Project Title/PI: Incision Decision: A Prospective Randomized Trial Comparing Longitudinal vs. Transverse A1 Pulley Release Outcomes

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Study Protocol

1. **Project Title/PI:** Incision Decision: A Prospective Randomized Trial Comparing Longitudinal vs. Transverse A1 Pulley Release Outcomes

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2. **Background & Rationale**

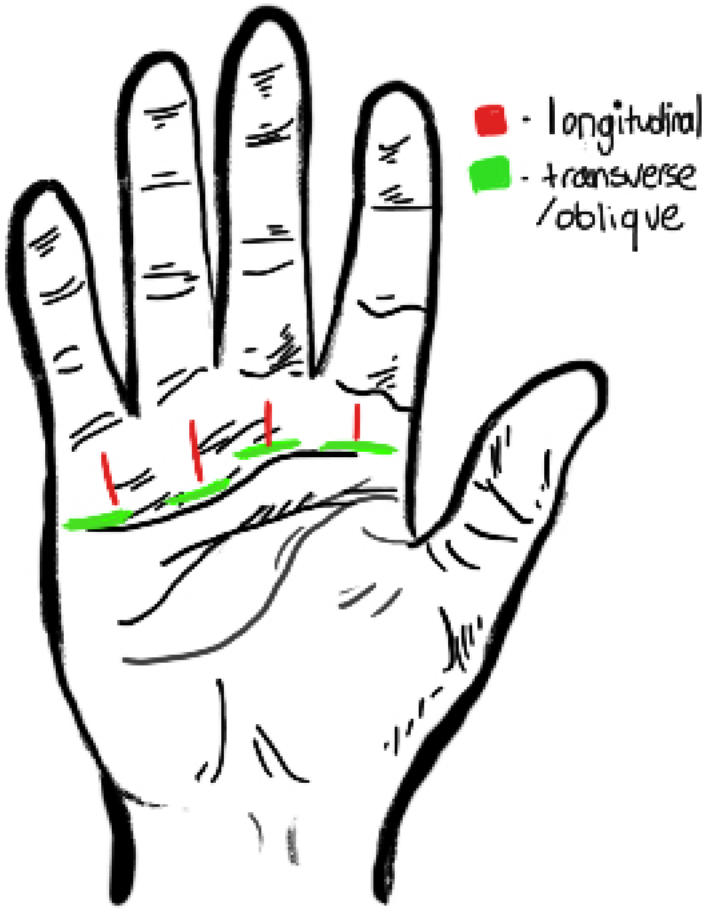
Stenosing tenosynovitis of a flexor tendon, also commonly described as "trigger finger" is a common hand pathology seen in hand surgery, with a lifetime incidence of 2.6%.[1,2] Trigger finger causes painful popping, clicking, or locking of a finger during flexion or extension. This condition results from inflammation causing a size mismatch between the flexor tendon and the first annular (A1-) pulley, causing impingement and catching. When conservative treatments like splinting and/or corticosteroid injections fail, surgical release of the A1-pulley is indicated.[3]

A1 pulley release for stenosing tenosynovitis is one of the most common procedures performed in hand surgery, known for its simplicity and effectiveness with few complications.[2] However, complications between 6 and 36% after surgical release of the A1-pulley have been reported, and include wound healing problems such as persistent triggering, recurrence of triggering, infection, wound dehiscence, or painful scar tissue and irritation.[4–9] Often, the most common patient complaint after this procedure is related to scar tissue and wound healing irritation/[4–6] Painful scar tissue at the A1 pulley site can disrupt the smooth gliding of the flexor tendon, limiting hand function and causing discomfort during gripping and flexing, and the cosmetic appearance of the scar can also bother patients. Thus, surgical technique and optimal surgical approach to limit the formation of scar tissue is critical to optimize the patient's post-surgical recovery, function, and overall satisfaction.

Surprisingly, despite the frequency with which this procedure is performed, limited data exist regarding the optimal surgical approach.[10] Two commonly used incisions are used for A1 pulley release, a longitudinal or a transverse/oblique incision in the palmar crease (Figure 1) Proponents of the longitudinal incision report improved visualization of the pulley and tendon, and its extensile nature for additional pathology.[10] Those utilizing transverse incisions report improved cosmesis and faster healing times. Although previous work has examined the etiology and effects of various treatment modalities including injection[2,4,11], open and percutaneous release[2,12], there is a paucity of evidence-based data to guide incision choice. To address this gap in knowledge, we propose a prospective randomized trial evaluating the effect of incision type on patient reported outcomes, incision healing and pain levels in patients treated with A1 pulley release.

At our center, surgeons are split in terms of preferred A1 pulley incision technique providing clinical equipoise. We are well positioned to answer these unanswered clinical questions with our established track record on this disease process having publishing on trigger finger treatments and challenges as well as outcomes and recently completed a study on ideal corticosteroid injection dose for trigger finger. Our center treats approximately 1200 patients per year with trigger finger and performs over 200 surgical releases. Two additional programs (University of Chicago, London Hand and Upper Limb center) have similar practices and dedicated research teams who may partner with our center for this multi-center research plan.

Using a randomized controlled trial design, we plan to assess outcomes with the PROMIS Physical Function score as the primary outcome measure at 6 weeks. Based on previous work by Kloeters et al, we plan to enroll 80 patients in each group to demonstrate a minimally clinically important difference at 6 weeks post-operatively using a power of 80%. The knowledge gained from this study will allow us to report the potential role of surgical incision on patient outcomes after A1 pulley release and may facilitate incision optimization to ensure clinical and patient reported success through improved guidance, recovery time, healing expectations and return to activities.



3. **Objective/Purpose/Aims/Hypothesis**

Purpose: To compare clinical and patient-reported outcomes between longitudinal and transverse incisions for A1 pulley release in trigger finger (stenosing tenosynovitis), guiding optimal surgical technique.

Specific Aims

The null hypothesis is that there are no differences in functional recovery, pain, return to work, or scar healing between longitudinal and transverse incisions.

Primary Objective/Hypotheses:

Aim 1 – Compare longitudinal and transverse incisions for A1 pulley release for trigger finger with outcomes of post-operative function and pain

Hypothesis: Incision type will not result in differences in post-operative function, pain, return to work, or time to pain-free finger extension.

- Patients randomized to longitudinal or transverse incisions for A1 pulley release.
- Post-operative pain (Numeric Pain Scale – NPS) reported on days 1–3, and at 2-week, 6-week, and 12-week visits.
- Days to return to work and time to pain-free finger extension
- PROMIS scores[13] (Physical Function [PF], Pain & Interference [P&I], Upper Extremity [UE], Depression Subscales) – PRIMARY OUTCOME: PROMIS UE
- Distance to palmar crease (DPC)

Aim 2 – Compare scar outcomes of longitudinal and transverse incisions

Hypothesis: Incision type will result in equivalent scar metrics and patient satisfaction.

- Scar metrics recorded at approximately 2-week, approximately 6-week, and approximately 12-week visits using validated scales:
    - POSAS (Patient and Observer Scar Assessment Scale).[14]
    - SCAR-Q (Validated Patient-Reported Outcome of scar healing).[15]
    - Global assessment of patient satisfaction with scar (0–10 scale).

Study Design

a. **Type of Study:**

This is an investigator-initiated, multicenter, randomized controlled trial involving approximately 160 patients with trigger finger (excluding thumb). Patients will be randomized to receive either transverse or longitudinal incisions for A1 pulley release.

b. **Study Population General Description**

Inclusion Criteria:

- Adult patients (age > 18 years).
- Diagnosed with trigger finger.

- Written informed consent obtained.

Exclusion Criteria:

- Revision surgery.
- Previous surgery on the affected finger.
- Patients refusing consent.

c. **Multi-center, International Site**

- Multicenter, international study.
- Sites:
    - All BJC hospital sites performing trigger finger surgery (Washington University, lead center), primary site
        - Only Washington University School of Medicine in St. Louis, Barnes Jewish Hospital, and Barnes Jewish West County are currently approved sites.
    - University of Chicago Hand and Upper Extremity Department. (Not yet approved)
    - London Hand and Upper Limb Center. (Not yet approved)

d. **Study Enrollment Process**

Patients diagnosed with trigger finger at participating sites will be identified through medical records or surgeon referrals. Research personnel will screen patients for eligibility based on inclusion/exclusion criteria. Eligible patients will meet with a research team member in a private clinical room to discuss the study. The consent form will detail the study's purpose, procedures, risks (e.g., infection, scar pain), benefits, and voluntary nature. Patients will have ample time to review materials, consult family/friends, and ask questions. Written informed consent will be obtained before randomization. Patient consent will be performed in a fashion to minimize coercion. Study coordinators, team members and surgeons will conduct consent discussions, and participation after surgical consent has been obtained and will emphasize the voluntary nature of participation with no impact on clinical care. All data will be stored on a WashU Instance of RedCAP.

e. **Study Procedures**

- **Cohort 1:** Patients randomized to transverse incisions for A1 pulley release.
- **Cohort 2:** Patients randomized to longitudinal incisions for A1 pulley release.

Randomization: Immediately after eligibility confirmation and consent, research personnel will randomize patients 1:1 to transverse or longitudinal incisions using an online Web Randomization System (WRS) managed by Washington University. Block randomization, stratified by site and surgery type, will use varying block sizes unknown to study personnel.

Procedures:

1. **Pre-operative:** Collect demographics (age, sex, depression/anxiety/pain disorders/chronic opioid use, diabetes [type, A1c, insulin use]), trigger finger details (affected finger, distance to palmar crease, number of triggers, prior treatments), surgeon's preferred incision, and baseline PROMIS scores (PF, P&I, UE, Depression).
2. **Surgery:** Standard A1 pulley release with transverse or longitudinal incision. Record intra-operative data (flexor digitorum superficialis [FDS] excision, incision extension).

3. **Post-operative Follow-up:**
    - Days 1–3: Patients report pain (NPS).
    - Approximately 2 weeks: Assess pain (NPS), scar metrics (POSAS, SCAR-Q, satisfaction [0–10]), complications (wound dehiscence, infection, return to OR, revision surgery).
    - Approximately 6 weeks (virtual): Assess pain, PROMIS scores, scar metrics, days to return to work, time to pain-free extension (tabletop test), complications.
    - Approximately 12 weeks (virtual or in-person): Assess pain, PROMIS scores, scar metrics, complications, photos of scar (if in-person).

f. **Study Duration and Frequency of Follow-Up**

- **Duration:** Approximately 12 weeks per participant.
- **Follow-Up:** Days 1–3 (pain reports), approximately 2 weeks (in-person), approximately 6 weeks (virtual), approximately 12 weeks (virtual or in-person with scar photos).

g. **Exposures/Risk Factors/Treatment Groups to be Compared**

- **Treatment Groups:** Transverse incision cohort vs. longitudinal incision cohort.
- **Exposures/Risks:** Risks include surgical complications (wound dehiscence, infection, scar pain, persistent/recurrent triggering, revision surgery). Risk factors include patient comorbidities (diabetes, depression, chronic opioid use) and prior treatments (injections, surgery).

h. **Study Outcomes/Endpoint**

Primary Outcome: PROMIS Upper Extremity (UE) score at approximately 6 weeks.

Secondary Outcomes:

- Pain (NPS) at days 1–3, approximately 2 weeks, approximately 6 weeks, approximately 12 weeks.
- Days to return to work.
- Time to pain-free finger extension (tabletop test).
- PROMIS scores (P&I, PF, Depression).
- Scar metrics (POSAS, SCAR-Q, satisfaction [0–10]) at approximately 2, approximately 6, and approximately 12 weeks.
- Complications (wound dehiscence, infection, return to OR, revision surgery).

The study will clarify the impact of incision type on outcomes, providing evidence to guide optimal incision choice, enhance recovery, and improve patient satisfaction.

6. **Demographics**

Data Collection

Patient Demographics:

- Age
- Sex
- Associated Diagnoses (Depression, Anxiety, Pain Disorder, Chronic Opioid Use)

- Diabetes Mellitus (Type, A1c, Insulin Use)

Trigger Finger Data:

- Affected Finger
- Distance to Palmar Crease
- Number of Triggers
- Prior Treatments (Injection, Surgery)

Surgeon:

- Preferred Incision

Patient-Reported Outcome Measures (PROMs):

- PROMIS Upper Extremity (UE)
- PROMIS Pain & Interference (P&I)
- PROMIS Depression

Intra-operative Data:

- Flexor Digitorum Superficialis (FDS) Excision Required
- Incision Extension

Post-Operative Data:

- SCAR-Q (Validated Patient-Reported Outcome of Scar Healing)
- Global Assessment of Patient Satisfaction with Scar (0–10 Scale)
- Post-operative Pain (Numeric Pain Scale – NPS) on Days 1–3, 2 Weeks, 6 Weeks, 12 Weeks
- Days to Return to Work
- Days to Pain-Free Finger Extension (Tabletop Test)

Complications:

- Wound Dehiscence
- Wound Infection
- Return to Operating Room
- Revision Surgery

7. **Patient Outcome Metrics**

Pre-operative Metrics:

- PROMIS Scores (Physical Function, Pain & Interference, Upper Extremity, Depression)

Post-operative Metrics:

- PROMIS Scores (Physical Function, Pain & Interference, Upper Extremity, Depression)
- POSAS (Patient and Observer Scar Assessment Scale)

- SCAR-Q (Validated Patient-Reported Outcome of Scar Healing)
- Global Assessment of Patient Satisfaction with Scar (0–10 Scale)
- Numeric Pain Scale (NPS)
- Days to Return to Work
- Days to Pain-Free Finger Extension (Tabletop Test)

8. **Statistical Methods**

a. **Statistical Analysis**

Outcomes will be compared between transverse and longitudinal incision groups. Continuous outcomes (e.g., PROMIS scores, NPS, days to return to work, tabletop test) will be analyzed using independent t-tests or Mann-Whitney U tests, depending on data normality. Categorical outcomes (e.g., complications) will be analyzed using chi-square or Fisher's exact tests. Mixed-effects models may be used to account for repeated measures (e.g., pain, scar metrics over time) and site-specific effects. All analyses will use a two-sided alpha of 0.05.

b. **Sample Size Determination and Power Analysis**

A power analysis was conducted to detect a 4-point difference in PROMIS Upper Extremity (UE) scores, corresponding to the minimally clinically important difference (MCID), with alpha = 0.05 and power = 80% (beta = 0.2). Based on a prior study reporting a standard deviation of 10, 99 patients per group (198 total) are required to reject the null hypothesis that the population means of the experimental and control groups are equal with 80% power. This sample size accounts for the MCID of 4 for PROMIS UE scores.

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