Mass General Brigham

Institutional Review Board
Intervention/Interaction Detailed Protocol

Principal Investigator:	Kyle Eberlin, MD
Project Title:	Pain Outcomes after Digital Amputation: A Randomized Controlled Trial Comparing Three Nerve Surgical Techniques
Version Date:	December 1, 2025

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

Digit amputations affect over 23,000 people in the US annually and may lead to neuropathic pain and symptomatic neuroma formation in the transected nerves.[1] Previous studies reported a 6.6% incidence of symptomatic neuroma, and more than 60% of these patients need surgery to reduce the negative effect on their daily living activities.[2–4]

To prevent painful neuroma formation after digital amputation, several techniques have been described, including traction neurectomy (TN), dorsal transposition without coaptation (DT), dorsal transposition with coaptation (DC).[5–7] Currently, there is no universally accepted standard of care, and data comparing these methods are scarce and inconclusive.[5,7] In a retrospective cohort study, Maslow et al. found a significant reduction in the incidence of painful neuromas and persistent pain with nerve coaptation compared to traction neurectomy.[7] However, no randomized controlled studies to date compare different methods of neuroma prevention in finger amputations.
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The only randomized controlled trial (RCT) on the prevention of painful neuroma formation after digit amputation was published in 2000 and compares two conventional techniques that have been modified in recent years to minimize neuroma formation or reduce mechanical pressure by transposing the nerve ends to the dorsal aspect of the stump.[11] Moreover, this RCT excludes digits with non-traumatic amputations, uses different scales to measure outcomes, and does not incorporate aspects of pain that influence patients' emotional and social life.[11]

Currently, there is one randomized controlled trial in the topic of digit neuroma management enrolling patients. However, it compares surgical techniques to treat the neuroma rather than prevent its formation and has shorter follow-up (6 months) than the proposed study.[12]

This randomized controlled trial seeks to close these evidence gaps by prospectively comparing neuroma prevention strategies — TN, DT and DC — in a diverse population undergoing digital amputation, including both traumatic and non-traumatic indications. Outcomes include not only pain, but also cold intolerance and functional interference as perceived by the patient. Ultimately, this study aims to guide best practices for peripheral nerve management in hand surgery and the results would benefit physicians and patients.

2. Specific Aims and Objectives

This study aims to investigate three different types of surgical methods for the prevention of painful neuroma in digit amputations:

1. Traction neurectomy (TN)
2. Dorsal transposition without coaptation (DT)
3. Dorsal transposition with coaptation (DC)

These three techniques are compared to investigate whether any of them leads to significantly better outcomes regarding pain and cold intolerance in patients undergoing digital amputation.

Primary null hypothesis: There are no differences in NRS pain scores or PROMIS pain interference scores between patients who underwent TN, DT or DC of digital nerves during digital amputation at 6-month follow-up.
Objective 1: Compare NRS pain scores between all 3 techniques.
Objective 2: Compare PROMIS pain interference scores between all 3 techniques.

Secondary null hypothesis: There are no differences in cold intolerance between patients who underwent TN, DT or DC of digital nerves during digital amputation at 6-month follow-up.
Objective 3: Compare Cold Intolerance Symptom Severity (CISS) scores between all 3 techniques.

While the primary outcome will be at 6 months, we also aim to collect data for long-term analysis up to 1 year postoperatively.

3. General Description of Study Design

This is a randomized, controlled, three-arm trial. A total of 120 patients undergoing digital amputation will be enrolled and randomized to receive one of the following interventions for nerve stump management: TN, DT or DC.
Patients will be blinded to group assignment. Surgeons will not be blinded due to the nature of the interventions. Randomization will be conducted using a pre-generated allocation sequence created with simple randomization in a 1:1:1 ratio. The sequence will be generated using a computerized random number generator prior to study initiation and stored in a secure file. For each newly enrolled participant, the next assignment in the sequence will be applied in the order of study inclusion. The sequence will be maintained by the study coordinator and accessed at the time of surgery.

Questionnaires will be administered to subjects at the first post-operative appointment and at follow-up dates of 1 month, 3 months, 6 months, and 1 year.

The following questionnaires will be administered to patients and measured throughout their participation in the study to investigate the primary and secondary null hypothesis:

- Numerical Rating Scale (NRS): is a standard pain scale measured on a 11 point (0-10) where 0=no pain and 10=worst possible pain. The NRS will be assessed separately for three aspects: pain at rest, pain during loading/movement and phantom limb pain. There are no values defined as a clinically important difference for painful conditions in amputated digits, but previous studies on chronic painful conditions have identified a reduction of 2 points as a clinically important difference.[13,14]
- Patient-Reported Outcomes Measurement Information System (PROMIS) Pain Interference (PI): this scale incorporates other aspects of pain that influence daily life. We will use the PROMIS Pain Interference Short Form 4a (SF4a). PROMIS scores have a mean of 50 and a SD of 10 in the reference population (U.S general population with a painful condition).[15,16]
- Cold Intolerance Symptom Severity score (CISS): is a 6 questions scale with a possible total score from 4-100. Each question has a score of 0=no symptoms to 10=the most severe symptoms you can possibly imagine (the first question does not count for the final score). Previous studies suggested CISS>50 as a clinical cut-off for pathological cold intolerance.[17]

In addition, a comprehensive set of validated outcome measures will be administered to assess global hand function, pain, and patient satisfaction. These include:

- PROMIS Physical Function SF6b
- Return to work (proportion of patients returning to work and by what time)
- Michigan Hand Questionnaire
- Quick-Disabilities of the Arm, Shoulder and Hand (QuickDASH) questionnaire
- Willingness to Undergo the Same Treatment Again (recorded as a binary yes/no outcome)
- Pain Sketches for Digit Amputation

The explanatory variables in this study are:

- Surgical technique (TN, DT, DC)
- Age at surgery (years)
- Sex (male, female)
- Smoking status (yes, no)
- Established diagnosis of diabetes (yes, no)
- Established diagnosis of perfusion-related conditions in the upper extremity (e.g., Raynaud's, PVD; yes, no)
- Established diagnosis of psychiatric disorder (yes, no)
- Established diagnosis of other chronic pain condition (yes, no)
- Established diagnosis of other neuropathic condition (yes, no)
- Hand dominance (left, right)
- Number of affected digits (1-10)
- Affected digit(s) (thumb, index, long, ring, small)
- Injury side (left, right)
- Mangled Digit Severity Score (0-80)

- Indication for amputation (trauma, infection or sepsis, oncology, dysvascularity, chronic pain or dysfunction, congenital deformity)
- Mechanism of injury [in traumatic amputations] (sharp, avulsion, burn, crush, blast, mixed)
- Level of amputation (specified per phalange and interphalangeal joint)
- Received desensitization physical therapy (yes, no)
- Use of medication against neuropathic pain (yes, no)
- Use of opioids (yes, no)

4. Subject Selection

We will identify all adult patients undergoing amputation of one or more digits at MGB. We will recruit patients with traumatic digit amputations before surgery at the emergency department or in the preoperative holding area. Those who require digit amputations for non-traumatic causes (infection, vascular, oncology) can be recruited during their pre-surgery clinical appointment. Clinically licensed study staff will introduce the study, treatment, potential benefits, risks, and alternative options. They will answer questions related to the surgical procedures or study participation. If the patient agrees to participate, the licensed physician investigator obtaining consent will give them a consent form to sign and then provide a copy of the completed form for their possession.

We will randomize patients to receive either TN, DT or DC. Patients will be blinded to their randomization. Surgeons will perform the procedure indicated by the randomization.

At baseline, data on demographics, comorbidities and injury characteristics will be collected by a research representative (e.g. research coordinator, research scholar) using a custom questionnaire in the MGB Research Electronic Data Capture (MGB RED Cap). This is preferred over retrospective data collection through medical chart review in order to minimize missing data on explanatory variables. If this prospective baseline data collection is not possible for whatever reason, retrospective data collection through medical chart review will be performed instead.

Inclusion Criteria:

- Patients undergoing amputation of one or more digits at MGB

Exclusion Criteria:

- Patients undergoing revision amputations of digits (prior surgical amputation)
- Patients with preexisting peripheral nerve injuries or diseases affecting the amputated digit
- Patients under 18 years old
- Patients who are pregnant and/or breastfeeding
- Unable or unwilling to participate in a trial study

All adult patients, satisfying the above inclusion and exclusion criteria, are eligible for enrollment in this study regardless of sex, race, or ethnicity. Vulnerable populations will not be recruited.

5. Subject Enrollment

Physicians will present the study to eligible patients in the pre-operative holding area. To patients who are interested in participating, a licensed physician investigator will provide more detailed information

about the study, and they will be handed a consent form. Subjects will be informed that their participation is voluntary, and they may withdraw consent at any time. It will also be emphasized that declining to participate in the study will not affect their care now or in the future. Enrollment of non-English speaking participants will be allowed. If a prospective subject does not speak English, an interpreter will be involved in the consent process, and the short form consent process will be used. Patients who consent to participate will be given a copy of their consent form and asked to fill out the electronic questionnaires on MGB RED Cap. The physician and study staff will be available to answer any questions the subject may have. Only surgeons who routinely perform all three techniques and are credentialed to do so at MGH will participate as study staff. This ensures that all procedures are performed by qualified surgeons within their standard clinical practice.

For guidance, refer to the following Mass General Brigham policy:

Informed Consent of Research Subjects

https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Documents/Informed%20Consent%20of%20Research%20Subjects.pdf

Post-consent, patients will be randomized to one of the three groups. Digit-level randomization will not be performed in cases of multi-digit amputation, all digits will be included into the same group.

6. Study procedures

Patients will be approached by the investigator during their (preoperative consultation) about the study. The study will be explained in detail to the participant, and any questions they may have will be answered. It will be clearly communicated that all participation is voluntary and that consent may be withdrawn at any time. Upon consent, participants will undergo the specific procedure (TN, DC or DT) randomly assigned to them.

All patients will be undergoing surgery regardless of their participation in the study. The three techniques TN, DT and DC are all of which are established techniques currently used in clinical practice at MGB. If the patient decides not to enroll in the study, the surgeon will perform the surgical technique they prefer instead of the procedure indicated by the randomization. Randomization does not impact patient care beyond the surgical technique applied to the transected nerve ends. Although randomization determines the surgical technique, all three approaches are currently used in clinical practice and represent standard-of-care options. No patient will receive an intervention that falls outside the accepted range of nerve stump management techniques. Therefore, the randomization process does not affect patient care beyond selecting among clinically accepted surgical options. All other surgical procedures will be performed in the standard fashion. All other aspects of the treatment care will not deviate from regular treatment for digit amputations.
The treating surgeon maintains full clinical discretion and may override the allocated technique if it is not appropriate for a specific case (e.g., due to local anatomy or tissue condition). In such cases, the reason will be documented.

The three surgical techniques differ in complexity and expected operative time. DT and DC typically require longer operative and anesthesia times compared to TN, with DC involving coaptation of nerve ends. However, all three techniques are considered safe, routine procedures with no known increase in

perioperative risk associated with these differences. Prolonged operative time due to nerve coaptation has not been associated with negative outcomes in this context. Only surgeons who routinely perform all three techniques and are credentialed to do so at MGH will participate as study staff. This ensures that all procedures are performed by qualified surgeons within their standard clinical practice.
After the surgery, patients who consented/agreed to participate in the study will be invited to complete:

- NRS pain scores (0-10)
    - In rest
    - During loading/movement
    - Phantom limb pain
- PROMIS Pain Interference SF4a
- CISS scores

These scales are the primary outcomes (quantitative outcomes) and will be completed at 5 points in time:

- First post-operative visit
- 1 month after surgery
- 3 months after surgery
- 6 months after surgery
- 1 year after surgery

Additional data will be collected in each visit using a custom questionnaire in RED Cap:

- PROMIS Physical Function SF6b
- Return to work (proportion of patients returning to work and by what time)
- Michigan Hand Questionnaire
- Quick-Disabilities of the Arm, Shoulder and Hand (QuickDASH) questionnaire
- Willingness to Undergo the Same Treatment Again: recorded as a binary (yes/no) outcome
- Pain Sketches for Digit Amputation
- Demographics survey
- Use of medication against neuropathic pain (yes, no)
- Use of opioids (yes, no)
- Receiving desensitization physical therapy (yes, no)

These questionnaires will be administered in clinic during the appointments of enrolled patients at the Orthopaedic Hand and Upper Extremity Department or the Division of Plastic Surgery at Massachusetts General Hospital (MGH). If patients do not come into clinic or would rather complete the questionnaires elsewhere, study staff will send subjects a RED Cap link to the questionnaires via email (encrypted or unencrypted based on participant preference) or administer it over the phone, whichever method the patient prefers. We will give participants a range of time for when to answer the questionnaires (2 weeks). If patients did not complete their questionnaires after the planned date, a research representative will attempt to contact them by phone. If the initial attempt to contact the patient via telephone is not successful, this will be repeated daily for the duration of one week; if by the end of that week no questionnaires have been completed, that follow-up point will be treated as missing data.

These are the study termination criteria:

- Participant’s decision to withdraw from the study.
- Loss of follow-up (missing data).

Regardless of their participation or decision to withdraw, subjects will continue receiving usual care. If patients withdraw from the study, they will be able to receive notice about their randomization upon

request. Physicians will be readily accessible for consultation if a subject experience discomfort or have questions independently of their decision. Participants will not receive financial compensation.

7. Risks and Discomforts

The three surgical techniques used in this study, traction neurectomy (TN), dorsal transposition without coaptation (DT), and dorsal transposition with coaptation (DC), are all accepted methods of nerve stump management following digital amputation. These procedures are routinely performed in clinical practice and selected based on surgeon preference. The purpose of the study is to evaluate outcomes across these standard approaches, not to introduce experimental techniques.

Randomization does not expose participants to additional or unnecessary risks. All patients enrolled in the study are already undergoing surgical treatment for their digit condition, and all require nerve stump management as part of that surgery.

While the techniques differ in technical steps, they do not differ in their safety profile. DT and particularly DC may require modestly longer operative time due to nerve transposition and/or coaptation. However, all procedures are performed under the same anesthesia and within the same surgical session. There is no evidence that the small increase in operative time with DT or DC results in longer recovery, increased complication rates, or worse outcomes.

Risks are primarily related to the underlying cause for amputation (e.g., trauma, infection, tumor) rather than the nerve management technique itself. All three procedures carry similar potential complications, including: infection, injury to the digital vessel, neuroma formation, hyperalgesia, cold intolerance and neuropathic pain. These risks are inherent to digital amputation itself and not uniquely associated with any of the nerve management techniques used.

Another risk for subjects involved in the study is breach of confidentiality. To minimize this, all electronic information will be stored on MGB secured password-protected computers to which only members of the study staff have access. Study data will be collected and managed electronically using MGB RED Cap, a secure, HIPAA compliant, web-based application hosted by Partners HealthCare Research Computing, Enterprise Research Infrastructure & Services (ERIS). No paper-based questionnaires will be used. Only the investigators and study staff will have access to this information. After data collection and analysis have been completed, all data will be de-identified.

8. Benefits

Currently, we cannot affirm which of these techniques is better in terms of pain, cold intolerance and pain interference outcomes. Subjects may or may not benefit from participating in this study. However, there are long-term benefits for the society. Improving the understanding of outcomes and neuroma prevention ability of these techniques, will contribute to filling the knowledge gap in the field and will provide a platform to select the most effective treatment to prevent neuroma formation in patients with amputation of one or more digits.

9. Statistical Analysis

Pain intensity at rest will be assessed as the primary outcome using an 11-point Numerical Rating Scale (NRS), where 0 indicates no pain and 10 the worst imaginable pain. Pain will be evaluated in three contexts: at rest, during movement/loading, and phantom limb pain.
In a prior study of patients undergoing surgery for symptomatic neuromas in different body regions, average pain intensity decreased from 6.6 to 4.9 — a mean reduction of 1.7 points, which was considered clinically meaningful in that setting.[18]
Assuming a standard deviation of 2.5 points, this corresponds to an effect size of 0.68. Using an alpha of 0.05 and power of 80%, a sample size of 34 patients per group would be required. To allow for potential attrition, we aim to enroll 40 patients per group, for a total of 120 participants across three arms.[19]

All collected data will be assessed for their normality of distribution and will be presented as means and standard deviations for parametric data, medians and interquartile ranges for non-parametric data, and frequencies and percentages for dichotomous and categorical data.

The association between explanatory variables and the continuous outcome variables will be assessed using simple linear regression and/or Pearson/Spearman correlation for continuous explanatory variables. Similarly, Mann-Whitney or unpaired t-tests will be used for dichotomous explanatory variables, and Kruskal-Wallis and one-way ANOVA for categorical variables. For these univariate analyses, significance will be set at $P \leq 0.05$.

Explanatory variables found to be statistically significant in univariate analysis will be entered into a multivariate linear regression analysis to identify independent predictors that influence the outcome of the surgery, with significance being set at $P \leq 0.05$. If the sample size prevents the inclusion of all variables into the multivariate model, we will choose those deemed clinically most relevant or modifiable.

An important aspect to consider for the analysis will be the need for stratification if there is an imbalance between groups despite the randomization. Based on previous articles and the biological mechanism, there are variables that could be potential confounders and/or effect modifiers.

10. 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. The research coordinator will review any monitoring or quality concerns with the PI. Deviations from the protocol will be immediately reported to the PI, who will be responsible for ensuring that any adverse events are reported to the IRB or federal agencies as necessary. Adverse Events and Serious Adverse Events will be reported to the IRB in compliance with Partners policy once discovered. The research coordinator, supervised by the principal investigator, will be responsible for cataloguing and tallying adverse events.

Study data will be maintained in a locked filing cabinet and/or on MGB password-protected computers. Questionnaires and self-reported responses will not become part of the subject's medical record. Hardcopies 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 to which only research coordinator and approved study personnel will have access. MGB RED Cap, secure and HIPAA-compliant, will be used to collect questionnaire answers.

All patient-identifiable information will be collected in a separate data log. The Principal Investigator oversees and monitors this process.

For guidance, refer to the following Mass General Brigham policies:

Data and Safety Monitoring Plans and Quality Assurance
https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Documents/Data%20and%20Safety%20Monitoring%20Plan%20in%20Human%20Subject%20Research.pdf

Reporting Unanticipated Problems (including Adverse Events)
https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Documents/Reporting%20Unanticipated%20Problems%20including%20Adverse%20Events.pdf

11. 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

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APPENDIX A

Data Monitoring Committee / Data and Safety Monitoring Board Appendix

- *To be completed for studies monitored by Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB) if a full DMC/DSMB charter is not available at the time of initial IRB review.*
- *DMC/DSMB Charter and/or Roster can be submitted to the IRB later via Amendment, though these are not required.*

A Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB) will be convened for safety monitoring of this research study. The following characteristics describe the DMC/DSMB convened for this study (Check all that apply):

☐ The DMC/DSMB is independent from the study team and study sponsor.

☐ A process has been implemented to ensure absence of conflicts of interest by DMC/DSMB members.

☐ The DMC/DSMB has the authority to intervene on study progress in the event of safety concerns, e.g., to suspend or terminate a study if new safety concerns have been identified or need to be investigated.

☐ Describe number and types of (i.e., qualifications of) members:
Click or tap here to enter text.

☐ Describe planned frequency of meetings:
Click or tap here to enter text.

☐ DMC/DSMB reports with no findings (i.e., “continue without modifications”) will be submitted to the IRB at the time of Continuing Review.

☐ DMC/DSMB reports with findings/modifications required will be submitted promptly (within 5 business days/7 calendar days of becoming aware) to the IRB as an Other Event.