The use of compression wraps in the management of lymphoedema

Steve Thomas

Key words

Compression wraps, hosiery, literature review

Steve Thomas is the owner of Medetec (www.medetec.co.uk)

Declaration of interest: None.

Abstract

There is increasing interest in the potential value of compression wraps in the management of lymphoedema and other disorders of the circulatory system. Given the significant unit cost of these materials, the All Wales Medical Devices Strategy Group commissioned an independent review of the literature to determine if these devices represent a cost-effective option for the treatment of lymphoedema. Although the evidence is by no means overwhelming, the controlled extended use of compression wraps for the treatment of lymphoedema appears to be supported both on clinical and financial grounds and, therefore, should be given serious consideration.

Lymphoedema is a chronic condition characterised by tissue swelling. Although it can affect any part of the body, it is most commonly encountered in the arms or legs. Early diagnosis and appropriate therapy can prevent, slow or delay the condition from progressing. Because of its chronic nature and the need for extended or lifelong treatment, the cost to the healthcare system of managing the condition is significant.

Primary lymphoedema is a genetic disorder affecting the development of the lymphatic system. This may develop at any age, but usually occurs in early adulthood. Primary lymphoedema is less common than secondary lymphoedema, and is estimated to affect around one in every 6,000 individuals (Lymphoedema Framework, 2006).

Secondary lymphoedema is caused by damage to the lymphatic system and exacerbated by excessive fluid loads, or poor movement or drainage of lymph fluid. It can be caused by infection, trauma, inflammation, a lack of limb movement or an underlying condition such as cancer.

In the UK, it is estimated that lymphoedema affects between 1.33 and 3.99 individuals per 1,000 (House of Commons Health Committee, 2013). Prevalence increases significantly with age, from 10.3 per 1,000 in those aged 65–74 to 28.6 per 1,000 in those over 85 years of age.

Compression wraps

There is increasing interest in the potential value of compression wraps in the management of lymphoedema and other disorders of the circulatory system. Available in a variety of forms, these devices essentially consist of fabric sheets made from one or more components with limited extensibility, which are applied to affected limbs and held in place with Velcro fastenings.

Unlike multilayer bandaging systems, wraps can be replaced or adjusted by patients themselves, which increases their acceptability and therefore, it is assumed, improves patient compliance, while reducing the need for professional interventions.

The All Wales Medical Devices Strategy Group is an NHS body that ensures that the purchase of new medical devices represents good value for money. Given the significant unit cost of compression wraps, the group commissioned an independent review of the literature to determine if these devices represent a cost-effective option for the treatment of lymphoedema.

Literature review

The review was undertaken to address four key questions:

- Does the literature contain clear evidence, generated by randomised controlled trials (RCTs), that is sufficiently robust to justify the widespread use of compression wraps in the treatment of lymphoedema on clinical grounds alone?
- If convincing evidence from RCTs is not available, are data available from other sources to support this proposition?
- Are there any safety implications associated with the use of compression wraps?
- What are the possible financial implications of increased usage of compression wraps?

Methods

This was not intended to be a formal systematic review, but rather a more wide-ranging narrative interpretation of the data obtained from various publications, which could be used to provide some basis for addressing the four research questions. Examination of the literature commenced in January 2016.

Initially, manufacturers and brand names of existing devices were identified so that these could be used as search terms in the subsequent literature review:

The products identified in this way were:

- Biacare: MedAssist, MedaFit, CompreFit, Compreflex and CompreSleeve
- JOBST FarrowWrap (BSN Medical)
- Juzo Compression wrap (Juzo)
- Circaid and Juxta-Cures (Medi)

- ReidSleeve, OptiFlow, the Cinch (Peninsula Medical)
- Solaris Readywrap (thought to be transferring to Lohmann Rauscher in UK market).

Search strategy

Searches were performed on PubMed, CENTRAL (Cochrane Library) and ClinicalTrials.gov, supplemented by an internet search, the authors' own electronic database and manufacturers' product literature. In every instance, free text searches were used, making no attempt to limit the occurrence of specific terms or phrases to particular fields within each record, and the using broad search terms shown in *Table 1* to minimise the chances of any relevant material being overlooked.

In accordance with the terms of reference, the literature review focused on the treatment of lymphoedema in the arms and lower limbs, irrespective of the underlying aetiology. If the condition coexisted with a leg ulcer, any relevant data would be included in the review, but publications relating to the use of compression wraps specifically for the treatment of venous leg ulcers were not deliberately sought out, because this topic formed the subject of an earlier systematic review published by NICE (2015).

The proprietary names of the compression wraps previously identified were also used as standalone search terms to find any references relating to these products that might otherwise have been missed.

Inclusion criteria were: English-language publications, published at any time up to the onset of the review, and observational studies, randomised controlled trials (RCTs), systematic reviews and meta-analyses.

Exclusion criteria were references relating to surgical or pharmacological treatments for lymphoedema, and editorials or advertorials. The local database, compiled as shown in *Table 1*, was then further interrogated to identify all relevant publications.

Outcomes of interest were clinical efficacy, safety, quality of life implications, resource use, and cost-effectiveness or other financial implications.

Evidence quality

The quality of evidence was variable. The case studies would have benefited from additional records of leg dimensions during treatment, which could have added to their value. Most case studies contain or represent a significant degree of bias in that most clinicians do not publish case studies detailing treatment failures or studies that show no significant differences between two forms of treatment.

In the context of this review, the quality of evidence from the larger experimental and haemodynamic studies was considered to represent a more reliable objective indicator of product performance.

Table 1. Initial PubMed search strategy.

	Primary search terms (all fields)	Hits	Comments
1	Lymphoedema	12,190	Ignored
1a	Management OR treatment OR control AND lymphoedema	8,139	Downloaded into local database
1b	Bandage OR bandaging OR compression OR pressure AND lymphoedema	1,102	Downloaded into local database
1c	Juxta Cures	1	Downloaded into local database
	Circaid	6	Downloaded into local database
2a	Compression wrap OR compression sleeve OR elasticated sleeve OR adjustable compression OR adjustable elasticated OR adjustable pressure	1,428	Downloaded into local database
2b	Non elastic AND adjustable	1	Downloaded into local database
2c	Bandage OR sleeve OR compression AND Velcro	20	Downloaded into local database
3a	Randomised control trial OR randomized control trial OR RCT OR clinical trial OR clinical study OR evaluation AND lymphoedema	1,459	Downloaded into local database
3b	Lymphoedema AND systematic review	216	Downloaded into local database

Results

Is sufficient high-quality evidence available from RCTs to justify the widespread use of compression wraps in the treatment of lymphoedema?

No RCTs were identified comparing compression wraps with an alternative form of therapy in the management of lymphoedema.

Are data available from other sources to suggest that compression wraps may be useful in the treatment of lymphoedema?

A number of articles were identified that were considered to be of some relevance to this topic. Three clinical publications described case studies involving the use of compression wraps in the treatment of lymphoedema.

Circaid wraps were successfully used to treat chronic lymphoedema and their use appeared to produce a clinical effect that was equivalent to multiple sessions of decongestive lymphoedema therapy (Lund, 2000). The wraps enabled the patients to wear normal clothing and footwear.

The FarrowWrap was as effective as a 2-week daily course of manual lymphatic drainage in terms of reducing limb volume (Lawrance, 2008).

Two people who were treated with Juxta-fit (Circaid) had the size of their grossly oedematous legs reduced to near-normal values (Mullings, 2012).

Three other publications, although not directly related to lymphoedema, were considered to be of interest because they contributed to an understanding of the mode of action of compression wraps.

Following a haemodynamic investigation in patients with chronic venous insufficiency (CVI), it was postulated that the Circaid improved calf muscle pump efficiency by the generation of higher compression and a reduction in venous pooling (Murthy et al, 1994). The authors also suggested that elastic leg compression applied over a long period in the recumbent posture may

impede microcirculation and jeopardise tissue viability.

In an experimental clinical study, Circaid wraps were compared with compression hosiery designed to produce 30–40 mmHg in people with CVI (Spence and Cahall, 1996). Both devices were applied immediately on rising. Venous volume at both 2 and 6 hours was reduced significantly by the Circaid garment when compared with baseline measurements and the stocking. The authors proposed that the Circaid serves as a closed container or a rigid external support that compresses superficial tissues and minimises flow through incompetent perforating veins by denying access to the superficial venous reservoir. The garment also serves as an unyielding resistance to calf muscle compression.

Mosti et al (2015) compared wraps with an multicomponent short-stretch bandaging system in a RCT of 36 patients with oedema caused by venous disease. After 1 week, the median percentage volume reduction in bandaged legs was 19%, compared with 26% for legs treated with compression wraps. Interface pressure was initially significantly higher with the bandages (63 mmHg versus 43 mmHg), but this decreased by >50% over time, while it remained unchanged with the compression wraps because the patients had been instructed periodically re-adjust these. Comfort was reported to be similar with the two compression devices. The authors concluded that adjustable wraps with a resting pressure of around 40 mmHg are more effective in reducing chronic venous oedema than short-stretch bandages with a resting pressure of around 60 mmHg. The wraps were well tolerated, in the initial decongestive treatment phase and during maintenance therapy.

Mosti at al (2015) made a number of important observations that are equally applicable to the treatment of oedema and lymphoedema:

- Many people with oedema can apply or re-adjust compression wraps themselves, but correct self-application may be difficult for those who are overweight or with severe malformations of the legs
- Generally, as long as the patient is able to put on shoes and handle shoelaces, they can use a compression wrap
- Patients did not complain about cosmetic appearance and the ability to wear shoes was significantly better with compression wraps
- The results have practical and economic implications. Usually oedema treatment starts with bandages applied by expert personnel, followed by elastic stockings to prevent recurrence. With compression wraps, only one device needs to be used
- When leg volume is reduced by the initial treatment, the device can be adjusted to fit the new leg volume, allowing considerable cost savings. Compression wraps can be washed and reused. They can also be cut and adjusted to a changed leg size, so the same device can also be used in the maintenance phase
- The most important factor concerning potential cost saving is not the price of the wrap, but that it can be applied without the assistance of medical staff.

These few studies suggest that there is good reason to believe that compression wraps may offer significant advantages over some other techniques used in the treatment of oedema and venous disorders. It is the view of the author that the clinical findings of these publications are also of direct relevance to the management of lymphoedema, but evidence from further trials specifically targeting this condition would greatly strengthen this proposition.

Are there any safety implications associated with the use of compression wraps?

The effectiveness of any compression system is determined by the magnitude and duration of the compressive forces applied. The optimal pressures required for treating lymphoedema of the lower limbs will be higher than that on the arm because of hydrostatic effects.

The principle challenge with any form of compression therapy is ensuring that the pressure provided is high enough to be effective, but not so high as to result in localised ischaemia and tissue damage.

Partsch et al (2011) measured the effects of levels of pressure on volume reduction in 36 people with arm lymphoedema and 42 with chronic oedema of the lower extremities. They found that there is an upper limit beyond which a further increase of compression pressure seems counterproductive. For inelastic bandages, this upper limit is around 30 mmHg on the upper limb and around 50–60 mmHg on the leg.

If inappropriately sized compression sleeves or compression hosiery are applied, which produces excessive pressure, this pressure is likely to be sustained for a significant period, as elasticated fabrics 'follow-in' as limb circumference reduces with a relatively small loss in tension. In some circumstances, this has the potential to lead to an adverse event, such as tissue necrosis over vulnerable areas.

With conventional bandaging systems, particularly those based upon short-stretch bandages, the potential for harm is reduced because the elastomeric properties of these fabrics are limited. As a result, the tension within the fabric (and, therefore, the pressure it produces on a limb) decays rapidly over time, which is one reason these materials require frequent replacement.

If the bandages function as intended and reduce the volume of the affected limb, the tension in the bandage fabric will decrease as the limb circumference reduces, and consequently the pressure it is able to apply will also decrease. These bandages therefore have an inherent safety feature and even if they are initially applied too tightly, this effect will be minimised fairly quickly over time as the bandage tension decays.

The pressure that compression sleeves and bandages apply depends on two factors – the elastomeric properties of the fabric and the technique of the operator, ie, the tension introduced into the fabric during application.

The descriptions of these materials in some of the publications are confusing because the same products may be referred to as both elastic and inelastic. It is therefore suggested that it would be useful to undertake a comparative laboratory study to address this issue and obtain further objective information on the products that are commercially available.

The pressure applied during application is almost entirely determined by the judgement and technique of the operator. Previous research with compression bandages has shown that the individual operator is a source of considerable variation in the levels of pressure achieved with these materials (Logan et al, 1992).

In an attempt to address this problem, Medi has developed an application aid, the Built-In-Pressure System (BPS). There are two marks on each strap, and the BPS card scale is placed against these to check how much pressure is being applied beneath the

garment. The scale will vary with the size of the garment and is dependent on the size of leg to which it is being fitted. Independent laboratory validation of the accuracy of this system would be very useful because there is no such information available in the public domain.

In practice, it is likely that compression wraps will perform in a similar way to short-stretch bandages, in that the initial pressure applied will reduce to some degree as the limb diameter decreases. Unlike the traditional bandage systems, if the wraps are applied with excessive tension they can easily be adjusted by the patient.

Mosti et al (2015) compared the difference in the pressure profiles achieved with the two types of devices. Interface pressures were initially significantly higher under multilayer bandages (63 mmHg versus 43 mmHg), but these decreased by more than 50% over 7 days. With compression wraps, the pressure remained unchanged, owing to the periodic re-adjustment by the patient.

It should be noted that although the pressure values quoted by Mosti et al (2015) are useful for comparison purposes, the reliability of the measuring equipment employed by these authors has been questioned in the past when they were used to obtain point pressure readings on human limbs (Thomas, 2014a).

One potential risk associated with all compression treatments is that these might be applied to patients who have not been correctly diagnosed. Vaassen (2015) urged that proper assessment, monitoring and adjustments to lymphoedema treatment should be paramount when treating patients with signs and symptoms of chronic obstructive pulmonary disease or congestive heart failure.

What are the financial implications of increased usage of compression wraps?

The literature review failed to identify any data on the relative costs of treating lymphoedema with compression wraps or conventional therapies. However, once again, data are available on the comparative costs of treating venous insufficiency, which is considered to be of some relevance.

NICE (2015) quoted financial savings reported in three studies.

A study of 14 patients showed that savings began to accrue 12 weeks after the purchase of a compression wrap (Harris, 2013). Over 6 months, there was a saving of £2,141 per patient. It is assumed that this saving also includes staff time.

Another study of 17 patients predicted an average saving of £881 in bandage costs alone in a 6-month period (Bianchi et al, 2013). Savings in clinician costs were estimated at £3,172.

The use of compression wraps in 17 patients resulted in average savings of £880 on bandaging costs and £3,174 on clinical costs (Elson, 2013). It is assumed that these are the same data published by Bianchi et al (2013).

These cost savings are based upon the assumption that a single Juxta CURES pack costs £151.50 excluding VAT and is guaranteed for 6 months of daily use. These two studies suggest that despite the significant initial outlay, replacing compression bandages with a compression wrap would generate savings. There was no evidence that the use of compression wraps would lead to increased costs.

These figures take no account of additional costs associated with hospital admissions or intensive physiotherapy.

Discussion

The inclusion of leg ulcer data

Compression is involved in treating both leg ulceration and lymphoedema. Most treatment regimens in common use for both conditions involve the application of pressure (compression) to force fluid from the tissue back into the circulatory system.

Despite the differences in underlying aetiology, the basic principles and mechanisms relating to the application of compression in both conditions are the same and may be predicated by calculation using Laplace's Law (Thomas, 2014b). Logic, therefore, dictates that published data on compression for the treatment of venous leg ulcers or simple oedema must also have relevance to lymphoedema management.

Numerous systematic reviews have been published on the efficacy of different compression systems in the treatment of lymphoedema. In the main, these are of limited value in terms of providing advice on optimum treatments and in some instances they provide conflicting conclusions. This is due at least in part to the poor design of some of the studies and the variability in pressures achieved by the various systems because of variability in operator technique.

For this reason, it is argued that studies involving oedema resulting from other conditions are worthy of consideration in this context.

Patient compliance

A potentially very important element of lymphoedema treatment, not widely considered in published studies, is the problem of patient compliance.

Conventional forms of compression therapy using various combinations of extensible or elasticated bandages are generally applied by healthcare professionals which, in theory at least, remain undisturbed until they are reapplied some days later by a clinician. Some patients may find it hard to tolerate the pain or discomfort associated with this form of therapy. As a result, adherence may be poor with obvious implications for treatment outcomes.

Compression wraps appear to offer a partial solution to this problem because they can be removed at night and reapplied by patients in the morning. However, little investigative work has been done to support the validity of this approach as the amount of pressure applied by different patients will inevitably vary, perhaps even on a daily basis. Further research is required in this area.

Limitations of review

As previously indicated, this was not intended to be a formal systematic review, but rather a more wide-ranging narrative interpretation of the data from various publications, which could be used to provide some basis for addressing the specific research questions.

The other principal limitation on this study, which contains data derived principally from patients who were believed to be mainly community-based relates to the lack of evidence derived from large, well-controlled studies that describe the use of compression wraps in the management of lymphoedema. However, the scientific basis and clinical evidence supporting this form of therapy for the treatment of other types of circulatory disorders is impressive and therefore the current absence of published data should not in itself be taken as evidence of lack of efficacy.

Conclusion

The literature found no records of large-scale trials on the use of compression wraps

in the treatment of lymphoedema, but case studies, together with data drawn from other sources, suggest that these devices may offer some advantages over existing types of compression therapy for this indication.

Despite their significant initial cost, the literature suggests that these items become cost neutral after about 12 weeks, after which their continued use results in savings in material costs. No published evidence was found to suggest that appropriate use of these new devices will contribute to increased expenditure.

No evidence was found that suggested that compression wraps are more likely than other commonly used lymphoedema treatments to cause adverse events. However, like any other form of compression therapy, these devices should only be supplied and administered by an experienced healthcare professional to an individual whose underlying medical condition has been properly diagnosed. This is to exclude the possibility that the oedema is caused by some other underlying condition such as untreated congestive heart failure or congestive pulmonary disease.

No adverse events were reported with compression wraps, which is due, at least in part, to the fact that patients can easily adjust or remove these devices should they feel excessively tight or uncomfortable.

As the pressure produced by compression wraps is determined by the tension imparted to them during application, it is suggested that these devices should incorporate some form of application aids or guide. This may be of particular importance in instances when the wraps are applied by patients themselves.

The absence of data from formal trials is unfortunate, but the case studies cited provide evidence that the judicious use of compression wraps can result in significant benefits to people with lymphoedema, leading to a marked improvement in quality of life.

The literature strongly supports the view that the basic principles of compression therapy apply equally to oedema caused by venous insufficiency and lymphoedema because devices and techniques such as compression hosiery and multilayer bandage systems are used in the management of both conditions. It is therefore not unreasonable to assume that data generated in one condition has some direct relevance to the other.

It also possible that the clinical benefits resulting from the use of compression wraps might be delivered at no additional cost to the NHS, and might even result in significant savings if the results of the small clinical studies reported to date are replicated more widely in clinical practice.

Box 1. Key recommendations.

As a result of this review, the following recommendations were made to the commissioning body (AWMCDSG)

- Although the evidence is by no means overwhelming, the controlled extended use of compression wraps for the treatment of lymphoedema appears to be supported both on clinical and financial grounds and, therefore, should be given serious consideration.
- Consideration should be given to implementing a simple system for recording the wear time of compression wraps supplied to a group of patients under normal conditions of use to determine if the financial savings predicted by some authors are realistic.
- The availability and value of application aids or guides should be assessed to see if such devices contribute to the successful use of compression wraps.
- A well-designed and controlled clinical study comparing compression wraps with one or more standard therapies would be highly desirable.
- The impact on treatment outcomes of patients removing and reapplying compression wraps themselves should also be investigated.
- Before clinical studies are initiated, it would be prudent to conduct an independent laboratory-based comparative examination of the brands currently available to better understand how their design and construction are likely to impact upon clinical performance.

Acknowledgements

Thanks to Peter Phillips, Director of SMTL, for commenting on early drafts of the original report. This review was funded by the All Wales Medical Devices Strategy Group.

References

Bianchi J, Mahoney K, Nugent L, Keen D (2013) A fresh way to treat venous leg ulcers with measured compression. *Br J Community Nurs* (Suppl): S34–40

Elson D (2013) The 21st century approach for cost effective healing of venous leg ulcers. Poster presentation, Wounds UK, Harrogate

Harris H (2013) Using an innovative compression system to improve patient concordance and quality of life whilst achieving clinical and financial outcomes. Poster presentation, Wounds UK, Harrogate

House of Commons Health Committee (2013) Written evidence from the Lymphoedema Support Network (LTC 10). Available at: https://www.publications.parliament.uk/pa/cm201415/cmselect/cmhealth/401/401vw09.htm (accessed 12.05.2017)

Lawrance S (2008) Use of a Velcro® wrap system in the management of lower limb lymphoedema/chronic oedema. *Journal of Lymphoedema* **3**(2): 65–70

Logan RA, Thomas S, Harding EF, Collyer GJ (1992) A comparison of sub-bandage pressures produced by experienced and inexperienced bandagers. *J Wound Care* **1**(3): 23–6

Lund E (2000) Exploring the use of CircAid legging in the management of lymphoedema. *Int J Palliat Nurs* **6**(8): 383–91

Lymphoedema Framework (2006) *Best Practice for the Management of Lymphoedema. International consensus*. MEP Ltd, London. Available at: http://bit.ly/1DJN476 (accessed 02.06.2017)

Mosti G, Cavezzi A, Partsch H, et al (2015) 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* **50**(3): 368–74

Mullings J (2012) Juxta-Fit compression garments in lymphoedema management. *Br J Community Nurs* **17**(10): S17–21

Murthy G, Ballard RE, Breit GA, et al (1994) Intramuscular pressures beneath elastic and inelastic leggings. *Ann Vasc Surg* **8**(6): 543–48

NICE (2015) *The Juxta CURES adjustable compression system for treating venous leg ulcers*. NICE, London. Available at: https://www.nice.org.uk/advice/mib25 (accessed 12.05.2017)

Partsch H, Damstra RJ, Mosti G (2011) Dose finding for an optimal compression pressure to reduce chronic edema of the extremities. *Int Angiol* **30**(6): 527–33

Spence RK, Cahall E (1996) Inelastic versus elastic leg compression in chronic venous insufficiency: a comparison of limb size and venous hemodynamics. *J Vasc Surg* **24**(5): 783–7

Thomas S (2014a) Practical limitations of two devices used for the measurement of sub-bandage pressure: Implications for clinical practice. *J Wound Care* **23**(6): 300–13

Thomas S (2014b) The production and measurement of sub-bandage pressure: Laplace's Law revisited. *J Wound Care* **23**(5): 235–46

Vaassen MM (2015) Manual lymph drainage in a patient with congestive heart failure: a case study. *Ostomy Wound Manage* **61**(10): 38–45