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Validation of a New Duplex Derived Haemodynamic Effectiveness Score, the Saphenous Treatment Score, in Quantifying Varicose Vein Treatments☆

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WHAT THIS PAPER ADDS

- This paper introduces the saphenous treatment score (STS). It is a novel duplex-derived haemodynamic assessment of the great saphenous vein. Reflux, competency and occlusion are recorded before and after treatment, above and below the knee. Descriptive outcome terms like recanalisation and length of obliteration are replaced with numerical scores. This study has demonstrated that the STS is responsive to different treatments and ongoing treatments and shown that it may be used to complement other assessment tools in evaluating outcomes.

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Objectives: To evaluate a duplex-derived score for varicose vein treatments using numerical values of haemodynamic effectiveness.
Design: The saphenous treatment score (STS) was developed prospectively to compare the effect of endovenous treatments on reflux within saphenous segments.
Patients: Sixty-six patients were randomised to endovenous laser ablation (EVLA) or ultrasound-guided foam sclerotherapy (UGFS) to the great saphenous vein (GSV).
Methods: Assessments included the Aberdeen varicose vein severity score (AVVSS), the venous clinical severity score (VCSS), the venous filling index (VFI) and the STS.
Results: A mean STS of 5.70 decreased to 3.30, $P < .0005$, post-treatment. The median (IQR) AVVSS, VCSS and VFI (ml/sec) decreased from 21.52(15.48) to 18.86(11.27), $P = .14$, from 6(4) to 3(4), $P < .0005$ and from 7.1(6.9) to 1.9(.9) $P < .0005$, respectively. In 15 patients requiring additional UGFS the mean STS values decreased from 5.8 to 4.13 and then to 2.6 $P < .0005$, respectively. The individual above and below knee mean treatment differences in STS on 38 EVLA and 28 UGFS patients were 1.92 and .87 (EVLA) compared to 1.57and .29 (UGFS) $P = .001$, respectively.
Conclusions: The STS has been shown to grade the haemodynamic effects of different treatments as well as ongoing treatments on the GSV.

Introduction

Endovenous treatments for varicose veins like foam sclerotherapy, laser and radio-frequency ablation have evolved alongside traditional sapheno-femoral ligation, stripping and multiple phlebectomies. Combinations of treatments are also popular with one technique used for the truncal veins and a different treatment used to obliterate the tributaries.

Treatments aimed at abolishing great saphenous vein (GSV) reflux can have varying results with co-existing areas of reflux, competency and occlusion in the above knee (AK) and below knee (BK) segments of the same saphenous trunk. These post-treatment patterns are difficult to standardise with most reports relying on descriptive terms, like partial recanalisation, rather than using numerical scores. This is in contrast to other scoring systems,which

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have a scale upon which to quantify severity and the results of treatment.

The current duplex-derived venous segmental disease score (VSDS)[1] has a single outcome value, 1 for reflux and 1 for occlusion, for the length of the GSV and consequently lacks the dynamic sensitivity to quantify saphenous treatments (Table 1). Thus a focused, dynamic scoring system on the effects of treatment on the saphenous trunk is proposed.

The saphenous treatment score (STS) is a duplex-derived haemodynamic outcome evaluation which grades the significance of co-existing haemodynamic patterns throughout the saphenous trunk. It is not an assessment which describes the length of GSV obliteration. Obliteration is a technical success but if reflux is present in other areas of the GSV this may result in haemodynamic failure, which will be recorded in the STS. The STS therefore has the potential to compare endovenous treatments to surgical solutions.

A refluxing BK-GSV has been demonstrated to be clinically significant. The extent of reflux below the knee leads to worse symptoms and signs, with a greater likelihood of residual varicose veins. If the GSV is ablated for a longer length it is associated with a better outcome and if a refluxing BK-GSV is neglected then there are often residual symptoms with an increased need for sclerotherapy.[2] It is therefore justified to include the BK-GSV in a scoring system following treatment since this is likely to have a clinical impact.

The STS focuses on the haemodynamic post-treatment effects on the GSV trunk compared to the pre-treatment value. It uses a weighting system to prioritize reflux, competency and obliteration, and assesses both the AK and BK segments of the GSV.

The aim of this study was to evaluate a haemodynamic scoring system, the STS, to grade different varicose vein treatments, ongoing treatments and compare them to other validated assessments.

Methods

Study design

This was a randomised study achieved using sealed envelopes. Sixty-six consecutive patients (66 legs) received either endovenous laser ablation (EVLA) or ultrasound-guided foam sclerotherapy (UGFS) for varicose veins during 2009–2010. Hospital rationing policy and pre-screening by the family doctor precluded treatment of patients with varicose veins which were only of cosmetic concern. Thus all patients had symptoms from their primary varicose veins and they had a C score of the CEAP classification of C_{2-6} and significant sapheno-femoral junction (SFJ) reflux extending for at least 10 cm from the junction as determined by duplex ultrasound. Patients with deep venous reflux, evidence of a current or past DVT, or sapheno-popliteal junction reflux were excluded from the study.

Pre-treatment assessments included the Aberdeen varicose vein severity score (AVVSS), the venous clinical severity score (VCSS), air plethysmography (APG) and a duplex examination. Follow-up was at 3 weeks and 3 months and included the AVVSS, the VCSS and colour duplex examinations. Follow-up VFI was performed at 3 months in all patients.

The STS scoring system was compared in five different situations:

a) In all patients undergoing endovenous treatment against AVVSS and the VCSS, before and 3 weeks after intervention.
b) In the subgroup of patients requiring additional foam sclerotherapy against the venous filling index (VFI).
c) Between EVLA and UGFS patients, AK and BK, before and 3 weeks after treatment.
d) Correlations between the absolute values of the STS and the AVVSS, VCSS and VFI assessments 3 months after treatment.
e) Improvements in the STS at 3 months compared with improvements in the AVVSS, VCSS and VFI measures. Improvement was defined as the difference between the pre and post-treatment values for each assessment tool.

Ethics committee approval was granted from the local ethics committee (No: 08/H0710) and informed consent was obtained from participating patients.

Scoring with duplex/STS

Scoring was performed using a portable Sonosite® Titan colour duplex scanner (SonoSite Inc, Bothell, WA98021-3904, USA) with a linear 7 MHz transducer. All examinations were performed by the same, experienced clinical vascular scientist (MA). Superficial and deep veins and their junctions were assessed for reflux, competence and occlusion. Reflux was induced using a manual calf compression and release manoeuvre in the standing position. Reflux duration of >.5 s for superficial veins and >1.0 s for deep veins was considered significant. Occlusion was defined as the presence of complete luminal obliteration of any length. The mean GSV diameter was calculated from the average of 3 measurements taken below the SFJ, at mid thigh and above the knee. Non-refluxing segments of the GSV, localised dilatations or a saphena varix were avoided.

An STS[1–3] was given to the above knee (AK) and the below knee (BK) parts of the GSV, demarcated by the popliteal skin crease, in a standing patient. Straight continuing tributaries of the GSV in patients with a hypoplastic distal GSV were considered as part of the GSV. A refluxing anterior-accessory saphenous vein (AASV) was also included as part of the GSV evaluation provided reflux originated from the proximal GSV. A score of 1 represented complete occlusion of any length without reflux, 2 represented competency without occlusion or reflux and 3 represented the presence of reflux irrespective of co-existing occlusion or competency. The AK and BK scores were then added to give an STS of 2–6 for the leg. The STS was then repeated after each treatment. When deriving the total score the appropriate number was used for each segment (AK or BK) in legs with co-existing haemodynamic patterns. The scores in the AK and BK segments were then combined to create the STS, as shown in Fig. 1 and Table 2.

Air plethysmography

This was performed using the APG-1000® apparatus comprising a sensor air-cuff, an air-pump and software (ACI Medical LLC, San Marcos, CA92078, USA).[3] The VFI represents the rate of venous filling of the calf when the patient stands up after lying supine with the leg elevated at 45°. If elevated (>2 ml/s), it provides a global assessment of reflux. The VFI was measured in all patients prior to and 3 months after the treatment.

Table 1
Clinical and duplex scoring systems for evaluating saphenous insufficiency. The VCSS and STS are relatively more dynamic systems.

	Static (stage/classification)	Dynamic (change)
Clinical	C part of CEAP	VCSS
Duplex	VSDS	STS

VCSS, Venous Clinical Severity Score; STS, Saphenous Treatment Score; CEAP, Clinical Etiological Anatomical Pathophysiological; VSDS, Venous Segmental Disease Score.

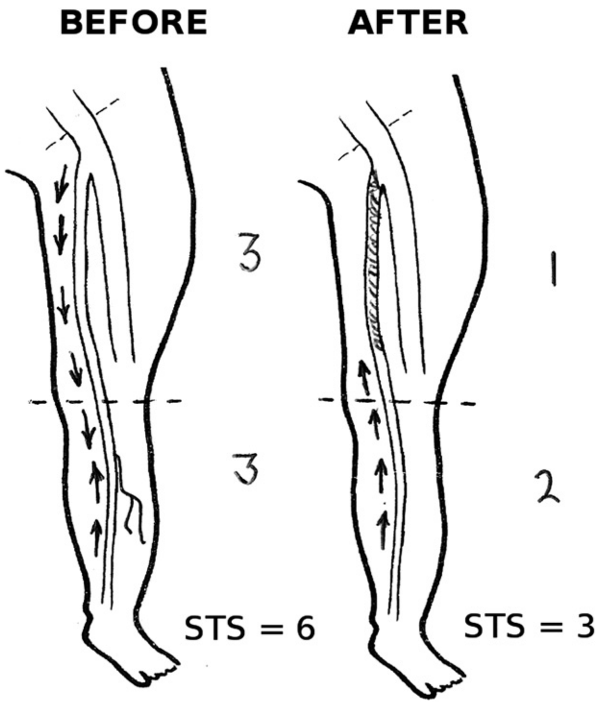

Figure 1. The STS derivation before and after endovenous treatment from duplex reports. Combinations of downward arrows (reflux), shaded areas (occlusion) and upward arrows (competency) define mixed disease patterns.

Laser treatment

All EVLA procedures were performed with the ELVeS® PainLess diode laser delivering intermittent energy using a 1470 nm wavelength fibre (Biolitec, Inc. East Longmeadow, MA, 01028, USA) at a power setting of 14 W. Tumescent anaesthesia (40 ml of .5% Bupivacaine in 1000 ml .9% saline) was infiltrated around the GSV throughout the length to be ablated and patients were placed in the Trendelenburg position prior to laser withdrawal. The distal access point was decided using a convenient location near the knee. The distal ablation end point relative to the knee and the energy delivered in joules/cm were recorded. Varicose tributaries were treated concurrently under local anaesthetic using phlebectomy hooks. Crepe bandages were applied for 1 day. A class I anti-embolism stocking was placed over the bandages at the time of treatment, and patients were advised to wear the stocking for 3 weeks, whenever ambulant.

Table 2
The saphenous treatment scoring system. The above knee (AK) and below knee (BK) segments are first individually evaluated and then combined to give the STS. All areas of GSV reflux and ante-grade flow (competency) are assessed even if they occur in short segments of the GSV.

Grade (AK or BK)	
1 =	Occlusion (luminal obliteration) anywhere along the GSV.
2 =	Competency anywhere along the GSV
3 =	Reflux anywhere along the GSV > .5 s[a]
Weight (AK or BK)	
3 =	Final score if it is present. It has precedence over 1 and 2.
1 =	Final score provided there is no reflux. It has precedence over 2 but not 3.
2 =	Final score provided there is no reflux or obstruction. This score should be present in health
STS	
2–6	Sum of the AK and the BK score

GSV, Great Saphenous Vein; STS, Saphenous Treatment Score.
[a] This does not included ambiguous flow patterns within the GSV 'stump' above an occluded GSV (like reflux from pelvic or epigastric veins) unless there is defined reflux (>0.5sec) from this into the AASV or thigh tributary.

Foam sclerotherapy

Foam sclerotherapy was initially used to treat the incompetent GSV. In only a few patients, access to the GSV was via a refluxing tributary. A maximum of 12 ml of foam was injected during a single session.[4] Foam was prepared according to the Tessari technique[5] by agitating 1.2 ml of 1% sodium tetradecylsulphate (Fibro-Vein®, STD Pharmaceuticals, Hereford, HR4 0 EL, UK) in 4.8 ml of air using a three-way tap and 2 syringes to produce 6 ml of foam. This was then injected into the saphenous trunk, at knee level, using an 18 G intravenous cannula, with the patient in the supine position and the leg elevated at 45°. Tumescent anaesthesia was used for UGFS if the GSV was ≥8 mm in diameter. Ultrasound was used to visualise the extent and direction of foam migration within the target vein. Sufficient foam was delivered to fill the GSV to the level of the SFJ.

All patients had a duplex examination at 3 weeks to screen for a deep vein thrombosis (DVT). This opportunity was used to assess the need for further sclerotherapy in both groups of patients (EVLA and UGFS) if there was persistent AK-GSV reflux. This was also offered to all patients with BK-GSV reflux or prominent varicosities. The final decision was made by the patient who was informed that there was a risk of DVT (<1%) and hyperpigmentation from sclerotherapy (<10%). A full length, class II, graduated elastic stocking with a waist attachment was fitted at the time of the initial and subsequent treatments with foam (Medi, D-95448 Bayreuth, Germany). Patients were advised to wear the stocking continuously for 3 weeks but could take it off at night during the 3rd week.

Statistical analysis

Data was analysed using SPSS Statistics 17 (SPSS Inc, Chicago, IL60606, USA). Non-parametric data analysis was used to determine significance between groups (Mann–Whitney *U* test), within groups (Wilcoxon signed rank test) and to illustrate the effects of ongoing treatments (Friedman test). Significance was achieved when $P < .05$. Medians with the inter-quartile range (IQR) were used to illustrate data in charts. Means were preferred to illustrate STS scores because they are a discrete variable with few categories in comparison to medians which are an uninformative measure of location.

Results

Patient characteristics

Thirty-eight patients were randomised to EVLA and 28 to UGFS. Patients were equally matched in terms of their baseline characteristics as shown in Table 3. The median GSV diameter in EVLA patients versus UGFS patients was 7.5[4–12] mm versus 8 (4.5–12) mm respectively, $P = .537$ (Mann–Whitney). In the EVLA group, the median energy delivered was 69 (53–90) joules/cm. The median distal ablation end point was 4 (−8–20) cm above the knee crease. The median volume of foam delivered was 12[6–12] ml. Three EVLA patients and 12 UGFS patients received additional sclerotherapy at 3 weeks.

Follow-up was complete in all assessments in 66 patients (66 legs) at 3 weeks and in 56 patients (56 legs) at 3 months. The VFI assessments were completed on 61 patients at 3 months.

The STS against other parameters

Over a quarter of patients started with a competent BK-GSV (STS = 5) and almost all patients achieved a reduction of 2–4

Table 3
Baseline values in 66 patients (legs) prior to endovenous treatment. Expressed in median (range, IQR) unless otherwise indicated.

	EVLA (n = 38)		UGFS (n = 28)		P value[a]
Age (yrs)	48.3 (15.2)[b]		50.0 (14.1)[b]		.647[c]
Male:Female	15:23		13:15		.268[d]
Unilateral:Bilateral	1:1.53		1:1.8		.064[d]
C of CEAP	C_2(16), C_3(6), C_{4a}(7), C_{4b}(3), C_5(4), C_6(2)		C_2(8), C_3(3), C_{4a}(13), C_{4b}(0), C_5(0), C_6(2)		–
AVVSS	19.38 (.86–52.93, 11.58)		24.79 (7.5–50.06, 13.47)		.078
VCSS	6 (2–20, 3)		6 (3–17, 5)		.508
VFI (ml/sec)	4.7 (1.2–17.8, 5.08)		4.8 (1.4–15.0, 3.63)		.977
STS AK	3 (3–3, 0)		3 (3–3, 0)		1.000
STS BK	3 (1–3, 1)	2.63[b]	3 (2–3, 1)	2.79[b]	.249
STS Total	6 (4–6, 2)	5.63[b]	6 (5–6, 1)	5.79[b]	.249

IQR, Inter-Quartile Range; AVVSS, Aberdeen Varicose Vein Severity Score; VCSS, Venous Clinical Severity Score; VFI, Venous Filling Index; STS, Saphenous Treatment Score; AK, Above Knee; BK, Below Knee; SD, Standard Deviation.
[a] Mann–Whitney U test.
[b] Mean (SD).
[c] t-test for equality of means.
[d] Chi–Square test.

points in the STS. The reduction in STS from pre-treatment values was significant at both 3 weeks ($P < .0005$) and 3 months ($P < .0005$).

The VCSS ($P < .0005$) and AVVSS ($P = .14$) improved at 3 weeks compared to their pre-treatment values (Fig. 2). Although a trend was observed in AVVSS it failed to achieve significance. After 3 months however, the median (IQR) AVVSS decreased from 21.52 (15.94) to 8.16 (13.3), $P < .0005$ (Wilcoxon).

At 3 months the VCSS, AVVSS and VFI all decreased significantly, $P < .0005$ (Wilcoxon). Correlations between the STS against the AVVSS, VCSS and VFI at 3 months were not significant at $P = .724$, $P = .659$ and $P = .054$ respectively (Spearman). Similarly, correlations on improvements (pre-treatment scores minus post-treatment scores) at 3 months (Table 4) also failed to reach significance except between the VCSS and the STS. However, this correlation, was too poor ($R^2 = .075$) to derive meaningful conclusions.

The STS with ongoing treatments

Fifteen patients received additional sclerotherapy. A stepwise reduction in the STS was observed after the first treatment and final treatment as shown in Fig. 3(A). The final treatment was able to achieve a further reduction of 1–2 points in the STS from a median of 4 as depicted in Fig. 3(B). It is interesting to note that for those patients who required additional treatment, the median pre-treatment VFI was 7.1 ml/s (Fig. 3(C)) compared to 4.6 ml/s for the whole group (Fig. 3(D)).

The STS with different treatments

The mean of the differences in the pre and post-treatment STS evaluations (MDSTS) have been used to illustrate the different effects of endovenous treatments with EVLA and UGFS as shown in Fig. 4(A). The MDSTS to 2 decimal places represents a scale of improvement with the higher values representing the greatest difference. The MDSTS after EVLA was 2.79 compared to 1.86 with UGFS at 3 weeks ($P = .001$, Mann–Whitney U test). Following EVLA, 26.3% of patients had a 4-point improvement in their STS compared to 7.1% of patients in the UGFS group at 3 weeks, as shown in Fig. 4(B).

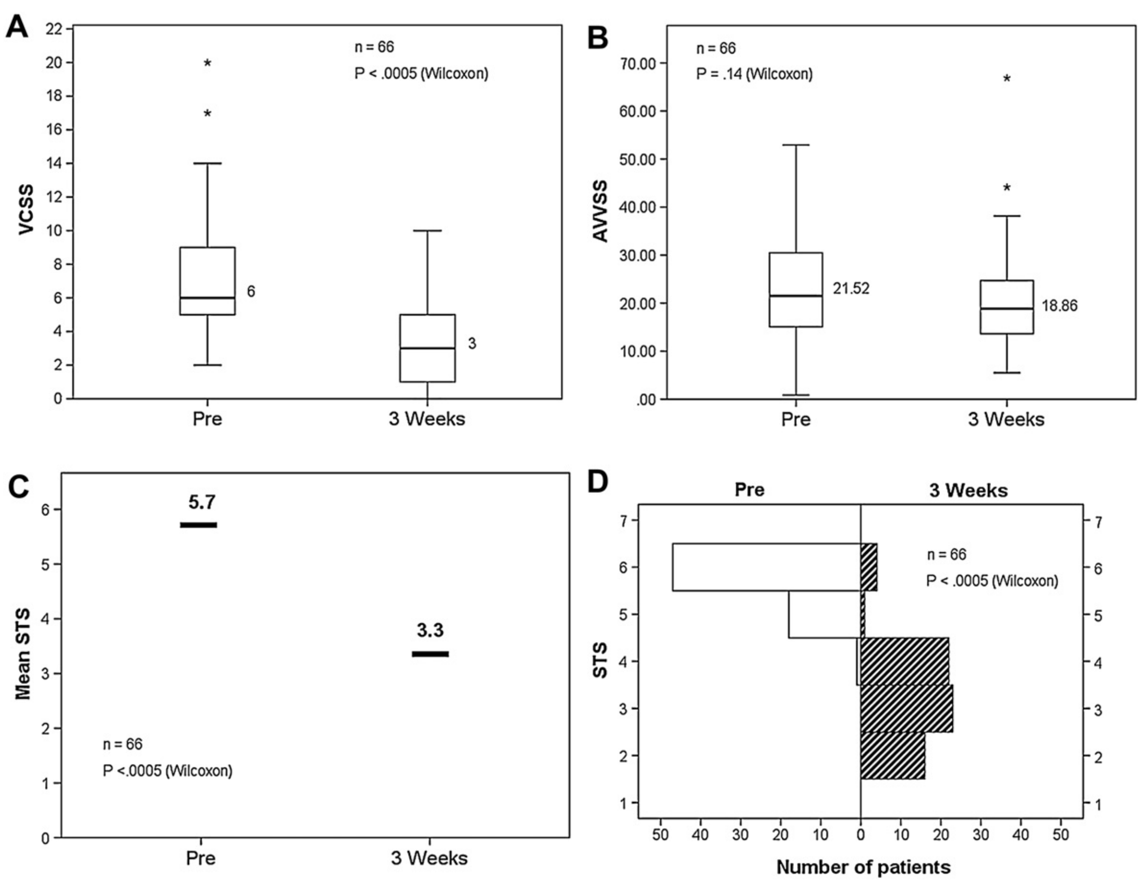

Figure 2. Improvements in the VCSS (A), AVVSS (B) and STS (C, D), three weeks after endovenous treatment.

Table 4
Improvements in the STS (absolute differences between pre and post-treatment values) at 3 months correlated against the improvements with other validated severity assessments ($n = 56$).

	AVVSS		VFI		STS	
	P value[a]	R^{2}[b]	*P* value	R^2	*P* value	R^2
VCSS	.110	.047	.051	.069	.041	.075
AVVSS	–	–	.538	.007	.708	.003
VFI	–	–	–	–	.748	.002

AVVSS, Aberdeen Varicose Vein Severity Score; VCSS, Venous Clinical Severity Score; VFI, Venous Filling Index; STS, Saphenous Treatment Score.
[a] Spearman's rho significance (2-tailed).
[b] Spearman correlation coefficient.

When the STS was separated into AK and BK components (each with a score between 1 and 3), the MDSTS for the AK and BK scores between EVLA and UGFS are illustrated in Fig. 4(C) and Fig. 4(D), respectively. With EVLA, 92.1% of patients achieved a 2-point STS reduction AK compared to 75.0% of UGFS patients (MDSTS: 1.92 and 1.57 for EVLA and UGFS respectively, $P = .039$, Mann–Whitney *U* test). When the BK part of the STS was evaluated this also decreased, but only 26.3% of EVLA and 7.1% of UGFS patients achieved a 2 point reduction (MDSTS: .87 and .29, respectively, $P = .002$, Mann–Whitney *U* test). Most of the UGFS patients (20/28) had no difference in the BK-STS because the primary treatment was directed at the AK-GSV (Fig. 4(D)).

Discussion

The STS is a flexible, duplex-derived scoring system, which is able to quantify the haemodynamic effectiveness of treatments for superficial venous insufficiency (SVI). It has the potential to complement the descriptive duplex evaluation with a graded haemodynamic outcome measure. Statistical evaluations of variance are therefore possible which can be used to assess effectiveness between both treatments and further interventions.

Air plethysmography is another assessment tool, which can quantify haemodynamic improvements. It measures the rate of venous filling to the calf using the VFI in ml/sec.[6,7] Similar to the VSDS it is a much broader assessment than measurements on the GSV alone because it quantifies the global haemodynamic effects in all leg veins. However, compared to duplex, APG is not widely available which limits its value as a useful assessment tool. It has been used in this study to support the haemodynamic improvements demonstrated by the STS.

The STS focuses on the haemodynamic effects of treatment on the saphenous trunks in patients with SVI. The GSV is first subdivided into AK and BK segments demarcated by the popliteal skin crease. The presence of co-existing reflux, obstruction and competency are then recorded within each segment. Since reflux is the primary pathophysiological abnormality in SVI it was given the maximum score of 3. Occlusion (luminal obliteration), anywhere within the segment, and of any length, was given the best score of 1, since this was the intended treatment effect. If several scores were

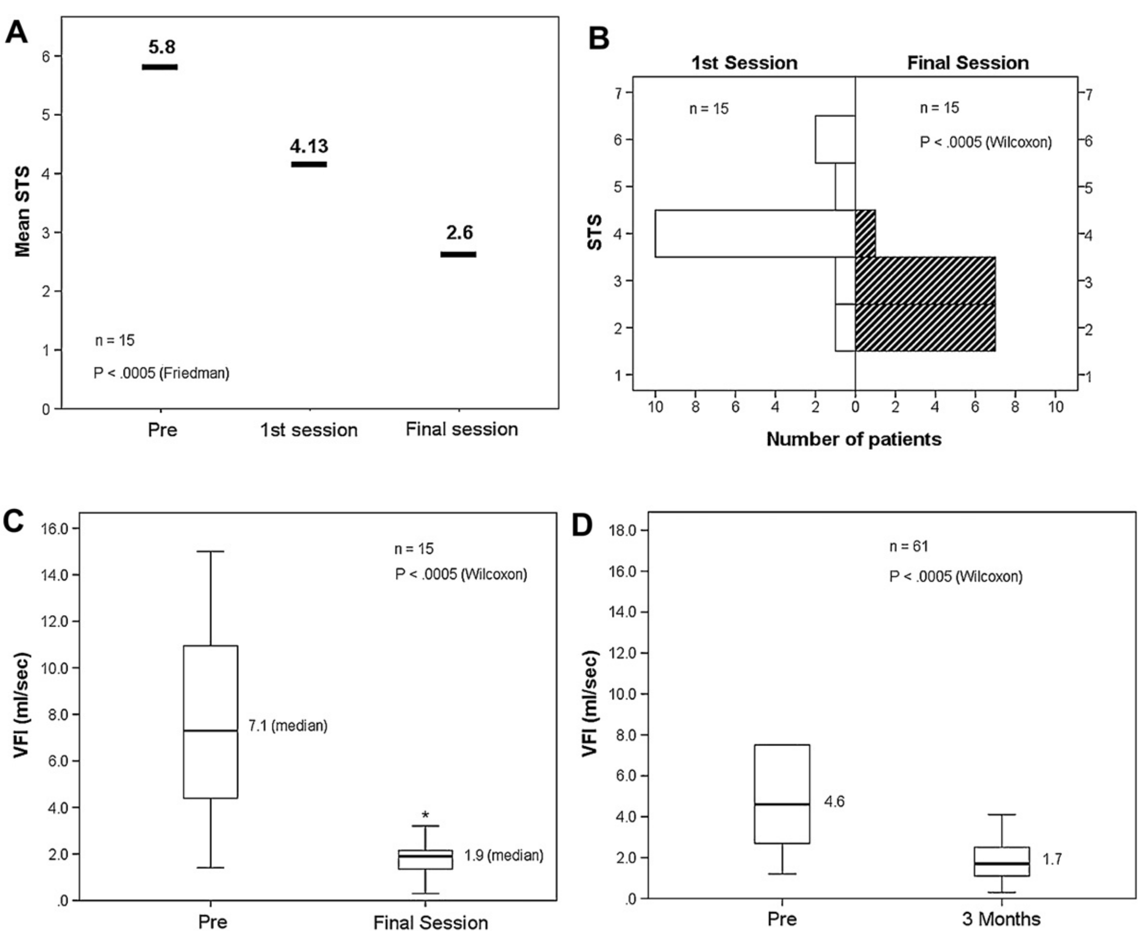

Figure 3. The stepwise change in mean STS during two treatment sessions (A). The additional beneficial effect of the second treatment (B). The improvement in the VFI is also shown in these patients (C) compared to the whole group (D).

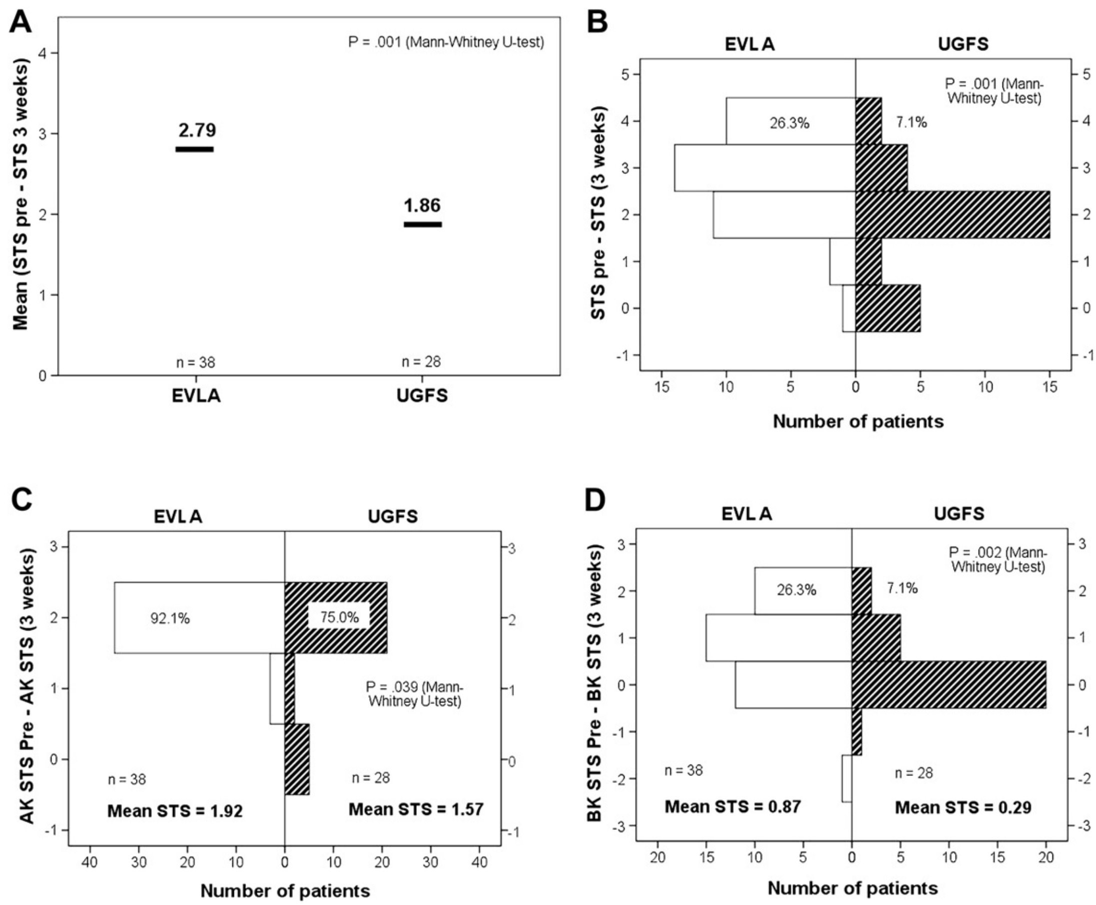

Figure 4. Patients have been divided into EVLA and UGFS groups. Three week improvements in the STS are illustrated (A, B). Above knee and below knee components of the STS have been separated in C and D respectively.

present, the final score was determined using an order of precedence (Reflux 3 > Occlusion 1 > Competence 2).

In haemodynamic terms it could be argued that competency is a favourable outcome. Competency is also a treatment aim in saphenous conservation surgery where reflux is abolished without saphenous occlusion. Occlusion is given the best score[1] after EVLA and sclerotherapy since it aims to obliterate the saphenous vein. A patent competent vein may have a greater potential for reflux (recurrence) later on but may also represent treatment (obliteration) failure, which is why it has been scored half-way between reflux[3] and occlusion.[1] Furthermore, competency may be visualised as an intermediate state, which could "improve" (obliteration) or deteriorate (reflux). If the BK-GSV was competent and patent, both pre and post-treatment, there would be no change in the STS.

Protagonists for saphenous conservation surgery (CHIVA) have the option to change the scoring by giving competency the improved score of 1 and occlusion a reduced score of 2. However, it is important that the order of precedence should remain the same with reflux prioritizing over occlusion and occlusion prioritizing over competency (Table 5). The STS can also be applied to the small saphenous vein (SSV).

The treatment of varicose tributaries may have indirect effects on the GSV. Obliteration of varicosities has shown to provide competency in saphenous trunks which were originally incompetent.[8–12] The STS values may change as a result and this may be useful for phlebologists who need to assess the haemodynamic effect of isolated phlebectomies. Nevertheless, the score would not fall below 1 for each GSV segment.

An ideal scoring system should be accurate, flexible, practical, universal, easy and representative of the disease and treatment being assessed. The proposed STS may fulfil many of these criteria but not all. If baseline assessments are undertaken then the greatest treatment effect would be possible only on those patients with the worst initial scores.

Occasionally patients may have a successful obliteration of the majority of the AK GSV but reflux can still remain within the upper or lower few centimetres of vein. This would be considered a failure under the STS with an AK STS score of 3 representing reflux. Although the appropriateness of this would be controversial, the principle of the STS relies on a haemodynamic outcome evaluation, and not a technical assessment. Descriptive terms like partial occlusion or recanalisation can therefore be replaced with numerical scores depending on their haemodynamic significance.

Table 5
Modifications of the standard STS to accommodate saphenous conservation surgery.

Endovenous obliteration	Saphenous conservation
Score	
Reflux = 3	Reflux = 3
Competency = 2	Occlusion = 2
Occlusion = 1	Competency = 1
Precedence	
3 > 1 > 2	3 > 2 > 1
Reflux > Occlusion > Competency	

STS, Saphenous Treatment Score.

The AVVSS did not improve significantly after 3 weeks ($P = .14$). Although a trend in improvement was observed, 3 weeks may be considered too early to assess improvements in quality of life. Patients may still have discomfort, which would not allow them to appreciate the benefits of treatment.

The use of the STS in evaluating treatment comparisons and ongoing treatments for SVI has been demonstrated. In common with other assessment systems it improves after endovenous treatment. The separate scores for AK and BK segments may also be used in the evaluation of different treatments or combination of treatments.

Limitations of study

No reproducibility or inter-observer variability measures were performed on the STS.

Conclusion

The STS is a quantitative, flexible, duplex-derived, scoring system, which has the potential to assess the haemodynamic effectiveness of treatments for SVI. This study has shown that the STS can score and differentiate between the therapeutic impact of EVLA and UGFS, AK and BK treatment effects, as well as assess the benefit of further interventions.

Conflict of interest

No competing interest declared.

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