# Comparison of interface pressures of three compression bandaging systems used on healthy volunteers


• **Objective:** To compare changes in interface pressures of three compression systems (four layer, two layer and short stretch) recorded over seven days in healthy volunteers in different positions: supine, sitting, active standing and working pressure during exercise.

• **Method:** Twenty-four volunteers were bandaged with one of the three compression systems on both legs. Interface pressures were measured at inclusion (day 0) and on days 1, 3 and 7 using an air sensor system, with the sensor placed in the medial B1 position above the inner ankle. In addition, the volume of the lower legs were also measured on days 0 and 7 using a three-dimensional imaging system. Comfort and tolerability were also assessed.

• **Results:** The performance, based on the loss of interface pressure compared with baseline, of the two-layer system was partially better than that of the short-stretch system for maximal working pressure and loss of volume. The two-layer system and short-stretch system had similar results for the supine, sitting and active standing positions. No difference was observed between the two-layer system and the four-layer system for the maximal working pressure. However, the two-layer system compared better than the two other systems for comfort and tolerability: 25% of the patients treated with the four-layer system discontinued the treatment after three days because of pain.

• **Conclusion:** The two-layer bandage system maintained, over one week, a similar level of sub-bandage pressure similar to a four-layer system and was partially better than short-stretch bandaging. However, the volunteers found the two-layer system more comfortable and tolerable than the other two systems.

• **Declaration of interest:** The investigators received an education grant from Urgo for the study. However, Urgo had no influence on the data analysis or interpretation.


compression therapy; two-layer bandaging system; comfort; tolerance

Compression therapy is the gold standard treatment for venous leg ulcers (VLUs). It is considered that compression of 30–50mmHg at the ankle will reduce venous hypertension without causing discomfort or damaging the skin,[1] although high compression is more effective than light compression in managing VLUs.[2]

Standardised measurements of the interface pressure between the skin and the compression bandaging can be used to objectively evaluate the bandage's biophysical impact, which in turn determines its haemodynamic efficacy.[3] However, interface pressures are not routinely measured,[3] even though they are predictors of tolerability and clinical efficacy.[4]

A Cochrane review found no clear differences in the efficacy between different types of high compression systems.[2] Furthermore, there is no clear evidence on whether four-layer or short-stretch bandaging is more effective in the treatment of venous leg ulcers.[5-7] The selection of compression therapy system therefore depends on parameters such as concordance, acceptability and ease of use for the practitioner as well as the patient.[8]

K-Two (Urgo) is a two-layer compression system whose two layers are designed to deliver the appropriate therapeutic pressure between them (40mmHg at the ankle). An open, non-controlled, clinical study involving 42 patients with VLUs found that it reduced the surface area by a mean of 58.5%, with 24% of the treated wounds healing in a mean time of 25.9 ± 9.46 days.[9]

This single-centre, open, randomised trial measured the interface pressures produced by this two-layer system on healthy volunteers over a seven-day period and compared these values with those achieved with short-stretch and four-layer bandages. Tolerability and comfort of the systems were also assessed.

## Method

### Inclusion and exclusion criteria

Healthy volunteers with no clinical signs of chronic venous insufficiency were recruited into the clinical trial by intranet, internet and local newspapers. They were informed about the details of the trial both verbally and in writing.


**M. Jünger**, MD, PhD, MScH, Chairman and Director, Department of Dermatology, University Hospital of Greifswald, Greifswald, Germany;
**A. Ladwig,** MD, Senior Registrar, Department of Dermatology; University Hospital of Greifswald, Greifswald, Germany;
**S. Bohbot**, MD, Research and Development, Urgo, Chenôve, France;
**H. Haase,** PHD, Mathematician, Department of Dermatology, University Hospital of Greifswald, Greifswald, Germany.
Email: juenger@uni-greifswald.de

Inclusion criteria were:
- Age between 18 and 60 years
- Healthy, intact skin with no signs of any dermatological conditions, such as eczema or psoriasis, as assessed by the investigating physician.

Exclusion criteria were:
- Peripheral arterial occlusive disease, assessed by anamnesis and palpable pulses of the ankle and foot
- Diabetes mellitus
- Cardiac insufficiency
- History, as recalled by the patient, of disease of the coronary arteries, such as myocardial infarction
- Cerebrovascular disease, such as transient ischaemic attack
- Liver or renal disease
- Use of diuretics, antihypertensives or drugs that influence the capillary filtration
- Comorbidities that could affect compression therapy, particularly diseases that cause oedema.

**Ethics committee approval**

The medical ethics committee approved the study, which was carried out in accordance with the Declaration of Helsinki and the applicable paragraphs of the Medical Devices Act MPG § 20-23.

Written informed consent was obtained from all of the volunteers before inclusion into the trial.

**Study protocol**

The three test treatments tested were:
- The two-layer compression system (KTwo)
- Four-layer bandaging (Profore, Smith & Nephew)
- Short-stretch bandaging (Actico, Activa Healthcare).

The systems were randomly allocated to the patients using the closed envelop method. Our statistician calculated that each compression system needed to be applied to 12 legs to produce meaningful results. The investigating physician (MJ) then applied the compression bandaging onto the volunteer in accordance with the manufacturer's instructions. The physician was familiar with all of the bandaging systems used in this study. Thirty-six of the possible total of 48 legs were used in this trial. In addition, each bandage type was tested on the right and left leg an equal number of times.

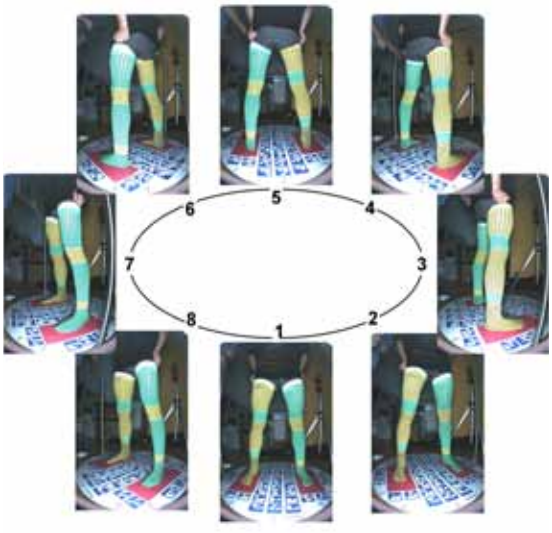



**Fig 1. A three-dimensional image was created using 10 images**

To minimise the risk of bias resulting from the application of incorrect compression at baseline, an 'etalonnage' was applied to all three systems tested. This means that ellipses were printed onto the bandages, which form circles when stretched correctly. The bandages were applied at baseline (day 0) and removed on day 7.

The volunteers were told not to shower during the test period or participate in excessive sports, as these variables could confound the results. Otherwise, they were told to continue with their usual activities.

**Measurement of interface pressure**

Interface pressure between the compression bandage and the skin was measured at the B1 level (proximal to the inner ankle) immediately after bandage application on day 0 and then on days 1, 3 and 7.

To achieve this, Elcat air-filled cushion sensors were applied at the medial B1 and left in place for the trial period. To measure the interface pressure, the sensors were connected to a multipurpose recorder (VQ 2000, Elcat), which converted the data from analog to digital for evaluation by computer software (National Instruments, Ireland). The sensors were disconnected from the recorder immediately afterwards.

Measurements were performed with the volunteers in the following positions:
- Supine
- Sitting
- Active standing (eg, standing absolutely straight).

In addition, the maximal working pressure was measured. This was recorded by asking the volunteers to undertake ankle dorsal extension and plantar flexion 10 times over 15 seconds. Their 10 peak values were recorded and the mean value was defined as the maximal working pressure.

**Volume of the lower limb**

This was determined using Image 3D (Bauerfeind Phlebologie, Zeulenroda). The volunteer was given a coloured stocking to wear for the measurement (Fig 1). Ten photographs were then taken of 10 different aspects of the limb. A three-dimensional image of the leg was then constructed using these 10 digital images. The volume from the B-level (ankle) to the

**Table 1. Parameters used to score comfort and tolerability**

| Answer | None | Slight | Moderate | Severe |
|---|---|---|---|---|
| Score | 0 | 1 | 2 | 3 |
| No. of cases | $a_0$ | $a_1$ | $a_2$ | $a_3$ |

**Table 2. Median baseline interface pressure values (mmHg)**

| Position | Two layer | Short stretch | Four layer |
|---|---|---|---|
| Supine | 47.81 | 48.47 | 51.54 |
| Sitting | 49.44 | 47.97 | 54.02 |
| Active standing | 55.81 | 64.72 | 62.08 |
| Maximal working pressure | 61.62 | 71.46 | 78.97 |

D-level (knee joint) was then calculated, based on these images. The volume was calculated immediately before bandage application on day 0 and after the bandages were removed on day 7.

### Comfort and tolerability

These were assessed using a questionnaire on day 0 immediately after bandage application and on days 1, 3 and 7. The questionnaire enquired about:

- Tolerance, based on tightness, pain, burning, sweating, itching, tickling and sensation of heat
- Comfort, which was assessed using the following parameters: dermal desiccation, immobility of ankle joint, slippage and/or loosening of the bandage, and concordance when sleeping, sitting and walking.

These assessments were based on the frequency and severity (none, slight, moderate, severe) of these events. Each parameter was scored as outlined in Table 1. A total was then determined using the following equation:

$s = a_1 + 2a_2 + 3a_3/a_0 + a_1 + a_2 + a_3$.

### Outcome measures

- The primary outcome measure was the loss of interface pressure after one, three and seven days of wearing each compression bandaging system.
- The secondary outcome measure was the reduction in volume of the lower limb.

### Statistical analysis

The primary hypothesis was that the relative loss of interface pressure after days 1, 3 and 7 would be smaller for the two-layer system than for the four-layer one.

A one-way analysis of variance (ANOVA) was used for interval data, such as interface pressure (for days 0, 1, 3 and 7) and volume of the lower leg. Additionally, the Dunnett post-hoc test was applied when the Levene test did not reject the hypothesis of homogenic variances.

Mean and standard deviations of all observations were calculated for all time points and measurements. Line plots were used to visualise the time changes of interval data and represent data of undesired events (the comfort/tolerability parameters assessed, as described above).

For the maximal working pressure and the volume of the lower leg, 95% confidence intervals were calculated for all time points (95% of all values lie within the plotted range and the midpoint is the mean).

## Results

Twenty-four patients were included in the trial, seven males and 17 females, with a mean age of 27.58 years ± 6.9.

Three patients discontinued the four-layer bandaging on day 3 because of pain.

### Interface pressures

Baseline interface pressures and maximal working pressure values are given in Table 2. Baseline maximal working pressures were higher for the short-stretch and four-layer bandages than for the two-layer bandage.

Interface pressures values for each bandage system reported on days 1, 3 and 7 show that:

- The loss of maximal working pressure was significantly lower for two-layer and four-layer systems compared with the short-stretch bandage on day 3 ($p=0.017$) but not on day 7 (Fig 2)
- There was no significant difference at any time point between the relative decrease (loss) of maximal working pressure for the two-layer and four-layer systems
- There was no significant difference at any time between the two-layer and the short-stretch systems in the relative decrease in interface pressure values for the supine, sitting and active standing positions
- The relative loss of interface pressure was smaller for the four-layer bandage when compared with the two-layer and short-stretch systems on day 7 for the active standing and sitting positions, but not for the supine position.

Throughout the trial period, the maximal working pressures reported for the two-layer and four-layer bandages exceeded the therapeutic value of 40mmHg.

### Tolerability

Values reported on days 1, 3 and 7 are given in Fig 3.

- There was no difference between two-layer and short-stretch bandaging for the following parameters: tightness, pain, burning, sweating and itching

- Two-layer bandaging had significantly lower scores than short-stretch bandaging (p<0.0001) for the sensation of heat
- There was no difference between two-layer and four-layer bandaging in terms of burning and tickling
- Two-layer bandaging had significantly lower scores than four-layer bandage for the following parameters: tightness (p=0.0003), pain (p<0.0001), sweating (p=0.0005), itching (p=0.01) and sensation of heat (p<0.0001).

As noted above, three patients stopped using the four-layer bandaging because of pain.

### Comfort

- The was no difference between two-layer and short-stretch bandaging for the following parameters: dermal desiccation and concordance when sleeping, sitting and walking
- Two-layer bandaging had significantly lower scores than short stretch for the following parameters: immobility of ankle joint (p=0.001), slippage (p=0.003) and loosening of bandage (p<0.0001)
- There was no difference between two-layer and the four-layer bandaging in terms of desiccation
- Two-layer bandaging had significantly lower scores than four-layer bandaging for the following parameters: immobility of ankle joint (p<0.0001), slippage (p=0.003), loosening of bandage (p=0.0003), concordance when sleeping (p<0.0001), sitting (p=0.0001) and walking (p<0.0001) (Fig 4).

### Volume reduction of the lower limbs

All of the compression systems achieved a significant reduction in the volume of the lower leg on day 7. The match pair design t-test for all groups gave at least $p \leq 0.024$ for all types of bandages.

However, two-layer bandaging resulted in a larger loss of volume than the short-stretch bandaging (t-test. p=0.0485), and no difference was observed between two-layer and four layer bandaging.

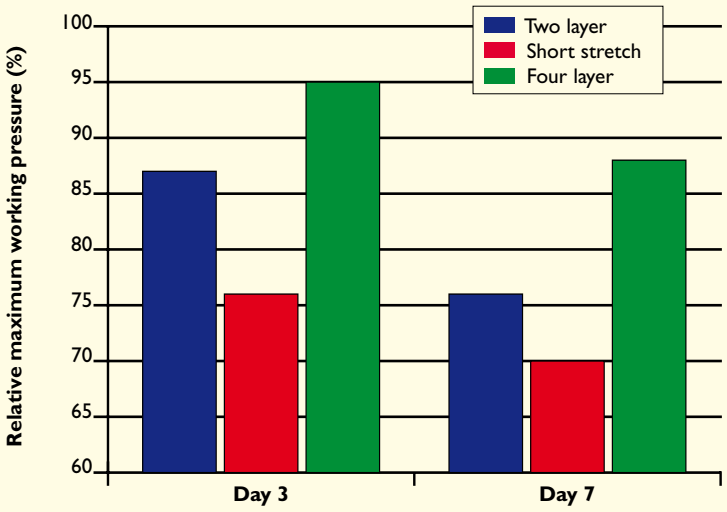
## Discussion

The interface pressure achieved by a compression system is not only operator dependent but may also vary between applications by the same operator, depending on the method of application (stretch, extension).[4] Furthermore, inexperienced or poorly trained clinicians have been found to apply inappropriate levels of compression.[10] This results in impaired quality of life, poor concordance and thus delayed healing.[11] The etalonnage was therefore used to ensure that the bandages were applied correctly in this trial. All assessments and measurements were performed by the same experienced operator at the B1 level, which is the reference location for such *in vivo* measurements.[3]

An earlier comparative evaluation in which 32 trained nurses applied the same three bandaging systems to healthy volunteers found that:

- Pressures between 30mmHg and 50mmHg were achieved with the two-layer system in 85% of cases
- Pressures between 30mmHg and 50mmHg were achieved with the four-layer system in 69% of cases. However, 25% of the nurses achieved >50mmHg, compared with 9% for the two-layer system.
- Seventy-five per cent of the short-stretch bandaging applications were <30mmHg.[12]

**Fig 2. Relative maximal working pressure on days 3 and 7, compared with baseline**




The y axis indicates the percentage reduction against baseline

**Fig 3. Tolerability of the tested bandages**

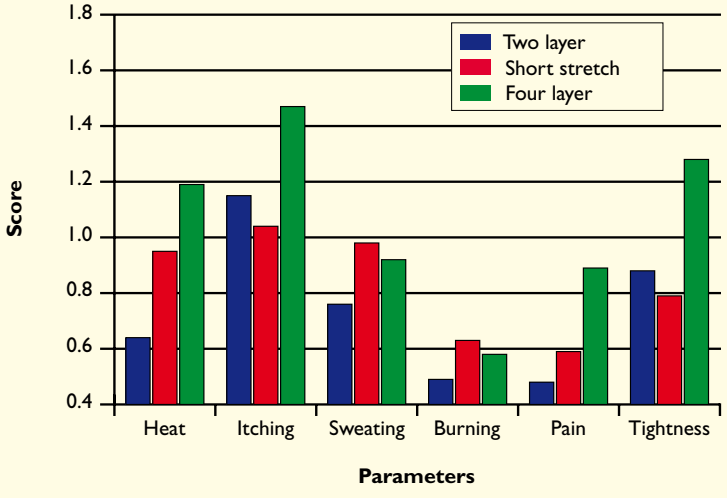
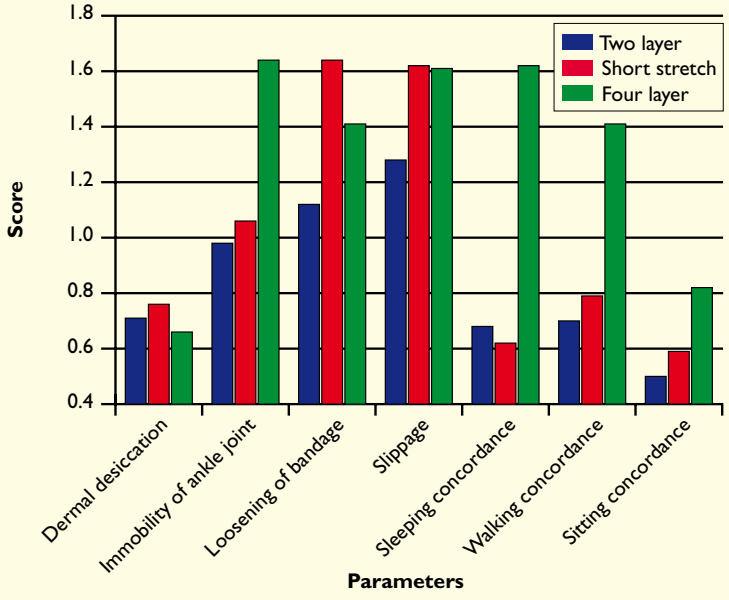


**Fig 4. Comfort of the tested compression systems**




However, unlike the present study, the etalonnage was not printed on the short-stretch and four-layer bandages.

Our study found no statistically significant difference between the two-layer and four-layer systems with respect to the maximal working pressure. The two-layer bandaging had a smaller maximal working pressure at baseline compared with four-layer bandaging, but this did not affect the subsequent interface pressures achieved for the two-layer system, which were all above the therapeutic level of 40mmHg.

Similar interface pressures were achieved with the two-layer and short-stretch systems in the supine and sitting positions at baseline. However, higher baseline values were reported for the short-stretch system in the active standing position and maximal working pressure.

While the two-layer system achieved a significantly smaller reduction in maximal working pressure than did the short-stretch system on day 3, there was no such difference between them on day 7.

Non-stretch and short-stretch materials with minimum extensibility can achieve a resting pressure of 30–60mmHg,[13] but this decreases over the first 24 hours with movement and/or as oedema reduces. The working pressure tends to decrease less, resulting in a bandage that provides tolerable resting pressures and higher working pressures.[14,15]

A previous comparative study found that another four-layer compression system retained a constant interface pressure for one week, while an adhesive plaster bandages lost 50% of its initial interface pressure after only four hours.[16]

When some short-stretch bandages were tested, there was a statistically significant drop in pressure after only 30 minutes.[17] Indeed, the main drawback of short-stretch bandages is a rapid loss of interface pressure after only a few hours of wear, even though they can correct deep venous reflux more effectively than long- stretch bandages[18] and produce high working pressures[19,20] and low resting pressures.[21] This rapid drop of interface pressure may be due to a reduction in oedematous swelling and a tendency to loosen and slip during wear.[22] This could explain why short-stretch bandages require more bandage changes than four-layer systems when used on venous leg ulcers.[15,20,23]

Less slippage may result in longer and more effective compression therapy. However, a crossover study that compared two-layer with four-layer bandaging found that, even though the two-layer bandage had significantly less slippage than the four-layer comparator, there was no difference in healing outcomes between them.[24]

In the present trial, despite the absence of oedema in these healthy volunteers, each of the three tested bandage systems induced a reduction in limb volume. However, this was more marked for the two-layer system as the mean volume was significantly higher at calf than for the short-stretch system; p=0.048).

The ability of the two-layer bandage to manage leg oedema has been reported in a clinical evaluation of leg ulcer patients: only 12% of the recruited patients were still presenting with leg oedema after the six weeks of treatment.[9] Although these results suggest that this two-layer system is suitable for the management of leg oedema, further clinical studies are needed to confirm these findings, specifically in lymphovenous disease and lymphoedema.

The two-layer system performed better than the short-stretch in terms of patient acceptability/tolerability. Other short-stretch systems have shown a high level of adverse events in clinical trials on patients with VLUs.[25,26]

A clinical study involving 42 patients with VLUs reported only two adverse events following the use of KTwo. Furthermore, all of the patients continued using the system during the six-week follow-up period.[9]

In contrast, in the present study 25% (3/12) of the treated legs discontinued the four-layer system because of poor acceptability and tolerance.

This may because of the high interface pressures reported in all positions, particularly the static ones, which induced complaints from the healthy volunteers.

Similar findings have been reported in other trials of four-layer systems on VLU patients.[7,11,25,27,28] Widely recognised for their clinical efficiency, such

complaints may reduce concordance with four-layer bandaging, particularly after when worn for a long period of time.

A crossover study[27] found a two-layer system achieved a greater improvement in physical symptoms and daily living scores (from the health-related quality of life assessments) when compared with four-layer bandaging ($p<0.05$). Furthermore, 72% of the patients said they preferred the two-layer system, stating that it was more comfortable and less bulky.

## Conclusion

This study adds to the understanding of, and relationship between, different compression systems and suggests the potential implications for clinical practice. However, the findings reported here are considering the level of pressure interface, acceptability and tolerance of different compression systems observed on healthy volunteers: some findings are already correlated to those observed in some clinical trials (if considering tolerance and acceptability) while some others (slippage, change frequency and healing process) have to be evaluated =and confirmed in patients suffering from ulceration caused by venous disease. ■

With thanks to Dr Ladwig for the examination and anamnesis of the study participants; Mrs Heitmann, Mrs Hinckfoth, Mr Rohde and Mr Röbisch for performing the interface pressure and leg volume measurements; Dr PD Haase for coordinating the project and biometrics

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