

Endovenous Laser Ablation

**Diagnose venous disease
and treat superficial venous incompetence
with Endovenous Laser Ablation
under Ultrasound Guidance**

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INTRODUCTION

This standard is for practitioners needing to diagnose the cause of venous disease in legs prior to using Endovenous Laser Ablation for treatment of superficial venous incompetence. It has been developed by Australasian College of Phlebology (ACP) doctors working in the Phlebology modality* 'Endovenous Laser Ablation' (ELA) to provide an assessment tool for doctors in training towards their ACP Fellowship, and for recertification of ACP certified doctors under the ACP Maintenance of Professional Standards (MOPS) programme.

The criteria and outcomes of this standard consider competency in terms of interpersonal, diagnostic and management interactions. It is strongly procedure based, while at the same time focusing on the systems and processes required to ensure a safe and responsive service is provided.

*ACP defined modalities of Phlebology:

• <u>Level 1</u> Microsclerotherapy
• <u>Level 2</u> Ultrasound Guided Sclerotherapy Endovenous Ablative techniques Ambulatory Phlebectomy

1 SCOPE OF APPLICATION

- 1.1 This Standard is copyright to ACP.
- 1.2 It is used by certified ACP phlebologists in their role as supervisors to assess trainee competence in diagnosing and treating superficial venous incompetence in legs using Endovenous Laser Ablation. In addition it is used on an ongoing basis, as a reassessment tool to ensure that doctors continue to meet the standard required in delivering this service to clients
- 1.3 This standard is used periodically during and at the end of the training period. It is also used by trainees and ACP certified doctors working in the modality of Endovenous Laser Ablation to self monitor their own performance.
- 1.4 Assessment as competent in this standard is not sufficient for doctors to gain ACP certification. For Fellowship of ACP trainees must have completed both the ACP Part 1 training and examination programme, and completed the Level 2 registrar training programme for advanced phlebology.

2 PURPOSE

Practitioners credited with this standard are able to establish client needs, communicate and manage risks and deliver safe, timely and appropriate endovenous laser ablation to treat superficial venous incompetence, which meets their clients' expectations.

3 CONTEXT/ENVIRONMENT/SERVICE DELIVERY

Premises used by practitioners in delivering this service must comply with the relevant sections of NZS 8164:2005 Day-Stay Surgery and Procedures, and NZS 8165:2005 Rooms/Office-based Surgery and Procedures.

The clauses in the NZS Draft Standard relevant to the delivery of this service are those pertaining to 'Office-based surgery, or other procedures' i.e. this standard does not require the equipment/facilities of an operating theatre.

These clauses require persons delivering this service to meet both facility requirements and those pertaining to consumer/patient rights, consent, Treaty of Waitangi (NZ), cultural safety issues, and complaints. In addition management specifications relating to clinical management and personnel, quality and risk management including Infection control, consumer/patient selection, clinical emergency response and transfer, clinical records, and medicine management must be met in the delivery of this service.

The facility requirements for EVLA include specifically, Section 5.5 Power and Lighting requirements including Notes 1 & 2:

Note 1. All areas where it is intended to use mains operated equipment for patient treatment or diagnosis meet the minimum requirements of Body Protected Areas, as specified in AS/NZS 3003.1:2003: Electrical installations – Patient treatment areas of hospitals and medical, dental practices and dialyzing locations. The provision of a residual current device (RCD) is an appropriate means of compliance.

Note 2. All body Protected Areas shall have an In-service Testing Programme to NZS 3003.1:2003: Electrical installations – Patient areas of hospitals and medical and dental practices – testing requirements.

4 ENTRY REQUIREMENTS

- 4.1 Doctors registered with the Australia or NZ Medical Council who are current members of ACP, have completed Part 1, and are in the registrar training programme at Level 2.
- 4.2 Doctors registered with the Australia or NZ Medical Council who are Fellows of ACP undergoing recertification.

5 REFERENCES

NZS 8164:2005 Day-Stay Surgery and Procedures.

NZS 8165:2005 Rooms/Office-based Surgery and Procedures.

ACP/NZCAM Maintenance of Professional Standards (MOPS) Programmes.

'Training Programme towards NZCAM Membership and Fellowship Certification' including NZCAM/ACP Protocols: 'Training', 'Informed Consent', 'Infection Control', 'Management of waste and hazardous substances', 'Clinical Records', 'Medicine management', 'Local and regional anaesthesia', 'Clinical emergency response and transfer, surgical emergencies, resuscitation, and referrals', 'New procedures/products Approvals', 'Advertising', 'Ethics'.

AND Modality specific Training Curriculum.

TAPS (Therapeutic Advertising Pre-vetting system) Guideline No. 16 'Advertising by Healthcare Professionals Appearance Medicine and Eye Clinics' (NZ)

Medical Practitioners Act (1995) (NZ)

Medicines Act 1981(NZ)

Medicines Regulations 1984(NZ)

Medsafe guidelines (January 2001) (NZ)

Health Practitioners Competency Act (Sept 2004)

AS/NZS 2211.1:1997 Australian/New Zealand Standard 'Laser Safety'

AS NZS 4173:1994 Australian/ New Zealand Standard 'Guide to the safe use of lasers in health care'

AS/NZS 3200.2.22:1997 'Diagnostic and therapeutic laser equipment'

6 RISK MANAGEMENT

6.1 ACP requires written informed patient consent before EVLA.

6.2 Because of the potential for equipment related hazards with the application of Laser irradiation, the recertification requirements of all fellows include ongoing mandatory attendance at approved ACP Medical Laser safety workshops, and adherence to the laser standards referenced above.

6.3 Duplex/Doppler Ultrasound equipment used in delivering this standard must include a high frequency linear array probe with colour flow and Doppler capabilities.

6.4 Where multi-use laser fibres are used, a pre-operative laser fibre calibration test is mandatory, and a 'pass' required to ensure the radiation dose is within the expected parameters.

6.5 The minimum resuscitation equipment required is:

Oxygen, intravenous fluids, adrenalin, blood pressure and cardiac monitor, pulse oximetry, defibrillator, and suction.

6.6 Where appropriate the saphenous and/or sural nerve is clearly identified on ultrasound to allow a clear separation from the saphenous vein by adequate tumescent anaesthesia

7 SPECIAL NOTES

7.1 Advertising in New Zealand

- Direct to consumer advertising for treatment of varicose veins must not mislead the public.
- Practitioners must not front, speak or appear in advertisements for medical clinics as this would be regarded as 'healthcare professional endorsement by implication' (Section 58 of the Medicines Act (1981).

7.2 Advertising in Australia

- Under development

7.3 Consent

Written informed consent is obtained following the ACP Informed Consent Protocol.

8 DEFINITIONS

ACP	Australasian College of Phlebology
EVLA	Endovenous Laser Ablation
TA	Tumescent Anaesthesia
UGS	Ultrasound Guided Sclerotherapy
Varicose vein	Any vein >2mm with demonstrated retrograde flow indicating incompetence.
SFJ	Sapheno-Femoral Junction
GSV	Great saphenous vein
SSV	Small saphenous vein
SPJ	Sapheno-Popliteal Junction
SVT	Superficial venous thrombophlebitis

CEAP Classification (basic):

i.e. C = Clinical E = Etiologic A = Anatomic P =Pathophysiologic

1. Clinical classification

C₀	No visible or palpable signs of venous disease
C₁	Telangiectasies or reticular veins
C₂	Varicose veins
C₃	Edema
C_{4a}	Pigmentation or eczema
C_{4b}	Lipodermatosclerosis or atrophie blanche
C₅	Healed varicose ulcer
C₆	Active venous ulcer
S	Symptomatic, including ache, pain, tightness, skin irritation, heaviness, and muscle cramps, and other complaints attributable to venous dysfunction
A	Asymptomatic

2. Etiologic classification

- Ec** congenital
- Ep** primary
- Es** secondary (postthrombotic)
- En** no venous cause identified

3. Anatomic classification

- As** superficial veins
- Ap** perforator vein
- Ad** deep veins
- An** no venous location identified

4. Pathophysiologic classification

- Pr** reflux
- Po** obstruction
- Pr,o** reflux and obstruction
- Pn** no venous pathophysiology identifiable

Definition of Consumer For the purposes of this Standard, patient or client refers to the consumer.

Definition of Phlebologist Fellow of ACP whose training includes vascular ultrasound, who is providing treatment to patients under this standard.

9 ATTACHMENTS

Appendix 1 'Endovenous Laser Ablation' - Clinical procedure' (CP-EVLA.doc)

Appendix 2 'ACP Training Handbook' – Specifications for the modality 'Endovenous Laser Ablation'

STANDARD ELEMENTS AND CRITERIA

1 Conduct initial consultation and clinical assessment

1.1 Information regarding venous incompetence, diagnosis and treatment alternatives

Outcome: The patient is fully informed of the nature of venous incompetence, understands the diagnostic process necessary to confirm the cause, and that the treatment alternatives available will depend on the diagnosis.

Criteria

- 1.1.1 The patient is assessed in person by the treating practitioner at the service delivery location.
- 1.1.2 The patient's expectations are discussed and documented.
- 1.1.3 The patient is informed that treatment of venous incompetence is a two stage process which comprises diagnosis followed by clinically appropriate treatment options.
- 1.1.4 The patient is given adequate opportunity to ask questions.
- 1.1.5 The patient understands that after diagnosis, s/he will be asked for written consent to authorise the treatment, and is offered more time to consider the treatment before proceeding if s/he is unsure in any way.

1.2 Patient assessment and initial consultation records

Outcome: A full medical history and clinical assessment of the patient is documented and discussed with the patient; contra-indications are excluded, and suitability for diagnostic and subsequent treatment confirmed.

Criteria

- 1.2.1 The following patient information is documented:
 - Age and ethnicity
 - Onset of vein problem
 - Onset of symptoms if appropriate
 - Past medical /surgical history and associated complications including thrombophilia
 - Previous vein treatment
 - Family History of vein disease and/or thrombophilia
 - Allergies
 - Current medications including oral contraceptives and hormone replacement therapy
 - Smoking history
- 1.2.2 Pre-operative blood tests appropriate to the patient and the proposed treatment are ordered.
- 1.2.3 The CEAP clinical classification of the chronic venous insufficiency is accurate and documented.

1.2.4 The following absolute contra-indication is excluded:

Acute Deep Vein Thrombosis

1.2.5 The following relative contra-indications are identified, risk/benefits evaluated, and any modifications clinically indicated are reflected in the dosage or method used, and agreed with the patient.

Deep venous obstruction

Peripheral vascular disease

Skin disease where infection is a possibility

Documented thrombophilia where the individual's relative risk of venous thromboembolism has been established

Inability to mobilize

Acute Superficial Venous Thrombosis

Pregnancy/breastfeeding

Oral contraceptives

Hormone replacement therapy

Uncontrolled asthma as diagnosed by the patient's general practitioner or respiratory physician

Uncontrolled migraine as diagnosed by the patient's general practitioner or neurologist

Poor tolerance of compression hosiery

1.2.6 Clinical examination identifies all visible secondary complications present which result from venous incompetence.

1.2.7 The patient is informed of the practitioner's initial assessment of the cause of the problem, and an anticipated course of treatments is explained, based on the assumption that the diagnostic process will confirm the practitioner's assessment.

1.2.8 A written estimate of cost for the anticipated course of treatments (to be confirmed post diagnosis) is given to the patient.

1.2.9 Consent for photography is obtained prior to pre-treatment photographs being taken.

2 Map deep and superficial veins with duplex/doppler ultrasound

Outcome: Cause and location of venous incompetence is identified and recorded, superficial thrombophlebitis and deep vein thrombosis is excluded, and suitability for subsequent treatment is confirmed.

Criteria

- 2.1** Incompetence in the superficial or in the deep vein system is identified and its location recorded in relation to an anatomical landmark.
- 2.2** All contributing sources of venous incompetence causing visible post surgical recurrences are identified and their location recorded.
- 2.3** Any pathology relevant to the venous incompetence or in close proximity to the incompetent veins is identified and its nature and location recorded.
- 2.4** A documented pictorial scheme/map records extent and location of incompetence in the venous system including its source i.e. saphenous trunks, tributary vessels, perforators, deep vein system.
- 2.5** If present, superficial thrombophlebitis and non-acute deep vein thrombosis are identified and considered as relative contraindications.
- 2.6** If present, Acute DVT is treated as an absolute contraindication, its extent measured in terms of its length in the vein and a management plan is initiated to minimise the risk of venous thromboembolism.
- 2.7** The diameter of each incompetent vessel at intervals throughout its length is accurately measured and recorded, with the GSV measured at the Sapheno-Femoral junction, at mid-thigh and knee; and the SSV measured at the Sapheno-Popliteal junction and mid-calf.
- 2.8** The straight component of an incompetent vein available to be treated by ELA is identified, its length and location recorded; and the optimal entry point for the laser fibre is identified and recorded.
- 2.9** Saphenous and sural nerves are identified where appropriate.

3 Establish and agree treatment plan

Outcome: The patient is fully informed of the diagnostic results, the suggested treatment plan, any potential risks, and results expected to be achieved at the end of the treatment period. The recommended treatment plan is clinically appropriate, and is the best option to addresses patients needs. Written consent is obtained.

Criteria

- 3.1 Findings are discussed with the patient, and treatment options recommended are clinically indicated and achievable within patient's expectations.
- 3.2 Risks of proposed treatment and possible actions in the event of adverse outcomes are explained.
- 3.3 If treatment is indicated, the interval between diagnosis by Duplex/Doppler ultrasound and treatment is no more than one year.
- 3.4 Instructions are given for pre-operative requirements and these are appropriate for the treatment method proposed.
- 3.7 Written informed consent for the proposed treatment is obtained following the ACP protocol 'Informed Consent', and is signed by both the treating phlebologist and the patient.
- 3.8 A copy of the diagnostic findings and proposed treatment plan is sent to the patient's GP and the referring practitioner.

4 Cauterise veins with endovenous laser ablation under ultrasound guidance

Outcome: Sclerosis of target vessels contributing to venous incompetence is achieved in a manner and timeframe which minimises risk and maximises achievable patient expectations.

Criteria

- 4.1 The laser fibre is not used unless
 - Physical examination of it shows no defects
 - Where applicable a laser calibration machine self test has been conducted on the fibre, and documented 'pass' status recorded (for 1320nm laser).
- 4.2 Tumescant anaesthesia solution is of correct formulation, concentration and condition.
- 4.3 Placement of the needle to introduce TA avoids intravascular injection.
- 4.4 TA infiltration of the target area around the saphenous vein is adequate and confirmation of this is recorded by Duplex ultrasound. Any suprafascial components of the treated vein will need additional TA to protect the skin and fat against thermal injury.

- 4.5 The laser is not activated before ultrasound confirms that the fibre tip is 1 cm distal to the SFJ or SPJ, in the correct position, and there has been adequate uniform distribution of TA along the target area surrounding the incompetent vein. Particular attention is applied to adequate TA immediately distal to the SFJ or SPJ to ensure adequate compression and insulation from the femoral vein. Ensure that saphenous and sural nerves are separated from saphenous veins by adequate TA.
- 4.6 The laser is not activated before the laser sheath and guide wire have been removed.
- 4.7 The withdrawal speed of the laser fibre is correct as monitored using ultrasound prior to and during laser pulsing.
- 4.8 Action in the event of inadvertent intravascular injection of TA is immediate cessation of TA injection, and patient monitoring of blood pressure, cardiac rhythm and pulse oximetry.
- 4.9 Excessive adjacent tissue damage is avoided by using appropriate energy settings and being responsive to patient feedback re discomfort. Appropriate energy settings are used depending on vessel size and wavelength of laser used.

5 Provide post treatment advice to patient and record treatment details

Outcome: Treatment outcomes are optimised in the recovery period and patient safety and welfare followed post treatment.

Criteria

- 5.1 The patient is reminded of the post operative requirements.
- 5.2 All possible symptoms which may be of concern post treatment are described and patient is instructed to contact practitioner urgently if they arise.
- 5.3 Practitioner follow-up of patient concerns is appropriate and in a timeframe that minimises risk to patient.
- 5.4 Contact details of the treating phlebologist or deputy are provided.
- 5.5 An assessment of the treatment is made by examining the patient on the following occasions:
- clinical follow up and DVT scan within one week
 - Review of treatment within 6 weeks to three months
 - Final review 1 year post treatment.

- 5.6** At each assessment the findings are recorded and discussed with the patient and include:
- Success of treatment including resolution of symptoms
 - Degree of sclerosis and any recanalisation
 - Any complications
 - Patient satisfaction
- 5.7** Where clinically indicated, further appropriate treatment is offered, or referral made.
- 5.8** Treatment and assessment records are complete and include:
1. Leg and vessels treated.
 2. Laser parameters used including results of the laser fibre test, settings (Watts and Hz), number of pulses fired.
 3. Length of vein treated
 4. Type and size of compression hosiery applied and recommended time of application.
 5. Post treatment assessment of resolution of symptoms
 6. After post treatment assessments, what further treatment is indicated/offered (e.g UGS or direct sclerotherapy) (if any), any referral made, and whether the treatment plan has been completed.
 7. Any adverse effects or interventions.