



SCIENTIFIC PROGRAMME
AND BOOK OF ABSTRACTS

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Venous Forum of the Society of Medicine
and the American Venous Forum

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EDIZIONI MINERVA MEDICA

Tripartite Meeting of the European Venous Forum, Venous Forum of the Royal Society of Medicine and the American Venous Forum

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1.1 EXCISION AND GRAFTING IN HARD TO HEAL LEG ULCERS

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Background: Wide local excision and meshed split skin grafting is used to treat refractory leg ulcers. Good early results have been widely reported, but long term studies are lacking.

Aim: To determine the short and long term success of wide local excision and application of meshed split thickness skin grafts in the treatment of chronic leg ulcers. The effect of different aetiologies and ulcer size on the outcome was also assessed.

Methods: A retrospective analysis was performed on all patients who had excision and mesh grafting for chronic leg ulcer ulceration between 1996 and 2004. Recurrence was classified as any breakdown of the ulcer during follow up. Results were analysed using a Kaplan-Meier life table and logrank test.

Results: Sixty two patients with 100 leg ulcers underwent surgery. More than two third of these ulcers were venous ($n=72$) with a mean ulcer size of 35 cm^2 (range $1.5\text{--}192 \text{ cm}^2$). Only three patients left the hospital with their ulcers unhealed. Fifty five % of all ulcers remained healed at 5 years follow up. Two thirds of all ulcer recurrences occurred in the first two months, as shown in life table (Fig. 1), 28 % had a recurrence by 2 months and a further 17% had recurred at 5 years.

There was no difference between the recurrence rate of venous ulcers and chronic ulcers of other aetiologies, p value = 0.98 as shown in life table (Fig. 2). There was also no differences between the recurrence rate of large ulcers (more than 10 cm^2) and small ulcers, p value = 0.65 as shown in life table (Fig. 3).

Conclusions: Wide local excision and application of meshed split skin graft gives good results in over half of the patients treated. Recurrence is most likely to occur in the first two months, and providing ulcers are healed at this point the incidence of further recurrence is low.

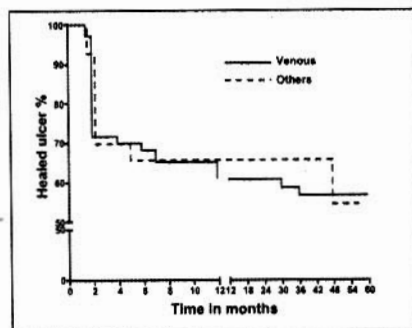


Figure 2. – Life table: success of skin grafts and aetiology.

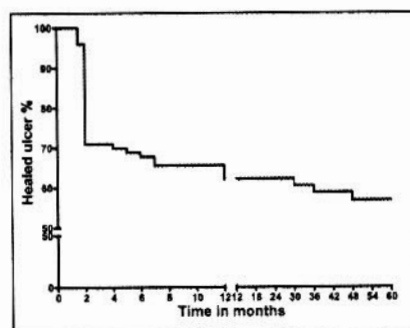


Figure 1. – Life table: success of skin grafts in all ulcers.

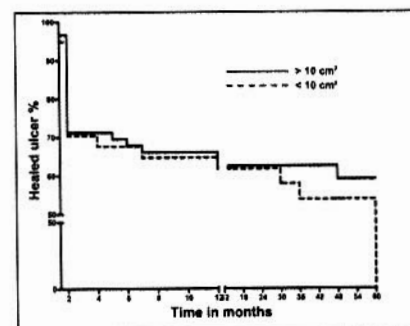


Figure 3. – Life table: success of skin grafts and ulcer size.

1.2 A PROSPECTIVE RANDOMISED TRIAL OF ICX-PRO (CULTURED FIBROBLASTS) IN HEALING CHRONIC LEG ULCERS

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Objectives: To determine the safety and efficacy of low and high dose ICX-PRO in healing chronic leg ulcers.

Methods: 92 patients with chronic venous leg ulcers which had failed to heal after a minimum of six months treatment, were randomised to receive either low dose (500 cells/mm^2) or high dose (1500 cells/mm^2) ICX-PRO. ICX-Pro is a second generation, allogeneic cultured skin graft which can be stored in a refrigerator for up to 3 weeks. Up to 8 treatments were given under a standard 4 layer compression bandage over a 12 week period. End points were the proportion healed, time to healing and % reduction in initial ulcer size. These end points were assessed weekly up to 24 weeks. Results were analysed using logistic regression and ANCOVA to compare the two groups.

Results: 48 patients were randomised to low dose and 44 to high dose ICX-PRO. There were no significant differences between the low and high dose groups at presentation. Healing rates for ulcers less than 14 cm^2 were 46% for low dose and 48% for high dose at 24 weeks. No ulcers larger than 25 cm^2 healed during this time frame, however the overall percentage reduction in wound area at 12 weeks was 40.5% for low dose and 51.5% for high dose ICX-PRO. Complete healing in both cohorts of any size ulcer was 35% at 24 weeks. No adverse safety issues were identified.

Conclusions: There were no statistical differences in healing rates between low and high dose ICX-PRO. No safety issues were identified. The data from the Topical 1 trial are very encouraging compared to historical controls. ICX-PRO is now the subject of a placebo controlled double blind randomised trial. (Topical II).

1.3 A WORLD'S NOVELTY: VENOTRAIN MICRO BALANCE COMBINING COMPRESSION THERAPY WITH EFFECTIVE SKIN CARE – A RANDOMISED, CONTROLLED, PROSPECTIVE, EXPLORATIVE STUDY

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Background: A major drawback of wearing conventional medical compression stockings is that the skin dries out fast and easily gets rough. The purpose of this study is to assess the effectiveness of an innovation – the Venotrain micro balance. This Bauerfeind product combines all advantages of classical medical compression stocking therapy by the Venotrain micro with a new function – the integrated skin care. While wearing this new product, a concentrated mixture of oils, vitamin E and urea is gradually released from the fibres onto the patient's legs. The skin only absorbs as much care as it needs in order to readjust its natural balance.

Method: In a randomised, controlled, prospective and explorative study, 42 patients (36 women, 6 men) suffering from vein disorders of different severity (35 with Widmer stage #1, 7 with Widmer stage #2) were randomised in two groups: 20 patients wearing Venotrain micro balance, 22 wearing Venotrain micro - for a minimum of 8 hours per day. Objective assessment of skin humidity, transepidermal condensation and skin roughness was done with standardised measurement devices (Corneo- and Tewameter and FOITS Dermatop). Patients' compliance was evaluated by a questionnaire every day.

Results: Whereas the skin of patients wearing the classical medical compression stocking showed a significant reduction of humidity ($p=0,004$), the Venotrain micro balance allowed all patients to maintain a normal moisture level of the skin. Transepidermal condensation was significantly decreased ($p=0,043$) in patients wearing the Venotrain micro balance. In contrast, the classical medical compression stocking created an increased water loss of the patient's skin ($p=0,024$). The difference between both groups for this criteria was significant ($p<0,01$). The skin condition was significantly different from one group to the other ($p<0,001$): an increasingly rougher skin could be observed in the group wearing classical medical compression stockings ($p<0,001$) whereas the skin surface was kept active in the group with the Venotrain micro balance ($p=0,109$). Increased sweating at the stocking's silicone top border was a side effect mentioned by patients wearing the new type of stocking whereas the majority of the people wearing the classical version complained about a temporary itchiness.

Conclusions: The Venotrain micro balance is a revolutionary medical compression stocking offering effective compression therapy in combination with a long-lasting and tangible skin care effect. This 'intelligent' combination allows to supply the skin with active ingredients over the course of the day. The study results proof a superiority of this new Bauerfeind product compared to classical versions of compression hosiery.

1.4 PREVENTION OF RECURRENCE OF VENOUS ULCERATION: RANDOMISED CONTROLLED TRIAL OF CLASS 2 AND CLASS 3 ELASTIC COMPRESSION

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Objective: To compare venous ulcer recurrence and compliance with two strengths of compression hosiery.

Design: Randomised controlled trial; five year follow up.

Setting: Leg Ulcer Clinics of a teaching and a district general hospital in Scotland, UK.

Patients: 300 outpatients with recently healed venous ulcers, with no significant arterial disease, rheumatoid disease or diabetes mellitus.

Interventions: Fitting and supply of Class 2 or Class 3 compression hosiery. Four monthly refitting by trained orthotists and surveillance by specialist nurses.

Main outcome measures: Recurrence of leg ulceration and compliance with treatment.

Results: Thirty six percent (107/300) of patients had recurrent leg ulceration by 5 years. Recurrence occurred in 59/151 (39%) in Class 2 elastic compression and in 48 (32%) in Class 3 compression. One hundred and six patients failed to comply with their randomised compression class, 63 (42%) in Class 3 and 43 (28%) in Class 2. The difference in recurrence is not statistically significant, but our estimate of the effectiveness of Class 3 hosiery is diluted by the lower compliance rate in this group. Restricted ankle movement and 4 or more previous ulcers were associated with a higher risk of recurrence.

Conclusions: There was no evidence of a difference in recurrence rates at the classical level of significance (5%) but lowest recurrence rates were seen in people who wore the highest degree of compression, then patients should wear the highest level of compression that is comfortable.

2.5 THE CLINICAL SIGNIFICANCE OF PERSISTENT BELOW-KNEE GREAT SAPHENOUS VEIN (BK-GSV) REFLUX FOLLOWING ENDOVENOUS GSV LASER ABLATION (EVLA): DO WE NEED TO MODIFY TREATMENT?

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Introduction: About 70% of primary varicose veins (VVS) due to GSV reflux are suitable for EVLA. The recommended technique is to ablate the GSV from knee level to the sapheno-femoral junction (SFJ). This study examines the clinical significance of persistent reflux in the untreated BK-GSV.

Methods: The GSV was ablated from the knee to the SFJ in 64 patients (69 limbs) with primary VVS: 810 nm diode laser, 12 watts power, 1 second pulses/1 second intervals, ≥ 60 J/cm, tumescent local anaesthesia. Ultrasound scans (US) were repeated 6-12 weeks post-EVLA to identify reflux in either the treated or distal untreated GSV. Aberdeen Varicose Vein Symptom Severity scores (AVVSS) pre- and post-EVLA (3 months) and the requirement for sclerotherapy for residual VVS were recorded.

Results: US confirmed complete occlusion of the treated GSV in all limbs. In the untreated BK-GSV 34/69 (49%) had normal forward flow (group A), 7/69 (10%) flash (<1 sec) reflux (group B), and 28/69 (41%) reflux of >1 sec duration, (group C). Although the AVVSS improved in all groups; Group A: 14.6 (8.4-19.3) to 2.8 (0.5-4.4), Group B: 13.9 (7.5-20.1) to 3.7 (2.1-6.8), group C: 15.1 (8.9-22.5) to 8.1 (5.3-12.6) the change was significantly less in group C ($p < 0.001$ v A,B). Further, sclerotherapy to complete treatment was required more often in group C (15/28 [53.6%] versus group A: 10/34 (29.4%); group B: 2/7 (28.5%), C v A+B, $p = 0.038$).

Conclusions: Although ablation of the thigh GSV improved symptoms regardless of persistent reflux in the BK-GSV the latter was associated with residual symptoms and a greater need for sclerotherapy. Thus, superior outcomes (symptom relief, less sclerotherapy) should be achieved if an incompetent BK-GSV is also ablated.

2.6 COMPARATIVE ANALYSIS OF USEFULNESS OF TWO SCORING SYSTEMS CEAP AND VSS IN ASSESSEMENT OF CVD SEVERITY AND OUTCOME OF SURGICAL TREATMENT

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Objective: Chronic venous disorder (CVD) is characterized by a wide range of symptoms and signs as well as a very complex etiopathogenesis. This is a reason a lack of a reliable scientific tool allowing comprehensive quantitative assessment of CVD of the lower limbs. However, the introduction of CEAP classification in early '90 with clinical, anatomical and venous disability scoring has allowed to make a comparison between phlebological patients and studies, but was not much appreciated by researchers and clinicians. Recently proposed Venous Severity Scoring seems to be more comprehensive and detailed in assessing lower limbs but it still needs to be validated.

Aim of study: Evaluation of usefulness of two scoring systems in assessment of CVD severity and outcome of surgical treatment.

Material and Methods: Ninety three individuals (32 males and 61 females) suffering from CVD were enrolled in the study. Altogether, 186 lower limbs were examined clinically by one physician (MS) using both scoring systems: CEAP and VSS. Duplex scan was performed in all patients and anatomical and hemodynamical findings were included to adequate segments of CEAP Anatomical Score and VSDS. 58 of all examined limbs were operated on. Three months after the surgical procedure, a follow-up examination was performed. All limbs were once again assessed by means of CEAP classification and CEAP and VSS scoring systems. Duplex scan examination was also performed. The results were presented in frequency tables and analysed statistically with the use of Kruskal-Wallis test, Spearman rank correlation test, Wilcoxon test.

Results: Both scoring systems, CEAP and VSS, have shown directly proportional accordance to higher Clinical Class C. Median CEAP Clinical Score increased from C_0 (0 points) to C_6 (12 points), median CEAP Anatomical Score increased from C_0 (0 points) to C_6 (5 points), median CEAP Disability Score increased from C_0 (0 points) to C_6 (3 points). Similar results were observed in VSS. Good correlation was found between CEAP Clinical Score and VCSS ($r = 0.85$), CEAP Anatomical Score and VSDS ($r = 0.89$), CEAP Disability Score and VDS ($r = 1$). 58 limbs were evaluated before and after surgery. There were found significant differences between pre and post operative results for CEAP Clinical Score ($Z = 3.77$), CEAP Anatomical Score ($Z = 5.88$), VCSS ($Z = 2.63$) and VSDS ($Z = 3.45$). No differences were observed between CEAP Disability Score ($Z = 0.73$) and VDS ($Z = 0.73$).

Conclusions: Our study revealed no significant differences between CEAP and VSS scoring systems. It has been proven that both systems are highly compatible and the CVD lesion's intensity assessed with the studied scoring systems are directly proportional to the Clinical Class (C) stages.

Based on our study it appears that there is still a need for further modification of the existing CEAP and VSS classification.

2.7 ULCERATED LEG SEVERITY ASSESSMENT (ULSA) SCORE: A NEW TOOL TO PREDICT HEALING IN VENOUS LEG ULCERATION

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Objective: To create a reliable scoring system to predict venous ulcer healing in patients treated with compression bandaging.

Methods: A prospective baseline study to identify potential risk factors for ulcer healing was performed between March 1999 and August 2001. A number of variables and 24 week healing rates were measured. All patients were treated with multilayer compression. Potential risk factors to predict ulcer healing were identified using a Cox regression model and a scoring system was devised. The scoring system was validated prospectively between February 2004 and March 2005.

Results: In the baseline study (n=229), patient age (years), ulcer chronicity (months) and venous refill time (VRT) >20 seconds with a below knee tourniquet were identified as potential risk factors. Using these factors and data from the Cox regression analysis, the following formula was devised:

ULSA score = Age + chronicity - 50 (if VRT>20s). Patients with ULSA score <50 had higher 24 week ulcer healing rates than patients with higher scores in both the baseline study (p<0.001, Log-Rank test) and the validation study (n=86; p=0.007, Log-Rank test) (Table I).

Table I.

ULSA score	Category	Baseline study (n=229)		Validation study (n=86)	
		n	24 week healing (%)	n	24 week healing (%)
<50	1	104	91	35	77
51-90	2	92	70	42	55
>91	3	33	46	9	33

Conclusion: The ULSA score may help identify those patients with venous ulceration unlikely to respond to conventional treatment. These patients may be offered alternative therapeutic strategies or participation in further research.

2.8 COMPARISON OF CONVENTIONAL STRIPPING VERSUS CRYO-STRIPPING: A PROSPECTIVE RANDOMIZED TRIAL

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Objective: To assess the quality of life and procedure-related complications on patients undergoing long saphenous vein stripping, using two different techniques.

Methods: 146 patients with primary varicose veins due to long saphenous vein incompetence were recruited and randomized to either conventional stripping (77) or cryo-stripping (69). Cryo-stripping, which can be considered as a type of invagination, and conventional stripping were performed just down to knee level. Apart from stripping, surgery involved standard high ligation and multiple stab avulsions in both groups. Patients were assessed by clinical examination (including hand held Doppler examination or Duplex scan) and completed the SF-36 questionnaire preoperatively, and postoperatively at 4 weeks, 3 and 6 months.

Results: At baseline, there was no significant difference between the two groups in terms of age, gender, SF-36 scores, or CEAP grade. SF-36 showed improvement of quality of life after surgery in bodily pain, physical function and social summary, which reached statistical significance (p<0.005) at 3 months visit. This improvement was observed in both groups without any substantial difference between them. The incidence of postoperative sensory abnormalities was significantly higher in the conventional stripping group (37% vs. 22%, p<0.001). Significantly smaller postoperative bruising was measured on the thigh area in the cryo-stripping group (264 cm² vs. 439 cm², p<0.005).

Conclusions: Primary varicose vein surgery is associated with significant improvement in quality of life scores, irrespective of the stripping technique. Cryo-stripping may have advantages over conventional stripping in terms of procedure-related complications.

2.9 WATER: THE ULTIMATE SCLEROSING AGENT? OCCLUSION OF VARICOSE VEINS BY IN-SITU GENERATED SUPERHEATED STEAM

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Aim of the study: To devise a safer heating technique for obliteration of varicose veins.

Principle: Steam has a high heat transfer coefficient. Superheated steam is obtained when water is submitted to high pressures, and vaporizes at more than 100 °C. To generate this high temperature steam, a pump drives water through a catheter or a needle. At the tip, a 200 nm microtube is heated by an electrical current. Water is then ejected under pressure as steam with temperatures up to 300 °C. The duration of pulses can easily be regulated by interrupting the power applied to the nanotube. After leaving the tube, steam transfers its heat very rapidly to surrounding tissues and returns to water. We are thus able to heat vein walls, destroy the endothelial layer and shrink collagen as in other thermal techniques: radio-frequency and endolaser, but in a more efficient way system, thus preventing the risk of skin burns.

Methods: In-vitro studies have been performed on 20 freshly harvested segments of varicose veins with external and internal temperature measurements and microscopic examination of the veins. Heating parameters were modified in order to obtain a reproducible protocol adapted to different sizes of vessels.

Material: Several applicators have been designed to heat different sizes of veins: from 0,2 mm telangiectasia to large Saphenous trunks up to 20 mm. The generator is the same: it works under a pressure of 80 bars. The small vein applicators are needles connected to a hand-piece which doubles as a cooling element. Varied lengths and diameter of catheters have been devised: for great saphenous veins, the heating element is inserted through a standard angiography catheter. The heat transfer is so efficient that 1 cc of water is enough to treat a great saphenous vein from knee to groin. Temperature outside the vein does not exceed 55 °C, while inside temperature stabilizes itself to 97 °C. Animal studies were performed on rabbit's ears for small veins and on lambs for larger trunks. Lastly, human testing began on volunteers.

Results: No complications occurred, particularly no skin burns. All veins were obliterated. Microscopic studies confirmed the destruction of endothelial layer with thickening of the media. Lesions on large veins were similar to those observed after radio-frequency heating. No perforations occurred. **Advantages:** This thermal technique allows *in-office treatment of small to large calibre veins* with an inexpensive generator. **Advantages over endolaser** are: no perforation of vein wall, thus no haematoma – treatment of trunks and collaterals in the same session – cheaper generator and single use devices – no safety risks for patient and people in the operating room (no safety glasses). **Advantages over foam sclerotherapy** are: no allergic reaction (the only end-product is water) – no risk of DVT – no risk of air embolism, thus no problems with persistent foramen oval – no superficial thrombosis – no sterility issue.

Conclusions: Steam vein obliteration is a safe and economical procedure. Its significant advantages as compared with existing techniques should make it a useful tool for the phlebologist.

2.10 VARICOSE VEIN TREATMENT AND RESTORATION OF SAPHENOUS VEIN COMPETENCE : THE FRENCH "ASVAL" METHOD

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Background: To evaluate results of selective ablation of refluxing varicose veins, preserving the great saphenous vein and evaluating competence by careful follow up. Saphenous vein ablation has been a cornerstone of successful varicose vein surgery but duplex ultrasound allows accurate assessment of alternative therapies including saphenous vein preservation. It relies on a concept of superficial venous insufficiency (SVI) in which reflux begins distally and progresses proximally until incompetence of the saphenous trunk is the last event.

Patients and Methods: A total of 303 limbs of 221 patients, 166 women, 55 men, ages 20 to 83 (Mean 52,7) were assessed by pre-operative duplex examination and treated by selective removal of refluxing varicose veins under local anesthesia. The great saphenous vein was carefully preserved and not treated by stripping, laser (EVLV) or RF energy (VNUS Closure[®]). Periodic post-operative standing duplex ultrasound and clinical examinations were done to record results.

Results: The great saphenous vein was preserved in all limbs and favorable patient assessment of symptom relief was achieved in 167 out of the 186 preoperative symptomatic limbs (89,8%). Saphenous vein competence was restored in 186 limbs (68,6%) and symptom relief and freedom from varicose recurrence correlated with this finding. Neither patient age, duration of varicose veins or combination of multiple other factors predicted this result. Aesthetic goals were reached in 243 limbs (89,7%) at a mean of 16,8 months post operatively. Only one patient required later great saphenous ablation in one limb.

Conclusions: Hemodynamic, symptomatic and aesthetic success is achieved by treating saphenous origin varicosities by selective varix excision. Great saphenous vein competence was restored in 68,6% of limbs treated but a means of predicting this result is at present unavailable.

3.11 REPEATED FAILURE OF APPLICATION OF HOSPITAL DVT PROPHYLAXIS PROTOCOL: WHAT IS REQUIRED TO ESTABLISH EFFECTIVE PROTOCOL COMPLIANCE?

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Background: There is a consistent failure of health professionals in the UK to comply with the use of thromboprophylaxis in hospitalised patients. Evidence demonstrating the efficacy and benefits of prophylactic modalities are collated by the Cochrane database, NICE and International consensus groups.

Methods: In an acute multidisciplinary university hospital, a number of measures were implemented to improve thromboprophylaxis, namely:

- education program for health professionals;
- development of a new evidence based simplified thromboprophylaxis protocol via a randomised clinical trial;
- hospital protocol publication and implementation by clinical governance;
- repeated annual audit with subgroup analysis.

Results: A single blanket protocol was successfully developed and tested in a pilot and then a large randomised clinical study. The initial application of optimal thromboprophylaxis improved significantly from 47% to 85%. However, repeated annual audit noted a downward trend in protocol compliance to 11%. Protocol enforcement via surgical pre-admission clinics increased protocol compliance to 18% (57 patients) out of a total of 317 in-patients.

Discussion: Education of health care professionals and the development of a new simplified single protocol of LMWH and thigh-length stockings for all patients (bar those with medical contraindications) improved the short-term thromboprophylaxis compliance to 85%. Despite these efforts, annual audit with clinical governance input demonstrated a persistent deterioration in protocol compliance. Standard methods have failed to maintain long-term compliance; we have therefore embarked on a patient education program in order to achieve this.

3.12 NEOVALVE CONSTRUCTION IN POSTTHROMBOTIC SYNDROME AND VALVE APLASIA

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Venous reflux is an important cause of severe chronic venous disease. The most frequent etiology of deep venous reflux is valve incompetence due to postthrombotic syndrome, while primary congenital reflux and congenital aplasia are less frequent. Deep venous reconstructive surgery is usually recommended for those cases not responding to conservative therapies.

Valve repair, firstly proposed by Kistner in 1968¹, is the elective operation to correct primary valve incompetence. In postthrombotic syndrome valves are usually completely destroyed thus femoral vein transposition² and venous segment transplantation³ may be the only available alternatives to valve reconstruction. When all these standardized procedures are not feasible, other techniques may be attempted such as cryopreserved valve implants⁴ and other technical options proposed by many Authors.

Our proposal⁵ is a further technical option of neovalve construction by means of intimal dissection. The femoral vein, at the thigh median third, is exposed; a longitudinal venotomy is carried out and intimal flaps are obtained by dissection of the thickened postthrombotic venous wall. The leaflets are then shaped to mimic a natural valve, monocuspid or bicuspid. The technique has been successively extended to primary venous insufficiency. From December 2000 to December 2005, 27 operations have been performed in 25 patients (11 males, 14 females; median age 55 years, range 29-79 years) affected by postthrombotic syndrome or valve agenesis.

The CEAP classification was C_{6S} E₅ A_{ED} P_R in 22 limbs and C_{6S} E₅ A_{ED} P_R in 5 limbs. Venous reflux was assessed at Kistner grade IV in all cases. All patients underwent preoperative Duplex Scanning, air-plethysmography and ascending/descending venography. Inclusion criteria were resistance to conservative therapies or frequent ulcer recurrence and non feasibility of standardized surgical procedures. Exclusion criteria were contraindications to anticoagulant therapy, severely impaired deambulation and thrombophylic syndromes. The median follow up is 27 months (range 1-60 months).

A postoperative descending venography was performed on 19 limbs. Air-plethysmography was performed one month after surgery. Duplex scanning was scheduled at 1 and 6 months after the operation and thereafter at one year intervals. Air-plethysmography assessment was also performed annually. All repair sites have remained patent with no thrombosis to date, with the exception of one case of late thrombosis (96%). Early thrombosis not involving the neovalve site was detected in two cases. The overall recurrence of thrombotic events was thus equal to 88%, with no pulmonary embolism been detected. Valve competence was observed in 88% with no deterioration of haemodynamic parameters during the follow up phase. Ulcer healing was achieved in 85% of cases with no recurrence to date. A larger series is required to validate this technique nevertheless the first results seems to be encouraging.

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3.13 ENDOVENOUS VALVE TRANSFER STENT (EVTS) FOR THE TREATMENT OF CHRONIC DEEP VENOUS INSUFFICIENCY

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Background: Venous disease poses a major problem for the medical community, with up to 50% of the world-wide adult population with some form of venous disease, and 2% of the population suffering from venous ulceration. It is known that venous disease is caused by failure of venous valves in the legs. Therefore, this project aims to design and test a novel Nitinol stent which will facilitate the autogenous transfer of a venous valve.

Methods: In consultation with surgeons, biologists, and biomedical engineers the EVTS was designed and put through in vitro testing. Sheep in vivo trials were conducted (n=16 Merino sheep), with the EVTS used to transfer a venous valve from one jugular vein to the contralateral side. Sheep were followed up for one, three, and six months using ultrasound, histology and scanning electron microscopy (SEM). A modification of this protocol has recently commenced human trials.

Results: The EVTS performed exceptionally through in vitro trials, far exceeding the requirements for regulatory acceptance. In vivo trials have demonstrated that the EVTS:

- facilitates rapid and accurate harvesting and autogenous transfer of a venous valve;
- restores partially incompetent valves to normal functioning;
- is self anastomosing in the target vein;
- becomes rapidly incorporated in the vein wall with no evidence of endoleak;
- shows no sign of thrombosis or stenosis.

Conclusions: The EVTS has been shown to be highly effective for the rapid and accurate autogenous transfer of a venous valve into an incompetent system. The EVTS may provide a restorative treatment for patients with deep venous incompetence.

3.14 IS FAILURE TO PROVIDE THROMBOPROPHYLAXIS NEGLIGENT?

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Over the last 30 years safe and effective venous thromboembolism (VTE) prophylaxis has been achieved and the patients at risk identified. International Consensus and Guidelines on the use of VTE prophylaxis have been available since the 1990s. Is failure to provide venous thromboprophylaxis now considered negligent?

One hundred consecutive medicolegal claims relating to VTE in surgical patients (1990 – 2003) is reported. Prophylaxis had been provided to 43 claimants with risk factors who unfortunately still developed a VTE and alleged negligence. Claims involving the development of VTE in 29 patients who had not received prophylaxis, because they were at low risk, were discontinued as long as their VTE had been diagnosed and treated according to standard medical practice. Claimants that developed a VTE that had been managed incorrectly were successful whether they had received prophylaxis or not.

In 25/28 claims where no prophylaxis was provided, despite identifiable VTE risks factors, the claimant was successful. Three claimants that developed VTE following orthopaedic surgery in the early 1990's, who had VTE risk factors and had not received prophylaxis, were unsuccessful as there was still a significant body of orthopaedic surgeons not using prophylaxis at that stage.

Failure to perform a risk assessment and provide appropriate venous thromboprophylaxis in surgical patients is considered negligent. Clinicians looking after all hospitalised patients who are not assessing their patients' risk for VTE and/or not providing appropriate prophylaxis are at risk of being accused of being negligent.

4.15 VENOUS HYPERTENSION INDUCED VENOUS INSUFFICIENCY AMELIORATED BY DAFLON® 500 MG

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Introduction: Venous reflux is caused by inflammation induced valve re-modeling. This presents a target for pharmacologic therapy.

Objectives: The purpose of this study was to assess by duplex Doppler ultrasound the pharmacologic amelioration of venous insufficiency, valvular reflux and limb edema following induction of venous hypertension by an arteriovenous (a-v) fistula in the Wistar rat.

Methods: The study was designed with 6 groups of animals to be sacrificed at day 1 (Group 1; n=8) and (Group 2 with treatment, n=8), at 7 days (Group 3; n=8) (Group 4 with treatment, n=8) and at 21 days (Group 5; n=8) (Group 6 with treatment, n=8) following the surgery. Twenty four animals in three groups received femoral a-v fistulas and twenty four received 100 mg/kg/day Daflon® 500 mg. Treatment has been administered by gavage 1 day before surgery and during all the study. A group of 4 sham-operated animals has been used as controls. A Duplex Ultrasound (ATL- Philips HDI 5000 and 7-15 MHz transducer Philips Medical Systems, Bothell, WA) was performed for repetitive examinations of the femoral vein, the saphenofemoral junction (SFJ), the saphenous vein and direction of venous flow. At the end of each time-point the animals were euthanized. Blood samples were drawn to test the protease activity (Enzcheck protease assay, Molecular Probes, Invitrogen, Carlsbad, CA). The saphenofemoral junctions of the pressurized limb were harvested to compare with the contralateral SFJ. The fresh specimens were frozen in liquid nitrogen and stored at -70°C. Longitudinal sections (7 microns) were cut across the Saphenofemoral Junction (SFJ) and the valve leaflets with a cryostat at -23°C, and air dried for 30 minutes. Tissue sections were studied by a Gomori Trichrome Technique (Richard Allan Scientific Kalamazoo, MI) while leukocyte infiltration (Granulocyte-CD 52, Serotec Raleigh, NC, Macrophage CD68, Serotec, Raleigh, NC, B Lymphocytes CD45RA, Caltag Burlingame, CA and T Lymphocytes (CD3, Caltag, Burlingame, CA) was investigated by immunofluorescence.

Results: At 21 days, six of eight untreated animals showed ectatic veins in the lower abdomen and in the medial aspect of the operated limb. An increase in thigh and leg circumference due to edema began at 14 days and progressed until sacrifice in untreated animals while treated animals showed significantly less edema. The untreated animals slept with legs elevated. The treated animals did not. Sixteen limbs were scanned with duplex ultrasound. In a-v fistula limbs the subterminal valve distal to the SFJ showed progressive increase in annulus diameter ($p<0.05$) and reflux flow began at 7 days. Daflon® 500 mg treatment reduced this reflux markedly. Reverse blood flow velocity distal to the SFJ was found to be progressively augmented in a manner that resembled human saphenofemoral reflux. This reflux flow was significantly decreased in treated animals ($p<0.05$). Blood flow velocities in the femoral vein, distal to the a-v fistula, showed a progressive increase in reflux throughout all time points and this was reduced by Daflon® 500 mg treatment ($p<0.05$). At 21-days, there was a progressive increase in granulocyte and macrophage infiltration in the junction in controls. The macrophage infiltration was significantly reduced in Daflon® 500 mg treated animals ($p<0.05$), but no significant increase in B and T lymphocyte infiltration in the junction vein wall compared to controls. There was an increase in plasma protease activity in controls that was markedly reduced in treated animals ($p<0.05$).

Conclusions: Venous hypertension produced by an arteriovenous fistula is associated with an increase in plasma serine proteases but decreased in Daflon® 500 mg treated animals. Saphenofemoral granulocyte and macrophage infiltration, venous annulus remodeling, and saphenous vein reflux are also significantly decreased under Daflon® 500 mg treatment.

4.16 ROLE OF TIMP-3 IN CAUSATION OF VARICOSE VEINS

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Background: Imbalance in matrix metalloproteinases, which are key proteinases involved in homeostasis of matrix components, are considered as the primary aetiology of varicose vein disease. TIMP's, which are tissue inhibitors of these matrix metalloproteinases, have an equally important role in this balance. Of the 4 different types of TIMP's, TIMP-3 is different as it has role in proliferation, apoptosis and angiogenesis. Moreover it is the only capable of inhibiting member's adamalysin family, another important proteinase in tissue.

Method: Varicose vein segments were obtained from patients undergoing corrective surgery. Proximal segments were obtained from the Sapheno-femoral junction while distal from the thigh end of the stripped vein segment. Long Saphenous vein from patients undergoing bypass operations were used for comparison. The segments were stained for EVG and Trichrome, to highlight the elastic lamina and smooth muscles, and immunostained for TIMP-3 (mouse monoclonal anti-human antibodies, Chemicon). The images were analysed using AnalySis software. The vein wall thickness was measured as the distance between the luminal endothelium to external elastic lamina. RNA extraction was performed on the vein tissue and the mRNA levels for TIMP-3 were obtained by PCR (Polymerase chain reaction).

Results: TIMP-3 was immunolocalised mostly to the disrupted elastic lamina (external and internal). The controls showed only diffuse staining of smooth muscle cells. The mean thickness of the varicose vein walls were 788 μ m (range 271-1841, n=48). The distal varicose vein segments were found to be thinner than proximal (766.6 vs 574 mm, $p>0.08$). On image analysis, the proximal varicose vein segments expressed more TIMP-3 than distal (0.94 versus 0.41 % median immunopositivity, $p>0.05$). When the vein wall thickness was categorised according to wall thickness, as below 500 mm (atrophic) and above 1000mm (hypertrophic), there was higher TIMP-3 expression in hypertrophic vein wall than atrophic (1.65 vs 0.08 % immunopositivity, $p>0.05$). PCR proved the presence of mRNA TIMP-3 in the varicose veins segments in comparison to controls.

Conclusions: We describe here for the first time the immunopositivity of TIMP-3 in varicose vein wall. TIMP-3 appears to have an affinity for elastic tissue of the vein wall, which was disrupted in varicose veins. Moreover, there was a higher expression of TIMP-3 in proximal vein wall, which was found to be thicker than distal by vein wall thickness measurement. Even more interesting is the higher expression in the hypertrophied varicose vein segments, which confirms the trend. Thus it can be postulated that TIMP-3 is part of the proteinase imbalance in varicose vein wall. The higher expression can be assumed to have a suppressive effect on the matrix turnover, resulting in the possible accumulation of matrix components and resultant thickening. We identified increased transcription of the TIMP-3 gene although protein expression appeared to be similar to that in normal veins.

4.17. LOCAL ANAESTHESIA FOR VARICOSE VEIN STRIPPING

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Objective: Avoidance of general anaesthesia (GA) is quoted as a major advantage of endovascular treatments for varicose veins (VVs). We postulated that junctional ligation, sequential stripping and avulsions for long or short saphenous VVs could be performed under local infiltration anaesthesia (LA) rather than GA in the majority of patients.

Methods: All patients presenting with primary VVs and normal health were offered a choice of LA or GA within a detailed prospective audit recording quantity of VVs and symptoms, operative discomfort and patient satisfaction. 20 patients who had undergone LA LSV surgery 4-5 years previously were recalled for clinical and Duplex ultrasound assessment.

Results: Prospective study: 35 patients chose LA, 13 GA. The groups were well-matched for age, symptoms and quantity of VVs. There were no procedural complications. Mean procedure times (mins): LA 45.7; GA 57.8. Mean pain scores: Day 0 - LA 4.6; GA 5.3. Day 4 - LA 4.5; GA 5.3. Pleasured at 6 weeks: LA 75.8% (15.2% would prefer GA for a re-do); GA 63%

Recall study: No patients had required further VV treatment. 10/20 had no recurrent veins or symptoms and another 2 had minor asymptomatic recurrence. Of 8 patients with symptomatic recurrence, in only 2 were these veins at the original site.

Conclusions: Conventional surgical removal of VVs can be performed quickly and safely under LA alone. Uptake, acceptability and outcomes suggest that LA surgery is a satisfactory option for most patients.

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4.18 THE PROFILES OF MMP-1, -2, -8, -9 AND TIMP-1 IN CHRONIC VENOUS ULCERS

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Introduction: Recalcitrant venous ulcers are characterised by an imbalance in extracellular proteolytic activity with abnormal collagen remodelling and turnover. Elevated expression of various matrix metalloproteinases have been implicated for the excessive MMPs activity. The aim of this study was to study the activity profile of MMPs in chronic venous ulcers.

Methods: Punch biopsies were performed on 63 patients with chronic venous ulcers of at least 6 months. All patients were treated with 3-layer compression bandages and were followed up for 3 months. A further punch biopsy was performed if the ulcer remained unhealed. Both the endogenously activated activity and protein levels of MMP-1, -2, -3, -8, -9 and TIMP-1 were determined using ELISA.

Results: Forty six patients (73%) achieved complete healing by 3 months. The activities of MMP-2 ($p=0.007$) and MMP-8 ($p=0.0007$) were decreased in patients who achieved complete healing. The non-healers demonstrated an reduced activity in MMP-3 ($p=0.004$). The differences in both MMP-1 and MP-9 activities did not reach any significance. Similarly, there was no difference in the total protein levels in all the MMPs between the 2 groups. Significantly increased protein levels of TIMP-1 ($p=0.001$) was noted in the non-healers.

Conclusions: Decreased MMP-2 and MMP-8 activities reflected by an elevated TIMP-1 protein levels may be a prerequisite for ulcers healing. There are no clear relationships between the MMPs and TIMP-1 in this study as evident by an elevated MMP-3 activity suggesting a possible existence of other MMP inhibitors. In addition, MMP regulation follows a distinct spatial and temporal pattern during wound remodelling. This study merely provides a snap shot of what is a complex process.

4.19. A PATIENT SELF-ADMINISTERED QUALITY OF LIFE QUESTIONNAIRE TO COMPLEMENT CLINICAL AND VASCULAR LABORATORY ASSESSMENTS OF VARICOSE VEINS

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Background: Varicose veins is one of the most prevalent surgical conditions in the community. Conventionally, standard clinical and vascular laboratory assessments are used to evaluate disease severity and outcomes from treatment. However, the patient's subjective experience of the condition is also an important severity and outcome parameter, which may differ significantly from other types of assessment. This study developed and validated a simple questionnaire for determining the impact of varicose veins on quality of life (QOL), and relates this to the standard assessments.

Methods: The Otago varicose veins condition-specific questionnaire (CSQ) was developed based on extensive literature review, expert opinion, and patient feedback. 133 patients with varicose veins completed the questionnaire, along with other QOL measures: the Aberdeen Varicose Veins Questionnaire (AVVQ), the Short Form-36 Health Survey (SF-36), and a single visual analogue rating scale asking about global condition impact (GR). Practicality, validity and reliability of the CSQ were assessed using standard psychometric criteria. The CSQ was correlated with standardised clinical and vascular laboratory measures including Venous Clinical Severity Score, the CEAP classification, as well as air plethysmography and ultrasound measures.

Results: Average completion time for the CSQ was 3.5 minutes (range 1.1-10.0), and patients found its content relevant and concise. The CSQ questions demonstrated excellent internal consistency (Cronbach's $\alpha=0.92$) and test-retest reliability (ICC=0.94). Validity was supported through high correlations with the AVVQ ($r=0.80$), the GR ($r=0.61$), and the related dimensions of the SF-36. However the relationship of the CSQ to the clinical and laboratory measures were not strong.

Conclusions: Our CSQ is a practical, valid and reliable tool for determining the impact of varicose veins on QOL. Failure to relate closely with the clinical and laboratory measures suggests that the CSQ captures important additional patient focussed information for evaluating disease severity and outcomes from treatment.

4.20. ELEVATED LIPOPROTEIN (A) LEVELS: A NEW BIOLOGICAL MARKER OF VENOUS THROMBOEMBOLIC RISK

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Introduction: Biological evidence suggest that lipoprotein (a) may modulate fibrinolysis, not only by competing plasminogen for binding sites to fibrin or over annexin in endothelial cells (both have similar structures), but also for enhancing functional levels of PAI-1 and inhibiting plasminogen activators. Highest levels of this lipoprotein are independently associated with increased risk of arterial thrombosis and premature atherothrombosis, on account of this important fibrinolysis dysregulation, we hypothesize, that furthermore highest lipoprotein (a) levels could be a prothrombotic risk factor for venous thromboembolism.

Material and methods: **Study design:** observational study. All patients were diagnosed, treated and followed by one of us (FC) in one University Hospital. **Study period:** all patients with definitively proved thromboembolism episode founded between 1996 and 2001. **Patients:** episodes of deep venous thrombosis were documented in all patients by phlebography or echo-doppler. Similarly pulmonary embolism was assessed by perfusion/ventilation lung scan. All patients were followed for at least one year. Additional hypercoagulable workup and cancer survey, clinical and biological, was carried out in all cases. **Methods:** blood levels of Lipoprotein (a) were measured by an immunoprecipitation technique (SPQTM Diasorin). At least two determinations were practiced, the first one: three months after the acute episode.

Results: The distribution curve of normal and pathological Lipoprotein (a) levels has a leptocurtosis form, founded in several studies, ei Munster Heart Study, Simo JL *et al* 2003, and correlate with the lipoprotein weight and size. We considered for evaluation, only patients with highest levels: above the upper 85th percentile of our distribution in normal subjects ($>55\text{mg/dl}$; median 18.4mg/dl). We found a total of 33 patients with Lipoprotein (a) levels above the pre-established values. Sex ratio was 14 men vs. 19 women. The mean age was 62 ± 14 years (eight patients were younger than 50). We found seven cases with pulmonary embolism and other six with iliac or subclavian deep vein thrombosis. In twenty cases no manifest cause was found that could have precipitated clinical thrombosis and were classified as of idiopathic origin. Relapse of the thrombotic condition was found in 18 % in the following years. Two patients developed myocardial infarction and six had associated chronic limb ischemia. Three patients were affected by malignancies. Average levels of Lipoprotein (a) were $80.8 \pm 28.2\text{mg/dl}$ (range $56 - 150\text{mg/dl}$) in the population described. With the exception of one patient, all others had persistently increased levels of Lipoprotein (a) in the follow-up. Cholesterol levels were below 220mg/dl in 17 patients. Hypercoagulable workup in these patients demonstrated Hyperhomocysteinemia in 3 cases, Activated Protein C Resistance in 3 others cases and associations of the previous condition in two more cases. No biological defects were detected in the remaining 25 patients (22 if patients with malignancies were excluded). Attempts to reduce Lipoprotein (a) levels with current therapies were unsuccessful.

Conclusions: In our experience, very high Lipoprotein (a) levels could become the third persistent biological anomaly found in patients with thromboembolism, after Activated Protein C Resistance and Hyperhomocysteinemia. Elevated Lipoprotein (a) levels would be immediately followed by the association of two or more thrombophilic factors. The high cut-off point employed in our study minimizes the effect of large right skewness found for Lipoprotein (a) level distribution in otherwise normal health population from different ethnics and gender. The elevation found in Lipoprotein (a) did not correlate with cholesterol levels. The alteration described was often observed in young women, frequently associated with other thrombophilic factors and corresponded with more severe form of the disease. Determining the rates at which the alteration in Lipoprotein (a) is a direct cause, a predisposing state or a part of some association will require more extensive study.

21 THE USE OF D-DIMER AND PRETEST CLINICAL PROBABILITY TO DETERMINE THE NEED FOR DUPLEX ULTRASONOGRAPHY IN THE DIAGNOSIS OF DEEP VEIN THROMBOSIS

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Background: Both d-dimer assay and duplex ultrasonography (DU) aid in the diagnosis of deep venous thrombosis (DVT). D-dimer assays are promptly attainable; however, DU may be less readily available during off hours at our Veterans Administration hospital system. To facilitate better vascular lab utilization and to standardize efforts of the emergency room, an algorithm was implemented for patients with possible DVT.

Methods: Emergency room patients with lower extremity complaints and a suspicion of DVT underwent d-dimer analysis. A separate pretest risk factor DVT probability calculation was performed, which consisted of ten clinical components, with the sum stratifying the clinical probability of DVT into either low, moderate, or high. Low-risk group (LRG) and moderate risk group (MRG) patients with an elevated d-dimer value were to be referred for DU. In addition, DU was recommended for MRG patients with a normal d-dimer, and all high risk group (HRG) patients required DU. All patients with high suspicion for DVT and negative DU were referred for additional follow-up with either the vascular lab or primary physician. In some cases, patients with a high DVT suspicion were discharged with lovenox therapy when DU was not readily available.

Results: 66 emergency room patients underwent d-dimer analysis for suspected DVT in the last year per protocol. In the LRG, 13 patients had a DU performed with no DVTs or related admissions. The MRG had 26 patients undergoing duplex testing, with 7 demonstrating a DVT on DU. In the HRG, 10 patients had an elevated d-dimer with 4 having a DVT diagnosed. As illustrated by the following table, there were significant differences in the d-dimer levels and the diagnosis of DVTs between the pretest groups. As expected, the frequency of DVTs increased with a higher clinical score, especially when associated with an elevated d-dimer.

	LRG (n=26)	MRG (n=30)	HRG (n=10)
Mean d-dimer (ng/ml)	907±878	1602±1559	3059±1931
Elevated d-dimer (p<.015)	13 (50%)	21 (70%)	10 (100%)
Duplexes performed (p<.001)	13 (50%)	26 (87%)	10 (100%)
With elevated d-dimer	9 (69%)	19 (73%)	10 (100%)
Acute DVT (p<.024)	0	7 (23%)	4 (40%)
Elevated d-dimer in patients with a DVT	—	7 (100%)	4 (100%)
DVT related admissions (p<.012)	0	2 (7%)	3 (30%)

Compliance with the algorithm was observed in at least 70% of the patients the LRG and MRG, and in all of the HRG patients. All patients with elevated d-dimers but no visualized DVTs were referred back to their primary care physician for follow-up. There was one patient where an afterhours DU was performed. The patient had a DVT and was treated as an outpatient. There have been no reported adverse events.

Conclusions: The implementation of this algorithm for DU testing and DVT analysis appears safe and practical. It seems that we can continue this algorithm with excellent patient care and resource utilization.

22 OPEN ENDOPHLEBECTOMY AND ENDOVENOUS STENTING FOR CHRONIC THROMBOSIS OF THE INFERIOR VENA CAVA AND THE ILOFEMORAL VEINS

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Purpose: Endovascular treatment for chronic thrombosis of the inferior vena cava (IVC) or iliofemoral vein (IFV) has a high chance of failure if venous inflow is poor due to occlusion or stenosis of the common femoral vein (CFV). This series describes our early results of combined CFV endophlebectomy and IFV±IVC stenting for patients with advanced post-thrombotic syndrome.

Methods: Data from eight consecutive patients who underwent combined open and endovascular recanalization of the IFV±IVC stenting between January 1st, 2002 and September 1st, 2005 were entered in a prospective database. All patients had open CFV endophlebectomy with bovine pericardial patch venoplasty, followed by recanalization and stenting of 12 chronically occluded (11) or stenosed (1) IFV (mean stented length, 14±3 cm). Four patients required IVC stenting (mean stented length, 16±9 cm). Pre- and post-operative CEAP classification was documented. Duplex ultrasound was obtained at dismissal and every six months.

Results: Six male and two female patients (mean age, 41±5 years) were treated. Preoperative CEAP classification in 12 limbs was class 3 in four limbs, class 4 in four, class 5 in one and class 6 in three. No patients died. Two patients had intraoperative CFV disruption from stents, successfully treated with venorrhaphy and covered stent (1 each). One patient had early IFV reocclusion, successfully treated with thrombectomy, femoral arteriovenous fistula and deep femoral vein stenting. Mean post-operative hospital stay was 4±3 days. All 12 limbs had early clinical improvement. Postoperative CEAP classification was improved to class 2 in five limbs, class 3 in three, and class 5 in four. All class 6 patients healed their ulcers at 2-, 2- and 3-months. At mean follow up of 10 months (range, 1-25 months), 3 late IFVs occluded and 2 restenosed in 5 limbs of 5 patients. One patient remained asymptomatic without further treatment. One patient had recurrent limb edema but failed attempted percutaneous recanalization. One patient had non-occlusive thrombus successfully treated with lytic therapy. Two patients underwent successful repeat stenting for restenoses. Primary, assisted-primary and secondary patency rates of IFV stents was 56%, 83%, and 100% at 6-months, respectively. All IVC stents and CFV endophlebectomy sites remained patent.

Conclusions: Combined open endophlebectomy and stenting of chronically occluded IFVs or the IVC carries low morbidity, no mortality and good early clinical results. Although reocclusion or restenosis occurs in 44% of the limbs at 6 months, symptomatic patients can be treated successfully with repeat catheter-based procedures. Femoral endophlebectomy may provide adequate venous inflow and allow endovascular treatment of patients previously considered unsuitable for IFV and IVC stenting.

5.23 STRIPPING VS HAEMODYNAMIC CORRECTION (CHIVA): A LONG TERM RANDOMISED TRIAL

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Background: Superiority of stripping procedure versus sclero-therapy has been assessed in the past in several controlled studies, whereas there are no randomised studies assessing in a long-term period the value of conventional stripping versus other surgical procedures.

Aims: To compare the long-term results of stripping vs. haemodynamic correction (CHIVA) in treatment of superficial chronic venous insufficiency (CVI).

Methods: 150 patients affected by CVI, CEAP clinical class 2-6, were randomised to stripping or to CHIVA, preceded by pre-operative Duplex mapping. End-points were: objective and subjective results assessed by the means of the Hobbs score (Hobbs score ranges from 1 to 4, with 4 representing the worst result), either by an independent assessor or by the patients at their own control, respectively; rate of recurrences assessed both by physical and duplex examinations in both groups.

Results: Mean follow-up lasted 10 years, 26 patients were lost, resulting in 54 patients (32 females, and 22 males) in the stripping group, and in 70 patients (59 females, and 11 males) in the CHIVA one. Subjective Hobbs score was not statistically different in both groups. On the contrary, objective assessment resulted significantly better in the CHIVA group (1.94 ± 0.09 vs 2.24 ± 0.12 , $P < 0.038$). Varicose veins recurrence rate was significantly higher in the stripping group as compared to CHIVA (18% and 35%, respectively, $P < 0.04$), without significant differences in the rate of recurrences from the sapheno-femoral junction.

Conclusions: This study demonstrates that varicose veins more easily recur along time in the Stripping group. Since, no significant differences were found in recurrences from the sapheno-femoral junction, such result could be speculatively related to the presence of a draining saphenous system in the CHIVA group.

5.24 FOAM INJECTION SCLEROTHERAPY CURES VEINS WITH A SINGLE INJECTION: FACT OR FICTION?

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In the current economic and political climate, public health sector hospital resources can be overwhelmed by the burden of work produced in treating the effects of venous hypertension. This results in long waiting lists for the treatment of varicose veins. Foam injection has been shown to be efficacious and safe. The aim of this analysis of a prospective database was to determine the efficacy and safety of polidocanol foam injection sclerotherapy in a clinical setting where intensive follow-up and treatment is not possible.

Patients and methods: 89 patients [69 females, mean age 59 (range 32-86) years] were treated with ultrasound guided foam injection sclerotherapy for symptomatic varicose veins. A total of 163 procedures were performed in 103 legs. 54/103 (52%) legs had previous surgery for varicose veins. 65/103 (62%) legs were classified as CEAP clinical class 2, 17 (17%) class 4, 11 (11%) class 5 and 5 (5%) class 6. All patients underwent a clinical examination and duplex ultrasound prior to treatment. Foam was produced using the Tessari method with a 4:1 ratio of polidocanol (0.5-3%) to air. Post-procedure compression was applied in the form of two class 2 stockings. Clinical and duplex examination and any necessary re-injection were performed at 6 weeks, 6 months and then 6 monthly intervals.

Results: The average follow-up post treatment was 6 (range 0-24) months. 17 patients were lost to follow-up. Complete abolition of reflux was achieved in only 49/86 (57%) legs after an average of 1.1 treatments. Of these 7/49 (14%) showed evidence of re-canalization an average of 11 (range 6-18) months post closure. Partial closure was achieved in 23/86 (27%), while 14/86 (16%) remained open.

	Duplex Success	Duplex Failure	
Peripheral veins occluded	39 (45%)	13 (15%)	52 (60%)
Peripheral veins open	10 (12%)	24 (28%)	34 (40%)
	49 (57%)	37 (43%)	86

33/86 (38%) legs showed skin staining and 11/86 (13%) patients reported phlebitis requiring analgesia. 1 patient suffered a peri-procedural stroke with full recovery and 1 patient developed a calf deep vein thrombosis.

Conclusions: A technical success rate of 60% suggests that a more aggressive follow-up and re-injection protocol is required to achieve the excellent results published in the literature. There is a significant incidence of skin staining. Patient consent needs to include the possibility of the rare, but potentially major complications that may accompany this procedure.

5.25 DISEASE SEVERITY SCORES FOR VARICOSE VEINS: THEIR RELIABILITY IN ASSESSING THE OUTCOME OF ENDOVENOUS LASER ABLATION (EVLA) AND RECOMMENDATIONS FOR FUTURE STUDIES

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Aims: The severity of symptoms attributable to varicose veins can be assessed by the CEAP clinical stage (C), the Venous Clinical Severity Score (VCSS) and the Aberdeen Varicose Vein Symptom Severity Score (AVVSS). The AVVSS also assesses the extent of the varicosities and the impact of these and associated symptoms on quality of life. This study examines the effectiveness of these scoring systems in determining the effect of varicose vein treatment by EVLA.

Methods: The clinical stage (C) of CEAP, and both the VCSS and AVVSS were recorded before and after great saphenous EVLA for varicose veins in 217 patients (most severely symptomatic leg score recorded if bilateral).

Results: Pre- and post-EVLA scores (\pm iqr) were: CEAP: C2 (C2-4) v C0 (C1-2), $p < 0.01$; VCSS: 4 (2-7) v 0 (0-1), $p < 0.001$; AVVSS: 14.7 (11.3-21.6) v 6.0 (3.4-8.7), $p < 0.001$. Although these differences were significant, 56/217 (26%) patients were classified as C2 both before and after EVLA. In these 56 patients the VCSS and AVVSS improved from 3 (2-4) to 1 (1-2), $p < 0.05$, and from 12.5 (4.6-15.8) to 4.8 (1.2-8.4), $p < 0.001$ respectively. Further, there were significant correlations between AVVSS and VCSS: pre-EVLA: $r = 0.726$, $p < 0.001$; post-EVLA: $r = 0.586$, $p < 0.001$; improvement in score post-EVLA: $r = 0.642$, $p < 0.001$.

Conclusions: The CEAP classification is insensitive in assessing the impact of great saphenous vein EVLA upon symptoms. In contrast both VCSS and AVVSS appear to be useful in gauging the effectiveness of therapy. One or both of these tools should be used in future studies examining the impact of new treatments for varicose veins.

5.26 SURGICAL TREATMENT OF VARICOSE VEINS: COMPARATIVE STUDY BETWEEN TWO DIFFERENT TECHNIQUES

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Objective: To compare the results obtained after five years of surgical treatment of varicose veins using two different modalities of treatment: long saphenous vein stripping and conservative haemodynamic surgical therapy (CHIVA).

Material and methods: Randomised prospective study on a population of 100 patients with varicose veins. 62 women/38 men. Mean age 49 years. Inclusion criteria: varicose veins with a long saphenous vein insufficiency. Exclusion criteria: any deep venous system pathology, previous treatment on varicose veins. All patients had a venous superficial system duplex mapping study (ATL Ultramark 9HDI). Patients were allocated into two groups. Group I: 49 submitted to stripping and Group II: 51 patients who underwent a CHIVA technique. There were any statistical differences according to CEAP classification. Patients were followed up to 5 years. Initially at 7 days, then at 3, 6 months and finally yearly. We evaluated clinical and aesthetic parameters (subjective and objective) and recurrences.

Results: Group I: working difficulties for 19.2 days and 22.4% of saphenous nerve neuritis as compared to 7.8 and 0%, respectively in group II. However in group II we detected 25.5% saphenous phlebitis (11.7% symptomatic) at first month, resolved after six months. At 5-year period:

	Group I	Group II	p
Clinical			
Asymptomatic	20	26	ns
Improved	25	20	ns
Failure	2	2	ns
Subjective esthetical			
Satisfied	43	45	ns
Not satisfied	5	3	ns
Objective esthetical			
No varicose veins	10	16	ns
Varicose veins < 5 mm	21	17	ns
Varicose veins > 5 mm in legs or thighs	9	13	ns
Varicose veins > 5 mm in legs and thighs	8	2	ns

Conclusions: There were no statistical differences on clinical and cosmetic parameters at 5-years follow-up between these two groups. Nevertheless, CHIVA technique offers better results related to clinical recovery and neuritis, but higher rate of LSV phlebitis.

6.27 ULTRASONIC VENOUS VALVE IMAGING - A PREREQUISITE FOR EXOSTENT REPAIR

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Background: Lower limb venous disease remains a significant problem in our community today. The condition has been treated mainly with ablative procedures such as stripping and or sclerotherapy. The aim of this study was to define the ultrasonic features of repairable venous valves by External Valvular Stenting (EVS). In addition, to assess the ability to predict success of EVS determined intra-operatively and at three-months post-operatively.

Methods: Valves considered for EVS were assessed with Brightness-Mode (B-Mode), Spectral Pulsed Doppler (PD), Colour Doppler Imaging (CDI) and Brightness-Flow (B-Flow). The ultrasonic features of the great saphenous vein (GSV), terminal valve (TV) and sub-terminal valves (STV) were considered. Inclusion criteria were; valvular ring dilation <12 mm in diameter, (GSV) internal diameter (ID) <12 mm along the entire length of the trunk, symmetry of the valve sinuses, positive identification of two valve cusps, and symmetrical reflux flow patterns through the incompetent valve. There were 69 limbs included in the study. All repaired TV's were tested intra-operatively for competence after application of the EVS. If there was evidence of residual reflux, the STV was also repaired. The operated limbs were assessed clinically 3 months after the procedure at which time ultrasound was also used to test the repaired valves.

Results: Of the 69 TV's that were examined pre-operatively, a total of 50 were considered repairable by ultrasonic features (72%). At operation, 44 of these valves were successfully repaired (88%). In the 6 limbs which had residual TV reflux, the STV was repaired. All 6 had competence in the GSV trunk following the STV EVS. Of the 19 TV's that were considered by ultrasonic features to be unrepairable, 18 had gross reflux following EVS with 1 only repaired being successful. All limbs that were successfully repaired at operation were followed up 3 months later, and re-examined with diagnostic ultrasound. Of this group; 3 GSV's had residual reflux at the TV and STV, 1 GSV had major reflux and 1 GSV developed thrombophlebitis. The overall figures for the predictability of successful EVS based on ultrasonic features of the valve were; sensitivity 97.8% (95% CI, 88.2 - 99.6), specificity 75% (95% CI 53.3 - 90.2) and accuracy 90.4%.

Conclusions: In the treatment of varicose veins, a combination of ultrasound modalities accurately predicts EVS outcomes at the TV and STV of the GSV.

6.28 SURGICAL SOLUTION OF THE ENIGMA OF THE GASTROCNEMIUS VEIN

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Background: Chronic Venous Insufficiency (CVI) with reflux from the Gastrocnemius Vein (GV) was defined by John Hobbs as the enigma of the GV, due to the difficulty in diagnosis and treatment. Nowadays, pre-operative assessment by the means of duplex allows further interpretation of such haemodynamic pattern.

Aims: To define the prevalence of GV reflux in patients affected by CVI of the Small Saphenous Vein (SSV) territory, the relative haemodynamic patterns, and finally the surgical management.

Methods: From May 2002 to November 2005 we performed 548 pre-operative mappings in patients affected by primary CVI of the SSV district. Patients were investigated in standing position by duplex scan (Esaote MyLab -probe 7.5 MHz), eliciting reflux in the different venous segments by both Valsalva and squeezing maneuvers. Reflux elimination was pre-operatively tested with finger compression of superficial veins representing the superficial re-entry of the GV. Operations consisted in flush ligation and surgical disconnection of such superficial veins in a Day Surgery setting.

Results: We found 19 cases (3.5%) of GV reflux associated with insufficiency of veins of the SSV territory, with 5 different haemodynamic patterns illustrated in the figure 1.

In all cases GV reflux was negative under Valsalva maneuver and positive under Squeezing. Furthermore, we pre-operatively demonstrated by finger compression of the insufficient superficial vein the elimination of reflux in the GV. This maneuver abolishes the gradient due to the insufficiency of the superficial vein connected with the GV. Surgical correction performed according to such test, persisted at mean follow up of 12 months.

Conclusions: GV reflux associated with insufficiency of vein of SSV territory is the haemodynamic consequence of a gravitational gradient. Haemodynamic correction surgery by acting indirectly on the insufficient superficial veins successfully manages deep reflux.

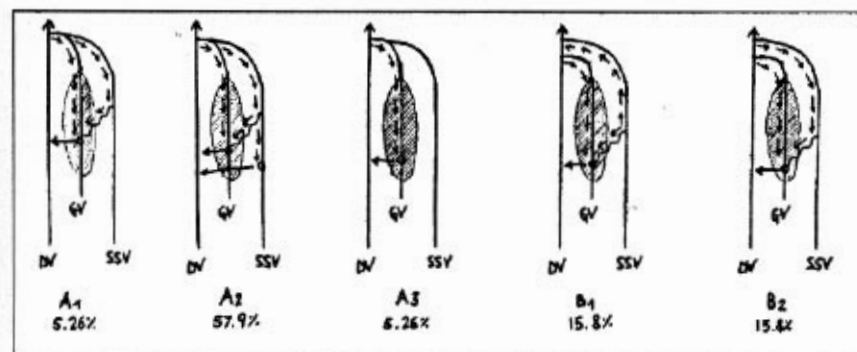


Figure 1.

6.29 CONTINUOUS AMBULATORY VENOUS PRESSURE MONITORING - A STEP FORWARD IN QUANTIFYING VENOUS REFLUX

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Aim: To compare the association of variables determined from a new technique of Continuous Ambulatory Venous Pressure Monitoring (CAVPM) and those of the gold-standard AVP measurement with the severity of chronic venous insufficiency as determined by the CEAP classification.

Materials and methods: Sixty-seven limbs of 62 patients with CVI and 15 normal controls were studied. CVI clinical severity was classified according to CEAP clinical groups as: C2&C3 (mild disease), C4 (moderate disease) and C5&C6 (severe disease). All participants underwent duplex ultrasound scanning to define the source of reflux and were classified anatomically as: "no reflux" (controls), superficial reflux (As2-5), superficial with perforator reflux (As2-5, Ap17,18) and any reflux with deep reflux (Ad11-16). Conventional tiptoe AVP measurements and 90% refilling time (RT90) were compared to the new CAVPM variables: mean walking pressure (MWP) and % fall in walking pressure (%FWP) during walking at 2 miles per hour. Data were analysed using Kruskal-Wallis tests, Mann-Whitney tests and discriminant analysis.

Results: Measurements of conventional AVP and RT90 were not significantly different between CEAP anatomical groups. Conventional AVP measurements could not differentiate between the control group and the presence of mild disease (C2&C3), ($p=0.56$) but differentiated between controls and severe disease (C5&C6) as well as mild and severe disease ($p<0.001$). RT90 was significantly different between controls and all patient groups ($p<0.001$), but not between groups of progressive CEAP clinical severity ($p=0.5$). MWP and %FWP measurements were significantly different between all CEAP anatomical reflux groups ($p<0.001$). MWP and %FWP showed significant differences between all CEAP clinical severity groups and controls ($p<0.001$). Based on discriminant analyses, the overall abilities of MWP and %FWP measurements to accurately classify limbs into correct anatomical CEAP classes were 51% and 58% respectively, compared with the ability of AVP and RT90; 34% and 44% respectively. The overall abilities of MWP and %FWP to accurately classify limbs into correct clinical CEAP classes were 53% and 48% respectively, compared with the ability of AVP and RT90; 31% and 38% respectively. Factors that correlate strongly with MWP and %FWP are the presence of 2 or more incompetent perforators and BMI.

Conclusions: The CAVPM variables, MWP and %FWP are more reliably associated with the CEAP clinical and anatomical classifications of CVI than the "gold standard" investigations; AVP and RT90 in the quantitative assessment of CVI.

6.30 COMPARISON OF THREE INTERMITTENT PNEUMATIC COMPRESSION SYSTEMS IN PATIENTS WITH VARICOSE VEINS: A HAEMODYNAMIC STUDY

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Objective: Previous studies have demonstrated the haemodynamic and clinical superiority of sequential leg compression, compared to uniform compression. The aim of our study was to compare the haemodynamic effectiveness of the portable sequential compression device (SCD Express) with a rapid inflation device (Venaflow) and a uniform compression device (Flowtron Universal).

Materials and methods: Twelve patients with primary bilateral varicose veins participated in this open, controlled trial. The three devices were tested in the semirecumbent position and thigh length sleeves were used. Augmented flow velocity and volume flow, including the total volume of blood expelled per hour during compression were measured with duplex ultrasound at the level of the common femoral vein. Postcompression refilling time determined from velocity recordings of the common femoral vein using duplex ultrasound.

Results: All three devices significantly increased venous flow velocity, up to 5.4 times the baseline (all $p<0.001$). The SCD Express by augmenting flow throughout its compression cycle achieved better flow enhancement [609.2 (492.2-694.2) ml/min] than the Flowtron device [441.0 (394.4-655.6) ml/min], $p=0.01$. Total volume of blood expelled per hour was significantly higher with the SCD Express device [7633.0 (6025.0-9064.5) ml/Hr], compared with both the Flowtron [5259.7 (4537.3-8079.3) ml/Hr, $p=0.002$] and Venaflow [3342.5 (2710.9-4973.0) ml/Hr, $p=0.002$]. Postcompression refilling time of the SCD Express [28.2 (23.7-29.8) sec] was significantly longer compared to Venaflow [19.7 (16.3-25.8) sec, $p=0.034$] and Flowtron [25.5 (22.3-31.8) sec, $p=0.48$] devices, indicating better vein evacuation.

Conclusions: Sequential compression showed haemodynamic superiority compared to uniform compression and rapid inflation devices. The relative effectiveness of the three devices in DVT prevention should be tested in future studies.

6.31 SHORT AND MID-TERM EVOLUTION OF ISOLATED SYMPTOMATIC MUSCULAR CALF VEIN THROMBOSIS

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Background: Although it is a common observation in everyday practice, scant publications address muscular calf vein thrombosis (MCVT).

Aims: to evaluate short and mid-term evolution of isolated symptomatic MCVTs.

Method: We have included prospectively and consecutively all patients referred to outpatient clinic for suspicion of Deep Vein Thrombosis and presenting with MCVT. Clinical signs were: pain and/or oedema of the calf. Diagnosis was established with duplex ultrasound examination (DUS). Non completely occlusive and non symptomatic MCVTs were excluded. Patients have been followed-up both clinically and with DUS at one, three and nine months and up to the 36th month. Full Anticoagulation, associated with compression, has been prescribed to all patients for one month and extended two more months in case of incomplete recanalisation at one month or in case of risk factors of Venous Thrombo Embolism (VTE): history of recurrent venous thrombosis, post-thrombotic syndrome, thrombophilia, cancer, etc.

Results: One hundred and twenty eight patients presenting with 131 MCVTs have been included; 78 (60.9%) females and 50 males; mean age was 57.02 years \pm 15.36 (median: 57; range 20-87). Seventy three (55.7%) thrombosis of medial gastrocnemius veins (MGV) and 58 (44.3%) thrombosis of soleal veins (SV) have been enrolled. Initial symptoms were: calf pain (n=125), isolated or associated to oedema (n=34); or isolated oedema (n=6). Anticoagulant therapy has been prescribed to 88 patients (67.2%) for one month, 62 (47.3%) for three months and 13 (9.9%) for 6 months or more, due to the presence of Pulmonary Embolism (PE) or major VTE risk factors. Nine PEs (6.9%), clinically suspected and confirmed with X Rays, complicated MCVT at initial examination, six (10.3%) in the MGV group, three (4.1%) in the SV group (P : NS). Two non lethal hemorrhagic events were observed; three patients died during the follow-up knowing that the anticoagulation was overed. Recanalisation of MCVT was considered satisfactory (i.e. complete recanalisation or presence of a simple venous wall or valvular thickening) at one, three, and nine months in respectively 54.8%, 85.7%, and 95.3% of cases, without significant difference between the MGV and the SV groups. Forty one VTE recurrences (other localization or new thrombosis after recanalisation) have been observed in 33 patients, with comparable figures in both thrombosis groups: none at one month, two at three months, 13 at nine months and 26 between 9 and 36 months. There were 6 non lethal PEs, 23 deep or muscular venous thrombosis and 12 superficial venous thrombophlebitis.

Conclusions: This study confirms the high prevalence of PE at initial diagnosis of MCVT; mid-term follow-up (mean 26.7 months) revealed that at least one VTE recurrence event occurred in 25% of patients. These results underline the need for clarifying the treatment of MCVTs as so far, no guidelines are available.

6.32 A REPRODUCIBILITY STUDY ON THE IMMEDIATE HEMODYNAMIC EFFECT OF THE ADDITIONAL USE OF THE SCD EXPRESSTM COMPRESSION SYSTEM IN PATIENTS WITH VENOUS ULCERS TREATED WITH THE FOUR-LAYER COMPRESSION BANDING SYSTEM

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Aim: The aim of this reproducibility study is to compare the ultrasound (U/S) measurements of the Volume Flow (VF) calculated individually (VFi) versus those provided by the in-build program of the U/S (VFt). Also whether measuring the VF and Peak Systolic Velocity (PSV) at a 10 versus 5 seconds sweep screen has any advantages.

Patients and methods: 18 venous ulcer patients, 9 male and 9 female, mean age 72 years (range, 47-85) provided 20 legs for this study. The VF, PSV and venous diameter (VD) were obtained at the popliteal vein with U/S. Measurements were performed (i) without bandage, with (ii) four-layer bandage and (iii) following the application of the SCD EXPRESSTM Compression System on top of four-layer bandage for at least 15 minutes. The VD and the VFi of each individual second (for 4 seconds) and that provided by the U/S over 4 seconds, VFt, were recorded. All measurements were repeated 5 times and the average value was recorded. In addition in nine patients the above measurements were repeated on 11 seconds on a 10 second sweep speed setting for the spectral Doppler.

Results: The mean VD was 88 mm without bandage, 91 mm with four-layer bandage and 89 mm with the addition of the SCD. The median & interquartile range of the VFi (in ml/min) recorded individually for each of the 4 seconds was: 75.68 (58.56-100.6) without bandage, 111.09 (89.84-157.30) with four-layer bandage and 293.92 (236.98-388.12) with the addition of the SCD. The median & interquartile range of the VFt (in ml/min) as calculated by the U/S was: 71.34 (57.42-100.65) without bandage, 111.59 (89.49-147.72) with four-layer bandage and 291.21 (241.06-391.96) with the addition of the SCD System (Kendall's coefficient of concordance .905). The median & interquartile range of the PSV (in cm/sec) was 8.4 (6.81-14.21) without bandage, 12.65 (8.98-18.64) with four-layer bandage and 27.39 (21.1-30.58) with the addition of the SCD System (p<0.001). As expected on the 10 seconds sweep speed the values of the VF between the 4 and 11 seconds were identical. The PSV measured at the 4 and 11 seconds had a Kendall's coefficient of concordance of 0.918.

Conclusions: The results indicate that in haemodynamic studies, measurements by the in-build program of the U/S are equally reliable as those recorded manually. Also the speed setting for the spectral Doppler whether 5 or 10 seconds does not affect the measurements. Both VF and PSV increased slightly with the addition of the four-layer bandage. However, with the addition of the SCD System these parameters increased three fold.