

Endovenous Laser Treatment to Promote Venous Occlusion

Eric J. Parente, DVM, Dipl. ACVS^{1*} and Melvin Rosenblatt, MD^{2**}

¹University of Pennsylvania, New Bolton Center, Kennett Square, Pennsylvania 19348

²Memorial Sloan-Kettering Cancer Center, New York, New York 10021

Background and Objectives: Current treatment methods of superficial venous insufficiency (SVI) can be painful or result in incomplete occlusion. The objective of this study was to evaluate a technique for laser endovenous ablation with a newly developed diffuser fiber.

Study Design/Materials and Methods: Six lateral saphenous veins in three goats were used. A specifically designed diffuser laser fiber tip was employed in all trials to deliver a wavelength of 1,064 nm. Each segment was treated with a different energy fluence by changing the power setting of the laser or the withdrawal rate of the fiber. Energy fluence was calculated by dividing the Joules employed for each segment over the internal surface area of the vessel. Segments were evaluated with ultrasound and histologically.

Results: Seventy-five percent of the segments were occluded when an energy fluence of greater than 85 J/cm² was employed. No perforations were observed, but perivascular changes were more common at higher energy fluence.

Conclusions: Endovenous laser occlusion of veins with minimal perivascular effects can be achieved with laser wavelengths of 1,064 nm if an energy fluence of 84.9–224 J/cm² is employed and circumferential effect is achieved. *Lasers Surg. Med.* 33:115–118, 2003.

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Key words: diffuser fiber; radial; varicosity; vein

INTRODUCTION

Superficial venous insufficiency (SVI) of the lower extremity is a very common problem affecting 25% of women and 15% of men [1]. This disease process, which almost always results in the formation of varicose veins, can also cause leg fatigue, heaviness, pain, and skin breakdown [2,3]. Traditional treatment of surgical “stripping” is painful, and has the associated risks of general anesthesia and surgery (paresthesia, bleeding, infection), and requires a prolonged recovery. Encouraging occlusion by heating the vein wall with radio frequency (RF) can be accomplished but incomplete obliteration, paresthesia, and recanalization still present a problem [4,5]. Recently, a new endovenous treatment has been introduced as an alternative to greater saphenous vein (GSV) stripping, and radiofrequency mediated occlusion. This treatment entails delivering laser energy directly into the blood vessel

lumen through a needle puncture site in the distal GSV [6,7]. The device is advanced within the vein to the saphenofemoral junction. Once the device is in position, energy is delivered through the device to obliterate the vein by producing endothelial damage and subsequent fibrosis.

The current laser technique, with a bare tipped fiber (nondiffuser), is faster than RF (i.e., 6–18 cm per min) and does not require the use of anti-coagulants but causes more postoperative discomfort and ecchymosis [8]. The higher morbidity is related to the way energy is delivered with this laser device. The bare tipped fiber directs the laser energy along the axis of the vein directly into the blood or asymmetrically at one side of the vein wall. As a result of this highly concentrated energy, perforations leading to bleeding are common [9].

The goal of this experiment was to evaluate a new device, which can deliver laser energy via a fiber optic diffuser. PhotoMedex’ SLT Venous Diffuser fiber distributes the greatest part of the laser energy radially over a cylindrical surface and has minimal energy directed axially in the blood path. By utilizing the diffusing fiber, there is a reduction of power density and thus a reduction in the potential for thermal perforations. Perforations should be eliminated and so too the post-operative bruising and pain. A secondary goal was to identify the amount of laser energy needed to cause the intended clinical effect.

The goat was chosen as a model since their lateral saphenous vein of the rear limb is similar in diameter (e.g., 5.3 mm) to that of a human’s saphenous vein and even though it is shorter, it is of adequate length to demonstrate the effectiveness of the technique.

This study was performed in accordance with university standards and approved by the University of Pennsylvania, Animal Use and Care Committee, Protocol No. 705101.

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*Correspondence to: Dr. Eric J. Parente, DVM, Dipl. ACVS, University of Pennsylvania, New Bolton Center, 382 West Street Road, Kennett Square, PA 19348. E-mail: ejp@vet.upenn.edu

**Dr. Melvin Rosenblatt’s current address is Connecticut Image Guided Surgery, 30 Commerce Park Drive, Milford, CT 06460.

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MATERIALS AND METHODS

Both lateral saphenous veins of three adult goats (50–75 kg) were treated by the use of endovenous-supplied laser energy (1,064 nm), with a desired result of complete occlusion of the vein. Color Doppler/duplex ultrasound imaging was performed in the standing unsedated animal to document vessel patency and vessel size prior to treatment, and again at 24 hours, 1 week, and 6 weeks after treatment. The goats were euthanized after 6 weeks by an overdose of intravenous barbiturate and the lateral saphenous veins and surrounding soft tissue were harvested for histologic evaluation. A pathologist blinded to the treatment groups determined vessel patency, pathology, and perivenous changes.

Treatments were performed on the goats while under general anesthesia, maintained on isoflurane in oxygen, in lateral recumbency. The hair over the length of both saphenous veins was clipped and the distal aspect of the vein prepared for aseptic surgery. A 21-gauge needle was used to access the vein with ultrasound guidance. A 0.018 guide wire was placed and over this a 5 Fr introducer sheath was placed to allow delivery of the device. The laser fiber with a specially designed diffuser tip (SLT Venous Diffuser Fiber; PhotoMedex, Montgomeryville, PA) was inserted through the sheath and its tip was positioned beyond the sheath into the vein. Confirmation that the sheath and laser fiber were positioned at the proximal treatment site was provided by direct visualization of the aiming beam (633 nm) through the skin and Doppler ultrasound imaging. The direct progress of the treatment was monitored with ultrasound imaging. Blood flow was impeded by the perivenous injection of saline or digital pressure, which compressed the vessel in most, but not all treatments. Butorphanol (0.04 mg/kg) was administered intravenously for analgesia during the first 20 minutes of anesthesia.

The uppermost rear limb was treated first and then the goat was rolled into the opposite recumbency to treat the other rear limb. Multiple treatments were employed in each goat to maximize the information obtained. The treatment sites were 4–6 cm in length for each treatment group with a distance 1–4 cm between treatment sites. This gap was adequate to prevent an effect of occlusion on the more proximal treatments from the distal treatments. The treatment groups were established by varying the power setting of the laser and the rate of withdrawal. The withdrawal was performed manually and the rate maintained by holding a ruler adjacent to the vessel and monitoring withdrawal rate with a stopwatch.

At the conclusion of the treatments, the limbs were placed in a light non-compression bandage that was maintained for 24 hours and then removed. The goats were monitored daily for limb swelling, discomfort, bruising, or signs of lameness for the first week and then weekly for the duration of the study. After 6 days, the goats were placed in a small paddock until the conclusion of the study.

A calculation of the internal surface area of the vessel was determined by using the formula $2\pi rL$, where L equals treatment site length. With a known surface area, rate of

withdrawal and the power applied, energy fluence for each treatment was determined in J/cm^2 .

RESULTS

A total of nine treatments were successfully performed on the three goats (6 veins). No goats experienced any noticeable pain, lameness, or bruising at any time during the study. There were no technical difficulties in the procedure except for two diffuser tip separations that occurred at 10 W. Despite this, no infection or other adverse histologic changes were found at these sites.

Ultrasound findings of blood flow and vessel size at 6 weeks showed a substantial decrease in vein size in most treatments and no recanalized vessels after 6 weeks (Table 1).

By calculating energy fluence for each treatment, six of eight vessels treated with an energy fluence exceeding $85 J/cm^2$ (Table 1) were completely occluded. Histology correlated well with the ultrasonographic findings except in treatment trial 7 in which a discrepancy is suspected between the treatment area position and the site of histologic sampling for those treatments. No vessels were perforated and there were minimal perivascular changes below $224 J/cm^2$. Endothelial and vein wall damage with subsequent fibrosis was attained if the fluence rate was above $85 J/cm^2$. Complete circumferential damage to the vessel wall was necessary for occlusion, even if fluence levels were above $84.9 J/cm^2$. In trials 3 and 8, it was suspected that inadequate digital pressure was applied during the firing of the laser, resulting in less than complete circumferential contact with the laser diffuser fiber.

DISCUSSION

Laser and RF ablation are two minimally invasive techniques for promoting occlusion of varicose veins. RF ablation of the GSV involves the use of a specialized bipolar radiofrequency catheter. The device is then slowly retracted, at a rate of 2–3 cm per minute, to occlude the vein. This technique has proven to be far less traumatic than surgical GSV stripping and was found to be effective. However, recanalization did occur in 10% of treated limbs at 12 months [4]. Reported complications included transient paresthesias, thermal skin injuries, thrombophlebitis, and pulmonary emboli [4,5]. To limit these complications leg compression with an Esmarch dressing and a head down position is recommended to exsanguinate the vein of blood [5].

Endovenous laser therapy is another minimally invasive technique for the ablation of the GSV [6,7]. This technique utilizes a bare tipped laser fiber to deliver thermal energy to occlude the vein. Similar to the RF technique, the laser tip is placed at the saphenofemoral junction and retracted to ablate the entire vein. The retraction speed for this device is much faster than the RF device at 6 cm per minute with reported speeds up to 18 cm per minute [6,7]. Recanalization with this technique has also been reported but is less than that reported with RF at 4% [7]. Unfortunately, post treatment perivenous bleeding resulting

TABLE 1. Nine Different Treatments of Laser Energy Employed on the Saphenous Veins From Altering Withdrawal Rate and Power Relative to the Internal Surface Area of the Vessel

Trial no.	Power (W)	Withdrawal rate (cm per minute)	Original vein diam. (mm)	Final vein diam. (mm)	Decrease in vein diam. (%)	Fluence (J/cm ²)	Blood flow (Y/N)	Histology
1	8	8	2.7	2.9	-7	70.7	Y	No abnormalities
2	8	8	2.2	1.6	27	86.8	N	360° Obliteration, fully occluded
3	10	4	5.5	1.6	71	86.8	N	360° Obliteration, fully occluded, perivascular steatitis
4	8	6	2.9	0	100	87.8	N	360° Obliteration, fully occluded, perivascular granuloma
5	8	4	3.1	1.9	39	123.2	Y	Incomplete occlusion, 180° fibrosis
6	10	2	7.5	4.2	44	127.3	Y	Incomplete occlusion, 180° fibrosis, perivascular granuloma
7	8	2	3.4	1.1	68	224.7	N	360° Obliteration, full occlusion, severe perivascular fibrosis, steatitis
8	10	4	2.0	1.8	10	238.7	Y	360° Obliteration, full occlusion, severe perivascular fibrosis and char
9	10	2	1.6	1.2	25	596.8	N	360° Obliteration, full occlusion, near patent section

Changes in vein diameter, as determined by ultrasound, and histologic findings 6 weeks after treatment—sorted by increasing energy fluence. Blood flow: Y, yes; N, no.

in echymosis and transient paresthesias occurs commonly [8]. The presumed etiology of this phenomenon is the disruption of the vein wall by the high thermal energy released at the laser fiber tip [9,10]. Other possible explanations for vessel wall disruption relate to the forward direction of the laser energy beam into the lumen of the vessel. With the laser energy primarily directed into the blood pool, boiling occurs resulting in rapid expansion and vessel disruption [10]. Furthermore, the possibility of not uniformly withdrawing the fiber may result in uneven expenditure of energy [11]. Thus, how the laser energy is delivered may play a major role in the clinical outcome of the procedure.

Laser energy delivered endovenously with a diffuser tip may provide several advantages over the previously described bare tipped fiber technique. The diffuser tip directs over 90% of the laser energy radially into the vessel wall. This property helps to deliver energy to the vein wall where it will be effective and reduces the likelihood of heating the blood in the vessel. Additionally, not directing the energy forward from the laser fiber tip, minimizes the possibility that injury could occur focally through the vein wall through perforations into perivenous structures. This is particularly important at the saphenofemoral junction where injury could occur to the common femoral vein, even though the laser fiber is positioned in the proximal GSV. Furthermore, a radial dispersal of energy helps reduce the trauma that could be created by not uniformly withdrawing the fiber.

In this study, our goal was to assess the effectiveness of the laser fiber diffuser tip, determine the power flux needed to occlude the vessel and assess, histologically and clinically, the treated vessel for perforation. Of the nine segments of treated vein with the diffuser tip, only one segment had no histologic abnormalities. This finding seems to be related to the power fluence generated by the laser. Most segments that were treated with power fluence of 86 J/cm² and greater occluded. Those that were not occluded had less than a 360 degree effect on the internal vessel wall. This further demonstrates the importance of uniform energy dispersal to reach the appropriate temperatures to achieve occlusion. Intuitively, more energy is needed to ablate larger diameter vessels but without appropriate dispersal of energy temperatures can be created within the vessel that are much higher than necessary [9]. There is no previously available data that relates the power flux to the pull back rate or to the vessel diameter. The data obtained in this study does just that and a calculation of pull back rates for various size vessels can be calculated as was done here. Although no echymosis was observed clinically in any of the animals treated, severe perivascular reactive changes were noted in vessel segments where power fluence was above 224 J/cm².

In conclusion, the laser fiber diffuser tip is effective in causing venous occlusion and therefore could be used as a tool to treat SVI. The added advantage of a radial disbursement of energy into the vein wall suggests that this device can provide effective treatment while minimizing the risk of vessel perforation and the subsequent complications.

This animal model provides good evidence to further investigate the use of this fiber tip with other in vitro and clinical studies.

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