Dornier MedTech

Therapy Guidelines for Endovenous Laser Treatment

Dornier *Medilas D LiteBeam+*
Medilas D MultiBeam
Medilas D FlexiPulse

Dornier *Medilas D* *LiteBeam+*

Dornier *Medilas D* *MultiBeam*

Dornier *Medilas D* *FlexiPulse*

Contents

1. Introduction

About 20% of all adults suffer from saphenous vein insufficiency, or varicose veins. These varicoses are not only a cosmetic problem but can also cause serious health damage. Varicophlebitis, open legs (ulcers), thrombosis or even a perilous pulmonary embolism can be caused by incompetent truncal or branch veins. Varicoses are mainly a hereditary disposition or originate from valvular incompetence of the Greater Saphenous Vein (GSV) or the Lesser Saphenous Vein (LSV).

Besides the traditional treatment methods, like surgical stripping, ligation or sclerotherapy, there is now a new method, endovenous laser treatment, developed in cooperation between Dornier MedTech Laser and Prof. Dr. Thomas Proebstle of the Ruprecht-Karls-University Clinic Heidelberg, Germany. Until July 2005 more than 700 treatments of the vena saphena magna and 150 treatments of the vena saphena parva have been carried out successfully.

Literature index:

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Reduced recanalization rates of the great saphenous vein after endovenous laser treament with increased energy dosing: Definition of a threshold for the endovenous fluence equivcalent
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Bush RG, Shamma HN, Hammond KA (2005)
940nm Laser for Treatment of Saphenous Insufficiency: Histological Analysis and Long-Term Follow-Up
Photomed Laser Surg, 23(1): 15-19

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Nonocclusion and Early Reopening of the Great Saphenous Vein After Endovenous Laser Treatment is fluence Dependent.
Dermatol Surg 2004, 30:174-178

Proebstle TM, Gül D, Lehr HA, Kargl A, Knop J (2003)
Infrequent early recanalization of the greater saphenous vein after endovenous laser treatment
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Proebstle TM, Lehr HA, Kargl A, Espinola-Klein C, Rother W, Bethge S, Knop J (2002)
Endovenous treatment of the greater saphenous vein with a 940 nm diode laser: thrombotic occlusion after endoluminal thermal damage by laser generated steam bubbles.
Journal Vasc Surg 35:729-36

Proebstle TM, Sandhofer M, Kargl A, Gül D, Rother W, Knop J, Lehr HA (2002)
Thermal damage of the inner vein wall during endovenous laser treatment: key role of energy absorption by intravascular blood.
Dermatol Surg 28:596-600

2. Laser Equipment

2.1 Laser systems:

Dornier diode lasers, with the special 940 nm wavelength, are proven particularly effective for endovenous laser treatment. Due to the strong light absorption of hemoglobin at 940 nm, the laser light penetrates only about 0.3 mm into the blood. This leads to a very efficient, local conversion of laser energy into a steam bubble, which damages the intima.

Currently there are three different, very suitable types of Dornier diode lasers for endovenous laser treatment:

- *Medilas D LiteBeam(+)*: diode laser with 1 - 30 Watt CW at tissue, 35 W pulse power
- *Medilas D MultiBeam*: diode laser with 1 - 60 Watt CW at tissue, 75 W pulse power
- *Medilas D FlexiPulse*: diode laser with 1 - 60 Watt CW at tissue, 120 W pulse power

Spider veins or angiomas can also be treated efficiently using the high-power laser *Medilas D Multibeam* or *FlexiPulse*. Please see our application handbook *"Treatment of vascular disorders."*

2.2 Laser Accessories:

The following accessories are needed during laser use:

- Dornier disposable lightguide

bare fibre 600 µm for the truncal veins;
bare fibre 600 µm or 400 µm for the smaller branch veins

- Laser safety goggles

shield google, type Nanospec, qualified for the wavelength 930-990 nm;
Laser safety L4

3. Clinical Equipment

3.1 Devices:

- Ultrasound device B-Scan

e.g. Sonosite 180plus, 4med Erlangen/Germany

3.2 Accessories (Disposables for Seldinger technique):

- Cannula with mandarin 18 G 1¾"

(Ø 1.3 mm, length 45 mm)
e.g. Vasofix® Braunuele®, Braun Melsungen/Germany
(for branch veins: I.V. cannula 16 G 1 ¾ ")

- Guide wire 0.035", length 150 cm

e.g. Medex Medical Ltd. Rossendale UK

- Opaque angiographic catheter 5 F,
length 65 cm or 100 cm, straight
e.g. Cordis

- Scalpel no. 11

- Compression stockings class II

- Bandaging material (see post-operative care)

4. Anaesthesia

Syringes and anaesthetic agent for local anaesthesia at the puncture spot, e.g. lidocain 1%

Equipment for tumescence local anaesthesia (TLA) roller pump

Anaesthetic agent for TLA, e.g.
1000 ml isotonic saline solution 0.9%
70 ml xylonest (prilocain 1%) or lidocain 1 %
10 ml sodium bicarbonate

5. Clinical Indications

5.1 Operative removal of the insufficient truncal vein:
Although not suited for a normal operations because of relative contraindications, like patients with an arterial bypass or high morbidity rate, these individuals can now be treated with the endovenous laser treatment modality.

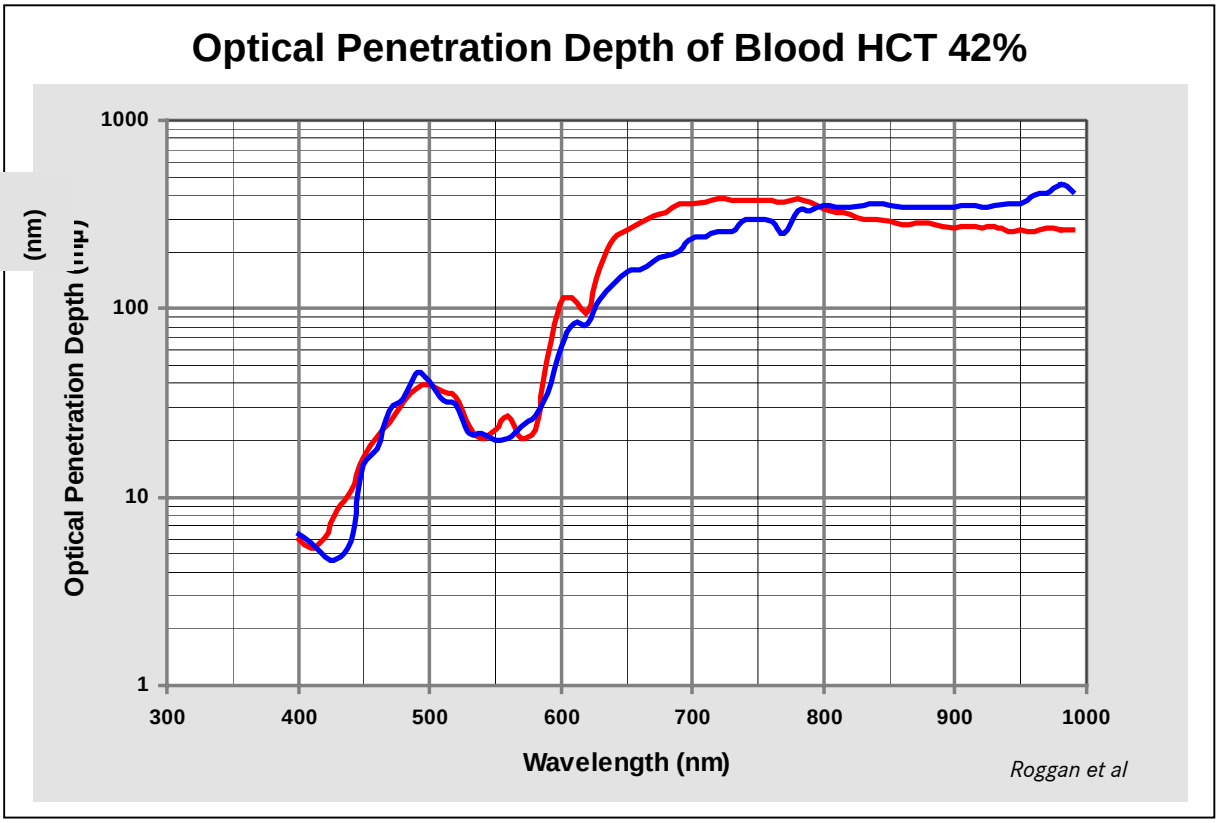
5.2 Treatment objectives to stop pathologic reflux by:
Closure of the affected truncal veins, such as:

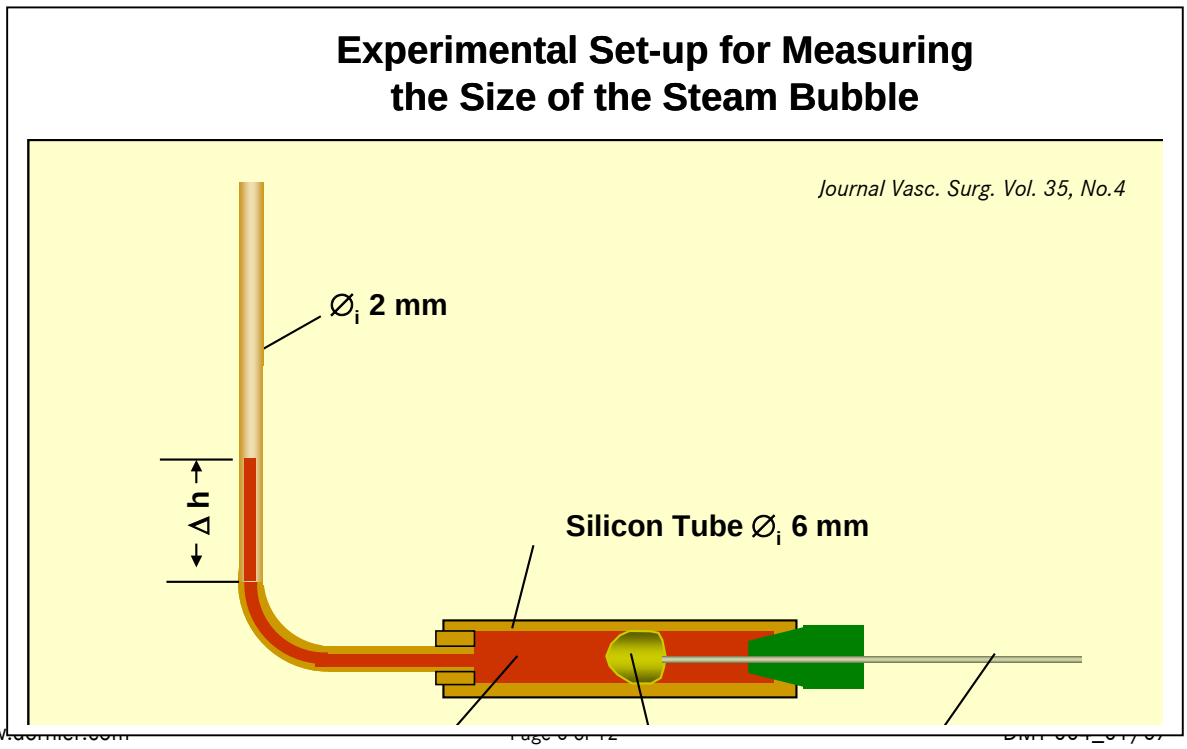
- Greater Saphenous Vein (GSV)
- Lesser Saphenous Vein (LSV)

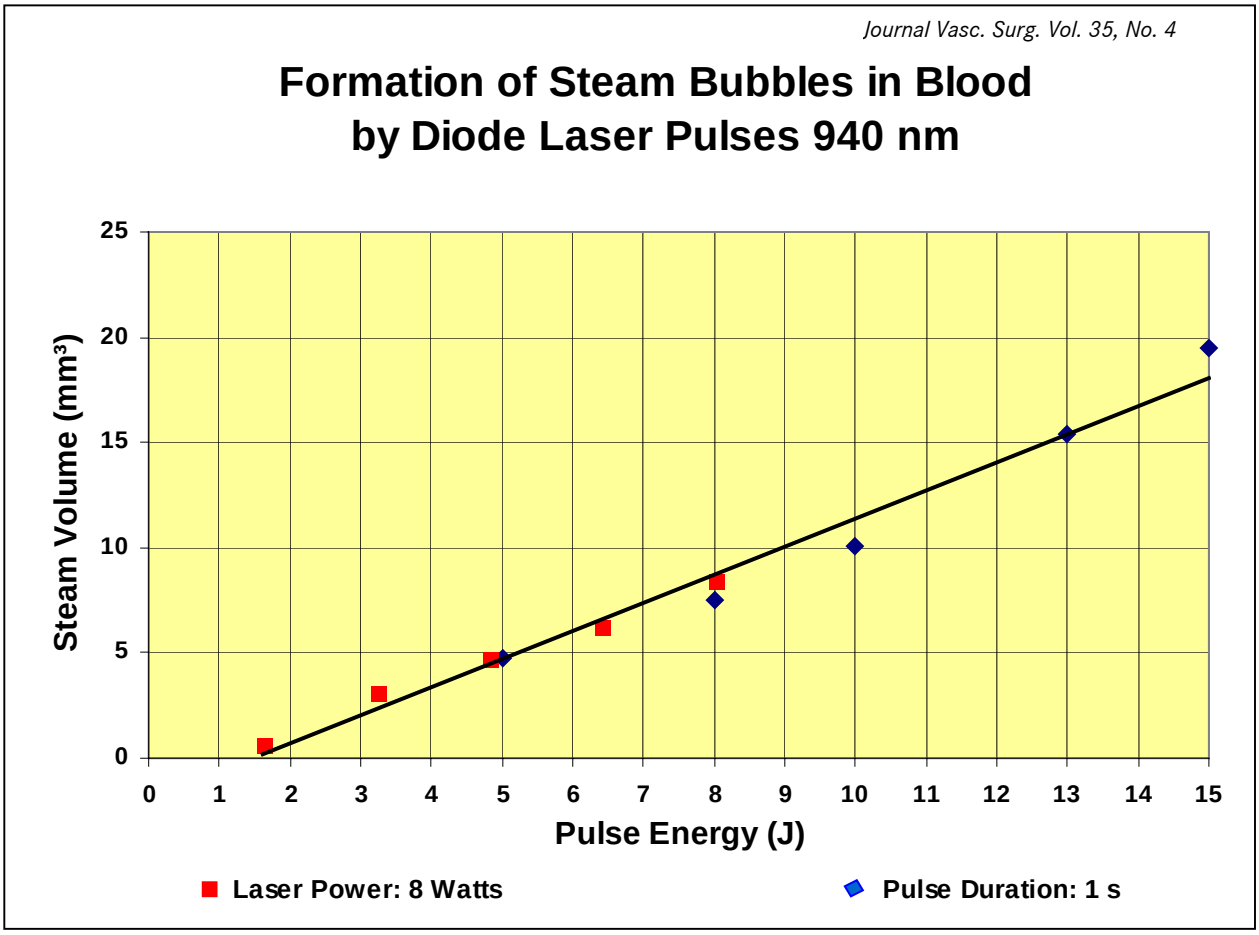
as well as of the smaller branch veins, if indicated.

6. Mechanism

A steam bubble is formed from the water in the blood by the laser pulse. This heats the endothelium of the vessel wall and causes thermal damage. Thrombotic occlusion occurs as a result of the endothelial damage. The vein is then transformed into a solid fiberous strand.
The injection fluid of the tumescence local anaesthesia pads the vein. Damages of the nerves and skin burning are thus avoided.

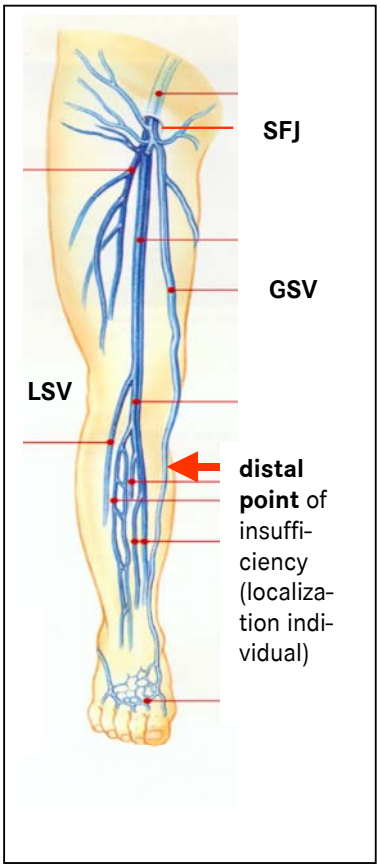





Journal Vasc. Surg. Vol. 35, No. 4
Formation of Steam Bubbles in Blood
by Diode Laser Pulses 940 nm
Steam Volume (mm³)
25
20
15
10
5
0
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Pulse Energy (J)
Laser Power: 8 Watts
Pulse Duration: 1 s

7. Procedure of Endovenous Laser Treatment

7.1 Introducing and positioning of the catheter and fibre according to Seldinger Technique



- puncture the GSV or LSV respectively to be treated at the distal point of insufficiency with a cannula under ultrasound imaging and venous stasis (blood pressure cuff)
- insert the guide-wire and push it up to the SFJ under ultrasound control
- forward the catheter over the wire
- remove the guide-wire and replace with the laser fibre, connect the fibre with the laser device
- duplex control: fibre tip must extrude 6-8 mm from the distal end of the catheter and kept in distance of 1-2 cm from the SFJ
- double check: verify the correct location of the tip by means of the trans-illuminating red light of the aiming beam

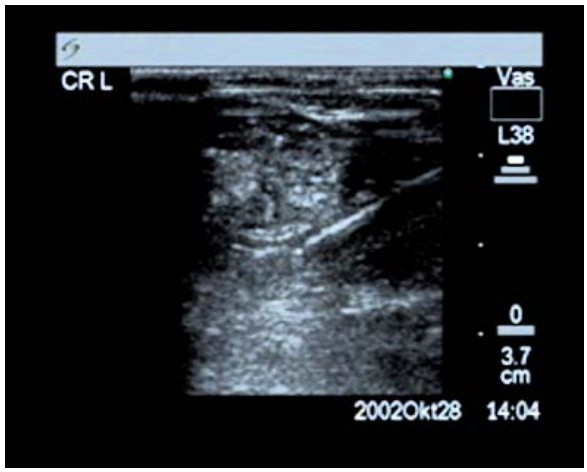
7.2 Carrying out the tumescence local anaesthesia along the vein

7.3 Carrying out the laser irradiation:

- set laser parameters to:
  power 30 Watt (LSV)
  30 Watt (GSV)
  CW mode
  LPS must be switched on!*
- withdraw the catheter with the fibre continuous: about 3-5 mm per second with CW application of the laser light
- document the emitted energy and duration of the laser application

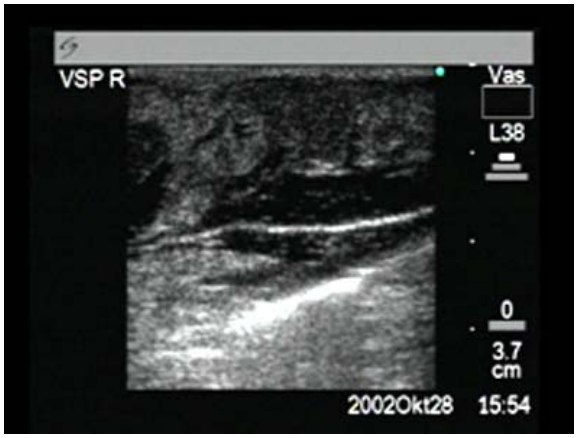
* If there are any problems with the LPS mode, switch it off for 1 second during lasering and on again.

application of the TLA under U/S control



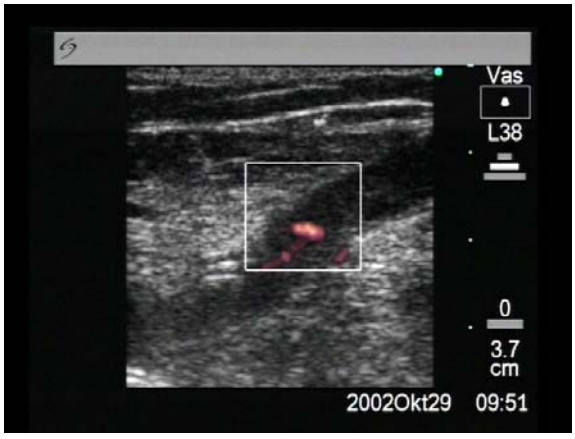
Laser pulse with laser beam

ultrasound image with small bubbles which are produced during application



Follow up examination by ultrasound control

control image clearly shows the occlusion of the GSV



8. Post-operative care

After the treatment a compression bandage is applied for one or two days or until the first check-up. Wearing compression stockings for one week all day and night inhibits the formation of thrombosis and recanalization.
A daily subcutaneous injection of low molecular heparin is used for 7 days to prevent thrombosis.

If the patient's overall conditions allows, he or she can return home right after the treatment.
Immediate mobility is a very important contribution to the healing process.
Follow-up checks to control the success of the treatment should be done on day 1 and 8 as well as 1 and 3 months post-operatively.

9. Side effects

- little to moderate ecchymosis for about 2 weeks (purpura, bruising)
- hyperpigmentation along the vein (very rare)
- occasionally pain and hardening along the leg during the first week (recommendation: Diclophenol 75 mg)
- incidentally thrombophlebitis of the untreated tributaries

10. Advantages of endovenous laser treatment

- in-office, minimally-invasive treatment
- short operation time (about 30 minutes)
- tumescence local anaesthesia
- safe procedure as the effect of the laser radiation and its low penetration depth is limited to a small area
- systematic temperature limit at 100°C by steam bubble
- continuous ultrasound control during operation
- back to normal activities at day 1 post operatively

Appendix

before

after

Photos Prof. Thomas Proebstle, Germany

before

after

Photos Dr. Ron Bush, USA

before

after

Photos Prof. Thomas Proebstle, Germany

11. Results to date

Up to July 2005, the following interventions have been performed at the University Hospital Mainz and Heidelberg, Germany:

- more than 700 interventions on truncal varicoses of the GSV
- more than 150 interventions on the LSV
- more than 70 interventions on others

The post-operative follow-up time for the treatment with 30 W CW is up to 12 months.
A primary occlusion rate of 100% was achieved at the first day after the treatment. The rate of complete recanalization 12 months post-op was below 2%.

Endovenous laser treatment, has already proven to be a very safe, efficient and effective treatment. Both patients and doctors are excited about the therapeutic outcome of endovenous laser treatment. More clinical studies with longer follow-ups will provide the scientific evidence of the high medical and economical value of endovenous laser treatment compared to established modalities.