**Primary surgical release of trigger digits in diabetic patients: A prospective case-control study.**

Michael Smith, MD Gary McGillivary, MD Claude Jarrett, MD

1/10/2012

**2. Precis/Abstract:**

This study will compare the outcome of primary surgical release of trigger digits in diabetic patients to non-diabetic age-matched controls. The primary outcome will be to determine if there is an increased risk of surgical or recurrence in diabetic patients who undergo primary surgical release of trigger digits. This will be a prospective case-control study. Outcome measures include: Infection rate, Effect of surgery on HgA1C, Recurrence rate, Subject’s self-assessment of improvement of triggering.

**3. Introduction and Background:**

Flexor tendon stenosing tenosynovitis, or trigger finger, is a common diagnosis in the adult population. It is characterized by inflammatory changes in the retinacular sheath and peritendinous tissue leading to tenderness over the A1 pulley, pain along the flexor sheath and locking or triggering of the finger. In diabetic patients, it has been estimated that as many as 10% to 15% of all diabetics will develop trigger finger during their lifetime, as opposed to the 1% to 3% incidence of trigger finger in the general population.1,2,3,4,5  While the pathogenesis of this increased incidence in diabetic patients is not fully understood, it has been proposed that chronic hyperglycemia results in increased intermolecular linking within peritendinous collagen. This increased intermolecular linking in turn impairs collagen breakdown, leading to collagen accumulation within the tendon sheath.6 In addition to an increased incidence of trigger finger in diabetics, it has also been found that diabetic patients are more likely to have triggering of the index finger6, multiple finger involvement7, and bilateral hand involvement6.

While the incidence of trigger finger is increased in diabetic patients, it has been found that the diabetic patients have had decreased rates of successful management with conservative treatment, including splinting and corticosteroid injections. Griggs et al reported a 50% success rate in non-insulin-dependent diabetic patients and a 44% success rate in insulin-dependent diabetic patients when treated with corticosteroid injection.8 Others have reported that only 32% of diabetic patients experience complete resolution of symptoms after corticosteroid injection.9 This is in contrast to a reported 57% success rate in non-diabetic patients treated with single corticosteroid injection.9 In addition to having a lower success rate with corticosteroid treatment of trigger finger, one study demonstrated that diabetics tend to have impaired glycemic control after corticosteroid injection into the flexor tendon sheath. 10 In addition, a double-blinded, prospective, randomized study demonstrated that after a trial of corticosteroid injection, diabetic patients are up to three times more likely to require operative management of their trigger digits when compared with non-diabetic patients.11 In addition, that study also found that individuals with systemic microangiopathies of diabetes, such as nephropathy or neuropathy, were more likely to fail conservative management with corticosteroid injections.11

While there is Level I evidence that corticosteroid injections as the primary treatment of trigger digits are less effective in diabetic patients, there is no corresponding level of evidence regarding the outcome of surgical treatment of trigger digits in the diabetic population. In one retrospective study7, patient-reported treatment response to trigger finger release in diabetic patients was 77%, compared with 94% in non-diabetic patients. This difference was not significant and no major complications were noted in either diabetic or non-diabetic patients. The incomplete success of the procedure was related mainly to discomfort at the operative site or incomplete resolution of a flexion contracture at the proximal interphalangeal joint. Other studies have noted a complication rate of approximately 5-7% following operative management of trigger finger, however this was not stratified to account for the presence of diabetic patients12

Given the lack of conclusive data regarding the surgical treatment of trigger digits in diabetics, it is unclear if trigger finger in diabetes should continue to be treated initially with corticosteroid injection or if primary surgical release should be offered to the patient. If it could be definitively shown that diabetic patients achieve similar rates of success after release of trigger digits, with no increase in major complications, it would then be appropriate to propose primary surgical treatment of trigger digits in diabetic patients, especially in those with long-standing diabetes and evidence of systemic complications of diabetes. In our study, we propose to prospectively follow diabetic patients with trigger finger treated with primary surgical release and compare their outcomes with appropriately matched non-diabetic controls. Our primary hypothesis is that there will be no difference in the rates of successful treatment and the rates of major complications after surgical release of trigger finger between diabetic and non-diabetic patients.

**4. Objectives**

The primary aim of this study is to measure the success rate after primary surgical release of trigger digits in diabetic patients compared to non-diabetic patients. Success rate will be determined both by objective findings on clinical exam by the operating surgeon and the subjective perception of surgical success by the patient. Patients will be followed for 12 months after surgery. Outcome measures for the primary aim will include: Successful intervention will be defined as absence of pain, triggering, discomfort or disability after surgical release. Failure of surgical release will be defined as persistence of local pain or tenderness at the A1 pulley, presence of a painful nodule, and recurrence of snapping and/or persistent pain after surgical release.

A secondary aim of this study is to determine the patient’s perception of function and surgical outcome after trigger finger release with the use of a self-reported questionnaire (See addendum). This questionnaire will be completed at each post-operative visit (at approximately six weeks, three months, and one year).

An additional secondary aim of this study is to measure the major complication rate after primary surgical release of trigger digits in diabetic patients compared to non-diabetic patients. Complications will be defined as surgical site infection, injury to the digital nerve, or bowstringing due to release of the A-2 pulley.

An additional secondary aim of this study is to determine if the type of diabetes (insulin-dependent v non-insulin-dependent diabetes), degree of glycemic control measured by HgA1C, presence of documented systemic manifestations of diabetes (retinopathy, neuropathy, or nephropathy), or duration of diabetes has an effect on the success rate or major complication rate following surgical release of trigger fingers.

**5. Study design and methods**

The procedures to be performed (distinguish between the procedures performed for

diagnostic or treatment purposes and those for research); risks/discomforts and potential benefits if any to subjects, patient class, science/society (whether direct or indirect); what type of information will be collected; what specimens will be collected, if any; and randomization and blinding.

If applicable: if data/samples collected for this study will be saved/banked/archived for

future uses beyond the scope of this study, describe plans for identifying and storing

data/samples for such future uses.

*Enrollment*

The study subjects will be selected from a consecutive group of patients seen in the clinics of two fellowship-trained hand surgeons (McGillivary and Jarrett) starting in March of 2012 and continuing for two years. All patients who are between eighteen and eighty years of age and have subjective symptoms of pain, catching, or triggering along the A1 pulley consistent with sterile flexor tenosynovitis will be eligible. If the symptoms are confirmed with objective findings such as tenderness over the A1 pulley, a palpable nodule at the A1 pulley or between the A1 and A2 pulleys, pain along the flexor tendon with resisted flexion or with passive stretch in extensions, and reproducible locking, triggering or catching. Both patients with and those without diabetes will be eligible for inclusion in the study. To be included in the diabetes cohort, the patient has to have a diagnosis of either insulin-dependent or non-insulin-dependent diabetes and be under the care of an internist or endocrinologist prior to his or her initial presentation to us for inclusion. Exclusion criteria for this study will be: 1) previous treatment of the trigger finger with surgical release of the A1 pulley; 2) an inflammatory or potentially pathologic etiology, such as rheumatoid arthritis, of the trigger finger; (3) patient’s unwillingness to undergo operative management of the trigger finger

Upon meeting eligibility criteria, patients will be offered enrollment in the study. The study rationale will be explained by the treating hand surgeon or study coordinator and patients will be given an opportunity to ask questions. If the patient decides to participate an informed consent form will be signed and a copy will be given to the patient. A standardized initial study interview and examination will be performed and patient’s will complete an initial study questionnaire (See Appendix). Initial data to be recorded will include age, body mass index, handedness, occupation, presence of diabetes, type of diabetes, duration of diabetes, amount and type of insulin used per day, other systemic diabetic manifestations (retinopathy, neuropathy, or nephropathy), carpal tunnel syndrome, Dupuytren disease, affected hand(s), affected digit(s), presence of a locked digit, and duration of symptoms. All patients will have blood drawn to determine the hemoglobin A1C level at the initiation of the study.

*Surgery*

Patients enrolled in the study will undergo A1 pulley release by the enrolling hand surgeon. This will be performed in the same manner, regardless of the patient’s diabetic status.

*Follow-up*

Patients will be interviewed and reexamined at approximately six weeks, three months and one year after surgery. If patients experience increased or persistent symptoms, they may be seen more frequently. Follow-up will include evaluation of the subjective symptoms and physical findings consistent with trigger finger (objective triggering, tenderness at the A1 pulley and the presence of a painful nodule) as well as any complications related to the treatment. The patient will be asked to complete the post-operative questionnaire (See Appendix) in which the patient’s impression of the success of the surgery will be evaluated. The patient will also be asked if there were any changes in regard to their diabetic management or if any systemic complications of diabetes had developed since their last clinical visit.

*Procedures*

The procedures performed during this study will include venipuncture for preoperative labs. In diabetic patients a hemoglobin A1C value will be drawn with the preoperative labs if the patient has not had a hemoglobin A1C within the preceding three months. This blood draw is for diagnostic purposes and is performed for all preoperative patients regardless of inclusion status in the study. The surgical treatment of the trigger digit is performed for treatment purposes and the procedure performed will not differ from the usual surgery performed on patients not enrolled in the study.

*Risks/Discomforts*

The risks and discomforts of our study include pain from venipuncture and surgery, possible infection, and possible complications from the operation including nerve injury, bowstringing of the flexor tendon and superficial or deep infection. The study, however, does not introduce additional risk above that of the normal risk inherent to surgical treatment of trigger finger. Our study could cause some anxiety in our patients, as they will be asked to complete questionnaires which will take an additional five to ten minutes during their pre-operative and post-operative visits.

*Benefits*

There are no direct benefits to the patients enrolled in the study, as this study will not be changing the management of their trigger finger, but may help influence the management of trigger finger in the future. The indirect benefit to the patients will be the altruism associated with participating in a scientific study which will advance the current body of knowledge in this area. An additional benefit of this study will be to the larger diabetic patient population that develops trigger finger in the future. Hopefully this study will elucidate the appropriate primary intervention for trigger finger in diabetics and save time and money to the patients and the health care system as a whole.

*Data*

Data from this study will be stored and collected on an institutional hard drive which is password protected. The patient’s names and MRN will be kept on a separate database which will then correspond to a separate patient identifier. The patient’s clinical data will only be associated with that separate patient identifier. While there are no further plans to use the de-identified data collected for future research endeavors, it will be archived for possible future use if the need arises.

**6. Participant selection**

Requested sample size and expected refusal or withdrawal rate; inclusion/exclusion

criteria with justification; subject recruitment plan; screening for eligibility; and

withdrawal from study. (Informed consent information may be included here in addition

to the eIRB section on Informed Consent Process.)

We propose to enroll forty-five patients in each cohort. Between the two hand surgeons, it is expected to take six to nine months to complete the cohort enrollments. Patients will be screened for eligibility by the operating hand surgeon. If found the meet the inclusion and exclusion criteria found below, the patient will be presented with the study and asked if they would like to participate. If the patient indicates that they would like to participate in the study, the informed consent form will be presented to the patient. Once informed consent is obtained the patient will complete the initial study questionnaire. Patient’s will be informed that they are free to withdrawal from the study at any time with no effect on their treatment.

*Inclusion criteria*

All patients who are between the ages of eighteen and eighty years and have subjective symptoms of pain, catching, or triggering along the A1 pulley consistent with sterile flexor tenosynovitis will be eligible. If the symptoms are confirmed with objective findings such as tenderness over the A1 pulley, a palpable nodule at the A1 pulley or between the A1 and A2 pulleys, pain along the flexor tendon with resisted flexion or with passive stretch in extensions, and reproducible locking, triggering or catching. Both patients with and those without diabetes will be eligible for inclusion in the study. To be included in the diabetes cohort, the patient has to have a diagnosis of either insulin-dependent or non-insulin-dependent diabetes and be under the care of an internist or endocrinologist prior to his or her initial presentation to us for inclusion.

*Exclusion criteria*

Exclusion criteria for this study will be: 1) previous treatment of the trigger finger with surgical release of the A1 pulley; 2) an inflammatory or potentially pathologic etiology, such as rheumatoid arthritis, of the trigger finger; (3) patient’s unwillingness to undergo operative management of the trigger finger

**7. Statistical analysis**

**Sample size determination and power; interim monitoring and early stopping; analysis plan; and statistical methods.**

A prestudy statistical analysis was performed to determine the number of digits required in each trial group to achieve an alpha value of 0.05 (degree of significance) and a power of 0.8 (a beta value of 0.2). At the interval follow-up periods (six weeks, three months and one year) data will be analyzed in order to determine if there is a significant number of unexpected complications in the diabetic cohort. If we determine that there is an unexpected number of complications at any of the follow-up periods, the study will be stopped.

8. Adverse event reporting

Description of plan for notifying the IRB of reportable events; whether the sponsor requires reporting above and beyond the Emory IRB reporting requirements, and if so, a description of the requirements and plan for meeting them.

9. Data and safety monitoring plan (DSMP)

Plans for monitoring the progress of the trial and safety of participants; description of the

mechanism for reporting adverse events to the IRB and federal agencies (see above, too);and plans for assuring data accuracy and protocol compliance. If a data and safety

monitoring board (DSMB) will be used, include information about its charter, frequency

of meetings, and constituents.

10. If applicable: pharmaceutical, biologic, and device information

Not applicable

11. References and appendices

1. Papanas N, Maltezos E. The diabetic hand: a forgotten complication? J Diabetes Complications 2010;24:154-162
2. Koh S, Nakamura S, Hattori T, Hirata H. Trigger digits in diabetes: their incidence and characteristics. J Hand Surg 2010;35E:302-305
3. Starkman HS, Gleason RE, Rand LI, Miller DE, Soeldner JS. Limited joint mobility (LJM) of the hand in patients with diabetes mellitus: relation to chronic complications. Ann Rheum Dis 1986;45:130-135.
4. Jennings AM, Milner PC, Ward JD. Hand abnormalities are associated with the complications of diabetes in type 2 diabetes. Diabet Med 1989;6:43-47
5. Chammas M, Bousquet P, Renard E, Poirier JL, Jaffiol C, Allieu Y. Dupuytren’s disease, carpal tunnel syndrome, trigger finger, and diabetes mellitus. J Hand Surg 1995;20A:109-114
6. Blyth MJ, Ross DJ. Diabetes and trigger finger. J Hand Surg 1996;21B:244-245
7. Stahl S, Kanter Y, Karnielli E. Outcome of trigger finger treatment in diabetes. J Diabetes Complications. 1997;11:287-290
8. Griggs SM, Weiss AP, Lane LB, Schwenker C, Akelman E, Sachar K. Treatment of trigger finger in patients with diabetes mellitus. J Hand Surg 1995;20A:787-789
9. Nimigan AS, Ross DC, Gan BS. Steroid injection in the management of trigger fingers. Am J Phys Med Rehabil 2006;85:36-43
10. Wang AA, Hutchinson DT. The effect of corticosteroid injection for trigger finger on blood glucose level in diabetic patients. J Hand Surg 2006;31A:979-981
11. Baumgarten KM. Current treatment of trigger digits in patients with diabetes mellitus. J Hand Surg 2008;33A:980-981.
12. Lapidus PW, Guidotti EP: Stenosing tenovaginitis of the wrist and fingers. *Clin Orthop* 83:87-90