

## Experience in Sealing of Truncal Varicose Veins - Treatment of 2202 Truncal Veins in 1180 Cases a 79 Months Follow - Up Study

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### ABSTRACT

*The paper is about our own experiences in sealing truncal varicose veins over exactly 79 months. Since 20 years by now, varicosis has been increasingly treated endovenously. At the 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 different techniques of radial laser. 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 have been developed. All vascular and phlebology societies have declared guidelines for this very in relation very minimal invasive techniques of therapy*

*The present research paper sheds light on the advantages and presents the 79 - month results of a single - center praxis study with a prospective design.*

*We will report about our experiences and results of a prospective comparative study of VenaSeal® - Closure in the treatment of 2202 saphenous veins (1515 GSV, 570 SSV, VSAL in 67 cases, VSAM in 43 cases, Giacomini's vein in 2 and femoropopliteal vein in 5 cases). Treatment included also lower leg ulcers in 13 cases.*

### Keywords

Truncal Veins, Ultrasound, VenaSeal®.

### Introduction

In the base, all we know that varicose veins should be treated actively. This we can find in nearly all guidelines worldwide. All the specialists know, that mobilization and compression alone cannot normalize the venous function of outflow venous blood from the leg. An insufficient varicose vein is working like a downpipe - the blood pressure at the lower leg is greatly increased chronically. And so we get the typical chronic venose disease. Nearly 70% of all adults in Europe have clinical signs of this CVD.

Since 19 years by now, varicosis has been increasingly treated endovenously. Before this, the varicose veins were treated radically with the "stripping" - method, a 112 years old radical surgery method. At the beginning, 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® ClosureFast system, and the radial laser. 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 have been developed [1-8,12-17,20].

One very important technical development combined with the beginning of the endovenous 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 i.v. contrast agents. There is a very important fact because working with an endovenous catheter without ultrasound isn't a fully noninvasive therapy because of using phlebography. Ratzek et al. have described exactly the sonographic appearances of common disorders of all tissues. They have worked about the high sensitivity of ultrasound in tissue diagnostics [1,18].

In addition, 16 years ago, 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 the USA since 2 / 2015.

The author has applied Venaseal for the first time in a great saphenous vein on 1st. August 2012.



Figure 1: Dr. Ulf Zierau and The Crew in Rostock.



Figure 2: VenaSeal - Closure technique.

### Materials and method

Based on the manufacturer's application instructions, sealing with the VenaSeal - the system was started 1 - 3 cm from the sapheno femoral junction, and a spot of glue was applied at intervals of 2 - 3 cm, depending on the diameter and the flow / the pressure of 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, ectatic veins, and perforators were treated. The follow - up observation period in our study was up to 79 months.

The great saphenous vein was treated in 1515 cases, in 570 cases the small saphenous vein was treated and in 110 cases the trunk of an inguinal accessories vein was sealed. Two of Giacomini's veins and five femoropopliteal veins also were treated.

VenaSeal® interventions were performed under light sedation with Dormicum or local anesthesia for venous access accompanied by music therapy, 124 patients (10,5% of all cases) didn't get any anesthesia or sedation. One patient performed pain acupuncture on herself.

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 / 14 - 30th. / 70 - 90th. day as well as after 6 and 12 months. After this, we controlled every following year. Nearly all duplex sonography examinations post intervention was done by another colleague, not by the vascular surgeon treated the truncal veins.



Figure 3: typical ultrasound of GSV after sealing.

### Results

During the time period from 1st. August 2012 to 28st. February 2019 (79 months), Venaseal® was applied to achieve closure of the vein in 2202 truncal varicose veins. In 350 patients one saphenous vein was treated; in 670 patients two saphenous veins were treated; in 129 patients 3 saphenous veins were treated. In 28 cases 4 truncal veins, and in two cases 5 veins, in one case 6 truncal veins were treated simultaneously.

Grade 2 - 3 saphenous varicosis of the GSV according to Hach, and in the case of the SSV and acc. saphenous varicose veins was the inclusion criterium. In accessory veins, we treated the inguinal trunk in length between 15 - 30 cm.

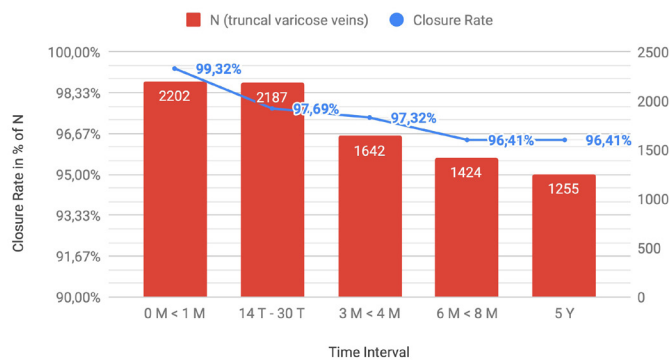
On the 1st day, all 2202 veins were checked (2187 veins were

closed initially = 99,32 %) in the scope of follow - up, and up to the 30th. day, partial recanalization was found in 41 veins, and complete recanalization was found in 10 veins. This corresponds to a closure rate of 97,69%.

Over a time period of 3 months up to 4 months after the treatment, we were able to follow up 1642 saphenous veins (74,6% of all veins that had been treated), and here we found 43 partial and 16 complete recanalizations. The closure rate is thus 97,32%.

In 1424 saphenous veins (64,7%) were followed up over a 6 - 8 month time period, and 50 partial and 29 complete recanalizations were found, resulting in the effectiveness of 96,41%. No further recanalizations were found after 79 months. In the follow - up period of 5 years after therapy we controlled 1265 truncal varicose veins (57,4%) up to now. All 13 leg ulcers were healed until to 12 weeks after intervention.

Closure rate VenaSeal® over 79 month



2202 truncal varicose veins having been sealed with Venaseal®, the results achieved over the entire time period of 79 months are equivalent to a closure rate of 96.41%.

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 175 treated veins (7,9%), we observed a postoperative unspecific inflammatory skin reaction after approx. 10 - 14 days in the Venaseal group; with appropriate antiphlogistic treatment with ibuprofen and ethanolic cooling bandages, this subsided within 3-5 days.

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. Only in 17 cases, we have seen a lymphatic fistula at the peripheral puncture.

In particular, even subcutaneously situated saphenous veins could be glued without any significant skin reaction (reddening, swelling). We also clearly prefer Sealing in the treatment of SSV and now also in GSV due to a large number of neurological sensations in connection with treatment by Laser and Radiofrequency [24,25].

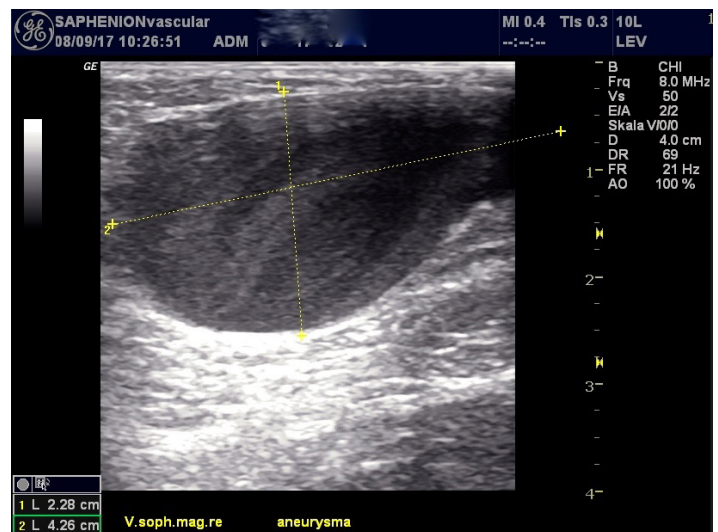


Figure 4: Aneurysma of GSV at the junction - sealing therapy possible.

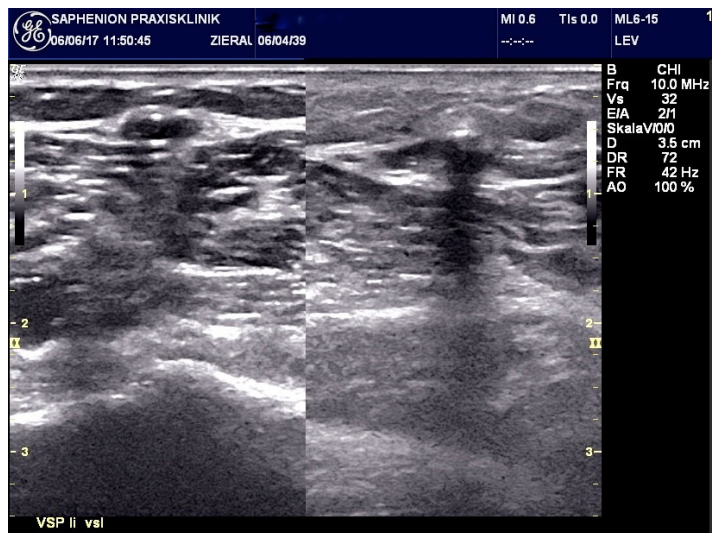


Figure 5: Sealing SSV is the first choice.

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 non tumescent, non thermal sealing we have up to now refrained from applying compression therapy in over 95% of all cases. We prefer to use compression stockings only in cases, the diameter of the treated vein is over 1,2 cm or in the treatment of a venous aneurysm or ectatic varicose veins.

## 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. 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!

But today we have the ultrasound and all colleagues who work with endovenous procedures meanwhile have reliable criteria for a high - quality therapy [2-8,12-17,20,24-26].



**Figure 6:** VenaSeal - treatment in Madrid: Assistant Claudia Reuter and Dr. Ulf Th. Zierau.

The VenaSeal® - closure procedure is the newest technical development in the series of endovenous 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. While the glue likewise gives rise to a certain temperature (approx. 45 - 50°C), the procedure is not a thermal one. Side effects as those known to occur in connection with laser and radio wave therapy ultimately play no significant role here.

The necessary reliable closure is achieved by means of a non tumescent non thermal cyanoacrylate superglue, the basic chemical formula of which has been known since several decades, and which is being used in neuroradiology in the treatment of vascular malformations since 1981. We also worked with this glue since 1988 in vascular surgery at the Charité - hospital Berlin.

By the way - the sealing therapy is not a new idea - also in the Golden Twenties, German surgeons and phlebologists were sealing truncal varicose veins with glucose solution. Also, the world known surgeon Ferdinand Sauerbruch was a friend of sealing. Since 1928 / 1929 all patients in Sauerbruch's hospital Charité Berlin, treated by truncal varicose veins, were sealed [27].

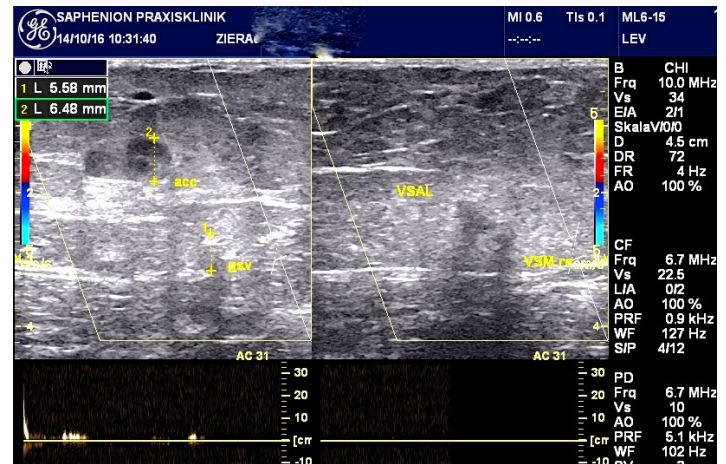
We do not need anesthetics anymore and can in most cases do without postoperative compression therapy. Elastic stockings

should nevertheless, by all means, be recommended after the treatment of thicker saphenous varicose veins measuring > 1,2 cm, and they become compulsory where we intend to apply sealing therapy in larger lumens measuring 1.5 cm and more, ectatic veins, junction aneurysms and also perforator veins.

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, no phlebitis, the extremely rare occurrence of skin pigmentations are 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. And as far as this aspect is concerned, both the first results of the eSCOPE study [15] and the results of single-center studies and also currently of the VeClose study [12] 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 Sealing - procedure appears to be on the same level with, or even superior to the high - frequency radio wave system [14,17]. 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%) [7,8,15,17] to laser therapy in terms of effectiveness.



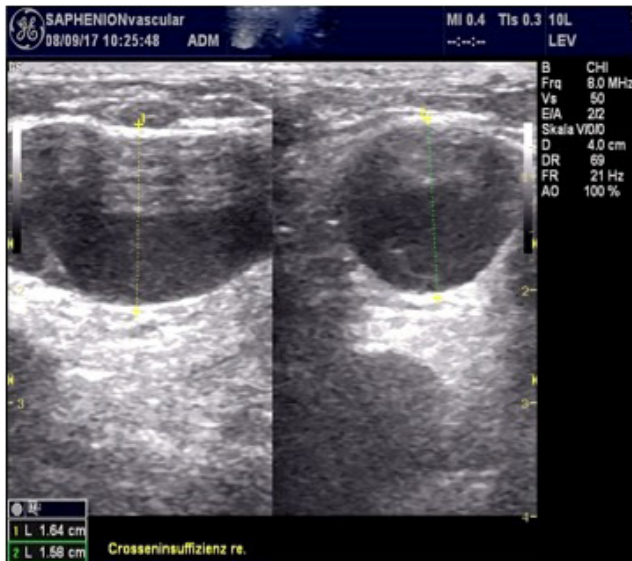
**Figure 7:** Sealing of GSV and VSAL simultaneously.

The results of first comparative studies show that the vein 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 [25].

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, especially in the therapy of lower leg veins like SSV.

By now, VenaSeal® has undeniably become at SAPHENION the therapy of the first choice for the treatment of the SSV. 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 [6,7,12-17].



**Figure 8:** Sealing ectatic and aneurysmatic parts of truncal veins is also possible - ultrasound from SFJ - aneurysm.

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®, all insufficient saphenous veins should as far as possible always be treated in one session.

*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 GSV, SSV or VSAA - varicosis. And we see this method as a very good method also in ultrasound - guided treatment of aneurysmatic and receive junctions and greater perforator veins.*

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