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Review Article

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8 years vein glue therapy with VenaSeal® – 8 special cases

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Abstract

Since 1949 the chemical compound of cyanoacrylate glue is known, first being used in operative medicine in the early 60s. Tissue adhesive or replacement of wound sutures Nearly all operative disciplines were / are using cyanoacrylate i.e. dermatology, ophthalmology, orthopedics, surgery, orthodontics, interventional radiologists.

The VenaSeal® - Closure System has been CE and ISO certified since 2011. The American health authority FDA announced the approval of the system in the USA in 2/2015. Until October 20th of 2020, vein glue is used successfully for the treatment of truncal varicose veins in over 160 000 cases worldwide.

The authors have been working with the VenaSeal®-Closure System since August 1th. 2012, and have so far successfully treated 2840 saphenous veins in 1476 patients with the vein glue. Closure effectiveness of 96,09% achieved over 98 months.

Introduction

The vascular glue cyanoacrylate has been known chemically since 1949, 10 years later the very good sealing property could also be proven in biological tissues for the first time. Since the mid-1950`s, fibrin and acrylate glue have been tested in various medical disciplines. And since 1960 it has been used frequently and increasingly in almost all disciplines.

Initially, the bio-adhesives were only used as wound adhesives to replace wound sutures on the body - the Vietnam War was a major area of an application here. Applications inside the body were soon added. Since then, almost all surgical disciplines have been using fibrin and cyanoacrylate to stop bleeding and also to close bleeding vessels. The bio-adhesive is also used to attach prostheses and other non-body organ replacements.

As early the 1960`s, the first vascular sutures were carried out using acrylate adhesive, and in the 1970`s the era of catheter-supported arteries and vein occlusions began in various organs, such as the splenic and renal arteries, gastric and esophageal veins. Since that time, these methods have also played a major role in the treatment of malignant tumors, since by gluing arteries supplying tumors together, cancer itself can be killed.

From 1981 the tissue glue found its way into the treatment of vascular malformations, especially of the brain and spinal arteries and veins. Neuroradiologists also began to use catheters positioned in the vessel to glue enlarged cerebral arteries to minimize the risk of stroke accidents. These methods remained largely without complications. The doctors did not see any rejection of the biodegradable material or permanent retention in the body. Embolism and other serious complications have also not been described.

Encouraged in this way the use of cyanoacrylate glue and chemically related bio-adhesives has been expanded even further. Adhesives are used to seal the arteries and veins of the spleen, kidneys, esophagus, stomach, intestines, and liver, short-circuit connections between veins and arteries (so-called av fistulas) in all vascular regions, varicose veins on the uterus and in the pelvis. Bleeding hemorrhoids are now also treated with the acrylate glue.

For about 6 years glue has also been used to make complicated holes on vascular prostheses, e.g. B. were used in the enlarged thoracic and abdominal aorta to close securely. Injuries to large abdominal veins, such as B. the lower and the upper vena cava can be successfully treated by injecting the bio glue.

In this context, it was also important that experimental tests succeeded in demonstrating the effects of the vascular glue on the individual vessels. Today we know that the arterial wall is not destroyed when the acrylate adhesive is used, but that this is exactly what happens with the vein wall. Here the inner wall and the mid-

dle layer of the wall are irreversibly damaged. Thus, when used correctly, an irreversible therapeutic effect is achieved.

It was precisely this knowledge that gave a big boost to the development of vein glue in the form of endo venous catheter systems for treating varicose veins.

VenaSeal®-therapy - Interesting patient cases: Vein glue in varicose vein aneurysm

In the very first year of using "VenaSeal®" as a therapy for the truncal varicose vein, in 2012, we saw a 47 year - old patient with a large vein aneurysm in the left cross. The aneurysm originated from a truncal varicose vein, the GSV on the left thigh. We treated both the truncal varicose vein and the aneurysm with the vein glue. To do this, we used the catheter and a separate special puncture needle. This made it possible to inject the vein glue directly into the aneurysm and to close it successfully.

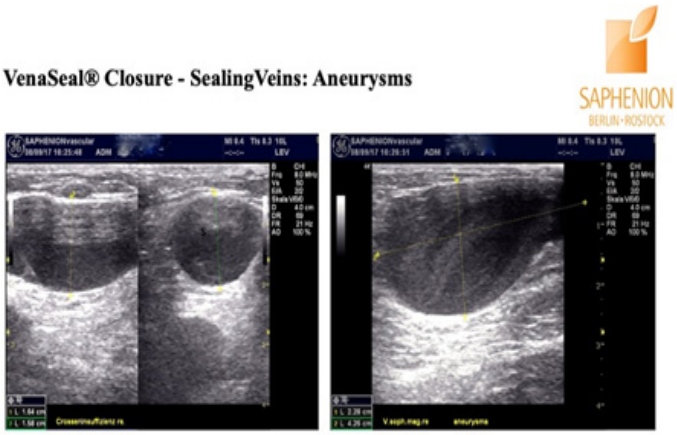

Figure 1: Venous aneurysm of GSV cross

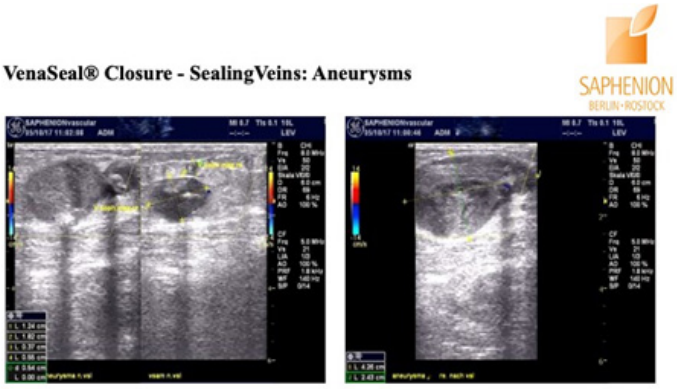

Figure 2: Venous aneurysm of GSV after sealing

Venaseal®-therapy - Interesting patient cases: The vein cross
From 2014 onwards, there was intense discussion in specialist circles about whether the vein glue was also able to treat the venous lesions, the confluence of the trunk varicose vein in the deep femoral vein on the groin. This discussion was justified, as there were no clear guidelines for the various catheter procedures (laser, radio wave, Clarivein, vein glue, etc.) for supplying the junction region. We were able to show that the cross-region can also be treated with "conventional medicine" with the vein glue.

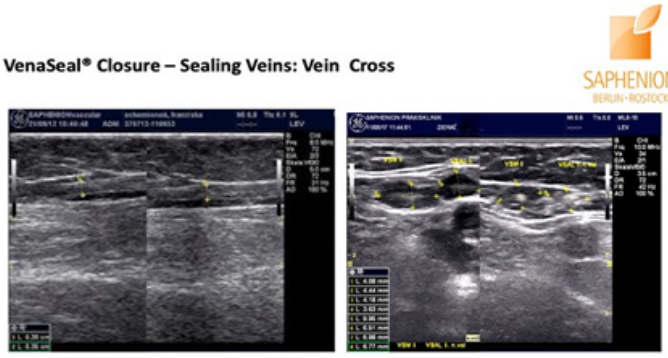

Figure 3: Glue therapy of GSV cross

VenaSeal®-therapy - Interesting patient cases: Vein glue for a ballet dancer

Ballet dancer Viktor Lebedew - It went very quickly! Arrived in Berlin from Japan on Sunday, on Monday for a preliminary examination at Saphenion, and then immediately on the left leg varicose veins (GSV, side branches) treated.

This had already been diagnosed in St. Petersburg. We'll be leading on December 2nd. -Monday morning therapy with the VenaSeal® - vein glue. Viktor wanted ballet music as musical accompaniment. And his varicose vein was sealed together while "Swan Lake" sounded.

On December 5th, 3 days after the treatment with VenaSeal®, Viktor danced the premiere of "Romeo and Juliet" in St. Petersburg! Videos of it can be found on his Instagram account! A video with an interview also can be watch:

https://www.instagram.com/p/B5pu8b-ooVv5nfzgjmv0qAKX-9GuuP5502IT9CI0/

https://www.instagram.com/p/B5tHkdjost4HYJ7e7AvJ62rv-J1CRSF6F58olPE0/

https://youtu.be/ufMNly6D2ls

Figure 4: Ballet dancer V. Lebedev after Venaseal®-therapy

VenaSeal®-therapy - Interesting patient cases: Vein glue in massive lymphedema

In 2020 we saw an 82-year old patient with three large ulcerations (open legs) on both legs. During the examination, it turned out that the patient had been dealing with the open leg wounds for 10 years and that no surgical therapy had taken place until then. Dressings were changed daily and multiple compression therapies took place to reduce the water in the legs. Unfortunately, however, no diagnosis had taken place either, so that the severe varicose vein findings remained hidden. The ultrasound examination showed 4 truncal varicose veins, a GSV massively enlarged on both sides, and also a very large SSV on both sides with heavy congestion and reflux. We treated all 4 saphenous veins simultaneously in one session. Very fast healing was achieved on the left leg, not on the right. After 4 months, we found recanalization of a treated GSV right side - this was treated again free of charge for our self - payers as part of the guarantee. After that, we also saw healing on the right. There is a clear healing tendency with a rapid reduction in the size of the large ulcer. Edema also decreasing significantly.

Figure 5+6: clinical and ultrasound pictures of massive edema

Venaseal®-therapy: Interesting patient cases. Vein glue in leg ulcers, massage therapy post-op.

It was in 2016 when Thomas, now 51 years old, came to our practice with his sister. Thomas also suffered from recurring open legs and severe swelling of the lower legs. Until then, these could not be treated effectively and led to a regular inability to work. The ultrasound diagnosis showed a triple of truncal varicose veins. The GSV was completely affected on both legs and the SSV on the left leg. Thomas, suffering from trisomy 21 and therefore not solely authorized to make decisions, decided, together with his sister, who acted as guardian, to undergo therapy with the vein glue. This successfully closed all three truncal varicose veins in a simultaneous therapy and led to the healing of the existing open leg on the left within 4 weeks. Lower leg. In parallel to the operative therapy with Venaseal®, the compression therapy was introduced in our practice immediately after the operation. This is possible immediately and promptly after the therapy with the vein glue as well as after the micro foam therapy and shows very good therapeutic effects with decongestion and healing of the treated veins.

Figure 7+8: Patient with cerebral defect – ulcera crures both legs, massage therapy post op.

Venaseal®-therapy - Interesting patient cases: Vein glue in peripheral artery occlusive disease

An 89 - year old patient visited us at the end of 2017. He reported stress complaints and walking difficulties such as a so-called "intermittent claudication" - complaints of a severe arterial circulatory disorder. The clinical examination also showed several ulcerations on the big toe and lower leg of the left leg. The ultrasound examination of the pelvic / leg arteries confirmed the suspected diagnosis of arterial occlusive disease. In addition, the examination carried out simultaneously on the venous system showed massive varicose veins of GSV on both sides and the SSV on the left leg.

We first had an MRI scan of the arteries carried out - this confirmed the severe changes in the arterial system. After that, in close consultation with the vascular surgery department of the neighboring hospital, we initially carried out the simultaneous rehabilitation of the 3 truncal varicose veins in our Rostock practice. The patient was then treated as an inpatient on the occluded pelvic arteries using catheter technology. As a result of the cooperative therapy between the practice and the hospital, we were able to achieve complete healing of the ulcerations within 12 weeks and the pa-

tient's quality of life improved considerably, also due to the regained opportunity to take long walks.

Figure 9+10: Patient with peripheral artery occlusive disease and chronic venous disease

VenaSeal®-therapy - Interesting patient cases: Vein glue in leg ulcers - glue allergy?
It was April 2019 when we were frightened. An 84-year-old patient who had been treated 3 weeks previously with vein glue on both GSV - also here with ulcerations on both lower legs - suddenly showed inflammatory spots and pimples all over the body. Both the operated legs were affected, as well as the groin regions, the chest, and the shoulders. We immediately thought of an allergic reaction to the venous glue. It would have been the first time that we saw an allergy! The patient was referred to the dermatology department at Rostock University Hospital for further diagnosis and therapy. There, the colleagues found an inflammatory body reaction (leukocytoclastic spread), the cause of which was definitely to be found in the ulcerations on the lower legs. An allergy to cyanoacrylate glue (VenaSeal®) could be excluded. The patient was discharged after 14 days under appropriate drug antibiotic therapy. When we came back to our practice in Rostock, the findings were almost pale. The ulcerations were clean and clearly healing. During a follow-up examination in 2020, we saw a new finding of varicose veins. The SSV on the right leg was now severely insufficient. We also performed venous glue therapy here. There were no after-effects in terms of intolerance or allergy.

Figure 11+12: Clinical pictures 14 days after VenaSeal®-therapy. Allergy reaction?

VenaSeal®-therapie - Interesting patient cases: Vein glue is broken down in 10-14 months.
In 2013 / 2014 / 2017 / 2018 we saw four cases (0,3% of all 1476 treated patients) with a "glue pimple" above the treated and sealed varicose GSV. We thought, that these pimples were a direct reaction after sealing the veins. In one case the treatment with VenaSeal® was 10 months ago, in 3 cases the therapy with the vein glue was 12 - 14 months ago. After information on the patient and getting the agreement, we have opened all the pimples with a scalpel, took a sharp spoon, and peel out all the whole content of the pimple including the pimple capsule. We sent all the material to a special institute for pathology.

Our question was: Ist there any glue inside, are there any chemical glue residues? The next question was: Can we find any vein structures, can we see any competent vein wall? The answer in all 4 cases was the same. You can read the result in our inserted publication.

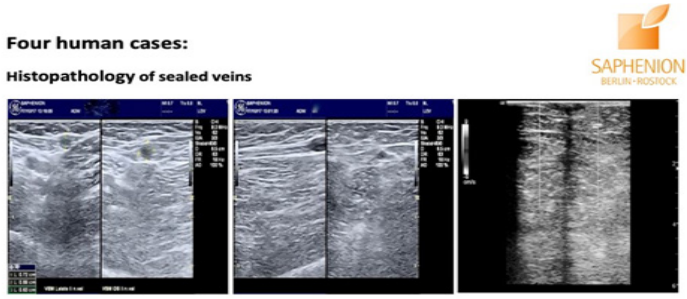

Figure13: Ultrasound of GSV sealing – right picture: glue pimple 12 months post op.

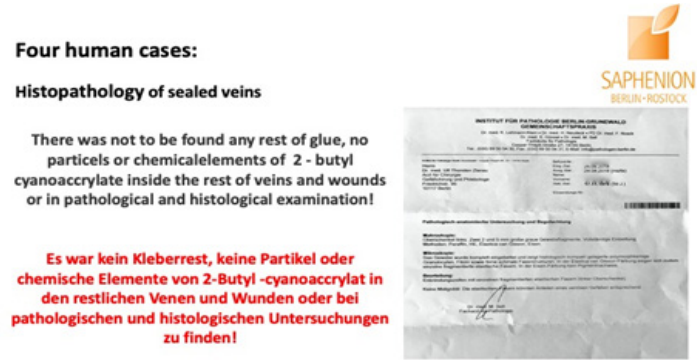

Figure14: Histopathology of sealed veins / glue pimple

Assessment of histopathology: Signs of inflammation with individual elastic fibers (left thigh), no malignancy: The elastic fibers could correspond to parts of a venous vessel, no foreign bodies to be seen! This the glue had already been largely broken down in the body and was no longer detectable in our 4 cases after the 10-14 months.

Finally, we would like to point out that the VenaSeal® - vein glue and the Turkish vein liquid currently (10/2020) are the only vein glues approved in Germany, and have a CE – certification [1-38].

Discussion

VenaSeal® is one of the endo venous techniques with a high standard of effectiveness – quality standards are the same like other procedures. VenaSeal® is safe in treatment of all truncal veins, side branches and perforator veins until a diameter of 1,5 – 2 cm. Higher diameters are possible! The advantages here are in radio wave ablation. We also recommend vein glue for ectatic veins (over 1.2 cm), aneurysms and post phlebitic truncal varicose veins.

VenaSeal® is first choice in treatment of truncal veins of the lower leg and truncal veins of GSV 3 – 4°. VenaSeal® is the much expensive of all endo venous techniques, that`s why therapy of more than one truncal vein simultaneously is recommendable – we can treat 2–3 truncal veins with one catheter!

Closure rate of VenaSeal® compared to radio wave is same / better – also general vein diameter more than 2 cm is possible to be treating with glue.

All the quality standards for endo venous therapy have been developed. All colleagues have secure quality criteria for all trans – catheter treatment methods. In contrast to most other methods VenaSeal® is performed without using thermal or mechanical energy – the side effects of laser or radio wave are not an issue.

The pain score compared to radio wave is significantly lower (1,3 – 3,4). We neither need general anesthesia or tumescence, nor do we need compression stockings. We can treat two to three truncal varicose veins simultaneously in one single session with one catheter.

The VenaSeal® -Therapy is suitable for almost all patients. This includes all age groups, patients with multiple allergies, very pronounced findings of chronic venous insufficiency and also peripheral arterial occlusive disease. Patients after Covid-10 infections can also be treated well with the VenaSeal® system. In particular, high-performance athletes and artists benefit from the rapid convalescence phase and the almost unrestricted physical resilience immediately after the procedure.

The laser – and radiofrequency catheters currently on the market achieve precisely this destruction of the vascular wall through a very strong heat effect on the vein wall (120-900 ° C) – they are supposed to „chare" or „boil off "all of the vascular wall layers. It was therefore to be assumed that the use of the adhesive VenaSeal® Closure and later the VariClose® system in the varicose vein would achieve a secure and permanent closure and that the defective vein would remain permanently switched off.

The advantage of the vein glue lies in closure effectiveness of 96 – 98%, identical to that of radiofrequency therapy. However, this is achieved through a significantly lower rate of side effects. The lack of high thermal stress on the tissue ultimately leads to a therapeutic effect that is significantly less painful and has fewer side effects. The authors have been working with the VenaSeal® - Closure System since August 1st., 2012, and have so far successfully treated 2840 saphenous veins in 1476 patients with the vein glue. Closure effectiveness of 96.09% was achieved over 98 months.

After 18 years working with endo venous techniques (Micro foam, laser, radio wave): Our experience with endo venous therapy and especially with vein glue VenaSeal® made it our basic therapy of truncal varicose veins! The thermal ablation is not out, but the way of therapy is much more differentiated. Radical surgical therapy is now normally only reserved for individual cases and should no longer be recorded as standard therapy for varicosis. Regardless of this, the surgical craft must still be learned.

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