RESEARCH

Adjustable Velcro® compression devices as compared to 4-layer compression bandages for the treatment of venous leg ulcers and optimisation of patient satisfaction

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Abstract

Aims To compare the efficacy, cost effectiveness and user satisfaction achieved when 4-layer compression bandages (4LCB) and adjustable Velcro® compression devices (AVCD) are used in the treatment of venous leg ulcers (VLU), in community dwelling adults.

Methods A prospective cross-over study was conducted. A convenience sample of 50 patients with VLUs were recruited. Patients were randomised to receive either 4LCB or AVCD for a period of 6 weeks, then crossed to the alternative treatment for an additional 6 weeks. Baseline and weekly wound assessments were recorded. Patients and nurses completed satisfaction surveys at the end of each arm. A cost analysis was completed.

Results Patients experienced a comparable reduction in ulcer size with both compression modalities.

Nurses and patients reported higher satisfaction with AVCD. The costs associated with a reusable AVCD as compared to single use 4LCB was dependent on the duration of treatment and frequency of changes. Cost benefits were associated with AVCD after 17 episodes of care where a single set of bandages was required and sooner in larger legs.

Conclusions The use of AVCD proved cost-effective and produced comparable healing rates in the community setting. Both nurses and patients expressed higher satisfaction scores when using AVCD.

Keywords Compression, venous leg ulcers, compression wraps, adjustable Velcro® compression devices, 4-layer compression bandaging

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Venous leg ulcers (VLU) are one of the most frequently encountered chronic wounds.[1] Recent data produced by the largest community nursing service in Australia found VLUs comprise the greatest proportion of wounds and subsequently generate the highest aggregate treatment costs.[2] Estimates of annual treatment costs for VLUs in Australia was estimated to be approximately A$1178 million.[3] Patients with VLUs suffer pain, impaired mobility and impaired quality of life.[4] Estimates of prevalence vary from 3% of people 60 years-and-over,[5] to 5% among those 80 years-and-over.[6] Gould, Abadir[7] reported an increased incidence of three to four times in those over 80 years of age compared to those aged 65 to 70 years. These estimates may under-represent the true extent of the problem as they fail to account for those

who self-manage their VLUs, a cohort which may be as high as 75% in people of working age.[8]

In 2020, Australians aged 65 years-and-over represented 16.3% of the population and those aged over 85 years 2.4% (n=527,400) with the number expected to double by 2042.[9,10] Hence the incidence, prevalence and associated fiscal burden of managing VLUs are expected to increase in coming decades, as will the significant detrimental effects on mobility, functioning and quality of life for those afflicted.

The pathophysiological aetiology associated with the development of a VLU is valvular incompetence of the lower leg veins. This leads to chronic venous insufficiency (CVI), venous hypertension, lower leg oedema and ultimately, ulceration.[11] Graduated lower leg compression therapy is the recommended treatment for VLUs.[12] It works by exerting external pressure on the veins which reduces venous hypertension and oedema and improves calf muscle pump performance.[13]

Compression therapy can be applied using a variety of modalities including single or multi-layer bandages, hosiery, pneumatic pumps, and Velcro® adjustable compression wraps.[14] However, many patients find it difficult to tolerate compression bandaging due to discomfort, and constraints in performing hygiene and wearing of preferred clothing and footwear.[4] Patient tolerance is also compounded by lack of engagement, lack of empowerment, poor health literacy, financial constraints, geographical isolation or psychosocial barriers that impact wellbeing and activities of daily living.[4,14-17] The proposal that compression wraps offer an efficacious alternative to compression bandaging[18,19] had, prior to this study, not been tested in a comparative study involving a cohort of patients receiving community based wound care in Australia.

Methods

A prospective crossover study was undertaken. A convenience sample of 50 patients with CVI who were receiving treatment for VLUs by a community health provider in metropolitan Perth, Western Australia, were invited to participate. Patients were eligible for recruitment if they were: over 18 years of age, without cognitive impairment, could provide informed consent and were able to launder the AVCD and liners. Significant arterial insufficiency was excluded on clinical assessment and when the ankle brachial pressure index (ABPI) was 0.8–1.2 or absolute toe pressure was >55mmHg. Prior to recruitment, potential recruits who were receiving care for a VLU underwent a comprehensive clinical lower leg assessment by a specialised wound nurse, which included documentation of clinical signs commonly associated with CVI: oedema, haemosiderosis, lipodermatosclerosis and this was used in combination with ABPI or absolute toe pressure to confirm a diagnosis of CVI and the presence of a VLU.

Computer randomisation allocated each patient to receive either 6 weeks (or less if healed prior) in four-layer graduated compression bandages (4LCB), which comprised a natural padding, crepe, light stretch and cohesive bandage which were reported to achieve 40mmHg graduated compression at the ankle. The alternative randomisation allocated participants received 6 weeks (or less if healed prior) treatment in AVCD (Jobst® AVCD BSN medical Aust Pty Ltd, an Essity company) and these were applied according to the manufacturer's instructions. Patients received their usual wound care: washing of the leg with potable water, application of moisturiser to surrounding skin, a primary dressing based on assessment of the wound bed conditions and amount of exudate and a secondary dressing if required.

Baseline and weekly wound assessment data and wound images were collected at point of care and uploaded on the organisation's electronic mobile wound module. Data included: wound dimensions; wound bed, edge and peri-wound characteristics; exudate type, amount and odour; and wound pain (self-reported using a numerical scale out of 10).

A patient-specific care plan was developed in accordance with the assessment outcomes and goals of care, and randomisation to the treatment group. All treatment consumables (solutions, dressings, bandages, instruments, dressing packs) used to treat each patient were recorded automatically on selection of consumables in the electronic care plan.

A seven question, five-level Likert survey in paper format was administered to nurses at the end of each treatment period. There was also room for free text nurse comments. The patients completed a 14 question, five-level Likert satisfaction survey, also in paper format, at the end of each treatment period.

Descriptive statistics were used to explore patient demographics and the percentage of wounds achieving complete healing. Chi square tests were employed to identify differences in percent healing between groups and Kruskal Wallis testing to identify differences in wound area reduction between groups. Patient and nurse satisfaction surveys were analysed using descriptive statistics.

Results

Demographic characteristics and healing information is contained in Table 1. Patients who did not complete at least one arm of the study (n=6) were excluded from this analysis. Information is based the on the client's initial treatment arm, so healing in the first 6 weeks is based on which group they were randomised to and in the second 6 weeks based on the same treatment type. The age of patients is calculated from the date of their entrance into the study. Table 1 shows that those patients who started in 4LCB were older, on average, but this difference was not statistically significant (t(42)=-

Table 1. Demographics and healing

Variable	AVCD	4LCB	All
Number	24	20	44
Age (mean, SD)	62.63 (17.17)	69.74 (8.87)	65.88 (14.33)
Gender (n (%))			
Male	19 (79.97%)	13 (65.0%)	32 (72.73%)
Female	5 (20.83%)	7 (35.0%)	12 (27.27%)
Healing (n (%))			
Healed in first 6 weeks	9 (37.5%)	9 (45.00%)	18 (40.91%)
Healed in second 6 weeks	2 (8.35)	1 (5.00%)	3 (17.65%)
Healed over 12 weeks	11 (45.83%)	10 (50.00%)	21 (47.73%)
Time to heal (days; mean, (SD))	33.91 (21.47)	36.20 (28.05)	35.00 (24.20)

1.6772; p= 0.1009). The majority of patients in the study were male (73%) and there was no difference in gender between those who started in AVCD and those who started with 4LCB (X2(1)= 1.038; p=0.293).

The mean ulcer size for patients starting in 4LCB was 2609mm^2 (median 780; SD 5219; range 104–24,050; IQR 270–3480) and for those starting in AVCD, 7341mm^2 (median 702; SD 15,100; range 12–57000; IQR 134–6194). Patients were reported as healed if they achieved complete epithelialisation of the wound during the study period.

Of all the patients in this study, 21 healed (48%), but significantly, of those who healed, 18 (86% of all healed) healed in the first 6-week period and there was no significant difference in the percentage healed (X^2(1)= 0.2538; p=0.614) between treatment types. There were also no significant differences between the number of days to heal between treatment types. Both groups healed in around 35 days (t(19)=-0.2114; p=0.8348).

Ten patients chose to withdraw from the study. Of those who chose to withdraw, six did so because they wanted to continue using the AVCD, one left who wanted to continue using 4LCB, two withdrew as they could not tolerate 4LCB, one person had a skin reaction to the AVCD liner, one had skin breakdown due to cessation of a prior treatment of zinc paste bandaging (which was ceased prior to commencing the AVCD treatment), and another was hospitalised for an unrelated health matter (see Table 2).

A total of 34 patients spent some time in 4LCB. One patient was not able to tolerate 4LCB and removed it shortly after application. Their data was excluded. Two patients had multiple small wounds and the absolute change in wound size could not be calculated. One was swapped to AVCD too soon and their data was excluded. One was hospitalised for an unrelated matter. The remaining 28 patients were analysed for relative wound area reduction (RWAR) in 4LCB.

Table 2. Reasons for early withdrawal from study.

Reason	Number
Patient preference to stay in AVCD	5 (50%)
Patient preference to stay in 4LCB	1 (10%)
Inability to tolerate 4LCB	2 (20%)
Unrelated hospitalisation	1 (10%)
Skin breakdown in AVCD	1 (10%)

Among the 38 patients who were treated with AVCD, one patient did not tolerate the AVCD and reverted to 4LCB after two hours wear time, hence no change in wound size was identified. A second patient spent four days in AVCD and experienced a skin breakdown due to the cessation of his previous zinc paste bandaging and reverted to 4LCB. Three patients had multiple small wounds and the change in wound size could not be accurately calculated. One was swapped to AVCD too soon and their data was excluded. A single participant developed a dermatological skin disorder and wound size was not collected. The remaining 31 patients were analysed for RWAR in AVCD. RWAR is presented in Table 3.

The median initial size of the clients' wounds taken at baseline shows a significant difference between those that healed in the first 6 weeks and those that did not (H(1)=4.402; p=0.0381). The median size of those that healed was smaller than those that did not heal. There was no difference between the baseline size of the wounds that healed in the first 6 weeks and the initial treatment arm (Table 4).

Satisfaction survey results

The responses in the seven question, five-level Likert survey administered to nurses at the end of each treatment period were clustered into three categories: disagree, neutral and agree. The responses are presented in Figure 1. The greatest satisfaction differences between modalities occurred in responses around the ease of application and removal of the compression system and perceived occupational health and safety issues. Both favoured AVCD. Nurse self-reported application times were also collected in the survey tool. The mean application time for AVCD was 12 minutes (median 8; SD 10; range 5–40; IQR 21) and for 4LCB, 21 minutes (median 18; SD 16; range 5–60; IQR 21).

Patient satisfaction survey

The greatest differences found in patient satisfaction scores concerned the ease of attending self-hygiene and the wearing of footwear (Figure 2). Many patients found they could wear their usual shoes, which had associated benefits involving cost savings, improved cosmesis, more comfortable rest and ambulation and consequently a potential reduction in falls risk.

Costs to treat

Consumable costs and nursing time were collected using the organisation's wound module. Mean costs for each type of treatment were calculated and are presented in Table 5. The mean difference in cost to treat, after the first treatment which included the cost of the AVCDs, was A$17.28 per treatment in favour of the AVCD.

Discussion

This study sought to compare the healing outcomes, costs and satisfaction scores associated with the use of 4LCB and AVCD in the community setting in Western Australia. A cross-over study was conducted on a convenience sample of 50 patients receiving compression therapy for the treatment of VLU. Results showed no significant differences between the two modalities with regard to wound healing, but higher satisfaction scores associated with the use of AVCD and cost savings with AVCD after 17 treatments.

In 2016, a similar cross-over pilot study was undertaken by the same community nursing organisation, which compared the use of AVCD to 4LCB in the treatment of VLU in community dwelling, bariatric patients. That study identified several

Table 3. Relative wound area reduction(%) by initial treatment*

Initial treatment	Mean	Standard Deviation	Median	IQR	Number
Weeks 1–6					
AVCD	-27.83	86.74	-49.09	-100 to 13.68	23**
4LCB	-58.62	54.88	-85.76	-100 to -29.11	20
Weeks 7–12					
AVCD	-11.28	-57.04	-8.99	-64.58 to -12.22	8
4LCB	69.36	240.36	-44.08	-86.84 to 160.84	8
Weeks 1–12					
AVCD	-66.72	55.61	-100	-100 to -58.91	18
4LCB	-52.88	125.49	-100	-10 to -60.52	17

*A negative score means a reduction in wound area
**One client who started at week 1 on AVCD healed but did not have an initial wound area recorded

Table 4. Initial size (mm^2) of wound and healing within the first 6 weeks

Initial treatment	Mean	Standard Deviation	Median	IQR	Number
Initial size of wounds at baseline					
Unhealed	7,138.42	14,467.21	1,450	440 to 4,800	26
Healed	2,153.53	4,371.83	270	120 to 800	17
Initial size of wounds healed at baseline					
AVCD	3422.37	6151.61	136	32.5 to 5815	8*
4LCB	1025.67	1439.70	300	198 to 800	9

*One client who started at week 1 on AVCD healed but did not have an initial wound area.

advantages associated with the use of AVCD, including: increased nurse and patient satisfaction, increased patient concordance with treatment, reduced treatment costs and reduced injuries among nurses while demonstrating that the overall treatment outcomes were comparable.[20,21] There is a high degree of agreement between the findings of the two studies with regard to wound healing, costs and satisfaction, indicating benefits are maintained across a range of body morphologies. While the later study did not specifically gather concordance data it did gather patient satisfaction scores which were higher for AVCD, and patient satisfaction with treatment does contribute to concordance.[4]

Patient satisfaction/concordance

Concordance with compression therapy is a principal driver for achieving optimal healing of VLUs. Higher participant satisfaction correlates with higher treatment concordance, better engagement with compression and consequently, potentially faster healing[4,22,23] and in this study the participants reported higher levels of satisfaction when wearing AVCD as compared to the 4LCB. The satisfaction scores were higher for AVCD for all questions posed and, in particular, the wearing of AVCD was found to be more comfortable and less of an encumbrance while performing activities of daily living and personal care.

Participants reported it was easier to wear their usual footwear which provided benefits around increased mobility and social functioning. This has implications for enhancing mobility and reducing the risk of falls and a consequent reduction in the psychological impact of VLU treatment.[16,24,25] Increased mobility and the coincidental increase in calf muscle pump function is one mechanism involved in the

Table 5. Mean cost to treat, in Australian dollars: Consumables and nursing cost

	4LCB	AVCD	Difference
Consumable cost per treatment. Excluding cost of AVCD	$30.85	$16.81	$14.04
Nursing cost per treatment	$37.92	$34.68	$3.24
Total cost of first treatment Including cost of AVCD	$68.77	$347.49	$278.72
Total cost of subsequent treatments per treatment	$68.77	$51.49	$17.28

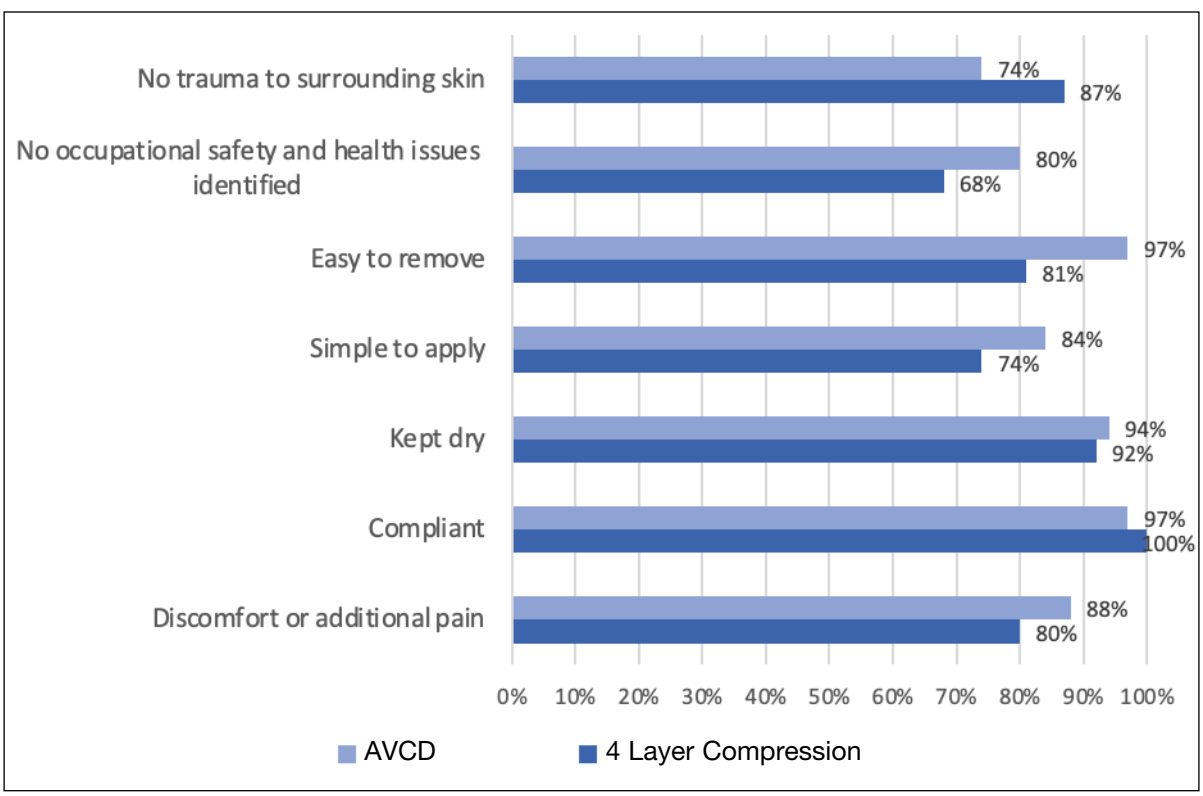

Figure 1. Nurse satisfaction: Percent of positive responses (%)

reduction of symptoms associated with VLU and chronic venous insufficiency,[13,26] as it improves venous return and reduces lower leg oedema and associated discomfort. This subsequently improves healing outcomes and quality of life.[13,27]

Some of the study patients complained of toe pain when using the sock-like liner. One patient cut the toes out of his stockings to increase comfort. A potential product innovation could be to develop open toe compression liners or alternatively, use a class one open toe compression stocking and a lighter AVCD thus further enhancing patient satisfaction.

Early exits from study

The methodology describes a treatment protocol whereby patients continued in the study for 12 weeks or until they achieve completed healing, whichever occuredk sooner. A total of ten patients (20%) chose to exit the study prior to completion, five (50%) of whom left the study to continue in ACVD and one (10%) who left to stay in 4LCB. It is acknowledged that higher attrition rates may introduce bias into a study, however, as the results of this study indicate a patient preference for ACVD, the reasons for withdrawal lend additional support to the findings.

Cost effectiveness

The treatment of VLUs poses a significant resource burden on individuals and health care providers.[3,28] This study demonstrated AVCD required less nursing time to apply than 4LCB and reduced consumable costs. Cost savings were demonstrated where participants required more than 17 episodes of care. The AVCD are reusable, hence the total cost of the devices is amortised over the duration of treatment. However, each patient required two devices to permit laundering between uses.

To complete the analysis of the relative costs of treatment it was necessary to ascertain the duration of treatments at which cost to treat with either compression modality equalised. This was calculated by dividing the difference

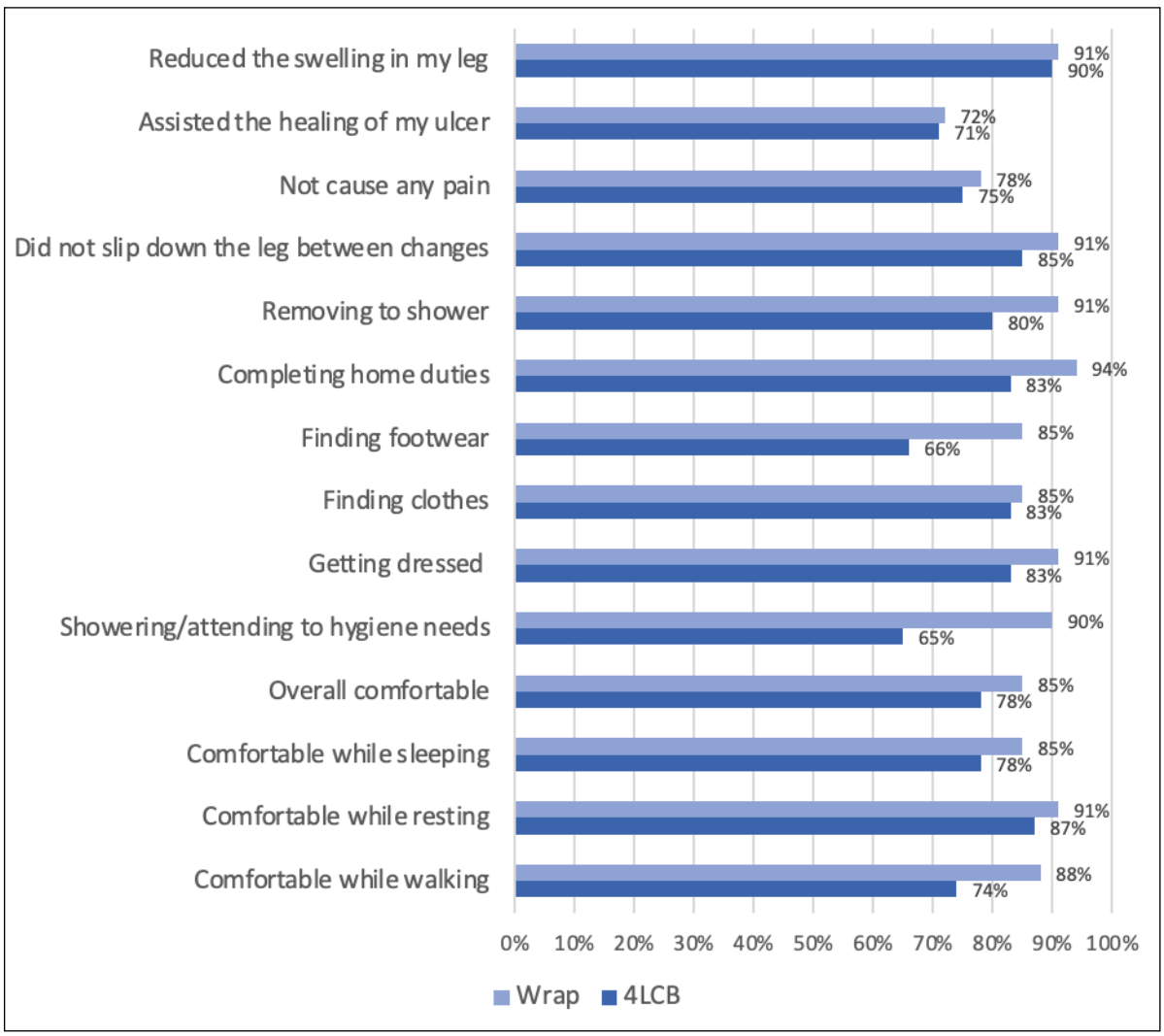

Figure 2. Client satisfaction: Percent of positive responses (%)

in total cost per treatment including the cost of the AVCD by the difference in total cost per treatment excluding the cost of the AVCD. In this investigation cost equivalence was realised at 17 treatments when patients required one set of bandages per leg per treatment. Should a patient require two sets of bandages per leg per treatment (nominal cost A$12 each), such as may be expected when treating the morbidly obese with overlarge legs, cost equivalence would be realised at ten treatments. Every treatment after this point, until replacement of the AVCD is required saved A$17.28, a saving approaching 25% of the treatment cost. Given that it is estimated the cost of treating an individual VLU in Australia is A$8106,[29] a cumulative A$1178 million per annum,[3] the potential savings are not insignificant.

Treatment Outcomes

This study has provided data to support the non-inferiority of AVCD in the treatment of VLU compared to the 'gold standard': 4LCB. There was no significant difference in the number of participants who achieved complete healing with either modality or in the time they took to do so. It was of interest that of the 21 wounds which healed during the study, 18 did so in the first 6 weeks of treatment, perhaps supporting the premise that effective compression rather than compression modality is the primary driver of VLU healing.

The wounds that did heal within the study period were in general smaller than those that did not (median 270mm^2; IQR 120–800mm^2 vs median 1450mm^2; IQR 440–4800mm^2). Larger wounds frequently take longer to heal than smaller wounds,[30] so this result is unsurprising. The length of this study was determined by research suggesting 2/3 (67%) of VLU heal within 12 weeks with effective compression therapy.[31,32] However, in this study the percentage healing within the 12 weeks was only 21/50 or 42%. Many of the participants were recruited from an active client list and consequently may have had already had compression, but not yet achieved healing. This may have caused bias in that the cohort may have contained a higher-than-average percentage of slow to heal wounds. Additionally, those who were first treated with AVCD and left the study to stay in AVCD were not followed for a further 6 weeks. It is unknown if these five participants healed within 12 weeks or not.

Study limitations

Some study limitations were identified. Ulcer duration was not collected; hence it was not possible to quantify how many of the patients had intractable ulceration. Likewise, history of previous compression therapy by type or duration was not collected. The high proportion of healing in the first versus second 6 weeks of the study regardless of compression modality, may actually reflect a response to effective compression in general. The literature reports great variation between target and achieved compression bandaging pressures.[33] It is possible that the enrolled patients had not received an appropriate level of compression prior to commencing the study. Additionally, we did not objectively collect application time, only self-reported. This introduced a potential confounder into the cost analysis.

There was a gender imbalance in the patient cohort. Venous leg ulcers are reported to affect more females than males,[32,34,35] however, in this investigation 70% of participants were male. Although the community nursing service offers both clinic and in-home wound care, the majority of participants in this study were receiving treatment in wound clinics. This was a result of using a convenience sampling method. The gender imbalance in this investigation may reflect an increased willingness among males to try new therapies or alternatively, reflect barriers to clinic attendance among females. It is not known if there is a gender imbalance in VLU healing rates generally. Further exploration of this gender imbalance may assist in identification of barriers to the use of AVCD in females and provide opportunity to enhance concordance in males.

Opportunities for future research

This study generated several opportunities for further research. These include accurate data collection of application times for each compression modality by a range of clinicians. It is known that compression bandage pressures reduce over time[36] but to the best of our knowledge no longitudinal study exists which examines the change over time of compression pressures beneath AVCD, particularly those subjected to home laundering. The development of a decision-making framework around compression modality rather than just compression pressure may facilitate the prescription of a compression modality best matched to the patients' individual preferences and circumstances.

The patients in this study describe being able to find suitable footwear more easily when using AVCD compared to 4LCB. Choice of footwear can influence gait, bandaging can limit range of movement, and both can affect the function of the calf pump,[37] which consequently drives venous return, reduces oedema and facilitates the healing of VLU. Examining the effect of compression modality on gait and ROM on specific patients could further inform the choice of the most appropriate and effective type of compression for each individual.

Conclusions

The AVCD has a role to play in the armamentarium of compression therapy and has cost, and acceptability advantages in the community setting. The application of 4LCB requires a trained clinician, however AVCD can be applied by carers and in many cases by patients themselves.[38,39] This improves access to compression therapy in rural and remote locations where access to health providers may be limited. Feelings of self-efficacy and empowerment are

gained when patients can contribute to their own care[16,40] and enhanced self-efficacy encourages concordance with treatment.[14,41]

Additionally, based on the research of Petrovska,[20] the use of AVCD may reduce the occupational injury risk to those applying compression therapy in a non-clinical setting, such as the home care environment. The costs associated with worker injury have not been factored into the cost analysis performed for this study but cannot be ignored when examining the total cost burden associated with VLU treatment.

Further research to develop a decision-making framework around choice of compression therapy modality would maximise the opportunity to target compression type to an individual's clinical and socio-economic situation, potentially enhancing patient concordance and optimising treatment outcomes.

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Conflict of interest

The authors declare no conflicts of interest.

Ethics statement

Ethics approval for this study was obtained from the Silver Chain Group Human The Silver Chain Group HREC (Ethics Application 130. Date: 1 April 2019).

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Author contribution

Sharon Boxall was involved in the study design, collection, analysis and interpretation of data and drafting and revision of the paper. Keryln Carville was involved in the conception, design, analysis and interpretation of data and critical revision of the paper as well as the final approval of the version of the paper to be published. Joanna Smith was involved in the analysis and interpretation of the data and drafting of the paper. Shirley Jansen was involved in the conception, design, analysis and interpretation of data and critical revision of the paper as well as the final approval of the version of the paper to be published.

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