of 4 months was accomplished in 96.2% (25 of 26) with the ulcer X kit and in 70.0% (21 of 30) with bandages ( $\chi^2 = 6.49$ ;  $p = 0.011$ ; Tab. 3). The use of the ulcer X kit was not associated with an overall reduction of the time to healing or fewer visits, but with prolonged intervals between visits ( $\chi^2 = 3.28$ ;  $p = 0.002$ ). However, a significant correlation was identified between the size of the ulcer and the time to healing. Smaller ulcers healed about twice as rapidly with the ulcer X kit than with bandages while the time to healing of larger ulcers was similar with either treatment (Fig. 2). Healing and its rate were both correlated with the patients' characteristics and ulcer features (Tab. 4). Patient age, pain, and some morphologic aspects of the ulcers were significantly correlated with the proportion and the rate of healing while the ulcer diameter, the presence of a PTS, and recurrence were correlated with the time to healing only.

## Results

### Subjective endpoints

Patients provided answers to the 10 items presented in the questionnaire. Comparison of the subjective outcome data revealed a clear benefit of the ulcer X kit as com-

pared with therapy with bandages (Tab. 2, Fig. 1). The sum of problems encountered was significantly greater with bandages than with stockings. Pain was markedly stronger when bandages were applied and removed than when the ulcer X stockings were donned and taken off. Pain during walking was also more intense with bandages. Discomfort during the night and in



**Fig. 1** Prevalence of pain, discomfort and hindrance of activities (percentage of patients with at least one point on each Likert scale)

## Discussion

Many professionals caring for patients with venous leg ulcers would agree that compression with inelastic multi-layer bandages exerting a high pressure is the most effective treatment modality. The notion, however, is not supported by evidence: Two meta-analysis found compression therapy supported rather by consensual experience than by data from controlled clinical studies (6, 7). MCS were much less propagated than bandages despite the fact that equal or even

better results have been reported more than 20 years ago already (8) and in all subsequent trials (9–14). Several studies were criticised because patient allocation favoured the stocking group. Currently, MCS are regarded as an alternative to bandages for small non-exudative ulcers and to prevent recurrence (16, 17). In our study, allocation of patients was well matched and ulcer severity evenly distributed. The use of wound dressings and application of compression bandages were the best available as the study was performed at centers recognized for their vast experience.

The study included a homogenous cohort of patients with medium size ulcers present for an average of 3.4 months and a post-thrombotic cause in 39%. Wound closure was achieved in 96% with the ulcer X kit and in 70% with bandages and ulcers of less than about 4cm diameter healed twice as rapidly. Discomfort, pain and hindrance of every day activities were also much lower. Pain at night was completely absent with the kit as the strong second stocking was removed before going to bed. In the bandage group, pain at night and in the morning was less severe than in the afternoon, but still reported by 40% and 20% of patients, respectively. Such pain may have been caused by wrinkles but most probably by too high pressure – despite the fact that bandages tend to lose pressure with time. The findings contradict the concept that inelastic multi-layer bandages (the type used in this study) would exert high pressures during walking but low pressures at rest. We did not measure the resting pressure beneath the bandages but it clearly was high enough to cause pain whereas the average pressure of 16 mmHg exerted by the under-stocking was well tolerated.

The use of the kit was not precluded by any of the ulcer's characteristics as appropriate dressings were applied to manage exudation, eczema or pain and care taken of the amount of oedema when fitting the stocking.

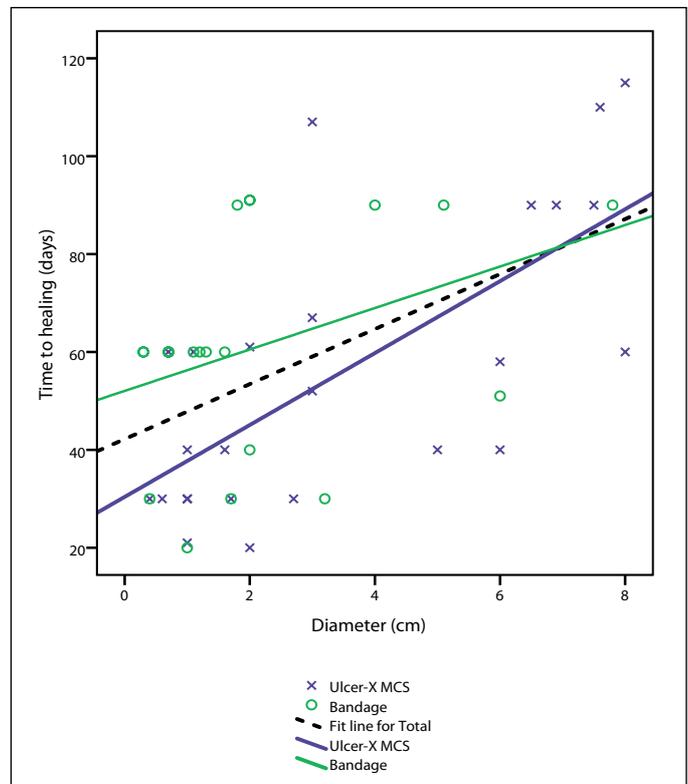
**Tab. 3**  
Comparison of objective outcome parameters between treatment groups

healing	Ulcer X kit		bandage		total		difference	
	n	%	n	%	n	%	chi <sup>2</sup>	p
no	1	3.8	9	30.0	10	17.9	6.49	0.011
yes	25	96.2	21	70.0	46	82.1		

	mean	SD	mean	SD	mean	SD	t	p
time to healing (days)	56.0	29.1	61.1	22.7	58.4	26.2	0.65	0.520
visits until healing	7.2	4.6	9.1	4.0	8.0	4.4	1.44	0.157
interval between visits	8.2	1.8	6.7	1.0	7.5	1.6	3.28	0.002

**Fig. 2**  
Effect of ulcer diameter (cm) on time to healing



**Our study raises questions**

**Is the double stocking system ulcer X the ultimate solution for healing medium-size venous ulcers?**

An affirmative answer can be given provided one contra-indication is observed: patients with severely restricted ankle movements are unable to put on the second stocking and experience intolerable pain if it is enforced.

**Are bandages rendered obsolete by the fact that they were clearly less effective and caused more problems than the ulcer X kit?**

The answer will be yes for most patients. Obviously, bandages remain the solution for patients not able to use MCS. In those, however, care must be taken to reduce the pressure at night. This could be achieved by removing the last sling of a multi-layer bandage when going to sleep.

**Tab. 4** Effect of patient characteristics and ulcer features on healing and time to healing (Pearson correlations)

	healing (n = 56)		time to healing (n = 46)	
	Pearson r	p-value	Pearson r	p-value
age	-0.31	0.022	0.33	0.026
female vs. male	0.08	0.535	0.10	0.493
PTS vs. CVI	-0.01	0.960	0.40	0.006
recurrence	-0.03	0.849	0.39	0.007
time of presence	-0.25	0.064	0.22	0.136
pain	-0.47	0.000	0.54	0.000
diameter	-0.15	0.280	0.54	0.000
ulcer ground	-0.20	0.145	0.47	0.001
exudation	-0.31	0.022	0.41	0.004
skin aspect	-0.27	0.048	0.45	0.002

### Are the results in accord with the concept that healing venous ulcers requires high pressure and inelastic material?

No definitive answer can be given. The pressure exerted with both stockings in place during the day is around 40 mmHg and thus within the recommended range. The interface pressure reigning at night is less than half (16 mmHg). The material of the under-stocking is highly elastic while the material of the second stocking, the Sigvaris Traditional, is less elastic – even less elastic than an often used flat knitted stocking (18). The superposition of the stockings leads to an only small decrease of elasticity.

### Why could less pressure and lower material rigidity perform better?

There is little doubt that chronic venous insufficiency is caused by ambulatory venous hypertension and therefore the use of high external pressure a reasonable therapeutic concept. However, disadvantages may overwhelm in the presence of an established skin defect. Phenomena other than venous hypertension may assume a crucial role. Poor fibrin and collagen synthesis due to inherited risk factors, microvascular thrombosis, bleeding and iron overload, tissue breakdown and repair, recurrent ischaemia and reperfusion, blood shunting, and the long-

## RIASSUNTO

Il trattamento tradizionale delle ulcere venose è di solito effettuato con bendaggio a scarso allungamento, anelastico o multistrato. La calza elastica terapeutica non è utilizzata come prima scelta, anche se recenti studi comparativi mostrano la sua efficacia rispetto al bendaggio.

**Materiale e metodi:** Il trial multicentrico randomizzato è stato eseguito in 3 Centri in Italia. Sono stati arruolati 60 pazienti affetti da ulcera venosa degli arti inferiori, suddivisi in 2 gruppi di 30 pazienti trattati con bendaggio e con un sistema di due calze sovrapposte (Sigvaris® ULCER X® kit). La randomizzazione è stata fatta per due gruppi di 10 pazienti per ogni Centro. Sono stati esclusi dallo studio 4 pazienti: 3 che presentavano scarsa mobilità articolare della caviglia e grave difficoltà ad indossare la calza, 1 paziente ha ritirato il consenso al trattamento. Le caratteristiche dei pazienti e delle ulcere erano uniformemente distribuite. I pazienti sono stati valutati in base alla guarigione delle ulcere entro 4 mesi dall'inizio della terapia ed è stata effettuata una valutazione della QoL attraverso apposito questionario.

**Risultati:** La guarigione completa è stata ottenuta nel 70% (21 da 30) dei pazienti trattati con bendaggio e nel 96% (25 da 26) con il kit ulcer X (p=0.011). La tollerabilità al trattamento è stata migliore nei pazienti trattati con le calze sovrapposte: il dolore alla notte ed al mattino è stato riferito dai pazienti trattati con bendaggio (nel 40% e nel 20% rispettivamente), mentre è stato assente in quelli trattati con ulcer X. Le ulcere sino a 4 cm di diametro sono guarite nel gruppo di pazienti trattati con ulcer X con una rapidità due volte maggiore rispetto al gruppo del bendaggio, le ulcere con diametro superiore con la stessa velocità.

**Conclusioni:** Le ulcere venose possono essere trattate con il kit compressivo ulcer X in tutti i pazienti, eccetto che in presenza di scarsa o assente mobilità articolare. Il bendaggio, anche se applicato da personale molto esperto, è meno efficace e causa problemi di tollerabilità maggiori.

standing absence of the barrier function may cause and maintain a state of chronic inflammation rendering the application of high pressure non-suitable and even detrimental (19, 20). Treatment of venous ulcers should respect the diverse features of ulcer pathology and consider appropriate adjustments of therapy. The excellent outcome observed with the two-stocking system may be related to the avoidance of too high pressure at night.

## Conclusion

Our study shows that most common venous leg ulcers can readily be brought to healing with the ulcer X compression kit provided the patients ankle movement is not severely restricted. Bandaging – even when performed by most experienced personnel – is less effective and causes more problems than the use of the stocking system we evaluated.

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**Correspondence to:**

Prof. Fabrizio Mariani

Via Beccafumi 9, 53100 Siena, Italy

E-mail: brtma@tin.it, ctg@terapiacompressiva.it

www.terapiacompressiva.it