Mass General Brigham

Institutional Review Board
Intervention/Interaction Detailed Protocol

Principal Investigator:	Rohit Garg, MD
Project Title:	Clinical and Patient-Reported Outcomes After Ultrasound-guided vs. Open Trigger Finger Release
Version Date:	6/6/2023

For Intervention/Interaction studies, submit a Detailed Protocol that includes the following sections. If information in a particular section is not applicable, omit and include the other relevant information.

1. Background and Significance

Trigger finger is initially treated conservatively. Conservative treatment options include modification of activities, painkiller administration, splinting, and corticosteroid injections (1). Open or minimally invasive surgical treatment can be considered if conservative treatment fails. Minimally invasive surgery options consist of ultrasound-guided or blind percutaneous trigger finger release.

Many studies have reported good clinical outcomes after ultrasound-guided trigger finger release, including low rates of catching or locking recurrence rates, high QuickDASH scores and high patient satisfaction (2-4).

Postoperative clinical outcomes of open surgery have been widely compared to percutaneous surgery (5-8). However, the comparison of postoperative results between ultrasound-guided and open trigger finger release has been scarcely reported. Nikolaou et al. reported that ultrasound-guided trigger finger release resulted in a significantly sooner return to normal activities and better patient-reported cosmetic outcomes than open trigger finger release (9). Success rates and mean QuickDASH scores did not differ significantly between these groups in this cohort.

The potential benefits of ultrasound-guided trigger finger release compared to open trigger finger release have yet to be investigated. This study aims to prospectively analyze patient-reported outcomes in patients undergoing open vs. ultrasound-guided trigger finger release.

2. Specific Aims and Objectives

This study aims to prospectively analyze clinical and patient-reported outcomes in patients undergoing open vs. ultrasound-guided trigger finger release. Patients will not be randomly assigned to one of these two groups; rather, they will undergo the type of trigger finger surgery that they already agreed to with their surgeon, and we will measure the outcomes. Because of this, the study does not change the patient's standard of care; we are simply looking to collect additional data points.

3. General Description of Study Design

Retrospective part
Patient characteristics and disease-related (trigger finger) variables will be collected retrospectively from patient charts on EPIC.

Prospective part
This will be a prospective two-arm study. Patients will either be treated with ultrasound-guided trigger finger release or open trigger finger release (conventional method). Dr. Rohit Garg is the only surgeon within the Mass General Brigham (MGB) hospitals that performs ultrasound-guided trigger finger release. All other surgeons perform open trigger finger releases.

Surgeons will measure range of motion and grip strength preoperatively and during postoperative visits, which is part of routine care. We will also administer questionnaires to see how patients are doing postoperatively. See the '6. Study Procedures' for a more elaborate description of the visits.

4. Subject Selection

Inclusion criteria:

1. ≥18 years of age
2. Clinical diagnosis of trigger finger
3. Patient has failed conservative treatment or elects not to undergo conservative treatment
4. Surgeon agrees that surgery is indicated
5. Subject agrees to complete follow-up questionnaires over a 6-month period

Exclusion criteria:

1. Prior surgery on the target finger
2. History of prior surgical pulley release in the target hand
3. History of prior surgical pulley release in the contralateral hand within 3 months of enrollment or with persistent symptoms that interfere with normal daily activities or work at the time of consent
4. Corticosteroid injection in the target finger or hand within 6 weeks of surgery
5. Presence of additional process in the target wrist or hand requiring additional intervention beyond pulley release (e.g., neurolysis, mass removal, tenosynovectomy)
6. Clinically significant trauma or deformity of the upper limb (shoulder to hand) on the target side
7. Clinically significant vascular disease (including Raynaud's phenomenon) of the upper limb (shoulder to hand) on the target side
8. Clinically significant neurological disorder (including complex regional pain syndrome) of the upper limb (shoulder to hand) on the target side
9. Planned surgical or interventional procedure on the contralateral wrist or hand

10. Systemic inflammatory disease (e.g., rheumatoid arthritis, lupus)
11. Amyloidosis
12. Diabetes not controlled by a stable dose of medication over the past three months
13. Pregnant or planning pregnancy in the next 6 months
14. Workers' compensation subjects
15. Inability to provide a legally acceptable Informed Consent Form and/or comply with all follow-up requirements, including patients who do not speak English
16. Subject has other medical, social, or psychological conditions that, in the opinion of the investigator, preclude them from receiving the pre-treatment, required treatment, and post-treatment procedures and evaluations.
17. Trigger Thumb

How individuals are identified for recruitment, including description of the use of recruitment materials such as flyers, brochures, advertisements, letters, etc.
We are selecting patients interested in undergoing surgical treatment for a trigger finger. Thus, these patients are being seen by a hand surgeon at one of the hospitals within the MGB system (MGH main campus, MGH MGH Waltham, MGH Danvers, BWH main campus, BWH Faulkner and BWH Foxborough) for a trigger finger.

Who is responsible (role on research team) for identifying and recruiting individuals
The orthopedic surgeons and study staff at one of the MGB hospitals (MGH main campus, MGH MGH Waltham, MGH Danvers, BWH main campus, BWH Faulkner, and BWH Foxborough).

When individuals are recruited
Individuals are recruited when indicated for trigger finger release at the outpatient clinic if eligible.

Where individuals are recruited
Patients are recruited at the outpatient clinic of one of the MGB hospitals (MGH main campus, MGH MGH Waltham, MGH Danvers, BWH main campus, BWH Faulkner, and BWH Foxborough).

How recruitment goals match the prevalence rates of the condition/disease being studied and the populations most impacted by the condition/disease being studied
Trigger finger release is a very common procedure to relieve symptoms of a trigger finger. Many patients get treatment for this disease within the MGB hospitals (MGH main campus, MGH MGH Waltham, MGH Danvers, BWH main campus, BWH Faulkner, and BWH Foxborough). The prevalence is higher in diabetic patients than in the general population (10, 11). The recruitment goals will match the prevalence rates of the condition as it is a very common disease, and many patients with comorbidities (i.e., diabetes, thyroid disease) receive treatment within the MGB hospitals (MGH main campus, MGH MGH Waltham, MGH Danvers, BWH main campus, BWH Faulkner and BWH Foxborough).

Methods to enhance enrollment of diverse individuals and under-represented populations
We will include all patients who meet the inclusion criteria. We do not exclude patients based on race, color, national origin, sex, sexual orientation, or religion. We will not enroll vulnerable patient populations in this study.

5. Subject Enrollment

Patients will be prescreened through retrospective manual chart review.

Patients will be contacted in person at one of the MGB hospitals (MGH main campus, MGH MGH Waltham, MGH Danvers, BWH main campus, BWH Faulkner, and BWH Foxborough). Patients who meet the inclusion criteria will get a summary of the study by an orthopedic surgeon or a study staff member to see if they are interested. If patients are interested, they will receive the study fact sheet, and the surgeon or study staff member will explain the study in more detail and answer any questions the patient may have. Subjects will be asked to complete the questionnaire either in person or over email or telephone before surgery. Subjects who opt to not complete the questionnaire in person will be contacted using the email or telephone script approved in this study. Subjects who do not complete the pre-op questionnaire before surgery will be withdrawn. Subjects can opt to receive an encrypted or unencrypted email. Subjects who indicate verbally in the outpatient clinic that they do not wish to participate will not be included in the study.

Depending on the treating surgeon, patients will either be treated with an open trigger finger release or an ultrasound-guided trigger finger release.

6. STUDY PROCEDURES

Study visits

Visits	**Procedures**
Visit 1 – before surgery	- Obtain informed consent - ADL questionnaire (see next section) - Visual analog scale for pain (VAS): pain on a scale of 1 to 10 **The measurements are part of standard care and performed by caregivers** - Perform the following measurements: range of motion of the PIP joint of the affected finger (including noting any flexion contracture), distance fingertip to distal palmar crease (DPC), and grip strength using Jamar 2 setting.
Visit/Telephone call 2 (2-4 days after surgery)	- Take the following questionnaire: 1. Are you able to return to activities of daily living, and what activities do you still have trouble doing? You can list the activities you are having trouble with. 2. VAS 3. How many oxycodone or other narcotic medications are you taking post-op 4. Are you able to return to work?

	5. Are you satisfied with the procedure, and would you choose to have it again for a similar problem? - Take the *ADL questionnaire* (see next section) - **If in person (part of standard care, only collected by study staff, measurements performed by caregivers):** Perform the following measurements: range of motion of the PIP joint of the affected finger (including noting any flexion contracture), distance fingertip to distal palmar crease (DPC), and grip strength using Jamar 2 setting.
Visit/Telephone call 3 (6-8 days after surgery)	- Take the following questionnaire: 1. Are you able to return to activities of daily living, and what activities do you still have trouble doing? You can list the activities you are having trouble with. 2. VAS 3. How many oxycodone or other narcotic medications are you taking post-op 4. Are you able to return to work? 5. Are you satisfied with the procedure, and would you choose to have it again for a similar problem? - Take the *ADL questionnaire* (see next section) - **If in person (part of standard care, only collected by study staff, measurements performed by caregivers):** - Perform the following measurements: range of motion of the PIP joint of the affected finger (including noting any flexion contracture), distance fingertip to distal palmar crease (DPC), and grip strength using Jamar 2 setting.
Visit/Telephone call 4 (13-15 days after surgery)	- Take the following questionnaire: 1. Are you able to return to activities of daily living, and what activities do you still have trouble doing? You can list the activities you are having trouble with. 2. VAS 3. How many oxycodone or other narcotic medications are you taking post-

	op 4. Are you able to return to work? 5. Are you satisfied with the procedure, and would you choose to have it again for a similar problem? - Take the *ADL questionnaire* (see next section) - **If in person (part of standard care, only collected by study staff, measurements performed by caregivers):** Perform the following measurements: range of motion of the PIP joint of the affected finger (including noting any flexion contracture), distance fingertip to distal palmar crease (DPC), and grip strength using Jamar 2 setting. -
Visit/Telephone call 5 (27-29 days after surgery)	- Take the following questionnaire: - 1. Are you able to return to activities of daily living, and what activities do you still have trouble doing? You can list the activities you are having trouble with. 2. VAS 3. How many oxycodone or other narcotic medications are you taking post-op 4. Are you able to return to work? 5. Are you satisfied with the procedure, and would you choose to have it again for a similar problem? - Take the *ADL questionnaire* (see next section) - **If in person (part of standard care, only collected by study staff, measurements performed by caregivers):** Perform the following measurements: range of motion of the PIP joint of the affected finger (including noting any flexion contracture), distance fingertip to distal palmar crease (DPC), and grip strength using Jamar 2 setting. -
Visit/Telephone call 6 (3 months +- 1 week after surgery)	- Take the following questionnaire: - 1. Are you able to return to activities of daily living, and what activities do you still have trouble doing? You can list the activities you are having trouble with.

	2. VAS 3. How many oxycodone or other narcotic medications are you taking post-op 4. Are you able to return to work? 5. Are you satisfied with the procedure, and would you choose to have it again for a similar problem? - Take the *ADL questionnaire* (see next section) - **If in person (part of standard care, only collected by study staff, measurements performed by caregivers):** Perform the following measurements: range of motion of the PIP joint of the affected finger (including noting any flexion contracture), distance fingertip to distal palmar crease (DPC), and grip strength using Jamar 2 setting. -
Visit/Telephone call 7 (6 months +- 1 week after surgery)	- Take the following questionnaire: - 1. Are you able to return to activities of daily living, and what activities do you still have trouble doing? You can list the activities you are having trouble with. 2. VAS 3. How many oxycodone or other narcotic medications are you taking post-op 4. Are you able to return to work? 5. Are you satisfied with the procedure, and would you choose to have it again for a similar problem? - Take the *ADL questionnaire* (see next section) - **If in person (part of standard care, only collected by study staff, measurements performed by caregivers):** Perform the following measurements: range of motion of the PIP joint of the affected finger (including noting any flexion contracture), distance fingertip to distal palmar crease (DPC), and grip strength using Jamar 2 setting.

We will call or e-mail patients to ask them to complete questionnaires (see above) through Redcap.

Procedures

The intervention groups consist of:

- Open trigger finger release
    - The A1 pulley is reached through a transverse incision under local anesthesia and monitored anesthesia care. It is then divided longitudinally. The patient is asked to flex and extend the affected finger. If triggering has been resolved, the wound is closed with sutures (12).
- Ultrasound-guided trigger finger release
    - The A1 pulley is identified with the use of ultrasound. The pulley is released with a trigger finger device under local anesthesia and monitored anesthesia care (9).

Specific data variables to be collected

The variables that will be collected are:

- Range of motion of the PIP joint of the affected finger using a goniometer (in degrees), including any flexion contracture + Distance of fingertip from DPC
- Grip strength in the affected as well as contralateral hand using a dynamometer at Jamar 3 setting (in lbs)
- Return to activities of daily living. One question is: 'What activities can't you do?'. We also take a questionnaire to rate their ability to do certain activities (see questionnaire under this section). Patients can rate their ability to perform each activity on a scale from 1 to 5 (1 indicating no difficulty and 5 indicating unable to perform).
- VAS (a pain scale from 1 – 10, reported by the patient)
- How many oxycodone or other narcotic medications are you taking post-op? The number of pills taken will be given.
- Return to work. Patients give a date of when they started working again. Then we'll calculate the return to work in weeks
- Are you satisfied with the procedure, and would you choose to have it again for a similar problem? Answered with yes or no.
- Complications (I.e., trigger finger recurrence, infection, bleeding, etc.)

ADL questionnaire

Opening jar	1	2	3	4	5
Driving	1	2	3	4	5
Household Chores	1	2	3	4	5
Carrying Groceries	1	2	3	4	5
Buttoning	1	2	3	4	5
Bathing	1	2	3	4	5
Cooking	1	2	3	4	5
Writing	1	2	3	4	5
Dressing	1	2	3	4	5
Shopping	1	2	3	4	5
Holding a book	1	2	3	4	5
Eating	1	2	3	4	5
Using a Computer	1	2	3	4	5
Holding a Phone	1	2	3	4	5
Using Toilet	1	2	3	4	5

Description of plans for return of research results as applicable
Not applicable

Definition of primary and secondary outcomes/endpoints
Primary endpoints:

- The 5 questions asked in the section above, together with the *ADL questionnaire*
- Recurrence of trigger finger or incomplete release

Secondary endpoints:

- Range of motion of the PIP joint of the affected finger (including noting any flexion contracture)
- Distance fingertip to distal palmar crease
- Grip strength in the affected hand
- Other complications than recurrence of trigger finger or incomplete release

Local site restrictions or site-specific procedures as applicable
The visits during the first 3 months are part of standard care. Patients with persistent problems will be seen at the 6-month follow-up as part of standard care. If they are doing well clinically, we will only contact them by phone or email to complete these questionnaires using Redcap (see above for the scheme).

Remuneration as applicable
There is no remuneration for this study.

2. Risks and Discomforts

Trigger finger release is a standard procedure (whether it is open or ultrasound-guided) for a trigger finger.

This study's foreseeable risks and discomforts include the time required to complete the measurements and questionnaires. All electronic information (like measurements in Excel files) will be stored on

password-protected computers in a locked office that only study staff members can access. Study data of the questionnaires will be collected and maintained electronically using REDCap, a secure and HIPAA-compliant web-based application to which only study staff will have access. This limits the risk of a data and confidentiality breach, though it is a possibility.

We do not foresee additional risks for subjects participating in the study. Subjects will receive usual care, regardless of their participation. Physicians will be readily accessible for consultation should a subject experience discomfort while completing the measurements and questionnaires or at any time during the study.

3. **Benefits**

Patients will not receive any direct benefits from this study. However, their participation will help us to determine clinical outcomes after ultrasound-guided and open trigger finger release, which can help patients and physicians in shared decision-making. Potential benefits of ultrasound-guided trigger finger release could be a faster recovery (faster return to work) and better patient-reported aesthetics.

4. **Statistical Analysis**

Normally distributed continuous data will be stated as mean ± standard deviations, non-normally distributed continuous data as medians with interquartile ranges and categorical data as frequencies and percentages.

We plan to statistically compare the postoperative clinical data of open trigger finger release to ultrasound-guided trigger finger release.

We will use a student t-test to analyze normally distributed continuous data. When we compare data at two different time points within a group, we will use a paired student t-test. When we compare continuous data of two different groups, we will use an unpaired student t-test.

We will use a Mann-Whitney U test if the continuous data is not normally distributed.

We will use Fischer's exact test or a Chi-squared test for differences in categorical variables, depending on the number of events in the different groups.

<u>Power analysis</u>
We have performed a power analysis to find differences between two independent means (normally distributed) with alpha = 0.05, power = 0.80, and effect size 0.5. This would require a total sample size of 102 patients (51 in each group). If the data is non-normally distributed with the same alpha, power, and effect size, we would need a total of 106 patients (53 in each group).
This power analysis is performed for our most important primary outcomes: the 5-question and ADL questionnaires.

5. Monitoring and Quality Assurance

The full-time research coordinator and principal investigator are responsible for adherence to all IRB policies and guidelines and for the accuracy and completeness of all forms, entries, and informed consent.

Study data will be maintained in a locked filing cabinet and/or on password-protected computers. Questionnaires and self-reported responses will not become part of the subject's medical record. Hard copies of study-related data and forms will be stored in a lockable file cabinet. Only the investigators and study staff will have access to this information. Any magnetic or electronic information will be saved in password-protected computers, which only study staff members can access. REDCap, secure and HIPAA-compliant, will be used to collect all answers.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/DSMP_in_Human_Subjects_Research.pdf

Reporting Unanticipated Problems (including Adverse Events)
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Reporting_Unanticipated_Problems_including_Adverse_Events.pdf

6. Privacy and Confidentiality

- ☒ Study procedures will be conducted in a private setting
- ☒ Only data and/or specimens necessary for the conduct of the study will be collected
- ☒ Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)
- ☐ Specimens collected will be maintained in a secure location with appropriate protections (e.g., locked storage spaces, laboratory areas)
- ☒ Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol
- ☒ Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g., encrypted files, password protection, using chain-of-custody procedures, etc.)
- ☒ All electronic communication with participants will comply with Mass General Brigham secure communication policies
- ☒ Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research

- ☒ All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens
- ☒ The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research
- ☒ Additional privacy and/or confidentiality protections

12. References

1. Fiorini HJ, Tamaoki MJ, Lenza M, Gomes Dos Santos JB, Faloppa F, Belloti JC. Surgery for trigger finger. Cochrane Database Syst Rev. 2018;2(2):Cd009860.
2. Colberg RE, Jurado Vélez JA, Garrett WH, Hart K, Fleisig GS. Ultrasound-guided microinvasive trigger finger release technique using an 18-gauge needle with a blade at the tip: A prospective study. Pm r. 2022;14(8):963-70.
3. Guo D, McCool L, Senk A, Tonkin B, Guo J, Lytie RM, et al. Minimally invasive thread trigger digit release: a preliminary report on 34 digits of the adult hands. J Hand Surg Eur Vol. 2018;43(9):942-7.
4. Lapègue F, André A, Meyrignac O, Pasquier-Bernachot E, Dupré P, Brun C, et al. US-guided Percutaneous Release of the Trigger Finger by Using a 21-gauge Needle: A Prospective Study of 60 Cases. Radiology. 2016;280(2):493-9.
5. Bamroongshawgasame T. A comparison of open and percutaneous pulley release in trigger digits. J Med Assoc Thai. 2010;93(2):199-204.
6. Dierks U, Hoffmann R, Meek MF. Open versus percutaneous release of the A1-pulley for stenosing tendovaginitis: a prospective randomized trial. Tech Hand Up Extrem Surg. 2008;12(3):183-7.
7. Gilberts EC, Wereldsma JC. Long-term results of percutaneous and open surgery for trigger fingers and thumbs. Int Surg. 2002;87(1):48-52.
8. Sato ES, Gomes Dos Santos JB, Belloti JC, Albertoni WM, Faloppa F. Treatment of trigger finger: randomized clinical trial comparing the methods of corticosteroid injection, percutaneous release and open surgery. Rheumatology (Oxford). 2012;51(1):93-9.
9. Nikolaou VS, Malahias MA, Kaseta MK, Sourlas I, Babis GC. Comparative clinical study of ultrasound-guided A1 pulley release vs open surgical intervention in the treatment of trigger finger. World J Orthop. 2017;8(2):163-9.
10. Abate M, Schiavone C, Salini V, Andia I. Management of limited joint mobility in diabetic patients. Diabetes Metab Syndr Obes. 2013;6:197-207.
11. Vance MC, Tucker JJ, Harness NG. The association of hemoglobin A1c with the prevalence of stenosing flexor tenosynovitis. J Hand Surg Am. 2012;37(9):1765-9.
12. Will R, Lubahn J. Complications of open trigger finger release. J Hand Surg Am. 2010;35(4):594-6.

Clinical and Patient-Reported Outcomes After Ultrasound-Guided vs. Open Trigger Finger Release
Fact Sheet

What is the research study's goal?

The Orthopaedic Hand & Arm Center is conducting a study on patients who are undergoing a trigger finger release. This study aims to analyze clinical and patient-reported outcomes in patients having surgery for trigger finger (open and ultrasound-guided trigger finger release). The only way to determine the long-term clinical outcomes of these treatments is to evaluate them consistently in patients who, like you, have been treated at Massachusetts General Brigham (MGB). We would appreciate your assistance in this critical study.

How did you get my name?

We are selecting patients who are interested in undergoing surgical treatment for a trigger finger.

What is involved?

You will be treated by your surgeon with a trigger finger release procedure. Depending on your treating surgeon, this procedure will be open or ultrasound-guided. You will return to clinic for postoperative visits as scheduled by your surgeon, and no extra visits will be needed for the research study. The study involves questionnaire completion over a phone call or email and will take 5 minutes to complete. You will receive a phone call/email at the following time points after your surgery: 2-4 days, 6-8 days, 13-15 days, 27-29 days, 3 months, and 6 months +/- 1 week.

Do I have to participate?

Participation in this research study is entirely voluntary, and you can stop participating anytime. Whether or not you participate will not affect any medical care you receive at any Mass General Brigham facility, now or in the future.

What are the risks or discomforts?

Trigger finger release is a standard procedure (whether it is open or ultrasound-guided) for a trigger finger. Additionally, administering painkillers (acetaminophen, ibuprofen and oxycodone) is also part of standard care after a trigger finger release.

If you choose to participate in this study, there is a risk of a breach of confidentiality. However, the survey entries will be collected through a secure, password-protected web application named REDCap. To protect your privacy, personally identifiable information will be securely stored in a password-protected Mass General Brigham computer. Additionally, no one except approved study staff will have access to your information.

What are the benefits to me?

There are no direct benefits to this study. However, participation will help us to determine clinical outcomes after ultrasound-guided and open trigger finger release, which can help patients and physicians in shared decision-making.

Who is doing the study?

Dr. Rohit Garg from Massachusetts General Hospital is leading this study. For questions about the study or your rights as a study participant, please contact Dr. Garg at 617-726-4700.

We are required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of health information obtained for research. This is an abbreviated notice, and does not describe all details of this requirement (see Partners Privacy Notice). During this study, identifiable information about you or your health will be collected and shared with the researchers conducting the research. In general, under federal law, identifiable health information is private. However, there are exceptions to this rule. In some cases, others may see your identifiable health information for purposes of research oversight, quality*

*control, public health and safety, or law enforcement. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. *Partners HealthCare Notice for Use and Sharing of Protected Health Information.*

Fact Sheet Version: March 9, 2023

E-mail Script for Contact with Subject After Obtaining Consent (to fill out the questionnaires)

From: <<Study Staff Email: #####>>

To: <<Subject e-mail>>

Subject: <<Name of the Research Study "Send Secure">>

Dear <<Subject Name>>,

Thank you for participating in our study regarding trigger finger release. [if encrypted - This is a secure e-mail you can use to communicate with our research team.]

Please use the link below to complete the survey:
[insert REDCap link]

Note that all answers to the questions will be kept strictly confidential, coded, and anonymous. These answers will not appear in your medical record or affect any clinical care you receive from any Partners facility.

If you have any questions, we are happy to address them. Please contact a member of the study staff at 617-726-1569. You can also contact the Principle Investigator, Dr. Rohit Garg, at 617-726-4700. If you would like to speak with someone not involved in this study, contact the Partners Human Research Committee at (857) 282-1900.

We thank you for your time and contribution to this study.
<<Study Staff>>

<<Study Staff>>
Clinical Research Coordinator
Hand and Upper Extremity Service
Massachusetts General Hospital
Phone: 617-726-1569
Email: <<Study Staff Email>>

Telephone Script – Clinical and Patient-Reported Outcomes After Ultrasound-guided vs Open Trigger Finger Release

"Hello, is this Mr./Mrs. X? My name is [name]. I am a researcher from the Hand and Upper Extremity Service at [Massachusetts General Hospital/Brigham and Women's Hospital]. I am following up with you about the study you are enrolled in titled, "Clinical and Patient-Reported Outcomes After Ultrasound-guided vs Open Trigger Finger Release" to see if you would be able to take our questionnaire. Would now be an OK time to speak about this?"
If no: "Is there a better time to speak in the future?"
If yes:
"I will first revise what the study is about that you are enrolled in. We are studying the clinical and patient-reported outcomes of patients who had ultrasound-guided or open surgery for a trigger finger. Basically, we would be interested in hearing about your symptoms, hand functionality, and return to work since the operation. The entire process should take less than 5 minutes of your time and would be very valuable to us as clinicians and surgeons in the care of patients like you. Would you be interested in filling out the questionnaire over the phone or through e-mail?
Alternatively, we would be happy to mail you the forms to complete with a self-addressed stamped envelope for return."
If yes:
Proceed with details of RedCap personalized sign-on or alternatively mailing of forms.
If no:
"We thank you for your time. Please do not hesitate to call if you would be willing to help in the future."