

True Long-term Healing and Recurrence of Venous Leg Ulcers Following SEPS Combined with Superficial Venous Surgery: A Prospective Study

O. Nelzén* and I. Fransson

Skaraborg Leg Ulcer Center and Vascular Surgery Unit, Skaraborg Hospital/KSS, Skövde Sweden

Background. The role of perforator surgery remains unclear in the management of patients with leg ulcers. The aim of this study was to assess long-term healing and recurrence rates of leg ulcers following surgical intervention with combined Subfascial Endoscopic Perforator Surgery (SEPS) and superficial venous surgery.

Method. Case series with prospective long-term follow-up of 90 consecutive patients operated on with open (CEAP C6) or healed (CEAP C5) venous ulcers in 97 legs. Popliteal vein reflux was present in 21 legs. All 97 legs were treated with SEPS and 87% had additional superficial venous surgery. Patients were follow-up for a median of 77 months (range 60–112 months) with a minimum of 5 years.

Results. 87% of all ulcerated legs healed. The three and five year recurrence rates were 8% and 18% respectively among survivors. In a multivariate Cox regression analysis previous vein surgery was the only factor significantly associated with recurrent ulceration ($p = .004$).

Conclusion. SEPS combined with superficial venous surgery leads to healing with a low recurrence rate in patients with open and healed venous ulcers. Previous venous surgery was found to be a significant risk factor for ulcer recurrence. This result emphasizes the importance of assiduous technique for varicose vein surgery and suggests a continuing role for perforator surgery in leg ulcer patients.

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Keywords: Leg ulcer; SEPS; Superficial venous surgery; Perforator surgery; Venous ulcer; Minimal invasive surgery; Endoscopic surgery; Leg ulcer healing; Leg ulcer recurrence; Prospective study.

Introduction

The issue of whether perforator ligation should be performed has not been assessed in a randomised trial and some consider that subfascial endoscopic perforator surgery (SEPS) is out of fashion.¹ Published clinical series suggest that where SEPS has been performed in patients with venous ulcers, lower recurrence rates were observed^{2,3} compared to another series where no perforator surgery was used.⁴ These retrospective data included only a small proportion of patients followed for 5 years with extrapolation of available data to obtain ulcer recurrence rates. The

actual long term estimates are therefore somewhat unreliable.^{5–8} A few prospective series have reported only a short follow up.^{9,10} There are no previous studies where all patients have been followed prospectively for five years, essential for obtaining an accurate estimate of recurrence rate for venous ulcers.

Since 1993 we have included all patients undergoing SEPS and superficial venous surgery in a prospective study, including all of those operated on for healed and open ulcers (CEAP C5 and C6). We have previously reported short term data on 149 SEPS procedures performed in patients with venous insufficiency C3 (varicose veins and oedema) to C6 (open leg ulcer).¹¹ We have since included more patients with leg ulcers to get more accurate data, and have followed these patients for a minimum of five years to assess the actual recurrence rate following these procedures. The aim of this investigation is to report the long term healing and recurrence data for patients with open or healed venous leg ulcers, and to try to assess possible risk factors for leg ulcer recurrence.

Interim data presented at the International Union of Phlebology World Congress Chapter Meeting, August 27–31, 2003 in San Diego, California.

*Corresponding author. O. Nelzén, MD, PHD, Skaraborg Leg Ulcer Center and Vascular Surgery Unit, Skaraborg Hospital/KSS, S-541 85 Skövde, Sweden.

E-mail address: olle.nelzen@vregion.se

Methods

Between March 1993 and September 1998, 97 SEPS procedures were performed in the limbs of 90 patients with open (C6) or healed (C5) venous ulcers. There were 54 women (56 legs) and 36 men (41 legs). Their median age at the time of surgery was 66 (range 34–87) years. Patients were included prospectively.

Preoperative assessment

The basic preoperative assessment included history, clinical examination and bidirectional Doppler ultrasonography. Prior to 1995 the diagnosis of perforator incompetence was established by phlebography. Since 1995 colour duplex ultrasonography (CDU) (Acuson 128XP; Acuson, Mountain View, California, USA) was used to map venous incompetence prior to surgery. Venous incompetence was considered present if there was reflux lasting >0.5 sec. Patients were examined in a semi-sitting position with legs dependent. Manual calf compression or compression technique by use of an inflatable cuff were used to provoke reflux. All major deep and superficial veins including perforators were scanned according to a standardized protocol used for venous assessments at our institution. Augmentation of flow in perforators was performed with manual compression of the foot and/or leg. Perforator incompetence was considered present if at least an outward flow lasting >0.5 sec. was detected in a perforator with a diameter exceeding 3 mm.

Based on preoperative examination and CDU result the venous insufficiency was initially classified according to recommendations from the Society for Vascular Surgery and The International Society for Cardiovascular Surgery.¹² The clinical classification was updated retrospectively when the CEAP (Clinical Etiological Anatomical Pathophysiological) classification appeared.¹³

Legs with venous incompetence involving the popliteal vein were considered to have clinically significant deep venous insufficiency (DVI).¹⁴ Assessment for evidence of previous venous thrombosis was not included in the protocol from the start of the study and was only assessed retrospectively. All other limbs were considered to have predominantly superficial venous incompetence (SVI) and/or perforator incompetence (PVI), although some had additional segmental deep incompetence in other deep veins excluding the popliteal vein. Patients with ulcers caused by DVI were offered surgery only if their ulcers did not heal with compression treatment or if their ulcers recurred. A chronic venous ulcer was defined as any

wound below the knee, with Doppler ultrasound confirmed venous reflux and an ankle brachial pressure index (ABPI) of 0.8 or more, which had been present for more than 6 weeks. Patients with chronically occluded deep veins were excluded.

Surgical procedure

Informed consent was received from all patients. Prophylactic antibiotics and thromboembolic prophylactics were only given selectively. A Storz 10 mm endoscope for perforating vein ligation (Karl Storz, Tuttlingen, Germany) and video-camera equipment were used. SEPS was performed in a bloodless field created by a Löfquist roll-on tourniquet (Boazul, Lidköping, Sweden). Insufflation of CO₂ has been used in recent years. The distal part of the deep compartment fascia was opened by sharp dissection to visualize the lower Cockett perforators. Lateral perforators were dealt with endoscopically by means of a further incision over the lateral compartment. Incompetent great and small saphenous veins were managed by junction ligation and stripping. Operations for groin recurrence were performed through a medial subfascial approach with repeat ligation at the sapheno-femoral junction using non-absorbable sutures. Avulsions were avoided in areas with lipodermatosclerosis.

Postoperatively patients with leg ulcers were treated with a zinc paste bandage (Zipzoc Salvstrumpa, Smith&Nephew, Mölndal, Sweden) with padding and a cohesive medium elastic bandage. Patients with healed ulcers received a full length class 1 support stocking (15–20 mm Hg).

Compression management

In patients with residual deep vein incompetence class 2 compression stockings (21–30 mm Hg) were prescribed for lifelong use. All other patients were advised to use class 1 support stockings for the first month after surgery or after ulcer healing and thereafter at their own discretion.

Short-term follow-up

Specially trained nurses saw the patients 7–10 days after operation at the outpatient clinic. Early complications were noted. Patients with healed ulcers received a below knee class 1 support stocking which they were encouraged to use during the day for one month. For patients ulcers, the zinc paste bandage was changed and the patients were referred to a district nurse for additional weekly changes. All C6

patients were seen by the doctor 3 to 4 months after surgery and patients with unhealed ulcers were reviewed regularly until the ulcer healed. All patients were contacted regularly to assess the outcome.

Long-term follow-up

Two postal assessments of the long term outcome were performed after a median of about 3 and 5 years respectively. Patients were asked about the outcome of ulcer healing and recurrent ulceration. If the questionnaire was not returned or the answers were unclear we contacted the patient, relatives or district nurses by telephone to establish the outcome.

A leg ulcer recurrence was defined as any wound below knee that did not heal within 6 weeks. A minor recurrence was defined as a single episode with duration of less than 3 months and a major recurrence was a recurrence of more than 3 months duration or more than one episode of re-ulceration regardless of duration.

All patients with ulcers that did not heal or who experienced a recurrent ulcer were reassessed and a CDU scan was repeated (GE Logic 9; GE Medical Systems Sverige AB, Stockholm). Patients with residual or new venous incompetence in superficial or perforator veins were offered a further operation.

A final assessment was performed for the subgroup of 20 patients that had not been followed for at least 60 months, at the time of the second follow-up, in order to achieve a follow-up of five years or more. No other patients were contacted at that time.

Statistics

The data was analysed with SPSS for Windows ver.13.0 (SPSS Inc., Chicago, USA). The data was analysed overall as well as in different subgroups. Descriptive data is presented as median values with corresponding ranges. Nonparametric tests were generally used for univariate group comparisons (Chi square or Mann-Whitney U). Leg ulcer recurrence was plotted by life table analysis, with healing of previous ulcer (C6) or time of surgery (C5) as the baseline. Subgroup comparisons regarding recurrence curves were done using Wilcoxon Gehan statistics. Cox regression analysis was used to assess possible risk factors for leg ulcer recurrence. A *p* value of <.05 was considered significant.

Results

In all but one leg SEPS was performed as planned. Severe obesity was the cause of the failure and that

patient was solely treated surgically by stripping of the GSV and her ulcer healed eventually after 41 months. Apart from one death due to suicide within 30 days, from undisclosed severe mental illness, no serious complications were observed. Details of complications have already been published¹¹ and do not differ from the series reported here. No DVT was observed. Details of surgery are shown in Table 1. Only one patient (C5) was lost to follow-up.

Leg ulcer healing

Fifty-three limbs were operated on for open ulcers, 24 (45%) were first time ulcers and 29 (55%) were recurrent ulcers. The median preoperative duration of the current ulcer was 20 months (range 1–168). Half of the legs were healed within two months from operation and the cumulative healing is shown in Fig. 1. Ulcers eventually healed in 87% of limbs (46/53). The reasons for failure to heal were early death (after 1 and 5 months respectively) in two cases, in three legs (2 patients) additional arterial disease developed, development of a squamous cell carcinoma in one patient and one limb developed new incompetence of the SSV in combination with renal failure. All three legs with deteriorating arterial disease underwent vascular surgical interventions, by pass surgery in two and percutaneous transluminal angioplasty (PTA) in one leg. Three legs had to be amputated, in the patient with malignancy and two of the limbs with arterial disease. Two patients died about three years after surgery, the patient with the malignant ulcer and the one who had been treated with PTA.

Three patients with delayed healing had repeat surgery, in two repeat SEPS was performed because of missed perforators and both healed shortly afterwards (at 10 and 16 months respectively) and for one patient with large ulcers healing was aided with a skin graft.

Table 1. Type of operation performed, frequency of deep vein involvement and previous venous surgery

	All legs <i>n</i> = 97	Open ulcer C6 <i>n</i> = 53	Healed ulcer C5 <i>n</i> = 44
Previous venous surgery	35 (36)	23 (43)	12 (27)
Day-case surgery	50 (52)	20 (38)	30 (68)
Popliteal vein incompetence	21 (22)	15 (28)	6 (14)
<i>Type of surgery performed</i>			
Great saphenous (GSV) + SEPS	59 (61)	31 (58)	28 (64)
Small saphenous (SSV) + SEPS	19 (20)	13 (25)	6 (14)
GSV + SSV + SEPS	6 (6)	1 (2)	5 (11)
SEPS only	13 (13)	8 (15)	5 (11)

Values in parenthesis are percentages.

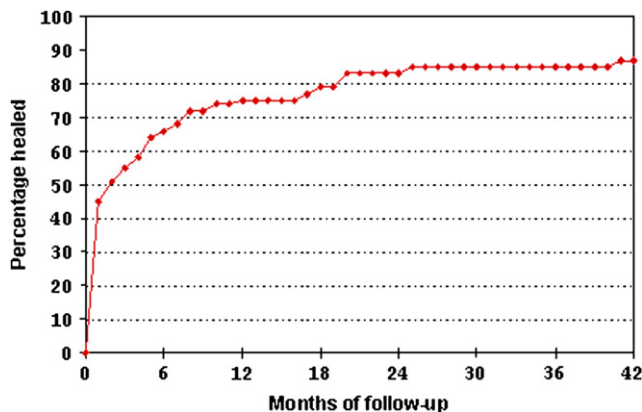


Fig. 1. Cumulated leg ulcer healing over time for all patients (legs) with open ulcers (C6) at the time of surgery.

Leg ulcer recurrence

Interim assessments

The first long term follow-up was performed after a median of 41 months (range 20–86). One patient (C5) was lost to follow-up. Ten patients had died, three with open ulcers at the time of death, three with ulcer healed and for four the ulcer status was unknown (two of them had healed ulcers at last contact). The outcome data is shown in Table 2.

The second assessment was performed after a median of 69 (range 48–112) months. One additional patient did not respond to the questionnaire but data regarding ulcer status was obtained later. Four additional patients had died (one with bilateral ulcers); one leg known to have an open ulcer, three with healed ulcers and unknown ulcer status for one. The data regarding outcome is summarized in Table 2.

Final assessment

After completing follow-up data for the 20 patients who had not been followed-up at five years, the total follow-up among survivors throughout the study was a median of 77 months (range 60–112). One additional minor recurrence was detected for a C5 patient after 64 months. Based on these accumulated data a detailed plot of ulcer recurrence and healing for each patient was finalized. Of the patients' legs that healed after SEPS or were already healed at the time

of the primary SEPS procedure 25/87 (29%) developed a recurrent ulcer during follow-up; C6 patients 16/46 (35%) and C5 patients 9/41 (22%). In three legs only a minor recurrence was recorded and so the total major recurrence rate was 22/87 (25%), C6 14/46 (30%) and C5 8/41 (20%). The crude cumulated recurrence over time since the date of surgery or healing of last ulcer for all legs and for the subgroups C5 and C6 and primary vs. redo-surgery is plotted in Fig. 2a–c. The time to recurrence based on the healing date of the previous ulcer was a median of 37 months (range 5–72) and significantly shorter than for C5 patients' 63 months (range 36–76) based on time of operation ($p = .017$ Mann-Whitney U) (Fig. 3).

True rates of recurrence

More than one third of recurrent ulcers developed later than five years after the initial operation. The actual 3 and 5 years recurrence rates were therefore calculated based on all patients alive at that time after the primary operation. Patients that did not heal their initial ulcer or that were lost to follow-up (1) were excluded. The actual three and five years recurrence rates are shown in Table 3. Including patients who died within 3 to 5 years of surgery the cumulated 5 years recurrence rate was 16/86 19%; C6 12/45 (27%) and C5 4/41 (10%).

Repeat CDU

Patients with recurrent or non-healing ulcers were offered further CDU. Two patients were excluded because of advanced age and one declined further investigation. The outcome of these scans is summarized in Table 4. Five patients were scanned more than once. In most legs CDU could identify a probable venous cause for the ulcer recurrence. Further surgery was offered when additional treatment was feasible. In three legs no remaining venous incompetence could be detected at all.

Repeat venous surgery

During the course of the study nine additional venous operations were performed in 8 legs and in one leg for

Table 2. Outcome ulcer healing and recurrence at the long-term assessments

Long term follow-up	Median follow-up months	Range months	Legs at risk n	Open ulcer* n (%)	Cumulated ulcer recurrence		
					All legs n (%)	C6 n (%)	C5 n (%)
First	41	20–86	86	11/86 (13)	11/82 (13)	10/41 (24)	1/41 (2)
Second	69	48–112	81	13/81 (16)	21/78 (27)	13/37 (35)	8/41 (20)

* includes amputated legs.

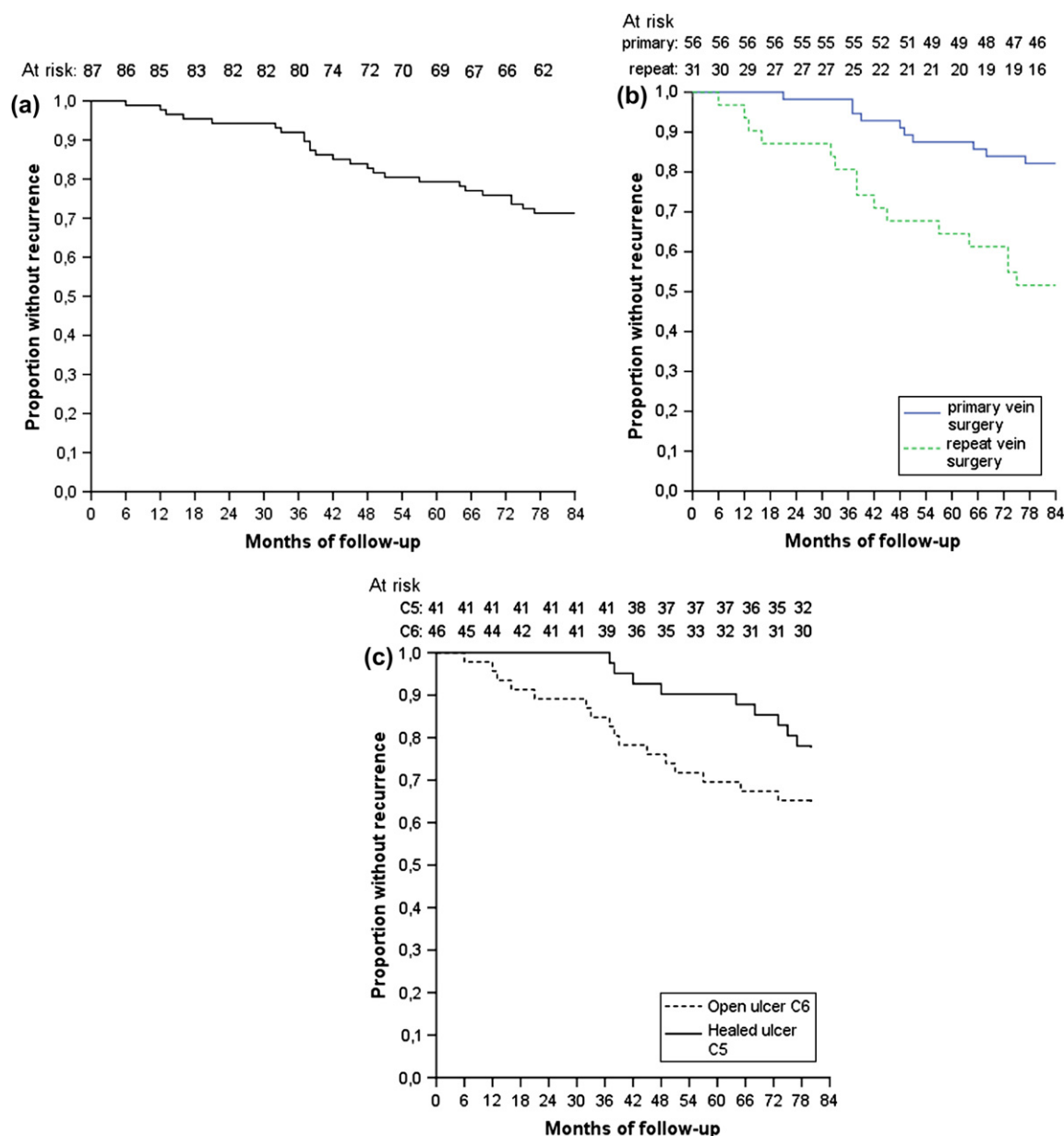


Fig. 2. Life table showing recurrence rate over time for all patients (legs). Baseline time of surgery for legs C5 and healing of original ulcer for legs C6. (b). Recurrence rates for the subgroups primary versus repeat vein surgery ($p = .002$, Wilcoxon Gehan). (c). Recurrence rates for patients with open (C6) or healed ulcers (C5) at the time of surgery ($p = .082$, Wilcoxon Gehan).

other reasons than ulceration. Four repeat SEPS procedures, one combined with a redo-fasciotomy because of severe scarring. In three legs open ligation of gastrocnemius veins or perforators were performed, in two of these together with a diagnostic negative subfascial endoscopy. One had open ligation of an incompetent perforator in the popliteal fossa. In one leg a residual incompetent anterior accessory GSV was stripped and one had SSV surgery and gastrocnemius vein ligation (the patient without ulcer recurrence).

Lateral perforators

Lateral perforators were treated with SEPS through a separate lateral incision, but never as the sole procedure. One patient died early due to suicide and one developed arterial insufficiency, had one additional PTA and eventually the leg had to be amputated. Of the remaining 12, two developed a recurrence (17%). One of the recurrences developed late and the true five year recurrence rate was 1/12 (14%).

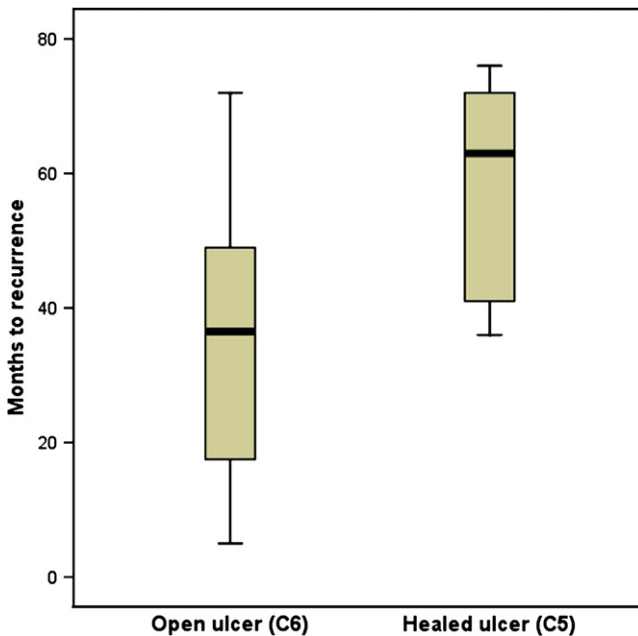


Fig. 3. Box-whisker plot of time to ulcer recurrence. Baseline for C5 was time of surgery and for C6 time of healing of previous ulcer. Central horizontal line indicates median, box ends give start of upper and lower quartiles ($p = .017$, Mann-Whitney U).

Deep venous incompetence

Deep venous incompetence of the popliteal vein was present in 21 legs; eighteen showed axial reflux, including the femoral vein, and the remaining three had only segmental reflux. Nine were post-thrombotic, based on a retrospective review. All but six limbs had ulcers. All except one leg healed, the one who developed a malignant ulcer had to be amputated. One patient (C5) died before the long-term follow-up and among the remaining, six ulcers recurred (32%); one of which was a minor recurrence. The actual five years recurrence rate was 4/15 (27%). All of these patients were prescribed prophylactic compression stockings class 2 in addition to performed surgery but the degree of compliance was not possible to assess.

Table 3. Actual long-term rates of leg ulcer recurrence among survivors with time of operation as the baseline

Time period following operation	All legs n (%)	C6 n (%)	C5 n (%)
3 years	7/84 (8)	6/43 (14)	1/41 (2)
5 years	14/80 (18)*	10/39 (26)*	4/41 (10)

* including two minor recurrences.

SEPS alone

SEPS alone was performed in 13 patients/legs as shown in Table 1. All but one had had previous vein surgery and 41% had DVI. One patient died early but the remaining twelve were followed for at least five years (range 60–92 months). Altogether 6/12 experienced a recurrent ulcer, 2/12 within 3 years and 4/12 (32%) within 5 years. The remaining two had late recurrences after 72 and 76 months respectively.

Risk factors for recurrence

In a univariate analysis previous venous surgery was the only factor that was significantly correlated to the risk of recurrence ($p = .003$). In a Cox regression model also including gender, age (in quartiles), popliteal vein incompetence and CEAP class, primary vein surgery showed a significant relative risk reduction regarding recurrent ulceration; odds ratio 0.30 95% CI (0.13–0.68) ($p = .004$) (Table 5).

Discussion

We acknowledge that this was a single centre study without a control group, but is of value since consecutive patients were included with lengthy follow-up. This is the only study so far that can report a five years result for almost all patients and it is one of the largest prospective series available. In comparable series, where the result of venous surgery has been assessed, the resulting long term data were based on Kaplan Meier estimates with only minor proportions of patients actually followed long term and most were retrospective.^{2,6–8,15} Data from the ESCHAR trial¹⁶ in the UK, show that superficial venous surgery and compression was proven superior to compression treatment alone for treatment of venous ulcers. The twelve month recurrence rate after surgery in that study was 12% without dealing with perforators. In our study the recurrence at 3 years was 8% or 18% at five years. Only two recurrences (2%) occurred within the first twelve months. The higher recurrence rate reported in the ESCHAR study may be the result of not treating incompetent perforators.

Perforators veins may become competent following superficial venous surgery¹⁷ but this is not invariable. In the ESCHAR study one third of limbs with incompetent perforators became competent after superficial venous surgery and compression but 12% of the legs developed new incompetent perforators.¹⁸ Two thirds of patients therefore had residual incompetent

Table 4. Result of CDU scanning in legs with non-healing or recurrent ulceration

Legs	Incompetent veins				CEAP				
	Deep				Superficial		Perforators		
	Femoral	Popliteal	Lower leg deep veins	Gastrocnemic	GSV	SSV	Popliteal or thigh perforator	Lower leg perforator	
1	-	(+)	(+)	-	-	-	-	-	C5a Ep As,d Pr(3,14,15) N2
2	-	+	-	-	-	0	+	-	C5a,Ep,Ap,d,Pr(14,17) N2
3	-	-	-	+	0	-	-	-	C5a Ep Ad Pr(16) N2
4	(+)	-	-	-	0	0	-	+	C6a Es As,p,d Pr(3,11,13,18) N2
5	(+)	(+)	-	-	+	+	-	-	C6a Es As,d Pr(3,4,11,13,14) N2
6	+	+	-	-	0	0	+	+	C5a Ep As,p,d Pr(3,13,14,17,18) N2
7	-	+	-	(+)	0	0	-	+	C5a Ep As,p,d Pr(5,14,16,18) N2
8	-	-	-	-	0	+	-	+	C6a Ep As,p Pr(3,4,18) N2
9	-	+	+	-	+	+	-	-	C6a Ep As,d Pr(2,3,4,14,15) N2
10	(+)	-	+	-	0	0	-	+	C6a Ep Ap,d Pr(13,15,18) N2
11	(+)	-	-	+	(+)*	0	+	+	C6a Ep As,p,d Pr(5,12,17,18) N2
12	-	-	-	+	0	0	-	+	C5a Ep As,p,d Pr(5,16,18) N2
13	+	(+)	-	+	0	0	+	-	C6a Es As,d Pr(5,11,12,13,14,16) N2
14	-	-	-	-	0	0	-	-	C6a Ep An Pn N2
15	-	-	-	-	0	-	-	-	C6a Ep An Pn N2
16	-	-	-	-	-	0	-	-	C5a Ep An Pn N2
17	-	(+)	-	-	-	0	+	-	C5a Ep Ap,d Pr(14,17) N2
18	-	-	-	-	(+)*	-	-	+	C5a Ep As,p Pr(2,18) N2
19	-	+	-	-	(+) [#]	-	-	-	C5a Ep As,d Pr(2,3,14) N2
Tot.	6	9	3	5	5	3	5	7	

+ indicates incompetence and - no incompetence 0 no remaining vein and no recurrence. Brackets indicate previously known incompetence.

* Previous high tie only.

[#] saphenous stump with recurrence.

perforating veins, suggesting a mechanism by which SEPS might improve the outcome.

In some series class 2 compression hosiery has been used for all patients long term.^{5,6,16} In our own patients, class 2 stockings were only prescribed for those with residual DVI. In the remaining patients after the first month, compression stockings were only worn at the patients discretion. We consider that compression hosiery is not needed if all sources of venous reflux can be removed. Our low recurrence rates confirm the validity of this policy.

Table 5. Evaluation of possible risk factors for leg ulcer recurrence in a Cox regression model

Variables	Odds Ratio	95.0% CI for OR		p-value
		Lower	Upper	
Open ulcer C6 vs. Healed ulcer C5	1.605	.681	3.782	.279
Male gender vs. Female gender	.946	.406	2.203	.897
Primary surgery vs. Re-do surgery	.296	.129	.679	.004
Agequartile 34-56 years				.799
Agequartile(1) 57-66 years	1.456	.380	5.576	.583
Agequartile(2) 67-73 years	1.120	.307	4.083	.864
Agequartile(3) 74-87 years	1.681	.507	5.577	.396
Popliteal vein incompetence vs. Purely superficial	1.562	.607	4.021	.355

OR = odds ratio.

The long-term outcome for patients with DVI in this series was much better than we expected, despite our policy of only using surgical treatment for those patients who failed with compression alone. On the other hand we excluded patients with deep vein obstruction from the start, which turned out to be a wise decision according to later reports on bad outcomes for that group of patients.^{2,5,15} The ESCHAR study also reported a benefit for superficial venous surgery in patients with segmental DVI and in fact also a positive trend for those with axial reflux.^{16,19} To offer patients with DVI, without obstruction, and with non-healing or constantly relapsing venous ulcers surgery for additional superficial and/or perforator vein incompetence seems to be a reasonable approach also for the future.

Lateral calf perforators were treated in our series, but never as the only procedure. In contrast to others who found high recurrence rates in these patients,²⁰ we found no difference between this group and the remaining patients. The reason for the difference is probably explained by the fact that not all associated superficial venous incompetence was dealt with in the Dutch study.²⁰

We found that patients undergoing surgery for recurrent superficial venous reflux were more likely to develop ulcer recurrence, in line with other clinical

series.^{10,19,21,22} This emphasises the need for an assiduous surgical technique for varicose vein surgery.

In our study the contribution to SEPS to our regime cannot be assessed, since a randomised trial would be required. A recent randomized study was not designed to assess the value of the perforator interruption and is thus of limited value.²³ Meanwhile we believe that the present results support future use of SEPS in leg ulcer patients with incompetent perforators. There are only few patients where SEPS alone will solve the problem and therefore a combined approach with superficial venous surgery is generally the most appropriate way of dealing with the problem, which is in line with recent reports.^{24,25} This approach gives durable results in our hands and therefore SEPS is definitely not yet outdated.

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Accepted 8 July 2007

Available online 22 August 2007