ORIGINAL ARTICLE



A service evaluation to examine the use of compression strapping for the management of patients with retromalleolar leg ulcers in a specialist community setting

Samantha Haynes¹ | Samantha Holloway²

¹Southampton Tissue Viability Team, Solent NHS Trust, Southampton, UK ²Centre for Medical Education, College of Biomedical and Life Sciences, Cardiff University School of Medicine, Cardiff, Wales, UK

Correspondence

Samantha Holloway, Centre for Medical Education, College of Biomedical and Life Sciences, Cardiff University School of Medicine, 9th Floor, Heath Park, Cardiff CF14 4YS, Wales.

Email: hollowaysl1@cardiff.ac.uk

Abstract

Leg ulcers are costly to the NHS, and they have a significant impact on patients' physical, social, and psychological well-being. Compression therapy is traditionally the "gold-standard" treatment for the management of venous leg ulcers and can be beneficial for those individuals with mixed ulcer aetiology. Evidence suggests that the application of standard, strong, graduated compression bandaging does not apply therapeutic compression to the retromalleolar fossa. The addition of compression strapping has been found to increase subbandage pressure, promote healing, reduce pain and increase quality of life in patients with retromalleolar leg ulcers. This service evaluation aimed at evaluating the use of compression strapping with patients with retromalleolar leg ulcers. The service evaluation included 24 patients with 41 ulcers treated with compression strapping by a specialist team. Patients treated with CS had multiple comorbidities and shared common characteristics including foot and ankle oedema, previous ulceration, reduced mobility, and failure to heal despite the application of "gold-standard" compression therapy. Following application of compression strapping, 17 patients (n = 27/41 ulcers) healed, mean pain scores decreased, and mean quality of life scores increased. The compression strapping was tolerated well, and patients reported a positive experience. This service evaluation has contributed towards a growing evidence base that supports the use of CS for the management of patients with retromalleolar leg ulcers.

KEYWORDS

compression, leg ulcers, pain, quality of life

Key Messages

- · leg ulcers are costly to the NHS, and they have a significant impact on patients' physical, social, and psychological well-being
- · evidence suggests that the application of standard, strong, graduated compression bandaging does not apply therapeutic compression to the retromalleolar fossa. The addition of compression strapping has been found

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- to increase sub-bandage pressure, promote healing, reduce pain, and increase quality of life in patients with retromalleolar leg ulcers
- patients treated with CS shared common characteristics including foot and ankle oedema, previous ulceration, reduced mobility, and failure to heal despite the application of "gold-standard" compression therapy
- the use of compression strapping can have a positive impact on patients reported pain and quality of life. Compression strapping was tolerated well, and patients reported a positive experience

1 | INTRODUCTION

Leg ulcers (LUs) are the most common wound type in the UK, representing about 28% of all wounds. Recent UK estimates have suggested that the number of individuals with LU is increasing from 0.73 million in 2012/13 to 1 million in 2017/18. LU can persist for months or even years, meaning that the experience of living with them has huge physical, social, and psychological costs to the individual. Vascular disease, both venous and arterial, is the most common cause of LU, but other aetiologies include sickle cell disease, rheumatoid arthritis, diabetes/peripheral neuropathy, vasculitis, and uncontrolled cardiac failure. The most common to the common cause of LU arthritis, and uncontrolled cardiac failure.

Compression therapy is traditionally considered the mainstay treatment for individuals with venous leg ulcers (VLUs) and recommended in clinical guidelines across the world.8-11 In the United Kingdom, the National Institute for Health and Care Excellence recommends the use of high, multilayer compression bandaging specifically, which is defined as providing compression of 35 to 35 mmHg at the ankle.^{8,11} The National Wound Care Strategy Programme has since advocated the use of strong compression, defined as an elastic compression system that is intended to apply at least 40 mmHg at the ankle or a non-elastic (e.g., short stretch) system applied at full stretch. 12 It has been recognised that early endovenous ablation of superficial venous reflux as an adjunct to compression therapy can result in faster healing of VLU.¹³ However, vascular interventions may be inappropriate for some due to frailty for example.

Where the underlying cause of LU is due to a combination of venous and arterial disease and where an individual has an ankle brachial pressure indexes (ABPI) of between 0.5 and 0.8, they may also benefit from the application of mild compression therapy^{6,7,14-16} under the supervision of a specialist team.

The application of compression therapy can promote LU healing by reducing venous reflux, improving calf muscle pump function and reducing ambulatory venous hypertension. Compression therapy also reduces oedema, improves lymphatic drainage, and enhances

blood flow in the microcirculation. ²⁰⁻²⁴ Compression bandaging has been found to reduce the pro-inflammatory environment that is characteristic of LU, reducing pro-inflammatory cytokines and elevating levels of anti-inflammatory cytokines. ^{25,26}

Despite the use of recommended compression therapy, some LU do not heal^{27,28} with authors proposing that the location of the wound can be the underlying cause.^{28,29} There is an increasing body of evidence to suggest that standard, strong, graduated compression bandaging can apply a hammocking effect over the retromalleolar fossa, pressure, and stiffness can be critically reduced to this area and the efficacy of the compression therapy is reduced.^{24,28-34} Consequently, LU located in the retromalleolar area may not receive therapeutic, sustained, localised compression from standard compression and as a consequence fail to heal in a timely manner.^{24,35}

Hopkins et al were the first group to report on the development of a compression therapy strapping technique, created to promote healing of LU in the retromalleolar area.²⁸ This technique involves the application narrow strips of 10 cm lengths of a cohesive bandage (Actico, Lohmann and Rauscher, UK) layered with a 50% overlap, in a fan distribution overlying the compression bandaging at the retromalleolar area (Figure 1). The pioneers of the strapping technique have since adapted the technique further and have recommended that the application can also be applied in a chevron shape (Figure 2). The addition of CS has been demonstrated to enhance compression therapy and promote healing in patients with retromalleolar ulcers, reduce pain, and improve quality of life (QoL) by increasing the sub-bandage pressure at the lateral and medial retromalleolar fossa. 28,35-37

The Solent Tissue Viability Team introduced the use of CS in October 2018, and subsequently, a service evaluation was conducted to evaluate the use of CS and to inform local decision-making with regard to its continued use. The evaluation aimed at describing the characteristics of the patients who were treated with strapping and at determining the effect of CS on their outcomes of



FIGURE 1 Compression strapping fan technique. Thanks to Solent Tissue Viability Team, Southampton, for kind permission to reproduce photo of fan strapping



FIGURE 2 Compression strapping in chevron technique. Thanks to Accelerate CIC for kind permission to reproduce photo of chevron strapping

healing, pain, and QoL. The evaluation also qualitatively evaluated the experience of CS from the patient's perspective during the treatment.

2 | MATERIALS AND METHODS

The service evaluation was conducted at a tissue viability specialist-led community leg ulcer clinic in the South of England. There were two phases to the service evaluation: the retrospective phase evaluated patients who had received CS from October 2018 to January 2020 and the

TABLE 1 Population inclusion/exclusion criteria

Inclusion criteria	Exclusion criteria
Adult aged over 18 years	Children aged under 18 years
Patient with a	Patient without a
retromalleolar leg ulcer	retromalleolar leg ulcer
 Patient had received	Patient had not received
compression strapping	compression strapping
treatment/were going to	treatment/were not going to
be treated with	be treated with compression
compression strapping	strapping
Patient had been under	Patients had not been under
the care of the Solent	the care of the Solent Tissue
Tissue Viability Team,	Viability Team,
Southampton	Southampton
 Patient had not opted-out of their confidential data being used beyond clinical care/ patient gave informed consent 	Patient had opted-out of their confidential data being used beyond clinical care/ patient declined to participate in the service evaluation

prospective phase evaluated patients who receive CS during the evaluation period. It was proposed that the prospective evaluation period would have a duration of 5 months, from January to June 2020. However, due to the COVID-19 pandemic, recruitment to the prospective phase was stopped at the end of March 2020. Consequently, there was a small number recruited to the prospective phase of data collection.

A purposive sampling method was utilised for practical purposes to enable a focus on the target population. Table 1 shows the inclusion and exclusion criteria for the service evaluation.

A data collection tool was developed to gather retrospective data from the electronic notes of patients attending clinic who had received CS from October 2018 to January 2020. The data collection tool was adapted to gather data during the prospective phase of the service evaluation, from January 2020 to March 2020. The data collection tools were designed to use information that is collected routinely during patient appointments including patient demographics, past medical history, leg ulcer history, patient characteristics such as presence of oedema to foot and ankle, previous treatments, healing time, pain, and QoL scores. In addition, the prospective data collection tool included a semi-structured interview that focused on the experience of CS from the patient's perspective.

Quality of life was assessed using a QoL VAS score (0 = worst QoL, 10 = best QoL). Pain was assessed using an 11-point NRS, (0 = no pain, 10 = worst pain). Healing was defined as 100% epithelialisation.

The results of the quantitative data collection were analysed using Microsoft Excel (version 365) and simple descriptive results were presented in a summary form. The qualitative data from the semi-structured interviews were analysed by a method of thematic analysis described by Pope (2008).³⁸

2.1 | Ethical considerations

Service evaluations do not require NHS Research Ethics Committee approval. Permission was required and gained from Solent NHS Trust prior to the commencement of the evaluation.

Participant consent was sought for the prospective phase of the service evaluation. Patient consent was not required for the retrospective phase, but the author ensured compliance with the national data-opt out policy, which applies to the disclosure of confidential information patient information for purposes beyond individual care (NHS Digital 2019).

3 | RESULTS

A total of 22 sets of clinical notes were reviewed in the retrospective phase and 19 patients with 34 retromalleolar LU met the inclusion and exclusion criteria. A further five consecutive patients with seven retromalleolar LU

met the inclusion and exclusion criteria for the prospective phase of the evaluation. There were no exclusions from the prospective phase. In total, 24 patients with a total of 41 ulcers were included.

3.1 | Demographics and characteristics

Twenty-two patients were diagnosed with VLU (91.7%), and two patients had mixed aetiology LU (8.3%). There were 16 men (66.7%) and 8 women (33.3%) with a mean age of 70.75 years (range 42–89 years). The majority of the patients were over 65 years old (n=16/24, 66.7%). The mean number of comorbidities was 2.7 per patient. Table 2 shows the most common comorbidities.

The mean duration of ulceration prior to the commencement of CS was 34.04 weeks (range 3–78 weeks). The majority of patients had been living with their ulceration for over 12 weeks (n=20/24, 83.3%) and 53.4% for more than 24 weeks (n=14/24). Figure 3 summarises the characteristics of the patients.

3.2 | Treatment prior to the commencement of compression strapping

All of the patients had received a variety of different types and strengths of compression therapy for the management of their LU prior to the commencement of CS

TABLE 2 Frequency table of comorbidities experienced by the patients in the retrospective (n = 19) and prospective groups (n = 5)

Co-morbidity	Retrospective group frequency (number of patients) $n = 19$	Prospective group frequency (number of patients) n = 5	Combined retrospective and prospective groups frequency (number of patients) $n = 24$
Peripheral vascular disease	2	0	2
Osteoporosis	2	0	2
Multiple sclerosis	2	0	2
Chronic obstructive airways disease	2	1	3
Hypothyroidism	2	0	2
Alcohol misuse	2	0	2
Rheumatoid arthritis	3	0	3
Diabetes	2	1	3
Chronic kidney disease	3	0	3
Cardiovascular disease	6	2	8
Hypertension	8	1	9
Obesity (BMI > 30)	8	3	11
Other, for example, lupus, bowel cancer, connective tissue disorder, Parkinson's disease, vascular dementia	11	1	12

(Table 3). Patients had been treated with two or more different antimicrobial and advanced dressings (n = 19/24, 79.1%) with 14 patients being treated with three or more different antimicrobial and advanced dressings (58.3%). Advanced dressings were defined as those dressings that provide the optimal environment for wound healing by simple physical or chemical means, typically by controlling moisture levels (for example, alginate, film, foam, hydrocolloid, and hydrogel dressings). 5

3.3 | Compression strapping treatment

Twenty patients received CS in the fan technique (83.3%), and four patients were treated with the chevron strapping technique (16.7%). Strapping was stopped in six patients in the retrospective group (n = 6/19, 31.6%), which represents 25% of the total sample (n = 6/24). Table 4

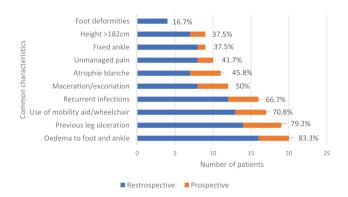


FIGURE 3 Characteristics commonly experienced by patients in the retrospective (n = 19) and prospective groups (n = 5)

summarises the reasons for stopping of treatment. Cessation of strapping did not occur in the prospective phase of the evaluation.

3.4 | Patient outcomes

In the retrospective group (n = 19), 13 patients with 21 ulcers healed (68.4%, 61.8%, respectively). In the prospective group (n = 5), four patients with six ulcers healed (80%, 85.7%, respectively). A total of 17 patients (n = 17/24, 70.8%) with 27 ulcers (n = 27/41, 65.8%) healed overall. Figure 4 shows time to healing post-strapping application. Mean healing time was 11.2 weeks (95% CI: 7.8, 14.6, SD = 6.6, median = 9 weeks).

Mean pain scores gradually decreased over 12 weeks, reducing from 3.46 at week 0 to 1.31 at week 8 (P=0.02) and 0.63 at week 12 (P=0.00) (Table 5). Mean QoL scores increased over 12 weeks from 5.42 at week 0 to 7 by week 12 (P=0.02) (Table 6).

TABLE 4 Reasons for stopping the use of compression strapping

Reason why strapping stopped	Patient numbers $n = 19^a$	Percentage
Not tolerated due to increased pain	2	10.5%
Admission to hospital	2	10.5%
Patient died	1	5.3%
Clinically ineffective	1	5.3%

^aRetrospective phase only.

TABLE 3 Types of compression therapy used prior to commencement of compression strapping

Type of compression therapy	Level of compression of product (mmHg)	Retrospective phase $n = 19$	Prospective phase n = 5	Retrospective and prospective phase $n=24$
Actico ^a (short stretch one layer applied to ankle circumference 18-25 cm after padding and 2 layers for ankle circumference > 25 cm after padding)	40	13	1	14 (58.3%)
Coban 2 ^b (Long stretch)	35–40	11	0	11 (45.8%)
Hosiery kit	40	3	1	4 (16.7%)
Wrap	40	2	2	4 (16.7%)
Coban Lite ^b (Long stretch)	25–30	7	1	8 (33.3%)
Hosiery	<40	4	0	4 (16.7%)

^aL&R Medical.

^b3 M.

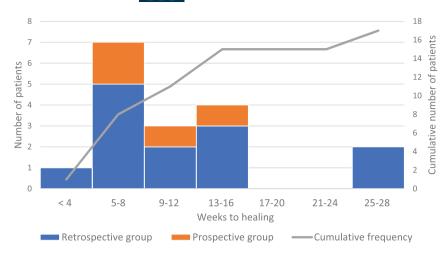


FIGURE 4 Time taken to healing postcompression strapping application (n = 17)

TABLE 5 Changes in mean pain scores of the combined retrospective and prospective groups over time (n = 24)

Time (weeks)	Mean pain score ^a (SD)	95% CI	Missing values	Number patients treated with compression strapping	Cumulative number patients strapping stopped	Cumulative number patients healed	P values
0	3.46 (3.79)	(1.86, 5.06)	0	24	0	0	
4	1.94 (2.33)	(0.96, 2.93)	2	20	4	0	P = 0.10
8	1.31 (2.00)	(0.47, 2.16)	0	15	5	5	P = 0.02
12	0.63 (1.33)	(0.07, 1.19)	0	9	5	10	P = 0.00

^awhere 0 = no pain, 10 = worst pain.

TABLE 6 Changes in mean QoL scores of the combined retrospective and prospective groups over time (n = 24)

Time	Mean QoL score ^a (SD)	95% CI	Missing values	Number patients treated with compression strapping	Cumulative number patients strapping stopped	Cumulative number patients healed	P value
Week 0	5.42 (2.39)	(4.44, 6.61)	5	24	0	0	
Week 4	6.58 (1.85)	(5.80, 7.36)	8	20	4	0	P = 0.07
Week 8	7.33 (1.99)	(6.49, 8.17)	2	15	5	5	P = 0.00
Week 12	7.00 (1.91)	(6.19, 7.81)	0	9	5	10	P = 0.02

awhere 0 = no quality of life, 10 = best quality of life.

3.5 | Patient experience

Data for patient experience were available from five respondents for the prospective phase only. Overall, the patients experience of CS was positive (Table 7). All of the participants talked positively about the CS working, faster healing and making the wound better. They also stated that the strapping provided the right pressure to the right place and it felt more supportive. When asked about their experience of the disadvantages of CS, the majority of patients in the prospective group stated that there were no disadvantages (n=3/5). Two patients highlighted discomfort as a disadvantage of the CS.

TABLE 7 Patient response to "What has been your experience of the compression strapping that you are currently having?"

Response	Number of patients $(n = 5)^a$
Good/very good	3
OK	1
Comfortable	1
It works so I'm happy	1
Compared to other bandages, I can feel the pressure on the wound	1
If it's too tight it's uncomfortable, but usually it's alright	1

^aProspective phase only.

3.6 | Follow-up

All patients who healed in the retrospective group were prescribed compression hosiery post-healing to prevent recurrence. At 3-month follow-up of the retrospective group, there was a loss of 3 patients (15.8%) due to death. Of the six patients that did not heal during the CS treatment, one died, and five remained unhealed 3 months later (26.3%). Of the 13 patients who had healed during the treatment with CS, seven remained healed (n = 7/13, 53.8%), four experienced a recurrence (n = 4/13, 30.8%), and two patients died (n = 15.8%). It was not possible to follow up the prospective group due to time limitations.

4 | DISCUSSION

Previous observational studies have suggested that the addition of CS can increase the pressure at the retromalleolar area, promote healing, reduce pain, and increase QoL.^{28,35-37} However, the evidence evaluating the use of CS is limited.

This service evaluation set out to evaluate the use of CS to treat patients with retromalleolar LU in a specialist leg ulcer clinic. The results identified that patients treated with CS had multiple comorbidities including obesity, cardiovascular disease, hypertension, diabetes, rheumatoid arthritis, kidney disease, alcohol misuse, and anaemia. Such comorbidities are consistently reported in the literature to be frequently experienced by patients with LU. 1,28,39-43 This high burden of disease reflects the advancing age of the patient population but also highlights the complexity of the patients with LU treated with CS.

Previous studies have consistently found that LU and VLU are more likely to occur in women rather than men. 40-44 In contrast, the results of this evaluation found

that the majority of the patients were men. Currently, there is no comparable literature regarding the location of ulcers and whether this correlates with gender. The findings of the current study suggest that retromalleolar ulcers are more commonly associated with men; however, more data would be needed to determine whether this holds true.

This evaluation identified a number of common characteristics shared by patients treated with CS, which were consistent with those reported previously.²⁸ In particular, oedema to the foot and ankle was the most common characteristic reported from the current evaluation and previous studies.²⁸ Unmanaged oedema is associated with excoriation and maceration, 45 an observation also seen in the current evaluation. The presence of maceration and excoriation are signs of poor exudate management, which is also associated with increased risk of local and systemic infection. 46,47 Recurrent infections were also experienced by the majority of the patients in the evaluation and the previous study by Hopkins et al.²⁸ Infection is a major factor affecting VLU healing.1 The recommendation from the findings of the current evaluation and previous studies is that compression techniques such as CS could be utilised and developed to reduce oedema, reduce the risk of infection, and prevent the development of a hostile wound environment that is recognised as being detrimental to healing.

This evaluation also identified that patients treated with CS frequently required the use of a mobility aid or wheelchair. A number of studies have highlighted that reduced mobility is commonly experienced in patients with LU. 40,43,48 The inability to walk more than 200 m during the day has been found to be associated with slow healing time of VLU. 49 Reduced mobility and reduced ankle movement affect the function of the calf muscle pump and exacerbate venous reflux, contributing towards chronic venous disease and subsequent ulceration.⁵⁰ Exercise programmes that include simple progressive resistance and aerobic activity have been found to improve healing in conjunction with compression therapy.⁵¹ This finding also highlights the need for a multidisciplinary approach to the care of patients with LU, with appropriate referral to podiatry, biomechanics, or physiotherapy to help to improve their mobility status, improve their venous return, and enhance healing.

Long duration of ulceration has been found to be associated with delayed healing. Patients in this evaluation had a mean duration of ulceration of 34.04 weeks with the majority of patients having had the ulcer for more than 12 weeks. This is consistent with Hopkins et al findings. Despite the application of compression therapy and the use of different dressings, their LU had failed to heal prior to the application of CS. This

highlights the complexity of the population of individuals with retromalleolar LU and the need for novel methods of compression therapy to be considered to meet their individual needs to promote healing. It was not possible to determine a relationship between duration and healing rate in this study due to the small sample size; however, it would be interesting to examine this further in a more prospective manner.

This evaluation found that the majority of ulcers healed between 3 and 27 weeks after the commencement of CS. The healing rate in the study by Hopkins et al was higher but healing took longer; 92% of the ulcers in their sample healed 3 months to 1 year after the commencement of CS (median 5 months).²⁸ The larger sample size in the current evaluation could account for the variation in healing rates. The difference could also be explained by experience; Hopkins et al were the pioneers of the strapping technique, which would suggest a degree of expertise. In contrast, the Solent Tissue Viability Team Southampton taught themselves how to apply CS, so could be considered novices. Nevertheless, this evaluation supported Hopkins et al's findings that CS has the potential to aid healing in those patients where "goldstandard" compression therapy alone had failed to heal their retromalleolus LU.

Evidence has consistently shown that the experience of living with a LU impacts negatively on physical functioning, social and psychological aspects of daily life, and overall QoL.²⁻⁴ Pain is frequently experienced by patients with LU and identified as one of the worst aspects of living with a LU, negatively impacting on QoL.3,48,53 The requirement to stop the use of CS was an issue for very few patients, but for some, it was due to increased pain following commencement. An interesting observation was that compression strapping was not stopped in the prospective phase of the service evaluation. It is not clear why, but anecdotally this may be due to increased practitioner confidence. Confidence, courage, and competence are required for the effective use of compression therapy. 54,55 Previous evidence suggests that CS is well tolerated.²⁸ Overall, this evaluation identified that the mean pain scores of patients reduced, and mean QoL scores increased following the commencement of CS, but further studies are required to confirm these findings.

Evidence regarding the patient's experience of CS is limited. The current evaluation established that patients found the CS to be comfortable and easy to apply and were of the opinion that it promoted healing. However, it should be borne in mind that the number of respondents for this aspect of the evaluation was small so cannot be generalised more widely. Future evaluations should focus on patient and clinician experience of the use of CS.

Reported recurrence rates for LU vary significantly across studies, with up to 70% VLU recurring. 15,56-58 The highest rates of recurrence are generally within the first 3 months after healing. 59,60 The results of this evaluation showed that recurrence at 3 months in the retrospective group post-healing was 30.8%, which is higher than Finlayson et al recurrence rate of 22% at 3 months posthealing.²⁷ It is recognised that maintenance compression hosiery therapy can help to prevent recurrence. 61 However, traditional compression hosiery can create a hammocking effect over the retromalleolus, reducing the pressure to this area.³⁴ As a result, recurrence could be more likely in patients with healed retromalleolus LU, but further evidence is required to confirm this finding. Clinicians and industry need to work together to find a solution in order to reduce recurrence in patients with healed retromalleolar LU.

Local recommendations for clinical practice include the continuation of the use of CS by Solent Tissue Viability Team and the development of "Strapping Superheroes" in the community nursing localities to extend CS use to housebound patients with LU. This evaluation also highlighted the importance of a multidisciplinary approach to care, recommending increased collaboration with podiatrists with biomechanics expertise, orthotists, physiotherapists, and the development of an exercise programme for patients with LU to focus on improvement of mobility.

5 | STRENGTHS AND LIMITATIONS OF THE EVALUATION

A service evaluation was an appropriate design to evaluate the use of CS, and this supported the development of recommendations to improve the quality of patient care and service provision locally. The pragmatic approach using retrospective and prospective, quantitative, and qualitative data enabled various strands of information to be bought together to provide a "real-world" clinical view of the use of CS by a specialist team. Selection bias was reduced by including all patients who has received CS in the retrospective phase and selecting consecutive patients in the prospective phase. The use of a data collection tool and coding manual is another strength of the evaluation as the use of a data collection tools is recognised to increase the reliability and rigour of data collection. 62

It is acknowledged that there are several limitations to this evaluation. Due to the method of this evaluation, the results are only applicable to the local population and the generalisability to the wider LU population is limited. The retrospective collection of the majority of the data is

also recognised as a limitation, as this can result in inconsistencies, loss of information, and potential confounding factors. The number of missing values for pain and particularly QoL scores, and the use of mean scores to replace the missing values, also reduced the reliability of the results of this study. Finally, the COVID-19 pandemic resulted in a small sample size in the prospective phase, which is a further limitation.

6 | CONCLUSION

Overall, this evaluation has identified a number of positive outcomes for patients with retromalleolar LU with the use of CS including ulcer healing, reduced pain, and improved QoL. The findings have added to the growing evidence base that supports the use of CS as an addition to current "gold-standard" compression therapy and further highlights that the application of compression therapy must be tailored to meet the individual needs of the patient. The use of CS can facilitate such an individualised approach to the care of patients with retromalleolar LU. Compression strapping continues to be used by Solent Tissue Viability Team, and there are plans to develop "Strapping Superheroes" in community nursing localities to extend CS use to housebound patients with LU.

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CONFLICT OF INTEREST

No conflict of interest to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID

Samantha Haynes https://orcid.org/0000-0002-9035-1888

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