A dual compression system: preliminary clinical insights from the US

**Abstract:** There is growing evidence on an interconnection between the venous and lymphatic systems in venous leg ulceration, and the possible effects of prolonged oedema and lymphatic impairment in delayed wound healing. Compression therapy is a widely accepted treatment for venous and lymphatic disorders, as it decreases recurrence rates and prolongs the interval between recurrences. Compression bandages improve venous return, increase the volume and rate of venous flow, reduce oedema and stimulate anti-inflammatory processes. The pressure at the interface (IP) of the bandage and the skin is related to the elastic recoil of the product used and its resistance to expansion. The pressure difference between the IP in the supine and standing positions is called the static stiffness index (SSI). Elastic materials provide little resistance to muscle expansion during physical activity, resulting in small pressure differences between resting and activity, with an SSI <10mmHg. Stiff, inelastic materials with a stretch of <100% resist the increase of muscle volume during physical activity, producing higher peak pressures, an SSI of >10mmHg and a greater haemodynamic benefit than elastic systems. UrgoK2 is a novel dual-layer high-compression system consisting of an inelastic (short stretch) and elastic (long stretch) bandage, resulting in sustained tolerable resting pressure and elevated working pressures over extended wear times. It is indicated for the treatment of active venous leg ulcers and the reduction of chronic venous oedema. Each bandage layer has a visual aid to enable application at the correct pressure level. Published European studies have assessed this compression system, exploring its consistency of application, tolerability and efficacy. This article presents the first reports of health professionals’ clinical experience of using the compression system in the US, where it has been recently launched. Initial feedback is promising.

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In December 2019, a panel of wound care experts (the authors) met in Fort Worth, Dallas, US, to examine the attributes of a compression system for venous leg ulcers (VLUs) that has been available in Europe for some time and was launched in the US in 2020. The dual-layer system consists of an inelastic (also known as short stretch) and an elastic (long stretch) layer; its primary purpose is to heal VLUs. The product has already been the subject of a number of clinical studies conducted in Europe to assess its efficacy, tolerability, comfort, ability to maintain pressure over an extended period, ease of use and ability to be applied in a consistent manner.1-4 The panel reviewed the evidence in the context of other compression systems on the market; here, they share their personal experience of using the product and assess whether it could be effective as a treatment for venous leg ulcers. This report summarises the evidence and discusses their findings.

**Incidence and prevalence data for venous and other leg ulcers**

In the US, chronic wounds affect 6.5–7 million patients,5,6 with most occurring on the distal part of the lower extremity. Chronic wounds include diabetic foot ulcers, VLUs, mixed-aetiology leg ulcers, pressure ulcers and arterial leg ulcers. Leg ulcerations, specifically VLUs, and chronic oedema are more common in the presence of underlying disease and in older patients.5,7 VLUs are the most common chronic wound on the lower extremities, with approximately 600,000 cases per year in the US, accounting for 70–90% of ulcers.5 In the US, VLUs affect 0.6–3% of people aged over 60 years, increasing to 5% in those aged over 80.8 Estimates of overall incidence are hard to come by, but one estimate suggests a mean figure of 2.2% in Medicare (US federal health insurance, mostly targeted at people aged over 65 years) patients and 0.5% in the privately insured population, reflecting that the Medicare patients tend to be older and have more risk factors than privately insured individuals, who generally tend to still be working.8

VLUs are typically located on the medial aspect of the lower leg and foot, with VLUs affecting the lower leg affecting the medial, lateral, and posterior aspects. Venous and arterial ulcers are typically classified as deep or superficial, with VLU’s being associated with deep structures.”

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**John C Lantis II,**1 Vice Chair and Professor of Surgery; **Christopher Barrett,**2 Program Director; **Kara S Couch,**3 Director, Wound Care; **Suzie Ehmann,**4 Clinical Specialist; **Emily Greenstein,**5 Wound/Ostomy Nurse Practitioner; **Marta Oster,**6 Owner; **Anthony Tickner,**7 Medical Director

*Corresponding author email: john.lantis@mountsinai.org*

lower leg, primarily in the gaiter area of the leg. They can be painful, are frequently colonised, are often highly exudative and may persist for months or years with frequent recurrences. Daily life can be affected, with sleep loss, impaired mobility, capacity to work and social activities resulting in significant morbidity, reduced quality of life and loss of productivity.

Socioeconomic impact of VLUs
A study of healthcare records (based on a 5% sample of nearly 11 million records from 2007 to 2011) calculated that the total incremental annual cost to the US healthcare system of treating VLUs could be as high as $14.9 billion. The incremental cost of treating VLUs is around $7000.

In a retrospective study of patients with active VLUs (clinical, etiologic, anatomic and pathologic (CEAP) class 6 disease), the total mean cost for patients whose VLUs healed without recurrence was $10,563 (equivalent to $86 per day of treatment) and ranged from $430 to $50,967, while patients whose VLUs did not heal incurred a total mean cost of $33,907, a three-fold increase. Costs related to the extended treatment of a non-healing VLU were a significant contributing factor and included $10,332 for outpatient facility fees and $11,365 for nurse visits. Patients whose ulcer recurred during the 1-year follow-up period incurred a total cost of $12,760 as opposed to $10,563.

Aetiology and development of VLUs
VLUs primarily arise from impaired circulation due to dysfunctional valves in the blood or obstructed veins, and often accompany underlying comorbidities such as rheumatoid disease, diabetes, osteoarthritis and morbid obesity.

Arterial insufficiency and mixed aetiology are other possible causes of leg ulceration. A minority of leg ulcers (5–25%) result from less common, difficult-to-diagnose pathophysiological causes such as rheumatological, metabolic or haematological disorders and infective diseases (the range in reported values is due to differences in study methodologies and definitions).

Hereditary factors play an important part, and the risk of developing leg ulcers increases with age. Phlebolymphoedema is also acknowledged to be an underlying cause of leg ulcers.

Although there are many causes of venous hypertension, the unifying hypothesis is that there is unrelieved ambulatory hypertension in the veins of the calf. Blood vessels distend to accommodate the increased venous pressure, while valves are unable to close effectively, resulting in retrograde flow and venous hypertension. High venous pressure is transmitted to the capillaries and epidermal veins, causing increased permeability, leakage and deposition of haemosiderin and increased venous pressure, while valves are unable to close effectively, resulting in retrograde flow and venous hypertension.

Role of the lymphatic system
There is growing evidence for an interconnection between the venous and lymph systems in the development of venous ulcers, and the possible effects of prolonged oedema and lymphatic impairment on delaying wound healing. An intact and functioning lymphatic system is critical for the maintenance of homeostasis and healing. Damage to the lymphatic vessels in the presence of chronic venous insufficiency (CVI) has been well documented, and studies of wounds and CVI associated with venous hypertension support this theory.

In cases of lymphatic impairment, interstitial fluid leaking from blood capillaries may overwhelm the lymphatic system, such that accumulation of fluid, along with macromolecules and cytokines, invariably lead to oedema, breakdown of subcutaneous tissue, and formation of ulcers. Oedema impairs blood flow, decreases the delivery and removal of key nutrients, causes increased bacterial colonisation and the trapping of peptides and cytokines, which, as stated, above cause pain and impair healing. Once it has developed, an ulcer will not heal until venous hypertension and excess lymphatic fluid are improved. There is evidence that most, if not all CVI CEAP ulcers at stage 3 and above show lymphatic dysfunction.

Despite evidence supporting the treatment of
lymphoedema in CVI patients, current VLU management ignores the role of the lymphatic system in the belief that chronic oedema in CVI patients can be resolved by addressing venous hypertension alone. However, interventions to correct severe venous obstruction, such as venous ablation or phlebectomy, may not be sufficient to resolve increased interstitial fluid load if lymphatic vessels are dysfunctional. There are some data to show that manual massage, sequential pneumatic compression and physical therapy aimed at increasing ankle range of motion and strength can be an adjunct to compression to help facilitate healing.

Evidence of macroangiopathic changes, such as increased permeability and fibrinogen leakage, affecting small vessels in the lymphatic and venous systems has been found in CVI patients with stasis dermatitis, a common inflammatory skin disease in these patients. Studies showed that lymphatic function and anatomy were abnormal in all patients with CVI and VLUs, when compared with healthy subjects: lymphatic dysfunction could occur early in the disease process and may precede clinically overt ulcer formation. Further evidence of structural lymphatic changes, such as collapsed lumens, has also been found. In addition, phlebolymphoedema hampering regular lymph flow and normal trafficking of immune cells was found to initiate an immunocompromised area in the affected body region.

**Effect of compression therapy on the underlying pathology**

Compression therapy is a widely accepted treatment for venous and lymphatic disorders and systematic reviews have consistently shown that it produces a higher ulcer healing rate compared with no compression. When applied correctly, compression has also been shown to decrease recurrence rates and prolong the interval between recurrences. However, compression therapy is also significantly underused, particularly in the community, for reasons including lack of knowledge or confidence by health professionals and an unwillingness by the patient to wear it.

The aim of compression therapy is to correct the effects of valvular incompetence and to reverse the effects of chronic venous hypertension. Compression bandages create pressure on the limb that is transmitted to all deformable internal structures (veins, lymphatics, tissues, fluid and tissue components) in a manner that is directly proportional to the tension of the applied fabric and the number of layers, and indirectly proportional to the radius of the limb and bandage width. Venous return is improved as vein diameter is reduced, the volume and rate of venous flow is increased, and venous reflux is reduced. Intermittent elevated pressure in the region of 50–70mmHg can, in effect, produce a vein occlusion at each step, restoring a kind of valve mechanism to the circulation, although there is no consensus on this, as some clinicians have commented that >50mmHg is too high.

Oedema is reduced as the applied pressure allows less fluid to leak out of the capillaries and encourages more fluid to be reabsorbed into the lymphatic system. Reduced ultrafiltration decreases the lymphatic load and increases interstitial pressure, reduces inflammation and breaks down fibrotic tissue.

Compression therapy has been shown to have anti-inflammatory effects: intermittent pneumatic compression creates an increase in shear stress in the microcirculation, leading to the release of anti-inflammatory mediators from the endothelial cells. It is thought that a similar effect will also occur through the massaging action of inelastic compression material during walking. An evaluation involving 30 patients that measured the levels of cytokines in ulcers before and after compression therapy found that 4 weeks of treatment was sufficient to bring about a significant decrease in levels of most of the pro-inflammatory ulcer cytokines. At the same time, levels of the anti-inflammatory proteins, TGF-β1 and IL-10, were increased, significantly in the case of TGF-β1. Positive effects are also seen on arterial inflow. However, to avoid reducing arterial inflow in patients with concomitant arterial occlusive disease, the applied pressure should never exceed the local arterial perfusion pressure at the ankle.

**How compression bandaging works**

Compression applied to a limb exerts a compression force on the tissue over which it is applied. The bandage acts like a closed system where the external pressure applied to the leg is transmitted equally in all directions within the leg. The pressure at the interface (interface pressure, IP) between the compression therapy and skin can be used as a surrogate measure of the pressure in the leg. The level of IP is related to the elastic recoil of the product used and its resistance to expansion. The pressure difference between IP in supine and standing positions is called the static stiffness index (SSI). The working compression pressure and the SSI, although clinically much more relevant than resting pressure, are rarely reported in studies or recorded in clinical practice.

Compression systems that have greater resistance and stiffness have been shown to produce greater pressure change between sitting and walking, and greater fluctuations in pressure during walking. Although there is some debate as to the exact definition, in general it can be stated that elastic materials have an extensibility of more than 100%; while inelastic bandages may be either ‘short-stretch’ with an extensibility of 10–100%, or ‘rigid’ with an extensibility up to 10%.

Elastic materials provide little resistance to the muscle expansion that occurs during physical activity, resulting in only a small pressure difference between resting and standing or walking, with an SSI <10mmHg. The tendency to ‘return’ to their initial length means that elastic materials can have a high resting pressure, which can be painful for patients, but a low working pressure, which is insufficient to exert a haemodynamic effect.

Inelastic materials, with a stretch of around 60%
extensibility are stiff, and resist the increase of muscle volume during physical activity, producing higher peak pressures compared with elastic devices. These materials contain limited amounts of elastic fibre and therefore have only limited inherent return force, meaning they can be applied at near full stretch without causing undue discomfort to the patient, while providing greater pressure fluctuations when the limb is moved. Stiff materials can achieve an SSI of >10mmHg which is maintained over time even when the IP drops due to reduction of oedema. High-stiffness systems therefore have a greater haemodynamic benefit than elastic systems, improving venous blood flow and multi-component elastic bandages with a higher stiffness have been shown to achieve better therapeutic benefit than single-layer systems.

Evidence to support current compression therapy practice

Published studies on the efficacy of specific compression applications in the management of VLUs are at times contradictory. Comparative assessment of study outcomes is hindered by methodological flaws, inconsistent or no documentation of the IPs used and few details of the characteristics of the compression textile. A leading theme throughout the literature is that the higher the pressure (up to a safe limit), the better the healing. However, evidence on the ability of particular bandaging techniques or materials to achieve a dynamic compression profile is contradictory and unreliable. In contrast, there are also published studies that report superiority of elastic stockings and bandages when compared with inelastic material. Despite the importance of the working pressure for clinical outcomes, this parameter is rarely reported. It is therefore impossible to know whether the devices were correctly applied and were achieving the intended or recommended pressures. If they were too slack, their efficacy would be impaired; if too tight, they may have been loosened or even removed by patients.

There is also a lack of understanding, in some cases, about the nature of the materials used. For example, a four-layer bandage may be considered elastic as it contains elastic components. However, friction between the components of the bandage may give it properties comparable to a stiff, inelastic device.

With this level of confusion, to make meaningful comparisons between devices, future studies should ideally specify the compression mode, textile components and dynamic compression profile (working and resting pressures, as well as SSI) of each system evaluated. There is also a need to look at the biophysical impact of pressure distribution across the skin or wound, as new research has demonstrated that alternating compression profiles have a positive effect. Requirement for these textile characteristics to be specified in future study designs will allow for more meaningful comparisons of compression systems, which will in turn help enable selection of a system that addresses individual patient needs. Recently published examples include Chohan et al. and Ehmann et al.

Adherence to compression therapy

Long-term adherence to compression therapy is essential for healing, but adherence to compression bandaging systems is generally poor:

- 60–70% of patients are non-compliant with compression due to bandages being ‘uncomfortable’
- Reasons cited by patients for not wearing compression stockings include itching, tightness, difficulty with application and removal, a sensation of pins and needles, and rashes
- Patient beliefs that compression therapy is unnecessary and ineffective for preventing ulcer recurrence are significantly related to non-adherence.

Characteristics of an ideal compression bandaging system, as proposed by the panel, include the ability to achieve continuous tolerable resting pressures for day and night wear with sufficient static stiffness to produce therapeutic working pressures with a change in position or with movement. The compression bandage system should accommodate a variety of limb sizes, and have a low profile so as to not impair functional mobility or normal shoe wear. An external indicator to optimise consistent therapeutic application with each dressing change is helpful. This is an important feature because compression applications applied with excessive tension can cause trauma in those with compromised sensation or circulation.

A new dual-layer compression bandaging system

Urgo K2 (hereafter referred to as the dual compression system (DCS)) is a dual-layer high-compression system consisting of an inelastic and elastic bandage. According to the manufacturer, when combined, the two layers constitute one compression bandaging system that provides both a dynamic static stiffness profile and tolerable resting pressures. The first layer, KTech, is an inelastic bandage (approximately 75% extensibility), consisting of viscose and polyester wadding with a knitted layer made of polyamide and elastane. The manufacturer states that, when in contact with the skin, the KTech layer distributes the pressure uniformly over the surface of the leg and provides compression, along with protection and absorbency. The manufacturer states that, because it is a relatively inelastic bandage, it provides a high working pressure with a low resting pressure, which in combination with the action of the calf muscle creates a massage effect, assisting venous return and reducing oedema levels. The manufacturer states that the second layer, KPress, is an elastic cohesive bandage of approximately 160% extensibility, made from synthetic components, such as acrylic, polyamide and elastane. According to the manufacturer, this outer bandage provides the additional compression necessary to achieve the required therapeutic pressure and, more
critically, maintains the recommended resting pressures necessary to maintain improved blood flow. The bandage contains an adhesive designed to enable it to stay in place for up to 7 days. These pressures have been shown to be consistently maintained over time, with sustained tolerable resting pressure and elevated working pressures over extended wear times.²

The DCS is indicated for the treatment of active venous leg ulcers and the reduction of chronic venous oedema. Each bandage layer displays a printed ellipse (the PresSure system, also known as the etalonnage) that expands into a circle when the correct pressure level is applied (Fig. 1). Proper application is further enhanced by guides for appropriate overlap of layering. Pressure marks should be lined up with each application to obtain the correct overlap and optimal therapeutic pressure, which may reduce variability in the application of the bandage.

Clinical studies on the DCS

A series of studies, undertaken in Europe, assessed the DCS with Profore as a comparator, progressively exploring the consistency of application, tolerability and efficacy.¹⁻³

Hanna et al.¹ comparative evaluation of three bandage systems to assess consistency of interface pressures on application

Thirty-two nurses experienced in compression therapy applied each of three systems, the DCS, Profore (four-layers, Smith + Nephew) and Actico (inelastic, Activa Healthcare) bandages, to one healthy volunteer. Nurses had regular experience of applying the four-layer bandages and inelastic bandages, and received training in use of the DCS. The sub-bandage pressure and the time taken to apply each system were measured.

Many nurses applied very high pressures with the four-layer system, with 25% applying pressures of over 50mmHg (mean 44.1mmHg), with the remainder applying it either correctly (69%) or too loosely (6%). Meanwhile, 75% of nurses applied the inelastic bandage at a pressure of <30mmHg (mean 23.2mmHg). In contrast, the nurses achieved consistent sub-bandage pressures with the DCS system (mean 39.8mmHg). Distribution of IP pressures achieved by the nurses is given in Table 1. The percentage of nurses achieving the desired therapeutic range of 30–50mmHg were 25% (inelastic), 69% (four-layer) and 85% (DCS), supporting the utility of the visible pressure indicator system in achieving the correct therapeutic pressure.

Jünger et al.² open randomised trial of three bandage systems to evaluate changes in interface pressure over 7 days. Importance of continuity

Twenty-four healthy volunteers were bandaged with one of three systems: the DCS, Profore (four-layers, Smith + Nephew) and Actico (inelastic, Activa Healthcare (now L&R)) systems; the sub-bandage pressure was measured at inclusion and at days 1, 3 and 7, while the volunteers were standing, resting and walking. The volume of the lower limb was also measured at days 0 and 7, and volunteers answered questionnaires on comfort and tolerability.

Median baseline IP pressures are given in Table 2. There was no difference between the DCS and four-layer systems over the 7-day period for maintenance of maximal working pressure and loss of volume, both of which performed better than the inelastic bandage. There was no difference in terms of pressure drop between the systems at day 7. The DCS was rated better than the other two bandages for comfort and tolerability: after 3 days, one-quarter of the four-layer bandage volunteers had discontinued due to pain, but no adverse events were reported for the DCS. The DCS performed better than the inelastic bandage on parameters of heat, sweating, burning and pain, with little difference between them for itching and tightness.

This study confirmed that the DCS can maintain a continuous working pressure of 40mmHg over a 7-day period and is tolerated well by healthy volunteers. It should be noted that volunteers are likely to have smaller ankles, be more ambulatory and have better goniometry than the average VLU/CVI patient. In addition, they do not have an open ulcer, which for most patients is very painful.

Benigni et al.³ prospective non-comparative study to evaluate efficacy, tolerability and comfort

Forty-two patients with venous or mixed-aetiology ulcers were recruited. Included ulcers had at least 50% granulation tissue, a surface area ranging from 2 to 20cm², and a duration of 1–24 months, while the patient’s ankle circumference had to be <28cm and there had to be no history of DVT in the 3 months prior to enrolment. Reduction in ulcer surface area was measured at 6 weeks; secondary endpoints included leg oedema and patient acceptability. The authors did not specify whether measures were taken to ensure inter- and intra-rater reliability; the participating health professionals were free to select the primary dressing of their own
Table 1. Hanna et al. evaluation: distribution of interface pressures achieved by nurses (%)

<table>
<thead>
<tr>
<th>Bandage system</th>
<th>&lt;29mmHg</th>
<th>30–35mmHg</th>
<th>36–44mmHg</th>
<th>45–50mmHg</th>
<th>≥51mmHg</th>
<th>Values between 30 and 50mmHg</th>
</tr>
</thead>
<tbody>
<tr>
<td>DCS</td>
<td>6%</td>
<td>28%</td>
<td>44%</td>
<td>13%</td>
<td>9%</td>
<td>85%</td>
</tr>
<tr>
<td>Four-layer bandage</td>
<td>6%</td>
<td>16%</td>
<td>34%</td>
<td>19%</td>
<td>25%</td>
<td>69%</td>
</tr>
<tr>
<td>Inelastic bandage</td>
<td>75%</td>
<td>12%</td>
<td>13%</td>
<td>0%</td>
<td>0%</td>
<td>25%</td>
</tr>
</tbody>
</table>

Table 2. Jünger et al. evaluation: median baseline interface pressure values (mmHg)

<table>
<thead>
<tr>
<th>Position</th>
<th>DCS</th>
<th>Inelastic</th>
<th>Four layer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supine</td>
<td>47.81</td>
<td>48.47</td>
<td>51.54</td>
</tr>
<tr>
<td>Sitting</td>
<td>49.44</td>
<td>47.97</td>
<td>54.02</td>
</tr>
<tr>
<td>Active standing</td>
<td>55.81</td>
<td>64.72</td>
<td>62.08</td>
</tr>
<tr>
<td>Maximal working pressure</td>
<td>61.62</td>
<td>71.46</td>
<td>78.97</td>
</tr>
</tbody>
</table>

choice (these were not recorded).

The median reduction in ulcer surface area at 6 weeks was 72.5% (median area at baseline, 4.96cm²; median area at 6 weeks, 1.05cm²) with 10 wounds (24%) healing in a mean time of 25.9 days (range 7–41 days). The bandage was also effective at reducing oedema: only 12% of patients still had oedema at 6 weeks compared with 69% at baseline.

The mean reduction in ulcer surface area was at least comparable with data recorded at 6 weeks in other VLU studies using other compression systems and compression bandaging plus a wound contact layer (lipidocolloid) primary dressings, where the baseline leg ulcer surface areas and durations were similar.

Three topical adverse events were reported: one small blister possibly caused by the primary dressing and two non-dressing-related local infections. Only three patients withdrew (for reasons unrelated to healing or the new system), which is indicative of a high level of adherence.

A high percentage of patients reported that the DCS was comfortable during the day (95%) and night (92%). A large majority (89%) thought it was more comfortable or equal to the system worn before entry into the study (subjective rating of ‘very poor’ to ‘very good’). Itching and sensation of heat under the dressing reduced compared with baseline.

Lazareth et al. randomised controlled trial to assess efficacy, tolerability and acceptability. The confluence of the three Cs of compression: consistency, continuity and comfort

Some 187 patients with VLUs received either DCS or the four-layer Profore bandage system for 12 weeks. Ulcers were non-infected and non-malignant and had a surface area of 2–50cm² and duration of 1–24 months. Healing rates at 12 weeks were assessed, along with absolute and relative wound area reduction (AWAR and RWAR) and percentage relative wound area reduction of >40% at 4 weeks. Comfort and tolerability were also assessed.

There were similar rates of healing at week 12: 44% for the DCS and 39% for the four-layer system (intention-to-treat (ITT) analysis). AWAR was 6.6cm² in the DCS group and 4.9cm² in the four-layer group, whereas a RWAR of ≥40% at 4 weeks was achieved by 47% and 44%, respectively. Pain between dressing changes was reported in 27% of the DCS group and 40% of the four-layer group. The DCS was considered significantly easier to apply.

The similar efficacy of the DCS to the well-established four-layer bandage system, along with its ease of application and good tolerability, suggest it would be associated with good patient adherence.

Overview of the studies’ design rigour

The above studies included effects to reduce bias, such as random allocation of the compression systems, objective wound measurement with photographic images and planimetry, and clearly defined instructions on how to measure interface pressures. The Lazareth RCT followed the Consort guidelines. However, it is not clear from the Jünger evaluation how the insertion of the printed ellipse onto the comparator compression systems used was validated.

Product information

The DCS is available in two sizes corresponding to ankle circumferences of 18–25cm and 25–32cm, in 10-cm widths. The two bandages making up the DCS are designed to be worn day and night, throughout the period between local dressing changes.

As the DCS is contraindicated in patients with arterial ulcers and arterial disease with an ankle–brachial pressure index (ABPI) <0.6. A reduced compression therapy system (UrgoK2 Lite) is available for patients with mixed-aetiology leg ulcers who do not have severe ischaemia. UrgoK2 Lite differs from the standard DCS in the nature and elasticity of its fibres.

Clinical product review

At the consensus meeting in December 2019, the panel members presented data on healing outcomes achieved following application of the DCS on their patients. Retrospective data from three panel members (JL, EG, AT) are summarised here to give an insight into the real-life clinical experience of using the DCS.

This retrospective sample comprises 20
non-consecutive patients with venous insufficiency (all diagnosed using duplex ultrasound) that resulted in ulceration. Twelve patients were female; the mean age was 68 years (range 51–86). The most commonly reported comorbidities were hypertension (n=14), obesity (n=9) and peripheral vascular disease (n=9). Two patients were current smokers. Fifteen patients had previously received compression, principally Coban 2 (3M), Circaid (Medi UK), or Unna’s boot. Patients who had not received compression were treated with bioengineered and synthetic skin substitute or Ace wrap/tubigrips (which was also widely used in combination with compression).

There were 23 wounds in these 20 patients; the median wound volume was 2.24cm³ (range 0.01–56cm³). The median wound duration was 4 months (range 2 weeks–7 years). All patients were indicated for the DCS.

Tolerability and acceptability of the DCS were recorded at each patient visit over 4 weeks from the initiation of treatment with the system. They were rated using a four-point Likert-scale: very easy/good; easy/good; difficult/poor; very difficult/poor. Other parameters evaluated were: ease of application, conformability, patient adherence, patient ability to wear footwear with the DCS, ability for the DCS to stay in place, general comfort, perceived application accuracy.

All of the parameters were rated as a minimum of easy/good. For every single patient, the perceived accuracy of application was rated as very easy/good, and, for all but one patient, ease of application was regarded as very easy/good. Accuracy was measured by the ease with which appropriate pressure was applied, as gauged by clinical observation of the PresSure system (when the ovals became circles). Similarly, a large majority rated the conformability of the DCS and its effect on adherence as very easy/good (17/20 and 18/20, respectively). Three-quarters of the sample (15/20) rated its ability to avoid slippage as very easy/good, and 14/20 gave this score for patient ability to wear footwear.

Data on reductions in wound size were available from only one of the three centres (n=10). Here, after 4 weeks of treatment with the DCS, there was a mean percentage reduction of 67.9% (median 80%, range 0–100%). The mean baseline wound volume was 18.4cm³ (median 8cm³, range 1.2–56cm³).

Clearly, a sample size of 10 patients is not enough to make meaningful statements about efficacy. These patients either had a contact dermatitis response to zinc oxide and glycerin, or were being managed with another commercially available two-layer system before starting management with the DCS. The main observation for this patient group is that all had been wearing compression for at least 4 weeks before switching to the DCS, yet they still showed a marked reduction in wound area at the end of this short follow-up period. In general, these patients had complex, longstanding wounds, many of which were post-phlebitic. Three wounds healed completely. It would be extremely unlikely for larger wounds to heal within a 4-week follow-up period. Figs 2–4 describe some individual case studies.

**Conclusion**

Although compression therapy is acknowledged to be the mainstay of treatment for VLUs, adherence to this therapy is commonly low, leading to poor healing outcomes in many patients. An ideal compression
Fig 4. A 61-year-old patient with lymphoedema and venous reflux presented with an ulcer on her posterior left leg of 3.5 years’ duration. For many years, she had used a pneumatic sequential compression pump for 60–70 minutes each day, and was unable to apply any other form of compression. Her comorbidities comprised morbid obesity and sleep apnoea, for which she uses a continuous positive airway pressure (CAP). Her mobility was impaired, requiring her to ambulate with a walker. She refused to undergo bariatric surgery. On presentation, the wound measured 35.2cm². Treatment comprised the DCS plus the pneumatic compression pump. The patient’s left great saphenous vein measured 1cm at the superficial femoral junction and 0.3cm at the thigh level, with severe incompetence at 3.0 and 0.5 seconds of reflux time. Given the patient’s obesity, impaired mobility and other calf muscle pump dysfunction, it was decided that endovenous laser ablation would not be effective for her. After 4 weeks of combined treatment with the DCS and pneumatic compression, the wound size reduced to 18.3cm² (52% reduction).

Bandaging system will have a good static stiffness, be able to maintain a good working pressure and have a tolerable resting pressure. It should remain in place during movement, be comfortable to wear, easy to apply and economical.

The DCS is an innovative two-layer system that, when applied together, functions as one. The distinctive combination of both inelastic and elastic compression textiles creates a bandage that provides intelligent compression at rest and during activity, thereby ensuring therapeutic levels and patient comfort. The first compression bandaging system of its kind in North America, it was designed to provide a continuous level of compression that can be consistently applied by health professionals and be comfortable for patients. This is achieved through the use of layers with different elasticities that together form a single bandage system that offers patients the benefits of compression as they undertake different levels of activity, day and night. The system’s elastic layer helps apply compression at rest; the inelastic layer helps apply compression during ambulation.

International guidelines have suggested that multi-component systems are more beneficial than those containing only inelastic components. The DCS design, which combines elastic and non-elastic technologies, has demonstrated design-driven clinical benefits. In a key clinical study,2 the system’s ability to deliver continuous, consistent compression over a 7-day period, with the subjects standing, resting, and walking, was demonstrated. A later clinical study supported Junger’s finding that the required pressure can be consistently applied, and also found that it was associated with patient comfort.3 A large randomised comparative clinical study demonstrated that the DCS had similar healing rates to a four-layer system, but was significantly easier to apply and much less painful. In summary, the combination of both elastic and inelastic components allows the DCS to efficiently deliver guideline recommendations in an intuitive, comprehensive system.

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