

Venous ulcer treatment requires inelastic compression

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Keywords

Venous leg ulcers, ulcer healing rate, compression therapy, elastic compression, inelastic compression, venous reflux, venous pumping function, venous hemodynamic impairment

Summary

Leg ulcers have a venous pathophysiology in the vast majority of cases (1–4). Superficial or deep venous insufficiency and deep vein obstruction produce ambulatory venous hypertension due to venous reflux and venous pumping function impairment. The impaired venous hemodynamics is the key pathophysiologic mechanism leading to skin damage through several intermediate steps. Fibrin cuff formation around the microvessels, impairing gases (O_2 , CO_2) exchange (5), white cells entrapment (6) causing skin necrosis, growth factors inhibition (7) producing a stagnation of the healing process have been considered involved in ulcer onset and maintenance. The treatment of venous leg ulcers (VLU) must be based on the correction of the hemodynamic impairment which can be achieved conservatively by means of compression therapy, walking and leg elevation or by means of invasive procedures (open surgery, endovascular procedures as endovenous Laser ablation, radiofrequency, foam sclerotherapy, conservative hemodynamic treatment). Compression therapy is frequently considered the first treatment option and it is the only therapeutical procedure which achieved the grade 1A in most recent guidelines or consensus documents (8–10). The crucial point is choosing the most effective

compression modality. There are clear evidences that inelastic is more effective than elastic material in counteracting the venous hemodynamic impairment (11–14) that should „ensure“ a superior effectiveness in promoting a higher healing rate of VLU, which are due to venous hemodynamic impairment. When looking at evidences we have some data showing that the higher the compression pressure the higher the healing rate (9, 15–17) and this is clearly in favors of inelastic bandages which exert a much higher pressure than elastic materials. On the other side we have many papers claiming a greater effectiveness of elastic stockings or elastic bandaged compared with inelastic material (18–30). Nevertheless studies comparing elastic and inelastic devices have so many flaws that their conclusions are hard to trust (31). Aim of this work is providing updated information about compression therapy effects on venous hemodynamic and the most effective compression modality to achieve the best outcome in VLU treatment.

Schlüsselwörter

Ulcus cruris venosum, Heilungsrate von Ulzera, Kompressionstherapie, elastische Kompression, inelastische Kompression, venöser Reflux, venöse Pumpfunktion, venöse hämodynamische Beeinträchtigung

Zusammenfassung

Beinulzera haben in der überwiegenden Mehrzahl der Fälle eine venöse Pathophysiologie (1–4). Eine oberflächliche oder tiefe venöse In-

suffizienz und eine tiefe Venenobstruktion führen zu einer ambulanten venösen Hypertonie aufgrund einer venösen Reflux- und venösen Pumpfunktionsstörung. Die gestörte venöse Hämodynamik ist der wichtigste pathophysiologische Mechanismus, der durch mehrere Zwischenschritte zu Hautschäden führt. An der Ulkus-Entstehung und Ulkus-Unterhaltung scheinen beteiligt zu sein: Fibrin-Manschetten-Bildung um die Mikrogefäße, Beeinträchtigung des Gasaustauschs (O_2 , CO_2) (5), Einklemmung weißer Zellen (6) (verursacht Hautnekrose), Hemmung der Wachstumsfaktoren (7), welche eine Stagnation des Heilungsprozesses verursacht. Die Behandlung von venösen Beinulzera (VLU) muss auf der Korrektur der hämodynamischen Beeinträchtigung beruhen, die konservativ mittels Kompressionstherapie, Gehen und Beinheben oder mittels invasiver Verfahren erreicht werden kann (offene Chirurgie, endovaskuläre Eingriffe als endovenöse Laserablation, Radiofrequenz-, Schaum-Sklerotherapie, konservative hämodynamische Behandlung). Die Kompressionstherapie wird häufig als erste Behandlungsoption angesehen und ist das einzige therapeutische Verfahren, das in neueren Leitlinien oder Konsensusdokumenten die Stufe 1A erreichte (8–10). Der entscheidende Punkt ist die Auswahl der effektivsten Kompressionsmodalität. Es gibt eindeutige Hinweise darauf, dass unelastisches Material wirksamer ist als elastisches Material, um der venösen hämodynamischen Beeinträchtigung entgegenzuwirken (11–14), die eine höhere Wirksamkeit bei der Förderung einer höheren Heilungsrate von VLU gewährleisten sollte, die auf eine venöse hämodynamische Beeinträchtigung zurückzuführen ist. Wenn wir uns die Evidenz anschauen, haben wir einige Daten, die zeigen, dass je höher der Kompressionsdruck ist, desto höher die Heilungsrate (9, 15–17). Dies spricht eindeutig für unelastisches Material, welches einen viel höheren Druck ausübt als elastische Materialien. Auf der anderen Seite

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Die Behandlung von venösen Ulzera erfordert eine unelastische Kompression

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haben wir viele Studien, die eine größere Wirksamkeit von elastischen Strümpfen oder elastischen Bandagen im Vergleich zu unelastischem Material (18–30) behaupten. Dennoch haben Studien, in denen elastisches und unelastisches Material verglichen werden, so viele Mängel, dass ihre Schlussfolgerungen schwer zu glauben sind (31). Ziel dieser Arbeit ist es, aktuelle Informationen über die Auswirkungen der Kompressionstherapie auf die venöse Hämodynamik und die effektivste Kompressionsmodalität bereitzustellen, um das beste Ergebnis bei der VLU-Behandlung zu erzielen.

Impaired venous hemodynamics

The venous pressure in the legs depends on body position. It is very low in supine position, it increases in the sitting position and it is maximal in standing position (about 70–80 mm Hg) both in normal individuals and in patients with venous disease. In normal subjects, muscle pumps and valvular function fragmenting the blood column get a significant pressure decrease to 20–30 during active movements (e.g. walking) (32). In patients with venous insufficiency, valves failure cause the column of standing blood in the vein to remain unbroken even during ambulation. Under these circumstances a minimal hydrostatic pressure decrease occurs or it can even increase during and immediately after ambulation in case of venous obstruction: this is what we call Ambulatory Venous Hypertension (AVH), which causes venous congestion.

Effectiveness of compression therapy in counteracting AVH

Compression therapy increases the transmural pressure increasing the extravascular pressure so narrowing or occluding the leg veins. This is the prerequisite for the hemodynamic effectiveness of compression therapy but venous narrowing-occlusion

can be possible only by applying an external pressure of the same magnitude or higher than intravenous pressure. Actually, it has been shown that due to different venous pressure in different body positions, a low external pressure in the range of 20 mm Hg is able to narrow or occlude the veins in the supine position, but the compression pressure must rise to 50 mm Hg in the sitting position and to close to 70–80 mm Hg in the standing position (33, 34) (that was defined as very strong in a recent consensus paper) (35) to exert the same effect. Such high external pressure approaching or overcoming the intravenous pressure may produce a vein occlusion at every step during physical activity so restoring a kind of valve mechanism which reduces the AVH (14) by reducing the venous reflux (10, 11) and increasing the calf pumping function (12, 13).

Which compression material is able to counteract AVH

All compression devices are basically made up with elastic or inelastic material. When wrapped on the leg they exert a compression pressure which, according to the Laplace law, depends on the stretch applied to the bandage, the number of turns and the radius of the leg-segment (36).

The two materials have completely different physical characteristics.

The elastic or long stretch material (represented by elastic stockings or elastic bandages with an extensibility higher stretch than 100%) gives way to the muscle expansion that occurs during standing and physical activity, resulting a very low pressure difference between the resting and standing or walking conditions. This difference, that was named Static Stiffness Index (SSI), is lower than 10 mm Hg with elastic materials (37, 38). Also the difference between diastolic and systolic pressure during muscular activity, responsible of the so called „massaging effect“ (39) of compression devices over the calf muscle, is very low. These characteristics are consistently maintained independently on applied pressure and material (if elastic stockings

or elastic bandages) producing quite a sustained pressure. In addition, elastic material tends to regain its initial length when stretched and this „return force“ is directly related to the stretch applied to the bandage. The „squeezing effect“ of a too stretched elastic material can be painful and not tolerated by the patients after a short time from application. As a consequence, when properly stretched, an elastic bandage will exert a supine pressure of 30–40 mm Hg. This pressure will rise by less than 10 mm Hg in standing position and will never approach the intravenous pressure resulting unable to narrow or occlude the veins and to exert a hemodynamic effect (► Fig. 1, 2). When we want to use elastic material to exert a very strong pressure in standing position, necessary to occlude the leg veins, elastic bandages must be applied with strong stretch (► Fig. 3) or several elastic stockings must be superimposed: in both these circumstances also the supine pressure will be very strong. The bandage will exert a very strong continuous pressure, which, in addition to the „squeezing effect“ of these materials, will make very painful and poorly tolerated the compression system, as reported.

Advantage of elastic materials: they are easy to apply, usually as single component.

The inelastic material (short stretch or inextensible bandages, Velcro® devices, hybrid pumps) exerts its effect by resisting the increase of muscle volume during muscular contraction in standing position and during physical activity (the leg will give way) so producing higher peak pressures when standing or walking compared with elastic, long-stretch devices. Inelastic material doesn't have any elastic fiber and doesn't have any return force: it doesn't „squeeze“ and can be applied with full stretch.

The modern composite, multilayer and multicomponent, inelastic bandages, including a padding layer with the inelastic material as last component, exert a relatively low and well tolerated pressure at rest but a much higher pressure often higher than 70 mm Hg during standing and walking. The SSI is always >10, which characterizes the inelastic range. The intermittently strong or very strong pressure peaks during muscular exercise will over-

come the intravenous pressure intermittently occluding the vein and so restoring a kind of valve mechanism (14) (► Fig. 4).

In a few words the inelastic material is able to adapt to the body position by exerting a relatively low pressure in the resting position (comfortable) and a strong or very strong pressure in standing position and during muscle activity (effective) coming close to an ideal compression device (40).

Unfortunately the multilayer, multicomponent inelastic bandages are difficult to apply and require expert and well educated personnel. In a series of papers it was demonstrated that only from 10 to 60% (depending on the paper) of expert healthcare providers treating ulcer patients were able to apply the target pressure with different inelastic bandages (41–45).

Hemodynamic effects of compression materials

The different physical properties of elastic and inelastic materials result in completely different effects on venous hemodynamics.

Inelastic is significantly more effective than elastic material in:

- reducing venous reflux both in patient with deep venous (10) or superficial venous incompetence (11).
- improving the venous pumping function severely reduced in venous insufficiency (12–13).
- reducing AVH (14).

Inelastic material is able to reduce venous reflux and increase venous pumping function even at a low/mild pressure range of 20–40 mm Hg (46) which has an important implication when inelastic compression necessary to improve venous hemodynamics loses pressure or must be applied with reduced pressure in patients mixed artero-venous ulcers.

Finally inelastic material maintains its hemodynamic effect overtime despite of a significant pressure drop as the stiffness of the bandage is well maintained as proved by the unchanged SSI and “massaging effect” (47).

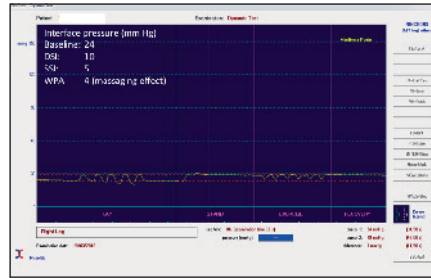


Fig. 1 Elastic stocking compression pressure record. Compression pressure increase by dorsiflexions, standing up and walking is very small: sustained pressure. DSI: Dynamic Stiffness index is the difference between diastolic and systolic pressure performing foot dorsiflexions in supine position; SSi: Static Stiffness Index is difference between standing and supine position. WPA: walking pressure amplitude is the difference between systolic and diastolic pressure while walking.

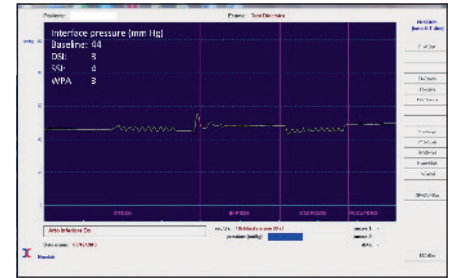


Fig. 2 Elastic bandage compression pressure record. The dynamic characteristics are the same as elastic stockings or kits.

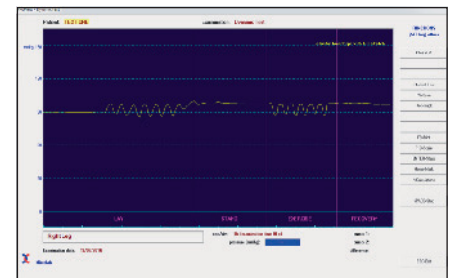


Fig. 3 Pressure curve of an elastic bandage applied with high stretch to exert a very strong standing pressure. It can be noticed that also the supine pressure is very strong due to the physical characteristics of elastic material. This strong and sustained pressure is painful and intolerable by the patient.

Which compression material for VLU

No doubt that inelastic material, exerting strong or very strong pressure, is an effective treatment modality to get the highest healing rate when looking for the best treatment option.

When correctly applied to exert a strong pressure inelastic bandages can achieve an ulcer healing rate close to 100% in three months treatment(48).

Based on clinical and hemodynamic data, is not easy to understand why many reports claim the superiority of elastic (both elastic stockings and elastic bandages) compared to inelastic material in improving the VLU healing rate (17–30). Nevertheless it is important to underline many methodological flaws of these studies.

Compression therapy exerts its effects by providing compression pressure to the leg. Compression pressure is the dosage of compression therapy but, contrarily to any other field in medicine, the compression dosage has almost never been measured and reported when dealing with compression therapy even if compression pressure measurement is easy to perform with accurate and cheap devices (49, 50).

Not measuring compression pressure it is impossible to know if the bandages were correctly applied. They could have been



Fig. 4 Pressure curve of an inelastic bandage exerting a supine pressure of 60 mm Hg. Compression pressure increase by dorsiflexions, standing up and walking is very high: intermittent compression with high pressure peaks that overcome the intravenous pressure (represented by the red line) restoring a kind of valvular function.

applied too stretched, so being painful and dangerous, and forcing the patients to remove them, or too loose, so being ineffective.

In addition not measuring the pressure or calculating the SSI produced an amazing mistake in almost all studies comparing elastic and inelastic bandages.

In these studies (17–24) the prototype of elastic material is the so called Four Layer Bandage which was considered elastic by definition as it is made up of four different elastic components. Nevertheless measuring supine and standing pressure and calculating the SSI of the final bandage, it was possible to show that SSI is in the inelastic range. It may happen that the superimposition of different components and the friction between the layers change the elastic properties of the final bandage, making it a highly stiff device (51). In conclusion all these studies report a comparison between two different inelastic compression devices and the reported different outcomes in terms of healing rate may depend on of the greater experience of dedicated personnel in applying the Four Layer Bandage.

Also the second comparison, inelastic bandages vs elastic stockings, has many major flaws.

First of all it has to be underlined that the elastic stockings taken into consideration for comparison are actually elastic kits or tubular devices exerting a supine pressure of 40 mm Hg or more and higher stiffness compared to a single stocking (although always in the range of elastic material) due to the friction between the 2 components (25–30). In addition the subbandage pressure was, once again, not measured and the skillness of “bandagers” not reported. In these studies we may roughly know the pressure of elastic kits which is declared by the producer but we do not have any information on the pressure of inelastic bandage that can be extremely variable (52, 53) as it only depends on the health personnel skillness which is usually poor (41–45). As a consequence it could well be that a good elastic kit, also named “ulcer kit”, was compared with a poorly applied bandage.

In a few studies where compression pressure is measured (16, 29, 54) it was demonstrated that the higher the pressure the higher the healing rate and this conclusion is in favor of inelastic bandages even despite of the conclusion of author's papers. In fact, as well proved, inelastic bandages, when correctly applied, exert a compression pressure definitely higher than elastic material.

Velcro devices may replace inelastic bandages providing an effective and cost effective VLU treatment modality.

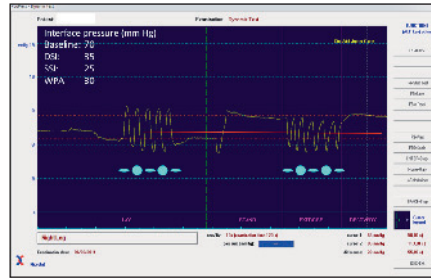


Fig. 5 Pressure curve exerted by a Velcro device designed for ulcer treatment. Also with this device compression pressure increase by dorsiflexions, standing up and walking is high overcoming the intravenous pressure and restoring a kind of valvular function.

When considering indications for compression in VLU treatment, it is also important to consider that compression therapy is not only generally poorly applied but also largely underused even in the western countries, ranging from 15 to 53% of patients who would need compression (55, 56). Many reasons can explain this lack of implementation of compression therapy in VLU treatment being lack of education in applying inelastic bandages, absence of self-confidence and fear to produce further skin damages some of the most important reasons.

Nowadays we need to consider another treatment option: the adjustable Velcro® compression devices (AVCD) which are becoming more and more widespread. These devices have a high SSI (so acting as inelastic material) when applied with strong pressure (► Fig. 5). Only for one of these devices (CircAid, Medi, Bayreuth, Germany) we have data showing it is effective in terms of improvement of the impaired venous hemodynamics (57, 58). At the same time, it is very easy to use and can be applied and re-adjusted even by the patients themselves after a very short wearing and education time (59, 60) so allowing self management and considerable cost savings. In addition this device has been reported to be more effective and cost effective in achieving VLU healing when compared with Four Layer bandages or with Unna Boot bandage (61–63). Finally it was proved to be more effective than inelastic bandages in phlebo-lymphedema treatment (59, 64).

Ulcer recurrence prevention

VLU may recur and the recurrence rate may be as high as almost 40% (65). Surgical correction of superficial venous incompetence was shown to prevent ulcer recurrence significantly more effectively than compression therapy (66, 67). Compression therapy is anyway effective in VLU recurrence prevention even if it must be considered as second choice. Elastic stockings are used in this indication with the highest tolerable compression (68). Compliance to compression by elastic stockings is considered even more important that compression pressure (69).

Conclusions

Compression therapy is the milestone of VLU treatment. Inelastic compression exerts a strong pressure and strong pressure peaks and can restore a kind of valve mechanism so significantly improving the impaired venous hemodynamics. It was proved to be the most effective compression modality to increase the VLU healing rate. Elastic material (bandages or stockings) are claimed to be as or more effective than inelastic material. The reported studies unfortunately are burdened with significant methodological flaws making their conclusions not trustable. Inelastic materials include inelastic bandages and the Velcro® devices. There are some evidences that one of these devices is even more effective than inelastic bandages to increase the ulcer healing rate and to treat venous edema and lymphedema. At the same time the device is easy to use and can be directly managed by the patients allowing cost savings. These data will be hopefully confirmed by new studies.

Conflict of interest

The author declares no conflict of interest.

Ethical guidelines

The manuscript was prepared according to national guidelines and the current Declaration of Helsinki.

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