Evaluation of Urgotul® plus K-Four® compression for venous leg ulcers

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Abstract

In this non-comparative clinical evaluation, 36 subjects with venous leg ulcers, 85% of which were indolent or deteriorating, were treated with Urgotul® lipidocolloid wound dressing and the K-Four® multilayer compression bandaging system for 12 weeks or to healing — whichever occurred first. Results show that Urgotul® was an ideal dressing in combination with K-Four®, being easy to apply (98.7%) and remove (98.1%), and largely pain-free (95.6%) and non-adherent (99.7%). In a patient group of 'hard-to-heal' ulcers, 50% of the ulcers healed within the treatment period. Ulcers not healed after 12 weeks achieved almost 50% area reduction on average. The treatment combination proved safe, with only one of seven adverse events reported being probably related to the products used. This study supports the use of a combination of Urgotul® dressing and K-Four® compression to provide a 'matched' treatment for venous leg ulcers.

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Compression bandaging remains the basis of venous leg ulcer management (Moffatt, 1995), and is regarded as the therapy of choice (Alexander House Group, 1992). The provision of graduated, sustained compression (with a sub-bandage pressure of 40 mmHg at the ankle, reducing to 17 mmHg below the knee) is generally regarded as satisfactory and will support healing (Simon, 1996). It is widely accepted that this goal is routinely achieved through the correct application of multilayer bandaging systems (Taylor and Taylor, 1999).

A wide variety of healing rates are reported by advocates of the various bandaging systems, ranging from 30% (Cornwall et al, 1986) to around 70% (Moffatt et al, 1992). However, healing rates must be interpreted in the context of the relevant characteristics of both the patient and his/her wound, as these may favour or compromise healing.

Following an analysis of the relevant literature, a recent Cochrane review (Cullum et al, 2003) reported on the effectiveness of compression bandaging in the treatment of venous leg ulcers. Selected findings included 'compression was more effective than no compression' and 'there was no statistically significant difference in healing rates between multilayered systems'. At face value these are fair and reasonable findings. However, there are parameters that are worthy of consideration if comparisons of efficacy between bandaging systems are to be made. The vagaries of bandaging (Taylor and Taylor, 1998; Reynolds, 1999), including poor knowledge and technique, should not be a factor as these studies were conducted in specialist centres where the expertise available is indicative of the quality of the skills available.

However, one factor that may impact on healing rates is the duration of the ulcer before study entry. This factor is noted by Vowden et al (2001), who recorded ulcer duration of patients entered into two studies. In the first study, which compared healing rates of three multilayer compression systems, ulcer duration was 112, 142 and 177 weeks. In the second, non-comparative study, ulcer duration was 205 weeks. These served to compromise healing as if an ulcer or a group of ulcers have a long history of non-healing then by definition resolution will be more difficult to achieve when compared with an ulcer that has a history of 12 weeks or less.

Other factors that may influence healing rates include size of ulcer, concurrent additional pathologies and ankle/brachial pressure index (ABPI). Variation in ulcer size was recognized as an independent variable by Meyer et al (2002). In this study, ulcers were stratified and randomized within one of three size groups when comparing healing rates of two different three-layer bandaging systems.

In recent years, wound pain has become a focus for those responsible for leg ulcer care (Hollinworth and Collier, 2000; Moffat et al, 2002). In particular, it is now accepted that venous leg ulcers are frequently the source of considerable pain, which impacts on patients' lives (Rich and McLachlan, 2003). While some of this pain is of endogenous origin, the dressing change procedure, including dressing-related trauma, is also a major contributor.

After informed consent had been obtained from the subjects, a detailed medical and ulcer history was taken and an ankle/brachial pressure index (ABPI) recorded. The ulcer and surrounding skin were assessed for condition, e.g. slough, granulation and maceration, and an area tracing was made using transparent film...

Historically, little consideration has been given to the role of the dressing in the management of venous leg ulcers with high compression. In terms of healing rates, this view is no longer appropriate. Stacey et al (1997) have demonstrated that the wound contact layer, when correctly selected, can have a positive influence on healing. Given our understanding of ulcer pain and the role of dressings, this becomes a critical aspect of care.

The current study examines the clinical outcomes of a primary dressing used under a multilayer compression system in the treatment of primary care patients with venous leg ulcers. The primary dressing, or wound contact layer, used was Urgotul®. This is a non-occlusive lipidocolloid dressing, comprising a polyester net impregnated with hydrocolloid particles dispersed in a petroleum jelly matrix. Urgotul® is classified as a non-adherent dressing and is indicated for the local treatment of acute wounds (superficial burns, abrasions, traumatic wounds) and chronic wounds in the granulation and epithelialization stage (ulcers, pressure ulcers). Although not marketed as possessing desloughing capabilities it was found that Urgotul® supports autolytic debridement of wounds and prepares them for the proliferative phase of healing.

Urgotul® has been clinically evaluated in a variety of acute and chronic wounds (Benbow, 2002; Blanchet-Bardon and Bohbot, 2002; Meaume et al, 2002; Benbow and Iosson, 2004) and found to be consistently easy to remove. However, these studies were mainly conducted in mainland Europe (where multilayer compression is not standard), they did not use multilayer compression, and there are no relevant data on the performance of this dressing with respect to factors that might be influenced by the longer wear time and unique environment provided by this compression system, such as ease of removal, adhesion and maceration. This is, therefore, the first study of K-Four® in combination with Urgotul®.

The compression system used was K-Four® multilayer system. This has proven performance characteristics in the effective treatment of venous leg ulceration, including recalcitrant or 'hard-to-heal' ulcers (Ballard et al 2000; Vowden et al, 2000, 2001). In keeping with other four-layer systems, it provides more consistent sub-bandage pressures than single-layer compression bandaging (Stockport et al, 1997; Taylor and Taylor, 1999). The marketed K-Four® kit is suitable for ankles of circumference 18–25 cm.

STUDY METHODS

Following relevant ethical approval this study involved eight centres in a non-comparative clinical study. It was conducted in the UK between March and August 2003 and each subject enrolled in the study supplied written informed consent. Consenting subjects who satisfied the inclusion and exclusion criteria were evaluated for 12 weeks or to healing, whichever occurred first.

After informed consent had been obtained from the subjects, a detailed medical and ulcer history was taken and an ABPI recorded. The ulcer and surrounding skin were assessed for condition, e.g. slough, granulation and maceration, and an area tracing was made using transparent film (Oien et al, 2002).

All subjects were treated with Urgotul® lipidocolloid primary dressing followed by K-Four® multilayer compression. All investigators were experienced in the application of multilayer bandage systems to ensure the consistency of the bandaging technique. Dressing changes were performed as required or every 7 days, whichever was the sooner. At each change the acceptability of the treatment was evaluated using the criteria of ease of dressing removal, pain during removal, adherence, odour, maceration and periskin condition, presence of infection and exudate levels. The presence of infection was assessed according to the criteria suggested by Cutting and Harding (1994). The safety profile, defined as the occurrence of local adverse events, was also assessed at each dressing change. The ulcer was assessed for slough, necrotic tissue and granulation (see results), and an area tracing (for planimetry) was made every 2 weeks (Oien et al, 2002).

For subjects completing the study before the 12-week end-point (ulcer healed, subject withdrawn or lost to follow-up) a final evaluation was conducted. All ulcers were photographed at regular intervals throughout the study period. The parameters of treatment response measured included clinical efficacy (ulcer healing, ulcer area reduction, tolerance) and safety (adverse effects).

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ULCER TREATMENTS

In this clinical evaluation, the two products used in combination were:

Table 1. Peri-ulcer skin condition and exudate levels at enrolment

Skin condition	*n*	%
Healthy/Normal		
No	29	82.9%
Yes	6	17.1%
Dry/Scaly		
No	22	62.9%
Yes	13	37.1%
Inflammatory		
No	32	91.4%
Yes	3	8.6%
Macerated		
No	28	80.0%
Yes	7	20.0%
Erythema		
No	24	68.6%
Yes	11	31.4%
Exudate level		
High	6	17.6%
Moderate	11	32.4%
Low	15	44.1%
None	2	5.9%

Data missing

Table 2. Ulcer duration

Duration (months)	
Mean	15.5
Standard deviation	19.7
Minimum	0.7
Median	10.5
Maximum	84.0
Recurrence	
No	15
Yes	18

- The bandages of the K-Four® system:
  K-Soft® (sub-bandage wadding): absorbs fluid and redistributes pressure to help prevent damage to bony prominences
  K-Lite® (British Standard type 2 light support bandage): aids absorbency and acts as a base compression
  K-Plus® (BS type 3a light compression bandage): the first compression layer, providing up to 20 mmHg at the ankle. Applied in figure-of-8 fashion
  Ko-Flex® (cohesive bandage): offers additional compression and maintains the position of the other layers
- Urgotul® lipidocolloid wound dressing: this dressing is indicated for use on a wide variety of acute and chronic wounds, and is available in three sizes: 10 cm x 10 cm, 15 cm x 20 cm and 10 cm x 40 cm.

STATISTICS

Statistical analysis was conducted on the 'intention-to-treat' population. The change in ulcer surface area was analysed by repeated measurement analysis of variance, to investigate the effect of time and treatment. In the case of missing data (planimetric area not done, premature withdrawal from the study), the last surface value was reported.

RESULTS OF THE ASSESSMENT

Thirty-six subjects from eight UK centres were recruited within the study period. Two subjects were withdrawn providing data on 34 subjects to undergo analysis.

Inclusion demographics

Subjects recruited were mainly female (21 females; 58%) and of mean age 73 years (range 42–89). Relevant medical history at enrolment included diabetes 87%, cardiovascular disease 31% and allergy 27%.

Existing lower limb vascular features included oedema 50%, venous insufficiency (determined by extracts from existing medical records) 77% and deep vein thrombosis 27%.

The ulcer history showed a mean duration of 15.5 months (SD 19.7; minimum 1 month, maximum 7 years) with a recurrence rate of 55%. Previous treatments included foams (6%), hydrocolloids (26.5%), silver dressings (12%), hydrogels (6%), alginates (3%), and various others (47%). Outcomes with these

dressings had been disappointing, with a high proportion either deteriorating (19/36; 53%) or indolent (11/36; 31%). However, only 65% of subjects had previously received compression bandaging (data on the type and outcome were not gathered).

The mean ABPI on enrolment was 1.06 (SD 0.18), indicating no arterial deficit. All ankle circumferences were measured and were found to be within the 18–25 cm range. A rate of 44.5% of ulcers had greater than 25% of the wound bed covered with slough at the start of the study. *Table 1* documents the peri-ulcer skin condition at baseline. Only 17% of the treated ulcers had a healthy peri-lesional skin.

Efficacy

The mean ulcer area at baseline ($n = 36$) was 15.2 cm^2 (SD 28.5) and *Table 2* shows the ulcer duration. At the final visit (week 12), 18 of 36 patients (50%) had healed in 46.8 (±27.4) days of treatment (*Tables 3* and *4*). In subjects who completed the 12-week study period without their ulcer healing (16/36), the ulcer area decreased by 49.3% from a mean of 15.2 cm^2 to 7.3 cm^2 (*Figure 1*). These data were influenced by a single large ulcer of 149 cm^2, which completed the study period unhealed at 56.5 cm^2. In addition, two subjects were withdrawn because of adverse events. The adverse events were one wound infection and one haematoma; both were deemed not related to the treatment.

A total of 317 dressing changes were performed during 2124 days of treatment and the average wear time was 6.7 (± 2.3) days (*Table 5*), which is comparable to the wear time noted by Benbow and Iosson (2004).

A key aspect of the product evaluations in this study was the dressing performance under compression. This was assessed by a variety of parameters, including skin condition, maceration, and wear time (comparing data in *Table 1* with those in *Tables 5* and *6*). The overall skin condition improved during the study period from 17.1% healthy at the outset (*Table 1*) to 49.7% healthy/normal on completion (*Table 6*). This is reflected in a reduction in maceration from 20% at the start to 16.8% on completion.

Ease of dressing removal was assessed as 'very easy' or 'easy' at 98.1% of dressing changes (*Table 6*) and pain on dressing removal was 'none' or 'minimal' at more than 95.6% of dressing changes. There were 317 dressing changes and *Table 6* shows that missing data led to lower figures in some cases. The practicality of this is reflected in the mean dressing and bandage change time of 17.8 minutes (*Table 7*).

Table 3. Study completion data

Outcome	*n*	%
Enrolled	36	100
Healed	18	50
Withdrawals	2	6
Completed 12 weeks not healed	16	44
Total not healed	18	50

Table 4. Ulcer healing time

Number healed	18
Mean healing time (days)	46.8
Standard deviation	27.4

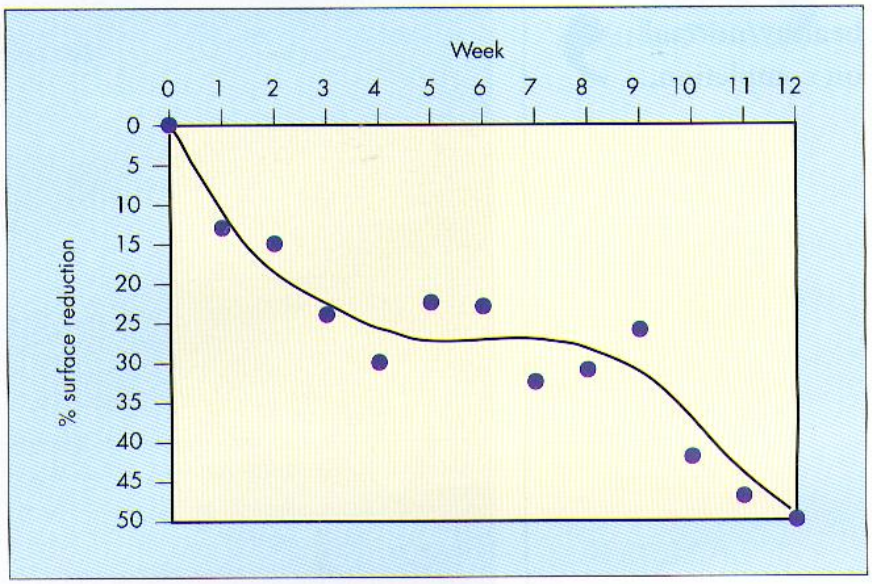

Figure 1. Percentage reduction in ulcer surface area over the study period.

Table 5. Dressing change data

Total number of days of treatment (all subjects)	2124
Total number of dressing changes (day 0 included)	317
Frequency of dressing changes (days)	
Mean	6.7
Standard deviation	2.3
Minimum	4.0
Median	7.0

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Table 6. Urgotul wound dressing performance

Feature assessed	*n*	%	Total	% of total
Ease of removal				
Very easy	274	86.4		98.1%
Easy	37	11.7		easy or very easy
Difficult	5	1.6		
Very difficult	1	0.3	317	
Pain during removal				
None	291	91.8		95.6%
Minimal	12	3.8		none or minimal
Moderate	9	2.8		
Severe	5	1.6	317	
Bleeding				
None	292	92.7		98.4%
Minimal	18	5.7		none or minimal
Moderate	0	0.0		
Copious	5	1.6	315	
Adherence to the wound bed				
None	300	95.2		99.7%
Minimal	14	4.4		none or minimal
Moderate	1	0.3		
Strong	0	0.0	315	
Odour				
None	243	77.4		93.9%
Minimal	52	16.6		none or minimal
Moderate	11	3.5		
Severe	8	2.5	314	
Maceration				
None	221	70.4		89.8%
Minimal	61	19.4		none or minimal
Moderate	30	9.6		
Significant	2	0.6	314	
Ease of application				
Very easy	288	92.3		98.7%
Easy	20	6.4		easy or very easy
Difficult	4	1.3		
Very difficult	0	0.0	312	
Conformability to the wound				
Very good	299	95.8		99.7%
Good	12	3.8		good or very good
Poor	1	0.3		
Very poor	0	0.0	312	
Surrounding skin				
Healthy/normal	169	49.7		49.7 % healthy/normal
Dry/scaly	75	22.1		50.3 % compromised
Macerated	57	16.8		
Erythematous	36	10.6		
Oedematous	3	0.9	340	
Exudate levels				
None (dry)	131	43.5		94.4%
Moderate	153	50.8		none or moderate
High	13	4.3		
Very high/copious	4	1.3	301	

Safety

During the 12 weeks of treatment, local tolerance of the treatment (Urgotul® under K-Four®) was examined and documented. A total of seven adverse events were recorded. Three were infections, one haematoma, one skin irritation, one deterioration in general health (heart disease) and one bleeding from the wound. Four were judged to be of 'moderate' severity and three 'severe'.

Only one event was deemed to be related to treatment: this was a case of skin irritation around the wound, which resolved spontaneously without exclusion of the subject from the study. Two subjects were excluded due to adverse events: a suspected infection and a haematoma.

DISCUSSION

The healing of venous ulcers is dependent upon reversing the underlying pathological changes due to venous hypertension. This has been shown to be the principal benefit of high compression bandaging. Healing in venous ulcers has been related to numerous parameters, including ulcer size and duration.

Although little credit has been afforded to the primary dressing function in promoting healing, there can be no doubt that some wound contact layers do have a positive influence (Stacey et al, 1997). The healing rate of 50% achieved in this study must be interpreted in the context of the nature of the ulcers on enrolment. *Table 1* indicates that 20% of ulcers were effected by peri-ulcer maceration and 50% of ulcers had high or moderate level of exudate on enrolment. Additionally, only 17.1% of ulcers were assessed as having healthy or normal skin (*Figures 2* and *3*).

Characteristics of the ulcer, and indeed the patient, have been associated with delayed or difficulty in healing, e.g. coexistent diabetes and ulcers of long duration (>3 months) tend to be associated with delayed healing. The majority of ulcers (85%) in the current study were either indolent or deteriorating on enrolment. Of all the remaining 50% of ulcers that did not achieve closure, the majority achieved a substantial reduction (average 49.3%) in area — suggesting that closure would follow had the study continued.

At the start of the study, 50% of all ulcers were of moderate or high exudate level, and 20% were described as macerated. The presence of maceration and exudate on enrolment (indicated above) is typically challenging for those responsible for managing venous ulcers and makes the selection of dressings and wear time a particularly complex procedure. The mean wear time (6.7 days) was close to the desired 7 days — widely considered ideal for cost-effective community leg ulcer care. It is clinically relevant that there were no adverse effects due to maceration during the study, and minimal or no maceration at 89.8% of dressing changes. Indeed, the overall skin condition improved from enrolment to

Table 7. Time taken for dressing change

Time for dressing + bandage change (minutes; $n = 36$)	
Mean time	17.8
Standard deviation	8.4
Median	19.6
Maximum	50.0

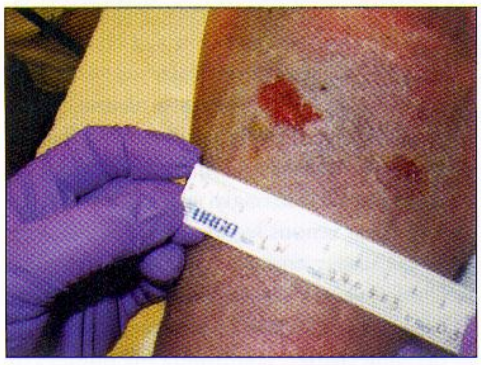

Figure 2. Ulcer upon commencement of treatment. Ulcer had been present for 11 years (prior to inclusion in the study patient had been non-compliant with compression therapy due to pain).

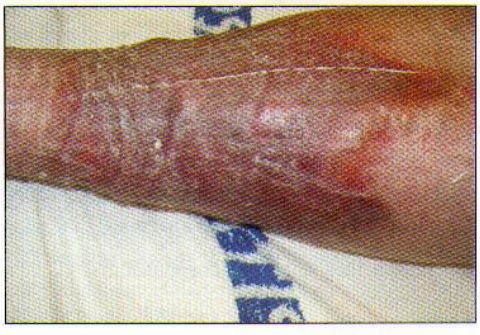

Figure 3. Ulcer healed after 10 weeks.

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completion; this is in accord with previous evidence on Urgotul® (Blanchet-Bardon and Bohbot, 2002). These findings indicate that exudate was well controlled by the dressing and bandage combination.

With respect to the other aspects of dressing performance measured in this study, Urgotul® proved to be easy to remove (98.1% of dressing changes were 'easy' to 'very easy') and notably pain-free on removal (96.7% of dressing changes were associated with 'none' to 'minimal' pain), with very little adherence to the wound bed ('none' to 'minimal' in 99.7%).

In addition to the data collected during the evaluation, reduction in wound pain at and between dressing changes was noted. Clinical experience shows us that quality of wound treatment affects quality of life and the patient's response to leg ulcer treatment; therefore it is essential that the correct dressing choice is made. Although venous leg ulcer pain is often underrated and receives limited attention in the literature (Charles, 2002), it is a clinician's priority to minimize pain and trauma to the patient and the wound bed at dressing change and to improve the patient's overall comfort between dressing changes.

These findings are clinically important in the context of 7 days' wear time and multilayer compression. The totally non-adherent dressing is currently impossible to make; thus, these data strongly support the use of Urgotul® on venous leg ulcers in combination with multilayer compression bandaging. The combination of Urgotul® and K-Four® has achieved good healing rates and reduced pain at dressing change, confirming the findings of Stacey et al (1997) that the correct dressing can indeed have a positive bearing on treatment outcome in venous leg ulceration. BJN

KEY POINTS

- The combination of Urgotul® dressing with K-Four® multilayer compression bandaging has been studied in 36 community patients with venous leg ulers.
- Both the dressing and the compression system were well tolerated, with very little difficulty, pain or bleeding on removal and little maceration.
- The healing rate achieved in a population of predominantly indolent or deteriorating venous ulcers was 50%.
- The combination of K-Four® with Urgotul® is ideal for the treatment of venous leg ulcers.
- The overall wear time achieved makes this dressing combination well suited to community leg ulcer care.

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