A new compression system for treatment of venous leg ulcers: a prospective, single-arm, clinical trial (FREEDOM)

Objective: To evaluate the efficacy, tolerability and acceptability of a new multicomponent compression system in one bandage for the local treatment of patients with venous leg ulcers (VLUs).
Method: This was an international, prospective, non-comparative, clinical trial, conducted in France and Germany. Eligible participants had a VLU with a wound area of 2–20cm², lasting for a maximum of 24 months. For a period of 6 weeks, patients were treated with a new multicomponent compression system in one bandage which was worn day and night, providing high working pressure and moderate resting pressure (UrgoK1). Clinical assessments, wound measurement and photographs were planned at weeks 1, 2, 4 and 6. The primary endpoint was the relative wound area reduction (RWAR) after 6 weeks of treatment. Secondary endpoints included wound closure rate, oedema resolution, change in patient's health-related quality of life (HRQoL), acceptability, adherence to the compression therapy, local tolerance, and physician's overall satisfaction with the evaluated compression system.
Results: A cohort of 52 patients (52% female, mean age 75.4±13.0 years) with VLUs, including oedema in 58% of cases, were recruited from 22 centres. At baseline, 42 patients had already been treated with a different compression system. VLUs had been present for 5.6±4.9 months and had a mean area of 5.7±4.3cm². After 6 weeks of treatment, a median RWAR of 91% (interquartile range: 39.4; 100.0) was achieved. Wound closure was reported in 35% of patients. A RWAR ≥40% at week 4, predictive of wound healing at 12 weeks, was achieved in 62% of patients. At the final visit, oedema present at baseline was resolved in 57% of patients. Substantial improvements in the HRQoL of the patients were reported with a decrease of the pain/discomfort and anxiety/depression dimensions. Comfort in wearing the evaluated system was reported as 'very good' or 'good' by 79% of patients, resulting in a high patient adherence to compression therapy. Compared to previous compression systems, half of the patients reported more ease in wearing shoes, and greater satisfaction and comfort with this new system. Nine non-serious adverse events related to the device or its procedure occurred in seven patients. At the final visit, the majority of the physicians were 'very satisfied' or 'satisfied' with the new compression system overall.
Conclusion: The new multicomponent compression system in one bandage has been shown to promote rapid healing of VLUs, reduce oedema, improve HRQoL and to be well tolerated and accepted. It appears to be a viable alternative to existing compression systems.
Declaration of interest: This study was sponsored by Laboratoires Urgo. AS and OT are employees of Urgo Research Innovation and Development. PS, JD and MS provide advisory and speaking services to pharmaceutical and other healthcare organisations including, but not limited to, Laboratoires Urgo. German data monitoring and regulatory management, data management and statistical analyses were conducted independently by ICTA PM, Dijon, France. The authors have no other conflicts of interest.

multicomponent compression bandage • oedema • venous leg ulcers • wound • wound care • wound dressing • wound healing

Patricia Senet,[1] MD, Head of Dermatology Unit*; **Azeddine Addala**,[2] MD, Hospital Practitioner; **Philippe Léger**,[3] MD, Hospital Practitioner; **Maxime Chahim**,[4] MD, Hospital Practitioner; **Julie Malloizel**,[5] MD, Hospital Practitioner; **Sophie Blaise**,[6] MD, Head of Vascular Medicine Department; **Anne Sauvadet**,[7] PhD, Clinical Project Manager; **Olivier Tacca**,[7] PhD, Clinical/Preclinical Development Director; **Markus Stücker**,[8] MD, Head of Dermatology Department; **Joachim Dissemond**,[9] MD, Head of Dermatologic Wound Care Centre
***Corresponding author email:** patricia.senet@aphp.fr
1 Department of Dermatology, Paris Est University Hospitals (AP-HP) - Tenon Hospital, Paris, France. **2** Department of Vascular Medicine, Edouard Herriot Hospital, Lyon, France. **3** Wound and Wound Healing Centre, Pasteur Clinic, Toulouse, France. **4** Department of Vascular Medicine, Corentin Celton Hospital, Issy Les Moulineaux, France. **5** Department of Vascular Medicine, Rangueil University Hospital, Toulouse, France. **6** Department of Vascular Medicine, Albert Michalon University Hospital, Grenoble, France. **7** Clinical Development Department, URGO Research Innovation and Development, Chenove, France. **8** Department of Dermatology, Ruhr-University Bochum, Bochum, Germany. **9** Department of Dermatology, Venerology and Allergology, University Hospital Essen, Essen, Germany.

Venous leg ulcers (VLUs) are defined as wounds of the lower limb, located between the knee and ankle joint, that occur in the presence of severe venous disease.[1–4] Accounting for 60–80% of all hard-to-heal leg ulcers, these wounds are characterised by slow progression healing and a high recurrence rate.[5–6] Often painful, prone to infection, associated with reduced mobility, self-isolation, anxiety and depression, these wounds have been shown to severely impair the health-related quality of life (HRQoL) of patients.[7–10] Moreover, with an incidence of 0.73 to 3.12 per 1000 persons per year, a prevalence increasing with age and aging populations, their management is also placing substantial and still-growing economic and clinical burden on healthcare systems.[8,11,12]

Table 1. Inclusion and exclusion criteria of the clinical trial

Inclusion criteria	Exclusion criteria
Hospitalised or ambulatory adult patient, aged ≥18 years, who signed and dated informed consent form	Patient with known allergy to any components of the tested compression system URGO BD001
Patient with venous leg ulcer (VLU) (ankle–brachial pressure index (ABPI) ≥0.8 and ≤1.3)	Diabetic patient with advanced diagnosed microangiopathy
Patient with ankle circumference between 18–25cm	Patient with a severe illness that might lead to premature discontinuation of the trial
Patient willing and able to wear the new compression system every day and night during the study period	Patient with systemic infection not controlled by a suitable antibiotic therapy
Patient who can be followed up by the same investigating team during the study period	Patient with a lymphoedema due to lymphatic obstruction
Patient with VLU between 2–20cm^2 in surface area	Patient who had a deep vein thrombosis within 3 months prior to the inclusion
Patient with VLU duration between 1–24 months	Cancerous lesions
Patient with wound in granulation phase (granulation tissue ≥50%)	Wound clinically infected
	Wound covered partially or totally by necrotic tissue
	Wound requiring surgical treatment or for which a surgery is scheduled during the study period
	Bedridden patient, or one spending less than one hour per day on their feet
	Target wound <3cm away from any edge of another wound

The mainstay of the aetiological treatment of VLUs consists of the use of compression (30–40mmHg at the ankle) with a pressure gradient on the lower limbs to counter the venous reflux and hypertension resulting from the chronic venous insufficiency (CVI).[1–4,13] Based on clinical evidence, this level of compression, recommended by current guidelines in association with appropriate local care, provides an increase in venous return, a reduction of oedema and improves lymphatic circulation.[14,15] Previous randomised controlled trials (RCTs) and systematic reviews have established that compression therapy significantly increases the wound healing rates of VLUs and contributes to an improvement in the HRQoL of patients, compared to no compression.[16–18] Different systems can be used to achieve such high pressures, including short stretch bandages, long stretch bandages or compressive hosiery, but multicomponent bandage systems are still widely considered to be the gold standard.[16–21] Although some systems appear to be similarly effective on the wound healing process, they can significantly differ in terms of ease and reliability of use, ease of removal, patient comfort and acceptability, which will affect adherence.[20,21]

Despite the diversity of options available, evidence from real-world studies has revealed that a significant proportion of patients with VLUs are still not receiving appropriate compression therapy or any compression therapy at all, as certain systems remain too difficult to apply with confidence or to remove easily, and many patients have difficulty tolerating and adhering to their treatment because of discomfort or pain, and overall poor acceptability.[22,23]

In this context, any solution that would improve patient comfort and adherence, or facilitate the application of the system, while achieving similar efficacy to established compression systems would be valuable. With this focus, a new system has been recently developed using an innovative textile three-dimensional (3D) knitting technology to provide the efficacy of multicomponent systems in just a single bandage. The performance of this new system has been assessed in an RCT conducted on healthy volunteers,[24] compared to another multicomponent system composed of two bandages and well established in the treatment of VLUs and lower limb oedema.[21,25–33] In the RCT, both legs of the participants were randomly bandaged with either the new generation of compression system or the control system. Both systems were worn day and night, while interface pressures were regularly measured (at 4 hours, 24 hours, 48 hours and 72 hours after bandage application) and the static stiffness index calculated over a 72-hour period.[24] The results showed that the new system provided high working pressure, moderate resting pressure and continuous static stiffness index ≥10mmHg, similar to that of the reference system. The new system was judged easy to apply, since the first application, and both systems presented good holding properties and were well tolerated. In addition, the new system was perceived as significantly more comfortable and eventually preferred to the control system by the majority of the volunteers, notably due to significantly less restriction of ankle mobility, less difficulty to wear

shoes and less warmth sensation.

Following these promising initial results achieved with healthy volunteers, this new clinical trial aimed to evaluate for the first time the efficacy, tolerability and acceptability of this new compression system in the treatment of patients with VLUs.

Method

Study design and participants

This prospective, single-arm, multicentre trial was conducted between December 2020 and June 2021, in 22 active centres (hospitals or private practices specialised in dermatology, vascular medicine and clinical gerontology) located in France and Germany.

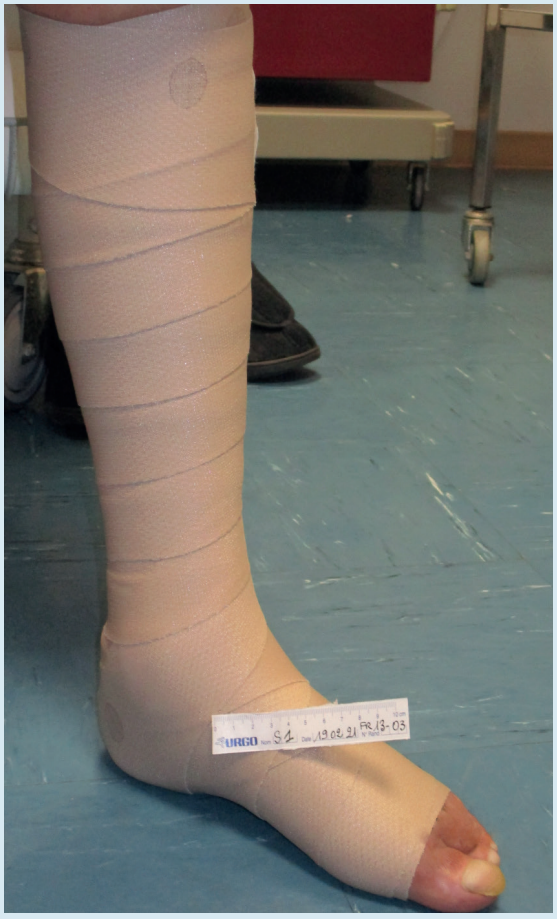
Eligible participants were hospitalised or ambulatory patients with a VLU characterised by an ankle–brachial pressure index (ABPI) value between 0.8 and 1.3, and had an ankle circumference of 18–25cm. The ulcer had to be of 1–24 months' duration, 2–20cm² surface area and covered by ≥50% of granulation tissue. Patients were excluded if they had a diagnosis of diabetic advanced microangiopathy, cancerous lesions, a lymphoedema due to lymphatic obstruction, a deep vein thrombosis within three months prior to the inclusion, a wound clinically infected, covered partially or totally by necrotic tissue. All inclusion and exclusion criteria are reported in the Table 1.

The patients were followed for a maximum period of 6 weeks, or until wound closure, defined as 100% re-epithelialisation, if this occurred earlier.

Compression system

The investigated compression system UrgoK1 (Laboratoires Urgo, France), the Dual Compression System, is a new generation of compression which is able to provide a sustainable high stiffness (>10mmHg), with high working pressure and moderate resting pressure, delivered by the application of one unique bandage.[24] This multicomponent compression system is composed of polyamide, elastane and polyester yarns, combined together in an exclusive structure, using an innovative 3D knitting technology. To guide the proper stretching and overlapping of the compression system, the bandage displays on its exterior face a visual indicator known as the PresSure system (a printed ellipse that expands into a circle when the correct pressure level is applied). The bandage is provided with a self-grip device to finalise its application and maintain the compression system in place over time. During the study implementation, the investigating teams (physicians and hospital nurses) were instructed in the application technique (spiral with overlap of the bandage, Fig 1). The patients recruited in this trial completed a questionnaire for the community nurses to assess the application of the compression system at each change. The explanation of the application technique was illustrated with a series of photos, and a USB key with the same video of the application presented to the investigating teams, if needed (video available at: https://www.youtube.com/watch?v=7JutFxtL5Yo).

Fig 1. Mode of application of the new Dual Compression System



According to the manufacturer's instructions, the compression system is designed to be worn continuously day and night until the next care visit, the change frequency being left to the discretion of the clinician. If needed, to protect from bony prominence and/or to shape the leg, an additional piece of foam padding can be used with the compression system.

Local care, primary dressings, additional materials, frequency of change

In this clinical trial, debridement, skin care, choice of primary dressings applied, frequency of dressing changes, use of additional materials to protect bony prominence or shape the legs and frequency of compression bandage changes were left to the investigators' discretion but were documented at each visit.

Clinical assessment

At the initial visit, the investigators recorded the relevant demographic information and medical history of the patients, their previous treatment, and the

Table 2. Characteristics of the treated patients (n=52)

Patient status	
Outpatient, n (%)	50 (96)
Hospitalised, n (%)	2 (4)
Demographics	
Male, n (%)	25 (48)
Female, n (%)	27 (52)
Age, years (mean±SD) [min–max]	75.4±13.0 [42–100]
BMI, kg/m² (mean±SD)	27.9±5.1
Medical history	
Vascular disorders, n (%)	
Arterial hypertension	36 (69)
Venous intervention	17 (33)
Deep vein thrombosis	13 (25)
Cardiac disorders	10 (19)
Depression/anxiety	9 (17)
Obesity (BMI ≥30kg/m²)	16 (31)
Diabetes	11 (21)
Current smokers	5 (10)

BMI—body mass index; max—maximum; min—minimum; SD—standard deviation

characteristics of their legs and ulcers. Diagnosis of oedema was based on the presence of Godet's sign or any other relevant medical assessment. Ankle circumference was measured at the reference point B (smallest circumference of the leg, 3cm above the medial malleolus) and calf circumference at point C (maximum circumference of the calf). Wound area was measured using planimetry and Universal Desktop Ruler (version 3.8, Universal On-screen Digitizer, AVPSoft). Photographs of the wound were taken after debridement and photographs of the compression system were taken after application and before removal at the following visits.

Investigator assessments were planned at weeks 1, 2, 4 and 6, including clinical examination, wound area measurement with planimetry and photographs. Dressing and compression system changes were conducted by the investigating team at the scheduled visits, and by community nurses between visits. At each compression system change, physicians and nurses documented whether the system was still in place, the reason for its early removal otherwise, and assessed the ease of removal and reapplication of the bandage, as well as its conformability to the leg. At the final visit, the physicians assessed the overall progression of the wound healing process ('healed', 'improved', 'stagnating' or 'worsened'), their overall satisfaction with the evaluated compression system and their willingness to continue to use it in the treated indication.

Each patient's HRQoL was assessed at baseline and at the last visit, using the validated EQ-5D-5L questionnaire.[34,35] Patient adherence to compression therapy ('every day, all the time', 'as often as possible', 'occasionally' or 'rarely or never') was documented at the initial visit for previously used compression systems, and at each follow-up visit for the evaluated compression system. Patient's acceptability of compression systems was assessed in terms of pain, itchiness sensation, feeling of heat, comfort, ankle mobility and ease of wearing shoes at the initial visit for previously used compression systems, and at week 1 and the last visit for the evaluated compression system. The patient's overall satisfaction with the evaluated compression system was also recorded at the last visit. The patient's preference between the evaluated compression system and a previously worn compression system was assessed in terms of comfort, ankle mobility, ease of wearing shoes at week 1, and in terms of overall comfort and satisfaction at the last visit.

Occurrences of adverse events (AEs) were recorded at each visit.

Endpoints

The primary endpoint was the relative wound area reduction (RWAR) after 6 weeks of treatment. Secondary endpoints included:

- Wound closure rate by week 6, and time to reach wound closure in days
- Wound area in cm² and RWAR versus baseline as a percentage at each visit
- Overall wound healing improvement at the final visit
- Percentage of patients with a RWAR ≥40% after 4 weeks of treatment, which has been shown to be predictive of complete wound healing at 12 weeks[36]
- Percentage of patients with oedema resolution (characterised by the disappearance of the previously identified sign) at the final visit, in patients who had oedema at the initial visit
- Change in calf and ankle circumference in cm in patients with oedema resolution
- Change in HRQoL of patients between the initial and final visit
- Change frequency of the dressings and compression system, assessment of the ease of application and conformability of the compression system by both the physicians and nurses, and overall satisfaction of the investigators regarding the evaluated compression system and their willingness to continue to use it in the treated indication
- A patient's adherence to the compression therapy throughout the study period, acceptability of the evaluated compression system, and preference between this new system and the previous system worn, at week 1 and final visit
- Local tolerance of the evaluated compression bandage with the nature, incidence, imputability and severity of the AE documented by the investigating physicians during the study period.

Table 3. Baseline characteristics of the included legs and ulcers

Leg characteristics	
ABPI (mean±SD) [min–max]	1.1±0.1 [0.8–1.3]
Ankle circumference, cm (mean±SD) [min–max]	22.7±1.9 [18–25]
Calf circumference, cm (mean±SD) [min–max]	34.6±5.9 [24–53]
Oedema, n (%)	30 (58)
Other clinical signs of venous disease, n (%)	47 (90)
Purpura jaune d'ocre (hyperpigmentation)	27 (52)
Stasis dermatitis (venous eczema)	26 (50)
Atrophie blanche	17 (33)
Others (lipodermatosclerosis, varicose veins, large telangiectasia, corona phlebectatica)	12 (23)
VLU characteristics	
Recurrent VLU, n (%)	32 (62%)
VLU location, n (%)	
Medial malleolus	18 (35)
Lateral malleolus	10 (19)
Anterior face of the leg	14 (27)
Other	10 (19)
VLU duration, months (mean±SD) [min–max] **Median (IQR)**	5.6±4.9 [1–24] 4 (2 ; 8)
<6 months, n (%)	33 (63)
≥6 months, n (%)	19 (37)
Wound area, cm² (mean±SD) [min–max] **Median value (IQR)**	5.7±4.3 [0.5–16.0] 3.7 (2.2 ; 9.1)
<10cm², n (%)	40 (77)
≥10cm², n (%)	12 (23)
Wound bed tissue, as percentage of wound bed area, (mean±SD) [min–max]	
Granulation tissue	77±21 [50 ; 100]
Sloughy tissue	23±21 [0 – 50]
Exudate level, n (%)	
None	4 (8)
Low	17 (33)
Moderate	27 (52)
High	4 (8)
Periwound skin condition, n (%)	
Healthy	23 (44)
Impaired (erythematous and/or squamous, irritated, eczematous, macerated)	29 (56)

ABPI—ankle–brachial pressure index; IQR—interquartile range; max—maximum; min—minimum; SD—standard deviation; VLU—venous leg ulcer

Table 4. Change in wound area and relative wound area reduction (RWAR) over the treatment period

	n	Wound area, cm², median value (IQR)	RWAR, %, median value (IQR)
Initial visit	52	3.7 (2.2 ; 9.1)	
Week 1	51	2.5 (1.5 ; 7.6)	26.4 (9.8 ; 50.4)
Week 2	46	1.9 (0.7 ; 4.0)	45.5 (24.1 ; 75.4)
Week 4	46	0.6 (0.1 ; 2.8)	76.0 (33.9 ; 95.5)
Week 6	46	0.2 (0.0 ; 1.8)	91.1 (39.4 ; 100.0)

IQR—interquartile range

Statistical analysis

Assuming a standard deviation of the RWAR after 6 weeks similar to the one reported in the literature with another dual compression system in the same indication,[25] it was calculated that 49 patients were required to obtain a 90% confidence interval with a precision of 13%. With an estimation of 5% of non-evaluable data for the primary criterion, it was decided to include 52 patients in the study.

Data management and statistical analyses were performed in accordance with the statistical analysis plan by an independent company (ICTA PM, France). Efficacy and safety analysis were performed on all the included patients (intention-to-treat basis). Data from final visits occurring before week 6 (due to premature study discontinuation or wound healing) were reclassified to the closest visit, or to the next visit if the closest visit already had data. For the calculation of wound area and RWAR, the value of healed wounds was reported at the following visits, while missing values were not replaced or taken into account. For the calculation of the index value of the HRQoL, French and German value sets were used. Continuous data are described by mean, standard deviation, minimum and maximum values, or median and interquartile range (IQR). Discrete data are described by absolute value and frequencies.

Ethics

This clinical trial was carried out in accordance with the ethical principles of the Declaration of Helsinki and the European and national regulations applicable on medical devices and research involving the human person (ISO 14155, European Directives 93/42/EEC, General data regulation protection). In France, authorisation to conduct research and favourable opinion were delivered by the National Agency for the Safety of Medicines and Health Products (ANSM) in September 2020, and by the Ethics Committee for the Protection of Persons of the North West Region 1 (CPP Nord Ouest 1) in November 2020, respectively. In Germany, exemption from the authorisation requirement was granted by the Federal Institute for Drugs and Medical Devices (BfArM) in April 2020, and favourable opinion was delivered by the Ethics Committee of the coordinating centre (Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen) in September 2020, and then by each investigating centre. Written informed consent was obtained from all patients before inclusion into the trial which included for the publication of photographs. The trial was registered with ClinicalTrials.gov (number NCT04 613 687).

Results

A total of 52 patients with VLUs were included and treated with the evaluated compression system for 43 days (median value, IQR: 36; 43). During the course of the study, seven patients were registered as premature

Table 5. Ankle and calf circumferences reduction associated with oedema resolution

	Initial visit		Last visit		Reduction	
	n	Mean±SD	n	Mean±SD	n	Mean±SD
Calf circumference, cm	17	36.4±5.1	16	35.2±2.7	16	2.0±2.8
Ankle circumference, cm	17	23.7±1.0	17	22.4±1.6	17	1.3±1.5

SD—standard deviation

study discontinuation: one due to withdrawn consent, five due to the occurrence of an AE, and one due to permanent treatment discontinuation (i.e., with an interruption >7 consecutive days). In accordance with the study statistical analysis protocol, the premature study discontinuation visits were reclassified at the closest visits (two being at week 6, one without planimetry).

Characteristics of patients and ulcers

The included cohort, with a mean age of 75.4±13.0 years, consisted predominantly of outpatients (96%), and slightly more women (52%) (Table 2). Patients typically had multiple comorbidities, including high blood pressure (69%), obesity (31%) and diabetes (21%).

Clinical signs of venous disease were very prevalent (90%): oedema (58%), hyperpigmentation (52%) and stasis dermatitis (50%) being the most common (Table 3). Patients presenting with the recruited leg ulcers had a mean ABPI value of 1.1±0.1, and their wound characteristics were those which are commonly encountered in this wound community. The majority of the ulcers were located on the malleolus area (54%), relatively recent (<6 months, 63%) but recurrent (62%, with a median time to relapse of 13 months, IQR: 3; 34), of small wound area (<10cm², 77%), predominantly covered by a granulation tissue (77% of the wound bed on average) and moderately exudative (52%), with an impaired periwound skin condition (56%).

Before inclusion, 42 patients (81%) had already been treated by compression therapy: 28 were prescribed multicomponent bandages, six compression hosiery, five short stretch bandages and three long-stretch bandages. For the majority of these patients, wearing these previous compression systems was associated with pain (24/42, 57%) and difficulties in wearing shoes (25/42, 60%), while itching, heat sensations and constrained ankle mobility were reported in 45% (19/42), 36% (15/42) and 29% (12/42), respectively.

According to the EQ-5D-5L questionnaire completed at baseline, a 'moderately', 'severely' or 'completely/extremely' impaired HRQoL was reported in terms of pain or discomfort by 36 patients (69%), affected mobility by 27 (52%), anxiety or depression by 19 (37%), problems with usual activities by 17 (33%) and problems with self-care by 12 patients (23%). The mean global health value, evaluated with the visual analytic scale (VAS), was 63.5±19.2 for the cohort.

Local wound care

At the initial visit, physicians performed a wound debridement in 30 patients (58%), and applied an absorbent dressing in 36 (69%), a contact layer in nine (17%) or another type of dressing in seven (13%).

Table 6. Changes in patients's HRQoL

	Initial visit	Final visit
Mobility, n (%)	n=46	n=46
I have no problems in walking about	14 (30.4)	18 (39.1)
I have slight problems in walking about	8 (17.4)	9 (19.6)
I have moderate problems in walking about	15 (32.6)	13 (28.3)
I have severe problems in walking about	8 (17.4)	5 (10.9)
I am unable to walk about	1 (2.2)	1 (2.2)
Self-care, n (%)	n=46	n=46
I have no problems washing or dressing myself	29 (63.0)	35 (76.1)
I have slight problems washing or dressing myself	6 (13.0)	2 (4.3)
I have moderate problems washing or dressing myself	9 (19.6)	7 (15.2)
I have severe problems washing or dressing myself	2 (4.3)	1 (2.2)
I am unable to wash or dress myself	0	1 (2.2)
Usual activities, n (%)	n=46	n=45
I have no problems doing my usual activities	22 (47.8)	25 (55.6)
I have slight problems doing my usual activities	9 (19.6)	7 (15.6)
I have moderate problems doing my usual activities	8 (17.4)	8 (17.8)
I have severe problems doing my usual activities	6 (13.0)	3 (6.7)
I am unable to do my usual activities	1 (2.2)	2 (4.4)
Pain/discomfort, n (%)	n=46	n=46
I have no pain or discomfort	5 (10.9)	14 (30.4)
I have slight pain or discomfort	9 (19.6)	13 (28.3)
I have moderate pain or discomfort	22 (47.8)	12 (26.1)
I have severe pain or discomfort	9 (19.6)	7 (15.2)
I have extreme pain or discomfort	1 (2.2)	0 (0.0)
Anxiety/depression, n (%)	n=46	n=46
I am not anxious or depressed	20 (43.5)	30 (65.2)
I am slightly anxious or depressed	10 (21.7)	6 (13.0)
I am moderately anxious or depressed	11 (23.9)	7 (15.2)
I am severely anxious or depressed	5 (10.9)	3 (6.5)
I am extremely anxious or depressed	0 (0.0)	0 (0.0)
Index value	n=45	n=45
Mean±SD	0.75±0.24	0.82±0.22
Min; max	0.2; 1.0	0.2; 1.0
Visual analogue scale of health (from 0 the worst to 100 the best imaginable)	n=46	n=44
Mean±SD	64.8±19.7	66.1±23.2
Min; max	20.0; 100.0	1.0; 100.0

SD—standard deviation

Table 7. Evaluation of the application of the compression system by both physicians and nurses

	First application by physicians	All applications by physicians*	All applications by nurses	All applications by nurses and physicians
Before the bandage application	**n=52**	**n=178**	**n=681**	**n=859**
Skin care protection	7 (13%)	37 (21%)	200 (29%)	237 (28%)
Bony protection	6 (12%)	26 (15%)	71 (10%)	97 (11%)
Leg shaping	1 (2%)	3 (2%)	37 (5%)	40 (5%)
Conformability to the leg	**n=52**	**n=178**	**n=678**	**n=856**
Very good	14 (27%)	49 (28%)	284 (42%)	333 (39%)
Good	31 (60%)	112 (63%)	383 (56%)	495 (58%)
Bad	7 (13%)	17 (10%)	10 (1%)	27 (3%)
Very bad	0 (0%)	0 (0%)	1 (0%)	1 (0%)
Ease of application	**n=52**	**n=178**	**n=686**	**n=864**
Very easy	25 (48%)	78 (44%)	366 (53%)	444 (54%)
Easy	25 (48%)	92 (52%)	312 (46%)	364 (44%)
Difficult	2 (4%)	8 (4%)	8 (1%)	16 (2%)
Very difficult	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*including the first application

Wound healing progression

Throughout the 6-week study period, the wound areas of the treated cohort progressively decreased (Table 4), to reach a median RWAR at the final visit (primary outcome) of 91.1% (IQR: 39.4; 100.0). A wound closure was achieved in 18 patients (35%), after a mean period of treatment of 33±12 days (range: 14–45 days). For the 34 remaining patients, at the last available visit the investigators evaluated an overall wound healing improvement in 27 patients (52%), a stagnation in two (4%) and a deterioration in four (8%) (evaluation was missing for one patient who removed his consent, 2%). A RWAR ≥40% at week 4, predictive of complete healing at 12 weeks, was also reported in 32 patients (62%).

Oedema

Among the 30 patients who had oedema diagnosed at the initial visit, 17 (57%) had no more oedema at the last visit available. The oedema resolution was associated in these patients with a reduction of the circumference of both the calf and the ankle, of 2.0±2.8cm and 1.3±1.5cm, respectively (Table 5). Of the 13 patients who still had oedema at their last available visit, three had their oedema resolved at the first follow-up visits but then it returned later, and three patients did not complete their six weeks of treatment (one due to wound healing, and two due to premature study discontinuation).

Quality of life

At the final visit, a substantial improvement in the HRQoL was registered by the 46 patients who completed the EQ-5D-5L questionnaire both at the initial and final visit, with notably a 41% reduction in the number of patients who expressed 'moderate' to 'extreme' pain/discomfort, a 38% reduction of the patients who reported being 'moderately' to 'extremely' anxious or depressed and a 21% reduction of the patients who had 'moderate' or 'severe' problems in walking (Table 6).

The index value of EQ-5D-5L increased from 0.75±0.24 at baseline to 0.82±0.22 at the last visit. This increase was observed both in the cases of healed and open ulcers at the final visit (from 0.80±0.19 to 0.86±0.21 and from 0.72±0.26 to 0.80±0.23, respectively). The global patient health score, evaluated with the VAS scale, also increased on average from 64.8±19.7 at baseline to 66.1±23.2 at the final visit. Of note, the six patients who did not complete their questionnaire included three premature study discontinuations, one patient who healed at week 2 and two patients who were treated and followed up over the six weeks.

Evaluation of the application of the compression system

During the 6-week study period, both dressings and bandages were changed on average every 2–3 days (minimum–maximum: once-a-week–once-a-day), and a mean number of 19±11 bandages were applied per patient (minimum–maximum: 2–44). Before the bandage application, physicians and nurses documented skin care or skin protection in 28% of the visits, protection of bony prominences in 11% and leg-shaping in 5% (Table 7). Both evaluated the bandage to have a 'very good' or 'good' conformability to the leg and to be 'very easy' or 'easy' to apply in the large majority of the cases, since the first application.

Adherence to the compression therapy

During the first week of the study, the evaluated compression system was reported to be worn 'every day all the time' by 44 patients (85%), 'as often as possible' by five (10%) and 'from time to time' by two (4%) (evaluation was missing for one patient, 2%). A similar

high level of adherence to compression therapy was recorded throughout the duration of the study (with 43 patients reporting wearing their compression system 'every day, all the time' at all investigator visits) and further supported by the fact that the compression system was 'still in place' at 567 of the 790 follow-up visits documenting it (72%). The compression system was then evaluated to be 'very easy' or 'easy' to remove by the nurses and physicians (561/567 and six missing data). When the bandage was not in place, it was most often because the patient had removed it before the arrival of the nurse (n=147 visits). A slippage or a lack of hold of the bandage was also reported at 34 of the 790 visits (4%), mostly during the first week.

Patient acceptability of the compression system

After wearing the new compression system day and night for one week, the majority of patients reported 'no' or 'mild' pain (73%), 'no' or 'mild' itching sensation (73%) and 'no' or 'mild' feeling of heat (79%). The patients also reported that they had a 'very good' or 'good' ankle mobility (85%), it was 'very easy' or 'easy' to wear shoes (77%) and they felt 'very comfortable' or 'comfortable' (79%) with this new compression system (Table 8). At the final visit, similar results were reported and an overall evaluation showed the majority of the patients were 'satisfied' or 'very satisfied' with their compression system (73%), while three patients (6%) were only 'moderately satisfied' and four (8%) were 'not satisfied' at all (missing data for seven patients, 13%). Of note, there were three missing questionnaires at week 1 from patients registered as premature study withdrawal and five missing questionnaires at the last visit: three from patients registered as premature study withdrawal, one from a patient with a healed ulcer and one from a patient followed up to week 6 (with a 93% RWAR and good acceptability at week 1). Additional missing values were missing responses to a specific question.

Patient satisfaction in comparison with previous compression system

Of the 42 patients who had already been treated by compression therapy prior to the start of the study, after wearing the new system for one week, half of the patients evaluated their comfort and ankle mobility better with the new system than with their previous one, and 25 patients found it easier to wear shoes (Fig 2). At the final visit, these evaluations were further supported with 24 patients expressing better overall comfort and satisfaction with the new system, seven similar outcomes, and six less comfort and satisfaction (the data were missing for five patients).

Tolerance of the compression system and AEs

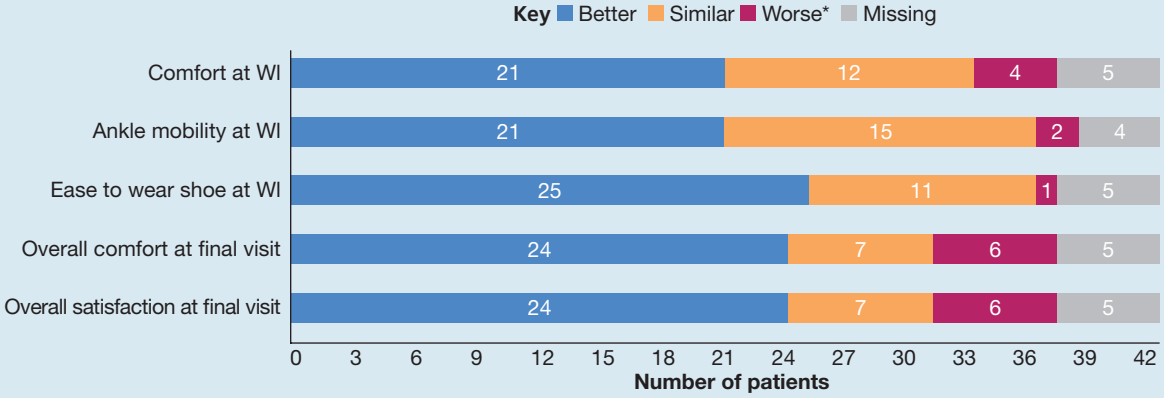
During the course of this study, 27 AEs were documented in 18 patients, including notably:

- Five serious AEs, not related to the investigating compression system and/or its procedure, which

Table 8. Patient acceptability after wearing the new compression system for one week

	After wearing the compression system for one week (n=52)	Last visit evaluation (n=52)
Pain, n (%)		
None	33 (63)	33 (63)
Mild	5 (10)	4 (8)
Moderate	7 (13)	6 (12)
Severe	3 (6)	4 (8)
Excruciating	0 (0)	0 (0)
Missing	4 (8)	5 (10)
Itching sensation, n (%)		
None	30 (58)	32 (62)
Mild	8 (15)	5 (10)
Moderate	8 (15)	6 (12)
Severe	3 (6)	4 (8)
Very severe	0 (0)	0 (0)
Missing	3 (6)	5 (10)
Heat feeling, n (%)		
None	40 (77)	38 (73)
Mild	1 (2)	1 (2)
Moderate	4 (8)	4 (8)
Intense	3 (6)	3 (6)
Very intense	1 (2)	0 (0)
Missing	3 (6)	6 (12)
Ankle mobility, n (%)		
Very good	19 (37)	21 (40)
Good	25 (48)	20 (38)
Poor	5 (10)	5 (10)
Very poor	0 (0)	1 (2)
Missing	3 (6)	5 (10)
Ease to wear shoes, n (%)		
Very easy	16 (31)	16 (31)
Easy	24 (46)	26 (50)
Difficult	6 (12)	4 (8)
Very difficult	2 (4)	1 (2)
Missing	4 (8)	5 (10)
Comfort, n (%)		
Very comfortable	13 (25)	17 (33)
Comfortable	28 (54)	24 (46)
Uncomfortable	5 (10)	3 (6)
Very uncomfortable	2 (4)	3 (6)
Missing	4 (8)	5 (10)
Overall satisfaction, n (%)		
Very satisfied		15 (29)
Satisfied		23 (44)
Moderately satisfied		3 (6)
Not satisfied		4 (8)
Missing		7 (13)

Fig 2. Patients' evaluation of the new compression system compared with the previous compression system they had worn. WI—week one



*Nine patients in total judged the previous bandage better than the new one. These patients used different bandage before inclusion: compression hosiery (one patient), short-stretch bandage (four patients), multi-layer bandage (four patients)

occurred in four patients and led to one premature study discontinuation (a case of Covid-19 infection)

- Nine non-serious AEs which were judged to be related to the investigating medical device and/or to the procedure of use and occurred in seven patients during the first weeks of the study:
  - o Five AEs of moderate intensity reported in four patients: two cases of 'allergy' and two cases of pruritus, one associated with pain, which led to a permanent study discontinuation for the patients
  - o Four new wounds reported in three patients, and described as events of mild intensity most likely due to slippage of the compression system or incorrect application of the self-grip device and friction of the skin with the bandage. For two patients, these wounds, documented at the first investigating visit, were resolved before the end of the study period. For the third patient, the wounds documented at the first and second visits were reported as still ongoing at the last visit.

Overall appreciation of the compression system by the participating physicians

At the final visit, the investigators reported being overall 'very satisfied' with the evaluated compression system in 24 cases (46%), 'satisfied' in 22 cases (42%), 'moderately satisfied' in two cases (4%) and 'not satisfied' in four cases (8%). For 25 of the 27 patients (93%) who completed the 6-week study period without wound closure, the investigators specified that they would continue to use the compression system in the future.

Discussion

The results of this clinical trial showed for the first time the good efficacy, acceptability and safety of a new multicomponent system in one bandage in the treatment of patients with VLUs.

The efficacy of the evaluated compression system in promoting rapid wound healing of VLUs was illustrated by a marked wound closure rate of 35% after 6 weeks of treatment, and an overall improvement of the wound healing process in 87% of the treated patients, as reported by the clinicians and corroborated by high RWAR values at the final visit. In addition, as percentage of RWAR was shown to be a marker to predict longer-term outcomes of complete healing,[36] a high probability of healing by week 12 can be expected in 62% of the patients who had a RWAR≥40% at week 4. Except for a high recurrence rate, which is common in this indication, the ulcers included in this study were overall of good healing prognosis due to their relatively recent duration and small size, and quite representative of the wounds usually reported in the literature or treated in the community.[25,29,37] Although it is not possible to compare the results of different studies to each other, due to the many variables that can influence the clinical outcomes, it can be noted that most clinical studies assessing multicomponent bandages, short-stretch bandages, or compression hosiery reported wound closure rates around 20–30% after 6 weeks of treatment, 40–60% after 12 weeks, 65–75% after 24 weeks and 75–80% after a year.[16–18,20,21,25,29,38] Therefore, in light of the results usually reported in the literature, in particular in studies where the included ulcers had similar wound area, duration and recurrence rate to those reported here,[21,25,29,37] the efficacy of the evaluated compression system seems promising. These results, showing promotion of the healing of VLUs, also make sense considering the previous evidence demonstrating that the continuous high working pressures, moderate resting pressures, and sustained static stiffness index ≥10mmHg achieved with the evaluated new system were similar to those of a two-layer multicomponent bandage system widely used for VLUs, while both systems were worn day and night by healthy volunteers.[24] Although in the present clinical

trial, pressure interfaces were not measured after application of the bandage, the achievement of effective pressures can be reasonably assumed considering the high healing rate and wound healing improvement obtained after 6 weeks of treatment. Besides, the visual indicator printed on the evaluated bandage and also displayed on the two-layer multicomponent system has been previously shown to help healthcare professionals confidently and consistently apply the intended effective pressures from the first applications.[21,24–27]

Previous research has established that high compression therapy, by reducing venous reflux, has been useful in promoting the healing of VLUs and reducing lower limb oedema.[5,16,18,39] In this trial, the resolution of oedema was determined by the disappearance of the clinical sign identified at baseline (i.e., Godet's sign), and further corroborated by the reduction of the circumferences of both the calf and the ankle in these patients. However, the satisfactory results on this rapid reduction of oedema should not overshadow the very present CVI in these patients and the constant risk of overflow of the venous and lymphatic system, but rather underline the importance of appropriate application of the compression system and good adherence throughout the course of the treatment.

During the study implementation, the investigating teams received training on the application technique of the evaluated bandage and the community nurses received the bandage instruction leaflet and had access to a video presentation of the application, if needed. The spiral technique, with an overlap of the bandage and the help of a visual indicator is one of the simplest techniques to apply a bandage (compared, for example, with the Pütter or Sigg techniques that require more time to master).[40] Unsurprisingly, both physicians and nurses evaluated the application of the new system 'very easy' or 'easy' in the majority of cases, and since its first application. The ease of this application does not, of course, exempt healthcare professionals from preparing the leg for compression therapy, providing skin care or protection, bony prominence protection or leg-shaping when necessary, as performed in this trial. These preliminary steps, recommended for any compression system, are essential to safe application and avoiding creation of zones of overpressure, on malleolus or tibial crest, or friction on skin that is already extremely fragile in patients who are often polysensitised after years of treatment. It can also be necessary to obtain an effective compression of the area under the malleolus, or when the shape of the limb would alter the intended pressure gradient. Due to the conformability of the bandage to the leg, and its good holding over time, only a few bandage slippages were documented between the planned visits of this study. These slippages, which were mostly reported during the first week, may be partly explained by the efficacy of the system in reducing oedema, and partly by a rapid learning curve of the application technique and fixation of the bandage.

The fact that the compression system was reported as being still in place at most of the follow-up visits is indicative of the good holding of the bandage but more importantly of the good adherence of the patients to their compression therapy. With 83% of the patients reporting wearing their compression system 'every day, all the time' at all investigator visits, a good level of adherence to compression therapy was achieved in this trial, but as patients may over-declare their adherence to their treatment, this additional parameter on the bandage presence confirms that the bandage was indeed worn day and night, every day between two visits.

Patient adherence is known to be critical in the success of compression therapy and, in this trial, wound closure was clearly related to the full adherence of the patients to compression therapy. In the literature, most of the time, patients justify their non-adherence by discomfort or pain.[20,23] In the worst cases, they ask to change their treatment or discontinue their therapy. Over a one-year follow-up period, Abshy et al. reported for example that a change of treatment was requested by 28% of the patients treated with 4-layer multicomponent bandages and 38% of those treated by 2-layer compression hosiery, due to discomfort of the compression system, lack of adherence, ulcer deterioration or another reason.[20] At least one non-serious AE event was reported in 63% of the patients and 76% of these events (n=617) were related to the compression system.[20] In the present trial, seven patients withdrew prematurely, four due to non-serious AEs related to the evaluated compression system, during the first two weeks of the treatment. No serious AE related to the system was reported. The majority of the patients judged that wearing the new compression system day and night was 'comfortable' or 'very comfortable', and associated with 'no' or 'mild' pain, heat or itching sensation. The compression system in one bandage allowed good ankle mobility and the patient was able to easily wear shoes. Eight of the ten patients who were under compression therapy for the first time had positive feedback regarding all the acceptability parameters assessed, while half of the patients who had previously worn other compression systems expressed their preference for the evaluated system, in terms of overall comfort and satisfaction but also for the ease of wearing shoes. Better patient acceptability with the multicomponent system in a single bandage than with a two-layer multicomponent bandage system was previously evidenced in an RCT conducted with healthy volunteers,[24] but is reiterated here in patients with VLU, with or without oedema.

The improvement in comfort and in the wound healing process led to substantial improvements of the HRQoL of the patients, notably regarding discomfort and pain, problems in walking about, and anxiety and depression. Alleviating walking difficulties can be a real asset in the management of patients with VLUs, since the working pressure targeted by wearing a compression

system is achieved while the patient is walking. Any restriction of this walking (due to a constrained ankle or difficulty wearing shoes with the compression system) may reduce the effectiveness of the treatment, limit patients' daily activities and aggravate their isolation. Conversely, a marked and visible progression of the healing process can contribute to reducing the patients' concerns about their wound and encourage them to maintain a good adherence to compression therapy over longer term.

At the final visit, based not only on the results achieved in terms of wound healing, but also on the good tolerance of the bandage and the good acceptance and adherence of the patients, the clinicians reported they were 'very satisfied' or 'satisfied' with this new compression system in the majority of the cases and would continue to use it in the future.

In order to improve the management of patients with VLUs, it is nonetheless essential to encourage discussions between physicians, nurses and patients about compression and close monitoring during the first days or weeks of treatment. In this study, although few in number, most difficulties with bandage application or fixation were identified and resolved during the initial visits. Similarly, most AEs and treatment discontinuations related to the evaluated system were also recorded during the first week of treatment. Implementing a compressive therapy that is not only effective but also well tolerated and comfortable will provide a better experience for patients, building their confidence in compression therapy and securing their adherence over the medium or longer term if necessary. Finally, once such compression therapy is in place, in combination with other recommended standard wound care, it is important to reassess the wound healing progress after one month of treatment and then regularly, and to consider adjustments if the expected outcomes are not achieved.

Limitations

This clinical trial, evaluating the new compression system for the first time in patients with VLUs, was conducted in a relatively small cohort of patients without a control group. The 6-week treatment period can also be seen as too short to fully appreciate the performance of a compression system, even if this was still sufficient to achieve a marked wound closure rate and improvement in the wound healing process. The promising performance reported here needs now to be compared with that of a reference system in an RCT, ideally with a longer follow-up period, and further evaluated in a large observational study conducted in real-life settings to confirm its benefits in an unselected cohort of patients.

Conclusions

The evaluated new multicomponent compression system in one bandage was shown to be effective in healing VLUs and in reducing lower limb oedema. These results were consistent with previous evidence demonstrating the system can provide continuous high working pressure and tolerable resting pressure while being worn day and night. The bandage efficacy and the simplicity and reliability of its application were well appreciated by clinicians and nurses, while its comfort and low impact on ankle mobility and daily activities such as wearing shoes and walking were found acceptable by the patients who have shown a high level of adherence to their compressive therapy and reported rapid improvement in their HRQoL. This new compression system appears to be a viable alternative to existing compression systems. **JWC**

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References

1 Scottish Intercollegiate Guidelines Network. SIGN guidelines 120: Management of chronic venous leg ulcers: a national clinical guideline. 2010. https://tinyurl.com/2p8azhyk (accessed January 2021)
2 Haute Autorité de Santé. Quick reference guide: Managing venous leg ulcers (excluding dressings). 2006. https://tinyurl.com/yeymcvhn (accessed 19 April 2022)
3 Neumann HA, Jünger M, Mosti G et al. Evidence-based (S3) guidelines for diagnostics and treatment of venous leg ulcers. J Eur Acad Dermatol Venereol 2016; 30(11):1843–1875. https://doi.org/10.1111/jdv.13848
4 O'Donnell TF Jr, Passman MA. Editorial. J Vasc Surg 2014; 60(2 Suppl):1S–2S. https://doi.org/10.1016/j.jvs.2014.04.058
5 Raffetto JD, Ligi D, Maniscalco R et al. Why venous leg ulcers have difficulty healing: overview on pathophysiology, clinical consequences, and treatment. J Clin Med 2020; 10(1):29. https://doi.org/10.3390/jcm10010029
6 Franks PJ, Barker J, Collier M et al. Management of patients with venous leg ulcers: challenges and current best practice. J Wound Care 2016; 25(Suppl 6):S1–S67. https://doi.org/10.12968/jowc.2016.25.Sup6.S1
7 Phillips P, Lumley E, Duncan R et al. A systematic review of qualitative research into people's experiences of living with venous leg ulcers. J Adv Nurs 2018; 74(3):550–563. https://doi.org/10.1111/jan.13465
8 Barnsbee L, Cheng Q, Tulleners R et al. Measuring costs and quality of life for venous leg ulcers. Int Wound J 2019; 16(1):112–121. https://doi.org/10.1111/iwj.13000
9 Leren L, Johansen EA, Eide H et al. Prevalence and factors associated with ulcer-related pain in persons with chronic leg ulcers—an explorative study. J Clin Nurs 2021; 30(17-18):2732–2741. https://doi.org/10.1111/jocn.15787
10 Green J, Jester R, McKinley R, Pooler A. The impact of chronic venous leg ulcers: a systematic review. J Wound Care 2014; 23(12):601–612. https://doi.org/10.12968/jowc.2014.23.12.601
11 Guest JF, Fuller GW, Vowden P. Venous leg ulcer management in clinical practice in the UK: costs and outcomes. Int Wound J 2018; 15(1):29–37. https://doi.org/10.1111/iwj.12814
12 Kolluri R, Lugli M, Villalba L et al. An estimate of the economic burden of venous leg ulcers associated with deep venous disease. Vasc Med 2022; 27(1):63–72. https://doi.org/10.1177/1358863X211028298
13 Haute Autorité de Santé. Bon usage des technologies de santé. La compression médicale dans les affections veineuses chroniques [article in French]. 2010. https://tinyurl.com/mapat6ac (accessed 19 April 2022)
14 Alavi A, Sibbald RG, Phillips TJ et al. What's new: management of venous leg ulcers. J Am Acad Dermatol 2016; 74(4):643–664. https://doi.org/10.1016/j.jaad.2015.03.059

15 Rasmussen JC, Aldrich MB, Tan IC et al. Lymphatic transport in patients with chronic venous insufficiency and venous leg ulcers following sequential pneumatic compression. J Vasc Surg Venous Lymphat Disord 2016; 4(1):9–17. https://doi.org/10.1016/j.jvsv.2015.06.001
16 O'Meara S, Cullum N, Nelson EA, Dumville JC. Compression for venous leg ulcers. Cochrane Database Syst Rev 2012; 11(11):CD000265. https://doi.org/10.1002/14651858.CD000265.pub3
17 Wong IK, Andriessen A, Charles HE et al. Randomized controlled trial comparing treatment outcome of two compression bandaging systems and standard care without compression inpatients with venous leg ulcers. J Eur Acad Dermatol Venereol 2012; 26(1):102–110. https://doi.org/10.1111/j.1468-3083.2011.04327.x
18 Shi C, Dumville JC, Cullum N et al. Compression bandages or stockings versus no compression for treating venous leg ulcers. Cochrane Database Syst Rev 2021; 7(7):CD013397. https://doi.org/10.1002/14651858.CD013397.pub2
19 Iglesias C, Nelson EA, Cullum NA, Torgerson DJ; VenUS Team. VenUS I: a randomised controlled trial of two types of bandage for treating venous leg ulcers. Health Technol Assess 2004; 8(29):iii:1–105. https://doi.org/ 10.3310/hta8290
20 Ashby RL, Gabe R, Ali S et al. VenUS IV (Venous leg Ulcer Study IV) – compression hosiery compared with compression bandaging in the treatment of venous leg ulcers: a randomised controlled trial, mixed-treatment comparison and decision-analytic model. Health Technol Assess 2014; 18(57):1–294. https://doi.org/10.3310/hta18570
21 Lazareth I, Moffatt C, Dissemond J et al. Efficacy of two compression systems in the management of VLUs: results of a European RCT. J Wound Care 2012; 21(11):553–565. https://doi.org/10.12968/jowc.2012.21.11.553
22 Moffatt C, Kommala D, Dourdin N, Choe Y. Venous leg ulcers: patient concordance with compression therapy and its impact on healing and prevention of recurrence. Int Wound J 2009; 6(5):386–393. https://doi.org/10.1111/j.1742-481X.2009.00634.x
23 Le Gloanec H, Boye T, Placidi E. [Non-observance of medical compression in venous ulcers treatment] [article in French]. Phlebologie 2017; 70(2):38–48. https://tinyurl.com/4d334wee (accessed 12 April 2021)
24 Benigni JP, Badet F, Guidet B, Tacca O. Static stiffness index of two multicomponent bandage compression systems: results of a randomized controlled trial on healthy volunteers. Phlebologie 2022; 51:21–30. https://tinyurl.com/3z8pay2h (accessed 3 August 2022)
25 Benigni JP, Lazareth I, Parpex P et al. Efficacy, safety and acceptability of a new two-layer bandage system for venous leg ulcers. J Wound Care 2007; 16(9):385–390. https://doi.org/10.12968/jowc.2007.16.9.27866
26 Hanna R, Bohbot S, Connolly N. A comparison of inferface pressures of three compression bandage systems. Br J Nurs 2008; 17 Sup9:S16–S24. https://doi.org/10.12968/bjon.2008.17.Sup9.31661
27 Jünger M, Ladwig A, Bohbot S, Haase H. Comparison of interface pressures of three compression bandaging systems used on healthy. J Wound Care 2009; 18(11):474–480. https://doi.org/10.12968/jowc.2009.18.11.45000
28 Conde-Montero E, Bohbot S, Grado Sanz R et al. Association of autologous punch grafting, TLC-NOSF dressing and multitype compression therapy to rapidly achieve wound closure in hard-to-heal venous leg ulcers. JMV-Journal de Médecine Vasculaire 2020; 45(6):316–325. https://doi.org/10.1016/j.jdmv.2020.10.123
29 Stücker M, Münter KC, Erfurt-Berge C et al. Multicomponent compression system use in patients with chronic venous insufficiency: a real-life prospective study. J Wound Care 2021; 30(5):400–412. https://doi.org/10.12968/jowc.2021.30.5.400
30 Crebassa C, Allaert JF. [Venous leg ulcers treated in the community with a multicomponent compression system] [article in French]. Phlebologie 2020; 73(4):67–77. https://doi.org/10.1016/j.jdmv.2022.01.044
31 Lantis JC 2nd, Barrett C, Couch KS et al. A dual compression system: preliminary clinical insights from the US. J Wound Care 2020; 29(Suppl 9):S29–S37. https://doi.org/10.12968/jowc.2020.29.Sup9.S29
32 Greenstein E, Tickner A. Addressing compression continuity, consistency, and comfort using a dual compression system. Wound Manag Prev 2020; 66(6):4–7. https://tinyurl.com/327evfyr (accessed 15 August 2022)
33 Tai HQ, Chaen LCR, Boey J et al. A dual pressure indicator, two-layer compression system for treatment of venous leg ulcers: a review. J Wound Care 2021; 30(Suppl12): S6–S12. https://doi.org/10.12968/jowc.2021.30.Sup12.S6
34 Cheng Q, Kularatna S, Lee XJ et al. Comparison of EQ-5D-5L and SPVU-5D for measuring quality of life in patients with venous leg ulcers in an Australian setting. Qual Life Res 2019; 28(7):1903–1911. https://doi.org/10.1007/s11136-019-02128-6
35 Feng YS, Kohlmann T, Janssen MF, Buchholz I. Psychometric properties of the EQ-5D-5L: a systematic review of the literature. Qual Life Res 2021; 30(3):647–673. https://doi.org/10.1007/s11136-020-02688-y
36 Cardinal M, Eisenbud DE, Phillips T, Harding K. Early healing rates and wound area measurements are reliable predictors of later complete wound closure. Wound Repair Regen 2008; 16(1):19–22. https://doi.org/10.1111/j.1524-475X.2007.00328.x
37 Ashby RL, Gabe R, Ali S et al. Clinical and cost-effectiveness of compression hosiery versus compression bandages in treatment of venous leg ulcers (Venous leg Ulcer Study IV, VenUS IV): a randomised controlled trial. Lancet 2014; 383(9920):871–879. https://doi.org/10.1016/S0140-6736(13)62368-5
38 Stather P, Petty C, Langthorne H et al. A randomised controlled clinical trial comparing the effectiveness of bandaging compared to the JuxtaCures device in the management of people with venous ulceration: feasibility study. Phlebology 2021; 36(7):505–514. https://doi.org/10.1177/0268355520988226
39 Berszakiewicz A, Sieroń A, Krasiński Z et al. Compression therapy in venous diseases: physical assumptions and clinical effects. Adv Dermatol Allergol 2020; 37(6):842–847. https://doi.org/10.5114/ada.2019.86990
40 Dissemond J, Protz K, Moelleken M, Kröger K. Compression therapy in patients with leg ulcers – which costs do really occur? [article in German]. Dtsch Med Wochenschr 2019; 144(16):e94–e101. https://doi.org/10.1055/a-0841-9726

Reflective questions

- What outcomes do you aim for when initiating compression therapy?
- What key challenges do you face with compression therapy in patients with venous leg ulcers?
- How do you discuss compression therapy with patients?