

## 10 Years Venaseal® - Our Long Time Experiences with Vein Glue

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**1. Abstract**

10 years facts and experience in using vein glue – today our patients are now very well informed about this therapy method for varicose veins, which has been offered for 11 years. After 10 years of use, we have so far treated 1874 patients on 3757 saphenous veins - over 800,000 patients worldwide have now been treated with the vein glue Venaseal®. In the meantime, we have successfully used the vein glue Venaseal® in 48 patients with COVID-19 infection after they have recovered. However, these are kept within practical limits in an outpatient specialist practice that works surgically and with catheter medicine, since the hygiene status is already primarily increased. This paper is about our 10 years - experiences in treatment of all kind of truncal varicose veins with the vein glue Venaseal®: 122 months - follow up of 1874 cases in treatment of 3757 truncal varicose veins (Figure 1).

Over 23 years, about from 1998 by now, varicosis has been increasingly treated endo venously by catheter technology. Thus, in the course of the last few years, plenty of experience has been gathered with endoluminal therapy, quality criteria have been defined and standards for the different techniques developed.

After 10 years of practical work with the vein glue, we see – like the international studies - the high effectiveness with a very low rate of side effects. Initially approved and used by the manufacturer exclusively for normal-caliber saphenous veins, the vein glue has conquered other areas of application in endo venous therapy. Dilated veins and aneurysms are now successfully treated.

The presented actual paper sheds light on the advantages and disadvantages of the vein glue Venaseal® and presents the 109 months results of a single - center praxis study with prospective design. We will report our 122 months experiences and results of our long time prospective comparative study of Venaseal® - Closure in the treatment of 3753 truncal varicose veins.



**Figure 1:** Dr. Ulf Zierau: Saphenion® Berlin/Rostock

**2. Introduction**

It's the base of varicose vein therapy, that all varicose veins should be treated actively. This we can find in 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, (Figure 3) that mobilization and compression alone cannot normalize the venous function of outflow venous blood from the leg. If we are passive in our treatment options, we get the typical chronic venous disease. Nearly 60% of all adults in Europe have clinical signs of this CVD.

Since, 23 years varicose veins have been increasingly treated endo venously. Before this, the varicose veins were treated with sclerotherapy, the 116 years old radically “stripping” - surgery method and since 1930 also as sealing method with high concentrated glucose solution (Figure 5).

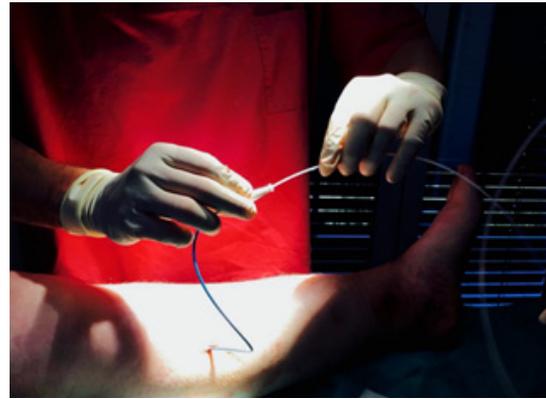
At the modern time start, the rather inconvenient VNUS® Closure Plus procedure and the more convenient linear laser procedure were used, and these were followed in 2006/2007 by the bipolar RFITT® catheter, the VNUS® Closure Fast system and the radial laser. These endo venous treatment techniques were followed by the Clarivein® System and the Venaseal® System in 2011/2012. Thus, (Figure 2) in the course of the last 11 years, plenty of experience has been gathered with endoluminal therapy, quality criteria have been defined and standards for the different techniques have been developed [2-4, 7, 8, 10, 11, 13-16, 18, 20, 21, 28-34].

One very important technical development combined with the beginning of the endo venous therapy was the color ultrasound (duplex) - we can see the catheter inside the veins, the glue and we can control the tip of catheter, the work inside the vessel and the effects inside the body - without any radiation and without iv. contrast agents. These is a very important fact, because working with an endo venous catheter without ultrasound isn't a fully noninvasive therapy because of using phlebography (Figure 6). have described exactly the sonographic appearances of common disorders of all tissues. They have worked about the high sensitivity of ultrasound in tissue diagnostics [1, 23, 24].

Nearly 19 years ago in 2003 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. The author has applied Venaseal® for the first time in a great saphenous vein on 1st. August 2012.



**Figure 2:** VenaSeal® hospitation at Saphenion® Berlin



**Figure 3:** VenaSeal® - Closure technique

### 3. Material and Method

With some light modifications of the manufacturer's application instructions of the sealing technique we are starting 1-1,5 cm from the saphenofemoral junction, and a spot of glue is applying at intervals of 2 - 3 cm, depending on the diameter and the flow and pressure of the vein. We measure this pressure with an endo venous catheter before application of glue inside the vein! Thick branch - offs of auxiliary side branches were additionally treated with a single - shot of glue. The maximal diameter of treated truncal veins was 2,3 cm, also venous aneurysms, dilated veins and perforators are treating (Figure 4).

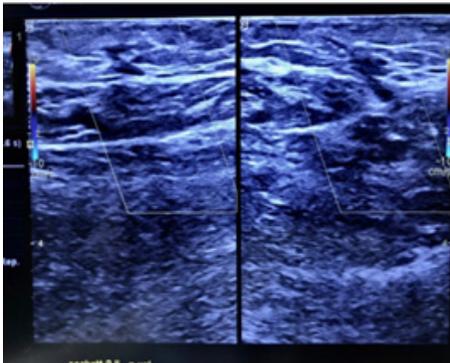
The great saphenous vein was treated in 2455 GSV, small saphenous vein in 945 cases, VSAL in 175 cases, VSAM in 114 cases, femoropopliteal vein in 55 cases, Giacomini's vein 5 cases. Also, ulcer cruris were included in 45 cases. A new therapy option is ablation of perforator veins with the glue (7 cases).

Venaseal® interventions were performed under light sedation with dormicum or local anesthesia for venous access accompanied by music therapy, in 310 cases (16, 6%) the patients dispensed and didn't get any anesthesia. One patient performed pain acupuncture on herself on point G4.

All patients are given a follow - up examination by duplex sonography in the scope of a prospective study (our own quality management) on the 1st day / 2-5 months / 6-8 months and 9-12 months. After this we controlled every following year. The most of all duplex sonography examinations post intervention were done by other colleague, not by the vascular surgeon treated the truncal varicose veins.



**Figure 4:** Venous aneurysm nearly junction of GSV, ultrasound transverse and longitudinal after VenaSeal®-therapy, (marker is showing the diameter of vein).



**Figure 5:** perforator veins lower leg after sealing



**Figure 6:** Typical ultrasound of GSV after sealing

#### 4. Results

During the time period from 1st. September 2012 to 19st. September 2022 (122 months), VenaSeal® was used for treatment of truncal varicose veins to achieve closure in 3757 truncal varicose veins. In 489 patients one saphenous vein were treated; in 999 patients two saphenous veins were treated; in 302 patients 3 saphenous veins were treated. In 76 cases 4 truncal veins, and in nine cases 5 veins, in two cases 6 truncal veins were treated simultaneously. So nearly 73% of all patients have got a treatment of all truncal varicose veins simultaneously in one session.

Grade 2 - 4 varicose veins of the GSV according to Hach, and in the case of the SSV grade 2 - 3 varicose veins acc. to Hach, was

the inclusion criterium. In accessory veins we treated the inguinal truncal in length between 12-25 cm.

On the 1st. day 3757 veins were checked - 3750 veins were closed initially = 99, 82%. In the scope of follow - up, and up to the 2. (Figure 7) Months partial recanalization was found in 74 veins, and complete recanalization was found in 17 veins. This corresponds to a closure rate of 97, 56%.

Over a time period of 6 - 8months after the treatment, we were able to follow up 3156 saphenous veins, and here we found 83 partial and 29 complete recanalization. The closure rate is 97, 01%.

Followed up over a 9 - 12months time period were 2696 saphenous veins, and 96 partials and 53 complete recanalization were found, resulting in an effectiveness of 96,07%.

No further recanalization was found after 122 months. All 44 leg ulcers were healed until to 20 weeks after intervention.

3757 truncal varicose veins having been sealed with Venaseal®, the results achieved over the entire time period of 122 months are equivalent to a closure rate of 96.07%.

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. In 268 treated veins (7, 44%), we observed a postoperative unspecific inflammatory skin reaction after approx. 10 - 14 days in the Venaseal® - group; with appropriate antiphlogistic treatment with prednisolone and cooling bandage, this subsided within 3 - 5 days. New therapy option seems to be the post op massage therapy in combination with oxygen multistep therapy: We have treated until today 270 patients with this adjuvant therapy and here we have seen a 39% reduction of inflammatory foreign body reaction in a 22 months study [35].

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

Only in 34 cases (0, 9%) we have seen a lymphatic fistula on the peripheral puncture. In particular, even subcutaneously situated saphenous veins could be glued without any significant skin reaction (reddening, swelling). In 5 cases we have seen a Long COVID vein wall reaction.

We also clearly prefer Venaseal® in treatment of SSV (Figure 8), and now also in GSV due to the large number of neurological sensations in connection with treatment by Laser and Radiofrequency [23, 24].

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 98% of all cases. We prefer to use compression stockings only in 2% of all cases – if the diameter of

the treated vein is over 1,5 cm - or in treatment of venous aneurysm or dilated varicose veins.

#### Closure rate & cases treated

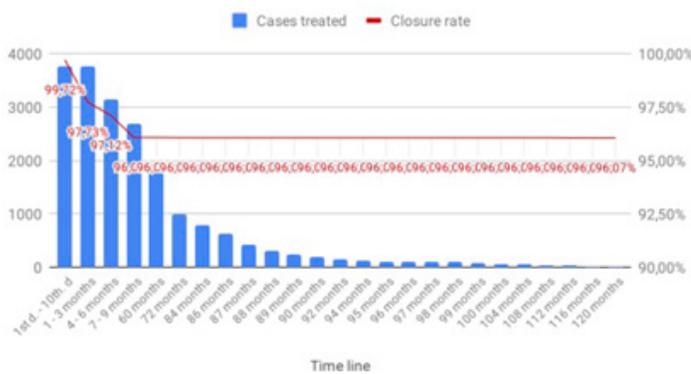


Figure 7: 122 months VenaSeal® - the closure rate in time line.



Figure 8: VenaSeal® is first choice in sealing SSV

## 5. Discussion

In the last 23 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 endo venous treatments on the other hand were furthermore conducted. 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. By now, it has emerged as an undeniable fact that endo venous interventions do not only exhibit a merely cosmetic advantage as was hitherto assumed.

Thus, the colleagues who work with endo venous procedures meanwhile have reliable criteria for a high - quality therapy [2-7, 10, 11, 13-16, 18, 20, 28, 29-32].

The Venaseal® - closure procedure is one of the new technical developments in the series of endo venous therapeutic procedures. Although it is a catheter - based procedure in terms of the basic principle of the therapeutic approach, it differs fundamentally with regard to the closure technique.

The procedure is not a thermal one, while the glue likewise gives rise to a certain temperature (approx. 40 - 45°C). The vein glue is fully biocompatible, so far, after nearly 10 years of use (122 months), we have not seen any allergies. There are two works in

the literature that describe a contact allergy of the skin after touching the glue. Allergies after injection into the varicose veins have only been described in one case worldwide.

The rate of side effects is therefore well below that of comparable thermal endo venous techniques (laser, radio wave) in the treatment of truncal varicose veins.

The bio resorption of the glue takes between 12 and 24 months. The same resorption processes can also be found in humans as in the more than 150 publications on bio resorption in animals. The resorption models in animal experiments all show a biological degradation of the cyanoacrylate glue between 4 and 9 months. The absorption of the vein glue can also be followed macroscopically with regular ultrasound controls.

But not only that: We now have our own histological findings from human veins 10 - 14 months after endo venous cyanoacrylate vein glue. All four cases examined, show a complete breakdown of the glue in the remnants of the vein.

Side effects as those known to occur in connection with laser and radio wave therapy ultimately play no significant role here. The thermal therapy (laser, radio wave, superheated steam) on the lower leg has now been put in a critical light internationally and nationally since the number of nerve lesions after thermal therapy cannot be neglected. At the annual meeting of the German Society for Vein Medicine in early September 2020 in Leipzig, this topic was discussed again openly. As a result, the majority took a critical distance on thermal therapy of the small saphenous vein and the great saphenous vein on the lower leg as well as the therapy of perforating veins using laser or radio waves. These reservations now also apply to the treatment of recurrent varicose veins after radical surgical stripping.

So, the necessary reliable closure is achieved by means of a no tumescent, no thermal cyanoacrylate glue. The basic chemical formula of which has been known since 1949. First being used in operative medicine in the early 60s as tissue adhesive or replacement of wound sutures.

Today it is using in nearly all operative disciplines, i. e. gastroenterology, children surgery, dermatology, ophthalmology, orthopedics, surgery, vascular surgery and orthodontics. Interventional radiologists use this cyanoacrylate glue in the treatment of vascular malformations since 1981. We also were using this glue in vascular surgery at the Charité – hospital Berlin since 1986!

Next advantage - we do not need anesthesia 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, dilated veins, junction aneurysm and also perforator veins [7, 28, 29, 30, 31, 32].

The significantly reduced side effects and a well - nigh negligible pain score are also clear advantages in comparison with laser and radio wave therapy. We didn't found any case, patient was reporting about problems of paresthesia or hypesthesia. Also, not phlebitis, extremely rare occurrence of skin pigmentations is only a few of the important advantages of the Venaseal® - procedure.

In the final analysis, the new procedure has to meet solely the hard criterion of efficacy, namely the permanence of an effective vein closure. The first results of the eSCOPE study [20] 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 [15, 19]. In the time periods between 12 and 36 months covered by follow - up examinations up to now, both procedures have proven quite clearly superior (99, 6%) [7,18,19, 22, 31] to laser therapy in terms of effectiveness.

The results of first 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, 28, 31]. 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, 10, 11, 13, 19, 21, 22, 28, 29-32, 34].

For us, this means also, that in practical work with VenaSeal®, all insufficient saphenous veins should as far as possible always be treated in one session [7, 29-34].

A simultaneous double therapy with micro foam (ethoxy sklerol) is possible but carries the risk of phlebitis. Scientific studies on this combination therapy have Gibson et al. submitted. It is essential to first wait for the truncal varicose veins to heal - in many cases, there is a significant decrease in the lateral branch varicose veins!

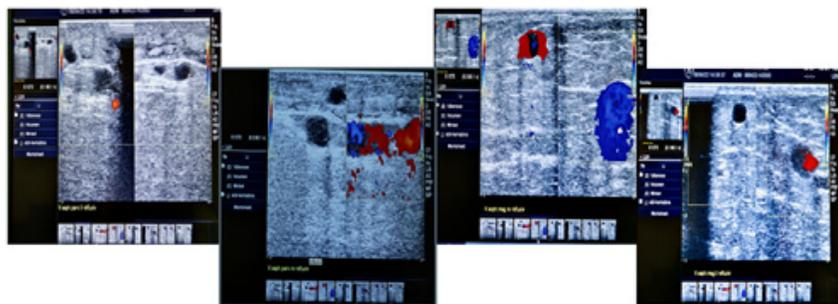
This is fact also taken into account with Saphenion® and we only carry out the necessary micro foam therapies 14-21 days after the Venaseal® - therapy [9, 7,30, 37].

In the light of 21 years using endo venous therapy, we recommend that every vein center, that applies endo venous treatment should have at least 2 alternative treatment procedures at its disposal.

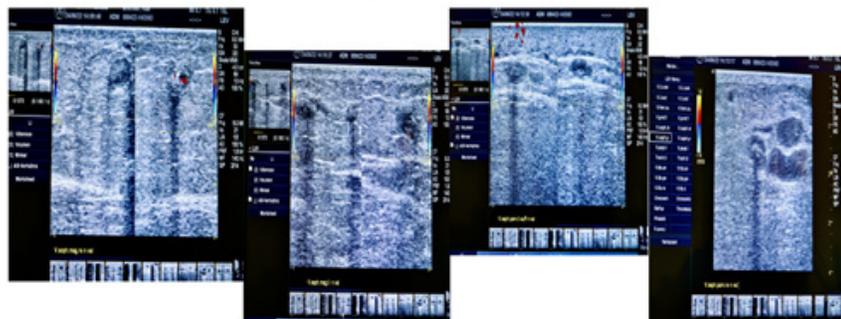
Actual we have to remember the Covid time and the new side effects after Covid vaccination and Covid infection. The described side effects after vein glue and micro foam therapy shortly after the Covid vaccination is completely avoided if the schedule is changed. This means that you should wait for approx. 4 weeks before vaccination after therapy or therapy should be carried out approx. 6-8 weeks after vaccination.

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 and older patients we see great advantages in using Venaseal® - Closure (Figure 9).

VenaSeal® Closure – our first interesting case/duplex prae op SSV left



VenaSeal® Closure – our first interesting case /duplex after VenaSeal® of all truncal varicose veins



**Figure 9:** VenaSeal® is first choice in therapy of obese patients, simultaneously sealing of GSV and SSV both legs in adipose man (BMI 54,6)

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