

ENDOASCULAR LASER VENOUS SYSTEM- Informed Consent Supplement

Introduction

Lasers have been used for numerous medical applications throughout the body. Recently, a novel technique utilizing laser energy delivered (directly inside the vein) has been developed to treat varicose veins. A 980 nm diode laser will be used to deliver the laser energy via a small laser fiber. Endovenous laser treatment is performed under local anesthesia in the doctor's office or in the hospital outpatient surgery center. There is little to no scarring and a relatively short recovery period after the procedure.

Procedure Description

At your procedural visit, an ultrasound will be performed on your legs for the purpose of identifying the location of the greater saphenous vein. A special pen for treatment purposes will mark this area. Photographs of the treatment area will be taken.

At the beginning of the next procedure, the correct leg will be prepped with 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 under ultrasound guidance. You will be given special goggles to protect your eyes against accidental laser light exposure. Selectively, laser energy will be delivered to the target vein. At the end of the procedure, a compression stocking will be applied and must be worn for at least one month.

You will return to the office within in one week for an ultrasound examination of the treated vein. Occasionally repeat laser treatment may be needed.

Risks and Discomforts

If you undergo endovascular laser treatment for varicose veins, your symptoms of varicose veins may improve, remain the same, or worsen.

The potential side effects are deep venous thrombophlebitis (clot in the deep vein), which could lead to pulmonary embolus (clot in the lungs), altered skin sensation, thermal injury (burn) to the overlying skin or intervening tissue, perforation of the vein, hemorrhage, breakage of the laser fiber, superficial phlebitis (inflammation of the vein), hyperpigmentation (darkening of the overlying skin), or neovascularization (growth of the new veins). These side effects include a risk of _____.

Problems and side effects that are not known at this time could occur.

For most people, needle punctures into the vein do not cause any serious problems. However, they may cause dizziness, minimal bleeding, bruising, discomfort, pain, and rarely infection. Local anesthesia will be used to minimize discomfort. Rarely, people can have an allergy to Lidocaine.

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. In cases of large varicose veins, spontaneous superficial phlebitis 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 get adequate symptomatic relief by wearing graduated compression stockings. Alternative treatments for varicose veins include surgical ligation and stripping, ambulatory phlebectomy, ultrasound-guided sclerotherapy, bipolar radiofrequency (heat setting), or a combination of these treatments.

Potential Benefits

The potential benefits of the procedure are 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.

Patient Signature

Date

Witness

Date

Physician

Date