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## Research Paper

## Hand therapy or not following collagenase treatment for Dupuytren's disease? A randomized controlled trial

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## ABSTRACT

**Background:** Collagenase treatment can improve finger extension and hand function in patients with Dupuytren's disease. The role of hand therapy in enhancing or prolonging these effects remains unclear.**Purpose:** The primary aim was to examine whether hand therapy, compared to no hand therapy, improves self-perceived occupational performance after collagenase treatment for Dupuytren's disease. The second aim was to investigate the effect of hand therapy on finger extension, grip strength, pain and overall patient impression.

A third aim was to investigate whether outcomes differed between patients with metacarpophalangeal joint involvement only and those with combined metacarpophalangeal joint and proximal interphalangeal joint involvement.

**Study Design:** Longitudinal randomized controlled trial with two parallel groups and four subgroups, registered at [ClinicalTrials.gov](http://ClinicalTrials.gov).**Methods:** Seventy-two patients with collagenase treated Dupuytren's disease were randomized to receive either hand therapy (Therapy group) or no hand therapy (Control group). Each group was stratified by joint involvement. The Canadian Occupational Performance Measure (COPM) was the primary outcome. Secondary outcomes were Unité Rhumatologique des Affections de la Main scale, finger joint goniometer, Jamar dynamometer, Visual Analog Scale for pain, and Patient Global Impression of Change and of Satisfaction.**Results:** At 1-year follow-up, no differences (mean difference (CI), p-value) were found between Therapy and Control groups in COPM scores:

Metacarpophalangeal joint groups: COPM-P -0.2 (-1.9-1.4), p=0.519; COPM-S -0.6 (-2.3,1.2), p=0.450.

Proximal interphalangeal joint groups: COPM-P -0.2 (-1.9,1.5), p=0.972; COPM-S -0.5 (-2.4,1.4), p=0.579.

No significant differences were noted in secondary outcomes, except for pain and grip force

**Conclusions:** Hand therapy did not improve COPM outcomes 1 year after collagenase treatment. Referral to hand therapy may be most beneficial for patients experiencing pain or requiring strong grip force. Whether more hand therapy improves residual proximal interphalangeal joint contractures remains unanswered.

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## Introduction

Dupuytren's disease is a progressive fibroproliferative disorder that affects the palmar fascia of the hand.<sup>1</sup> The etiology is unknown. Dupuytren's disease results in accumulation of collagen nodules and

CORDS in the palm that may cause progressive contractures of the fingers, and a decreased ability to perform daily activities.<sup>1-3</sup> The disease is autosomal dominant with variable penetrance.<sup>4</sup> The prevalence in Sweden was 1.35% among men and 0.5% among women, becoming more frequent with increasing age.<sup>5</sup>

An ideal cure to prevent or manage Dupuytren's disease has not yet been developed.<sup>2</sup> Symptomatic treatment aims to reduce finger joint contractures, with the aim of improving hand function and activity performance.<sup>6</sup> Collagenase treatment is a minimally invasive and effective symptomatic treatment, in which collagenase from

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*Clostridium histolyticum* is injected into the contracted collagen cord (s), followed by manipulation of the affected digits with a flexion contracture of  $\geq 20^\circ$ .<sup>7</sup> Treatment outcomes appear to depend on the affected joints, with less success for the extension of the proximal interphalangeal joints (PIPJs) than for the metacarpophalangeal joints (MCPJs) (36% vs 77%).<sup>8</sup> Residual PIPJ contracture after collagenase treatment can be explained by the particular anatomy of the joint and persistent joint flexion.<sup>9</sup> Recurrence of joint contracture are also reported.<sup>10</sup> Short-term adverse effects following collagenase treatment can occur, such as edema, pain and contusion.<sup>8</sup> Despite this, patients report that the collagenase treatment is well worth it.<sup>11</sup>

Collagenase treatment for Dupuytren's disease is commonly followed by hand therapy interventions, including edema control, pain and scar management, use of hand orthoses, physical hand exercises and encouragement to use the hands in daily life activities.<sup>12</sup> Previous research indicates that 3 months use of an individually molded volar night-time orthotic for the treated finger with MCPJ contracture, after collagenase treatment may not have effect.<sup>13</sup> An individually molded dorsal orthotic for severe,  $\geq 40^\circ$ , PIPJ contractures, used continuously for 1 week and then at night, alongside a cylinder keeping the PIPJ straight at daytime, showed improvement at 4 weeks, and needs to be studied further.<sup>14</sup> Patients with hand injuries showed more improvement after an occupation-based intervention with purposeful activities combined with hand exercises than those engaging in hand exercises alone.<sup>15,16</sup> To the best of our knowledge, no studies have compared the outcomes of hand therapy followed by collagenase treatment vs collagenase treatment and no hand therapy in Dupuytren's disease.

The primary aim of the present study was to examine the effect of hand therapy compared to no hand therapy on self-perceived occupational performance of activities in patients with Dupuytren's disease 1 year after collagenase treatment. Second, we aimed to investigate the impact of hand therapy on finger extension, grip strength, pain levels, and the patients' overall impression of change and satisfaction with hand function following collagenase treatment. Third we wanted to investigate whether involvement of the MCPJ alone or combined involvement of the MCPJ and PIPJ affected the outcomes.

## Methods

We adhered to the reporting standards of the Consolidated Standards of Reporting Trials (CONSORT) checklist.<sup>17</sup> The protocol is published.<sup>18</sup> The study is registered at ClinicalTrials.gov as NCT03580213 (April 5, 2018). All participants signed a written, informed consent form before baseline testing. The Regional Committees for Medical and Health Research Ethics (REC) approved the study (2017/613).

### Design

We conducted a randomized controlled trial with two parallel groups: a Therapy group and a Control group. Both groups received the same collagenase treatment. The Therapy group then received hand therapy, whereas the Control group did not. Within each group there were two subgroups according to which finger joints were affected, MCPJ or PIPJ with or without additional MCPJ affection. All groups were assessed at baseline, the day of collagenase treatment (only range of motion), 6 weeks, 4 months and at 1 year post collagenase treatment.

### Setting of the study

The study was conducted from April 2018 to May 2023, in an outpatient clinic in Haukeland University Hospital, Norway.

### Participants

Patients on the hospital's waiting list to receive collagenase treatment for joint contractures resulting from Dupuytren's disease were eligible to participate. Adult men and women who have had their Dupuytren's disease treated with one collagenase injection in one-free fingers with joints summarized to  $\geq 30^\circ$  extension deficit (normal practice at the hospital) were eligible. Patients could participate only once. Patient exclusion criteria were as follows:

- Received previous treatment(s) for Dupuytren's disease in the specific finger considered for the current study.
- Already a current participant in the trial.
- Had previous surgery or experienced a major injury affecting the movement of the finger considered for the current study.
- Experienced complex regional pain syndrome, infection, or an allergic reaction to the collagenase treatment before randomization.
- Experienced a tendon or ligament rupture in the hand before randomization.
- Incapable of completing the hand therapy intervention because of cognitive or language deficits.

### Interventions

A hand surgeon performed the collagenase injection procedure on all the participants. If a wound occurred during the extension procedure, it was dressed appropriately, and infection prevention information was given to the participant. A sick note for the participants' employer was provided if needed. Further intervention depended on the group assignment. Participants in the Control group were discharged from the hospital without receiving any further intervention. This is a common practice in our hospital for patients not receiving hand therapy. The Control group participants were not given information about doing exercises or about using their hand in daily life, nor did they receive any kind of orthotic. If an infection emerged or if a general practitioner or a surgeon diagnosed the participant with complex regional pain syndrome, these conditions were treated promptly and accordingly.

Hand therapists, experienced in treatment for Dupuytren's disease post-collagenase treatment, treated the participants in the Therapy group. The therapy consisted of instructions on how to use the hand in daily activities, how to perform the prioritized activities listed in the participant's COPM as exercise, how to do specific hand exercises at home, use of extension orthotic, and how to treat any subsequent wounds/scars and/or edema, should these occur. The Therapy group were seen by a hand therapist for interventions the day of the extension procedure, with additional visits scheduled as needed based on individual clinical requirements (normal practice in the clinic).

The Therapy group participants were shown how to carry out these instructions with live demonstrations, and they were given the opportunity to practice the activities and exercises outlined in the written instructions under the guidance of their hand therapist.

The Therapy group received a routine extension orthotic custom molded of thermoplastic to each participants' hand. It was volar hand based, made for the affected finger and neighbor finger, with elastic bands dorsally over the proximal phalanx and the PIPJ to give gentle dynamic tension to the PIPJ. The orthotic was to reduce scarring, prevent contracture, and improve joint extension further. The instructions were to use the orthotic every night, preferably for 4 months, or longer if the participant wished. If the orthotic caused pain, the participants were urged to contact their hand therapist for adjustments or were instructed to loosen the velcro on the orthotic if that helped. The participants were informed that they could also

adjust the amount of orthotic use; the whole night, part-time at night and/or for daytime sessions but not to the point of causing pain. Painful pressure from the orthosis can cause micro tissue tears leading to more scarring and contracture.<sup>19,20</sup> For those participants with severely contracted PIPJ ( $\geq 40$  degrees) post collagenase, a more dedicated orthotic for the affected finger was designed at the second visit, to elongate structures around the joint. This orthotic was either a “gutter-orthotic” or a prefabricated finger three-point orthotic. The “gutter-orthotic” was placed volar, hand based with PIPJ in full extension and MCPJ in flexion. It was custom molded of thermoplastic with an elastic velcro dorsally to give dynamic tension for the PIPJ. The participants were instructed to use this extra orthosis in daytime sessions in addition to the night orthotic or sometimes replacing the night orthotic if it was not painful.

The timing, number, and intensity of hand therapy sessions varied individually, depending on the participants' needs. Several factors were considered to determine whether a participant required more frequent visits to the hand therapist. These factors included the status of edema, excessive scarring, orthotic needs adjustment, worsening of range of motion, severe joint contracture, and reduced ability to carry out everyday activities. The Therapy group was encouraged to contact the hand therapist at any time during working hours throughout the trial. Other details about each therapy intervention are thoroughly described in the published protocol.<sup>18</sup> To encourage the participants to adhere to their treatment, a leaflet was given to them with a summary of the above information.

### Outcome measures

#### Participant information

Basic demographic information was collected at baseline. In addition, it was assessed whether any indications for Dupuytren's disease treatment were present in other fingers in the hand being treated or in the other hand. Other conditions like osteoarthritis in the treated hand, and whether the participant experienced cold hypersensitivity were also noted. At the 6 weeks follow-up, present edema and/or scarring after collagenase treatment were recorded. To look at the participants compliance with the therapy protocol, the Therapy group recorded in a diary whether they had a scar, edema and if they used the orthotic as instructed, the extent of their orthotic use, and whether they performed the recommended exercises. The treating therapist recorded whether participants in the Therapy group received any additional orthotic for PIPJ contracture.

To assess treatment progress, we applied established tests used previously for assessing Dupuytren's disease symptoms.<sup>21,22</sup> The primary outcome measure was patient self-reported performance of activities of daily living on the Norwegian version of the Canadian Occupational Performance Measure (COPM).<sup>23</sup> Secondary outcome measures were performance on the Norwegian version of the Unité Rhumatologique des Affections de la Main (URAM-N) scale,<sup>24</sup> a Dupuytren's disease-specific questionnaire; physical measures of active and passive range of joint motion, as assessed with a goniometer<sup>25</sup>; grip force, as measured with a Jamar hand dynamometer<sup>25</sup>; measurements on Visual Analog Scale (VAS) for pain<sup>26</sup>; the Patient Global Impression of Change, and the Patient Global Impression of Satisfaction.<sup>27</sup> As hand therapy started on the day of the collagenase treatment extension procedure, it was not possible to assess the participants' experience with their activity performance between the collagenase treatment and hand therapy.

#### The Canadian Occupational Performance Measure (COPM)

The COPM was designed to identify and assess challenges patients experience in carrying out everyday activities.<sup>28,29</sup> It can also be used to monitor changes over time in self-perceived performance (COPM-P) and satisfaction with performance (COPM-S). During this

interview, the participants prioritize a maximum of five important activities they would like to address as part of an agreed intervention. In the present study, we included only activity limitations caused by Dupuytren's disease. At baseline and follow-up assessments, participants scored their performance on the prioritized activities and their satisfaction with their performance of these; each was rated on a scale from 1 to 10. Higher scores indicate better performance and greater satisfaction.<sup>29</sup>

In the literature, a change score of 2 is considered a clinically important change for COPM, although this score is not empirically supported.<sup>30</sup> The COPM is presented in the literature with good construct validity for Dupuytren's disease<sup>31</sup> and good criterion validity and responsiveness.<sup>5,28</sup> The Norwegian-translated version of COPM used in this study is reported to have excellent test-retest reliability.<sup>23</sup>

#### Unité Rhumatologique des affections de la Main (URAM) scale

The URAM scale measures the self-reported performance of nine Dupuytren's disease-specific, predefined items.<sup>24</sup> Total scores are calculated (0–45), with higher scores indicating worse performance.<sup>24</sup> The URAM scale is reported to have moderate to good convergent validity, good test-retest reliability,<sup>32</sup> and acceptable responsiveness.<sup>33</sup> It is claimed to be the most documented Dupuytren's disease-specific patient-rated outcome measure. One drawback, however, is that it has a high minimal clinically important difference of 1.5–10.5.<sup>32</sup> We used a translated Norwegian version of the URAM scale (URAM-N), which has shown preliminary good content validity (I-CVI)  $> 83\%$  and (S-CVI) of 97%.<sup>34</sup> We will use the acronym URAM for the original French version and URAM-N for the Norwegian translated version in our study.

#### Range of motion and total active extension deficit

Range of motion is the most common outcome measure used in studies on Dupuytren's disease.<sup>35</sup> In the present study, we assessed finger joint range of motion by using a goniometer,<sup>25</sup> following testing procedures recommended by the Swedish Hand Surgical Quality National Register (HAKIR).<sup>25</sup> We assessed only the joints that were treated, measuring both active and passive extension and flexion, joint by joint. A goniometer reading of 0° indicated full extension, hyperextension was not assessed. We did not have a clinically important change value to use, because measurement properties of range of motion for Dupuytren's disease are highly variable.<sup>35</sup> We set baseline for this measurement to be immediately after collagenase treatment, as it was the hand therapy effect, not the collagenase treatment effect, we wanted to evaluate.

#### Grip force

We used a protocol described in the Swedish HAKIR manual for measuring grip force with a Jamar hand dynamometer (0–90 kg).<sup>25</sup> Here, the reliability of the Jamar dynamometer is reported to be good when using a standardized protocol.<sup>25</sup> Grip force measurements have good test-retest, inter-tester, and intra-tester reliability.<sup>36–38</sup>

#### Pain

To assess pain, we used a self-report VAS. We asked the participants to identify their perceived pain intensity on a 10 cm line, with 0 indicating no pain and 10 indicating the worst pain possible.<sup>26</sup> We assessed pain in the hand included in the study. The minimal clinically important difference on VAS pain is reported to be 1.6–1.9 for a postoperative hand surgery population.<sup>39</sup>

#### Patient global impression of change and satisfaction

The participant global impression of change and participant global impression of satisfaction<sup>27</sup> with the change in hand function

from before collagenase treatment were asked for. At 4 months and 1 year, we asked the participants how satisfied they were with their hand function now and their satisfaction with the changed hand function since before the collagenase treatment. Global rating of change scales are reported to be clinically relevant and have adequate reproducibility and sensitivity to change.<sup>40</sup> We optimized the interpretability and reliability of the test using recommendations for global rating scales.<sup>40</sup> We used a balanced seven-point numerical scale with written descriptors, and a standardized administration mode.<sup>40</sup> The seven response categories for assessing change in our study were as follows: very much improved, much improved, minimally improved, no change, minimally worse, much worse, and very much worse. For satisfaction, the response categories were as follows: very pleased, well satisfied, satisfied, neutral, dissatisfied, little satisfied and very dissatisfied. The patient global impression of change and satisfaction was included after the trial commenced. This was to have the opportunity to future validation of the Norwegian version of the URAM-N scale.

#### Sample size

Assuming Cohen's *d* of 0.5, we estimated that 64 participants per group were needed to achieve a t-test having a significance level of 0.05 and power of 0.8. We decided to enroll 80 participants for each group as we assumed a dropout rate of 20%. These 80 participants per group were distributed equally according to the MCPJ and the PIPJ contractures. More details are reported in the study protocol.<sup>18</sup>

#### Enrollment and assessment schedule

To identify candidates for the present study, a hand therapist and member of the research group evaluated patients listed in the hospital's waiting list for Dupuytren's disease collagenase treatment, against our inclusion/exclusion criteria. An office receptionist not directly involved in the study sent the invitations by mail to study candidates identified in the previous step. No earlier than 2 weeks before the collagenase treatment was scheduled, another hand therapist, the main author of this study, collected demographic and medical information from participants. This hand therapist also conducted baseline testing, including range of motion assessments, and all the follow up testing. Immediately after the collagenase treatment, each participant's range of motion was assessed a second time. This measure was set as baseline only for the range of motion of the finger joints. Follow-up assessments for both the Therapy and Control group for outcome measures were then done at 6 weeks, 4 months, and 1 year post collagenase treatment. However, patient global impression of change and satisfaction was administered only at the assessments at 4 months and 1 year. The diaries from the Therapy group were collected and locked in safely by a receptionist when the participants came in for their 4-month follow-up.

#### Randomization and blinding

Participants were randomly allocated into two groups: Therapy group and Control group. We hypothesized that patients with Dupuytren's disease-associated PIPJ involvement would benefit more from post collagenase hand therapy than patients not receiving hand therapy. Therefore, within the Therapy and Control groups, we created two equally sized subgroups according to joint involvement. The participants were allocated to the four subgroups by a block randomization method, stratified for PIPJ and MCPJ contractures; one with only the MCPJ involved (MCPJ group) and one with the PIPJ involved, either alone or in addition to the MCPJ (PIPJ group).

The randomization schedule was prepared using software written by an independent statistician not involved in the study. All

members of the project group were blinded for the block size. Participant assignment to either the Therapy group or the Control group was put in sealed envelopes identified by numbers, following an order generated by the software. A receptionist not involved in the study gave the assignment envelope to the participant. The surgeons and the therapist performing and managing the assessments were also blinded. Participants were instructed not to inform the assessor of their allocation group, nor to reveal any other related aspects during the assessments that might unveil their group membership. Because of the physical nature of PIPJ and MCPJ, it was impossible to blind the subgroup allocation. Diary data and data from the treating therapist, were read and plotted at the end of the study by the main author, after the other analyses were completed.

#### Statistical methods

Descriptive methods were used to characterize the sample. The effect of hand therapy at the primary time point (1 year) for the primary outcome COPM and for the secondary outcomes URAM-N, pain, grip force, and extension deficit were evaluated using the ANCOVA. For secondary analyses, we fitted a linear mixed-effects model of the mentioned outcomes at all measured time points, depending on intervention type and time. The interaction between treatment and time was assessed by using an individual random intercept and simple contrasts. Note that baseline values for the extension deficit were taken before hand therapy, and the baseline for all other outcomes was taken before collagenase treatment.

For range of motion analysis, we used the sum of the active extension for both PIPJ and MCPJ in the worst finger, hereafter referred to as extension deficit. All models were estimated using four groups (MCPJ Therapy group, PIPJ Therapy group, MCPJ Control group and PIPJ Control group), with MCPJ/PIPJ Controls serving as a reference, and two groups (Therapy vs Control) serving as the treatment-effect comparison. The models for the two groups were estimated unadjusted, adjusted for MCPJ/PIPJ, and stratified for MCPJ and PIPJ. Due to a lack of power, we did not estimate models for interactions between treatment and which joints were contracted. The adjusted and stratified analyses were used to assess the effect of hand therapy, while the unadjusted and the four-group model were used as the sensitivity analysis. The general significance level was set to 0.05. The COPM-P and COPM-S were expected to be strongly correlated, ie, we did not adjust for multiple comparisons. Missing data were only observed in the outcome measures and assumed to be missing at random. This motivated our decision to abstain from doing imputations. All computations were done using SPSS 29 (IBM Corp, Armonk, NY) and R 4.2.3.<sup>41</sup> Graphics were derived using Matlab 2022 (The Mathworks Inc, Natick, MA).

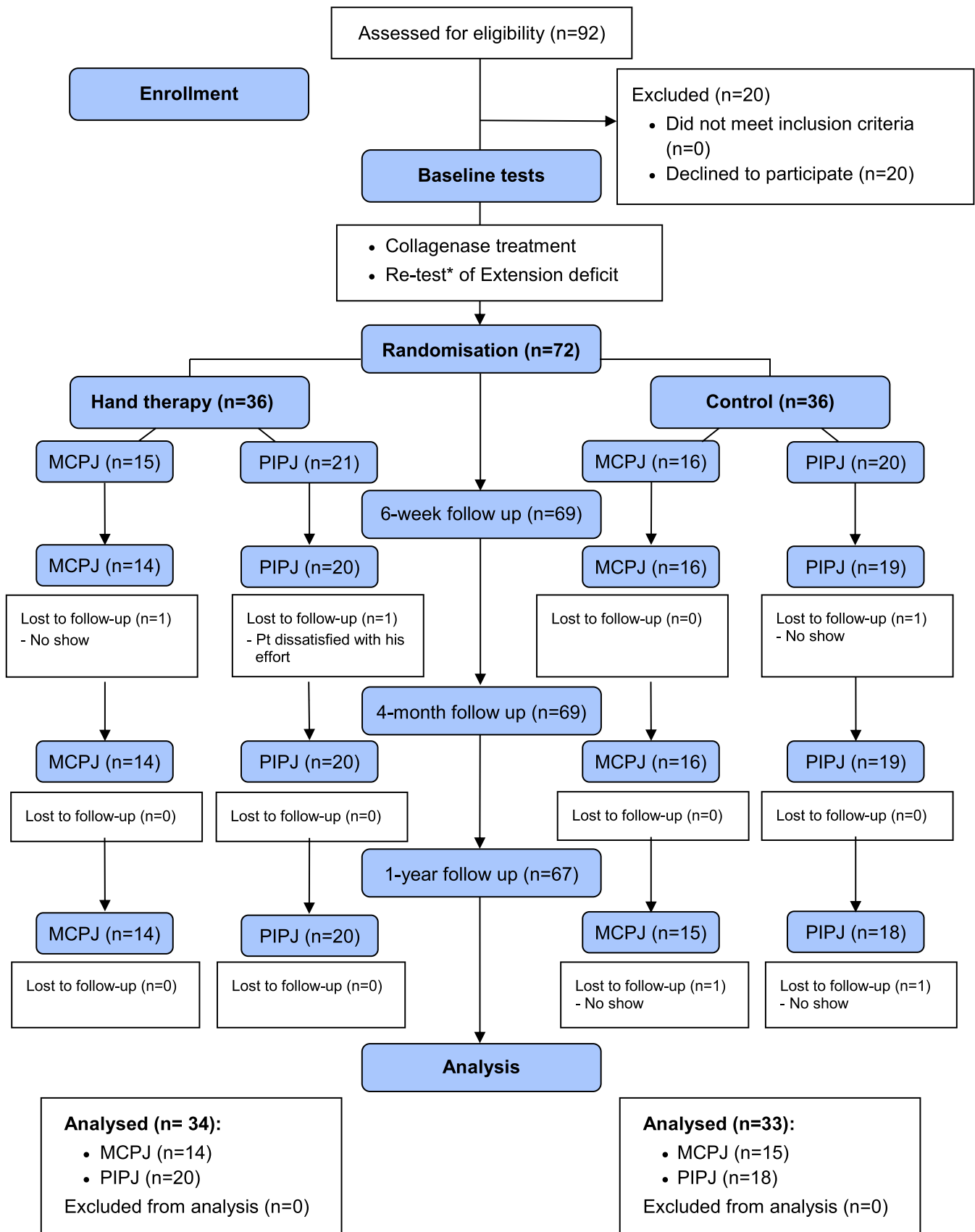
#### Results

Figure 1 presents the CONSORT Flow diagram showing the participant flow throughout the study.<sup>17</sup>

Baseline characteristics from the 72 participants included are presented in Table 1.

Participants were 58 men and 14 women, aged 48–84 years, and most were retired from work. The collagenase treatment was most often done on one finger, usually the ring or little finger (see Supplementary Table 1).

After 1 year, we examined the outcomes of 67 participants. Among them, 34 received hand therapy (14 in the MCPJ group and 20 in the PIPJ group), and 33 were in the Control group (15 in the MCPJ group and 18 in the PIPJ group) (Fig. 1). The mean number of hand therapy consultations per participant in the Therapy group was two consultations in the MCPJ subgroup (minimum one, maximum four), and three consultations in the PIPJ subgroup (minimum two,



**Fig. 1.** CONSORT 2010 flow diagram of the study. The flow of participants enrolled in the study, tested at baseline, randomized to Hand therapy group or Control group, and data analyzed. \*First test of extension deficit occurred at patient intake. MCPJ = metacarpophalangeal joint; PIPJ = proximal interphalangeal joint; pt = participant.

**Table 1**  
Baseline characteristics of study participants with Dupuytren's disease

	Therapy group (n = 36)		Control group (n = 36)	
	MCPJ (n = 15)	PIPJ (n = 21)	MCPJ (n = 16)	PIPJ (n = 20)
Age, y, median (min-max)	64 (49-75)	66 (50-83)	72 (56-85)	69 (48-75)
Sex, men, n (%)	13 (87%)	15 (71%)	13 (81%)	17 (85%)
Treated dominant hand, n (%)	4 (27%)	10 (48%)	9 (56%)	15 (75%)
Work status, n (%)				
Fulltime	7 (47%)	6 (29%)	3 (19%)	4 (20%)
Part-time, n (%)	1 (7%)	2 (10%)	1 (6%)	4 (20%)
Retired, n (%)	7 (47%)	13 (62%)	12 (75%)	12 (60%)
Cold hypersensitivity, yes, n (%)	6 (40%)	5 (24%)	7 (44%)	7 (35%)
Additional DD treatment indication	4 (27%)	8 (38%)	2 (13%)	5 (25%)
in the other hand, n (%)				
in the treated hand, n (%)	1 (7%)	1 (5%)	0	0
Number of prioritized activities in COPM (0-5), n (%)				
0	1 (6.7%)	2 (9.5%)	2 (12.5%)	5 (25%)
1	3 (20%)	0	2 (12.5%)	3 (15%)
2	1 (6.7%)	5 (23.8%)	5 (31.3%)	3 (15%)
3	4 (26.7%)	4 (19%)	3 (18.8%)	5 (25%)
4	1 (6.7%)	2 (9.5%)	1 (6.3%)	2 (10%)
5	5 (33.3%)	8 (38%)	3 (18.8%)	2 (10%)

COPM = Canadian Occupational Performance Measure; DD = Dupuytren's disease; MCPJ = metacarpophalangeal joint; PIPJ = proximal interphalangeal joint.

maximum five). Excessive scarring in need of therapy was observed for three participants, none needed edema treatment and four participants in the PIPJ subgroup got an additional orthotic (a "gutter-orthotic" or three-point orthotic) for their PIPJ.

An overview of the specific COPM-prioritized activities is presented in [Supplementary Table 2](#). The most frequent activity limitations were putting on gloves, washing oneself, lifting/carrying/gripping or holding things, and typing on a computer. In the COPM interview, 10 participants reported no activity limitations when asked for. They were satisfied with their performance of everyday activities because they had adapted to the challenges from finger contractures and managed to do activities in a different way.

At the 4-month follow-up, 22 of the 34 Therapy group participants returned their self-reported diaries. Of these, 14 participants reported having edema soon after collagenase treatment, and one reported to still have edema at 6 weeks. The diary entries revealed that 20 of the 22 participants complied with the recommendations for hand therapy. Regarding the orthotic use, 13 of the 22 participants used their orthotic the entire night, the remaining participants used their orthotic for some hours per night, or some nights during the week, or only during daytime sessions. The diaries provided descriptive information about the participants' treatment adherence and actual orthotic use, presented in [Supplementary Table 3](#).

### Primary outcome

Performance on the primary outcomes COPM-P and COPM-S was improved for both groups between baseline and 6 weeks. The outcome showed no significant change at the 4-month and 1-year follow-up assessments. The COPM results are presented in [Figure 2](#).

No significant differences were found between the Therapy and Control groups for the entire group nor for the stratified groups ([Table 2](#) and [Supplementary Table 4](#)). One year after collagenase treatment, there were no significant differences between the Therapy and Control groups in COPM scores. Results for the MCPJ groups were as follows; COPM-P mean difference (CI) = -0.2 (-1.9 to 1.4)  $p = 0.519$ , COPM-S mean difference (CI) = -0.6 (-2.3,1.2)  $p = 0.450$ . Results for the PIPJ groups were as follows; COPM-P mean difference (CI) = -0.2 (-1.9,1.5)  $p = 0.972$ , COPM-S mean difference (CI) = -0.5 (-2.4,1.4)  $p = 0.579$ .

### Secondary outcomes

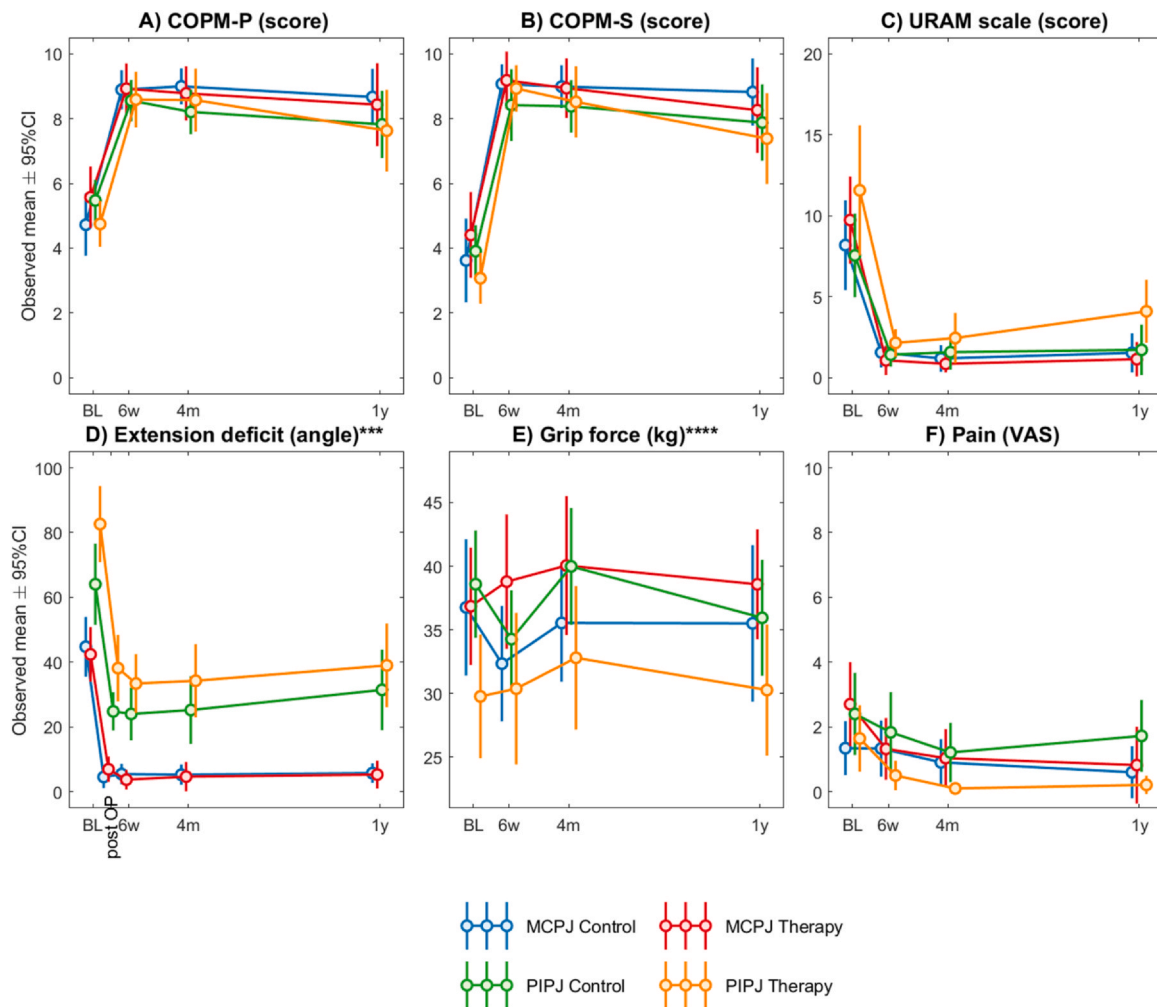
As with the improvement we observed in the primary outcome, we also observed a similar improvement in the URAM-N scale and the extension deficit throughout all the timepoints as presented in [Figure 2](#) and [Table 3](#).

However, the sum of active extension of the MCPJ and the PIPJ of the worst treated finger, was still substantial with a mean (CI) 38° (32, 44) in the PIPJ Therapy group and mean (CI) 25° (19, 31) in the PIPJ Control group post collagenase, meaning the baseline for extension deficit ([Table 3](#)). Looking at the PIPJ groups, the changes from post collagenase to 1 year on extension deficit were 7° for the Control group and 1° for the Therapy group, with a group difference of mean difference (CI) 8 (-11, 26) ( $p = 0.693$ ) ([Table 3](#)). The four participants who had an additional dedicated PIPJ orthosis had a mean improvement from post collagenase to 6 weeks of 20°, at baseline a mean (min-max) of 77° (50-82), and at 6 weeks a mean (min-max) of 57° (45-75). At 4 months, mean (min-max) extension deficit was 59° (47-75) and at 1 year it was mean (min-max) 80° (44-127), which results in a change of 3° from start. One of the four became a lot worse from 4 months to 1 year (from 75° to 127°) which affects the result negatively.

At 6 weeks, 4 months and 1 year, scores on the URAM-N scale and joint extension in the Therapy and the Control groups were not significantly different ([Tables 2 and 3](#), [Supplementary Tables 4 and 5](#)).

At 6 weeks, we detected a significant deterioration in the grip force of participants in the Control group ( $p < 0.001$ ) with some improvement at 4 months and 1 year, but still weaker than before collagenase treatment ([Fig. 2](#) and [Supplementary Table 5](#)). At the 1-year assessment grip force was significantly different between the groups B (CI) = 2.8 (0.15, 5.45),  $p = 0.039$ . The Therapy group stayed as strong as before treatment throughout the study, whereas the Control group were weaker than at baseline.

For pain, we observed a decrease in all the groups at 6 weeks and 4 months post collagenase treatment compared to before collagenase treatment and hand therapy ([Fig. 2](#)). At 1 year, participants in the MCPJ groups continued to report less pain. Participants in the PIPJ groups, however, reported more pain compared to the 4-month assessment. One year after collagenase injection, the PIPJ Therapy group reported significantly less pain than the PIPJ Control group ([Table 3](#)), mean difference (CI) = -1.5 (-2.7 to 0.3),  $p = 0.025$ .



**Fig. 2.** Outcome scores for study participants with Dupuytren's disease treated with collagenase followed by hand therapy or no hand therapy, stratified for joint affection of MCPJ\* therapy/control or PIPJ\*\* therapy/control. Mean outcome scores ( $\pm$  95% CI) are plotted over time for tests in test battery (A-F). \*Only MCPJ is affected. \*\*PIPJ and maybe also MCPJ are affected. \*\*\*The total active extension of MCPJ and PIPJ of the worst finger. \*\*\*\*Mean grip force is plotted only for the hand receiving collagenase injection. BL = baseline; 6 w = 6 weeks follow-up; 4 m = 4 months follow-up; 1 y = 1-year follow-up; MCPJ = metacarpophalangeal joint; PIPJ = proximal interphalangeal joint; COPM-P and COPM-S = Canadian Occupational Performance Measure of Performance and -of Satisfaction; URAM-N = Unité Rhumatologique des Affections de la Main (Norwegian translation); VAS = visual analog scale.

The participants' global impression of change and participants' global impression of satisfaction with hand function after collagenase treatment were generally positive at the two timepoints it was measured; 4 months and 1 year (Fig. 3). Some negative impressions were reported only for the participants in the PIPJ groups. The differences between the Therapy and Control groups were not significant at 4 months or at 1 year.

## Discussion

At 6 weeks, 4 months and 1 year, we found no differences on self-perceived occupational performance between the group receiving collagenase treatment with hand therapy (Therapy group) and the group receiving collagenase treatment without hand therapy (Control group). This was also the result for finger extension and patients' overall impression of change and satisfaction. However, the PIPJ Therapy group reported significantly less pain than the PIPJ Control group, and the Therapy group showed greater grip force than the Control group. There was not enough statistical power to conclude on the results for the PIPJ residual joint contractures. The four

participants with an additional orthotic for their PIPJ, improved finger extension in the intervention period.

Our findings that hand therapy following collagenase treatment for Dupuytren's disease had no effect compared to no hand therapy on performance of daily activities surprised us. We reasoned that one possible explanation for our findings is that collagenase treatment improved the performance to a nearly maximal level on our primary outcome COPM and that hand therapy could not produce additional benefits. The results on URAM-N scale scores (secondary outcome) are consistent with these findings.

Hand therapy did have a positive effect at all time points on grip strength in the Therapy group compared to the Control group. This difference can be explained by the focus in hand therapy on using the hands for daily activities earlier than the Control group maybe would dare to. Strengthening exercises exceeding the advice of strengthening daily life tasks, were not given. A focus in hand therapy is to use the hands to perform daily activities regularly from the start of therapy.<sup>42</sup> The use of daily activities as exercise in hand therapy, is described in the literature.<sup>19,42</sup> Grip force was unchanged at 1 year for the Therapy group, which is in line with another

**Table 2**  
Baseline scores and 1-year follow-up for COPM-P, COPM-S and URAM-N scale

		Control group		Therapy group		Difference		*p-value	
		Valid n	Mean (CI)	Valid n	Mean (CI)	Valid n	Mean (CI)		
COPM-P	All participants								
		Baseline	29	5.1 (4.5-5.7)	33	5.1 (4.5-5.7)	62	0 (-0.8-0.8)	0.693
		1 y	27	8.2 (7.5-8.9)	31	8 (7.3-8.7)	58	-0.3 (-1.4-0.9)	
	MCPJ								
		Baseline	14	4.7 (3.8-5.7)	14	5.6 (4.6-6.5)	28	0.8 (-0.6-2.3)	0.519
		1 y	13	8.7 (7.8-9.5)	13	8.4 (7.6-9.3)	26	-0.2 (-1.9-1.4)	
PIPJ									
	Baseline	15	5.5 (4.8-6.1)	19	4.7 (4.1-5.4)	34	-0.7 (-1.7-0.3)	0.972	
	1 y	14	7.8 (6.8-8.9)	18	7.6 (6.6-8.7)	32	-0.2 (-1.9-1.5)		
COPM-S	All participants								
		Baseline	29	3.8 (3.0-4.5)	33	3.6 (2.9-4.4)	62	-0.1 (-1.2-0.9)	0.430
		1 y	27	8.3 (7.5-9.1)	31	7.8 (7.0-8.5)	58	-0.6 (-1.9-0.7)	
	MCPJ								
		Baseline	14	3.6 (2.3-4.9)	14	4.4 (3.1-5.7)	28	0.8 (-1.2-2.7)	0.450
		1 y	13	8.8 (7.8-9.9)	13	8.3 (7.2-9.3)	26	-0.6 (-2.3-1.2)	
PIPJ									
	Baseline	15	3.9 (3.1-4.7)	19	3.1 (2.3-3.9)	34	-0.8 (-2.0-0.3)	0.579	
	1 y	14	7.9 (6.7-9.1)	18	7.4 (6.2-8.6)	32	-0.5 (-2.4-1.4)		
URAM-N scale	All participants								
		Baseline	36	7.8 (6.0-9.7)	36	10.8 (8.9-12.7)	72	3 (-0.3-6.2)	0.339
		1 y	33	1.6 (0.6-2.6)	34	2.9 (1.9-3.9)	67	1.2 (-0.4-2.9)	
	MCPJ								
		Baseline	16	8.2 (5.4-11.0)	15	9.7 (7.0-12.5)	31	1.5 (-2.5-5.6)	0.546
		1 y	15	1.5 (0.3-2.7)	14	1.1 (-0.1-2.4)	29	-0.4 (-2.1-1.3)	
PIPJ									
	Baseline	20	7.6 (5.0-10.1)	21	11.6 (9.0-14.2)	41	4 (-0.9-9.0)	0.172	
	1 y	18	1.7 (0.2-3.3)	20	4.1 (2.5-5.7)	38	2.4 (-0.2-5.0)		

CI = 95% confidence interval; COPM-P = Canadian Occupational Performance Measure-Performance; COPM-S = Canadian Occupational Performance Measure-Satisfaction; DD = Dupuytren's disease; MCP = metacarpophalangeal joint; PIP = proximal interphalangeal joint; URAM-N scale = Unité Rhumatologique des affections de la Main-scale (Norwegian translation).

Group differences assessed using Analysis of covariance, ANCOVA, with \*significant differences compared to control group performance ( $p \leq 0.05$ ).

study.<sup>43</sup> We did not find studies to support our findings of reduced grip force in the Control group.

One explanation to why the PIPJ Therapy group reported less pain than the PIPJ Control group can be that they continued to use their hands despite feeling some pain. This could be attributed to guidance from their therapists, who reassured them that using the hand within reasonable pain thresholds was permissible.<sup>44</sup> Hand therapy post collagenase gave patients a sense of security.<sup>2</sup> The orthotic provided some support to mitigate pain.<sup>19</sup> Further studies are necessary to determine what lessened the pain of patients with PIPJ contractures receiving hand therapy. Pain lessened over time for all the groups, which is in line with a systematic review reporting that pain was a minor, self-resolving adverse effect of collagenase treatment.<sup>8</sup>

In the MCPJ Control group, the MCPJ became nearly fully extended following collagenase treatment. This can explain why we did not observe an additional effect of hand therapy in the corresponding Therapy group. The situation was somewhat different for patients with PIPJ involvement. Less effect of collagenase treatment for PIPJ compared to MCPJ extension is in line with other findings.<sup>8</sup> Surprisingly, hand therapy did not improve residual contracted PIPJs as expected. This may have to do with the complexity of long-standing PIPJ flexion contractures,<sup>45</sup> which means the therapeutic effort could have been even more directed toward managing the PIPJ stiffness. The protocol in our study for orthotic wear was planned to be inconsistent to avoid painful orthotic use. This is supported in the literature.<sup>20,46</sup> However, it is suggested more effect from orthotics on stiff PIPJs used for longer periods a day.

According to the literature, extension orthoses have been an integral component of hand therapy that follows collagenase

treatment. The rationale behind using orthoses is that it is assumed that orthoses prevent further deterioration of the contracture and improve extension of the affected joint, especially for affected PIPJs.<sup>12,45</sup> More recent research findings, however, questioned the short-term effect on MCPJ contractures.<sup>13</sup> This is in line with our present findings regarding the MCPJ groups. However, for PIPJ contractures,  $\geq 40^\circ$ , short term results suggest effect of a dorsal orthotic used continuously for 1 week and then at night alongside a cylinder keeping the PIPJ straight at daytime.<sup>14</sup> This result differs from our present findings. An explanation for these disparate findings is that we used different orthotics and a different protocol.

Another reason why we did not find the expected effect on joint extension, might be that we did not have enough participants using the customized PIPJ orthotic to detect a statistically significant improvement. Indeed, only four of our participants used this kind of orthotic for their PIPJ contracture. Given that it appears that dedicated PIPJ orthoses for a longer period a day can improve PIPJ contractures,<sup>14,46</sup> we can question whether all our participants with PIPJ contractures should have used orthoses specifically designed for the PIPJ. It might also mean they could benefit from using it from the start, and for a longer period of the day. More studies on orthotic use for PIPJ residual contractures from Dupuytren's disease are needed to better understand to what extent orthoses can improve this kind of residual contracture and determine the most optimal parameters for orthotic use.

### Limitations

Evaluation of the efficacy of hand therapy for Dupuytren's disease is challenging, because therapists often use individualized treatment

**Table 3**  
Long term changes in participants' extension deficit, grip force, pain, and patient global impressions

		Control group		Therapy group		Difference		p-value*	
		Valid n	Mean (CI)	Valid n	Mean (CI)	Valid n	Mean (CI)		
Extension deficit <sup>†</sup>	All patients								
		Baseline <sup>‡</sup>	36	15.8 (10.9-20.7)	36	25.1 (20.3-30.0)	72	9.3 (-0.2-18.9)	0.574
		1 y	33	19.8 (11.6-27.9)	34	25.1 (17.0-33.3)	67	5.4 (-7.4-18.2)	
	MCPJ								
		Baseline	16	4.5 (1.1-7.9)	15	6.9 (3.5-10.3)	31	2.4 (-3.0-7.8)	0.548
		1 y	15	5.7 (2.7-8.8)	14	5.3 (2.3-8.3)	29	-0.4 (-6.0-5.1)	
PIPJ									
	Baseline	20	24.8 (18.9-30.7)	21	38.1 (32.2-44.0)	41	13.3 (-1.0-25.7)	0.693	
	1 y	18	31.4 (19.0-43.9)	20	39 (26.6-51.4)	38	7.6 (-11.0-26.1)		
Grip force <sup>§</sup>	All patients								
		Baseline	36	37.8 (34.5-41.1)	36	32.7 (29.4-36.0)	72	-5.1 (-10.0--0.1)	0.125
		1 y	28	35.7 (32.1-39.4)	33	33.8 (30.2-37.4)	61	-2 (-7.3-3.3)	
	MCPJ								
		Baseline	16	36.8 (31.4-42.1)	15	36.8 (31.5-42.2)	31	0.1 (-7.3-7.5)	0.247
		1 y	12	35.5 (29.3-41.7)	14	38.6 (32.4-44.7)	26	3.1 (-4.9-11.1)	
PIPJ									
	Baseline	20	38.6 (34.4-42.8)	21	29.8 (25.5-34.0)	41	-8.8 (-15.5--2.2)	0.160	
	1 y	16	35.9 (31.4-40.5)	19	30.3 (25.7-34.8)	35	-5.7 (-12.8-1.5)		
Pain (VAS) <sup>§</sup>	All patients								
		Baseline	36	1.9 (1.1-2.7)	36	2.1 (1.3-2.9)	72	0.2 (-1.0-1.3)	0.091
		1 y	33	1.2 (0.5-1.9)	33	0.5 (-0.3-1.2)	66	-0.7 (-1.7-0.2)	
	MCPJ								
		Baseline	16	1.3 (0.5-2.2)	15	2.7 (1.9-3.5)	31	1.4 (-0.3-3.0)	0.840
		1 y	15	0.6 (-0.2-1.4)	14	0.8 (0.0-1.6)	29	0.2 (-1.3-1.7)	
PIPJ									
	Baseline	20	2.4 (1.1-3.7)	21	1.6 (0.4-2.9)	41	-0.8 (-2.4-0.9)	0.025	
	1 y	18	1.7 (0.6-2.8)	19	0.2 (-0.9-1.3)	37	-1.5 (-2.7--0.3)		
PGI-C at 1 y	All patients	33	1.8 (1.4-2.2)	33	2.1 (1.7-2.5)	66	0.2 (-0.4-0.8)	0.447	
	MCPJ	15	1.5 (1.2-1.7)	14	1.6 (1.4-1.9)	29	0.2 (-0.3-0.7)	0.470	
	PIPJ	18	2.1 (1.4-2.8)	19	2.4 (1.7-3.1)	37	0.3 (-0.7-1.2)	0.600	
PGI-S at 1 y	All patients	33	1.9 (1.5-2.4)	33	2.4 (2.0-2.9)	66	0.5 (-0.4-1.3)	0.266	
	MCPJ	15	1.5 (1.1-2.0)	14	1.8 (1.4-2.2)	29	0.3 (-0.8-1.3)	0.609	
	PIPJ	18	2.3 (1.6-3.0)	19	2.9 (2.2-3.6)	37	0.6 (-0.6-1.9)	0.328	

CI = confidence interval; MCPJ = metacarpophalangeal joints; PGI-C = Patient Global Impression of Change; PGI-S = Patient Global Impression of Satisfaction; PIPJ = proximal interphalangeal joints; VAS = Visual Analog Scale.

\* Between-group differences assessed by Analysis of covariance.

† Between-group differences assessed by sum of extension of both MCPJ and PIPJ in the worst finger-extension deficit.

‡ Between-group differences assessed by the baseline for extension deficit is post collagenase treatment.

§ Between-group differences assessed by treated hand only.

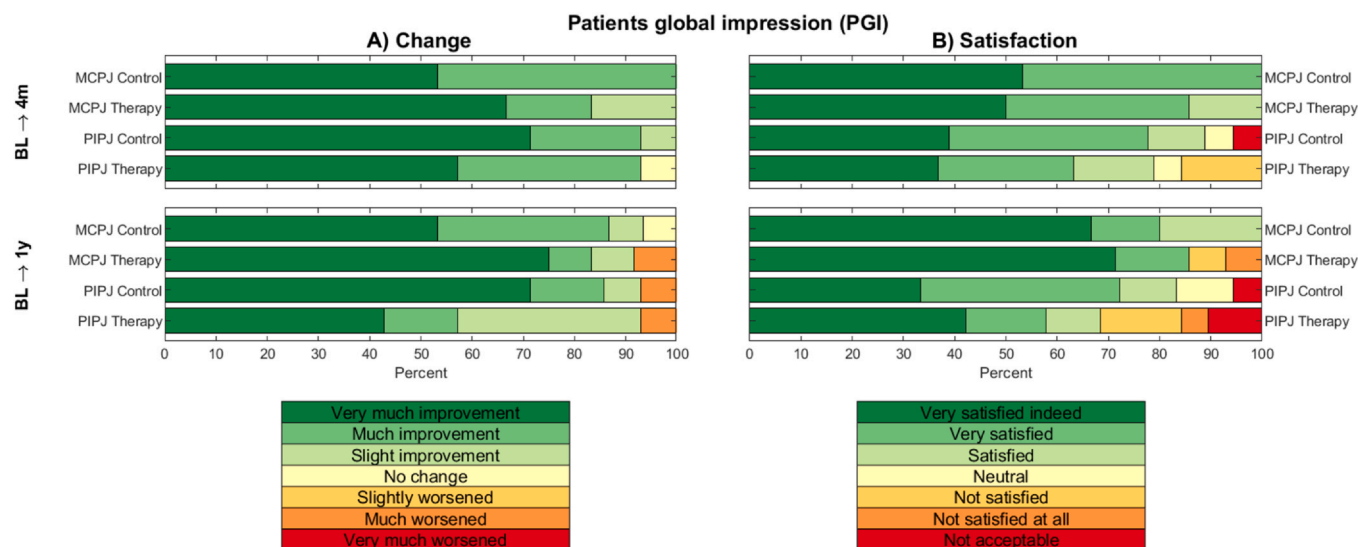
plans and multiple treatment modalities.<sup>12</sup> The variability in the timing, frequency, and intensity of hand therapy in our study represents a potential limitation of the study. Owing to individual differences in clinical needs, it is often not feasible to fully standardize all aspects of therapy. The present study comprised a trial with multiple comparisons, which can elevate the risk of false positive findings.<sup>17</sup> Hence, we present the multiple analyses in [Supplementary Tables 3-5](#). Except for the extension deficit, all baseline outcomes were measured before collagenase treatment, meaning our results include the results for the collagenase treatment.

The analysis of the summarized active extension of the MCPJ and PIPJ in the worst finger for each patient, might show worse results than if the other treated fingers were included, or if we looked at one joint isolated. Other studies also summarized joints for analysis, which is why we decided this method.<sup>13</sup>

Our results suggest that the COPM and URAM-N scale are suitable for detecting changes in activity performance for Dupuytren's disease patients, a result that is supported by other studies.<sup>6,47</sup> Some argue that the Michigan Hand Questionnaire has more acceptable psychometric properties than the URAM scale.<sup>32</sup>

URAM-N needs further testing for clinometric properties. We observed that the number of activity challenges and how important activities are to the participants in COPM varied greatly in our study. This observation is consistent with a study on people living with Dupuytren's disease.<sup>48</sup> Ten participants in our study reported no COPM activity challenges. They reasoned this to have adapted to the situation and learned different ways to perform activities leading to acceptance.

The medication used for collagenase treatment stopped being sold for the purpose in Europe in November 2019,<sup>49</sup> however it is still sold in other parts of the world. This affected the number of participants possible to include in the study. The worldwide challenge of the pandemic COVID-19 also severely affected the study, as candidate patients with Dupuytren's disease could not be recruited and enrolled during this period. Thus, the study is not optimally powered. One implication is that individual cases we did enroll had the potential to have disproportional impact on the results. However, because collagenase treatment by itself greatly improves the outcomes, increased statistical power by increasing sample size in the present study, probably would not have helped much.



**Fig. 3.** Patient global impression of change and patient global impression of satisfaction at 4 mo and at 1 y. The percentage of patients reporting their impression of how much their hand has changed since before collagenase treatment, and how satisfied they are with the hand function compared to before collagenase treatment. BL = baseline; 4 m = 4 months follow-up; 1 y = 1-year follow-up; MCPJ = metacarpophalangeal joint; PIPJ = proximal interphalangeal joint.

## Conclusions

This randomized controlled trial on the 1 year efficacy of hand therapy after collagenase treatment for Dupuytren's disease indicates that hand therapists should see the patients that experience significant pain or require strong grip force. In the long term, it seems not necessary for these patients to visit a hand therapist for better activity performance. Whether PIPJ residual joint contractures post collagenase treatment can be improved with more dedicated treatment for stiff PIPJs, remains unanswered.

## Author contributions

**Terese Aglen:** Writing – original draft, Visualization, Validation, Resources, Project administration, Methodology, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Karin Hoegh Matre:** Writing – review & editing, Resources, Project administration, Investigation, Conceptualization. **Ruud W. Selles:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Jörg Ålsmus:** Writing – review & editing, Visualization, Validation, Supervision, Software, Resources, Methodology, Formal analysis, Data curation, Conceptualization. **Tina Taule:** Writing – review & editing, Writing – original draft, Validation, Supervision, Methodology, Conceptualization.

## Declaration of Competing Interest

None.

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## Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.jht.2026.02.004](https://doi.org/10.1016/j.jht.2026.02.004).

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