

Healing of Excisional wounds on Lower legs by Secondary intention (HEALS) cohort study. Part 2: feasibility data from a multicentre prospective observational cohort study to inform a future randomized controlled trial

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Abstract

Background. Compression therapy is considered beneficial for postsurgical lower leg wound healing by secondary intention; however, there is a lack of supportive evidence. To plan a randomized controlled trial (RCT), suitable data are needed.

Aim. To determine the feasibility of recruitment and estimate recruitment rate; to understand the standard postoperative wound management pathway; to determine uptake of optional additional clinic visits for healing confirmation; and to explore patient acceptability of compression bandaging and plan a future RCT.

Methods. Participant recruitment was performed from secondary care dermatology clinics, during a period of 22 months. Inclusion criteria were age ≥ 18 years, planned excision of keratinocyte cancer on the lower leg with healing by secondary intention and an ankle–brachial pressure index of ≥ 0.8 . Exclusion criteria were planned primary closure/graft or flap; inability to receive, comply with or tolerate high compression; planned compression; or suspected melanoma. Patients were followed up weekly (maximum 6 months) in secondary care clinics and/or by telephone. Information was collected on healthcare resource use, unplanned compression, wound healing and an optional clinic visit to confirm healing.

Results. This study recruited 58 patients from 9 secondary care dermatology clinics over 22 months. Mean recruitment/centre/month was 0.8 (range 0.1–2.3). Four centres had dedicated Research Nurse support. The analysis population ($n = 53$) had weekly follow-up assessments. Standard care clinical contacts were: general practitioner (7 visits; 1.2%), community nurse (169; 28.5%), practice nurse visits (189; 31.8%) and dermatology clinic visits (138; 23.2%). Participants whose wounds healed (34 of 45; 75.6%) attended an optional clinic visit.

Conclusion. Data were obtained to inform a future RCT. Recruitment rates were found to be higher in centres with dedicated research support. People

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would be willing to take part in a trial and attend a confirmation of healing visit.

Introduction

For many keratinocyte cancers (KC) on the lower leg treated by excision, the wounds are left to heal by secondary intention. However, there is a paucity of research on effectiveness of interventions for secondary intention wound healing following cutaneous surgery,¹ and there are no standardized methods for the treatment of secondary intention surgical wounds on the lower leg.

Compression therapy has been established by primary research and systematic review evidence as the first-line treatment for venous leg ulcers.^{2,3} It reduces oedema, improves venous return and tissue oxygenation, and prevents dressings from moving.² It is likely that secondary intention surgical wounds on the lower leg may also benefit from compression. Compression therapy following dermatological surgery on the lower legs is often practised,^{4,5} with the intention of improving wound healing, but without strong supporting evidence. A randomized controlled trial (RCT) would confirm whether standard wound care with compression therapy is more effective than standard wound care alone. As we found no suitable data on healing rates,² we carried out a feasibility study in this patient population.

Clinical healing and safety data of the Healing of Excisional wounds on Lower legs by Secondary intention (HEALS) cohort study have already been reported.⁵ This paper reports on the additional aims of understanding the feasibility of recruitment, the patient pathway and patient acceptability of the interventions in preparation for a large-scale definitive Phase 3 trial.

Methods

Study design

This was a multicentre prospective observational cohort study in patients with planned excision of KC on the lower leg and healing by secondary intention, and a Patient and Public Involvement (PPI) workshop.

Objectives

The primary objective of the study was to determine the feasibility of performing an RCT comparing

standard wound care plus compression therapy with standard wound care alone in patients with surgical wounds left to heal by secondary intention following excision of KC on the lower leg. Secondary objectives were: to determine feasibility of recruitment and estimate the predicted recruitment rate; to provide healing outcome data for the control arm of a future RCT to inform trial design (length of follow-up and sample size estimate); to describe standard postoperative wound care (i.e. primary and secondary dressings, and topical antimicrobials); to describe the standard postoperative clinical pathway (i.e. secondary care, community care, primary care and self-care); to determine the uptake of an optional additional clinic visit for confirmation of healing for patients in whom healing was reported; and to explore patient acceptability of compression bandaging and participation in a future RCT.

Setting

Nine UK secondary care dermatology clinics participated. The first centre opened to recruitment in February 2016, and the last centres closed to recruitment in November 2017. The final recorded follow-up assessment took place in June 2018.

Participants

Patients were recruited from secondary care dermatology clinics when attending for planned excision of KC and healing by secondary intention. Assenting eligible patients were identified to the research team and given a patient information leaflet. Participants were free to withdraw at any time without reason and without prejudicing further treatment.

Eligibility criteria

Inclusion criteria were age ≥ 18 years; planned excision of KC on lower leg with healing by secondary intention; ankle-brachial pressure index (ABPI) ≥ 0.8 (measured within previous 3 months); and provision of written informed consent.

Exclusion criteria were planned primary closure, skin graft or flap; receipt of compression therapy for another indication; inability to receive high compression due to ≥ 1 contraindication(s), on the basis of

clinical judgement or local guidelines; inability to comply with or tolerate high compression therapy (delivery of 40 mmHg pressure at the ankle); suspected non-KC diagnosis; or planned postoperative compression therapy.

Data collection

Following surgery, data were collected on wound characteristics and management strategies. Participants were followed up, as per local protocols in individual centres, in standard secondary care clinics until discharge and by weekly telephone calls until healing or until end of study (maximum 6 months). When a wound was reported as healed, the participant was invited to attend the secondary care clinic for a confirmatory healing assessment. The variables collected are detailed in the previous publication,⁵ and with additional data collected for this study on screening, patient pathway details [including which healthcare professional (HCP), or the participant themselves] treated the wound, where the patient was seen and whether they attended the optional wound-healing-confirmation visit.

Study size

The sample size was based upon the expected number of recruits at each centre required to provide sufficient data to estimate the feasibility of recruitment and the healing event rate in the standard-care control arm to inform sample size estimation for an RCT that will compare compression as an adjunct to standard care with standard care alone. The planned target number for recruitment was 55 participants to ensure 50 in the evaluable patient population.

Patient and Public Involvement and engagement

In order to inform a future RCT, it was important to gain the patients' perspective on their willingness to take part, views on different treatments for lower leg wounds, locations for follow-up care and ability to self-care. To achieve this, a meeting was held in one of the recruitment centres. Local patients who had recently undergone surgical excision of KC lesions were invited. The participants were shown different types of leg compression treatments: two-layer compression bandaging and compression hosiery. They were then asked to share their opinions on how it might feel to wear compression, what they thought the practical issues might be and how they would deal with them. A discussion then took place on their

willingness to take part in a trial and other issues that had been raised during the meeting.

Statistical analysis

The number of centres, participant flow diagram and summary statistics of recruitment rates by centre and overall are presented, including numbers of participants per centre, the time periods the centres were open and the number of days from centre opening to first recruit. Data on dressings, topical applications and wound 'crust' formation were tabulated using frequencies and summary statistics. For the postoperative patient pathway, summary statistics were tabulated on the number of follow-up visits per participant (including the optional visit to confirm healing), whether unplanned compression was used and the frequencies of postoperative contacts between participant and clinician or clinical setting contacts [general practitioner (GP), practice nurse (PN), community nurse (CN), dermatology clinic visit].

Results

Centre participation

Nine secondary care clinics participated. The first centre opened to recruitment in February 2016 and the last centres closed to recruitment in November 2017 (Table 1). The final recorded follow-up assessment took place in June 2018.

Recruitment

Eligibility and recruitment are detailed in Fig. 1. The overall mean number of participants recruited per month per centre was 0.8 ± 0.77 . Centres with a

Table 1 Periods of recruitment by centre.

Centre	Date open	Date closed
Harrogate	12 February 2016	06 July 2016
West Suffolk	18 May 2016	30 November 2017
Liverpool	23 May 2016	30 November 2017
Leeds	27 May 2016	30 November 2017
Cardiff (period 1 ^a)	06 June 2016	16 August 2016
Shropshire	22 June 2016	30 November 2017
Newport	06 October 2016	01 January 2017
Newcastle	07 November 2016	30 November 2017
Leicester	05 July 2017	30 November 2017
Cardiff (period 2 ^a)	17 August 2017	30 November 2017

^aTwo separate recruitment periods for Cardiff due to change in principal investigator.

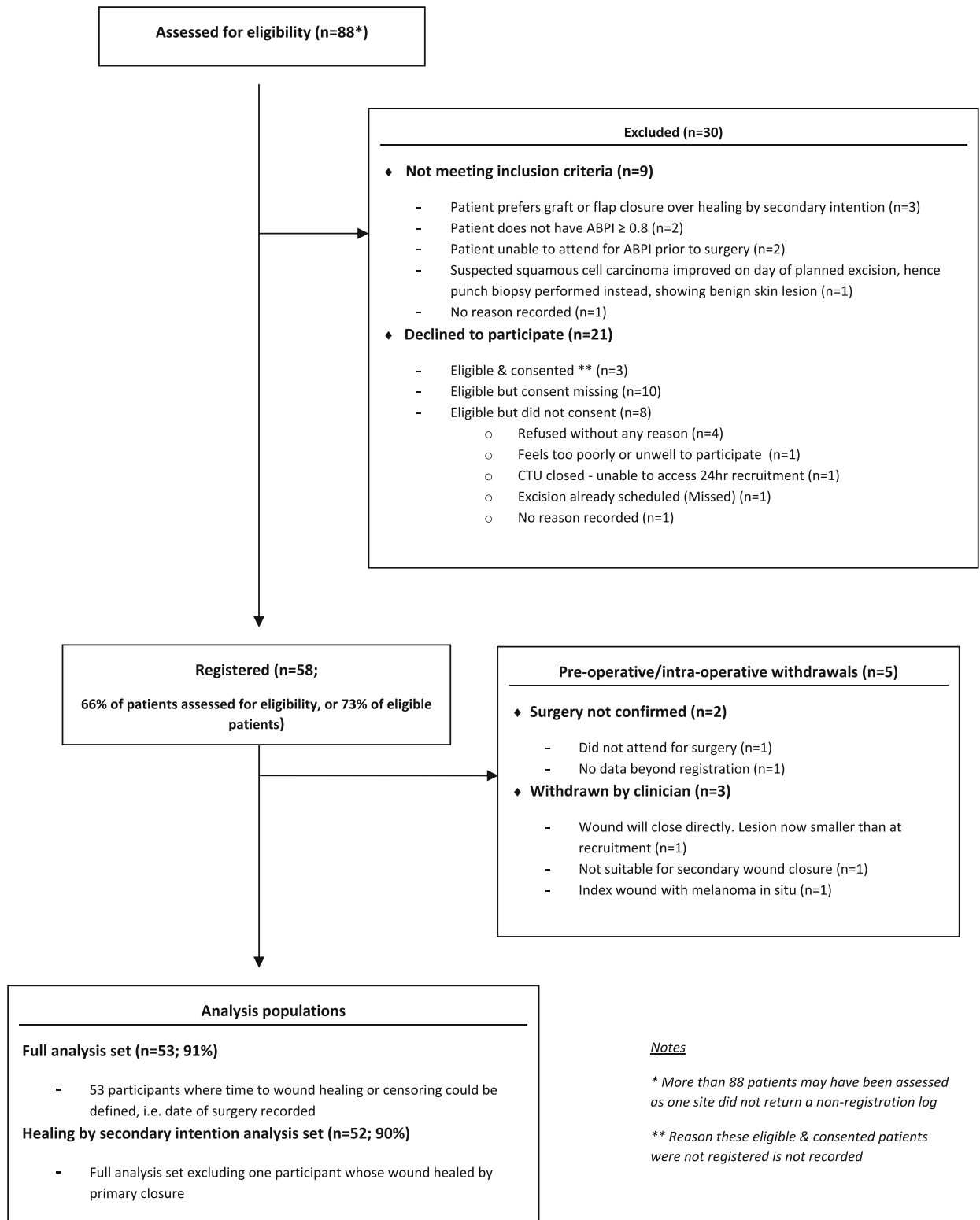


Figure 1 Study flow diagram. ABPI, ankle–brachial pressure index.

dedicated research nurse (RN) resource in place ($n = 4$; 44%) time recruited the majority of participants ($n = 41$; 70.6%) and recruited more participants per month compared with centres without dedicated RN time (1.4 ± 0.82 vs. 0.4 ± 0.30 per month per centre, respectively) (Tables 2 and 3, Fig. 1). Median time from centre opening to first participant recruited across all centres was 39 days (IQR 13–63). Centres with existing research infrastructure within the dermatology department started recruitment more quickly and at higher rates than those without this model in place (Fig. 2).

Standard care pathways and follow-up

Dressing use. The dressing usage suggested that alginate dressings were the most frequently applied (Tables 4 and 5). Nearly half the wounds in the study developed a ‘crust’.

Unplanned compression. Four participants (7.5%) received unplanned compression post surgery, and for a

further three participants, no information was available on whether postsurgical compression was applied.

Postoperative patient pathway

Follow-up clinical care for patients was spread between Dermatology outpatient clinics (138 patients; 23.2%), GP visits (7; 1.2%), community nurse (169; 28.5%) or practice nurse (189; 31.8%) (Table 6). This may have varied depending on local protocols, geographical locations, and patient or practitioner preferences.

There were 45 reports of a healed wound, and 34 of these participants attended an optional clinic visit to confirm healing. Healing was confirmed in all cases. The frequency of the reference wound developing a crust and if so, whether it went on to heal, is presented in Table 7. Although no unplanned compression was reported immediately postoperatively, it was used for four participants (7.5%) during the follow-up period (Table 8).

Study follow-up. All 53 patients attended the main follow-up consultations, of which the majority (74.6%)

Table 2 Recruitment summary by centre.

Centre	Dedicated nurse time	Total participants recruited, n	Mean participants recruited per month	Time from centre opening to first participant recruited, days
Harrogate	Yes	11	2.3	6
Leicester	Yes	9	1.8	13
Liverpool	Yes	11	0.6	32
Newcastle	Yes	10	0.8	9
Cardiff	No	5	0.9	44
Leeds	No	5	0.3	89
Newport	No	1	0.3	39
Shropshire	No	5	0.3	63
West Suffolk	No	1	0.1	240

Table 3 Numbers of participants recruited and numbers of days from centre opening to first participant recruited for centres with and without dedicated research nurse time.

	Centres with dedicated nurse time		
	Yes ($n = 4$)	No ($n = 5$)	All centres ($n = 9$)
Participants recruited per month			
Mean \pm SD	1.4 ± 0.82	0.4 ± 0.30	0.8 ± 0.77
Median (range)	1.3 (0.6–2.3)	0.3 (0.1–0.9)	0.6 (0.1–2.3)
IQR	0.7–2.1	0.3–0.3	0.3–0.9
Total participants, n	41	17	58
Time to first recruitment, days ^a			
Mean \pm SD	15.0 ± 11.69	95.0 ± 83.40	59.4 ± 72.85
Median (range)	11 (6–32)	63 (39–240)	39 (6–240)
IQR	7.5–22.5	44–89	13–63

^aTime from centre opening to first participant recruited.

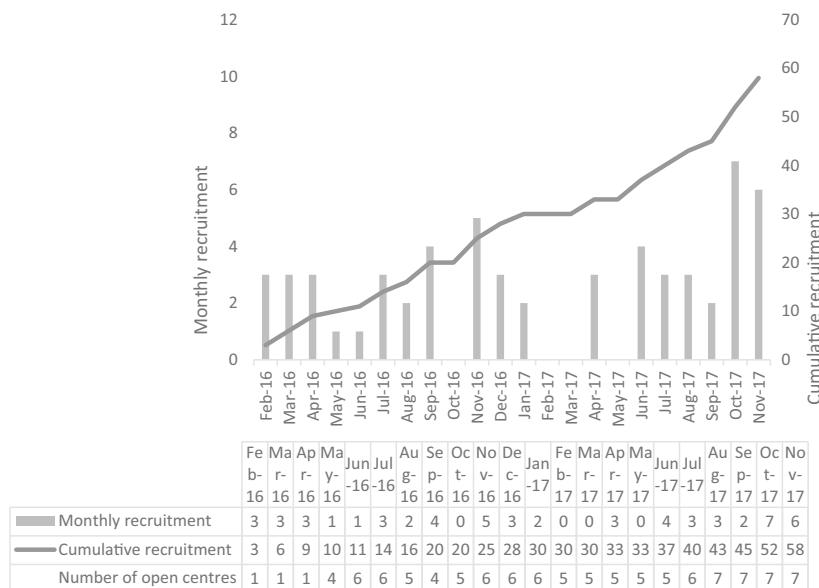


Figure 2 Recruitment by month.

Table 4 Individual dressings/topical applications applied and/or prescribed by type.

	Applied or prescribed immediately postoperatively, n (%)	To be applied by participants, n (%)
Dressings		
Dry dressing	36 (67.9)	36 (67.9)
Nonadherent wound contact layers	28 (52.8)	28 (52.8)
Alginates	40 (75.5)	2 (3.8)
Antimicrobials	17 (32.1)	8 (15.1)
Film dressings or film and pad	2 (3.8)	1 (1.9)
Foam dressings	5 (9.4)	1 (1.9)
Hydrocolloids	2 (3.8)	7 (13.2)
Hydrogels	0 (0.0)	1 (1.9)
Protease modulators	4 (7.5)	0 (0.0)
Topical applications		
Antiseptics/antimicrobials	7 (13.2)	3 (5.7)
Emollients	0 (0.0)	11 (20.8)
Total participants	53 (100)	53 (100)

were telephone assessments (Table 6). Of the 53 participants, 34 (75.6%) attended the healing-confirmation visit, which was an optional, voluntary visit.

Patient and Public Involvement and engagement meeting

The PPI meeting had eight participants (four men, four women), of whom one had undergone arm

Table 5 Combinations of dressings and topical applications applied and/or prescribed immediately postoperatively: n (%).

	With dry dressing or nonadherent		Total
	Yes	No	
Alginates + antimicrobials/antiseptics ^a	12 (22.6)	3 (5.7)	15 (28.3)
Alginates ^b	21 (39.6)	4 (7.5)	25 (47.2)
Antimicrobials/antiseptics ^c	7 (13.2)	1 (1.9)	8 (15.1)
Dry dressing and/or nonadherent wound contact layers only	5 (9.4)	NA	5 (9.4)
Total	45 (84.9)	8 (15.1)	53 (100)

NA, not applicable. ^aMay also include foam, film and/or hydrocolloid. ^bMay also include foam, film and/or hydrocolloid, but not antimicrobials/antiseptics. ^cMay also include protease and/or foam but not alginates.

surgery and seven had previously undergone leg surgery; of these seven patients, two had previously received lower leg compression following the surgery. Although the participants raised several concerns about having compression, they did identify some benefits. They felt that willingness to participate would be improved if there was a choice of bandages or stockings for compression and if follow-up could take place in the community. They would be willing to return to the hospital for a healing-confirmation visit. Further details of meeting can be found in Supplementary Data S1.

Table 6 Postoperative research visits/contacts and optional visit to confirm healing.

Parameter	Result
Participants, <i>n</i>	53
Follow-up visits, <i>n</i> (%)	594 (100)
Number of follow-up visits per participant	
Mean ± SD	11.2 ± 6.6
Median (range)	9.0 (0–31)
IQR	7–14
Days between follow-up visits	
Mean ± SD	8.6 ± 5.38
Median (range)	7 (1–51)
IQR	7–8
Type of weekly follow-up assessment, <i>n</i> (%) ^a	
Phone call	443 (74.6)
Postop dermatology clinic visit	134 (22.6)
End of study visit	8 (1.3)
Unscheduled visit	16 (2.7)
Total	594 (100)
Type of clinical contact, <i>n</i> (%) ^b	
GP	7 (1.2)
Practice nurse	189 (31.8)
Community nurse	169 (28.5)
Dermatology clinic visit	138 (23.2)
No clinical contact recorded	117 (19.7)
Total	594 (100)
Reference wound confirmed healed, <i>n</i> (%)	
Yes	34 (75.6)
Did not attend optional clinic visit	11 (24.4)
Total	45 (100)
Timing of reference wound confirmed healed, where optional confirmation visit took place, <i>n</i> (%)	
On same day as healing reported	25 (73.5)
Within 1–7 days of healing reported	6 (17.6)
> 7 days after healing reported	3 (8.8)
Total	34 (100)

GP, general practitioner. ^aPercentages add up to > 100% due to two different types of follow-up assessment recorded for some weeks (eight instances: six had phone call + postop dermatology clinic visit, one had postoperative dermatology visit + unscheduled visit, one had phone call + unscheduled visit). In one instance no type was specified. ^bPercentages add up to > 100% due to 2 different types of clinical contact recorded for some weeks (26 instances: 3 had GP + practice nurse, 2 GP + community nurse, 1 had GP + dermatology clinic, 2 had practice nurse + community nurse, 3 had practice nurse + dermatology clinic, 15 had community nurse + dermatology clinic).

Discussion

In this study, we assessed data that might inform a future RCT.

We found that centres with RNs in place recruited the majority of participants and also recruited more participants per centre. In these centres, the research team are embedded within the dermatology department, and RNs are a permanent resource to support a portfolio of dermatology studies. Where this infrastructure is in

Table 7 Development of crust (postoperative).

Parameter	Result, <i>n</i> (%)
Reference wounds that developed a crust	
Yes	22 (41.5)
No	27 (50.9)
Unsure ^a	1 (1.9)
Missing	3 (5.7)
Total	53 (100)
Of these, how many healed	
Yes	20 (90.9)
No	2 (9.1)
Total	22 (100)

^aDevelopment of crust not clear due to wound being dressed.

place, working relationships exist between research team and clinicians to aid communication about studies and potential participants, and RNs are well placed to screen clinics and approach participants.⁶

The time between centre opening to first participant recruited had a wide range, from 6 to 240 days. For the RCT, barriers to recruitment will be explored, e.g. the patient not having an ABPI. Equipment and resource issues will be taken into account in the planning of the RCT. PPI involvement will be key to study design to maximize recruitment.

Although the study only recruited patients with no planned compression, a small number later received unplanned compression (*n* = 4; 7.5%). This suggests the need to consider treatment switching as a secondary analysis in a future RCT.

The majority of dressings used for compression were alginate-based. This is expected as alginates have haemostatic properties and are often used on postsurgical wounds. Alginates require a secondary dressing, which for these participants, was most likely to be a dry dressing, although hydrocolloids/film dressings could also have been used. Dry dressings alone (or in combination with alginates) are highly vapour-permeable, do not maintain a moist wound-healing environment, and can lead to scab or crust formation. Nearly half the wounds in the study developed a crust. It is thought that most wounds healing by secondary intention will heal quicker and with less pain if there is a moist environment,⁷ and formation of a crust can make identifying the endpoint of healing difficult. Future study design considerations need to incorporate measures to prevent crust formation, i.e. moist wound healing or how the endpoint is defined.

Follow-up care for patients was spread between different settings and HCPs. This may have varied depending on local protocols, geographical locations, and patient or practitioner preferences. Planning for a future

Table 8 Incidence of unplanned compression use immediately postoperatively and during follow-up by type of wound closure.

Unplanned compression	Immediately postoperatively	Type of wound closure			Total
		Secondary intention healing			
		No additional closure	Additional closure ^a	Missing or primary closure	
Yes	0 (0.0)	3 (13.6)	1 (3.4)	0 (0)	4 (7.5)
No	52 (98.1)	18 (81.8)	28 (96.6)	0 (0)	46 (86.8)
Missing	1 (1.9) ^b	1 (4.5)	0 (0.0)	2 (100)	3 (5.7) ^c
Total	53 (100)	22 (100)	29 (100)	2 (100)	53 (100)

^aPurse string, pulley sutures or partial closure. ^bThe participant with unplanned compression status not recorded immediately postoperatively was lost to follow-up. ^cThe missing values were for three participants who had surgery recorded but no follow-up visit data.

RCT will need to be mindful of this variation. Visits can be expected to occur on average once weekly. In the current study, the majority of follow-up visits in the current study were telephone assessments. This suggests that telephone appointments could be used for follow-up data collection, as they (i) provide additional flexibility and/or are easier for participants, and (ii) require less RN time to complete. A future trial design incorporating telephone (or video) calls may benefit follow-up compliance and has been an acceptable method for both participants and research teams in this study. An exploratory study of postoperative wounds has found that patients were willing to take photographs of their healed wounds and send these to the HCP.⁸

Blinding in a future RCT of compression therapy may be problematic as the bandage will be visible at the assessment. It is thought that open trials can increase recruitment,⁹ although lack of blinding increases the risk of bias. However, some wound-healing studies have used blinded endpoint assessment of healing.^{10,11}

Around three-quarters of the patients attended the optional healing-confirmation visit. The attendance rate was higher in centres with RNs in place. Ways to improve attendance for healing confirmation (e.g. travel expenses; there was no funding for patient travel expenses in this study) will be planned into the RCT. Exploring alternatives to verify healing, such as home visits, GP/PN visit or patient photographs of the wound returned to research team could also be useful to increase compliance with this visit.

Conclusion

This study has highlighted important factors to consider in the design of a future RCT alongside the important clinical data we have reported in this patient group.⁵ Recruitment to trials is challenging,¹² and realistic recruitment predictions are a key consideration at the grant-application stage to ensure a trial

is achievable within its proposed timeframes and associated funding. Recruitment predictions should take account of participating centres and their research infrastructure, and robust centre feasibility assessments will inform prioritization of centres to open to recruitment. Endpoint assessment should be carefully considered to minimize the risk of bias.

What's already known about this topic?

- Compression therapy is first-line treatment for lower leg ulceration and is theoretically beneficial for postoperative wounds healing by secondary intention.
- Information on patient characteristics, healing times, prognostic factors and safety data have been published from a multicentre prospective observational cohort study performed to inform a future trial.
- Details of recruitment feasibility, potential recruitment rates, standard postoperative wound management pathway and acceptability of compression therapy to patients are still unreported.

What does this study add?

- This paper is the first, to our knowledge, to report details of standard postoperative wound management pathways and acceptability of compression therapy to patients undergoing excision of keratinocyte carcinoma of the lower leg.
- It reports the additional feasibility information needed to plan an RCT.
- These results, along with the previously published findings will also be helpful to clinicians and patients who are currently undergoing lower leg excision of KC.

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Conflict of interest

BW has received honoraria, clinical trial funding or travel scholarships from AbbVie, Lilly, Jansen, Sanofi, Leo and Galderma. The other authors declare that they have no conflict of interest.

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Ethics statement

Ethics approval was given by the South Central – Oxford B Research Ethics Committee (15/SC/0598). Patients provided written informed consent for participation.

Data availability

Data are available on request from the corresponding author.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Summary of findings from the Patient and Public Involvement meeting.