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SUMMARY

This is a report of our experience based on the current results of a retrospective study dealing with the application of the VenaSeal™ Sapheon Closure system after the treatment of 795 truncal veins (561 great saphenous veins, 234 small saphenous veins). This study presents our own experiences, collected during a retrospective single-center trial after 33 months of application.

Since 31st July 2012, VenaSeal® has been successfully in use at the SAPHENION® clinic in Berlin and Rostock, Germany. As of 12IIIh April 2015, VenaSeal® had been used in the treatment of 795 truncal veins (439 patients). In 561 cases, the great saphenous veins were treated (GSV) and in 234 cases the small saphenous veins were treated (SSV). Anesthesia was not needed in a single case, skin incisions did not have to be made, and in 98% of the cases, the patients went without compression stockings. However, we recommend that patients who have been treated with VenaSeal® for venous aneurysms or enlarged veins beginning at a diameter of 1.0 cm (while standing) wear compression stockings for seven days.

RESULTS

One day after the procedure, all veins were re-examined. 793 of the veins were already sealed (99.75%). After 30 days, we diagnosed nine partially and four completely re-canalized veins. This equals a closure rate of 98.36%. After three months, we observed three further partial re- canalizations sonographically for 595 veins (74.8%), which equals a closure rate of 98.0% for the total number of patients. Over the course of six months, we re-examined 565 veins (71.07%), and found two complete re-canalizations. Thus, the closure rate was 97.74%. No further re- canalizations were observed at 33 months. In total, we were able re-examine 467 veins (58.74%) (see Table 1).

Time Period	Closure Rate	Partial Recanalization	Full Recanalization
1 day	99.75%		
30 days	98.36%	9	4
3 Months	98.0%	3	0
6 Months	97.7%		2
33 Months	97.75%		

TABLE 1

We treated 795 veins with the VenaSeal™ closure system method. The results obtained over a time period of nearly 33 months reveal a closure rate of 97.75%. In 101 cases, we performed only one treatment for an insufficient truncal vein. In 306 cases, we performed treatment simultaneously on both sides, or simultaneous treatment of the great saphenous vein and small saphenous vein. In the cases of 29 patients, we treated three truncal veins simultaneously with a repositioning of the patient. In three cases, the great saphenous veins and small saphenous veins were treated simultaneously on both sides. The patients' pain scores ranked between one and three on the first day after surgery.

In 93 cases (11.7%), we discovered unspecified, inflammatory reddening of the skin approximately five to eight days after surgery. In no case was an endoluminal, superficial thrombophlebitis of the treated vein present. This inflammatory response may have been associated with an increased amount of sealant used in the case of frequent and simultaneous intervention on several truncal veins in one leg. In seven cases, microfoam therapy was carried out on the same leg at the same time the sealant was implanted. The skin and tissue reactions regressed after two to four days when Ibuprofen was taken and cooling bandages were applied. No hypoesthesia, paraesthesia, or permanent skin responses occurred, nor did we observe any phlebitis or thrombosis.

DISCUSSION

In the last 15 years, the quality standards for endovenous methods for the treatment of varicose veins have been developed and defined. Colleagues who specialize in endovenous treatments have standard quality criteria at their disposal for endoluminal treatment methods. The effectivity of a permanent sealing of a truncal vein is the most significant criterion in the guideline for the treatment of varicose veins.

The VenaSeal™ closure system is a unique, minimally invasive, non-tumescent, non-thermal and non-sclerosant procedure that uses an advanced medical adhesive to close diseased veins in patients with symptomatic venous reflux disease. Unlike other treatments, the VenaSeal™ closure system does not require tumescent anesthesia, allowing patients to return to their normal activities following the procedure. The VenaSeal™ procedure also eliminates the risk of nerve or other heat-related injury associated with thermal-based procedures, and may reduce the need for compression stockings post-procedure.[1,2,3]

The VenaSeal™ closure system uses an advanced medical adhesive to safely and effectively close diseased vein segments.[4,5] The adhesive is a medical grade cyanoacrylate-based adhesive. Cyanoacrylates are strong adhesives capable of instantaneous bonding and hemostasis.[6] Cyanoacrylates have been used successfully for over 50 years in a wide variety of medical applications.[7,8]

The VenaSeal™ adhesive is a custom blend, formulated to achieve specific performance requirements associated with closure of the GSV and associated varicosities in the treatment of venous reflux disease.

In the cases re-examined over the course of the 33 months, none of the complications that are known to occur with other methods were observed. We observed no postoperative vein inflammations or thrombosis. No neurological abnormalities or wound healing disorders were detected.

In contrast to the comparable endothermal systems, in our experience, the pain scores were significantly lower (1.9 : 4.1). Our patients did not report experiencing any unusual sensations or numbness. There were no permanent reactions on the skin. In particular, we were able to seal superficial truncal veins, which were situated directly beneath the skin, without causing visible reddening or pigmentation.

After 1,000 days of collecting information on 795 treated truncal veins, VenaSeal™ therapy has become our first choice treatment, especially for varicoses in small saphenous veins.

REFERENCES

1. **Almeida JI, Javier JJ, Mackay E, Bautista C, Proebstle TM.** First human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. Journal of Vascular Surgery: Venous and Lymphatic Disorders 2013;1:174-180.
2. **Almeida JI, Javier JJ, Mackay EG, Bautista C, Cher DJ, Proebstle TM.** Two-year follow-up of first human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. Phlebology / Venous Forum of the Royal Society of Medicine 2014.
3. **Proebstle TM, Alm J, Dimitri S et al.** The European multicenter cohort study on cyanoacrylate embolization of refluxing great saphenous veins. Journal of Vascular Surgery: Venous and Lymphatic Disorders.
4. **Almeida J. et al.** Two-year follow-up of first human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. Phlebology / Venous Forum of the Royal Society of Medicine 2014.
5. **Gibson K. A Randomized,** Controlled Study Comparing Cyanoacrylate Adhesive Embolization With Radiofrequency Ablation For Treatment Of Incompetent Great Saphenous Veins VeClose Study. German Society of Phlebology, 2014.
6. **Spotnitz, WD. (1996). History of Tissue Adhesives. In D. Sierra & R. Saltz (Eds.),** Surgical Adhesives and Sealants: Current Technology and Applications (pp. 4). Lancaster, PA: Technomic Publishing Company, Inc.
7. **Lawson J, Gauw S, VanVlijmen C, et al.** Phlebology 2013;28. Suppl1:2-9 Review article p3,1.
8. **Min RJ, et al.** Vein closure using cyanoacrylate adhesive: 30 day swine model results. Phlebology 2012:1-6 p1-2.