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CASE REPORT

Kikuhime Device in the Management of Venous Leg Ulcers

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Abstract: The effectiveness of compression therapy in the treatment of venous leg ulcers has been confirmed in many scientific studies. The healing process depends on many of its parameters, such as the type of compression bandages, their elastic properties and sub-bandage pressure. However, there is no standard protocol that would ensure success for all patients. A pressure of about 83 mmHg provides complete compression for both superficial and deep veins; however, applying compression bandages under such high pressure is a difficult task, even for experienced therapists. Here, we present the case of a 61-year-old woman with approximately 2.5-year-old venous ulcer in her left leg due to chronic venous insufficiency (CVI). Our study aimed to show that routine pressure control at each bandage renewal using the Kikuhime device, as well as their twice daily application in the first week of therapy reduced the healing time of a venous leg ulcer with an area of about 20 cm^2 to four weeks.

Keywords: venous ulcers, compression therapy, sub-bandage pressure, Kikuhime device

Introduction

Chronic leg ulceration is defined as a deep skin loss below the knee with poor healing tendency. This frequent presentation in clinical practice most commonly occurs due to chronic venous insufficiency (CVI), chronic arterial insufficiency, or diabetes.[1] The evidence demonstrates that the frequency of CVI is ten times higher compared to peripheral arterial disease (PAD). In 92 cases per 100,000 patients every year, CVI leads to venous leg ulcers. It has been reported that these clinical manifestations are observed annually in about 0.1–0.3 % of the western population, increasing with age up to 2% of patients over the age of 80 years.[2] Generally, it affects about 1% of the middle-aged population and 3.6% of patients over 65 years of age, having significant psychosocial consequences.[1] All information about past and present medical conditions of the patient, physical examination, laboratory testing, or hemodynamic evaluation may help clinicians to determine a diagnosis as well as a type of leg ulceration and its cause.[3] This last medical tool allows us to assess arterial supply to leg by determining the Ankle-brachial Pressure Index (ABPI) using Duplex ultrasound.[4] Different endovenous interventions such as endovenous ablation of superficial reflux, thermal ablation and foam sclerotherapy are universally acknowledged techniques for reducing healing time of leg ulcers and increasing ulcer-free time. However, compression therapy still remains the gold standard in the management of venous leg ulcers.[5] Correctly applied compression therapy is useful for treating venous ulcers because it successfully prevents volume overload in the venous system,

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lowering pressure and leading to reduced pain and wound healing. Compression therapy includes three phases such as, edema reduction and wound healing, maintenance, and long-term prevention.[6] The evidence shows high ulcer recurrence rates in conservatively treated patients when compression therapy is not applied and venous hypertension is not controlled. According to epidemiological data, it may occur in 26–70% of patients.[3]

Patient and Methods

This study was conducted in Policlinic evi-MED in Gdynia in Poland from January 2019 to February 2019. After detailed information that her anonymity would be preserved, the individual in this case study has given written informed consent to publish the details of her case and her images. The study was approved by the Bioethics Committee of the Medical University of Gdansk, Poland (approval no. KB–1/18). The patient with venous leg ulcer was treated for four weeks with compression therapy using inelastic multicomponent compression bandages (Table 1); (Lohmann & Rauscher, Germany) and skin care (Octenisept®, Schülke; Dermopanten, Chema-Elektromet, Poland).

During the first week of therapy, bandages were re-applied twice daily (between 08:00 and 09:00 am and 13:00 and 14:00 pm), for three weeks every 24 h, on an ambulatory basis. The bandaging system was worn day and night. Each time the sub-bandage pressure was measured at B1 point (the point at which, the gastrocnemius muscle changes into its tendon) using the Kikuhime device (HPM-KH-01, TT Meditrade, Soro, Denmark) with sensor dimension of 30 × 38 × 3 mm[7] (Figure 1). In supine position it was always more than 35 mmHg and in standing position approximately 70 mmHg. After four weeks of therapy, when the ulcer was healed and a scab appeared, the patient was instructed to wear the adjustable compression wrap (CircAid Juxta-Lite™ standard legging compression wrap, Medi, Germany), while in the recurrence prevention phase, the patient was wearing the below knee compression stocking with open toe (Mediven plus, class 2, Medi, Germany). The ulcer area calculations at each step of therapy were carried out using CorelDraw 2018 with macro function.

Table 1 Short-stretch Bandage Materials

Trade Name	Length (Stretched)	Longitudinal Extensibility	Composition
Rosidal K	6 × 500 cm	~90%	100% cotton
Rosidal K	8 × 500 cm	~90%	100% cotton
Tg-tube	To be cut		67% cotton, 33% viscose
Rosidal soft	10 × 250 × 0.2 cm	Padding	100% polyurethane

Case Report

The patient was a 61-year-old woman with an approximately 2.5-year-old venous ulcer of her left leg due to CVI. At the start of compression therapy the ulcer area was approximately 20 cm^2. Her clinical history indicates that she suffered from hypertension, she was diagnosed with type 2 diabetes and she developed a post-thrombotic syndrome (PTS). During the physical examination, varicose ulceration of the left lower leg was found with the presence of serous-purulent contents, while the skin area around the wound was clean. Moreover, the trophic changes and lower leg edema were confirmed. Doppler ultrasound showed nonthrombotic vein lesions in superficial veins and deep venous system with efficient valves. The removal of small saphenous vein (SSV) and great saphenous vein (GSV) was observed, while additional GSV was winding, enlarged and inefficient in the segment when GSV drains from the medial malleolus to join the common femoral vein at the saphenofemoral junction (with vein diameter=18 mm). Additional GSV was inefficient and enlarged in the place where the dorsal vein of the big toe joins the dorsal venous arch of the foot, near complete recanalization of this inflow with post-thrombotic lesions was noted. Enlarged and incompetent leg perforator 6 cm above the medial malleolus was demonstrated on duplex ultrasound. Before referring to our clinic, the patient was treated only with Novate cream 0.05% (ICN, Polfa Rzeszów S.A., Poland), Mepilex® Border foam dressing 12.5 × 12.5 cm and Mepilex® Ag (Mölnlycke, Germany).

Results

At the start of therapy, the ulcer area obtained from computer calculations was approximately 20 cm^2. After one week of compression therapy, the beginning of the healing process was observed and the area of the wound with visible fragments of epidermal tissue was ~15 cm^2. In the last week of therapy, the scab was formed with the area of about 5 cm^2 (Figure 2).

The pressure values under compression bandages were measured and presented in Table 2. These results showed that on the first day of therapy, after five hours of wearing

Figure 1 Measurement of sub-bandage pressure using the Kikuhime device.

bandages in a standing position, the pressure dropped from 80 mmHg to 50 mmHg (37.5%), and overnight to the next day from 77 mmHg to 37 mmHg (~52%). After the third day of bandaging, it was observed that the pressure loss under bandages between 08:00 and 09:00 am and 13:00 and 14:00 pm stabilized as the limb edema was reduced. Bandages application was continued twice daily in the first week of therapy due to the presence of an oozing wound.

Discussion

Measuring the dorsal foot vein pressure is useful for determining the intravenous circulation in the lower limb and in a normal-sized adult person it should range from 80 to 100 mmHg in the standing position.[8,9] It was observed that in healthy patients the superficial venous pressure tends to fall below 30 mmHg during walking and is defined as Ambulatory Venous Pressure (AVP).[10] In the standing upright position, the calf muscle pump starts working and the subsequent muscle contraction by squeezing the veins, pumps blood from the limb against gravity toward the heart, while the presence of vein valves prevents reflux in the muscle relaxation phase. In most cases, patients showing symptoms of CVI have incompetent valves and cause of reflux, a smaller reduction in venous pressure than physiological is observed. This disorder is defined as ambulatory venous hypertension and leads to venous ulcer development.[8] Untreated or incorrectly treated long-lasting venous leg ulceration is still a medical challenge.[11] Noninvasive treatment options for venous leg ulcers include skin care, physical and pharmacological therapy as well as compression therapy. The latter still remains the gold standard used in the healing and recurrence prevention process.[12–15] The evidence showed that compression therapy participates in the ulcer healing process by reducing the amount of pro-inflammatory cytokines and matrix metalloproteinases as well as by increasing the amount of anti-inflammatory cytokine IL-1 Ra.[8] The main two parameters deciding the effectiveness of compression therapy are the pressure value exerted by the fabric of the compression garment or bandages on the affected leg and their elastic properties.[15–17] A correlation between body position and improving venous return to the heart by compression therapy has been demonstrated. It was proved that compression therapy by exerting constant pressure on veins leads to a reduction of vessel diameter and transmural pressure value what results in almost two-fold increase in flow rate. During lying position, constriction of superficial and deep veins are observed under the pressure equal 15 mmHg. Because, in the upright posture, these veins are slightly larger comparing to the lying position, higher pressure values such as 60–90 mmHg are required.[18,19] The first phase of compression therapy is focused on the

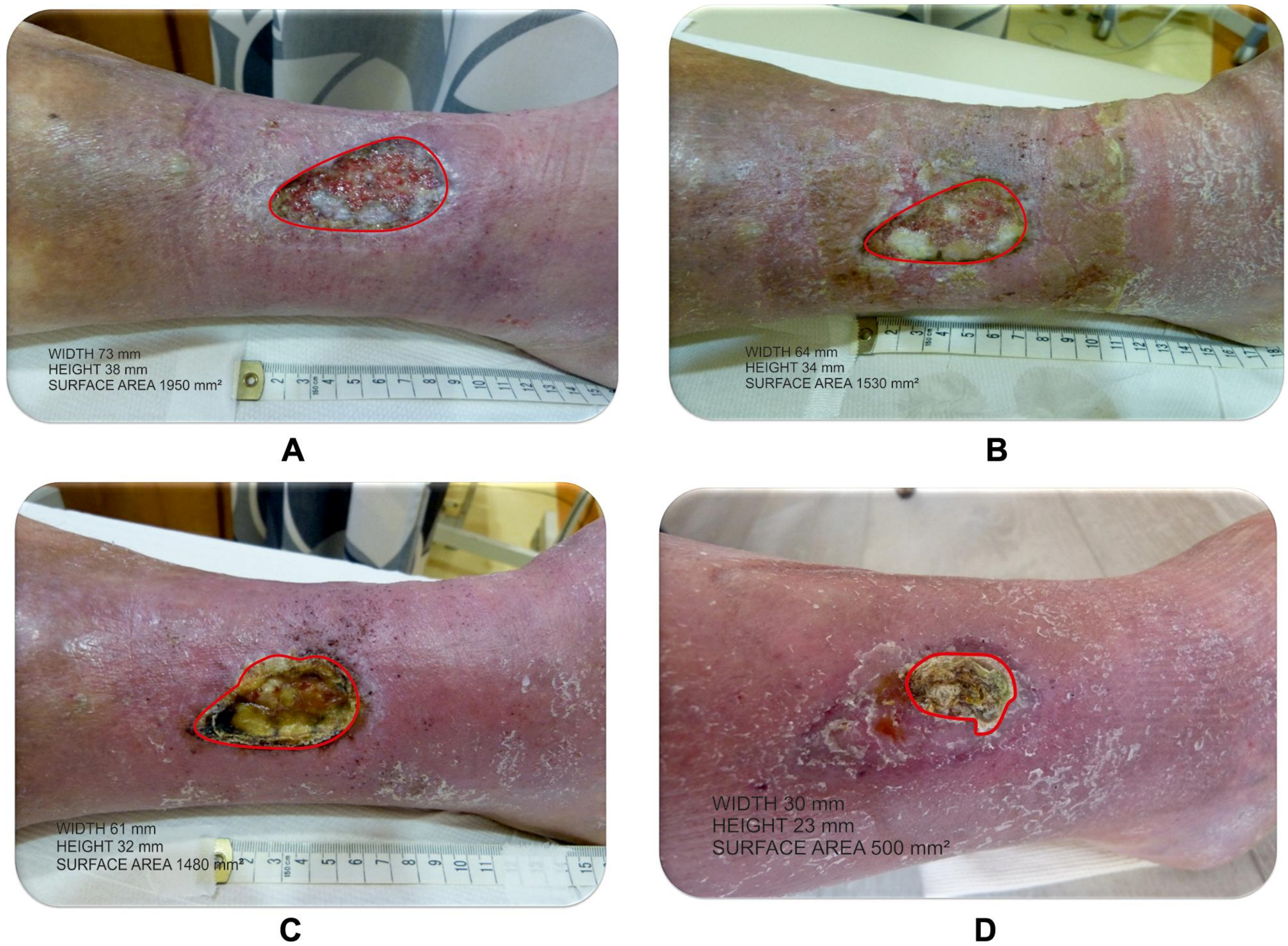

Figure 2 (**A**) venous leg ulcer at the medial ankle region in a 61-year-old female patient, (**B**) one week after starting compression therapy, (**C**) two weeks after starting compression therapy, (**D**) four weeks after starting compression therapy.

edema reduction and ulcer healing. Partsch et al in their study showed that only a strong compression (the pressure of 51 mmHg) exerted by inelastic short-stretch bandages is able to narrow both superficial and deep veins, while in the upright position under the pressure of 83 mmHg, the complete compression of these veins is observed.[19,20] In their study the authors aimed at measuring pressure values under different compression materials in patients with venous leg ulcers and demonstrated that the highest drop pressure was observed under inelastic short-stretch bandages mainly due to edema

Table 2 Pressure Values (mmHg) in Supine and Standing Positions Under Compression Bandaging System in the First Seven Days of Therapy Measured Using Kikuhime Device

Day	8–9 am		Before Re-application 13–14 pm		After Re-application 13–14 pm		After Night 8–9 am	
	Standing	Supine	Standing	Supine	Standing	Supine	Standing	Supine
1	80	66	50	25	77	64	37	21
2	77	65	55	33	79	65	47	32
3	71	55	54	32	74	59	45	30
4	73	57	56	33	77	63	49	33
5	75	63	59	36	72	56	48	33
6	77	64	61	39	75	63	49	32
7	72	57	57	35	70	54	47	31
8	75	62	59	35	71	54	50	33

volume reduction and patient's movement.[21] The loss of pressure equal to 25–50% of initial value in the passive standing position in two hours after bandage application has already been reported.[22] In a different study, Mosti and Partsch showed that despite a high pressure loss, inelastic short-stretch bandages in comparison with elastic stocking were able to maintain their hemodynamic effect after seven days of wearing.[23] Our results (Table 2) showed that on the first day of therapy, after five hours of wearing bandages in a standing position, the pressure dropped from 80 to 50 mmHg (37.5%), and overnight to the next day from 77 to 37 mmHg (~52%). In the study evaluating the long-term (over seven days) stability of pressure levels under different compression bandage systems, in seven hours after application of inelastic short-stretch bandages a pressure drop of 50% was observed. Moreover, none of the patients participating in this study was able to wear inelastic short-stretch bandages until the end.[24] Published data suggest that the pressure loss under inelastic short-stretch bandages determines the time of their re-application.[21] On the basis of these results, on the first week of therapy, in our patient bandages were re-applied twice daily to achieve a hemodynamic effect. However, we did not use any special pad directly on the oozing wound to avoid uncontrolled local change in pressure value under it, what resulted in a more frequent bandages change to maintain hygienic conditions. Numerous studies showed that, despite the fact that all bandage systems were applied by experienced medical staff, obtaining the the correct pressure level was not possible without its control by a pressure measuring device such as PicoPress®.[24] Many authors emphasize that the use of pressure indicators may be helpful in the proper control of pressure under bandages, as well as the education of the medical staff and continuous improvement of their qualifications are needed in the future.[21,24] In our experiment, each time the sub-bandage pressure was measured using Kikuhime device and was equal approximately 70 mmHg. During the last three weeks of therapy, as it is recommended a multicomponent system was re-applied on a daily-basis (every 24 h).[20] Kikuhime device used in many scientific studies was shown to be a suitable and reliable tool to measure sub-bandage pressure.[25] Numerous studies have demonstrated that compression therapy using bandaging systems is successful in the management of patients with leg ulcers. Despite this, it is not strictly specified what type of compression and sub-bandage pressure give the best results in ulcer healing.[26] However, evidence suggests that using a compression system showing a relatively low pressure during rest (sleeping position) corresponds to better patient tolerance. In the upright position, cause of great increase in hydrostatic vascular pressure, higher pressure values are required.[10,26] Such change in pressure occurring between both supine and standing positions is defined as statistic stiffness index (SSI) and its value over 10 is reserved for inelastic compression systems.[26] Milic et al, in a randomized and prospective study, showed that the best ulcer healing rate was observed in the group with the highest pressure values under compression system (87.4 mmHg) and the median healing time of 14 weeks.[26] Scotton et al, in the series of 94 patients with leg ulcers, treated approximately 70% with elastic bandages and 40% with an Unna boot showed that ulcers areas were significantly reduced in 12 months of therapy.[27] Nevertheless, it has been proved by various authors that compression systems composed of inelastic materials better control deep venous reflux than elastic bandages and lead to faster healing of venous leg ulcers.[16,28] Margolis et al, in a retrospective cohort study, suggested the influence of the ulcer duration and its area on the healing process in patients treated with compression for 24 weeks.[29] In many studies, it has been proved that in small area (<5 cm^2) and short-time ulcers (less than six months) 95% are curable in less than 24 weeks, while much more time to close the extensive ulcer is required.[3]

In our study, the 2.5-year-old ulcer with the area of about 20 cm^2 was completely healed and a scab with the area of about 5 cm^2 appeared within four weeks without the use of antibiotics. It would seem that the key to success was not only the use of inelastic multicomponent bandages with proven effectiveness, but above all frequent bandage renewal in the first week of therapy and constant sub-bandage pressure control using the Kikuhime device. Due to high recurrence rate of venous leg ulcers reaching 26–69% of patients within a year, it is equally important to properly protect the patient in the maintenance phase. In our study, the patient has worn a Velcro-adjustable compression device (CircAid Juxta-Lite™ standard legging compression wrap) which is considered an innovative alternative for bandaging systems. Moreover, it saves cost in dressings and because of not limiting joint movements, Juxta-Fit increases patient mobility and thus improves their quality of life.[30] This adjustable compression wrap was worn until the time the scab was completely removed. After that, the patient started to wear the below knee compression stocking class 2 with open toe.

Conclusions

The final effect of the venous leg ulcer treatment using compression depends on many factors, including the type of material used, the size of the ulcer, its duration, patient coexisting diseases, or the therapist's experience. The pressure under the bandages should be adjusted to the individual needs of the patient.[8] Many studies have shown that this is not an easy task and few therapists, despite many years of experience, were able to apply bandages under the enough pressure.[31,32] This suggests that pressure control under bandages plays an important role in the therapy of such patients and that some reliable instruments such as the Kikuhime device should be used routinely. The results obtained in our study allow us to suppose that not only high pressure under bandages of approximately 70 mmHg, but also their frequent renewal, twice a day in the first week of therapy contributed to faster ulcer healing in four weeks.

Abbreviations

CVI, chronic venous insufficiency; PAD, peripheral arterial disease; ABPI, ankle-brachial pressure index; PTS, post-thrombotic syndrome; SSV, small saphenous vein; GSV, great saphenous vein; AVP, ambulatory venous pressure; SSI, statistic stiffness index.

Disclosure

The authors report no conflicts of interest in this work.

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