Imperial College London

Multicentre Randomised Controlled Trial of Compression Therapy following Endovenous Thermal Ablation of Varicose Veins

FULL TITLE

A multicentre randomised controlled trial of compression therapy following endovenous thermal ablation of varicose veins.

SUMMARY

This study will be looking at the effect of compression therapy in patients having endovenous treatment for truncal incompetence of their varicose veins using either radiofrequency ablation (RFA) or endovenous laser therapy (EVLT). Patients will be randomised to either the compression group (group A) or the no compression group (group B).

The pain scores, compliance, quality of life scores, occlusion rate at 6 months as well as the cost effectiveness of each intervention will be assessed.

OBJECTIVES

- Primary Objective

  Patient's pain score for the first 10 days post-procedure using the visual analogue scale (VAS)

- Secondary Objective

  The secondary objectives would be to compare the two treatment groups with respect to:
  - The quality of life scores at baseline, 2 weeks and 6 months using the EQ-5D, AVVQ and CIVIQ scores
  - The clinical change using the VCSS at baseline, 2 weeks and 6 months
  - The degree of bruising and phlebitis at 2 weeks and 6 months
  - The patient compliance with the intervention
  - The time taken to return to work and normal activities
  - Occlusion rates at 6 months
  - Comparison of the cost effectiveness of the intervention

Background

Varicose veins are common and are known to affect approximately one third of the population[1]. Chronic venous disease (CVD) has been shown to have a negative impact on the quality of life of patients and treatment of varicose veins has been demonstrated to lead to improvement in the quality of life of patients[2-4]. Over the past decade, new endovenous techniques have been introduced and these are felt to be cost-effective, especially, when performed in an outpatient or 'office-based' setting[5].

There is currently uncertainty about the use of compression stockings following treatment of varicose veins. In their consensus statement in 2008, the International Union of Phlebology (IUP) stated that there is good evidence for using compression in certain clinical indications[6]. These include the management of telangiectasia after sclerotherapy, varicose veins in pregnancy, prevention of thromboembolism and healing of ulcers. However, a few questions remain unanswered, such as the length of treatment and level of compression to be used[6]. The Society for Vascular Surgery and the American Venous Forum recommend using compression stockings post-operatively for 1 week to prevent haematoma formation, pain and swelling[7]. The 2013 NICE Guidelines on Varicose Veins in the Legs recommended the use of compression hosiery for no more than 7 days after interventional treatment for varicose veins[8]. However, due to current uncertainty of compression bandaging or hosiery compared to no compression after interventional treatment for varicose veins, the NICE Guideline Development Group have advocated further research to evaluate the clinical and cost effectiveness of this post-procedure intervention[8]. The guidelines also suggested looking into the length of time compression bandaging should be worn if it shown to be beneficial[8].

Several researchers have looked into the practice of using compression after venous ablation. In a survey of the management of varicose veins by the members of the Vascular Society of Great Britain and Ireland, Edwards et al. found that the majority of surgeons used bandages post-operatively, with 49% using elastic bandages[9]. The literature on the use of compression stockings following treatment of varicose vein is limited.

Between December 2006 and February 2008, Bakker and colleagues conducted a prospective randomised controlled trial on the use of compression stockings after endovenous laser ablation of the great saphenous vein[10]. One hundred and nine patients were approached with 93 finally randomised to use compression stockings for 2 days (Group A) and 7 days (Group B), respectively. All patients were followed up for 3 months post-treatment and the visual analogue scale (VAS) for pain was recorded at 48 hours, 1 week and 6 weeks. A physical examination and quality of life was assessed at 1 week and 6 weeks. Occlusion rate at the 3 month point was also evaluated. Physical function and vitality was shown to be significantly better in group B at 1 week follow-up, but there was no statistically significant difference at 6 weeks. At 1 week, it was also noted that the VAS score in group B (VAS score 2.0 ± 1.1) was significantly lower than in patients wearing compression stockings for 48 hours (VAS score 3.7 ± 2.1) ($p \leq 0.001$)[10]. No significant difference was, however, observed at 6 weeks post-procedure. Limitations of the study include the high drop out of the trial (40 out of the initial 109 approached) and the absence of any phlebectomies or sclerotherapy in the patients.

Elderman et al. carried out a randomised trial to assess the effect of compression stockings after endovenous laser therapy (EVLT) for great saphenous vein incompetence[11]. Patients' reported pain scores and quality of life scores was evaluated on the day of the procedure, 2-3 days afterwards and 2-6 weeks post-procedure. A total of 111 patients were randomised to stockings (n=55) and no

stockings (n=56). There was a statiscally significant difference in the pain scores in favour of the stockings group up to day 7, but this difference was no longer present by week 6. There was also a greater use of analgesia in patients in the no stockings group compared to patients wearing stockings ($p<0.05$). In addition, patients wearing stockings reported a statistically significantly higher score of satisfaction at 2 days (4.44 vs 4.15) and at 6 weeks (4.59 vs 4.18). The absolute difference was, however, small. Two notable limitations of the study were the high level of drop outs (16 from each group) and the absence of any blinding.

Hamel-Desnos et al. undertook a randomised controlled trial looking at the effect of compression in patients receiving foam sclerotherapy of the saphenous vein[12]. They noted that patients with compression had similar pain and quality of life scores to patients not wearing any compression. They concluded that additional use of compression had no impact on the effectiveness of obliteration of veins, satisfaction scores, symptoms and quality of life, and that further controlled trials was needed to answer the question of whether using compression results in any difference to the outcome of varicose vein procedures.

We, therefore, propose to undertake a multicentre randomised study looking at the effect of compression therapy after endovenous thermal ablation.

Description

This will be a multicentre randomised clinical trial looking at the impact of wearing or not wearing compression stocking following endothermal ablation (either endovenous laser treatment (EVLT) or radiofrequency ablation (RFA)) of incompetent truncal veins. If clinically indicated, patients will receive adjuvant treatment (e.g., concurrent phlebectomies or foam injection).

Patients will be randomised to group A (compression) and group B (no compression). Only the use of compression will be randomised while the decision as to which treatment to use will be at the discretion of the clinical team.

Target Population

Patients referred for treatment of symptomatic varicose veins will be recruited if they are found to have primary great saphenous (GSV) or small saphenous vein (SSV) incompetence on colour duplex scan.

Inclusion Criteria

- Adults over 18 years of age
- Symptomatic GSV or SSV vein reflux > 0.5 seconds on colour Duplex
- Recurrent varicose veins (if suitable for endothermal treatment)

Exclusion Criteria

- Current DVT

- Arterial disease (ABPI<0.8)
- Vein diameter < 3mm
- Patient who are unwilling to participate
- Inability or unwillingness to complete questionnaires

Intervention

Patients will be randomised to have compression (group A) or no compression (group B). The compression therapy used will be Class II compression stockings. The treatment offered will be endothermal ablation (either endovenous laser treatment (EVLT) or radiofrequency ablation (RFA)) of incompetent truncal veins. Adjuvant treatment to tributaries (e.g., concurrent phlebectomy or foam sclerotherapy) will be carried out, if indicated.

Patients randomised to group A will be asked to wear compression stockings for 1 week.

Patients randomised to group B and undergoing endothermal ablation only will not be provided with any compression. However, if they receive adjuvant treatment to their tributaries, they will be provided with bandages to wear for 24 hours only, with no further compression afterwards.

At baseline, patients will be asked to fill quality of life questionnaires (EQ-5D, AVVQ and CIVIQ) and will have their clinical scores assessed (CEAP and VCSS). On discharge after their varicose vein intervention, they will then be provided with a diary to record their post-procedural pain every day for 10 days using a validated visual analogue scale (VAS) as well as to record when they return to their normal activities and are back to work. They will also be asked to attend a follow-up in 2 weeks and at 6 months.

Patients' GP will also be sent a letter to inform them of their patient's participation in the study.

Follow-up

Patients will be followed up in the outpatient clinic at 2 weeks and 6 months.

Follow-up at 2 Weeks

At the 2 weeks' follow-up, the diary containing details of the pain scores and how soon patients were able to return to normal activities/work will be collected. In addition, patients will be asked about any bruising or phlebitis they have had in the two weeks after their procedure and how compliant they have been with the compression. They will be examined and the Venous Clinical Severity Score (VCSS) will be recorded. They will also be asked to fill in the EQ-5D, AVVQ and CIVIQ scores.

Follow-up at 6 Months

At the 6 months follow-up, patients will be examined and their VCSS will be recorded. They will also be asked to fill the EQ-5D, AVVQ and the CIVIQ scores. They will have a venous Duplex scan to determine occlusion of the treated vein.

Sample Size and Study Duration

We estimated the sample size needed to observe a difference of at least 10mm in the VAS score, with a standard deviation of 20mm. With power at 90% and 5% significance equivalence, we would need to recruit 174 patients (87 per group).

Previous studies looking at compression stockings have shown drop out rates close to 37% at 3 months[10]. Therefore, if we estimate a drop out rate of about 50% by 6 months, we would need to recruit at least 348 patients. If we recruit at least 7 patients per week, this will be approximately a total of 364 patients that could potentially be randomised over the year. With 6 months follow-up, therefore, the study will be running for 18 months with a target recruitment of 350 patients.

Settings

Two hospital trusts in London will be recruiting patients for the study. These will be the:

1. Imperial College NHS Trust
2. North West London Hospitals NHS Trust

ETHICAL ARRANGEMENTS

Ethical approval will be sought from a Regional Research Ethics Committee as per the National Research Ethics Service. Patients will be screened by Roshan Bootun (or another research fellow), who is also members of the direct care team, and patients thought eligible will be provided with information material about the trial and varicose veins and its treatments.
They will be invited to attend for their varicose vein procedures another day and will have until then to consider their participation into the trial (more than 24 hours to consider).
On the day of their procedure, they will be asked by Roshan Bootun (or another research fellow) to confirm their consent by providing a written consent prior to participating in the trial.
The National Health Service (NHS) Trust Research and Development approval will also be sought prior to starting the trial.

DATA HANDLING & DISSEMINATION OF RESULTS

All patient data will be anonymised and stored on a password protected access database under the guidelines of the Data Protection Act 1998. Patient records will be kept on paper in the form of the diary card questionnaires and clinical scoring sheets. These will be kept in a locked filling cabinet at the and stored at the Charing Cross Hospital for 10 years in accordance with the Imperial College Trust Policy.

Data and study findings will be presented locally within the hospital, as well as national and international peer reviewed presentations and peer-reviewed journals.

Criteria for Electively Stopping the Trial or Other Research Prematurely

The trial may be stopped prematurely due to loss of equipoise or any major adverse effect as a result of treatment in any of the treatment arms.

Adverse events

No significant adverse events are expected.

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*
- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

REPORTING PROCEDURES

All adverse events should be reported.

Depending on the nature of the event the reporting procedures below should be followed.

Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

Adverse Events (AE)

All such events, whether expected or not, should be recorded.

Serious Adverse Events (SAE)

An SAE form should be completed and faxed to the Chief Investigator within 24 hours.

All SAEs should be reported to the Research Ethical Committee where in the opinion of the Chief Investigator, the event was:

- 'related', ie resulted from the administration of any of the research procedures; and
- 'unexpected', ie an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies.

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

In the event of any harm to participants in the trial, Imperial College holds Public Liability ("negligent harm") and Clinical Trial ("non-negligent harm") insurance policies which apply to this trial.

ETHICS APPROVAL

The Chief Investigator has obtained approval from the National Research Ethics Service (NRES) Committee - London (Fulham). The REC reference is **15/LO/0181**. The study protocol will be submitted for Site Specific Assessment (SSA) at each participating NHS Trust. The Chief Investigator will require a copy of the Trust R&D approval letter before accepting participants into the study. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

CONSENT

Consent to enter the study will be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent will be obtained. The right of the participant to refuse to participate without giving reasons will be respected. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant's best interest, but the reasons for doing so will be recorded. In these cases the participants remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study.

SPONSOR

Imperial College London act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

FUNDING

There are no funders for this study.

AUDITS

The study may be subject to inspection and audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the NHS Research Governance Framework for Health and Social Care (2nd edition).

Reference:

1. Evans CJ, Fowkes FG, Ruckley CV and Lee AJ. Prevalence of varicose veins and chronic venous insufficiency in men and women in the general population: Edinburgh Vein Study. *Journal of epidemiology and community health*. 1999; 53: 149-53.
2. Smith JJ, Garratt AM, Guest M, Greenhalgh RM and Davies AH. Evaluating and improving health-related quality of life in patients with varicose veins. *J Vasc Surg*. 1999; 30: 710-9.
3. MacKenzie RK, Paisley A, Allan PL, Lee AJ, Ruckley CV and Bradbury AW. The effect of long saphenous vein stripping on quality of life. *J Vasc Surg*. 2002; 35: 1197-203.
4. Biemans AA, Kockaert M, Akkersdijk GP, et al. Comparing endovenous laser ablation, foam sclerotherapy, and conventional surgery for great saphenous varicose veins. *J Vasc Surg*. 2013; 58: 727-34.e1.
5. van den Bos R, Arends L, Kockaert M, Neumann M and Nijsten T. Endovenous therapies of lower extremity varicosities: a meta-analysis. *J Vasc Surg*. 2009; 49: 230-9.
6. Partsch H and Baccaglini U. Consensus conference on sclerotherapy of lower limbs varicose veins. *Journal des maladies vasculaires*. 1995; 20: 134-5.
7. Gloviczki P, Comerota AJ, Dalsing MC, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *J Vasc Surg*. 2011; 53: 2s-48s.
8. Marsden G, Perry M, Kelley K and Davies AH. Diagnosis and management of varicose veins in the legs: summary of NICE guidance. *BMJ (Clinical research ed)*. 2013; 347: f4279.
9. Edwards AG, Baynham S, Lees T and Mitchell DC. Management of varicose veins: a survey of current practice by members of the Vascular Society of Great Britain and Ireland. *Annals of the Royal College of Surgeons of England*. 2009; 91: 77-80.
10. Bakker NA, Schieven LW, Bruins RM, van den Berg M and Hissink RJ. Compression stockings after endovenous laser ablation of the great saphenous vein: a prospective randomized controlled trial. *European journal of vascular and endovascular surgery : the official journal of the European Society for Vascular Surgery*. 2013; 46: 588-92.
11. Elderman JH, Krasznai AG, Voogd AC, Hulsewé KWE and Sikkink CJJM. Role of compression stockings after endovenous laser therapy for primary varicosis. *Journal of Vascular Surgery: Venous and Lymphatic Disorders*. 2014.
12. Hamel-Desnos CM, Guias BJ, Desnos PR and Mesgard A. Foam sclerotherapy of the saphenous veins: randomised controlled trial with or without compression. *European journal of vascular and endovascular surgery : the official journal of the European Society for Vascular Surgery*. 2010; 39: 500-7.

APPENDIX 1: Quality of Life Questionnaire

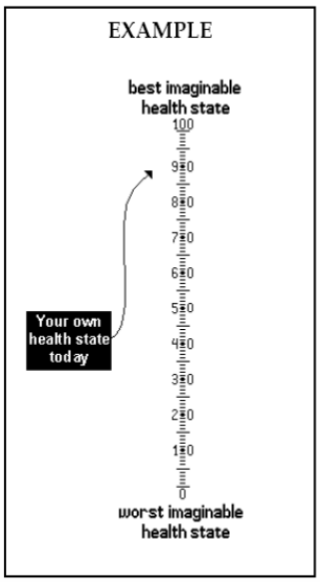
Pre-op questionnaire version 1- 6th August 2009

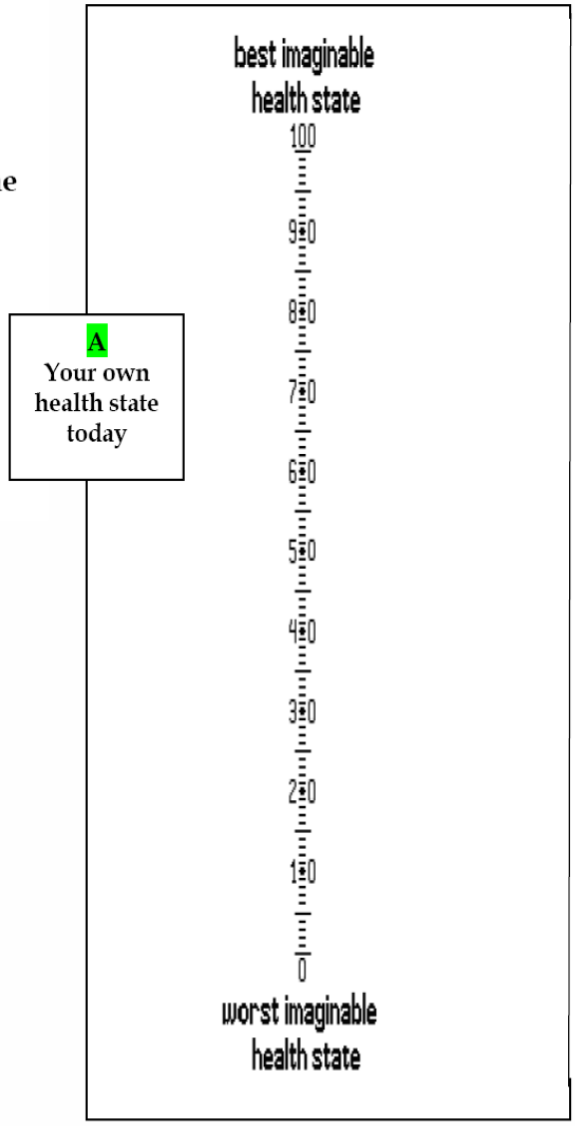
DESCRIBING YOUR OWN HEALTH TODAY

Please indicate on this scale how good or bad your own health state is today.

The best health state you can imagine is marked 100 and the worst health state you can imagine is marked 0.

Please draw a line from box A to the point on the scale that best indicates how good or bad your health state is today.





EQ-5D

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

I have no problems in walking about ☐
I have slight problems in walking about ☐
I have moderate problems in walking about ☐
I have severe problems in walking about ☐
I am unable to walk about ☐

SELF-CARE

I have no problems washing or dressing myself ☐
I have slight problems washing or dressing myself ☐
I have moderate problems washing or dressing myself ☐
I have severe problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ☐
I have slight problems doing my usual activities ☐
I have moderate problems doing my usual activities ☐
I have severe problems doing my usual activities ☐
I am unable to do my usual activities ☐

PAIN / DISCOMFORT

I have no pain or discomfort ☐
I have slight pain or discomfort ☐
I have moderate pain or discomfort ☐
I have severe pain or discomfort ☐
I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION

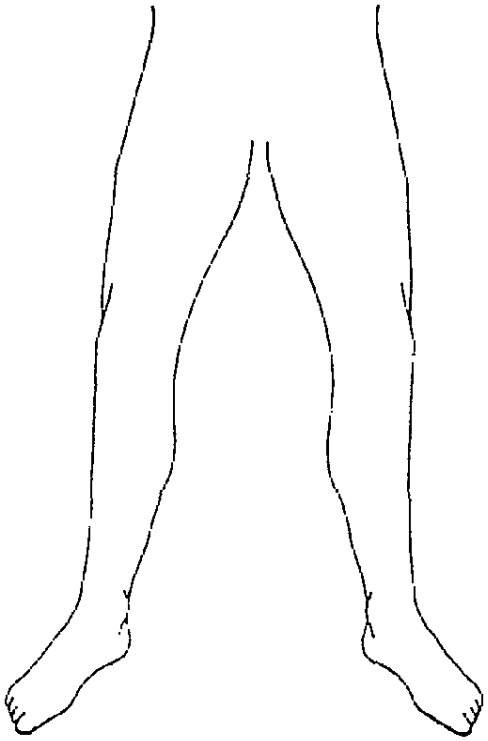
I am not anxious or depressed ☐
I am slightly anxious or depressed ☐
I am moderately anxious or depressed ☐
I am severely anxious or depressed ☐
I am extremely anxious or depressed ☐

Appendix 2: Aberdeen Varicose Vein Questionnaire

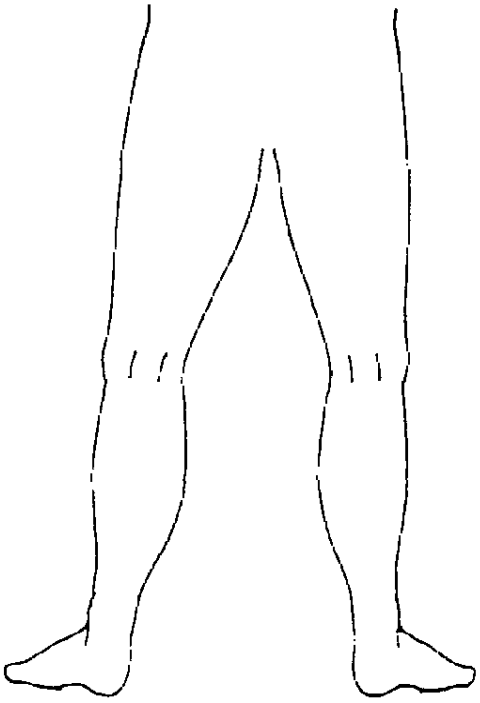
YOUR VARICOSE VEINS

1. Please draw in your varicose veins in the diagram(s) below:-

Legs viewed from front



Legs viewed from back



2. In the last two weeks, for how many days did your varicose veins cause you pain or ache?
(Please tick one box for each leg)

	R Leg	L Leg
None at all	☐	☐
Between 1 and 5 days	☐	☐
Between 6 and 10 days	☐	☐
For more than 10 days	☐	☐

3. During the last two weeks, on how many days did you take painkilling tablets for your varicose veins?
(Please tick one box for each leg)

	R Leg	L Leg
None at all	☐	☐
Between 1 and 5 days	☐	☐
Between 6 and 10 days	☐	☐
For more than 10 days	☐	☐

4. In the last two weeks, how much ankle swelling have you had?

(Please tick one box)

- ☐ None at all
- ☐ Slight ankle swelling
- ☐ Moderate ankle swelling (eg. causing you to sit with your feet up whenever possible)
- ☐ Severe ankle swelling (eg. causing you difficulty putting on your shoes)

5. In the last two weeks, have you worn support stockings or tights?

(Please tick one box for each leg)

	R Leg	L Leg
No	☐	☐
Yes, those I bought myself without a doctor's prescription	☐	☐
Yes, those my doctor prescribed for me which I wear occasionally	☐	☐
Yes, those my doctor prescribed for me which I wear every day	☐	☐

6. In the last two weeks, have you had any itching in association with your varicose veins?

(Please tick one box for each leg)

	R Leg	L Leg
No	☐	☐
Yes, but only above the knee	☐	☐
Yes, but only below the knee	☐	☐
Both above and below the knee	☐	☐

7. Do you have purple discolouration caused by tiny blood vessels in the skin, in association with your varicose veins?

(Please tick one box for each leg)

	R Leg	L Leg
No	☐	☐
Yes	☐	☐

8. Do you have a rash or eczema in the area of your ankle?

(Please tick one box for each leg)

	R Leg	L Leg
No	☐	☐
Yes, but it does not require any treatment from a doctor or district nurse	☐	☐
Yes, and it requires treatment from my doctor or district nurse	☐	☐

9. Do you have a skin ulcer associated with your varicose veins?

(Please tick one box for each leg)

	R Leg	L Leg
No	☐	☐
Yes	☐	☐

10. Does the appearance of your varicose veins cause you concern?

(Please tick one box)

- ☐ No
- ☐ Yes, their appearance causes me slight concern
- ☐ Yes, their appearance causes me moderate concern
- ☐ Yes, their appearance causes me a great deal of concern

11. Does the appearance of your varicose veins influence your choice of clothing including tights?

(Please tick one box)

- ☐ No
- ☐ Occasionally
- ☐ Often
- ☐ Always

12. During the last two weeks, have your varicose veins interfered with your work/ housework or other daily activities?

(Please tick one box)

- ☐ No
- ☐ I have been able to work but my work has suffered to a slight extent
- ☐ I have been able to work but my work has suffered to a moderate extent
- ☐ My veins have prevented me from working one day or more

13. During the last two weeks, have your varicose veins interfered with your leisure activities (including sport, hobbies and social life)?

(Please tick one box)

- ☐ No
- ☐ Yes, my enjoyment has suffered to a slight extent
- ☐ Yes, my enjoyment has suffered to a moderate extent
- ☐ Yes, my veins have prevented me taking part in any leisure activities

Appendix 4: Clinical assessment of Varicose Veins

Hospital Number----------

Date of birth----------

Age **----------**

Occupation----------

Date----------

MALE **FEMALE**

Number of Pregnancies		
Weight/ Kg		
BMI>30	Yes	No
OCP or HRT	Yes	No
Smoker	Yes	No

Past Medical History

	Yes	No		Yes	No
Bleeding disorder			IHD		
DVT/PE			Leg ulcers		
Diabetes			Hypertension		

Medications

Previous treatment to Varicose Veins

Side	Site	Date	Treatment type

Appendix 5: Pre Operative Clinical Assessment

Score	Definition
0	**Asymptomatic**
1	**Symptomatic, but able to carry out usual activities with out compressive therapy**
2	**Able to carry out usual activities only with compressive therapy and/or limb elevation**
3	**Unable to carry out usual activities even with compression and/or elevation**
	Usual activities = patients activities before the onset of disability due to venous disease

Appendix 6: Venous Clinical Severity Score (VCSS)

Please indicate right or left leg or bilateral (R, L or B)

	Absent	Mild	Moderate	Severe
Pain	None	Occasional, non/ no analgesia restricting	With moderate activity, occasional analgesia	Daily, severe limitations, regular analgesia
Varicose veins>4mm	None	Few	Multiple GSV	Extensive GSV and LSV
Venous oedema	None	Evening/ankle	Afternoon/ above knee	Morning/requiring elevation
Skin pigmentation	None	Limited and old/brown	Diffuse lower third/ purple	Wide/ purple
Inflammation	None	Mild cellulitis in marginal area	Moderate involving most of gaiter area	Severe cellulitis or significant eczema
Induration	None	Focal <5cm	Medial or lateral less than lower 1/3	1/3 of lower leg or more
Number of active ulcers	0	1	2	3
Active ulcer duration	None	<3 months	>3 months <12 months	>12 months
Active ulcer diameter(cm)	None	<2	2-6	>6
Compression	Not used or non compliant	Intermittent use	Stockings worn most days	Stockings worn daily
Total				

Appendix 7: Clinical-Etiology-Anatomy-Pathophysiology (CEAP Classification)

Clinical	0	1A	1S	2A	2S	3A	3S	4aA	4aS	4bA	4bS	5A	5S	6
Etiology	Congenital			Primary			Secondary			No venous cause identified				
Anatomy	Superficial			Deep			Perforating			No venous location identified				
Pathology	Reflux			Obstruction			Both			No venous pathology identified				

Class 0 No visible or palpable veins
Class 1 Telangiectasia, reticular veins
Class 2 Varicose Veins
Class 3 Oedema without skin changes
Class 4 Skin changes ascribed to venous disease
4a) Pigmentation or eczema
4b) Lipodermatoscerosis or atrophie blanche
Class 5 Skin changes and healed ulceration
Class 6 Active venous ulcers

A= Asymptomatic
S= Symptomatic

Appendix 8

C I V I Q-14

SELF-QUESTIONNAIRE PATIENTS

In English language for UK

Many people complain of leg pain. We would like to find out how often these leg problems occur and to what extent they affect the everyday lives of those who suffer from them.

Below you will find a list of symptoms, sensations or types of discomfort that you may be experiencing and which may make everyday life hard to bear to a greater or lesser extent. **For each symptom, sensation, or type of discomfort listed, we would like you to answer in the following way:**

Please indicate if you have experienced what is described in each sentence, and if the answer is 'yes', how **intense** it was. There are five possible answers, and we would like you to circle the one which best describes your situation.

Circle 1	if you feel the symtom, sensation of discomfort described does not apply to you
Circle 2, 3, 4 or 5	if you have felt it to a greater or lesser extent

QUALITY OF LIFE WITH VENOUS INSUFFICIENCY

1) During the past four weeks, have you had any **pain** in your **ankles** or **legs**, and how severe has this pain been?
Circle the number that applies to you.

No pain	Slight pain	Moderate pain	Considerable pain	Severe pain
1	2	3	4	5

2) During the past four weeks, how much trouble have you experienced at **work** or during your **usual daily activities because of your leg problems**?
Circle the number that applies to you.

No trouble	Slight trouble	Moderate trouble	Considerable trouble	Severe trouble
1	2	3	4	5

3) During the past four weeks, have you **slept badly** because of your leg problems, and how often?
Circle the number that applies to you.

Never	Rarely	Fairly often	Very often	Every night
1	2	3	4	5

	During the past four weeks, how much **trouble** have you experienced **carrying out the actions and activities** listed below b**ecause of your leg problems**? *For each statement in the table below, indicate how much trouble you have experiened by circling the number chosen.*				
	No trouble	Slight trouble	Moderate trouble	Considerable trouble	Could not do it
4) Climbing several flights of stairs	1	2	3	4	5
5) Crouching, Kneeling down	1	2	3	4	5
6) Walking at a brisk pace	1	2	3	4	5
7) Going out for the evening, going to a wedding, a party, a cocktail party…	1	2	3	4	5
8) Playing a sport, exerting yourself physically	1	2	3	4	5

	Leg problems can also affect your mood. How closely do the following statements correspond to what you have felt during the past four weeks? *For each statement in the table below, circle the number that applies to you.*				
	Not at all	A little	Moderately	A lot	Completely
9) I have felt nervous/tense	1	2	3	4	5
10) I have felt I am a burden	1	2	3	4	5
11) I have felt embarrassed about showing my legs	1	2	3	4	5
12) I have become irritated easily	1	2	3	4	5
13) I have felt as if I am handicapped	1	2	3	4	5
14) I have not felt like going out	1	2	3	4	5

Appendix 9. Patient Diary

Please indicate at what stage you were able to return to work and your normal daily activities (the activities you were able to do prior to treatment).

Please also indicate the day when you stopped wearing the compression stockings (if provided).

(Please tick one box)

	Day I was able to resume my normal activities	Day I returned to work	Day I stopped wearing compression stockings (if provided)
Day of surgery			
Day after surgery			
2 days after surgery			
3 days after surgery			
4 days after surgery			
5 days after surgery			
6 days after surgery			
7 days after surgery			
8 days after surgery			
9 days after surgery			
10 days after surgery			
>10 days after surgery			

Please return to:

Professor Alun Davies
Academic Department of Vascular Surgery
Floor 4 East
Charing Cross Hospital
Fulham Palace Road
London
W6 8RF
Tel.: 02033117320

Appendix 10. Patient Pain Diary (VAS)

Please put a mark on the line to indicate your maximum pain score on each day.

Please also write a score from 0 to 10 for your maximum pain on each day.

***Example**: If your pain score on day 4 is roughly about 5 over 10 (10 being the worst pain imaginable), you might want to indicate it as below:*

Day 4	No pain 0	5 / ———	Worst pain imaginable 10

Study Diary:

(0 = no pain and 10 = worst pain imaginable)

Day 0	No pain 0	——— ———	Worst pain imaginable 10
Day 1	No pain 0	——— ———	Worst pain imaginable 10
Day 2	No pain 0	——— ———	Worst pain imaginable 10
Day 3	No pain 0	——— ———	Worst pain imaginable 10
Day 4	No pain 0	——— ———	Worst pain imaginable 10
Day 5	No pain 0	——— ———	Worst pain imaginable 10
Day 6	No pain 0	——— ———	Worst pain imaginable 10
Day 7	No pain 0	——— ———	Worst pain imaginable 10
Day 8	No pain 0	——— ———	Worst pain imaginable 10
Day 9	No pain 0	——— ———	Worst pain imaginable 10
Day 10	No pain 0	——— ———	Worst pain imaginable 10

Appendix 11. Trial Flowchart