

36 Months Sealing Microfoam in Varicose Veins - Our Results

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Abstract

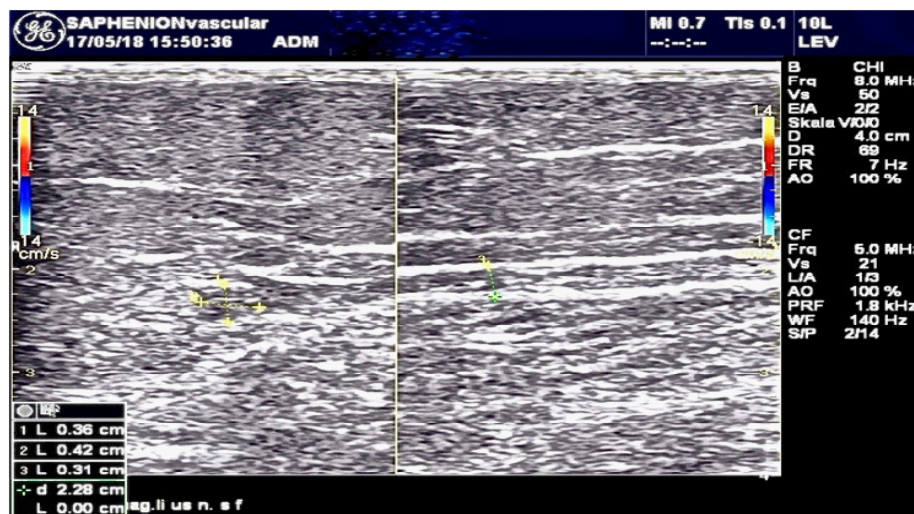
Sealing truncal varicose veins with microfoam - The microfoam for the treatment of varicose veins has been known since 1938 (12). He established himself in the 90s as a solid therapy of varicose veins and spider veins. The treatment management of the varicose disease was clearly facilitated and the therapy was gentle. Since 2010, the United States Food and Drug Administration (FDA) has approved micro foam therapy using ethoxycylerol foam for the treatment of varicose veins and has declared it the "gold standard" of spider vein and retinal vein therapy.

Keywords: *Sealing truncal varicose veins, microfoam therapy, endovenous therapy truncal varicose veins, Sealing Microfoam.*

INTRODUCTION - SEALING VARICOSE VEINS WITH FOAM

Saphenion has been using microfoam therapy for 13 years. We have introduced some changes in injection technique and microfoam. The nearly seven-year successful work with the vein glue „VenaSeal“ suggested the idea to give the microfoam additionally an sealing effect (2,4,6,8,9). These technical improvements, the modifications of the foam and the permanent use

of the ultrasound, the therapy of side branches and partially or completely defective truncal varicose veins (up to a maximum of 5 - 6 mm in diameter) is possible (4,6,7,10,12). It is also recommended after diagnosis in all clinically possible cases. Even with cost aspects - especially with the self payer - the sealing microfoam is an excellent alternative. We no longer have to use only the expensive thermal catheter procedures or the vein glue for the treatment of truncal varicose vein sections. The closure rate is 88 - 95%.



Ultrasound picture of GSV left leg 6 months after treatment with Sealing Microfoam

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OUR RESULTS IN SEALING FOAM THERAPY

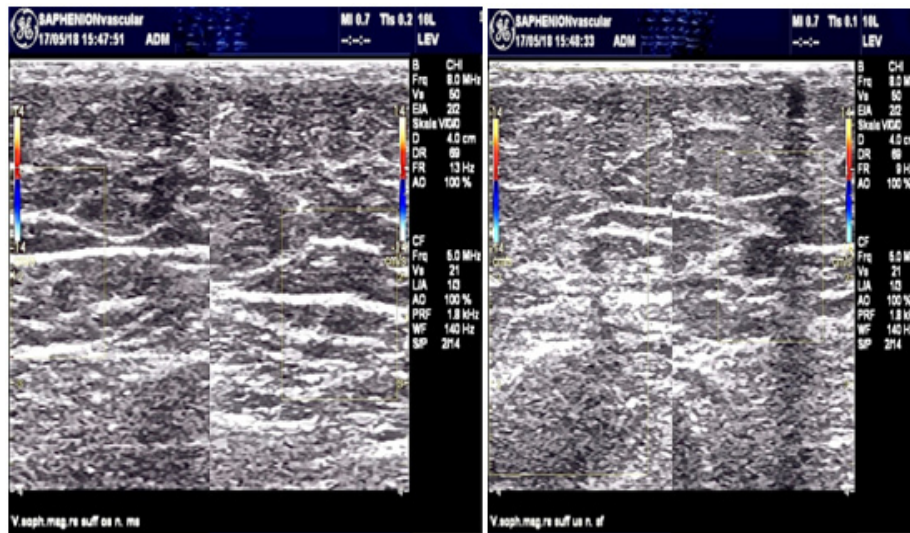
Since December 2006, we have performed over 13822 microfoam treatments (ca. 92 therapies/month).

In the last 36 months (5/2016 - 5/2019) Saphenion was used in 4104 cases for the treatment of Sealing Microfoam.

In 394 cases truncal varicose veins were treated. Specifically, this involved the small saphenous vein (SSV) in 145 cases, the great saphenous vein (GSV) in 118 cases, and the accessory veins in 131 cases. The

mean age of the patients was 47 years (18-90 years). The therapy of incomplete truncal varicose veins is 100% successful over a period of 36 months. The small saphenous vein is closed in 95.1% (138 veins). The great saphenous vein was closed in 88.5% (105 veins) over the 36 month - period. Accessory veins could be permanently closed in 94.7% (124 veins).

Thus, the microfoam therapy is also predestined for use in cosmetically therapy and for the elderly patient.



Sonographic pictures of GSV right leg after treatment with Sealing Foam

OUR DISCUSSION

In the last 20 years, the necessary quality criteria for endovascular interventions on veins with varicose changes were largely laid down, and several comparative studies on functional efficiency of radical stripping surgery on the one hand and endovenous treatments on the other hand, were furthermore conducted (1,2,3,11). By now, it has emerged as an undeniable fact that endovenous interventions do not only exhibit a merely cosmetic advantage as was hitherto assumed. They also have clinical advantages and quite significantly reduce side effects and complications such as still occur regularly today as in the past in connection with the conventional surgical technique. This is not a new knowledge. Also the surgeons of the „Golden Twenties“ didn't love the radical surgery (12,14,16)!

But today we have the ultrasound and all colleagues who work with endovenous procedures meanwhile have reliable criteria for a high - quality therapy.

We do not need anesthetics anymore. Elastic stockings should be for 10-14 days. Working and sports is possible one day after treatment.

The significantly reduced side effects and a well - nigh negligible pain score are also clear advantages in comparison with laser and radio wave therapy. No paresthesias, no hypesthesias, phlebitis in 2% of all cases, rare occurrence of skin pigmentations are sure.

In the final analysis, the new sealing procedure has to meet solely the hard criterion of efficacy, namely the permanence of an effective vein closure in our defined cases.

Likewise, the foam therapy is found in the guidelines of the German Society for Phlebology. The European Vascular Surgeon's Guidelines see the use of second-choice therapy in the field of truncal varicose veins in microfoam therapy - before radical surgical stripping. With the success of the vein glue, the idea was close to developing the Sealing Microfoam (6,7,8,9,10,12,13).

LOWER SIDE EFFECTS

In addition to improving permanent venous occlusion, the rate of side effects is also reduced. We see less frequently the ugly post-therapeutic brown lines and spots, so-called hyperpigmentations. Ecchymoses (bleeding under the skin) have become very rare (<5%). We have seen phlebitis in 9 cases. A partial deep vein thrombosis of lower leg veins was seen in 2 cases. This has led us to carry out single thrombosis prophylaxis for all microfoam therapies in the truncal vein system (the guideline for microfoam therapy does not demand this!). Neurological abnormalities were also not reported. In one case, we saw multiple puncture ulcerations after therapy - however, treatment was given abroad with various ointment dressings.

In addition to visible small puncture hematomas, our patients report primarily extrinsic pressure and tenderness over the treated vein. Muscular catlike symptoms also appeared (this is similar to the symptoms after VenaSeal - superglue).

Other side effects did not occur in any case. Thus, endovenous sealing foam therapy is a very good, effective, effective and inexpensive alternative to the also frequently used catheter methods laser, radio wave, superheated steam, Clarivein, and vein glue (2,4,6,7,8,9,10,12,13).

CLOSURE RATE IN RELATION

Thus, the Sealing procedures appears to be on the same level with, or even superior to the laser system. In the time periods between 12 and 36 months covered by follow-up examinations up to now, both procedures have proven quite clearly superior (100% incomplete truncal veins, 95% small saphenous vein) to laser therapy in terms of effectiveness. So Sealing Microfoam has the nearly same closure rate then radiofrequency over 3 years in treatment of SSV and incomplete truncal varicose veins (2,4,9,10,12,13,15,17).

By now, Sealing Microfoam has undeniably become at SAPHENION the therapy of the first choice for the treatment of the SSV to a vein diameter of 6mm. Here, we meanwhile consider the well-known risk of

neurological side effects and complications associated with the application of the laser and radio frequency techniques as being too high.

In the light of the 18 years of experience, we have gathered by now, we recommend that every vein center that applies endovenous treatment should have at least 2 alternative treatment procedures at its disposal. For us, this means that in practical work with VenaSeal®, with Sealing Microfoam and Radiofrequency all insufficient saphenous veins should as far as possible always be treated.

Independently of this and including all experiences with modifications of the sealing technique we at SAPHENION® meanwhile regard the non tumescent, non thermal Sealing Therapy as treatment of the first choice in the range of catheter - supported therapeutic procedures in truncal varicose veins, SSV or VSAA - varicosis.

And we see this method as a very good method also in ultrasound - guided treatment of great saphenous veins, recurrent veins, side branches of truncal veins and greater perforator veins.

Comment: Therapies with saline solutions and pre coagulated blood are not carried out for technical reasons (14,15,16).

REFERENCES

- [1] http://www.der-niedergelassene-arzt.de/fileadmin/user_upload/zeitschriften/vasomed/Artikel_PDF/2017/01-2017/Murena.pdf
- [2] Carlton R, Mallick R, Campbell C, Raju A, O'Donnell T, Eaddy M. Evaluating the Expected Costs and Budget Impact of Interventional Therapies for the Treatment of Chronic Venous Disease. Am Health Drug Benefits. 2015 Oct;8(7):366-74. PubMed PMID: 26557230; PubMed Central PMCID: PMC4636275.
- [3] <http://www.phlebology.de/leitlinien-der-dgp-mainmenu/280-leitlinie-zur-diagnostik-und-therapie-der-krampfadererkrankung>
- [4] Todd KL 3rd, Wright DI; VANISH-2 Investigator Group. The VANISH-2 study: a randomized,

- blinded, multicenter study to evaluate the efficacy and safety of polidocanol endovenous microfoam 0.5% and 1.0% compared with placebo for the treatment of saphenofemoral junction incompetence. *Phlebology*. 2014 Oct;29(9):608-18. doi: 10.1177/0268355513497709. Epub 2013 Jul 17. PubMed PMID: 23864535.
- [5] <http://gesundheitsnews.imedo.de/news/1017861-krampfadern-minimalinvasive-therapien-auf-dem-vormarsch>
- [6] King JT, O'Byrne M, Vasquez M, Wright D; VANISH-1 Investigator Group. Treatment of Truncal Incompetence and Varicose Veins with a Single Administration of a New Polidocanol Endovenous Microfoam Preparation Improves Symptoms and Appearance. *Eur J Vasc Endovasc Surg*. 2015 Dec;50(6):784-93. doi: 10.1016/j.ejvs.2015.06.111. Epub 2015 Sep 16. PubMed PMID: 26384639.
- [7] Carugo D, Ankrett DN, Zhao X, Zhang X, Hill M, O'Byrne V, Hoad J, Arif M, Wright DD, Lewis AL. Benefits of polidocanol endovenous microfoam (Varithena®) compared with physician-compounded foams. *Phlebology*. 2016 May; 31(4): 283-95. doi: 10.1177/0268355515589063. Epub 2015 Jun 1. PubMed PMID: 26036246; PubMed Central PMCID: PMC4838175.
- [8] Deak ST. Retrograde administration of ultrasound-guided endovenous microfoam chemical ablation for the treatment of superficial venous insufficiency. *J Vasc Surg Venous Lymphat Disord*. 2018 Jul; 6(4): 477-484. doi: 10.1016/j.jvsv.2018.03.015. PubMed PMID: 29909854.
- [9] Star P, Connor DE, Parsi K. Novel developments in foam sclerotherapy: Focus on Varithena® (polidocanol endovenous microfoam) in the management of varicose veins. *Phlebology*. 2018 Apr; 33(3): 150-162. doi: 10.1177/0268355516687864. Epub 2017 Feb 6. Review. PubMed PMID: 28166694.
- [10] Coleridge Smith P. Foam and liquid sclerotherapy for varicose veins. *Phlebology*. 2009;24 Suppl 1: 62-72. doi: 10.1258/phleb.2009.09s007. Review. PubMed PMID: 19307442.
- [11] Wittens C, Davies AH, Bækgaard N, Broholm R, Cavezzi A, Chastanet S, de Wolf M, Eggen C, Giannoukas A, Gohel M, Kakkos S, Lawson J, Noppeney T, Onida S, Pittaluga P, Thomis S, Toonder I, Vuylsteke M, Esvs Guidelines Committee, Kolh P, de Borst GJ, Chakfé N, Debus S, Hinchliffe R, Koncar I, Lindholt J, de Ceniga MV, Vermassen F, Verzini F, Document Reviewers, De Maeseneer MG, Blomgren L, Hartung O, Kalodiki E, Korten E, Lugli M, Naylor R, Nicolini P, Rosales A. Editor's Choice - Management of Chronic Venous Disease: Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS). *Eur J Vasc Endovasc Surg*. 2015 Jun;49(6):678-737. doi: 10.1016/j.ejvs.2015.02.007. Epub 2015 Apr 25. Review. PubMed PMID: 25920631.
- [12] Gibson K, Kabnick L; Varithena® 013 Investigator Group. A multicenter, randomized, placebo-controlled study to evaluate the efficacy and safety of Varithena® (polidocanol endovenous microfoam 1%) for symptomatic, visible varicose veins with saphenofemoral junction incompetence. *Phlebology*. 2017 Apr;32(3):185-193. doi: 10.1177/0268355516635386. Epub 2016 Jul 9. PubMed PMID: 27013511; PubMed Central PMCID: PMC5405826.
- [13] Todd KL 3rd, Wright DI; VANISH-2 Investigator Group. The VANISH-2 study: a randomized, blinded, multicenter study to evaluate the efficacy and safety of polidocanol endovenous microfoam 0.5% and 1.0% compared with placebo for the treatment of saphenofemoral junction incompetence. *Phlebology*. 2014 Oct; 29(9):608-18. doi: 10.1177/0268355513497709. Epub 2013 Jul 17. PubMed PMID: 23864535.
- [14] <http://www.saphenion.de/news/schon-sauer-bruch-tat-es-stammkrampfadern-kleben/>
- [15] <http://www.saphenion.de/news/kochsalzloesung-zur-veroedung-ein-fall-fuer-die-justiz/>

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- [16] <http://www.saphenion.de/news/stripping-radikales-entfernen-von-krampfadern-gold-standard/>
- [17] van den Bos R. et al. : Metaanalyse randomisierter klinischer Studien und Fallserien, J Vasc Burg., 2008, Aug. 8
- [18] Bier, Braun, Kümmel: Chirurgische Operationslehre, begründet. von F. Sauerbruch; Johann Ambrosius Barth, Leipzig; 1958
- [19] https://youtu.be/UepVWe8SW_k
- [20] <https://youtu.be/qskRdOLLU90>

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