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Abstract

Compression therapy is extremely effective in promoting ulcer healing. Which material to use, if elastic or inelastic, is still a matter of debate. This paper will provide an overview on the recent findings in compression therapy mainly for venous or mixed ulcers which are the great majority of leg ulcers. In this paper it will be demonstrated that inelastic compression has been proved to be significantly more effective than elastic compression in reducing venous reflux, increasing venous pumping function and decreasing ambulatory venous hypertension. In addition it is comfortable, well accepted by patients and achieved an extremely high healing rate in venous ulcers. With reduced pressure inelastic compression is able to improve venous pumping function in patients with mixed ulcers without affecting but improving the arterial inflow. It will be also clearly shown that studies claiming a better effect of elastic compression compared to inelastic in favouring healing rate have significant methodological flaws making their conclusions at least doubtful. In conclusion inelastic- is significantly more effective than elastic compression in reducing ambulatory venous hypertension which is the main pathophysiological determinant of venous ulcers and demonstrated to be very effective in getting ulcer healing. New multicentric, randomized and controlled studies, without methodological flaws, will be necessary to prove that elastic- is at least as effective as inelastic compression or, maybe, more effective.

Keywords

Venous ulcer, mixed ulcer, inelastic compression, elastic compression, ulcer healing rate

Introduction

Compression therapy is extremely effective in promoting ulcer healing. A Cochrane review[1] reported that, in favouring venous ulcer leg (VLU) healing compression therapy is better than no compression, that multi-component systems are more effective than single component systems and, finally, that a multi-component systems containing an elastic bandage appear more effective than those composed mainly of inelastic constituents.

Compression therapy is so effective in ulcer treatment that it was given a Grade A in Evidence Based Medicine.[2]

In conclusion the effectiveness of compression therapy in ulcer treatment is well established. Which material to use to apply compression is still a matter of debate and elastic or inelastic materials are used according to personal belief due to lack of objectives data coming from multicentric, controlled, randomized trials.

Aim of this work is to provide an overview on the recent findings in compression therapy so that deciding which material to use could be more evidence-based and less to personal belief. As the great majority of leg ulcers are due to venous or mixed (venous and arterial) pathophysiology this overview will deal mainly with venous and mixed leg ulcer.

Venous leg ulcer, compression pressure and patient's compliance

VLU healing is directly correlated with compression pressure. In a recent paper[3] patients with venous

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ulcers were randomized to treatment with elastic bandages (EB) exerting three pressure ranges: 36–54 and 74 mm Hg. The third group treated with the strongest compression pressure showed the greatest healing rate which was lower in the second group and even lower in the last group treated with the lowest compression pressure. These outcomes confirm the statement of a previous Cochrane review:[4] compression with strong pressure is more effective than compression with low pressure.

A strong compression pressure is necessary to counteract the high ambulatory venous pressure in patients with VLU. A compression pressure strong enough to overcome the intravenous pressure may restore a kind of valve mechanism[5] so reducing ambulatory venous hypertension (AVH) which is the main responsible for ulcer formation.

Venous pressure in the lower leg equals, by physics law, the height, in centimetres, of a water column from the right heart to the lower leg. Water centimetres correspond to mm Hg (1,359 cm $H_2O = 1$ mm Hg). When transforming water centimetres in mm Hg, the average venous pressure at ankle level is about 70 mm Hg. A compression pressure higher than 70 mm Hg is necessary to compress the lower leg veins so reducing the AVH.

This was confirmed by studies with Duplex scanner[6] and Magnetic Resonance Imaging[7] showing venous occlusion of the lower leg by a compression pressure higher than 70 mm Hg.

Stretching the bandage is necessary to get such a strong pressure as the bandage pressure mainly depends on bandage tension and bandage turns number according to Laplace Low.[8] Every material, when firmly stretched may exert such a strong pressure. The main problem of compression therapy is exerting a strong but, at the same time, comfortable pressure as the patients will not tolerate a painful compression.

Inelastic bandages (IB) combine a relatively low and comfortable pressure at rest with a standing pressure strong enough to overcome the intravenous pressure and to restore the so called "valve mechanism".[5] Therefore IB is effective in reducing ambulatory venous hypertension in standing position and during walking (Figure 1). EB exerts a standing and working pressure which is only slightly higher than supine pressure (Figure 2) and never strong enough to overcome the intravenous pressure and significantly improve venous hemodynamics. If applied with strong stretch (Figure 3) in order to exert a strong pressure able to narrow/occlude the venous diameter, EB exerts a very strong pressure not only in standing but also in supine position. This strong and sustained pressure is painful and not tolerated by patients in the clinical setting. Actually, in his third group of patients treated by EB exerting a very strong pressure, Milic reported that more than one out of five patients didn't tolerate the applied compression.[3]

Elastic and inelastic material: hemodynamic effects

Due to their completely different pressure ranges, IB has been proved to be significantly more effective than EB in reducing venous reflux in patients with deep[9] and superficial[10] venous insufficiency. Venous reflux, measured by Air Plethysmography[9] and Duplex scanner,[10] was significantly more reduced by IB when applied with a supine pressure of 20 and 40 mm Hg. Applying the material with a strong supine pressure of 60 mm Hg, both bandages are almost equally effective but EB is painful and not tolerated for long periods.[10]

IB is more effective than EB also in increasing the venous pumping function as reflected by Ejection Fraction (EF) from the lower leg.[11] It is effective also when applied with low and moderate pressure and not only with strong pressure.[12] IB is effective also after some days despite of its significant pressure loss.[13] In fact mainly the supine pressure falls down while the standing pressure is better maintained overtime. The pressure peaks and the massaging effect (the difference between diastolic and systolic pressure) during walking contribute to maintain IB effectiveness on venous pumping function.

Elastic compression, mainly elastic stockings (ES) or elastic kits (EK), are claimed to be effective in improving the microcirculatory flow and favour the ulcer healing through a positive effect at microcirculatory level even if they have a poor effect on venous hemodynamic impairment. Actually strong compression of 60 mm Hg was shown to be more effective than low pressure in improving microcirculatory flow.[14] Once again IB may easily exert this pressure range without provoking pain or discomfort; ES or EK never reach this pressure level and EB can exert 60 mm Hg only when strongly stretched so causing discomfort or pain.

Clinical effectiveness of inelastic bandage in venous ulcers treatment

IB are very effective in promoting ulcer healing. In a comparison between two inelastic materials applied with a measured pressure higher than 50 mm Hg and recorded for all the wearing time, both materials were extremely effective in ulcers treatment favouring the ulcer healing within 12 weeks in 92% of patients.[15] Seven remaining patients healed shortly afterward and only one dropped out because of ulcer infection.

The effectiveness of this compression modality was associated with an high compliance and QoL

Figure 1. Inelastic bandages exert a comfortable supine pressure of 40 mm Hg. With dorsiflexions in supine position the exerted pressure rises to 100 mm Hg; when the patient stands up the pressure increases to 80 mm Hg and with tip-toeing in standing position the pressure oscillates between 50 and 90 mm Hg. If the intravenous pressure is about 70 mm Hg (red line) the compression pressure overcomes this pressure with every muscle exercise so producing intermittent vein occlusion simulating a kind of artificial valve mechanism.

improvement as all patients referred a significant reduction of pain ulcer-related a few weeks after treatment started.

Elastic or inelastic compression in venous ulcer treatment?

IB is more effective than EB in improving the impaired venous hemodynamics in patients with venous disorders, without any doubt and showed an impressive clinical effectiveness in promoting ulcer healing. Nevertheless there are some comparative studies claiming that EB and ES are more or, at least, as effective as IB in promoting ulcer healing.[16–18] Unfortunately in almost all trials comparing IB with EB and IB with ES the pressure exerted by the compression devices was not measured. Compression pressure represents the dosage of compression and its measure is mandatory when we compare different compression devices and we want to get outcomes of scientific relevance; furthermore compression pressure can provide some information on bandage application, if it was correct or too loose or too thigh.

The lack of compression pressure measurements in trials on compression therapy represents a major flaw in these studies leading to mistakes and misinterpretation of outcomes.

For instance the so called 4-Layer, made up with four elastic components, has been always considered an EB. But when finally pressure and stiffness were measured in vivo, the stiffness of this bandage turned out to be in the same range as IB. As a consequence, all studies reporting a comparison between IB and EB and considering the 4-Layer as the prototype of an EB, actually compared two IBs. The conclusion coming from these studies claiming the superiority of EB when compared with IB is obviously wrong.

The conclusions of studies in favour of ES, when compared with IB in ulcer treatment, are even more misleading. When compression pressure is not measured we may know approximately the pressure of the ES because it is declared by the manufacturer but we do

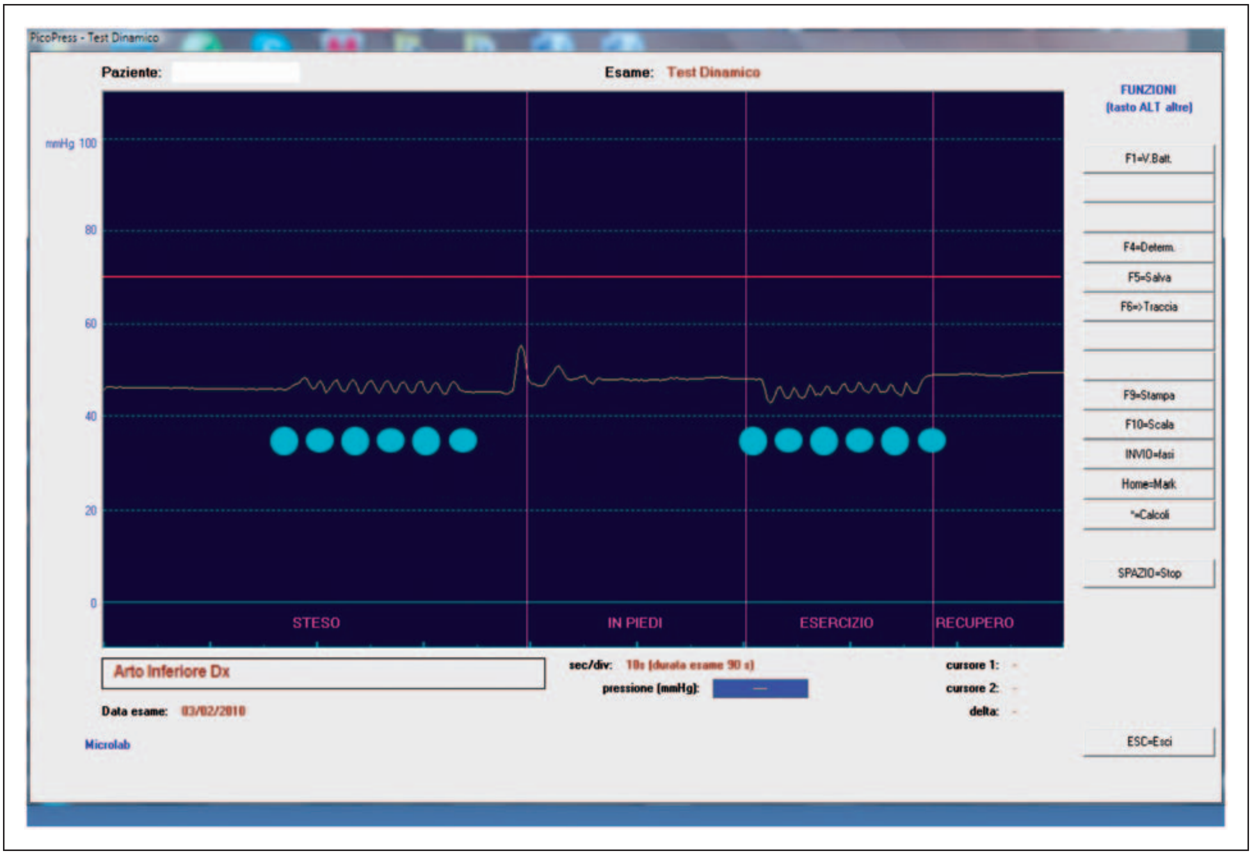


Figure 2. Elastic bandage are applied with the same supine pressure but the pressure peaks during muscle exercise are very low and they never overcome the intravenous pressure (red line). Elastic bandage has a minimal effect on venous diameter.

not know anything about the pressure of the bandage which can be extremely variable,[19] both intra and inter bandage applicator, as it mainly depends on the stretch applied to the bandage.

As a consequence we cannot have any idea on compression pressure of a bandage as well as we have no idea on bandage applicator expertise, bandage slippage, rolling, strangulation and other unwanted effect.

When such studies report better outcomes with ES compared to IB the suspicion that a good ES was compared with a poorly applied IB is very strong.

In some papers[3,20–22] the pressure exerted by the compression devices was measured.

In the first study[3] comparing the influence of three pressure ranges on ulcer healing, the authors have clearly shown that the best results were obtained in the group treated by the highest compression pressure.

In the second study[20] a very loosely applied inelastic bandage exerted a pressure which was lower than that exerted by an EK in every body position (supine, sitting and standing). It is not surprising that the EK achieved a greater effectiveness in promoting ulcer healing under these circumstances.

In the third study[21] a control group treated by EB was compared with a treatment group in which an elastic tubular device was added to the same EB. The interface pressure was obviously higher in the treatment group and the healing rate was significantly higher in this group than in the control group.

In the fourth study in which pressure measurements are reported[22] an ES was compared with an IB exerting a much higher interface pressure and the healing rate was much higher in the bandage group.

The common conclusion of these four studies is, again, that the higher the pressure the higher the healing rate. This conclusion is clearly in favour of IB that, when correctly applied, exerts a compression pressure definitely higher than ES or EK.

Compression in mixed ulcers

About 15–20% of patients with VLU have a reduced ankle brachial pressure index (ABPI) causing retarded healing. In these mixed ulcers compression could improve venous haemodynamics but also reduce arterial inflow. To define a safe range of compression pressure able to improve the venous hemodynamics and, at

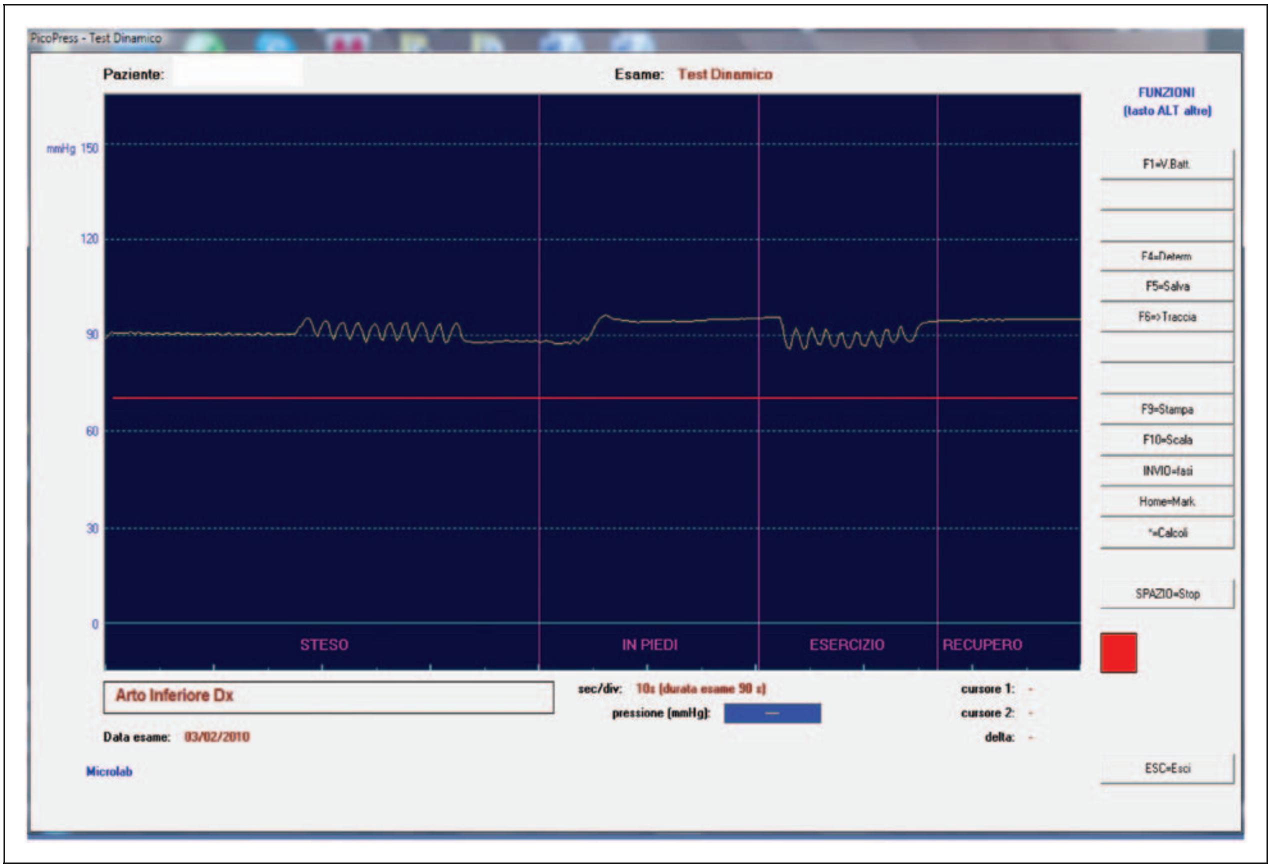
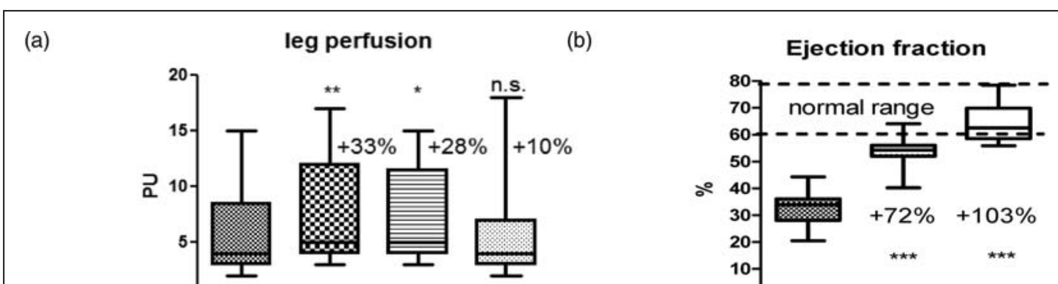


Figure 3. When strongly stretched to achieve a very strong standing pressure able to occlude the vein lumen the elastic bandage will exert a very strong pressure also in supine position. This very strong and sustained pressure is painful if applied for long period of time.



	baseline	20-30	31-40	41-50
Minimum	2.000	3.000	3.000	2.000
25% Percentile	3.000	4.000	4.000	3.000
Median	4.000	5.000	5.000	4.000
75% Percentile	8.500	12.00	11.50	7.000
Maximum	15.00	17.00	15.00	18.00

	0	20-30	31-40
Minimum	20.50	40.20	55.90
25% Percentile	28.10	52.00	58.60
Median	33.90	54.30	62.60
75% Percentile	36.10	56.00	69.90
Maximum	44.30	64.10	78.50

Figure 4. (a) Peri-wound skin perfusion, assessed by LaserDopler fluxmetry, increases by a small but significant amount compared to baseline perfusion, with low compression pressure in the range of 20–30 and 30–40 mm Hg. Increasing the pressure to 40–50 mm Hg, skin perfusion starts to fall down but it is still higher than baseline perfusion although the difference is not significant. (b) With this low and safe pressure the Ejection Fraction increases significantly and is restored into its normal range with a pressure of 30–40 mm Hg.

the same time, not impede the arterial flow we examined[23] 25 patients with mixed ulcers presenting with a mean ABPI of 0,57 ± 0,09 and a systolic ankle pressure of 91,8 ± 18,3 mm Hg. We assessed skin flow in the periwound area and in the plantar surface of the first toe by means of LaserDoppler flowmetry and simultaneously we measured the toe pressure. The measurements were carried out in baseline conditions and after inelastic bandage from the base of the toes to the popliteal area, applied with different pressure ranges of 20–30, 30–40 and 40–50 mm Hg. The pressure exerted by the bandage was measured by a pneumatic device with its probe placed next to the LaserDoppler probe. We could observe that, compared with baseline conditions, skin perfusion increases significantly with a bandage pressure of 20–30 and 30–40 mm Hg and returns to the baseline level with 40–50 mm Hg (Figure 4a).

Absolute ankle pressure values are more reliable than ABPI to assess the individual risk concerning compression pressure.

In the same patients we measured the Ejection Fraction from the lower leg applying an inelastic compression with a reduced pressure in the range of 20–30 and 30–40 mm Hg. EF increased significantly with both pressure ranges and was restored in the normal range by a compression pressure of 30–40 mm Hg (Figure 4b).

In conclusion a reduced compression pressure within the limit of 40 mm Hg may increase the venous pumping function and, at the same time, the arterial inflow provided that the arterial ankle pressure is higher than 60 mm Hg.

Conclusions

When correctly applied IB is significantly more effective than EB in improving the impaired hemodynamics and microcirculatory flow in patients with VLU and has been shown to be extremely effective in favouring the ulcer healing. With a reduced pressure within the range of 40 mm Hg it can be safely applied even in patients with arterial impairment.

EB and ES is claimed to be more or, at least, as effective as IB but the reported studies have relevant flaws making doubtful their conclusion.

In conclusion, at present time, IB exerting a strong pressure should be recommended in the treatment of venous ulcers and with reduced pressure in the treatment of mixed ulcers. Large multicentric, randomized, controlled trials without methodological flaws are necessary to show that elastic- is equally or, eventually, more effective than inelastic material.

Declaration of interest

The authors has no conflict of interest and nothing to disclose.

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