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A review of the evidence for adjustable compression wrap devices.

FINAL ACCEPTED MANUSCRIPT

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Key words: Adjustable compression wrap devices; compression therapy; lymphoedema;
chronic oedema; lipoedema; venous ulceration

Compression therapy is a key component in the effective management of people with lower limb problems associated with venous, lymphatic and fat disorders such as lipoedema (Fetzer & Wise 2015; International Lymphoedema Framework (ILF) 2012; Wounds UK Best Practice Statement 2015). Individuals with lymphoedema, venous ulceration and lipoedema often require long term compression therapy to prevent and manage problems such as chronic ulceration and skin changes, persistent swelling and shape distortion (Lymphoedema Framework 2006). Challenges remain in achieving acceptable, safe, effective and cost-efficient compression therapy choices (Dowsett 2011). Adjustable compression wrap devices using hook and loop fasteners, commonly called “VELCRO®*” brand fasteners, present new opportunities for improving treatment outcomes, supporting patient independence and self-management in the use of compression therapy. This paper reports the findings of an evidence review of adjustable compression wrap devices in people with lymphoedema, chronic oedema, venous ulceration and lipoedema.

Compression therapy

There is a relatively wide choice of compression therapy products and devices currently available in the UK (Wounds UK Best Practice Statement 2015). These include a variety of elastic and inelastic compression bandaging systems, circular and flat-knit hosiery, and adjustable compression (VELCRO®*) wrap devices. A skilled person-centred assessment underpins treatment choices in compression therapy, taking into account the pathophysiology of a condition, symptoms experienced by the person, their social and personal context, and the treatment aims. Compression therapy has various pathophysiological effects such as reducing capillary filtration, minimising accumulation of tissue fluid and inflammatory processes, enhancing venous return and improving lymphatic transport capacity (Partsch & Moffatt 2012). Compression therapy promotes venous ulcer healing (Kelechi et al 2015). It also reduces limb volume and enhances physical functioning in those with lower limb lymphoedema (Franks et al 2006). Individuals using compression garments are less likely to report pain, numbness and poor range of movement than those not using compression (Deng et al 2014; Fetzer & Wise 2015). Self-application of compression is reported as providing greater independence, self-efficacy, and a sense of control for people with lymphoedema (Tidhar et al 2014).

Intensive treatment using compression therapy can be demanding for patients and professionals, particularly if regular bandage application is necessary due to severe ulceration, leakage of exudate, or problematic skin conditions. Miller *et al.* (2011) described more than 50% of patients treated with multi-layer bandaging as non-concordant, possibly due to a variety of reasons such as poor tolerance of treatments or limited motivation. Furthermore, the transition from one type of compression therapy such as regular bandaging to wearing compression stockings, can be challenging (Lymphoedema Framework 2006) due to difficulties in applying compression stockings, deterioration in skin condition or rebound oedema. This suggests that choice is required in compression therapy, to better address clinical problems, and achieve cost-effective treatment outcomes.

Adjustable compression wrap devices

These devices consist of low-elastic material sections that wrap across the limb and are secured with hook and loop fasteners. They are designed for self-application over the short or long term, enabling the patient or carer to apply or adjust the device as required, in their own setting (Mullings 2012; Wigg 2012; Partsch 2014). Several product types are described in the literature, including the CircAid[®], the Juxta-Fit[™] and JuxtaCURES[™] systems from medi UK, the Jobst[®] FarrowWrap[®], and the ReadyWrap[™] adjustable compression garments from Lohmann and Rauscher. The devices are available in different sizes and various foot piece, leg piece or thigh piece sections. Some are also available in different types of material, to suit contrasting patient groups such as those with severe lymphoedema, or those with more palliative needs who require lighter compression. Most devices are available on prescription and can also be custom-made, or available to cut and reshape according to individual patient needs.

Aims of the review.

The review aimed to address the following questions:

- What is the clinical evidence for the use of adjustable compression wrap devices in people with lower limb conditions such as ulceration and chronic oedema, lymphoedema and lipoedema?
- What are the economic implications of using these devices?

The review also aimed to identify recommendations and future directions for practice and research.

Review methodology

Databases used: Medline; CINAHL; PsycINFO; Cochrane Library; Joanna Briggs Institute. Google Scholar was also searched, conference proceedings, and citations on individual papers were also checked.

Search terms: Velcro® Compression Wraps; compression-wraps; CircAid®; Juxta-Fit™; JuxtaCURES™; FarrowWrap®; ReadyWrap™ VELCRO® Brand fasteners combined with: venous ulceration; chronic oedema; lymphoedema; lymphedema; lipoedema; lipedema.

Inclusion criteria: date 1996-March 2016; research studies; review papers; Consensus and Best Practice Documents and Guidelines; descriptive papers; conference papers and posters.

Exclusion criteria: papers not in English language.

Search results: a total of 65 articles were identified with 25 meeting the inclusion criteria for the review. There were no review papers, consensus or best practice guidelines on the topic, with no current literatures on the use of Velcro® Compression wraps in people with lipoedema.

Use and clinical effects of adjustable compression wraps devices

Adjustable compression wrap devices in people with chronic oedema or lymphoedema

The first description of a Velcro®-Wrap product in the UK literature was the CircAid, developed by a US-based family business, and presented in three case studies by a lymphoedema practitioner (Lund 2000). More recently, the Juxta-Fit™ product was reported in lymphoedema case studies, illustrating its' use as a stand-alone garment or for use in conjunction with compression garments (Linnet & Hunt 2011; Mullings 2012). The device is described as providing sustained pressure using the 'Juxta-lock' system of interlocking bands that can be loosened or tightened (Mullings 2012).

The ReadyWrap™ adjustable compression wrap system has been reported in one conference poster from the USA as being well tolerated and reducing limb volume reduction in three patients with bilateral lower limb oedema (Ehmann 2016). A more substantial series of descriptive papers has discussed the FarrowWrap® system for lymphoedema, originally brought to the UK market by Haddenham Healthcare (Lawrance 2008; Wigg 2009; Wigg 2012;

Wigg & Lee 2014). FarrowWrap® is an adjustable hook and loop fastener system with multiple overlapping neoprene bands, interconnected by a spine. A case study described its' use in a young woman with low mood who was not keen to have intensive bandaging treatment (Lawrance 2008). Hobday and Wigg (2013) describe the product as encouraging practitioners to take a creative, problem-solving approach to care, working in partnership with the patient. Both devices are reported as versatile and easily adjusted to a change in limb size to enable self-management of oedema reduction (Mullings 2012; Wigg 2012), while also allowing for skin care to be carried out on a regular basis (Wigg & Lee 2014). FarrowWrap® has also been suggested as a useful garment for night use and compared favourably to short stretch bandaging (Lanhaus-Nixon *et al.* 2013), although research evidence is lacking and the above papers are all descriptive in nature with only two research studies identified.

In the first research paper, Damstra and Partsch (2013) undertook a prospective, randomised controlled trial of 30 hospitalised patients with unilateral primary or secondary lymphoedema of the leg (Stage 2-3). In one group, 15 patients with a mean age of 54.5 years had the Adjustable Compression Wrap (ACW) applied at Time 0 by the clinician, removed at two hours (T2) and replaced by the patient. The ACW was then worn for a further 22 hours (until T24) during which time the participants were instructed to adjust it as required. A second group of 15 patients with a mean age of 59.9 years wore inelastic multi-component compression bandages on the leg, removed and replaced by staff after two hours, and then worn for a further 22 hours. The researchers measured reduction in leg volume (using the water displacement method), in terms of the reduction in excess limb volume, and recorded interface pressures using a PicoPress monitor.

The mean volume reduction at two hours was not significantly different between the two groups at T2. However, after 24 hours, the group wearing ACW had a mean 339mls reduction in excess limb volume, compared to a mean 190mls reduction in the bandaged group ($p < 0.05$). Interface pressures measured after the patient reapplied the ACW at T2 were very similar to those obtained when it was applied by the nurse at Time 0. The researchers concluded that there was a more pronounced reduction in volume with the JuxtaFit™ ACW than bandages. Furthermore, the ability to adjust and apply at the same pressures as the health professional indicated the suitability of the product for self-management. However,

outcomes were limited to a 24 hour period, and details of clinical effectiveness or patient comfort over a longer period were not reported.

In the second research paper, Mosti *et al.* (2015) compared the efficacy and comfort of inelastic bandaging (IB) and an Adjustable Velcro® Compression Device (AVCD) in 36 patients (40 legs) with untreated venous oedema due to superficial or deep venous insufficiency. Patients had a mean age of 71.4 years. One group was randomised to a week of treatment with a short stretch bandaging system applied in a spiral method to achieve a supine sub-bandage pressure of 60mmHg (as measured by the PicoPress). The second group was treated with the Juxta-Fit garment applied to achieve a pressure of 40mmHg when supine, with the instruction to adjust the device if they became aware of a decrease in the compression. Leg volume was calculated using the truncated cone formula (at 4cm interval circumferences along the limb) at Time 0, Day 1 (Time 1) and Day 7 (Time 7). Reduction in volume was calculated in millilitres and expressed as a percentage of the initial limb volume. Interface pressures were measured at the B1 point using the PicoPress monitor. Measures of comfort were completed at Time 1 and 7 using visual analogue scales to subjectively assess symptoms such as pain, heaviness, swelling sensation, discomfort, itching and restless leg using scores from 0-10. Subjective measures such as wearing a shoe, ease of application and readjustment at T0, T1 and T7 were similarly scored. The sum of scores was calculated to provide a comfort index and an index of other parameters.

The researchers reported that mean interface pressures were higher in the bandaging group than the AVCD group at supine and standing at application; however, at Time 1 (24 hours) this was reversed. Mean volume reduction at Time 1 and 7 was significantly higher in the AVCD group than the bandaging group ($p > .001$). However, it is important to note that the method used for calculating change in limb volume as a percentage of the initial limb size is less accurate than monitoring change in excess volume when compared to an unaffected limb (Williams & Whitaker 2015). Comfort scores decreased in both the bandaging and AVCD groups. Patients found reapplication of the AVCD relatively easy, and scored this more favourably for cosmetic appearance and ease of putting on shoes than the bandaging system. The researchers concluded that the AVCD was ideal for self-management as it is easily applied and adjusted correctly by the patient following a simple teaching session (Mosti et al 2015). Furthermore, they identified that interface pressures were able to be maintained as the

device was readjusted, unlike bandaging systems where pressures drop once oedema reduces. Limitations of the product were also reported, for example, difficulties with application when someone is overweight and inflexible, or there is severe shape distortion on the limb (Mosti *et al.* 2015).

Adjustable compression wrap devices in venous ulcer management

Lawrence (2014) described the JuxtaCURES™ as an innovative method for leg ulcer management, combining a liner, anklet and legging garment that can be adjusted, particularly useful for self-management and when a leg is too large to be accommodated in a leg ulcer kit. DePalma *et al.* (1999) undertook a comparative study of CircAid (Theraboot or TB) and the Unna Boot (UB) in 28 patients with small leg ulcers eligible for conservative treatment, across six community centres in the USA. The mean time to healing in the UB group was 9.69 weeks and the TB group was 7.98 weeks ($p = 0.41$) with a non-statistically significant trend to faster healing times in the TB group (DePalma *et al.* 1999). Similar results were recorded in another small randomised controlled of 12 patients of a mean age of 61 years with bilateral leg ulcers (24 extremities) randomised to four layer elastic bandaging system and the although the patients were not then monitored to healing, or followed up (Blecken *et al.* 2005).

Various authors have used case studies to showcase the products and explore outcomes. Bock (201X) described the use of the ReadyWrap™ adjustable compression garment in three patients with chronic venous ulceration and oedema. The device was shown to be successful in managing oedema, healing complex ulcers, and in preventing ulcer re-occurrence (Bock 201X). Bianchi *et al.* (2013) reported improvements in quality of life, pain, well-being and cost effectiveness in three patients with venous leg ulcers. Others have described improvements in pain and depression, improved skin integrity, and enhanced self-care when patients were changed to an adjustable compression wrap system from traditional compression bandaging (Davies 2013, Dowsett & Elson 2013; Elson 2013; Harris 2013) although details of how these outcomes were measured are not clear. In a conference poster, Elson (2013) reported the JuxtaCURES™ product as useful for patients with ulceration in addressing problem with bandages, such as inconsistent pressures, bulkiness, inability to wear shoes and bandage slippage. Another poster provided a report on the JuxtaCURES™ system with 17 patients with chronic ulceration (Elson 2012). Clinicians recorded progress over six months of standard compression and six months of the use of the adjustable compression wraps; the poster

indicated that all patients showed improvement in the ulcer, with favourable cost comparisons (Elson 2012), although precise details of the evaluation methodology are not given. Similarly, use of an adjustable compression wrap product to replace bandaging patients with ulceration was reported as improving patient concordance, satisfaction and independence with staff and carers quickly able to learn the application method (Elvin 2015). Nugent (2013) also described the devices as having a positive impact on patients' quality of life, while Oates *et al.* (2013) also reported improved independence and concordance; however claims of reduced wound size and oedema are not clearly substantiated by data in the poster.

Economic implications of using adjustable compression wrap devices

The search did not identify any robust economic evaluations but many papers suggested that self-care adjustable compression wrap devices provide cost savings associated with reduced use of bandaging materials, time saved due to quicker and easier application of the devices, application by the person or their carer, and fewer nurse visits or appointments for bandaging (Elvin 2015; Nugent 2013; Wigg & Lee 2014). Further economic advantages are also identified as the VELCRO® compression wrap devices can be washed, cut, adjusted and reused (Mosti *et al.* 2015).

Conclusions

In summary, the review provides some descriptive insights and anecdotal evidence for practice. However, the research evidence for the use of adjustable compression wrap devices in people with lymphoedema, chronic oedema, venous ulceration and lipoedema is very limited. Most evidence is in the form of descriptive papers, case studies, or relatively small research studies that are undertaken over a short period of time, and do not reflect the long term nature of these chronic conditions and their treatment. Despite the lack of robust economic evaluation, claims regarding cost savings are compelling, alongside the clinical evidence that an adjustable VELCRO® compression wrap device provides scope for improved quality of life and independence for patients with distressing long term conditions.

Recommendations

Further research is required to evaluate the effectiveness and efficacy of adjustable VELCRO® compression wraps in symptom management, oedema reduction and ulcer healing. Research should also focus on generating evidence to enable practitioners better understand how adjustable compression wraps influence self-management over the longer term, identifying the self-management support and education needs of individuals using the devices. While two studies report data on sub-garment pressures, more work is required to better understand the physiological and clinical effects of the devices in patients with different conditions. For example, exploring claims that a VELCRO® compression wraps work in a similar way to inelastic bandages (Mullings 2012; Wigg 2012). Further work is required to evaluate and contrast the effect of the products with different groups: for example, individuals who undergo liposuction for lymphoedema or lipoedema (Forner-Cordero et al. 2012); or in different skin and tissue conditions such as the soft pliable tissues in someone with lipoedema, and the hard fibrotic tissues characteristic of late stage lymphoedema (International Society of Lymphology (ISL) 2013). Self-management remains poorly understood and researched (Long Term Conditions Alliance 2008), so further work is required to ensure practitioners and patients have appropriate support with new and different ways of working with patients, and are familiar with the various key aspects of self-management that complement the use of an adjustable compression wrap device.

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