IRB ID#:	202506034	PI:	Jason Strelzow, MD	PT ID#	

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

Protocol ID: 202506034

Date: 3/31/26

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Consent Documentation			
Consent Approval Date:		**Consent Expiration Date:**	

Participant's Name (print): _____

Research team member completing consent discussion with participant:
(*only add people who are listed as "**yes**" to being involved in the consent process in myIRB*):

☐ Jason Strelzow ☐ Ryan Calfee
☐ Rishikesh Sattaluri ☐ Nisha Kale

Where did the consent discussion occur?
☐ In person ☐ Other, explain: _____

Documentation of consent conversation *(check off to verify that each of the following items were completed)*:

☐ The informed consent was reviewed in its entirety with the participant and the following major points were reinforced:

- ☐ They may or may not receive any benefit from participating in this study, their participation is completely voluntary, and they may quit at any time.
- ☐ The potential risks for participating include the possibility for pain or discomfort at the incision site, scar tissue causing pain or irritation when gripping, infection or wound opening, persistent or recurrent trigger finger symptoms, or the rare need for additional surgery. The risks are the same for both incision types and standard trigger finger surgery, whether or not participants are part of the study. There is also a risk of a breach of confidentiality and the potential to elevate negative feelings. Every effort will be made to keep their information confidential, minimize risk and provide them with services as needed.
- ☐ Participation in this study includes screening for eligibility to participate in the study and randomization to either lengthwise or crosswise incision for their trigger finger surgery. Before surgery, participants will be asked about their health, finger condition, and to complete questionnaires about their finger function, pain, and mood. Participants will undergo their standard of care trigger finger surgery. After surgery, participants will be asked to complete a pain diary for the first 3 days. At 2 weeks post-surgery, participants will have an in-person clinic visit. A 6-week post-surgery visit will be conducted virtually. The 12-week visit may be conducted either virtually or in-person. The study involves about 5-6 hours total over 12 weeks, including visits and questionnaires.
- ☐ They will not be paid for participating
- ☐ They can take all the time needed to consider participation.

Did the participant have any questions regarding the study or the consent document? ☐ Yes ☐ No
(If yes, summarize below):

Summary of conversation:

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Consent Permissions:

The participant provided consent permissions for the following optional study items:	Initials
Permission for Future Use of Data	☐ Yes ☐ No
Permission to email PHI *(Only if yes—Email address: _____)*	☐ Yes ☐ No
Permission to text PHI *(Only if yes—Phone number: _____)*	☐ Yes ☐ No

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Did the participant consent to participate in the study?

☐ Yes, the participant *agreed and provided written consent* to participate in the research study

☐ No, the participant *declined participation* and they were thanked for their time and consideration.

END Date & time of consent discussion:	/ /	:	☐am ☐ pm
	MM/DD/YYYY	HH:MM	

☐ **By signing and dating below I am confirming that all of the above information is correct and is an accurate account of the informed consent discussion, the consent was reviewed in its entirety, adequate time was given for participation consideration and that the participant confirmed their willingness to participate in the research study.**

Signature of the Person Who Obtained Consent from the Participant	**Date**

A copy of the informed consent was provided to the participant via (*check off which method was used*):

☐ In-person on the date consent was obtained ☐ other: _____ on: ____/____/____

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Inclusion/Exclusion

Instructions: Add supporting documentation to the subject's research record and/or indicate in the source section where the criterion was verified from.

Inclusion Criteria	Source/Comments	Yes	No	Initials & Date of Verifier
1. Adult patients (age > 18 years)	DOB: _____/_____/_____ Age at time of written consent: _____ Source (*check all that apply*): ☐ Verified with participant ☐ Verified in EPIC ☐ Other: _____			
2. Pre-operative proximal interphalangeal joint (PIPJ) contractures	Source (*check all that apply*): ☐ Verified with participant ☐ Verified in EPIC, clinician assessment dated ___/____/_____ (add assessment to research record) ☐ Other: _____			
3. Diagnosed with trigger finger	Source (*check all that apply*): ☐ Verified with participant ☐ Verified in EPIC, clinician assessment dated ___/____/_____ (add assessment to research record) ☐ Other: _____			
4. Written informed consent obtained	Source (*check all that apply*): ☐ Verified with participant ☐ Verified in EPIC, clinician assessment dated ___/____/_____ (add assessment to research record) ☐ Other: _____			
Exclusion Criteria	**Comments**	**Yes**	**No**	**Initials & Date of Verifier**
1. Revision surgery	Source (*check all that apply*): ☐ Verified with participant ☐ Verified in EPIC, clinician assessment dated ___/____/_____ (add assessment to research record) ☐ Other: _____			
2. Previous surgery on the affected finger	Source (*check all that apply*): ☐ Verified with participant ☐ Verified in EPIC, clinician assessment dated ___/____/_____ (add assessment to research record) ☐ Other: _____			

3. Patients refusing consent	Source (*check all that apply*): ☐ Verified with participant ☐ Verified in EPIC, clinician assessment dated ___/____/_____ (add assessment to research record) ☐ Other: _____			

Eligibility Confirmation

Eligible subjects must have all inclusion criteria marked "**Yes**" and all exclusion criteria marked "**No**".

Please check one:

☐ I verify that this subject ***meets*** all criteria required for enrollment and does not have, in my opinion, any findings or factors that may negatively impact compliance or the subject's safety by participation in this study.

☐ I verify that this subject ***does not meet*** all criteria required for study enrollment. This subject is considered a screen failure. **The reason for exclusion is summarized below.**

Additional Comments:

PI/Designee Signature	Date

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Procedure Checklist

Instructions: Insert all study procedures to be completed at this visit.
Mark off each procedure completed during the visit. If any procedures or assessments are missed/not completed, indicate reason for incompletion in the comments section to the right of the assessment.
Add all supporting documentation to the subject's research record.

Study Procedures	Completed?	Comments	Initials & Dates
1. **Demographics data collection**	☐ **Yes** ☐ **No,** *if no, explain in comments*	**Age: _____ years** **Sex: _____** **Depression:** ☐ Yes ☐ No **Anxiety:** ☐ Yes ☐ No **Pain Disorder(s):** ☐ Yes ☐ No **Chronic Opioid Use:** ☐ Yes ☐ No **Diabetes:** ☐ Yes ☐ No; **Diabetes Type:** ☐ Type I ☐ Type II **Insulin Use:** ☐ Yes ☐ No **A1C: _____** **Source of data: _____**	
2. **Trigger Finger Details**	☐ **Yes** ☐ **No,** *if no, explain in comments*	**Affected Finger: (Left/Right) _____** **Distance to Palmar Crease: _____** **Number of triggers: _____** **Prior Treatments: _____** **_____** **_____** **Surgeon's Preferred Incision:** ☐ Longitudinal ☐ Transverse **Source of data: _____**	
3. **Baseline PROMIS scores:**	☐ **Yes** ☐ **No,** *if no, explain in comments*	**PROMIS Scores:** **PF: _____** **P&I: _____** **UE: _____** **Depression: _____** **Source of data: _____**	
4. **Surgery (standard of care)**	☐ **Yes** ☐ **No,** *if no, explain in comments*	**Incision:** ☐ Longitudinal ☐ Transverse **Intra-operative Data:** **Flexor Digitorum Superficialis (FDS) Excision:** **_____** **Incision Extension: _____** **_____**	

		Source of data: _____	
Post-Operative Follow-Up			
5. Pain Diaries (Days 1-3)	☐ **Yes** ☐ **No,** *if no, explain in comments*	**Pain Diaries Completed:** ☐ **Day 1 - Date:** ___/____/_____ ☐ **Day 2 - Date:** ___/____/_____ ☐ **Day 3 - Date:** ___/____/_____ **Contact attempts/reminders to complete diaries:** _____ _____ _____	
6. 2 week visit (in-person) **Date:** ___/____/_____	☐ **Yes** ☐ **No,** *if no, explain in comments*	**NPS:** _____ **Scar Metrics** ☐ **POSAS:** _____ ☐ **SCAR-Q:** _____ **Participant Satisfaction:** 1 2 3 4 5 6 7 8 9 10 **Complications:** ☐ Wound Dehiscence ☐ Infection ☐ Return to OR ☐ Revision Surgery ☐ None **Complication Details:** _____ _____ _____ **Source of data:** _____	
7. 6-week visit (virtual) **Date:** ___/____/_____	☐ **Yes** ☐ **No,** *if no, explain in comments*	**NPS:** _____ **PROMIS Scores:** **PF:** _____ **P&I:** _____ **UE:** _____ **Depression:** _____ **Scar Metrics** ☐ **POSAS:** _____ ☐ **SCAR-Q:** _____ **Participant Satisfaction:** 1 2 3 4 5 6 7 8 9 10 **Days to return to work:** _____ **days** **Time to pain-free extension:** _____ **Complications:**	

		☐ Wound Dehiscence ☐ Infection ☐ Return to OR ☐ Revision Surgery ☐ None **Complication Details:** _____ _____ _____ **Source of data:** _____	
8. 12-weeks visit **Date: ___/____/_____** ☐ In person ☐ Virtual	☐ **Yes** ☐ **No,** *if no, explain in comments*	**NPS:** _____ **PROMIS Scores:** **PF:** _____ **P&I:** _____ **UE:** _____ **Depression:** _____ **Scar Metrics** ☐ **POSAS:** _____ ☐ **SCAR-Q:** _____ **Participant Satisfaction:** 1 2 3 4 5 6 7 8 9 10 **Complications:** ☐ Wound Dehiscence ☐ Infection ☐ Return to OR ☐ Revision Surgery ☐ None **Complication Details:** _____ _____ _____ **Photos of scar:** ☐ **Yes** ☐ **No, visit was virtual** ☐ **No, incomplete because:** _____ **Source of data:** _____	
Participant Notes (*initial and date each entry***):**			

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Additional Comments:

_____ _____

PI/Designee Signature **Date**