

BACKGROUND

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FOR MORE INFORMATION

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Saphenous Vein Occlusion: The Closure® System

The Problem: Leaky Valves

A saphenous vein runs up the leg from ankle to groin. Its job is to help return oxygen-depleted blood to the heart. In the majority of people, this vessel functions properly.

Vein valves prevent blood from flowing backwards in the saphenous vein. If the valves do not function properly -- a condition known as superficial venous reflux -- numerous problems occur. Symptoms can include swelling, pain, fatigue and varicose veins.

Varicose veins are known for their distinctive blue color and bulging appearance on the skin. Resembling large, elongated worms, they afflict an estimated 10%-20% of the adult population. In the United States, which translates into 20-25 million people, the majority of whom are women.

Whether the initial cause is genetics, pregnancy, prolonged standing, excess weight, inadequate exercise, or a damaged saphenous vein, the physiology of varicose veins is nearly always the same. The valves in the saphenous vein are damaged -- physicians call them "incompetent" -- and the veins near the skin surface are stretched and distorted from the increased pressure caused by blood flowing in the wrong direction. Venous reflux (or incompetent valves) in the saphenous vein is often the underlying cause of varicose veins. Although the condition is rarely life-threatening, it is often painful and unattractive.

Treatment Options

Historically, patients have had several choices for treating varicose veins, depending on the severity. They could make lifestyle changes, such as eating less, exercising more and wearing support hose. This regimen has proven helpful in somewhat reducing leg pain and further deterioration of the vein, particularly in mild cases, but is not a curative treatment. Furthermore, most patients return to their previous lifestyles sooner or later, and thus their previous symptoms typically re-occur.

Patients could also have the visible varicose veins removed in a procedure called "phlebectomy." This surgical technique was developed in the 1950s. A specially trained physician removes diseased veins through a series of very small punctures or incisions with a variety of specialized hooks. However, phlebectomy alone does not address the incompetent valves in the saphenous vein, which created the problem and can cause varicose veins to recur. Some physicians thus advocate the removal, or stripping of, the saphenous vein. By removing the saphenous vein, blood is diverted to other veins with competent valves. In many cases, stripping eliminates the pain associated with varicose veins and greatly reduces their potential for recurrence without the need for further intervention. Stripping involves making an incision in the groin region and surgically

tying off the top of the saphenous vein. An instrument resembling a thin rod with a bulbous end is then inserted into the saphenous vein and passed through to the upper calf. Another incision is made at the upper calf. The stripping device is then tied to the vein, which is pulled out through the second incision. This typically causes significant bruising and can create post-operative pain, nerve damage and poor short-term cosmetic outcomes. The resulting postoperative convalescence lasts weeks. This procedure is still widely performed.

Closure ®

The Closure ® System was developed over a four-year period to treat superficial venous reflux, providing the benefits of stripping without the associated drawbacks, e.g. invasive surgical procedure, general anesthesia, post-operative pain, bruising and prolonged recovery period. This patented technology uses a very small catheter and radiofrequency energy to occlude, or seal shut, the saphenous vein. The Closure procedure is an outpatient technique that is often performed in a physician's office. The physician typically makes a single needle puncture or small incision near the knee and inserts the slender Closure catheter into the saphenous vein. The catheter is then positioned near the top of the leg, energized and slowly withdrawn, sealing the vein shut. There are no stitches, and most patients return to normal activity within a day or two.

The Closure procedure has been the subject of numerous studies and journal articles. The results from a peer-reviewed, multi-center, randomized trial comparing recovery rates and quality of life between patients treated with conventional varicose vein stripping surgery and the Closure procedure (radiofrequency vein ablation) appeared in the August 2003 edition of the Journal of Vascular Surgery. This is the third randomized trial showing that the Closure procedure resulted in:

- Less post-operative recuperation time
- Faster return to work and normal activities
- Less post-operative pain and limitation of physical activity

Like other venous procedures, the Closure procedure involves risks and potential complications. All patients should consult their doctors to determine whether or not they are candidates for this procedure, and if their conditions present any special risks. Complications reported in medical literature include numbness or tingling (paresthesia), skin burns, blood clots and temporary tenderness in the treated limb.