

Study Protocol

Clinical outcomes after Trigger Finger Release: A Prospective Comparison of Ultrasound-Guided and Open Techniques

1. Rationale for the study

Trigger finger release is one of the most frequent and well-known conditions in hand surgery. Surgical release can be performed using several techniques, namely open, blind percutaneous release and more recently, ultrasound-guided percutaneous release. To date, the available evidence has not demonstrated a clear superiority of one technique over another. Existing comparative studies have mainly compared open and blind percutaneous releases, with high-quality comparative data lacking for evaluation of the ultrasound-guided technique. Therefore, there is a need for prospective comparative research assessing functional outcomes and safety across these techniques. We hypothesize that the ultrasound-guided technique might provide faster functional recovery, due to the minimally invasive aspect of the technique, while maintaining equal safety.

2. Study design

This study is designed as a prospective, observational cohort study including all patients undergoing surgical treatment for trigger finger at a single referral hand surgery centre (Maria Middelares Hospital, Ghent, Belgium) beginning in May 2025. A minimum of 100 patients (50 per treatment arm) will be enrolled and managed using one of two established surgical techniques for trigger finger release: open release or ultrasound-guided release.

Allocation to surgery

Treatment allocation followed a pragmatic, patient-preference design. Patients selected their treating surgeon, and since each participating surgeon exclusively performed one standardized technique, this results in an expertise-based allocation model. Although non-randomized, this design reflects real-world clinical practice and minimizes the "learning curve" bias often seen in randomized trials. To minimize intra-group variability, all participating surgeons are fellowship-trained hand surgeons with high annual volumes in their respective techniques.

Accordingly, two cohorts were defined:

- **Group A:** Open trigger finger release performed by surgeon P.C.
- **Group B:** Ultrasound-guided release performed by M.C., J.G. and P.B.D.K.

This pragmatic allocation method ensures that each technique is performed by a highly skilled surgeon while minimizing variability within treatment groups. In addition, surgeon-related variation will be addressed analytically as described in the statistical analysis section below. Preoperative and postoperative assessments were standardized, and all patients received the same postoperative rehabilitation protocol and analgesics.

Patients will be followed prospectively using standardized questionnaires and clinical examinations at the following postoperative time points: 1, 2, 3 and 4 weeks, 3 months, and 6 months. An overview of the questionnaires is provided as appendix 2. Clinical follow-up will be performed preoperatively, at 4 weeks, and at 3 months. The standardized questions and clinical examinations are listed as appendix 3 for each time point. No additional study procedures or deviations from routine clinical care will be performed. All patients will receive standard postoperative management according to institutional practice. An overview of the questionnaires is provided as appendix 2.



The follow-up schedule is summarized below:

Visit	Preoperative	1W	2W	3W	4W	3M	6M
Questionnaire	✓	✓	✓	✓	✓	✓	✓
Clinical examination	✓	–	–	–	✓	✓	–

3. Endpoints

Our endpoints include:

Primary endpoint:

- The primary endpoint is early functional recovery following trigger finger release.
- This will be assessed by the change in validated patient-reported outcome measures between baseline and 4 weeks postoperatively, including in order of importance:
 - o Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH)
 - o Visual Analog Scale (VAS) for pain
 - o Grip strength (Kg)

Secondary endpoints:

- Early postoperative pain measured as daily VAS scales for the first 14 days
- Scar characteristics and patient satisfaction measured by Patient and Observer Scar Assessment Scale (POSAS) [3]
- Use of analgesics postoperative (duration and cumulative dose)
- Time to return to daily activities, return-to-work
- Patient satisfaction
- Postoperative complication rate including but not limited to nerve injuries, infection, persistent symptoms, etc.
- Revision surgery rate and indications for revisions
- Longer term functional outcome (at 3 and 6 months)
- Health-economic evaluation such as cost-effectiveness and ecological footprint

4. Patient Selection

Inclusion criteria:

- Age ≥ 18 years
- All consecutive patients receiving surgical treatment for solitary trigger finger release
- Undergoing surgery at VZW AZ Maria Middelares hospital

Exclusion criteria:

- Concomitant surgical procedures in the same hand
- Symptomatic osteoarthritis of the hand or wrist
- Symptomatic confounding pathology of elbow or shoulder
- Pregnancy
- Dupuytren's disease with symptomatic MCP or PIP contracture
- Bilateral trigger finger surgery within a 3-month interval
- Active chemotherapy or malignancy
- Inability to complete the follow-up questionnaires (language barrier, cognitive impairment, etc.)
- Revision surgery

5. Data Collection

Data will be collected prospectively using standardized patient-reported outcome measures and structured clinical examinations. Questionnaire-based outcomes will be obtained at baseline and at all predefined postoperative time points. Clinical examinations will be performed at 4 weeks and 3 months as part of routine postoperative follow-up. All instruments used in this study are validated and internationally recognized. Copies of the questionnaires are provided in the appendices.

Outcome scales:

QuickDASH [1]

- Contains 11 items scored from 1 (no symptoms) to 5 (most severe).
- A minimum of 10 questions must be completed.
- Raw scores are converted to a 0–100 scale, where 0 represents no disability and 100 represents maximum disability.

Patient and Observer Scar Assessment Scale (POSAS) [2]

- Six scar-related items scored from 1 (normal) to 10 (most severe abnormality).
- The total score is the sum of all items, with a possible range from 6 to 60.

Visual Analog Scale (VAS) (appendix 1)

- Pain intensity is measured on a 10-cm visual scale.
- Scores are converted to a 0–100 scale by measuring to the nearest millimetre (0 = no pain, 100 = worst imaginable pain).

6. Statistical analysis

Statistical analysis will be performed on anonymized data using IBM® SPSS® Statistics. A two-sided p -value < 0.05 will be considered statistically significant except where multiplicity adjustments are needed. Descriptive and comparative analyses will be performed. All primary analyses will follow an intention-to-treat (ITT) principle, with patients analysed in the group corresponding to the surgical technique performed. A per-protocol analysis will be performed as sensitivity analysis.

Baseline characteristics will be summarized using descriptive statistics. Between-group comparisons (open versus ultrasound-guided trigger finger release) will be performed using independent-samples t -tests or Mann–Whitney U tests for continuous variables, and chi-square or Fisher's exact tests for categorical variables, as appropriate.

Analysis of covariance (ANCOVA) will be used to compare between-group outcomes while adjusting for baseline values of the outcome measure, in order to account for potential baseline imbalance and to increase statistical power in this non-randomized study design.

Power calculation and sample size rationale for the primary outcome (QuickDASH change at 4 weeks) was performed. We plan a pragmatic, prospective, 2-arm study with equal allocation to open and ultrasound-guided trigger finger release. Assuming a literature-derived minimal clinically important difference (MCID) of 14 points and a standard deviation of 20 points, a two-sample t -test with a two-sided $\alpha = 0.05$ requires 32 patients per group to achieve 80% power [3]. To account for an anticipated



10% loss to follow-up and to increase the robustness and reliability of the findings, we plan to include 50 patients per group. Since ANCOVA typically increases power the above power calculation should be sufficient.

To address potential confounding due to non-randomized treatment assignment multivariate regression models will adjust for baseline characteristics such as age, sex, symptom duration, hand dominance, diabetes, severity scores, occupation (manual vs administrative). Propensity score matching or weighting may be performed as sensitivity analysis if group imbalance occurs. Results will include estimates, 95% CIs and exact p-values. We will follow STROBE guidelines for observational cohort reporting and provide a flowchart of included/excluded patients.

7. Ethical approval and informed consent

All participants were adequately informed about the purpose and procedures of the study and provided written informed consent prior to participation. The study received approval from the Ethics Committee of AZ Maria Middelares Hospital (reference: MMS.2025.027 – B0172025000003). The study will be conducted in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines. The trial will be reported using the STROBE protocol.

8. Data processing

All data are processed in compliance with the General Data Protection Regulation (GDPR), Belgian privacy legislation, and institutional policies. Data will be pseudonymized prior to analysis and stored on secure hospital servers with restricted access. Only authorized study personnel will have access to identifiable information. No personal identifiers will be included in publications or presentations of study results.

9. Researchers:

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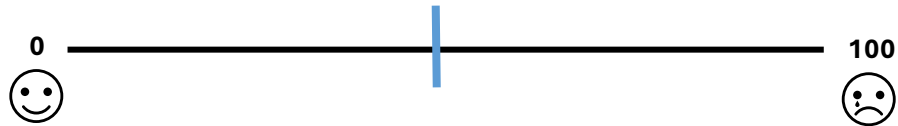
10. References

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2. Draaijers LJ, Tempelman FR, Botman YA, Tuinebreijer WE, Middelkoop E, Kreis RW, van Zuijlen PP. The patient and observer scar assessment scale: a reliable and feasible tool for scar evaluation. *Plast Reconstr Surg*. 2004 Jun;113(7):1960-5; discussion 1966-7. doi: 10.1097/01.prs.0000122207.28773.56. PMID: 15253184.
3. Sorensen AA, Howard D, Tan WH, Ketchersid J, Calfee RP. Minimal clinically important differences of 3 patient-rated outcomes instruments. *J Hand Surg Am*. 2013 Apr;38(4):641-9. doi: 10.1016/j.jhsa.2012.12.032. Epub 2013 Mar 6. PMID: 23481405; PMCID: PMC3640345.

Appendix 1

VAS Scale example

A ten cm or 100mm long line is drawn. The patient draws a line where he feels his pain level is now and this is measured up to 1mm to obtain a 0 to 100 pain scale.



**Appendix 2****Overview patient-reported questionnaires:**

Timeline	Questionnaire
Preoperative	- QuickDASH - Visual Analog Scale (VAS) - Satisfaction
Daily 0 to 2 weeks postoperative	- Visual Analog Scale (VAS)
1 week postoperative	- QuickDASH - Visual Analog Scale (VAS) - Satisfaction
2 weeks postoperative	- QuickDASH - Visual Analog Scale (VAS) - Satisfaction
3 weeks postoperative	- Visual Analog Scale (VAS)
4 weeks postoperative	- QuickDASH - Visual Analog Scale (VAS) - Patient and Observer Scar Assessment Scale (POSAS) - Satisfaction
3 months postoperative	- QuickDASH - Visual Analog Scale (VAS) - Patient and Observer Scar Assessment Scale (POSAS) - Satisfaction
6 months postoperative	- QuickDASH - Visual Analog Scale (VAS) - Patient and Observer Scar Assessment Scale (POSAS) - Satisfaction

**Appendix 3****Standardized clinical follow-up**

Timeline	Anamnestic and clinical examinations
Preoperative	Anamnestic: - Symptomatic side - Symptomatic digit(s) - Most prevalent symptom (triggering vs pain) - Most prevalent when - Nightly complaints - Duration of symptoms - Subjective loss of strength - Infiltrations (last time and frequency) - Dominant side - Occupation - Self-employed or employee - Admin job or (heavy) manual labour - Hobbies - Allergies - Smoking and alcohol consumption (or other drugs) - Diabetes (type 1 or 2) - Rheumatologic disorders (type) - Thyroid disorders (type) - Previous (hand) surgery - Other important features Clinical examination: - Pressure pain A1 pulley - Pressure pain PIP joint - Finger oedema - Hyperextension pain - Nodular swelling - Range of Motion (ROM) - o PIP joint - o Contact Pulp Palm (CPP) - o Distance Pulp Distal Palmar Crease (DPDPC) - Strength (Kg) - o Precision pinch - o Jamar grip strength
4 weeks postoperative	Anamnestic: - Subjective feeling - Satisfaction - Pain - Triggering - Time to wound healing (defined as a dry without exudate and no further need for dressing) - Duration of pain medication (including daily dosage and type of pain killer) - Time to return-to-work - Return to Activities of Daily Living (ADL)



	- Return to hobbies Clinical examination: - Triggering - Swelling - Synovitis - Hyperextension pain - Wound state (e.g. colour, texture, sensibility, etc.) - Tenodesis scar (amount of cohesion with subdermal tissue and tendons) - Hyperesthesia scar - Range of Motion (ROM) - o PIP joint - o Contact Pulp Palm (CPP) - o Distance Pulp Distal Palmar Crease (DPDPC) - Strength (Kg) - o Precision pinch - o Jamar grip strength
3 months postoperative	Anamnestic: - Subjective feeling - Satisfaction - Pain - Triggering - Time to wound healing (defined as a dry wound without exudate and no further need for dressing) - Duration of pain medication (including daily dosage and type of pain killer) - Time to return-to-work - Return to Activities of Daily Living (ADL) - Return to hobbies Clinical examination: - Triggering - Swelling - Synovitis - Hyperextension pain - Wound state (e.g. colour, texture, sensibility, etc.) - Tenodesis scar (amount of cohesion with subdermal tissue and tendons) - Hyperesthesia scar - Range of Motion (ROM) - o PIP joint - o Contact Pulp Palm (CPP) - o Distance Pulp Distal Palmar Crease (DPDPC) - Strength (Kg) - o Precision pinch - o Jamar grip strength