



# COOLTOUCH

## **Long Term Experience with CoolTouch 1320nm Endovenous Ablation**

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### **Introduction**

The first procedure to replace ligation and stripping of the great saphenous vein was radiofrequency mediated ablation. It gained FDA clearance in March 1999 as the Closure® procedure, and it was followed quickly by endovenous obliteration or ablation with lasers. None of these treatments was optimized initially but still were superior to more invasive stripping procedures. In 2003, however, we (Dr. M. Goldman as well) started thinking in terms of refining endovenous ablation in order to maximize success, increase patient comfort and improve safety. It was realized that the physics of laser tissue interaction and consideration of targeted chromophores was critical in designing a system to insure maximum efficacy, maximum patient comfort and lowest risks of side effects. While 810 nm was the laser endovenous technique initially introduced, (termed EndoVenous Laser Therapy or EVLT) it became clear that this wavelength was not optimized for the endovenous application because of relatively high absorption by hemoglobin. Other wavelengths such as 940 nm and 980 nm, also employed initially and in rapid succession, had similar absorption profiles by hemoglobin and were not optimal. We posed the question, “Why target hemoglobin when what we really want to do is heat the vein wall? Considering that the vein wall is comprised of collagen suspended in water, why heat hemoglobin when water-targeting wavelengths such as the 1320 nm CTEV were available for clinical development?”

### **Problems with hemoglobin as the target**

Endovenous laser treatment with 810, 940 and 980 nm are designed to produce endothelial and vein wall shrinkage by non-specific heating of the vessel. This is accomplished by creating a superheated coagulum at the fiber tip or by the heating of hemoglobin within red blood cells to create steam bubbles and extremely high temperatures. <sup>(1)</sup> Without the presence of blood in the vein, such as an experimental situation in which the vein is filled with saline, laser induced vessel wall injury is confined to the site of direct laser impact. By contrast, blood-filled veins exhibit extensive thermal damage even in remote areas from the laser fiber including the vein wall opposite to the laser impact. Without the presence of blood, the situation is even worse with areas of vein wall injury or burning resulting in intense post-operative pain and early recanalization of the treated vein. <sup>(2)</sup> More importantly, superheating of hemoglobin leads to

high temperatures, often higher than 1200°C. <sup>(2)</sup> This results in vein perforations, hematoma and post-operative pain. Consistent results may be very difficult to achieve and numerous site to site and practitioner to practitioner variations in success rates and post-operative pain for EVLT have been reported. <sup>(3:4)</sup> This is understandable given that these hemoglobin-targeting lasers are dependent on a variety of factors many of which are difficult to control, such as the exact amount of blood in the lumen.

Our experience with 810nm diode laser reveals increases in post-treatment purpura and tenderness when compared with treatment with RF or 1320 nm CTEV laser ablation. The majority of 810 nm treated patients do not return to complete functional normality for 2-7 days as opposed to virtually no downtime with 1320nm CTEV. Our experience with trying to vary the fluence and treating with a continuous laser pullback vs. pulsed pullback for 810 nm endovenous ablation has not resulted in an elimination of vein perforation using 810nm diode laser. Using hemoglobin targeting wavelengths results in many patients experiencing major degrees of post-operative ecchymosis and discomfort. Saphenous nerve injury, skin burns and deep venous thrombosis have occurred due to the high temperatures of blood heating from these wavelengths, although the overall safety and efficacy record is better than ligation and stripping. From our point of view and experience, it makes far more sense to use a predominantly water absorbing wavelength to treat incompetent saphenous and tributary varicose veins by endovenous laser.

### **Water is the target to heat a vein wall**

Tissue water within the vein wall is the specific target of the 1320nm laser and the presence or absence of red blood cells within the vessels is unimportant. Water is the main component of vein walls, which are comprised mainly of water and collagen. The chromophore for the 1.32 μm or 1320 nm wavelength laser is water, with this wavelength penetrating as deep as 500μm in tissue. This provides a safety margin by reducing the risks of penetration of laser energy beyond the vein wall. For even greater control of energy distribution, the 1320nm CTEV is coupled with an automatic pullback device that can retract the fiber at the rate 0.5, 1 or 2 mm/sec. The penetration of the 1320 nm wavelength is unique in that it is effectively heats and contracts the vein with far less heat generation and risks than with the hemoglobin absorbing wavelengths. The 1320nm wavelength for endovenous ablation was initially explored and clinical trials performed in 2003 resulting in FDA clearance in September 2004 for treatment of the great saphenous vein. By August 2005, sufficient data for approval for obliteration of reflux in the small saphenous vein was also cleared by the FDA.

Numerous advantages have become apparent over almost a decade of experience. There is reduced pain for 1320 nm versus 810 nm, 940 nm and 980 nm due to infrequent vein perforations and more uniform heating by 1320 nm targeting water in the vein wall combined with a defined pullback speed for uniform distribution of energy. <sup>(3)</sup> Although patients rarely experience mild pain after 1320nm, the incidence is less than 1% in our experience and is not related to vein perforations. Hematomas from vein perforations are rarely if ever observed. Energy treatment ranges from 5-8 watts with 8 watts used for larger veins and 5 watts for smaller veins. We have treated veins measuring up to 15mm in diameter by Duplex ultrasound under maximum venous pressure conditions, such as after the patient has been standing all day. For

treatment of larger veins, higher energy range is required as well as vein compression by tumescent anesthesia. In our own studies we have found that treatment with 5 watts of 1320 nm through a 600 $\mu$ m fiber moving at 1 mm/sec in a 2mm thick vein wall with diameter of 5mm, the highest temperature recorded on the exterior of the vein wall is 48 °C. In a saline bath, the temperature does not rise above the baseline saline temperature.

Proebstle et al. demonstrated a statistically reduced rate of post-op pain accompanied by a higher initial success rate using 1320 nm vs. 940 nm.<sup>(3)</sup> With the 1320 nm group, treatment-related pain and the need for analgesics were significantly reduced ( $p < 0.005$ ) in comparison with treatment-related pain (81%) and the need for analgesics (67%) for the 940 nm laser group. Ecchymosis was also significantly reduced ( $p < 0.05$ ) using 1320 nm. Our own experience reflects this, with a reduction in pain and bruising of 90% when switching from 810 nm endovenous to 1320 nm endovenous. Having treated over 600 greater saphenous veins with 1320 nm, with follow-up as long as 8 years, our incidence of mild pain lasting less than 24 hours is 5%, with pain lasting greater than 24 hours less than 1%. No significant pain interfering with walking has been observed with the 1320 nm laser but has been observed in up to 50% of patients who underwent 810 nm laser treatment in our clinic. A clinical example of varicose veins resulting from reflux at the sapheno-femoral junction pre and post treatment with a 1320 nm laser is shown in Figure 1.

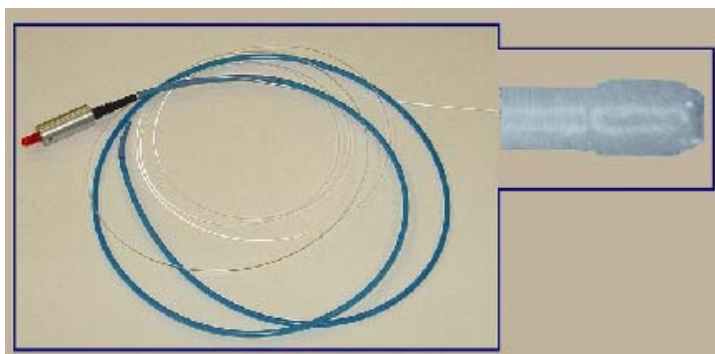


**Figure 1. Examples of clinical improvement with 1320nm CTEV. Two months after CTEV, dramatic improvement on large great saphenous varicosities. No scars, no pigmentation, no skin changes.**

## Materials and Methods

This report summarizes the retrospective analysis of treatment of 582 patients with CTEV for saphenous vein incompetence. The procedure was performed in an outpatient setting with local tumescent anesthesia alone without sedation. Once access is obtained using a micropuncture set

under Duplex guidance, the CTEV™ 600um laser fiber is inserted. With the development of a single use rounded or protected tip in 2005, (SaphFire™ tip) (Figure 2 ),



**Figure 2, Design of the SaphFire® fiberoptic**

no sheath is required as there is minimal danger of puncturing the wall of a vein while advancing the optical fiber. This also allows greater flexibility to get past S-shaped curves and allows much more maneuverability than with thicker RF catheters, radial-tipped or stiffer sharp-edged glass optic fibers. Once the fiber is in the vein, tumescent anesthesia is injected along the vein and injected subfascially to separate and dissect the targeted vein from the surrounding superficial and deep fascia.

Prior to firing the laser, correct placement of the laser fiber at least 2 cm distal to the sapheno-femoral junction or 3 cm distal to the sapheno-popliteal junction is confirmed with Duplex ultrasound. Pullback rate is set for 0.5 mm/sec for the first 3 cm of the GSV and then 1mm/sec for the remainder of the segment. The laser is set for 5 – 8 watts at 50Hz. Compression stockings are used by the patient for three days and normal activity is encouraged immediately after the procedure. Veins treated included 81% great saphenous, 16% small saphenous and 3% antero-lateral tributary veins.

## **Results**

Patients can return to work the next day, discomfort is minimal and the rate of successful long-term vein closure and elimination is 98%. The longest follow-up is 8 years. Duplex ultrasound follow-up at yearly intervals on 520 of the 584 patients reveals no evidence of the targeted saphenous veins or antero-lateral vein. Results at 6 months by Duplex ultrasound are maintained long term. None of the patients having successful elimination of a saphenous vein at 6 months has ever demonstrated recurrence at any subsequent follow-up visit at any time point. Additionally we have noted during treatment that 1320 nm energy traveling into tributaries which appears as steam bubbles heading by Duplex ultrasound effectively treats many incompetent tributaries. This results in less need for follow-up sclerotherapy for primary tributaries connected to the targeted saphenous trunk.

Side effects have included 4 patients with decreased sensation to touch limited to 2 cm<sup>2</sup> above the knee which has resolved within 6 months. No paresthesias have been observed. Post-operative pain as previously mentioned is less 1%. No DVTs have been detected by Duplex

ultrasound at routine 6-week follow-up. No clinical DVTs have been noted. No adverse skin side effects have been observed. Specifically no skin burns have ever been observed in our patient population.

## Discussion

Other laser wavelengths are currently being explored for endovenous laser obliteration of varicose veins, but they are all water-targeted wavelengths. For example, a 1470nm diode was studied in the treatment of 134 saphenous veins. It showed high rates of occlusion at one year but patients had a 7.6% rate of paresthesia at one year. <sup>(4)</sup> An additional study concluded that closure of the varicose veins were possible with a marked reduction in energy, postoperative pain, and ecchymosis with the 1470 nm as compared to the 980 nm wavelength. <sup>(5)</sup> 1470 nm, 810 nm, and 980 nm continuous wave diode lasers were compared to the pulsed 1320 nm laser in extracted human veins filled with blood and suspended in saline. The continuous wave lasers demonstrated perforations in the vein wall while the pulsed 1320 did not, indicating that the delivery mode of a laser may be as important as the wavelength. <sup>(6)</sup> Even 1470nm, which targets water led to perforations in the vein wall, which we have never seen with 1320nm and the CTEV delivery system. The 980 nm wavelength was compared again with another new laser with a 1500 nm wavelength in an animal model. This study found that the 1500 nm laser correlated with a more homogeneous vein wall destruction and less perivenous tissue destruction which could possibly lead to less postoperative pain. <sup>(7)</sup> The study of new wavelengths is focused on our original concept of targeting water, not hemoglobin. The coefficient of water absorption by 1320 nm and its penetration of several hundred microns make it the ideal wavelength for endovenous ablation. <sup>(8)</sup> The method of delivery with automatic pullback and specifically designed fiber optics for optimal energy transfer to the vein wall as well as wavelength are all components for the great success of CTEV endovenous ablation.

## Conclusions

Endovenous occlusion techniques have become the gold standard for saphenous incompetence replacing stripping and ligation. **The CTEV 1320 nm** is the ideal wavelength and delivery system for endovenous ablation based on our experience in treatment of over 600 patients with Duplex ultrasound follow-up data on a yearly basis for nearly a decade. The SaphFire™ tip makes the technique faster and safer and negates the need for a protective sheath. Targeting of water rather than hemoglobin is conclusively proven to be superior for higher efficacy, lower side effects and reduced risks of patient discomfort. Excellent long-term outcomes have been observed. Clinical experience with CTEV in thousands of patients worldwide shows a high degree of success with minimal side effects, most of which can be prevented or minimized with use of tumescent anesthesia. Side effects are far less than with any of the other reported endovenous ablation techniques and efficacy is higher than with any other endovenous ablation technique.

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## **Figure Legends**

Figure 1. Examples of clinical improvement with 1320nm CTEV

Figure 2, Design of the SaphFire® fiberoptic