EDITOR'S CHOICE

Comparison of Treatment Outcome After Collagenase and Needle Fasciotomy for Dupuytren Contracture: A Randomized, Single-Blinded, Clinical Trial With a 1-Year Follow-Up

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Purpose This study compared the efficacy of collagenase treatment and needle fasciotomy for contracture of the metacarpophalangeal (MCP) joint in Dupuytren disease.

Methods This is a prospective, single-blinded, randomized study with follow-up 1 week and 1 year after treatment. One hundred and forty patients with an MCP contracture of 20° or more in a single finger were enrolled, of whom 69 patients were randomized to collagenase treatment and 71 patients to needle fasciotomy. The patients were followed at 1 week and were examined by a physiotherapist after 1 year. Measurements of joint movement and grip strength were recorded as well as patient-perceived outcomes measured by the Unité Rhumatologique des Affections de la Main (URAM) questionnaire and a visual analog scale (VAS) for the estimation of procedural pain and subjective treatment efficacy.

Results Eighty-eight percent of the patients in the collagenase group and 90% of the patients in the needle fasciotomy group had a reduction in their MCP contracture to less than 5° 1 week after treatment, and the median gains in passive MCP movement were 48° and 46°, respectively. The median VAS score for procedural pain was 4.9 of 10 in the collagenase group and 2.7 of 10 in the needle fasciotomy group. After 1 year, 90% of the patients in both groups had full extension of the treated MCP joint. One patient in each group had a recurrence of the contracture. The median improvement in URAM score was 8 units in both groups and the VAS estimation of treatment efficacy by the patients was 8.7 of 10 in both groups.

Conclusions There was no significant difference between the treatment outcomes after collagenase and needle fasciotomy treatment after 1 year. *(J Hand Surg Am. 2016;41(9):873–880.*

Type of study/level of evidence Therapeutic I.

Key words Dupuytren, collagenase, needle fasciotomy, needle aponeurotomy, percutaneous needle fasciotomy.

Podcast

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THE DIVISION OF THE CORD THAT TETHERS the finger in Dupuytren disease (DD), open fasciotomy, was described as early as the 18th century.[1] Corticosteroid injection in the cord, followed by manipulation, was described in 1957,[2] and this method was eventually developed into needle fasciotomy,[3] which became a popular method in some European countries in the 1990s.[4] Collagenase *clostridium histolyticum* (CCH) was introduced in 2009[5] and was approved by the European Medicines Agency in 2011 as a treatment for DD. Collagenase treatment and needle fasciotomy have common characteristics in their mode of action: both methods disrupt the cord while leaving the bulk of the pathological collagen intact and both methods allow an outpatient treatment option compared with more invasive surgical treatments, such as limited fasciectomy. A retrospective study comparing the 2 methods was published in 2013[6] and indicated that both methods were useful in early cases of DD. However, the differences in costs are considerable.[7] In this study, the cost of 1 dose of CCH was 650 euros (approximately $730 USD) compared with approximately 15 euros (approximately $20 USD) for material, local anesthetics, and corticosteroids for needle fasciotomy. There are also differences in the resources that are needed, because collagenase treatment requires 2 visits to the outpatient clinic, whereas needle fasciotomy can be performed on a single visit.

The hypothesis for the current study was that there would be no significant difference in outcome between the 2 methods, either directly after treatment or after 1 year. The metacarpophalangeal (MCP) joint was chosen as the primary joint to compare the 2 methods, because this joint is not prone to secondary stiffness and is generally easier to treat than the proximal interphalangeal (PIP) joint.[8]

MATERIALS AND METHODS

Study design

This is a prospective, single-center, randomized, single-blinded, parallel-group study. The study took place at the department of hand surgery where all patients were included and treated by the same hand surgeon (J.S.) between October 2012 and May 2014, with follow-up 1 year after treatment by a physiotherapist who was unaware of which of the treatments each patient had received. The primary end point was a straight finger, defined as reduction in extension deficit in the affected MCP joint to 5°. Secondary end points were patient-reported outcomes and the presence of complications such as skin ruptures and hematomas. Patient evaluation used the visual analog scale rating for pain,[9] as well as a specific questionnaire for Dupuytren contracture, the Unité Rhumatologique des Affections de la Main (URAM) scale.[10]

The study was approved by the Regional Ethical Committee (Etiska Prövnings Nämnden 513-12).

Patient population

Eligible participants were all adults with DD with a palpable cord and an extension deficit of at least 20° in the MCP joint in a single finger. Concomitant PIP joint contracture was not regarded as an exclusion criterion if the patient accepted that the MCP joint contracture was the primary joint to be treated.

Exclusion criteria included any other prior treatment or operation on the finger to be treated, any other pathological condition or limited range of motion in the finger to be treated, any contraindications to CCH treatment—for example, anticoagulant therapy or treatment with acetylsalicylic acid exceeding 150 mg/d—any clinical signs or medical records indicating ongoing alcohol or drug abuse, and any chronic neuromuscular disease compromising hand function. All patients with DD referred to the department of hand surgery were assessed for the study and those who met the inclusion criteria signed a letter of consent after receiving full written information.

The patients were included consecutively throughout the study, with a new treatment cycle initiated whenever 10 patients had been accumulated on the waiting list. A treatment cycle included treatment (either collagenase or needle fasciotomy, with 1 visit in the needle fasciotomy group and 2 in the collagenase group), a 7-day follow up, and a blinded follow-up after 1 year (Fig. 1). Groups of 10 patients were treated in 1 cycle, in which 5 patients were randomized to collagenase and 5 to needle fasciotomy, according to computer-generated block randomization prior to treatment. The administration of both collagenase and needle fasciotomy was performed under sterile conditions in a minor procedure room on the outpatient ward for logistical reasons, but the extension maneuver after collagenase, as well as the follow-up visit after 1 week, took place in an office examination room. One specific goniometer (Zimmer, Lauf/Baden, Germany) and 1 dynamometer (North Coast Medical, Gilroy, California) were used for measurements throughout the study.

Collagenase group: Day 1: The patient's forearm was prepared to sterile conditions and draped with an arm cover in the operating room. Collagenase *clostridium histolyticum* 0.58 mg (Xiapex; Pfizer, New York, NY) was reconstituted in 0.39 mL of sterile diluent