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Efficacy, safety and acceptability of a new two-layer bandage system for venous leg ulcers

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Efficacy, safety and acceptability of a new two-layer bandage system for venous leg ulcers

• **Objective:** To evaluate the efficacy, tolerability and acceptability of a new two-bandage compression system in the local management of venous or mixed aetiology ulcers predominantly of venous origin.
• **Method:** This was a prospective non-comparative open label phase III clinical study. Forty-two patients were recruited from 12 centres. Inclusion criteria included ulcers with at least 50% granulation tissue, a surface area of 2–20cm^2, an ulcer duration of 1–24 months, an ankle circumference of less than 28cm, and no history of deep vein thrombosis in the three months before enrolment. The primary endpoint was reduction in ulcer surface area, and secondary endpoints were the evolution of leg oedema and patient comfort. During the six-week follow-up, patients underwent weekly clinical assessments and their ulcer surface area was measured by planimetry and photography every alternate week.
• **Results:** The mean ulcer surface area at inclusion was 7 ± 6cm^2. The mean surface reduction after six weeks was 58.5%, with 24% of the treated wounds healing in a mean time of 25.9 ± 9.46 days. The patients considered that the new compression system had a better effect on quality of life, evaluated by parameters such as pain, heat, itching and general comfort, than the system worn before entry into the study. Patient concordance with the new system was excellent and 86% of leg ulcers improved or healed after six weeks. Local tolerance was considered very good.
• **Conclusion:** This new two-bandage compression system is effective and well accepted by patients.
• **Declaration of interest:** This study was sponsored by Laboratoires Urgo, Chenôve, France.

multi-bandage system; compression therapy; clinical trial; venous leg ulcers

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The pain and isolation caused by chronic venous leg ulcers has a major impact on patients' quality of life.[1-3] There are two complementary local treatments for these ulcers:[4]

• Topical treatment (such as zinc paste bandage) plus a primary dressing that uses the principles of moist wound healing to recover the wound bed and the surrounding skin[5,6]
• Compression therapy, which addresses the aetiological cause of the ulceration by promoting venous return and restricting venous stasis.[7,8] Compression therapy systems include elastic or non-elastic bandages, monolayer or multilayer bandaging, short-, medium- or long-stretch bandages and hosiery.[9]

A better understanding of the pathophysiology of venous disease and the advent of systems that can measure the interface pressures exerted by compression bandages have led to the development of reliable and effective compression systems.[10] Selection depends on parameters including patient preference, patient concordance and acceptability and ease of use for both the practitioner and patient.[11]

There are wide variations in venous leg ulcer management. In the US Unna's Boot is favoured, while in the UK multilayer elastic compression is widely used and in continental Europe short-stretch bandaging is standard practice.[12] However, each type of compression has disadvantages[13] that can limit patient concordance. In addition, numerous randomised clinical studies have been unable to show the superiority of one multilayer compression system over another,[14-17] while others have found no differences between short-stretch and multilayer bandages.[18-21]

Laboratoires Urgo has recently developed a two-bandage compression system, K-Two. This is the first two-bandage system in which the two layers are designed to spread the pressure evenly between them. This clinical trial set out to evaluate the therapeutic efficacy, tolerability and acceptability of this new compression system in the management of venous leg ulcers.

Materials and method

This multicentre non-comparative phase III open-label clinical trial was conducted in France by private specialist physicians (angiology-phlebology) and physicians from hospital dermatology and vascular medicine units. One physician from each of the 12 participating centres recruited adult outpatients into the six-week trial.

The inclusion criteria were:
- Ulcer size of 2–20cm²
- Ulcer duration of 1–24 months
- Venous aetiology, confirmed by Doppler
- Patients who had already been treated with multilayer compression (two-, three- or four-bandage)
- Ulcers with more than 50% granulation tissue
- Patients who could be followed up by the same investigator for the six-week treatment period.

Exclusion criteria were:
- An ankle circumference over 28cm
- Dry, non-exuding, sloughy ulcers (as these would be unsuitable for the primary dressings supplied to the investigators)
- Ulcers with clinical signs of infection
- Malignant ulcers
- Progressive neoplasic lesions being treated with radiotherapy or chemotherapy, immunosuppressive drugs or high-dose corticosteroids
- Patient who had presented with deep vein thrombosis in the three months before inclusion.

The Versailles medical ethics committee approved the study, which was conducted in concordance with the principles of good clinical practice and the Declaration of Helsinki. Written informed consent was obtained from each patient before inclusion.

The new compression system

The K-Two system comprises two bandages:
- K-Tech — the primary bandage, which is composed of viscose and polyester wadding within a knitted compressive layer. According to the manufacturer, it offers good absorbency and protection and a light compression
- K-Press — a secondary, woven, cohesive, stretch bandage.

When applied with the recommended 50% overlap, the two bandages produce an average pressure of 40mmHg at the ankle.[22,23] Both bandages have elliptical patterns on them that form circles when applied (stretched) correctly — this is referred to as the 'etalonnage'. According to a paper presented at a recent conference, this simplifies application and makes it easier to ensure the correct pressure is given.[23]

K-Two is contraindicated in patients with arterial ulcers and arterial disease, and is not recommended for those with an ABPI less than 0.8.

Primary dressings

The study sponsor provided the investigators with two primary dressings — UrgoCell Non-Adhesive (Cellosorb Non-Adhesive, Laboratoires Urgo) or Urgotul (Laboratoires Urgo), with the intention of avoiding the potential for bias resulting from the use of different primary dressings. However, the physicians were free to use other primary dressings if they thought the wound required it, although in the event none did so.

Table 1. Patient demographic data (n=42)

Gender:	
• female	22 (52%)
• male	20 (48%)
Age (years)	70.5 ± 14.1 (37.5–92.9) 73.9
Weight (kg):	
• female	78.3 ± 20.9 (52–130)
• male	92.4 ± 24.9 (56–140)
Height (cm):	
• female	162 ± 10 (142–180)
• male	177 ± 7 (160–195)
Body mass index (kg/m²)	29.5 ± 6.8 (19.8–45.2) 27.7
Medical history:*	
• hypertension	18 (43%)
• heart disease	9 (21%)
• cigarette smoker	9 (21%)
• diabetes mellitus	8 (19%)
• allergy to a previous wound dressings	4 (10%)
Phlebological history:*	
• previous history of leg ulceration	36 (86%)
• phlebitis	21 (50%)
• stripping	21 (50%)
• sclerosis	12 (29%)
• family history of chronic venous disorders	28 (68%)

Data were given for more than one category
Results are given as mean ± SD (range) followed by the median unless otherwise indicated

The primary dressing was changed at the same time as the K-Tech bandage. The investigators, who were experienced in the use of multilayer compression therapy, all received the same training on the application of the new system. The frequency of dressing changes was determined by the physicians, based on clinical need.

Clinical assessment

The physicians measured the ulcer surface area using planimetry and photographs at entry and then every two weeks. Clinical assessments, recorded at baseline and then weekly, included:
- The condition of the surrounding skin
- Ankle brachal pressure index measurements
- The presence of oedema on the lower limb (circumference measured using a tape measure)
- Presence of trophic disorders on the contralateral lower limb
- Exudate level
- Spontaneous wound pain (that occurring between dressing changes).

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191063 June 2014

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Table 2. Baseline leg ulcer characteristics (n=42)

Ulcer duration (months)	8.1 ± 10.4 (1–60)
Ulcer surface area (cm^2)	6.97 ± 6.43 (0.78–27.76)
Recurrent ulcer	26 (62%)
Venous insufficiency:	
• superficial venous system	26 (62%)
• superficial and deep systems	11 (26%)
• Deep	5 (12%)
ABPI	1.0 ± 0.1 (0.8–1.3) 1.0
Ulcer location:	
• right lower limb	15 (36%)
• left lower limb	27 (64%)
Ulcer position:	
• malleolar	12 (29%)
• supramalleolar	15 (36%)
• submalleolar	4 (10%)
• other	11 (26%)
Condition of the surrounding skin:*	
• healthy	3 (7%)
• erythematous	23 (55%)
• eczematous	10 (24%)
• oedematous	18 (43%)
• irritated by the dressing(s)	7 (17%)
• macerated	6 (15%)
• other	3 (7%)
Exudate level:	
• absent	1 (3%)
• moderate	30 (79%)
• heavy	7 (18%)
• very heavy	–
Oedema in the lower limb under study	29 (69%)
Spontaneous wound pain:	
• absent	4 (10%)
• minor	8 (19%)
• moderate	16 (38%)
• intense	14 (33%)
Response to previous treatment:	
• clear improvement	5 (12%)
• moderate improvement	14 (33%)
• stagnation	11 (26%)
• worsening	12 (29%)

* More than one response could be given
Results are presented as mean ± SD (range), followed by the median unless otherwise stated
ABPI = ankle brachial pressure index

Endpoints

The primary endpoint was the reduction in wound surface area during the six-week follow-up period. Secondary endpoints were:

- An improvement in the clinical condition of the wound, as assessed above
- Occurrence of adverse events: clinical signs of wound infection as diagnosed by the investigators, and bleeding from the wound or damage to the surrounding skin
- Acceptability of the new system to the patient: defined as concordance and its effect on quality of life, measured as pain intensity, frequency of pain, itchiness, sensation of heat under the compression bandages, ease of wearing shoes, and general comfort both during the day and during the night.

Statistical analysis

A descriptive statistical analysis was performed on all patients included in the trial, conducted on an intention-to-treat (ITT) basis for the primary and secondary endpoints. If the patient withdrew or healed before week 6, the efficacy analysis took account of the last evaluation available (last observation carried forward, LOCF). Continuous data are described by sample size, mean, standard deviation, median and range; discrete data are described by absolute and relative frequencies.

Results

Baseline population

Forty-two outpatients were recruited from the 12 investigating centres. This was considered sufficient to determine the efficacy of the new system, as defined by the study. Patient demographic data are given in Table 1.

The gender distribution was evenly balanced, while the mean body mass index (BMI) was 'overweight' at 29.5 ± 6.8 kg/m^2. There was a relatively high incidence of high blood pressure (43%) and diabetes mellitus (19%).

Ulcer history

Baseline ulcer characteristics are given in Table 2. Most of the ulcers were recurrent (62%), and in only three cases (7%) was the surrounding skin 'healthy'. Spontaneous pain was moderate to intense in over 70% of the patients, even when venous origin was confirmed by Doppler (ABPI: 1.0 ± 0.1).

Twenty-nine patients (69%) presented with oedema in the lower ulcerated limb.

All but one had been wearing compression bandaging applied by the investigators — the exception being a patient who was presenting with an ulcer for the first time:

- 32% used a single bandage (long-stretch)
- 39% used a two-bandage system
- 29% used a three- to four-bandage system.

Nearly 55% of the treated ulcers had not improved despite the compression therapy.

Effect of the prior treatment on quality of life

At the inclusion visit, the investigators evaluated the acceptability of the previous compression system used and its effect on quality of life:

- Thirty-three patients (81%) had experienced pain, which was 'intense' in 13 (40%) and 'continuous' in 10 (32%)
- Twenty-three (57%) perceived that their skin felt moderately or intensely itchy under the previous compression system
- Eighteen (44%) considered that their skin felt moderately or intensely hot under the compression system
- Ten (24%) had difficulty putting on their shoes when wearing the compression bandages
- Nine (22%) and five (19%) reported that the compression bandaging was uncomfortable during the day and at night respectively.

Full results are given in Table 3.

Efficacy

Planimetric measurements for all patients identified a mean reduction in wound surface area of 58.51% after six weeks (median value: 72.5%). Fig 1 illustrates the mean reduction that occurred during the course of the treatment.

At the end of the six-week treatment, the mean surface area was 2.42 ± 3.60cm² (median 1.05cm²) $p<0.0001$), compared with 6.97 ± 6.43cm² (median 4.96cm²) at baseline.

Ten ulcers (24%) healed in a mean of 25.9 ± 9.46 days (range 7–41). Their baseline mean surface area was 6.2cm² and the mean duration was 6.7 months. The baseline surface area reduced by more than 40% in 32 of the 42 patients in a mean of 18.8 days.

At six weeks, the investigators considered that 10 ulcers had healed, 26 had 'improved', four had stagnated and two had increased in size.

Secondary endpoints

- ***Clinical assessments*** At week 6, only five patients (12%) still had clinical oedema of their lower limb compared with 29 (70%) at baseline. Ten ulcers (30%) had a healthy surrounding skin, compared with only three (7%) at baseline.
- ***Impact on quality of life*** Patients reported that they had experienced spontaneous pain in 53% of the weekly assessments conducted throughout the course of the study. It was considered 'intense' in 25% of the study assessments, compared with 45% at baseline. When present, pain was reported as 'continuous' in 9% of the study assessments, compared with 32% at baseline.

Less itchiness was perceived underneath the new system: patients reported no itchiness in 59% of the

Table 3. Acceptability and effect on quality of life of the compression systems used at baseline and throughout the study

	Baseline	Throughout study*
	No. (%)	No. (%)
Pain under compression system?		
• Yes	33/41 (81)	115/215 (53)
• No	8/41 (20)	100/215 (47)
Intensity of pain:		
• minor	6/33 (18)	29/115 (25)
• moderate	12/33 (37)	52/115 (45)
• intense	13/33 (40)	29/115 (25)
• very intense	2/33 (6)	5/115 (4)
Frequency of pain**		
• continuous	10/31 (32)	10/115 (9)
• intermittent	21/31 (68)	105/115 (91)
Itchiness†		
• none	18/41 (44)	159/268 (59)
• moderate	17/41 (42)	87/268 (32)
• intense	6/41 (15)	21/268 (8)
• very intense	—	1/268 (0.3)
Sensation of heat†		
• none	23/41 (56)	175/268 (65)
• moderate	14/41 (34)	78/268 (29)
• intense	4/41 (10)	12/268 (5)
• very intense	—	3/268 (1)
Ease of wearing shoes†		
• very easy	7/41 (17)	59/268 (22)
• easy	24/41 (59)	166/268 (62)
• difficult	7/41 (17)	35/268 (13)
• very difficult	3/41 (7)	8/268 (3)
General comfort during the day†		
• very good	4/41 (10)	107/268 (40)
• good	28/41 (68)	147/268 (55)
• poor	9/41 (22)	14/268 (5)
• very poor	—	—
General comfort during the night‡		
• very good	4/26 (15)	92/262 (35)
• good	17/26 (65)	149/262 (57)
• poor	5/26 (19)	19/262 (7)
• very poor	—	2/262 (0)

*To give a full picture of the effects of the new two-bandage compression system on quality of life, results are given for all weekly clinical assessments conducted throughout the six-week follow-up period
** Data are missing for two of the 33 patients who experienced pain at baseline
† One patient had not been prescribed compression before inclusion
‡ The total is different to 41 for baseline general comfort during the day because some patients did not wear compression system during the night

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study assessments, compared with 44% at baseline, when it was noted as more intense. In addition, less heat sensation was perceived underneath the new system: patients reported they had felt no heat in 65% of the study assessments versus 56% at baseline.

More people did not experience difficulty putting their shoes on while wearing the new system (84% versus 76% at baseline, of whom 33% had worn a monolayer system before entry).

More patients considered the new system very comfortable or comfortable during the day (95% versus 78% at baseline). However, 50% considered it generally more comfortable during the day than the compression system worn before inclusion.

More patients considered the new system very comfortable or comfortable during the night (92% versus 80% at baseline). However, 41% of the patients who wore multilayer bandages at baseline thought the new system was generally more comfortable at night, while 48% thought it was as comfortable as their previous compression system and 11% thought it was less comfortable. Full results for the quality-of-life data are given in Table 3.

- ***Adverse events*** Three topical adverse events were reported:
- A small blister on the anterior side of the leg in one patient, which disappeared after five days without treatment. The investigator thought this might have been caused by the dressing
- Two local infections (*Pseudomonas aeruginosa*) occurred at weeks 4 and 6, causing one patient to withdraw prematurely. In the investigators' opinion, based on their clinical experience, the infections were not dressing-related.

Only three patients (7%) withdrew from the study, all for reasons unrelated to healing or the new system. This is indicative of a high level of patient concordance.[15,17-19]

Use of the compression system therapy

The results on ease of use are given in Table 4. The investigators considered the new system 'very easy' or 'easy' to apply in almost all cases. The primary dressing remained completely in place beneath the new system between changes in 91% of the cases (196/215).

Discussion

This clinical trial aimed to evaluate the efficacy (primarily defined as the reduction in ulcer surface area), tolerability and acceptability of a new two-bandage compression system for venous leg ulcers. None of the patients was lost to follow-up despite its ambulatory nature.

As this was a non-comparative trial, it is not possible to compare the results on efficacy with those of other compression bandaging systems. Indeed, a key objective was to determine if the product is safe and well accepted by patients and practitioners. However, it is of interest that the physicians considered its efficacy to be satisfactory in 36 of the 42 ulcers, which either healed or improved by week 6. At baseline, the mean ulcer surface area was more than 5cm^2 and the mean duration was more than six months, which are not associated with a good prognosis.[24,25] Furthermore, just over half of the ulcers (55%) were stagnating or worsening at baseline and the condition of the surrounding skin was not healthy in 93%.

It would be inappropriate to compare the percentage of healed ulcers recorded in this six-week study with the results of studies where the follow-up was 12 weeks. (Six weeks was chosen because the endpoint was not total wound closure.) However, it is worth noting that the mean reduction in ulcer surface area observed after six weeks of treatment (58.51%) is at least comparable with data recorded at six weeks in venous ulcer studies that used other compression therapy systems[26-28] or compression bandaging plus lipidocolloid primary dressings,[29-31] where the baseline leg ulcer surface areas and durations were similar. The fact that compression was used in combination with the lipidocolloid dressing in the latter three studies[29-31] suggests that the primary dressing was not solely responsible for the positive outcomes recorded here.

More than 75% of the leg ulcers in our study showed a 40% or more reduction of their initial surface area in a mean time of 18.8 days. In venous leg ulcers a reduction of 40% of the initial surface area after four weeks of treatment is highly predictive of complete healing at 20–24 weeks.[32-34]

Efficacy was also evaluated in terms of the system's effect on lower leg oedema: only 12% of patients still had oedema after six weeks compared with 69% at baseline.

Only three topical adverse events were recorded during trial, which is lower than reported elsewhere in the literature.[15,17-19]

Table 4. Ease of use of the new compression system

	No. (%)
Ease of application of the first bandage (n=227)	
• very easy	105 (46)
• easy	120 (53)
• difficult	2 (0.8)
• very difficult	—
Ease of application of the second bandage (n=227)	
• very easy	121 (53)
• easy	104 (46)
• difficult	2 (0.8)
• very difficult	—
Ability to hold primary wound dressing in place (n=215)	
• Yes	196 (91)
• No	19 (9)

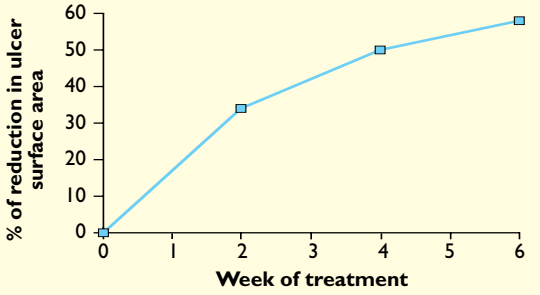
The improvement in the condition of the surrounding skin recorded here may be due to the use of the lipidocolloid primary dressing, which has shown similar improvements in clinical or observational leg ulcer studies.[29,35]

In terms of its impact on patients' day-to-day quality of life, patients considered that sensations of pain, heat and itchiness decreased with the new system and found it easier to put their shoes on. Furthermore, 50% and 40% reported that general comfort during the day and at night, respectively, was better than with their previous system.

In order to document the interface pressures sustained by three compression therapy systems over seven days (a four-layer bandage [Profore, Smith and Nephew] and a short stretch [Actico, Activa]), a prospective randomised study involving 24 healthy volunteers was conducted.[22] The K-Two system was able to sustain an effective interface pressure (>40 mmHg) for one week, like the four-layer bandages system. No adverse events were noted in the K-Two group, whereas 25% discontinued the four-bandage system after three days due to pain. The investigating physicians noted the new system was easy to apply in all cases, probably due to the 'etalonnage'.

This was confirmed when 32 nurses tested the same three compression systems on a healthy volunteer; the results, presented at the same conference, showed that K-Two was easier to apply and delivered effective therapeutic pressure (level superior to 40mmHg, as measured by the Kikuhime sub-bandage pressure monitor).[23]

Fig 1. Mean percentage reduction in ulcer surface area over the six-week treatment period with the new compression system (n=42)



Conclusion

Our results indicate that K-Two is effective in the management of venous leg ulcers. Compared with the compression therapy systems used before entry, clinical benefits included increased patient comfort, which was reflected by total concordance with the new system, the avoidance of dressing slippage and the reduction in bulk.

These preliminary results indicate that the two-bandage compression system represents a suitable alternative to other compression systems, enabling an improvement of the patient's quality of life. ■

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COMPRESSION
KTWO

Treatment of venous and mixed aetiology leg ulcers, venous oedema and lymphoedema

KTwo

2 DYNAMIC LAYERS WORKING IN HARMONY

KTwo DOING MORE IN COMPRESSION

PRESSURE SYSTEM

Thanks to its unique "PresSure System" and its 2 dynamic layers, KTwo ensures consistent application of the recommended therapeutic pressure of 40 mmHg*, without over pressure and slippage[1].

KTwo Reduced is available for patients with mixed aetiology leg ulcers or those intolerant to full compression and donates 20mmHg*

KTwo is available in a Latex Free version and 2 ankle sizes (18-25 cm and 25-32 cm) to be adapted to all of patients.

Two dynamic layers:

- "Gold Standard" efficacy[2]
- Improves patient comfort and concordance[3]
- Easy application with consistent pressures[4]

• Contraindications: arterial conditions (arterial or predominantly arterial ulcers ; known or suspected arterial disease). Ankle Brachial Pressure Index (ABPI) <0.8 for KTwo or <0.6 for KTwo Reduced. Patients suffering from diabetic microangiopathy, ischaemic phlebitis (phlegmatia coerulea dolens), septic thrombosis. Ulceration caused by infection. Allergy to any of the components, in particular latex for the "non-latex free" version.
*average donated pressure at the ankle. Please read the product pack insert carefully before use.

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