

Questions & Answers: The Closure® Procedure

BACKGROUND

10/14/2005

FOR MORE INFORMATION

Allyson Landphair, MSN, ARNP, CVN
319.233.6211

What is superficial venous reflux?

Superficial venous reflux is a condition that develops when the valves that usually keep blood flowing out of your legs become damaged or diseased. This causes blood to pool in your legs. Common symptoms of superficial venous reflux include pain, swelling, leg heaviness and fatigue, as well as varicose veins in your legs.

What is the Closure® procedure?

The Closure procedure is a minimally invasive treatment for superficial venous reflux. A thin catheter is inserted into the vein through a small opening. The catheter delivers radiofrequency (RF) energy to the vein wall, causing it to heat, collapse, and seal shut.

How does it work to treat superficial venous reflux?

Since valves can't be repaired, the only alternative is to re-route blood flow through healthy veins. Traditionally, this has been done by surgically removing (stripping) the troublesome vein from your leg. The Closure procedure provides a less invasive alternative to vein stripping by simply closing the problem vein instead. Once the diseased vein is closed, other healthy veins take over and empty blood from your legs.

How is the Closure procedure different from vein stripping?

During a stripping procedure, the surgeon makes an incision in your groin and ties off the vein, after which a stripper tool is threaded through the saphenous vein and used to pull the vein out of your leg through a second incision just above your calf.

In the Closure procedure, there is no need for groin surgery. Instead, the vein remains in place and is closed using a special (Closure) catheter inserted through a small puncture. This may eliminate the bruising and pain often associated with vein stripping (i.e., that may result from the tearing of side branch veins while the saphenous vein is pulled out). Vein stripping is usually performed in an operating room, under a general anesthetic, while the Closure procedure is performed on an outpatient basis, typically using local or regional anesthesia.

Three randomized trials of the Closure procedure vs. vein stripping, including the most recent multi-center comparative trial, show very similar results. In the multi-center comparative trial, the Closure procedure was superior to vein stripping in every statistically significant outcome. In the study, 80.5% of patients treated with the Closure procedure returned to normal activities within one day, versus 46.9% of patients who underwent vein stripping. Also, Closure patients returned to work 7.7 days sooner than

surgical patients. Patients treated with the Closure procedure had less postoperative pain, less bruising, faster recovery and fewer overall adverse events.¹

How long does the Closure procedure take?

The Closure procedure takes approximately 45-60 minutes, though patients normally spend 2-3 hours at the medical facility due to normal pre- and post-treatment procedures.

Is the Closure procedure painful?

Patients report feeling little, if any, pain during the Closure procedure. Your physician will give you a local or regional anesthetic to numb the treatment area.

Will the procedure require any anesthesia?

The Closure procedure can be performed under local, regional, or general anesthesia.

How quickly after treatment can I return to normal activities?

Many patients can resume normal activities immediately.² For a few weeks following the treatment, your doctor may recommend a regular walking regimen and suggest you refrain from very strenuous activities (heavy lifting, for example) or prolonged periods of standing.

How soon after treatment will my symptoms improve?

Most patients report a noticeable improvement in their symptoms within 1-2 weeks following the procedure.

Is there any scarring, bruising, or swelling after the Closure procedure?

Patients report minimal to no scarring, bruising, or swelling following the Closure procedure.

Are there any potential risks and complications associated with the Closure procedure?

As with any medical intervention, potential risks and complications exist with the Closure procedure. All patients should consult their doctors to determine if their conditions present any special risks. Your physician will review potential complications of the Closure procedure at the consultation, and can be reviewed in the safety summary. Potential complications can include: vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, paresthesia (numbness or tingling) and/or skin burn.

Is the Closure procedure suitable for everyone?

Only a physician can tell you if the Closure procedure is a viable option for your vein problem. Experience has shown that many patients with superficial venous reflux disease can be treated with the Closure procedure.

Is age an important consideration for the Closure procedure?

The most important step in determining whether or not the Closure procedure is appropriate for you is a complete ultrasound examination by your physician or qualified clinician. Age alone is not a factor in determining whether or not the Closure procedure is appropriate for you. The Closure procedure has been used to treat patients across a wide range of ages.

How effective is the Closure procedure?

Published data suggests that two years after treatment, 90% of the treated veins remain closed and free from reflux, the underlying cause of varicose veins.^{3,4,5}

What happens to the treated vein left behind in the leg?

The vein simply becomes fibrous tissue after treatment. Over time, the vein will gradually incorporate into surrounding tissue. One study reported that 89% of treated veins are indistinguishable from other body tissue one year after the Closure procedure was performed.⁶

Is the Closure treatment covered by my insurance?

Many insurance companies are paying for the Closure procedure in part or in full. Most insurance companies determine coverage for all treatments, including the Closure procedure, based on medical necessity. The VNUS® Closure procedure has positive coverage policies with most major health insurers. Your physician can discuss your insurance coverage further at the time of consultation.

What are patients saying about the Closure procedure?

98% of patients who have undergone the Closure procedure are willing to recommend it to a friend or family member with similar leg vein problems.⁴

¹ Lurie F, Creton D, Eklof B, Kabnick LS, Kistner RL, Pichot O, et al. Prospective randomized study of endovenous radiofrequency obliteration (Closure) versus ligation and stripping in a selected patient population (EVOLVES study). *J Vasc Surg* 2003;38:207-14.

² Goldman, H. Closure of the greater saphenous vein with endo radiofrequency thermal heating of the vein wall in combination with ambulatory phlebectomy: preliminary 6-month follow-up. *Dermatol Surg* 2000; 26:452-456.

³ Merchant RF, DePalma RG, Kabnick LS. Endovascular obliteration of saphenous reflux: a multicenter study. *J Vasc Surg* 2002;35:1190-6.

⁴ Weiss RA, et al. Controlled radiofrequency endovenous occlusion using a unique radiofrequency catheter under duplex guidance to eliminate saphenous varicose vein reflux: a 2-year follow-up, *Dermatologic Surgery*, Jan 2002; 28:1: 38-42

⁵ Whiteley, MS, Holstock JM, Price BA, Scott MJ, Gallagher TM. Radiofrequency ablation of refluxing great saphenous systems, giacomini veins, and incompetent perforating veins using VNUS Closure and TRLOP technique. Abstract from *Journal of Endovascular Therapy* 2003; 10:I-46.

⁶ Pichot O, Sessa C, Chandler JG, Nuta M, Perrin M. Role of duplex imaging in endovenous obliteration for primary venous insufficiency. *J. Endovasc Ther* 2000;7:451-9.