

**Trigger finger corticosteroid injection with and without lidocaine with epinephrine; a randomized, double blind controlled trial**

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## Abstract

**Objective:** To determine if there is less pain from a corticosteroid injection with or without lidocaine with epinephrine when pharmacologically treating trigger finger (stenosis tenosynovitis).

**Research Plan:** The treatment of trigger finger involves an injection of corticosteroid (e.g., 40 mg Kenalog). Kenalog treats the underlying inflammatory pathology. Some surgeons add lidocaine with epinephrine as a local anesthetic with the injection. Lidocaine with epinephrine is associated with a burning sensation and may be the primary pain associated with the injection. We hypothesize that a corticosteroid injection without lidocaine with epinephrine will be less painful, and equally effective in treating trigger finger. This hypothesis is based on experience injecting without lidocaine with epinephrine (i.e., Kenalog only) in clinic. Comparison of these two methods has not been done previously. Patients presenting to our clinic with trigger finger will have the option to electively enroll in this study comparing the two methods.

**Methods:** Patients will be randomized into two groups with randomizing software. The two groups will include (1) 1mL corticosteroid + 1mL Lidocaine with epinephrine vs (2) 1mL corticosteroid + 1mL saline. The surgeon (injector) will also be blinded to the selected treatment to avoid bias. The pain levels will be assessed at 1 minute after the injection using the VAS pain scale.

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## 1. Introduction

Trigger finger is a pathology of the flexor tendons in the fingers. Under normal physiologic conditions, the flexor tendon slides under a close-fitting tendon sheath when the finger extends or flexes. However, in some patients, the flexor tendon can become irritated and subsequently develop inflammatory nodules. When this happens, the nodules catch the tendon sheath during finger extension and flexion. This can cause pain and dysfunction.

The treatment for trigger finger involves the injection of a corticosteroid to shrink the inflammatory nodule on the flexor tendon. Often, the injection involves a 50:50 mixture of local anesthetic and corticosteroids<sup>5,6,7,8</sup>. The lidocaine with epinephrine component of the injection causes a burning sensation, which causes discomfort during the procedure. Lidocaine with epinephrine is not anti-inflammatory and does not treat the underlying pathology. To date, there are no formal studies that have compared the pain outcomes and long-term efficacy of using corticosteroids + lidocaine with epinephrine vs corticosteroid injections alone.

Trigger finger is present in 3-5% of the general adult population, and up to 10% of diabetic patients<sup>8,9</sup>. This project hopes to establish a treatment method that is less painful and involves fewer medications without sacrificing long-term efficacy. If this project yields significant results, it could change the practice of trigger injections on the national level, this would impact millions of patients.

## 2. Objective and hypothesis

The purpose of this study is to see if removing lidocaine with epinephrine from trigger finger injections decreases pain of the shot without decreasing the effectiveness of the treatment. We hypothesize that using an injection of corticosteroids (without lidocaine with epinephrine) will reduce the need for treatment.

## 3. Study Procedures

### 3.1 Study Design

This study will be a prospective randomized control trial. The study will also be double blind, as the patient and physician will not know which injection is being used. Both interventions (Kenalog + Lidocaine with epinephrine and Kenalog alone) can be classified as standard of care, as they are already being used in our clinic and by surgeons around the world in a similar fashion.

Syringes will be pre-filled by the study personnel with either:

1. 1mL 1% lidocaine with epinephrine with epinephrine and 1ml of Kenalog 40 (2 mL total)

2. 1mL of 0.9% saline and 1ml of Kenalog 40 (2 mL total)

Patients will have an equal (50% chance) of receiving either injection that will be determined by using randomizer software.

### **3.2 Data points**

We will keep track of the following:

- Patient identification (medical record number)
- Age
- Gender
- Type of Injection
- Date of injection
- Digit/Hand
- Reported Pain Score at 1 minute
- Adverse effects of injection (infection, skin pigmentation, atrophy)

We will also be keeping track of the following comorbid conditions to better analyze our data:

- Diabetes (insulin dependent, non-insulin dependent)
- Hypothyroidism
- Chronic opioid use
- Smoking history
- Carpal tunnel syndrome
- Rheumatologic conditions

### **3.3 Study Risk**

This study is categorized as less than minimal risk. We are comparing two treatment methods that are accepted as standard of care, and are already used on the clinic population being studied on a daily basis. There is no new experimental intervention that would put patients at greater than minimal risk

To minimize procedural risks, an experienced clinician will perform all injections. A standardized procedure will also be used for each injection. There will be a timeout before each procedure to

ensure all information is correct and accurate. The skin surrounding the injection site will be throughout cleaned with rubbing alcohol to minimize the risk of infection.

### **3.4 Informed Consent Procedures**

Informed consent will be obtained before performing any procedures. The Principle Investigator or Co-investigator will be obtaining informed consent. All study personnel have successfully completed human subjects training.

### **3.5 Inclusion/Exclusion Criteria**

Inclusion Criteria:

- >18 years

Exclusion Criteria:

- Unconsentable
- Not a candidate for injections

### **3.6 Statistical Analysis**

We are planning a study of a continuous response variable from independent control and experimental subjects with 1.1538 control(s) per experimental subject. In a previous study the response within each subject group was normally distributed with standard deviation 0.3. If the true difference in the experimental and control means is 0.2, we will need to study 34 experimental subjects and 39 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05.

Demographic data and adverse events will be assessed with the chi-square analysis.

Pain scores will be assessed with the Manny-Whitney U test.

### **3.7 Withdrawal of Subjects**

There are no anticipated circumstances under which subjects would be withdrawn from research without their consent. If subjects withdraw, there will be no penalty or consequences.

## **4. Adverse Reporting**

Adverse events will be reported to the IRB immediately through standard reporting mechanisms. The attending surgeon will be involved with the post-care along with any necessary physician staff.

## 5. Privacy and Confidentiality

Private health information (PHI) will be used in the study, but not disclosed. All PHI will be stored on a secure, password-locked server. All participants in the study have obtained Human Research certification to have the necessary authorization to PHI. When collecting patient data, only medical record numbers will be used to identify patients.

## 6. Communication Plan

Reporting will occur through standard process for the IRB. There is one clinic at a single site performing this study.

## 7. References

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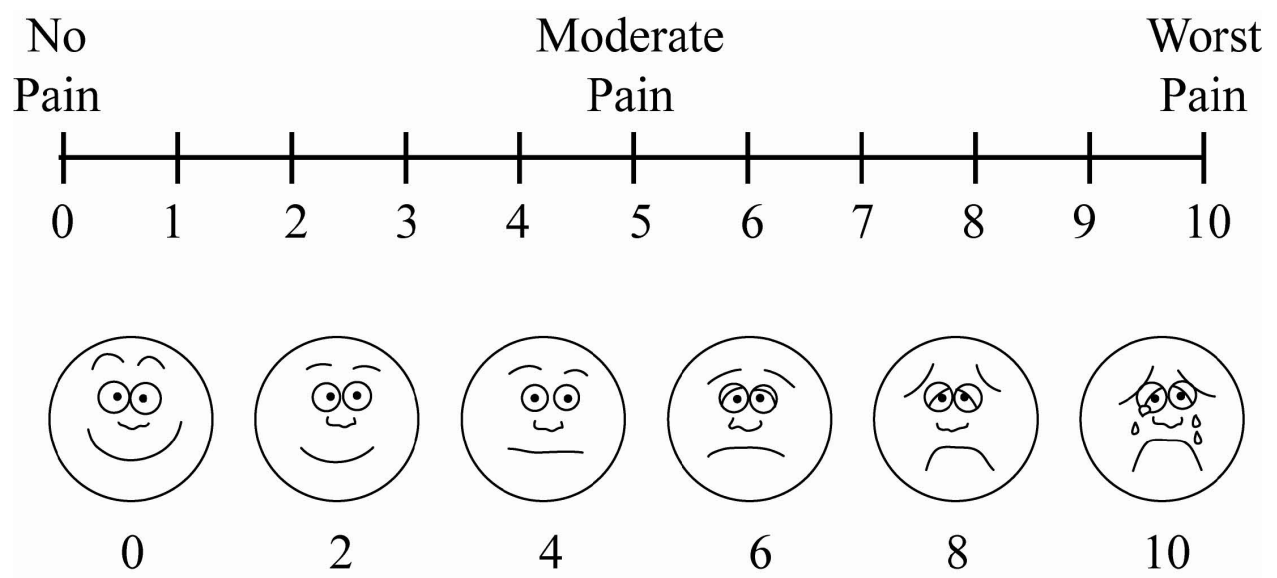
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## 8. Appendix

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| Grade I   | Pain/history of catching                                 |
| Grade II  | Demonstrable catching, but can actively extend the digit |
| Grade III | Demonstrable locking, requiring passive extension        |
| Grade IV  | Fixed flexion contracture                                |

### Appendix Item 1: Green's Classification of Trigger Finger Severity



### Appendix Item 2: VAS Pain Score