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

Traditional 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 yet 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

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Table 1. Adjustable Velcro wrap characteristics

Device ID	Application method	Sizes available circumference (cm) min/max ankle min/max calf	Foot coverage	Pressure measuring aid	Posterior spine
A	Overlapping	S M L XL XXL Lengths: Avg/Tall Ankle 18/38 Calf 28/68 *extender piece available	Available but not included Comes with liner	No	Yes
B	Interlacing	S M L XL XXL Full calf M L XL Lengths: short/long Ankle 19/42 Calf 26/64	Circular knit anklet and separate liner included	Yes	No
C	Interlacing	S M L XL XXL Lengths: Reg/Tall	Available but not included Comes with liner	No	No
D	Overlapping	XS S M L XL Lengths: Reg/Tall Ankle: 21/50 Calf: 36/68	Available but not included Comes with liner	No	Yes
E	Interlacing		Compression on anklet and separate liner included	No	No

Product A
ReadyWrap — L&R, US

Product B
CircAid Juxta Lite Lower Leg — Medieven US

Product C
CompreFlex Lite — Sigvaris

Product D
Farrow Lite – BSN Medical

Product E
Compression Wrap — Juzo

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

Table 2. Interface pressure measurement with PicoPress

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

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**)

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**)

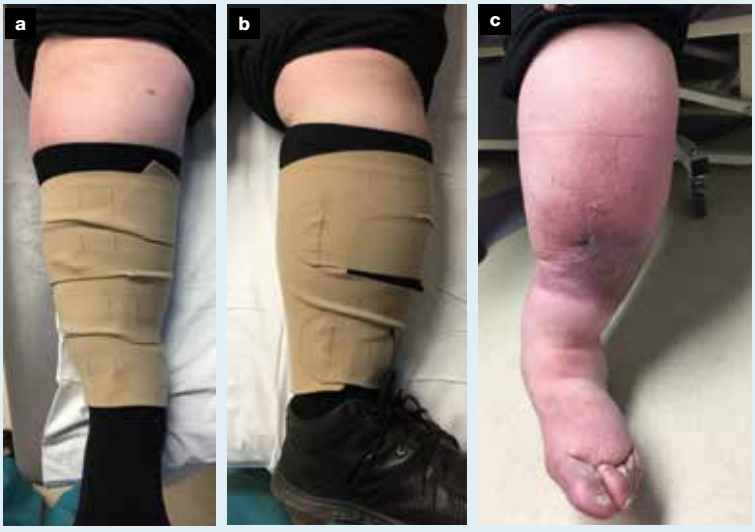

Fig 6. Product A. First visit post instruction (**a**), Even with less than perfect application note the skin intact and even compression (**b**). Although not perfectly donned, there is less risk for re-ulceration with this style garment. It is essential to follow up use/care of all compression products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

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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?

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