

REVIEW ARTICLES

From the American Venous Forum

In search of optimal compression therapy for venous leg ulcers: A meta-analysis of studies comparing divers bandages with specifically designed stockings

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Objective: In search of an optimal compression therapy for venous leg ulcers, a systematic review and meta-analysis was performed of randomized controlled trials (RCT) comparing compression systems based on stockings (MCS) with divers bandages.

Methods: RCT were retrieved from six sources and reviewed independently. The primary endpoint, completion of healing within a defined time frame, and the secondary endpoints, time to healing, and pain were entered into a meta-analysis using the tools of the Cochrane Collaboration. Additional subjective endpoints were summarized.

Results: Eight RCT (published 1985-2008) fulfilled the predefined criteria. Data presentation was adequate and showed moderate heterogeneity. The studies included 692 patients (21-178/study, mean age 61 years, 56% women). Analyzed were 688 ulcerated legs, present for 1 week to 9 years, sizing 1 to 210 cm². The observation period ranged from 12 to 78 weeks. Patient and ulcer characteristics were evenly distributed in three studies, favored the stocking groups in four, and the bandage group in one. Data on the pressure exerted by stockings and bandages were reported in seven and two studies, amounting to 31-56 and 27-49 mm Hg, respectively. The proportion of ulcers healed was greater with stockings than with bandages (62.7% vs 46.6%; $P < .00001$). The average time to healing (seven studies, 535 patients) was 3 weeks shorter with stockings ($P = .0002$). In no study performed bandages better than MCS. Pain was assessed in three studies (219 patients) revealing an important advantage of stockings ($P < .0001$). Other subjective parameters and issues of nursing revealed an advantage of MCS as well.

Conclusions: Leg compression with stockings is clearly better than compression with bandages, has a positive impact on pain, and is easier to use. (J Vasc Surg 2009;50:668-74.)

Venous leg ulcers represent a heterogeneous group of skin defects that result from a micro-circulatory damage triggered by chronic venous hypertension. It is estimated that 1% to 2% of the population will have one or more episodes of leg ulcer during life. Ulcer treatment remains essentially empirical. Bed rest combined with leg elevation

represents an effective option. Local treatments belong to the therapeutic armamentarium for centuries but the relative value of the various techniques is not clear.¹ Compression therapy (CT) is considered to be the most important conservative treatment modality.² Evidence from the current literature suggests that it is not less effective alone than when combined with superficial venous surgery.³ The heuristic principle holds that it corrects, at least in part, the underlying ambulatory venous hypertension. The classical approach of phlebologists makes use of bandages. High compression strength and multilayered systems appears to perform better than low compression and single-layered bandages but differences in effectiveness are not really evident.^{4,5} The potential of stocking based compression systems remains to be evaluated. As medical compression stockings (MCS) promise many advantages, we performed a systematic review and meta-analysis of randomized studies comparing their effectiveness with bandages.

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Competition of interest: none.

Presented at the Twenty-first Annual Meeting of the American Venous Forum, Phoenix, Ariz, Feb 11-14, 2009.

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doi:10.1016/j.jvs.2009.05.018

Table I. Design of trials

<i>Trial</i>	<i>Design</i>	<i>Endpoint set at [weeks]</i>	<i>Stockings</i>	<i>Interface pressure [mmHg]</i>	<i>Bandages</i>
Hendricks 1985	sc	78	Futur (3M)	24 ^a	Unna's boot
Partsch 1994	sc	13	Sigvaris Thrombo & Sigvaris 503 (Ganzoni)	31 (± 4) ^b	Rosidal K (Lohmann & Rauscher)
Koksal 2003	sc	16	Sigvaris 503 (Ganzoni)	23-32 ^a	Unna's boot
Polignano 2004	mc	12	SurePress Comfort, (ConvaTec)	—	Comprilan, (BSN)
Jünger, Partsch 2004	mc	12	Tubulcus (Innothéra)	30-40 ^a	Rosidal K (Lohmann & Rauscher)
Jünger, Wollina 2004	mc	12	Venotrain Ulcertec (Bauerfeind)	43 (± 13) ^b	Roselastic S530 (Karl Otto Braun)
Milic 2007	mc	29	Tubulcus (Innothéra)	46-56 ^c	Niva (Novi Sad)
Mariani 2008	mc	16	Sigvaris Ulcer X (Ganzoni)	37-41 ^c	Multilayer
Overall	3 sc 5 mc	12-78		31-56	

sc, Single center; mc, multi-center.

^aPressure indicated by the manufacturer (mean or range).

^bPressure measured in individual patients (mean and 1 SD).

^cPressure measured in individual patients (range).

METHODS

The literature search covered six sources. Medline, Current Contents, Embase, and the Cochrane Library were checked electronically using the following terms: Venous insufficiency, leg, pain, edema, ulcer, compression therapy, bandages, stockings, hosiery, and randomized trials, in various combinations. EUROCOM, the scientific platform of companies producing medical compression stockings in Europe, was asked to provide information on studies sponsored by their members. The reference lists of all publications were screened for further studies. Studies in English, French, or German were considered but no unpublished or ongoing studies.

All randomized studies comparing stocking based compression with any type of bandages for the treatment of venous leg ulcers were subject to an independent systematic review. No restriction was defined for any ulcer features. In the case of missing relevant data, we inquired with the authors by e-mail. The primary endpoint of the survey was an objective outcome assessment of complete ulcer healing within a prespecified or reasonably long time frame. Secondary endpoints were a statement of the time required to achieve healing and quantitative data on pain. Subjective endpoints, like discomfort, hindrance, quality-of-life, and issues of practicability were also analyzed, but not entered into the meta-analytic model as these dimensions were too heterogeneous and data reporting often incomplete.

For statistical work-up, data were pooled using a fixed effects method which weights each study by the inverse of its variance. We selected this method as systematic changes in the condition and treatment of ulcers over time were expected. Data of the proportion of healing were presented as odds ratios (OR) with 95% confidence interval (CI) and the time to healing was shown as the standardized mean difference (SMD) with 95% CI. Statistical analysis was performed according to the Cochrane Handbook for Systematic Reviews of Interventions, where I^2 serves to describe the inconsistency or the amount of heterogeneity

between the studies, respectively, and Z-values are used to test the significance of overall effects.⁶ The analysis was executed with the Review Manager 4.2 of the Cochrane Collaboration. Furthermore, the logarithm of the weighted mean ulcer size was graphically compared with the proportion of healing within 12 weeks for both treatment groups of each study.

RESULTS

Eight trials fulfilling the predefined criteria were identified (Table I). All studies were prospective and open-label. Randomization was in two parallel groups except for the first study which had a cross-over design.

All patients featured clinically distinct venous ulcers (classification C6 or Widmer III). The more recent studies provided details of a diagnostic work-up.

The following exclusion criteria were commonly observed: cause of ulcer other than venous, infection, ankle-brachial pressure index <0.8 or <0.9 , diabetes, heart failure, and cancer.

Calf length stockings or stocking systems were used in all studies. Seven studies provided data on the pressure exerted by the stockings and two reported individually measured pressures exerted by stockings and bandages. These measurements were made above the ankle on the inner aspect of the leg immediately after donning of the stocking or applying the bandages and expressed in mm Hg. Eccentric compression using pads was not reported. All studies presented some information on who donned the stockings and applied the bandages, and how often these were changed.

Local ulcer treatment was identical in the treatment groups except in those studies where it was part of the investigation. Description of local treatment was generally poor.

The number of randomly allocated subjects ranged from 21 to 178. The studies included a total of 692 patients, 277 men, and 359 women. The sex of 56 patients

Table I. Continued.

<i>Interface pressure [mmHg]</i>	<i>Type of stockings</i>	<i>Stockings changed</i>	<i>Bandages changed</i>	<i>Stockings removed at night</i>
— 27 (± 9) ^b	single two stockings	by pts understocking in study center	in study center in study center	removed 2 nd stocking remove
— — —	single two stockings single	dressing in study center by pts in study center	in study center in study center in study center	removed — left on leg
—	two stockings	by pts or in study center	by pts or in study center	patient's choice for both groups
37-49 ^c — 27-49	single two stockings 4 single stockings 4 two stocking systems	in study center understocking in study center	in study center in study center	left on leg 2 nd stocking removed 4 removed 1 patient choice 2 left on leg 1 no information

was not mentioned. The overall mean patient age was 60.7 years with a range per study between 56 and 65 years. The meta-analysis included 688 subjects, 342 in the stocking group and 346 in the bandages group.

Description of the individual studies (Tables I and II). Hendricks et al reported the first trial, a single-center crossover study with 24 legs of 18 patients.⁷ It compared 24 mm Hg stockings (Futuro, Style 50, 3M) with Unna's boots. The stockings were removed at night while the bandages were changed at the center every 3 to 9 days. Ulcer size and presence were not predefined and very heterogeneous. Randomization favored the stocking group. We assigned the study a poor quality and included it for historical reasons.

The study of Partsch et al with 59 patients was the first to investigate the treatment with two stockings.⁸ In the stocking group, hosiery designed for the prophylaxis of deep venous thrombosis (Sigvaris Thrombo, Ganzoni, St. Gallen, Switzerland) was donned over the dressing. The patient pulled a second stocking (Sigvaris Traditional 503, 23-32 mm Hg) over it each morning and removed it in the evening. In the bandage group, a single short-stretch bandage was applied by trained personnel and left on the leg day and night for up to 1 week. The interface pressure was measured in every patient. Ulcer size and presence were not prespecified. The primary endpoint was healing within 90 days. Randomization was not perfect. Ulcers were half as large in the stocking as in the bandages group and present for 2 and 5 months, respectively. In the stocking group, six patients were unable to don the stockings themselves and in the bandage group, three patients refused to come for follow-up visits. Despite the fact that randomization favored the stocking group to some extent, we consider this trial informative.

The work of Koksai et al included 60 clinically diagnosed venous ulcers of 5 to 8 cm² with other features not prespecified.⁹ It compared two treatment regimes: hydro-

colloid dressings combined with a Sigvaris Traditional 503 stocking vs a not further specified dressing combined with an Unna's boot. The paper refers to a sub-stocking pressure of 30-40 mm Hg but our inquiry with the company which provided the stockings revealed that indeed the 503 stockings were delivered which exert a pressure of 23-32 mm Hg. The stockings were removed at night and the bandages changed at the center every 3 to 7 days. The primary outcome was healing within 16 weeks. We consider this an important study.

The study of Polignano et al included 56 clinically diagnosed venous ulcers of at least 2 cm² and a diameter not bigger than 10 cm.¹⁰ The SurePress Comfort (Convatec) stocking kit was compared with a Comprilan (BSN) bandage. Compression in both groups was applied by professionals at intervals that were not reported. Compliance was checked. No information is given whether compression was removed at night or not. The primary endpoint was healing within 12 weeks. Four patients in the stocking group dropped out (one because of inefficacy) and 11 patients in the bandage group (nine because of inefficacy and/or adverse events). An error regarding time to healing was found in the paper and corrected. The study provided all relevant data and is considered useful.

The study reported by Jünger et al is the largest performed so far.¹¹ It included 188 ultrasound documented venous ulcers of less than 5 cm diameter and a presence of no longer than 3 months. A tubular compression device (Tubulcus; Inothéra, France) was compared with a single short-stretch bandage (Rosidal K; Lohmann and Rauscher, Rengsdorf, Germany). Stockings and bandages were put on at the center, left in place at night and changed at least weekly. Compliance was assessed and found equal in both groups. There were "more major clinical conditions" in the bandage group. The primary endpoint was healing within 12 weeks. We consider this an important study.

Table II. Characteristics of patients and ulcers

<i>Trial</i>	<i>Patients</i>	<i>Mean age [years]</i>	<i>Ulcer size*</i>	<i>Presence [months]</i>	<i>Group inequalities</i>	<i>Patients dropped out</i>
Hendricks 1985	21 ITT 12 m, 9 w	61	S: 0.3-11.0 cm B: 0.3-23.7 cm	S: 13 (± 17) B: 29 (± 35)	Older ulcers in B	—
Partsch 1994	59 ITT, 50 PP 27 m, 23 w	62	S: 3.2 cm ² (0.8-10) B: 6.0 cm ² (0.8-26)	S: 2 (0.25-36) B: 5 (0.25-36)	Older/larger ulcers in B	S: 6 B: 3
Koksai 2003	60 ITT, 53 PP 23 m, 37 w	50	S: 6.2 cm ² (± 0.8) B: 6.4 cm ² (± 1.2)	S: 3.9 (± 1.4) B: 3.8 (± 0.3)	None	S: 4, B: 3
Polignano 2004	56 ITT sex not mentioned	—	S: 9.7 cm ² (± 9.4) B: 9.3 cm ² (± 8.1)	—	More “major clinical conditions” in B	S: 4 B: 11
Jünger, Partsch 2004	188 ITT, 178 PP 72 m, 106 w	65	S: 2.4 cm ² (± 2.3) B: 2.4 cm ² (± 2.3)	S: 1.3 (± 0.8) B: 1.4 (± 0.8)	None	Early discontinuation: 10
Jünger, Wollina 2004	121 ITT, 109 PP 47 m, 74 w	63	S: 5.6 cm ² (± 7.9) B: 5.9 cm ² (± 9.0)	S: 3.8 (± 3.3) B: 5.1 (± 3.9)	Older/larger ulcers in B	Early discontinuation: 11 Drop outs: S: 6, B: 6
Milic 2007	150 ITT, 138 PP 73 m, 77 w	56	S: 72 cm ² (24-210) B: 64 cm ² (20-195)	S: 84 (7-336) B: 72 (7-252)	None	S: 3 B: 9
Mariani 2008	60 ITT, 56 PP 23 m, 33 w	64	S: 3.4 cm (± 2.7) B: 2.8 cm (± 2.4)	S: 3.2 (± 3.0) B: 3.6 (± 4.0)	Ulcer ground worse in S	S: 4
Overall	692 patients ITT 277 m, 359 w, 56 sex not mentioned Entered into analysis: 688 legs	60.7	0.1 cm ² -210 cm ²	1 week-9 years	3 studies no inequalities 4 studies B worse 1 study S worse	S: 27 patients B: 32 patients

S, Stocking group; B, bandage group; ITT, intended to treat; PP, per protocol.
*Largest diameter (cm) or surface (cm²).

Table III. Outcome of studies with P values published in the papers

<i>Trial</i>	<i>Percent of ulcers healed</i>			<i>Time to healing [weeks]</i>			<i>Subjective outcome</i>
	<i>Stockings</i>	<i>Bandages</i>	<i>P</i>	<i>Stockings</i>	<i>Bandages</i>	<i>P</i>	
Hendricks 1985	71.4	70.0	Ns	18.4 ^a (without outlier 11.8)	7.3 ^a	Ns	—
Partsch 1994	84.0	52.0	<.05	5.5 (± 2.5)	7.2 (± 3.0)	<.1	—
Koksai 2003	80.8	73.1	Ns	6.7 (± 3.3)	6.9 (± 3.6)	Ns	Pain, ease of use better in S
Polignano 2004	44.4	17.2	<.05	10.3 (± 5)	14.4 (± 7)	<.05	Pain ^a , comfort and ease of use better in S
Jünger, Partsch 2004	58.0	56.7	Ns	6.1 (± 2.6)	6.2 (± 2.6)	Ns	—
Jünger, Wollina 2004	47.5	31.7	<.05	8.7 (± 3.7)	9.7 (± 3.6)	Ns	4 of 9 items valued by patients 2 of 4 items valued by nurses better in S
Milic 2007	68	24	<.001	22.9 (± 15.4) ^b	31.9 (± 18.0) ^b	<.01	—
Mariani 2008	96.2	70.0	<.05	8.0 (± 4.2)	8.7 (± 3.2)	Ns	Inhibition of activities, pain at donning/removal significantly, daytime discomfort/pain trend better in S
Overall	65	47		11.6 (± 6.6)	14.8 (± 7.4)		All subjective outcome measures equal or better in S

Ns, Not significant; S, stocking group.

^aData not useful for meta-analytic model (missing SD).

^bMean and standard deviation estimated from cumulative healing rates.

Jünger et al examined 121 ultrasound verified venous ulcers with a diameter of 1-10 cm and a presence of not more than 12 months.¹² The study compared a two-stocking system (Venotrain; Ulcertec, Bauerfeind, Zeulenroda, Germany) with a single short stretch bandage (Roselasti S 530; Karl Otto

Braun, Wolfstein, Germany) applied by professionals or the patients themselves. The intervals of dressing change are not mentioned. The outer stocking as well as the bandages could be removed in the evening. The decision was left to the patient. Compliance was measured by the time of

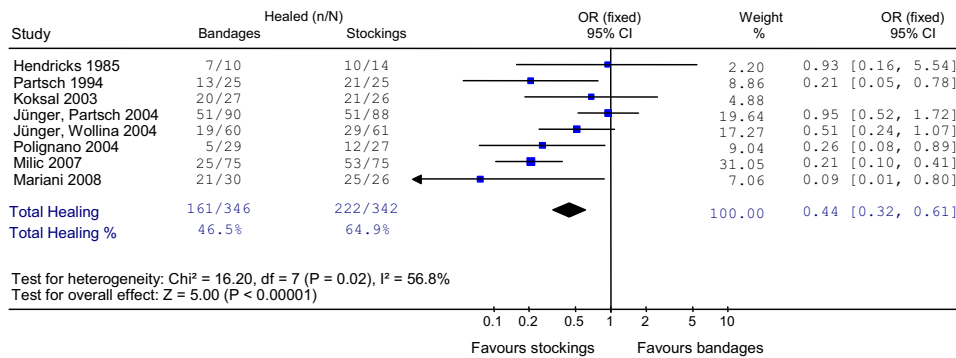


Fig 1. Comparison of ulcer healing with stockings and bandages.

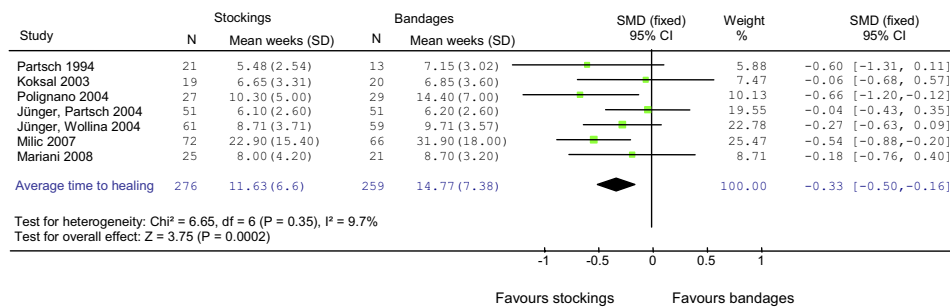


Fig 2. Time to healing with stockings and bandages.

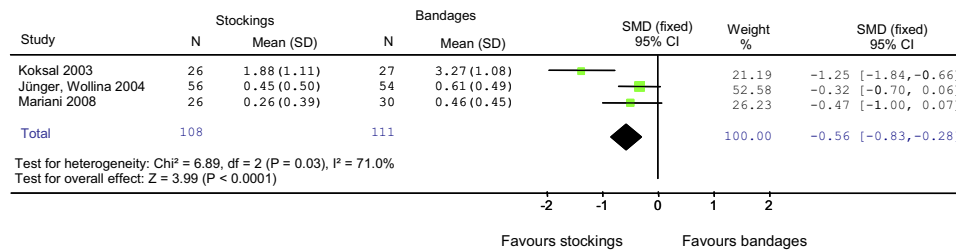


Fig 3. Various scores of pain with stockings and bandages.

wearing stockings or bandages. The primary endpoint was the proportion of ulcers healed after 12 weeks of treatment. We consider this a relevant contribution.

The trial of Milic et al included 150 ultrasound documented venous ulcers larger than 20 cm² and older than 6 months.¹³ It compared a tubular compression system (Tubulcus) with an elastic multilayer bandage (Niva; Novi Sad, Serbia). Both compression systems were applied at the center at intervals of 1 to 7 days and worn day and night. Healing was assessed at three predefined points in time. The healing rates with stockings compared with bandages were 31% and 7% at 100 days, 68% and 24% at 200 days, and 93% and 51% at 500 days, respectively. In the bandage group, nine patients dropped out, eight of them wanted to switch to the stocking group. The design of this study and some of the results are not easy to understand. Nevertheless, we consider this a valuable trial, especially as it included very severe venous ulcers.

The study of Mariani et al entered 60 ultrasound proven venous ulcers with a diameter not larger than 8 cm.¹⁴ It compared a double-stocking system (Sigvaris Ulcer X; Ganzoni, St. Gallen, Switzerland) with a multilayer short-stretch bandage. Compression was applied at the centers at weekly intervals which were shortened if necessary. The outer stockings were regularly removed before going to bed. The primary endpoint was healing after 16 weeks of treatment. Four patients were excluded from the study, three because they were unable to put on their stockings due to a severe restriction of ankle movement and one for a reason not associated with the treatment. This is a straight forward study providing clear results.

Results of the meta-analysis (Table III, Figs 1 to 3). This survey covered eight studies with 342 patients in the stocking and 346 in the bandage group. The primary outcome of all studies was ulcer healing or nonhealing. Five studies demonstrated a statistically significant and clinically

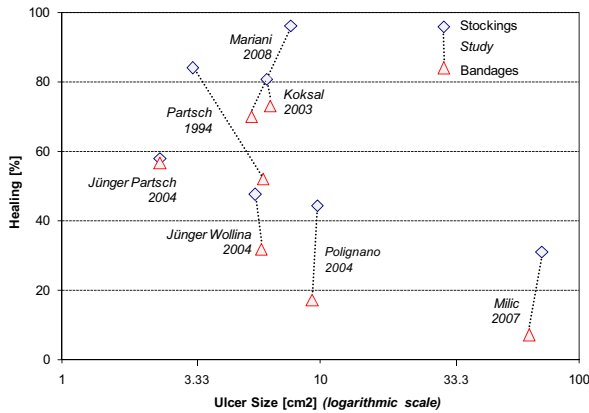


Fig 4. Relation between ulcer size and proportion of healing within 12 to 13 weeks as a result of compression with stockings or bandages.

meaningful benefit of stockings over bandages while in the other three studies the proportion of complete healing was not different between the stocking and the bandage group. A simple numeric analysis shows that ulcer healing within 12 to 16 weeks was achieved in 65% with stockings and in 47% with bandages. The formal meta-analysis revealed a mean weighted OR of 0.44 ($P < .00001$) (Fig 1).

Time to healing could be analyzed in seven studies covering 535 patients (Fig 2). The time windows in which healing was expected to occur ranged from 12 to 78 weeks. Ulcers that healed did so within 11 weeks (range 5.5-31.9), an average of 5 weeks before the end of the prespecified observation period. Healing with stockings occurred an average of 3 weeks earlier than with bandages ($P = 0002$).

Subjective factors. Pain and ease of application was assessed in detail in four studies. All data showed a significant benefit of stockings over bandages both in the patient's opinion and the nursing staff's judgment. The benefiting items were overall effectiveness, comfort and satisfaction, nursing time, and ease of application and removal. A detailed report described less hindrance of normal daily activities and shorter intervals between visits in the stocking group.¹⁴ Reporting of the subjective factors was very heterogeneous precluding the use of a meta-analytic model. The assessment of pain, however, was comparable in three studies covering 219 patients which allowed statistical treatment. The benefit of stockings was confirmed ($P = .0001$) (Fig 3).

DISCUSSION

We scrutinized all eight studies published over a period of 23 years and found substantial heterogeneity with regard to ulcer features, treatment modalities in either groups or study duration. To reconcile for ulcer size and study duration, we conceived a plot presenting the proportion of healing within 12 weeks as a function of the logarithm of the ulcer size. The graph reveals consistent data: a clear correlation between ulcer size and

healing rate for either treatment documenting the relatively small influence of other potential determinants. Six of seven studies revealed a better outcome with stocking based systems compared with bandages and one study had no difference. The documented data steadiness supports our decision to perform a formal meta-analysis using common statistical procedures.

The emerging key message is straightforward: stockings are better than bandages for the treatment of chronic venous ulcers of any size, time of presence, and various features of their potential cause. The benefit regarded primarily the proportion of healing within the reasonable time frame of 12 to 16 weeks, but also time to healing, pain and other subjective issues, ease of use, nursing time, etc. The impact on subjective endpoints and presumably compliance was not assessed in most studies. The mutual advantages and disadvantages of stockings and bandages when applied by the patients themselves were not evaluated since handling of stockings and bandages was mostly done by experienced staff at the wound centers.

All studies were open-label with an inherent risk of bias. Centers caring for patients with severe venous insufficiency are focused on the use of bandages. Indeed, of the 47 separate comparisons reported in the newest Cochrane review,⁴ only seven covered the use of stockings. It is noteworthy that the traditional approach has been put on the test-bench of an RCT against stockings as these are viewed as an alternative for small ulcers of short duration.^{15,16} So, if bias would have been a problem, it probably would have benefited bandages.

Notes of eventual caution are first, patients with more severe disease may have been excluded from the studies because of fears they would not do well with MCS. The notion is not supported by the trials we reviewed and appears unwarranted. Appropriate data processing revealed that the benefit of healing with stockings was independent of the initial size of the ulcer, which is the most important parameter of disease severity and poor healing¹⁷ (Fig 4). Second, donning of stockings requires the preservation of minimal ankle mobility, an often lacking prerequisite. However, as exemplified by three studies (176 patients) only 6.5% of randomized patients were unable to put on the stockings.^{8,10,14} The proportion of patients not fit to handle stockings by themselves or with little help might well be larger in a real world situation. Third, critiques may say that bandages were inferior because materials and application techniques were inadequate. This is an invalid reproach as all study centers are recognized for their expertise with application of bandages. Fourth, it is not clear why compression with stockings is better than compression with bandages. Potential differences, e.g., more rapid loss of pressure¹⁸ or lower elastic properties of bandages¹⁹ were not investigated in the trials included in this review. Donning convenience and subjective endpoints might have played a certain role. However, in six of the eight studies stockings and bandages were changed at the centers, minimizing the influence of such issues. Fifth, the survey does not permit to distinguish between the various types of

stockings or bandages. Nevertheless, subjective endpoints were particularly favorable in the trials testing two-stocking kits with removal of the second stocking at night.^{8,14} Comparative studies assessing this practical issue are welcome.

In summary, our review revealed a higher rate of healing with stockings compared with bandages. The findings contradict traditional beliefs and pave the way for a more widespread use of stockings, which seem not only more effective but also better tolerated. The benefit of stocking based systems remains to be proven in real-world situations. Future studies should compare the use of stockings at home with the use of bandages, either at home or in specialized centers.

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Submitted Feb 5, 2009; accepted May 11, 2009.