TITLE: Proposal for Treatment of Severe Dupuytren Disease in 2 Steps: Progressive Distraction With External Fixator and Collagenase - A Preliminary Case Series

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INTRODUCTION

Dupuytren disease (DD) is characterized by progressive flexion deformity of one or more fingers due to a benign proliferation of fibroblasts associated with increased accumulation of collagen in the palmar aponeurosis. In the late stages of DD, surgical treatment is challenging due to limited anatomical space and soft tissue contracture, increasing the risk of complications and incomplete correction. Over the past 10 years, nonsurgical treatments, like collagenase, have represented another therapeutic option for managing this as-yet incurable disease. For these severe cases, we propose a 2-step technique based on external fixation followed by collagenase injection, aiming at extension of the contracted fingers. Indications for this treatment are severe DD stages 3 and 4 affecting no more than 2 fingers, even if recurrence, without contracted arthritic joint.

Due to its dorsal positioning, the device we used is particularly comfortable for patients, leaving free the other finger sides. As for the collagenase, the European Commission's approval for the only formulation available (Xiapex) was obtained in 2010. The product was approved in Italy in February 2013 (GU Serie Generale n.49 del 27-02-2013)[1], for contractures of the metatarsophalangeal joint (MPJ) ranging from 20° to 50° and for contractures of the proximal interphalangeal joint (PIPJ) between 15° and 40° (eligibility criteria, source AIFA—the Italian Drugs Agency).

Our proposal for treatment arises from the fact that even if the common algorithm of single joint injections with monthly intervals has changed (following multiple reported experiences in the medical literature)[2], the Italian National Health System covers only the expense for one collagenase injection per hand for DD stages 1 and 2. Given that severe DD stages 3 and 4 generally involve MPJ and PIPJ simultaneously, a single injection is not enough to treat both of the articulations[1]. Therefore, it is mandatory to decrease the severity of the disease; in such cases, patients can benefit from a completely public health system–covered treatment.

MATERIALS AND METHODS

Between October 2014 and September 2016, we performed 22 treatments in 18 patients with DD stages 3 and 4 according to the Tubiana classification[3]. Seven cases were recurrences of DD previously treated with open aponeurectomy. Informed consent was collected from each patient, and approval by our ethics committee was obtained before study initiation (code: Miniflo-ITAl4) for the use of external fixator (EF) MiniFlo, developed by Citieffe (Bologna, Italy). This device is a single-bar articulated transarticular hinged EF, placed dorsally on the affected fingers via 4 self-drilling pins, applied using a percutaneous technique after determination of the joint center of rotation. The device is available in 2 different configurations to treat a single affected joint (PIPJ and MPJ—model R25) or for treatment of both PIPJ and MPJ simultaneously (model R30).

Increasing digital extension was performed by the patients by operating a worm screw in the hinge of the EF with a custom wrench. The palmar side of the treated fingers remained free to perform daily life activities. Inclusion criteria for participation in the trial were the following: adults aged 18 years or older, DD stages 3 to 4, absence of arthritis at MPJ-PIPJ, no more than 2 fingers treated simultaneously, and patient's motivation; exclusion criteria were the following: mental illness; unwillingness to undergo follow-up visits; DD stage 0, 1, or 2; joint ankylosis; and pregnancy and nursing mothers.

The treatment protocol was the same in all cases and comprised 2 steps:

Step 1: Fixator Application and Progressive Distraction

The EF is applied by placing the patients in the supine position in the operating, with the affected limb placed on a radiolucent arm board for fluoroscopy. Local anesthesia (10 mL mepivacaine chlorhydrate—20 mg/mL—digital block) is performed in the affected fingers. The choice between the 2 EF models depends on the contraction discrepancy at the MPJ and PIPJ: in our cases, if the contraction severity was similar in both of the articulations, we used the R30 model to treat them together; the R25 model was used instead to correct a more contracted PIPJ compared with a less involved MPJ. In this way, it is also possible to treat a "reverse" situation, that is, a more contracted MPJ opposed to a less severe PIPJ. Under fluoroscopic control, in lateral view a 1.5-mm Kirschner wire is inserted percutaneously with a power drill on the dorsal aspect of the bone: for PIPJ correction, it is directed to the joint center of rotation, corresponding to the center of the head of the proximal phalanx in lateral view; for simultaneous correction of PIPJ and MPJ, the center of rotation is established by considering the bisector of the angle between the axes of the metacarpal and the middle phalanx. Hence, the Kirschner wire direction lies approximately on a perpendicular line to the middle point of the proximal phalanx in the lateral view. A ruler guide is stored in the device container, to be more precise. The EF slides along the Kirschner wire and, once in place, is fixed with a self-drilling pin in the most proximal clamp; the second pin is inserted in the distal clamp followed by the remaining 2 pins. At the end of the procedure, the Kirschner wire is removed. It is important to leave at least 5 mm between the skin and the EF for pin care.

The patients start progressive extension the day after surgery by turning the worm screw 1 full turn a day, corresponding to 3°. Usually, we suggest patients to split the full turn into 2 half turns, one in the morning and the other in the evening, for better compliance and pain control.

Weekly checks are planned to evaluate pain and discomfort and any adverse events and to check whether the patients were applying the correct amount of distraction. The EF is removed in the outpatient clinic without anesthesia, after reaching a complete device extension at an average of 19 days (15-22 days).

After EF removal and before collagenase injection, all the patients had undergone physiotherapy and local skin treatments plus capsuloligamentous stretching, associated with splinting and assisted mobilization, for a mean period of 20 days (18-24 days).

Step 2: Collagenase Procedure

According to international guidelines Clostridium histolyticum collagenase (Xiapex [Sobi]) is injected in the residual palmar MPJ cord in the treated digital ray. The next day, cord rupture is obtained by finger manipulation and distraction under local anesthesia (4 mL mepivacaine chlorhydrate—20 mg/mL). Previous distraction with EF considerably decreases the risk of skin lacerations after manipulation, a rather common eventuality especially in high-grade contractures with tight skin adhesion.

Subsequently, a customized thermoplastic dorsal traction splint is applied. Patients wear the splint for 21 days, around 22 hours a day, whereas the remaining 2 hours are dedicated to active and passive finger mobilization assisted by physical therapist. After that, the splint is worn only at night for an additional 6 weeks.

STATISTICAL ANALYSIS PLAN (SAP)

The study is designed as a preliminary case series without a control group, and the statistical analysis is primarily descriptive. Continuous variables, such as angular deformity and correction degrees, are summarized using means and ranges, allowing a quantitative assessment of treatment effect across time points (pre-treatment, post–external fixation, and follow-up). Pain intensity is evaluated using the Visual Analog Scale (VAS) and similarly reported as mean values with ranges. No inferential statistical tests (e.g., hypothesis testing, p-values, or confidence intervals) are described, reflecting the exploratory nature and limited sample size of the cohort. Outcomes are reported longitudinally, with comparisons made within subjects over time rather than between groups, and results are presented in tabular form to illustrate individual and aggregate changes in joint contracture.

REFERENCES

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