

Saphenion®: 11 Years of Vein Glue for Varicose Veins - Our Review

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1. Abstract

The paper is a review about our 11 years of vein glue for varicose veins. Since August 1, 2012 we have been working officially and certified with the VenaSeal® - vein glue. Regular work with this innovative and gentle therapy - system began in the Rostock practice.

Medical therapy with cyanoacrylate – glue history: The chemical components have been known since 1949, the first use in surgical medicine is described at the beginning of the 60s as a tissue

adhesive or suture substitute in wound care. Almost all surgical disciplines have already used cyanoacrylate, e.g. dermatology, ophthalmology, orthopedics, surgery / vascular surgery, neuroradiology, orthodontics. The risk of an allergic reaction is not really real - we have found eight publications or scientific studies with the assumption in medline or pubmed so far.

The FDA approval from 2/2015 stated: VenaSeal® is bio-compatible and bio-resorptive, non - carcinogenic and non – allergenic (Figure 1)!



Figure 1: Dr. Ulf Zierau in Saphenion® Berlin/Rostock – Thanks!

2. Introduction

It's the base of varicose vein therapy, that all varicose veins should be treated actively. This we can find in nearly all guidelines worldwide. An insufficient varicose vein is working like a downpipe - the blood pressure at the lower leg is increased chronically. All the specialists know, that mobilisation and compression alone can not normalize the venous function of outflow venous blood from the leg. If we are passive in our treatment options, we get the typical chronicle venose disease. Nearly 70% of all adults in Europe have clinical signs of this CVD.

11 years of vein glue for varicose veins – Our Selection criteria for vein glue:

VenaSeal® is one of the endovenous techniques with a high effectiveness, the quality standards are similar to those of other treatment options (laser, radio wave). VenaSeal® is safe in the treatment of all truncal veins and side branches up to a diameter of 1.5 - 1.8 cm. Larger diameters are possible. VenaSeal® is now also used successfully for perforating veins. We also recommend vein gluing for ectatic veins (over 1.5 cm), effective results are also

possible here. The therapy of post-inflammatory (- thrombotic) truncal veins is very well possible. VenaSeal® is the first-choice therapy for truncal veins in the lower leg. VenaSeal® is the most expensive endovenous catheter when used on one truncal vein, but simultaneous therapy on several truncal veins reduces costs compared to laser/radiowave therapy and classic radical surgical therapy [1, 2, 3, 4, 7, 8, 9, 10, 12, 13, 14, 15, 17, 19, 20, 27, 28, 29, 30, 31, 32, 33, 35, 36].

In addition, 20 years ago in 2003, far from the beaten tracks of radio wave and laser, the development of a fascinatingly simple, yet nevertheless highly effective method of sealing veins - the VenaSeal®-Closure-technique - was initiated. After CE - approval had been granted in the autumn of 2011, a number of vein centers in Germany and Europe started using the VenaSeal® - system. By now, 35 centers are working successfully with the new therapy system in Germany alone. Today there is an approval in all countries, also in USA since 2 / 2015. The author has applied VenaSeal® for the first time in a great saphenous vein on 1st. August 2012 (Figure 2).



Figure 2: VenaSeal® - Closure technique – hospitalation

3. Material and Methods

In the last 132 months we have treated the great saphenous vein in 2666 cases, the saphenous vein in 1042 cases, the VSAL in 200 cases, VSAM in 126 cases, the femoropopliteal vein in 69 cases, the Giacomini vein in 5 cases and the connecting veins in 15 cases with the vein glue alone. The age of the patients ranged from 13 - 94 years.

Within the total number of operations, one truncal vein was treated

in 495 cases, two truncal veins simultaneously in 1062 cases, three truncal veins in 344 cases, 4 truncal veins in 98 cases, and 5 truncal veins simultaneously in 16 cases. Two patients were treated with 6 truncal veins and one aneurysm in one session (total number of 2017 patients). In 61 cases we simultaneously treated a leg ulcer - these healed completely between 2 and 16 weeks. We also treated patients with HIV, Parkinson's disease/epilepsy, COVID-19 (59), multi-allergies, or hepatitis without clinical problems.

Almost all patients received analgesia; in 332 cases, patients did not request sedation (16.5% of all operated patients). One patient underwent pain acupuncture, and one patient came with oxygen equipment. Only in 1% of our patients, we saw the need for post-operative compression stocking - therapy after vein glue. Oxygen

- multistep - therapy was performed in 373 patients (18,3%) within the last 38 months. The follow - up observation period in our study was up to 132 months. For the treatment of one truncal vein, we use 1.5 - 2.0 ml of glue. The operation time for one great saphenous vein is 10 - 15 min. and for 2 veins 15 - 25 min (Figure 3,4).

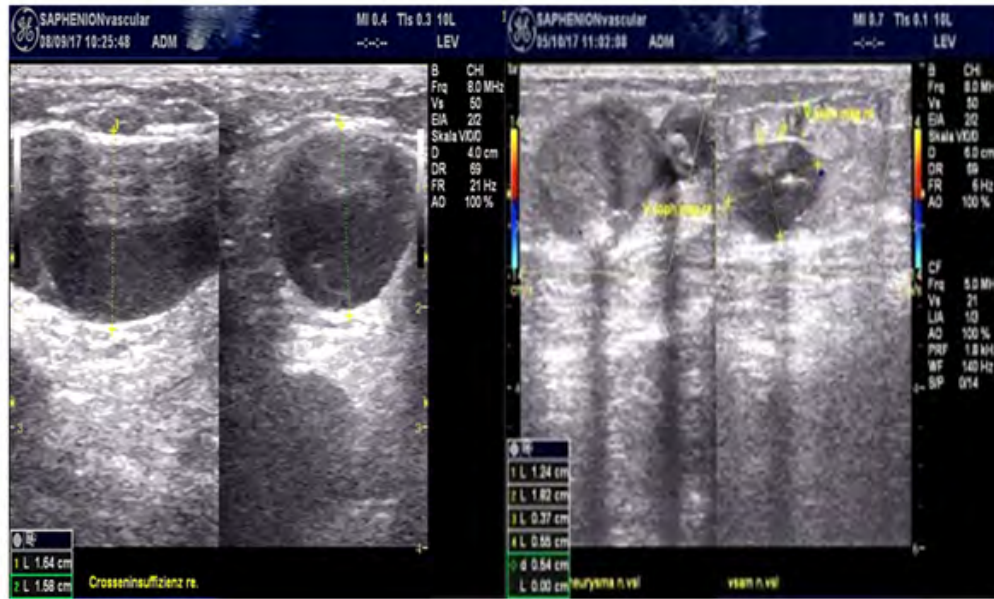


Figure 3: Venous aneurysm nearly the junction of GSV, ultrasound after VenaSeal®-therapy, (marker is showing the diameter of vein)



Figure 4: Typical ultrasound of GSV after sealing

4. 11 Years Vein Glue for Varicose Veins – Results

Duplex - Follow up over 132 months: On the first day all 4109 veins were reexamined - 4104 veins were initially occluded = 99.82% occlusion rate. After 1 - 3 months we found 78 partial and 17 complete recanalizations with a follow-up of 4098 veins = 97,68% occlusion rate. At 4 - 6 months post-op we saw 88 partial

and 31 complete recanalizations with a follow-up of 3363 veins = 97.09% closure rate. After 7 - 9 months 101 partial and 56 complete recanalizations could be detected by sonography with a follow-up of 3058 veins = 96.16% occlusion rate. No further recanalizations were seen over the overall period. The occlusion rate over 132 months of treatment is therefore 96.16% (Figure 5).



Figure 5: 132 months VenaSeal® in 4109 veins and 2017 cases - the closure rate in time line.

5. Results

The pain score (range 1-10) for subjectively felt pain on the 1st day post - sealing was between 1,6 and 3,4 (2.1) - in RFITT between 3,8 and 4,1. We saw non-specific tissue inflammation in 257 veins (6.1%, no phlebitis!). In our 39-months SMT study, we saw tissue inflammation in only 3.8% of the 387 patients who underwent follow-up [34].

Long-term discoloration of the skin was seen in 0.6% of treated cases, especially in epifascial (directly under the skin) veins. A bleeding tendency from the puncture site was seen in 49 cases (1.2%) in patients on antithrombotic drugs. We found a lymphatic fistula at the puncture site in only 36 veins (0.9%). Glue - spots (granulomas) 10 - 14 months after VenaSeal® therapy were diagnosed in 4 veins. In particular, even subcutaneously situated saphenous veins could be glued without any significant skin reaction (reddening, swelling). A long covid - vascular reaction was found

in 12 cases. In all other cases subjected to follow - up examinations, no complications of any kind, no paresthesias or hypesthesias, no permanent skin reactions, no phlebitis or thrombosis or infections were observed.

We also clearly prefer VenaSeal® in treatment of SSV, and now also in GSV due to the large number of neurological sensations in connection with treatment by Laser and Radiofrequency [22, 23] (Figure 6). Nearly all patients were greatly surprised at the fully ambulatory intraoperative procedure and the brief and pleasant postoperative convalescence phase. All patients were able to leave the office between 30 and 120 minutes after the intervention. In the case of VenaSeal, we have up to now refrained from applying compression therapy in over 90% of all cases. We prefer to use compression stockings only in cases, the diameter of the treated vein ist over 1,5 cm or in treatment of venous aneurysm or ectatic varicous veins (Figure 7).

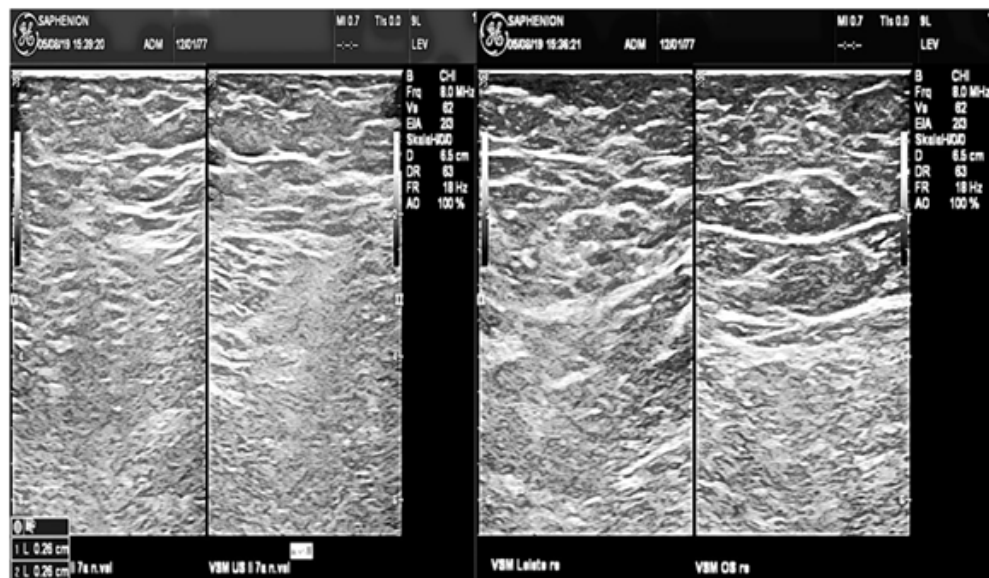


Figure 6: VenaSeal® - ultrasound control after seven years



Figure 7: VenaSeal® therapy both GSV and SSV in 37 minutes

6. 11 Years of Sealing of Varicose Veins - Our Discussion

Quality standards for all endovenous procedures have been developed. We have safe criteria for all catheter-based therapeutic procedures. VenaSeal® works without mechanical or thermal energy, side effects of laser or radio waves are not an issue here. The pain score - both during and after therapy is significantly lower (1.3 VenaSeal - 3.4 radiofrequency). And, we can treat all diseased truncal varicose veins (with max. 2 catheters) in one session.

After 22 years of work with endovenous technology: Our experience with endovenous therapy, and for 11 years specifically with the glue VenaSeal®, makes it our basic therapy for truncal varicosis. Thermal therapy (laser, radio wave) is not out, but the therapy path has become more diverse and differentiated! This certainly also includes economic aspects! [2, 3, 4, 5, 6, 7, 9, 10, 12, 13, 14, 15, 17, 19, 27, 28, 29, 30, 31,36].

We do not need anesthetics anymore and can in most cases do without postoperative compression therapy. Elastic stockings should nevertheless by all means be recommended after the treatment of thicker saphenous varicose veins measuring > 1,2 cm. They become compulsory where we intend to apply gluing therapy in larger lumens measuring 1.5 cm and more, ectatic veins, junction aneurysms and also perforator veins [7, 27, 28, 29, 30, 31, 34, 35, 36]. The significantly reduced side effects and a well - high negligible pain score are also clear advantages in comparison with laser and radio wave therapy. No paresthesias, no hypesthesias, no phlebitis, extremely rare occurrence of skin pigmentations are only a few of the important advantages of the VenaSeal® - procedure.

In the final analysis, the procedure has to meet solely the hard criterion of efficacy, namely the permanence of an effective vein closure. And as far as this aspect is concerned, both the first results of the eSCOPE study [19] and the results of single - center studies,

and also currently of the VeClose study [15] and last but not least, the German Multicenter study 2020 [7] are very good. The closure rate is similarly high as that achieved with radio waves, namely between 93 - 100% when all results are summarized.

Thus, the VenaSeal® - procedure appears to be on the same level with, or even superior to the high - frequency radio wave system (14,18). In the time periods between 12 and 36 months covered by follow - up examinations up to now, both procedures have proven quite clearly superior (97,6%) [7,17,18, 21, 30, 36] to laser therapy in terms of effectiveness. The results of all comparative studies show that the VenaSeal® -glue is clearly superior with regard to postoperative side effects though. Both the pain score and the rate of side effects are very low in comparison [7, 27, 30]. Particularly pain as well as the neurological side effects no longer play any significant role at all. These are the main problem associated with laser and radio wave therapy though. By now, VenaSeal® has undeniably become at SAPHENION® the therapy of first choice for the treatment of the SSV. Here, we meanwhile consider the well - known risk of neurological side effects and complications associated with application of the laser and radio frequency techniques as being too high [7, 8, 9, 10, 12, 18, 20, 21, 27, 28, 29, 30, 31, 33, 35, 36].

For us, this means that in practical work with VenaSeal®, all insufficient saphenous veins should as far as possible always be treated in one session [7, 28, 29, 30, 31, 32, 33, 35, 36]. Independently of this and including all experiences with modifications of the sealing technique we at SAPHENION® meanwhile regard VenaSeal®-closure as treatment of first choice in the range of catheter - supported therapeutic procedures for GSV and SSV or VSAA - varicosis. Also in obese patients (Figure 8) and older patients we see great advantages in using VenaSeal®-Closure.

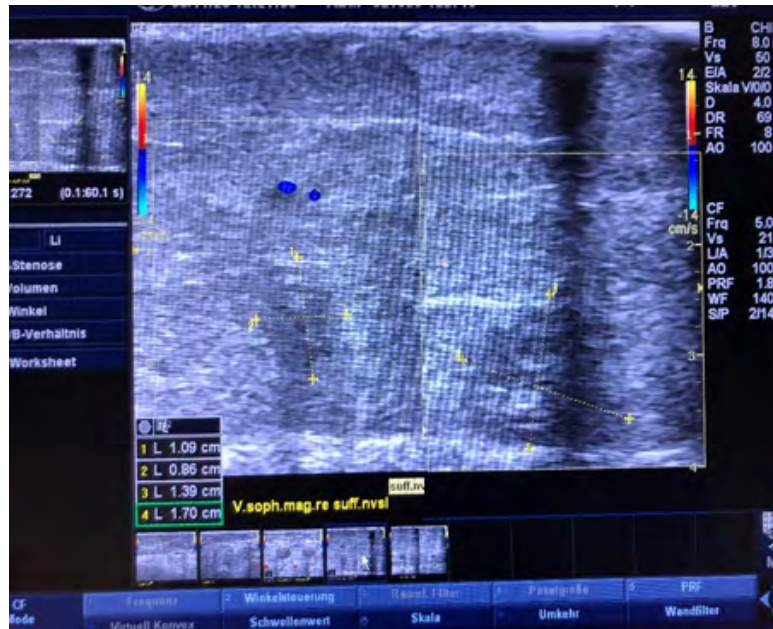


Figure 8: VenaSeal® is first choice in therapy of obese patients

7. Conflict of Interest

There are no conflicts of interest; the present research paper was not sponsored.

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