

Saphenion®-Fact Check Venaseal®-Vein Glue for Varicose Veins

Ulf Th Zierau*, L Martell, W Lahl

Founder and CEO of Saphenion®-Surgeon, Vascular Surgeon, Phlebologist, Endovascular Specialist Artery, Endovenous Specialist Berlin/Rostock, Germany

ABSTRACT

The Saphenion® fact check vein glue for varicose veins has been published by us in regular succession for 6 years and aims to compare international publications on the subject with our own experiences and to remain meaningful. Our patients are now very well informed about this therapy method for varicose veins that have been offered for 10 years. After more than 8 years of use, we have treated 1537 patients on 2970 saphenous veins by 2/2021-over 170,000 patients worldwide have now been treated with the VenaSeal® vein glue.

Keywords: VenaSeal® vein glue, VenaSeal® closure system, Endovenous therapy of varicose veins, Non-tumescent non-thermic therapy truncal varicose veins

INTRODUCTION

After more than 8 years of use, we have treated 1537 patients on 2970 saphenous veins by 2/2021-over 170,000 patients worldwide have now been treated with the VenaSeal®-vein glue. In the meantime, we have also successfully used the vein glue in three patients with COVID-19 infection to cleanse the venous system after they have recovered. At her personal request, a pregnant patient was also treated for very painful varicose veins using the VenaSeal® vein glue.

Of course, slightly adapted hygiene measures in the operating room and in the practice are necessary. However, in an outpatient practice that works surgically and with catheter medicine, these are kept within practicable limits, since the hygiene status is primarily increased. The German Society for Vein Medicine (DGP) also includes therapy with the vein glue VenaSeal® as a therapy recommendation for the therapy of truncal varicose veins in the current guidelines "S2k-guideline for diagnosis and therapy of varicose veins".

Together with colleagues from Munich, Hildesheim, Cologne, Düsseldorf, Berlin / Rostock, Saphenion® discussed and founded a "VenaSeal® network" in spring 2020 on the occasion of the "Bonn Vein Days". Our aim is to summarize the results of the therapy with the vein glue, to exchange experiences and communicate them to our patients and also to become scientifically active. In November 2020 our joint "German Multicenter Study VenaSeal®" was published (Figure 1).

SAPHENION® FACT CHECK VEIN GLUE FOR VARICOSE VEINS-OUR THERAPY EXPERIENCES

Nearly 102 months ago we started using the venous glue in the treatment of varicose veins. There are more than 2970 treated veins in the surgery book. So far we have used the vein glue in 1537 patients.

In addition to many well-informed patients who are now directly requesting this therapy method, statutory Germany health insurance companies have also recognized the no longer so new-procedure in some cases.

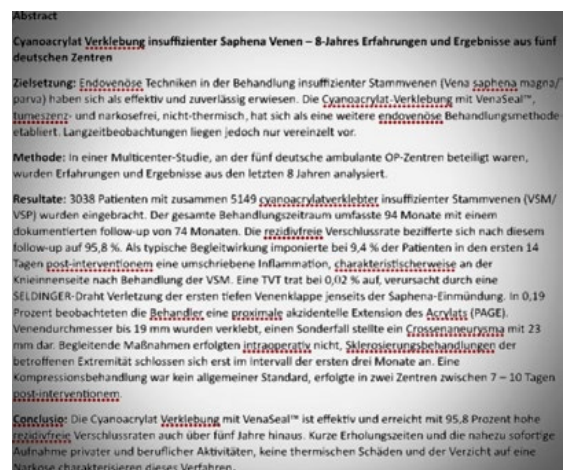


Figure 1: Saphenion fact check vein glue for varicose veins-abstract multicenter study "Network VenaSeal®".

Correspondence to: Ulf Th Zierau, Founder and CEO of SAPHENION®-Surgeon, Vascular Surgeon, Phlebologist, Endovascular Specialist Artery, Endovenous Specialist Berlin/Rostock, Germany, E-mail: dr.zierau@yahoo.de

Received: February 08, 2021, **Accepted:** February 25, 2021, **Published:** March 05, 2021

Citation: Zierau UT, L Martell, W Lahl. (2021) Saphenion®-Fact Check Venaseal®-Vein Glue for Varicose Veins. J Vasc Med Surg. 9:411.

Copyright: © 2021 Zierau UT, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

Most private insurance companies have also accepted the therapy option of gluing varicose veins in the context of the cost estimates presented. Likewise, according to reports from our patients, the state aid offices of the federal government, the states of Berlin / Brandenburg, Mecklenburg, Saxony / Anhalt, Saxony and Thuringia as well as Lower Saxony and Schleswig-Holstein are ready to cover the costs of this therapy method approved in Europe in 2011.

After the long time period 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-calibre saphenous veins, the adhesive has conquered other areas of application in endovenous therapy. In the meantime, ectatic veins and aneurysms are also successfully treated with venous glue.

This becomes clear in the literature analysis. Colleagues from the USA, Korea and Holland, Russia and Hong Kong have presented 3 to 5-year studies. In addition to our own 8-year long-term study and the German VenaSeal® multicenter study, Morrison et al. a 5-year study was presented, as was Gibson et al. The results are almost identical in all studies; the closure rate after these long periods is between 94-97% [1-9].

Our results after 102 months of use are 96.09% closure effectiveness

This means that the vein glue is more effective than the established radio wave system-but with significantly fewer side effects and a shorter post-op recovery phase.

The ability to work is restored on the same day approx. 3 hours after the therapy-or-if sedation is used, the following day [10-12,6,13,14].

Varicose veins-sticking together in the open leg

The treatment of the so-called "open leg" (ulcer cruris) has become much simpler, and more effective. The vein glue can also be used in a minimally invasive manner for the most severe findings. So far, we have used the venous glue in 19 patients with leg ulcers-with great success (Figure 2) [7,15,13].

Varicose veins in arterial occlusion

Saphenion® has also started to treat patients who suffer from the

arterial occlusive disease (smoker's leg) and also has functionally defective truncal varicose veins using VenaSeal® at the same time, or first on the diseased veins before the operation on the arteries. With this, a weighty dogma of vascular surgery-the primacy of arterial therapy-could now be repealed (Figure 3) [13,14].

Varicose veins-outpatient therapy for seriously ill patients

We now treat dementia or debilitated patients with Parkinson's disease and trisomy patients on an outpatient basis with light sedative medication.

Systemic infectious diseases such as hepatitis, Covid-19 or HIV are also not a contraindication - patients with these underlying diseases have been successfully treated with the venous glue several times-without side effects.

Multi-allergic diseases are also not contraindications for treatment with the venous glue.

Patients with lifelong thrombosis / embolism therapy can be successfully treated on an outpatient basis without discontinuing or changing the permanently necessary medication [3,4,14,7,16].

SAPHENION® FACT CHECK VEIN GLUE FOR VARICOSE VEINS-SIDE EFFECTS AND COMPLICATIONS

A current search in the international specialist literature in preparation of this update has described the occurrence of contact dermatitis (skin inflammation after contact with cyanoacrylate) in 4 cases (in > 170,000 patients!) And in only one case a-supposed-VenaSeal®-allergy. Further complications during use or in the post-op course are still not shown. We have not yet seen a VenaSeal® allergy after 1537 patients and 2970 veins treated. Our own experiences with the allergy in question to the vein glue have recently been presented in an international publication. We have not seen any allergic reaction over all the time.

Our statement on the alleged phlebitis after the vein glue-it is a tissue reaction of the surrounding tissue-has also been confirmed many times in further scientific work: In a large American meta-analysis, all results and experiences on VenaSeal® therapy published by us and presented in our news were confirmed [17,11,6,18,15, 19].

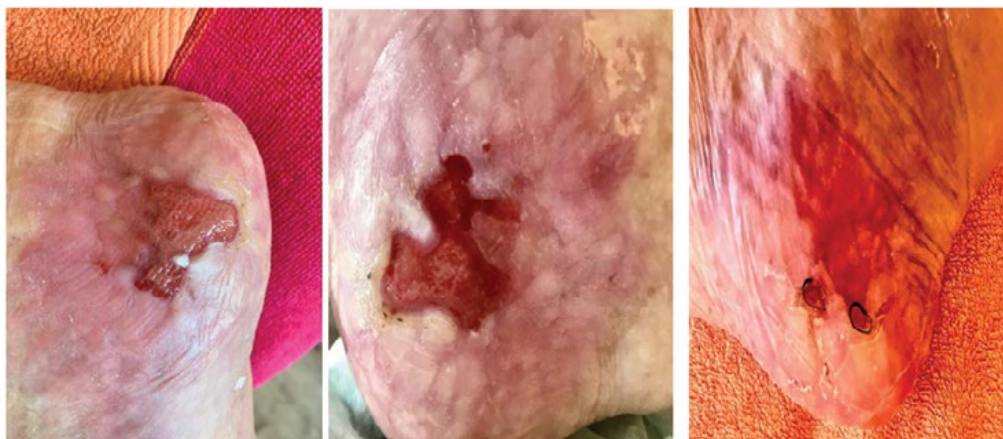


Figure 2: Saphenion fact check vein glue: Therapy for ulcer-10 years old heel ulcer (left pictures), after vein glue of GSV and SSV simultaneously. Now almost healed (right picture, markings show minimal residual findings).



Figure 3: Our publication on the simultaneous therapy of varicose veins and arterial occlusion.

SAPHENION® FACT CHECK VEIN GLUE-102 MONTHS OF APPLICATION EXPERIENCE-THE DISCUSSION OF EXPERIENCES

Based on the 102 months of practical experience with 2970 treated saphenous veins in 1536 patients, we would like to confirm from our clinical-professional point of view for the fact check:

The vein glue is fully biocompatible, so far, after more than 8 years of use (102 months), we have not seen any allergies. Two works in the literature describe a contact allergy of the skin after touching the adhesive. 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 endovenous techniques (laser, radio wave) in the treatment of truncal varicose veins.

The bio-resorption of the adhesive takes between 12 and 24 months. The same resorption processes can also be seen 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 adhesive between 4 and 9 months. The absorption of the adhesive can also be followed macroscopically with regular ultrasound checks.

But not only that: We now have our own histological findings from human veins 10-14 months after cyanoacrylate (CAC) sealing therapy. In all four cases examined, these show a complete breakdown of the glue in the remnants of the vein [1,2,4,20-24] (Figure 4). And here too, in addition to our own results, there is now another publication.

On the lower leg, thermal therapy (laser, radio wave, hot steam) has now been put in a critical light internationally and also nationally, since the number of nerve lesions after thermal therapy cannot be neglected. At the annual meeting of the German Society for Vein Medicine at the beginning of September 2020 in Leipzig, this topic was discussed almost openly. As a result, the majority took a critical stance 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.

Many colleagues now recommend doing without the thermal laser and radio wave methods, as an alternative, catheter-supported micro-foam therapy or vein glue are possible. According to our experience, based on our own study on over 800 patients, we have defined an indication for micro-foam or VenaSeal®. We treat truncal veins on the lower leg with a diameter of up to 0.45 cm with micro-foam, truncal veins with a larger diameter are treated with vein glue. And we also treat perforator veins with a great diameter over 4 mm with vein glue.

This means that our alternative recommendation for radio waves for the saphenous veins on the lower leg, as we have previously expressed in our educational discussions, is no longer applicable. We are now treating the lower leg exclusively with non-thermal methods [25-30].

This procedure was also currently anchored in the "Current guidelines for the therapy of varicosis" of the DGP:

From our point of view, radical stripping is no longer indicated at all on the lower leg (Figure 5).

Saphenion® fact checks vein glue-spider veins and reticulated veins?

The vein glue for varicose veins is not as can be read here and there and also requested-suitable for the treatment of cosmetically disturbing reticular veins and spider veins. The micro-foam, which has been the "gold standard" since 2010, is available as a combination therapy.

A simultaneous double therapy with micro-foam (ethoxysklerol) is possible but carries the risk of phlebitis. Scientific studies on this combination therapy have Gibson et al. submitted. It is important to first wait for the trunk varicose vein to heal-in many cases, there is a significant decrease in the lateral branch varicose veins this fact is also taken into account with Saphenion® and we only carry out the necessary micro-foam therapies 14-21 days after the VenaSeal® therapy.



Zierau et al.



Figure 13 Inflammation reaction leg and vein a few days after VenaSeal



Figure 14 The inflammation - After vein therapy and the treatment

Inflammation of an allergy to the vein glue VenaSeal could not be provided

DISCUSSION

We believe that treatment with the adhesive use of vein glue is a safe and effective method for the treatment of truncal varicose veins...

In our study we found an allergic reaction to the vein glue VenaSeal... The allergic reaction to the vein glue VenaSeal could not be provided...

REFERENCES

1. Nasser H, Ivanics T, Shakarou D, Lin J. Severe phlebitis-like abnormal reaction following great saphenous vein cyanoacrylate closure. J Vasc Surg Venous Lymphat Disord. 2019;7(4):578-582.
2. Park I, Kim D. Correlation Between the Immediate Remnant Stump Length and Vein Diameter After Cyanoacrylate Closure Using the VenaSeal System During Treatment of an Incompetent Great Saphenous Vein. Vasc Endovascular Surg. 2020;54(1):47-50.
3. Fuchs J, Thum J, Zierau UT, Bernheim C. SaphenionScience: Results of the VenaSeal® multicenter study - aim and method of the study. Saphenion Berlin-Rostock. 2020.
4. Gibson K, Morrison N, Kolluri R, Vasquez M, Weiss R, Cher D, et al. Twenty-four months results from a randomized trial of cyanoacrylate closure versus radiofrequency ablation for the treatment of incompetent great saphenous veins. J Vasc Surg Venous Lymphat Disord. 2018;6(5):606-613.
5. Lam YL, De Maeseneer M, Lawson J, De Borst GJ, Boersma D. Expert review on the VenaSeal® system for endovenous cyanoacrylate adhesive ablation of incompetent saphenous trunks in patients with varicose veins. Expert Rev Med Devices. 2017;14(10):755-762.
6. Lane TR, Kelleher D, Moore HM, Franklin IJ, Davies AH.

Saphenion science - vein glue allergy? is there a significant risk? This article discusses the potential for allergic reactions to the VenaSeal adhesive and provides clinical evidence.

1. Nasser H, Ivanics T, Shakarou D, Lin J. Severe phlebitis-like abnormal reaction following great saphenous vein cyanoacrylate closure. J Vasc Surg Venous Lymphat Disord. 2019;7(4):578-582.
2. Park I, Kim D. Correlation Between the Immediate Remnant Stump Length and Vein Diameter After Cyanoacrylate Closure Using the VenaSeal System During Treatment of an Incompetent Great Saphenous Vein. Vasc Endovascular Surg. 2020;54(1):47-50.
3. Fuchs J, Thum J, Zierau UT, Bernheim C. SaphenionScience: Results of the VenaSeal® multicenter study - aim and method of the study. Saphenion Berlin-Rostock. 2020.
4. Gibson K, Morrison N, Kolluri R, Vasquez M, Weiss R, Cher D, et al. Twenty-four months results from a randomized trial of cyanoacrylate closure versus radiofrequency ablation for the treatment of incompetent great saphenous veins. J Vasc Surg Venous Lymphat Disord. 2018;6(5):606-613.
5. Lam YL, De Maeseneer M, Lawson J, De Borst GJ, Boersma D. Expert review on the VenaSeal® system for endovenous cyanoacrylate adhesive ablation of incompetent saphenous trunks in patients with varicose veins. Expert Rev Med Devices. 2017;14(10):755-762.
6. Lane TR, Kelleher D, Moore HM, Franklin IJ, Davies AH.

Figure 4: Our publication on the risk of an allergic reaction when using the vein glue VenaSeal® therapy on truncal varicose veins

Empfehlung 100: Um sensible Nervenschädigungen zu vermeiden kann es sinnvoll sein, die VSP nicht unterhalb der Wadenmitte thermisch zu behandeln.

Die intravasale Lage des endovenösen Katheters in der zu behandelnden Vene soll auf der gesamten Länge sonographisch kontrolliert werden. Die Sondenspitze ist am proximalen Insuffizienzpunkt mündungsnah an den Übergang zur tiefen Vene vorzuschieben und unter Ultraschallkontrolle zu platzieren. Die endgültige Position der Sondenspitze ist durch ein Ultraschallbild zu dokumentieren. Eine thermische Schädigung der tiefen Vene ist zu vermeiden. Gleichzeitig sollte eine mündungsnah Okklusion erreicht werden. Das Belassen eines langen stumpfes sollte vermieden werden, um das Risiko eines Rezidiv-Reflexes zu minimieren^{320,328,344}.

Figure 5: Actual Guidelines of DGP for treatment of lower leg truncal varicose veins.

CONFLICT OF INTEREST

There are no conflicts of interest.

REFERENCES

1. Kopie von Seite 11 des FDA-Approvals zur Biokompatibilität des VenaSeal®-Venenklebers: Quelle: Summary-Food and Drug Administration / FDA.
2. Almeida JI, Murray SP, Romero ME. Saphenous vein histopathology 5.5 years after cyanoacrylate closure. J Vasc Surg Venous Lymphat Disord. 2020;8(2):280-284.
3. FUCHS J. Verklebung insuffizienter Stammvene-80-Monate Erfahrungen und Ergebnisse mit dem VenaSeal®-Closure Verfahren, Zeitschrift für Gefäßchirurgie, im Druck.
4. Gibson K, Ferris B. Cyanoacrylate closure of incompetent great, small, and accessory saphenous veins without the use of post-procedure compression: Initial outcomes of a post-market evaluation of the VenaSeal System (the WAVES Study). Vascular. 2017;25(2):149-156.
5. Morrison N, Gibson K, Vasquez M, Weiss R, Jones A. Five-year extension study of patients from a randomized clinical trial (VeClose) comparing cyanoacrylate closure versus radiofrequency ablation for the treatment of incompetent great saphenous veins. J Vasc Surg Venous Lymphat Disord. 2020;8(6):978-989.

6. Nasser H, Ivanics T, Shakarou D, Lin J. Severe phlebitis-like abnormal reaction following great saphenous vein cyanoacrylate closure. J Vasc Surg Venous Lymphat Disord. 2019;7(4):578-582.
7. Park I. Initial Outcomes of Cyanoacrylate Closure, VenaSeal System, for the Treatment of the Incompetent Great and Small Saphenous Veins. Vasc Endovascular Surg. 2017;51(8):545-549.
8. Park I, Kim D. Correlation Between the Immediate Remnant Stump Length and Vein Diameter After Cyanoacrylate Closure Using the VenaSeal System During Treatment of an Incompetent Great Saphenous Vein. Vasc Endovascular Surg. 2020;54(1):47-50.
9. Fuchs J, Thum J, Zierau UT, Bernheim C. SaphenionScience: Results of the VenaSeal® multicenter study - aim and method of the study. Saphenion Berlin-Rostock. 2020.
10. Gibson K, Morrison N, Kolluri R, Vasquez M, Weiss R, Cher D, et al. Twenty-four months results from a randomized trial of cyanoacrylate closure versus radiofrequency ablation for the treatment of incompetent great saphenous veins. J Vasc Surg Venous Lymphat Disord. 2018;6(5):606-613.
11. Lam YL, De Maeseneer M, Lawson J, De Borst GJ, Boersma D. Expert review on the VenaSeal® system for endovenous cyanoacrylate adhesive ablation of incompetent saphenous trunks in patients with varicose veins. Expert Rev Med Devices. 2017;14(10):755-762.
12. Lane TR, Kelleher D, Moore HM, Franklin IJ, Davies AH.

- Cyanoacrylate glue for the treatment of great saphenous vein incompetence in the anticoagulated patient. *J Vasc Surg Venous Lymphat Disord.* 2013;1(3):298-300.
13. Zierau UT and Lahl W: Recurrence Discussion in Varicose Veins Therapy-A Critical Examination of the Vein Stump discussion. *J Vasc Endovasc Therapy.* 2019;4(2):13.
 14. SaphenionScience-VenaSeal® meta-analysis: comparison with other therapy methods. Saphenion Berlin-Rostock.
 15. Tang TY, Tiwari A. The VenaSeal™ Abnormal Red Skin Reaction: Looks Like but is not Phlebitis!. *Eur J Vasc Endovasc Surg.* 2018;55(6):841.
 16. Morrison N, Gibson K, McEnroe S, Goldman M, King T, Weiss R, et al. Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). *J Vasc Surg.* 2015;61(4):985-94.
 17. Kolluri R, Chung J, Kim S, Nath N, Bhalla BB, Jain T, et al. Network meta-analysis to compare VenaSeal with other superficial venous therapies for chronic venous insufficiency. *J Vasc Surg Venous Lymphat Disord.* 2020;8(3):472-481.e3.
 18. Navarro-Triviño FJ, Cuenca-Manteca J, Ruiz-Villaverde R. Allergic contact dermatitis with systemic symptoms caused by VenaSeal. *Contact Dermatitis.* 2020;82(3):185-187.
 19. Goã-Ratgeber. Abrechnung der endovenösen Radiofrequenzobliteration der Stammvenen. Impressum. 2016.
 20. Chan YC, Law Y, Cheung GC, Ting AC, Cheng SW. Cyanoacrylate glue used to treat great saphenous reflux: Measures of the outcome. *Phlebology.* 2017;32(2):99-106.
 21. Chan SSJ, Yap CJQ, Tan SG, Choke ETC, Chong TT, Tang TY. The utility of endovenous cyanoacrylate glue ablation for incompetent saphenous veins in the setting of venous leg ulcers. *J Vasc Surg Venous Lymphat Disord.* 2020;8(6):1041-1048.
 22. Cho S, Park HS, Lee T, Byun SJ, Yun WS, Yang SS, et al. CASS (CyanoAcrylate closure versus Surgical Stripping for incompetent saphenous veins) study a randomized controlled trial comparing clinical outcomes after cyanoacrylate closure and surgical stripping for the treatment of incompetent saphenous veins. *Trials.* 2020;21(1):460.
 23. Zierau UT, Martell L and Lahl W: Vein glue VenaSeal® for the Therapy in Case of Varicose Vein Thrombosis; A Case Report; *Journal of Medical Research and Surgery.* 2021;2(1):1-4.
 24. Fiengo L, Gwozdz A, Tincknell L, Harvey V, Watts T, Black S. VenaSeal closure despite allergic reaction to n-butyl cyanoacrylate. *J Vasc Surg Cases Innov Tech.* 2020;6(2):269-271.
 25. Jones AD, Boyle EM, Woltjer R, Jundt JP, Williams AN. Persistent type IV hypersensitivity after cyanoacrylate closure of the great saphenous vein. *J Vasc Surg Cases Innov Tech.* 2019;5(3):372-374.
 26. Park I. Successful use of VenaSeal system for the treatment of large great saphenous vein of 2.84-cm diameter. *Ann Surg Treat Res.* 2018;94(4):219-221.
 27. Shaĭdakov EV, Mel'tsova AZ, Porembaskaia OI, Kudinova EA, Korzhevskĭĭ DĖ, Kirik OV, et al. Experience with using cyanoacrylate glue in endovascular treatment of varicose veins. *Angiol Sosud Khir.* 2017;23(4):62-67.
 28. Watts TJ, Thursfield D, Haque R. Allergic contact dermatitis caused by VenaSeal tissue adhesive. *Contact Dermatitis.* 2019;80(6):393-395.
 29. Zierau, UT. 100 Months Experiences with VenaSeal® Vein Glue: Long Time Follow-Up Study Conducted on 2912 Truncal Saphenous Veins in 1509 Cases: *J Angiol Vasc Surg.* 2020;5:054.
 30. Saphenion® Faktencheck Venenkleber für Krampfadern-update 15. Saphenion Berlin-Rostock.