Sub-bandage pressure difference of tubular form and short-stretch compression bandages: *in-vivo* randomised controlled trial

Weller CD, Jolley D & McNeil J

Abstract

This research report outlines the findings of a sub-bandage pressure randomised controlled trial (RCT). The aim of the sub-bandage study was to estimate the difference between mean interface sub-bandage pressures of two multi-layer compression bandage systems during supine position, standing, exercise and recovery. This open-label, prospective, single factor crossover, randomised within person RCT was designed to measure the sub-bandage pressure difference in two compression systems *in vivo* to inform a current pilot clinical RCT that is comparing the effectiveness of a three-layer straight tubular (elastic) bandaging system with a short-stretch (inelastic) compression bandaging system in the management of people with venous ulceration (3VSS2008). In the sub-bandage *in-vivo* study the inelastic and elastic compression bandages were randomised to opposite limbs of 42 healthy adult volunteers. Sub-bandage interface pressures for both bandages were compared within person. Interface sub-bandage pressures varied between different activities but the mean difference in interface pressures between inelastic and elastic bandages was consistently at least 13mmHg. Stiffness was 7.3mmHg higher in the inelastic group (95% CI: 5.1 to 9.5). The estimated difference in amplitude of sub-bandage pressure between the bandages during exercise was 15.5mmHg (95% CI 12.2 to 18.9). We found *in-vivo* interface sub-bandage pressures varied with the type of bandage and activity phase. These baseline results will be useful to inform future compression bandage studies that plan to measure venous ulcer healing rates.

Keywords: sub-bandage pressure, RCT, elastic and inelastic compression bandages.

Background

Venous leg ulceration is a global healthcare problem, imposing a growing burden on primary, subacute and acute healthcare systems. It is estimated that up to 2% of the population in Western countries are affected. Prevalence increases with age and is higher in women than men at a ratio of 1.25:1 [1,2]. The most common cause of lower extremity ulceration is venous insufficiency, which accounts for nearly 80% of all ulcers[3]. Estimates of the prevalence and incidence of ulceration vary [4] and the wide variations can probably be explained by the different survey and sampling methods used (for example, whether only people whose ulcers are known to health services are identified and whether case validation is undertaken). There is some agreement that open venous ulceration is present in 0.1 to 0.3% of the adult population of developed countries though some estimates have been as high as 4.3% [2,3,5-7]. It is thought that 1 to 2% of the population are likely to experience a leg ulcer at some time in their lives, with only 10 to 20% of leg ulcers being active at any point in time [3,8]. There is an increased incidence of diabetes and obesity [9] and anecdotally we are seeing more people with chronic venous ulcers in a much younger cohort than the demographic often quoted in the literature.

Venous ulceration is a common and recurring condition that imposes a considerable burden on patients and clinicians[1,10]. Compression systems improve the healing of venous leg ulcers and should be used routinely in uncomplicated venous ulcers [11,12]. Compression of the lower leg is an effective intervention in the prevention and treatment of venous ulcers [11,13] but insufficient reliable evidence exists to indicate which system is the most effective [14] and even though compression has been used for many decades in the treatment of venous ulcers, its mode of action is still poorly understood [15,16].

Although venous ulcers are not typically seen as a pressing healthcare problem, the impact of leg ulcers is felt both in physical suffering and reduced quality of life (QoL) of those affected and in financial costs to the community [17]. Analysis

Carolina D Weller M Ed [1]
Damien Jolley M Sc (Epidemiology) [1]
John McNeil PhD [1]:
[1] Monash University School of Public Health and Preventive Medicine, Melbourne, VIC
Carolina.Weller@med.monash.edu.au
[1] NHMRC Centre of Research Excellence in Patient Safety, Department of Epidemiology and Preventive Medicine
School of Public Health and Preventive Medicine, Monash University
The Alfred Centre, 99 Commercial Road
Melbourne VIC 3004
Tel (03) 9903 0623 Fax (03) 9903 0576

performed more than 10 years ago in Australia estimated that venous ulcers were responsible for about $400 million annually in healthcare costs. The high prevalence of venous ulcers has a significant socio-economic impact in terms of medical care, days off work and reduced QoL[18]. The projected cost of management of venous ulcers is significant. Currently, up to 20 per 1000 individuals over the age of 80 have an active leg ulcer. One in eight Australians are aged over 65 years. By 2044 those aged over 65 years will account for one in four Australians. The expected number of people aged over 65 years living in Western societies is anticipated to double within the next 40 years or so[19]. Because the cost and resource implication of management of venous ulcers will cause considerable strain on the health system, strategies to improve management and cost-effectiveness of this condition must be seen as a priority. The increased incidence of diabetes and obesity has meant that more recently more people who are in the 40–50 age bracket are presenting to speciality wound clinics with recurrent venous ulcers. Even though venous ulcers are a substantial medical problem, it is not common to admit patients with uncomplicated venous ulcers to hospital. Patients are usually treated with compression bandaging in the community and encouraged to mobilise. In such ambulatory treatment leg ulcer management concordance to bandaging is of high clinical importance.

Compression

Compression is the main conservative treatment of uncomplicated venous ulcers, especially for those suffering venous ulcers in the community. The literature has demonstrated that compression systems improve the healing of venous leg ulcers and should be used routinely to heal uncomplicated venous ulcers [20,21]. The effectiveness of compression systems is dependent on the amount of compression applied during rest and while walking [22]. More recent reviews have reported that the use of compression systems increases ulcer healing rates when compared with no compression.

We also know that patients with venous ulcers are often unable to tolerate therapeutic compression [23]. Operator technique and competence have implications for bandage application and, as reported by Newell and her team, community nurses (CNs) lack confidence in compression bandaging and often do not use bandages according to the manufacturer's instructions [24]. Another recent study explored the reasons CNs were unwilling to use compression bandages and found that CNs were uncertain of which type of compression bandage to use and were unsure of how to apply compression bandages [25].

Even though compression is the first-line treatment to treat venous ulcers and best practice evidence has demonstrated that multi-layer compression is the best way to heal uncomplicated venous ulcers [12], and we know that many patients with venous ulcers are unable to tolerate compression [23,26] we have yet to find out why people are unable or unwilling to adhere to compression therapies [27] or what types of specific interventions would help people to adhere to compression bandages [26]. As clinicians, we encounter patients with venous ulceration who are unable to tolerate therapeutic compression bandaging. Managing this group of patients is a challenging clinical problem.

Bale and Harding [23] conducted a study that followed a group of 28 patients who were unable to tolerate compression and these patients were treated with three layers of graduated Tubigrip® (tubular form in Australia) as an alternative to therapeutic compression. Patients were treated until their ulcers healed or for a maximum of 12 weeks. Fourteen patients' ulcers had healed within the 12-week study period. The remaining 14 patients had a mean reduction in ulcer area of 4.6 cm^2 (SD=7.4), and median of 2.3 cm^2 (range 28.5). The authors found three layers of graduated Tubigrip® useful for managing patients who cannot tolerate therapeutic forms of compression [23].

Sub-bandage study background

It was with the Bale and Harding [23] study in mind that the 3VSS2008 pilot randomised controlled trial (RCT) [17] was designed. In our clinical practice we had used tubular form bandaging system for patients who were unable to tolerate other versions of commercially available compression bandaging. What we didn't know was the healing capability of tubular form compression in comparison to other multi-layer compression bandaging systems. The tubular form compression system was economical and had several advantages, one of which was that the tubular system was easily applied – by the patient, their carer or the nurse.

The pilot RCT was designed as a randomised, multi-centre clinical trial to evaluate the efficacy and safety of graduated lengths of three-layer, straight tubular bandaging (intervention arm) compared with standard compression therapy (short-stretch bandage) in participants with chronic venous ulceration. Participants will be randomised (1:1) to either treatment arm. We used the statement CONSORT to guide the protocol [17,28]. The study protocol was divided into screening, treatment and follow-up periods. The screening period was one week. The treatment period is up to 12 weeks, and the follow-up period is three months. The primary outcome measure is to assess the rate of percentage reduction in wound size from baseline compared to week 12 following randomisation. Further information is available on the Australian New Zealand Clinical Trial Registry ACTRN12608000599370.

Why did we do the sub-bandage study?

Recent papers had reported that in future compression trials, pressure and stiffness measured *in vivo* should be declared [22,29]. As we were unable to find information about the sub-bandage pressure difference between the tubular bandaging system and the short-stretch bandage we were trialing in the pilot RCT, we decided to measure the sub-bandage pressure difference in healthy volunteers. This *in-vivo* difference in effect size for both bandages will inform our results when we analyse the healing results in the pilot RCT.

The aim of the sub-bandage *in-vivo* study was to compare the interface sub-bandage pressure between two multi-layer bandage systems; three graduated layers of tubular bandage (elastic) and a short-stretch bandage (inelastic), during rest, standing, exercise and recovery. We were keen to find out the difference in effect size between the two bandages. This study has approval from Monash University, ethics approval number 2009000388. Consent was obtained from all participants. The study is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12609000941268.

Materials and method

The legs of 44 healthy participants (32 female; 12 male; mean age 39 years; SD 11; range 21–64 years) were measured for appropriately sized bandages. The type of bandage (tubular form [elastic] or short-stretch [inelastic]) was randomised to either right or left leg. Randomisation followed a computer-generated allocation schedule, using allocation concealment to prevent prior knowledge of treatment assignment and to ensure that elastic and inelastic bandages were allocated equally between right and left legs between participants.

Consistency of measurement

For each participant, ankle circumference, at the point of minimum girth and calf circumference at its maximum girth, was measured prior to bandage application. This was to ensure that the correct choice of bandage size was made for each participant. While ankle size usually ranges from 20 to 25cm, there was a proportion with very small or large limbs [30]. To ensure consistency of measurement the PicoPress® pressure sensor was always positioned on the leg while the participant was supine (Figure 1), before the compression bandage was applied. To determine the B1 position, the participant was asked to perform one complete dorsiflexion to aid the location of B1. The sensor was applied at point B1, the area at which the Achilles tendon changes into the calf muscle (Figure 2). Point B1 is one of the anatomical locations described in the European document on normalisation, which was used to define the position on the leg [22]. The consensus statement [22] also reports that the best discrimination between elastic and inelastic material is demonstrated at the B1 level, using the pressure difference between standing and lying. After application of the compression bandage, pressures were measured, with the *in-vivo* measurements of interface pressure measured at resting, supine and standing and working pressure during movement, maximum pressure peaks (systolic working pressure) and minimal pressure (diastolic working pressure).

Compression materials

The following bandages were tested:

1. Elastic bandages – Existing, ready-made tubular bandage (tubular form by Sutherland Medical; Photo 1) were applied in three graduated lengths. Layer one was from the base of the toes to below the knee, layer two from the base of the toes to above the gaiter region, and layer three, the shortest layer, from the base of the toes to just above B1 position (Illustration 1 [23]).
2. Inelastic bandages, often referred to as 'short-stretch' bandages, contain few or no elastomeric fibres. These bandages include materials which have minimal extensibility <100%. A commercially available short-stretch bandage was applied according to manufacturer instructions.

Trial procedure and measurement parameters

The compression bandages were always applied by the same experienced bandager to ensure consistency. The pressure measurements were carried out on each limb for each participant after the bandage was applied. The experiment took place in a clinical laboratory simulation ward. The pressure measurements were taken within minutes of the compression sensor and bandage being applied. The interface pressure was measured at 0.25-second intervals continuously during the test. The difference of the pressure between standing and supine position was taken as a parameter for characterising stiffness [31].

Pressure measuring device

The PicoPress® (Figure 3) compression measurement system displays digital output of the pressure transducer. This is recorded visually; the output is directly plotted and sent to the computer capture system (Figures 4 & 5). The

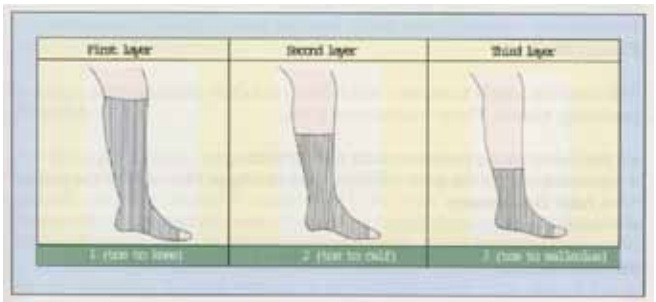

Illustration 1. Acknowledgement Bale and Harding [23].

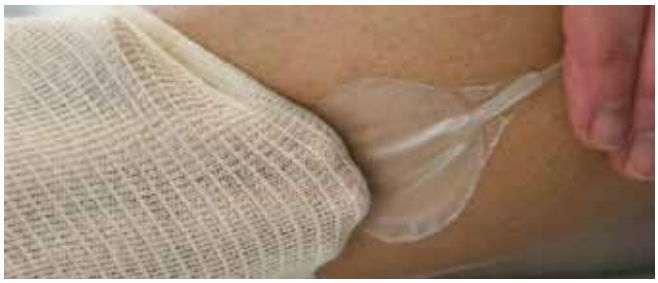

Figure 1. PicoPress® pressure measurement probe.

Figure 2. Pressure measurement probe positioning at B1 prior to bandage application.

advantage of the continuous measurement, in addition to static measurement, is the ability to obtain a pressure profile of the device during standing and exercise.

Calibration of PicoPress®

A zero adjustment to correct for atmospheric pressure was performed before each measuring period according to the manufacturer's recommendations.

What did we find?

Figure 6 shows the effect size (difference between inelastic and elastic bandage pressures), with 95% confidence intervals, by activities. The greatest effect sizes were evident in the standing and exercise phases. The estimated difference in amplitude of SBP between inelastic and elastic bandages during exercise was 15.5mmHg (95% CI 12.2 to 18.9). In addition, the range (maximum SBP – minimum SBP) during this activity was greater for the inelastic bandages.

What next?

We will use the information from the sub-bandage *in-vivo* RCT to inform the 3VSS2008 RCT**.** The primary outcome of the 3VSS2008 RCT is to assess the rate of percentage reduction in wound size from baseline compared to week 12 following randomisation. One secondary outcome is to assess the proportion of ulcers healed within the trial period. At this stage we are still recruiting for the 3VSS2008 RCT, which is due to be completed at the end of 2010. We have collated a brief vignette of the outcome of a patient who was part of the pilot RCT and was randomised to the elastic tubular form three-layer compression system. We believe that the simplicity of application of the elastic tubular form in three layers as reported by Bale and Harding has merit; it may be because patients find it comfortable and leave it on. If adherence to compression is improved and nurse operator/application is simplified this compression system may improve healing for people with venous ulcers.

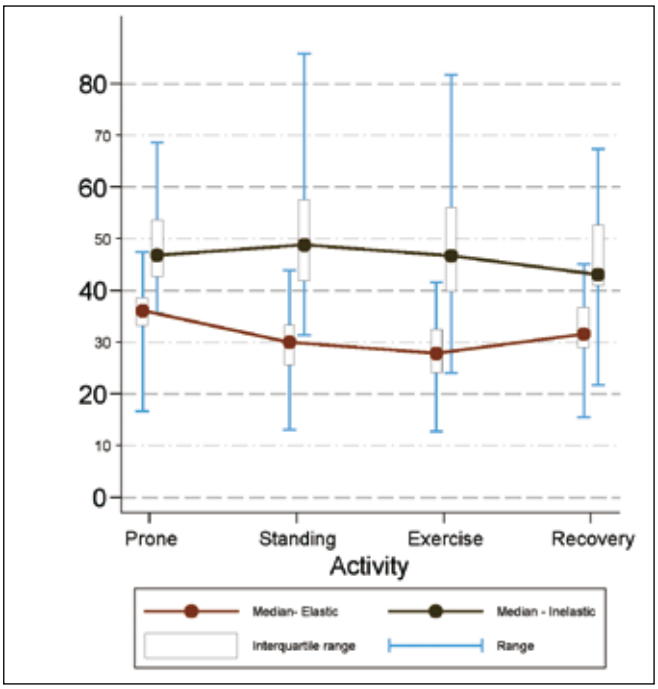

Figure 6. Median, interquartile range and overall range of sub-bandage pressures, by bandage type and activity (n=42 healthy adult volunteers, Melbourne, 2009).

Figure 3. PicoPress® compression measurement instrument.

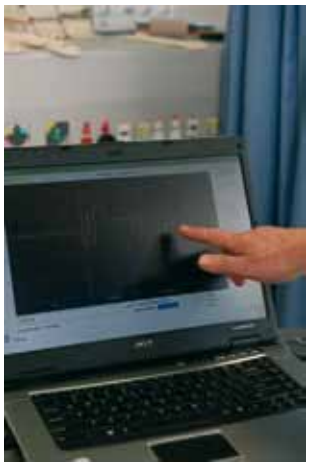

Figure 4. PicoPress® data capture example.

Photo 1. Tubular form.

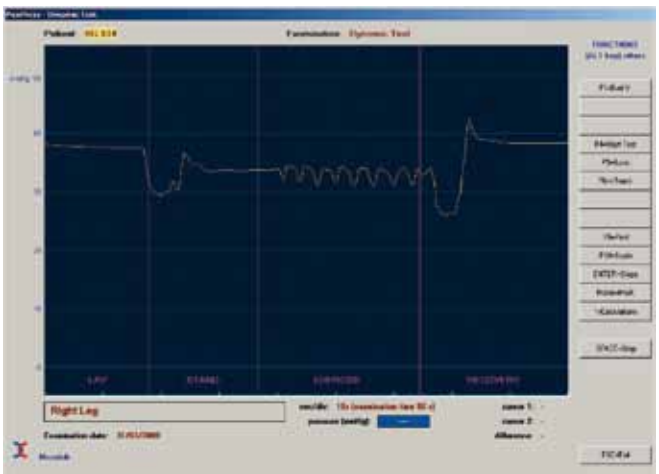

Figure 5. PicoPress® data capture: dynamic test.

Many clinicians use three-layer elastic tubular form as a compression system for people with venous ulcers and even though we have anecdotal evidence of healing we did not have any best practice evidence to inform this practice. Our sub-bandage pressure study will add to the body of evidence of efficacy of different types of high compression.

The three-layer elastic tubular system is very simple to apply and does not require a trained health professional, whereas the inelastic short-stretch bandage needs to be applied by a trained health professional and, if used incorrectly, can cause damage to underlying tissues. In view of recent literature that has demonstrated that CNs are unwilling to use compression bandages, because they were uncertain of which type of compression bandage to use and how to apply bandages [32], the three-layer elastic system may increase compression use by CNs. If our anecdotal evidence is correct, it may also increase the number of patients who are willing to wear compression bandages, which may improve healing rates even though it gives a lesser sub-bandage pressure at standing and exercise.

Generalisability

Application of the three-layer tubular system is very simple and does not require trained health professionals. The short-stretch bandage needs to be applied by a trained practitioner and takes longer to apply. In some instances, if the short-stretch bandage is applied incorrectly it can cause damage to underlying tissues on the lower limb. In view of recent literature that has demonstrated that CNs were unwilling to use compression bandages, because they were uncertain of which type of compression bandage to use, and also how to apply bandages, the three-layer elastic system may improve the number of nurses who may be more willing to use the elastic system and also increase the number of patients in the community who are willing to wear the compression.

What do we already know?

- Venous ulceration is a common and recurring condition that imposes considerable burden on patients and clinicians [10].
- Compression is the first-line treatment to treat venous ulcers [12].
- Many patients are unable to tolerate compression [23].
- Some CNs are uncertain how to apply compression [25].
- *In-vivo* measurement of the interface pressure is encouraged when clinical and experimental outcomes of compression treatment are to be evaluated [22,33].

What is this study going to add?

- Evidence-based study affects size and magnitude of difference in sub-bandage pressure of three-layer (elastic) and short-stretch (inelastic) compression bandage systems at rest, standing, exercise and recovery.
- The concept that lower sub-bandage pressure may be useful for improving patient adherence to compression for patients with venous ulcers; it may also be enough to help people with venous ulcers heal.

Jane is an 84-year-old woman with diagnosed chronic venous disease. Jane has a long-standing previous history of venous ulcers on both lower limbs. Jane had been treated by her GP for the target venous ulcer for two years prior to her presentation to a subacute wound clinic service in Melbourne. Jane wore compression stockings on her unwounded left leg.

At the time of her outpatient visit, Jane had been attending her GP clinic three times a week for wound care, dressing and bandage changes. Jane found it hard to sleep as her wound was painful at night. Jane also had difficulty tolerating the compression bandage during the day. Ankle Brachial Index was 0.8.

Jane met the inclusion criteria and was invited to participate in the 3VSS2008 pilot clinical RCT, investigating the effectiveness of a graduated, three-layer, straight tubular bandaging system when compared to a standard short-stretch compression bandaging system in the management of people with venous ulceration.

Jane was randomised to the three layers of tubular form bandage compression system.

Wound assessment:

- located on her right lateral lower leg-gaiter area
- 9 cm^2, irregular in shape
- granulation and slough (50%/50%) in wound bed
- superficial in depth
- exudate level medium

Standard ulcer management care was provided with the intervention compression over the trial 12-week period.

Initially Jane's wound was painful most of the time during the trial period, but after four weeks' trial participation Jane reported very little pain and was sleeping well. She was very happy with the progress of her wound as it was decreasing in size consistently for the first time in two years.

At week eight, Jane was hospitalised with a bowel obstruction and underwent a laparoscopy and bowel resection. Jane had a fairly smooth recovery from the surgery. During her hospitalisation, the study coordinator provided the weekly treatment regime and by the end of the treatment period 12 Jane's wound was healed.

Jane's wound did recur 10 days later – approximately 2–3mm^2 in size. Jane was instructed on how to care for the venous ulcer and to continue with the tubular compression and it healed within a week.

At the first month follow-up, Jane's wound remained healed. Jane was fitted for compression hosiery and was given a patient education overview of how to look after her legs and hosiery to maintain healthy legs. Jane consistently wore her compression hosiery every day and the target ulcer did not recur in the following two-month follow-up period.

Acknowledgement Kristin Cooper

Acknowledgements

Carolina Weller is funded by Monash University Postgraduate Scholarship.

We are grateful to:

Professor Hugo Partsch for suggestions and study analysis advice.

Chris Selwa/Antonio Berto, for providing PicoPress® Microlab, Padua, Italy.

Joseph Toscone, Sutherland Medical for providing tubular-form bandages.

A/Prof Andrew Forbes, Prof Rory Wolfe and Dr Sue Evans for study design guidance.

Kristin Cooper for providing first draft of vignette.

Dr Ken Myers for providing comment on earlier drafts.

Competing interests

Tubular form bandages were provided by Sutherland Medical.

PicoPress® was provided by MediGroup.

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