Study Protocol

Prospective Multicenter Study Comparing Open Surgical Decompression with Minimally Invasive Ultrasound-Guided Carpal Tunnel Release

(Prospective Multicenter Trial Comparing Open Surgical Decompression versus minimally invasive Ultrasound-Guided Carpal Tunnel Release)

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Short title: Open vs. Ultrasound-Guided Carpal Tunnel Release

Study type: prospective, multicenter

Confidentiality

The information contained in this project description must be treated as confidential.

This document must not be disclosed to unauthorized persons without the consent of the responsible coordinators.

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Summary

Carpal Tunnel Syndrome (CTS) is the most prevalent entrapment neuropathy. While Open Surgical Decompression (OSCTR) remains the gold standard, minimally invasive Ultrasound-Guided Carpal Tunnel Release (USGCTR) offers a potential reduction in postoperative morbidity and faster recovery. Evidence comparing these two methods in a prospective, multicenter setting is currently limited.
Objective:
This study aims to compare the clinical efficacy, patient-reported outcomes, and socioeconomic impact (return to work) of USGCTR versus OSCTR.
Methods:
In this prospective, multicenter observational study, 200 patients (100 per cohort) will be recruited. Patient assignment is based on the participating center's specialized standard of care: USGCTR at the UI for Radiology (PMU) and OSCTR at the UKH Salzburg. Eligible participants must have electrophysiologically confirmed CTS and failed conservative treatment. Follow-up assessments occur preoperatively and at 2 weeks, 6 weeks, 3 months, and 12 months post-surgery.
Outcome Measures:
The primary endpoint is the functional improvement measured by the Boston Carpal Tunnel Questionnaire (BCTQ). Secondary endpoints include pain levels (VAS), the Single Assessment Numeric Evaluation (SANE), patient satisfaction, and the duration of postoperative sick leave (return to work).
Significance:
The results of this trial will provide high-quality data to optimize surgical decision-making and potentially improve patient recovery trajectories in the treatment of CTS.

Study Objective

Primary objective:
The primary objective of this study is to evaluate and compare functional recovery and symptom relief in patients with Carpal Tunnel Syndrome (CTS) following Open Surgical Decompression (OSCTR) versus minimally invasive Ultrasound-Guided Carpal Tunnel Release (USGCTR). The change in the Boston Carpal Tunnel Questionnaire (BCTQ) serves as the primary outcome parameter.
Secondary objectives: Pain course: Quantification of postoperative pain reduction using the Visual Analogue Scale (VAS).
Subjective outcome: Assessment of health-related quality of life and global subjective improvement using the SANE score (Single Assessment Numeric Evaluation).
Socioeconomic factors: Comparison of the time to return to work ("Return to Work").
Patient satisfaction: Assessment of satisfaction with the selected surgical method after 3 months.
Safety: Documentation and comparison of complication rates (infections, persistent paresthesia, reoperations, nerve injuries, wound-healing disorders).

Introduction

Carpal Tunnel Syndrome (CTS), with a prevalence of approximately 3–5% in the general population, is the most common compression neuropathy of the median nerve. Pathophysiologically, increased pressure within the carpal tunnel leads to ischemia of the nerve, which clinically manifests as paresthesia, nocturnal pain, and, in advanced stages, thenar muscle atrophy and loss of strength. Open Surgical Decompression (OSCTR) has been the clinical gold standard for decades. It provides excellent visualization of the flexor retinaculum; however, it involves a postoperative incision in the palm, which may lead to scar pain (Pillar Pain) and delayed return to manual activities. Pillar Pain refers to load-dependent pain in the thenar and hypothenar eminences following carpal tunnel surgery. As an innovative alternative, minimally invasive Ultrasound-Guided Carpal Tunnel Release (USGCTR) has become established. This technique allows division of the flexor retinaculum under continuous sonographic visualization through a minimal incision at the distal forearm or wrist crease. Theoretical advantages include avoidance of a painful scar in the load-bearing area of the hand and potentially faster recovery.

Scientific question: Despite the increasing use of USGCTR, there is a lack of high-quality prospective studies directly comparing this method with OSCTR, particularly in a multicenter setting reflecting routine care. As UKH Salzburg and the University Institute of Radiology of PMU each specialize in one of these methods, this collaboration provides a unique opportunity to evaluate both procedures under real-life conditions (high-volume centers).

Benefit and Significance of the Study

The study provides essential data for evidence-based surgical treatment of CTS. The multicenter approach increases the external validity of the results. The findings will contribute to refining clinical guidelines and clarifying which procedure provides the greatest benefit for which patient groups.
Patient benefit: The immediate benefit for study participants consists of close, structured follow-up over 12 months. If the hypothesis that USGCTR leads to a significantly faster return to daily activities is confirmed, this may provide future patients with a more informed basis for decision-making and minimize postoperative morbidity (e.g., Pillar Pain).
Socioeconomic significance:
CTS frequently affects people of working age. A reduction in work incapacity through minimally invasive procedures has considerable economic relevance. By collecting “Return to Work” data, the study provides important metrics for the healthcare system and accident insurance institutions (AUVA).

Study Design and Study Population

Study Type

This study is a prospective, multicenter observational study (cohort study). Since allocation of patients to the intervention groups (OSCTR vs. USGCTR) is not performed by randomization but by the choice of treatment center and its respective standard procedure, an observational design is used to reflect clinical reality (real-world evidence). Patients independently choose the treatment center and the associated procedure (OSCTR or USGCTR) based on referral by their previously treating neurologist or on personal information. The study team does not interfere with this decision at any time.
The procedure (USGCTR and OSCTR) is an established standard procedure at the respective institution and is routinely performed.

Study Duration

Planned study start date: Q3 2026
Planned study end date: Expected 01/05/2029

Planned total duration: 2 years
FPFV (first patient first visit): Q3 2026
LPLV (last patient last visit): Q3 2029
Expected final data analysis: Q4 2029

Participating Study Centers

The study will be conducted at two specialized centers, each representing a specific surgical focus:
University Institute of Radiology of PMU Salzburg: Performance of minimally invasive, ultrasound-guided release (USGCTR).
Investigators:
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Supporting Infrastructure/Cooperation Partners

The collaboration is between the University Institute of Radiology of the Paracelsus Medical Private University (PMU) and the AUVA Unfallkrankenhaus Salzburg. Statistical analysis and central data management are coordinated by the research team of the participating institutes.

Study Population

The target population comprises patients with clinically symptomatic and objectively confirmed Carpal Tunnel Syndrome for whom there is an indication for surgical intervention. A sample size of 100 patients per group (total n = 200) is targeted.

Inclusion Criteria

The following criteria must be met to participate in the study:
Electrophysiologically (EMG/nerve conduction studies) verified Carpal Tunnel Syndrome (the finding must not be older than 6 months at the time of inclusion).
Previous, documented, and exhausted conservative treatment measures.
Existing indication for surgery that has been discussed with the patient, as well as the patient's explicit wish to undergo surgical treatment.
Capacity to provide informed consent and written informed consent.
Age ≥ 18 years

Exclusion Criteria

Patients with the following characteristics are excluded from the study:
Previous surgery at the affected site or revision procedures.
Known pre-existing nerve lesions of the upper extremity (e.g., traumatic transections or proximal injuries).
Manifest polyneuropathy.
Foreseeable “Loss to follow-up” (e.g., inability to contact the patient or insufficient compliance) before the critical 3-month follow-up.
Age under 18 years

Recruitment

Recruitment takes place during regular clinical consultations at the outpatient clinics of the participating centers. Patients who meet the inclusion criteria are informed about the study by the treating physicians. Participation is voluntary and does not affect the quality of medical care.

Handling of Withdrawals and Loss to Follow-up

Patients who withdraw their participation (Withdrawal of Consent) or do not attend follow-up appointments (Loss to follow-up) will be documented.
As the primary endpoint is functional improvement at 3 and 12 months, withdrawals before the 3-month follow-up will be documented as early termination.
For telephone assessments, the Study Nurse will attempt to contact patients at different times of day to maximize the response rate.
The statistical analysis will define an appropriate approach to missing values (e.g., Last Observation Carried Forward or Multiple Imputation) to minimize bias.

Study Procedures

Patient Information and Informed Consent

The information and informed consent process takes place during the regular consultation of patients at the specialized outpatient clinics of UKH Salzburg or the University Institute of Radiology of PMU.
Initial contact: Potential participants are informed by the treating physician about the possibility of participating in the study if the clinical inclusion criteria (EMG/nerve conduction study-verified CTS, indication for surgery) are met.
Information discussion: During a personal consultation, the patient is comprehensively informed by the respective treating and informing investigator about the study objective, the follow-up procedures (in particular the telephone follow-ups), the type of data collected, and data protection rights.
Consideration period: The patient is given sufficient time (24 hours) to decide whether to participate and to clarify any questions.
Consent: Written informed consent must be signed before any study-related data collection. A copy of the signed information document is provided to the patient.
Right of withdrawal: Participants are explicitly informed that they may withdraw their consent at any time without giving a reason and without disadvantage to their further medical treatment.

Procedures and Timelines

Time Point	Mode	Parameters / Measures Collected
T0: Preoperative	In person (outpatient clinic)	Information & inclusion, baseline data, SANE, VAS, BCTQ;
Intervention*	Inpatient/Outpatient	Performance of OSCTR (UKH) or USGCTR (UI Radiology)
T1: 2 weeks postoperative	**In person (follow-up)**	Clinical wound assessment, SANE, VAS, BCTQ
T2: 6 weeks postoperative	By telephone (Study Nurse, Investigator)	SANE, VAS, BCTQ
T3: 3 months postoperative	By telephone (Study Nurse, Investigator)	SANE, VAS, BCTQ, satisfaction with the method (Likert scale), days until “Return to Work”

Time Point	Mode	Parameters / Measures Collected
T4: 12 months postoperative	By telephone (Study Nurse, Investigator)	SANE, VAS, BCTQ

*no study-related measure

Methods

Measures at the Individual Time Points

Data collection follows a strict protocol to ensure comparability of the cohorts. The measures are structured as follows:

- T0 – Preoperative (baseline data): Collection of demographic data (age, sex, handedness, occupational group). Clinical verification of the inclusion criteria and review of radiological/electrophysiological findings.

  Initial assessment of patient scores: SANE, VAS, and BCTQ.
  Intervention: Performance of open surgical decompression (OSD) at UKH Salzburg or ultrasound-guided release (USGCTR) at the UI for Radiology. Documentation of intraoperative findings or immediate complications.
- T1 – 2 weeks postoperative (in-person visit): Clinical examination of the wound and assessment for neurological deficits.

  Assessment of scores: SANE, VAS, and BCTQ.
- T2 – 6 weeks postoperative (telephone follow-up): Structured interview by the Study Nurse. Assessment of scores: SANE, VAS, and BCTQ.
- T3 – 3 months postoperative (telephone follow-up): Assessment of scores: SANE, VAS, and BCTQ.
  Additional variables: Assessment of patient satisfaction with the surgical method (Likert scale) and documentation of the exact date of return to work (“Return to Work”).
- T4 – 12 months postoperative (telephone follow-up): Final assessment of the long-term stability of the results.

  Assessment of scores: SANE, VAS, and BCTQ.

Primary Hypothesis

H0: There is no significant difference in the mean change in the Boston Carpal Tunnel Questionnaire (BCTQ) score between the ultrasound-guided release (USGCTR) group and the open surgical decompression (OSD) group at 3 months postoperatively.
H1: There is a significant difference in the mean change in the BCTQ score between the USGCTR group and the OSD group at 3 months postoperatively.

Secondary Hypothesis/Hypotheses

There is a significant difference between USGCTR and OSD in postoperative pain intensity (VAS) during the first 6 weeks.
The time to return to work (“Return to Work”) differs significantly between the two treatment pathways.
There is a significant difference in global patient satisfaction after 3 months between the two surgical procedures.

Endpoints

Primary Endpoint

The mean difference in the change in the Boston Carpal Tunnel Questionnaire (BCTQ) score (combined Symptom Severity Scale and Functional Status Scale) from the preoperative time point (T0) to the 3-month follow-up (T3).

Secondary Endpoint(s)

Pain course: Change in the Visual Analogue Scale (VAS) (0–10) at all assessment time points.
Subjective hand function: SANE score results (0–100%).
Return to work: Number of days from surgery until full return to work.
Method satisfaction: Score on a 5-point Likert scale at time point T3.
Complication rate: Frequency of wound infections, persistent numbness, or required revisions within 12 months.

Statistics and Data Analysis

Sample Size

Planned number of participants: A total of 200 patients will be included, with 100 participants recruited per group (OSD cohort at UKH Salzburg and USGCTR cohort at the UI for Radiology).
Justification: This sample size is based on comparable clinical studies on Carpal Tunnel Syndrome that use the Minimal Clinically Important Difference (MCID) of the Boston Carpal Tunnel Questionnaire (BCTQ) as a reference.
Power consideration: A group size of n = 100 provides sufficient statistical power (more than 80%) to detect clinically relevant differences in the early recovery phase (T1 to T3) at a significance level of alpha = 0.05.

Statistical Methods

Descriptive statistics:
Demographic baseline data (age, sex, CTS severity) will be presented using means, standard deviations, and absolute and relative frequencies.
Inferential statistics:
The primary and secondary endpoints (BCTQ, VAS, SANE) will be compared between the two groups using an independent-samples t-test (for normally distributed data) or the Mann–Whitney U test (for non-normally distributed data). To analyze the temporal course across the five assessment time points, repeated-measures analysis of variance (ANOVA) or a Linear Mixed Model will be used to account for center and time effects and their interaction.
Categorical data (e.g., complication rates) will be compared using the Chi-square test or Fisher's Exact Test.

Data Collection, Source Data and Data Storage

Source data: The primary data consist of findings collected as part of routine treatment (EMG/nerve conduction studies), operative reports, and standardized questionnaires completed by patients (BCTQ, VAS, SANE).
Data collection method: Data are collected partly in person on site (T0, T1) and partly by telephone by a trained Study Nurse (T2–T4), and are transferred to a Case Report Form (CRF) in Excel format.
Data storage: Data are stored on the highly secure internal clinical servers of the participating centers (UKH Salzburg and UI for Radiology).
Access protection: Access is strictly limited to authorized study physicians and is provided exclusively through password-protected computers.

Data Analysis and Expected Results

Expected outcome: It is expected that the USGCTR group will show significantly faster functional improvement (BCTQ) and an earlier return to work (“Return to Work”) during the early postoperative phase (2 to 6 weeks).
Long-term course: At 12 months, equivalence of the two procedures is expected with regard to symptom relief and patient satisfaction.
Scientific relevance: The analysis is intended to demonstrate that the minimally invasive procedure provides significant socioeconomic benefits (shorter duration of work incapacity) with equivalent safety.

Data Analysis

Software: Statistical analysis will be performed using modern statistical software (e.g., SPSS or R).
Handling of missing values: To avoid bias, the analysis will primarily follow the Intent-to-Treat (ITT) principle. Missing data points will, where methodologically appropriate, be addressed using multiple imputation or “Last Observation Carried Forward” (LOCF) to ensure the validity of the long-term follow-up (12 months).
Significance level: A two-sided significance level of $p < 0.05$ is defined for all tests.

Data Management

Study data are managed in strict compliance with the applicable data protection regulations (GDPR). All collected data are managed in a manner that protects participants' privacy at all times while maintaining scientific integrity and traceability.

Pseudonymization

To protect the anonymity of study participants, a pseudonymization procedure is applied:
Identity separation: Directly identifying information (such as name, date of birth, or social security number) is kept strictly separate from the medical study data (SANE, VAS, BCTQ scores).
Patient ID: Each participant is assigned a unique sequential identification number (Patient ID) upon inclusion. All questionnaires and clinical findings are recorded under this ID.
Patient identification list: The only list that permits linkage between the Patient ID and the participants' names is stored securely and separately from the research data.
Access restriction: Only authorized members of the research team (study physicians and the responsible Study Nurse) who are directly involved in patient care or data collection have access to the identification list.

Technical security: The pseudonymized datasets are stored on the internal clinical servers of UKH Salzburg and the University Institute of Radiology. Access is exclusively through password-protected workstations in locked premises.

Archiving

Study documents are retained in accordance with the legal requirements for clinical investigations:
Retention period: All study-relevant documents (original questionnaires, informed consent forms, patient identification list) are securely archived for a period of at least 15 years after completion of the study.
Place of archiving: Physical documents are stored in locked archive rooms of the respective participating institutes (UI for Radiology and UKH Salzburg). Digital data are protected against loss through regular backups on the institutions' secure server structures.

Responsibility: Responsibility for proper archiving and protection against unauthorized access lies with the respective lead investigators of the centers.

Destruction: After expiry of the statutory retention period, personal data and the identification list will be destroyed or deleted in compliance with data protection requirements, unless another legal basis for longer retention exists.

Ethical Aspects and Safety Considerations

Potential Risks and Emergency Plan

Routine procedures: As this is an observational study, only medically indicated routine procedures corresponding to the clinical standard of the respective center are performed. Patients are not exposed to additional surgical risks beyond normal clinical care.
Specific risks: OSD: Typical risks include postoperative infections, hematomas, delayed wound healing, or scar pain ("Pillar Pain"). USGCTR: As a minimally invasive procedure, there is a theoretical risk of incomplete division of the flexor retinaculum or rare injury to nerve branches (e.g., the palmar branch), which is minimized by continuous sonographic visualization.
Emergency management: In the event of complications (e.g., postoperative bleeding or acute neurological deterioration), the full infrastructure of a specialized hospital is available at all times at both participating centers (UKH Salzburg and UI for Radiology) for immediate surgical intervention.

Data Protection

Legal basis: The GDPR in its currently applicable version applies.
Responsibility:
For UKH Salzburg:
AUVA Data Protection Officer, Vienna Twin Towers, Wienerbergstraße 11, 1100 Vienna (E-mail: dsb@auva.at, Tel.: +43 5 93 93-21102).
For the UI for Radiology (PMU): Alexandra Graf, (alexandra.graf@salk.at, +43 5 7255 30010)alexandra.graf@salk.at

Data minimization: Only data that are strictly necessary for the scientific research question are collected. All data are stored in pseudonymized form so that unauthorized persons cannot infer the identity of participants.

Funding

No external funding or sponsors.

Insurance

Not required

Conflict of Interest

None, see COI

Qualifications

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Dr. Gebhart Woisetschläger (Statistician, Ludwig Boltzmann Institute for Traumatology)

Local Infrastructure and Facilities

AUVA Unfallkrankenhaus Salzburg
UI for Radiology of the Paracelsus Medical Private University Salzburg

Publications

A publication in a high-impact journal is planned. Selection will be based on the impact factor and/or the subject-matter alignment with the participating specialties.

References/Literature

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Abbreviations

ANOVA: Analysis of Variance
AU: Work incapacity
AUVA: Allgemeine Unfallversicherungsanstalt
BCTQ: Boston Carpal Tunnel Questionnaire
COI: Conflict of Interest
CTS: Carpal Tunnel Syndrome

GDPR: General Data Protection Regulation
eCRF: electronic Case Report Form
EMG: Electromyography
FPFV: First Patient First Visit
ITT: Intent-to-treat
CTS: Carpal Tunnel Syndrome
LOCF: Last Observation Carried Forward
LPLV: Last Patient Last Visit
MCID: Minimal Clinically Important Difference
NCS: Nerve Conduction Study
OSCTR / OSD: Open Surgical Decompression (Open Surgical Carpal Tunnel Release / Open Surgical Decompression)
PMU: Paracelsus Medizinische Privatuniversität
SAE: Serious Adverse Event
SANE: Single Assessment Numeric Evaluation
UI: University Institute
UKH: Unfallkrankenhaus
USGCTR: Ultrasound-Guided Carpal Tunnel Release
VAS: Visual Analogue Scale