Mass General Brigham

Institutional Review Board
Intervention/Interaction Detailed Protocol

Principal Investigator:	Kyle Eberlin, MD
Project Title:	Postoperative outcomes of digital nerve coaptations using a sutureless coaptation device
Version Date:	July 28, 2026

1. Background and Significance

Digit nerve lesions represent around 40% of all upper extremity nerve injuries (1). Microsurgical repair using epineural coaptations is the standard treatment for these injuries. While most patients regain protective sensation, less than 25% return to normal levels of sensibility in the injured digit (2). Therefore, the repair of digital nerve injuries remains a persistent challenge in hand surgery. The Nerve Tape device offers a novel suture-free coaptation method, in which nitinol micro-hooks embedded in a flexible biologic wrap secure and align nerve ends with minimal trauma (3–5). Preclinical biomechanical studies have demonstrated that Nerve Tape repairs achieve equivalent or superior tensile strength compared to traditional microsuture techniques (4,5). Preclinical data show promising results for nerve regeneration in a rat peripheral nerve injury model (3). Early in-vivo feasibility data suggest significantly reduced repair time and a higher proportion of clinically acceptable coaptations versus suture repair in a breast-neurotization cohort (6).

Digital nerve lesions can serve as a standardized environment to investigate Nerve Tape in a rigorous clinical model. Previously, this model has been used in other studies, including a randomized controlled trial investigating if the addition of a Chitosan-based nerve tube around epineural coaptation sites could improve outcomes compared to suture only (7,8). Given the present data demonstrating significantly faster coaptation times with Nerve Tape, an evaluation of actual clinical performance in a comparable model could provide solid data on clinical outcomes.

2. Specific Aims and Objectives

The aim of this study is to investigate the outcomes of the sutureless nerve coaptation device Nerve Tape when used for digital nerve repair following digital nerve injury regarding: (1) sensory outcomes, (2) pain outcomes, and (3) functional outcomes in patients undergoing digital nerve repair. This information can be used as the basis for a future randomized controlled clinical trial.

Objective 1: Assess sensation using the static two-point discrimination at 1, 3 and 6 months postoperatively

Objective 2: Assess pain using the Visual Analog/Numerical Rating Scale (VAS/NRS) scores at 1, 3 and 6 months postoperatively
Objective 3: Assess function using QuickDASH questionnaire scores at 1, 3 and 6 months postoperatively

3. General Description of Study Design

This is a prospective, single-arm study. A total of 20 patients undergoing digital nerve repair using Nerve Tape will be enrolled. Informed written consent will be obtained by approved study staff. Questionnaire-based assessments and examinations will be performed at the first post-operative appointment and at follow-up dates of 1 month, 3 months and 6 months. Any approved member of the study staff can collect this data.

The following outcome measures will be evaluated in participating patients and measured throughout their participation in the study:

- Static two-point discrimination: is a clinical sensory test that assesses tactile spatial resolution in the affected digit. Using a two-point discriminator (or calipers), one or two light touch stimuli are applied perpendicular to the skin while the patient's eyes are closed, and the patient reports whether they perceive "one" or "two" points. The smallest distance (in millimeters) at which the patient can reliably distinguish two points is recorded as the s2PD value, with lower values indicating better sensibility. The test will be performed in the autonomous sensory territory of the injured digital nerve (and, when feasible, compared with the contralateral corresponding digit) using a standardized protocol and consistent test site(s) across follow-up visits.
- Numerical Rating Scale (NRS) for pain: is a standard pain assessment, measured on a 11 point scale (0-10) where 0=no pain and 10=worst possible pain. The NRS will be assessed separately for two aspects: pain at rest and pain during loading/movement.
- Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH): is a validated, patient-reported outcome measure assessing upper-extremity symptoms and functional limitations over the past week. The QuickDASH consists of 11 items rated on a 5-point Likert scale, and scores are transformed to a 0–100 scale, where higher scores indicate greater disability. A QuickDASH score is calculated when at least 10 of 11 items are completed.

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

- Semmes–Weinstein monofilament (SWM) testing
- PROMIS Pain Interference SF4a
- DN-4 Neuropathic Pain Questionnaire
- EQ-5D-5L Quality of Life Questionnaire

Further, the coaptation time, defined as the time between completed preparation of the nerve and completed coaptation using Nerve Tape, will be recorded by a study surgeon or a member of the study staff.

The explanatory variables in this study are:

- Demographics
    - Gender (male/female)
    - BMI (at time of surgery)

    - Race/ethnicity (Black, Asian, Native American/Alaskan, Hawaiian/Pacific, Middle Eastern, White, Other, Unknown)
    - Age at initial surgery (years)
    - Age at surgery (years)
    - Follow-up duration (months)
    - Insurance type (Medicare/Medicaid/workers comp/private/none/other)
    - Employment status (full-time/part-time/retired/unemployed/student/other)
    - Hand dominance (left/right/both)
- Injury/surgery characteristics:
    - Injured side (left/right/both)
    - Injured nerve (N1-N10)
    - Injured digit (D1-D5)
    - Injury level (distance to fingertip)
    - Injury mechanism
    - Time/date of injury
    - Time/date of surgery
    - Vascular injuries/treatment
    - Tendon injuries/treatment
    - Bone injuries/treatment
    - Revision surgery (yes/no)
      if yes:
        - Date of revision surgery
        - Reason for revision surgery
- Comorbidities (at time of surgery)
    - Alcoholism (yes/no/former)
    - Smoking status (yes/no/former)
    - Chronic regional pain syndrome (yes/no)
    - Comorbidity index (Elixhauser)
    - Diabetes Mellitus (yes/no)
    - HbA1c at surgery (%)
    - Hypothyroidism (yes/no)
    - Malignant tumors (yes/no/former)
    - Chronic kidney disease (yes/no)
    - Peripheral vascular disease (yes/no)
    - Peripheral neurological degenerative diseases (yes/no)
    - Psychiatric comorbidities (≥ 1 of the following)
        - Depressive disorder (yes/no)
        - Anxiety disorder (yes/no)
        - Personality disorder (yes/no)
        - Post-traumatic stress disorder (yes/no)
- Additional variables recorded at each follow-up:
    - Employment status (full-time/part-time/retired/unemployed/student/other)
    - Return to work (same work as before injury/different work than before injury/not able to work)
    - Pain medication (substance, dose, frequency)

4. Subject Selection

We will identify all English-speaking adult patients undergoing digital nerve repair with Nerve Tape as part of their standard clinical care at Mass General Hospital (MGH) of Mass General Brigham (MGB). Patients with traumatic digital nerve injuries and undergoing repair with Nerve Tape will be approached for enrollment prior to surgery in the emergency department or in the preoperative holding area in a private setting. The treating surgeon will either identify patients to enroll in the study, or confirm that patients are appropriate to enroll in the study. The surgeon will introduce the study and obtain permission from the patient to be approached by the research team. Once the patient gives their permission, approved study staff will introduce the study, explain its observational nature, outline potential benefits and risks of participation and describe alternative options (including non-participation). It will be communicated to the participant that participation is entirely voluntary and they can withdraw at any time. Further, it will be communicated that non-participation or withdrawal of consent will not affect their standard clinical care at any point in time. The study staff will answer any and all questions related to study participation and the planned surgical care. If the patient agrees to participate, a study physician or a member of the study team will obtain written informed consent and provide the participant with a copy of the signed consent form as required by IRB guidelines.

Accurate comprehension of the study materials is essential to ensure participant safety, informed consent, and data integrity. This study involves procedures and assessments that require clear communication without risk of misinterpretation. To ensure the integrity of informed consent and the reliability of data collected, participants must be able to fully understand and engage with study materials and instructions in English. Including non-English speakers without validated translations and linguistic equivalency assessments could compromise both ethical standards and scientific validity.

This is a prospective validation study with no randomization and no control group. All enrolled participants will receive digital nerve repair using Nerve Tape as part of their planned surgical management, with the specific operative details (i.e. positioning and size of Nerve Tape) determined by the treating surgeon based on routine clinical judgment and injury characteristics. Study participation will not dictate intraoperative decision-making, including the use of Nerve Tape, as this device would be used as standard care.

If the surgeon decides against using Nerve Tape for whatever reason, the patient will be excluded. This way, we ensure that enrollment in this study does not affect treatment or intraoperative decision-making. Only patients who are planned to receive digital nerve repair using Nerve Tape as part of their planned surgical management will be enrolled before surgery. If the surgeon changes the procedure to a conventional microsurgical suture coaptation, the patient will be excluded from the study.

At baseline, demographics, comorbidities, and injury and treatment characteristics will be collected by a research representative (e.g., research coordinator, research fellow) approved as study staff using a standardized case report form in MGB Research Electronic Data Capture (MGB REDCap). Prospective baseline collection is preferred to minimize missingness in key explanatory variables and to ensure standardized documentation of injury features and operative details. If prospective baseline data collection is not feasible, the same variables will be abstracted retrospectively from the medical record.

Inclusion Criteria:

- Patients with complete traumatic digit nerve transections between the MCP and the DIP joints, suitable for direct end-to-end coaptation that are treated with Nerve Tape as part of their standard clinical care
- Age between 18 and 67 years
- Trauma occurred in the previous 72 hours
- Able to provide informed consent
- Use of Nerve Tape for standard care surgical procedure for digital nerve repair

Exclusion Criteria:

- Nerve lesions proximal to the MCP joint of the digital nerve that would be treated with NerveTape
- Nerve injuries with a gap requiring auto- or allograft interposition
- Amputated or avascular fingers
- Active infection of the wound
- Known pre-existing impaired sensibility of the injured finger or the opposite side
- Allergy to the contents of Nerve Tape
- Known immunodeficiency
- Inability to provide informed consent
- Surgeon decision to not use Nerve Tape during digital nerve repair

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

Study staff will present the study to eligible patients in a private setting within the pre-operative holding area. To patients who are interested in participating, a study staff member 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. Patients who consent to participate will be given a copy of their completed 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.

6. Study procedures

During the surgery, the coaptation time, defined as the time between completed preparation of the nerve and completed coaptation using Nerve Tape, will be documented only by authorized study team members such as the operating surgeon if the surgeon is a study team member, or by a designated study team member present in the operating room. The measured time will be recorded on a study source document on the day of surgery, and subsequently entered into the secure MGB REDCap database by authorized study staff only. No non-study personnel will access or enter data into the study database.

If study staff are present in the operating room for research-related observation or timing, this will occur only with the permission of the appropriate operating room and institutional leadership and in accordance

with applicable institutional policies. Study staff present in the OR will not participate in clinical care unless separately credentialed and authorized to do so.

After the surgery, patients who consented/agreed to participate in the study will be examined using the following end-points:

Questionnaires:

- Numerical Rating Scale (NRS) for pain at rest and during loading/movement: assesses patient-reported pain intensity at rest and with activity using a numeric rating scale
- Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH): assesses upper-extremity physical function and symptoms related to the arm, shoulder, and hand
- PROMIS Pain Interference SF4a: assesses the extent to which pain interferes with daily activities and social, emotional, and physical functioning
- DN-4 Neuropathic Pain Questionnaire: screens for features suggestive of neuropathic pain and helps differentiate neuropathic from non-neuropathic pain
- EQ-5D-5L Quality of Life Questionnaire: assesses health-related quality of life across five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression
- Return to Work: documents whether and when the participant resumed work following injury or treatment (information obtained by directly asking the participant)
- Social Status: documents the participant's current employment situation (information obtained by directly asking the participant)
- Medication Therapy: documents the use of pain medication, including current or recent analgesic treatment (information obtained by directly asking the participant)

Objective Sensory Testing

- Static two-point discrimination: assesses discriminatory sensibility by measuring the minimum distance at which two simultaneously applied points can be distinguished as separate
- Semmes–Weinstein monofilament (SWM) testing: assesses cutaneous pressure sensation by determining the threshold at which light touch can be perceived

These questionnaires and sensory tests are the primary outcomes (quantitative outcomes) and will be completed at 4 points in time:

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

These examinations and questionnaires will be performed 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). The questionnaires and sensory testing will take approximately 20 minutes in total at each study follow-up visit. Whenever possible, these assessments will coincide with the patients routine clinical follow-up visits. The questionnaires will be completed by the participant either independently or with assistance from trained study staff if needed. 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 five times within the following two weeks; if by the end of that period no questionnaires have been completed, that follow-up point will be treated as missing data. Participants may continue in the study and complete future assessments.

Objective sensory testing will be performed by trained study personnel using standard clinical methods. These sensory tests are standard, noninvasive clinical examinations. They do not involve needles, electricity, or any break in the skin. The testing may cause brief mild discomfort or temporary sensitivity, but it is not expected to be painful and does not pose significant risk.

Static two-point discrimination:
This is a simple sensory test that checks how well a participant can tell the difference between one point and two separate points touching the skin. During the examination, the study team member gently touches the skin with either one tip or two tips at the same time, while the participant indicates whether they feel one point or two. The distance between the two points is gradually changed to determine the smallest distance at which the participant can still distinguish two separate touches. This helps assess fine sensory recovery and discriminatory touch in the affected area. Sensation in the hand may be tested clinically using two-point discrimination.

Semmes–Weinstein monofilament (SWM) testing:
This is a standard light-touch test that checks how much pressure is needed before the participant can feel touch. A trained member of the study team gently presses a small nylon filament against the skin until it bends, then asks the participant whether the touch was felt. Different filaments apply different amounts of pressure, so the test helps determine the participant's touch sensitivity threshold. In simple terms, it measures how light a touch the participant can still detect. Monofilament testing is a standard way to assess pressure sensation, and the 10-g monofilament is commonly used to assess protective sensation.
These examinations are noninvasive and are performed at the affected anatomical area as part of the postoperative assessment.

Additionally, at each follow-up, we will also collect information about any complications or adverse events you may have experienced.

These are the study termination criteria:

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

If the patient chooses to withdraw, study staff will ask if they would like to continue receiving follow-up surveys or if they prefer to end their participation entirely.

Regardless of their participation or decision to withdraw, subjects will continue receiving usual care (i.e. use of Nerve Tape for digital nerve repair but without questionnaires, assuming the treating surgeon used Nerve Tape in their standard care). Non-study staff physicians will be readily accessible for consultation if a subject experiences discomfort or has questions independently of their decision. Participants will not receive financial compensation.

7. Risks and Discomforts

Only patients who will undergo digital nerve coaptation using Nerve Tape as part of their standard treatment will be enrolled. Therefore, the use of Nerve Tape does not lead to additional risks or discomfort associated with study participation. The standard risks of Nerve Tape used in surgery are:

- Routine surgical risks: postoperative pain, swelling/bruising, and anesthesia-related risks.
- Inflammatory response: localized inflammation or irritation at the implant/repair site.
- Hypersensitivity: reaction to porcine-derived ECM and/or nickel/titanium (nitinol) components.

All digital nerve procedures can lead to potential complications, including: infection, injury to the digital vessel, neuroma formation, hyperalgesia, cold intolerance and neuropathic pain. These risks are inherent to the nerve surgery itself and not uniquely associated with study participation.

Participation in the study itself involves minimal risk. Risks are primarily limited to the time required to complete questionnaires and undergo noninvasive sensory and pain assessments. Some survey questions related to pain, function, quality of life, mental health, employment, and return to work may cause mild emotional discomfort. Sensory testing procedures, including static two-point discrimination and Semmes–Weinstein monofilament testing, may result in brief physical discomfort due to experienced numbness but are noninvasive and low risk.

A 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 REDCap, 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 if the use of Nerve Tape leads to improved outcomes following digital nerve surgery. There is no predictable direct benefit to individuals. Participants may or may not benefit from the use of Nerve Tape. However, there are long-term benefits for society. Improving the understanding of outcomes will contribute to filling the knowledge gap in the field.

9. Statistical Analysis

This is an exploratory study using static two-point discrimination at 6 months postoperatively as the primary outcome. There is currently no data upon which a sample size calculation could be based. Based on other exploratory studies in the field of peripheral nerve surgery, we aim to include 20 patients.

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. Unanticipated Problems and other 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.

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.