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HANDSURGERY

Range of motion, postoperative rehabilitation and patient satisfaction in MCP and PIP joints affected by Dupuytren Tubiana stage 1–3: collagenase enzymatic fasciotomy or limited fasciectomy? A clinical study in 52 patients

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Abstract

Introduction In Switzerland, collagenase *Clostridium histolyticum* therapy (CCH) for Dupuytren's disease was introduced in 2011. This study analyzes possible differences between CCH and limited fasciectomy (LF) in terms of range of motion, patient satisfaction and postoperative rehabilitation.

Materials and methods This retrospective study included 52 patients with Dupuytren's disease stage 1–3 according to Tubiana, treated with CCH or LF between January 2012 and December 2013. Complications were analyzed for each patient. The contracture of each treated joint measured on average at the 3 months and up to 2 years follow-up was compared with the preoperative values. The Michigan Hand score was evaluated at 2 years and the patients were asked to subjectively evaluate the outcome of the treatment and whether they would repeat it if necessary. Postoperative rehabilitation was also precisely quantified.

Results 11 minor complications were reported for a complication rate of 29% in the CCH group. No major complications were reported in both groups. In the CCH group, mean MCP joint contracture was, respectively, $44° \pm 20°$, $9° \pm 2°$ (gain of mobility compared to the preoperative situation 35°, $P < 0.001$), and $10° \pm 3°$ (gain 34°, $P < 0.001$), respectively, before, at the 3 months' control and at the 2-year clinical control. In the LF group, mean MCP joint contracture was, respectively, $30° \pm 21°$, $2° \pm 0.5°$ (gain 28°, $P < 0.001$), and $1° \pm 0.5°$ (gain 29°, $P < 0.001$) for the same control periods. In the CCH group, mean PIP joint contracture was, respectively, $51° \pm 21°$, $18° \pm 3°$ (gain of mobility compared to the preoperative situation 33°, $P < 0.001$), and $32° \pm 4°$ (gain 19°, $P < 0.001$), respectively, before, at the 3 months' control and at the 2-year clinical control. In the LF group, mean PIP joint contracture was, respectively, $30° \pm 20°$, $2° \pm 0.5°$ (gain of mobility compared to the preoperative situation 28°, $P < 0.001$), and $11° \pm 4°$ (gain 19°, $P < 0.001$) for the same control periods. Outcomes were compared across the LF and CCH groups: surgery performed better than collagenase for PIP joint treatment at early ($P < 0.001$) and 2-year follow-up ($P = 0.004$) controls. However, patient satisfaction was higher in the CCH group: 92% were satisfied or very satisfied of the treatment compared to 71% in the LF group. All patients would reiterate the treatment in the CCH group if necessary compared to only 71% in the LF group. Rehabilitation was highly reduced in the CCH group compared to the LF group.

Conclusion In this study, surgery performed better than collagenase at early and 2-year follow-up in PIP joints and similar in MCP joints. While surgery seems to achieve better results, collagenase is considered in Switzerland as an off-the-shelf therapy that provides consistent results without scars, with shorter rehabilitation time, minor hand therapy, shorter splinting time, and applicability.

Level of evidence and study type Level III.

Keywords Flexion-contracture · Dupuytren's disease · Xiapex · Limited fasciectomy

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Introduction

Dupuytren's disease is a benign connective tissue disorder affecting the palmar fascia [1–4] that can lead to flexion contracture of the metacarpophalangeal (MP) joints and the proximal interphalangeal (PIP) joints [5–12]. Controversy exists about the relative efficacy of injectable collagenase *Clostridium histolyticum* (CCH) and limited aponeurectomy in the treatment of Dupuytren's contracture in long term [13–16]. Recently, Smeraglia et al. performed a comprehensive review of studies dealing with CCH for Dupuytren's disease [17]. They concluded that the use of collagenase provides better short-term outcomes in patients with mild to moderate joint contracture, with lower complications and side effects than open fasciectomy.

In Switzerland CCH therapy was introduced in 2011, 11 years after the first study on patients with dupuytren disease was approved [18]. The first German-speaking Switzerland prospective study was performed in our hand center as early as 2012 [19]. Published in 2013, results demonstrated the efficacy and low rate of complications of CCH [19]. Five years after the initial treatment this new study aims to compare the efficacy, postoperative rehabilitation, and patient satisfaction after CCH or segmental fasciectomy using the gold standard mini incision technique. We discuss our results and the limitations of our study.

Materials and methods

This retrospective clinical study was conducted in accordance with the ethical guidelines of the University of Bern (KEK Nr.: 147/11, Kantonale Ethikkommission Bern). Study inclusion criteria were patients with Dupuytren's disease stage 1–3 according to Tubiana, aged 18 years or older, treated at the university hospital with injectable collagenase or limited fasciectomy, between January 2012 and December 2013. Exclusion criteria included concomitant hand conditions or surgeries (e.g., carpal tunnel release) on the affected side, and the lack of baseline data on the degree of contracture, as well as fixed joint contractures of the involved ray. 54 patients met the study criteria. Two patients were lost to follow-up.

Patients

Patients were divided into two groups depending on the type of treatment performed for their affected fingers. Group 1 included 50 fingers in 38 patients treated with collagenase (CCH). Group 2 included 18 fingers in 14 patients treated with limited fasciectomy (LF). There was no statistical difference in the terms of baseline parameters (age, gender, digit, Tubiana stage) in both groups. However, collagenase patients had slightly worse mean extension deficits (MCP: $44° \pm 20°$, PIP: $51° \pm 21°$) than surgery patients (MCP: $30° \pm 21°$; PIP: $30° \pm 20°$) (Table 1).

Technique in group 1

The size and extension of the Dupuytren's cord was analyzed with Ultrasonography (iU-22 system, 17.5 MHz, Philips Medical Systems, Andover, MA, USA) before Orphan Biovitrum AB collagenase *Clostridium histolyticum* (Xiapex®, Sobi Swedish, Orphan Biovitrum AB) was administered according to the manufacturer's recommendations, without local anesthesia but along the cord according to the sonographic clinical findings. Injections were limited to 0.25 ml and 0.20 ml for metacarpophalangeal and proximal interphalangeal joint contractures, respectively, corresponding to a dose of constituted Xiapex of 0.58–0.78 mg. Compressive dressings were applied afterwards.

Post treatment, patients received anti-inflammatory medication to mitigate potential adverse effects such as pain, inflammation, lymphangitis or lymphadenopathy. Treated fingers were manipulated at 24 h under local anesthesia (Mepivacain 1%) to attempt rupturing the weakened cords. Up to three injections were offered at a minimal of 4-week intervals if subjects were dissatisfied with the achieved level of contracture correction. All patients were put on an extension splint covering the palm and the involved and neighboring fingers, but without the wrist at night. Patients got night splinting until 3 months and minor hand therapy after the first instructions and fitting of the splints.

Surgical technique in group 2

Limited fasciectomy was performed with tourniquet exsanguination and loupe magnification under axillary block or general anesthesia in an operating theater. Cords were approached and excised using Bruner type incisions with Z-plasties in the digit but with skoog type incisions in the palm. Care was taken to prevent injury to the digital neurovascular bundles. The surgically treated patients received a scotch cast splint in extension of wrist and all involved digits after surgery that was changed after 3–5 days to a short splint like in CCH patients. Treatment of the scars started after removal of the stitches and or complete wound healing at 2 weeks. The extension splint was worn at night and in some patients for an additional 2–3 h at daytime when extension remained a problem. All patients were offered intensive hand therapy 1–2 times a week with instructed use of removable night splints for 3–6 months according to the scar maturation and remaining extension deficit.

Table 1 Patient demographics and baseline pre-intervention characteristics

	All patients	Collagenase	Surgery	*P* value
No. of patients	*N* = 52	*N* = 38	*N* = 14	
Age at baseline	64.0 ± 10.4	64.7 ± 9.7	61.9 ± 12.2	0.391
Sex (w)	8 (15%)	5 (13%)	3 (21%)	0.666
Multiple collagenase injections		5 (13%)		
No. of digits treated per patient				0.508
1	38 (73%)	28 (74%)	10 (71%)	0.738
2	12 (23%)	8 (21%)	4 (29%)	0.485
3	2 (4%)	2 (5%)	0 (0%)	1.000
No. of digits	*N* = 68	*N* = 50	*N* = 18	
Right hand	36 (53%)	27 (54%)	9 (50%)	0.790
Digit				0.858
DIG II	1 (1%)	1 (2%)	0 (0%)	1.000
DIG III	4 (6%)	3 (6%)	1 (6%)	1.000
DIG IV	33 (49%)	23 (46%)	10 (56%)	0.586
DIG V	30 (44%)	23 (46%)	7 (39%)	0.783
MCP joints treated	53 (78%)	39 (78%)	14 (78%)	1.000
PIP joints treated	40 (59%)	29 (58%)	11 (61%)	1.000
MCP and PIP treated	25 (37%)	18 (36%)	7 (39%)	1.000
Pre PED MCP (°)	40.2 ± 21.3	43.7 ± 20.4	30.4 ± 21.2	0.062
Pre PED PIP (°)	45.4 ± 23.0	51.3 ± 21.3	30.0 ± 20.9	0.012
Pre PED Total (°)	58.0 ± 36.1	63.8 ± 36.7	41.9 ± 29.5	0.033
Days from procedure to follow-up	44.1 ± 21.9	44.6 ± 23.7	42.8 ± 16.7	0.727

Assessment of complications

Patient charts and 2-year follow-up examination were used to assess complications. Complications were divided into minor (that did not require surgery) and major (that did require surgery) complications. Regarding minor complications, special attention was given to local hematoma, edema, intradermal blistering, per secundam wound healing, lymphangitis, lymphadenopathy hyperpigmentation, and prolonged alterations in sensitivity.

Objective assessment

Patient charts and 2-year follow-up examination were used to assess the mobility of the involved finger joints, wound healing, and scar maturation. Active and passive motion of the MCP and PIP joints was measured with a goniometer before the operation and 3 months (< 100 days) and 2 years post treatment. Postoperative rehabilitation including the number of required hand therapy sessions was noted.

Subjective assessment

At the 2-year follow-up checkup, patients were asked to score the pain during the whole follow-up on a visual analogue scale (VAS: 0 = no pain; 10 = excruciating pain). The Michigan Hand Questionnaire (MHS) was evaluated at the final follow-up [20]. The six subscales were calculated using the algorithm published by Chung et al. [21]. Raw figures were converted into a score ranging from 0 to 100. Higher scores indicate better performance, except for the pain subscale, where a higher score denotes more pain. The MHQ total score was obtained by adding the scores for all six subscales (after reversing the pain scale) and then dividing the sum score by 6 [20]. The patients were asked to evaluate their satisfaction (very satisfied, satisfied, mild satisfaction, poor satisfaction) and whether they would repeat it if necessary.

Statistical analysis

Baseline pre-procedure patient demographics were compared with Fisher's exact test (categorical variables) or linear models with cluster-robust variance estimators (continuous variables). Outcomes were compared across the groups with generalized linear models with identity or log-link (to account for asymmetric distribution of some endpoints), or with binomial model with logit-link for categorical endpoints. All models were based on cluster-robust variance estimators that account for the non-independence of digits from the same patient. Extension deficit (PED) prior to procedure (pre-PED) was higher in the collagenase-treated group than in the surgery group, suggesting a selective allocation of treatment based on

pre-PED values. Pre-PED is expected to have an impact on post-procedure PED. Therefore, we also performed an inverse propensity of treatment weighted analysis (IPTW) of the endpoints. This analysis reweighs the follow-up estimations as if patients had been randomly allocated with respect to pre-PED values. Propensity score (PS) for being allocated to collagenase conditional on the pre-PED angle values (MCP, PIP, or total) were obtained from probit regression models and inverse probability of treatment weights (IPTW) were then obtained from the PS. Statistical analyses were performed with Stata (StataCorp, College Station, TX, USA). All reported *P* values are two-sided and confidence intervals have 95% coverage.

Results

Immediate assessment and complications

Intraoperative results among groups are presented in Tables 1, 2 and 3. In group 1, repetitive injection was performed in 11 patients (29%): 2 infiltrations were done in 9 patients and 3 infiltrations in 2 patients with at least 2-month interval between the infiltrations. No major complications were demonstrated in either group. In the collagenase group there were per secundam wound healing in five patients (Fig. 1), bleeding in three patients, lymphangitis in one patient, and lymphadenopathy in two patients, accounting for a minor complication rate of 29%. All skin lesions healed

Table 2 Objective outcomes in CCH and LA groups on average 3 months post surgery

	Collagenase	Surgery	*P* value
Changes baseline to follow-up			
Absolute PED improvement MCP (°)	34.4 (28.4–40.4)	28.2 (17.8–38.6)	0.319
Absolute PED improvement PIP (°)	33.1 (26.1–40.0)	27.9 (14.8–41.0)	0.499
Absolute PED improvement total (°)	46.0 (35.9–56.1)	39.0 (24.9–53.1)	0.438
Percent PED improvement MCP (%)	81.0 (72.2–89.7)	95.2 (88.3–100.0)	0.017
Percent PED improvement PIP (%)	67.7 (59.0–76.4)	91.5 (82.6–100.0)	0.001
Percent PED improvement total (%)	74.9 (67.3–82.5)	93.0 (87.0–99.0)	0.001
Unweighted comparison of endpoints			
Follow-up PED MCP (°)	9.3 (5.5–15.8)	2.1 (0.5–9.5)	0.068
Follow-up PED PIP (°)	18.2 (13.4–24.8)	2.1 (0.8–5.6)	0.000
Follow-up PED total (°)	17.8 (12.8–24.9)	3.0 (1.2–7.2)	0.000
Propensity score weighted comparison of endpoints–adjust for pre-intervention PED angle			
Follow-up PED MCP (°)	8.4 (5.0–14.3)	2.7 (0.6–11.9)	0.157
Follow-up PED PIP (°)	16.0 (11.3–22.6)	1.6 (0.5–5.2)	0.000
Follow-up PED total (°)	16.0 (11.2–22.8)	3.1 (1.5–6.5)	0.000

Table 3 Objective outcomes in CCH and LA groups at the last-follow-up control on average 2 years after surgery

	Collagenase	Surgery	*P* value
Changes baseline to follow-up			
Absolute PED improvement MCP (°)	34.6 (27.9–41.3)	26.5 (14.4–38.6)	0.266
Absolute PED improvement PIP (°)	25.1 (15.8–34.4)	15.0 (1.3–28.7)	0.246
Absolute PED improvement total (°)	38.1 (27.9–48.4)	30.8 (20.4–41.3)	0.336
Percent PED improvement MCP (%)	81.3 (67.5–95.1)	97.2 (91.7–100.0)	0.047
Percent PED improvement PIP (%)	45.8 (31.4–60.2)	46.1 (9.7–82.5)	0.989
Percent PED improvement total (%)	64.7 (52.5–76.8)	84.4 (70.3–98.4)	0.045
Unweighted comparison of endpoints			
Follow-up PED MCP (°)	10.1 (5.1–20.1)	1.0 (0.1–7.1)	0.029
Follow-up PED PIP (°)	31.5 (23.5–42.2)	10.7 (5.5–20.8)	0.004
Follow-up PED total (°)	25.4 (16.6–38.8)	7.1 (2.6–19.0)	0.020
Propensity score weighted comparison of endpoints to adjust for pre-intervention PED angle			
Follow-up PED MCP (°)	8.4 (3.9–17.8)	1.2 (0.2–8.8)	0.075
Follow-up PED PIP (°)	27.3 (18.8–39.5)	10.6 (6.4–17.3)	0.003
Follow-up PED total (°)	21.9 (14.0–34.3)	10.5 (3.7–29.8)	0.202

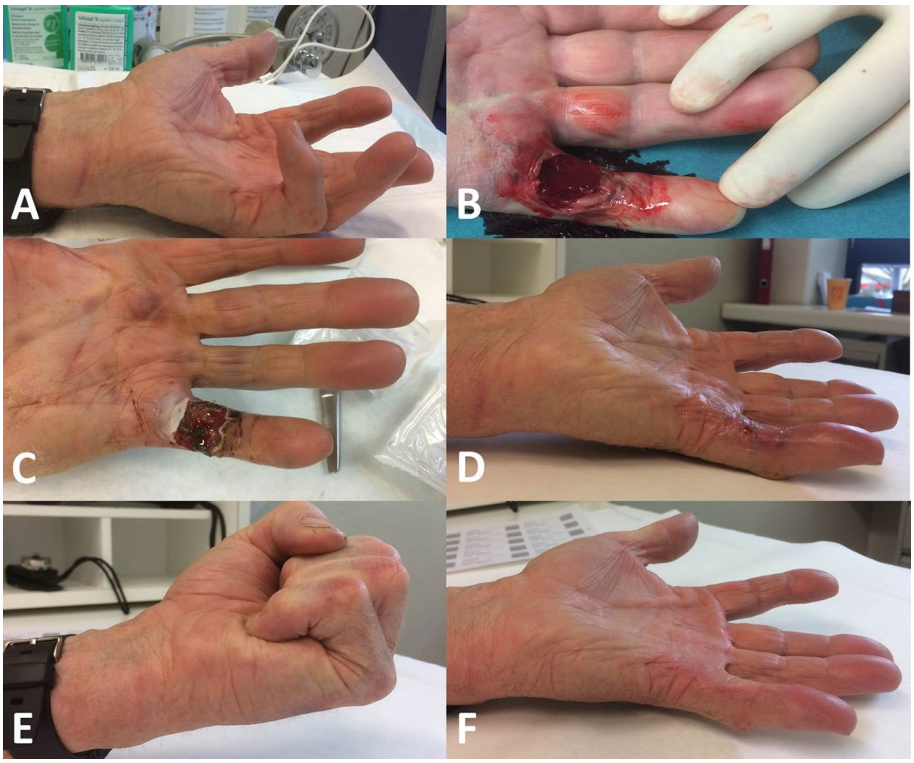

Fig. 1 Patient before (**a**), just after CCH (**b, c**), and 3 months (**d**) and 2 years (**e, f**), respectively, after CCH for Dupuytren's disease

within 10–28 days. 2 patients were lost to follow-up after 3 months and excluded.

Postoperative rehabilitation

Rehabilitation time was 15 ± 4 days after operation in the CCH group compared to 47 ± 8 days in the Surgery group. CCH patients wore the splint on average 12 ± 1 weeks (range 10–16 weeks). In average, they visited the hand therapist 8 ± 2 times post-procedure. In the surgery group, patients wore the splint on average 25 ± 2 weeks (range 20–32 weeks). On average, they visited the hand therapist 24 ± 2 times after operation.

Objective assessment

In the CCH group, mean MCP joint contracture was, respectively, 44° ± 20°, 9 ± 2° (gain of mobility compared to the preoperative condition 35°, $P < 0.001$), and 10° ± 3° (gain 34°, $P < 0.001$), respectively, before, at the 3 months' control and at the 2-year clinical control. In the LF group, mean MCP joint contracture was, respectively, 30° ± 21°, 2° ± 0.5° (gain 28°, $P < 0.001$), and 1° ± 0.5° (gain 29°, $P < 0.001$) for the same control periods. In the CCH group, mean PIP joint contracture was, respectively, 51° ± 21°, 18° ± 3° (gain of mobility compared to the preoperative situation 33°, $P < 0.001$), and 32° ± 4° (gain 19°, $P < 0.001$), respectively, before, at the 3 months' control and at the 2-year clinical control. In the LF group, mean PIP joint contracture was, respectively, 30° ± 20°, 2° ± 0.5° (gain of mobility compared to the preoperative situation 28°, $P < 0.001$), and 11° ± 4° (gain 19°, $P < 0.001$) for the same control periods (Fig. 2). Outcomes compared across the LF and CCH groups are reported in Tables 2 and 3 Surgery performed better than collagenase for PIP joint treatment early on ($P < 0.001$) and 2-year follow-up ($P = 0.004$). Pre procedure extension deficit was higher in the CCH group compared to LF group, suggesting a selective allocation to treatment according to prior extension deficit. Propensity score weighted comparison was used to adjust for differences in pre-intervention PED between collagenase and surgery. The results are presented in Tables 2 and 3: for PIP joint, this confirmed that surgery performed clearly better than collagenase early on ($P < 0.001$) and at the 2-year follow-up ($P = 0.003$).

Subjective assessment

In the CCH group, mean Michigan Hand score was 91%, and 94% ($P < 0.001$), respectively, before and at the 2-year clinical control. In the surgery group, mean Michigan hand score was 89 and 94% ($P < 0.001$), respectively, before and at the 2-year control. Before treatment, the subjective evaluation of the functional outcomes scored 80% ranging from 60 to 100% in the CCH group, and 87% (range 75–100%) in the surgery group. Results for each of the six domains are reported in Table 4.

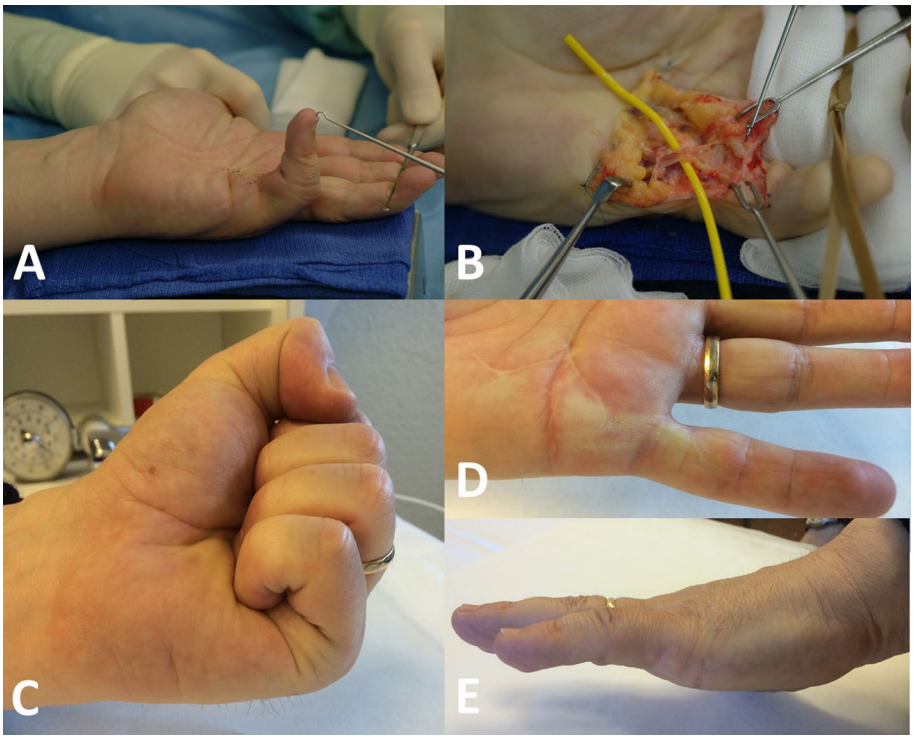

Fig. 2 Patient before (**a**), during limited fasciectomy (**b**), and 2 years (**c**–**e**), respectively, after limited fasciectomy for Dupuytren's disease

Table 4 Michigan hand score for both groups at the last-follow-up control on average 2 years post surgery

	Pre-op	Post-op
Collegenase group		
Functional outcome	80 (60–100)%	87 (60–100)%
Activities of daily life	96 (75–100)%	98 (75–100)%
Job	92 (60–100)%	95 (60–100)%
Pain	98 (85–100)%	98 (85–100)%
Aesthetic result	85 (44–100)%	90 (56–100)%
Satisfaction	93 (75–100)%	96 (79–100)%
Total	91%	94% ($P<0.001$)
Surgery group		
Functional outcome	89 (75–100)%	91 (60–100)%
Activities of daily life	98 (90–100)%	99 (95–100)%
Job	69 (60–100)%	80 (60–100)%
Pain	98 (90–100)%	100 (100–100)%
Aesthetic result	89 (81–100)%	95 (88–100)%
Satisfaction	92 (75–100)%	97 (92–100)%
Total	89%	94% ($P<0.001$)

Patient satisfaction was higher in the CCH group: 92% were satisfied or very satisfied with the treatment compared to 71% in the LF group. All patients would repeat the treatment in the CCH group if necessary compared to only 71% in the LF group.

Discussion

In this study, we analyzed extension deficits in MCP and PIP joints in patients treated with collagenase ($N=38$) and segmental aponeurectomy using a mini incision technique ($N=14$). Our results underlined that surgery performed better than collagenase (CCH) at the early and 2-year follow-ups in PIP joints and had similar outcomes in MCP joint. However, while surgery achieved better results, patients treated with collagenase recovered much faster, with minor hand therapy and shorter splinting times.

Despite solid results obtained with CCH, it should be noted that several non-invasive enzymatic therapies were first tried in the past, with often disappointing results. These include treatments using radiotherapy, dimethylsulfoxide, vitamin E, methylhydrazine, allopurinol, gamma interferon, corticosteroids, or even physical therapy assisted by ultrasound [22–31]. The concept of enzymatic lysis of collagen appeared with the work of Bassot [32]. He advocated the injection of a mixture of trypsin, alpha-chymotrypsin, hyaluronidase, thiomucase, and lidocaine to destroy the cords found in patients with Dupuytren's disease [32]. He published promising results on 34 patients. In 1971, Hueston et al. [33] advocated the use of a simple injection of trypsin, hyaluronidase, and marcaine. In 1992, the concept of specificity was underlined by McCarthy [34]: if the enzymatic lysis is not specific, it may result in tendinous and nerve injuries. Armed with this experience found in the literature, our first open label study on patients with Dupuytren's disease

was approved and its conclusions published in 2000 [18]. Afterwards several clinical trials were undertaken in USA, Europe, and Australia. The FDA approved the collagenase *Clostridium histolyticum* for the management of Dupuytren's disease in 2010. Recently, Smeraglia et al. performed a comprehensive review of studies dealing with collagenase for Dupuytren's disease [17]. They concluded that the use of collagenase provides better outcomes in patients with mild to moderate joint contracture, with lower complication rates and side effects than open fasciectomy. Our results, however, suggest that surgery performed better than collagenase at the early and 2-year follow-ups in PIP joints and similar to collagenase for both controls. With those in mind, the high rate of CCH in our university hand center should be brought into question. In other words, should we continue to use a less efficacious therapy? Five key points from the results section may be used to answer this question. (1) First, CCH is an off-the-shelf therapy applied by hand surgeons who have performed an instructional course. In other words, if CCH treatment fails or needs to be completed, a second line of defense remains. (2) Our study emphasizes that collagenase causes only minor complications: In the collagenase group there were per secundam wound healing, bleeding, lymphangitis and or lymphadenopathy for 24–48 h. However, all skin lesions healed within 10–28 days. Complications of this therapy have been detailed by Smeraglia et al. [17]. In their review of the literature, minor complications were widely reported, but major adverse effects were only seen in seven studies [35–41]. (3) Additionally, injections can be repeated, which may enhance the efficacy of the procedure [42]. As explained by Degreef et al. [42] although enzyme treatment may increase the risk of immunological response, particularly when considering repeated long-term treatment logarithms, safety findings and adverse event reports and problems of immunogenicity typically remain mild. In this context, we should underline that Gajendran et al. [43] reported good results in a patient receiving 12 dosages in 15 injections over a 4-year period. (4–5) Finally, two evidence-based medicine arguments must be made: On the one hand, CCH for Dupuytren's disease seems to be a simple and short procedure when compared with surgical options. As explained in this study, patients appreciate the simplicity of the procedure, the lesser invasiveness, and painless dressings after the initial 48 h. In rare cases, surgery may be contraindicated owing to the patient's health. On the other hand, the economic impact of CCH is not negligible. Faster rehabilitation, on a regular post treatment course, minor hand therapy, and minor impact on daily activity and sport are highly appreciated by patients. This clearly appears in the subjective evaluation of patients.

In this study, we pointed out the importance of both the objective and subjective evaluation in the treatment of Dupuytren's disease; however, four methodological limitations remain. (1) First, this was a retrospective study. That said, all the data were precisely registered in our electronic database. (2) Moreover, a longer follow-up would allow to appreciate precisely the recurrence rate after CCH. In a recent study with a similar follow-up (2 years), Van Beeck et al. concluded that collagenase injection is a safe and effective treatment option for Dupuytren's disease, but recurrence is common, especially for the PIP joint [44]. Studies with a longer follow-up should be conducted so as to evaluate mid-term and long-term recurrence rates. (3) Additionally, the therapeutic impact of hand therapy was not precisely measured in this study. (4) Finally, we used ultrasound to accurately perform the CCH injections [19], without which results might have been slightly different.

Conclusion

In this study, Surgery performed better than collagenase at the early and 2-year follow-up in PIP joints, and similar to collagenase at both controls in MCP joints. While surgery seems to achieve better results, collagenase is considered in Switzerland as an off-the-shelf therapy that provides consistent results without causing scars only with minor possible complications but shorter rehabilitation time and only minor hand therapy.

Compliance with ethical standards

Conflict of interest The author(s) declare that they have no competing interests. No benefits in any form have been received or will be received related directly or indirectly to the subject of this article.

Informed consent The research protocol was approved by the appropriate ethical committee. Informed consent of all involved patients was obtained.

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