# Nonthermal Ablation for the Treatment of Varicose Veins

The evolving minimally invasive methods for saphenous vein ablation.

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Thermal ablation for closure of an incompetent saphenous vein came on the scene just over 10 years ago; in the United States, it has virtually replaced traditional surgical saphenectomy (high ligation and stripping). Thermal ablation—either in the form of radiofrequency or laser electromagnetic energy—exemplifies the principles of the endovascular revolution. The minimally invasive solutions to vascular disease using image guidance offer a short hospital stay, quick recovery, durability, improved quality of life, minimal scarring, and an overall high-tech vibe. Since the advent of endovascular technology, most American patients now enjoy catheter-based solutions to their vascular problems on both the venous and arterial sides.

Endovenous thermal ablation of saphenous vein trunks has proven safe and durable. Currently, there are many devices available to physicians who are interested in treating patients with venous disease. All of the current devices boast excellent closure rates, and the differences lie mostly in postprocedure recovery.[1] All procedures require the use of perivenous tumescent anesthesia to mitigate the side effects of vein heating. There has been an interest in developing technology that eliminates the percutaneous placement of perivenous tumescent anesthesia, thus avoiding multiple noxious needle punctures.

Sclerotherapy, which does not require tumescent anesthesia for the treatment of varicose veins, has been available for decades. However, saphenous trunk closure with a variety of sclerosants has proven unreliable, with numerous publications showing high recanalization rates. To potentiate vein closure, sclerosants have been used as gaseous foams. Foam sclerotherapy has had a difficult time garnering approval from the US Food and Drug Administration because it has been shown to embolize systemically into the venous circulation and, rarely, into the arterial circulation via patent foramen ovale.

**Figure 1. Sapheon closure system (Sapheon, Inc., Santa Rosa, CA).**

## SAPHENOUS VEIN CLOSURE WITH CYANOACRYLATE ADHESIVE

Cyanoacrylate (CA) adhesives, commonly referred to as "super glue," have gained momentum in recent years for intravascular use in treating conditions such as arteriovenous malformations and pelvic congestion syndrome. When used intravascularly, CA triggers an acute inflammatory reaction in the vessel wall via a polymerization reaction. An inherent risk of an overdiluted CA compound (a polymerization rate that is too slow) is migration of the CA into unwanted areas because of low viscosity. Conversely, a polymerization rate that is too rapid may induce unwanted adhesion of the delivery catheter to the vessel because the compound cures

**TABLE 1. SUMMARY OF ANIMAL STUDIES USING THE SAPHEON CLOSURE SYSTEM[a]**

| Model | Study Type | No. of Animals | Implant Sites | Implant Days |
|---|---|---|---|---|
| Swine | Acute | 14 | 26 | n/a |
| | 30-day | 4 | 8 | 240 |
| | 60-day | 2 | 4 | 240 |
| | **Total** | **20** | **38** | **480** |
| Goat | Acute | 2 | 4 | n/a |
| | 30-day | 3 | 6 | 180 |
| | 90-day | 3 | 6 | 540 |
| | 180-day[b] | 2 | 4 | 720 |
| | **Total** | **10** | **20** | **1,440** |
| Rabbit | 30-day | 1 | 3 | 60 |
| | 90-day | 2 | 6 | 360 |
| | **Total** | **3** | **9** | **420** |
| **Summary** | | **33** | **67** | **2,340** |

*[a]Completed > 2,000 implant days with complete closure with no adverse events, no evidence of recanalization, and no evidence of neoplasia.*
*[b]Histological normal healing and foreign body responses.*

too quickly. A new CA by Sapheon, Inc. with a proprietary blend of additives to affect polymerization is in the process of clinical testing. One advantage of a CA adhesive saphenous closure system is that the capital investment required to treat the saphenous vein is markedly reduced because a generator—such as those used for radiofrequency or laser ablation—is no longer required.

### Animal Models

Care of the live animals complied with the National Institutes of Health guidelines for laboratory animals, and they were housed with care in accordance with United States Department of Agriculture regulations. Superficial epigastric veins from different animal models were used because of their similarity to the human great saphenous vein. Access was obtained using a standard micropuncture kit, and a 5-F sheath was advanced 2 cm caudad to the junction with the abdominus rectus veins. A dispenser gun attached to a catheter was used to inject 0.16 mL of CA, while compression was applied to occlude the venous junction (Figure 1). After delivery, the catheter was pulled back 3 cm, and manual venous compression was employed for 30 seconds over the CA delivery site. Animals were euthanized and examined either immediately, at 30 days, or at 60 days postimplantation.

The most exciting finding from the animal work was the fibrosis seen at 60 days postimplantation. The vein walls were segmentally thickened by fibrous tissue, and the lumen was filled with coalescing, arborizing bands of macrophages and spindle cells. The changes observed in the treated veins are consistent with chronic foreign

**Figure 2. Disposable Vein Hook (Vascular Solutions, Inc., Minneapolis, MN; developed by AM Phleb Device LLC, Miami, FL).**

body–type inflammatory response. Others have observed fibrosis at 2 to 3 months postimplantation using other CA formulations.[2] A summary of animal studies is shown in Table 1.

### First-in-Man

The protocol for this procedure was approved and performed in accordance with the Dominican National Council on Bioethics in Health (CONABIOS). Eight consecutive patients with incompetent great saphenous veins and signs or symptoms of chronic venous disease underwent saphenous vein closure with CA adhesive. The mean treatment time was 17 minutes, the mean treatment length was 31 cm, and the mean CA injected volume was 1.58 mL. All veins were closed at 1 month. Serious adverse events were nil. We concluded from this small pilot study that CA adhesive as an alternative treatment for the incompetent saphenous vein was feasible. A more robust study began in March 2011.

## ADDRESSING THE VARICOSITIES

With respect to working with a saphenous vein closure device, which does not require tumescent anesthesia, the question becomes, "What is the compelling reason for using this device when the patient will need tumescent anesthesia regardless for phlebectomy of the varicosities?" There has been great debate (and sparse data) addressing the timing for treatment of the varicosities after saphenous ablation. Some operators prefer to deal with the varicosities at the same time as saphenous trunk ablation, while others prefer to stage the two procedures at different time intervals. The alternative, sclerotherapy treatment of the varicosities, is vexed with staining problems and a high recurrence rate.

## PHLEBECTOMY

Tumescent anesthesia provides a safe, easy-to-administer technique for use with a phlebectomy procedure. The anesthetic preparation is administered subdermally under pressure. The tumescent fluid hydrodissects the subcutaneous fat from the venous tissue and also offers a bacteriostatic effect. Phlebectomy surgery requires a scalpel to make an incision, a hook to exteriorize the vein, and a hemostat for vein removal under traction.

The most popular instruments for creating phlebectomy incisions are No. 11 scalpel blades or 18-gauge needles. Incision length should correspond to vein size, but is usually in the range of 1 to 3 mm. Hooking the target vein through the small incision is the next step. There are multiple instruments available for hooking the vein, which are usually known by the inventor's name. These instruments are made of nondisposable stainless steel and require autoclaving.

### Disposable Vein Hook

The Disposable Vein Hook consists of a plastic handle with a blade and a retractable safety guard on one end and a hook on the opposite end, allowing physicians to quickly perform a phlebectomy procedure by making the incision with the blade end and then turning the device around and using the hook end to remove the varicosity (Figure 2).

The Disposable Vein Hook is intended for single-patient use for the treatment of superficial varicose veins associated with superficial reflux and incompetence of the great saphenous vein in the lower extremities. This procedure can be performed in conjunction with saphenous ablation or as a stand-alone procedure. The sterile, single-use Disposable Vein Hook is offered along with the Disposable Hemostat Pack (Vascular Solutions, Inc.), thereby eliminating the need and expense of an autoclave system.

## CONCLUSION

As nonthermal technology for saphenous vein ablation develops, we are seeing a potential trend that minimizes capital outlay for vein center start-up and improves the patient experience. Because the devices are disposable, one-time-use products, autoclaves and infectious disease policy and procedure protocols may no longer be necessary. One could argue further, that staging the saphenous closure followed by phlebectomy at a later stage may optimize the patient experience. Early data with CA saphenous closure demonstrates an innocuous postoperative recovery; therefore, if one allows 6 weeks for varicose vein shrinkage, the subsequent phlebectomy would be minimized, requiring only a disposable kit and a little local anesthetic. The minimally invasive revolution continues to evolve for the better. ■

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1. Almeida JI, Kaufman J, Göckeritz O, et al. Radiofrequency endovenous ClosureFAST versus laser ablation for the treatment of great saphenous reflux: a multicenter, single-blinded, randomized study (RECOVERY study). J Vasc Interv Radiol. 2009;20:752-759.

2. Wang YM, Cheng LF, Li N. Histopathological study of vascular changes after intra-arterial and intravenous injection of N-butyl-2-cyanoacrylate. Chin J Dig Dis. 2006;7:175-179.