Film compression bandage

New modality for continuous and sports-suitable compression therapy of varicose veins following foam sclerotherapy

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Keywords

Film bandage, compression, sports, varicose vein, foam sclerotherapy

Summary

Purpose: Textile compression stockings or bandages are limited in comfort; they do not allow uninterrupted wearing. A novel elastic film bandage was evaluated regarding practicability, patient comfort and effect on vein regression. Main endpoint was the frequency of symptomatic inflammatory reactions.

Methods: In a comparative pilot study, a compression film bandage (CFB, investigational) comprising an elastic, self-adhesive breathable polymer film of d <20 µm was continuously worn for 14 d after foam sclerotherapy. Inclusion: 62 patients (26–68 y.) frequently doing sports and taking daily showers, 90 legs with superficial varicosities, 5–12 mm ø (MW: 7.3 mm), randomized to A) CFB + medical compression stocking (MCS), B) MCS alone, C) CFB alone. Follow-up examinations including ultrasound and photography were performed after 2, 4 and 8 weeks.

Results: Continuous wearing time of 14 days was completed in 57/60 cases with CFB (95.0 %, A+C), while 3/60 (5.0 %) finished wearing after 8–10 d. There were no adverse skin reactions except minor irritations at the upper edge (n = 2). Vein diameters were reduced within 14 days by 29–54 % (mean: 43.5 %) in group A, 16–44% (mean: 39.1 %) in group B, and 24–50 % (mean: 37.3 %) in group C. Symptomatic inflammation, induration or discolouration was observed within 28 days in 5/60 cases (8.3 %) when using CFB (A, C) versus 19/30 (63.3%) related to stocking compression (B). Comfort was rated by the patients 6.6 (A), 4.3 (B) and 9.2 (C) on a 10 degree scale. This difference was statistically highly significant (p <0.01).

Conclusions: The film bandage is an effective and safe compression modality. For superficial varicosities the adhesive bond to the skin seems to be relevant additional to the elastic properties. The device significantly improves vein regression of foam-treated superficial varicosities when combined with compression stockings or even as stand-alone modality. Continuous wearing for two weeks is well tolerated. The bandage may also offer an alternative for patients not tolerating textile compression media, or during summer.

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Folienkompressionsverband

Neue Modalität zur kontinuierlichen und sporttauglichen Kompressionstherapie oberflächlicher Varizen nach Schaumverödung

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Schlüsselwörter

Folienverband, Kompression, Sport, Varizen, Schaumverödung

Zusammenfassung

Ziel: Ein kontinuierlich zu tragender Folienkompressionsverband (FKV, Prototyp) wurde bei Patienten mit großen oberflächlichen Beinvarizen nach Schaumverödung auf Anwendbarkeit, Verträglichkeit, Wirkung und Komfort untersucht.

Methodik: Der FKV besteht aus einem elastischen, selbstklebenden und dampfdurchlässigen Polymerfilm von <20 µm Dicke. 62 Patienten (90 Beine) mit Varizen von 5–12 mm Ø, die regelmäßige sportliche Aktivitäten und tägliches Duschen angaben, wurden randomisiert: Gruppe A: FKV + medizinischer Kompressionstrumpf KKl. 2 (MKS); Gruppe B: nur MKS, Gruppe C: nur FKV.

Ergebnisse: In 57/60 Fällen (95,0 %) wurde der FKV 14 d ununterbrochen getragen. Die Reduktion der Venendurchmesser (14 d) betrug 29–54 % (MW: 43,5 %) für A, 16–44 % (MW: 29,4 %) für B und 24–50 % (MW: 37,3 %) für C. Die Inzidenz symptomatischer Verödungsreaktionen (28 d) war unter FKV mit 5/60 Fällen (8,3 %; Gr. A+C) gegenüber MKS (B) mit 19/30 Fällen (63,3 %) erheblich geringer (statistisch hoch signifikant, p < 0,01). Der Tragekomfort wurde auf einer subjektiven Skala von 1 bis 10 (optimal) mit 6,6 (A), 4.3 (B) und 9,2 (C) bewertet.

Schlussfolgerung: Der Folienkompressionsverband stellt in dieser Anwendung eine effektive, sichere und komfortable Modalität mit Alltags- und Sporttauglichkeit dar.

Sclerotherapy leads to better results with fewer symptomatic reactions to treatment, if consistent and long-term minimisation of the venous lumen can be achieved after an effective injection; this has already been known for decades (5, 25, 26). Compression is therefore also generally recommended after foam sclerotherapy (1, 14, 20, 24).

To date, large superficial varicose veins have only rarely been treated with foam sclerotherapy: in such cases, the incidence of unwanted inflammatory symptoms and discolouration is so high that such veins are usually removed surgically. Textile compression systems, such as stockings or bandages, can alleviate the problem of a reaction to sclerotherapy (11, 15, 17, 29), but their wearing comfort is limited, thus reducing compliance (16). Their use is usually interrupted, at least overnight and when showering or bathing, if physical hygiene is not to suffer unduly. Recently, there have been indications from the author's own ultrasound investigations that phases with little or no compression during the first weeks lead to partial reperfusion of veins treated with foam sclerotherapy (▶ Fig. 1), which is counterproductive to achieving rapid and asymptomatic occlusion.

If it were possible to establish continuous compression that could be worn easily during everyday stresses, sporting activities and even while showering, this could considerably improve the convenience and quality of foam sclerotherapy of superficial varicose veins.

With this aim in mind, a novel compression bandage has been developed that uses a vapour-permeable polymer film instead of textile materials. Thin elastic polymer films have been used for decades in medical practice, *inter alia* for the transparent covering of wounds, sutures or catheter access points (7, 10, 28). In order to position such highly flexible films on the skin, they usually consist of a basic and a covering film as carrier and stabilising material, respectively. The basic film protecting the adhesive layer is removed, the plaster is positioned and the stabilising covering layer is then removed. This design is unsuitable for circular compression, as the elastic material has to be pre-tensioned when bonded to the skin. To achieve this, the covering layer, at least, must also be elastic or segmented. In addition, it must be possible to remove the basic film in segments on unwinding (▶ Fig. 2).

This first clinical investigation of a venous film compression dressing designed with these considerations in mind served to determine its usability, tolerability, efficacy and convenience.

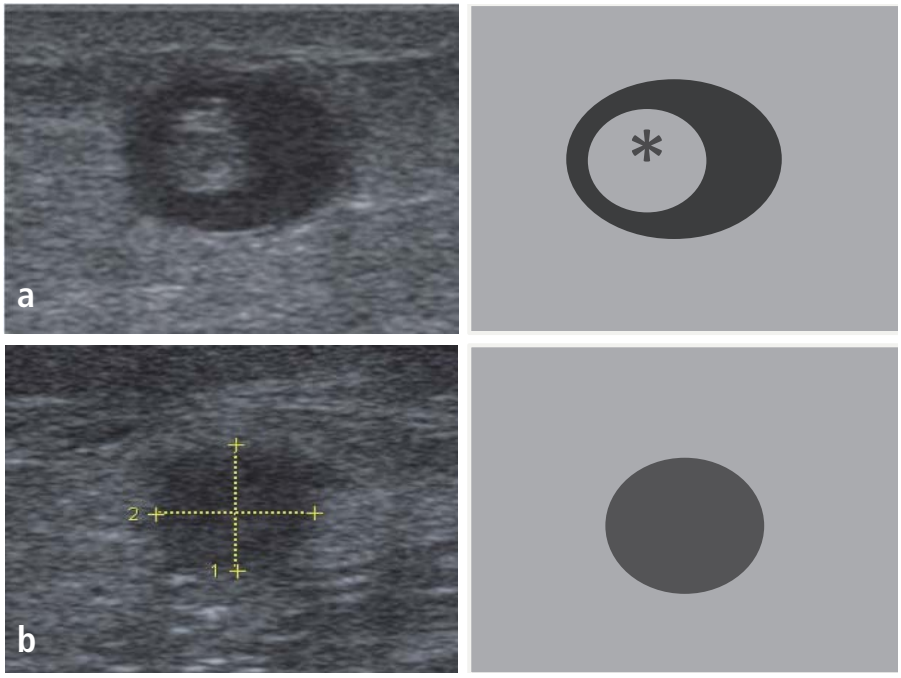

Fig. 1 Typical ultrasound models of large veins treated with foam sclerotherapy a) without continuous compression, b) with continuous compression. The echogenic subsection in the lumen in a) corresponds to the markedly smaller diameter of the vein at initial coagulation. Continuous compression results in homogeneous thrombogenic models (b).

Patients and methods

After preliminary testing of various polymer films of 12–20 µm thickness, the film "Tegaderm Roll" (3M Inc.) consisting of 100 mm-wide polyurethane was used for this first clinical application. Its supplementary films were modified, however (▶ Fig. 2). The film covers a large area with a hypoallergenic acrylic adhesive for reversible fixation on the skin and has vapour-permeable micropores. Catheter access points >2 mm Ø were covered with a sterile dressing once blood had dried (Steristrip, 3M Inc./plaster).

The inclusion criteria were:

1. superficial varicose veins of 5–12 mm Ø suitable for foam sclerotherapy, for which patient consent had been obtained,
2. sporting activities of 30–90 minutes' duration on at least 4 days a week
3. daily showering.

"Superficial" was defined to be at least 50 % of the varicose vein volume lying above skin level and, in case of doubt, this was determined using ultrasound without pressure. Exclusion criteria were known allergies to plaster or acrylate adhesives, skin disease, skin injuries and anticoagulant intake.

A total of 62 patients (23–68 years of age, mean age: 41.5 years, C2–C4a) with suitable varicose veins on one or both legs (n = 90) were selected between 4/2013 and 3/2015. The most frequently performed sports were jogging (n = 13), tennis (n = 12), cycling (n = 8), Nordic walking (n = 6), riding (n = 5), gym (n = 5), swimming (n = 5), football (n = 3), dancing (n = 2) and handball (n = 1). During the day, all the patients worked and spent >75 % of their time either sitting (n = 31), standing (n = 11) or changing between sitting and standing

(n = 18). The varicose veins were located on the thigh (n = 23), lower leg (n = 50) or above and below the knee on the thigh and lower leg (n = 17, ▶ Fig. 7).

The legs to be treated were randomised into three groups and patients with bilateral varicose veins were assigned to one group each: Group A: Film compression bandage (FCB) combined with a compression class 2 medical compression stocking (MCS) for 14 days, and MCS for 14 further days; Group B: MCS only for 28 days; Group C: FCB only for 14 days. Randomisation was performed using a computer-generated random assignment with four diameter categories of 5–6 mm, 7–8 mm, 9–10 mm and 11–12 mm Ø. The mean varicose vein diameter was 7.3 mm in the total population, 7.4 mm in Group A, 7.1 mm in Group B and 7.3 mm in Group C.

The FCB was applied to the disinfected and shaved skin of the varicose vein area in a helical form or in overlapping, circular segments, preferably with an overlap of 1 cm ± 5 mm, in order to maintain maximum vapour permeability.

In addition to foam sclerotherapy of superficial varicose veins (n = 90, Aethoxysklerol 1–2 %, 1 + 4 with filtered room air, 4–6 ml) with ultrasound-guided injection, 28 patients (42 legs) received saphenous vein treatment in the same session using ELVeS (n = 23), ClosureFast (n = 2), F-Care (n = 5), PhleboCath foam catheter (n = 10) or valvuloplasty (n = 2).

Clinical follow-up examination using ultrasound and photographic documentation was performed after 2, 4 and 7–8 weeks. Venous diameters were determined using ultrasound scans at 2 cm intervals.

After 14 days, patients were questioned about the subjective comfort of the compression media and asked to award a score of between 1 (very poor) and 10 (excellent).

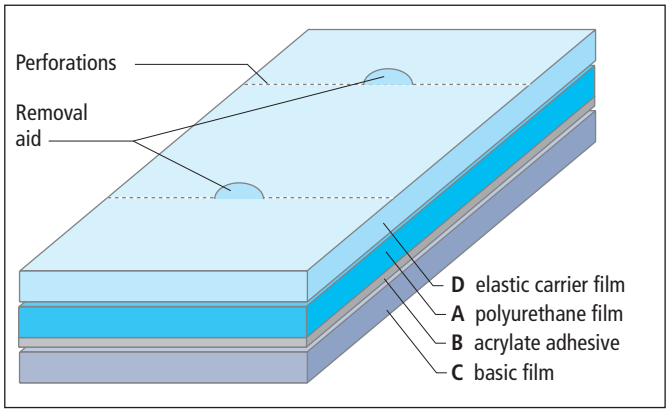

Fig. 2 Diagram showing the structure of a film compression bandage with a thin polymer film (A), adhesive glue (B), basic film (C) and covering film (D).

Results

In all 90 cases, application of the film compression bandage was achieved with the desired overlap of below 10 %. The application time required was between 2.1 and 5.5 minutes (M: 3.5 min). In 7/90 cases (7.8 %), the bandage was renewed prior to discharge due to fold development (n = 3), insufficient compression (n = 3) or excessive compression with an unpleasant sensation of pressure (n = 1).

In 57/60 cases (95 %), the planned wearing time of 14 days and nights was achieved. In 3/60 cases (5.0 %), the wearing time was ended prematurely after 8–10 days due to skin irritation (n = 2) or detachment of the bandage (n = 1). In 8/60 cases (13.3 %), the FCB had to be completely or partially renewed, e.g. after frequent swimming (n = 2), after strenuous sporting activity at temperatures above 25°C during the summer months (n = 4), or because the edges of the bandage had become detached after rubbing against clothing (n = 2). Appreciable skin irritation was observed in 2/60 cases (3.3 %) at the upper edge of the film. In 5/60 patients (8.3 %), parts of the film bandage showed tears or detachment at areas subject to particular mechanical stress, such as the kneecap after frequent kneeling (▶ Fig. 7). Removal of the film was easy in all cases.

Out of 60 patients with MCS, 41 (68.3 %) reported a wearing time of >12 h daily, 13/60 (21.7 %) a time of 10–12 h and 4/60 (6.7 %) a time of 8–10 h. 39/60 (65 %) removed the MCS when doing sport.

After 14 days, the treated varicose veins were completely occluded in 82/90 cases (91.1 %) and largely occluded in 8/90 cases (8.9 %; A: n = 2; B: n = 3; C: n = 3).

Open segments were treated with supplementary injections (n = 8; foam basis: Aethoxysklerol 1–2 %). After 4 and 8 weeks, all treated varicose veins were completely occluded. Complete occlusion was seen in all cases (42/42) that had undergone saphenous vein treatment. With regard to the superficial varicose veins, no

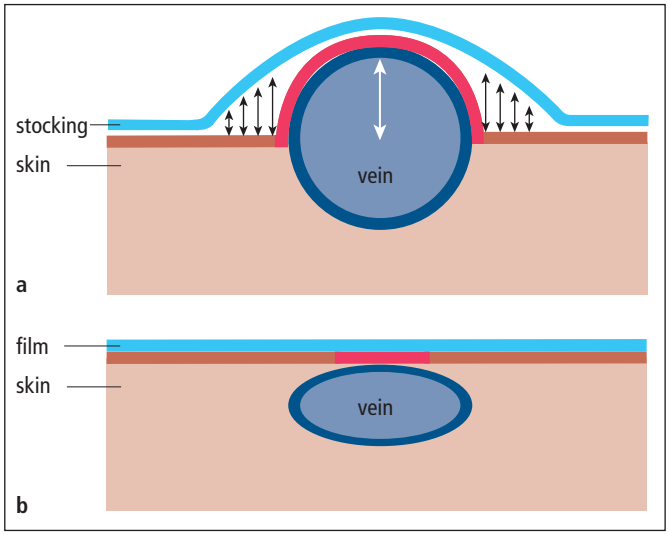

Fig. 3 Diagram showing film compression of superficial varicose veins: In addition to circular compression, a compression effect also occurs due to the adhesive forces (black arrows) (a). The contact area to sensitive skin (marked in red) is reduced and the distance increased (b).

Tab. 1 Symptomatic reactions to sclerotherapy and their manifestation as painful resistance, discomfort at rest or on movement, pain on pressure and longer-term discolouration.

Group (n=30 per group)	Mode	Reactions to sclerotherapy (28 d)	Painful resistance (28 d)	At rest (28 d)	On movement (28 d)	Pressure (28 d)	Discolouration (6–8 weeks)
A	FCB + MCS	2	2	2	1	2	1
B	MCS only	19	19	17	14	19	11
C	FCB only	3	3	1	2	3	1

differences were determined between cases with saphenous vein therapy and those without.

The reduction in the venous diameter of the occluded varicose segments after 14 days was 29–54% (M: 43.5%) in Group A with combined FCB and MCS, 16–44% (M: 29.4%) in Group B with MCS only and 24–50% (M: 37.3%) in Group C with FCB only.

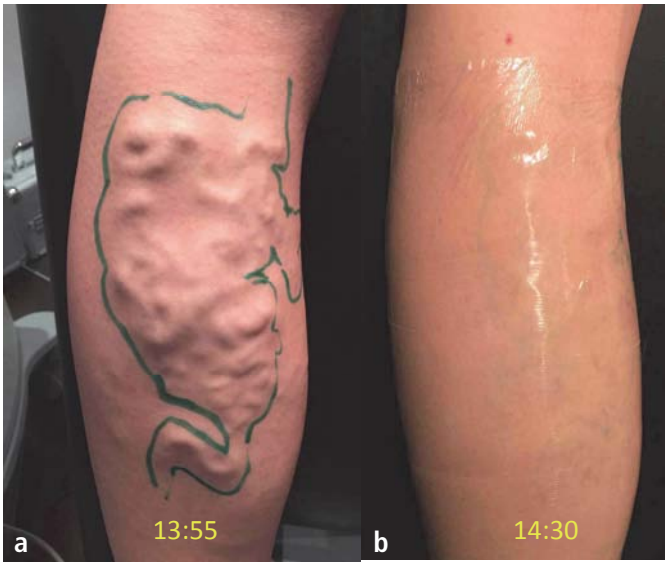

Fig. 4 Varicose vein in the calf region, 5.9–8.2 mm Ø, originating from a severely incompetent small saphenous vein; a) before, b) 25 min later after foam sclerotherapy with filling of the convolution via a 2.3 mm small saphenous vein catheter without separate punctures. The upper edge of the film has not been optimally tensioned.

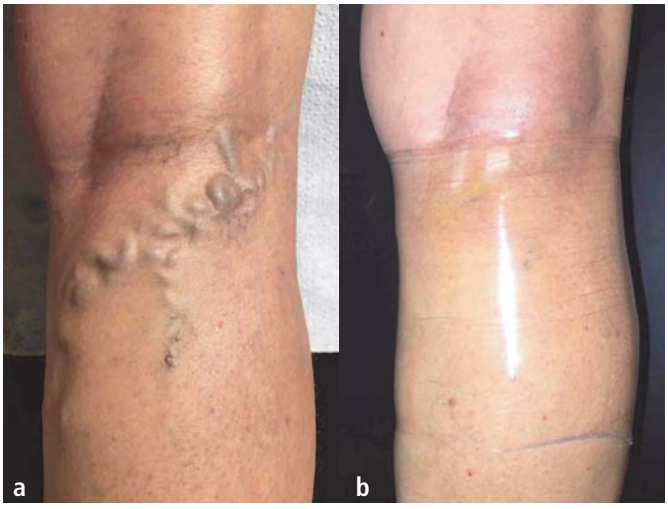

Fig. 5 Varicose vein in the popliteal cavity, 3.5–5.6 mm Ø; a) before, b) 2 days after treatment. Good overall appearance. Minimal rolling up of the lower film edge (jeans, no MCS).

Symptomatic reactions to sclerotherapy were observed under film bandages in the first 28 post-interventional days in 5/60 cases (8.3%, Group A: n=2; Group C: n=3), whereas, during the same period, they occurred in 19/30 cases (63.3%) in Group B with MCS only (▶ Tab. 1). The difference is statistically highly significant ($p < 0.01$). The somewhat less frequent occurrence of symptomatic reactions to sclerotherapy in Group A compared with Group C is not statistically significant due to the given sample size in our investigation.

The symptomatic cases developed in Group B after 5–18 days (n=19), in Group A after 19 and 23 days (n=2) and in Group C after 17, 19 and 26 days (n=3). No differences were determined between varicose veins on the thigh and lower leg. All cases showed varicose diameters of >7.2 mm and all underwent mini-thrombectomies (n=24).

All patients, including those with a reaction to sclerotherapy, were able to continue with their occupations. Oral analgesics were only taken by 4 patients (13.3%) due to complaints while wearing MCS (Group B). In Groups A and C with film bandages, no patient reduced his/her sporting activity. The following were reported as minor limitations: Mild pain on pressure at the medial lower leg while riding (A, n=1), not playing tennis – tournament match (C, n=1), not running a half-marathon (A, n=1). In the group with MCS only (Group B), 7/30 patients (23.3%) did no sport at all and 13/30 (43.3%) limited the duration or intensity of their sporting activity.

In the final examination after 7–8 weeks, no varicose vein residues were either visible or painful to pressure in Group A and C patients, although minor discolouration occurred in 1/30 cases (3.3%). In Group B (MCS only), residues were visible in 6/30 cases (20%) and/or still painful to pressure in 4/30 cases (13.3%) despite mini-thrombectomies in weeks 3–4. Discolouration occurred in 11/30 cases (36.7%) (▶ Tab. 1).

With regard to the wearing comfort of the compression materials after 4 weeks, on a subjective scale of 1 (very unpleasant) to 10 (excellent, nothing felt), the patients awarded a score of 5–7, M: 6.6 (A); 3–6, M: 4.3 (B) and 8–10, M: 9.2 (C). Wearing an

MCS was perceived as more comfortable by a score of 2.3 points in cases where the compression film was additionally used (Group A) compared with cases using an MCS only (Group B).

Discussion

The appearance of a leg recently treated with foam sclerotherapy and with application of a film compression bandage is astounding (▶ Fig. 4, ▶ Fig. 5) and this impression remains largely unchanged during further progress after successful sclerotherapy (▶ Fig. 6, ▶ Fig. 7).

The most important physical difference to normal textile compression media is that the film material forms a mechanically stable bond with the skin thanks to the adhesive layer. If a varicose vein treated with foam sclerotherapy is covered with an adhesive film during the vasospastic phase, the remaining space available for its further course is limited not only by the film's longitudinal elasticity, but also by the adhesive bond between the film and the skin (▶ Fig. 3). Another crucial difference is the continuous effect, which was sustained over 14 days and nights in this study.

Inflammatory reactions are inherent in all endovenous procedures due to the thermal or chemical destruction of the endothelium and parts of the media and also because of the formation and degradation of the deliberately created thrombus (14, 17, 20, 24). Such reactions are only clinically relevant if they become symptomatic and only cosmetically important in the event of discolouration. The symptoms are determined not only by the reaction to sclerotherapy, whose extent increases in proportion to the size of the vein; proximity to nerve structures, particularly those of the skin, also plays a part (17). The FCB reduces the frequency of symptomatic reactions to sclerotherapy by approximately 80 % during the first 28 post-interventional days and saves the need for micro-thrombectomies to the same extent (▶ Tab. 1).

Reactions to sclerotherapy resulting from falling levels of compression for physical reasons could be limited as effectively on the thigh as on the lower leg. Use of a compression class 2 MCS in addition to the film (Group A) caused only a minimal reduction in the frequency of reactions to sclerotherapy. While searching for an explanation, it became clear that the adhesive FCB together with the lumen reduction also causes a reduction in the area in contact with sensitive skin due to subcutaneous displacement (▶ Fig. 3). This displacement appears relevant to both the reduction in symptoms and the avoidance of discolouration. In varicose veins, discolouration occurs more frequently as leaked bilirubin due to inflamed wall structures than as hyperpigmentation (17).

It can be assumed that the film type investigated did not even reach the pressure

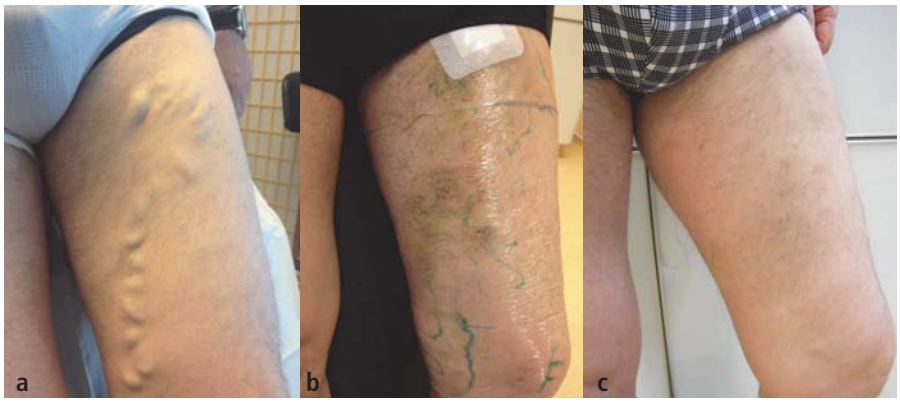

Fig. 6 Varicose vein on the ventral thigh, 6.6–11.8 mm Ø, a) before, b) after 7 days with FCB and MCS; the plaster and one film segment (mainly due to incorrect overlap) were subsequently renewed on the proximal thigh, c) after 4 weeks.

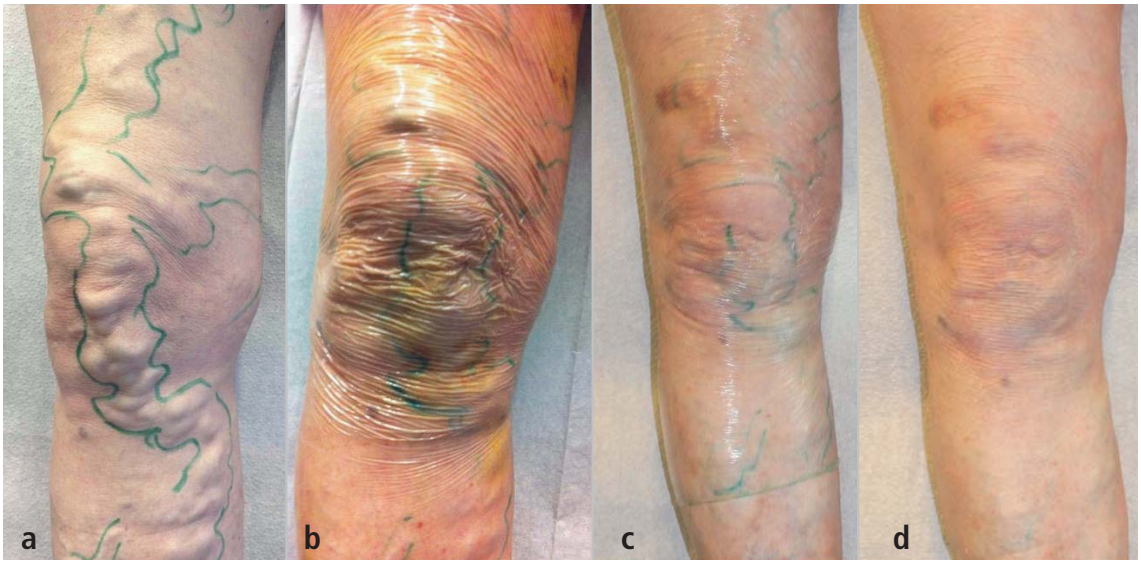

Fig. 7 Varicose vein extending beyond the knee, 6.4–10.1 mm Ø, a) before foam sclerotherapy after mapping, b) after FCB application at approximately 30 degree flexion, standing with the leg extended, c) after 14 days, d) after removal of the FCB. Study group C = FCB only, no MCS. Occupation: Cleaning operative who has to kneel frequently. Film lesions in the knee area.

values of a compression class 1 MCS. A high level of compression, which is always considered desirable (11), is possibly of less relevance in this specific application than the mechanism and the continuity of compression (13, 15, 19, 26). The study population was relatively healthy and athletic. If the FCB is used in patients with concurrent incompetence of the deep veins of the legs, oedema, post-thrombotic syndrome or ulcer, media will be required that can produce higher pressures and/or have a higher stiffness index (12, 18).

New evidence is being acquired about compression media (2, 6, 12) and new discussion of the indications is required, including the situation following foam sclerotherapy: Assuming modern injection and monitoring techniques (20, 23, 24), saphenous veins and other structures with moderate diameters (<7 mm) do not require any compression (9), with the exception of those veins with a very superficial course (21). Larger saphenous veins benefit from compression. The required pressures are only reached concentrically at the thigh with bandages, however, and not with MCS (3, 11, 19). Following foam sclerotherapy, superficial varicose veins very clearly benefit from compression (1, 8, 13, 15, 20).

Various circumstances can limit the tolerability and efficacy of FCB: Although not observed in this investigation, allergic reactions can develop to the acrylate-based adhesives. Skin irritation can also occur, particularly at the edges due to tensile stress. The film must therefore be removed at the first signs of itching, redness or discomfort. As a result of the limited vapour permeability, skin reactions are also possible following profuse sweating, such as may occur at summer temperatures or during strenuous sporting activity or hyperhidrosis.

Compared with compression stockings, no increase in bacterial colonisation occurs beneath the type of film bandages used in this investigation during a 14-day period of wear (22). Based on this experience, the duration of use of the FCB was set at 14 days. No investigations have yet been performed in athletes who sweat profusely or in patients whose skin is at risk of infection, e.g. diabetic patients. The delayed onset of symptoms at the end of the 14-day film application indicates that some cases may benefit from wearing the FCB for an even longer period (13).

Although current scores, such as the revised Venous Clinical Severity Score (rVCSS), react better to clinical changes and try to take everyday circumstances into account (4, 27), they are not appropriate instruments for assessing venous compression media: There is an overlap between clinical effects due to the invasive treatment and the compression and it is difficult to determine the degree of comfort, as poor efficacy can be confused with a sensation of comfort. Even the pressure of a compression class 2 MCS can be perceived as unpleasant by patients whose veins are otherwise normal or have been effectively treated (2). If the film bandage is only used in the varicose area and without an MCS, temporary congestion can occur distally to the area covered by the film. Combination with an MCS can prevent this, so that this procedure represents first-line treatment. The significance of an additional initial increase in compression using bandages for approximately the first 24 hours has not yet been investigated (15).

Due to the transparent film material, future studies can also present the effects of venous compression using ultrasound. This opens up new possibilities, for both concentric and eccentric compression in combination with silicone pads transparent to ultrasound (21), for evaluating and obtaining more precise indications as to which medium exerts which effect in which region on superficial varicose veins, saphenous veins and the deep veins of the legs (2, 6, 19).

Summary

Nowadays, the longstanding concept of continuous compression (5, 25, 26) can be implemented with a medium that is perceived to be very comfortable and allows practically unlimited work, sport and daily showering.

Due to adhesive fixation, the film compression bandage investigated considerably improves the care of large superficial varicose veins that have undergone foam sclerotherapy. Future clinical options include combination with textile compression media and as an independent single application. Both functionally and aesthetically, an alternative to phlebectomy now exists that is well worth considering for large varicose veins.

Further studies are planned as soon as the industrial products become available.

Conflict of interest

According to the author, there are no financial relations with manufacturers or suppliers of compression media or medical films. The investigations were not remunerated or supported by third parties, either directly or indirectly.

Ethical guidelines

The investigations were performed in compliance with national legislation and the current Declaration of Helsinki.

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