A pilot study to evaluate the potential of SurePress Comfort®

Sue Bale, Keith Harding

Abstract

Background: Compression hosiery was originally designed to manage venous disease for patients without ulceration, and to prevent ulceration or its recurrence. However, there is now a view that compression hosiery has a role to play in managing patients with active venous leg ulcers. *Aims:* Primary objectives were to assess the ease of application and removal, comfort on sitting and walking, and patient satisfaction with SurePress Comfort® *vs* usual compression system in 20 patients with venous leg ulceration (10 with chronic ulcers; 10 with new ulcers). *Methods:* A pre- and post-intervention design was used to evaluate SurePress Comfort® *vs* usual compression system. Patients were followed for 4 weeks using their usual compression therapy, and then changed to SurePress Comfort® for a further 4 weeks. Newly ulcerated subjects then continued for a further 4 weeks. *Results:* Patients rated the comfort positively; ease of application and removal improved with time, as the patients gained experience. *Conclusions:* Despite a small study size, preliminary data suggested that there is potential to treat patients with venous leg ulceration with SurePress Comfort®. *Declaration of interest:* This study was kindly funded by an educational grant from ConvaTec.

KEY WORDS

Compression
Hosiery
Venous ulcers
Usability
Comfort

The treatment most likely to achieve healing for patients with venous leg ulceration is high compression (Cullum et al, 1999). Compression works by supporting and compressing the damaged veins in the lower leg, and reducing oedema by aiding venous return. A gradient of compression is best, providing more compression at the ankle and less at the knee. A range of bandages are available to provide therapeutic compression, including multi-layer extensible and short-stretch.

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Bandages are classified according to their strength and function, for example, from Class 1 (for light support or retention) through to Class 3 (for very strong compression). Bandage pressures are measured in millimetres of mercury (mmHg), and the strongest compression bandages are capable of applying in excess of 50 mmHg.

Thomas and Nelson (1998) suggested that consistent pressures are only achieved when bandages are applied in a spiral with a 50% overlap between turns, so producing a double layer at any point on the limb. They also described how different methods of applying bandages can alter the pressures achieved. A systematic review by Fletcher et al (1997) drew attention to the failure by researchers to report the method of bandage application, the experience of staff, other aspects of bandaging and patients' mobility. Fletcher et al (1997) argued that all these factors could influence ulcer healing.

To be effective, compression bandages need to be applied according to manufacturers' instructions. It follows that nurses experienced in bandaging are more likely to be able to apply bandages in a way that meets the manufacturers' requirements than nurses with less or no experience.

Researchers have investigated nurses' use of bandages with respect to their ability to deliver appropriate, effective compression (Logan et al, 1992; Roe et al, 1994; Nelson et al, 1995).

Logan et al (1992) explored the differences between experienced and inexperienced bandagers who used two different types of bandage. They concluded that sub-bandage pressure is essentially a function of the bandage type and application technique used, and experienced bandagers were more consistent in applying bandages (in-line with the recommended 40mmHg pressure) than inexperienced bandagers when they used a bandaging aid.

A descriptive survey of the leg ulcer practice of 146 community nurses was undertaken by Roe et al (1994). Only 23% of nurses reported that they used bandages that provided therapeutic compression. The authors argued that nurses require education to help and support them to use compression bandages effectively. Research by ▸▸

Nelson et al (1995) supported these findings in a study of pressures achieved by compression bandages, reporting that nurses' bandaging technique was poor. Nurses applied bandages too tightly, too loosely, or failed to achieve a gradient of pressure from ankle to calf.

Expert opinion also supports the research into the use of bandages by nurses. Bandaging technique has been linked to patient outcomes. Nelson (1996) and Vowden et al (2001) argued that the experience of, and differences between, bandagers is more influential on healing rates than differences in individual bandages. They suggested that studies investigating the efficacy of compression bandages fail to take account, or report the effect, of the experience of the bandager and the application technique used. There would appear to be a case for arguing that a compression system that negated the need for bandaging expertise would be useful in the care of patients with venous leg ulceration. Compression hosiery is one such system.

Although compression hosiery was originally designed to manage venous disease in patients without ulceration, to prevent ulceration or recurrence of ulceration, specialist practitioners express the opinion that compression hosiery has a valuable role to play in the healing of patients with venous leg ulcers. In particular, Keachie (nee Cornwall 1985, 1993) suggests that elastic compression hosiery have certain advantages over bandages. She describes compression hosiery as maintaining a high level of compression consistently over time. Keachie also describes the convenience of compression hosiery, in that it can be taken off at night and reapplied in the morning or left on 24 hours a day. Another feature of compression hosiery is that it is available as a sock or stocking and in a choice of colours.

For many years, research has supported the use of compression hosiery in the care of patients with active venous leg ulceration, reporting similar healing rates to those achieved by using compression bandages (Hendricks and Swallow, 1985; Burgess and Robinson, 1993; Samson, 1993; Horakova and Partsch, 1994; Samson and Showalter, 1996). In addition, Mulder et al (2001) reported that the consistent and reproducible pressures that are obtained when using compression hosiery, are an advantage over other methods of compression. Compression hosiery is recommended as an option in selecting compression therapy in the EWMA Position Document (Marston and Vowden, 2003).

However, there have been practical challenges associated with the use of compression hosiery; namely, difficulties in application and removal and patient discomfort during wear (Gilliland and Wolfe, 1991). These may also affect patient concordance with compression hosiery, and concordance with compression has received considerable attention in recent years (Bale and Harding, 2003; Edwards, 2003). These authors recommend that patients' are engaged in therapeutic relationships where their lifestyle and views are comprehensively accommodated.

The potential role of compression hosiery in treating patients with venous leg ulceration

The development of a compression system that avoids the need to use bandages while also applying graduated compression to the lower leg could be advantageous to both patients and nurses. Avoiding the use of bandages would remove the potential for inappropriate or badly applied compression bandages by nurses. Bandages applied too tightly can cause tissue ischaemia and bandages applied too loosely are likely to be ineffective. A stocking that applied graduated compression and was easy to put on would remove many of these problems and may have other, patient-convenience benefits.

SurePress Comfort® is an example of a two-layer compression stocking that can be used, as an alternative to compression bandages, to treat patients with active venous leg ulceration. It consists of an understocking containing 20% Spandex and 80% Nylon, and an overstocking consisting of 18% Spandex and 82% Nylon. The system is available in five sizes to accommodate a wide range of ankle and calf girths. It produces an anticipated pressure of 35mmHg at the ankle.

The potential benefits of using this system were anticipated to be improved patient outcomes, cost savings associated with delivering effective treatment, and standardisation of the one therapy.

Study aims

This study aimed to explore the use of SurePress Comfort® to treat patients with active venous leg ulceration. It was hypothesised that this compression hosiery system would have advantages over compression bandages in terms of ease of application and removal, and comfort.

Primary objectives of the study were to assess ease of application and removal, comfort and patient satisfaction. Healing was a secondary objective.

Methods

A pre- and post-intervention design was used to evaluate the use of the patients' usual compression bandages, compared to the use of SurePress Comfort®. Twenty patients were included; 10 with newly-ulcerated legs (ulcer present for <6 months) and 10 with long-standing ulceration (ulcer present for >6months). Arterial disease was excluded with an ABPI of <0.85, and this in conjunction with a history of venous disease confirmed venous ulceration. The patient's experience of using their usual compression system over a 4-week period was assessed, followed by the use of SurePress Comfort®for a further 4-week period. After this time, the patients with newly-ulcerated legs were followed for a further four weeks using SurePress Comfort®, due to their greater chance of healing than those patients with long-standing ulceration.

Descriptive data were collected: patient age, sex, and type of ulcer (long-standing or newly-ulcerated).

Ulcers were traced and wound area measured using computerised planimetry, at baseline, at week 4, and at week 8. The newly-ulcerated patients were also assessed at week 12.

Data were also collected regarding ease of application and ease of removal. Patients were asked to rate these using a five-point scale – 'very easy'; 'easy', 'neither easy nor difficult', 'difficult', and 'very difficult'. Patients were also asked to rate the comfort of wearing compression while seated, and when walking. This was also measured using a five-point scale – 'very comfortable', 'comfortable', 'neither comfortable nor uncomfortable', 'uncomfortable', and 'very uncomfortable'. Patients were also asked to rate their overall level of satisfaction using a five-point scale – 'very pleased', 'pleased', 'neither pleased nor disappointed', 'disappointed', and 'very disappointed'. Patients were then invited to make additional comments.

Results

Twenty patients were entered, 7 (35%) male and 13 (65%) female. The ratio of males to females was approximately 1:2. Mean age was 69 years (SD 13.5), and the median age 68.5 years (minimum age = 40 years; maximum = 90 years). This sample of patients is typical of those with venous ulceration. Prevalence studies have reported similar findings, for example, Callam et al (1985) and Cullum and Roe (1995).

On entry into the study, 10 patients had long-standing ulceration, and 10 were newly-ulcerated. Nine of these (45%) patients healed, 8 with newly-ulcerated legs and one with long-standing ulceration. The mean time to healing was 9.9 weeks (SD 2.02), and the median was 9 weeks (minimum no of weeks = 8, maximum =12). The patients who did not heal achieved a mean reduction in wound area of 1.72cm^2 (SD 1.61) and a median reduction in wound area of 1.1cm^2 (min 0.1, max 4.75). In terms of percentage reduction, these patients had a mean reduction in wound size of 59.9% (SD .51), and a median reduction in wound size of 81.6% (min 9%, max 98.3%).

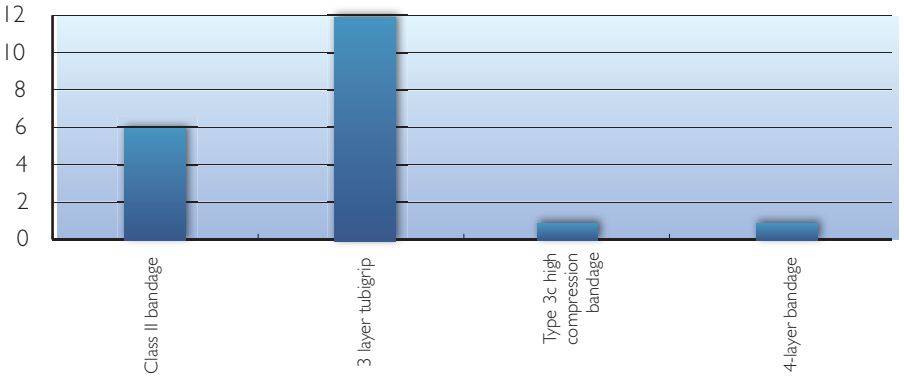

Figure 1. Existing compression system used (n=20).

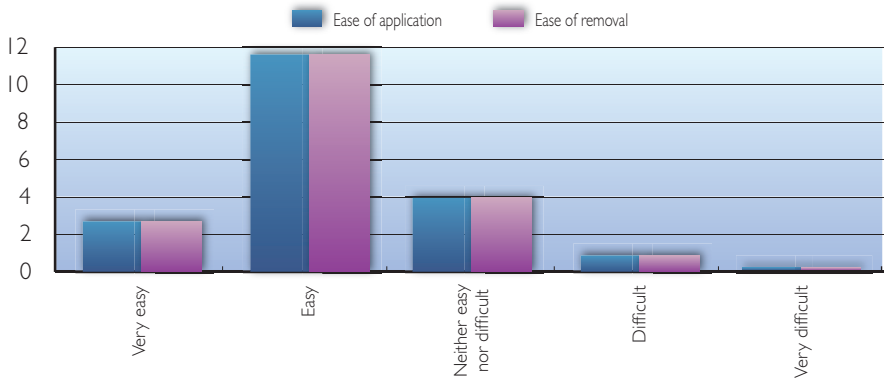

Figure 2. Ease of application and removal of existing compression system at Week 4 (n=20).

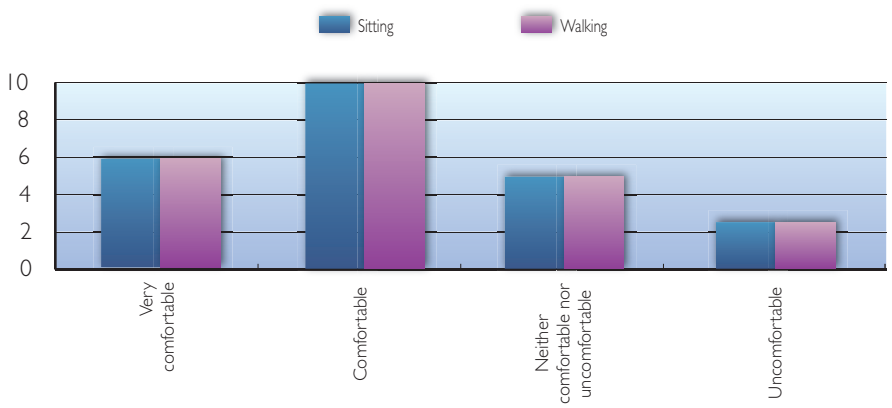

Figure 3. Comfort of existing compression system at Week 4 (n=20).

Experience using existing compression

On entry, 6 (30%) patients were wearing a Class II bandage, 12 (60%) three layers of graduated tubigrip, one (5%) a type 3C high compression bandage (40mmHg at ankle) and one (5%) four-layer bandage (*Figure 1*).

Ease of application and removal

Patients were asked to rate the ease of application of their usual compression system at week 4 (*Figure 2*). Fifteen (75%) patients reported it to be either 'easy' or 'very easy' to apply, 4 (20%) as 'neither easy nor difficult', one reported application

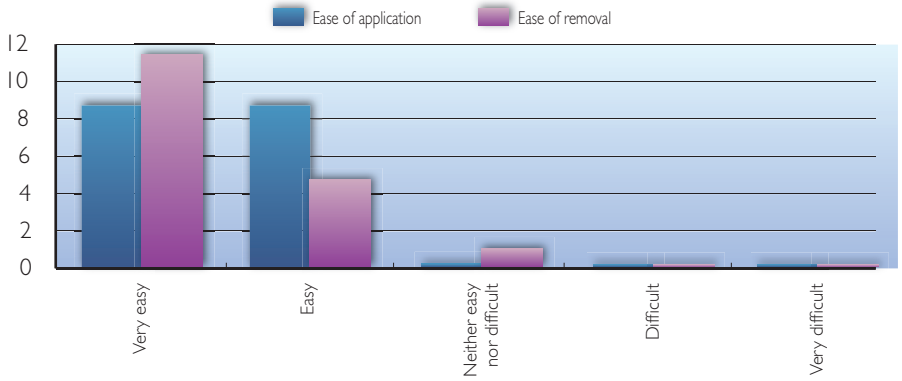

Figure 4. Ease of application and removal of SurePress Comfort® at Week 8 (n=18).

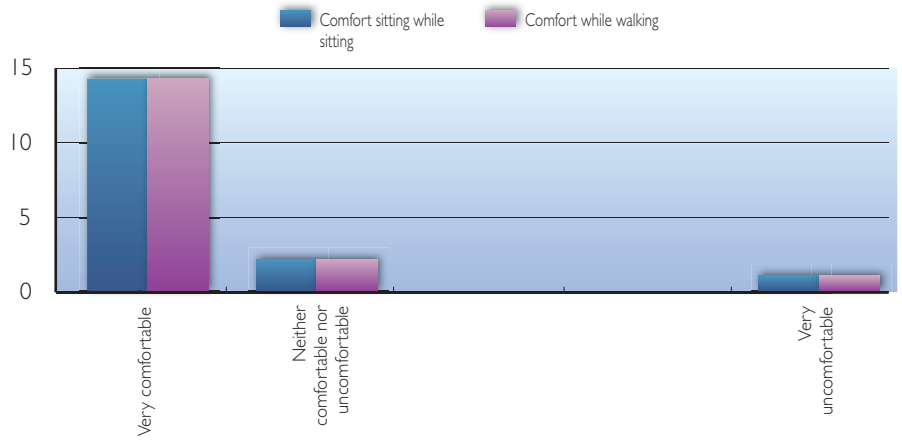

Figure 5. Comfort of SurePress Comfort® at Week 8 (n=18).

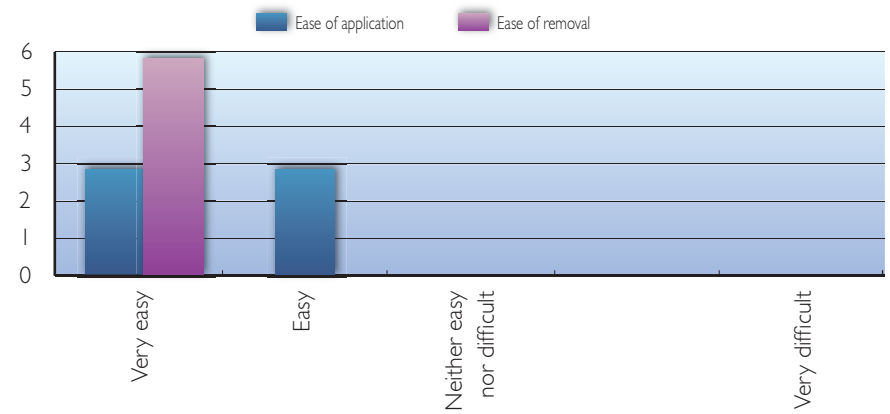

Figure 6. Ease of application and removal of SurePress Comfort® at Week 12 (n=6).

as 'difficult', and no patients reported their usual compression system as being 'very difficult'. Ease of removal was rated in a similar way: 3 (15%) patients rated removal as very easy', 12 (60%) as 'easy', 4 as 'neither easy nor difficult' and one rated it as 'difficult'. No patients reported removal of their usual compression system as 'very difficult'.

Comfort when sitting/walking

Patients were asked to rate the comfort of their usual compression system while sitting and when walking. *Figure 3* summarises these data. Here, 14 (70%) patients rated their usual compression system as either 'comfortable' or 'very comfortable', and 5 (25%) rated them as 'neither comfortable nor uncomfortable'. One (5%) patient reported their usual compression system to be 'uncomfortable'. Overall, patients reported a high level of satisfaction with their usual compression system, 16 (80%) patients were 'pleased' or 'very pleased', and a further 3 (15%) were 'neither pleased nor disappointed', with one patient 'disappointed'.

Following the week 4 assessment, patients were measured and fitted with SurePress Comfort®.

Week 8

Patients were assessed following 4 weeks of using the new compression hosiery system, at week 8. At this time point, 4 patients had healed, one with long-standing ulceration and 3 with newly-ulcerated legs. Two patients had been withdrawn from the study, one had a severe infection of an ulcer adjacent to the study ulcer, and another experienced severe discomfort using SurePress Comfort®. The remaining 18 patients were asked to rate the ease of application and removal of SurePress Comfort®, the comfort of the system while sitting and when walking, and their satisfaction with the system.

Ease of application and removal

Following 4 weeks' experience of using SurePress Comfort®, all patients rated this system as being 'easy' or 'very easy' to apply. No patients rated this system as 'difficult' or 'very difficult' to apply, and 17 rated it as 'easy' or 'very easy' to remove. The remaining one patient reported that this system was 'neither easy nor difficult' to remove (*Figure 4*).

Comfort while sitting and when walking around

Of the 18 remaining patients, 17 rated SurePress Comfort® as 'comfortable' or 'very comfortable' to wear while sitting and when walking around (*Figure 5*). However, the remaining one patient's (Patient 5) experience was less positive, he reported difficulties with pain and exudate. The researcher noted that the ulcer exhibited clinical signs of

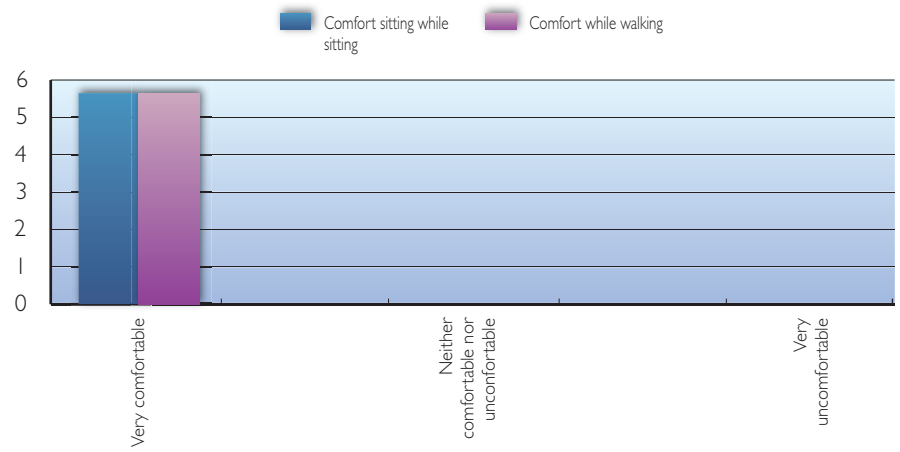

Figure 7. Comfort of SurePress Comfort at Week 12 (n=6).

infection and patient 5 was prescribed antibiotic therapy and withdrawn from this study. Patient 5 rated it as 'very uncomfortable' because it dug into his leg and this caused pain. This gentleman had a large, infected, heavily exuding ulcer that required changing 4 times a day because wound exudate leaked through the system. There was not enough room to get a large dressing pad under the hosiery to absorb this heavy exudate.

Patient satisfaction

Of the patients 14/18 were 'very pleased' with SurePress Comfort®, and a further 3 were 'pleased'. Patient 5 who had experienced discomfort was 'very disappointed' with it.

Week 12

Of the 10 patients with newly-ulcerated legs that were eligible to continue in this study using SurePress Comfort Graduated Compression System® for a further 4 weeks, 4/10 had healed. The remaining 6/10 patients were assessed at week 12, and 5 of these 6 patients healed during this period.

Ease of application and removal

Following another 4 weeks experience of using SurePress Comfort®, all patients rated this system as being 'easy' or 'very easy' to apply. No patients rated this system as 'difficult' or 'very difficult' to apply. All 6 (100%) patients rated SurePress Comfort® as being 'very easy' to remove (*Figure 7*).

Comfort while sitting and when walking around

All 6 (100%) patients taking part rated SurePress Comfort® as being 'very comfortable' to wear while sitting and when walking around.

Patient satisfaction

All 6 (100%) patients were 'very pleased' with SurePress Comfort®.

Discussion

The patients entered were typical of patients who experience leg ulceration in terms of age and sex distribution (Callam et al, 1985; 1986; Nelzen et al, 1991; Cullam and Roe, 1995). Healing was achieved in 9/20 patients, 8 were in the newly-ulcerated group and one in the long-standing group. The patients who did not heal achieved a mean reduction in wound area of 1.72cm^2 (SD 1.61) and a median reduction in wound area of 1.1cm^2 (min 0.1, max 4.75). Two patients were withdrawn, one with a non-device related problem and one experienced pain. Patients rated the comfort of the compression hosiery positively, with many responses being 'very comfortable' or 'comfortable'.

Researchers have reported that patients can have difficulties with concordance to compression therapy (Douglas, 2001; Bale and Harding, 2003; Edwards, 2003) where discomfort and pain have been cited as problematic for patients. Managing pain has been reported to be a major challenge in treating patients with leg ulceration (Phillips et al, 1994; Roe et al 1994; Douglas, 2001). In this study, patients reported that SurePress Comfort ® on most occasions was 'very comfortable'. In addition, ease of application and removal improved with time, as the patients gained experience. By week 12, all patients reported it as 'very easy' to remove, and all rated this system as 'easy' or 'very easy' to apply.

While recognising that the sample size included in this study was small, these preliminary data suggests that there is potential to treat patients with venous leg ulceration with SurePress Comfort®. **WUK**

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Key Points

- This pilot project explored the use of compression hosiery to treat patients with venous ulcers.
- Patients reported that compression hosiery was easy to use and comfortable.
- Healthcare professionals might consider offering this as an alternative to compression bandaging for some of their patients.

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