

Eccentric compression of large varicose veins after foam sclerotherapy using a novel silicone gel pad

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Keywords

Compression, silicone gel, gel pad, foam sclerotherapy, analgetics

Summary

Aim: After sclerotherapy of varicosities, eccentric compression is meant to provide rapid and symptom-free vein regression. We evaluated a new compression modality consisting of thin adhesive films and ultrasound transparent silicone gels, individually applied along treated veins.

Methods: 120 patients were included with 148 superficial varicosities of 5.1–13.7 mm in diameter (mean: 7.6) undergoing foam sclerotherapy (Aethoxysklerol 1%, filtrated room air; ratio: 1+4). Postinterventional treatment was randomized to A) silicone gel pad (SGP, Venartis® Inc.) on one half of the vein length for 2 weeks plus compression stocking (German class 2) for 4 weeks, or B) compression stocking alone. The SGP consists of a thin adhesive film sheet to serve as a mechanical skin protection, silicone gels with final hardness of Shore-A 5–22 applied on the film from cartridges along the vein following all curves, and a second adhesive film sheet to cover the silicone. Patients were allowed to take daily showers with SGP in place. Vein diameters were measured by ultrasound and clinical criteria determined after 2, 4 and 8 weeks.

Results: Vein segments receiving focal compression with SGP showed a faster regression: 52.5% (22.4–74.2%) vs. 23.1% (8.1–36.7%) after 2 weeks, 48.4% (33.2–64.5%) vs. 28.9% (26.1–43.1%) after 4 weeks and 66.7% (31.1–82.4%) vs. 39.2% (21.0–61.8%) after 8 weeks. The frequency of inflammatory reactions was lower when using SGP (12.4 vs. 39.9%). The frequency of minithrombectomies was lowered to 8.1% with SGP, versus 29.7% in non-SGP segments, and oral analgetics were given in just 6.8% (vs. 19.6%). Discolorations were observed at week 8 in 10.8% of the cases, vs. 35.1% when using concentric compression only. Unwanted side effects of SGP were marginal skin irritations (10.1%), leading to a wearing time of 5–12 days in 2.0% of the cases (3/148). There were no other adverse reactions, in particular no allergies.

Conclusion: Venartis® SGP is a safe, effective and comfortable modality to support vein regression after sclerotherapy of varicosities. The indications for hard and soft silicones, the dosage in relation to vein diameter and position, wearing times and external pressure have to undergo further studies. As the device is ultrasound transparent, examinations of treated veins will be possible with the pad in place to optimize the degree of vein compression.

Schlüsselwörter

Kompression, Silikon-Gel, Gel-Polster, Schaumverödung, Analgetika

Zusammenfassung

Ziel: Wir evaluierten eine neuartige exzentrische Kompression, die ultraschalltransparentes Silikon-Gel zwischen selbstklebenden Folien als individuelles Druckpolster verwendet. **Methodik:** Es wurden 120 Patienten mit 148 oberflächlichen Varizen (Ø 5,1–13,7 mm; MW: 7,6) nach Schaumverödung einbezogen: A) segmental randomisiert mit fokaler Kompression durch Silikon-Gel-Polster (Venartis® SGP) für 14 Tage plus Kompressionsstrumpf KKL 2 (KS) tagsüber für 28 Tage, oder B) nur KS. Das SGP-System besteht aus einer selbstklebenden Basisfolie, auf die Silikon dem Venenverlauf folgend aufgetragen wird. Eine zweite Folie bedeckt Gel und Basisfolie. Den Patienten war Duschen erlaubt. Ermittelt wurden Querschnittsreduktion (QR, Ultraschallscans) sowie klinische Parameter nach 2, 4 und 8 Wochen.

Ergebnisse: Segmente mit SGP zeigten gegenüber KS eine höhere QR, im Mittel 52,5 vs. 23,1% (2 Wo), 48,4 vs. 28,9% (4 Wo) und 66,7 vs. 39,2% (8 Wo). Entzündungsreaktionen waren unter SGP mit 12,4 vs. 39,9% signifikant seltener, ebenso Verfärbungen mit 10,8 vs. 35,1%. Minithrombektomien (8,1 vs. 29,7%) und orale Analgetika (6,8 vs. 19,6%) wurden seltener benötigt. Unerwünschte Wirkungen: Diskrete Hautirritationen (10,1%).

Schlussfolgerung: Indikationsspezifische Silikonhärten, Dosierungen, Tragezeiten und die Höhe externer Drücke bedürfen weiterer Untersuchungen, wobei die Ultraschalltransparenz neue Wege eröffnet.

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Compression of one leg using functional venous bandages or compression stockings is called “concentric” compression. It is a standard treatment for a range of indications from prevention to postoperative care (6, 12, 13). By contrast, “eccentric” compression involves the additional use of pressure devices when attempting a specific increase in local pressure, such as along the course of an extracted or sclerosed vein (1, 8, 9).

Whereas the primary aim of post-surgical compression is the avoidance of haemorrhage, oedema and thrombosis, these risks are only of secondary importance following non-incisional interventional venous procedures (e.g. foam sclerotherapy). Sclerotherapy techniques leave the pathological substrate in situ and the challenge, which increases with the growing venous diameter, is to achieve an imperceptible and invisible residual vein. This must also be performed rapidly and without causing any symptoms.

Knowledge of compression use after sclerotherapy to avoid thrombosis, inflammation and discolouration originates from the time of liquid sclerotherapy, when the first indications of the benefits of eccentric compression became apparent (23, 25). At a consensus conference in the early days of foam sclerotherapy (2), the meeting deliberately refrained from making a recommendation, indicating that the majority of participants were using eccentric compression, which sustained a small venous lumen, thus avoiding inflammatory reactions. To date, nothing concrete has been added to this recommendation (15, 12, 22). As a result of more recent investigative methods, e.g. measuring the venous diameter in MRI in the standing patient, there are growing indications that superficial veins and varicosities require unexpectedly high pressures to ensure adequate compression, which can only be achieved using eccentric compression (3, 14).

Particularly in the case of large varicose veins treated with foam sclerotherapy rather than phlebectomy, there is a risk of painful phlebotic phases (“sclerotherapy reaction”), long-term induration and discolouration, despite the use of concentric compression (4, 13, 15). This is often remedied by performing so-called mini-

thrombectomies, whereby thrombotic masses are expressed after puncture or incision. This is usually unpleasant for the patients. It can also result in an aesthetically less pleasing appearance than is seen after phlebectomy. However, as endovenous procedures in general and foam sclerotherapy in particular have a very favourable risk profile and provide a high degree of comfort for patients, the question arises as to whether and how the medical and aesthetic aspects of the procedures can be optimised.

Also available but seldom used are compression stockings with inserts, which approximately cover the area of the great saphenous vein, as well as a number of variously shaped, ready-made compression devices made from foam or rubber with a circular or trapezoidal cross-section. For eccentric compression, the devices are mainly improvised from surgical cotton wool, cotton rolls, swabs or rolled gauze compresses, which are affixed with plaster strips or bandages. A compression bandage or compression stocking is then worn on top (8, 23, 24). The pressure achieved varies greatly: soft materials, such as loose cotton wool, can only compress gradually but are well tolerated. Harder materials compress more effectively but can lead to skin damage due to pressure and chafing, particularly near the joints during movement. With all these variations, the patient must either endure a long period of insufficient personal hygiene or frequently re-apply the materials, which is a laborious process.

After preliminary work on foam compression devices (16, 17), with the development of optimised profiles with atraumatic borders and very stable positioning (► Fig. 1), four ideas led to the development of a new compression device (18): Firstly, it should be a modality that can be quickly and easily adapted to every venous anatomy, in terms of course, diameter and depth. Secondly, it should be possible to monitor the pressure exerted by the compression device in situ using ultrasound, i.e. it should be transparent to ultrasound. Thirdly, it should be capable of permanently maintaining a lumen reduction of at least 50%, and fourthly, patients should be able to wear the device continuously for at least two weeks while performing all the

usual activities of daily life, including sport and daily showering. The investigation presented here describes initial experience with prototypes of this modality.

Patienten und Methoden

In the first trial of an innovative silicone compression device (prototypes: Venartis Silicone Gel Pad “SGP”, Venartis® Inc.), 120 patients (26–74 years of age, mean: 55.2 years; 78 w, 42 m) were enrolled. The inclusion criteria were:

1. the presence of superficial varicose veins of the leg, 5 to 15 mm in diameter and at least 15 cm long
2. the indication and suitability for foam sclerotherapy.

Exclusion criteria were intolerance of external compression, skin disorders and known allergies to silicone, acrylate adhesives, stocking or bandage material. The criterion “superficial varicose veins” was defined as being partially or completely above skin level.

148 varicose segments fulfilled the requirements at a length of 15–53 cm (mean: 26.7 cm), on the thigh n=58 ventral, n=15 dorsal, on the lower leg n=31 ventral and n=24 dorsal, in addition n=14 in the popliteal cavity and n= 8 prepatellar.

The segments were randomised:

- Half the vein length for SGP treatment for 14 days plus a compression class 2 compression stocking for 28 days (n = 148),
- The other half for concentric compression only using a stocking (n = 148).

The mean venous diameter was 7.4 mm (5.2–13.2 mm) in the total population, 7.6 mm (5.5–13.2) in the partial population with focal compression and 7.2 mm (5.2–12.8) in the partial population without focal compression.

The patients underwent microfoam sclerotherapy using the double-syringe system (DSS) with aethoxysclerol 1% at a proportion of 1+4 with filtered room air (3–7 ml), applied using a microcatheter (Ø 1.3–1.5 mm) or butterfly (Ø 0.5–0.65 mm). In 13/120 patients, in addition to foam sclerotherapy, a further procedure was per-

formed in an adjacent area (laser occlusion at the opening of the anterior accessory saphenous vein, $n=6$; opening of the great saphenous vein: $n=7$). The treatment with compression devices was initiated 5–10 min. after completion of sclerotherapy.

The new compression device consists of two transparent, elastic and self-adhesive film sheets (thickness approximately $15\mu\text{m}$, 3M) with micropores and silicone gel, which is individually applied from cartridges (20–50 ml, diameter at the opening 5–8 mm). After the skin has been disinfected with alcohol and dried, the first film sheet is affixed along the course of the vein, maintaining a required distance of at least 3 cm between the vein and the film border. This film sheet firstly serves to avoid contact between the silicone and the skin and secondly to distribute an external pressure over a larger area (► Fig. 2a, ► Fig. 2b). The silicones are applied as precisely as possible along the course of the vein, with the aim of producing a strip centred on the vein. The width of the strip is three times that of the venous diameter and its height is the same (► Fig. 2c).

The second film sheet is the same size as the first and is affixed on top of it. It covers the freshly applied silicone strip, limits its area of spread and thus determines the final shape (► Fig. 2c). During the hardening phase of the silicone (2 min. to 24 h), the covering film sheet protects the patient's clothes and the compression stocking. The compression stocking provides the decisive pressure (► Fig. 2d).

The silicones were selected from a group of neutral- or addition-cure, thixotropic (gel-like, not liquid) silicones approved for skin contact, whereby in the 2-component system final hardnesses (Shore A) were adjustable from 5 to 45.

During initial experience, 1-component silicone was used (cases 1–65, Shore A hardness 22). Thereafter, 2-component silicones with two hardness grades were used: Shore A 22 as standard and Shore A 10 for zones subjected to particular stress on movement or for sensitive zones (knee area). The tensile strength was 2.2–7.0 MPa, the elongation at break was 100–400%. The colours “transparent” (► Fig. 4) and “beige” were used.



Fig. 1 a. Physical features of a compression device for a focally centred pressure, b. First implementation with foam. Aim: atraumatic borders and very stable positioning after contact pressure through concentric compression. c. Cross-section through an individual silicone compression device.

Measurement of venous diameter was performed every 2.5 cm with ultrasound while the patient was in the standing position, using a scan technique in which a video documentation of the venous cross-section is performed manually at uniform speed. This is converted to individual images on the PC and measured on the screen.

The patients were instructed to resume all their usual daily activities, including sport, immediately with no limitation. Daily showering was expressly permitted. The endpoints of the comparison of segments with and without focal compression were the reduction in venous diameter achieved (ultrasound scans), the frequency of inflammations, discolouration and induration and the use of analgesics and throm-

bectomy. The examinations in question were performed after 2, 4 and 8 weeks.

Results

After two weeks, the mean reduction in venous diameter was 52.50% (22.4–74.2%) in segments with focal compression with silicone pads, compared with 23.10% (8.1–36.7%) in segments without focal compression. After four weeks, a slightly smaller difference was measured, at 48.40% (33.2–64.5%) in segments compressed with silicone, compared with 28.90% (21.1–43.1%) in segments without focal compression. After eight weeks, the mean reduction in diameter was 66.70% (31.1–82.4%) in segments with focal compression, compared with 39.20%

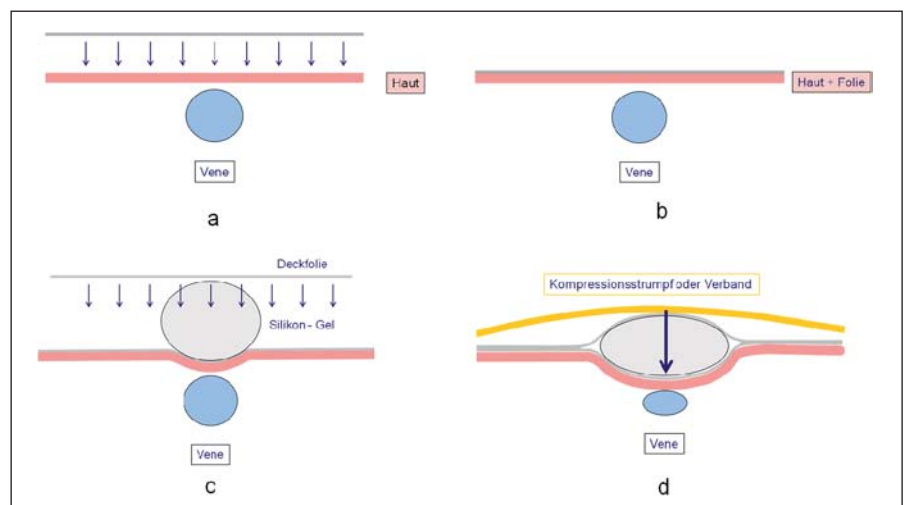


Fig. 2 Diagram of the film sheet-gel combination. a. Application of the base self-adhesive film sheet, b. Combination of skin and film sheet, c. Application of silicone and second (covering) adhesive film sheet, d. Compression by means of bandage or stocking. (Vene = Vein, Haut = Skin, Folie = Film sheet, Deckfolie = second (covering) film sheet, Silikon-Gel = Silicone gel, Kompressionsstrumpf oder Verband = Compression stocking or bandage).



Fig. 3 Skin lesions with silicone with Shore A hardness 22, athlete, asymptomatic.

(21.0–61.8%) in segments where only concentric compression was applied (► Table 1).

Symptomatic inflammatory reactions, defined as subjective resistance painful to pressure or movement with or without redness, were observed in a total of 78/148 patients (52.7%). 19 (12.8%) of these reaction occurred in segments with silicone compression compared with 59 cases (39.9%) in segments with only concentric compression (► Table 2). In all cases in which phlebotic symptoms occurred in segments with focal compression (n=19), corresponding symptoms also occurred in the comparative segment under concentric compression only and in the majority of cases (13/19) the symptoms were more marked.

The patients affected were mainly offered mini-thrombectomies for local relief.

These were accepted in 56 cases and performed as aspiration thrombectomy (microcatheter Ø 2.2 mm, n=38) or thrombus expression after puncture (Ø 1.6–2.1 mm, n=18) under local anaesthesia. Twelve cases were affected (12/148; 8.1%) in segments compressed with silicone compared with 44 cases (44/148; 29.7%) in segments without silicone pads. Regions in which thrombectomies were performed were not included in the comparison of the reduction of venous diameter and postinterventional changes.

Local symptoms, for whose treatment mini-thrombectomies were either not desired (n=22) or were felt to provide insufficient relief after 24 hours (n=17), led to the prescription of analgesics (ibuprofen 400 mg, 2–3 times daily for 5–10 days). In 6.8% (10/148) of cases, this involved a segment covered with a silicone pad and in 19.6% (29/148) of cases, a segment without silicone. Cases in which both segments were affected and cases without any clear allocation were counted in both groups.

Discolouration was registered as an adverse effect of foam sclerotherapy, if it was still visible after eight weeks. This was the case in 10.8% (16/148) of segments with silicone compression and in 35.14% (52/148) of segments without focal compression.

3/148 patients (2%) removed the silicone bandage prematurely. This was due to local paraesthesia and all cases involved initial application in the popliteal cavity (3/6,

50%, days 5–12, Shore A hardness 22), with no visible skin lesion on the 14th day. The affected segments were not included in follow-up examinations of the venous diameter or post-interventional changes. After changing to soft silicones, no further irritation occurred during use in the popliteal cavity (n=8). After obtaining agreement, three patients interrupted wearing time on one occasion for a maximum of 4 hours due to sporting competitions and reapplied the dressing (► Fig. 4). Overall, patients reported being aware of the focal compression in only 8.8% of localisations (13/148).

Visible skin irritation without curtailment of application time was observed in 10.1% of cases (15/148). Without exception, it affected the borders of the pads during initial experience with hard silicone (Shore A 22) in applications applied transversely or diagonally to the direction of movement (► Fig. 3).

No further adverse effects of the compression device were reported.

Discussion

Focal venous compression is a complex process, which, in addition to the external pressure exerted by the stocking or bandages, largely depends on the type of pressure device (size, shape and hardness), venous diameter, and its position vis-à-vis the skin surface and the bony structures.

It is only a small initial step to provide a modality that can be simply adapted to every anatomical situation. This was achieved with the Venartis system, as the cartridge can easily follow every marked venous contour. A set of replaceable nozzles would be desirable, e.g. with a diameter of 5, 10, 20 and 30 mm, in order to allow even faster application. Compared with the concept and implementation, it was noticed in the case of venous convolutions that the silicone was applied over a wide surface area rather than following every curve (► Fig. 4) and the instructions for use should be altered accordingly.

The position of the veins relative to the skin surface, the depth of the regional fatty and muscle tissue (important on the thigh) and the varying distance to bony structures were not taken into consideration in this



Fig. 4 Example of a silicone application: **a.** before sclerotherapy (anterior accessory saphenous vein, also laser treatment of the great saphenous vein), **b.** silicone pad on 5th day, **c.** after removal on the 5th day (special case: re-application after a 4 h interval, at patient's request due to a sporting competition).

investigation, as the initial objective was to obtain basic knowledge about the compression required.

For varicosities lying completely above skin level, focal compression will be less important and unnecessary in the vicinity of the bones. The situation is different with deep veins: the deeper the position, the higher the pressure required. This means that, with the same concentric compression device (e.g. compression class 2 stocking), a device with higher compression is necessary, which must also be proportionately wider to obtain the optimal cross-sectional shape (► Fig. 1). The technical implementation is simple, as slower retraction of the cartridge results in a thicker silicone strip with the same ejection pressure, but the optimal dosages are still unclear and have yet to be determined (20).

In the event of incompetent veins well below skin level (>2–3 cm), indications will be limited, as the extent of focal pressure decreases with depth in homogeneous tissue and external pressures cannot be arbitrarily increased without becoming unpleasant. An alternative to focal compression of deeper veins, such as intrafascial saphenous veins in those of normal weight or in obese patients, could be perivenous or paravenous injection of viscous fluids or gels to evoke a regional pressure increase. This is currently being evaluated for hyaluronic acid preparations (21).

A major objective was to develop a compression device that can be monitored in situ with ultrasound. The materials used (film sheet and silicones) fulfil this objective, provided that air bubbles are avoided on application. The effect of the compression can be examined in thrombosed veins without removing the silicone pad (► Fig. 5). This is not possible prior to thrombosis, as the medical stocking required for compression prevents ultrasound examination. Hopes now rest on the development of a film dressing that provides concentric compression. The compression status achieved immediately after application of the silicone pad was not determined, as no conclusions are possible at this time, due to foam residues and venous spasm.

It is conceivable that silicone masses could be added or removed through a covering film sheet using a cannula, in

Fig. 5 Typical ultrasound image at the transitional area between venous segments with eccentric compression (with a silicone pad) and purely concentric compression.



order to obtain a focal increase or reduction in the pressure applied, whereby the effect on the target vein can be directly monitored using ultrasound, optionally with correlation to the local pressure (9, 10, 11).

The morphological objective of eccentric compression in this investigation was a 50% reduction in diameter. On average, this was approximately achieved (► Table 2), but with considerable fluctuations from 22.4–82.4%. As uniform silicone cross-sections were usually selected, this variation reflects both anatomical differences (proximity to bones, depth of fatty tissue) and the pressure increase in the distal direction achieved with concentric compression. The results confirm that even a mean diameter reduction of 50% leads to a decrease in symptomatic courses of 60–70% (► Table 2). In future, a differentiation will have to be made regarding the optimal degree of focal compression after sclerotherapy, taking into account efficiency and comfort and depending on the region and venous anatomy.

Most patients were able to maintain a wearing time of two weeks without any

problems, despite a full programme of everyday and sporting activities. Patients found it very pleasant that showering was not limited and the overall tolerability of the compression devices was very good, particularly the use of soft silicones (Shore A 10). In the 3rd and 4th weeks, after removal of the silicone pad, there was a temporary reduction in the relative advantage of focal compression (► Table 1). It is conceivable that an even longer period of eccentric compression would have been beneficial in some cases.

In this investigation, in contrast to very light compression materials, such as cotton wool or gauze (8, 23, 24), the concept of a compression device with a density similar to that of the body was followed. To avoid the development of shear stress on the skin due to mass effects, the compression device must be tightly bound to the skin. This is satisfactorily achieved with the self-adhesive film sheet, whose adhesive (water-soluble acrylate adhesive) has the property of binding the film sheet very strongly to itself, so that the base film sheet and the covering sheet form a very strong material bond (► Fig. 2). The covering film sheet

Tab. 1 Decrease in venous diameter.

Week	with silicone pad		without silicone pad	
	values	mean	values	mean
2	22.4–74.2 %	52.50 %	8.1–36.7 %	23.10 %
4	32.2–64.5 %	46.40 %	26.1–43.1 %	28.90 %
8	36.1–82.4 %	66.70 %	21.0–61.8 %	39.20 %

	with SGP	without SGP	Reduction
Symptomatic inflammation	12.8%	39.9%	67.8%
Mini-thrombectomies	8.1%	29.7%	72.7%
Analgesics	6.8%	19.6%	65.5%
Discolouration week 8	10.8%	35.1%	69.2%

ensures a very smooth surface, allowing textiles to slide over it almost without friction. As the compression device is largely integrated into the leg shape, it is scarcely visible under the stocking. It can be removed easily at the end of the wearing period, provided that it was applied to shaved or hairless skin.

The system also has potential disadvantages: it is impermeable to vapour, although vapour-permeable film sheets are used, because with two layers the micropores are hardly ever positioned one on top of the other. The covered area must therefore be kept as small as possible. This depends on the performance of the adhesive, which has to ensure that the silicone also remains in place between the film sheets at increased external pressure during the hardening phase. The film sheet zone of 3 cm maintained on both sides of the silicone can probably be reduced by 50–70% without compromising safety, particularly with the use of the rapidly hardening 2-K silicones. Further trials are required.

If profuse sweating occurs, e.g. during sporting activities in mid-summer, the film sheet could detach prematurely or a new application may be required. A routine new application, e.g. after two weeks, may also be advantageous for reasons of hygiene, if the aim is to achieve longer wearing times. To date, hygiene beneath film dressings has only been investigated for conventional applications (e.g. wound covering, catheter fixation) and not in longer-term use. According to a recommendation by the Commission for Hospital Hygiene, transparent dressings used to cover puncture sites and gauze bandages should only be changed if there is a visible necessity, e.g. due to dirt (7). The author's preliminary investigations did not indicate any increased occurrence of resident or

transient micro-organisms under film dressings during a wearing period of up to 4 weeks (19).

Individual silicone pads should also be useable after thermo-occlusive procedures (laser, radio wave, steam) on saphenous veins. In such cases, small diameters require no compression (5). For large diameters, on the other hand, compression is decisive if symptoms are to be avoided (8). Other possible applications are large-diameter spider-burst veins, in anatomical niche areas (e.g. Bisgaard's regimen) or in circular form to relieve pressure on ulcers.

Although the mechanism of post-sclerotherapy problems and their remedy through use of compression have been known in principle for many years (13), the type, degree and duration of optimal compression is only now being gradually understood. There is hope that modern techniques such as MRI (3, 9–11, 14) and now ultrasound in combination with a compression device transparent to ultrasound can provide important contributions.

Conflict of interest

The author is the inventor of the compression devices described. These are currently prototypes and not commercial products. The material for the devices described was provided free of charge by Venartis Inc. (USA). The support had no influence on the preparation of the article.

Ethical guidelines

The data were compiled in compliance with national legislation and the currently valid Declaration of Helsinki.

Tab. 2
Adverse reactions after foam sclerotherapy.

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