

# Adjustable compression wrap devices are cheaper and more effective than inelastic bandages for venous leg ulcer healing. A Multicentric Italian Randomized Clinical Experience

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## Abstract

**Introduction:** Compression therapy by inelastic bandages is highly effective in achieving venous leg ulcer healing. Inelastic bandages may be expensive as they need to be changed and discarded at every dressing change. In addition, correct application is difficult in the clinical practice, even by expert healthcare personnel. The aim of our work was to assess whether adjustable compression wraps are more cost effective and more effective than inelastic bandage to achieve venous leg ulcer healing.

**Methods:** Sixty-six venous leg ulcer patients were randomized to be treated by adjustable compression wrap (CircAid<sup>®</sup> JuxtaCure<sup>®</sup>) ( $n = 33$ ) and inelastic bandage (Coban 2 Layer<sup>®</sup>) ( $n = 33$ ). Study duration was 12 weeks. During weekly visits, the ulcers were cleansed and dressed with the same products, and the only variable was the compression device. Ulcer size, ulcer pain, patient's perception of compression systems, and compression pressure were assessed during the visits, and the material cost was evaluated at the 12th week.

**Results:** Adjustable compression wraps were significantly cheaper than bandages ( $p < 0.0001$ ) and were also more effective (not significantly) in achieving ulcer healing. To heal one ulcer patient, €228 had to be spent when applying an adjustable compression wrap and €381 if inelastic bandages were used. About 26/33 (78.8%) patients in the adjustable compression wrap group were healed after 12 weeks versus 23/33 (69.7%) in the inelastic bandage group (n.s.). Ulcer pain was reduced by both compression devices. Patient perception of compression pressure was similar with both compression devices. Compression pressure was similar at application but better maintained by adjustable compression wrap over time.

**Conclusions:** Adjustable compression wraps are significantly cheaper and more effective (not significantly) in achieving venous leg ulcer healing. Self-applicable, adjustable compression wraps are therefore a powerful, cost-effective alternative to inelastic bandages in treating venous leg ulcer.

## Keywords

Venous leg ulcers, compression therapy, adjustable compression wraps, inelastic bandages, costs

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## Introduction

Compression therapy is the mainstay of venous leg ulcer (VLU) treatment, recommended by all present guidelines and meta-analyses with a strong recommendation level.<sup>1-7</sup> Inelastic bandages (IB), exerting a strong standing pressure starting from a significantly lower resting pressure, showed to be comfortable and hemodynamically effective and have been highly recommended in VLU treatment.<sup>1-7</sup>

Unfortunately, wrapping IB around the leg to correctly exert the necessary strong pressure requires education, and, in daily clinical practice, the target pressure is rarely achieved, even by expert personnel.<sup>8-12</sup> This implies that patients cannot manage the bandage themselves but need expert healthcare providers every time they have to change the bandage that usually has to be discarded. Finally, IB tend to lose pressure overtime even if this does not seem to be a major problem as hemodynamic effectiveness is maintained, despite their pressure loss.<sup>13</sup> Adjustable compression wraps (ACW) are compression devices (CDs) that can exert a strong pressure when applied with stretch to the leg. They do not lose pressure as the patients themselves, after a short education period, can effectively re-adjust the pressure when they feel a looseness sensation,<sup>14,15</sup> proving the feasibility of self-management of compression treatment. Finally, ACW can be washed and reused, so that one device can be enough for the whole treatment period. Using just one CD and taking advantage from self-management may allow considerable cost savings in terms of reduced working time of healthcare professionals and reduced compression material requirement.

The aim of our work was to compare the costs of materials when using an ACW or an IB to treat patients with venous ulcers. Secondary outcome was the assessment of ulcer healing rate, ulcer size reduction, compression pressure, ulcer pain, and patient's perception of both compression systems.

## Methods

### Patients

Sixty-six patients affected by VLUs were enrolled in six Italian wound care clinics to participate in this randomized, multicentric, prospective, controlled trial comparing two different CDs: an ACW and an IB exerting a strong pressure with high stiffness when correctly applied.

### Inclusion criteria

Patients of both sex, venous ulcer (also with minimal arterial impairment and Ankle Brachial Pressure Index

(ABPI) > 0.8), wound size from 5 to 100 cm<sup>2</sup>, ulcer duration > 3 months, and age between 20 and 85 years.

### Exclusion criteria

Clinically infected ulcers, arterial disease with ABPI < 80, insulin-dependent diabetes mellitus, cytostatic or immunosuppressive drugs, allergy against one of the used materials, immobile/bedridden patients, pregnancy and period of lactation, age under 20 years or over 85 years, and recent intervention (e.g. reflux abolition, drugs) during study.

The incompetence of the superficial and/or venous system was assessed by Duplex scanner with the patient in standing position leaning on the not examined leg. Superficial and/or deep venous reflux was elicited by manual calf compression and was always longer than 3 s. None of these patients was affected by clinically or echographically relevant deep obstruction. Leg arterial system was also checked by Duplex, and a continuous wave-Doppler was used to measure ankle and brachial pressure and to calculate the ABPI.

All individuals were informed about the study and gave their written informed consent.

### Study protocol

After enrolment patients were evaluated for ulcer size and ulcer pain, and they were asked to fill a well-being questionnaire. Visits for removal and reapplication of the CD and ulcer dressing were scheduled on a weekly basis for 12 weeks. Patients were allowed to come for additional visits for any problem related to their ulcer or CDs. In order to avoid additional variables, we tried to make the all case series as consistent as possible:

- venoactive drugs when routinely used by the patients were stopped at enrollment. Only continuation of drugs to treat comorbidities (e.g. anti-hypertensive drugs in hypertensive patients) was allowed.
- local ulcer treatment was exactly the same in all patients. Ulcer was cleaned by Ulcer Cleansing System UCS<sup>®</sup> (Welcare Industries SpA, Orvieto, Italy) and dressed by the same hydrofiber dressing (Aquacel Extra<sup>®</sup>; ConvaTec Group PLC, Reading, UK).
- no additional treatment (e.g. endovascular procedures, sclerotherapy) was allowed during the study time.
- all the patients were encouraged to maintain their usual life style.

### CDs/randomization

Patients were randomized by means of a list randomizer (<https://www.random.org/lists/>) to receive either CircAid<sup>®</sup> JuxtaCure<sup>®</sup> (Medi GmbH; Bayreuth;

Germany), (ACW-treatment group), or an IB, Coban 2 Layer<sup>®</sup> Compression System (3M Health Care; Neuss, Germany) (C2L), as the control group.

The CircAid<sup>®</sup> JuxtaCure<sup>®</sup> is adjusted at the first visit to fit the patient leg size. Further size adjustments are possible in case of reduced leg size due to edema control. The device consists of a series of individually adjustable Velcro<sup>®</sup> bands from the ankle to the knee. The bands can be stretched and fastened to the fabric. The more they are stretched, the higher the compression pressure. An elastic anklet was applied from the base of the toes to 5 cm above the malleoli.

C2L consists of two components: one inner comfort component made up of foam with a cohesive layer and one outer compression component that is a cohesive bandage. Both components are short stretch and cohere to each other resulting in a bandage with high stiffness. Both devices were wrapped around the patient's leg so as to exert a supine pressure of at least 40 mm Hg classified as strong, according to the International Compression Club classification of compression materials.<sup>16</sup> Both CDs were applied by well-trained and experienced staff that also measured the interface pressures (IPs). Patients in the C2L group were instructed not to manipulate their bandages during wearing time. Patients with ACW were instructed to readjust the Velcro<sup>®</sup> straps when they felt a decrease or "loosening" of the compression pressure so to feel again a tight, but not painful, sensation. Previous studies<sup>14,15</sup> already showed that patients are able to handle and re-adjust the system after a short instruction.

### Measurements

Ulcer size was measured by digital planimetry, and ulcer pain was assessed by Visual Analogue Scale (VAS).

Patient's perception of the compression systems was assessed by a specifically designed questionnaire directly derived from International Compression Club compression questionnaire.<sup>17</sup> The following items were evaluated by the VAS:

- wearing comfort of the CDs (pain, heaviness sensation, swelling sensation, oedema-related discomfort, itching).
- parameters specifically related to the CD: (application difficulty, symptoms worsening, difficulty to wear shoes, readjustment difficulty).

All these parameters were graded at enrollment and after 4, 8, and 12 weeks using a VAS. Absence of symptoms was graded zero increasing to 10 for the most severe symptoms.

The IP between the CDs and the skin was measured in every patient by means of Picopress<sup>®</sup> (MicrolabItalia, Padua, Italy), an accurate, linear, and reproducible pneumatic pressure transducer.<sup>18</sup> The pressure probe, filled with 2 ml of air during measurement, was placed at the B1 point, which is the area at the medial aspect of the leg where the gastrocnemius muscle turns into its tendinous part<sup>19</sup> and left in place between compression application and removal. The compression pressure was measured at CDs application and before removal, both in supine and standing position. The Static Stiffness Index (SSI), the difference between standing and supine pressure,<sup>20</sup> was calculated.

### Statistical analysis

Based on the expectation that the material costs to heal an ulcer for ACW would be about 70% of those of the bandages,<sup>21,22</sup> our calculation revealed that a sample size of 30 in each group has a 99% power to detect a risk reduction of 0.70 with a significance level (alpha) of 0.05 (two-tailed). We enrolled 66 patients taking in consideration possible drop-outs. Medians with interquartile ranges and maximal and minimal values are given. For repeated measures, ANOVA was used to compare compression pressure and stiffness. The non-parametric Mann–Whitney test was used to compare the effects of the CDs. The healing time was compared by Kaplan–Meier method curves analysis and the log-rank test. Finally, we simultaneously tested the patient groups (independent variables) by multivariate Cox proportional hazard model for the unadjusted hazard ratios of healing time (dependent variable). The analysis was adjusted for sex, age, ulcer size (cm<sup>2</sup>), ulcer duration (months), and body mass index (BMI). A p value < 0.05 was considered significant.

Sample size calculation was performed by GraphPad StatMate 2.00 (Graph Pad, San Diego, CA).

The statistical analysis and the graphs were generated by using statistical packages SPSS (21.0) and Graph Pad Prism, version 7 (Graph Pad, San Diego, CA).

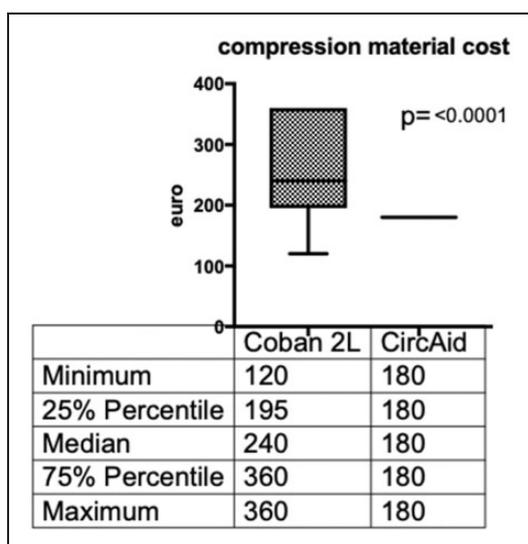
### Results

All the 66 patients completed the study, and all of them were included in the results analysis.

Fifteen women and 18 men aged  $69.6 \pm 7.71$  years with a median ulcer surface area of 16 cm<sup>2</sup> (IQR 8.5–25.5) were treated with ACW, while 18 women and 15 men aged  $71.3 \pm 6.81$  years with a median ulcer surface area of 12.5 cm<sup>2</sup> (IQR 9–27.5) were treated with C2L. The main characteristics of the two groups (Table 1) were comparable concerning sex, age, ulcer size, ulcer duration, ulcer pathophysiology, pain level, and BMI (no statistically significant differences).

**Table 1.** Demographic characteristics of the case series.

	ACW	I.B.	p
Males	18	15	n.s.
Females	15	18	n.s.
Age (years, mean, st.dev.)	69.66 ±7.71	71.3 ± 6.81	n.s.
Ulcer size in cm <sup>2</sup> (cm <sup>2</sup> , median, IQR)	16 (8.5–25.5)	12.5 (9–27.5)	n.s.
Ulcer duration in months (median, IQR)	9 (7–10)	8 (7–10)	n.s.
Ulcer pain by VAS (median, IQR)	5 (3.5–6)	5 (4–6)	n.s.
SVI	22	24	n.s.
DVI	6	5	n.s.
SVI + DVI	5	4	n.s.
ABPI 0.8-1	7	8	n.s.
BMI	29 (25–33.5)	29 (25.5–34)	n.s.

**Figure 1.** Cost of compression material.

### Costs

Dressing change and CDs re-application were performed on weekly base in all the patients. The cost of the compression material during the study time was €180 (IQR 180–180) for each patient in the ACW group (just one CD was necessary to complete the ulcer treatment) and €240 (IQR 195–360) for the patients in the C2L group as the bandage had to be changed and disposed at every dressing change ( $p < .0001$ ) (Figure 1). The cost for each patient in the bandage group ranged from €120 to €360 but additional material cost for patients who did not heal during the study period has to be considered. If we calculate the material cost per healed patient by dividing the total material cost for all patients by the number of healed patients in each group (26 in the ACW group and 23 in the C2L group), we will get €228.46 for ACW and €380.87 for C2L (Table 2) ( $p < .0001$ ).

### Healing

Ulcer healing rate was higher with ACW compared to C2L: 26 out of 33 patients (78.7%) healed in the ACW group and 23 out of 33 patients (69.6%) healed in the C2L group. According to Kaplan–Meier analysis, there was no significant difference between the two groups of patients (Figure 2(a)). As the Kaplan–Meier analysis does not take into consideration any correction variable, the multivariate Cox model analysis, adjusted for sex, age, ulcer size, duration, pathophysiology, and BMI, was performed, but also this analysis did not show any statistically significant difference between the groups. The ulcer size in not healed patients decreased by 80% in the ACW patient group (from 25 cm<sup>2</sup> (IQR 20–26) to 5 cm<sup>2</sup> (IQR 3–12)) and by 71.2% in the C2L group (from 27.7 cm<sup>2</sup> (IQR 23.7–43) to 8 cm<sup>2</sup> (IQR 3.75–25.5)) ( $p$ : n.s.) (Figure 2(b)). Deep venous incompetence was responsible for delayed healing but we were not able to identify the factor/s responsible for not healing in 12 weeks as all clinical features were equally distributed in the two groups.

All patients eventually healed in the subsequent weeks but provided data refer to the first 12 weeks according to the protocol. After ulcer healing, patients were recommended to keep on with compression. Patients in the ACW continued with their device. Elastic compression stockings were prescribed to patients in the bandage group. Patients with superficial incompetence were submitted to superficial venous ablation.

### Compression pressure

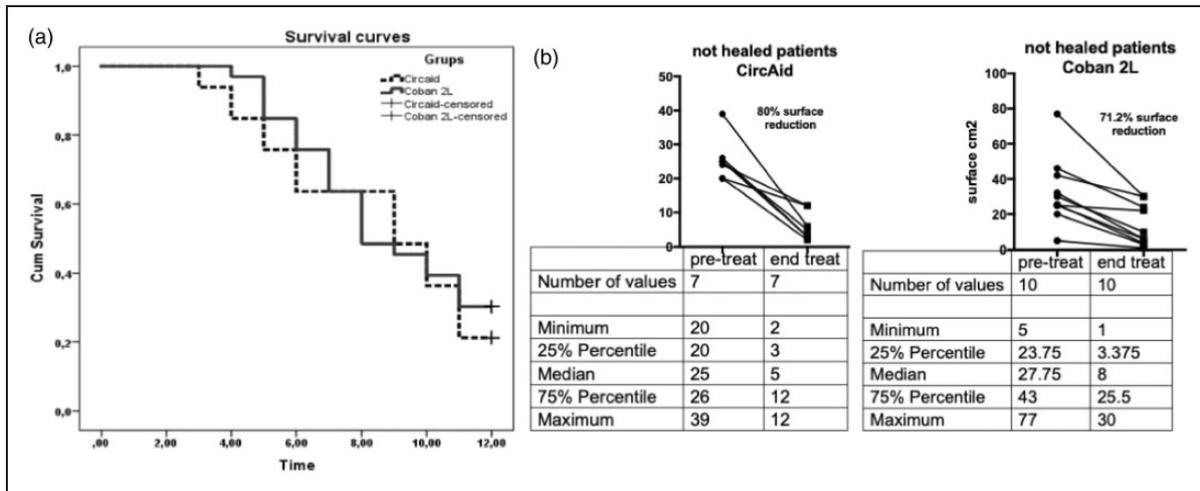
Compression pressure exerted by ACW and C2L at application was about the same in supine position 48 mm Hg (IQR 43–53) and 48 mm Hg (IQR 44–55), respectively. It increased in standing position to 56 mm Hg (IQR 52–62) with ACW and significantly more with C2L up to 60 mm Hg (IQR 56–69) ( $p < .0001$ ) (Figure 3(a)). After one week, the supine and standing

**Table 2.** Material cost (expressed in euro).

Bandage group					ACW group				
Patients' number	Bandage number to healing	Bandage cost	Cost per patients	Total	Patients' number	Bandage number to healing	Bandage cost	Cost per patients	Total
1	4	30	120	120	33 <sup>a</sup>	1	180	180	5490
4	5	30	150	600					
3	6	30	180	540					
4	7	30	210	840					
5	8	30	240	1200					
1	9	30	270	270					
2	10	30	300	600					
3	11	30	330	990					
10 <sup>b</sup>	12	30	360	3600					
				8760					5490

<sup>a</sup>Seven patients did not heal. Total material cost: euro 5940/26 healed patients. Cost to heal one ulcer patient= 228.46 euro.

<sup>b</sup>Ten patients did not heal. Total material cost: euro 8760/23 healed patients. Cost to heal one ulcer patient= 380.87 euro.



**Figure 2.** (a) Ulcer healing rate. The survival curves were generated including all the patients. Not healed patients (+) are reported at the last visit before study end. (b) Ulcer surface (cm<sup>2</sup>) in not healed patients.

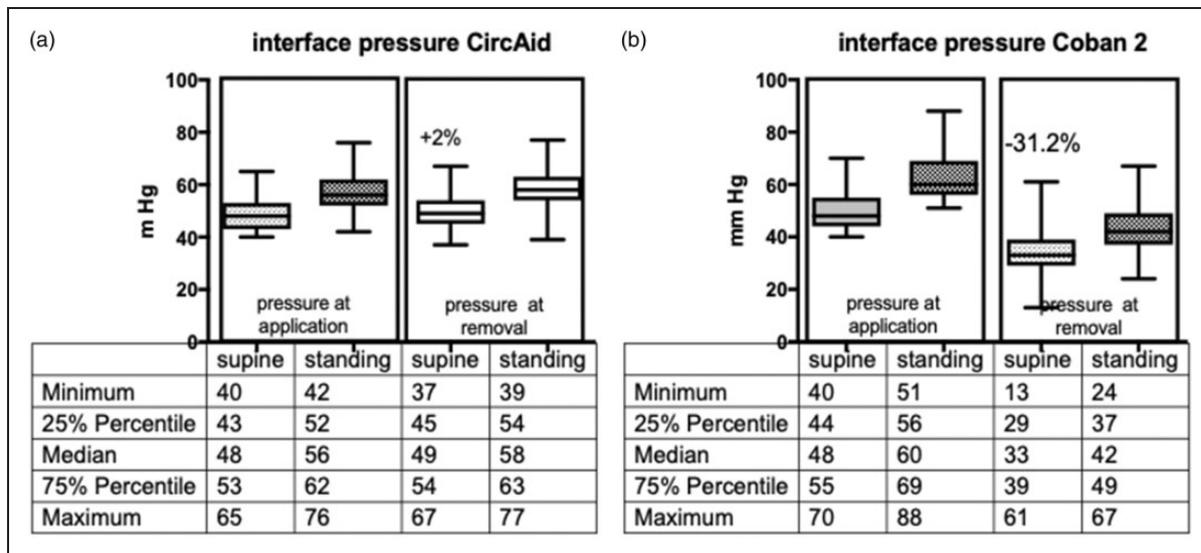
pressure with ACW were very slightly (+2%) but significantly higher compared to application: 49 mm Hg (IQR 45–54) and 58 mm Hg (IQR 54–63), respectively (p = .03 and .02, respectively). Under C2L, the supine and standing pressures were significantly reduced (–31.2%) to 33 mm Hg (IQR 29–39) and 42 mm Hg (IQR 37–49), respectively (p < .0001 for both supine and standing pressure). The resulting SSI at application was 9 mm Hg (IQR 8–10) with ACW but significantly higher (p < .0001) with C2L: 12 mm Hg (IQR 11–14) (Figure 4(a)). At bandage removal, SSI remained about the same with ACW: 9 mm Hg (IQR 7–11) but significantly decreased with C2L to the same level as ACW: 9 mm Hg (6–11) (p < .0001) (Figure 4(b)) due to the pressure loss of the bandage.

**Patients' perception**

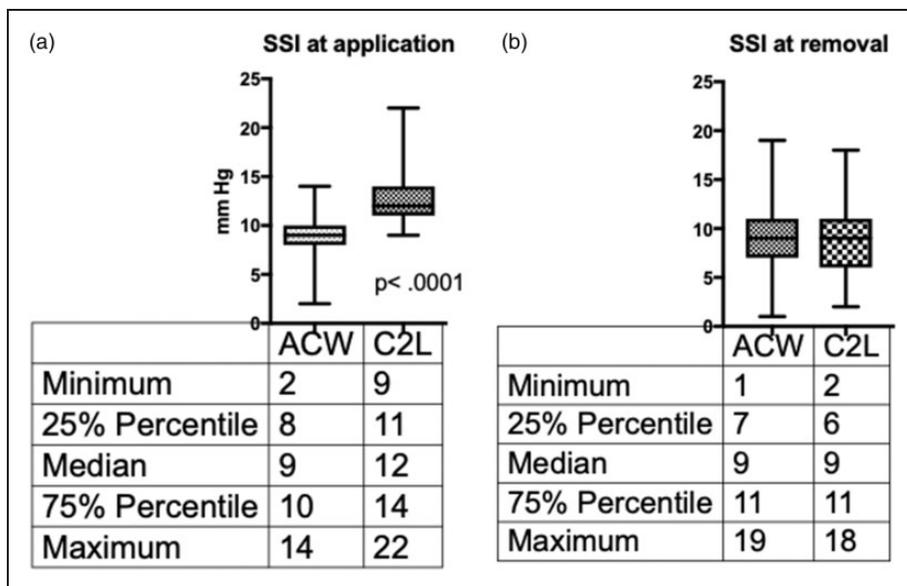
Ulcer pain was significantly reduced by compression with both devices without any statistical difference at every compression and dressing change (Figure 5).

Both devices were very well accepted by the patients. However, ACW was significantly better tolerated than C2L especially in the first weeks (p < .0001). The comfort of patients treated by C2L increased in the last treatment weeks (Figure 6). We did not find any particular problem by using the stockinette in our ACW group of patients.

All other parameters are summarized in Table 3. Main differences, worthwhile to be mentioned, are (a) self-management possible with ACW and impossible



**Figure 3.** Compression pressure exerted by ACW (a) and C2L (b) in supine and standing position both at bandage application and removal.



**Figure 4.** Static stiffness index at application (a) and removal (b) both for ACW and C2L.

with C2L ( $p < .00001$ ), help requirement almost never needed with ACW, mandatory with C2L ( $p < .00001$ ); (b) normal shoes wearing with both CDs but easier with ACW ( $p < .001$ ); (c) itching sensation was very light with both compression modalities but slightly more annoying with C2L. No significant differences were observed for other parameters as dress wearing, skin irritation or damage, heating, throbbing, cutting sensations, and cramps.

### Discussion

The main aim of our work was focused on compression material's cost assessment between two different compression modalities and, as secondary but very important outcome, their efficacy in getting ulcer healing or ulcer size reduction. In order to achieve reliable data, the case series was effectively randomized, and no statistical differences were reported concerning the main characteristics of patients. As comparator for our

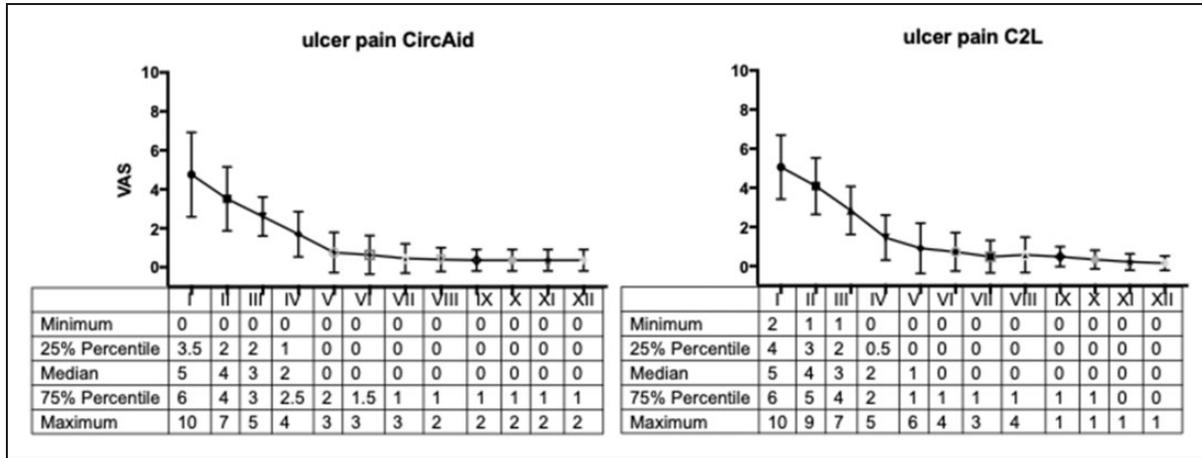


Figure 5. Pain level under ACW and C2L during the study period.

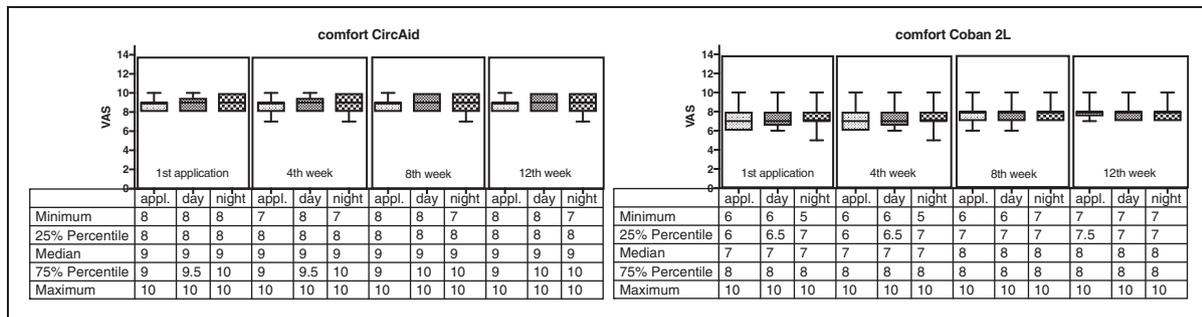


Figure 6. Comfort under CircAid and C2L.

Table 3. Patient's perception of the compression systems.

	ACW	I.B.	p
Self-management	9 (8–10)	0 (0–0)	<.00001
Help required	0 (0–2)	10 (10–10)	<.00001
Normal shoes	9 (8–10)	8 (7–8)	<.001
Itching sensation	1 (0–2)	2 (0–3)	<.0.5
Normal dress	9 (8–10)	9 (8–10)	n.s.
Skin irritation /damage	0 (0–0)	0 (0–1)	n.s.
Heating sensation	0 (0–2)	0 (0–3)	n.s.
Throbbing sensation	0 (0–0.5)	0 (0–0.5)	n.s.
Cutting sensation	0 (0–0)	0 (0–1)	n.s.
Cramps	0 (0–0)	0 (0–0)	n.s.

treatment group, based on a new ACW, we choose C2L that already showed to be one of the most effective CD to promote ulcer healing.<sup>21,22</sup>

Several studies have already demonstrated that ACWs provide cost savings due to reduced use of compression materials, time saved due to quicker and easier

application of the devices, self-management, and fewer nurse visits or appointments for bandaging.<sup>23–27</sup>

A careful analysis of nine cost studies of Juxta Cures is reported in a guidance program of the British health authorities NICE 2015. This document came to the conclusion that all reports suggest that the device is cost saving compared to compression bandaging.<sup>28</sup>

All these newer data confirm the results already reported by De Palma et al.<sup>29</sup> in 1999, despite technological improvement of compression materials and their cost increase.

In our study, we have just concentrated on the cost of the material that resulted much lower with ACW. The reason seems to be very simple: with ACW only one device is necessary for the whole duration of treatment while compression bandages need to be changed and discarded at every dressing change that occurs at least once per week. In our study, the material costs to achieve ulcer healing in one patient was 40% less with ACW compared to C2L. Actually, the difference in costs in favor of ACW could have been much higher when considering four additional points:

1. Frequently, dressing changes are necessary more than once per week, and this would increase the cost of the disposable C2L.
2. Expenses will further increase after 12 weeks, when ulcer patients who were not healed (whose number is higher in the group treated by C2L than in the group treated by ACW) will need new bandages while the patients in the ACW group could keep their CD.
3. Patients in the ACW kept on applying their device after healing while patients in the bandage group had to buy elastic compression stockings to keep on with compression therapy.
4. Finally, the material's cost is only a minor factor contributing to the total treatment cost. If we hypothesized a more extensive self-management in the future allowing the patients to perform dressing change by themselves, this would be possible just using the ACW that can be self-applied and adjusted but not with IB that require expert personnel to be applied.

This would really significantly change the treatment cost as personnel cost is the most important cost of ulcer treatment, certainly much more important than material's cost.<sup>30</sup>

The compression pressure, the dosage of compression therapy, was measured in all patients both at compression application and removal for dressing change. We took care to achieve about the same pressure range at application for both CDs in order to avoid questionable outcomes due to wrong application of the CDs or different pressure ranges. All other potential variables concerning general or local treatment were minimized asking the patients to keep on with their usual treatment and life style, not to add new treatments, adopting the same local cleansing system and dressings.

Regarding ulcer healing rate and ulcer surface reduction, both of them were not significantly higher with ACW than with C2L ( $p$ : n.s.) which could rise some doubts on the real difference between these treatment modalities. Actually, it is important to underline that our study was concentrating on differences in costs and not on healing rate or ulcer size reduction. A much greater number of patients would have been necessary to find a significant difference for ulcer healing.

Both CDs exerted about the same median resting pressure of 48 mm Hg. Main differences concern the SSI that was significantly higher with C2L and pressure maintenance overtime that was significantly more consistent with ACW than with C2L. Due to readjustment by the patients, the ACW compression pressure was higher by 2% before the CD was removed while it decreased by 31% with C2L. The higher pressures under ACW over time may explain the better results compared to those achieved with C2L raising the

concept (if confirmed in future studies) that the pressure maintenance overtime may be more important than stiffness especially when the compression material is comfortable as it happens with the ACW tested in this study.

The patient's feedback regarding comfort was very positive for both compression materials but even more positive for ACW both during day and night ( $p < .0001$ ), which could be not expected for a less stiff device compared with a stiffer one. Patients in the C2L group became more tolerant to the CD while approaching the end of observation period maybe because they were getting more used to their device (Figure 6). Regarding other patients reported outcomes concerning compression (Table 3), the results were self-explaining: that ACWs allows self-management and patients do not need help to manage the CD while patients with C2L cannot manage their CD themselves and need expert personnel to have the bandage wrapped around the leg. Both compression modalities allow normal dressing and shoes wearing even if some more difficulties were reported by the C2L patients regarding shoes. Concerning other potentially annoying sensations coming from the CDs, they were practically absent with both CDs ( $p = \text{n.s.}$ ).

Last but not least, both CDs were able to significantly reduce ulcer-related pain (Figure 5) confirming what was already widely reported: compression therapy is not only the main therapeutical procedure to get the ulcer healed but also improves the quality of life of patients by reducing pain.<sup>31-33</sup> This is due to the micro-circulatory effects of compression that are able to reduce inflammatory mediators promoting pain and to increase the anti-inflammatory mediators globally contributing to pain reduction.<sup>34-36</sup>

## Conclusions

Compression therapy is able to significantly improve the ulcer healing rate. In our study, an ACW was compared with a traditional inelastic CD proven already of being very effective in promoting ulcer healing. The material costs of ACW were significantly lower, since one device is enough for the whole treatment period while the IB must be renewed and thrown away at every dressing change. An even more important economic factor which has not considered in our analysis is the fact that ACW can be self-managed by the patient allowing major costs savings. ACW showed to be more effective than C2L in achieving ulcer healing, even if the difference concerning this item was not statistically significant raising the need of larger study to definitely assess the greater effectiveness. Both CDs were well tolerated but ACW was even better tolerated than C2L. For all these reasons, the tested ACW

represents a further advancement of compression therapy for VLU treatment.

### Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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### Contributorship

Giovanni Mosti wrote the protocol, prepared the randomization, collected, and examined all the data and wrote the manuscript. Hugo Partsch wrote the manuscript together with Giovanni Mosti. Mancini Stefano, Bruni Sergio, Serantoni Simone, Gazzabin Luca, Bucalossi Matteo, Polignano Roberto, and Mariani Fabrizio enrolled and treated the patients collecting the data of their group of patients. They contributed in reviewing the paper before their approval. Bastiani Luca performed the statistical analysis and supervised all the parts of manuscript were data from statistics were mentioned and described.

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