Chronic venous leg ulcers benefit from surgery: Long-term results from 173 legs

Alfred Obermayer, MD,[a] **Katharina Göstl, MSc,**[b] **Gerald Walli, MD,**[a] and **Thomas Benesch, PhD,**[c]
Melk and Vienna, Austria

Objective: **The purpose of this retrospective study was to present 7 years of data from operations of currently active, chronic venous leg ulcers (CEAP: C6), focusing on the short- and long-term effects of healing and recurrence and considering concomitant risk factors.**
Methods: **Between January 1997 and March 2004, 173 patients (239 legs) with a currently active, chronic venous leg ulcer were surgically treated. The surgical procedures included two main steps: (1) the surgical interruption of reflux in the superficial and perforating veins to reduce venous hypertension in the entire leg and/or the affected area and (2) the surgical procedure involving the ulcer. A total of 123 patients (173 legs) who came to the follow-up were examined. The follow-up period ranged from 3 months to 7 years. The data collection integrated a preoperative examination that included medical history and clinical diagnoses and incorporated measurements such as body mass index, ankle-brachial pressure index, and the neutral position method at the follow-up. The function of the veins was measured with duplex ultrasonography. Finally, the data were analyzed by using various statistical methods, including Kaplan-Meier analysis, Cox regression analysis, and paired *t* tests.**
Results: **Initially, ulcer healing occurred in 87% of the cases (151 legs). A total of 13% (22 legs) of the venous ulcers never healed, and recurrent venous ulcers occurred in 5% (9 legs). The Kaplan-Meier analyses of ulcer healing showed a healing rate of 85% in 6 months for all legs. The mean time of healing was 1.5 months. Furthermore, the Kaplan-Meier analyses of ulcer recurrence showed a 1.7% rate of recurrence in 6 months for all legs. The 5-year ulcer recurrence rate was 4.6%. The mean time of recurrence was 70.4 months.**
Conclusions: **On the basis of the results from the 7 years of data from functional surgery of venous leg ulcers and as a result of the outcomes of our study, we recommend surgical treatment of venous leg ulcers at any stage. We therefore conclude that surgery is indicated before an ulcer is intractable to treatment. In general, our findings are based on the understanding and identification of the causes and symptoms of venous ulceration and illustrate that standard surgical methods can be applied for the therapy of venous leg ulcers at any stage. (J Vasc Surg 2006;44:572-9.)**

Venous leg ulcers are the most serious type of chronic venous incompetence.[1] The prevalence of healed and active leg ulcers is approximately 1% of the adult population in Western countries,[2] and an estimated 1% of total health costs in the Western world result from the therapy costs of chronic leg ulcers.[3] Nelzen[4] defined the ideal benefit for a patient with a leg ulcer as the complete healing of the ulcer in the shortest possible time at a low frequency of dressing changes, associated with an adequate quality of life and no recurrence. Various methods, such as compression treatment, wound dressing materials, and surgical modalities, are used for venous leg ulcer therapy.[5]

A wide variety of different surgical intervention approaches has been proposed. The Effect of Surgery and Compression on Healing and Recurrence (ESCHAR)[6] study illustrated that there is no significant difference in healing time and healing rate between superficial venous surgery plus compression and compression alone. However, the 12-month recurrence rate in the study was considerably lower for patients treated with surgery. Zamboni et al[7] found similar results. The ESCHAR study[6] emphasized that 85% of the patients with chronic venous leg ulcers would benefit from surgery. In a recent study, Danielsson et al[8] advocated surgery in most patients with chronic leg ulcers.

Up to now, compression therapy was considered the basic treatment in venous leg ulcers. Its value has been clearly demonstrated in several randomized controlled trials and systematic reviews.[9] Nelzen[10,11] reported that compression regimens help to heal ulcers in many cases but often do not satisfactorily solve the problem of recurrence. We report experiences and results from a retrospective analysis of a 7-year period of operations, focusing on healing time, recurrence, and concomitant risk factors of leg ulcers treated surgically.

PATIENTS AND METHODS

Patients. Between January 1997 and March 2004, 173 patients (239 legs) with a currently active, chronic venous leg ulcer (CEAP: C6) were surgically treated by a single surgeon. Patients with a healed ulcer (CEAP: C5) who were surgically treated during the same period of time were not included in these analyses.[12] Because patients

From the Surgical Department, Wachauklinikum Melk, Melk,[a] Department for Functional Phlebosurgery, Karl Landsteiner Society, Melk,[b] and Section of Medical Statistics, Medical University of Vienna.[c]
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Reprint requests: Alfred Obermayer, MD, Linzerstraβe 10, A-3390 Melk, Austria (e-mail: alfred.obermayer@gmx.at).
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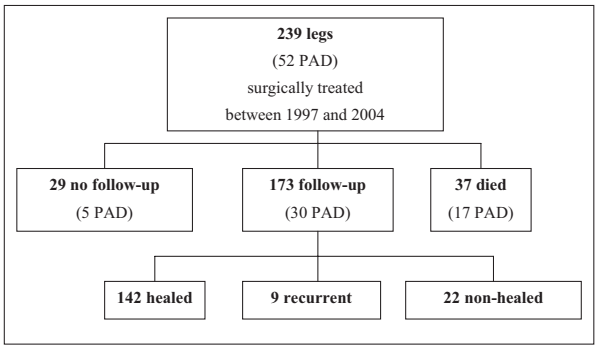

Fig 1. Trial profile. *PAD*, Peripheral arterial disease.

come to the surgical department for an operation, the patient population was preselected. In our cases, previous alternative treatments had failed, and all patients were referred by phlebologists or by other hospitals. In the absence of contraindications, surgery was performed in every case. Consequently, this study focuses on a surgical approach.

All patients were invited to a follow-up between March and June 2004, as shown in Fig 1. The follow-up rate was approximately 72%, thus allowing examination of 173 legs (123 patients). More than half of the limbs lost to follow-up were due to unrelated death.

The patient group characteristics were as follows: 42 men and 131 women, with a mean age of 66 years at the time of the operation, ranging from 25 to 88 years (median, 67.42 years). The time between operation and follow-up ranged between 3 months and 7 years (median, 3.11 years). In addition, the patient population included patients with arterial diseases (mixed ulcers), which were treated at the operation like venous ulcers.

Methods. Presurgical and postsurgical parameters were compared to evaluate the success of the surgical therapy and to describe different risk factors.[13] Immediately after surgery, all patients were supplied as described in "Surgical Procedures" and documented until complete wound healing. These data from just after surgery address the healing time. The follow-up data show the long-term results with a focus on recurrence.

Information about the duration of ulceration and family history was obtained in interviews. All legs were photodocumented before surgery and at follow-up. Ulceration size was quantified manually by planimetry. The grade of sclerosis of the tissue around the ulcer was described according to dermatoliposclerosis, including the fascia, palpable calcification, or both.

The ankle-brachial pressure index was measured with a bidirectional Doppler scan (SONODOP 3000, ELCAT; Sonotechnik GmbH, Germany). Indices of 0.8 and lower were taken as a sign of peripheral arterial disease (PAD).[14] The range of movement of the ankle joint was described by the neutral position method.[15] Starting from dorsiflexion over the neutral position to plantar flexion, free mobility of the ankle joint was indicated by 15°-0°-40°, restricted mobility by 10°-0°-40°, excessively restricted mobility by 0°-10°-40°, and stiffness by a contraction in the plantarflexed position.

The grade of edema was described on a score from 0 (no edema) to 3 (severe edema) according to the venous clinical severity score.[16] Allergic reactions to topical applications were verified by previous patch tests of 95 legs.[17]

Obesity was characterized by the body mass index (BMI). A BMI less than 19 kg/m^2 was defined as underweight, 19 to 24.9 kg/m^2 was considered normal, from 25 to 29.9 kg/m^2 was considered overweight, and 30 kg/m^2 or above was classified as obese.

Duplex scanning. Reflux in the superficial, deep, and perforator veins was evaluated with duplex ultrasound scanning (TITAN; SonoSite, Bothell, Wash) in the standing position to define the anatomy and pathophysiology of the venous insufficiency according to the CEAP system.[12]

The Valsalva maneuver was used to evaluate saphenofemoral and femoroiliac reflux. To evaluate the saphenofemoral reflux, the popliteal vein, and the perforators, manual compression and release of the calf or foot were used. Reflux time exceeding 0.5 seconds was considered pathologic.[18] Additionally, the reflux routes were detected directly by soft manual compression and release of the ulcerated area. During the duplex examination, no extended systematic search was performed for venous obstructions or remnants of venous obstructions in the deep veins.

Quality of life. Suitable diagnostic tools such as the Nottingham Health Profile,[19] the visual analogue scale,[20] and the grade of subjective health (on a score from 1 [very good] to 5 [very bad]) were used to determine health-related quality of life before the surgery and at follow-up.

Surgical procedures. There were two surgical goals. The first goal was to abolish venous refluxes in the superficial and perforating veins as detected and marked by duplex scan to reduce venous hypertension in the affected area or the entire leg. To accomplish this goal, surgery of the great saphenous vein, the short saphenous vein, and/or surgery of the perforator veins was performed (Fig 2). No surgery of deep veins was performed.

Surgery of the great saphenous vein. Ligation of the saphenofemoral junction, selective partial stripping of the incompetent great saphenous vein by invagination from groin to knee, and minisurgical phlebectomy of bigger side branches were performed.

Surgery of the short saphenous vein. Ligation of the saphenopopliteal junction, selective partial stripping of the incompetent short saphenous vein by invagination from knee to the calf, and minisurgical phlebectomy of bigger side branches were performed.

Surgery of the perforator veins. Open ligation, subfascial endoscopic perforator vein surgery (SEPS), and direct ligation in case of fasciectomy during preparation were performed.

These were followed by the local procedure targeting the ulcer, the second goal. Local procedures were selected

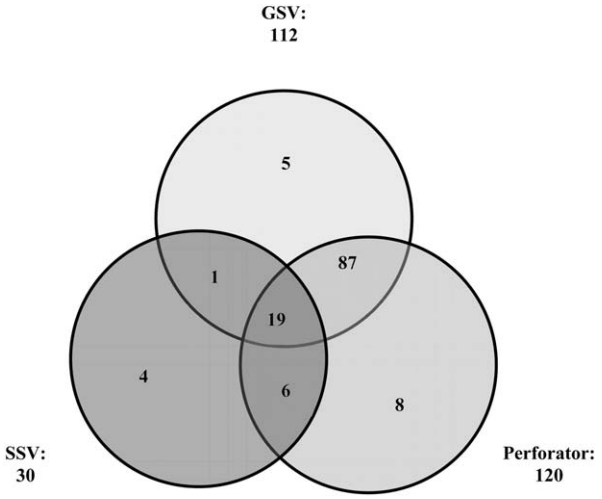

Fig 2. Schematic diagram of applied surgical procedures of the veins, illustrating the occurrence and combinations of surgical techniques. *SSV,* Short saphenous vein; *GSV,* great saphenous vein. The numbers indicate patients who received these (combined) procedures. Of the 120 surgical interventions of perforators, subfascial endoscopic perforator vein surgery was performed in 12 legs.

Table I. Local procedure for the ulcer

Variable	*No. legs (n = 173)*
Surgery for the ulcer	
Fasciectomy	57
Shave	31
Debridement	85
Procedure for the defect	
Mesh graft transplantation	86
Full-thickness graft transplantation	21
Without graft transplantation	66

depending on the grade of palpable sclerosis of the tissue around the ulcer (Table I).

Debridement. Surgical debridement of small superficial ulcers was manually performed by scalpel or sharp spoon and treated primarily with simple local postsurgical wound management without grafting.

Shaving. In case of palpable dermatoliposclerosis involving the fascia or, typically, if the ulceration exceeded 2 cm^2, shaving was performed with an electric shaver (Acculan Dermatome; Aesculap Ag & Co KG, Tuttlingen, Germany). The lesion was always covered with a mesh graft or a full-thickness graft transplantation.

Fasciectomy. En-bloc resection of the ulcer, including the crural fascia, was performed in case of induration or palpable calcification. If the muscle was elevated above the fascial level after that procedure, fasciotomy, a subcutaneous longitudinal decision of the crural fascia, was performed.

After surgery, all patients, excluding those with PAD (30 legs), were treated with compression bandaging (Porelast and Panelast; Lohmann & Rauscher GmbH, Wien, Austria) lengthwise and lengthwise/widthwise elastic adhesive bandages until healing and afterward with elastic compression stockings (Sigvaris, No. 702, class II, 30 mm Hg; Ganzoni & Cie AG, St Gallen, Switzerland).

Statistical analyses. Statistical analysis was performed with SAS (SAS Institute, Cary, NC) and SPSS (SPSS Inc, Chicago, Ill) software. Patients lost to follow-up were compared with those attending follow-up by using one-way analysis of variance and the Tukey post hoc test for multiple comparisons.

The results for the time of ulcer healing and recurrence were analyzed with Kaplan-Meier life tables. Furthermore, Cox regression analysis was used to show the association between the risk factors of healing time and recurrence time.

The differences in the outcome for patients with PAD and those with venous dysfunction of unknown cause and secondary etiology due to a postthrombotic syndrome were analyzed with two-by-two contingency tables and Fisher exact tests. Paired *t* tests were used to compare the presurgical and postsurgical outcome of the Nottingham Health Profile and visual analogue scale. Finally, Wilcoxon analysis was used to compare the outcomes of the subjective state of health evaluated by questionnaires. $P < .05$ was considered statistically significant.

RESULTS

Presurgical visit

Comparing the patients who did not attend follow-up and those who were deceased at the time of follow-up, we identified a significant difference between these groups in the presence of diabetes (χ^2 test: $P < .0001$), coronary artery disease (χ^2 test: $P < .0001$), and PAD (χ^2 test: $P = .001$). Among these three groups, significant differences in BMI ($P = .007$) and size of ulceration ($P = .001$) and no significant differences ($P = .114$) in the duration of the ulcer were identified.

Clinical characteristics before surgery. The duration of the leg ulcer before the operation ranged from 0.1 to 55 years (median, 5 years). During that time, some ulcers temporarily healed as a result of different therapies but then recurred. Before surgery, the patients had been permanently resistant to treatment for a period ranging from 2 weeks to 30 years (median, 1 year).

A total of 66% of the patients had a family history of varicose veins, deep vein thrombosis, and/or leg ulcers. Of the group, 36% (n = 63) and 29% (n = 51%) reported at least one episode of cellulitis or deep vein thrombosis, respectively, before the surgical treatment. All tested patients (95 legs) showed an allergic reaction to the topical application of ointments, and 28% (49 legs) of the cases showed a reaction to more than 5 allergens.

The area of ulceration ranged from 0.25 to 500 cm^2 (median, 12 cm^2). Nine patients had a circumferential ulcer. In 13% of the cases (23 legs), tendons, bones, and joints were involved; in 49% (84 legs), the fascia was in-

Table II. Risk factor: obesity

BMI at operation (kg/m²)	*Classification*	*No. legs*	*%*
<19	Underweight	1	1
19-24.9	Normal	32	18
25-29.9	Overweight	61	35
>30	Obese	79	46

BMI, Body mass index.

Table III. Risk factor: peripheral arterial disease

ABPI	*No. legs*	*%*
<0.5	2	1.2
0.5-0.8	26	15.0
0.81-1	13	7.5
>1	130	75.1
Mönckeberg sclerosis	2	1.2

ABPI, Ankle-brachial pressure index.

volved. Only in 38% (66 legs) were the ulcerations restricted to the dermis and subcutis. Wound secretion was severe in 65% (112 legs) and moderate in 26% (45 legs). All patients had dermatoliposclerosis, with fascia involved in 69%, which was frequently calcified (40 legs).

Edema was severe in 15% (26 legs), mild in 65% (112), and moderate in 17% (29 legs). Only 3% (6) had no edema.

According to the CEAP classification at the time of the operation, all limbs had active ulcers (C6), 68% (118 legs) had a primary reflux (venous dysfunction of unknown cause), and 32% (55 legs) had a secondary etiology due to a postthrombotic syndrome.

Concomitant risk factors. At the time of the operation, the BMI calculations indicated that 46% were obese, 35% were overweight, 18% were normal weight, and 1% were underweight (Table II). In addition, 13% had diabetes, with an average duration of 10 years (median, 6 years), ranging from 1 to 40 years, and 91.9% (159 legs) had noticeable varicose veins, which had existed in 50% of the legs for more than 30 years and a maximum of 68 years (median, 30 years). At the time of operation, 24% of the patients had coronary heart disease.

In 17% of the cases (30 legs), the ankle-brachial pressure index was less than 0.8 or showed a Mönckeberg sclerosis (Table III). In terms of ankle mobility, 42% (73 legs) showed free mobility of the ankle joints, 23% (40 legs) exhibited restricted mobility, and 32% (55 legs) showed excessively restricted mobility; in 3% (5 legs), the ankle joint was stiff.

Duplex findings. All patients had venous refluxes, as shown in Fig 3. The clinical symptoms of the venous leg ulcer resulted in all cases from a reflux (P_R); we did not attempt to detect obstruction.

Postsurgical follow-up

Clinical outcome. The mean follow-up was 3 years and ranged from 3 months to 7 years (median, 3.11 years; SD, 5.22 years). In 1% (two legs), postoperative complications occurred. These complications included subsegmental pulmonary embolism in one patient and a hematoma that needed to be evacuated in another patient.

Complete ulcer healing was defined as a full reepithelialization of the wound with an absence of secretions; recurrence was defined as an epithelial breakdown in the healed limb. Initial ulcer healing was achieved in 87% (151 legs). Recurrent venous ulcers occurred in 5% (nine legs; Fig 4).

The Kaplan-Meier analyses of ulcer healing for all legs (Fig 5) showed an 85% healing rate in 6 months. Quartile estimates showed a healing rate of 75% in 2.3 months. The mean time of healing was 1.5 months. In addition, the Kaplan-Meier analyses of ulcer recurrence (Fig 6) showed for all legs a 1.7% recurrence rate at 6 months. The 5-year ulcer recurrence rate was 4.6%. The mean time to recurrence was 70.4 months.

Assessment of 10 risk factors related to prolonged healing time and recurrence time showed that healing time was significantly related to age at the time of the operation (Table IV). The effect of surgery on ulcer recurrence time was significantly affected by age and the presence of severe edema. No other factor showed an effect (Table V).

There was no significant difference in the comparison (healing and recurrence) between the groups with PAD ($P = .999$) and those without it. In the case of patients with and without postthrombotic changes (secondary etiology due to a postthrombotic syndrome), there also was no significant difference in the outcome ($P = .999$), as was the case with patients with or without venous dysfunction of unknown cause ($P = .571$).

Duplex findings. Refluxes were identified at follow-up in 77% (135 legs) of cases, as detailed in Fig 3. The discrepancy between the different numbers of refluxes can be explained by the persistence of remnant deep refluxes combined with recurrent superficial and/or perforating refluxes after surgery or recovered deep reflux after surgery of the superficial and/or perforating veins. The group experiencing deep and perforating reflux (18 legs) at the time of operation had the highest percentage (seven legs; 39%) of nonhealed ulcers. Refluxes in the perforating veins were localized in 58% (100 legs). Deep reflux was localized in 44% (76 legs).

Quality of life. For 120 patients (169 legs), quality-of-life data were available. Between the preoperative and postoperative situations, in every dimension of the Nottingham Health Profile there was a highly significant outcome ($P < .0001$), and there were significantly reduced levels of pain on the visual analogue scale pain score ($P < .0001$). There was also a significant ($P < .0001$) benefit from the surgical treatment in terms of the subjective state of health (Fig 7).

DISCUSSION

As this study shows, there were good short- and long-term results for all groups, including those with mixed

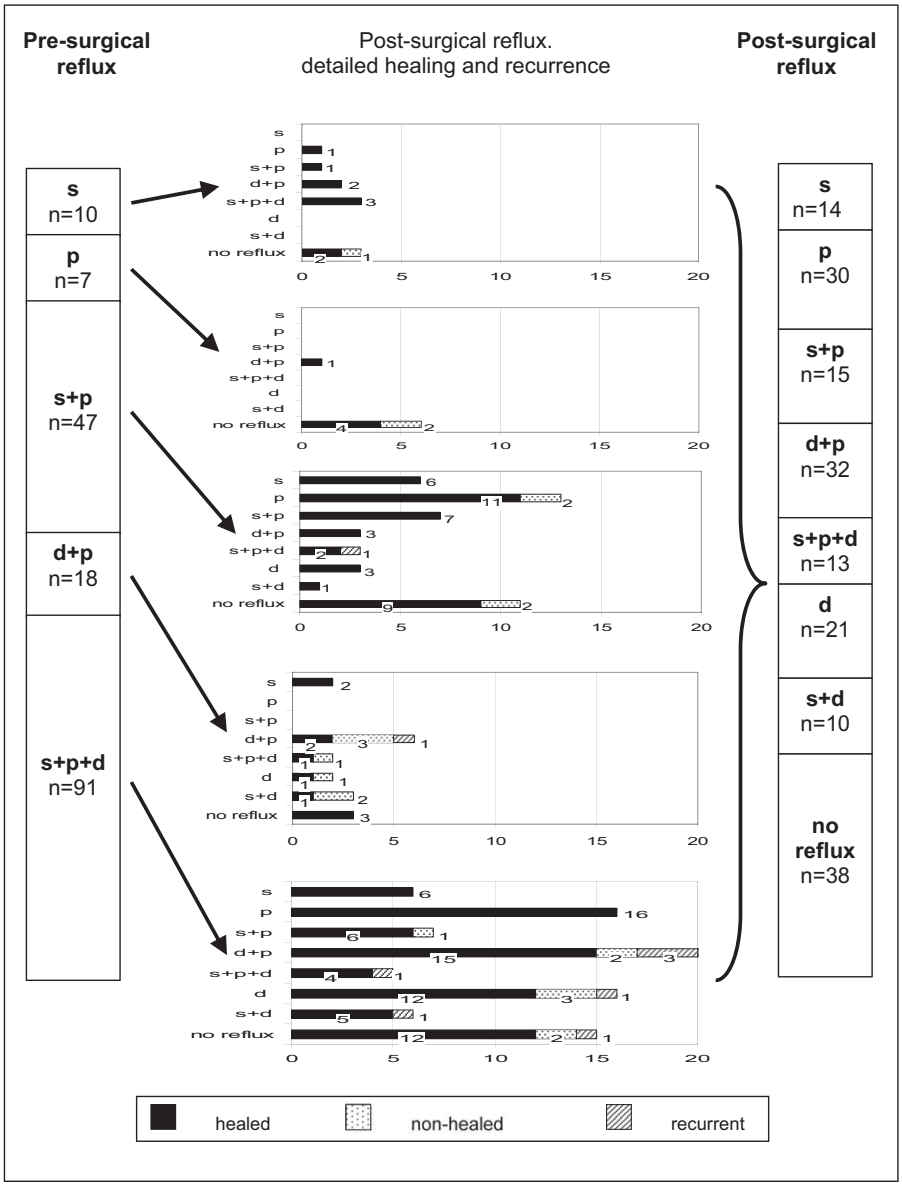

Fig 3. Schematic diagram of the number of presurgical reflux cases (*s*, superficial; *p*, perforantes; *d*, deep) and description of common and detailed postsurgical reflux and its healing/recurrence.

ulcers. Approximately 16% of patients died before follow-up; the deaths were unrelated to surgery, and approximately half of those who died had prior PAD. Nelzen et al[21] documented high death rates of nearly 50% at the 5-year follow-up for similar groups of patients. Their subgroup analyses also showed that the poor survival was caused by higher mortality related to PAD, coronary artery disease, and diabetes.

Our results demonstrate that surgical methods play an important role in the management of recalcitrant leg ulcers. Basically, the surgical therapy has to be adjusted to fit the type of chronic venous incompetence and the degree of tissue destruction.[22]

We did not use deep valve reconstruction in any case. The number of primary nonhealed ulcers could have been lower because deep reflux was present in most. Correction of reflux of the superficial and perforator system, as shown in this study, remains useful even with the advent of endovenous laser treatment. We did not include patients treated with endovenous laser treatment in this study; however, our experience shows that even though endovenous laser treatment is an advance in the minimized surgical approach, it can never fully displace accepted surgical procedures.

In addition, even with SEPS, previously used surgical procedures cannot be fully displaced. As our experience shows, only 12% of perforators were suitable for treatment

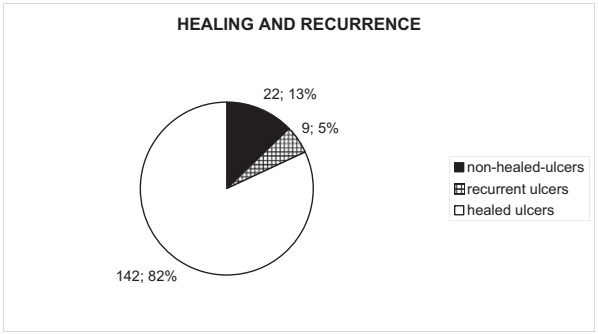

Fig 4. Healing and recurrence rates.

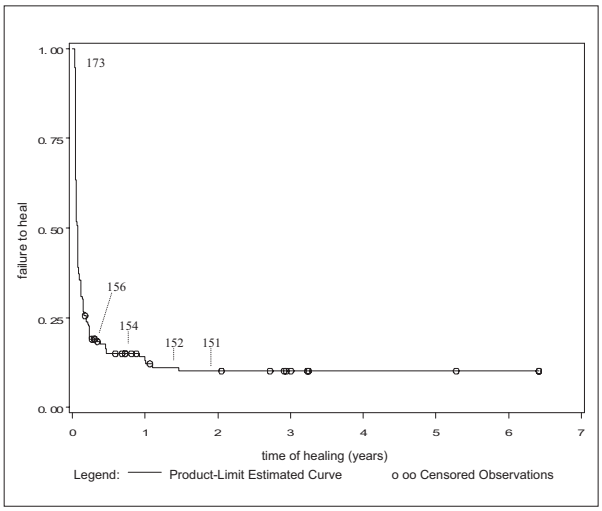

Fig 5. Kaplan-Meier analyses of failure-to-heal ulcers in surviving patients, including several time points (number of legs remaining) and time of healing (in years). Deaths are censored.

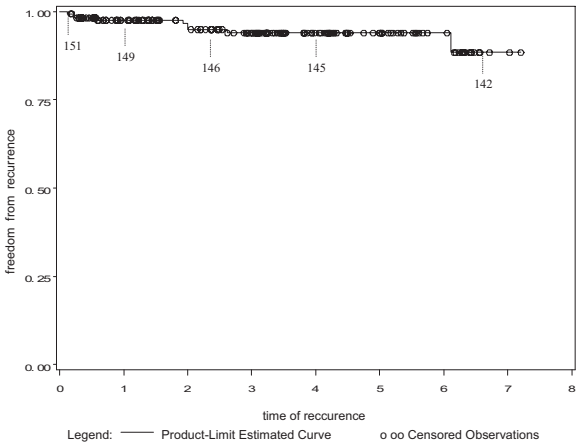

Fig 6. Kaplan-Meier analyses of freedom from ulcer recurrence among surviving patients, including several time points (number of legs remaining) and time of recurrence (in years). Deaths are censored.

Table IV. Risk factors related to healing time

Variable	P *value*
Age at operation	.0138
Size of ulceration	.1176
PAD, index ≤0.8, and Mönckeberg sclerosis	.8116
Reflux in the deep veins, presurgical	.3265
Reflux in the deep veins at follow-up	.4337
BMI at operation	.6936
Duration of ulceration	.5646
Mobility of the ankle joint	.8977
Presence of severe edema	.6228

PAD, Peripheral arterial disease; *BMI,* body mass index.

Table V. Risk factors related to recurrence

Variable	P *value*
Age at operation	.0004
Size of ulceration	.8068
PAD, index ≤0.8, and Mönckeberg sclerosis	.3946
Reflux in the deep veins, presurgical	.2361
Reflux in the deep veins at follow-up	.8922
BMI at operation	.1064
Duration of ulceration	.2877
Mobility of the ankle joint	.6493
Presence of severe edema	.0357

PAD, Peripheral arterial disease; *BMI,* body mass index.

with SEPS, especially in cases of more than one perforator. SEPS should be considered a minimized approach compared with other surgical techniques and is often not useful if there is only one perforator.

Our experience showed that a skin graft is necessary only for big and/or deep ulcers. In cases of small and superficial ulcers, shaving with a scalpel or a sharp spoon can impede self-healing without a graft. In cases of large ulcers combined with induration or calcification, fasciectomy should be performed to remove the defect and help facilitate short healing times.

Compression bandaging is not advisable in cases of PAD,[23] but surgical therapy concentrating on venous reflux is a viable alternative. The current recommended approach to mixed ulcers is to correct the arterial component first; for example, Treiman et al[24] describe this approach, which is more likely to achieve satisfactory ulcer healing. As we determined before surgery, all ulcers included in this study were caused by venous insufficiency; mixed ulcers were treated accordingly, and the arterial disease was handled as a secondary manifestation. From our point of view, which the current results emphasize, treatment of the arterial disease is not required for initial healing of the ulcer. Even in these cases, which will be separately reported in more detail, surgery was not followed by any complications.

Some possible complications,[25] such as thrombosis or iatrogenic lymphedema, did not occur in our patients. The

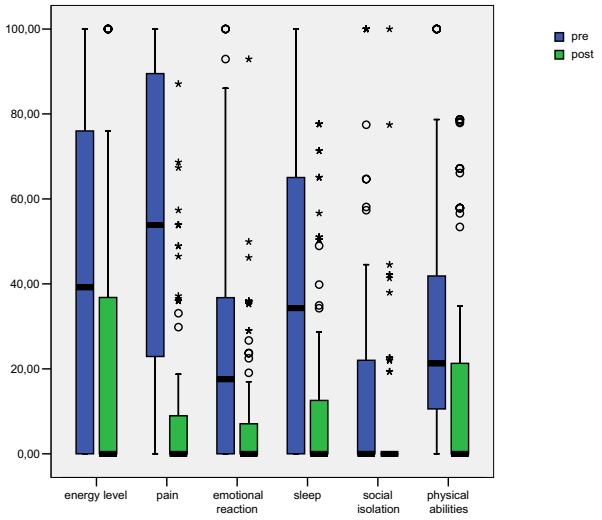

Fig 7. The preoperative *(Pre)* and postoperative *(Post)* situation in every dimension of the Nottingham Health Profile (n = 169; $P < .0001$).

leg ulcer restricts the patient's quality of life and subjects the patient to unbearable pain, and we consider it reasonable to correct venous hemodynamics with the help of immediate surgery at any state of venous insufficiency.[26] Therefore, we propose that surgery should be considered before the patients are intractable to treatment.[27] Those patients whose causes for venous ulcers are eliminated in time require no more than surgical intervention of superficial and perforating veins. The initial healing rate is comparably high at 87%, and the recurrence rate after 5 years is low (5%), especially with a focus on the outcome of nonsurgical techniques. Six months after surgery, the recurrence rate was 1.7%, thus emphasizing the need for long-term follow-up, which may be difficult in an older population.[6,28] Comparing these results with those from compression therapy alone, a benefit from surgery can be shown in both healing time and recurrence. Ennis and Meneses[29] reported that the standard of care for venous leg ulcers is based on local wound care and application of compression therapy. Published rates of healing with this standard of care are between 45% and 83% with 24 weeks of treatment.[30,31] Partsch et al[32] found in their multicenter, randomized controlled trial that total healing rates for four-layer bandages and short-stretch bandages were 62% and 73% and that median healing times were 57 and 63 days, respectively. This outcome highlights the fast healing times after surgical techniques. Regarding low compliance as a disadvantage of compression therapy,[33-35] a reduced incidence rate of recurrence after surgery can be expected. Comparing the results of our study with recurrence rates of nonoperative techniques (reported as 28% and 57% after 2 years[36,37] and 38% after 3 years[33]), ours are quite low and support the efficacy of surgical techniques.

As Machet et al[38] described, the prevalence of sensitization is still high in leg ulcer patients. In addition, the 100% positive results in all tested persons in our study suggest a large number of potentially undetected allergies; however, allergy in patients with leg ulcers is primarily iatrogenically compromised and makes subsequent treatments, including surgery, more difficult: 21 of 22 nonhealed ulcers in our study were concurrent with allergies. This result also supports a surgical approach at an early stage.

Analyses of demographic or anatomic factors and their influence on healing and recurrence also have to be considered. In concordance with our results, Gohel et al[39] found that patient age and ulcer chronicity were significant risk factors for recurrence. Danielsson et al[40] identified a high rate of obese patients in their study and described obesity as a risk factor. The high rate of 81% of overweight and obese patients in our study confirms this idea.

This study showed that venous surgery is possible and indicated at any stage, whether years of conservative therapy have failed or whether patients have an ulceration for only a few weeks. There exists no universal recipe to treat a leg ulcer. On the basis of detailed diagnosis with duplex ultrasonography, there are many different surgical procedures with different benefits, and the most pertinent goal is to determine an individual strategy for every patient. Randomized controlled trials will be indispensable to demonstrate clearly the superiority of surgery in comparison with the usual conservative treatment.[13]

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AUTHOR CONTRIBUTIONS

Conception and design: AO
Analysis and interpretation: AO, KG, GW, TB
Data collection: AO, KG, GW
Writing the article: AO, KG
Critical revision of the article: AO, KG, GW, TB
Final approval of the article: AO, KG, GW, TB
Statistical analysis: TB
Obtained funding: AO, KG
Overall responsibility: AO

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