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Skin closUre in carPal tunnEl Release (SUPER): protocol for a blinded randomised controlled trial comparing absorbable and non-absorbable sutures in carpal tunnel release

Aukusti Savolainen ,[1] Yrjänä Nietosvaara,[1,2] Joonas Sirola,[1,3] Mikael Hytönen,[1] Aleksi Reito ,[4] Noora Heikkinen,[1] Mikko Petteri Räisänen [2,5]

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For numbered affiliations see end of article.

Correspondence to
Mr Aukusti Savolainen; aukusa@student.uef.fi

ABSTRACT

Introduction Carpal tunnel syndrome is a common disorder affecting a substantial portion of the general population. Surgical intervention is often deemed necessary, with the median nerve release being one of the most frequent operations. Optimising all the aspects of this procedure can enhance patient satisfaction with the treatment.

Methods and analysis We aim to determine the differences in the aesthetic outcome of the scar as well as the pain experienced during the healing process between the use of absorbable and non-absorbable sutures. The primary outcome measure will be the patients' subjective satisfaction with the aesthetic appearance of the scar 1 year after the operation. Secondary outcomes will include a similar evaluation of the aesthetics performed by a blinded outcome assessor, as well as pain experienced by the patients during the 2 weeks postoperatively. The severity and improvement of the patients' symptoms will also be measured by a Finnish version of the Boston Carpal Tunnel Questionnaire. Costs will be evaluated for both groups. Safety of the wound closure will be followed and reported.

Ethics and dissemination This protocol was approved by the Research Ethics Committee of the Northern Savo Hospital District (2319/2021). The trial will be conducted in accordance with the principles of Good Clinical Practice and the Declaration of Helsinki. The results will be disseminated through publication in peer-reviewed journals.

Trial registration number NCT05503719.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Adequately long follow-up of 1 year to evaluate final aesthetic outcome of the scar.
⇒ The comparatively large sample size should grant statistically and clinically relevant and robust results if they exist.
⇒ Due to the nature of the trial, neither the participants, nor the performing physicians can be blinded to the intervention.

INTRODUCTION

Background

Carpal tunnel syndrome (CTS) is the most common type of entrapment neuropathy in the upper extremity occurring by estimate in 3.8% of the general population.[1] Two non-operative treatment options with at least moderate evidence of effectiveness are splinting and corticosteroid injection.[2] Glucocorticoid treatment has the adverse effect of causing further degeneration,[3] and both splinting and steroid treatment have been shown to yield mixed results long term.[4 5] While non-operative treatment is the primary option, invasive treatment is often necessary. According to a recent study, 77% of patients undergoing median nerve release surgery had previously received some form of non-operative treatment.[6] Carpal tunnel release surgery is considered the gold standard and has been shown to give excellent results in 75% of cases.[7] Another study found a significant reduction in Symptom Severity Scale for 88% of patients treated.[8] Common reasons for dissatisfaction among patients include a failed diagnosis, incomplete release, iatrogenic nerve injury, scarring of the nerve and inappropriate expectations.[9] Despite the high success rate, there is a notable risk of long-term complications such as a variety of problems with the healing of the scar.[10]

Rationale

Due to the frequent nature of the surgical treatment for CTS, there is an increasing demand for a high-quality trial with sufficient statistical power to determine the optimal wound closure method for maximising patient satisfaction and clinical outcome.

A recent integrative literature review reached similar conclusions to previous studies and emphasised the need for a new high-quality randomised controlled trial (RCT) on the subject.[11] It is important to note that non-absorbable sutures require removal, leading to additional clinic visits, increased costs and redundancy compared with absorbable sutures. Additionally, there have been no studies addressing suture removal pain.

The two most common methods to close a surgical wound are absorbable and non-absorbable sutures. Some articles have been published on the subject comparing the two methods. Past RCTs comparing absorbable and non-absorbable sutures have primarily focused on assessing pillar pain and scar tenderness,[12–14] while others also included steel sutures in their comparisons.[15] The results of these studies are somewhat contradictory, and it remains unclear whether absorbable sutures perform differently from non-absorbable sutures. The limited sample sizes of just 33–64 patients in total increase the likelihood of coincidental findings and hinder the attainment of reliable results.

More recent studies have placed a greater emphasis on the aesthetic outcome of the scar.[16 17] Nevertheless, even in these studies, the sample sizes were relatively small, with only 38 and 50 patients, and the follow-up periods were short. None of these studies found a significant difference between the groups compared. In 2010, a prospective cohort study on the aesthetic outcome after any elective day-case hand surgery was made. The study featured a more substantial sample size of 70 patients and found no statistically significant difference in the aesthetic outcome of the scar between absorbable and non-absorbable sutures.[18] However, it is worth noting that this study included other surgical operations beyond carpal tunnel release, and the follow-up period was relatively short at only 6 weeks.

Contrary to traditional teaching, absorbable sutures may lead to fewer cases of dehiscence, infections and fewer clinical encounters related to wound-related concerns.[19] In conclusion, there is not enough evidence for clinicians to make well-informed decisions regarding the choice of suture material. Thus, there is a clear and pressing need for a well-planned, well-executed and adequately powered RCT with reasonably long follow-up periods to compare non-absorbable and absorbable sutures.

Objectives

Our primary objective is to ascertain whether an absorbable suture is non-inferior to a non-absorbable suture concerning the aesthetic outcome of the scar 1 year after the operation. The secondary objective is to examine postoperative pain in the scar area, relief of symptoms, patient satisfaction, costs and safety.

Trial design

The trial is designed as a randomised controlled non-inferiority trial with two parallel trial groups with a 1:1 allocation ratio. A blinded outcome assessor is used and the triallists are blinded for the group assignments in data analysis phase.

Table 1 Eligibility criteria for the trial

Inclusion criteria	Exclusion criteria
CTS diagnosed with ENMG	Repeat surgery[27]
Symptoms typical of CTS[28]	Known allergy to suture materials
Referral to CTR	Ongoing systemic steroid treatment[3]
Informed consent signed	Ongoing chemotherapy
The ability to receive the virtual questionnaire via email and answer it	Ongoing immunomodulatory treatment
The ability to understand and answer the Finnish questionnaires	Past hypertrophic or keloid scars or other severe disturbances in wound healing
	Age under 18 years
	Pregnancy or breast feeding

CTR, carpal tunnel release; CTS, carpal tunnel syndrome; ENMG, electroneuromyography.

METHODS

The Standard Protocol Items: Recommendations for Interventional Trials statement was followed in this protocol.[20]

Trial setting

The trial will be conducted at Kuopio University Hospital in the Department of Orthopaedics, Traumatology and Hand Surgery which serves as a tertiary care unit in Eastern Finland.

Eligibility criteria

This trial aims to be practical and readily applicable to common treatment practices. Therefore, it is crucial to compile a trial population that closely mirrors the average patient undergoing median nerve release. We do not exclude patients based on gender, ethnicity or any specific medical condition.[21] Nevertheless, some technical considerations restrict the trial population. Furthermore, a few factors have the potential to obscure the results or hinder the operation's success. These are detailed in the exclusion criteria (table 1).

Interventions

The patients participating in the trial will be randomly allocated to one of two equal groups and treated with either the absorbable or the non-absorbable suture. Regardless of the trial group, the operation will be conducted in the same manner. The operating surgeons will make a skin incision distally from the distal wrist crease and ulnar to the thenar crease. The appropriate tissues including the subcutaneous tissue, palmar fascia, flexor retinaculum and antebrachial fascia will then be divided. After

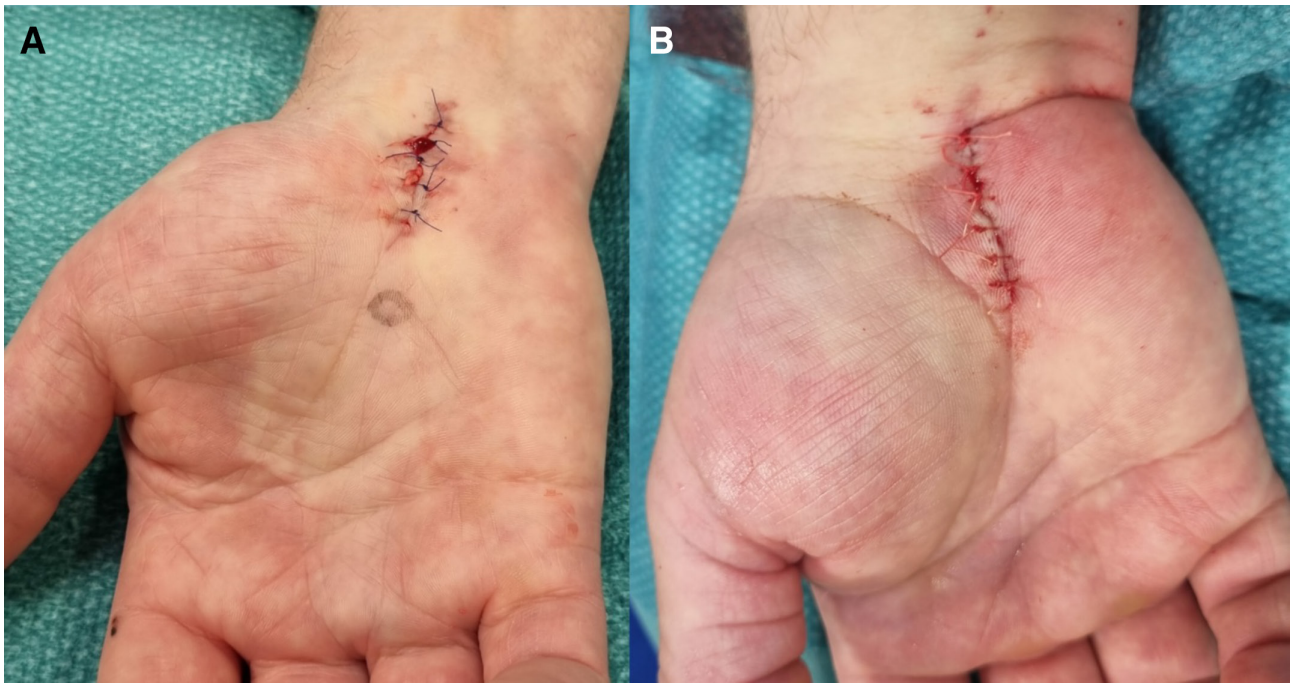

Figure 1 Carpal tunnel release skin incision closed with (A) non-absorbable and (B) absorbable sutures.

the release of the median nerve is complete, the incision will be closed by the randomly determined type of transcutaneous suture, with simple single stitches 0.6 cm apart from each other (figure 1). The sutures used are a 5-0 Vicryl Rapide (Ethicon, Raritan, New Jersey, USA) absorbable suture and a 5-0 Dafilon (B Braun Melsungen, Melsungen, Germany) non-absorbable suture. The operating surgeons will be informed of appropriate wound closure. At the end, a light surgical dressing is applied to the hand, to be removed after a few days based on the surgeon's evaluation. The patient has the option to either remove the dressing themselves or seek assistance from a healthcare professional, such as a nurse from basic or occupational healthcare. Patient are instructed to start immediate use of the operated hand, but heavier hand use is recommended to be avoided for 2 weeks. The patient is advised to schedule the removal of non-absorbable sutures at the basic or occupational healthcare centre after 2 weeks. For absorbable sutures, patients are encouraged to wipe the wound with a coarse towel after 2 weeks if the stitches have not naturally fallen out. If the absorbable sutures do not fall out even with this procedure, patients are instructed to seek assistance from a healthcare professional. After surgery, the nurse provides self-care instructions to the patient and reviews them (online supplemental appendix 1). Non-steroidal anti-inflammatory drugs or paracetamol is used for post-surgical topical pain management.

Modifications

The treatment has been performed for decades. Therefore, all the initiated operations are likely to be completed without any modifications.

Adherence

Specific measures have been implemented to facilitate trial adherence. The trial flow and guidelines will be comprehensively explained to the participants in advance, and they will receive all the necessary information in written form. Preoperative surveys will be completed with the recruiter. Two weeks after the surgery, the participants will receive the first survey via email, which will include additional instructions for response. In cases of non-adherence, participants will be contacted directly. One year after the surgery, a face-to-face appointment will be scheduled during which all remaining surveys will be completed. Participants can contact the trial officials at any time. The appointment letters will be sent to the patients and those who miss their appointments will be offered rescheduled appointments. If a patient is unable to attend the follow-up visit in person, the necessary information can be collected over the phone. Patients can send a picture of the scar to the research nurse and the scar will be evaluated based on the picture.

Outcomes

Primary outcome measures

The primary outcome will be the mean difference between the two study arms in the aesthetic outcome of the scar, which will be assessed on a 10 cm Visual Analogue Scale (VAS) ranging from 'the ugliest scar possible' to 'the most beautiful scar possible'. The evaluation will be performed by the patient 1 year after the operation.

The patient has been selected as the outcome assessor for the primary outcome measure, as the primary aim of the trial is to enhance patient satisfaction with carpal tunnel release surgery. The VAS was selected to avoid

Table 2 Secondary outcome measures

Secondary outcome	Variable
Scar aesthetics evaluated by an outcome assessor	The mean difference between the two study arms in the aesthetic outcome of the scar evaluated on a 10 cm VAS ranged from 'the ugliest scar possible' to 'the most beautiful scar possible'. This will be performed by a blinded outcome assessor 1 year after the operation. The outcome assessor will be a trained healthcare professional, for example, a nurse, a physiotherapist or an occupational therapist, who will evaluate all the scars in this trial. All the scars will be photographed.
Postoperative pain	The mean difference in the mean postoperative pain experienced between the two study arms. Pain will be measured on a 10 cm VAS ranging from 'the worst pain imaginable' to 'no pain at all'. Two weeks after the operation, both groups will rate the maximum pain experienced in the region of the scar during the past week. The evaluation will be performed at home on a survey sent to them via email.
Boston Carpal Tunnel Questionnaire	The mean difference in the proportional change in CTS symptoms preoperatively and postoperatively. A Finnish version of the Boston Carpal Tunnel Questionnaire by Levine *et al* (1993) will be used. The patients will complete the survey preoperatively and 1 year after the operation at their appointment.
Patient satisfaction	The mean difference between the two study arms in the NPS survey measuring client experience and the likelihood of them recommending the operation to a friend or a colleague. The patients will complete the survey 1 year after the operation.
Costs	The mean difference between the two study arms in the costs will be assessed. The required data will be analysed from the trial data and Finnish healthcare registries.
Adverse events	Adverse events will be monitored throughout the trial, and patients will be instructed to promptly report any potential serious adverse events. At the 1-year follow-up point, the questionnaires will include an inquiry about whether the patient has experienced any adverse events.

CTS, carpal tunnel syndrome; NPS, Net Promoter Score; VAS, Visual Analogue Scale.

overemphasising scar assessment items that may not contribute to patient satisfaction. It is widely used in clinical practice and is straightforward for the patient to complete.[22]

Secondary outcome measures

With the secondary outcome measures, we will assess the scar with a blinded outcome assessor, postoperative pain, the subjective result of the treatment using the Boston Carpal Tunnel Questionnaire patient satisfaction by the Net Promoter Score (NPS), costs and safety (table 2).

Participant timeline and recruitment

Recruited patients will be individuals attending the outpatient clinic of Orthopaedics, Traumatology and Hand Surgery at Kuopio University Hospital. Recruitment commenced on 21 September 2022 and is anticipated to continue until the end of 2025. The recruitment and screening process will occur before each patient's operation, during which the recruiter will inform the patient about the trial. Eligible patients who provide consent may then enrol in the trial by completing the trial consent form. The recruiter will assist the patient in filling out the preoperative questionnaire. A postoperative questionnaire will be sent to the patient via email. One year postoperatively, patients will be scheduled for an appointment during which they will complete the remaining postoperative surveys with a trial nurse. An outcome assessor will assess scar aesthetics using a dedicated form (figure 2).

Sample size

Based on an assessment of clinical wound evaluation scales, a VAS cosmesis scale should be able to detect the minimal clinically important difference (MCID) of 15 points on a 100 mm VAS.[23] The non-inferiority margin was set to 10 points considering the MCID and by using clinical judgement. Assuming a common SD of 20 points, a sample size of 50 patients per group is required to have 80% confidence that the lower limit of a one-sided 95% CI will be above the non-inferiority margin of −10 points.[24] To account for a 15% attrition rate, the group size is increased to a final size of 58 patients. Thus, the total sample size is 116 patients.

Allocation

Participants will be randomly assigned to one of two experimental groups with a 1:1 ratio and stratified by hand dominance. Two randomised computer-generated stratification lists will be created before the recruitment phase and will not be accessed by those involved in recruitment or allocation. Allocation will be conducted by a specific nurse via phone, who is not otherwise associated with the enrolment process. While the nature of the intervention will eventually make the patient, recruiter and care providers aware of the trial group, the outcome assessor evaluating scar aesthetics at the 1-year follow-up will remain blinded to the allocation.

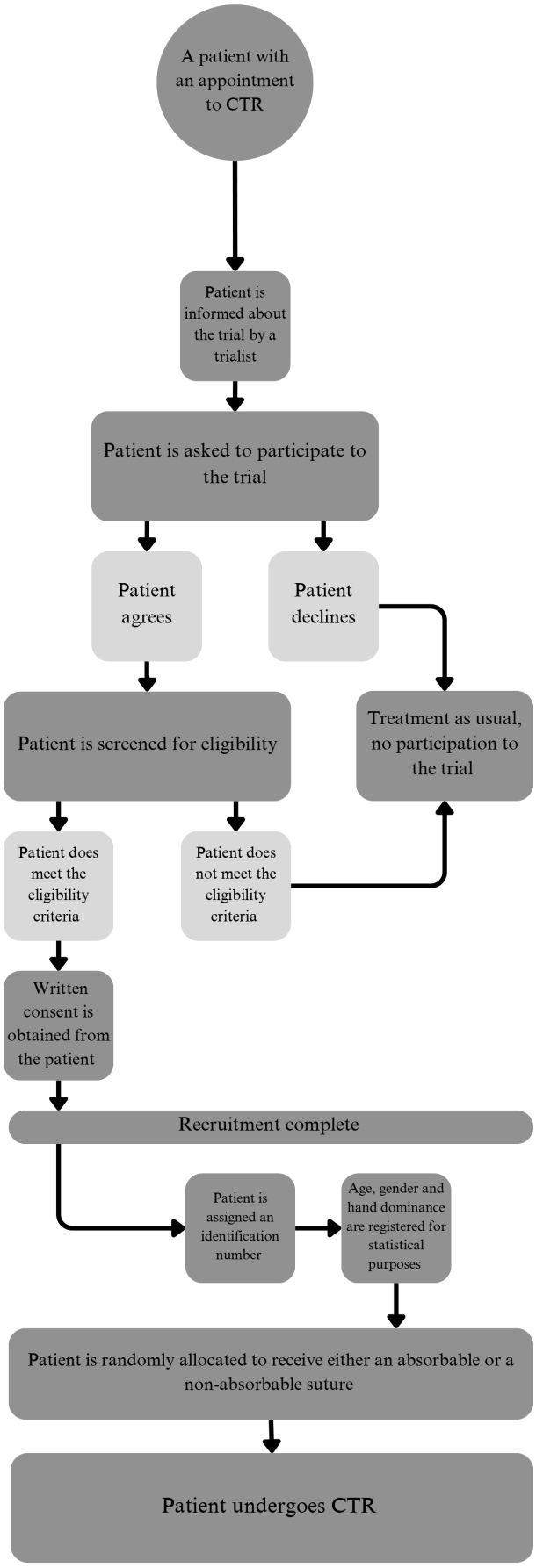

Figure 2 Participant recruitment flow chart. CTR, carpal tunnel release.

Blinding

Participants receiving non-absorbable sutures will be aware of the suture type due to the need for an additional appointment to remove them. Similarly, the surgeon and the other care providers will be aware of the suture type. It is therefore impossible to blind these groups to the intervention. Instead, a blinded outcome assessor will be used at the 1-year follow-up visit. They will not be in contact with the patient prior or after the evaluation. The allocation is not revealed to them by the nursing staff or the patient, and they do not have permission to access the patient's medical reports and will thus be unaware of the allocation. Additionally, the triallists performing data analysis will be blinded to the group assignments.

Data collection methods

Data will be collected directly from the patient in the form of paper and online surveys. Participants retain the right to revoke their consent and withdraw from the trial at any time. In such cases, data collection will cease, but all data collected up to that point will be retained and used.

Primary outcome

The scar cosmesis-evaluating scale will be completed at the 1-year appointment with a nurse. The nurse will measure the VAS result and log the number (mm) into an online survey. For this trial, SurveyMonkey (Momentive, 1999, San Mateo, California, USA) will be used for the online surveys.

Secondary outcomes

Participants will complete the Boston Carpal Tunnel Questionnaire with the recruiting staff member preoperatively on a paper form (figure 3). The same process will happen at the postoperative 1-year appointment, with a nurse present.

The participants will be sent an online survey via email present 2 weeks after the operation. In the survey, the participants are asked to evaluate pain around the scar during the past week on a VAS pain scale. The participants are explicitly instructed to include pain caused by potential suture removal in this assessment.

At the 1-year appointment, the outcome assessor will visit the consulting room to assess the aesthetic outcome of the scar on a VAS similar to the patient's. The result will be measured by the nurse and logged online. Additionally, the participants will complete the NPS survey on a paper form. Costs will be assessed based on healthcare resources used, extracted from trial data and relevant registries. Any potential adverse events will be inquired about and recorded in the 1-year follow-up questionnaires.

Retention

The 1-year-long follow-up period is a risk for non-retention. After 2 weeks, participants will answer an online survey independently. To reduce non-retention, all other surveys will be answered in the presence of a triallist. The ability of participants to receive information and answer surveys online has been considered during

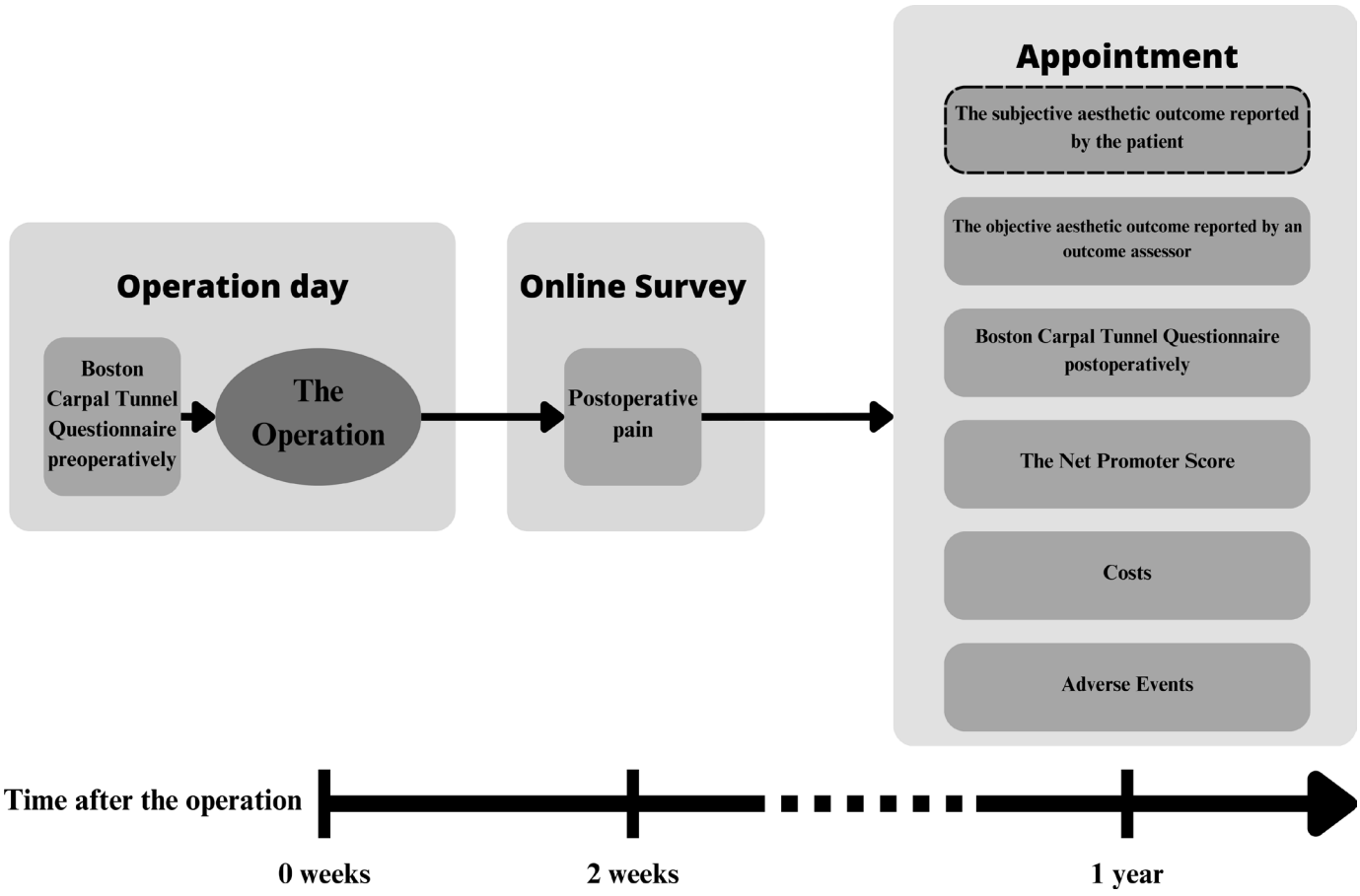

Figure 3 Data collection timeline.

enrolment. Absence from the 1-year appointment is a possible way to lose participants to follow-up. However, the recruiters will be instructed to emphasise the importance of the appointment before the patients consent to participate. The presence of a triallist at most of the data collecting points should diminish non-retention. A triallist and a trial nurse will actively monitor the progress of patients in the trial and non-adherent patients will be actively contacted by phone. At recruitment, patients will receive written instructions on how to contact the trial personnel in case of queries regarding the trial.

Data management

Surveys completed in the presence of staff members are in paper form. All the data from both SurveyMonkey and paper forms are transferred into R Statistical Software (V.4.3.1; R Core Team 2023) after the recruitment phase ensuring that all data are input at least twice.

All personal information about the enrolled participants will be stored in a locked cabinet at the trial site with access limited to trial personnel. All logs containing personal information to identify a participant are stored in a separate file. The written consent forms and all collected surveys are similarly stored in their respective files separately. The online survey database is protected by two-factor identification. Access to all stored information is limited to the authors.

Statistical methods

Aesthetic VAS will be used as the outcome variable, with group allocation as the independent variable, and age, gender and hand dominance as covariates as these may be prognostic for the main outcome. The primary analysis will involve age and gender-adjusted group differences, with the crude group difference reported based on the Welch t-test. Linear regression analysis will be used to estimate the treatment effect.

To minimise potential bias in interpreting the findings, the triallist, who will be blinded to the treatment allocation, performs data analysis. Blinded results (groups A and B) will be presented to the writing committee, where a collective consensus on the interpretation of the findings will be reached. Once a consensus is achieved, the groups will be unblinded.[25]

Data monitoring

No new or experimental treatments are being conducted, and both suture types under study are commonly used in open carpal tunnel release surgery. The associated risks can be considered minimal. Therefore, a formal data monitoring committee is not required. There will be no interim analysis to terminate the trial for similar reasons.

Harms

Adverse events will be monitored at the 1-year appointment. Patients are instructed to immediately report potential serious adverse events to the Department of Orthopaedics, Traumatology and Hand Surgery at Kuopio University Hospital. Adverse events include, for example, scar tearing requiring medical attention or a superficial infection necessitating oral antibiotic treatment. Serious adverse events include, for example, deep scar infection requiring hospital care, nerve, tendon or arterial injury, and complex regional pain syndrome. All adverse events are promptly treated with necessary measures, following standard treatment protocols, as both wound suture methods used have been proven to be safe.

Patient and public involvement

Patients were not actively involved in the trial.

ETHICS AND DISSEMINATION

Research ethics approval

The trial protocol and materials distributed to participants were approved by the Medical Research Ethics Committee of Wellbeing Services County of Northern Savo (5.1.2022). Any potential modifications to the research plan will also be submitted to the Research Ethics Committee following their guidelines. Additionally, any changes will be communicated to other potential trial participants if relevant.

Consent

Informed consent will be obtained from patients by a designated group of recruiters during the recruitment phase of the trial. The recruiting staff include members of the research team and a trial nurse, all of whom will undergo proper training and receive written instructions before the enrolment begins. The nature of the trial will be thoroughly explained to potential participants and written informed consent will be obtained by the recruiter.

Dissemination policy

The results of the trial will be published in a peer-reviewed journal, and all participating patients and healthcare workers will be informed about the article. Access to the article will be arranged if necessary. The pseudonymised data supporting the findings stated in the results article are available upon request from the corresponding author (AS) (online supplemental table 1).

DISCUSSION

Carpal tunnel release surgery is a common and essential treatment due to the relatively high prevalence of CTS in the general population. Therefore, it is highly appropriate to optimise the procedure as far as possible. This trial focuses on absorbable and non-absorbable sutures, both widely used in open carpal tunnel release surgery.

Previous studies have investigated the relationship between suture material and scar cosmesis in carpal tunnel release surgery. However, these studies had limitations. For instance, a prospective cohort study by Dosani *et al*[17] using the Stonybrook Scar Evaluation Scale found no statistical significance between the two most used suture materials. Similarly, a prospective cohort study by Kundra *et al*[18] and an RCT by Theopold *et al*[16] did not yield different results. These past studies had relatively small sample sizes of 70 and 38, limiting their statistical power. Similarly, the follow-up times were 3 months and 6 weeks, respectively. Postoperatively, the scar undergoes changes and requires time to heal to its more stable form.[26] Therefore, a longer follow-up period is necessary to account for individual differences in wound healing.

Aside from the method of wound closure, various factors can affect the patient's overall experience. One such factor is the pain caused by the removal process of the non-absorbable suture, which must be considered when measuring postoperative pain as it can significantly impact patient satisfaction.

Due to the nature of the intervention being studied, it is not possible to blind the recruiting staff, the patients or the healthcare workers to the treatment. To address this limitation, a specifically assigned blinded outcome assessor is used to mitigate potential subjective biases that could skew the results.

This study aims to be practical and easily applicable to common treatment practices. The wound healing process is lengthy, and it may take up to a year for the resulting scar to reach its final form.[26] This aspect is considered in the trial's design. The trial's strengths include evaluating results at 1 year postoperatively, allowing most patients' scars to settle. Additionally, the trial features a relatively large sample size compared with previous studies on the subject, enhancing the likelihood of detecting clinically relevant results.

This trial seeks to address the limitations of past studies on this topic. A Cochrane literature review by Wade *et al*[11] found similar conclusions, highlighting the need for a high-quality RCT with sufficient evidence to assist healthcare professionals in making informed decisions regarding suture material choice. This trial aims to address this identified need.

Author affiliations
[1]University of Eastern Finland School of Medicine, Kuopio, Finland
[2]Department of Orthopaedics, Traumatology and Hand Surgery, Kuopio University Hospital, Kuopio, Finland
[3]Kuopio University Hospital, Kuopio, Finland
[4]Department of Orthopaedics and Traumatology, Tampere University Hospital, Tampere, Finland
[5]Tampere Universities, Tampere, Finland

X Mikko Petteri Räisänen @raisanen_mikko

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and planning the data management and collection. MH—writing the protocol. NH—writing the protocol.

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ORCID iDs
Aukusti Savolainen http://orcid.org/0009-0001-0012-8157
Aleksi Reito http://orcid.org/0000-0002-6903-6461
Mikko Petteri Räisänen http://orcid.org/0000-0002-5680-4898

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SUPPLEMENTAL MATERIAL

This appendix provides readers with additional information about the authors' work.

Supplement to:

Skin closUre in carPal tunnEl Release (SUPER): Protocol for a Blinded Randomized Controlled Trial Comparing Absorbable and Non-absorbable Sutures in Carpal Tunnel Release

Authors:

Aukusti Savolainen, Yrjänä Nietosvaara, Aleksi Reito, Joonas Sirola, Mikael Hytönen, Noora Heikkinen, Mikko P. Räisänen

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Supplementary Appendix I:

Self-care Instructions

Description	Patient instructions for self-care after carpal tunnel release or trigger finger release surgery

In carpal tunnel release surgery, the pressure to the median nerve in the wrist is relieved by opening the structure that forms the roof of the carpal tunnel, which compresses the nerve. The alleviation of the symptoms is related to how long and how strongly the nerve has been under pressure. Pain, tingling and numbness may take several months to disappear. Sometimes the symptoms disappear immediately, but mostly gradually. In trigger finger release surgery, the compressive area of the tendon sheath is released, and the gliding of the flexor tendon becomes normal.

PAIN MANAGEMENT
Take painkillers at home according to the doctor's instructions. The pain should subside within a few days. After surgery, keep the arm elevated to reduce pain and swelling. When resting, support your arm in an elevated position with pillows.
If necessary, use cold therapy to
• reduce the inflammatory reaction
• reduce swelling
• raise the pain threshold.
Put a thin cloth towel between the cold pack and the skin to prevent frostbite injuries. Keep the cold pack in place for 20-30 minutes. The cold treatment can be repeated several times a day.

HAND REHABILITATION
Swelling of the hand after surgery is normal. Keeping the hand in a raised position and doing movement exercises of the fingers and the entire upper limb reduce swelling. Using the hand as a helping hand in everyday activities (eating, dressing and other light chores under 1 kg) is good rehabilitation for the hand. After about two weeks, gradually increase the use of the hand (e.g. lifting and carrying) within the limits allowed by the pain. If there is still pain, temporarily reduce the load to the hand.

FINGER AND WRIST MOVEMENT EXERCISES
Movement exercises promote the mobility of the fingers and the wrist, the smoothness of the median nerve and flexor tendons, and reduce swelling. When doing movement exercises, keep your neck and shoulders relaxed. Start doing range of motion exercises one day after surgery. Do the movements calmly and within the limits allowed by the pain. You can gradually increase the repetitions and the range of motion as the training progresses.
Repeat the sets 5 times a day.
Keep your wrist and fingers straight.
Make a fist and straighten your fingers.
The movement is repeated 5-10 times.

Take the tip of the thumb alternately with each finger
to the tip and form the letter o with your fingers.
Extend the thumb fully after each touch.
The movement is repeated 5-10 times.

Extend and flex your wrist slightly.
Avoid extreme flexion and extension during the first two weeks.
The movement is repeated 5-10 times.

Keep your wrist straight. Stretch out your fingers and relax.

The movement is repeated 5-10 times.
If necessary, you can enhance the stretching with the help of the other hand after two weeks.

WOUND CARE
The surgical wound is closed with either removable or self-dissolving sutures. After surgery, the wound is bandaged with a hand surgical bandage. Keep the dressing from getting wet during showering. Replace the bandage with a new one if it comes off, gets wet or if the wound oozes through the bandage. Wash your hands thoroughly before changing the dressing. You can remove the wound dressings three days after the surgery yourself, or you can have them removed at the health centre at the nurse's office. Make an appointment yourself if necessary. Spray the surgical area with water after removing the bandages and pat dry with a clean towel. The wound and the scar can be protected and supported with wound tape or a bandage for 2-4 weeks. Keep the wound area from getting dirty and avoid sweating until the stitches are removed or they melt and come off on their own. You can buy wound tape at a pharmacy. Saunas and swimming are allowed one day after the stitches are removed or after the self-dissolving stitches have come off by themselves in about three weeks. The stitches are removed two weeks after the operation. Make an appointment to have the stitches removed by a nurse at a health center or occupational health care. Contact a health centre if the surgical wound is bleeding or if you suspect a wound infection.
The symptoms of a wound infection are:
• persistent pain that doesn’t go away with painkillers
• fever
• intense redness and heating
• increasing swelling
• wet discharge from the wound

SCAR TREATMENT
Start treating the scar after the sutures are removed or when the wound has healed, and the absorbable sutures have dissolved. Massage the scar and its surroundings with the fingers or palm of the other hand so that the skin moves along with the massage movements in longitudinal and transverse directions and with rotating movements. At first, the pressure can be lighter, but gradually increase the pressure to increase the elasticity of the scar. Grease the wrist with base cream after the massage. Massage and grease the scar several times a day. Massaging and greasing the scar promotes the flexibility of the scar and keeps it soft and loose from the underlying tissues. Massage the scar even if it is tender to the touch get the skin used to the touch. Sometimes there might be scar hypertrophy which you can treat with silicone scar care tape available at the pharmacy. The healing and whitening of the scar are individual and may take months. When healing, the scar may redden, itch, harden, be raised or be tender to the touch. A hard and inflexible scar can limit the movements of the joints and make certain hand movements difficult. An untreated scar may also become an aesthetic problem.

CONTACT INFORMATION
If you have any questions about your treatment, you may call the orthopedic outpatient clinic: mon - fri from 8:00 a.m. to 1:00 p.m. tel. 044 717 5694.
In urgent matters, contact the emergency department of your health center.

Supplementary Appendix II:

Table S1. Data Sharing Statement

Data Sharing Statement	
Will individual data be available (including data dictionaries)?	Not before the study has been finished
What data in particular will be shared?	Pseudonymised data
What other documents will be available?	Study Protocol*, Informed Consent Form, Analytic Code
When will data be available (start and end dates?)	Anonymous patient level data will be available if the European Union regulations permit after the study has been finished. The end date is estimated to be 1 January 2027.
With whom?	Researchers who provide a methodologically sound proposal and reviewers of the journal where article will be published.
For what types of analyses?	To achieve aims in the approved proposal.
By what mechanism will data be made available?	Proposals should be directed to aukusa@student.uef.fi. To gain access, data requestors will need to sign a data access agreement.

* Study protocol is published

Supplementary Appendix III:

SPIRIT Checklist

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	supplementary appendix IV
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	18
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 17-18
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	supplementary appendix IV
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-5

Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	4
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5-6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6-7
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	7
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	7
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8-10

Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	10
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	10
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how	11
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	11
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to	11-12

		promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12-13
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	n/a
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	n/a
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	14
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events	14

		and other unintended effects of trial interventions or trial conduct	
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	14
Protocol amendments	#25	Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	14
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	15
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	15, supplementary appendix II
Ancillary and post-trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	15
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a

Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	15, supplementary appendix II
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	supplementary appendix V
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

Supplementary Appendix IV:

World Health Organization Trial Registration Data Set

Data Category	Information
Primary Registry and Trial Identifying Number	ClinicalTrials.gov: NCT05503719
Date of Registration in Primary Registry	10.5.2022
Secondary Identifying Numbers	MRECWSCNS: 2319/2021
Sources of Monetary or Material Support	Kuopio University Hospital
Primary Sponsor	University of Eastern Finland
Secondary Sponsor	n/a
Contact for Public Queries	Aukusti Savolainen, BM, aukusa@uef.fi University of Eastern Finland, Yliopistonranta 8, 70210 Kuopio, Finland, (+358)29 4451111
Contact for Scientific Queries	Aukusti Savolainen, BM, aukusa@uef.fi University of Eastern Finland, Yliopistonranta 8, 70210 Kuopio, Finland, (+358)29 4451111
Public Title	Skin Closure in Carpal Tunnel Release (SUPER)
Scientific Title	Skin closUre in carPal tunnEl Release (SUPER): Protocol for a Blinded Randomized Controlled Trial Comparing Absorbable and Non-absorbable Sutures in Carpal Tunnel Release
Countries of Recruitment	Finland
Health Condition or Problem Studied	Carpal tunnel syndrome, Median nerve release surgery
Interventions	Study intervention: absorbable suture used in carpal tunnel release surgery
	Active comparator: non-absorbable suture used in carpal tunnel release surgery

Key Inclusion and Exclusion Criteria	Ages eligible for study: ≥18 years Sexes eligible for study: both Accepts healthy volunteers: no
	Inclusion criteria: CTS diagnosed with ENMG, symptoms typical of CTS, referral to CTR, informed consent signed, the ability to receive the virtual questionnaire via email and answer it, the ability to understand and answer the Finnish questionnaires.
	Exclusion criteria: Repeat surgery, known allergy to suture materials, ongoing systemic steroid treatment, ongoing chemotherapy, ongoing immunomodulatory treatment, past hypertrophic or keloid scars or other severe disturbances in wound healing, age under 18 years, pregnancy, or breastfeeding.
Study Type	Interventional
	Allocation: Randomized intervention model. Parallel assignment masking: single blind (outcome assessor and trialists in the data analysis phase)
	Primary purpose: guiding future interventions
Date of First Enrolment	21.9.2022
Target Sample Size	116
Recruitment Status	Recruiting
Primary Outcome	Outcome name: Scar aesthetics according to the patient
	Method of measurement: Visual Analog Scale ranging from “the ugliest scar possible” to “most beautiful scar possible”
	The timepoint of interest: 1 year postoperatively
Key Secondary Outcomes	Outcome name: Postoperative pain; Method of measurement: Visual Analog Scale ranging from

	"no pain at all" to "the worst pain imaginable"; The timepoint of interest: 2 weeks postoperatively
	Outcome name: Scar aesthetics according to an outcome assessor; Method of measurement: Visual Analog Scale ranging from "the ugliest scar possible" to "the most beautiful scar possible"; The timepoint of interest: 1 year postoperatively
	Outcome name: Patient-Reported Outcome Measures; Method of measurement: The Boston Carpal Tunnel Syndrome Questionnaire; The timepoints of interest: Preoperatively on the operation day, postoperatively 1 year postoperatively
	Outcome name: Patient satisfaction; Method of measurement: Net Promoter Score®; Timepoint of interest: 1 year postoperatively
	Outcome name: Costs; Method of measurement: Use of health care resources; Timepoint of interest: 1 year postoperatively
	Outcome name: Safety; Method of measurement: Question; Timepoint of interest: 1 year postoperatively
Ethics Review	Status: Approved
	Date of approval: 5.1.2022
	Name and contact details of ethics committee: Medical Research Ethics Committee of Wellbeing Services County of North Savo, Pohjois-Savon hyvinvointialue, Puijonlaaksontie 2, PL 1711, 70211 Kuopio, Finland, tutkimuseettinentoimikunta@pshyvinvointialue.fi

IPD Sharing Statement	Plan to share IPD: Yes, after the trial finishes (see Supplementary Appendix Table S1)

Supplementary Appendix V:

Participant consent form

CONSENT FOR PARTICIPATION IN THE TRIAL

Randomized Controlled Trial Comparing Absorbable and Non-absorbable Sutures in Carpal Tunnel Release, Kuopio University Hospital, Department of Musculosceletal Surgery

I _____ have been requested to participate in the scientific study mentioned above. The purpose of this study is to evaluate the impact of the suture material on the result of the scar.

I have read and understood the provided study information bulletin. The bulletin has provided me appropriate clarification on the study and concomitant collection and handling of personal data. the contents of the bulletin have been disclosed to me verbally as well. I have had the possibility to ask questions and I have received sufficient responses to all my study-related questions. The verbal information was provided to me by _____ ___/___ 20___.

I have had enough time to consider my participation in the study. I have received sufficient information about my rights, the purpose, and the execution of the study as well as possible advantages and risks related to the study. I have not been pressed or tempted to participate.

I know my personal information will be handled confidentially and will not be handed over to outsiders.

I understand my participation is voluntary. I am aware that I can revoke this consent at any time without a reason and that the revocation will not affect my treatment in any way.

I am aware that if I revoke my consent or abort my participation in the study, any information collected by then can be used as part of the research material.

With my signature I confirm my participation in this study and agree to be a voluntary research participant.

_____ _____
Participant name Date

_____ _____
Time of birth of the participant Participant signature

_____
Participant address

Consent received

_____ _____
_____

Name of trialist	Date	Trialist signature

The original signed consent form and a copy of the study information bulletin will be stored in the trial archive. The study information bulletin and a copy of the signed consent form will be given to the participant.