Royal Devon and Exeter
NHS Foundation Trust

Timing of Suture Removal to Reduce Scarring in Skin Surgery

End Date 26th October 2022

IRAS Number: 303519

Sponsor: Royal Devon and Exeter NHS Trust

Chief Investigator:
Dr Emily McGrath, Consultant Dermatologist, Royal Devon and Exeter NHS Trust

Co-Principle Investigators:
Dr Alistair Brown, Dermatology Registrar, Royal Devon and Exeter NHS Trust
Dr Ellen Richards, Academic Foundation Doctor, Royal Devon and Exeter NHS Trust

Royal Devon and Exeter
NHS Foundation Trust

Timing of Suture Removal to Reduce Scarring in Skin Surgery

1. HRA PROTOCOL COMPLIANCE DECLARATION

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:

..../...../.....

Name (please print):

.....

Position:

.....

Chief Investigator:

Signature: Date:

..../...../.....

Name: (please print):

.....

Timing of Suture Removal to Reduce Scarring in Skin Surgery

2. CONTENTS

Timing of Suture Removal to Reduce Scarring in Skin Surgery

Timing of Suture Removal to Reduce Scarring in Skin Surgery

3. KEY STUDY CONTACTS

Chief Investigator	**Dr Emily McGrath** Consultant Dermatologist Royal Devon and Exeter NHS Trust Emily.mcgrath@nhs.net
Study Co-ordinators	**Dr Ellen Richards** Academic Foundation Doctor Royal Devon and Exeter NHS Trust Ellen.richards6@nhs.net **Dr Alistair Brown** Dermatology Registrar Royal Devon and Exeter NHS Trust Alistair.brown4@nhs.net
Sponsor	Royal Devon and Exeter NHS Trust
Funder	Dermatology Department Royal Devon and Exeter NHS Trust

4. STUDY SUMMARY

Study Title	Timing of Suture Removal to Reduce Scarring in Skin Surgery
Study Design	Prospective randomized assessor blinded parallel group feasibility study
Planned Size of Sample	60
Follow up duration	3 months
Research Question/Aim(s)	In patients undergoing wide local excision and primary wound closure for treatment of skin cancer, does earlier removal of percutaneous sutures (7 days rather than 10 days) reduce the incidence of suture marks assessed at 3 months post-operatively.

5. FUNDING

FUNDER	FINANCIAL AND NON FINANCIAL SUPPORT GIVEN
Dermatology Department Royal Devon and Exeter NHS Trust Heavitree Hospital	Financial support for printing patient information sheets and other required documentation. Facilitating space for clinic follow-up.

Gladstone Road Exeter EX1 2ED	Support of the dermatology team helping with recruitment to trial.
Royal Devon and Exeter NHS Trust Barrack Road, Exeter, EX2 5DW	Support in the form of allocation of an academic foundation doctor as co-principle investigator.

6. ROLE OF SPONSOR AND FUNDER

Sponsor: Royal Devon and Exeter NHS Trust

Role of Sponsor:

- To take overall responsibility for the research
- Ensuring appropriate indemnity or insurance for the study
- Ensuring patient/participant safety and rights

Role of Funder:

- To aid in financial support for printing and dissemination of patient information sheets and postage of trial information to participants
- To provide healthcare professionals within the dermatology department to help with execution of patient recruitment and follow-up

7. PROJECT MANAGEMENT

Dr Emily McGrath Consultant Dermatologist Royal Devon and Exeter NHS Trust	**Primary responsibility for conduct of trial** **Adverse event assessment** **Responsible for concealment of patient randomization** **Trial recruitment and consent** **Protocol contributor**
Dr Ellen Richards Academic Foundation Doctor Royal Devon and Exeter NHS Trust	**Initiation and conduct of trial** **Day to day running of project** **Reporting of adverse events** **Maintenance of regulatory documents and spreadsheet** **Review of patients at 3-month follow-up** **Study write-up** **Protocol contributor**
Dr Alistair Brown Dermatology Registrar Royal Devon and Exeter NHS Trust	**Initiation and conduct of trial** **Data analysis** **Study write-up** **Protocol contributor**
Dr Roy Powell	**Protocol contributor**

Timing of Suture Removal to Reduce Scarring in Skin Surgery

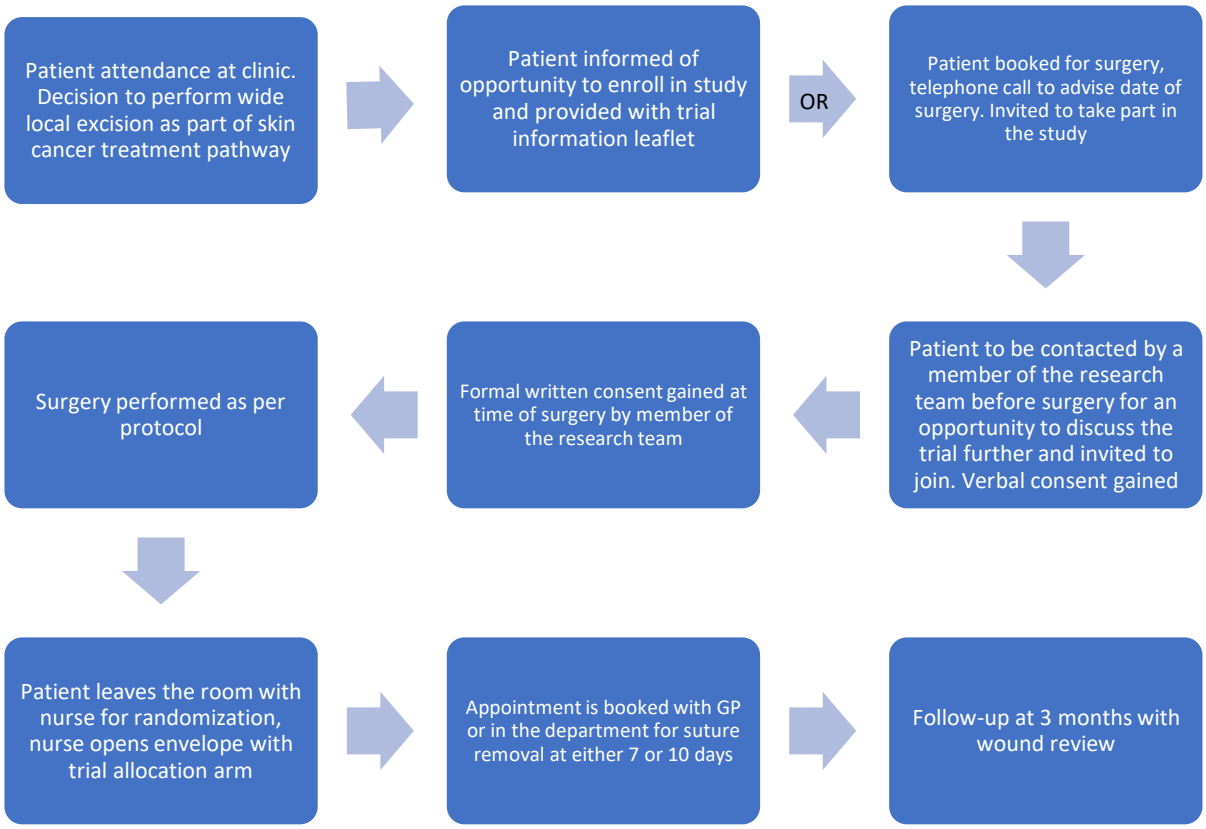
Research Statistician Royal Devon and Exeter NHS Trust	
All doctors within the dermatology department	**Trial recruitment and consent** **Data collection prior to procedure** **Data collection in theatre**

8. TIMELINE

Months				
	0	3-6	6-12	12-15
Finalize protocol	x			
Ethics submission	x			
Patient recruitment		x		
3 month follow-up			x	
Data entry			x	
Data analysis				x
Project write up				x

Timing of Suture Removal to Reduce Scarring in Skin Surgery

9. STUDY FLOW CHART



Royal Devon and Exeter
NHS Foundation Trust

Timing of Suture Removal to Reduce Scarring in Skin Surgery

Protocol

Timing of Suture Removal to Reduce Scarring in Skin Surgery

10. BACKGROUND

A suture mark (also known as stitch mark or track mark) is scar tissue thought to be caused by local tissue necrosis following suture placement. The risk of suture marks appears to be associated with the timing of suture removal. Sutures left in situ for longer than seven days increase the risk of permanent scarring.

Percutaneous sutures are commonly used in dermatological surgery to achieve wound edge apposition, eversion and to prevent a depressed scar. Despite the risk of suture marks they are often left in situ for longer than seven days especially on sites of skin tension. On the chest or back it is common practice to wait up until 14 days before suture removal. The timing of suture removal is guided by surgeon preference and concern about wound dehiscence. However, wound dehiscence is unlikely to occur where there is adequate placement of dermal or subcuticular sutures (sutures beneath the top layer of skin, otherwise known as buried sutures). Where there is adequate subcuticular suturing to close the wound the percutaneous sutures may be removed earlier. There is currently no clear consensus on the timing of suture removal and the current standard of care varies between 7 and 14 days.

We hypothesize that earlier removal of percutaneous sutures (7 days rather than 10 days) reduces the incidence of suture marks in patients undergoing excision and primary wound closure for treatment of skin cancer. We are also interested to study whether early suture removal has an impact upon overall scar cosmesis, patient reported outcome measure, and wound complications including bleeding, infection, and dehiscence.

11. RATIONALE & LITERATURE REVIEW

Medline and CENTRAL were searched using the following terms “scar” and “skin” and (“suture” or “stitch”). 1585 titles were reviewed. 60 articles were identified for potential relevance and abstracts reviewed. 12 full text articles were reviewed.

Suture marks, sometimes described as ‘track marks’, ‘railroad tracks’, ‘cross hatching’ or ‘fishbone scars’ are a known complication of suture placement. The incidence of this occurrence and the impact on the patient is not known although they are seen as an unfavourable scar characteristic [1]. Surgical technique (tissue handling, suture technique, layered closure, use of lines of natural skin tension, close approximation and eversion) and patient factors (keloid tendency, skin type or body site) are thought to play an important role [2]. Another factor that is thought to play an important role is the timing of suture removal. Sutures left in place for more than seven days are thought to increase the risk of suture marks [3].

Percutaneous sutures are generally left in place for longer due to concern about wound dehiscence. However, several alternative wound closure techniques have been described to negate the use of percutaneous sutures or to reduce suture marks [4]. These studies demonstrate that adequate subcuticular suturing is sufficient for prevention of wound dehiscence. These include the use of adhesive glue following dermal closure with buried sutures [5], the use of buried subcuticular sutures alone [6], and suture removal and replacement of sutures at 3 days post operatively [7]. Another

study that assessed the use of adhesive strips following subcuticular running vertical mattress sutures found that adhesive strips provided no additional benefit to subcuticular sutures alone [8].

Despite alternatives to percutaneous closure, the use of percutaneous sutures is still common practice in dermatological surgery in the UK. This is because percutaneous sutures are considered best practice in order to achieve wound edge eversion and help prevent a depressed scar. There is insufficient evidence to guide the length of time until suture removal but common practice dictates that on sites of tension percutaneous sutures should remain in situ for longer until removal. On the chest or back suture removal between 7 and 14 days is normally suggested for suture removal.

Adequate approximation of the wound edges with placement of dermal sutures should negate the requirement for percutaneous sutures to remain in situ for longer than seven days even in sites of tension.

12. THEORETICAL FRAMEWORK

We are interested to assess whether earlier suture removal reduces stitch marks in wounds where close approximation of wound edges can be achieved with dermal sutures. In doing so we hope to provide evidence that earlier suture removal reduces the risk of suture marks without increasing wound complications.

As the incidence of suture marks is currently uncertain and the impact that these have on the patient is unknown we intend to perform a feasibility study prior to conducting a randomized controlled trial. This study would give as indication as to the sample size required to power our RCT correctly. It will also provide an indication as to the ease of recruitment, patient participation, loss to follow-up, and complication rate. Furthermore, it will allow us to evaluate the use of our chosen assessment tools.

We have designed a single centre, randomized, blinded, parallel group feasibility study to assess viability of a randomized control trial (RCT) to answer this question.

13. RESEARCH QUESTION

In patients undergoing wide local excision and primary wound closure for treatment of skin cancer does earlier removal of percutaneous sutures (7 days rather than 10 days) reduce the incidence of suture marks assessed at 3 months post-operatively.

Secondary questions:

Does earlier suture removal have an impact (negative or positive) on overall scar cosmesis and wound complication rates* (as assessed by the clinician and the patient)?

Timing of Suture Removal to Reduce Scarring in Skin Surgery

**Risk of post-operative bleeding, risk of surgical site infection, risk of wound dehiscence (opening up of scar)*

14. AIMS AND OBJECTIVES

Aim:

To test the feasibility of conducting a definitive trial looking at outcomes for earlier removal of percutaneous sutures (7 days versus 10 days) for patients undergoing wide local excision and primary closure for treatment of skin cancers on the chest or back in dermatology.

Objectives:

1. To work out the standard deviation of the outcome measure (suture marks versus no suture marks) in order to estimate a sample size required for a properly powered RCT. (The incidence of 'suture marks' and the impact that these have on patients is currently unknown).
2. To provide some preliminary data on the incidence of wound complications and overall scar cosmesis in each group and ensure that this does not differ from expected:
    a. *Overall cosmesis*
    b. *Risk of post-operative bleeding*
    c. *Risk of surgical site infection*
    d. *Risk of wound dehiscence (opening up of scar)*
3. To assess the willingness of participants to be randomized.
4. To assess the willingness of clinicians to recruit patients.
5. To assess follow-up rates and adherence.
6. To assess the characteristics and ease of use of the proposed outcome measures including POSAS for scar assessment, a VAS, and patient reported outcome for complications including dehiscence and infection.
7. To gain feedback from patients at their three month follow up appointment on the patient pathway including the trial information leaflet and consent process.
8. To collect data on any additional costs that we may incur that have not been planned for, to inform costing for a future trial e.g. additional printing of PIS or consent forms or additional clinic booking slots
9. To use the gathered data to refine the design of the proposed RCT.

15. LAY SUMMARY

Stitch marks (also known as suture marks or track marks) are permanent marks left in the skin where the stitch has caused local tissue damage and scarring. The risk of these marks is in part thought to be related to the length of time that the stitches are left in place before removal. Stitches are normally left in place for longer on sites where the skin is under greater tension such as the chest or back because there is a concern that the wound may be more likely to open up on these sites. On

the chest or back, stitches may be left in place for up to 14 days even though the chest or back is a common site for stitch marks to form.

In skin surgery, wounds are commonly closed in two layers. A layer of dissolving stitches is placed under the top layer of the skin to bring the wound edges together. These stitches do not need to be removed. Another layer of stitches is then placed along the top of the wound, often with non-dissolvable stitches that need to be removed. If the wound edges can be brought closely together with the deeper stitches, then we do not believe that the top stitches need to stay in place for longer than seven days, even on sites of tension. This is because the deeper stitches should prevent the wound from opening up. We believe that stitch removal at 7 days rather than 10 days reduces the risk of stitch marks without increasing the risk of the wound opening up.

We would like to perform a small study to assess how practical it will be to perform a full study to look at whether earlier removal of superficial stitches (7 days rather than 10 days) reduces the risk of stitch marks.

We would also like to assess the impact that stitch marks have on patients, the effect of early stitch removal on the overall appearance of the scar, and the effect of early stitch removal on the number of wound complications.

We aim to invite patients to join the study who are having a wide local removal of skin on the back or chest. These patients will be randomly assigned to two groups: stitch removal at 7 days and stitch removal at 10 days. The two groups will otherwise be treated the same. Patients will be reviewed again at 3 months to assess their scar and the presence of stitch marks, and to record information about any complications they experienced and information about their experience. This information will be used to assess the feasibility of a larger study to answer the question 'does earlier removal of superficial stitches (7 days rather than 10 days) reduce the risk of stitch marks?'

16. STUDY DESIGN

16.1 Study Setting, Population and Patient Identification

This is a **single centre prospective randomized assessor blinded parallel group feasibility study** that will be undertaken in the Royal Devon and Exeter Dermatology department, Heavitree Hospital. The initial skin cancer clinic, surgical procedure and follow-up will all be undertaken within the department.

Our patient population is all patients attending the dermatology department for wide local excision as part of their skin cancer treatment and primary closure of the subsequent wound.

Clinicians will identify potential participants during routine practice at their clinic visit. Patients who fulfil the entry criteria will be invited at that appointment to take part and given a patient information sheet (PIS). They will be offered and consented for a further telephone call to discuss the study further.

Alternatively, when patients are telephoned to inform them of the date of their surgery, they will be informed of the study then. If patients are interested in the study, they will be offered a further telephone appointment with a member of the research team to discuss the study further, answer any questions and gain verbal consent. The PIS can be emailed or posted to the patient at their request. All patients will be offered a telephone call between clinic visit and their date of surgery for any questions to be answered and verbal consent to be gained.

16.2 Data Collection Prior to Surgery

On the day of their surgery, patients will be reminded of the trial and written consent will be sought by an appropriate member of the research team. Patients will then have their procedure performed and the randomization process will occur.

Data collection prior to procedure will include smoking status, history of immunosuppression, diagnosis of diabetes, full drug history (including steroid and anticoagulants use), age, ethnicity and history of keloid scarring or hypertrophic scarring. We will specifically ask for history of steroid use as this may affect the healing of scars post-surgery. This should all be recorded as standard practice and should not add additional workload, however this will be assessed in the feasibility study.

Data collection after the surgical procedure will include the size of the wound (maximal width and length), number of dermal sutures, type of dermal sutures used and number of percutaneous sutures used. Again, these should all be recorded as standard practice.

16.3 Surgical Procedure

The surgical procedure will be performed by one of the dermatological surgeons within the department.

All patients will have a standard local anaesthetic comprising lidocaine 1 or 2% with adrenaline 1:200000.

Patients will have their wide local excision with adequate margin as per regional guidance by an appropriately trained practitioner. The wound edges may be undermined if necessary or according to surgeon preference in order to achieve primary closure (documented accordingly).

The wound edges will be closely approximated with buried subcuticular interrupted vertical mattress sutures using 3/0 PDS (synthetic dissolvable mono filament suture) or equivalent. The number of sutures will be recorded. If the wound edges cannot be closely approximated then the patient will be withdrawn from the study. Interrupted percutaneous sutures will then be placed using ethilon 4/0 (non-absorbable, nylon monofilament suture) or equivalent in order to achieve optimal wound edge eversion.

16.4 Randomization and Blinding

Timing of Suture Removal to Reduce Scarring in Skin Surgery

Patients will be randomized into two groups following acceptance into the trial. A dermatology nurse, independent to the research trial and not involved in data collection or analysis, will use a random number generator to prepare 60 sealed envelopes, labelled 'participant 1' to 'participant 60'. These sealed envelopes will contain a slip of paper that either says 'suture removal at 7 days group' or 'suture removal at 10 days group'. During preparation of these envelopes using the random number generator, an odd number produced will be 'suture removal at 7 days group' and an even number will be 'suture removal at 10 days group'. The nurse who prepares these envelopes will be independent of the research trial to avoid any selection bias and maintain concealment. They will also have completed a 'Good Clinical Practice' (GCP) certificate. The surgeon and members of the research team involved in data gathering and analysis will be blinded to allocation.

After written consent to the trial has been gained, and excision of the lesion performed, the patient will leave the theatre room alongside one of our dermatology nurses/HCAs who is independent of the research team in order to maintain concealment and prevent selection bias. The patient and nurse/HCA will open one of the sealed envelopes, in numbered order, to reveal which arm of the trial they have been allocated to. The patient will be requested not to disclose which arm of the trial they were in. The theatre nurse or healthcare assistant will then discuss the post-operative wound care and timing of suture removal with the patient.

Patient blinding is not feasible as patients need to know which day to have their sutures removed post-surgery.

Before the patient leaves the department, an appointment will be booked with their GP for suture removal at either 7 or 10 days. If their GP does not have the capacity to remove the sutures on the given day, an appointment will be booked within the dermatology department on the given day for suture removal.

If the patient cannot attend the appointment for suture removal specifically on day 7 or 10, they will be removed from the study.

The envelope containing the slip of paper with the randomized trial arm will be re-sealed and placed in a larger envelope labelled with the participant number. The signed consent form will also be kept in this labelled participant envelope, which will be placed in a secure location in line with data governance.

Concealment of the trial arm allocation will be maintained until trial completion. However, the code could be broken in the event of a significant adverse event.

All recorded data will be anonymized prior to statistical analysis by the statistician.

16.5 Wound Dressing and Post-operative Care

Following wound closure, the wounds will be dressed with steristrips, a sterile film and pad dressing as per protocol after skin surgery. After 48 hours, the patients will be instructed to remove the dressing and then gently cleanse the wound and apply petroleum jelly to it twice daily until suture removal. This advice will be given to all patients independent on which trial arm they have been allocated.

On the day of suture removal, either at GP or in the dermatology department, sutures will be removed as per our standard operating procedure (SOP), available in the department or emailed to the GP practice performing the suture removal (please see appendices).

If there are any signs of wound dehiscence, or that the wound may dehisce on suture removal, the suture may be kept in, as per advice on our SOP. These patients will be withdrawn from the study.

16.6 Data Collection at 3 Month Follow Up

Patients will be booked in for a 3 month follow-up appointment, as per their standard care pathway. Data collection at 3 month follow up will include completing a patient and observer scar assessment scale (POSAS) with regards to overall scar cosmesis, and also a visual analogue scale (VAS) in relation to suture marks specifically. We have chosen these tools as they are validated, well known scales to characterise scars subjectively and objectively [10].

The patient will be asked about any post-operative complications that were not detected at suture removal including wound infection, dehiscence, and significant post-operative bleeding (defined as bleeding requiring assessment by a healthcare professional). Assessment will be carried out by a member of the research team who will be blinded to trial allocation.

Photographs of the scar will be taken at the follow-up visit using the departmental camera to allow review of scar assessment at a later date if required. This will be directly uploaded onto their electronic patient record in line with Trust policy. Patients will be verbally consented for this at time of follow up, as per usual practice.

17. DATA ANALYSIS METHODS

Dr Roy Powell, Statistical advisor, Royal Devon and Exeter hospital has been consulted.

Data collection and input will be carried out by the research team who will be employed by the RDEFT and will comply with local and national information governance standards. A password-protected Excel spreadsheet will be set up on a Trust computer in the Dermatology Department - also password protected. All paper and electronic data will be collected and stored in compliance with data protection guidelines, good clinical practice in research guidance and Trust clinical governance policy.

A feasibility study will provide an opportunity to assess the data to be collected and the choice of appropriate statistical tests for a future definitive trial. Data analysis will involve statistical methods appropriate to the data collected. The statistical analysis for the feasibility study will be descriptive for each group as hypothesis testing is not an aim of the feasibility study and it is likely to be underpowered for that anyway. Descriptive statistics of baseline characteristics will be compared between study groups to demonstrate the effectiveness of randomisation. Continuous outcome

data will be tested for normality using the Shapiro Wilks test. If the data are found to be normally distributed, central tendency will be expressed using means and dispersion using standard deviation. If the data prove not to be Gaussian, and cannot easily be transformed, they will be summarized using medians, interquartile ranges and ranges. Mean (or median) differences and the standard deviation of the differences will be used to inform sample size calculations for a definitive trial. Confidence intervals will be derived wherever possible. Categorical data will be summarized as proportions and percentages as appropriate with associated confidence intervals. No attempt will be made at this stage to make formal comparisons of outcome measures – this will be done in the eventual definitive study. Summaries of secondary outcome measures will also be produced in a similar manner to the above.

All data management will adhere to GDPR compliance. Statisticians will be blinded to allocation arms.

18. SAMPLE AND RECRUITMENT

18.1 Study Population, Sampling and Recruitment

All patients attending the dermatology department for wide local excision as part of their skin cancer treatment and primary closure of the subsequent wound will be considered for entry into the trial.

Clinicians will identify potential participants during routine practice at their clinic visit. Patients who fulfil the entry criteria will be invited at that appointment to take part and given copies of the PIS. They will also be offered a telephone appointment with a member of the research team for further information about the trial.

Alternatively, patients will be informed of the study when telephoned to confirm the time and date for their surgery. If they express interest in the study, they will be offered a further telephone call with a member of the research team to answer any questions they may have about the study and gain verbal consent. The PIS can be emailed or posted to the patient at their request.

All patients will be offered a telephone call between clinic visit and their date of surgery for any questions to be answered and verbal consent to be gained.

18.2 Inclusion Criteria

- Patients of 18 years old or above who had capacity to consent to surgery who were willing to attend follow-up appointments within the department
- Patients undergoing wide local excision as part of their skin cancer treatment pathway
- Lesions excised from the anterior chest or back
- Post-operative wound >/= 10mm width

- Wound could be closed with primary intention healing

18.3 Exclusion Criteria

- Inability to provide valid informed consent and/or unwilling to attend for follow-up
- Wounds where the edges could not be closely adhered with dermal sutures alone.
- Wounds requiring a flap or graft for closure.
- Patients requiring further treatment following original excision eg. Further WLE, radiotherapy etc.

18.4 Sample Size

As this is a feasibility study, it will not be powered to find significant differences between the groups. Instead it is an opportunity to test the feasibility of collecting the specified outcome data and describing it in terms of central tendency (mean, median) and dispersion (standard deviation or interquartile range as appropriate). A feasibility study provides an excellent opportunity to uncover problems ahead of time, minimizing the need to adapt procedures or to develop contingency plans at short notice when the larger study is being conducted. A simple method for choosing a sample size for a feasibility study that ensures the discovery of potential problems with high confidence is employed here [9]. The method is used to determine the necessary sample size so that a problem is likely to be observed at least once during the course of the feasibility study. The emphasis therefore is on "problem detection" and not on the estimation of the "problem frequency." If the probability (p) of a problem arising is 0.05, then a sample size of 59 would be required to detect at least one instance of the problem. The formula for calculating this is approx. 3/p participants if one wants to be approximately 95% certain that the problem will manifest itself at least once during the feasibility study. We will aim for 30 analysable cases per group in the final dataset giving a total of 60 cases.

18.5 Sample Identification

As mentioned previously, all patients attending the dermatology department for wide local excision as part of their skin cancer treatment will be considered for entry into the trial. Only the members of the existing clinical care team will have access to patient records in order to identify potential participants during their clinic visit. Any patients that have been informed of the study whilst having the time and date of their surgery confirmed, and have expressed interest, will be offered a further telephone call to discuss the study in depth and have any questions answered.

18.6 Consent

All patients who express interest in the study will be given the patient information leaflet either in physical form, post or email. They will be invited to discuss the project further with a member of the research team by means of a telephone call between their clinic attendance and surgical

appointment. Participants will be given sufficient time to read the information sheet and ask any further questions prior to consenting. Verbal consent will be gained on the telephone.

Participants willing to join the trial will have written informed consent obtained by a member of the research team at the time of their surgery attendance. A electronic copy of this research consent will be placed on the participants electronic hospital record. Only once they are fully informed will they be asked to make a decision to enter the trial.

The patient will be informed that they do not have to take part in the study and if they choose not to take part, refusal to enter into the study will not compromise their care.

The patient will also be informed that if at any time they wish to withdraw from the study they can do so, without having to give a reason and again this will not compromise their care.

The patient's GP will be informed by letter of the patient's inclusion in the study.

If any new information becomes available which may be relevant to the patients consent, forms will be revised and informed consent sought again.

Once the decision to take part has been agreed, randomization will occur.

Please seen appendix for patient information leaflets and consent documents.

19. ETHICAL AND REGULATORY COMPLIANCE

19.1 Patient Safety and Serious Adverse Events

A serious adverse event (SAE) is any untoward medical occurrence that:

- Results in death;
- Is life-threatening;
- Requires inpatient hospitalization or prolongation of existing hospitalization;
- Results in persistent or significant disability/incapacity;
- Consists of a congenital anomaly or birth defect.

Adverse events (AE) that may occur and for which patients will be consented include:

- Bleeding
- Infection
- Scarring
- Wound dehiscence
- Pain

We do not anticipate there being any increase in adverse events in either arm. The aim of the study is to assess whether early suture removal reduces scarring. It may become apparent that scarring is

less in the early suture removal arm. We will record the incidence of adverse events in both treatment arms to ensure that patients are not experiencing a greater number of adverse events in either treatment group

This is a pragmatic trial: the nature of the study means that it involves routine clinical practice. There should be no additional risk to patients beyond routine care. With good participant information and subsequent post-trial engagement, we would hope to recruit rapidly to the trial.

All AE's and SAE's will be reported to R&D within 24hrs of the investigator being made aware of the event. An SAE occurring to a participant will be reported to the REC that gave a favourable opinion of the study where the event was related or unexpected. This will be reported within 15 working days.

19.2 Assessment and Management of Risk

The principle investigators have a professional obligation to closely monitor participants and in the event of an adverse event being identified, follow established clinical treatment or referral protocols.

19.3 Quality Assurance Procedures

The study will be monitored in accordance with the current approved protocol and good clinical practice. Surgical technique, methodology and outcome will all be monitored and audited in accordance with current departmental practice.

19.4 Research Ethics Committee (REC) Review and Reports

Before the start of the study, a favourable opinion will be sought from a REC for the study protocol, informed consent forms and other relevant documents.

Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site. All correspondence will REC will be retained.

It is the Chief Investigator's responsibility to produce the annual reports as required and they will notify the REC at the end of the study. An annual progress report will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, if the study has not been declared ended by then.

If the study is ended prematurely, the Chief Investigator will notify the REC including the reasons for the premature termination.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

19.5 Amendments

If any substantial amendments to the protocol or supported documents is required, a notice of amendment will be submitted to the REC.

19.6 Protocol Compliance

Any deviations from the planned protocol will be documented and reported to the Chief Investigator and Sponsor immediately.

19.7 Data Protection and Confidentiality

The patients will be recruited to the trial and all data will be stored anonymously against a participant number. Only the clinical team will have access to the single table correlating patient name and participant number. This information will not be shared. All clinical and routine data will be collected and placed in a database by the clinical team preserving anonymity throughout the trial. It has been considered that the feasibility trial may begin to demonstrate clear advantages of one technique over the other. However, with the patient numbers involved, it seems unlikely that differences in the technique will be observed at levels that are statistically significant.

Data will be stored for 5 years then destroyed appropriately.

All paper and electronic data will be collected and stored in compliance with data protection guidelines, good clinical practice in research guidance and Trust clinical governance policy.

Please see 'Data Analysis Methods' for further information.

19.8 Access to the Final Study Dataset

The final data set will be able to be accessed by the Chief Investigator and Principle Investigators.

20. DISSEMINATION POLICY

On completion of the study, the data will be analysed and tabulated and a final study report will be prepared and issued to the Chief Investigator and Principle Investigator. Based on the results of this feasibility study, we may be in the position to write a grant proposal in order to conduct a definitive RCT in the future.

20.1 Authorship

Those who participated in study design, execution and analysis will be granted authorship

21. REFERENCES

[1] Weitemeyer MB, Bramsen P, Klausen TW, Hölmich LR, Gjorup CA. Patient-and observer-reported long-term scar quality of wide local excision scars in melanoma patients. J Plast Surg Hand Surg. 2018 Dec;52(6):319-324.

[2] Prowse P. , Shokrollahi K. Leaving our mark – are suture marks acceptable? Sept 2014, V96 (8) pp. 264-266

[3] Crikelair G. Skin suture marks. Am J Surg 1958: 96; 631–639

[4] Moy RL, Waldman B, Hein DW. A review of sutures and suturing techniques. J Dermatol Surg Oncol 1992; 18: 785–795

[5] Hasan Z , et al. Sutureless skin closure with isoamyl 2-cyanoacrylate in pediatric day-care surgery. Pediatr Surg Int 2009; 25: 1,123–1,125. Crossref, Google Scholar

[6] Hohenleutner , et al. Intradermal buried vertical mattress suture as sole skin closure: Evaluation of 149 cases. Acta Derm Venereol 2000; 80: 344–347. Crossref, Google Scholar

[7] Wolf R. Serial replacement of sutures for preventing suture marks. J Dermatol Surg Oncol 1993: 19: 1131

[8] Kobayashi S, Ito M, Yamamoto S, Kinugasa Y, Kotake M, Saida Y, Kobatake T, Yamanaka T, Saito N, Moriya Y. Randomized clinical trial of skin closure by subcuticular suture or skin stapling after elective colorectal cancer surgery. Br J Surg. 2015 Apr;102(5):495-500. doi: 10.1002/bjs.9786.

[9] Viechtbauer W, Smits L, Kotz D, Bude L, Spigt M, Serroyen J and Crutzen R. (2015) A simple formula for the calculation of sample size in pilot studies. Journal of Clinical Epidemiology, 68 (11) 1375-79.

[10] Fearmonti R, Bond J, Erdmann D, Levinson H. A review of scar scales and scar measuring devices. Eplasty. 2010;10:e43. Published 2010 Jun 21

22. APPENDICIES

22.1 Appendix 1 - Required Documentation

- CV's of research team
- Patient information sheet
- Patient informed consent form
- Data collection form
- POSAS Observer Scale
- POSAS Patient Scale

- VAS scale
- Standard Operating Procedure (SOP) for suture removal

22.2 Appendix 2 - Amendment History

Protocol version no.	Date issued	Author(s) of changes	Details of changes made
v1	June 2021	Ellen Richards	Protocol for submission
V2	19th Sep 2021	Ellen Richards	Protocol updated with REC comments

22.3 Appendix 3 – CV of Chief Investigator (Dr Emily McGrath)

22.4 Appendix 4 – CV of Co-Principle Investigator (Dr Ellen Richards)

22.5 Appendix 5 – CV of Co-Principle Investigator (Dr Alistair Brown)

22.6 Appendix 6 – Patient Information Sheet

Timing of Suture Removal to Reduce Scarring in Skin Surgery

Patient Information Sheet

v3, 19th September 2021

Timing of Suture Removal to Reduce Scarring in Skin Surgery

We are inviting you to take part in a research study called 'Timing of Suture Removal to Reduce Scarring in Skin Surgery'

- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide whether or not you wish to take part.
- You are free to decide whether or not to take part in this research study. If you choose not to take part, this will not affect the care you get from your own doctors in any way.
- You can stop taking part in the study at any time, without giving a reason.
- Ask us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information. If you decide to take part you will be given a copy of this information sheet and asked to sign a consent form. You'll get a copy of that as well.

Important things that you need to know

- Suture marks are permanent marks left in the skin where suture placement has caused local tissue damage and scarring.
- We want to find out whether earlier suture removal prevents suture marks without affecting wound healing on the chest and back.
- We are testing suture removal at 7 days vs 10 days in patients undergoing excision and repair of suspected skin cancers on the chest and back.
- The study will fit into your normal treatment if you require follow-up following your surgery, so that no extra hospital visits are required. However, if no routine follow-up is required the study will require you to visit the hospital once more than if you were being treated in the usual way.

Royal Devon and Exeter
NHS Foundation Trust

Timing of Suture Removal to Reduce Scarring in Skin Surgery

Contents

Sponsor: Royal Devon and Exeter NHS Trust

How to contact us
If you have any questions about this study, please talk to your dermatology doctor or nurse. The Chief Investigator (CI) and Principle Investigators (PI) can be contacted via the below details:

Dr Emily McGrath (CI), Dr Ellen Richards (PI), Dr Alistair Brown (PI)
Dermatology Department
Heavitree Hospital
Royal Devon and Exeter NHS Foundation Trust
EX1 2ED
01392 405512

Timing of Suture Removal to Reduce Scarring in Skin Surgery

1 Why are we doing this study?

What are suture marks?

Suture marks, otherwise known as stitch marks or track marks, are permanent marks left in the skin where suture placement has caused local tissue damage and scarring.

How common are suture marks?

At the moment we do not know the answer to this question but they occur more commonly on sites of skin tension such as the chest and back.

Why do suture marks develop?

The risk of developing suture marks is probably affected by a number of factors including surgical technique and the patient's own skin and health. Some sites on the body (such as the chest and shoulders) are more prone to scarring. The risk of these marks is also thought to be in part related to the duration of time that the sutures are left in place before removal.

How long are sutures normally left in place?

When a wound is closed in dermatology a layer of dissolving sutures is placed under the top layer of skin to bring the wound edges together. These sutures do not need to be removed. Another layer of sutures is placed along the top of the wound. These sutures are normally removed between 7 and 14 days post-surgery. Sutures may be left in place for longer if there is a concern about the wound opening up. This is more common on sites of tension such as the chest and back.

Why is a study needed?

There are several questions that we want to answer:

1. At the moment, we do not have good evidence that removing sutures early will prevent suture marks or have an effect on the appearance of the scar. We hope to demonstrate that early suture removal reduces scarring.

2. We hope to estimate how commonly suture marks occur.

3. We also do not know whether removing the sutures early will have any other consequences such as opening up of the wound.

4. Finally, we hope to assess the impact that suture marks have on patients

Timing of Suture Removal to Reduce Scarring in Skin Surgery

2 Why am I being asked to take part?

You are being asked to take part in the study because you are planned to have an excision of a suspected skin cancer from your chest or back in the dermatology department. We anticipate that the wound will be closed directly without involving any complex repair or skin graft.

3 What do I need to know about the intervention proposed?

Your surgery will be performed in the same way regardless of whether you choose to be involved in the trial or not and will be performed in accordance with departmental practice.

After the surgery you will be allocated to have your sutures removed at either 7 days or 10 days post operatively.

4 What will I need to do if I take part?

Can I definitely take part?

Not everyone may be able to take part in this study. We need to check your eligibility first to see whether you are suitable to take part. If we are unable to close your wound adequately using the buried dissolving sutures you will be excluded from the trial.

What if I am eligible to take part?

If you are eligible and you agree to join the study, we will ask you to sign a consent form.
There will be two different procedure groups in this study. These are: suture removal at 7 days and suture removal at 10 days.

Which group will I be in?

It is important that the groups receiving suture removal at 7 and at 10 days are as similar as possible at the start of the study. To ensure that this happens, randomisation is used to allocate people to each group. You will find out which group you are in immediately following your surgical procedure.

What will happen to me during the study?

Timing of Suture Removal to Reduce Scarring in Skin Surgery

You will be identified by a clinician or member of the research team prior to your skin surgery. You will be provided with a patient information sheet (PIS) either in person, or emailed/posted. All patients identified will be offered a telephone appointment to further discuss the project and gain verbal consent.

If you have consented to take part in the study your surgery will then be carried out as per departmental practice. This will not differ whether you are involved in the trial or not. Immediately after your surgery your trial allocation will be revealed and the timing of your suture removal will be discussed with you. This will either be at 7 days or 10 days. We will book an appointment with your GP for you in order to ensure your sutures are removed on the correct day. If your GP does not have capacity to perform suture removal on the specific day, you will be booked for suture removal in the dermatology department. If you cannot attend for suture removal on the specific day you have been randomised to, you will be withdrawn from the study. This will not affect your ongoing care.

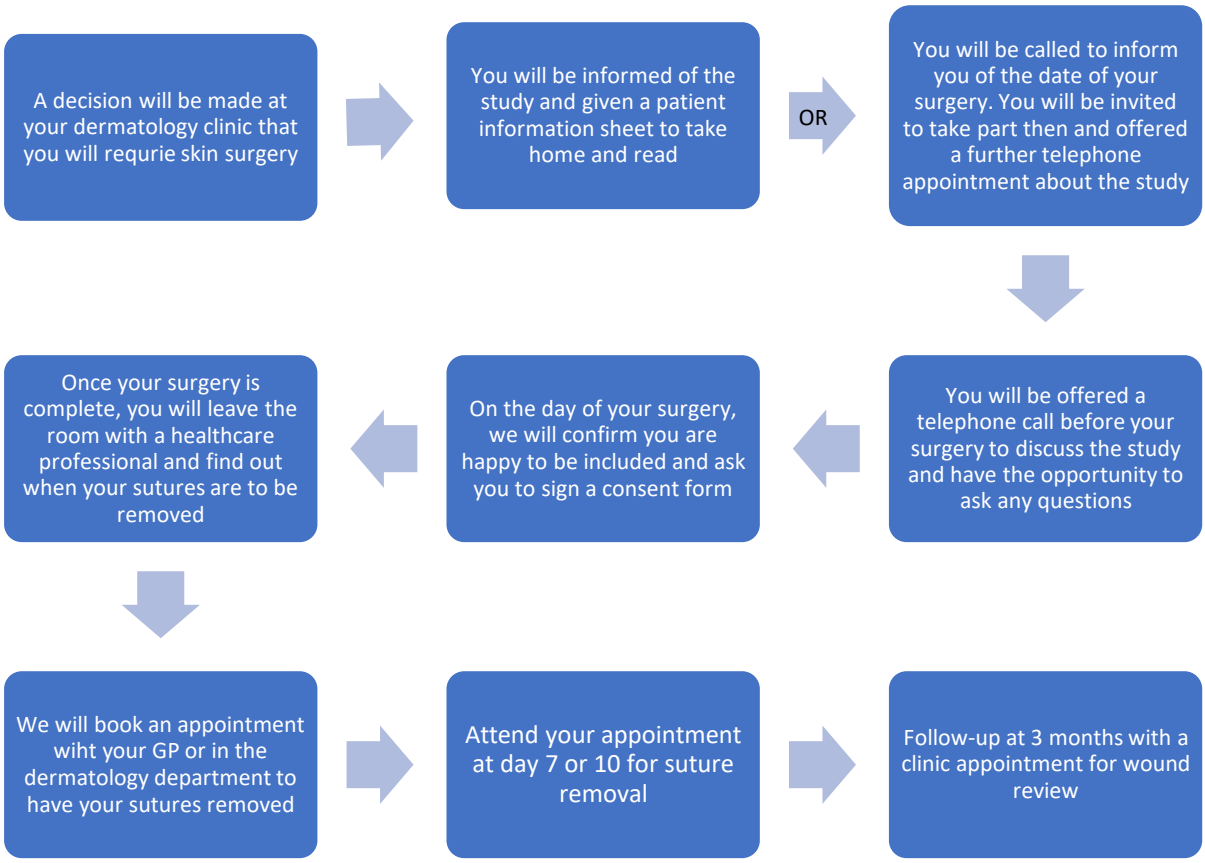
We would ask that if you do take part in this study, to not discuss the timing of your suture removal with the research team.

On the day of your suture removal, either at GP or in the dermatology department, sutures will be removed as per our standard operating procedure (SOP) for suture removal. If there are any signs of wound dehiscence (your wound coming apart), or that the wound may dehisce on suture removal, the sutures may be kept in for an additional amount of time, as per advice on our SOP. If this is the case, you will be withdrawn from the study. This will not affect your ongoing care.

You will then be reviewed at 3 months post operatively for a review of your scar and completion of a questionnaire about your subjective and objective opinion of your scar. We will ask you to rate on a scale of 1 to 10 about your opinion on the overall colour, thickness and appearance of your scar, using a validated tool called the ‘patient and observer scar assessment scale’ (POSAS). We will also ask for your opinion on the appearance of suture marks specifically using a ‘visual analogue scale’ (VAS). A healthcare professional will also assess the appearance of your scar and suture marks and take photographs that will be uploaded directly to your patient record. Again, we would kindly ask you to not discuss timing of suture removal with the research team at this point.

If you are being followed up routinely for your skin cancer we will arrange this in the same visit.

Timing of Suture Removal to Reduce Scarring in Skin Surgery



Will I get back any travel costs?

Travel costs for the follow-up clinic visit will not be re-imbursed.

5 What are the possible benefits of taking part in this study?

The information we get from this study will help us to improve treatment for present and future patients undergoing skin surgery.

We are aiming to gather data to determine whether a large scale trial can be performed to answer the question of whether early suture removal may reduce scarring in skin surgery. By participating in this study, you will be helping us to gather data required to perform a larger scale trial which may affect medical practice in the future.

Timing of Suture Removal to Reduce Scarring in Skin Surgery

6 What are the possible disadvantages and risks of taking part?

All surgical procedures have some associated risks. The most common adverse effects of skin surgery are:

- Risk of bleeding post operatively
- Risk of surgical site infection (2-5%)
- It may be painful when the local anaesthetic is inserted and when this wears off
- You will be left with a permanent scar which may fade over time
- Wound dehiscence (opening up of the wound) due to stretching of the scar or failure of the sutures

It may be possible that early suture removal may increase your risk of wound dehiscence. However, if at day 7 or 10 your healthcare professional has concerns that removing sutures on the day will cause wound dehiscence or complications, your sutures will not be removed and you will be excluded from the study. Your healthcare professional will be able to give you additional advice in this instance.

If you become concerned about any side effects, please tell the study staff as soon as possible. We do not anticipate there being any increased risks in either group but it may become apparent that one procedure reduces the risk of scarring or wound dehiscence more than the other following the study.

7 More information about taking part

Do I have to take part in the "Timing of Suture Removal to Reduce Scarring in Skin Surgery" study?

No, it is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form. Your GP will also be informed of your participation in this study.

If you decide not to take part in this study, you are likely to receive the standard treatment, which is removal of sutures between 7 and 14 days at the discretion of the operating surgeon. A decision to not take part at any time will not affect the standard of care you receive.

Can I stop taking part after I've joined the study?

You can stop taking part in all of this study, or in any part of it, at any time and without giving a reason. However, you must talk to your study doctor or nurse first so that they can advise you about

any concerns you may have. A decision to stop taking part at any time will not affect the standard of care you receive.

How will we use information about you?

We will need to use information from you and the follow up from your procedure for this research project. This information will include your name, NHS number, contact details and procedure details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email or by ringing us on the contact details supplied on page 3 of this patient information sheet

What will happen to the results of this study?

When the study is completed, we will publish a summary of the results on our website.
We will also publish the results in a medical journal, so that other doctors can see them.
You can ask your doctor for a copy of any publication. Your identity and any personal details will be kept confidential. No named information about you will be published in any report of this study.

Data will be stored for 5 years then destroyed appropriately.

Timing of Suture Removal to Reduce Scarring in Skin Surgery

Who is organising and funding the study?

This study is organised by the Dermatology department at the Royal Devon and Exeter NHS Foundation Trust.

Your doctor is not receiving any money or other payment for asking you to be part of the study. The Royal Devon and Exeter NHS Foundation Trust has overall responsibility for the conduct of the study. It is responsible for ensuring the study is carried out ethically and in the best interests of the study participants.

Who has reviewed the Timing of suture removal to prevent suture marks in skin surgery study?

It has been authorised by the Essex Research Ethics Committee (REC) and the hospital's Research and Development Office.

What if new information becomes available during the course of the study?

Sometimes during a study, new information becomes available about the procedures that are being studied. If this happens, your doctor will tell you about it and discuss with you whether you want to continue the study. If you decide to stop taking part, your doctor will arrange for your care to continue outside of the study.

Your doctor might also suggest that it is in your best interests to stop taking part in the study. Your doctor will explain the reasons and arrange for your care to continue outside the study.

What happens if the Timing of Suture Removal to Reduce Scarring in Skin Surgery study stops early?

Very occasionally a study is stopped early. If it happens, the reasons will be explained to you and your doctor will arrange for your care to continue outside of the study.

What if something goes wrong for me?

If you have any concerns about the way you have been approached or treated during the study, please talk to your study doctor or nurse. If you are still unhappy, or if you wish to complain, please use the normal NHS complaints process. Our local Patient Advice and Liaison Service will be able to advise you further and they can be contacted by phone (01392 402093) or email (rde-tr.PALS@nhs.net).

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Royal Devon and Exeter NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Timing of Suture Removal to Reduce Scarring in Skin Surgery

8 Contacts for further information

If you want further information about the Timing of Suture Removal to Reduce Scarring in Skin Surgery study, please contact your dermatology doctor or nurse, otherwise see page 3 for contact information for Chief Investigator and Principle Investigators.

Timing of Suture Removal to Reduce Scarring in Skin Surgery

22.7 Appendix 7 – Patient Informed Consent Form

Participant Consent Form

IRAS ID: 303519
Participant Number: Initials:

I confirm that I have read the patient information sheet, v3, dated 9th September 2021 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
I agree to my General Practitioner being informed of my participation in the study.	
I agree to having photos taken of my skin lesion, which will be uploaded directly to my electronic patient record	
I agree to my medical records being accessed by the research team for routinely collected data such as age, past medical history and surgical procedure notes	
I agree to take part in the above study.	

Participant:

Signature: Date: ...../...../.....

.....
Name (please print):

.....

Consenter:

Signature: Date: ...../...../.....

.....
Name: (please print):

22.8 Appendix 8 – Data Collection Form

Data Collection Form	
Participant Number:	
Data Collection at Time of Surgery	
Age:	
Ethnicity:	
Clinical diagnosis (pre-op):	
Site:	
Length of wound (mm):	
Width of wound (mm):	
Number and type of interrupted subcuticular sutures:	
Number and type of interrupted percutaneous sutures:	
Drug history (immunosuppressants or anticoagulants):	
Diabetic diagnosis:	
Smoking history:	
History of keloid scar or hypertrophic scarring:	
Normal length of time recommended for suture removal in this case:	

Timing of Suture Removal to Reduce Scarring in Skin Surgery

Data Collection at 3 Month Follow-up			
Stitch marks visible (yes/no):			
POSAS:	**Patient scale**	Pain:	
		Itch:	
		Colour:	
		Stiffness:	
		Thickness:	
		Irregular:	
		Overall Opinion (not part of total score):	
		Total:	
	Observer Scale	Vascularity (pale; pink; red; purple; mix):	
		Pigmentation (hypo; hyper; mix):	
		Thickness (thicker; thinner):	
		Relief (more; less; mix):	
		Pliability (Supple; stiff; mix):	
		Surface area (expansion; contraction; mix):	
		Overall Opinion (not part of total score):	
		Total:	
VAS:			
Wound infection (defined using CDC criteria for surgical site infection)*:			
Wound dehiscence:			
Significant post-operative bleeding:			
Any other comments:			

* Infection occurs within 30 days after the operation and infection involves only skin and subcutaneous tissue of the incision and at least one of the following:
1.Purulent drainage with or without laboratory confirmation, from the superficial incision
2.Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision

Timing of Suture Removal to Reduce Scarring in Skin Surgery

3.At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative 4.Diagnosis of superficial incisional SSI made by a surgeon or attending physician

Timing of Suture Removal to Reduce Scarring in Skin Surgery

22.9 Appendix 9 – POSAS Observer Scale

POSAS Observer scale

The Patient and Observer Scar Assessment Scale v2.0 / EN

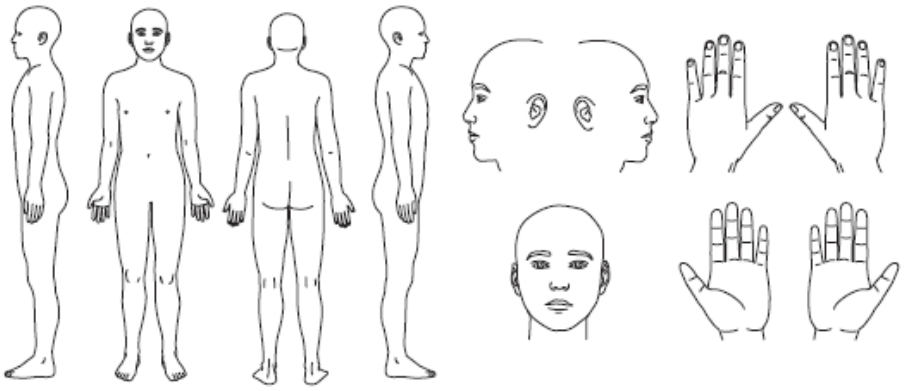
Date of examination:

Observer:

Location:

Research / study:

Identification number:



1 = normal skin — worst scar imaginable = 10

PARAMETER	1	2	3	4	5	6	7	8	9	10	CATEGORY
VASCULARITY	○	○	○	○	○	○	○	○	○	○	PALE | PINK | RED | PURPLE | MIX
PIGMENTATION	○	○	○	○	○	○	○	○	○	○	HYPO | HYPER | MIX
THICKNESS	○	○	○	○	○	○	○	○	○	○	THICKER | THINNER
RELIEF	○	○	○	○	○	○	○	○	○	○	MORE | LESS | MIX
PLIABILITY	○	○	○	○	○	○	○	○	○	○	SUPPLE | STIFF | MIX
SURFACE AREA	○	○	○	○	○	○	○	○	○	○	EXPANSION | CONTRACTION | MIX
OVERALL OPINION	○	○	○	○	○	○	○	○	○	○	

Explanation

The observer scale of the POSAS consists of six items (vascularity, pigmentation, thickness, relief, pliability and surface area).
All items are scored on a scale ranging from 1 ('like normal skin') to 10 ('worst scar imaginable').
The sum of the six items results in a total score of the POSAS observer scale. Categories boxes are added for each item. Furthermore, an overall opinion is scored on a scale ranging from 1 to 10.
All parameters should preferably be compared to normal skin on a comparable anatomic location.

Explanatory notes on the items:

- **VASCULARITY** Presence of vessels in scar tissue assessed by the amount of redness, tested by the amount of blood return after blanching with a piece of Plexiglas
- **PIGMENTATION** Brownish coloration of the scar by pigment (melanin); apply Plexiglas to the skin with moderate pressure to eliminate the effect of vascularity
- **THICKNESS** Average distance between the subcutical-dermal border and the epidermal surface of the scar
- **RELIEF** The extent to which surface irregularities are present (preferably compared with adjacent normal skin)
- **PLIABILITY** Suppleness of the scar tested by wrinkling the scar between the thumb and index finger
- **SURFACE AREA** Surface area of the scar in relation to the original wound area

COPYRIGHT © P.P.M. VAN ZUIJLEN, BEVERWIJK-NL

Timing of Suture Removal to Reduce Scarring in Skin Surgery

22.10 Appendix 10 – POSAS Patient Scale

POSAS Patient scale

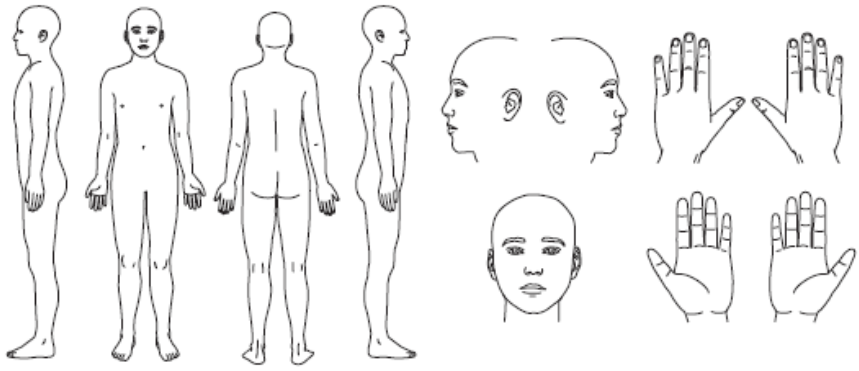
The Patient and Observer Scar Assessment Scale v2.0 / EN

Date of examination:

Observer:

Location:

Research / study: **Identification number:**



1 = no, not at all — yes, very much = 10

	1	2	3	4	5	6	7	8	9	10
HAS THE SCAR BEEN PAINFUL THE PAST FEW WEEKS?	○	○	○	○	○	○	○	○	○	○
HAS THE SCAR BEEN ITCHING THE PAST FEW WEEKS?	○	○	○	○	○	○	○	○	○	○

1 = no, as normal skin — yes, very different = 10

	1	2	3	4	5	6	7	8	9	10
IS THE SCAR COLOR DIFFERENT FROM THE COLOR OF YOUR NORMAL SKIN AT PRESENT?	○	○	○	○	○	○	○	○	○	○
IS THE STIFFNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT?	○	○	○	○	○	○	○	○	○	○
IS THE THICKNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT?	○	○	○	○	○	○	○	○	○	○
IS THE SCAR MORE IRREGULAR THAN YOUR NORMAL SKIN AT PRESENT?	○	○	○	○	○	○	○	○	○	○

1 = as normal skin — very different = 10

	1	2	3	4	5	6	7	8	9	10
WHAT IS YOUR OVERALL OPINION OF THE SCAR COMPARED TO NORMAL SKIN?	○	○	○	○	○	○	○	○	○	○

COPYRIGHT © P.P.M. VAN ZUIJLEN, BEVERWIJK-NL

Timing of Suture Removal to Reduce Scarring in Skin Surgery

22.11 Appendix 11 – Numerical Visual Analogue Scale (VAS)

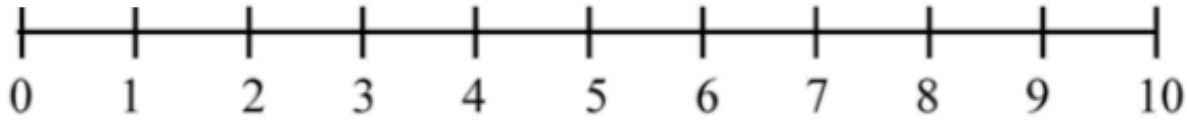
Numerical Visual Analogue Scale (VAS)

Participant Number:

Please make a mark on the line below where you feel the appearance of your scar lies, **with regards to suture marks.**

Poor appearance of suture marks

Excellent appearance of suture marks



Royal Devon and Exeter
NHS Foundation Trust

Timing of Suture Removal to Reduce Scarring in Skin Surgery

22.12 Appendix 12 – GP letter

Dermatology Department
Heavitree Hospital
Gladstone Rd
Exeter
EX1 2ED
Ellen.richards6@nhs.net

INSERT DATE

Dear INSERT NAME OF GP

TIMING OF SUTURE REMOVAL TO REDUCE SCARRING IN SKIN SURGERY

Re: PARTICIPANT DETAILS

The above named person has kindly agreed to take part in this research study. The objective of the study is to determine whether suture removal at day 7 or day 10 post skin surgery will affect suture marks and overall cosmesis of scars.

Your patient has been chosen to take part because they have been booked for a wide local excision for their skin cancer surgery.

Should you have any queries about this, please do not hesitate to contact me on the details above.

Yours Sincerely,

Dr Ellen Richards
Academic Foundation Doctor
Royal Devon and Exeter Hospital NHS Trust

22.13 Appendix 13 – Standard Operating Procedure (SOP) for Suture Removal

Standard Operating Procedure (SOP) for Suture Removal

Aim:

The nurse or healthcare assistant is able to assess the wound post operatively, remove the superficial sutures appropriately and recommend simple post-operative wound care

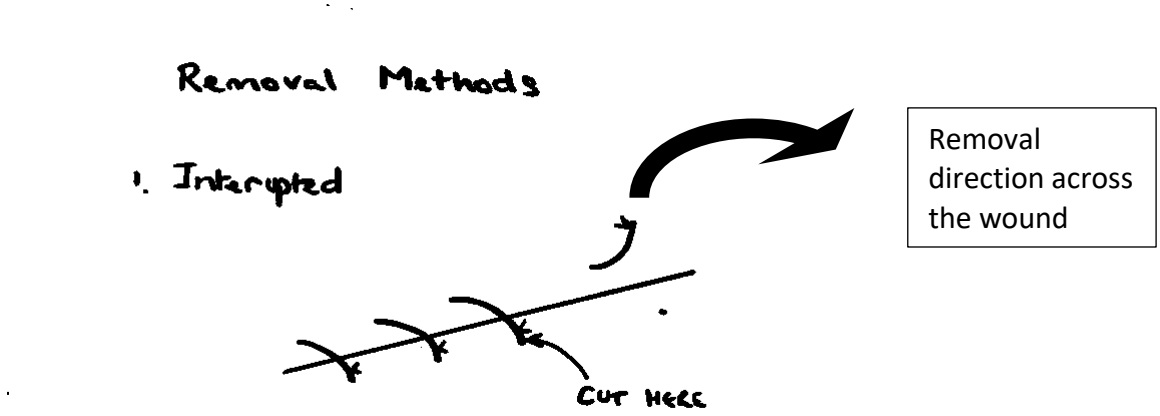
Procedure:

1. Confirm the patients identity and gain consent for removal of sutures
2. Wash hands and prepare procedure trolley surface aseptically with correct equipment:
    a. Disposable Fine tipped non toothed forceps
    b. Dressing pack – containing sterile gloves and gauze
    c. Disposable sharp surgical scissors
    d. Sterile normal saline if required
3. Wash hands and use non-sterile gloves to remove current dressing (if any)
4. The wound should specifically be checked for signs of dehiscence, infection or poor wound healing. If this is the case, medical advice should be sought
5. If the wound shows signs that it may dehisce if sutures are removed at the time, then consider keeping sutures in for removal at a later date at the discretion of the healthcare professional. These patients will be excluded from the study. If this is the case, it is important that you let the study team know by contacting us on the below details.
6. Removal of simple percutaneous interrupted sutures:
    a. Wash hands and don sterile gloves
    b. Gently grasp the knot of a suture with forceps and raise it slightly
    c. Place the tip of the suture scissors directly under the knot or on the side close to the skin
    d. Gently cut the suture and pull it out gently across the wound with the forceps
        i. Remove the suture across the wound to minimise any exposed suture passing through the skin and wound during the removal, this can lead to infection. Cutting the correct part of the suture (part directly under the knot on the side closest to the skin), will bypass this from happening
    e. Place steri-strips on the sites that sutures have been removed. These are applied in opposite directions with a small amount of tension to take tension away from the wound. Educate patient to let the steri-strips fall off naturally (usually 1-2 days). No further treatment to the wound should be required.

Timing of Suture Removal to Reduce Scarring in Skin Surgery

f. Continue to remove sutures until all sutures have been removed
g. The application of a suitable wound dressing can be applied at the healthcare professionals discretion
h. Discard sutures as per local policy and record the intervention in the medical notes
i. Dispose any sharps and used instruments safely according to trust policy

If there have been any early post-operative complications, such as dehiscence, infection or poor wound healing, please could you contact the study organisers on the details below.



Dr Emily McGrath (CI), Dr Ellen Richards (PI), Dr Alistair Brown (PI)
Dermatology Department
Heavitree Hospital
Royal Devon and Exeter NHS Foundation Trust
EX1 2ED
01392 405512
ellen.richards6@nhs.net