

# May technology reduce incidents on injection sclerotherapy?

## Background and objective

Nowadays, injection sclerotherapy is the most common treatment for leg veins, such as reticular veins telangiectasias with feeder veins, and also as an alternative to phlebectomies.

Injection sclerotherapy by itself has been associated with a number of unpleasant conditions and adverse effects, among multiple needle punctures, hyperpigmentation and ulcerations, as well as unsatisfactory outcomes.

The expectation to diminish unsatisfactory outcomes encouraged the use of stronger sclerosants (such as STS or Polidocanol). However the use of such substances may lead to a range of complications, from minor (like local urticaria) to severe (brain ischemia and even death).

Most of these veins are functionally asymptomatic, but their aesthetical appearance leads patients to seek treatment. The sole aesthetical concern is tied to the maximum levels of expectation by patients, as well as their complete disregard to risks, thus demanding informed consents and, in our opinion the use of a safe therapeutic option.

Another way to perform sclerotherapy is by foam injection. Inflammation by foam sclerosant shows a tendency to be broader and more intense than other agents, consequently more adverse effects can be verified, including pain, inflammation of the skin and subcutaneous tissue, as well as residual pigmentation. The list of complications by foam sclerotherapy can extend to deep venous thrombosis, pulmonary embolism and the feared paradoxical embolism, going through visual disturbances, peripheral embolism and brain strokes.

The several complications (mild or severe) associated with injection sclerotherapy led the FDA to recently order Bioniche, the manufacturer of Sotradecol, to communicate phlebologists and patients that "at least 6 deaths have been reported with the use of Sotradecol".

Since the 70's, laser is used to treat veins in lower limbs, but the first thirty years of vein treatment using laser did not show satisfactory results. Skin burns, hypo and hyper-pigmentations were common.

After 2000, new 1064nm laser parameters improved vein selective photothermolysis. Since then, new devices have been developed and the ability to treat veins with laser became wider. At this time, skin burns were rarely observed consequently to a more selective laser action in veins/blood.

For the past 12 years our group has been studying the synergy of intense pulsed light and injection sclerotherapy with 75% dextrose (D75), and more recently, 1064nm laser and D75. It is an allergy-free method option. The association of injection and laser sclerotherapy (thermal sclerotherapy) to treat leg veins embodies a more recent and technological method to perform a very safe treatment.

Yet, some may argue the results of D75 sclerotherapy, combined to laser or not, may be frustrating by times to doctors and patients. It is only just argument to stress that the reason is the lack of careful diagnosis.

Poor visualization of the underlying blood vessels poses as one of the limitations during laser and injection sclerotherapy. Although varicose veins and telangiectasias are clearly visible to the naked eye, feeder veins are often not. It is hypothesized that the inefficiency of the treatment modalities in the past was due to invisible feeder vein(s), rather than any inherent weakness of the laser/sclerotherapy technique. Varicose veins and telangiectasias (spider veins) are generally nourished by a single (or just a few) feeder veins. Only when these are identified and closed during the procedure, one can expect a successful therapy with permanent results.

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Figure 1: Vein Viewer™.

**Table 1: Summary of adverse effects of a treating group with STS and POL**

Adverse effect	STS	POL	Total
Ecchymosis	70%	58%	64%
Hyperpigmentation	64%	53%	59%
Vein thrombosis 46%	42%	44%	
Local urticaria	36%	23%	30%
Telangiectatic matting	11%	7%	9.2%
Skin necrosis	6.6%	0%	3.5%
Allergic reaction	0%	1%	0.6%

From Goldman MP. Treatment of varicose leg veins. *Dermatol Surg* 28:1, 2002

Subcutaneous veins that are invisible to the naked eye can easily be made discernible using the VeinViewer™ (V-V), which projects an enhanced image of the subcutaneous vein net onto the skin (Figure 1).

The objective is to demonstrate rates of incidents of 1064nm laser and injection sclerotherapy with D75 treating lower limbs veins.

## Patients and method

### Patients

This study was conducted between July 2005 and December 2005 in our clinic.

Patients with telangiectasias and feeder vein(s) were selected to start treatment. Exclusion criteria were:

- Ongoing diseases, treated or not;
- Previous surgery for varicose veins;
- Saphenous incompetence;
- Impossibility of follow-up (just one session without return);
- Loss of contact.

### Imaging System

The V-V operates by illuminating the subject's skin with near infrared (NIR) light. This NIR light penetrates skin and subcutaneous fat effectively because of the low absorption of these tissues in the NIR-wavelength range. NIR light is absorbed or scattered in the forward direction by blood, whereas it is scattered in all directions in skin and subcutaneous fat. Hence, blood reproduces as dark, whereas

**Table 2. Complications in patients treated with sclerosing foam**

Pigmentation
Varicophlebitis
Transient confusional status
Transient visual disturbances
Partial popliteal DVT
Skin necrosis
Malaise
Lymphedema worsening

Adapted from Frullini and Cavezzi. Sclerosing foam for varicose veins and telangiectases. *Derm Surg* 28:1, 2002

skin and fat appear lighter. The image reflected back from the subject is detected with a video camera. An IR filter prevents any visible light from reaching the video camera. The resulting NIR image is processed by a computer and then projected back onto the subject's skin with a projector using green light.

### Laser System

The Nd:YAG 1064nm laser module (Harmony™, Alma Lasers Ltd - Caesarea, Israel) allows the use different spot sizes (6 and 2mm), long (40, 60ms) and short (10ms) pulse durations, and fluence of up to 150J/cm<sup>2</sup> with 6mm spot size and up to 450J/cm<sup>2</sup> when using the 2mm spot size, respectively.

### Cooling System

The Cryo6™ cold air device (Zimmer Elektromedizin™ - Ulm, Germany) is intended to minimize thermal injury during laser and dermatological procedures, as well as pain. It was used to relieve pain during injections and laser shots. The Cryo6 cold air is directed upon the region of interest via a plastic sterile tip connected to a flexible hose.

### Clinical Protocol

Initially, patients were treated with laser guided by the V-V. The laser session comprehended 100 to 300 shots. Right after the laser session, the V-V showed where the laser had more effect and where the vein was still filled of blood (coagulated or not) or partially open. On such segments, D75 sclerotherapy was done, also guided by the V-V. Both sclerotherapy techniques were applied with pre, parallel and post air-cooling. Laser was applied with the 6mm spot size, 40ms pulse-width and 130J/cm<sup>2</sup> fluence (energy). If the patient was comfortable with the laser shots, fluence

**Table 3. Summary of adverse effects of a treating group with CLaCS**

Adverse effect	CLaCS
Ecchymosis	30%
Hyperpigmentation	28%
Vein thrombosis	14%
Local urticaria	0%
Telangiectatic matting	5%
Skin necrosis	0%
Allergic reaction	0%

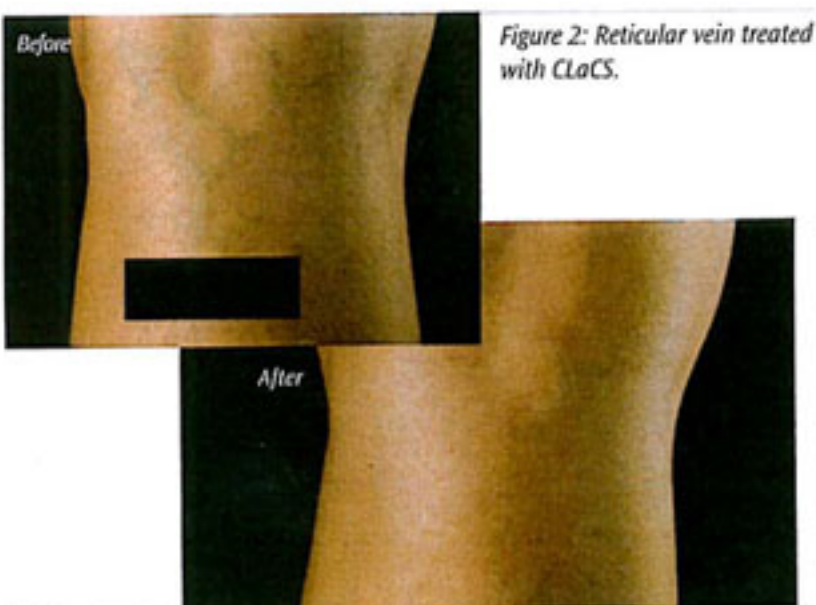
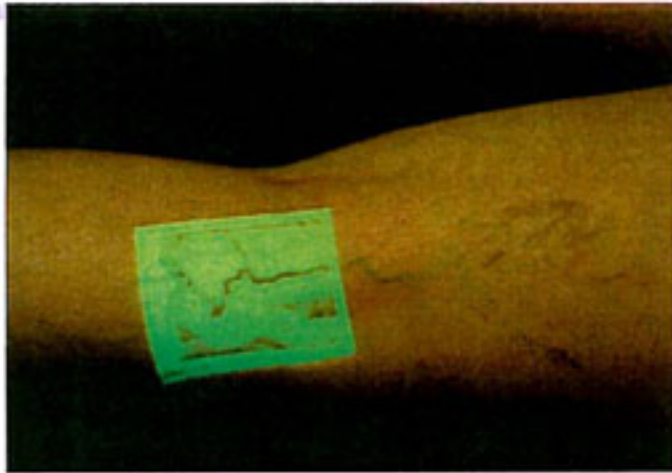
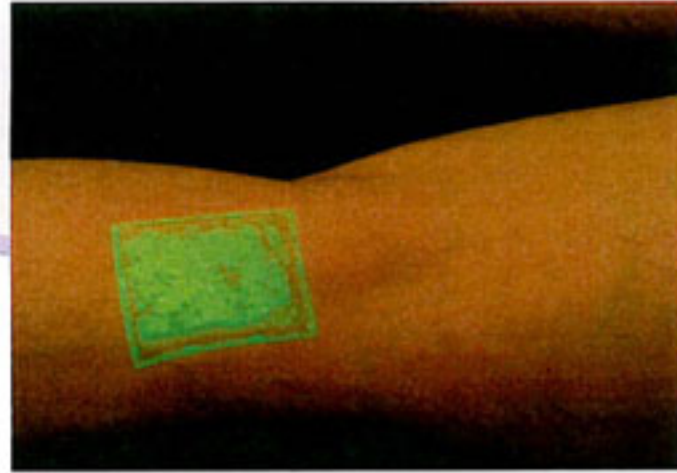


Figure 2: Reticular vein treated with CLaCS.



Reticular vein treated with CLaCS showed by VeinViewer™.



was increased up to 150j/cm<sup>2</sup>, in 10j/cm<sup>2</sup> steps. For feeder veins, 60ms pulse duration was selected. Fan speed was set between 3-6 (it can be set between 1-6). If the skin started to freeze, the fan speed was lowered. Injection sclerotherapy was done with 3ml syringes and 27<sup>1</sup>/<sub>2</sub> needles. We named this combination CLaCS (Cryo-LASER & Cryo-Sclerotherapy).

The suggested interval between sessions was 2 weeks. The cited D75 (one of the most common in Brazil) is just the same as the intravenous solutions commonly used in hospitals (5% and 25%), but in a higher concentration.

#### Photography And Outcome Analysis

A Tripod mounted Nikon D70 with 28-70mm lens was used. The pictures were acquired in 6Megapixel RAW files, and then converted to JPEG set to "Best quality" (lossless compression). Results were analyzed by comparing before and after photos, mainly considering the subject's opinion on the outcome. Response to treatment was rated on:

- 1. Total or partial improvement with patient satisfaction (Group 1);
- 2. Partial or no improvement without patient satisfaction (Group 2).

Adverse effects could be reported by the patient along the whole follow-up period.

#### Statistical analysis

Data are presented as mean values and results classification in each group are cited as percentages.

#### Results

A total of 466 patients visited the clinic and 191 were selected to start CLaCS treatment during the period of the study. Exclusion criteria left a total of 140 patients for analysis.

Mean age of the patients was 37 years (16 to 72), with prevalence of women (98%).

No allergic reactions, systemic reactions, skin burns, infection or crustings were observed. Neither was there frostbite from cold air. Hematomas or ecchymosis were observed in 30% of the cases, and venous clots in 14% of them. The summary of adverse effects is demonstrated in Table 3.

In 121 patients (86%), partial or total lesion improvement was obtained, with satisfactory cosmetic results.

#### Discussion

Aesthetical treatments require safe techniques. Because patients are generally healthy and these telangiectasias and

veins have but aesthetical concerns, no harm is tolerated during the treatment. There are several techniques to treat these veins but none of them are free of adverse effects. In fact, some complications are so severe that some techniques are almost prohibitive when dealing with aesthetical problems.

Nowadays, lawsuits claiming medical malpractice are increasing in number and figures. Looking for safer techniques supported by technology is mandatory as a way to diminish complications during treatments. Hopefully, in time, insurance companies will eventually understand these concerns and recalculate fees.

One important advantage of the D75 is the fact that it is allergy-free. Pointed as a limitation, many practitioners consider it a medium-power sclerosing agent.

Our group have been using CLaCS since 1999 (Vasculight DL) with good results (Figure 2). It has already been demonstrated in the ALMS Annual Conference in 2004. We observed after more than 1 million shots its safety and effective. The method has the smallest incidence of complications, all of those mild.

It is well established that lower extremity telangiectasias can be effectively treated with either injection sclerotherapy or 1064nm long pulsed Nd:YAG laser. Injection sclerotherapy may provide an earlier clinical response and be more cost effective, and at the same time laser treatment can bring good results, as it can also be used in patients with telangiectatic matting, needle phobia, or sclerosant allergy.

Injection sclerotherapy is still seen as the first therapeutic option for leg telangiectasias. But laser devices are getting cheaper, more selective to the hemoglobin. Nevertheless, laser treatment failure was one of the reasons that made practitioners lose confidence in it. The presence of feeder veins explains part of the weak outcomes.

Up until 2005, the physician's experience was the best tool for finding and treating feeder veins, regardless the choice of technique. Failure to treat one of the feeder veins in a compound telangiectasia will imply poor results.

During phlebectomy, feeder veins can be found by traction of related visible reticular veins, even if the eyes initially miss them. During sclerotherapy, the liquid agent may treat feeder veins by the blood flow that carries it. But this condition may sometimes lead to partial lesion of the vessel valves, consequently increasing local reflux and pressure, ultimately worsening the telangiectasia and/or causing telangiectatic matting.



Figure 4: Facial vein treated with 1064nm laser.

There are veins in layers normally too deep for naked eye visualization and too shallow for ultrasound detection. When ultrasound is used for feeder vein detection, merely positioning the ultrasound's gel and probe can entirely collapse a small feeder vein. Even so, if the operator manages to locate the vein, its image only appears on the machine's monitor, and it becomes difficult to tell precisely where it actually lies. In addition, the necessary gel makes it a hassle to mark the skin with a pen.

The V-V employs light technology (in acquisition and projection) that is completely harmless. It was initially developed as an aid to collect blood and inject IV medications, but it proved to offer excellent detection of feeder veins. In a previous study, feeder veins were diagnosed in all subjects. One unique feature of the V-V is the fact that the processed digital image is projected directly over the vein, onto the skin, enabling easy marking and transoperative checking. Moreover, the room illumination does not need to be special, nor does it have to be turned off such as for IR transillumination application.

The low index of complications of this allergic-free therapeutic method is very appealing to laser practitioners willing to treat telangiectasias with feeder veins.

Our goal is to treat patients with the safest, less painful and more effective technique. Our patients want less sessions and less expenses. That is the reason we combined techniques. The Cryo-laser guided by the V-V (without the combination of Cryo-sclerotherapy) should be an option for the majority of the leg veins lesions (as it is for all facial lesions) and its effectiveness should be tested Figure 3 and Figure 4).

### Conclusion

The described method is a new and safe option to treat veins. The use of these technologies may contribute to pursuit better results lowering the risk of unwanted adverse effects.



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