



Managing venous leg ulcers using compression therapy and dressings

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Graduated compression and moist wound healing are the foundation of venous leg ulcer management (Partsch, 2014). Compression increases ulcer healing rates compared with no compression (O'Meara et al, 2012).

The recently published results from the VenUS IV trial [3] (Ashby et al, 2014) found no evidence of a difference in ulcer healing for venous leg ulcers treated with two-layer hosiery and the four-layer bandage. Ashby et al (2014) concluded that two-layer hosiery may reduce ulcer recurrence rates when compared with the four-layer bandage, and be a cost-effective treatment, but that more research was required.

It is important that, as well as appropriate wound and skin management, the compression treatment suitable both for the aetiology of the wound and the patient's lifestyle is selected. The patient experience is recognised as central to the plan of care (Department of Health, 2012), so the degree of satisfaction with treatment, mobility and quality of life are factors in wound healing which are now included as endpoints in clinical research into the efficacy of treatment (Green et al, 2014).

This article presents a case series of 22 patients being treated at leg ulcer clinics. The objective of the series was to observe the clinical efficacy and the impact on the patient's comfort and mobility of an integrated range of wound management devices including dressings, compression hosiery and a skin protectant, from a single supplier, designed to be used in conjunction with one another. The possible benefits of using such a range are: simplified training, less use of dressings inappropriate for the wound and patient, and rationalisation of the supply of dressings carried by the clinician.

This study may be considered a precursor to looking at the whole set of clinical and non-clinical benefits of using an integrated product range. A search of PubMed and Cochrane databases in English was made going back to 1999 and using the search terms: vascular leg ulcer, venous leg ulcer, compression, compression hosiery, compression bandaging, integrated approach, dressings, foam, alginate, advanced dressings. Results were filtered to find studies where all the products used to treat patients were from one manufacturer. In the literature only two publications were found; one from 2004 (Smith et al, 2004) and the other from 2013 (Brambilla et al, 2013) presenting the results of a similar approach.

The products used in this evaluation consisted of non-adherent foam dressings (Cutimed® Siltec or Cutimed® Siltec L), antimicrobial dialkylcarbamoyl chloride-coated (DACC-coated) dressing (Cutimed Sorbact®), peri-wound skin barrier film (Cutimed PROTECT) and two-layered zippered graduated compression hosiery system (JOBST®

Abstract

Patient comfort and satisfaction with both compression therapy and wound care are critical to the success of venous leg ulcer treatment. This study observed 22 patients with venous leg ulcers treated over 12 weeks with two-layer compression hosiery and a range of wound dressings. The mean duration of the ulcers was 10.5 months and 48% had a history of recurrent ulcers. Half the ulcers healed within 12 weeks; there was an increase in the proportion of patients reporting 'no impairment' to their mobility, but it was not significant. The ease of donning the two-layer hosiery was rated as excellent or good at 86% of control visits and the ease of doffing at 78%. In 95% of cases the clinicians said they would use the same combination of products again and 73% of patients were satisfied with it.

Key words: Venous leg ulcer ■ Concordance ■ Integrated wound therapy ■ Patient comfort ■ Mobility ■ Two-layer compression hosiery

UlcerCARE), all from BSN medical Ltd. JOBST Comprifore compression bandage, also from BSN medical, was used by one patient for 7 weeks before using the hosiery.

Methodology

A non-comparative observational case series was conducted as it is an appropriate model for the generalisation of outcomes (Carlson and Morrison, 2009; Association of British Pharmaceutical Industry, 2011)

As all the products included in the evaluation are on the Drug Tariff (England) (2012) and were used as recommended by the manufacturer, ethics committee approval was not required. Local permissions were obtained from the direct line manager of the author in Bristol and the Trust Research Officer in Trowbridge. The case series was carried out by two tissue viability nurses at each site.

Patients with superficial venous leg ulcers for whom compression therapy was indicated were observed in the study. Written informed consent was obtained at the enrolment visit. The evaluations were carried out during

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Accepted for publication: July 2015



Box 1. Fields included in the mobility and quality of life questionnaire

- Carrying and lifting of heavy objects
- Standing for long periods of time
- Putting on shoes
- Light outdoor activities
- Heavy outdoor activities
- Shopping
- Walking
- Housework
- Climbing stairs

Degrees of impairment per field

- No such activity undertaken
- No impairment
- Slightly impaired
- Moderately impaired
- Mostly impaired
- Completely impaired

Table 1. Selected demographics and baseline characteristics

Category	Mean	Median
Age (years) (n=21*)	67.4	70
Body mass index (BMI) (kg/m ²) (n=17*)	27.3	25.6
Ankle brachial pressure index (ABPI) (mmHg) (n=22)	1.05	1.05
Duration of ulcer (months) (n=21*)	10.52	6
Ulcer surface area at screening (n=22)	7.05 cm ²	3.88 cm ²
*Missing data were not collected		

Table 2. Ulcer status at baseline

Category	Percentage (n=22)
Recurring ulceration at same location	45%
Multiple ulcers	50%
Moderately exuding	59%
Low exudate level	36%
Clinical signs of infection	14%
Partial granulation	64%
Complete granulation	14%
General wound pain	36%

patients' scheduled visits for treatment. Only patients with an ankle-brachial pressure index (ABPI) ≥ 0.8 were included in the study.

All patients wore the JOBST UlcerCARE two-layered compression stockings. Cutimed Siltec or Cutimed Siltec L dressings were applied as primary dressings, Cutimed Sorbact as an antimicrobial dressing and Cutimed PROTECT as a peri-wound skin protectant where indicated. The patient's largest ulcer which could be dressed with the sizes of dressings available, was chosen as the single reference ulcer for the evaluation. Dressings were provided in sizes 5 x 6 cm, 10 x 10 cm and 15 x 15 cm. Patients were observed until this ulcer healed or up to a maximum period of 12 weeks, whichever took place first. The patients were reviewed at four mandatory visits and one optional control visit: week 1, week 2 (optional), week 4, week 8 and week 12. The

decision to make the optional week 2 visit was made by the tissue viability nurse who enrolled the patient. The reference ulcer was photographed at each control visit and measured by tracing on a gridded acetate sheet.

Patients whose wounds were fully epithelialised or on the point of healing at their regular visit to the clinic, were not called back for a control visit. These wounds were judged to have healed.

A questionnaire on the patient's degree of mobility and quality of life at each visit was administered. This questionnaire was adapted from the Tübinger Fragebogen (Klyszcz et al, 1998). The fields covered and the degrees of impairment recorded per field are shown in *Box 1*.

A four-point scale was used to assess the ease of donning and doffing the compression hosiery and the degree of comfort wearing the hosiery including whether the patient experienced sweating and constriction of the limb. The degree of wound pain at dressing change was also assessed on a three-point scale: 'no pain', 'bearable' or 'severe'.

At the conclusion of the study period for each patient, the clinician was asked for an overall assessment of the performance of each product type used and an overall assessment of the integrated use of the products. Patients were asked for their degree of satisfaction with using the combination of dressings and compression garments.

Results

Of the 22 patients, 1 from Trowbridge and 20 from Bristol were treated exclusively with the JOBST UlcerCARE two-layer compression hosiery system, and 1 from Trowbridge with JOBST Comprifore bandage for 7 weeks followed by JOBST UlcerCARE for 4 weeks. The demographic characteristics broadly reflect the caseload to be expected in a leg ulcer service as evidenced by an audit of leg ulcers in community care in Bradford (Vowden and Vowden, 2009) where 42.5% of all leg ulcers were recurrent, 20.6% of venous leg ulcer patients were diabetic and the mode ulcer surface area was 2–5 cm². The patient characteristics can be seen in *Table 1*. In total 23% (n=5) of patients were diabetic, 9% (n=2) smoked and 23% (n=5) had hypertension.

The status of the ulcers at the start of the evaluation can be seen in *Table 2*.

The ulcer locations on the lower limb were: medial 67% (n=14), lateral 14% (n=3), anterior 9.5% (n=2) and posterior 9.5% (n=2). (The missing data were not collected.)

Eleven patients were recorded as wearing compression before the study: 4 wore short-stretch bandages, 3 wore 'class II hosiery' (not further defined), 3 wore hosiery kits and 1 wore two-liner stockings.

There were a total of four withdrawals from the 22 patients in the study. One was withdrawn for reasons of non-concordance due to underlying pain at week 1, one withdrew at week 1 because she felt the outer open-toed stocking was not suitable for her legs, one patient withdrew between weeks 4 and 8 because she found the stockings too tight, despite the ulcer progressing well, and one withdrew after 7 weeks as she found Cutimed Siltec uncomfortable but wished to continue wearing the hosiery.

Table 3 shows the healing outcomes and withdrawals as





Table 3. Healing outcomes at each control point.					
Ulcer status	Week 1	Week 4	Week 8	Week 12	Total
Healed		1	8	2	11 (50%)
Withdrawn	2	1	1		4 (18%)

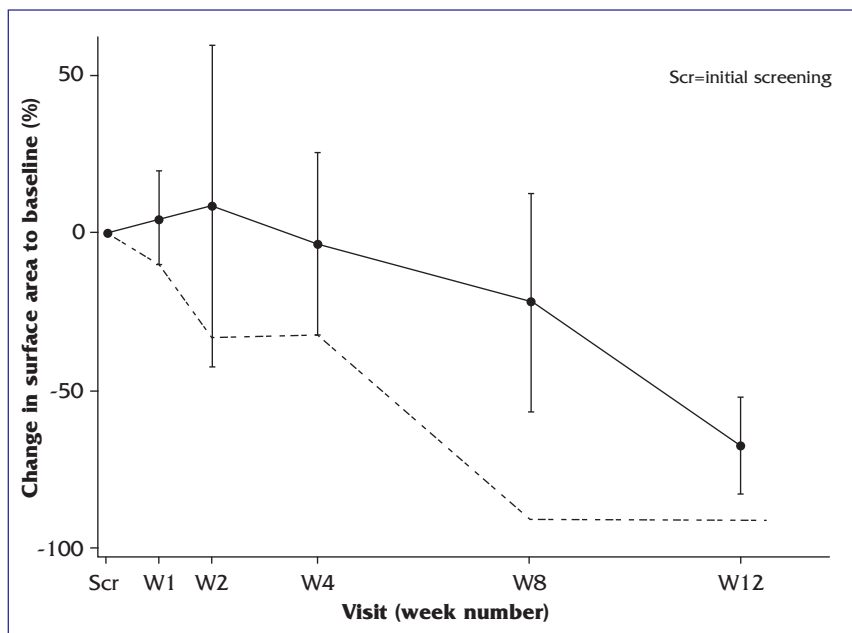


Figure 1. Relative reduction in wound surface area

Table 4. Proportion of subjects reporting 'no impairment' or 'no activity'				
Category	At screening (%) (n=22)		At week 12* (%) (n=9)	
	No activity	No impairment	No activity	No impairment
Carrying and lifting heavy objects	50%	27%	56%	22%
Standing for long periods	32%	18%	22%	33%
Putting on shoes	5%	64%	0%	67%
Light outdoor activities	36%	36%	44%	44%
Heavy outdoor activities	64%	18%	56%	33%
Shopping	14%	73%	0%	78%
Walking	5%	59%	0%	78%
Housework	14%	73%	22%	67%
Climbing stairs	18%	50%	0%	78%
*The degrees of mobility recorded at week 12 were from those patients whose ulcers had not yet healed				

recorded at the control visit. The mean ulcer surface area at week 12 was 3.16 cm² (median 0.09 cm²) for the 9 patients who still had an ulcer, representing an average reduction of

55%. At the start of the evaluation, the mean ulcer surface area was 7.05 cm² and the median was 3.88 cm² (Figure 1).

Mobility assessments and impact on quality of life

The degree of mobility experienced by each patient was collected at enrolment and at each visit during the study period. For the categories of 'carrying and lifting of heavy objects' and 'shopping' there was no significant change in the proportion of patients reporting 'no impairment' at initial screening and at week 12 ($p=1.0$), nor for 'putting on shoes' ($p=0.73$). In all other activities there was an increase in the proportion reporting 'no impairment', but this was not statistically significant (Table 4).

Product assessment

JOBST UlcerCARE Two-layer compression hosiery system

All patients were instructed in the recommended use of JOBST UlcerCARE by the clinician enrolling them; 12 hours wearing both the outer stocking and inner liner, followed by the removal of the outer stocking and continued wear (i.e. 24 hours of wear in total) of the inner liner (BSN Medical, 2012). A total of 88% of patient responses (71/81 responses across the 5 control visits including the optional visit) liked JOBST UlcerCare.

Patients were asked about their experiences including, their overall experience (Table 5) across the control visits. When given a multiple choice question on constriction (none/acceptable/not acceptable), 69% recorded 'none', 19% 'acceptable', 2% 'unacceptable' and 11% gave no answer. Wear time for patients is shown in Table 6. By week 12, just under half the patients recorded a wear time of over 16 hours. Discomfort does not seem to have been a significant factor in shortening wear time. In total, 86% of patient responses (70/81) across five visits said they experienced no sweating under the hosiery, only 4% (3 responses) said some was experienced and 11% (9 responses) recorded no answer.

Case studies

The following two case studies are two of the patients who took part in the evaluation.

Case study 1

Figure 2 shows the 2-month old venous leg ulcer of an 89-year-old female. The surface area was 1650 mm² and it was inflamed but not clinically infected, with 40% slough. After one week using Cutimed Siltec with JOBST UlcerCARE, 90% of the wound bed was covered with granulation tissue. At this stage, Cutimed Sorbact was applied under Cutimed Siltec with treatment reverting to Cutimed Siltec only at week 4. Figure 3 shows the ulcer at week 4. The ulcer healed at week 8 and the patient experienced significant improvements in mobility.

Case study 2

An 82-year-old female with cancer and hypertension had two venous ulcers. The ulcer in Figure 4 is 2 months old



PRODUCT EVALUATION

and was the first occurrence of ulceration in this location on the posterior malleolus. The surface area was 100 mm². The ulcer was inflamed but not clinically infected. There was 100% granulation tissue but also maceration of the peri-wound skin. Cutimed Siltec was applied and the maceration resolved in week 1. The ulcer was 90% epithelialised at week 8 and healed at week 12. *Figure 5* shows the ulcer at week 8.

Cutimed Siltec and Cutimed Siltec L

Frequency of dressing changes

There were no fixed intervals for dressing changes and they were permitted as clinically required by the condition of the wound between control visits. The total number of dressing changes recorded at control visits was 58 (72%). A total of 40% of the dressing were changed once a week, 27% were changed twice a week, 5% were changes daily and there were no data for 29%. These dressing changes were not documented individually in the study.

In 45% of cases the reason for dressing change was not recorded by the clinician. The two main reasons for dressing change were the volume of wound exudate (15%) and change after showering (12%). Other reasons cited were:

- Regular weekly dressing change
- Dressing becoming wet in the rain
- Patient comfort (unspecified).

Each report of severe pain at dressing change (there were three in total) was from a different patient; one was associated with signs of clinical infection and two with reports of general pain in the wound not characterised by the clinicians as a sign of infection. A total of 70% of patients across all the dressing changes over 12 weeks had no pain at dressing change, 21% found the pain bearable, 3% had severe pain and there were no data for 6%.

Exudate management and skin protection

Cutimed Siltec was rated as excellent or acceptable in speed of absorbency in 93% of recorded control visits. There were a total of 81 control visits in the study. The average incidence of maceration was 11%, with none by week 12.

Cutimed PROTECT

Cutimed PROTECT had an average use of 12% (n=10). In all cases of use the adhesion of the dressing to the treated area was recorded by the clinician as 'excellent', 'good' or 'satisfactory'.

Clinical infection

One patient who had signs of infection at screening, weeks 1 and 2 also had them at week 12; one patient had two episodes of infection (at weeks 1 and 4) and two patients each had one episode of infection.

Cutimed Sorbact was recorded as having been applied at 22% (18) of the control visits. 'No pain' on application of Cutimed Sorbact was recorded in 67% of cases (12) and pain was considered 'bearable' in the remainder. The management of infection by Cutimed Sorbact was considered 'excellent', 'good' or 'satisfactory' in 89% of applications (16); no data were available for the remaining two applications.

Table 5. Average of responses over five control visits

Experience	Excellent	Good	Acceptable	Unsatisfactory	No answer
Ease of donning	66%	20%	2%	0	12%
Ease of doffing	66%	12%	10%	0	12%
Comfort	71%	14%	1%	2%	11%

Table 6. Wear time

Wear time	Week 1	Week 8	Week 12
24 hours a day	64%	42%	44%
Wore only inner liner at night	23%	16%	n/a
16 hours a day	n/a	n/a	11%



Figure 2. Case study 1: Venous leg ulcer (2 months old)



Figure 3. Venous leg ulcer at week 4

Patient satisfaction with integrated therapy

Patients were asked whether they were satisfied with the combination of dressings and compression garments. A total



Figure 4. Case study 2: At initial screening

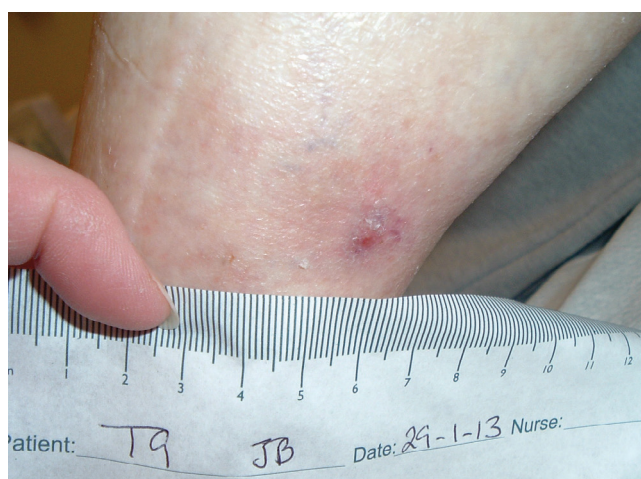


Figure 5. At week 8

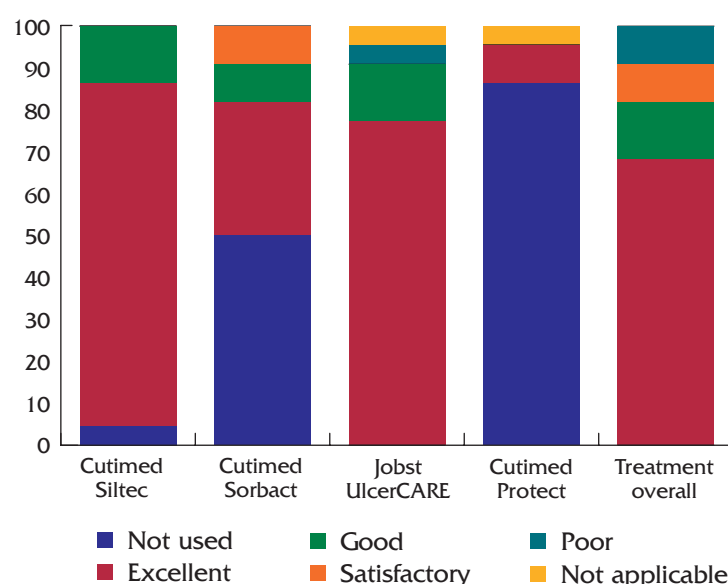


Figure 6. Overall treatment assessments by clinicians

of 73% of patients (16) were satisfied; two patients (9%) did not give an opinion. Of the patients who withdrew from the study, one found JOBST UlcerCARE comfortable at first but, because of pain, had to stop wearing it; one patient found

wearing compression hosiery too painful from the start (this patient was withdrawn from the study in week 1); 1one felt it was 'not suitable' for her legs.

Overall assessments by clinicians

The clinicians undertaking the case series were three tissue viability nurses and a leg ulcer nurse specialist. An overall evaluation of each product at final visit is summarised in Figure 6.

In 95% (n=21) of the patients the clinicians said they would use the same treatment again. During the study JOBST UlcerCARE two-layer compression hosiery system was rated as 'good' or 'excellent' as a bandaging compression system.

All clinicians using either the combination of Cutimed Siltec together with JOBST UlcerCARE and Cutimed Sorbact or Cutimed Siltec with JOBST UlcerCARE reported that they would use the treatment again.

Limitations

This study was designed as a case series with the last two control points at 4-week intervals. This length of interval meant that some ulcers healed between control visits. This made it difficult to assess actual healing times in relation to the products used.

Although recurrent ulcers were recorded at the start of the study, no long-term follow up was planned to show whether compression hosiery has a significant effect on reducing the incidence of recurrence.

The mobility categories were not defined in detail and so were subject to interpretation by the clinicians and the patients. No mobility assessment follow-up was planned for patients whose ulcers healed before the end of the study. In addition, no degree of maceration was defined in the assessment of the peri-wound skin.

Conclusion

The authors intended to assess the effect of using an integrated therapeutic approach, including dressings, compression systems and skin protectants from the same manufacturer, on patients with venous leg ulcers. Parameters evaluated included wound size, management of exudate, management of peri-wound skin maceration and quality of life (pain, comfort, mobility).

The study sample was broadly representative of a usual primary care leg ulcer clinic case load. The proportion of healed wounds either recorded as healed at a control visit or between control visits was 50% (n=11). Dressing changes between control visits were carried out either by the clinician conducting the study, or the patient's carer or the patient. As patients presented for each control visit with the same brands of dressing as those used in the study, it would be reasonable to assume that dressing use was consistent.

The proportion of ulcers healed is in line with other results reported in the literature on the treatment of venous leg ulcers (O'Meara et al, 2012; Zenilman et al, 2013; Green et al, 2014; Valle et al, 2014). It is worth noting that the study population had a significant proportion of patients with comorbidities (Vowden and Vowden, 2009); 48% of patients had a long-term history of recurring ulcers in the same location and 43% of patients had multiple ulcers.





Two of the four withdrawals illustrated the need to be sensitive to the preferences of patients as well as their clinical condition as they were related to discomfort with either the design of the stocking or the wound dressing.

The treatment combination proved safe, with no adverse events related to the products used. This study supports the combined use of the JOBST UlcerCARE two-layer compression hosiery system and Cutimed dressings to improve clinical outcomes and the quality of life of patients with venous leg ulcers.

The results showed that the majority of the patients were comfortable when using these products and their degree of mobility was not impaired by the compression hosiery. There was an overall increase in the number of patients reporting no impairment of mobility, but not a significant difference to the degree of impairment reported for the individual activities at the start of the study. Overall, 73% (16/22) of the participants were satisfied with the treatment and found the dressing and compression combination comfortable. Compliance with wearing compression garments is essential to the healing of venous leg ulcers and therefore patient satisfaction with the garment is a critical factor for a successful treatment outcome. **BJN**

Conflict of interest: this article was supported by BSN medical.

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KEY POINTS

- To achieve healing of venous leg ulcers and patient concordance with treatment it is important that the appropriate wound management is matched with the appropriate compression therapy suited to the patient's lifestyle
- This study observed the impact of the use of an integrated range of two-layer compression hosiery, dressings and skin protectants on patients' mobility and comfort, as well as on wound healing and the condition of the wound bed
- The range of comorbidities and the proportion with recurrent ulcers of the 22 patients observed reflects that discussed in the literature
- A total of 73% of patients found the treatment comfortable and in 95% of cases the clinicians said they would use the same combination of products again

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