





On the 1<sup>st</sup> day, all 2162 veins were checked (2147 veins were closed initially=99.31%) 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 97.64%.

Over a time period of 3 months up to 4 months after the treatment, we were able to follow up 1627 saphenous veins

(75.2% of all veins that had been treated) and here we found 43 partial and 16 complete recanalizations. The closure rate is thus 97.27%.

In 1408 saphenous veins (65.1%) were followed up over a 6-8 month time period and 50 partial and 29 complete recanalizations were found, resulting in the effectiveness of 96.35% (Figure 4).

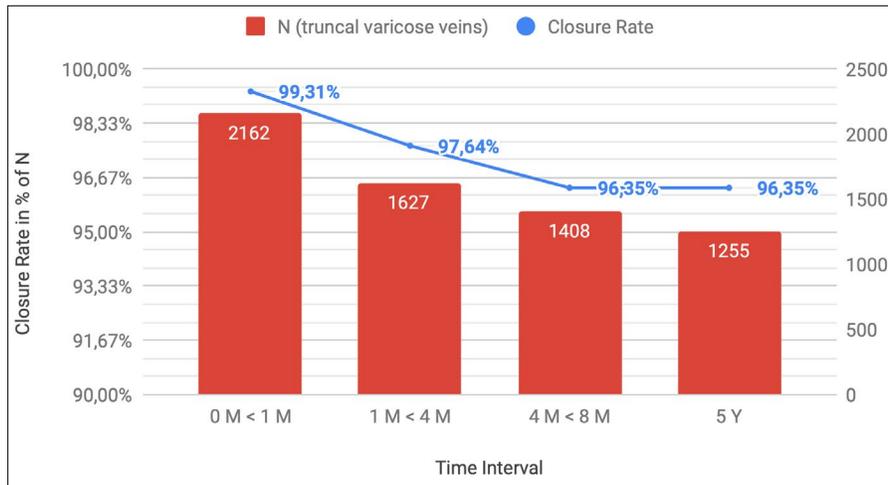


Figure 4. Closure rate VenaSeal<sup>®</sup> over 78 months.

No further recanalizations were found after 78 months.

In the follow-up period of 5 years after therapy we controlled 1255 truncal varicose veins (58.0%) up to now.

All 12 leg ulcers were healed until to 12 weeks after intervention.

2162 truncal varicose veins having been sealed with Venaseal<sup>®</sup>, the results achieved over the entire time period of 78 months are equivalent to a closure rate of 96.35%.

The pain score (range 1-10) for subjectively felt pain on the 1<sup>st</sup> day post - sealing was between 1.6 and 3.4 (2.1) - in RFITT between 3.8 and 4.1.

In 174 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 11 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 [11,12] (Figures 5 and 6).



Figure 5. Aneurysma of GSV at the junction sealing therapy possible.



**Figure 6.** 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 min 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 1.5 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.

Thus, the colleagues who work with endovenous procedures meanwhile have reliable criteria for a high - quality therapy [1,4,6,12-16].

The VenaSeal<sup>®</sup> - 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 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.

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 [17].

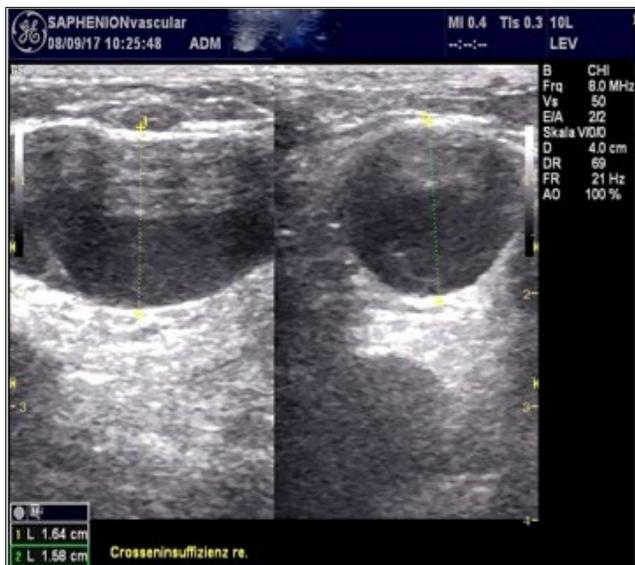
We do not need anesthetics anymore and can in most cases do without postoperative compression therapy. Elastic stockings should nevertheless, by all means, be recommended after the treatment of thicker saphenous varicose veins measuring >1.2 cm and they become compulsory where we intend to apply sealing 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<sup>®</sup> - 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** [14] 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 [5,18]. In the time periods between 12 and 36 months covered by follow-up examinations up to now, both procedures have proven quite clearly superior (99.6%) [13,15,18] to laser therapy in terms of effectiveness.

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 [12]. Particularly pain, as well as the neurological side effects, no longer plays 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 (**Figure 7**).



**Figure 7.** Sealing ectatic and aneurysmatic parts of truncal veins is also possible - ultrasound from SFJ - aneurysm.

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 [3-6,13-15,18].

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 perforator veins.

#### CONFLICT OF INTERESTS

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

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