

Long term results of compression therapy alone versus compression plus surgery in chronic venous ulceration (ESCHAR): randomised controlled trial

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ABSTRACT

Objective To determine whether recurrence of leg ulcers may be prevented by surgical correction of superficial venous reflux in addition to compression.

Design Randomised controlled trial.

Setting Specialist nurse led leg ulcer clinics in three UK vascular centres.

Participants 500 patients (500 legs) with open or recently healed leg ulcers and superficial venous reflux.

Interventions Compression alone or compression plus saphenous surgery.

Main outcome measures Primary outcomes were ulcer healing and ulcer recurrence. The secondary outcome was ulcer free time.

Results Ulcer healing rates at three years were 89% for the compression group and 93% for the compression plus surgery group ($P=0.73$, log rank test). Rates of ulcer recurrence at four years were 56% for the compression group and 31% for the compression plus surgery group ($P<0.01$). For patients with isolated superficial reflux, recurrence rates at four years were 51% for the compression group and 27% for the compress plus surgery group ($P<0.01$). For patients who had superficial with segmental deep reflux, recurrence rates at three years were 52% for the compression group and 24% for the compression plus surgery group ($P=0.04$). For patients with superficial and total deep reflux, recurrence rates at three years were 46% for the compression group and 32% for the compression plus surgery group ($P=0.33$). Patients in the compression plus surgery group experienced a greater proportion of ulcer free time after three years compared with patients in the compression group (78% v 71%; $P=0.007$, Mann-Whitney U test).

Conclusion Surgical correction of superficial venous reflux in addition to compression bandaging does not improve ulcer healing but reduces the recurrence of ulcers at four years and results in a greater proportion of ulcer free time.

Trial registration Current Controlled Trials ISRCTN07549334.

INTRODUCTION

In recent years the importance of the effect of venous leg ulceration on healthcare expenses and patients' quality of life has been recognised.¹⁻⁴ European studies have reported a prevalence of 1% in the adult population, increasing dramatically in those aged more than 80.⁵⁻⁷ The precise pathophysiological mechanisms causing ulceration remain debatable, although chronic venous hypertension (usually as a result of venous reflux) is generally accepted to play a major part.^{5,8}

Chronic venous hypertension may be countered by high elevation of the leg and multilayered compression bandaging, applied by trained staff within the setting of a specialist leg ulcer service. Excellent healing rates have been reported with this approach.⁹⁻¹¹ Strategies to prevent ulcer recurrence include patient education and class 2 elastic compression stockings.¹² Stockings are often difficult to put on and uncomfortable,¹³ however, resulting in poor patient compliance.¹³ Moreover, conservative approaches do little to correct the underlying problem of chronic venous hypertension.

Anatomical studies using colour venous duplex ultrasonography have shown that incompetence in superficial veins (long or short saphenous) is present in most legs with chronic ulceration, sometimes in combination with deep venous reflux.¹⁴⁻¹⁶ Isolated reflux in deep or perforating veins is uncommon.^{15,16} Several surgical strategies to correct the underlying venous anatomical abnormalities have been attempted. Deep venous procedures may be associated with high complication rates, and studies have shown little clear benefit.¹⁷ However, several studies have suggested that corrective surgery for superficial venous reflux may have clinical benefits for ulcer healing and recurrence.¹⁸⁻²⁰

The effect of surgery and compression on healing and recurrence (ESCHAR) study aimed to assess these outcomes in patients with chronic venous leg ulceration. The early results have been published and suggested that compression along with superficial venous surgery may reduce recurrence rates.²¹ We present the long term findings.

METHODS

The ESCHAR study started recruitment in January 1999 at three centres in south west England, serving a population of about 800 000. Since 1995 at two of the centres (Cheltenham General Hospital, Gloucestershire Royal Hospital) the management of leg ulcers has been directed by a specialist nurse led leg ulcer service. No such service existed at the third centre (Southmead Hospital), but the Gloucestershire model of leg ulcer care was extended to Southmead for the duration of this trial for recruited patients.

Referrals were received from community nursing teams, general practitioners, and other hospital medical specialists. Patients underwent a standardised leg ulcer assessment, consisting of medical history and clinical examination, assessment of ankle brachial pressure index, and colour venous duplex scanning. Routinely insonated segments included femoral vein, above and below knee popliteal vein, long and short saphenous veins, and calf perforating veins. We defined disease as being present if retrograde flow was more than one second after calf compression. Duplex scanning was carried out by trained vascular scientists. We assessed consecutive patients referred to the vascular services in the three centres and recruited those with open or recently healed leg ulceration (within six months) between knee and malleoli of greater than four weeks' duration, an ankle brachial

pressure index of 0.85 or greater, and superficial or deep venous reflux on duplex scanning. We excluded patients in whom duplex scanning was not possible or multilayer compression therapy not practical, those who were unable or unwilling to give informed consent, those with deep venous occlusion, those unfit for surgery (even under local anaesthetic), and those with malignant ulceration. For the purposes of this study we classed patients without deep reflux as having isolated superficial reflux. Patients with reflux in some, but not all, deep veins were described as having superficial and segmental deep reflux, whereas patients with reflux throughout the deep system were described as having superficial and total deep reflux. The diagnosis of superficial venous reflux was made purely on findings from duplex scans rather than the presence of visible varicosities.

If patients had ulceration of both legs, we studied the clinically worse leg, as decided by the patient. Treatment was the same for both legs. Written informed consent was obtained from the patients.

Randomisation and treatments

Patients were randomly allocated to treatment with multilayered compression therapy alone or compression plus superficial venous surgery. Computer generated random numbers were sealed in sequentially numbered envelopes and group allocation was independent of time, place, and person delivering the treatment.

Compression therapy

Patients with open ulceration were treated weekly with multilayered compression bandaging (Smith & Nephew, Hull) aiming for 40 mm Hg of pressure at the ankle graduated to 17-20 mm Hg at the upper calf. Patients with healed legs were prescribed class 2 elastic stockings (Medi, Hereford) and advised to wear these during the day. All patients were given standard written and verbal advice to elevate the affected leg and to exercise.

Surgical treatments

Patients randomised to compression plus surgery were offered superficial venous surgery guided by findings on duplex scans. Patients with reflux at the saphenofemoral junction or long saphenous vein were offered saphenofemoral junction disconnection, stripping of the long saphenous vein to below the knee, and calf varicosity avulsions. Venous reflux in the short saphenous vein was treated with saphenopopliteal junction disconnection and calf varicosity avulsions. We treated patients who were considered unfit for general anaesthesia with saphenofemoral or saphenopopliteal junction disconnections, or both, under local anaesthetic.

Follow-up and outcome measures

Patients with open ulceration were reviewed monthly in the clinics until ulceration had healed, or more often if clinically necessary. After healing, patients were reviewed at one month then every three months for

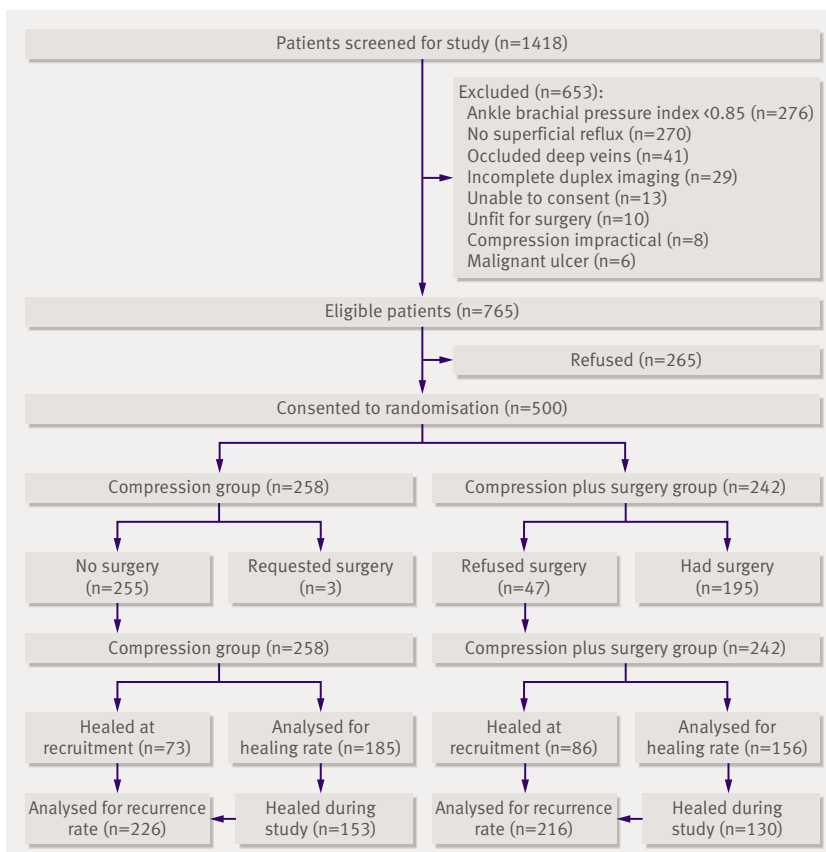


Fig 1 | Patient flow through trial

one year and every six months thereafter. Patients were given instructions to contact the service immediately for possible ulcer recurrence. After recurrence, intensive follow-up was continued to three years in two of the centres (Cheltenham and Gloucester) when details of further episodes of ulcer healing and recurrence were recorded.

Primary outcome measures were ulcer healing and ulcer recurrence. Ulcer free time was assessed as a secondary outcome measure. Ulcer healing was defined as complete re-epithelialisation of the leg. We classified any breakdown of epithelium between knee and malleoli after ulcer healing as ulcer recurrence. Ulcer free time was defined as the total time with a healed leg and was calculated to three years.

Statistical analysis

We calculated the sample size using previous non-randomised study data for ulcer recurrence rates at 12 months. Details have been published previously.²¹ Allowing a wide margin for mortality, losses to follow-up, protocol violations, non-healing ulcers, and extended follow-up, we estimated a recruitment target of 500 patients. Analyses were carried out on an intention to treat basis with no per protocol analyses planned. We calculated ulcer healing and recurrence using Kaplan-Meier survival analysis with log rank comparisons. For the purposes of the Kaplan-Meier analysis we took time zero as the date of recruitment for patients with healed legs and date of healing for patients recruited with open ulceration. We planned subgroup analyses for patients with isolated superficial reflux, superficial with segmental deep reflux, and superficial with total deep reflux. Tests for interaction were carried out using Cox regression analysis. All analyses were carried out using SPSS for windows version 13.0.1, with P values less than 0.05 considered as significant.

RESULTS

Between January 1999 and August 2002, 1418 consecutive patients with open or recently healed leg ulcers and superficial venous reflux were screened for inclusion in the study, of whom 500 consented (fig 1). A total of 258 patients were randomly allocated to compression alone and 242 to compression plus surgery. Fifty four patients were lost to follow-up or withdrew from the trial (27 compression, 27 compression plus surgery) and were censored from Kaplan-Meier analyses. Forty seven patients randomised to compression plus surgery did not attend for surgery and three randomised to compression requested surgery.

The groups were well matched for age, sex, ulcer chronicity, and ulcer size (table 1). Of the 500 patients, 300 had isolated superficial reflux, 126 had superficial with segmental deep reflux, and 74 had superficial with total deep reflux. Overall mortality was 17% at three years, with the groups showing similar mortality (19% compression, 16% compression plus surgery; $P=0.245$, log rank test). No deaths occurred within 30 days of surgery or as a direct result of surgery.

Baseline characteristics of patients with open or recently healed ulcers and superficial venous reflux by treatment group. Values are medians (interquartile ranges) unless stated otherwise

Characteristic	Compression alone (n=258)	Compression plus surgery (n=242)
Age (years)	72 (60-79)	74 (60-80)
No (%) of men	114 (44)	98 (40)
Ulcer diameter (cm)	2 (1-4)	2 (1-5)
Ulcer chronicity (months)	5 (3-11)	5 (3-11)
No (%) with diabetes	27 (10)	12 (5)
No (%) with previous deep vein thrombosis*	26 (10)	19 (8)

*As reported by patient.

Of 242 patients randomised to compression plus surgery, 195 (81%) attended for their operation; surgery was carried out to the long saphenous vein in 141 (72%), the short saphenous vein in 27 (14%), and both the long and the short saphenous veins in 21 (11%). Six patients (3%) underwent calf perforator surgery only. Surgical complications were seen in eight patients, as reported previously.²¹ Temporary hospital admission was necessary in two cases.

Ulcer healing

Overall ulcer healing rates at three years were 89% in the compression group and 93% in the compression plus surgery group ($P=0.737$, log rank test; fig 2). Numbers were too small to calculate healing rates at three years for the subgroups stratified by venous reflux pattern. Analysis for interaction showed that the effect of surgery on healing did not differ between the subgroups stratified by venous reflux ($P=0.053$, hazard ratio 0.756, 95% confidence interval 0.513 to 1.004).

Ulcer recurrence

Ulcer recurrence rates at four years were significantly lower in the compression plus surgery group

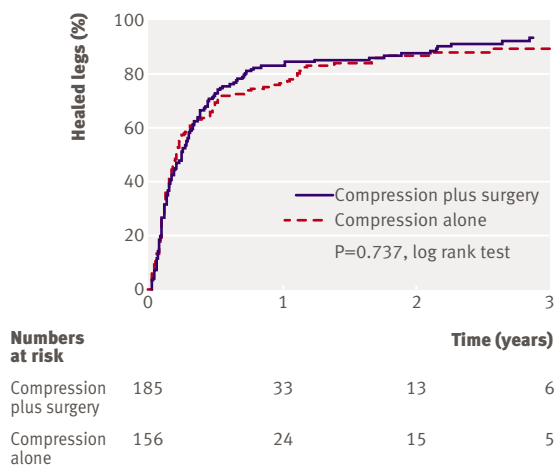


Fig 2 | Kaplan-Meier survival analysis showing ulcer healing at three years

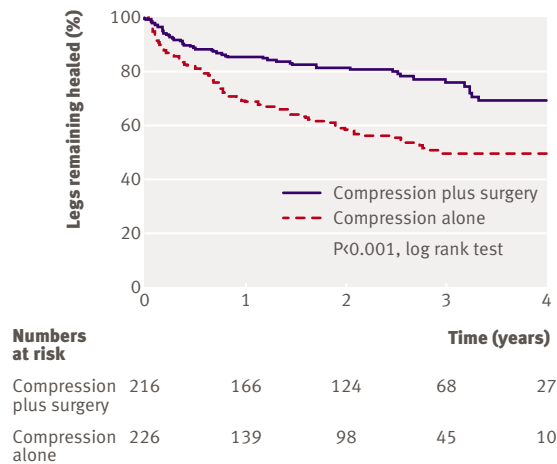


Fig 3 | Kaplan-Meier survival analysis showing ulcer recurrence at four years

compared with the compression group (31% v 56%; $P<0.001$, log rank test; fig 3). For patients with isolated superficial reflux, recurrence rates at four years were 27% in the compression group and 51% in the compression plus surgery group ($P<0.001$; fig 4). For patients with superficial plus segmental deep reflux, recurrence rates at three years were 24% in the compression plus surgery group and 52% in the compression group ($P=0.044$; fig 4). For patients with superficial plus total deep reflux, recurrence rates at three years were 24% in the compression plus surgery group and 46% in the compression group, although this was not a statistically significant finding ($P=0.23$; fig 4). Cox regression analysis confirmed that randomisation to surgery significantly reduced ulcer recurrence ($P<0.001$, hazard ratio 2.926, 95% confidence interval 1.723 to 4.133), although the influence of surgery on recurrence was not shown to differ between the subgroups with differing patterns of venous reflux

($P=0.227$, hazard ratio 0.833, 95% confidence interval 0.479 to 1.191).

Ulcer free time

Ulcer free time was assessed to three years in 365 of the 500 (73%) patients. Patients randomised to compression plus surgery experienced significantly longer absolute (100 v 85 weeks, $P=0.013$) and proportional (78% v 71%, $P=0.007$) ulcer free time up to three years than those randomised to compression. A total of 122 episodes of recurrent ulceration occurred during the study; 81 in the compression group compared with 41 in the compression plus surgery group ($P=0.001$, Mann-Whitney U test).

DISCUSSION

Superficial venous surgery in addition to compression therapy for chronic venous leg ulceration reduced ulcer recurrence and improved ulcer free time when compared with compression alone. In accordance with previous, smaller studies, the clinical benefit seemed greatest for patients with isolated superficial reflux¹⁸⁻²⁰ but was also present for patients with co-existent segmental deep reflux. For patients with isolated superficial reflux, four would need to undergo surgery to prevent one episode of ulceration in four years.

Although the improvement in ulcer recurrence rates was less impressive in the groups with segmental and total deep reflux, the subgroups were smaller and the actual benefit of surgery may have been underestimated. Other authors have reported reversal of venous reflux in deep and perforating veins after superficial venous surgery,²²⁻²⁴ and postoperative duplex scans of patients in our study showed a similar effect.^{25,26} Therefore deep venous reflux should not be considered an absolute contraindication to superficial venous surgery as patients may experience significant haemodynamic and clinical benefits. Ulcer healing was not improved by superficial venous surgery possibly because the haemodynamic benefit of multilayer

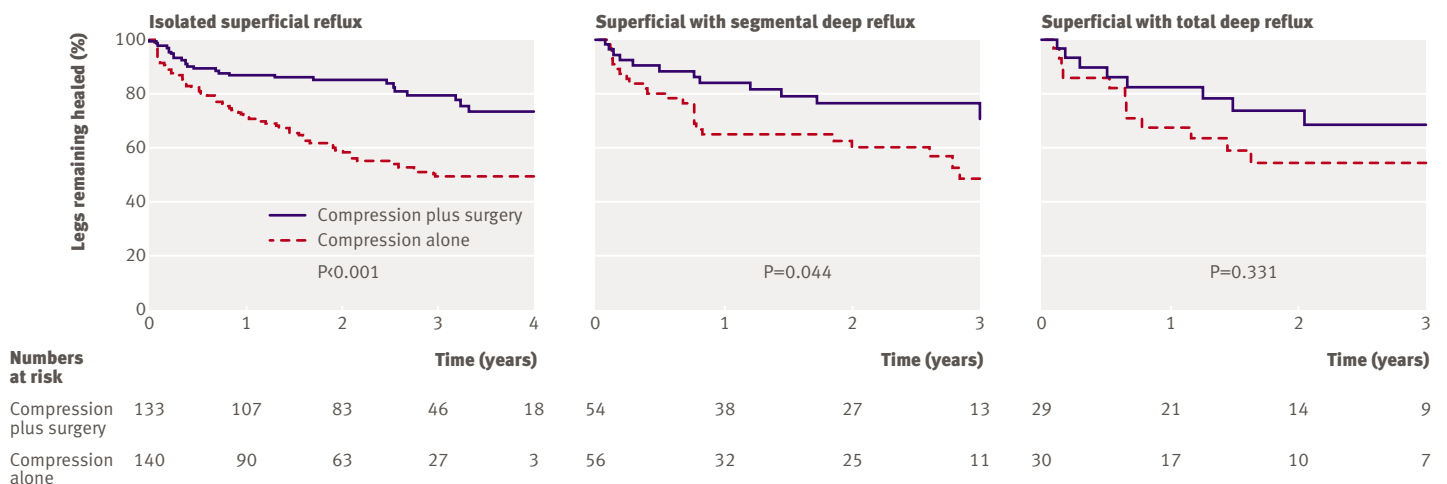


Fig 4 | Kaplan-Meier survival curves showing ulcer recurrence stratified for venous reflux pattern. Groups compared using log rank test

WHAT IS ALREADY KNOWN ON THIS TOPIC

Chronic venous ulceration is a common and expensive clinical problem
Venous reflux in superficial veins is commonly seen in these patients

WHAT THIS STUDY ADDS

Surgical correction of superficial venous reflux in addition to compression bandaging does not improve ulcer healing rates
Surgical correction can, however, reduce the chance of recurrent ulceration and increase ulcer free time

compression bandaging was not significantly improved by the addition of surgery.^{27,28}

Strengths and weaknesses of the study

Our study was set within an established leg ulcer service across three vascular centres, and we considered consecutive patients. Inclusion criteria were deliberately open and surgery was carried out by competent surgeons of varying grades consistent with standard patient care. The study was designed to emulate standard clinical practice to ensure that results could be widely applicable to the patient population with leg ulceration. Our choice of surgery and patient stratification were based solely on findings from colour venous duplex scanning. Other studies have suggested that non-invasive assessment of venous refill time using photoplethysmography may help predict success after surgery.²⁹ Further refinement of the selection process could improve the identification of patients most likely to derive a clinical benefit from the addition of venous surgery.

Poor compliance with surgical treatment for patients with leg ulceration has been reported.³⁰ In our study 24% of patients randomised to surgery refused to attend for their operation despite extensive counselling before recruitment. Moreover, patients waited a median of seven weeks for their operation and therefore may not have received an immediate benefit. Despite these factors we carried out all analyses on an intention to treat basis, suggesting that the benefits of surgery may have been underestimated. In recent years several less invasive procedures for the treatment of superficial venous reflux have been forwarded, including foam sclerotherapy,³¹ radiofrequency ablation,³² and endovenous laser.³³ These techniques, often carried out under local anaesthetic, may have a role for patients reluctant to undergo traditional surgery, although long term durability remains unproved.

Class 2 stockings have been shown to reduce ulcer recurrence and we prescribed them for all patients after ulcer healing.¹² We did not formally assess compliance with stocking use, although patients were given similar written and verbal advice. Other authors have reported poor compliance with stocking use,¹³ which may partly explain the high incidence of recurrent ulceration without surgery (56% at four years in this study). Of the patients randomised to compression plus surgery, 31% had recurrent ulceration within four years. Some did not attend for their operation

and others underwent surgery under local anaesthetic without stripping of the long saphenous vein. Factors other than venous reflux, such as coexisting medical problems or ankle stiffness causing poor calf muscle function,³⁴ may have contributed to recurrent ulceration in individual cases. Whether these patients experienced more ulcer free time after surgery as a result of less frequent or shorter episodes of recurrent ulceration remains unproved. Nevertheless, residual venous reflux and neovascularisation are common after superficial venous procedures, and stripping of the long saphenous vein to the knee is preferable.³⁵

Future research

The recent introduction of novel, endovenous techniques for the correction of venous incompetence may provide a more acceptable treatment option for elderly patient groups with chronic venous ulceration.³¹⁻³³ Further studies are needed to ascertain the haemodynamic benefits, durability, and clinical efficacy of these techniques compared with traditional venous surgery. Further work is also needed to help identify those patients who would benefit most from correction of venous incompetence and to determine why some patients experience recurrence despite the abolition of reflux.

Conclusions

Chronic leg ulceration is common and distressing for patients and an important financial burden for health-care providers. These long term findings support the early results from the effect of surgery and compression on healing and recurrence study and present a cogent argument for the widespread provision of colour duplex scanning and superficial venous surgery for patients with chronic venous leg ulcers.

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Contributors: MG was involved with data acquisition, management and analysis, and wrote this report. JB, JE, MW, and KP were involved with study concept and design, performed surgery, and critically revised this report. BH and DM performed surgery, were involved with data acquisition, and critically revised this report. MT, TC were involved with data acquisition, and critically revised this report. CF provided statistical guidance and critically revised this report.

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Competing interests: None declared.

Ethical approval: Gloucestershire and Southmead research ethics committees.

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