

Varicose Vein Recurrence and Patient Satisfaction 10–14 Years Following Combined Superficial and Perforator Vein Surgery: A Prospective Case Study, ☆

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WHAT THIS PAPER ADDS

This study adds information regarding the durability of open primary and redo superficial vein surgery and subfascial endoscopic perforator surgery, both by means of duplex detected recurrence and patient reported satisfaction. It is also the first true long-term follow-up regarding the efficiency of SEPS, indicating a low tendency for perforator recurrence. Groin neovascularization developed in less than half of the legs but seems not to affect patient satisfaction negatively and is seldom a reason for repeat surgery. Disease progression seemed to mainly engage the deep venous system, which is new knowledge.

Objective: To assess real long-term varicose vein recurrence and patient satisfaction following surgical intervention with combined subfascial endoscopic perforator surgery (SEPS) and superficial venous surgery.

Method: Prospective consecutive case study (C3–C4). Patients were included March 1993 to September 1998 and 83/104 legs of 80/100 patients were re-assessed 2008; 71 legs underwent duplex ultrasound scanning (DUS).

Results: The median follow up was 12 years (range 10–14). Twelve patients/legs had undergone additional vein surgery during follow-up. Incompetent lower leg perforators were noted in 18/71 limbs (25%). Following groin surgery 23/51 (45%) showed a duplex detected groin recurrence, neovascularization dominated 18/23. In legs where primary great saphenous vein (GSV) surgery had been performed, groin recurrence was found in 14/37 (38%). Previously unknown deep vein incompetence was detected in 14/71 legs (20%), six had axial reflux. The correlation between DUS-detected recurrence and remaining symptoms and cosmetic result was low. The overall satisfaction was high, 70/82 (85%). Patient satisfaction did not deteriorate over time ($p < .557$).

Conclusion: Despite a fair number of DUS-detected recurrences, the overall long-term result, from the patients' point of view was surprisingly favorable. Technically well performed open venous surgery seems to result in a durable long-term outcome.

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INTRODUCTION

Recurrence of varicose veins following treatment remains a major challenge despite the introduction of new endovascular treatment techniques. Often disease progression has been blamed for recurrence, although tactical and technical errors perhaps more often should be blamed. Proponents for endovascular interventions often relate to the fact that

neovascularization frequently is encountered following open surgery, whereas its occurrence following endovascular treatments seems rare.^{1,2} Data regarding real long-term recurrence rates are scarce for open surgery and non-existent for perforator treatment.

Regarding perforating vein recurrence, data from a small randomized series comparing subfascial endoscopic perforator surgery (SEPS) with open perforator ligation in leg ulcer patients showed incompetent perforators (IPs) in 40% of both groups after 4 years.³ But little is known about patients with less severe venous disease. There are 3-year data from a prospective study of open perforator surgery in New Zealand, where the majority was C1–C3 and 43% was redo procedures.⁴ They showed disappointing figures showing recurring or new IPs in 75% of the legs. There are

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no real long-term data regarding SEPS, which potentially should be less invasive and that would theoretically lower the risk of neovascularization.

Neovascularization in the groin following open surgery has been reported in up to 20% already within 1–2 years after traditional surgery from randomized studies comparing open with endovascular techniques.^{1,2} Similar rates of neovascularization also have been reported from surgical series.^{5,6} But the question is if neovascularization is as clinically important as other types of recurrence or just an innocent bystander?⁷

This paper reports the final outcome results of a prospective study that started in 1993 when SEPS was introduced.⁸ The long-term outcome for leg ulcer patients has previously been reported.⁹ The aims of this report were to assess patient satisfaction, frequency and types of varicose vein recurrence in a cohort with chronic venous insufficiency (C3–C4) which had been operated on with combined SEPS and superficial open venous surgery.

METHODS

Between March 1993 and September 1998, 104 consecutive legs were operated on and registered in 100 patients. The median age at the time of surgery was 54 years (range 25–83) and 60% were females. Primary interventions dominated (70%), and 30% were redo procedures already at the index operation.

Preoperative assessments

Only patients with chronic venous insufficiency, CEAP clinical classes C3 and C4, were included. The venous incompetence was mapped using hand held Doppler, and about one-quarter also had duplex or phlebography. Duplex was not available during the first years of this study and, therefore, SEPS was used at that time as a tool for diagnosing IPs based on size (>3 mm) in patients with clinical or Doppler signs of possible IPs. Further details regarding the assessments were published in the safety report.⁸

Surgical procedures

Informed consent was received from all patients prior to surgery. Formal ethical approval was not necessary at the time when this pragmatic quality assurance study was initiated, and the study was therefore approved only by the hospital. SEPS was performed with a single port technique with a dedicated instrument (Karl Storz, Tuttlingen, Germany). SEPS was performed in a bloodless field, created by a rubber roll-on tourniquet. General or spinal anesthesia was used. Additional superficial surgery included flush high ligation and stripping of the great saphenous vein (GSV) down to or slightly below the knee, ligation and stripping of the short saphenous vein (SSV) and local avulsions through stab incisions. Redo procedures in the groin were done from the medial aspect isolating the saphenous stump, dividing it flush to the femoral vein and suturing the defect in the common femoral vein with a continuous polypropylene

suture. Stab incisions were avoided in areas with lipodermatosclerosis or skin changes.

Follow-up

All patients were seen by a specially trained nurse after 7–10 days, and thereafter there were no scheduled clinical controls. In May 2000 all patients received a questionnaire regarding patient satisfaction. The questions concerned remaining symptoms, cosmetic result, and overall satisfaction. The final assessment was made in 2008 with an identical questionnaire and an invitation to a final color duplex ultrasound scan (DUS) to evaluate the long-term outcome. Data regarding additional vein surgery during follow-up were checked through the questionnaires and medical records.

Follow-up duplex

A full venous DUS was performed in our accredited venous laboratory, performed by medical technology assistants not involved in the study. The ultrasound machine used was a General Electric Logic 9 (GE, Milwaukee, WI, USA) and patients were examined in a standing or semi-standing position, and for perforators in a sitting position. A rapidly inflatable pneumatic cuff was used for calf-compression and for perforators manual compression of the calf and/or foot was used. The number, size, and location of IPs were documented. Incompetence was defined as reflux >0.5 seconds. Regarding superficial recurrence in the groin, all examiners were trained to look for saphenous stumps and neovascularization.¹⁰ A saphenous stump was defined as a remaining sapheno-femoral junction (SFJ) of more than 5 mm in length. Neovascularization was graded in two severity grades, grade 1 a diameter of vessels <4 mm and grade 2 a diameter of 4 mm or more, and these vessels had to be in continuity with the common femoral vein.⁵ The type of groin recurrence was classified according to Stonebridge.¹¹ The locations of additional incompetent venous segments were noted in the protocol.

Statistics

For group comparisons of proportions, the chi-squared test was used. An independent samples Mann–Whitney U test was used to assess patient satisfaction. Repeated answers regarding patient satisfaction were analyzed using the related samples Wilcoxon signed rank test. $p < .05$ was considered statistically significant. Data were analyzed using SPSS version 19.0 (SPSS, Chicago, IL, USA).

RESULTS

The first questionnaire follow-up was performed in year 2000 and 93 patients responded regarding 97 operated legs. The study diagram is shown in Fig. 1. The long-term follow-up was performed after a median of 12 years (range 10–14). During follow-up, 10 patients with 10 operated legs died. Of the remaining 87 patients/91 legs, we were able to get questionnaire assessment regarding

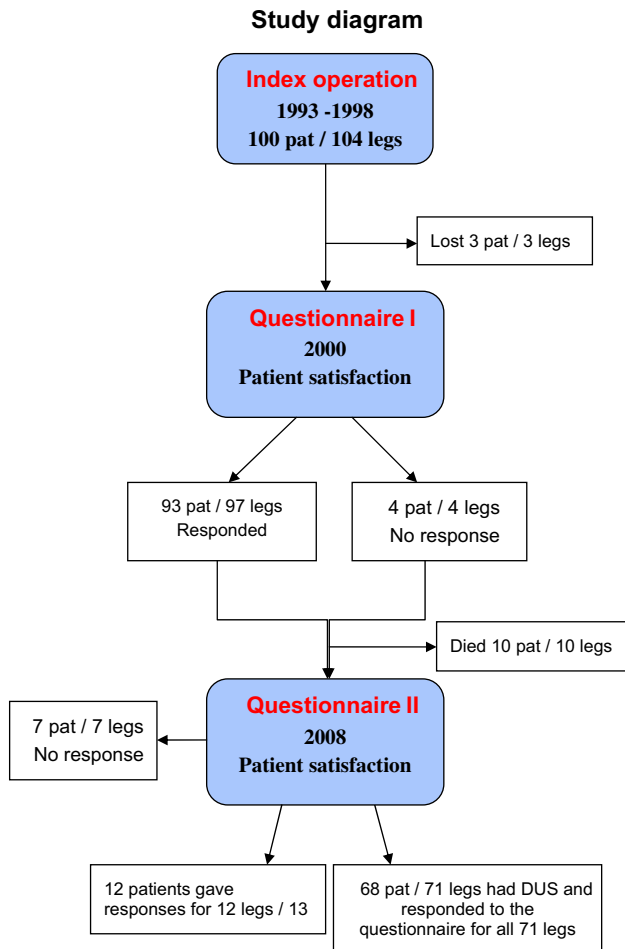


Figure 1. Study diagram.

patient satisfaction for 80/91 operated legs (88%) and 71/91 legs (78%) were reassessed with DUS, which equals 68% of the original cohort. Patient demographics and data regarding the index operation are given in Table 1. During follow-up, repeat venous surgery had been performed in 12 legs and mostly (9/12) in legs where the index operation had been a redo procedure. The reasons for repeat surgery are listed in Table 2.

Table 1. Patient demographics, CEAP clinical class, previous vein surgery and type of operation performed.

	All legs <i>n</i> = 104	Control DUS <i>n</i> = 71
Age at inclusion, median (range)	54 years (25–83)	52 years (28–83)
Gender female/male	62/42	45/26
CEAP clinical class C3/C4	56/48	43/28
Previous venous surgery	31 (30)	23 (32)
Day-case surgery	97 (93)	68 (96)
<i>Type of surgery performed</i>		
Great saphenous (GSV) + SEPS	73 (70)	49 (69)
Small saphenous (SSV) + SEPS	17 (16)	14 (20)
GSV + SSV + SEPS	5 (5)	1 (1)
SEPS ± local excisions	9 (9)	7 (10)

Values in parenthesis are percentages. DUS = duplex ultrasound scan.

Table 2. Causes for repeat surgery during follow-up.

Causes for repeat surgery	Frequency
Disease progression in other area	3 (2)
Residual varices	3 (3)
Perforator recurrence	3 (2)
SSV recurrence	2 (2)
GSV recurrence	1 ^a (0)

Values in parenthesis represent index redo cases.

^a High perforator.

Duplex results

In most legs some remaining veins with reflux could be observed and the scan was only perfectly normal in 7/71 legs. In many legs the detected reflux was minor representing small residual varicosities and areas of segmental reflux in, for example, the GSV below knee or the distal part of the SSV that we deliberately never treat. Based on the locations operated on at the index operation, the type of recurrence was assessed and is summarized in Table 3. Recurrent or new IPs were observed least often (18/71 legs, 25%). Overall recurrence or residual veins in operated areas were noted in 36/71 legs (51%), there was no significant difference between primary surgery (21/48) and redo surgery (15/23) ($p < .09$), without taking into account the redo procedures done during follow-up. In legs where the index procedure was a redo procedure, additional recurrence from operations performed earlier in another vein area was observed in 4/23 legs. Overall disease progression involving a previously healthy stem vein was observed in four legs and previously unknown deep venous incompetence was detected in 14/71 legs (20%), segmental in 8 legs and axial in six. Two legs showed remaining deep incompetence, one axial.

Following groin surgery 23/51 (45%) showed a DUS detected groin recurrence and neovascularization dominated (78%) (Table 4). In legs where primary GSV surgery had been performed, groin recurrence was found in 14/37 (38%).

Lower leg GSV was assessed in all legs that had ever undergone GSV surgery ($n = 57$) and eight were normal, 18 were incompetent without IPs, seven were incompetent with associated IPs and 24 were not visible. There seemed to be no correlation between remaining incompetent GSVs and a worse outcome for the patients.

Table 3. Recurrence related to the vein segments operated on at the index operation and progression to DVI in operated legs.

Type of recurrence	Total	Primary surgery	Redo surgery
GSV groin recurrence	23/51 (45%)	14/37 (38%)	9/14 (64%)
Types 1a–c			
SSV recurrence	7/15 (47%)	3/8 (38%)	4/7 (57%)
Perforator	18/71 (25%)	14/48 (29%)	4/23 (17%)
incompetence			
Other GSV	3/51 (6%)	2/37 (5%)	1/14 (7%)
recurrence			
Type 2a			
Progression to DVI	14/71 (20%)	9/48 (19%)	5/23 (22%)

Table 4. Classification of recurrence following GSV groin surgery.¹¹

Type of recurrence	No/51 legs (%)
1a — Main stem intact	0/51 (0)
1b — Intact SFJ (stump)	5/51 (10)
1c — gr1 Neovascularisation	11/51 (22)
1c — gr2 Neovascularisation	7/51 (14)
2a — Cross groin	3/51 (6)
2b — Mid thigh IP	1 ^a /51 (2)

2a = recurrence bridging the groin from pelvic veins.

^a Combined with a recurrence 1c — gr1.

Patient satisfaction

Overall, 70/82 (85%) reported that they were very satisfied or fairly satisfied with the long-term outcome. Patient satisfaction with the overall result was significantly better for patients who had primary surgery compared with redo procedures ($p = .004$) (Fig. 2C). This was also true for the effect on symptoms and for the cosmetic result ($p = .001$ and $p < .001$) (Fig. 2A and B).

There was no obvious correlation between DUS detected recurrences and remaining symptoms, 17/26 with GSV recurrence reported no remaining symptoms, 3/7 with SSV

recurrence reported no remaining symptoms, and 13/18 with IPs reported no symptoms. Equally there was no correlation between DUS detected recurrence and the cosmetic result, as 15/27 having a GSV recurrence reported excellent cosmetic result, 4/7 with SSV recurrence reported excellent result and 13/18 with IPs reported excellent result.

Most patients responded twice to the questionnaire regarding patient satisfaction, and a comparison of their responses in 2000 and 2008 revealed no significant differences, the outcome seemed not to have deteriorated over time, not for symptoms ($p < .153$), not for cosmetic result ($p < .182$), or total result ($p < .557$).

Lost to follow-up

We had no follow-up data for three patients. For the others that did not participate in the final long-term evaluation or had died, all had responded to the questionnaire regarding patient satisfaction in the year 2000. At that time six were fully satisfied with the result, 10 were fairly satisfied, and only one regarded the result as questionable. Their responses indicated that their outcome results were not substantially different from the rest of the studied patients.

DISCUSSION

As SEPS was combined with saphenous surgery in the majority of cases, this gave an opportunity to assess the long-term outcome after GSV and SSV surgery as well. Following groin surgery, less than half developed a recurrence, of which the great majority were caused by neovascularization. Recurrence and neovascularization were most common after redo surgery (Table 3). There were only five recurrences that were deemed caused by technical errors in the form of residual stumps usually combined with neovascularization, indicating a reasonably good quality of the open surgery performed.

The common denominator in this study was that SEPS was performed in all legs and IPs were treated in all but two limbs. A weakness is that only one-quarter had IPs verified with DUS prior to surgery. The interesting long-term finding was that rather few legs (25%) showed IPs after 10–14 years follow-up. This is dramatically less than the 75% reported 3 years after open IP surgery in New Zealand.⁴ In that report, 40% were deemed caused by neovascularization or recanalization, and the remaining newly developed. Our results are more in line with retrospective medium-term results from Austria that showed recurrent IPs in 22% of limbs following SEPS.¹² In view of this, SEPS appears to be a better and more durable alternative compared with open IP surgery. There are as yet no valid long-term data following IP treatment with endovascular techniques. Short-term data for these techniques describes technically demanding techniques, with a substantial need for early retreatments and around 20% recurrence already within 1 year.^{13–15} But whether you need to treat IPs primarily in patients with combined superficial incompetence and less severe disease C2–C3 is questioned, and in fact not even scientifically proven for patients with skin changes

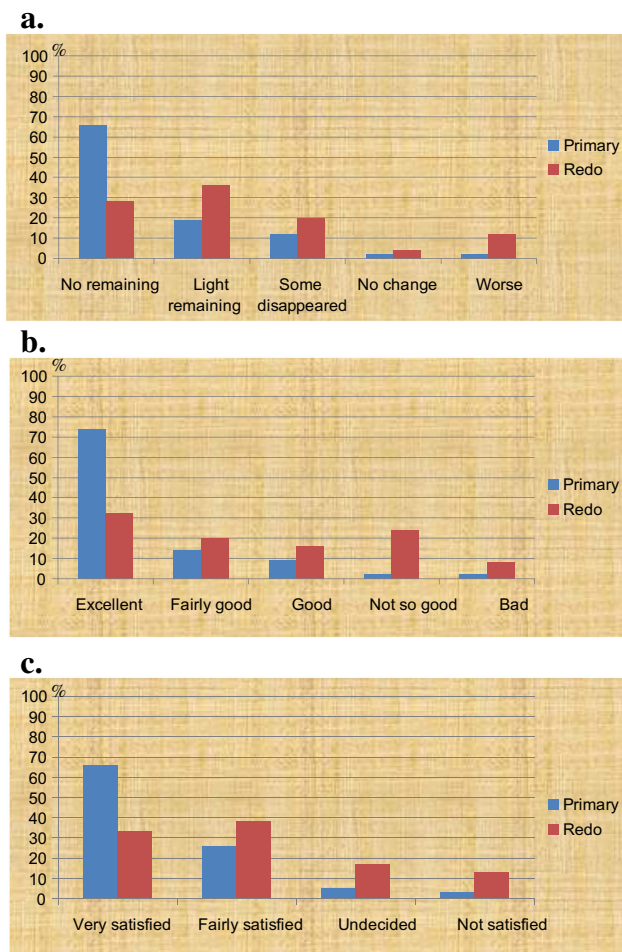


Figure 2. (A) Patient reported symptom outcome after 12 years median follow-up ($p = .001$). (B) Patient reported cosmetic result after 12 years median follow-up ($p < .001$). (C) Patient reported overall satisfaction after 12 years median follow-up ($p = .004$).

or ulceration. Today we no longer offer SEPS primarily for IPs combined with superficial incompetence in C3 patients, but prefer to treat the superficial incompetence first.

True long-term outcome results after open varicose vein surgery are relatively rare and only a few included DUS. Fisher reported the longest follow-up, some 34 years, from a retrospective study where only a minority of the patients were still alive and he examined 66% of those.¹⁶ In that study only patients who had primary GSV surgery were included, and the study showed groin recurrence in 43%, mainly neovascularization. A higher cumulated rate of neovascularization (65%) was reported from a long-term follow-up study (11 years) of 74/133 legs (51 patients) from a previous RCT, which compared high ligation with and without stripping of the GSV.¹⁷ Patient satisfaction in that study (86%) was comparable with our results, although we also included patients who had redo procedures and skin changes (C4). In a Swedish RCT,¹⁸ with a mean follow-up of 7 years, results were reported comparing outcome based on preoperative DUS versus no imaging before primary varicose vein surgery. They re-examined 227/343 legs (66%) with DUS. That study showed neovascularization in only 14% after 7 years, but in addition numerous technical and tactical failures especially in the non-DUS group. This present prospective study adds information on the true long-term outcome (12 years in median) also for patients who had more severe disease (C3–C4), redo procedures, and perforator interruption by using SEPS. All studies have shown that neovascularization is a major cause for DUS detected recurrence but not necessarily affecting the patient reported outcome, and thus the need for further interventions because of neovascularization seems very low.

The high risk of developing neovascularization after open GSV surgery is often used by promoters of endovascular ablation techniques. One can question if this really is a valid argument in light of the present results. Duplex detected neovascularization is not always combined with visible varicose veins and rarely leads to symptoms requiring further interventions.^{16,18} Patients with duplex detected recurrence often reported excellent outcomes regarding symptom relief, cosmetic result, and overall satisfaction. Similar findings have been reported by others.^{18–20} A DUS detected recurrence is far from always a bad thing for the patient unless the patient also experiences relevant symptoms. There are reports indicating that invagination of the stump endothelium might lower the risk of developing neovascularization,^{21,22} leaving a disadvantage in the groin for the endovascular techniques by leaving stumps and thereby possibly introducing a higher risk of developing a late clinically important recurrence.^{7,23}

The problem of stumps and indeed remaining entire saphenous veins, is a problem that may require further interventions in contrast to pure neovascularization. Stumps are a dominating reason for re-interventions.^{7,23} The stump problem is indeed unsettled for endovascular procedures where leaving a stump is more or less a part of the technique. Reports are beginning to emerge of recurrences through incompetent stumps and anterior

accessory saphenous veins in addition to recanalization of the GSV over time.^{21,24,25} Whether such recurrences are more easily treated and lead to a full recovery without further progression of disease remain to be shown, as for similar patients treated surgically the prognosis is not as good, as shown in this study. Patient-reported long-term outcomes were significantly worse for patients whose index operation was because of a recurrence (Fig. 2A–C), and they also showed more DUS detected venous incompetence (Table 3).

Varicose vein disease is generally considered as an ongoing disease, but whether this is true for all patients can be questioned based on our results. It has been calculated that you could give a prognosis for the 5 year outcome based on whether the patient showed DUS recurrence in the groin or not after 1 year,⁵ although others have indicated that neovascularization can appear later than after 5 years.¹⁷ Redo procedures seem to have a worse long-term prognosis and 9/12 patients who had repeat procedures during follow-up were redo patients. This underlines the importance of performing the primary procedure properly, as we have previously shown for patients with venous ulcers.⁹ Despite this, based on the patients' repeated responses regarding patient satisfaction, we saw no significant trend of disease progression during the 8 years between the two inquiries, and following primary surgery the majority seem to have had a long-lasting good outcome.

Although progression of superficial vein disease was not obvious, for the majority of patients, we noted that the deep veins seemed to deteriorate somewhat over time. Previously unknown deep venous incompetence was detected in one fifth of treated legs, of which 6/14 had axial deep vein reflux. A weakness is that only a quarter of the legs had DUS prior to the index operation. We did use hand held Doppler and assessment of patency of the popliteal vein was performed, but segmental femoral vein incompetence could have been missed. However, almost all segmental refluxes involved the popliteal vein and it is unlikely that would have been missed with hand held Doppler before the index operation. Therefore, these observations indicating increased involvement of the deep veins over time ought not to be disregarded.

In summary, it seems clear that a certain amount of neovascularization is to be expected following open varicose vein surgery, at least in the groin, as has been shown in the present study and by others.^{16,18,19,26} The frequency seems to vary and might be a result of the surgical technique and patient-derived factors.²⁷ The late outcome following redo surgery is worse than after primary surgery, and the risk of IP recurrence following SEPS seems low. The strengths of this study are that it is prospective and truly long-term, including repeated assessments regarding patient satisfaction and DUS assessments performed by Duplex technologists not involved in the study. The weaknesses are that only a minority had preoperative DUS assessment and that the study was initiated before the introduction of specific outcome scoring systems such as the venous clinical severity scoring (VCSS) and disease-

specific quality of life instruments. It was also a single centre cohort study.

CONFLICT OF INTEREST

None.

FUNDING

None.

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