ADVANCED VEIN CENTER

Sclerotherapy/Laser of Spider Veins: Information and Consent Form

There have been many methods tried to remove unsightly "broken" or enlarged veins on the legs. Sclerotherapy is still the “gold standard” although we have several lasers that we use with or in place of sclerotherapy depending on the clinical situation.

With sclerotherapy, a very tiny needle is inserted into the blood vessel and a small amount of a sclerosing agent is gently injected. This may sting for a few seconds. The injection "flushes" out the red blood cells temporarily, leading to an inflammatory reaction. This reaction causes "sclerosis,” or the formation of fibrous tissue within the vessel, leading to the gradual disappearance of the vessel. This fading can take from a few weeks to a few months. It is difficult to predict the number of treatments needed to clear or improve the condition. A vein may need to be injected repeatedly over a period of several months in order to resolve. Improvement is usually seen over a period of months, not weeks. In each treatment session, multiple areas can be treated, thus reducing the total number of sessions required. Compression stockings must be worn daily (not in bed) for 1 week.

The total number of treatment sessions needed depends on the amount and severity of the veins (the average is three to five), with severe cases requiring as many as ten or more. Our goal is 70% improvement in 3 sessions. There can be no guarantee, however, that it will be effective in every case. Less than 10% of patients undergoing sclerotherapy will have poor results, in which the veins do not improve despite multiple injections. It is extremely rare for anyone's condition to worsen because of treatment.

It is important to realize that sclerotherapy does not prevent development of new spider veins or varicose veins over the years. Many people will require treatments from time to time to keep their legs clear. This is primarily a hereditary condition. Standing occupations, pregnancy, and hormones may increase this tendency.

There is only one FDA approved sclerosant in the U.S. (Sotradecol liquid). Making it into a foam is therefore "off label.” Saline is another sclerosant used but is also "off label" when used to treat spiders. Worldwide, polidocanol is the most popular product because in many studies has been shown to be one of the safest, most effective agents available with the fewest side effects. In the whole world there has been 1 reported death after literally millions of injections. It is in the process of FDA approval in the US. For these reasons we prefer to use it in a foam consistency.

Some of the possible risks with sclerotherapy or the laser include:
1. The appearances of the veins may not improve. However, over 90% of patients see improvement.
2. Brown spots may appear that look like bruises or follow the path of the vein. These brown areas take several weeks to months to go away. It is rare for any discoloration to be permanent. Patients with naturally darker skin are more likely to experience this.
3. Blistering, redness, itching and irritation may develop as reaction to the adhesive tape used for compression.

4. Blistering, infection, ulceration, and scarring may develop if someone is exceptionally sensitive to the tiny amount of solution that may leak out during the injection. This occurs in less than 1% of patients. An allergic reaction to some of the solutions is also a rare possibility.
5. Tenderness, bruising, or a firmness (especially along the larger vessels) in the treated area may last for varying periods of time. This can be minimized by the use of support hose after the treatment.
6. Some people (less than 10%) may develop a "matt", or pink blush of the skin, which comes from a temporary enlargement of the tiny capillaries. This is rarely permanent, and can be treated.
7. Sometimes blood may accumulate in the larger veins treated by sclerotherapy. This "trapped" blood may be easily treated by the physician to decrease any discomfort. Strict use of support hose minimizes this possibility.
8. Rarely, this accumulation of blood may form a clot. Although this is usually trapped in the treated vein, an extremely rare possibility is the extension of this clot into a deeper vessel causing phlebitis. The risk of this occurring is much less than 1%.
9. People with significant circulatory problems, uncontrolled diabetes or pregnant women should not undergo this procedure.
10. Stroke or death as mentioned earlier have been reported but worldwide this is an incredibly rare complication.

CONSENT

By signing this form, I attest that I have read and understand the procedure and its risks, and that it has been explained to my satisfaction. I understand the above details including possible complications and risks of the procedure. I also agree to the use of an off label or non-FDA approved sclerosant. I have had the opportunity to ask questions about this procedure and alternatives including no treatment and my questions have been answered to my satisfaction. I agree to proceed with the treatment today.

Photographs: I consent to the taking of photographs while I am undergoing treatment and the use of those photos for scientific, educational or research purposes. I understand that I will never be identified personally with the photos.

_____ _____

Signature Date

_____

Print Name

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