



Praveen K. Malhotra, M.D.

Manu B. Aggarwal, M.D.

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INFORMED CONSENT

Patient Name: _____

Date: _____

INTRODUCTION:

Lasers have been used for numerous medical applications throughout the body. A newer technique utilizing laser energy delivered endovenously (directly inside the vein) has been developed to treat the incompetent saphenous vein resulting in varicose veins.

Most patients, unless they are known to be allergic to Xylocaine, will be given a prescription for topical application of Emla Cream to numb the skin prior to the procedure. Most patients will also be prescribed an oral anxiolytic and anti-inflammatory medications prior to the procedure.

Treatment (also called *ablation*) is performed under local anesthesia in the doctor's office or in the hospital outpatient surgery center. Local tumescent anesthesia (Lidocaine) is injected around the incompetent vein once the laser fiber is in place to minimize discomfort. Since the skin is already numb because of topical application of Emla cream, the injections are minimally uncomfortable. Rarely, people can have an allergy to Lidocaine. During endovascular laser treatment, a diode laser will be used to deliver the laser energy via a small laser fiber into the incompetent vein.

Some patients may require microphlebectomy with or without the laser procedure. Microphlebectomy is performed to remove unsightly and painful bulging varicose veins. After numbing the skin around the varicose vein and making a small 1-2mm nick in the skin, a small vein hook is inserted through the incision. Following the removal of a small segment of the vein, a steri-strip is used to close the skin.

Foam echosclerotherapy is a method used for eliminating perforator veins that have reflux. This is sometimes used in conjunction with microphlebectomy or laser ablation procedures. Foam echosclerotherapy is performed by forcibly mixing a solution known as Sotradecol (FDA approved) with air. This procedure turns the liquid into foam that has the consistency of shaving foam. This is then injected into the veins. This causes an irritation to the inner lining of the vein resulting in closure of the vein. A small- gauged needle is used to perform the injections.

The total procedure time is between 60-90 minutes. You will walk out of the procedure room. There is minimal pain / discomfort during the procedure and a relatively short recovery period after the procedures.

PROCEDURE DESCRIPTION:

Prior to arrival at the office on the day of your procedure, you will have been advised (proper prescriptions) to ingest oral anxiolytic and how to apply the Emla cream on the leg on which the procedure is to be performed. Ultrasound will be performed on your leg for the purpose of identifying the location of the vein to be treated. A special pen for treatment purposes will mark this area and

the areas of microphlebectomy. Photographs of the treatment area may be taken for advertisement, marketing or other material to show before and after treatment success, if you so consent.

During your procedure, your leg will be prepped with Exidine or Betadine (to cleanse the skin of bacteria contamination). Next, the treatment area will be anesthetized with Lidocaine. A sterile laser fiber will be inserted into the vein and positioned appropriately under ultrasound guidance. You will be given special goggles to protect your eyes against accidental laser light exposure. By signing below, you understand that once the laser fiber is positioned and anesthetic is injected around the vein, that the physician will activate the laser and pull all the components down the inside of the vein, closing the vein with heat energy.

I understand that the reason for this procedure is to correct my venous insufficiency caused by the reflux, or backward flow, of blood down my leg. _____ initial

Microphlebectomy, as described above, may be performed in the same sitting or at a separate scheduled time. Sometimes sutures may be necessary. At the end of the procedure, a compression bandage will be applied and must be worn for 48 hours after the procedure. You will return to our office for a one or two week follow-up including an ultrasound examination of the treated vein.

RISKS AND DISCOMFORTS:

If you undergo endovascular laser treatment for varicose veins, your symptoms of varicose veins will most likely improve, but occasionally may remain the same or rarely worsen.

The risks pertaining to the performance of the procedures have been thoroughly explained to me, and include but are not limited to: infection, bleeding, scarring, allergic reaction to medications, nerve injury (paresthesia), clot in the deep vein (DVT-Deep Venous Thrombosis) with pulmonary embolus (clot in lungs), thermal injury (burn), pigmentation changes (lighter or darker) on the skin over the vein area, perforation of the vein, breakage of the laser fiber, perforation of the vein, breakage of the laser fiber, neo vascularization (growth of new veins) and bleeding. Problems and side effects that are not known at this time could occur. _____ initial

NOTE: These are all uncommon, and risks are relative to your disease and risk factors.

POTENTIAL COMPLICATIONS OF NOT UNDERGOING TREATMENT:

The potential complications of not undergoing treatment are most often limited to merely a worsening of the condition (i.e. an increase in the number of veins, or enlargement in the existing veins, and delayed or poor ulcer healing). In cases of large varicose veins, spontaneous superficial phlebitis/thrombophlebitis or bleeding may occur. Patients with varicose veins associated with underlying venous insufficiency may develop ankle swelling and/or skin changes (eczema, hyperpigmentation, ulceration).

ALTERNATIVE TREATMENTS:

Since varicose veins and spider veins are not life threatening, treatment is not mandatory. Some patients may get adequate symptomatic relief by wearing graduated compression stockings.

I understand there are alternatives to this procedure, and they have been explained to me. These procedures include: Surgical Stripping and Ligation, radiofrequency ablation (VNUS) and Ultrasound Guided Sclerotherapy. Despite these alternatives, I consent to the Endovenous Laser procedure understanding that there are risks with any surgical procedure. _____ initial

POTENTIAL BENEFITS:

The potential benefits from the procedure are a reduction in the size or closure of the treated varicose veins and improvement in varicose vein-related symptoms. There is no guarantee that you will receive any medical benefit as a result of endovenous laser treatment. It is also possible that your condition may remain the same or worsen. Microphlebectomy minimizes the risks of intra-arterial injection, skin necrosis, and residual hyperpigmentation while also producing great cosmetic results.

It has been explained that though the procedure is about 95-98% effective, no guarantees have been made to me. It has been explained that in 2-5 % of the cases the treated vein may re-open (recanalize) and may need to have the endovenous laser procedure repeated. _____ initial

It has also been explained that based on my exam and ultrasound, as well as symptoms and history, I have a chronic progressive venous condition and that valves in my other veins may become incompetent in my legs as time goes on which may need additional treatment. _____ initial

By signing below, I acknowledge that I have read and understand the above, and I have been adequately informed of the nature, intended purpose, significant risks and consequences of endovenous laser treatment (as well as the alternative treatment methods). I acknowledge that I have been given ample opportunity to ask questions about my condition and options.

*I hereby authorize consent to the following treatments performed by: **Praveen K. Malhotra, MD and/or Manu B. Aggarwal, MD**, and their associates and assistants, to perform the following procedures:*

RIGHT LEG _____		LEFT LEG _____	
<input type="checkbox"/>	Endovenous laser greater saphenous vein	<input type="checkbox"/>	Endovenous laser greater saphenous vein
<input type="checkbox"/>	Endovenous laser of small saphenous vein	<input type="checkbox"/>	Endovenous laser of small saphenous vein
<input type="checkbox"/>	Endovenous laser of the accessory vein	<input type="checkbox"/>	Endovenous laser of the accessory vein
<input type="checkbox"/>	Endovenous laser of additional accessory vein	<input type="checkbox"/>	Endovenous laser of additional accessory vein
<input type="checkbox"/>	Microphlebectomy	<input type="checkbox"/>	Microphlebectomy
<input type="checkbox"/>	Echosclerotherapy (Ultrasound guided sclerotherapy) of incompetent perforator veins or varicose veins	<input type="checkbox"/>	Echosclerotherapy (Ultrasound guided sclerotherapy) of incompetent perforator veins or varicose veins

I also authorize the taking and usage of photographs for promotional, marketing and advertising purposes.

Patient's Signature _____ Date _____

Witness _____ Date _____

I have discussed the nature and purpose of endovenous laser treatment and the associated risks, consequences and available alternatives with the person signing above, and I am satisfied that she/he understands them.

_____, M.D Date _____
(Signature of Physician Providing Explanation)



Praveen K. Malhotra, M.D.
Manu B. Aggarwal, M.D.
419-227-4472 or 1-866-472-4472

Post Operative Instructions

Patient Name: _____ **Date:** _____

Type of Procedure:

RIGHT LEG _____

LEFT LEG _____

Endovenous laser greater saphenous vein	Endovenous laser greater saphenous vein
Endovenous laser of small saphenous vein	Endovenous laser of small saphenous vein
Endovenous laser of the accessory vein	Endovenous laser of the accessory vein
Endovenous laser of additional accessory vein	Endovenous laser of additional accessory vein
Microphlebectomy	Microphlebectomy
Echosclerotherapy (Ultrasound guided sclerotherapy) of incompetent perforator veins or varicose veins	Echosclerotherapy (Ultrasound guided sclerotherapy) of incompetent perforator veins or varicose veins

During the first 48 hours:

1. For the first 48 hours following the procedure, it is important that you remain active during your waking hours. You should walk 15 to 20 minutes each hour while you are awake. When you are inactive, keep your legs elevated and wear the compression dressing. Should you feel the bandage is too tight and is uncomfortable, you may loosen it slightly. It is recommended that you apply ice to the treated area for 20 minutes every 2-3 hours while awake.
2. Take anti-inflammatory medications for 7 days as ordered, even if you currently do not feel bad. Your pain will be better managed by taking the medications before your pain is uncomfortable.
3. If antibiotics are prescribed be sure to complete the treatment cycle. Antibiotics are not effective if the full course is not completed.

After the first 48 hours:

4. Remove dressing. You may shower at this time. If steri-strips have not fallen off in 7-10 days, then gently remove them.
5. Begin wearing your compression stocking daily from morning through the evening for 14 days. Compression stockings are to be worn during your waking hours only. You DO NOT need to wear the stockings at night (during sleeping hours).
6. Normal activity may be resumed. Research has shown that patients who are more active post procedure heal more quickly and have less discomfort. Very strenuous exercise can cause the vein to reopen, so please avoid vigorous activity such as intense gym workouts until at least 10-14 days post procedure.
7. Do not swim or use a hot tub or bath for at least 2 weeks following the procedure.
8. Recovery from your procedure is usually trouble-free but every individual is different. You may have a lot of bruising and may be tender to the touch for a few days. You may also have a warm sensation and some itching as your body works to re-absorb the treated vein. You may also feel a tightening or

pulling sensation along the track of the treated vein. You may also have hard or lumpy areas as the vein scars down. Some loss of sensation over the shin & ankle is to be expected. Ultimately, the vein will be re-absorbed by your body and blood will be re-routed to your deep veins. Discomfort can generally be managed with over-the-counter analgesics like Ibuprofen or Aleve (follow recommended dosage on bottle). Please avoid aspirin-based products unless otherwise recommended or prescribed.

9. It is recommended that you do not fly for at least 7 days post procedure. If an issue arises where you feel the need to fly, please contact the office and we will inform the doctor. Each patient is different and may need instructions before flying.
10. **If you experience any sudden onset of pain, swelling, fever or a large amount of bleeding please contact our Lima office immediately at 419-227-4472 or 1-866-472-4472. If it is after office hours, first call Dr. Malhotra's cell phone (419-236-1803) or Dr Aggarwal's cell phone (567-712-0408). If they cannot be reached, call Rick (419-303-7462) or Robin (419-230-7423).**
11. It is important that you keep your scheduled post-operative appointment with us.

These post-operative instructions were reviewed with me prior to discharge, and I understand the expectations of my physician. I understand I must call the office if any unexpected side-effects arise.

Patient Signature: _____ Date: _____

Witness: _____ Date: _____

POST OPERATIVE APPOINTMENT

DATE : _____ **TIME** _____ **a.m. / p.m.**

OFFICE LOCATION: LIMA - FINDLAY - CELINA