Intravascular 1320-nm Laser Closure of the Great Saphenous Vein: A 6- to 12-Month Follow-up Study

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OBJECTIVE. **The objective was to determine the safety and efficacy of an intravascular laser with a novel wavelength to close the great saphenous vein.**

METHODS. **Twenty-four cases of an incompetent great saphenous vein (0.5–1.2 cm in diameter) associated with distal varicose veins were treated with a 1320-nm intravascular laser at 5 W with an automatic pullback mechanism at 1 mm/s. Patients were evaluated with duplex ultrasound to determine efficacy of treatment at various time periods to at least 6 months after the procedure.**

RESULTS. **All patients demonstrated complete closure of the incompetent great saphenous vein. In most cases, the treated great saphenous vein was not identifiable 6 months postoperatively. There was no recurrence of any varicose veins. All preoperative symptoms resolved after treatment, and no complications were noted. All patients were very pleased with the outcome of the procedure.**

CONCLUSIONS. **At 6 months or greater follow-up, a 5-W, 1320-nm intravascular laser with 1 mm/s automatic pullback, delivered through a diffusion-tip fiber, is safe and effective in treating an incompetent great saphenous vein up to 1.2 cm in diameter.**

THE 1320-NM COOLTOUCH LASER WAS LOANED FOR THE STUDY. COOLTOUCH PROVIDED ALL DISPOSABLE MATERIALS FOR THE STUDY. DR GOLDMAN HAS RECEIVED PRECEPTORSHIP FEES FOR TEACHING OTHER PHYSICIANS HOW TO USE THIS LASER.

SURGICAL LIGATION and stripping of the great saphenous vein with incompetence through the saphenofemoral junction has been demonstrated to result in a high degree of recurrence.[1–5] This is secondary to reanastomosis through hemodynamically significant perforator veins present extending from the knee to the groin that is often not eliminated during the surgical procedure. Therefore, to provide the maximal degree of improvement in abnormal venous hemodynamics, complete removal of the great saphenous vein from the saphenofemoral junction to the knee is recommended after ligating the saphenofemoral junction. This surgical procedure is most often performed under general anesthesia with patients usually taking 1 week or so to get back to normal activities.

Radiofrequency energy can be delivered through a specially designed endovenous electrode to accomplish controlled heating of the vessel wall, causing vein shrinkage or occlusion by contraction of venous wall collagen. With worldwide clinical experience on thousands of patients since its introduction in 1999, this technique is rapidly being added to the armamentarium of ways to deal with axial venous reflux.[6–14] All studies demonstrate an efficacy equal to that of ligation and stripping with few if any adverse sequelae. The Closure procedure (VNUS Medical Technologies, Inc., San Jose, CA) is performed entirely under local tumescent anesthesia with more than 90% of patients resuming normal activities 1 to 2 days postoperatively. Its main drawback is the high cost of disposable catheters (approximately $750 per catheter) and the necessity of withdrawing the catheter manually at a speed of 2 to 3 cm/min, which makes the procedure tedious especially when long segments of the great saphenous vein are treated.

Simultaneous with development of radiofrequency closure, endoluminal lasers have also been demonstrated to effectively close axial veins through thermal damage to endothelium with subsequent thrombosis and resorption of the damaged vein. Endoluminal laser closure has lower disposable costs (less than $100/procedure) and is much quicker with the speed of pullback 10 to 20 cm/min.

These endovenous occlusion techniques are less invasive alternatives to saphenofemoral ligation and/or stripping. They are typically performed under local anesthesia with patients returning to normal activities within 1 to 2 days.

Endovenous laser treatment (EVLT, Diomed Inc., Andover, MA) allows delivery of laser energy directly into the blood vessel lumen to produce endothelial and vein wall damage with subsequent fibrosis (Figure 1). It is presumed that destruction of the great saphenous vein with laser is a function of thermal destruction.

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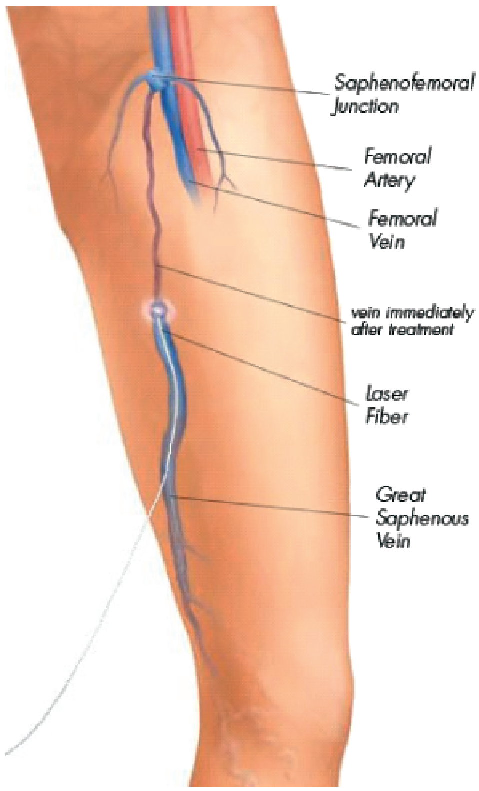

Figure 1. Diagrammatic representation of endoluminal laser treatment of the greater saphenous vein.

The absorption target for lasers with 810-, 940-, 980-, and 1064-nm wavelengths is intravascular red blood cells. Thermal damage, however, with resorption of the great saphenous vein has also been seen in veins emptied of blood. Therefore, direct thermal effects on the vein wall probably also occur. The extent of thermal injury to tissue is strongly dependent on the amount and duration of heat to which the tissue is exposed. Moritz and Henriques[15] investigated the time–temperature response for tissue exposed to up to 70°C. They found that skin can withstand temperature rises for very short exposure times and that the response appears to be logarithmic as the exposure times become shorter. For example, an increase in body temperature to 58°C will produce cell destruction if the exposure is longer than 10 s. Tissues, however, can withstand temperatures up to 70°C if the duration of the exposure is maintained less than 1 s. Thus, any tissue injury from brief exposure to temperatures less than 50°C would be expected to be reversible.

One in vitro study model has predicted that thermal gas production by laser heating of blood in a 6-mm tube results in 6 mm of thermal damage.[16] These authors used a 940-nm diode laser with multiple 15-J, 1-s pulses to treat the great saphenous vein. A median of 80 pulses (range, 22–116) were applied along the treated vein every 5 to 7 mm. Histologic examination of one excised vein demonstrated thermal damage along the entire treated vein with evidence of perforations at the point of laser application described as "explosive-like" photo-disruption of the vein wall. This produced a homogeneous thrombotic occlusion of the vessel. Because a 940-nm laser beam can only penetrate 0.3 mm in blood,[17] the formation of steam bubbles is the probable mechanism of action.

Another possible mechanism of action of endovenous laser treatment is that postulated for radiofrequency closure, namely, collagen contraction. Collagen has been noted to contract at about 50°C, whereas necrosis occurs between 70 and 100°C.[18] It is possible that collagen contraction, thermal damage or a combination of these two effects is responsible for destruction and resorption of the great saphenous vein.

Initial reports have shown this technique with an 810-nm diode laser to have excellent short-term efficacy in the treatment of the incompetent great saphenous vein, with 96% or higher occlusion at 9 months with a less than 1% incidence of transient paresthesia (Todd KL, Issacs MN, Mackay EG, Fronek HS, "Endovenous Laser Treatment: A Long-Term Follow-up Study," presented at the 2003 UIP World Congress Chapter Meeting, San Diego, CA, September 2003; Min RJ, "Endovenous Laser Treatment: Long-Term Results", presented at the 2003 UIP World Congress Chapter Meeting, San Diego, CA, September 2003; Navarro L, Bone C, "Endolaser: Four Years of Follow-up Evaluation," presented at the 2003 UIP World Congress Chapter Meeting, San Diego, CA, September 2003).[19,20] Although most patients experience some degree of postoperative ecchymosis and discomfort, no other major or minor complications have been reported. The lack of significant heating of perivenous tissues owing to the effect of perivascular lidocaine fluid probably explains the low complication rate found and argues well for the continued lack of significant complications.

Our patients treated with endovenous laser treatment with an 810-nm diode laser have shown an increase in posttreatment purpura and tenderness compared to radiofrequency closure. Most of our patients do not return to complete functional normality for 2 to 3 days as opposed to the 1-day "downtime" with radiofrequency closure of the great saphenous vein. Because the anesthetic and access techniques for the two procedures are identical, we believe that nonspecific perivascular thermal damage is the probable cause for this increased tenderness. In addition, recent studies suggest that pulsed 810-nm diode laser treatment with its increased risk of vein perforation, as opposed to continuous treatment that does not have intermittent vein perforations, may be responsible for the increase symptoms with endovenous laser

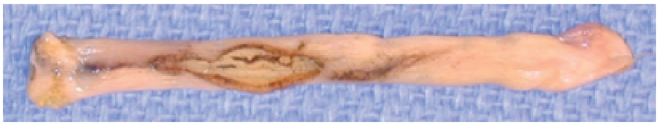

Figure 2. Vein perforation with a 810-nm diode intravascular laser.

treatment versus radiofrequency treatment (Figure 2) (Goldman MP, "Endovenous Laser Treatment of the Greater Saphenous Vein: Continuous vs. Pulsed Treatment," presented at the International Union September 11, 2001, of Phlebology World Congress, Rome, Italy).[16] In fact, trying to vary the fluence and treating with a continuous laser pullback versus pulsed pullback has not resulted in an elimination of vein perforation (Goldman MP, Iyer S, "Comparison of Various Fluences Using an 810 nm Intravascular Laser for the Treatment of Varicose Great Saphenous Veins," presented at the annual meeting of the American College of Phlebology, November 2002, Scottsdale, AZ).

A longer wavelength such as 940 nm has been hypothesized to penetrate deeper into the vein wall with resulting increased efficacy. A report of 280 patients with 350 treated limbs with an 18-month follow-up demonstrated complete closure in 96%.[21] Twenty vein segments were examined histologically. Veins were treated with 1-s pulses at 12 J. Perforations were not present. When the fluence was increased to 15 J with 1.2- and 1.3-s pulses, microperforations did occur and were said to be self-sealing. The author suggests that his use of tumescent anesthesia as well as the abovementioned laser parameters are responsible for the lack of significant perforations and enhanced efficacy.

A study of intravascular laser ablation of an explanted great saphenous vein was performed with an 180-, 940-, and 980-nm laser with the vein filled with saline, plasma, or hemolytic blood.[22] With this experimental model, steam bubbles producing remote thermal damage only occurred in blood-filled veins. Thus, intravascular blood plays a key role for distributing thermal damage to the inner wall with these three wavelengths.

This excessive and nonspecific thermal damage has led to 67% of patients complaining of pain along the treated vein for 1 week in one study using the 940-nm intravascular laser.[23] In this study, 47% of 109 treated veins had palpable induration of the vein for at least 3 weeks after treatment. In 10% of patients thrombophlebitis with redness and swelling over the treated vein lasted for at least 2 weeks. An additional study of 15 great saphenous vein treated with either the 810- or the 980-nm intravascular laser also demonstrated a 26.7 and 13.3% incidence of superficial thrombophlebitis, respectively (Kabnick L, "Comparison of 980 nm and 810 nm Diode Endovenous Ablation Lasers for Treatment of the Great Saphenous Vein," presented at the 2003 UIP World Congress Chapter Meeting, San Diego, CA, September 2003). Yet another study in 39 great saphenous veins reported an 11% incidence of paresthesia for 3 to 8 weeks after treatment with a 940-nm intravascular laser despite all patients being treated with low-molecular-weight heparin and postoperative graduated compression for 8 days.[24] One final study of the treatment of 15 great saphenous veins with a 980-nm intravascular laser described mild tenderness in 8 legs with one episode of superficial thrombophlebitis.[25] It is therefore clear than a significant percentage of patients treated with the 810-, 940-, and 980-nm intravascular lasers develop tenderness and superficial thrombophlebitis after treatment.

Three studies have evaluated a 1064-nm Nd:YAG endolumenal laser.[26–28] In one study,[21] the lateral saphenous goat vein was used. Occlusion was more likely when fluence exceeded 84 J/cm^2. More importantly, treated vessels were not perforated even with a fluence of 224 J/cm^2. A diffusing fiber was also used to obtain circumferential damage.

A clinical study using an endolumenal 1064-nm Nd:YAG laser in the treatment of incompetent great saphenous vein in 151 men and women with 252 treated limbs was also reported.[27] Unfortunately, the surgeons also ligated the saphenofemoral junction, which did not allow for a determination of the efficacy of saphenofemoral junction ablation. Spinal anesthesia was used and the laser was used at 10 to 15 W of energy with 10-s pulses with manual retraction of the laser fiber at a rate of 10 s/cm. Skin overlying the treated vein was cooled with cold water. Unfortunately, this resulted in superficial burns in 4.8% of patients, paresthesia in 36.5%, superficial phlebitis is 1.6%, and localized hematomas in 0.8%.

In an attempt to bypass absorption of hemoglobin, we have examined a 1320-nm endolumenal laser. At this wavelength, tissue water is the target and the presence or absence of red blood cells within the vessels is unimportant. In addition, our technique utilizes a mechanical catheter drawback system to provide uniform heating of the vessel (Figure 3). Studies in the porcine great saphenous vein demonstrate full-thickness thermal damage at 5 W with the 1320-nm laser and 20 W with the 1064-nm laser.[28] This article presents our experience in the first 24 cases treated, with at least 6 months of follow-up.

Materials and Methods

Twenty-two patients with 24 varicose great saphenous veins demonstrating incompetence at the saphenofemoral junction were treated as described below (Table 1). All patients were followed with a duplex ultrasound

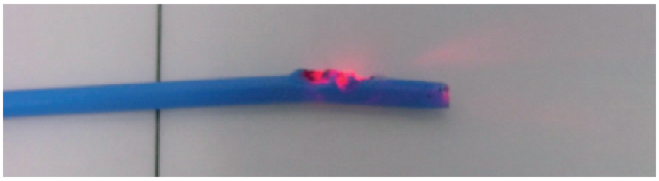

Figure 3. Protective sheath destroyed by a 810-nm diode laser that was pulled back too rapidly.

Table 1. Final evaluation results in all patients

Procedure No.	*GSV Treated (Left/Right)*	*Follow-up Time (months)*	*Duplex Ultrasound Evaluation*	*Clinical Evaluation*
1	Left	12	GSV not seen	VV resolved
2	Right	10	GSV not seen	VV resolved
3	Left	10	GSV not seen	VV resolved
4	Right	8	GSV not seen	VV resolved
5	Left	9	GSV not seen	VV resolved
6	Right	9	GSV not seen	VV resolved
7	Right	12	GSV not seen	VV resolved
8	Right	12	GSV not seen	VV resolved
9	Left	7	GSV not seen	VV resolved
10	Right	6	GSV not seen	VV resolved
11	Right	6	GSV closed	VV resolved
12	Right	6	GSV not seen	VV resolved
13	Left	10	GSV not seen	VV resolved
14	Right	8	GSV not seen	VV resolved
15	Left	7	GSV not seen	VV resolved
16	Right	7	GSV not seen	VV resolved
17	Left	6	GSV not seen	VV resolved
18	Right	6	GSV not seen	VV resolved
19	Right	6	GSV not seen	VV resolved
20	Left	6	GSV not seen	VV resolved
21	Right	6	GSV closed	VV resolved
22	Right	7	GSV not seen	VV resolved
23	Left	11	GSV not seen	VV resolved
24	Left	7	GSV not seen	VV resolved

*Mean follow-up time, 8 months; mean diameter, 8.4 mm (range, 5.5–12 mm).
Abbreviations: GSV, great saphenous vein; VV, varicose vein.

and clinical examination at various time periods to at least 6 months postoperatively. Informed consent was obtained from all subjects. The study protocol conformed to the guidelines of the 1975 Declaration of Helsinki and was approved by our institutional review board.

Technique for Closing the Great Saphenous Vein Using a 1320-nm Endoluminal Laser

Varicose veins are marked with the patient standing with a duplex ultrasound and again with the patient lying down in the operative position with transepidermal illumination as previously described.[29,30] After appropriate marking, the area surrounding the great saphenous vein and distal tributaries to be treated is infiltrated with 0.1% lidocaine with 1:1,000,000 epinephrine tumescent anesthesia. The amount of tumescent fluid averaged 800 mL with a lidocaine dose approximately of 8 mg/kg. The great saphenous vein is then accessed through a 2- to 3-mm incision in the medial midthigh usually 20 cm inferior to the saphenofemoral junction with a No. 3 or 4 Mueller hook.

A 500- to 600-μm laser fiber is inserted into the vein within an introducer protective sheath to just distal to the saphenofemoral junction. The introducer sheath is then removed to prevent inadvertent laser exposure to the sheath. A helium:neon aiming beam that is continuously illuminated when the laser is on ensures that the laser fiber is distal to the saphenofemoral junction. If the laser fiber extends past the saphenofemoral junction the aiming beam is not seen. The location of the distal aspect of the laser fiber is also checked with intraoperative duplex ultrasound.

The laser is set at 5 W of power in a near continuous fire mode of 30 Hz.The laser fiber is first withdrawn automatically at a rate of 1 mm/s, and then the laser is activated. The proximal portion of the great saphenous vein is treated with laser closure. The mean length of great saphenous vein treated was 17.45 ± 3 cm.The mean pullback time was 160 ± 20 s with an average energy of 4.7 J/s. The distal portion of the great saphenous vein including all varicose tributaries are treated with intravascular laser or removed with a standard ambulatory phlebectomy technique.

The treated leg is then wrapped in gauze to absorb the tumescent fluid and then with a short stretch overlying compression bandage. The patient returns the next day when the bandage is changed to a 30 to 40 mmHg graduated compression stocking. The compression stocking is then worn for 7 days continuously and then while the patient is ambulatory for an additional 7 days.

Patients are evaluated both with duplex ultrasound and clinically at 1 day, 7 days, and 3 weeks postoperatively as well as every 3 months (some patients every 6 months based on their ability to come back for follow-up exams) to determine treatment efficacy. Some authors propose retreating the patient if there is recurrent reflux in the great saphenous vein. We have not found this to be necessary in my patients (Figures 4–6).

Patients were followed for at least 6 months (Table 1). There were no episodes of postoperative pain. Each duplex evaluation showed 100% occlusion without evidence of flow. Of note was that there was no duplex evidence of the great saphenous vein after 5 months postoperatively. Preoperative symptoms resolved in all patients. Ten of 10 biopsies of the treated distal portion of the great saphenous vein (which was accessed

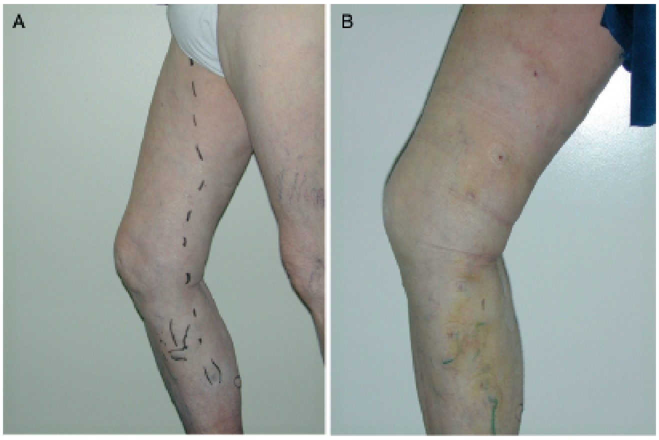

Figure 4. (A) Clinical appearance of varicose vein before treatment. (B) Clinical appearance 1 week after treatment.

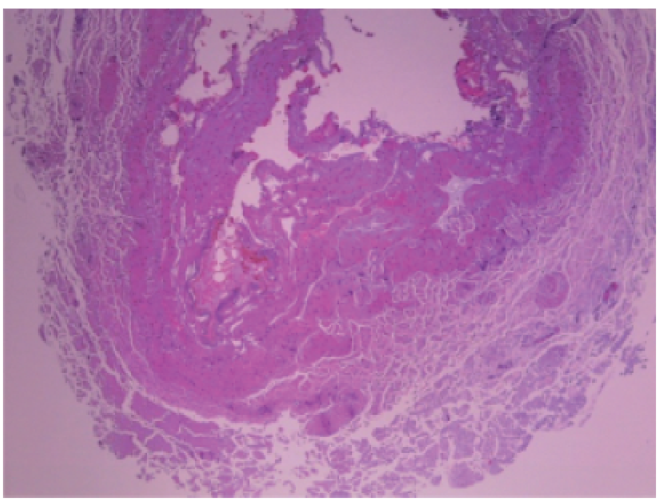

Figure 5. Full-thickness thermal damage affecting the endothelium, smooth muscle, and adventitia 1.3 to 1.5 mm after endolumenal laser treatment with a 1320-nm laser at 5 W with continuous pullback at a rate of 1 mm/s.

with the phlebectomy technique as previously described) showed no great saphenous vein perforations with nearly the entire vein wall thermally coagulated (Figure 2).

Results and Discussion

We have demonstrated that the 1320-nm intravascular laser at 5 W with an automated pull-back rate of 1 mm/s results in 100% occlusion of the great saphenous vein without evidence of recurrence of reflux or flow at 6- to 12-month follow-up. This technique has not been complicated by postoperative pain or ecchymosis as that which occurs with all other lower laser wavelengths used for intravascular treatment of

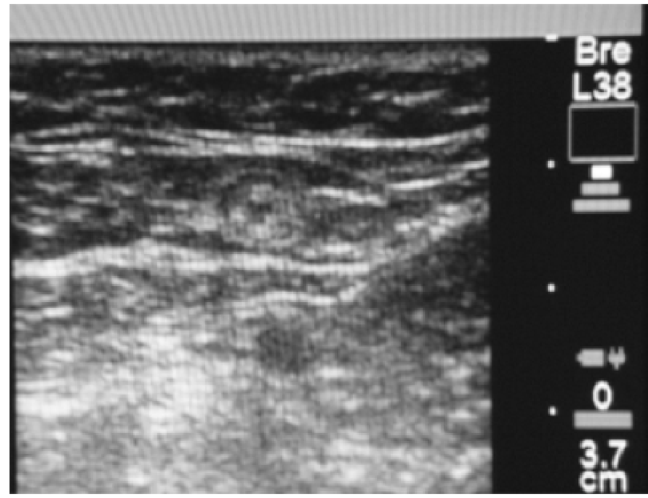

Figure 6. Duplex ultrasound image of the great saphenous vein 4 weeks after treatment, clearly opaque secondary to fibrosis thus indicating complete closure.

the great saphenous vein. We hypothesize that the reason for the safety of this laser wavelength and technique is due to the lack of interaction of the 1320-nm wavelength with hemoglobin.

At 1320 nm, the absorption is limited to water that is present in the endothelial cells. Therefore, it is not necessary to use a laser wavelength that interacts with hemoglobin in red blood cells such as 810, 940, 980, and 1064 nm.With wavelengths bellow 1320 nm, there must be some blood within the vein to act as a conduit for laser-thermal reaction to destroy the endothelium. The variability in the amount of blood within the vein produces steam bubble formation with intravascular lasers below 1320 nm in wavelength. Generation of intravascular steam bubbles leads to pulmonary reactivity seen in some patients as well as patients remarking on a smoky taste during the procedure.

In addition, the present laser technique with a 1320-nm laser uses a water-specific, and a non-vascular-specific wavelength allows the use of a lower laser fluence. This results in a decrease in excessive laser energy. The use of a mechanical pullback device standardizes the technique among patients and among surgeons and further simplifies the procedure.

The results of this study have been confirmed by Weiss et al. (Weiss R, Munavalli G, Beasley K, Weiss M, "1320 nm Endovenous Laser with a 280 Micron Fiber—Equivalent to Phlebectomy?" presented at the 2003 UIP World Congress Chapter Meeting, San Diego, CA, September 2003) who recently reported 100% closure at up to 6-month follow-up in nine patients treated exactly as we have described. There were no episodes of pain, superficial thrombophlebitis, or hematoma.

Summary

A new technique for endovenous occlusion using endoluminal laser offers a less invasive alternative to ligation and stripping as well as a faster and less expensive method to treat varicose saphenous trunks and junctions. Initial clinical experience shows a high degree of success with minimal side effects. A novel motorized pullback system should eliminate the variability in vessel heating between surgeons.

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