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Multinational, pilot audit of a Velcro adjustable compression wrap system for venous and lymphatic conditions

S. Ehmann,[1] DPT CWS CLT-LANA, Clinical Specialist;
J.C. Whitaker,[2] MSc, RN, Director and Nurse Consultant, Senior Lecturer - University of Central Lancashire;
S. Hampton,[3] MA BSc (Hons) DpSN RGN, Wound Care Consultant Nurse;
A. Collarte,[4] Tissue Viability Specialist Nurse
E-mail: suzie.ehmann@carolinashealthcare.org
1 Carolinas HealthCare System Stanly.
2 Northern Lymphology Ltd.
3 74 Battle Road, Hailsham, UK.
4 University of Central Lancashire UK.

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Objective: The aim of this small pilot audit was to record the performance of an adjustable Velcro compression wrap, ReadyWrap, and the experiences of patients and health-care professionals using the system as a self-care option for the management of venous and lymphatic leg conditions in both the treatment and maintenance phases.
Method: This audit was held within a 4-week review period. Participants included venous leg ulcer (VLU) patients with and without oedema, and patients with lymphoedema. Where open wounds were present they were managed with debridement, skin care and dressings according to clinical need. Lymphoedema patients received manual lymphatic drainage and skin care regimens as per standard practice. The Velcro system evaluated formed part of a treatment pathway with compression bandages and/or compression hosiery as clinically indicated. Patients, carers and health-care professionals applied the garments following assessment and training. Objective data recorded included change in circumferential measurements and improvement in wound status. Observation of health-care professionals, patients and carers with regard to the comfort and ease of application/removal of the device were recorded.
Results: There were 17 patients included in the audit. Within the 4-week period a reduction in limb circumference was recorded in all cases. Improvements in open wounds were recorded in most cases. Following the 4-week audit period 94% of the application of the device was performed by either the patient (59%) or the carer (35%) thereby reducing the health-care professional contact that was required for application.
Conclusion: Early results in this small audit demonstrate that this adjustable Velcro compression wrap may provide a simple, clinically effective and patient-acceptable solution for self-care with compression. Use of this type of device could have the potential to reduce overall health-care burden by reducing necessary skilled treatment visits and/or cost while still achieving good clinical outcomes. Further studies are required to confirm this pilot study and provide additional data.
Declaration of interest: Lohmann & Rauscher GmbH provided financial support to the project, assisted with the protocol and supplied the materials.

lymphoedema • venous leg ulcer • compression therapy • Velcro wraps • self-care

The European Wound Management Association (EWMA) Leg Ulcer Best Practice Document (2016)[1] predicted in westernised countries an age-related 3% global rise in prevalence of venous leg ulcers (VLUs). The document states that 93% of VLUs will heal in 12 months with 7% remaining unhealed after 5 years. A study by Guest et al.[2] analysed the data from the Health Improvement Network (THIN) and identified 730,000 patients in the UK with leg ulcers within a one-year study period. Direct treatment costs and indirect associated costs through loss of work, complications that arise through non-healing, loss of independence and hospital bed stays present challenges to patients, providers and purchasers.

Similarly, prevalence for those suffering with chronic oedema/lymphoedema has been estimated to be between 3 and 5 million.[3] Moreover, this assessment is thought to an underestimation due to insufficient awareness of the condition in both medical and public domains.[4] As such, the ability to evaluate the economic burden of the disease has not adequately been completed.

Around the world, compounding this problem, is the decline in service resources (specialised trained staff and financial) to treat and manage long-term care for those individuals with these chronic conditions. The Royal College of Nursing for England (RCN) warned that district nurses will disappear by 2025,[5] with a 47% reduction over the past decade. This is due in part to an ageing workforce and the retirement of existing nurses over 50 years of age.

Despite the Queen's Nursing Institute's recommendation in the UK, that 'The future imperative will be for more people to be nursed at home',[6] the NHS monitor voiced concerns that the policy to shift care to the community did not correspond with the support allocated to community care.

Reimbursement for health-care services are also being reviewed. In the Netherlands, it has been proposed that in the near future insurance companies will only pay for the outcome of total treatment.[7] This could mean that there will be a fixed financial fee regardless of the

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treatment frequency or products that are used. The same fee will apply for all patients with the same indication. For this prospective payment model, it would make sense therefore to have products that facilitate fewer visits by the health-care professional while still providing good clinical outcomes.

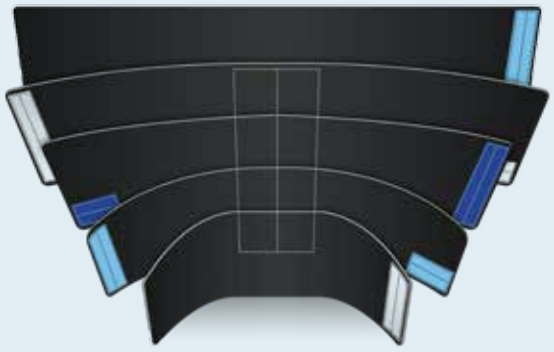
Similar burdens are seen in the US. Sweeping changes in insurance coverage has shifted the increased financial burden onto consumers for health-care costs with significantly higher deductibles and co-pays. Additionally, health-care entities are required to be more frugal with their staffing thereby limiting the resources available to treat those individuals with chronic conditions such as chronic oedema, lymphoedema and/or VLUs. Beyond the rise in costs to the consumer there are limitation in the numbers of visits to certain health-care providers (Therapy Cap) allowed on the federal health insurance programme for those over 65 (Medicare) and for those with low income unable to afford health insurance (Medicaid). Fewer clinical visits with good clinical outcomes would be beneficial to the consumer as well as the insurance companies.[8]

For these reasons, care providers involved in the management of those with chronic oedema, lymphoedema and/or VLUs would be wise to seek out treatment options that would allow good clinical outcomes that could be provided with minimal time and cost.

Current compression regimens for those with VLU/chronic oedema management consist of minimum weekly visits; those with severe lymphoedema may even require visits three to five times per week. Additional downfalls of traditional compression bandage systems include bandage bulk restricting mobility, complicated application methods requiring extensive training and specialist referrals. Although compression hosiery offers a viable alternative for some patients,[9] the compression hosiery is unable to cope with limb changes following oedema reduction. Furthermore, applying compression stockings can certainly present difficulties of its own,[10] particularly for frail older people who may struggle to don and doff firm hosiery.

Compression wraps are now seen as another form of delivering compression for patients with oedema and may be applied by caregivers or patients who have been trained.[10] These garments have been developed to assume short stretch properties with good static stiffness indices, which have been shown to be most effective at improving venous return and function for optimal oedema reduction and wound healing with maximum patient comfort.[11,12] These advances in textile technology allow the adjustable Velcro wrap to be suitable throughout the continuum of oedema management, in both the intensive and maintenance phases. Intermittent, targeted pressures help the garments to adapt to the limb size ensuring continuation of therapeutic pressures as oedema fluctuates for venous and oedematous conditions.[13] A comprehensive literature review by Williams[14] highlighted evidence that already exists to position

Fig 1. Short, colour coded straps and wide blocked spine



Velcro wraps for the management of venous leg ulcers and lymphatic conditions.

This pilot audit of a Velcro compression wrap sought to assess clinical effectiveness, tolerability and comfort for the wearer as well as ease of application and removal for the applier, whether clinician, caregiver or patient. The intended use was to aid VLU healing, reduce oedema and prevent recurrence of ulcer and oedema formation with improvements in functionality and independence thereby using patients and caregivers as a valuable resource as active participants.

Materials and method

ReadyWrap is a Velcro wrap used as an alternative or supplement to traditional compression bandages or hosiery and is positioned as a management solution for the treatment and maintenance of patients with chronic

Table 1. Patient characteristics

	Mobility Status	VLU present	Oedema present	Hosiery	Bandages	Wraps
FS	M		√	√		
SA	WC		√	√	√	
RM	RM	√		√	√	
MF	RM		√	√		
TT	M		√	√		
KS	M	√			√	
FB	RM	√			√	
EE	RM	√			√	
SB	M		√	√	√	√
HG	M		√	√		
AC	M		√	NONE	NONE	NONE
DC	M	√			√	
JH	RM	√		?	?	
JJ	M	√			√	
PH	RM		√			√
WV	WC		√		√?	
LIP	M		√		√?	

M–mobile; RM–restricted mobility; WC–wheelchair bound/non ambulatory
Previous compression modalities used including hosiery, bandages, or wraps noted

Table 2. Limb volume and size changes

ID		Before						At end						Start to end	Tissue density firm/ moderate/soft
Lymphoedema patients															
		Foot	Ankle	Calf	Below knee	Knee	Thigh	Foot	Ankle	Calf	Below knee	Knee	Thigh		Tissue changes
FS	LL	25.6	25	44.3	42.2	48.5	53.1	25.5	23.8	43.7	41.7	46.1	51	4 episodes	Firm → moderate
	RL	26.2	24.5	43.8	43.6	47.5	52.8	25.5	24.5	42.5	42.8	45.4	50.8	4 episodes	Firm → moderate
RM	RL	26	28	44	45.5	54.2	61	24.7	26.2	42	44.2	54	59	4 episodes	Moderate → soft
MF	RL	27.2	28.2	40.4	45.4	48.8	51	25.8	25.8	37	42.8	47.2	48.2	10 days	Firm → soft
TT	LL	24.2	27.2	40.8	42	43.5	52.5	23	25.4	37	39.4	42.2	51	10 days	Moderate → soft
Venous patients															
FB	LL		25.5	39.5					25	25.8				13 days	
EE	LL		21.6	33.8					21.5	33.2				2 weeks	
SB	RL		26.5	42.5					24.5	41				2 weeks	
AC	LL		30	45					26.4	40.3				4 weeks	
PH	LL		27	38.5	40				24.5	34.5	38.5			4 weeks	

venous disease with and without oedema. The calf piece with a liner were used with each patient. For those patients with foot oedema, a foot piece and/or hybrid liner were added to the system. Additionally, some patients with swelling in the thigh used a thigh Velcro wrap. Unique features of this Velcro wrap system include a wide blocked spine and colour-coded short straps that fastened in the front of the limb enabling them to be seen clearly (Fig 1). Unlike other Velcro wraps, the wide straps overlap eliminating the possibility of gapping or leaving an area of the limb uncovered.

Before the audit, the physical properties of this Velcro wrap were studied using the validated Picopress pressure monitor. Sub garment pressures were measured by three internationally respected experts in three different countries on four different legs. Findings of these tests revealed that when applied according to the manufacture's standardised application method, the pressure profile of this particular wrap was similar to short stretch bandage system with high therapeutic working pressures and lower tolerable resting pressures. The pressures observed were similar to those seen with cohesive short-stretch bandage systems at time 0 hours and at 24 hours. The clinical results presented in the audit that follows corroborate these findings. Additionally, the balance between garment performance and wearer tolerability were also noted even at night, another indication of good short-stretch properties.

Following local permission at each site the audit was commenced in three centres in the UK and one in US and included patients with venous and lymphatic conditions with varying degrees of tissue density and mobility (Table 1). Exclusion criteria were patients who were unable to understand and consent to be treated, clinically assessed to be unsuitable for compression or where there was a known sensitivity to the compression material. Where limbs were grossly misshapen requiring padding for reshaping, compression bandages were used before treatment with the wraps. As this was an audit, treatment was implemented according to standard practice for each patient.

Practitioners included lymphoedema specialists, tissue viability nurses and a physical therapist. Where appropriate, patients were taught to apply and remove or adjust the garments overnight. Understanding and the skills to apply the garments were evaluated where self-care was a possibility. For these patients the health-care professional instructed the patient and demonstrated application of the wrap. Patients observed the technique and applied the wrap at the second visit under supervision. The patients remained under the care of the health-care professional for monitoring and adjunct treatments such as debridement, skin care and wound dressings. Clinic visits were once, twice or three times a week depending on severity of the condition and progress of the patient. Only one patient required daily visits in the initial stages of treatment.

Patients in the audit had presented with VLUs and/or all levels of oedema including lymphoedema. Standard skin and wound care including debridement were selected and used in conjunction with compression according to individual clinical needs. Patients were encouraged to walk wherever possible or to perform foot movements to aid venous return and assist lymphatic flow. Garments were worn continuously or removed/adjusted overnight according to the condition

and for patient comfort. The garments were used during the intensive treatment and maintenance phases, followed by hosiery for prevention of recurrence where possible and preferred.

Clinician were asked to track wound area (length x width), limb circumference (at B1 and calf), rate tissue density (soft/moderate/firm), mobility levels (wheelchair, restricted, mobile) and to rate the comfort and ease of use of the Velcro wrap weekly. Patients/caregivers were also asked to provide verbal feedback about the comfort of the product and ease of application and removal.

Results

Completed audit forms on 17 patients (23 legs) presenting with varying aetiologies of oedema with and without wounds and having all degrees of mobility levels, were reviewed. Subjects included 10 females and 7 males between the ages of 51 and 75 years. Mobility levels varied from 2 wheelchair-bound paralysed patients, 6 with restricted mobility and 9 with normal walking ability. Previous treatments were adjunct skin and wound care, compression bandaging, with and without manual lymphatic drainage, compression hosiery or other Velcro compression wraps (Table 1). Location of care by all health-care professionals (specialists) on referral were clinic or home based. Once treatment with Velcro had started, early transfer to self-care at home was implemented depending on the clinical condition, underlying pathology and ability of the patient.

Of those with wounds, improvement occurred in six of the seven patients. As there were inconsistent reporting of wound dimensions, no formalised objective information could be obtained. It was reported that the one patient whose wound did not demonstrate improvement was found to have an initial infection which may have impacted the progress with wound healing.

Limb circumference reductions were recorded where oedema was present (Table 2, Fig 2). The results all showing reductions within the anticipated period of 21 days or sooner for certain patients (Table 2). More detailed volumetric measurements were submitted for three of the participants allowing for more objective measurement of change in volume. Percentage volume reduction within the limb ranged from 5% to 25% for those patients undergoing intensive phase of CDT using the Velcro wrap. Furthermore, it was observed in one patient a further reduction of 5% after completion for formal intensive therapy, with ongoing use of the Velcro wrap. Improvement in tissue density was observed 100% and was visibly evident in photos submitted (Fig 3). Additional information gathered from the audit reviews revealed that 92% of mobile patients reported no interference with walking or the ability to wear footwear.

Clinician's, patient's and caregiver's experiences were also recorded. Out of the 12 patients who commented on comfort, 9 patients found them comfortable. One patient withdrew from the audit due to unacceptance of any compression; one found the thigh garment to be too bulky; one reported discomfort at first but got used to wearing the garment as the treatment progressed. There was only one report of slippage during wear on an active patient, and with all others it remained in place. This may have been attributed to the frequent re-application and adjustability according to changes in the limb size. There were no reported incidents of skin damage following removal of the wrap.

The majority of appliers (91%) reported easy application with the colour-coded short straps that fastened in the front of the limb enabling them to see

Fig 2. Change in limb circumference

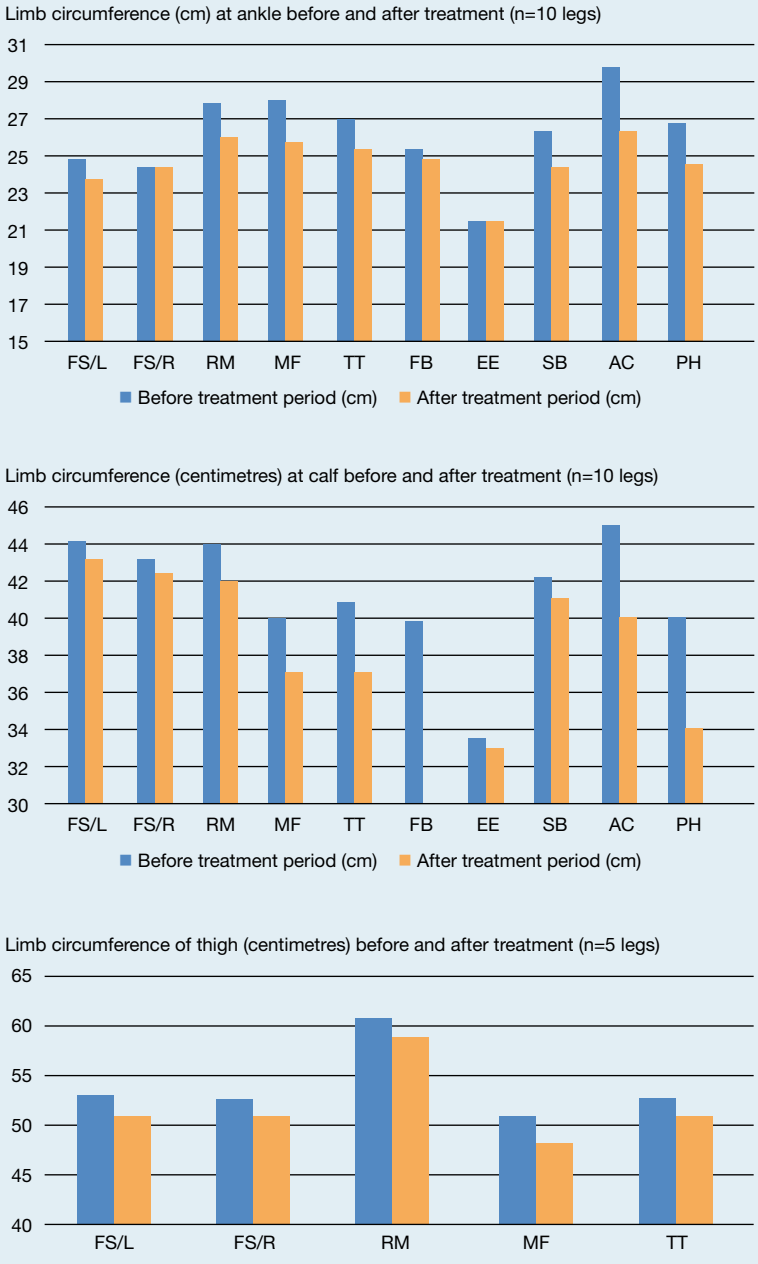
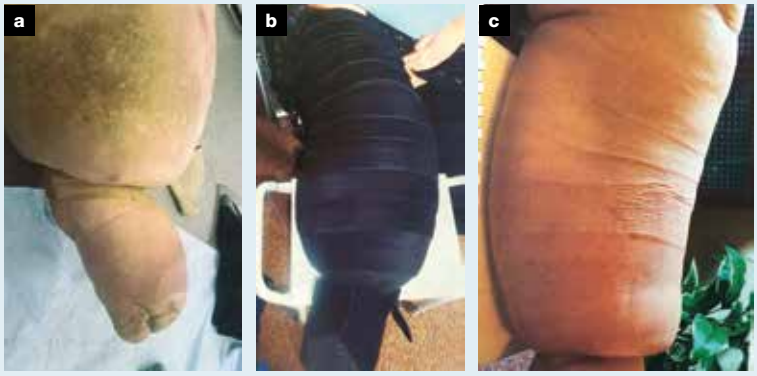


Fig 3. Example of Improved tissue density visualized after use of the Velcro wrap. Leg prior to debridement, skin care and compression **(a)**. Velcro compression wrap in place **(b)**. Post-compression. The markings on the skin were superficial and temporary **(c)**



clearly where to overlap and set the straps without creating gaps. For those patients who had experience with other Velcro compression products, respondents stated the overlapping mechanism was favourable to the other systems. The wide blocked spine was recorded as a benefit for comfort and to keep the garment stable during application. One negative comment was the bulkiness of the foot piece and this would be valuable information for product improvement. Patient and clinician comments are recorded in Fig 6.

Discussion

Desirable characteristics for a compression product include a short-stretch compression profile that maximises vascular haemodynamics; should be comfortable and easy to apply/remove; durable with an extended use period; and should be reasonable in cost. The result of this small pilot audit would offer some encouragement that the Velcro wrap product reviewed would be able to meet these demands.

Fig 3. Clinician and patient comments provided valuable qualitative data from the applier and wearer perspectives.

Patient comments
• Looks natural and feels comfortable • Felt lighter than previous compression with bandages • Did not like the thigh piece; it felt bulky (very active patient) • Patient liked the wrap because she could remove it before taking a shower and it allowed her to continue therapy while waiting for stockings even though the clinic was closed
Clinician comments
• It is very easy to apply with the 'roll and lock' technique • I am convinced I achieve pressure easily, it never cuts into skin folds • The foot piece is bulky for some patients who wish to wear normal shoes • Initially could not fit into shoes due to swelling on either foot, within 2 sessions was able to get into shoes • Much easier to apply than compression hosiery for some patients with limited dexterity. Easy for patients, family to apply after one training session
Overall comments
• Volume decreased within a few treatment episodes • Wound improved within a few treatment episodes • Reduced clinic visits

Although not a formal part of the audit, validated assessment of the Velcro wrap used in this audit demonstrates that it met short-stretch compression profile with a static stiffness index consistently >10 that was maintained over a 24 hour period. It has been well documented that short-stretch compression profile provides for optimal haemodynamic efficiency to maximise VLU healing and reduction of oedema.[11,15,16]

With regards to ease of use, the participants, both health-care providers and patients/caregivers, reported the Velcro wrap used in this audit was easy to apply/remove. A general criticism of Velcro wraps is that elderly patients do not have the strength and/or dexterity to apply the wrap with consistent pressure to be effective. The design of the product offers a viable alternative with wide straps that overlap eliminating the need for interlacing, or pulling in opposition direction simultaneously in order to achieve proper fit. The participants in this audit were able to appropriately apply the device after instruction, which allowed them to actively participate in their care, perform daily hygiene at home when needed, and adjust the wrap for more snug fit as swelling was reduced. Additionally, the option of a full under-stocking with compression only in the foot minimised the number of pieces they were having to apply. Self-application and the adjustability of the garments provided the opportunity for patients to take control of their care, promoting independence and involvement. This demonstrates the value of this technology for elderly patients who may be able to participate in their own care or who may have non-medical assistance.

The financial implication of incorporating the device into a compression treatment regime cannot be overlooked. The role of the reviewed Velcro wrap to reduce clinic visits from three times a week to twice a week and then to once a week in some cases[14] have cost implications for those patients with co-pays/visit as well for clinic efficiency where available appointments may be limited. Further study to specifically document cost savings would be beneficial to justify the one-time cost of the Velcro wrap to the consumer as well as to commercial/government payers.

Finally, the audit results highlighted aspects of good compression therapy such as stability of gait that were not initially projected. In previous US conference posters two physical therapists recorded improvements in gait and stability with the wrap using the validated Timed Up and Go test.[17,18] The scores of 20 seconds reduced to 10 seconds had significant implications for improvements in mobility and the reduction in the risk of falls. Further research to look at the impact of oedema management on balance and falls would be a worthy endeavour.

Compression bandaging may still be the most effective solution in the initial stages of oedema management for limb shaping or softening, or if the wound requires frequent dressing changes to manage excess fluid or significant infection. However, adjustable Velcro wraps could have an important part to play in

managing the limb in the semi-acute conditioning phase before, or in place of, final transition to hosiery. Thorough evaluation of the different Velcro adjustable wraps on the market is necessary to validate the efficacy of each of the products, individually. Furthermore, thorough assessment of the patient and the condition will also help to identify the optimum treatment pathway and timing of when to incorporate a Velcro adjustable product to maximise clinical outcomes and treatment fiscally.

Limitations

Limitations of the current audit include small sample size, lack of homogeneity of the patient population, and multiple outcome measures. More complete data on wound measurements, volume measurements and patient characteristics would have been useful. This small pilot audit does establish the use of the product across the continuum of compression, in multiple health-care settings across the globe. A large observational study could provide more information on clinical practice with this technology within the compression pathway.

Conclusion

Self-care, management by trained relatives or inexpert wound care professionals for the right patients, with the appropriate training, may provide the solution to an increasing demand for care in a world of dwindling resources. This is only possible with therapies that lend themselves to simple methods of use and the support from manufacturers to provide training, clear instructions and on-going customer care. The Velcro adjustable compression wrap as a simple solution has the potential to save costs by reducing treatment times, facilitating self-care and early resolution with transfer to hosiery for long-term care. More importantly, patient participation and comfort improve concordance and independence. **JWC**

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