

ARTÍCULO REPUBLICADO

# Comparison of low-strength compression stockings with bandages for the treatment of recalcitrant venous ulcers: A randomized trial

AUTORS:

EUGENIO BRIZZIO, MD<sup>A</sup>, FELIX AMSLER, MS<sup>B</sup>, BERTRAND LUN, R&D ENG<sup>C</sup>,  
WERNER BLÄTTLER, MD<sup>C,D</sup>.

BUENOS AIRES, ARGENTINA, BIEL-BENKEN, SWITZERLAND, WINTERTHUR, SWITZERLAND, AND BERN, SWITZERLAND.

Correspondencia: ebrizzio@fibertel.com.ar

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## Abstract

**Objective:** To compare the proportion and rate of healing, pain, and quality of life of low-strength medical compression stockings (*MCS*) with traditional bandages applied for the treatment of recalcitrant venous leg ulcers.

**Methods:** A single-center, randomized, open-label study was performed with consecutive patients. *Sigvaris prototype MCS* providing 15 mm. Hg-25 mm. Hg at the ankle were compared with multi-layer short-stretch bandages. In both groups, pads were placed above incompetent perforating veins in the ulcer area. The initial static pressure between the dressing-covered ulcer and the pad was 29 mm. Hg and 49 mm. Hg with *MCS* and bandages, respectively. Dynamic pressure measurements have shown no difference. Compression was maintained day and night and it has change every week. The primary endpoint was healing within 90 days. Secondary endpoints were healing within 180 days, time to healing, pain (weekly *Likert scales*), and monthly quality of life (*Chronic Venous Insufficiency Quality of Life [CIVIQ] questionnaire*).

**Results:** Of 74 patients screened, 60 fulfilled the selection criteria and 55 completed the study; 28 in the *MCS* and 27 in the bandage group. Ulcers were recurrent (48%), long lasting (mean, 27 months), and large (mean, 13 cm<sup>2</sup>). All but except one patient had deep venous reflux and/or incompetent perforating veins in addition to trunk varices. Characteristics of patients and ulcers were evenly distributed (exception: more edema in the *MCS* group;  $P = .019$ ). Healing within 90 days was observed in 36% with *MCS* and in 48% with bandages ( $P = .350$ ). Healing within 180 days was documented in 50% with *MCS* and in 67% with bandages ( $P = .210$ ). Time to healing was identical. *Pain* scored 44 and 46 initially (on a scale in which 100

From the Grupo Internacional de la Compresion, Buenos Aires,<sup>a</sup> Amsler Consulting,<sup>b</sup> the Sigvaris Research Center,<sup>c</sup> and the Department of Clinical and Interventional Angiology, Inselspital, Bern University Hospital, and University of Bern.<sup>d</sup> Supported by a grant from Ganzoni Management SA, Winterthur, Switzerland. Felix Amsler and Dr. Werner Blättler are consultants for Ganzoni Management SA, Switzerland. Bertrand Lun is an employee of Sigvaris (France) SA. The study was presented at the Twenty-First Annual Meeting of the American Venous Forum, Phoenix, Ariz, February 11-14, 2009. Author Contributions: Conception and design: WB, FA, EB. Analysis and interpretation: WB, FA. Data collection: EB, BL. Writing the article: WB, FA. Critical revision of the article: WB, FA, EB, BL. Final approval of the article: WB, FA, EB, BL. Statistical analysis: FA. Obtained funding: WB. Overall responsibility: WB. Copyright © 2009 by the Society for Vascular Surgery. doi:10.1016/j.jvs.2009.08.048

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referred to maximum and 0 to no pain) and decreased within the first week to 20 and 28 in the *MCS* and bandage groups, respectively ( $P < .001$  vs  $.010$ ). Quality of life has shown no difference between the treatment groups. In both groups, pain at 90 days had decreased by half, independent of completion of healing. Physical, social, and psychic impairment improved significantly in patients with healed ulcers only.

**Conclusion:** Our study illustrates the difficulty of bringing large and long-standing venous ulcers to heal. The effect of compression with *MCS* was not different from that of compression with bandages. Both treatments have alleviated pain promptly. Quality of life was improved only in patients whose ulcers had healed. (*J Vasc Surg* 2009).

## RESUMEN

### Comparación de la compresión de baja resistencia a las medias con vendajes para el tratamiento recalcitrante de úlceras venosas: un estudio randomizado.

**Objetivo:** Comparar tanto la proporción como el porcentaje de curación, dolor como así también de calidad de vida de la baja resistencia médica a la compresión de medias (*MCS*) con vendajes tradicionales aplicados al tratamiento de úlceras venosas recalcitrantes de piernas.

**Métodos:** Un estudio abierto, randomizado de un simple centro se realizó con pacientes consecutivos, el prototipo de *MCS Sigvary* de 15 mm. Hg-25 mm. Hg en el tobillo se comparó con el vendaje multi-capa de poca elasticidad. En ambos grupos, se colocaron almohadillas sobre las venas perforantes incompetentes en el área de la úlcera. Ésta presión estática inicial entre la úlcera cubierta y la almohadilla fue de 29 mm. Hg y de 59 mm. Hg con *MCS* y en el de los vendajes, respectivamente. Las mediciones de presiones dinámicas no mostraron diferencias. La compresión se mantuvo durante el día y la noche cambiando todas las semanas. El punto final primario se curó dentro de los 90 días. Los puntos finales secundarios se curaron dentro de los 180 días como así también el tiempo de curación, el de dolor, (escalas semanales *Likert*) y mensualmente la calidad de vida (según el Cuestionario de la calidad de vida de insuficiencia venosa crónica) (*CIVIQ*).

**Resultados:** De la proyección de 74 pacientes, 60 cumplieron el criterio de selección y 55 completaron el estudio; 28 en el *MCA* y 27 en el grupo del vendaje. Las úlceras fueron recurrentes (48%), de larga prolongación (promedio, 27 meses) y grandes (promedio, 13 cm<sup>2</sup>). Todos excepto un paciente sufrió un reflujo venoso profundo y/o venas perforantes incompetentes además de várices de tronco. Las características de los pacientes como así también las úlceras se encontraron igualmente distribuidas (excepción: más edemas en el grupo de *MCS*;  $P = .019$ ). La curación dentro de los 90 días se observó en el 36% en el grupo de *MCS* y en el 48% en el de los vendajes ( $P = .350$ ). La curación dentro de los 180 días se documentó en el 50% con *MCS* y en el 67% con vendajes ( $P = .210$ ). El tiempo de curación fue idéntico. El dolor rangueó entre el 44 y el 46 en forma inicial (en una escala en la cual 100 era el máximo y 0 el mínimo) disminuyendo el dolor durante la primer semana a la 20 y a la 29 en los *MCS* y en los grupos de vendajes, respectivamente ( $P < .001$  vs  $.010$ ). La calidad de vida no mostró ninguna diferencia entre los grupos de tratamiento. En ambos grupos, el dolor a los 90 días había disminuido a la mitad en forma dependiente de la curación. La discapacidad tanto física, social y psíquica mejoró en forma significativa en aquellos pacientes que únicamente tenían la úlcera curada.

**Conclusion:** Nuestro estudio ilustra la dificultad que traen las úlceras venosas grandes y de alta data para su curación. El efecto de la compresión con *MCS* no fue diferente al de la compresión con vendajes. Ambos tratamientos aliviaron el dolor prontamente. La calidad de vida se mejoró solamente en aquellos pacientes cuyas úlceras se curaron (*J. Vasc Surg.* 2009)

**Palabras Claves:** Compresión de baja resistencia- Úlceras venosas recalcitrantes- Insuficiencia venosa crónica- Vendajes.

Chronic venous ulcers are non-healing skin defects on the distal lower limb. They occur as a late consequence of chronic ambulatory venous hypertension, which is caused by outflow obstruction and reflux due to superficial or deep venous valve incompetence.<sup>1</sup> Secondary phenomena such as repetitive ischemia and reperfusion cause further tissue injury and trigger a self-perpetuating inflammatory process that ultimately impedes wound healing<sup>2</sup>.

Treatment is essentially empirical and addresses both the hemodynamic and the dermatologic aspects of the disease. Bed rest and leg elevation are known to bring about 20% of ulcers to heal.<sup>3</sup> Dressings are part of the therapeutic arsenal but their precise value remains only poorly understood<sup>4</sup>.

Surgical elimination of insufficient superficial veins prevents recurrence but it does not increase the proportion and rate of healing<sup>5</sup>. Leg compression aimed at lowering venous hypertension has the greatest potential. It enjoys a long tradition and it has been the subject of several consensus conferences and meta-analyses<sup>6-11</sup>. The application of inelastic bandages exerting high pressures has been advocated.

According to the most recent survey, it appears that multi-component systems containing an elastic bandage are more effective than single-component bandages and those composed mainly of inelastic material<sup>12</sup>.

We were concerned that high pressure might exert unfavorable effects on the wound healing process. The clinical notion was generated from data of a non randomized pilot study that had shown an advantage of low-strength medical compression stockings (*MCS*) over bandages<sup>13</sup>. Furthermore, the latest randomized trials reported a higher rate of healing with elastic graduated stockings as compared with bandages and a possible advantage when the stockings were removed at night<sup>14,15</sup>.

In view of the various potential benefits of low-strength *MCS*, we performed the present prospective randomized open-label trial. Our hypothesis was that low strength *MCS* would perform better than traditional inelastic multilayer bandages in patients with recalcitrant venous ulcer

## Methods

This randomized open-label trial was performed at a specialized outpatient clinic for venous diseases in Buenos Aires, Argentina. The protocol was approved by the Bioethical Committee of the Medical Association of Argentina. Study participants granted written informed consent prior to inclusion in the study.

Patients were referred from outpatient clinics of general hospitals. They were allocated to the study when they fulfilled the following criteria: presence of one or more unior bilateral ulcers on the medial side of the lower leg, of venous origin according to the clinical aspect, larger in size than 3 cm<sup>2</sup> but smaller than 50 cm<sup>2</sup>, present for at least 2 months, and not treated with compression during the last 2 months.

Patients were not included if they suffered from concomitant diseases: known malignancy, respiratory or cardiac failure (exertional dyspnoea, edema), liver disease (elevated enzymes), kidney disease (elevated serum creatinine levels) or a mental disorder (eg, depression), severe peripheral neuropathy of diabetic or other origin, peripheral arterial disease (foot pulses not palpable and ankle brachial index <0.8), and osteoarthritis of hips or knees.

The primary end-point was the proportion of healing within 90 days. Secondary end-points were proportion of healing within 180 days, time to healing, pain and quality of life. All ratings were done by the first author (*EB*) or the patients, respectively.

At the first visit, the compromise of venous function (drainage and reflux) was assessed by standard duplex scanning (*Aloka* [Tokyo, Japan] *SSD 630* scanner; 7.5 MHz probe). The findings were categorized into three groups of presumed hemodynamic severity using the terms of the *CEAP* classification:<sup>16</sup> presence of superficial reflux only (*Ep*, *As*, *Pr*); additional presence of one or more insufficient perforating calf veins but no deep venous reflux (*Ep*, *As*, *p*, *Pr*); or presence of deep venous reflux at any level of the cruro-femoral axis, with or without varicose veins (*Es*, *Ad*, *±s*, *±p*, *Pr*).

Further visits were scheduled at weekly intervals. Ulcer assessment included photo documentation, measurement of the size of the ulcer(s) with the transparent foil technique,<sup>17</sup> and quantification with scores of drainage from the wound, and the amount of edema. Ulcer care was performed by experienced staff at the center only. At each visit, ulcers were cleaned and debrided with *Ringer's* lactate using the *Jetox-ND™* (*TavTech Ltd, Yehud, Israel*). The surrounding skin was treated with *Gentiana violet* and a moistening ointment, and the ulcer ground covered with paraffin gauze (*Bactigras, Smith & Nephew, Hull, England*). Compression was then applied and left in place day and night until the next visit 1 week later.

Leg compression was carried out randomly with either stockings or bandages. In both groups, additional eccentric compression was applied to reduce venous hypertension in the ulcer area. A rubber-foam pad (5 cm. thick) was cut to fit the space above insufficient perforating and/or large communicating veins identified by duplex ultrasound. Calf-size *MCS*

knitted to exert a pressure above the ankle of 15 mm Hg-20 mm Hg and fitted with an it open tip were provided by *Sigvaris, Inc. (Peachtree City, Ga)*. These graduated prototype stockings were constructed using a doublecovered Lycra spandex lay-in yarn in every course having a fiber percentage of 92% nylon and 8% Lycra. They came in four ankle sizes suiting the legs of all patients. They were pulled over the gauze bandage with the help of a donning device. In the control group, bandaging was performed with the technique in use at the center for many years<sup>18</sup>. Three short-stretch

slings were applied (*Texadur*, 40% elongation, 10 cm. wide, 7 m long, obtained from *Filmar, Divisione Sanitaria, Caselle Torinese, Italy*). Static and dynamic measurements of pressures beneath the pad were taken immediately after application of stockings or bandages in a subgroup of randomly selected patients using the *Sigvaris Interface-pressure Gauge advanced Tester (SIGaT)* system (*Table I*)<sup>19</sup>.

Pain in the ulcer area and the lower leg were assessed weekly using *Likert* scales adjusted to a scale ranging from 0-100 in which 0 meant no pain and 100 meant maximum pain.

Quality of life was monitored using the Spanish version of the *Chronic Venous Insufficiency Quality of Life (CIVIQ)* questionnaire<sup>20</sup> provided by *Servier International, Neuilly-Sur-Seine, France*. It included four dimensions: pain, physical, social, and psychological aspects of quality of life. The results are depicted both as the original total score (20-100) and in an adjusted form (0-100), in order to permit a direct comparison of the different dimensions. The questionnaire was applied at the beginning of the study and after 4, 8, and 13 weeks.

A power analysis was performed on the basis of a recent pilot study of our group<sup>13</sup>, where the effect size  $w (\sqrt{X^2/N})$  was 0.39 regarding to healing. This revealed the necessity to include 52 ulcers to ascertain a difference between the two groups with a power of 0.8 at a two-sided  $P < .05$ .

Patients with and without deep venous reflux were randomized separately using sealed envelopes in blocks of four and six, respectively. Dropouts were not replaced.

Data were analyzed using *SPSS for Windows 13.0 (SPSS Inc, Chicago, Ill)*. All statistical tests were twotailed, and  $P < .05$  was considered significant. Student's t test for independent and paired samples were used for comparisons of means in normally distributed data of continuous variables; Chi-Square analysis was used to test categorical data. Pearson's correlations were calculated to test the influence of patient characteristics on healing and time to healing. For multivariate testing of risk factors associated with failed or delayed healing and impaired quality of life, stepwise regression analyses were calculated with patient and ulcer characteristics in a first block. Each variable was entered if the F value showed  $P < .1$  and it was removed if it showed  $P > .2$ . The treatment group was forced into the model in a second block. Logistic regression was used for healing as a dependent variable, *Cox's* regression for time to healing and linear regression for quality of life data. Natural logarithmic values (ln) of ulcer size and duration of presence were therefore used.

	Stockings	Bandages
Ankle pressure indicated by manufacturer	15-20	
Recommended ankle pressure (3-7)		40-50
Pressure above the ulcer area with no rubber foam pad (± SD)	20.7 (± 5.5)	
Pressure above the ulcer area with the rubber foam pad in place (± SD)	28.6 (± 9.2)	48.6 (± 15.1)
Pressure amplitude during foot movement	15.6 (± 12.1)	15.2 (± 5.5)

Measurements made in 21 randomly selected patients; numbers are mm Hg (± SD).

**Table I.** Pressure exerted by stockings and bandages.

	Stockings	Bandages	P for difference
N	28	27	
Women (n; %)	19 (68%)	17 (63%)	.703
Age (mean ± SD, median)	62.1 (± 9.9) md = 62	61.4 (± 13.1) md = 64	.833
Body mass index (kg/m <sup>2</sup> ) (mean ± SD, median)	31.4 (± 7.0) md = 31.3	32.2 (± 6.2) md = 30.5	.682
Superficial reflux only (Eq, Aa, Pr, n, %)	1 (4%)	0 (0%)	
Perforating vein incompetence (Eq, Aa, p, Pr, n, %)	16 (58%)	15 (56%)	.996
Deep venous reflux (Eq, Ad, vs, sp, Pr, n, %)	11 (39%)	12 (44%)	.698
Recurrent ulcer (n, %)	12 (43%)	15 (56%)	.346
Presence of ulcer (mean) (mean ± SD, median)	26.9 (± 44.7) md = 11.5	26.7 (± 29.7) md = 12.0	.985
Initial ulcer size (cm <sup>2</sup> ) (mean ± SD, median)	13.1 (± 14.5) md = 5.0	12.2 (± 12.8) md = 6.0	.809
Edema score 0-5* (mean ± SD, median)	3.04 (± 1.07) md = 1.5	2.33 (± 1.07) md = 1.0	.019
Secretion score 0-3** (mean ± SD, median)	1.37 (± 1.07) md = 3.0	1.48 (± 0.94) md = 2.0	.741

\*Edema score: 0: none; 1: very little; 2: little; 3: medium; 4: important; 5: very important.  
\*\*Secretion score: 0: dry; 1: humid; 2: wetting; 3: point added if swelling bad.

**Table II.** Characteristics of patients and ulcers.

	Stockings	Bandages	P for difference
Number of ulcers healed within 90 days (%)	10 (36%)	13 (48%)	.350
Average time to healing within 90 days (mean ± SD, median)	46 (± 16) md = 42	48 (± 20) md = 49	.750
Average size of ulcers not healed at 90 days (cm <sup>2</sup> ) (mean ± SD, median)	7.4 (± 9.8) md = 3.1	10.4 (± 14.8) md = 2.8	.501
Number of ulcers healed between 90 and 180 days (% of unhealed ulcers at 90 days)	4 (22%)	5 (36%)	.400
Cumulative number of ulcers healed within 180 days (%)	14 (50%)	18 (67%)	.210
Average cumulative time to healing within 180 days (mean ± SD, median)	68 (± 40) md = 56	69 (± 39) md = 60	.942
Average size of ulcers not healed at 180 days (cm <sup>2</sup> ) (mean ± SD, median)	10.0 (± 15.1) md = 2.2	16.1 (± 19.1) md = 4.9	.406

**Table III.** Ulcer healing achieved with stockings and bandages.

	Stockings	Bandages	P for difference
<i>CIVIQ</i> total (± SD)			
Before treatment	53 (± 18)	53 (± 15)	.999
At 35 days	44 (± 16)	44 (± 19)	.944
At 90 days in patients with healed ulcers	44 (± 18)	45 (± 17)	.825
At last assessment in patients with healed ulcers	39 (± 18)	30 (± 17)	.109

*CIVIQ*, Chronic Venous Insufficiency Quality of Life.  
Original total *CIVIQ* score (20-100) where 20 represents best and 100 worst quality of life.

**Table IV.** Quality of life of patients treated with stockings or bandages.

## Results

Patient allocation started in April 2007 and it ended in February 2008. Within this time period, 74 patients presented with leg ulcers. Fourteen patients were excluded, two for exceeding ulcer size, six due to small ulcer extent, three had vasculitic, two ischemic, and one traumatic ulcers. Sixty patients were enrolled. Five patients dropped out, four in the stocking group (one sudden death unrelated to the venous disease or their treatment, one did not return to the clinic after 11 weeks, as his ulcer had almost healed, two due to systemic infection requiring antibiotic treatment), and one in the bandage group (because of rapid worsening). Fifty-five patients completed the study protocol; 28 (50.9%) in the stocking and 27 (49.1%) in the bandage group. Patient's characteristics and ulcer features were evenly distributed between the study groups with the exception of edema, which have showed higher prevalence in the stocking group (Table II). Ulcers were present for an average of more than 2 years and the mean baseline surface amounted to 13 cm<sup>2</sup>. Almost half of the lesions were recurrent. Deep venous reflux was present in 42% of patients and 56% had varicose veins with incompetent perforating veins. Pain amounted to 45 ± 29 on the adjusted *Likert's* scale and 49 ± 26 on the adjusted *CIVIQ* scale where 0 represents no pain and 100 represents the most pain. Physical, social, and psychic dimensions of quality of life scored at 41 ± 27, 41 ± 28, and 37 ± 23, respectively. Differences between treatment groups were not observed with the exception of slightly more edema in the *MCS* group. Right after application, the pressure exerted by stockings and bandages donned over the dressing and pad averaged 29 mm. Hg and 49 mm. Hg, respectively (Table I). The change of pressure produced by foot movements, an index of elasticity was identical with either type of compression.

Ulcer healing occurred in 42% and 58% of patients within 90 and 180 days, respectively. Ulcers smaller than 10 cm<sup>2</sup> healed in 61% and 75%, respectively, while larger ulcers healed in 5% and 26% only. No statistically significant difference was revealed between stockings and bandages (Table III, Fig 1).

In a univariate analysis, non-healing at 180 days was associated with distinct ulcer features: time of presence (ln; r= 0.61, P< .001), ulcer size (ln; r= 0.52, P< .001) and the extent of wound secretion (r 0.48, P .001). Further, absence of healing at 90 days correlated significantly with older age (r= 0.31, P< .05) and higher body-mass index (*BMI*) (r= 0.30, P<.05). The influence of these patient characteristics had vanished at 180 days. The difference of edema between groups observed at the beginning had no effect on outcome.

The score of pain in the stocking group decreased from 44.2 ± 33.1 (range, 0-100) to 17.7 ± 18.8 (range, 0-63) within the first week (P< .001). In the bandage group, it decreased from 45.8 ± 26.4 (range, 0-100) to

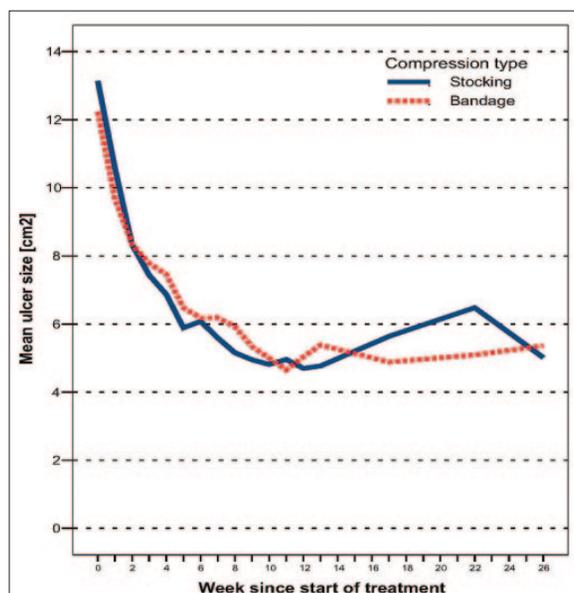


Fig 1. The mean ulcer surface area as a function of time of compression therapy with either stockings or bandages. The graph includes all patients up to a 26<sup>th</sup> week; healed ulcers are counted as 0 cm<sup>2</sup>.

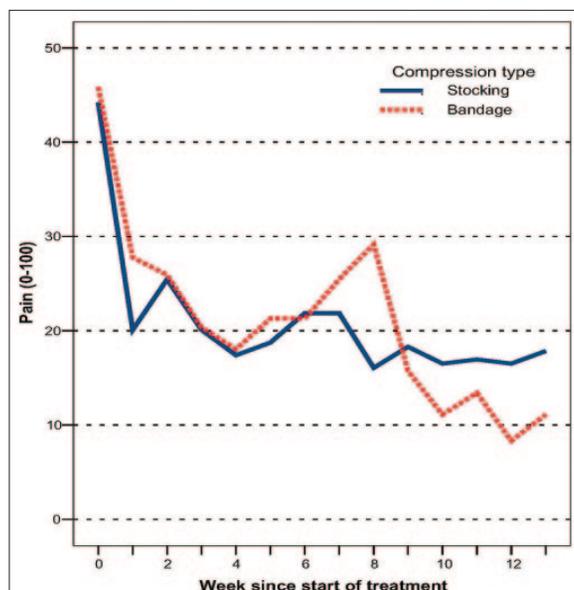


Fig 2. Pain in the lower leg and ulcer area assessed weekly. An adjusted sum score of 0 denotes no pain; a score of 100 indicates maximum pain. The graph includes all patients up to the 13<sup>th</sup> week.

11.1 15.6 (range, 0-63) (P .01). The course of pain was similar in both groups (Fig 2).

Quality of life was investigated repeatedly using the CIVIQ questionnaire. Neither the total original score nor its four dimensions have showed a difference between the types of compression (Table IV).

The proportion of healing as evidenced by multivariate analyses was lower in older patients (at 180 days) and in patients with a lower BMI (at 90 days) (Table V). Further, larger ulcer size revealed a lower proportion of healing at 90 and 180 days while duration and recurrence showed their adverse influence after 180 days only. After correction for risk factors, a non-significant association between the modality of compression was observed in favor of bandages. Time

to healing revealed no such association. The model revealed no correlation with overall quality of life.

The impact on the different aspects of quality of life was studied further (Table VI). Pain decreased with treatment by 50% whether ulcers were healed or not. The physical, social, and psychic dimensions revealed a significant improvement only in patients whose ulcers had healed.

### Discussion

Our study scrutinized the relative value of low-strength MCS and traditional bandages for the treatment of severe chronic venous ulcerations. It included ulcers that were recalcitrant but they also did not receive adequate treatment prior to inclusion. Prior experience with patients having less severe ulcers in Argentina<sup>13</sup> formed the basis of a power analysis that revealed a minimum sample size of 52 to secure an advantage of one treatment strategy over the other. In contrast to our hypothesis, we could not secure a benefit of stockings, neither with regard to the proportion and time to healing nor with concerning to pain and quality of life. The characteristics of patients and ulcers were evenly distributed in the treatment groups with the exception of edema, which was slightly more important in the stocking group. As edema was no predictor of healing in this trial, we do not attribute a great value to this inequality. In a recent systematic survey and meta-analysis, eight randomized clinical trials were identified comparing treatment with stockings and bandages. Five studies revealed a benefit of stockings over bandages and three studies, as the present one, showed no difference. In six studies, the mean ulcer size was smaller and the presence shorter than in our study<sup>21</sup>. One study reported a mean ulcer size comparable with ours<sup>22</sup> and another one included much larger and older ulcers.<sup>14</sup> Comparison of these studies with ours shows a correlation for treatment with stockings between ulcer size and healing. A similar correlation is found for treatment with bandages with the exception of this study (Table VII).

Why were stockings in our study not better than bandages as they have been demonstrated in the majority of previous studies? And further, why was treatment with bandages so much better when they were compared with published data? We can not come up with a straight forward explanation. The main difference between this study and all previous ones is the systematic use of padding. The comparably better performance of bandages in this trial could be due to this fact. Why then was this benefit not also observed in the MCS group? We might speculate that the

	Logistic regression				Cox regression		Linear regression			
	Healing 90 d		Healing 180 d		Time to healing		CIVIQ 35 d		CIVIQ last	
	OR	P	OR	P	OR	P	Beta	P	Beta	P
Gender	.550		.616		.242		.657		.753	
Age	.133	0.91	.028		.818		.880		.979	
BMI	1.16	.032	.297	1.05	.857		.398		.380	
Initial ulcer size (ln)	0.15	.001	0.33	.033	0.58		.084		.880	.494
Presence of ulcer (ln)		.229		.002		.249		.532		.673
Recurrent ulcer		.743		.044		.695		.396		.665
Deep venous reflux		.129		.691		.634		.835		.309
Edema score		.129		.449		.219		.767		.517
Compression type	2.11	.296	7.42	.067	1.04	.907	-0.01	.944	-0.11	.408
Compression type alone	1.67	.351	2.90	.213	0.98	.946	-0.01	.944	-0.11	.408

BMI, Body mass index; CIVIQ, Chronic Venous Insufficiency Quality of Life; ln, logarithmic values; OR, odds ratio.

**Table V.** Influence of patient and ulcer characteristics on healing, time to healing and quality of life (total CIVIQ score) using stepwise regression analysis.

Dimension	Ulcer status	Initial value (mean ± SD)	Last value (mean ± SD)	P
Pain	Healed	48 (± 20)	12 (± 11)	<.001
	Not healed	50 (± 29)	18 (± 19)	<.001
	P	.803	.174	
Physical	Healed	38 (± 27)	17 (± 19)	.001
	Not healed	43 (± 28)	38 (± 31)	.527
	P	.555	.012	
Social	Healed	37 (± 28)	22 (± 27)	.020
	Not healed	44 (± 28)	47 (± 23)	.624
	P	.404	.001	
Psychic	Healed	40 (± 23)	20 (± 20)	.003
	Not healed	36 (± 24)	29 (± 25)	.139
	P	.487	.208	
CIVIQ total	Healed	41 (± 20)	18 (± 15)	<.001
	Not healed	41 (± 21)	31 (± 21)	.030
	P	.974	.025	

CIVIQ, Chronic Venous Insufficiency Quality of Life. Adjusted CIVIQ scores (0-100) of patients with healed (N = 23) and not healed ulcers (N = 32).

**Table VI.** Quality of life assessed before treatment and either after 90 days or as the ulcer had healed.

Study	Mean ulcer size (cm²)	Percent of ulcers healed			
		Within 12-16 weeks		Within 20-28 weeks	
		Stockings	Bandages	Stockings	Bandages
Six studies including benign ulcers (N = 479)	4 cm²	65	54	—	—
Study including severe ulcers (N = 56) <sup>20</sup>	4 mo	—	—	—	—
This study including severe ulcers (N = 55)	9.5 cm²	44	17	—	—
	No data	—	—	—	—
	13 cm²	36	48	50	67
	27 cm²	—	—	—	—
Study including very severe ulcers (N = 56) <sup>11</sup>	68 cm²	31	7	68	24
	78 mo	—	—	—	—

**Table VII.** Data on healing of venous ulcers with stockings and bandages compiled from published randomized trials.

increase of the local pressure might have diminished the elastic properties of the MCS, cancelling out its potential advantage<sup>12</sup>. We can not exclude that the relative low pressure acting outside of the ulcer area (15 mm. Hg-20 mm. Hg) was responsible for the worse-than-expected result.

Investigations on quality of life revealed no difference between the modality of leg compression but unveiled hitherto little-recognized through comprehensible findings: Pain assessed weekly with *Likert's* scales was rapidly decreasing to a constant low level. Pain reporting was similar when measured with the *CIVIQ* tool. After 90 days of treatment, it improved by about two thirds and to the same extent in patients with healed and non-healed ulcers. Physical, social, and psychic quality of life was somewhat less impaired than pain. Improvement by about 50% with treatment was limited to patients whose ulcers had come to complete closure. Thus, the decrease of pain was probably a consequence of compression, while quality of life improved as wound closure was achieved. The finding that quality of life remained substantially impaired even after skin closure reflects the burden of the underlying venous disease. In conclusion, our study failed to confirm an advantage of MCS over bandages for the treatment of venous ulcerations. It illustrated the difficulty to bring such large and long-standing venous ulcers to heal. Nevertheless, it revealed that pain is rapidly alleviated with compression of even modest strength. The reason for poor healing is not determined by baseline clinical data. Other than the commonly assessed risk factors must play a role. Their identification will help to develop better therapeutic strategies.

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