Limited Fasciectomy Versus Collagenase *Clostridium histolyticum* for Dupuytren Contracture: A Propensity Score Matched Study of Single Digit Treatment With Minimum 5 Years of Telephone Follow-Up

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Purpose The purpose of this study was to compare reintervention and perceived recurrence, with minimum 5 years of telephone follow-up, after limited fasciectomy or collagenase *Clostridium histolyticum* (CCH) in the treatment of Dupuytren contracture affecting a single digit.

Methods We performed a retrospective cohort study of 48 patients with single digit treatment who underwent limited surgical fasciectomy at one hospital and 111 patients who underwent CCH treatment at a second hospital from 2010 to 2013. Patients were contacted by telephone about reintervention and perceived recurrence. Average length of telephone follow-up was 7.3 years in the CCH group and 7.4 years in the surgery group. The 2 groups were compared using 2 methods to control for potential confounding bias: (1) propensity score matching and (2) multivariable analysis accounting for potential confounders.

Results After propensity score matching, there were 44 patients in each group with similar disease and demographic characteristics. Rates of reintervention and perceived recurrence were significantly higher in the CCH group than the surgery group at a minimum of 5 years following treatment.

Conclusions Long-term overall reintervention and perceived recurrence following treatment of Dupuytren contracture affecting a single digit were higher with CCH treatment than surgical fasciectomy when comparing groups with similar baseline characteristics. Our findings may be used to counsel patients on the durability of the outcomes of treatment when considering treatment options for Dupuytren contractures. *(J Hand Surg Am. 2021;46(10):888−895. Copyright © 2021 by the American Society for Surgery of the Hand. All rights reserved.)*

Type of study/level of evidence Therapeutic IV.

Key words Collagenase *Clostridium histolyticum*, Dupuytren contracture, fasciectomy, patient satisfaction, recurrence.

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Dupuytren disease is a fibroproliferative disorder of the palmar fascia that can cause considerable functional impairment due to formation of progressive digital flexion contractures.[1] Treatment options for Dupuytren contracture include limited surgical fasciectomy, needle aponeurotomy, and collagenase *Clostridium histolyticum* (CCH) treatment.[2] Since its inception, CCH treatment has been increasingly utilized for the treatment of Dupuytren contracture[3,4]; however, its long-term durability is not well described.

Comparative studies between CCH treatment and surgical fasciectomy for Dupuytren contracture are limited.[5–7] To our knowledge, no study has directly compared long-term disease reintervention and recurrence following CCH treatment and surgical fasciectomy.

The primary objective of this study was to determine rates of reintervention after limited surgical fasciectomy compared to CCH treatment for Dupuytren contracture of a single digit with minimum 5 years of follow-up by phone. The secondary objective was to evaluate differences in perceived contracture recurrence between the 2 groups. Our null hypothesis was that there was no difference in patient-reported reintervention between limited surgical fasciectomy and CCH treatment of Dupuytren contractures.

MATERIALS AND METHODS

Study design

This study was performed with institutional review board approval. A retrospective study was performed comparing surgical fasciectomy and CCH treatment for the primary treatment of single digit Dupuytren contractures at 2 tertiary referral centers in the same metropolitan region from 2010 to 2013. Exclusion criteria included treatment of more than 1 digit simultaneously, previous treatment of the affected finger prior to enrollment, lack of contracture (ie, nodule excision only), treatment for first web space contracture, and follow-up less than 5 years. If a patient had more than 1 qualifying intervention during the study period, only the first intervention was included to maintain the assumption of independent observations. Patient selection was stratified by hospital because, during the study period, surgical fasciectomy was the sole treatment offered at hospital 1, and only CCH treatment was performed at hospital 2.

Patients who underwent surgical fasciectomy at hospital 1 were identified using Current Procedural Terminology (CPT) codes 26121 (Fasciectomy, palmar only, with or without z-plasty, other local tissue rearrangement, or skin grafting [includes obtaining graft]) and 26123 (Fasciectomy, palmar only, with or without z-plasty, other local tissue rearrangement, or skin grafting [includes obtaining graft]; partial palmar excision with release of single digit including proximal interphalangeal joint). Fasciectomies were performed by 1 of 6 subspecialty-certified hand surgeons at hospital 1.

Patients who underwent CCH treatment at hospital 2 were identified using an internal billing records database for CCH treatment. CCH injections and subsequent manipulation were performed by 1 of 4 subspecialty-certified hand surgeons practicing at hospital 2. All patients received 0.58 mg CCH per digit per treatment. All manipulations were performed in the office 1 to 8 days after CCH injection, using local anesthesia. The median and mode day of manipulation was 1 day after CCH injection.

All patients were prescribed a splinting and therapy protocol after treatment; however, the protocol was not standardized among providers.

Outcome variables

Patients in our final cohort were contacted by telephone at a minimum of 5 years after intervention for Dupuytren contracture. Telephone follow-up was conducted by a hand-fellowship trained orthopedic surgeon, an orthopedic resident, and a research assistant using a script.[8] Patients were asked (1) whether they underwent any type of reintervention for the affected digit and (2) whether their contracture recurred. Additional CCH treatment was defined as CCH injection and manipulation for the same digit at least 3 months after the initial CCH treatment. Repeat CCH treatments within 3 months of the initial CCH injection were counted as part of the initial treatment plan, similar to the treatment approach described in the phase 3 clinical trial establishing its efficacy.[9]

Explanatory variables

The following patient-related explanatory variables were studied: age, sex, body mass index, diabetes mellitus, smoking status, American Society of Anesthesiologists Physical Status Classification, and Charlson Comorbidity Index.[10] Body mass index closest to the date of CCH injection, within 1 year before or after CCH injection, was used for analysis.

The following disease-specific explanatory variables were studied: laterality, digit treated (little finger, ring finger, or other), isolated metacarpophalangeal joint (MCP) involvement, isolated proximal interphalangeal joint (PIP) involvement,

TABLE 1. Comparison of Baseline Patient and Disease Characteristics of Patients Undergoing CCH Versus Surgical Fasciectomy Before and After Propensity Score Matching

	Before Propensity Score Matching (n = 159)			After Propensity Score Matching (n = 88)		
Patient Disease Characteristics	CCH (n = 111) Mean (SD)	Surgery (n = 48) Mean (SD)	Std. Diff.	CCH (n = 44) Mean (SD)	Surgery (n = 44) Mean (SD)	Std. Diff.
Age	64 (9.2)	71 (8.6)	0.74	68 (7.2)	70 (8.8)	0.34
Body mass index*	26 (3.8)	25 (4.7)	−0.09	26 (3.7)	26 (4.9)	−0.04
	Median (IQR)	Median (IQR)		Median (IQR)	Median (IQR)	
Modified CCI	2 (2 to 4)	3 (2 to 4)	0.23	2 (2 to 3)	3 (2 to 4)	0.16
	n (%)	n (%)		n (%)	n (%)	
Male	81 (73)	33 (69)	0.09	31 (70)	31 (70)	0.00
Smoking	12 (11)	6 (13)	0.05	5 (11)	6 (14)	0.07
Diabetes mellitus	9 (8.1)	3 (6.3)	0.07	2 (4.6)	3 (6.8)	0.10
ASA						
I	31 (28)	13 (27)	0.57	14 (32)	12 (27)	0.23
II	60 (54)	34 (71)		30 (68)	31 (70)	
III	20 (18)	1 (2.1)		0 (0)	1 (2.3)	
Right laterality	66 (59)	27 (56)	0.07	26 (59)	26 (59)	0.00
Digit affected						
Little finger	67 (60)	29 (60)	0.23	28 (64)	28 (64)	0.08
Ring finger	33 (30)	11 (23)		11 (25)	10 (23)	
Other finger	11 (9.9)	8 (17)		5 (11)	6 (14)	
Isolated MCP disease*	41 (37)	9 (22)	0.33	13 (30)	9 (20)	0.21
Isolated PIP disease*	32 (29)	25 (61)	0.68	20 (45)	22 (50)	0.09
MCP & PIP disease*	33 (30)	7 (17)	0.30	6 (14)	7 (16)	0.06
	Median (IQR)	Median (IQR)		Median (IQR)	Median (IQR)	
MCP FFC*	35 (0 to 55)	0 (0 to 45)	−0.51	0 (0 to 40)	0 (0 to 40)	0.00
PIP FFC*	35 (0 to 50)	45 (15 to 60)	0.26	45 (0 to 52.5)	40 (15 to 55)	0.07
DIP FFC*	0 (0 to 0)	0 (0 to 0)	0.12	0 (0 to 0)	0 (0 to 0)	−0.14
Total FFC*	60 (45 to 85)	50 (45 to 80)	−0.18	55 (45 to 72.5)	60 (47.5 to 60)	−0.05

ASA, American Society of Anaesthesiologists Physical Status Classification; CCI, Charlson Comorbidity Index; DIP, distal interphalangeal; IQR, interquartile range; MCP, metacarpal; PIP, proximal interphalangeal; Std. Diff., standardized difference.

*Body mass index was available for 151 (95%) patients, joint involvement for 152 (96%) patients, MCP and DIP FFC for 152 (96%) patients, and PIP and total FFC for 149 (94%) patients.

both MCP and PIP involvement, and fixed flexion contracture (FFC) of the MCP, PIP, distal interphalangeal joint (DIP), and total digit (combined MCP, PIP, and DIP).

Patient selection

From the initial screen, 180 patients from hospital 1 treated with surgical fasciectomy for Dupuytren contractures were identified, and telephone contact for follow-up was attempted. Sixty-seven patients were excluded for treatment of 2 or more digits simultaneously, 21 patients were excluded because they had undergone prior treatment on the affected finger, and 2 patients were excluded for nodule excision only. Three patients were deceased at time of follow-up, and 6 patients had no available telephone number in our medical records. Twenty-four patients were unable to be reached, and 6 patients declined to participate. Our response rate was 63% (51/81). Three additional patients were excluded for

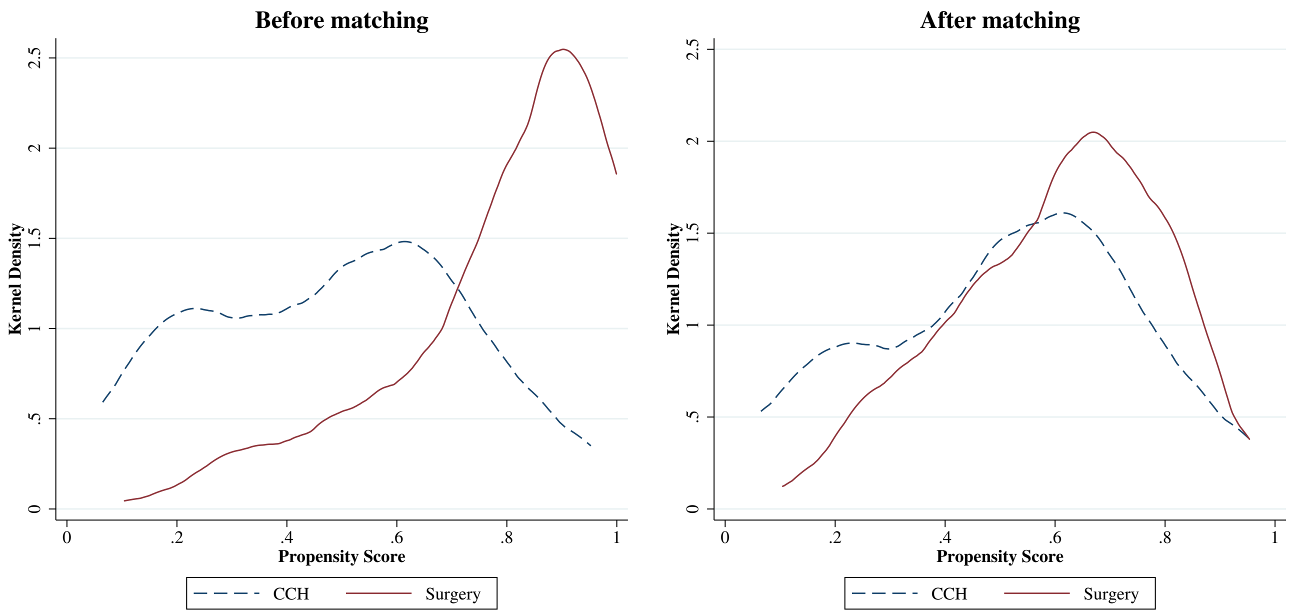

FIGURE 1: Kernel density plot shows the distribution of the propensity score before and after matching, demonstrating the adequacy of propensity score matching.

missing primary outcome variable data. A final cohort of 48 patients with single digit fasciectomy were included.

From the initial screen, 261 patients from hospital 2 treated with CCH for Dupuytren contractures were identified, and telephone contact for follow-up was attempted. Sixty-three patients were excluded for treatment of 2 or more digits simultaneously, 25 patients were excluded because they had undergone prior treatment on the affected finger, and 4 patients were excluded for treatment of first web space contractures. Twenty-one patients were deceased at time of follow-up, and 10 patients had no available telephone number in our medical records. Seven patients were unable to be reached, and 16 patients declined to participate. Our response rate was 78% (115/148). Four additional patients were excluded for missing primary outcome variable data. A final cohort of 111 patients treated for single digit CCH were included.

Statistical analysis

Descriptive statistics for explanatory variables were calculated for the study cohort. Histograms were created to assess normal versus non-normal distribution of continuous variables. For continuous variables, bivariate analysis was performed using a *t* test or Mann-Whitney U test, depending on normality of distribution. Fisher exact test was used for categorical variables. Missing values were excluded case-wise in bivariate baseline analyses and are indicated in Table 1.

Two methods were used to control for potential confounding bias: (1) propensity score matching,[11] and (2) multivariable analysis accounting for potential confounders.[12] Propensity score matching was performed to reduce imbalance in potentially confounding explanatory variables that could exist between the 2 study groups. Propensity score matching utilized a probability score of group assignment (limited fasciectomy versus CCH treatment) based on all included explanatory variables using a logistic regression model. This so-called propensity score was then used to match patients in both treatment groups. Subsequently, balance in specific covariates (explanatory variables) was assessed between groups. A kernel density plot demonstrated the overlap of propensity score distribution of both groups before and after matching and helped elucidate balance. Finally, differences in outcome were tested between matched groups. Propensity score matching was conducted using a 1:1 nearest-neighbor matching in a random order without replacement and with a caliper fixed at 0.2 based on propensity score calculated through a logit model including all explanatory variables. Single median imputation was used for the missing values to allow for calculation of a propensity score through the logit model (See Table 1 footnote). Propensity score matching with these parameters matched 44 surgical cases (92%) to 44 CCH cases. Matched dichotomous variables were compared using the McNemar test. A kernel density plot was

TABLE 2. Bivariate Analysis of Outcomes in Patients Undergoing CCH Versus Surgical Fasciectomy After Propensity Score Matching

	Injection Group (n = 44)	Surgery Group (n = 44)	
Outcomes (n = 88)	n (%)	n (%)	*P* Value
Reintervention	22 (50)	7 (16)	<.05*
Recurrence	35 (80)	15 (34)	<.05*

*Indicates statistical significance.

used to illustrate the propensity score before and after matching, demonstrating the adequacy of matching (Fig. 1). Standardized differences were calculated to further demonstrate differences between treatment groups before and after propensity score matching by dividing the difference in mean or proportion of the covariates in both treatment groups by the pooled SD.

A nonmatched multivariable analysis of outcome measures was also performed by using logistic regression for dichotomous outcome measures and linear regression for continuous outcome measures as a second method of controlling for confounding bias. Multiple imputation (40 times) was used to account for missing values, and explanatory variables with a *P* value less than .10 were included in multivariable analyses.

With our sample size, we had over 80% power to detect a 35% difference in reintervention and perceived recurrence assuming a baseline recurrence rate of 50%. A 2-tailed *P* value less than .05 was considered significant.

RESULTS

The final cohort of 159 patients, including 111 patients treated with CCH and 48 patients treated with surgical fasciectomy, were matched by propensity score. Before propensity score matching, the 2 groups differed considerably with respect to age, American Society of Anesthesiologists Physical Status Classification, isolated PIP disease, and preintervention MCP FFC. After propensity score matching, there were 44 patients in each group with similar patient and disease characteristics (Table 1). The mean age was 68 years in the CCH group and 70 years in the surgery group, and most patients were males in both groups (70%). The little finger was the most involved digit in both groups (64%). The median preintervention total FFC was 55° in the CCH group and 60° in the surgery group. The average length of telephone follow-up was 7.3 years in the CCH group and 7.4 years in the surgery group.

TABLE 3. Multiple Imputed* Multivariable Analyses of Outcomes in Patients Undergoing CCH Versus Surgical Fasciectomy

Outcomes (n = 159)	Odds Ratio (95% Confidence Interval)	*P* Value
Reintervention	4.1 (1.6 to 11)	<.05†
Recurrence	6.0 (2.5 to 14)	<.05†

CCH, collagenase clostridium histolyticum.

*Missing values were imputed using multiple chained imputation (40x). Multivariable analysis accounted for age, ASA score, isolated PIP contracture, and MCP flexion contracture (variables with a *P* value <.10 on bivariate analysis).

†Indicates statistical significance.

After propensity score matching, reintervention was significantly higher in the CCH group (50%) than the surgery group (16%, *P* <.05). Perceived disease recurrence was significantly higher in the CCH group (80%) than the surgery group (34%, *P* <.05) (Table 2).

Nonmatched multivariable analysis of outcome measures demonstrated the same statistically significant relationships (Table 3). CCH treatment was associated with reintervention (Odds ratio [OR] 4.1, 95% confidence interval [CI] 1.6 to 11) and perceived disease recurrence (OR 6.0, 95% CI 2.5 to 14) compared with surgical fasciectomy at minimum 5 years of follow-up (Tables 4 and 5).

DISCUSSION

Comparative studies of the objective and subjective outcomes of various treatments for Dupuytren contractures are limited. Existing evidence often carries the risk of confounding bias, and studies with long-term follow-up are sparse.[6] In this study, we have

TABLE 4. Multiple Imputed* Multivariable Analyses of Outcomes in Patients Undergoing CCH Versus Surgical Fasciectomy

Outcomes (n = 159)	Odds Ratio (95% Confidence Interval)	*P* Value
Recurrence	6.0 (2.5 to 14)	<.05†
Reintervention	4.1 (1.6 to 11)	<.05†
Choose treatment again	0.60 (0.23 to 1.6)	.295
	Beta regression coefficient (95% confidence interval)	
Satisfaction	−1.5 (−2.6 to −0.35)	<.05†

*Missing values were imputed using multiple chained imputation (40x). Multivariable analysis accounted for age, ASA score, isolated PIP contracture, and MCP flexion contracture (variables with a *P* value of <.10 on bivariate analysis).

†Indicates statistical significance.

retrospectively compared objective and subjective treatment outcomes of surgical fasciectomy and CCH treatment with minimum 5 years of follow-up. To limit against physician selection bias, this study was performed at 2 tertiary referral centers with differing treatment approaches for Dupuytren contracture. To mitigate the risk of confounding bias, we performed propensity score matching as well as nonmatched multivariable regression analysis.

The rate of reintervention was higher after CCH treatment than surgical fasciectomy, which was consistent with the existing literature. At an average 7 years of follow-up, we found a reintervention rate of 50% for CCH treatment and 16% for surgical fasciectomy, which closely reflected the 5-year reintervention rate of 55% for CCH treatment and 4% for surgical fasciectomy reported by Leafblad et al.[13] The difference in reintervention rate after surgical fasciectomy between our study and the previously published literature may reflect longer duration of follow-up, surgeon differences, or patient preferences. In addition, our study excluded patients who had previously undergone treatment of the affected finger, which may have affected rates of recurrence and reintervention in both groups. However, the objective of our study was to determine outcomes of index procedures rather than revision procedures.

The rate of patient-perceived contracture recurrence after CCH treatment was significantly higher than after surgical fasciectomy. Our finding of an 80% perceived recurrence rate is higher than most reports in the literature, which may be partly attributable to longer follow-up in our study.[13] Peimer et al found recurrence rate to be 35% and 47% at 3 years and 5 years, respectively, following CCH treatment.[10,11] However, recurrence in these studies was defined as 20° or worsening of index contracture, whereas recurrence in our study was based on patient perception. Recurrence rates after surgical fasciectomy have ranged widely in the literature, from 0% to 73% depending on length of follow-up and definition of recurrence.[14,15] For example, studies on subtotal fasciectomy with 4 years of follow-up had recurrence rates of 14% and 23%,[16,17] and studies on fasciectomy with 6 years to 7 years of follow-up had recurrence rates of 39% and 73%.[18,19] However, the study by Jurisic et al that reported a 73% recurrence rate defined recurrence as development of any new lesion, such as a nodule, regardless of contracture. Our perceived recurrence rate of 34% was within this range.

TABLE 5. Stepwise Backward Multivariable Linear Regression Analysis* of Baseline Patient and Disease Characteristics Associated With Satisfaction After Treatment

Treatment (n)	Beta Regression Coefficient (95% Confidence Interval)	*P* Value
CCH (111)		
Isolated MCP disease	1.4 (0.23 to 2.6)	<.05†
Surgery (48)		
Diabetes mellitus	−3.2 (−6.2 to −0.29)	<.05†

*Explanatory variables with a *P* value below .10 on bivariate linear regression were included in the initial multivariable linear regression model. Stepwise backward selection was then used to select only those variables significantly (*P* < .05) associated with satisfaction per treatment group.

†Indicates statistical significance.

There are several limitations to this study. First, our follow-up was conducted over the telephone rather than in person. Although there are disadvantages to telephone follow-up,[20] our questions on reintervention and recurrence prompt binary answers, which may not vary as much between data collection methods. Second, 2 statistical methods were used to control for confounding bias (propensity score matching and multivariable analysis), but residual confounding might persist in both statistical approaches. Residual confounding can occur in both observed (but insufficiently balanced) and unobserved (not included/identified) variables. However, we feel that covariates were reasonably balanced after propensity score matching (Table 1, Fig. 1), and we feel that we included all known risk factors for reintervention and recurrence based on previous literature. We, therefore, believe that our findings are a result of difference in treatment and not a result of residual confounding. Only an experimental study design, like a randomized trial, would further eliminate confounding. The multivariable analysis supports the findings of our propensity score matched analysis; however, while the odds ratios suggest significant effects, the magnitude of the effects are unclear due to the wide confidence intervals. Third, in our study, CCH treatment and surgical fasciectomy were performed at 2 different tertiary referral centers by 2 different sets of surgeons, without standardization in preintervention counseling, which may have introduced variability. Similarly, although all patients were prescribed a splinting and therapy protocol postmanipulation and postoperatively, protocols were not standardized among providers, which may be a source of confounding bias. Fourth, patients' perception of their own recurrence is subjective and may not correspond to clinician-measured recurrence. In addition, many years after the intervention, patient-reported outcomes may be susceptible to recall bias. However, especially in the context of a process like Dupuytren disease, which is nonlethal and in which treatment is indicated for subjective functional limitations, we believe that patient perceptions of treatment success or failure are germane. Fifth, we have studied the results of CCH treatment at a single hospital in the early years after U.S. Food and Drug Administration approval. It is possible that techniques may have evolved over time, limiting the generalizability of our results to present-day treatment. Sixth, after matching, both groups have more PIP joint involvement compared to MCP joint involvement, and CCH is less effective in treatment of PIP contractures, which may account for differences in reintervention and perceived recurrence.[10,11] However, poorer outcomes of PIP contractures following fasciectomy have also been reported.[21] The baseline characteristics of our cohort limit the generalizability of our results to isolated MCP contractures. Finally, while we have compared CCH treatment and surgical fasciectomy, we are unable to comment on the comparative outcomes of needle aponeurotomy in this study.

We have presented a propensity score-matched comparative study of single digit Dupuytren contracture treatment with surgical fasciectomy versus CCH with minimum 5 years of follow-up. CCH treatment is associated with higher rates of long-term reintervention and perceived disease recurrence compared with surgical fasciectomy. When deciding between CCH treatment and surgical fasciectomy for the treatment of single digit Dupuytren contractures, our results reiterate the importance of counseling patients on not only short-term recovery but also on long-term durability of treatment options.

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