Case report to demonstrate the need for selection criteria for optimal adjustable Velcro wrap prescription

Abstract: Compression, in the form of either a compression bandage or a compression stocking, has been touted as the gold standard for treatment of swelling and venous leg ulcers (VLUs). Adjustable Velcro wraps have been marketed as compression alternative. Although there is a growing body of evidence to support use of these products, there has not been a critical evaluation of the functionality of the devices to best matching product to patient presentation and ability to use the device effectively. Unlike compression garments, which are classified

by compression category (class I/II or flat knit/circular), there is not an algorithm to direct health professionals to best match a specific adjustable Velcro wrap to an individual patient presentation. This small case series demonstrates that although each product performed as marketed in vitro, performance in clinical setting varied greatly dependent on patient presentation and functional skill level. Declaration of interest: The authors have no conflict of interest to declare.

compression • compression wraps • adjustable velcro wraps • venous leg ulcer

raditional compression, in the form of compression bandages or compression garments, has been cited as the standard of care for the management of chronic oedema, lymphoedema and venous leg ulcers (VLU).^{1–10} Although there is strong evidence in the literature to support the efficacy of both forms of compression, implementation of a compression regimen can be viewed as laborious to both the caregiver and the patient. It requires multiple visits to a clinic for assessment, evaluation and application of the compression system by a skilled health professional.^{6,11} Furthermore, incorrect prescription and application of compression therapies can contribute to non-compliance or poor tolerance of compression. cause pain, impair functional mobility, and limit good hygiene practices and/or clothing fit.^{5,11-14} As a result, there is a demand for products that can be correctly applied and/or adjusted by non-health care individuals vet still offer effective oedema management solutions. The adjustable Velcro wrap (AVW) has emerged as a bandage or hosiery alternative, offering advantages for both the patient and the health care system.

Adjustable velcro wraps

AVW are constructed from short-stretch materials which are applied as straps that wrap around the limb and are secured with hook and loop Velcro fasteners. They are designed to be easily applied or removed as needed. The short-stretch materials incorporated into these devices produce a therapeutic compression profile (low resting pressure, high working pressure) which has been shown to be most effective for oedema reduction, maximise venous return, reduce venous hypertension, and promote wound healing regardless of the patient's

level of activity.^{11,15-18,21} Advantages of the AVW include patient involvement in self-application and adjustability, product conformability, and cost.

Patient involvement, self-application and adjustability An advantage of the AVW is the ease of application for both health professionals and patients alike. Unlike a compression bandage, which must be applied by a skilled trained health professionals, non-healthcare trained individuals or patients themselves can be instructed with the use/care of the AVW. This feature allows for self-management of dressing changes when necessary (i.e. excessive drainage, need to apply topical treatment, regular hygiene /skin care) and an option for modification of the compression level should the patient experience pain without completely removing the compression. Traditional compression bandage systems and stockings do not have a way to adjust the compression level once the limb has been reduced. The AVW is unique in that it can be made smaller by the patient or caregiver without the need to return to the health professional. This opportunity for the patient to continuously self-adjust the fit of compression has been shown to have a positive impact on patient's pain, compliance with compression, and overall effectiveness.11,18

Conformability

The AVW is available in different pieces and sizes which allows for more customisation of the compression without the need for a custom garment. Unlike

^{*}Suzie Ehmann,¹ PT DPT CWS CLT-LANA; Karen Bock,² PT CWS CLT-LANA *Corresponding author email: suzie.ehmann@carolinashealthcare.org 1 Carolinas HealthCare System Stanly, US. 2 Truman Medical Center Hospital Hill, US.

Device ID	Application method	Sizes available circumference (cm min/max ankle min/max calf	Foot coverage)	Pres meas	sure Poste suring aid	erior spine
A	Overlapping	S M L XL XXL Lengths: Avg/Tall Ankle 18/38 Calf 28/68 *extender piece availa	Available but not Comes with liner able	included No	Yes	
В	Interlacing	S M L XL XXL Full calf M L XL Lengths: short/long Ankle 19/42 Calf 26/64	Circular knit ankle separate liner inc	et and Yes luded	No	
с	Interlacing	S M L XL XXL Lengths: Reg/Tall	Available but not Comes with liner	included No	No	
D	Overlapping	XS S M L XL Lengths: Reg/Tall Ankle: 21/50 Calf: 36/68	Available but not Comes with liner	included No	Yes	
E	Interlacing		Compression on and separate line	anklet No r included	No	
	2		F			
Product A ReadyWrap —	Pro L&R, US Circ Leg	duct B Aid Juxta Lite Lower — Medieven US	Product C CompreFlex Lite – Sigvaris	Product D Farrow Lite – BSN Medical	Product E N Compressio — Juzo	n Wrap

Table 1. Adjustable Velcro wrap characteristics

packaged compression bandage kits, AVW allow for oedema management of the whole limb, with coverage available for the foot, leg, knee and thigh sized separately (Table 1). This feature allows for customisation

Device ID	Resting pressure (mmHg)	Working pressure (mmHg)	Static stiffness index (mmHg)
Α	41	57	16
В	42	56	14
с	42	53	11
D	55	66	11
E	40	51	11

of compression on the limb, even when the limb does not conform to the normal shape patterns.

Cost

There are potential cost savings to the consumer as well as to health professionals with the incorporation of the AVW into the compression continuum. The AVW can be used during both the intensive and the maintenance phases, negating the cost of disposable wrap systems or cost of purchasing multiple sizes of compression stockings to accommodate changing limb size.^{11,19} Once the patient demonstrates good understanding and use of the product, the self-adjustments at home could translate into fewer health professional visits. There is a need for additional study with regard to all of the potential cost saving implications in the different care settings.

Fig 1. Product A. Patient with weakness one hand and unable to manage interlacing straps (**a**). Available size for thigh coverage, also overlapping straps for containment for larger limb (**b**)



Fig 2. Product A. Patient with spongy/redundant tissue; overlapping straps provided structure for better containment



Need for guidelines to assist product selection

Unlike other compression modalities for which there are clinical guideline to direct product selection (light, moderate, high compression) based on patient clinical picture, i.e. ankle ankle brachial index (ABI), size of limb, tissue texture, presence of a wound, functional status, there is no similar guide for the AVWss currently available on the market.^{20,24–26} Although the evidence supporting the use of AVW is growing, as detailed by Williams' review, a key element of product selection is not considered.¹¹ Furthermore, the current literature presents outcomes using one specific product style (i.e. – Juxta-Fit or FarrowWrap Classic).^{26–29} Publication of the outcomes of one style to be representative of the whole product line makes it difficult for a consumer

(health professional or a patient) to interpret and make an appropriate choice of product. Everett's reference was the only article reviewed that detailed the full continuum of product selections and cost differences.³⁰ In the US, choice of compression (garment or wrap) is heavily driven by reimbursement categories. At the time of writing, federally funded insurance programmes (Medicare/Medicaid) will only cover AVW for an active venous leg ulcer (VLU). The Healthcare Common Procedure Coding System (HCPCS) A6545 limits product coverage to five AVW.³¹ These products are all equally covered, however, the authors of this review note inconsistency in the performance of the products dependent on individual patient presentation.

Aim

Compression, in the form of either a compression bandage or a compression stocking, has been touted as the gold standard for treatment of swelling and VLUs.^{1–10} AVWs have been marketed as compression alternative.¹¹ Although there is a growing body of evidence to support use of these products, there has not been a critical evaluation of the functionality of the devices to best match product to patient presentation and ability to use the device effectively. Unlike compression garments, which are classified by compression category (class I/II or flat knit /circular), there is not a classification system to direct health professionals to best match a specific AVW to an individual patient presentation. This observational study, using multiple single case reports, demonstrates the need for additional research to define characteristics of AVW to allow practitioners to guide AVW selection.

Method

Patients who were referred to oedema management clinics at two separate facilities and presented with diagnosis including chronic venous insufficiency, lymphoedema, obesity, and chronic non-healing wounds. Each patient was prescribed an AVW by the treating clinician. AVW chosen were those garments currently covered by Medicare (HCPCS code A6545) (gradient compression wrap, non-elastic, below knee, 30–50mmhg, each) for patients with open ulceration. Evaluation of performance of each device was documented by the patient and the clinical staff to include ease of application, volume containment, and any subject feedback of the patient or clinician. AVW characteristics are detailed and pictured in Table 1. To further assess products use for the observational case reports, a validated tool (PicoPress, MediGROUP, Australia), was used to measure resting pressure and working pressure on a healthy volunteer by a single clinician. The results of the findings are detailed in Table 2.

Results

We assessed nine patients (four females, five males) between the ages 39–82 years. The highlights of the

Fig 3. Product B. Chosen due to normal shape limb, with minimal foot involvement, patient with good dexterity able to manage two-hand application (a). Product C. Chosen due to lower cost and product design (b and c)



findings are depicted in Fig 1–6. All patients were pleased with their AVW compared with bandaging, as it allowed for hygiene daily. However, it was noted for

those patients prescribed AVW with an interlacing application method, self-donning was subjectively more difficult. Furthermore, two of the subjects using

Fig 4. Product E. Chosen due to minimum number of straps – normal shape/size leg accommodated, correct application. Potential for interlacing straps if not adjusted correctly to create wounds/blisters if skin is left exposed to areas of low pressure. Patient donned garment (**a**). Wounds due to improperly donned or adjusted garment (**b**). Garment correctly donned by therapist (**c**)



THIS ARTICLE IS REPRINTED FROM THE JOURNAL OF WOUND CARE NORTH AMERICAN SUPPLEMENT, VOL 27, NO 1, JANUARY 2018

Fig 5. Product B. Gaps in this product when donned incorrectly (a and c) can lead to poor volume containment and/or re-ulceration (a)



Fig 6. Product A. First visit post instruction (**a**), Even with less than perfect application note the skin intact and even compression (**b**). Although not perfectly donned, there is less risk for re-ulceration with this style garment. It is essential to follow up use/care of all compression products to ensure proper use (**c**)



an interlacing style AVW incorrectly self-applied, resulting in reaccumulating oedema and sliding down of the device in one instance (Fig 5a–c), and an area of

References

 Moffatt C, Partsch H, Schuren J. A Position Document on Compression Bandaging. International Lymphoedema Framework in Association, 2012. https://tinyurl.com/yd328xrz (accessed 13 December 2017)
 Wounds UK Best Practice Statement. Compression hosiery (2nd

edition) Wounds UK. 2015; https://tinyurl.com/qgchajt (accessed 13 December 2017)

3 Scottish Intercollegiate Guidelines Network (SIGN). Management of chronic venous leg ulcers. A national clinical guideline. SIGN, 2010. www. sign.ac.uk/pdf/sign120.pdf (accessed 13 December 2017) 4 ODonnell TF Jr, Passman MA, Marston WA et al. Management of re-ulceration in another (Fig 4b–c). Those patients prescribed the overlapping style AVW, even when applied incorrectly, did not experience the re-ulceration as there was not an exposed area (Fig 6a–c). Additionally, the interlacing AVW did not maintain the volume of the very large limb reviewed in this case report (Fig 5a–c).

Discussion

These observational case reports demonstrate that although the AVW on the market provide the advertised compression profile, the realistic operational use of these products may not be equal. Appropriate AVW prescription involves matching patient characteristics and patient's functional ability with AVW product characteristics. From these initial case reports, patient characteristics that would guide prescription choice for AVW are suggested below:

- Limb size/shape—Regularly shaped, average size limbs with minimal swelling are equally contained by all products; limbs with irregular contour, excessive size, dense swelling appeared better contained by products with posterior 'spine' to provide vertical stability throughout the day and overlapping straps that afforded additional containment. Additionally, those products with overlapping straps appeared to eliminate the potential for skin trauma that was observed in one case, with the interlacing garment applied inappropriately by patients/caregivers
- Physical ability of patient/caregiver using the product—Patients in the case reports struggled with the interlacing strap application if they had upper extremity weakness and/or reduced trunk mobility due to body habitus
- Tissue texture—Limbs with marked tissue texture changes appeared better managed with overlapping straps which afforded additional containment.

Conclusion

This case series demonstrates that although the AVW on the market equally produce the marketed compression profile, the functional operational use of these products may not be equally effective for all patient presentations. A larger study to further identify specific performance characteristics of AVW that could be used to develop guidelines in order to maximise health-care dollars by better matching a product to an individual patient presentation. **JWC**

venous leg ulcers: Clinical practice guidelines of the Society for Vascular Surgery® and the American Venous Forum. J Vasc Surg 2014; 60(2 Suppl):3S–59S. https://doi.org/10.1016/j.jvs.2014.04.049

5 Stout N, Partsch H, Szolnoky G, Forner-Cordero I, Mosti G, Mortimer P et al. Chronic edema of the lower extremities: international consensus recommendations for compression therapy clinical research trials. Int Angiol 2012; 31(4):316–329

6 Harding K et al. Simplifying venous leg ulcer management. Consensus recommendations. Wounds International 2015. https://tinyurl.com/jrxfcrj (accessed 13 December 2017)

7 Principles of compression in venous disease: a practitioner's guide to treatment and prevention of venous leg ulcers. Wounds International, 2013. https://tinyurl.com/yd4ssoy5 (accessed 13 December 2017)
8 Framework L. Best Practice for the Management of Lymphoedema. International consensus. MEP Ltd, 2006.

9 Partsch H, Flour M, Smith PC; International Compression Club. Indications for compression therapy in venous and lymphatic disease consensus based on experimental data and scientific evidence. Under the auspices of the IUP. Int Angiol 2008; 27(3):193–219

10 OMeara S, Cullum N, Nelson EA, Dumville JC. Compression for venous leg ulcers. Cochrane Database Syst Rev 2012; 11:CD000265 11 Williams A. A review of the evidence for adjustable compression wrap devices. J Wound Care 2016; 25(5):242–247. https://doi.org/10.12968/ jowc.2016.25.5.242

12 Hampton S, Gray S. Selecting a compression wrap when treating lymphoedema. Br J Community Nurs 2016; 21(Sup10 Suppl 10):S37–S39. https://doi.org/10.12968/bjcn.2016.21.Sup10.S37

13 Farrelly I. The importance and function of footwear in managing lymphoedema. Br J Community Nurs 2008; 13 Sup5:S10–S14. https://doi. org/10.12968/bjcn.2008.13.Sup5.31190

14 Skills for practice: management of chronic oedema in the community. Wounds UK, Aberdeen 2009.

15 Mosti G, Mattaliano V, Partsch H. Inelastic compression increases venous ejection fraction more than elastic bandages in patients with superficial venous reflux. Phlebology 2008; 23(6):287–294. https://doi. org/10.1258/phleb.2008.008009

16 Mosti G. Relevance of stiffness of compression material on venous hemodynamics and edema. Veins and Lymphatics 2013; 2(1):9. https://doi.org/10.4081/vl.2013.e9

17 Caprini JA. Velcro compression devices. Veins and Lymphatics 2017; 6(1):6624. https://doi.org/10.4081/vl.2017.6624

18 Mosti G, Čavezzi A, Partsch H, Urso S, Campana F. Adjustable Velcro®Compression Devices are More Effective than inelastic bandages in reducing venous edema in the initial treatment phase: A randomized controlled trial. Eur J Vasc Endovasc Surg 2015; 50(3):368–374. https://doi.org/10.1016/j.ejvs.2015.05.014

20 Neumann HA, Partsch H, Mosti G, Flour M. Classification of compression stockings: report of the meeting of the International Compression Club, Copenhagen. Int Angiol 2016; 35(2):122–128.

Reflective questions

- Would an algorithm for product selection for adjustable Velcro wrap (AVW) improve clinical outcomes?
- How does limb size and shape impact AVW function?
- How can the current AVWs on the market be altered to improve both functionality and clinical effectiveness?

22 Mosti G, Partsch H. Inelastic bandages maintain their hemodynamic effectiveness over time despite significant pressure loss. J Vasc Surg 2010; 52(4):925–931. https://doi.org/10.1016/j.jvs.2010.04.081
23 Partsch H. Compression for the management of venous leg ulcers: which material do we have? Phlebology 2014; 29(1_suppl):140–145. https://doi.org/10.1177/0268355514528129

24 Ratliff CR, Yates S, McNichol L, Gray M. Compression for primary prevention, treatment, and prevention of recurrence of venous leg ulcers [Web]. J Wound Ostomy Continence Nurs 2016; 43(4):347–364. https://doi.org/10.1097/WON.0000000000242

25 Kimmel HM, Robin AL. An evidence-based algorithm for treating venous leg ulcers utilizing the cochrane database of systematic reviews. Wounds 2013; 25(9):242–250

26 Dissemond J, Assenheimer B, Bültemann A et al. Compression therapy in patients with venous leg ulcers. JDDG 2016; 14(11):1072–1087. https://doi.org/10.1111/ddg.13091

27 Wigg J. Supervised self-management of lower limb swelling using FarrowWrap®. Br J Commu Nurs 2012;17(4): S22–S29 https://doi. org/10.12968/bjcn.2012.17.Sup4.S22

28 Linnitt N, Hunt K. Use of Juxta-Fit[™] to reduce oedema and promote self-management. J Lymphoedema 2011; 6(2):94–99.

29 Lawrence S. Use of a Velcro wrap system in the management of lower limb lymphoedema/chronic oedema. J of Lymphoedema 2008;3(2):65–70.
30 Everett J. The use of pressure wraps in treating lymphedema in care. NRC 2016; 18(6). https://doi.org/10.12968/nrec.2016.18.8.417

31 Durable Medical Equipment Coding System. https://www.dmepdac. com/dmecsapp/do/search/ProductClassification/Search (accessed 3 January 2018)