journal of wound care JWC
VOLUME 30. NUMBER 5 MAY 2021

Multicomponent compression system use in patients with chronic venous insufficiency: a real-life prospective study

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Multicomponent compression system use in patients with chronic venous insufficiency: a real-life prospective study

Objective: Compression therapy is the cornerstone of therapeutic management of patients with chronic venous insufficiency (CVI). This study aimed to evaluate the efficacy and safety of a multicomponent compression system in an unselected population of patients with CVI problems under real-life conditions.
Method: A prospective, multicentre, observational study with a multicomponent two-bandage compression system (UrgoK2, Laboratoires Urgo, France) was conducted in 103 centres in Germany. Main outcomes included wound healing rate, wound healing progression, assessment of oedema and ankle mobility, local tolerability and acceptance of the compression therapy.
Results: A total of 702 patients with venous leg ulcers (VLU) and/or with lower limb oedema due to CVI were treated with the evaluated system for a mean (±standard deviation) duration of 27±17 days. By the last visit, 30.9% of wounds had healed and 61.8% had improved. Limb oedema was resolved in 66.7% of patients and an improvement of ankle mobility was reported in 44.2% of patients. The skin condition under the compression therapy was also considered as improved in 73.9% of patients and a substantial reduction of pain was achieved, both in number of patients reporting pain and in pain intensity. Compression therapy with the evaluated system was 'very well' or 'well' tolerated and 'very well' or 'well' accepted by >95% of patients. These positive outcomes were in line with the general opinion of physicians on the evaluated compression bandages, which were judged 'very useful' or 'useful' for >96.6% of patients. Similar results were reported regardless of the treated condition, VLU and/or limb oedema.
Conclusion: Real-life data documented in this large observational study of non-selected patients receiving compression therapy in daily practice confirm the benefits and safety profile of the evaluated compression system. This study also confirms the high-level of performance and acceptability of the system, regardless of the characteristics of the wounds or patients at initiation of the treatment. The data support the use of this multicomponent compression system as one first-line intervention in patients with symptoms caused by CVI.
Declaration of interest: This study was supported by a grant from Laboratoires Urgo. UM is an employee of Laboratoires Urgo. MS, KCM, CEB, SL, SE and JD provided advisory and speaking services to pharmaceutical and other healthcare organisations including, but not limited to, Laboratoires Urgo. Data management and statistical analyses were conducted independently by INPADS GmbH, Germany.

chronic venous insufficiency • compression therapy • leg ulcers • lower limb oedema • observational study • oedema • wound • wound healing

Chronic venous insufficiency (CVI) of the lower limbs is a common condition affecting 5–30% of the adult population worldwide, with a prevalence that is consistently increasing with age.[1–5] Caused by functional abnormality of the venous system, CVI encompasses the more advanced and severe stages of chronic venous disease (CVD), from oedema and skin changes to active leg ulcers (stages C3 to C6 of the CEAP (clinical, etiological, anatomical and pathophysiological) classification, respectively).[6,7]

Various symptoms, such as feelings of tightness, itching, muscle cramps, swollen legs or pain when standing or walking, manifest themselves along with CVD; then as the disease progresses, with CVI, with increasing intensity over time.[3] However, because these symptoms can be initially overlooked by patients and healthcare providers, it is suspected that CVI may be diagnosed too late in a number of cases.[8,9] Improperly treated, this chronic and disabling disease progresses and gradually impairs the health-related quality of life (QoL) of patients, who may experience substantial pain, reduced mobility, increased anxiety, depression and social isolation.[10–15]

The ultimate stage of CVI, according to the CEAP classification (C6), i.e., the venous leg ulcer (VLU), can often take several months or even years to heal; and only 30–75% of patients seem to achieve wound closure after six months of treatment, depending on the severity of the ulcer and the patients' health status.[16,17] The high rate of complications associated with these VLUs, such as local wound infection, lower

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limb cellulitis or contact dermatitis, can cause further delay to an already slow healing process.[18] In addition, with recurrence rates of 20–50% within one year post-healing, the chronicity of these wounds eventually entails life-long patient management.[19] Ultimately, the management of CVI constitutes a significant burden on healthcare systems and health economics, representing 1–2% of the healthcare budget in the US and in European countries.[20,21] The mean total cost of a VLU, estimated for example in Germany at around €9600 per year and per patient while including essentially direct costs, supports the need for early and appropriate management of these patients.[15]

The initial management of CVI involves, after adequate diagnosis, conservative measures to reduce symptoms such as oedema, to prevent disease progression and to heal the leg ulcer when present, in order to prevent the development of secondary complications.[8] Compressive therapy is the mainstay of all therapeutic strategies due to its ease of use, non-invasive nature and efficacy in counteracting the pathophysiological mechanism of CVI.[6,7,18,22–26] The efficacy of compression therapy depends mainly upon the applied pressure and stiffness of the compression system. According to guidelines, and based on systematic reviews, high-compression therapy—applying 40mmHg at the ankle—is the first-line option in the acute decongestion phase of oedema and for the treatment of active VLU, while graduated compressive hosiery is usually recommended for the maintenance stage of venous oedema and to prevent recurrence of VLU in patients where leg ulcer closure has been achieved.[6,7,18,23–28]

Among the various systems available for applying high compression, multicomponent systems have been shown to be more effective than single component systems, and two-layer component systems to perform as well as four-layer systems.[27–29] Multicomponent systems containing an elastic bandage are also reported to be more effective than those composed mainly of inelastic constituents.[27] Although the systems appear to be similar when considering effectiveness, they can differ significantly in comfort, patient acceptability and adherence to treatment.[29,30]

UrgoK2/UrgoKTwo bandages (Laboratoires URGO, France) is a multicomponent high-compression system indicated for the treatment of VLU, venous oedema and lymphoedema which require full compression, i.e. around 40mmHg at the ankle. It has been previously shown to be easy to apply due to the visual guide printed on each bandage, with therapeutic pressure achieved from the first application and sustained for up to seven days.[31–33] Its clinical efficacy on the treatment of VLU has been evaluated in a European randomised controlled trial (RCT) conducted in France, Germany and the UK.[29] The results of this Odyssey study, carried out on 187 patients and followed-up during 12 weeks of treatment with either the two-layer multicomponent compression system or with a four-layer compression system, demonstrated the clinical efficacy and good patient tolerance of the two-layer compression system, as well as an easier application than that of the reference system.[29]

While a high level of clinical evidence is required to establish the performances of any treatment, real-life data are also sought to ensure the appropriate use of available treatments and to confirm their performance and acceptability in current practice. Thus, the aim of this study was to document the performance, local tolerability and acceptability of the two-layer multicomponent compression system on a large, unselected cohort of patients with VLU and/or lower limb oedema caused by CVI, treated under real-life conditions.

Methods

Study design and patients

This observational study was a prospective, multicentre study conducted with physicians (general practitioners, phlebologists, surgeons, dermatologists, vascular surgeons and internists) located across Germany.

Any patient with a VLU and/or an oedema caused by CVI that the participating physician had decided to treat with the compression system between September 2010 and September 2011 was eligible for inclusion. In the case of patients with multiple VLUs, the largest wound was recommended to be selected for the evaluation. It was expected that the precautions of use and contraindications specified in the manufacturer's instructions for use of the compression system would be followed. All decisions regarding diagnosis and therapy were made exclusively by the treating physician. No recommendations were made to them regarding concomitant treatments. Patients were followed up in the outpatient setting or during home visits for a maximum duration of six weeks, and with a maximum of four documented visits. The participating physicians could discontinue the use of the evaluated compression system and the patient's participation in the study at any point of the follow-up as their therapeutic procedure was not influenced in any way by this observational study.

Evaluated compression system

The UrgoK2 multicomponent compression system evaluated in this study has been CE-marked since 2005 and available in Germany since 2009. It combines a padded inelastic bandage with short elongation (with viscose-polyester cotton padding on a knitted polyamide-elastane layer), providing compression, protection and absorption, and a cohesive elastic bandage with lengthy elongation, made of acrylic, polyamide and elastane.

The system is compatible with day and night wearing. The high working pressure provided by the compression system, in combination with the action

of the calf muscle, creates a massage effect, assisting venous flow and reducing oedema levels, while the low resting pressure provided maintains the improved blood flow. Each bandage layer of the system displays a unique visual indicator in the form of a printed ellipse that expands into a circle when the correct pressure level is applied. This visual indicator guides both the proper stretching and overlapping of the bandages, thus facilitating their application and the reproducibility of the procedure, while guaranteeing the application of the required pressure (~40mmHg at the ankle).[31–37] The bandages can stay in place for up to seven days.[29,31,37]

In this observational study, the bandages were expected to be applied, and the frequency of change to be carried out, according to the manufacturer's instructions for use.

Outcomes and assessments

At the initial visit, the relevant demographic information (sex, age, body mass index (BMI)) and medical history of the patient were recorded along with their leg characteristics, wound characteristics when a wound was present, and the previous compression therapy used by the patient. The circumference of the ankle was measured with a tailor meter.

At each follow-up visit, the investigators documented the change frequency of the compression system since the last visit, ankle circumference and mobility, the presence of oedema, skin condition, wound characteristics where relevant, local tolerance of the compression therapy, and its acceptance and perception by the patient (i.e., feelings of discomfort such as tingling, itching, sensation of warmth or cold, sweating, tightness, constriction, bandage slippage).

The outcomes documented in the final evaluation visit included:

- Treatment and evaluation duration (in days)
- Frequency of compression system changes
- Oedema resolution, improvement of the ankle circumference and mobility
- Overall wound healing progression ('wound healed', 'greatly improved', 'slightly improved', 'unchanged', 'slightly deteriorating' or 'greatly deteriorating'), and reduction of wound length, width and area (in cm and cm^2) since the initial visit
- Change in skin condition under the compression therapy ('improved', 'unchanged', 'deteriorating')
- Pain reduction during the course of the study
- Local tolerance and acceptability of the evaluated system by the patients, including their perception when wearing it
- Evaluation by the physicians of the usefulness of the evaluated multicomponent compression system ('very useful', 'useful', 'hardly useful', 'not useful'), their general opinion on the performance of the system in relation to their previous experience with other compression therapy devices ('better', 'similar' or 'worse'), and the factors that influence their choice of one compression system over others (clinical evidence, ease of handling, patient comfort, wearing duration, possibility of self-care, recommendations from colleagues, manufacturer's information, washability, cost-effectiveness).

Pain was assessed at the initial and final visits using a visual analogue scale (VAS) from 0 for 'no pain' to 10 for 'worst possible pain', and through a 'yes' or 'no' question, to which was added a question on pain intensity ('mild', 'moderate', 'strong') in case of a positive answer.

The local tolerability of the compression therapy was assessed at each visit according to three gradations defined as followed:

- 'Very good': no local tolerance problem during the evaluation period
- 'Good': no more than one temporary tolerance problem of low or moderate intensity during the evaluation period
- 'Poor': more than one occurrence, or at least one persistent tolerance problem, or one severe but temporary tolerance problem.

The acceptance of the compression therapy was assessed at each visit according to the four following gradations:

- 'Very good': the patient feels the compression system, but does not have any unpleasant feeling
- 'Good': the compression system sometimes disturbs the patient but does not interfere with everyday activities
- 'Moderate': the compression system is often uncomfortable during the day and disturbs everyday activities
- 'Poor': the compression system is often or always uncomfortable during the day, disturbs the patient's activities of daily living and sleep.

Data management

The data collected during the study were documented by the investigators in a standardised electronic Case Report Form (eCRF). All the physicians received specific access codes to enable them to enter their data with a patient identification number. All personal data on the patients were only accessible to the treating physicians. The data collection form guaranteed all data protection requirements for the individual patient, since only pseudonymous data were made available for the evaluation. The electronic system performed automatic checks for data completeness and inconsistency, and incorrect entries could be corrected directly by the physicians.

The data management and quality assurance of the study were carried out by an independent contract research organisation (INPADS GmbH, Germany) in accordance with the recommendations on planning, conducting and analysing of post-marketing surveillance studies of the Federal Institute for Drugs and Medical Devices.[38]

Statistical analysis

The estimation of the cohort size required for this observational study was based on the literature and on experience from previous clinical studies, in order to allow a pragmatic evaluation of the compression system's performance in a sufficiently diverse and representative cohort of patients and physicians.[15,29,31–33,39]

The statistical analyses were performed according to the statistical analysis plan, by an independent contract research organisation (INPADS), using SAS 9.1 for Windows program (Statistical Analysis System, SAS Institute, US). The biometric analyses and bandages performance evaluations were descriptive, and no statistical tests were used. Values were reported as mean ±standard deviation (SD); median and interquartile range (IQR), or count and percentage. Efficiency and safety analyses included all patients for whom the initial visit and the final visit were documented, even if some questions during these visits were not answered. Missing values were listed in the statistical tables and not removed.

Due to reduced numbers of patients at interim visits, changes in outcomes, including the four visits (initial, both interim and final visits), are presented for the cohort of patients who had all visits completed. Wound area was calculated using the following elliptic formula:

$$(\text{length}/2) \times (\text{width}/2) \times 3.14$$

Ethical approval

The study was conducted in accordance with the Declaration of Helsinki, the German Medical Devices Act and Federal data protection law.[40] Before their inclusion, patients were informed by their physicians about the purpose and conduct of the observational study, in particular about the processing of personal and health data in pseudonymous form, and gave their explicit oral consent to their participation in the study and to the processing of their data. Due to the non-interventional design of this study performed with a CE-marked device, used according to the manufacturer's instructions, no ethics committee or authority approvals were required, as this type of observational study presents no particular harm to or benefits for the patients, provided they are treated with the appropriate standard of care as they would be in real life.

Results

Baseline characteristics of the included patients

In this observational study, a total of 721 patients with a VLU or an oedema of venous origin, treated with the evaluated compression system, were included by one of the 103 active centres. The median number of patients recruited per centre was nine (IQR: 4–9). Due to incomplete documentation, 19 files (2.6%) were excluded and the evaluations of 702 patients were taken into account in the final analyses. Patients were followed on average for 27±17 days. In addition, two interim visits, respectively performed after 7±5 days and 15±10 days of treatment, were also documented for 695 (99.0%) and 624 patients (88.9%). In total, 622 (88.6%) patients had all four visits completed and documented.

Table 1. Demographics and anamnesis of the treated patients

Patients (n=702)	
Male/Female, n (%)*	304 (43.3)/396 (56.4)
Age, years, n, (mean±SD)	
Male	292 (65.6±13.5)
Female	384 (67.8±14.9)
Body mass index, kg/m^2, n, (mean±SD)	
Male	284 (29.8±5.3)
Female	367 (29.1±6.6)
Medical/surgical history, multiple answers possible, n (%)	
High blood pressure	304 (43.3)
High blood pressure duration, years, n (mean±SD)	257 (12.9±10.0)
Diabetes, n (%)	185 (26.4)
Diabetes duration, years, n (mean±SD)	140 (10.9±7.0)
Diabetes type 2/type 1†, n, (%)	157 (84.9)/18 (9.7)
Heart disease, n (%)	99 (14.1)
Articular rheumatism, n (%)	57 (8.1)
Osteoarthritis, n (%)	34 (4.8)
Latex allergy, n (%)	1 (0.1)
Other pre-existing conditions, n (%)	195 (27.8)
History of venous conditions on study leg, multiple answers possible, n (%)	
Varicose	531 (75.6)
Phlebitis	160 (22.8)
Varicose vein surgery	96 (13.7)
Venous thrombosis	81 (11.5)
Pulmonary embolism	12 (1.7)
Ankle–brachial pressure index, n (mean±SD)	532 (1.1±0.2)
Patient mobility, n (%)	
Walking without assistance	525 (74.8)
Walking with help	158 (22.5)
Wheelchair	10 (1.4)
Bedbound	9 (1.3)

*missing data=2; †missing data=10; SD—standard deviation

Demographics and anamnesis of the treated patients are reported in Table 1. The evaluated cohort was typical of that treated with compression therapy, comprising more female patients (n=396, 56.4%), with a mean age of 66.9±14.3 years (range: 20–96 years), and patients were, on average, overweight (mean BMI 29.4±6.1kg/m^2). High blood pressure and diabetes were particularly prevalent (n=304 (43.3%) and n=185 (26.4%) patients, respectively). A history of marked CVI also characterised this cohort, with varicose veins documented in 531 (75.6%) of the patients, history of phlebitis in 160 (22.8%), of varicose vein surgery in 96

Table 2. Characteristics of the leg treated (n=702)

Characteristic	n	%
Presence of oedema		
Oedema	520	(74.1)
No oedema	171	(24.4)
Missing data	11	(1.6)
Ankle circumference (narrowest point), cm, mean±SD	690 (27.8±5.7)	
Ankle mobility	**n**	**%**
Good	386	(55.0)
Moderate	267	(38.0)
Poor	18	(2.6)
Missing data	31	(4.4)
Presence of a leg ulcer	**n**	**%**
Leg ulcer	414	(59.0)
No leg ulcer	248	(35.3)
Missing data	40	(5.7)
Ulcer characteristics	**n**	**Median value (IQR)**
Wound duration, days	407	42.0 (10.0; 122.0)
Wound length, cm	411	2.5 (1.5; 4.5)
Wound width, cm	412	2.0 (1.0; 3.2)
Wound area, cm² (calculated)	411	3.5 (1.2; 11.3)
Skin condition on a 1–5 scale	**n**	**%**
1—Healthy	67	(9.5)
2	217	(30.9)
3	206	(29.3)
4	88	(12.5)
5—Severely damaged	39	(5.6)
Missing data	85	(12.1)
Pain score on VAS, n (mean±SD)	556 (3.64±2.72)	
Presence of pain	**n**	**%**
Pain	449	(64.0)
No pain	236	(33.6)
Missing data	17	(2.4)
Intensity of pain, n=449	**n**	**%**
Mild	169	(37.6)
Moderate	203	(45.2)
Severe	66	(14.7)
Missing data	11	(2.4)

SD—standard deviation; IQR—interquartile range; VAS—Visual Analogue Scale

(13.7%) and of venous thrombosis in 81 (11.5%). At the initial visit, an ankle–brachial pressure index (ABPI) was available for 532 (75.8%) patients with an average value of 1.1±0.2. The distribution of patients according to their ABPI value is illustrated in Fig 1. The majority of the patients (n=525, 74.8%) could walk without help and 19 (2.7%) patients were mobile using a wheelchair or were bedbound.

Fig 1. Patient distribution according to their ankle–brachial pressure index (ABPI) value (n=702)

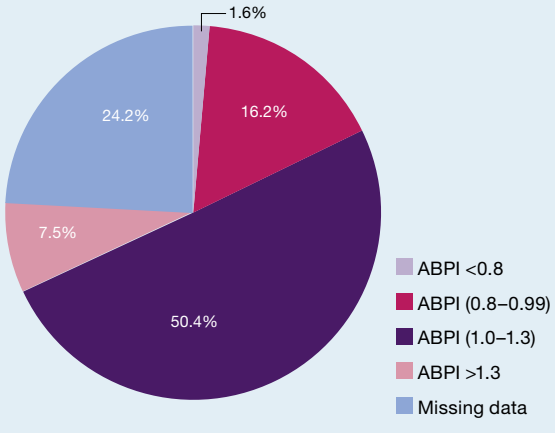


Table 3. Previous compression systems used by the patients (multiple answers possible) (n=702)

Systems	n	%
Medical compression stockings	303	(43.2)
Class 3 (34–46mmHg)	5/303	(1.7)
Class 2 (23–32mmHg)	278/303	(91.7)
Class 1 (18–21mmHg)	18/303	(5.9)
Missing data	2/303	(0.7)
Two-short-stretch bandage system	161	(22.9)
One-short-stretch bandage	130	(18.5)
Two-long-stretch bandage system	4	(0.6)
One-long-stretch bandage	32	(4.6)
Zinc paste bandages	61	(8.7)
Multicomponent bandage system	29	(4.1)

The characteristics of the leg treated with the evaluated bandages are reported in Table 2. At the inclusion visit, 520 (74.1%) patients had a leg oedema and 414 (59.0%) had a leg ulcer. Average ankle circumference was 27.8±5.7cm. Ankle mobility was rated 'good' in more than half of the patients (n=386, 55.0%). The majority of the treated ulcers were recent (50% lasted <1.5 months' duration) and of relatively small size (2.5cm×2.0cm, median values). The condition of the skin was assessed on a scale of one ('healthy') to five ('severely damaged'). The condition of the skin was rated as 'healthy' in only 67 (9.5%) of the patients. In most cases (n=423, 60.3%), the skin condition was assessed with a score of two or three. The skin was assessed as 'severely damaged' in 39 (5.6%) patients. At the beginning of the study, almost two thirds of patients (n=449, 64.0%) reported they were experiencing pain, mostly of 'moderate' or 'mild' intensity.

Finally, as reported in Table 3, before inclusion, patients had used different compression therapy systems, most often medical compression stockings

Fig 2a. Proportion of patients with oedema throughout the study period (patients completing all four visits, n=622)

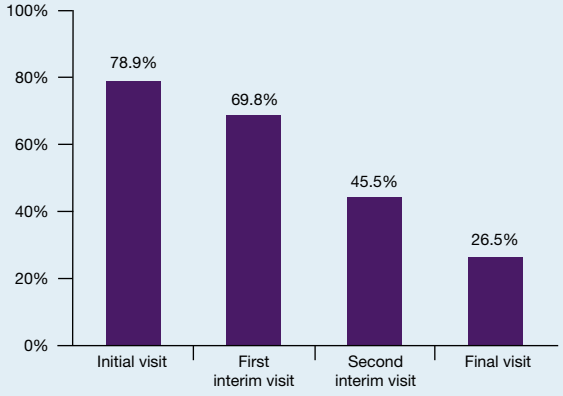
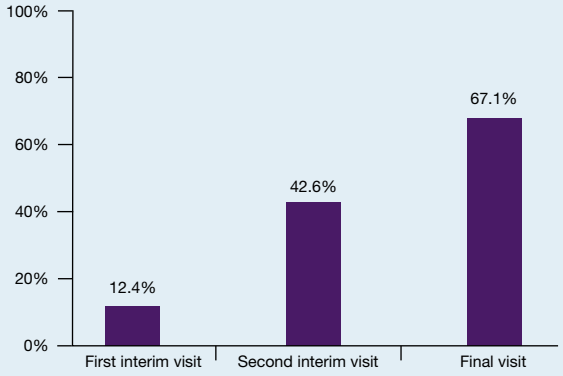
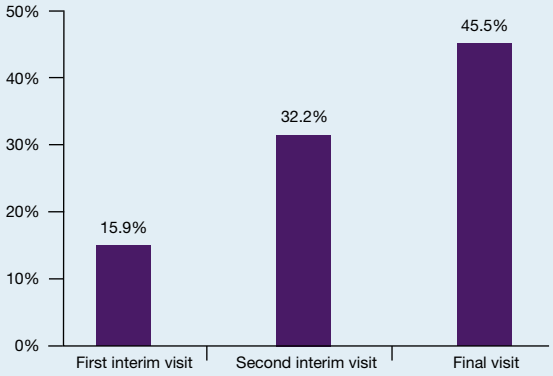


Fig 2b. Proportion of patients with resolved oedema under the multicomponent compression therapy (patients with oedema at baseline and with all four visits completed, n=491)



(n=303, 43.2%) (usually of class 2, according to the German classification) or short-stretch bandages (n=161, 22.9%).

Fig 3. Proportion of patients with improved ankle mobility under the multicomponent compression therapy (patients with a 'moderate' or 'poor' ankle mobility at the baseline visit and who had both interim visits completed, n=264)



Oedema reduction under compression therapy

During the study period, and under the evaluated compression therapy, the percentage of patients with oedema (with or without ulcer) decreased from 74.1% (n=520) at baseline to 24.6% (n=173) at the final visit. Hence, at the final visit, the oedema was resolved in 66.7% (n=347) of the patients who had an oedema at the initial visit. Fig 2a shows over time the percentages of patients with oedema (among patients who had all four visits completed, n=622). Fig 2b shows the progression of oedema resolution in patients who had an oedema at baseline and all visits completed (n=491).

Ankle circumference reduction and ankle mobility improvement

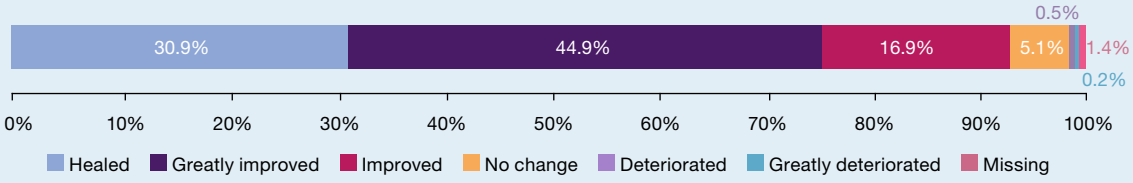
The average ankle circumference showed a continuous reduction from 27.8±5.7cm at baseline to 25.9±4.9cm at the final visit (n=702, missing data=4). Table 4 reports the changes in ankle circumference in patients who had all four visits completed (n=622). The different values calculated for each patient (the ankle circumference in the follow-up visits minus the baseline ankle circumference) also confirmed on average, and for the

Table 4. Ankle circumference of the study leg throughout the treatment period (n=622)

	Initial visit	First interim visit	Second interim visit	Final visit
Ankle circumference in cm (narrowest point)				
Mean value±SD	28.0±5.7	27.1±5.3	26.4±5.1	26.0±4.9
Median (IQR)	27.0 (24.0; 30.0)	26.0 (23.5; 29.5)	25.5 (23.0; 29.0)	25.0 (23.0; 28.5)
Missing data, n	12	0	1	3
Reduction of ankle circumference in cm (follow-up visit minus initial visit)				
Mean value±SD		–0.8±1.1	–1.5±1.6	–2.0±1.9
Median (IQR)	—	–0.5 (–1.0; 0.0)	–1.0 (–1.2; –0.5)	–1.5 (–2.6; –0.8)
Missing data, n		12	13	15

SD—standard deviation; IQR—interquartile range

Fig 4. Wound healing rate and wound healing progression with the evaluated compression system (n=414)



majority of the patients, a continuous reduction of the ankle circumference.

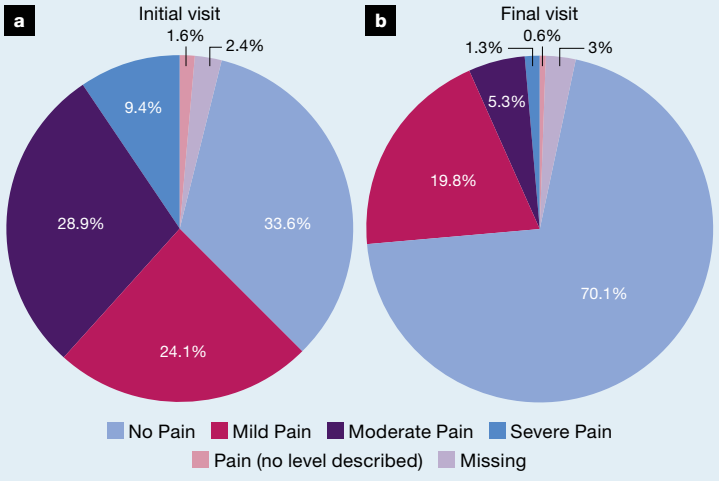
In addition, a clear improvement in patients' ankle mobility was reported during the course of the compression therapy. The percentage of patients with 'good' ankle mobility increased from 55.0% (n=386) at the initial visit to 71.4% (n=501) at the final visit, while the proportion of patients with 'moderate' or 'poor' ankle mobility decreased from 40.6% (n=285) to 28.3% (n=199). Hence, among the 285 patients who had a reduced ankle mobility ('moderate' or 'poor') at the initial visit, the proportion of patients with an improvement in ankle mobility continuously increased at each visit and reached 44.2% (n=126/285) by the final visit. Fig 3 illustrates the progression of ankle mobility improvement in patients who had a 'moderate' or 'poor' mobility at baseline and all four visits completed (n=264).

Table 5. Wound measurements at initial and final visits

Measurement	Initial visit		Final visit	
	n	Median (IQR)	n	Median (IQR)
Wound length (cm)	411	2.5 (1.5; 4.5)	409	1.0 (0.0; 2.8)
Wound width (cm)	412	2.0 (1.0; 3.2)	408	0.7 (0.0; 2.0)
Calculated wound area (cm²)	411	3.5 (1.2; 11.3)	408	0.6 (0.0; 4.1)

IQR—interquartile range; patients with healed ulcer had values equal to zero

Fig 5. Pain reported by the patients at the initial (**a**) and final (**b**) visits (n=702)



Wound healing outcomes by the final evaluation

For patients who presented with a VLU at the initial visit (n=414, 58.9%), wound closure in 30.9% (n=128) of patients and improvement in wound healing in 61.8% (n=256) of patients by the final visit was reported by the investigating physician (Fig 4). No change was reported in 21 (5.1%) patients and deterioration of the wound was reported in three (0.7%) patients. Data were missing for six (1.4%) patients.

The measurements of the wounds, when reported, also confirmed a clear reduction in wound size (Table 5). The median wound length of the ulcers decreased from 2.5cm at baseline to 1.0cm at the final visit. The median wound width decreased from 2.0cm to 0.7cm, and the wound area decreased from 3.5cm² to 0.6cm².

Improvement of skin condition

At the initial visit and the two interim visits, the physicians assessed the patient's skin condition on a scale of one ('healthy' skin) to five ('severely damaged' skin). Analysing the skin condition changes in patients who had both interim visits (n=622), the percentage of patients with a score of one or two increased from 38.1% (n=237/622) at baseline to 65.4% (n=407/622) at the second interim visit, while the percentage of patients with a score of three, four or five decreased from 49.5% (n=308/622) to 19.1% (n=119/622). Data were missing for 77 patients at the first interim visit, and for 96 patients at the second interim visit.

This development towards better skin score values in the course of the compression therapy was also confirmed at the final visit. According to the physician's final assessment, and compared with the initial visit (n=702), the skin condition was 'improved' in 519 (73.9%) patients, 'unchanged' in 142 (20.2%) patients and 'deteriorated' in three (0.4%) patients. Data were missing for 38 (5.4%) patients.

Pain reduction during the course of the study

As wound healing progressed and oedema resolved, an important reduction in pain associated with the venous disease status was reported at the final visit compared with the initial visit. This reduction was expressed both in the percentage of patients reporting pain—down from 64.0% (n=449) to 26.9% (n=189)—and in the level of pain intensity, as most patients described only mild pain at the final visit (73.5%; n=139/189) and the average pain score on the VAS scale fell by 67.0% (Fig 5 and Table 6).

Frequency of application of the compression system

Throughout the study period, the frequency of application of the compression system was documented in 1560 visits. Overall, the bandages were changed only 1–2 times a week in 806 (51.7%) visits, 3–4 times a week in 448 (28.7%), and >4 times a week in 306 (19.6%) visits.

Patient comfort while wearing the compression system

At the follow-up visits, 55.1% (n=343/622, first interim visit) to 60.9% (n=379/622, final visit) of patients reported no particular sensation while wearing the bandages. At the first interim visit, a feeling of tightness was reported by 123/622 (19.8%) patients, but as these patients adjusted to their therapy, this proportion decreased steadily to 62/622 (10.0%) at the final visit.

During the study period, wearing the compression system was also associated with a feeling of warmth in 14.6% (n=91/622, first interim visit) to 13.8% (n=86/622, final visit) of patients, and with pain, reported by 10.1% (n=63/622, first interim visit) to 7.9% (n=49/622, final visit) of patients. The other sensations mentioned by the patients are presented in Fig 6.

Table 6. Pain score on Visual Analogue Scale (VAS)

VAS score	Initial visit	Final visit	Difference (initial–final)
Patients, n	556	458	436
Mean±SD	3.64±2.72	1.15±1.86	2.44±2.45
Median (IQR)	4.0 (1.5; 5.5)	0.0 (0.0; 2.0)	2.0 (4.0; 0.0)

SD—standard deviation; IQR—interquartile range

Bandage slipping was reported by <4% of the patients (n=16/622, first interim visit, and 19/622, final visit). At the final visit, the category of patients who most frequently reported at least one feeling of discomfort was patients with oedema but no ulcer (n=143/248; 57.7%), while patients with an ulcer (with or without oedema) reported no feeling of discomfort in 68.4% of cases (n=283/414) (supplementary information on this is available from the authors).

Fig 6. Patient discomfort parameters reported at each visit (patients completing all four visits, n=622)

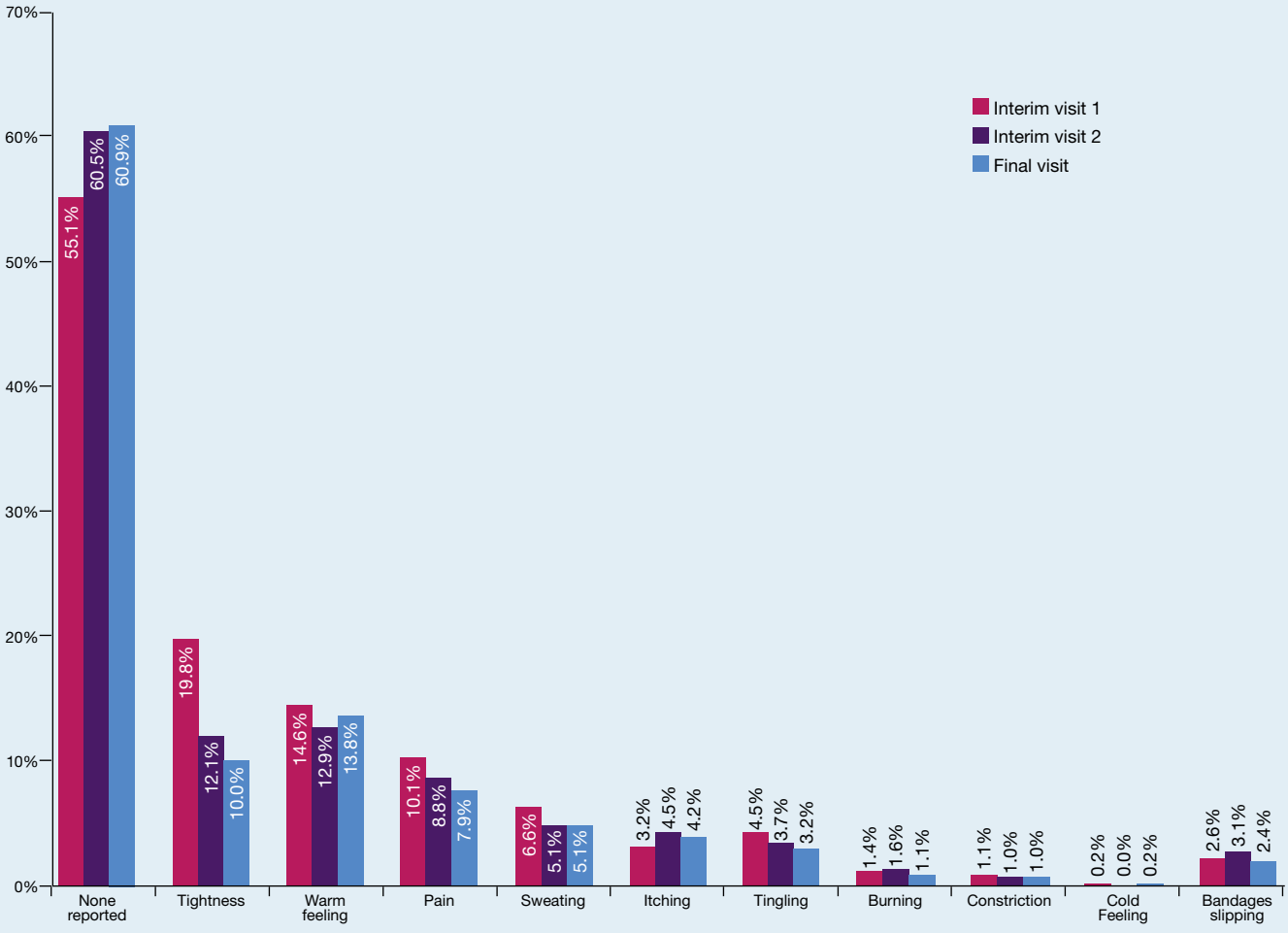
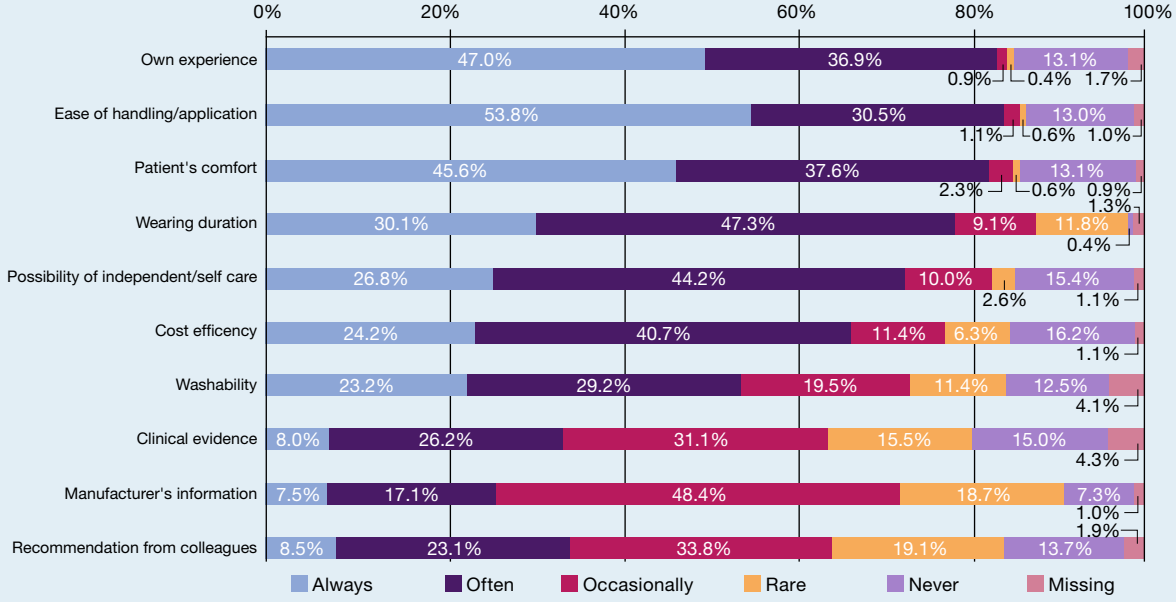


Fig 7. Factors influencing the selection of the compression therapy system (n=702)



Acceptability of the compression therapy

At the final visit, the acceptance of the multicomponent compression therapy was rated 'very good' by 500 (71.2%) of the patients, 'good' by 171 (24.4%), 'moderate' by 17 (2.4%) and 'poor' by 10 (1.4%) patients (1.4%) (data were missing for four patients; 0.6%). The percentage of patients reporting that the compression therapy did not interfere with their everyday activities reached 85.6% (n=595/695) at the first interim visit and increased to 95.6% (n=671/702) at the last visit, while the number of patients reporting that it had often disturbed their sleep ranged between five and 10 during the study period. Patient ABPI and the presence of a wound or oedema at the initial visit had no significant influence on the good acceptance of the evaluated compression system (supplementary information on this is available from the authors).

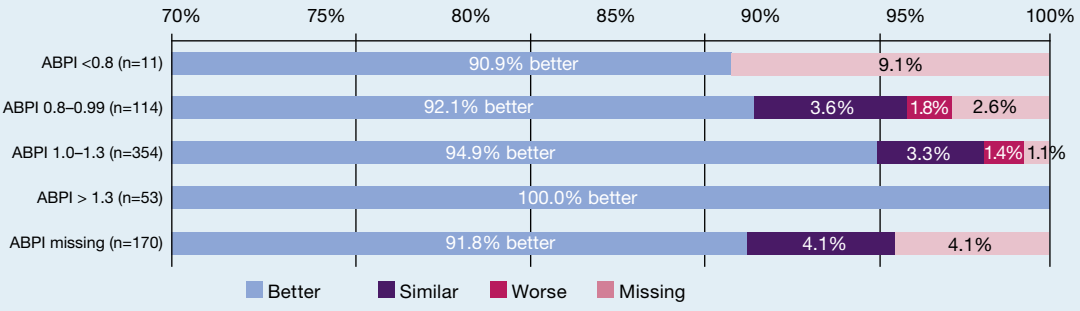
Local tolerance of the compression therapy

The local tolerance of the compression system was assessed by the physicians as 'very good' in 79.9% of the 2021 documented visits, 'good' in 18.4% and 'poor' in 0.9%. The evaluation was missing in 0.8% of the visits. There was no difference between the interim visits and the final visit. Neither the ABPI, nor the presence of a wound or oedema at the beginning of the study had a significant influence on this assessment (supplementary information on this is available from the authors).

Usefulness of the multicomponent compression therapy

According to the overall assessment made by the physicians at the final visit, for most patients, the multicomponent compression system has been judged 'very useful' (n=546, 77.8%) or 'useful' (n=132, 18.8%).

Fig 8. Performance of the multicomponent compression system, compared with previous experience with other compression systems, according to the physicians' point of view, stratified by ankle–brachial pressure index level (n=702)



The bandages were assessed as 'hardly' or 'not useful' in only seven (1.0%) and five patients (0.7%), respectively. The evaluation was missing for 12 (1.7%) patients. Neither ABPI value nor the presence of a wound or oedema at the beginning of the study had a significant influence on the assessment of the usefulness of the evaluated compression system (supplementary information on this is available from the authors).

Factors influencing the selection of the compression therapy system

As reported in Fig 7, according to the physicians, the five most important factors that 'always' or 'often' influenced their selection of compression bandages were:

- The ease of handling/application of the bandages (n=592, 84.3%)
- Their own previous experience with the bandages (n=589, 83.9%)
- The patient's comfort at wearing the bandages (n=584, 83.2%)
- The length of time the bandages can be worn without having to be changed (n=543, 77.4%)
- The possibility of independent/self-care (n=498, 70.9%).

Comparison with previous compression therapy

At the final visit, the physicians evaluated the performance of the multicomponent compression system compared with their experience with previous compression systems applied on their patient. In 660 (94.0%) patients, the compression therapy with the evaluated system was rated 'better' than with the previous compression systems used; 'similar' in 20 (2.8%) patients and 'worse' in seven (1.0%) patients. An evaluation was missing for 15 (2.1%) patients. Similar results were reported regardless of the type of compression systems previously used by the patients (supplementary information on this is available from the authors) and regardless of patient's ABPI at baseline (Fig 8).

Discussion

Real-life data on the treatment of patients with CVI are still quite scarce in the literature, notably regarding the compression treatment of venous oedema, or patients' perception and acceptability of wearing high-compression bandages. This study confirmed the good performances of the evaluated multicomponent compression system on the wound healing process of VLUs that were previously established in a European RCT.[29] In addition, the results highlighted the beneficial effect of the compression system in reducing CVI symptoms such as oedema, as well as the good tolerance and acceptability of the bandages by patients with a wide range of characteristics.

The good results in terms of wound healing reported here, with 30.9% of wound closure after 27 days of treatment, may be explained in part by the good prognosis of the VLUs treated. The treated ulcers were of mild to moderate severity, with half of the ulcers presenting with a surface area of <5cm² and with short duration ulcer (lasting for less than a month), and high-compression therapy was prescribed as first-line treatment in a quarter of the patients. These results support the fact that the sooner an appropriate therapy is implemented, the better the outcomes. The rapid resolution of the oedema reported in 66.7% of the patients is also consistent with the performance reported in previous multicentre clinical trials conducted in France and in the US.[33,36] However, to our knowledge, our study is the first to report the good acceptability, tolerance and usefulness of this compression system in the treatment of patients with venous oedema, regardless of the presence of a concomitant VLU.

We know that bandage performance and thus clinical outcomes, are related to the achieved pressure over time. Even if the applied pressure was not measured in this observational study, the rapid and good clinical results achieved, in terms of wound healing and oedema reduction, support that the application method was appropriate and the targeted therapeutic pressure was adequately achieved. Users were expected to apply the bandages according to the manufacturer's instructions for use, and the visual indicator system printed on the evaluated bandages has been previously proven to help the accurate, safe and consistent application of the bandages.[29,31–36,41] In two clinical studies conducted in England and in the US, 85% and 87%, respectively, of the users achieved the required therapeutic interface pressure (30–50mmHg) on their first application of the evaluated bandages, despite being unfamiliar with it, and the mean pressure of 40mmHg did not change between successive applications.[32,34] This type of experience and evidence reinforces health professionals' confidence in their ability to effectively apply the intended therapeutic pressure, and could also possibly support self-care. According to the result of an RCT assessing the effectiveness of different bandages in self-care, when using customised bandages with visual markers, 60.0% of patients were able to achieve, at their first attempt at applying the bandage, the required 35–45mmHg therapeutic pressure compared with 33.3% of patients using unmarked bandages.[42]

In another clinical study conducted in Germany, it was shown that the mean pressure values achieved by lay persons with the compression system used in this current study were very close to the one achieved by nurses (42.5±12.1mmHg versus 42.3±9.1mmHg, respectively), which was not the case with unmarked bandages (28.8±12.8mmHg versus 40.0±12.5mmHg, respectively), demonstrating the ease of application of this specific system.[41]

With the major disruptions in healthcare services caused by the current COVID-19 pandemic, preventing

serious complications and minimising hospitalisation, where possible, has become even more essential for patients with CVI, as these patients, due to their age and chronic underlying conditions, are also at high risk for developing a severe form of the coronavirus disease.[43] Effective therapy with rapid outcomes and which is well tolerated by patients is critical to avoiding these complications. Furthermore, while health professional visits are postponed or replaced by video calls or telehealth consultations, compression systems that are easy to apply and able to stay in place for several days may be a substantial asset for the successful management of patients with CVI.[42,44] In our study, the compression system was changed in the majority of the cases once or twice a week and <4% of the patients reported bandage slippage throughout the study period. These real-life data corroborate those of a previous RCT that established the ability of the bandages to remain in place and maintain working pressure over seven days, compared with four-layer bandages and inelastic bandages.[31]

A frequency of bandage changes similar to the one mostly reported in our study has also been described in a clinical trial carried out in Spain with the same multicomponent compression system. This study evaluated the efficacy of a therapeutic strategy combining an autologous graft, a sucrose-octasulfate (TLC-NOSF) dressing and multicomponent compression therapy in achieving rapid wound closure in patients with long-standing ulcers.[37] In such a procedure, the spacing of wound care (for example, wound cleaning, dressing change and compression system change) and the acceptability by the patient are two key factors in the success of the entire procedure. Consistent with the data reported here, Conde-Montero et al.[37] reported no bandage slippage over time and that the evaluated bandages were well tolerated and accepted by patients.

Compression therapy is the most important therapeutic measure to treat patients with CVIs, with even better outcomes when combined with venous reflux control.[45] In addition, despite high-compression being recommended as a first-line treatment for VLUs, 30–50% of patients with leg ulcers are not treated with adequate compression.[46] It is often suggested that when high-compression therapy is not prescribed, it is because the patients cannot tolerate it and would not adhere to the treatment.[47,48] In our study, the good acceptability of the treatment was most likely related both to the rapid and visible outcomes in terms of wound healing and oedema reduction, and to the bandages being well tolerated by the patients.

Only a few perceptions of discomfort were reported throughout the treatment period, and some of them, such as tightness, tended to disappear while patients adjusted to their treatment. The beneficial outcomes were also accompanied in the majority of patients by a marked improvement in skin condition and in the QoL of the patients, when considering the reduction in pain. Patient mobility, although not directly assessed in this study, is also likely to have been improved through the improvement in ankle mobility observed in 44.2% of the patients treated. Patient comfort and QoL can be very much affected by CVI and its treatment. The perception of improved comfort with the evaluated bandages, compared with other compression systems, was reported in various previous studies, notably with the reduction of pain intensity, itchiness or heat, better wear time with reduced slippage, or increased ability to wear footwear, which altogether consequently improve the adherence of the patients to their treatment.[29,33,35,49] As new approaches are still being sought to improve patients' adherence to their compression therapy,[50] it seems that taking the time to explain to the patients the different benefits of their treatment and a fair description of the type of perceptions that they could potentially experience might be a simple but effective way to help them better understand and accept their treatment. Based on the aforementioned clinical evidence, high-compression therapy can indeed be well accepted by patients, regardless of their characteristics at baseline.

The results analysis of the tolerance or acceptability of high-compression therapy depending on a patient's ABPI level is one of the interesting findings of this observational study. According to these results, similar performances were achieved with the evaluated compression system regardless of the level of ABPI of the patients. Of note, 11 patients (1.7%) identified as having an ABPI value of between 0.6 and 0.8 (i.e. with a leg ulcer which also included an arterial component) had been treated with the evaluated compression system. While this condition is clearly mentioned as a contraindication in the instructions for use of all high-compression systems, the local tolerance, the acceptability and the usefulness of the compression therapy in these patients were somewhat similar to that reported in patients with an ABPI ≥0.8. However, caution should be taken regarding these outcomes due to the very small size of this subgroup of patients. It should also be noted that bandage slippage appeared to be three times more frequent in these patients than in the global cohort, and it is highly probable that the bandages were applied more loosely in these particular cases to reduce the level of compression applied. Experimental studies showed that leg ulcers of mixed origin (moderate peripheral arterial disease with an ABPI between 0.5 and 0.8) could benefit from modified compression systems that applied pressures of 31–40mmHg.[51–53] According to current guidelines, patients should be offered the strongest compression that maintains patient adherence, and in patients with an ABPI <0.8, compression should only be used under specialist advice and with close monitoring.[25] We also would like to emphasise that the use of mild compression systems, applying a reduced pressure level of 20mmHg at the ankle, could be more appropriate for these patients.

In this study, it should also be noted that an ABPI value was available for 75.8% of the patients, which can be considered as a high level, especially in a community setting. While it is recommended that ABPI should be measured before any compression therapy is started, it is not always done in current practice. It is important to remember that the diagnosis of CVI and VLU is firstly based on clinical history and presentation. Additional tests and procedure are then used to confirm or exclude concomitant arterial or other disease when they are suspected. Thus, in the absence of serious cardiovascular risk factors, or clinical signs or symptoms that could be indicative of an arterial impairment (such as leg pain at night, legs turning pale at elevation, atrophic, shiny or hairless skin, affected area being cool or cold to the touch, or of a lateral or anteral location of an ulcer), concerns about possible peripheral arterial occlusive disease (PAOD) may be relatively limited since ulcers of arterial and mixed origin represent only 10% and 20% of leg ulcers, respectively.[18] As recently reiterated by Eder et al., '*if the tibialis posterior and dorsalis pedis arteries are easily palpated, a relevant PAOD can be ruled out as a contraindication to compression therapy. If the pulses are not palpable, the next step is usually to measure the ABPI with Doppler ultrasound*'.[54] When ABPI measurement is not possible or difficult to interpret, other well validated, simple test procedures, such as Buerger's test or the pole test, can be used to check whether there is sufficient arterial perfusion of the foot to tolerate compression therapy.[54] Contraindications to compression therapy are regularly reviewed by experts and patients should not be denied early initiation of the therapy they need based only on suspected PAOD or due to the lack of formation of health professionals.[54–56]

These clinical data support the first-line position of high-compression bandages in the treatment of VLU and limb oedema caused by CVI. Although dating from 2010, they are consistent with the published evidence from clinical studies recently carried out in Europe and in North America.[34–37,49] As soon as they became available, the bandages were found to be, in general practice, easy to apply, well accepted and tolerated by patients, supporting rapid wound healing and a reduction of CVI symptoms.

Limitations

As is often the case with prospective observational studies, the non-comparative design of this large real-life study may be seen as a limitation. However, as previously pointed out, the efficacy and safety of the compression system, compared with other systems, have been established in other comparative studies, including a European RCT. [29,31,32,34]

Conclusion

This clinical evaluation, based on a large cohort of 702 patients treated under real-life conditions, confirms and complements the efficacy and safety profile of the multicomponent compression system. This therapy is effective in supporting healing in VLUs, reducing lower limb oedema caused by CVI and improving the QoL of patients experiencing these complications, regardless of their characteristics at baseline. The bandages were well tolerated and accepted, and rated highly by patients and clinicians. These results join the growing evidence base supporting the use of this compression system, as a first-line intervention and until wound healing, in the treatment of VLUs and to reduce oedema causedby CVI. **JWC**

Acknowledgements The authors would like to thank S Bohbot, MD and L Thomassin, PhD (Medical Affairs Department, Laboratoires URGO Medical, France) for their help in the writing process for this article, and all of the physicians who have contributed to making this study possible, for their commitment, time and effort.

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Reflective questions

- What is the cornerstone of treatment of patients with venous leg ulcers and/or oedema caused by venous insufficiency?
- What are the key elements to consider when selecting a compression therapy?
- What benefits can be expected by treating patients with leg ulcers and/or oedema caused by venous insufficiency with multicomponent compression system such as that used in this study?

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