Static Stiffness Index of Two Multicomponent Bandage Compression Systems: Results of a Randomized Controlled Trial on Healthy Volunteers

Statischer Stiffness-Index von zwei Multikomponenten-Bandagen-Kompressionssystemen: Ergebnisse einer randomisierten kontrollierten Studie an gesunden Probanden

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ABSTRACT

Purpose To compare the performances of two multicomponent compression systems.

Methods In this randomised controlled trial, both legs of 25 healthy volunteers were randomly bandaged with either a new generation of compression system (UrgoK1, one unique bandage) or an established system (UrgoK2, two bandages), as a control. Both systems were worn day and night. Working and resting interfaces pressures were measured, and Static Stiffness Index (SSI) calculated, immediately after application and after 4 h, 24 h, 48 h and 72 h.

Results After 4 hours, similar high working pressures and moderate resting pressures were registered with both systems. Over time, changes in pressures and in SSI followed the same curves. After 48 h, a SSI ≥ 10 mmHg was reached with 88 % and 76 % of the tested and control systems, respectively, validating the non-inferior rigidity of the tested system ($p = 0.016$). Both systems presented good holding properties and were well tolerated, but the tested system was perceived as significantly more comfortable and eventually preferred to the control system by the majority of the volunteers.

Conclusion The new compression system achieved similar performances to the control, but its better acceptability could become an asset for patients' compliance. These promising results need to be confirmed in a clinical study on patients with leg ulcers and/or oedema.

ZUSAMMENFASSUNG

Zweck Vergleich der Leistung von zwei Mehrkomponenten-Kompressionssystemen.

Methoden In dieser randomisierten, kontrollierten Studie wurden beide Beine von 25 gesunden Probanden nach dem Zufallsprinzip entweder mit einem Kompressionssystem der neuen Generation (UrgoK1, eine einzige Binde) oder einem etablierten System (UrgoK2, zwei Binden) als Kontrolle bandagiert. Beide Systeme wurden Tag und Nacht getragen. Arbeits- und Ruhegrenzflächendruck wurden unmittelbar nach dem Anlegen und nach 4 h, 24 h, 48 h und 72 h gemessen und der Static Stiffness Index (SSI) berechnet.

Ergebnisse Nach 4 Stunden wurden mit beiden Systemen ähnlich hohe Arbeitsdrücke und mäßige Ruhedrücke registriert. Im Zeitverlauf folgten die Druckänderungen und des SSI den gleichen Kurven. Nach 48 h wurde ein SSI ≥ 10 mmHg bei 88 % der getesteten und 76 % der Kontrollsysteme er-

reicht, was die Nichtunterlegenheit des Testsystems bestätigt (p = 0,016). Beide Systeme wiesen gute Halteeigenschaften auf und waren gut verträglich, aber das getestete System wurde von der Mehrheit der Probanden als deutlich angenehmer empfunden und schließlich dem Kontrollsystem vorgezogen.

Schlussfolgerung Das neue Kompressionssystem erreichte ähnliche Leistungen wie die Kontrolle, aber seine bessere Akzeptanz könnte ein Vorteil für die Patientencompliance sein. Diese vielversprechenden Ergebnisse müssen in einer klinischen Studie an Patienten mit Unterschenkelulcera und/oder Ödemen bestätigt werden.

Introduction

Compression therapy remains the cornerstone of all therapeutic strategies in the management of chronic venous insufficiency (CVI), a venous circulation disorder characterised by venous hypertension, venous stasis, oedema and, at its ultimate stage, venous leg ulcers that require several months to heal, with high recurrence rate [1–3].

In order to counteract the hydrostatic forces of venous hypertension and restore the impaired venous flow, a certain amount of external pressure needs to be continuously exerted on the leg of the patients. In a working position (when a patient is sitting, standing or walking), a high pressure of at least 30–50 mmHg is required to narrow the leg veins, while in a supine position, a lower pressure above 15–25 mmHg is said to be sufficient to constrict deep veins and accelerate the venous flow [4]. Compression with a stiff material will also increase the massaging effects of the muscle pump of ambulatory patients and thus improve venous return. High level of venous compression has been proven to restore valve function, reduce venous reflux and improve venous return, relieve pain, reduce oedema and promote the wound closure of leg ulcers caused by CVI [4–6].

To apply such pressures, health professionals have at their disposition a variety of medical devices including: short-stretch bandages, long-stretch bandages, multicomponent systems, compression stocking kits, or adjustable compression wraps. Based on meta-analysis and systematic reviews of clinical evidence, current guidelines recommend multicomponent systems in first-line treatment of venous leg ulcers, due to higher closure rate and faster healing [1, 2, 6–10].

In theory, all these multicomponent systems are expected to deliver working pressures high enough to counteract gravity in upright position, but not so high that it could cause damages or pain, and tolerable resting pressures, so as to be comfortable enough for the system to be worn day and night. The stiffness of these systems, defined by a static stiffness index ≥ 10 mmHg [11–14], is also expected to be sustained over time in order to limit the frequency of bandage reapplication and the associated economic burden and workload. But various parameters still need to be considered when selecting the most appropriate system for a patient. In particular, an ideal system should enable healthcare professionals to easily, confidently and consistently apply the effective and secured pressures to all their patients, and its acceptability by the patients should be the highest possible to support patient compliance.

In real-life practice, a substantial proportion of patients are still not receiving an appropriate compression therapy or any compression therapy at all [15–19]. According to these reports, the most often cited reasons for this management failure appear to include poor acceptability of the treatment by the patient [15–19], a too complex application technique for some systems or difficulties to achieve the appropriate pressures with others [16–18]. In this context, new solutions that would improve patient comfort and acceptability or facilitate bandage application while keeping the acknowledged efficacy of multicomponent compression systems are still actively sought.

As a preliminary step in the clinical development of such a system, the objective of this study was to compare, in healthy subjects, the performances in terms of rigidity, interfaces pressures and acceptability of a new generation of multicomponent compression system, delivered in one unique bandage, to that of a well-established control multicomponent system, widely used in the treatment of venous leg ulcers and oedema of venous origin [20–26].

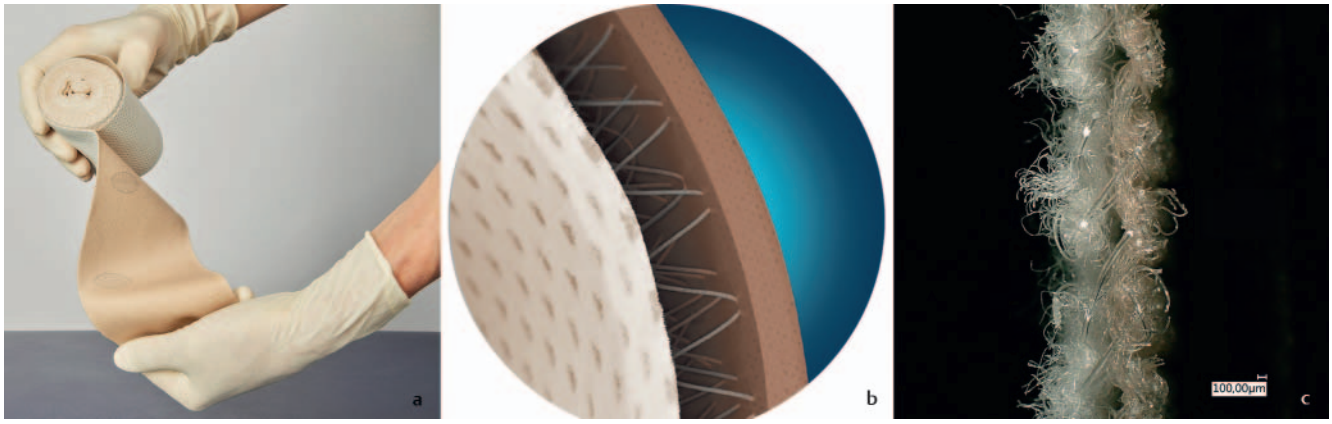
Patients and Methods

Design of the clinical trial

The FUSION study was a mono-centre randomised, controlled clinical trial, carried out on healthy volunteers in France in September 2019.

Criteria for inclusion

Healthy volunteers agreeing to wear the compression systems on both legs during the three-day study period were eligible. Males or females, aged between 18 and 65 years old, could be included if they had a body mass index below 30 kg/m². Both of their legs were required to have a circumference between 18 and 25 cm, a healthy skin without any sign of dermatological conditions (eczema, psoriasis…), posterior and both tibial and pedal pulses palpable at clinical examination, an ankle-brachial pressure index greater than 0.9 and less than 1.3, and a venous echo-doppler without any detectable anomaly. Subjects were excluded if they presented with a chronic insufficiency stage greater than or equal to two (Clinical condition, Etiology, Anatomic location, Pathophysiology [CEAP] Classification of Chronic Venous Diseases), were allergic to any component of the compression systems under evaluation, had diabetes, a progressive neoplastic pathology, any arterial disease history, any medical condition or surgery history affecting their mobility, or if they were treated with drugs affecting their arterial circulation or by a systemic treatment that may lead to the occurrence of oedema of the lower limbs, or if they



▶ **Fig. 1** Presentation of the tested system. **a** The two faces of the new Dual Compression System, with the printed pressure indicators on the beige outer face. Source: Laboratories Urgo. **b** Sectional illustration of the exclusive structure of the multicomponent system resulting in one unique bandage. Source: Laboratories Urgo. **c** Microscopic photograph of a sectional cut of the system (×50). The scale bar represents 100 µm. Source: Laboratories Urgo.

took a flight of more than seven hours in the last 15 days. Pregnant or breast-feeding woman or woman of childbearing potential not protected by an effective contraceptive method of birth control, and the persons who were taking part in another therapeutic study were also excluded.

The evaluated compression systems

The new compression system investigated in this trial (UrgoK1, Laboratoires Urgo, France) represents the new generation of Dual Compression Systems. It claims to provide sustainable high working pressure and moderate resting pressure, delivered by the application of one unique bandage (with two different faces), resulting from an innovative technology. This multicomponent compression bandage system is composed of polyamide, elastane and polyester yarns, combined together in an exclusive structure, using three-dimensional knitting technology (▶ **Fig. 1**). 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, which is also displayed on the other compression bandages commercialised by the company). The bandage is provided with a gripping system which was used to finalize its application and maintain the compression system in place over time.

The compression system used as control was a multicomponent compression system combining a padded short-stretch bandage and a cohesive long-stretch bandage (UrgoK2, Laboratoires Urgo, France). This system is widely used in the treatment of venous leg ulcers and oedema of venous origin (commercialised since 2007) and its efficacy and safety profile has been previously established through a RCT and several interventional and observational studies [20–28].

All the applied bandages were 10 cm width and suitable for ankles with a circumference of 18 to 25 cm.

Randomisation procedure

One compression system was randomly applied to one of the subject's lower limbs and the other compression system to the other limb. The randomisation list was prepared via a computer-generated block randomisation procedure by an independent company, which was also in charge of the data analysis for this study (Soladis, Lyon, France).

Study procedure

All the study visits were conducted at the investigation centre (Intertek, Paris, France), specialised in clinical studies with healthy volunteers. Participants were recruited by this accredited research site, prior to the inclusion visit, using its Clinical Studies website and healthy volunteer database.

At the initial visit, both compression systems were applied by the same experienced nurse, with a 50 % overlap, according to manufacturers' instructions. The interface pressures achieved were verified immediately after application.

The interface pressures between the compression systems and the skin were measured at the anatomical B1 point using the Picopress device (MicrolabItalia, Italy) with a round pressure sensor of 5 cm diameter. Anatomical point B1 is located on the medial aspect of the leg, behind the tibia, in front of the Achilles tendon, above the soleus muscle and at the origin of the medial gastrocnemius muscle. The sensor was left in place throughout the study period and connected to the recorder at each pressure measurement.

Subjects were followed up for a maximum of three days, including evaluation visits 4 h, 24 h, 48 h and 72 h after the application of the compression systems. At each visit, interface pressures were registered both in supine and standing positions, and bandage slippage were measured, as long as the systems were still in place. Subjects' perceptions of comfort were collected on the evening of the application day and the following day, as well as during the final visit. On the final visit, and based on the previous three days of wearing both systems, subjects were asked to indicate their preferred compression system.

Outcomes

The primary outcome was the proportion of participants with an SSI ≥ 10 mmHg, 48 hours after the application of the compression system. The SSI was defined as the difference between the working and resting interface pressures (mmHg), achieved in standing and supine positions, respectively [11].

Secondary outcomes included the changes in the interface pressures and in SSI, the proportion of participants with an SSI ≥ 10 mmHg and the bandage slippage (in cm, since the application at T0) at each evaluation visit. Subjects' comfort when wearing the compression systems was assessed on the basis of the following perceptions: ease of footwear, ankle mobility, warmth sensation, itchiness sensation, and pain. The subject's preference for one of the two systems was asked in terms of aesthetics, tactile sensation, comfort and ease of footwear.

The tolerance of each compression system was evaluated based on the skin condition examined by the investigating physician at the final visit and on the number and nature of adverse events reported throughout the study period.

Statistical analysis

Data analyses were conducted by an independent company (Soladis, Lyon, France), in accordance with the statistical analysis plan.

The statistical unit was the subject's leg. Based on an hypothesis of 93 % of legs presenting an SSI ≥ 10 mmHg in the control group, an expected ratio between the groups of 1.05, and a non-inferiority margin of 15 percentage points, it was calculated that 22 subjects (corresponding to 22 right legs and 22 left legs) were necessary to demonstrate the non-inferiority of the tested system versus the control with 85 % power and an alpha risk of 5 % (one-sided situation). Assuming a dropout rate of broadly 10 %, 25 subjects (50 legs) were planned to be included in this clinical trial. The non-inferiority analysis was done on the per protocol (PP) population, and a superiority analysis was planned on the intention-to-treat (ITT) population, both using Farrington-Manning score test. Secondary outcomes were evaluated using Chi-squared test or Fisher's exact test for categorical parameters, with p values less than 0.05 considered as significant. Preferences were described with a 95 % confidence interval using the Clopper-Pearson method. All analyses were performed using SAS software (v9.4; SAS Institute, USA).

Ethics

This clinical trial was carried out in accordance with the ethical principles of the Declaration of Helsinki and the European and French regulatory requirements relating to Medical Devices and research involving the human person (ISO 14 155, European Directives 93/42/EEC, and the Jardé Law). Favourable opinion and approval were delivered in August 2019 by the Committee for the Protection of Persons (C.P.P.) West VI of Brest and the National Agency for the Safety of Medicines and Health Products (ANSM), respectively. This trial was registered with ClinicalTrials.gov, number NCT04 159 844. Written informed consent was obtained from all of the volunteers before inclusion into the trial.

Results

Characteristics of subjects at baseline

Twenty women and five men were included in this study, with age ranging from 25 to 65 years and BMI ranging between 18.1 and 29.3 kg/m² (▶ **Table 1**). At baseline, all subjects had an ankle circumference comprise between 18 and 24 cm and all had a healthy skin. Tibial and pedal pulses were palpable on all legs and the performed echo-doppler were normal. The mean ABPI value was 1.1 ± 0.1 in each leg group.

The interface pressures obtained at application were appropriate from the first attempt with both systems, confirming an easy, consistent and safe application for each system. The mean values were also similar between the two groups regarding both the working and resting positions, confirming the group comparability at baseline.

During the study period, the control compression system was removed in one subject after 48 h due to moderate pain and two pressure measurements at 72 h were not possible in the tested group due to shifted bandages.

SSI after 48 h (the primary endpoint)

After 48 h, a SSI ≥ 10 mmHg was reached with 88 % of the tested systems and with 76 % of the control systems (▶ **Table 2**). The non-inferiority hypothesis was validated: the new compression system is not inferior to the control system in terms of stiffness (p = 0.016).

The superiority test conducted on the ITT population didn't identify a significant difference between the two groups (p = 0.135).

Changes in interface pressures and SSI over time

The mean interfaces pressures and SSI obtained with the two compression systems at each visit are reported in the ▶ **Table 3**.

The results showed that:

- Over time, the interface pressures tended to change similarly with both systems. As it's often the case with compression systems, a drop in pressure was observed in the first few hours following the application. Thereafter, each of the two systems appeared to stabilise with a slower pressure decrease of only slight intensity in the following days.
- Working pressures above 30 mmHg were maintained with both compression systems until the last visit, i. e. 72 hours after the system application, with mean values ranging from 45.5 mmHg to 33.0 mmHg for the tested system and from 49.4 mmHg to 35.0 mmHg with the control system, between T4 h and T72 h.
- The resting pressures recorded in both groups stayed in the safe and well tolerated range expected for compression systems compatible with night wearing.
- Changes in SSI with both compression systems also followed the same curves (▶ **Fig. 2**), with no significant difference in the proportion of subjects with an SSI ≥ 10 mmHg at each visit (▶ **Fig. 3**). Even after three days of wearing, 68 % of the applied compression systems still ensure an SSI ≥ 10 mmHg (72 % of the tested system and 64 % of the control system).

▶ **Table 1** Subjects and legs characteristics at baseline and interface pressures applied at T0.

compression systems	tested system	control system
number of subjects	25	
male/female. n (%)	5 (20 %)/20 (80 %)	
age (years), mean ± SD	43.1 ± 11.1	
BMI (kg/m²), mean ± SD	23.4 ± 3.2	
ABPI, mean ± SD	1.1 ± 0.1	1.1 ± 0.1
ankle circumference at B point (cm), mean ± SD	21.3 ± 1.5	21.3 ± 1.5
calf circumference at B1 point (cm), mean ± SD	29.3 ± 2.5	29.1 ± 2.6
resting interface pressure at T0 (mmHg), Mean ± SD	42.1 ± 1.9	44.2 ± 2.3
working interface pressure at T0 (mmHg), Mean ± SD	66.5 ± 8.2	65.3 ± 5.5

Bandage slippage over time

During the three-day study period, bandage slippage from the top line of the initial application was minimal in both groups. After 4 hours and 72 hours of wearing, respectively, the mean values ranged from 0.4 ± 0.5 to 1.0 ± 1.2 cm in the tested group (with a peak at 2.0 ± 3.1 at 48 h) and from 0.8 ± 0.8 to 4.9 ± 3.3 cm in the control group, indicating the good holding of both systems, while being worn day and night (▶ **Fig. 4**). As previously mentioned, at the final visit, the analysis was done on 23 legs in the tested group as two systems were not in place anymore at the time of the measurements and on 24 legs in the control group, due to an early withdrawal.

Comfort at wearing the compression systems and preference

The perception of comfort reported by the subjects under compression therapy was generally better with the tested system than with the control system. Notably, discomfort perceptions were significantly less frequently reported with the tested system in terms of ankle mobility limitation ($p = 0.022$), footwear fitting ($p = 0.025$) and warmth sensation ($p = 0.024$) (▶ **Fig. 5**), while no difference was reported in terms of itching or pain sensations between the two systems.

After three days wearing both systems, the majority of the healthy volunteers expressed a marked preference for the tested system over the control system, for each of the four criteria considered (▶ **Fig. 6**). The tested device was judged more comfortable by 76 % (95 % CI 54.9 %; 90.6 %) of the subjects, more pleasant at touch by 84 % (95 % CI 63.9 %; 95.5 %), more aesthetic by 88 % (95 % CI 68.8 %; 97.5 %), and to be easier to wear shoes with by 88 % (95 % CI 68.8 %; 97.5 %) than the control system.

▶ **Table 2** Comparison of the proportion of patients with a SSI ≥ 10 mmHg after 48 h.

compression systems	tested system	control system
SSI ≥ 10 mmHg after 48 h, n/N (%)	22/25 (88 %)	19/25 (76 %)
odd ratio [90 % Confidence Interval]	1.16 [0.92; 1.50]	
non inferiority test (PP analysis)	p = 0.016	

Safety criteria

Both systems were very well tolerated. The clinical examination of the subjects' skin during the study reported no skin dryness under the compression systems. Four non-serious adverse events of mild intensity were documented by the investigator as imputable to the procedure: the occurrence of one blister under the pressure sensor in the tested group, the occurrence of one blister, one erythema, and one oedema in the control group. A pain of moderate intensity reported at the end of the 48 h visit, judged by the investigator as imputable to the compression system, led to an early discontinuation of one leg in the control group. No serious adverse event occurred throughout the study period.

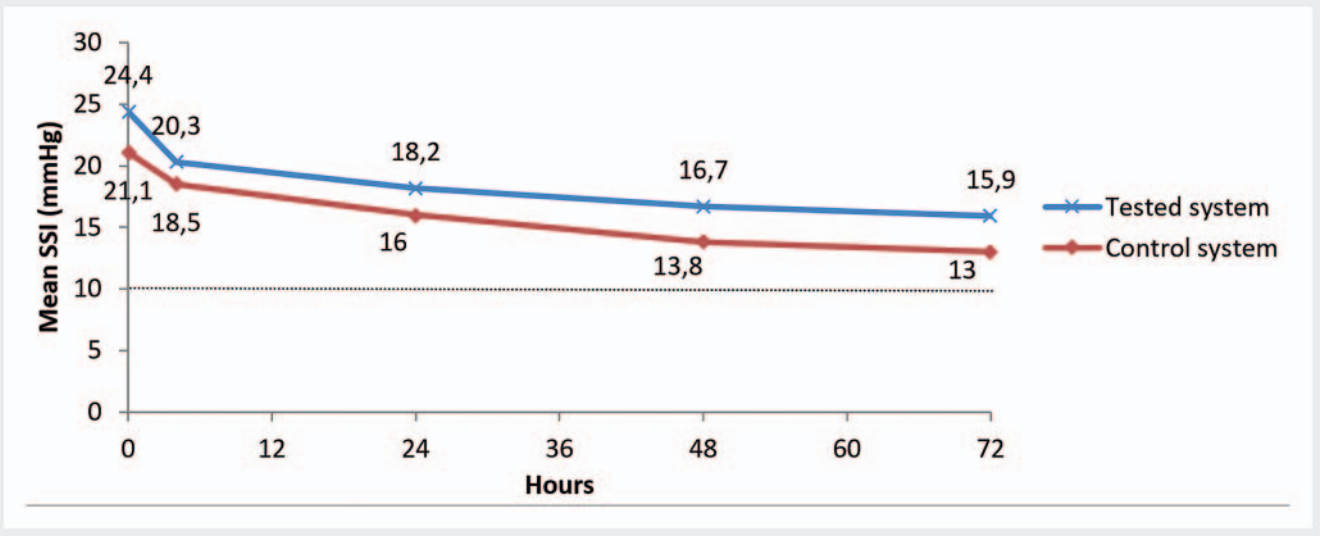
Discussion

The FUSION study evaluated for the first time the performances on healthy volunteers of a new generation of multicomponent compression system, combining two different structures of compressive layers in one unique bandage. The results of this RCT showed that this new system presents a similar profile to the control system, a multicomponent system composed by a short-stretch bandage and a cohesive bandage, widely used in the treatment of venous leg ulcer and oedema of venous origin [21–23, 25]. Four hours after their application, both systems exerted similar stiffness, with high working pressures and moderate resting pressures. In the following days, both systems continue to achieve and sustain a SSI above 10 mmHg, confirming their rigid properties. However, the acceptability of the new system was significantly higher than that of the control and the healthy volunteers, who have worn both systems day and night during three days, expressed a marked preference towards the new system at the final evaluation.

For clinicians, SSI and applied interface pressures are important indicators to estimate the clinical efficacy that can be expected from compression systems [28–32]. While the principles of compression system rigidity were introduced more than 15 years ago and SSI was rapidly acknowledged as a key element in the characterisation of compression system [11–14, 33–35], studies evaluating the change over several days of both working and resting pressures, with or without their associated SSI, remains scarce [28, 31, 36, 37]. In our study, the high working pressures and moderate resting pressures achieved after 4 hours seemed to similarly change in the following days between both multicomponent systems. The interfaces pressures exerted by the tested

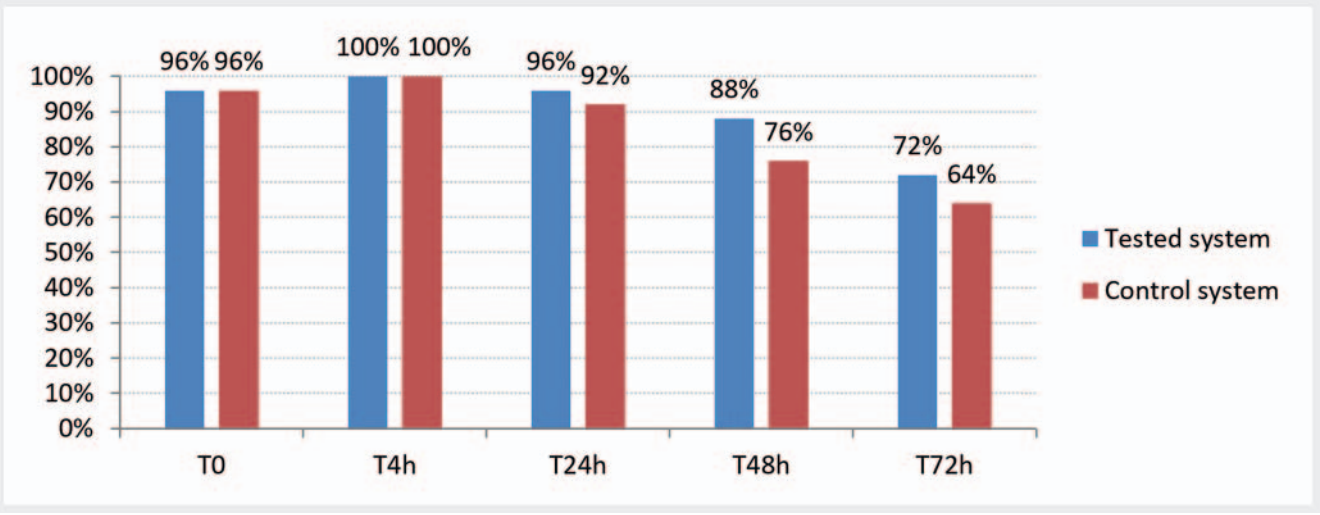
▶ **Table 3** Interface pressures in standing and supine positions and SSI throughout the study period.

compression systems	tested system			control system		
interface pressures and SSI (mmHg), mean ± SD	working pressure	resting pressure	SSI	working pressure	resting pressure	SSI
At T0	N = 25 66.5 ± 8.2	N = 25 42.1 ± 1.9	N = 25 24.4 ± 7.9	N = 25 65.3 ± 5.5	N = 25 44.2 ± 2.3	N = 25 21.1 ± 5.2
At 4 h	N = 25 45.5 ± 5.3	N = 25 25.3 ± 2.9	N = 25 20.3 ± 4.9	N = 25 49.4 ± 4.1	N = 25 30.9 ± 2.8	N = 25 18.5 ± 3.9
At 24 h	N = 25 38.7 ± 6.6	N = 25 20.4 ± 3.7	N = 25 18.2 ± 5.0	N = 25 42.3 ± 6.4	N = 25 26.3 ± 4.0	N = 25 16.0 ± 4.9
At 48 h	N = 25 35.1 ± 7.6	N = 25 18.4 ± 4.4	N = 25 16.7 ± 4.8	N = 25 37.7 ± 8.4	N = 25 23.9 ± 4.7	N = 25 13.8 ± 5.4
At 72 h	N = 23 33.0 ± 7.7	N = 23 17.2 ± 2.9	N = 23 15.9 ± 5.6	N = 24 35.0 ± 9.7	N = 24 22.1 ± 5.7	N = 24 13.0 ± 5.8

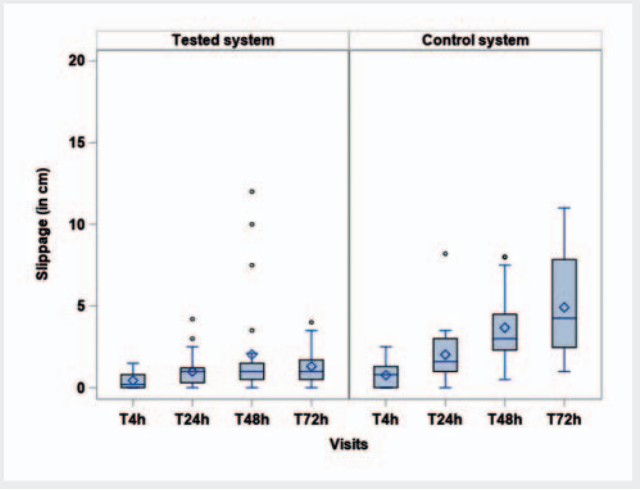


▶ **Fig. 2** Changes in mean SSI throughout the study period.

system may be seen as dropping slightly more in the few first hours than with the control, but this difference was not significant regarding the main outcomes at 48 h. Loss of interface pressures in the hours following application have been reported with all types of compression systems [31, 36, 37]. Based on these studies, long stretch bandages and elastic systems showed the smallest pressure loss over several days, however they also showed the smallest difference between working and resting pressure and therefore they are known to not be very well supported during the night (due to a too high resting pressure in lying position) or to be applied too loosely and not always exerting enough working pressure during the day (in standing or walking position) [36]. Besides, due to their lack of stiffness, there is little improvement in the functioning of the venous pump, as there is no self-massaging effect on the calf as demonstrated in patients with chronic venous insufficiency by Mosti et al. [38]. On the opposite, short-stretch bandages are characterized by high stiffness, with very strong working pressure and very low pressure in supine position, but they are also reported to lose a lot of their pressures within the first hours of wear, and therefore to require more frequent re-application [31, 37]. Between these extremes, multicomponent bandages are usually considered to represent a good compromise, with moderate pressure loss over time, high working pressure and moderate pressure, compatible with being worn day and night [31]. The control system used in our study had been previously assessed by Protz et al., and it was the only system, among other multicomponent systems composed by four or two bandages, and short-stretch bandages, to maintain high working pressure above 40 mmHg up to seven days [31]. It is very difficult to compare the pressures applied by compression systems based on the results from different studies due to the heterogeneity of influencing parameters between them [29, 32, 33, 39]. This is particularly true for systems where the instructions for use provided by the manufacturers leave a considerable



▶ **Fig. 3** Proportion of patients with an SSI ≥ 10 mmHg at each visit.



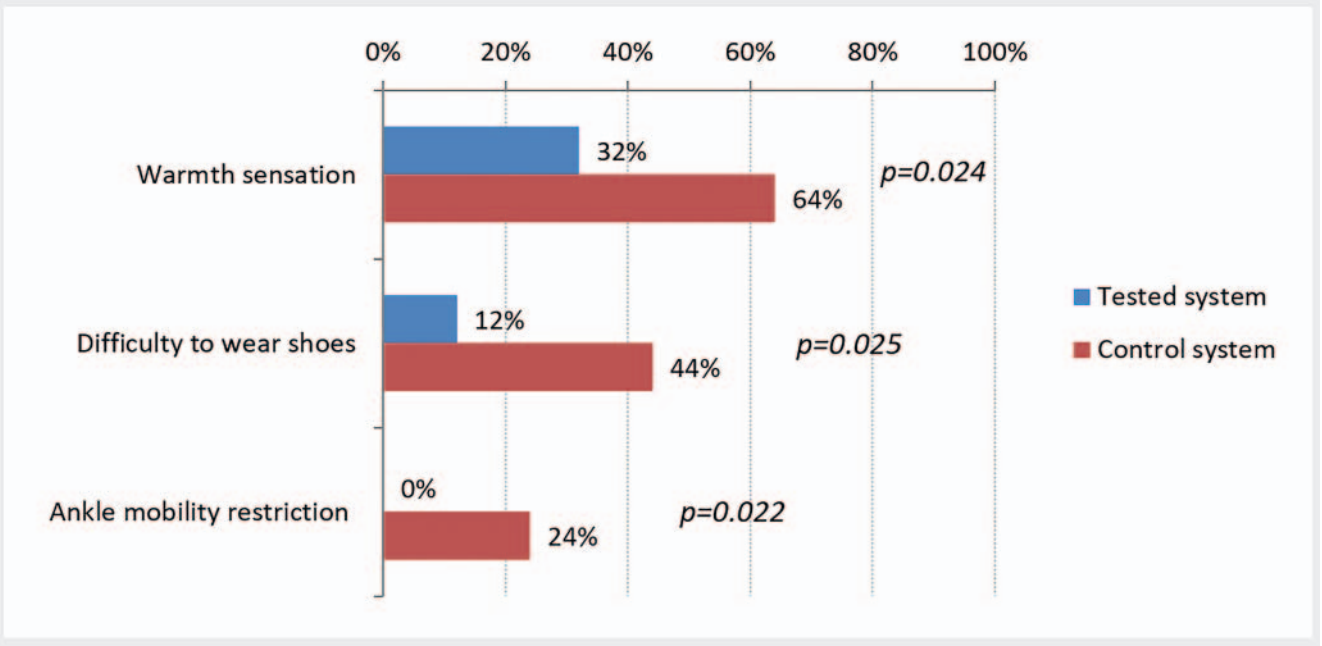
▶ **Fig. 4** Bandage shifting in cm at each visit. The diamond symbols indicate the mean values. The boundaries of the box indicate the 25th and 75th percentiles, the line within the box marks the median. Error bars indicates the extremes values inside the 1.5 times the interquartile range. The round symbols represent outliers, i. e. values which are > 1.5 times the interquartile range.

margin in terms of application techniques, use of sub-bandage padding, level of stretching or overlap of bandages. With only one experienced person in charge of applying all the bandages, a common application technique, using the same level of overlapping and stretching for both systems, and the application of the two systems on both legs of each volunteer for intra-individual comparison, this RCT was designed to minimise the number of variables that could limit the comparison between the two evaluated systems.

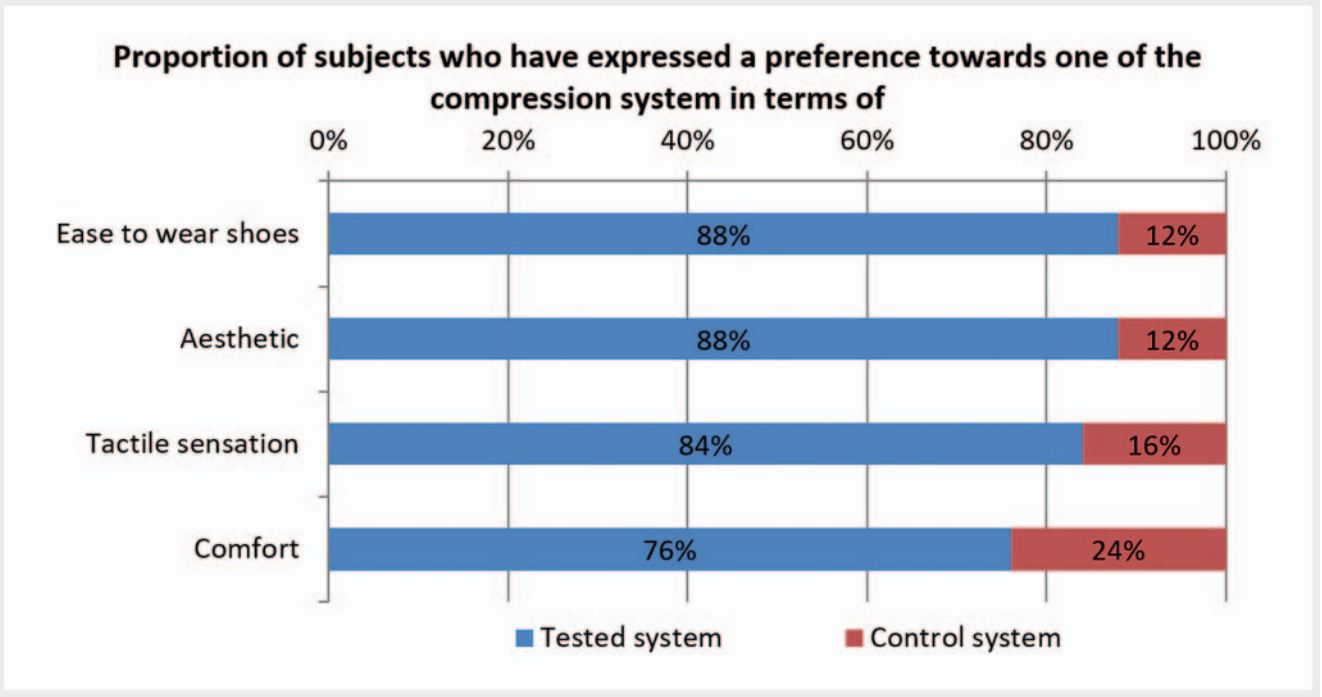
The control system used in this study is a well-established multicomponent system. Its efficacy and safety profile has been previously established in a RCT, where similar wound closure rates were achieved compared with a four-bandage system, while a significant easier application of the two-bandage system was reported by the investigators ($p = 0.038$) [20]. Since this RCT, the good acceptability of the system and its capacity to confidently apply and maintain high working pressure and moderate resting pressure, up to seven days had been confirmed in numerous clinical trials and observational studies [21–23, 25–28, 31]. Visual indicators, like the PresSure system displayed on the bandages of the two systems evaluated in this study, have been shown to significantly facilitate and ease the application of bandages with the achievement of the intended pressures [40].

In our study, similar good holding properties with minimal slippage of the bandages were reported, while both systems were worn day and night. As in the majority of the clinical studies measuring interface pressures, this study was conducted with healthy volunteers [28–31]. The younger age and greater mobility of the participants, compared to patients with venous leg ulcers, can increase the slippage of the bandages and therefore only reinforces the finding of the good holding of both systems over time reported here. As the participants of this study did not have oedema, the need to reapply the systems after oedema reduction (and thus a loosening of the applied bandages) could not be assessed. The simple spiral method used for the application of the evaluated bandages is one of the easiest techniques to master. However, with poorly cohesive bandages, it's also known as a technique that lead to substantial bandage slippage and pressure losses, which explained why some bandages still required more complex and time-consuming application technique, such as the Pütter technique [29, 32, 39].

The new multicomponent compression system with its unique bandage achieved similar performances than the established multicomponent system associating two bandages. A compression system in the form of one single bandage can be particularly appreciated by both healthcare professionals and patients. Obviously, it means less time to apply the bandage and therefore less time to mobilize for bandage changes for both patients and healthcare professionals. As reported in this study, the wearing of a single bandage was also associated with significantly less warmth sensation, less constraint for ankle mobility and to be easier for foot



▶ **Fig. 5** Discomfort perceptions at wearing the compression systems.



▶ **Fig. 6** Preferences expressed by the subjects towards the compression systems worn.

wearing. Thus, the improved comfort perceived by the volunteers resulted in a marked preference for the new system by the majority of the volunteers. As comfort is a key element for the compliance of compression therapy, this new multicomponent system in one bandage may be a real asset in the treatment of patients with venous leg ulcer and/or oedema of venous origin.

In conclusion, based on the results of this first clinical trial conducted on healthy volunteers, this new compression system meets the key expectations for an efficient, well-tolerated, and well-accepted compression system. This new generation of Dual Compression System sustained over the 72 hours of the study period similar performances in terms of rigidity and interface pressures than the control system, while both systems were

worn day and night. Both systems presented good safety profile and good holding properties, however, the volunteers expressed their preference for the new system that they perceived as more comfortable and acceptable. These promising results support the performances of the new compression system but need to be confirmed in a clinical study on patients with venous leg ulcers and/or oedema.

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Conflict of interest

Olivier Tacca is an employee of Urgo Research Innovation and Development. Jean-Patrick Benigni provided advisory and speaking services to pharmaceutical and other healthcare organisations including, but not limited to, Urgo Research Innovation and Development. Data management and statistical analyses were conducted independently by Soladis, Lyon, France.

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