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# CHAPTER 6

## EARLY POSTOPERATIVE RESULTS OF ULTRASOUND-GUIDED PERCUTANEOUS NEEDLE FASCIOTOMY IN 451 PATIENTS WITH DUPUYTREN'S DISEASE

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## Abstract

**Background:** Percutaneous needle fasciotomy (PNF) is a minimally invasive treatment modality for Dupuytren's disease. In this study we analysed the efficacy and complication-rate of PNF using a statistical method that takes the multi-level structure of data, regarding multiple measurements from the same patients, into account.

**Methods:** The data of 470 treated rays from 451 patients with Dupuytren's disease that underwent sonographic assessment of Dupuytren's cords subsequently treated with percutaneous needle fasciotomy (PNF), were analyzed retrospectively. We described the early postoperative results of PNF and we applied linear mixed models to compare mean correction of PED between joints and efficacy of primary versus secondary PNF.

**Results:** Mean preoperative PED's at the metacarpophalangeal (MCP), proximal interphalangeal (PIP) and distal interphalangeal (DIP) joints were 37°, 40° and 31° respectively. Mean preoperative TPED was 54°. Results were excellent, with a mean TPED correction of 85%. PNF was most effective for MCP-joints and less effective for PIP and DIP-joints. Secondary PNF was as effective as primary PNF. Complications were rare and mostly minor.

**Conclusions:** The results of this study confirm that PNF is an effective and safe treatment modality for patients with mild to moderate disease who prefer a minimally invasive procedure.

## Background

Percutaneous needle fasciotomy (PNF) is a minimally invasive treatment modality for Dupuytren's disease, that was first described by Henry Cline in 1777 (1). He proposed to section the cords percutaneously, using a small slender surgical knife with a sharp point (bistoury). Astley Cooper was the first to actually perform the procedure in 1822, which is why it was first called Cooper's fasciotomy (2). In the late 1970's the procedure was reinvented by French rheumatologists, who introduced the use of a disposable needle (3). Since then, the procedure has gained popularity, primarily because of its minimal invasiveness and short recovery period. PNF is not the only minimally invasive treatment modality for Dupuytren's disease. In 2000 Collagenase clostridium histolyticum was first used on Dupuytren's disease patients for enzymatic lysis of cords (4). However, the efficacy and patient satisfaction of PNF and Collagenase are similar (5,6).

Several studies have reported good outcomes of PNF, especially in patients with mild to moderate disease (7-10). Nerve-laceration and tendon-rupture are potential and the most feared complications, although most studies report very low complication rates (7,9,11). A disadvantage of PNF is the high recurrence rate. In a randomized clinical trial by van Rijssen *et al*, the 5-year recurrence rate of PNF was 85% compared to a 5-year recurrence rate of limited fasciectomy (LF) of 21% (12). It is important to realize that the definition of recurrence in this study was an increase in total passive extension deficit (TPED) of the complete ray of 30°. Such an increase does not necessarily mean that secondary treatment is necessary at that point. Therefore, for patients who are willing to accept this possibility of early recurrence, PNF is at least an effective method to postpone more aggressive procedures (7,13,14).

In this article we describe the early postoperative results of PNF for patients with Dupuytren's disease. Data were analyzed for correction of PED between joints and efficacy of primary and secondary PNF using multi-level analysis, which is a statistical method that takes correlation of multiple measurements from the same patients into account.

## Methods

In this retrospective study we analyzed data of 953 rays from 569 patients who underwent PNF for Dupuytren's disease between 2004 and 2014. All procedures were performed by the senior author. No institutional review board approval was required according to our national guidelines, because this retrospective study was the evaluation of standard care (15).

We included all patients with primary Dupuytren's disease who chose to undergo PNF and had a TPED of at least 15 degrees. TPED was calculated by summing the PED of all joints per ray. Thumbs were excluded because of the difference in anatomy. Rays with missing data regarding pre- and postoperative PED's were also excluded. In total, 237 rays had to be excluded because they did not exhibit primary Dupuytren's disease or TPED was lower than 15 degrees. Furthermore, the data of 246 rays had to be excluded due to an incomplete case record form. From the remaining 471 rays, one thumb had to be excluded. Because all cords that were treated caused flexion contractures of the affected fingers, it is most likely that they consisted of longitudinal fibers.

Efficacy of treatment was calculated by subtracting preoperative (T)PED data with postoperative data. All patients who were found to have undergone PNF at the same ray for a second time during our study period (recurrent disease), were entered in a different database.

#### Procedure

Before treatment, the PED per joint was measured using a goniometer and registered on a case record form. Subsequently, patients underwent ultrasonographic assessment of the hand, in order to gain information about the spatial relation of the cords to the flexor tendons and the neurovascular bundles. For the first two patients, ultrasonographic assessment was not part of the procedure. It was introduced, after a tendon rupture had occurred during the second procedure.

PNF was performed in an outpatient setting using a similar technique as described by Lermusiaux and Debeyre (3). Lidocaine without adrenaline was used as local anesthetic for the skin only. The cord was palpated and the level of the needle was aligned perpendicular to the cord. In case ultrasound showed close proximity of the cord to the flexor tendons or neurovascular bundle, the needle was inserted with extra caution. Then the finger was flexed and extended to ensure no simultaneous movement of the needle was induced, which would indicate tendon contact. Cords were sectioned at multiple levels in the palm and finger, depending on extent and location of the contracture, using a 25-gauge, 16mm needle and making a perforating maneuver. During the procedure the patients were asked if they felt any electric discharge along the finger, indicating proximity of the neurovascular bundle (16). Finally, the cords were ruptured using passive extension. A small dressing was applied for 24 hours. Patients were reviewed after an average of 8 weeks post-operatively. They were asked if any postoperative complications had occurred and postoperative PED's were measured.

### Statistical methods

PED corrections were normally distributed, so linear mixed models could be applied to compare mean correction of PED between MCP-, PIP- and DIP-joints. Hands, rays and joints were entered as different subject levels within this multilevel structure. Type of joint was used as fixed effect and patient as random effect. The effect of joint was corrected for the baseline value of PED, since baseline PED correlates with the outcome (PED correction) as well as the predictor (joint). An unstructured covariance structure was chosen and robust parameter estimate covariance was used. Parameters were estimated using restricted maximum likelihood.

To compare the efficacy of primary PNF versus secondary PNF, linear mixed models were applied again. TPED correction was used as outcome variable. PNF (primary or secondary) was entered as fixed factor, and its effect was corrected for baseline TPED.

All statistical analyses were done using SPSS version 22. Significance was set at  $p < 0.05$ .

## Results

In total, 470 rays from 451 patients met our inclusion criteria. This led to the patient characteristics described in table 1. In total, 669 joints were treated: 373 metacarpophalangeal (MCP) joints, 274 proximal interphalangeal (PIP) joints and 22 distal interphalangeal (DIP) joints. Mean pre-operative PED was  $37^\circ$  at the MCP-joint,  $40^\circ$  at the PIP-joint and  $31^\circ$  at the DIP-joint. Mean preoperative TPED was  $54^\circ$  (table 2). It should be noted that most patients had contractures involving one or two joints, which is why mean preoperative TPED does not correspond to the sum of the mean preoperative PED of the three joints.

**Table 1. Patient Characteristics**

	n (%)
<b>Gender</b>	
Male	345 (77)
Female	106 (23)
<b>Mean age at time of PNF (y)</b>	66
<b>Associated diseases (diabetes, liver disease)</b>	41 (9.1)
<b>Rays</b>	470 (100)
Index	5 (1)
Middle	39 (8)
Ring	185 (39)
Little	241 (51)

**Table 2. Efficacy of PNF per joint**

<b>Joint</b>	<b>Pre-operative PED (°) (mean ±SD)</b>	<b>Post-operative PED (°) (mean ±SD)</b>	<b>Correction of PED (°) (mean ±SD)</b>
MCP	37±19	2±7	35±18
PIP	40±20	11±12	30±17
DIP	31±9	8±13	23±15
TPED	54±35	8±15	46±28

The mean correction of PED was 95% at the MCP-joint, 75% at the PIP-joint and 74% at the DIP-joint. Mean correction of TPED was 85% (table 2). Linear mixed models showed us that correction of MCP-joint contractures was significantly more effective than correction of PIP-joint contractures ( $P<0.001$ ) and correction of DIP-joint contractures ( $P=0.008$ ). There was no statistically significant difference between correction of PIP- and DIP-joint contractures ( $P=0.697$ ). (table 3)

**Table 3. Comparison of mean correction of PED between joints**

<b>Joints</b>	<b>P-values</b>
MCP vs. PIP	< 0.001
MCP vs. DIP	0.008
PIP vs. DIP	0.697

Most patients were classified as Tubiana I or II (17). Efficacy of the correction declined progressively from a pre-operative Tubiana stage of I to IV, as shown in table 4.

**Table 4. TPED corrections according to Tubiana Classification**

<b>Tubiana Stage</b>	<b>N</b>	<b>TPED correction (%)</b>
<b>I</b> (TPED 0°-45°)	252	94
<b>II</b> (TPED 46°-90°)	150	87
<b>III</b> (TPED 91°-135°)	53	80
<b>IV</b> (TPED > 135°)	15	69

A total of 21 patients underwent secondary PNF at a previously treated ray during our study period. The median durability of the primary PNF was 32 months (range, 9 to 97 months). Mean reduction of TPED was 46° for primary and 36° for secondary PNF (table 5). Linear mixed models showed no significant difference between efficacy of the two procedures ( $P=0.134$ ) when correcting for pre-operative TPED.

**Table 5. Efficacy of Primary and Secondary PNF**

<b>PNF (n=21)</b>	<b>Pre-operative TPED (°) (mean ±SD)</b>	<b>Post-operative TPED (°) (mean ±SD)</b>	<b>Correction of TPED (°) (mean ±SD)</b>	<b>P-value</b>
<b>Primary</b>	51±39	5±11	46±34	
<b>Secondary</b>	44±27	8±13	36±23	0.134

Complications occurred in 56 (11.9%) of the treated rays. Most of these were skin tears, which occurred in 43 rays (9.1%). All tears healed without intervention. Five (1.1%) procedures were complicated by a superficial wound infection, which was treated using antibiotics. Temporary paresthesia was found in 6 (1.3 %) rays and there was one case of permanent sensory loss, which was attributed to a partial nerve laceration (0.2%). One tendon rupture occurred (0.2%), for which surgical intervention was necessary.

In the group with recurrent disease complications occurred in 3 (14.3%) of the re-treated rays. All of these were skin tears, that healed without further intervention.

## Discussion

Although LF still is the most often used treatment for patients with Dupuytren's disease, similar outcomes of less invasive procedures like PNF have been reported for patients with Tubiana stage I and II (7,9-11,18). It has been shown to be an effective procedure with a low complication rate and short recovery period (7,9,11). The main disadvantage is the high recurrence rate. But when patients prefer a minimally invasive procedure instead of LF, PNF can also effectively be performed for recurrent disease (19).

The number of studies regarding the results of PNF with a large sample size is limited. Also, most previous studies have enlarged their sample size by treating rays or even joints as subjects, without sufficiently describing what statistical method was used to compare these multiple measurements from the same patients (7,8,10,11,20). However, including multiple measurements from the same patient without the use of an appropriate statistical method violates the assumption that observations must be independent and results in underestimation of within-group variability and inflation of sample size (21). Both effects may lead to unrealistically low P-values, which increases the chance of a type I error (22).

In this study we present an overview of the postoperative results of PNF in a large population using linear mixed models. With the use of this statistical method we were able to take the multi-level structure of our data into account.

The results of previous studies regarding the early post-operative results of PNF are shown in table 6. In our study immediate correction of TPED was 85%, which is slightly higher than the number reported by Foucher *et al.* and van Rijssen *et al.* (7,10). The other did not report mean TPED-correction. The mean correction at the MCP-joint found in our study (95%) falls within the range reported in the literature (79-99%). Numbers regarding PIP-correction found by others vary widely (46-89%). We found a mean correction of 75% at the PIP-joint, which also falls within this range (7,8,10,11). Furthermore, 22 of our patients were treated for a DIP-contracture, mean correction was 74%. Van Rijssen *et al.* reported on only one case of a DIP-contracture in which they achieved a correction of 75% (7). Other studies do not report percentages regarding DIP-contractures. Our results show that PNF is an effective treatment modality for all joints.

All studies shown in table 6 reported that correction of MCP-contractures was significantly more successful than correction of PIP-contractures. Our results confirm that correction of MCP-contractures is significantly more effective than correction of PIP-contractures. They also show that correction of MCP-contractures is significantly more effective than correction of DIP-contractures and there is no significant difference between correction of PIP- and DIP-contractures.

**Table 6. Previous studies on results of PNF**

<b>Authors</b>	<b>N</b>	<b>MCP correction</b>	<b>PIP correction</b>	<b>DIP correction</b>	<b>TPED correction</b>
<b>Foucher <i>et al</i> (2001)<sup>7</sup></b>	211 (311 rays)	79%	65%	-	76%
<b>Van Rijssen <i>et al</i> (2006)<sup>4</sup></b>	52 (74 rays)	88%	46%	75%	77%
<b>Pess <i>et al</i> (2012)<sup>8</sup></b>	474 (1013 rays)	99%	89%	-	-
<b>Abe <i>et al</i> (2015)<sup>5</sup></b>	51 (103 rays)	98%	89%	-	-

In the small group that underwent PNF for recurrent disease, treatment was as effective as the primary intervention. The study by van Rijssen *et al.* on effectiveness of PNF for recurrent Dupuytren's disease supports our finding (19). We can conclude that secondary PNF is a good treatment option for patients who wish to postpone LF for a second time.

The median durability of the first procedure was 32 months. However, no definition for recurrence was used in our study. Patients presented with recurrent disease when they experienced enough complaints to be willing to undergo a second procedure. Since this is a very subjective measure we were not able to calculate a reliable recurrence rate that is comparable to the literature.

Our complication rate was 11.9%. Similar to other studies most of these complications healed without further intervention. Right after the beginning of our study there was one case of a flexor tendon rupture that needed operative repair. This complication was taken very seriously and led to the introduction of pre-operative ultrasonographic assessment of the affected ray(s), in order to gain information about the location of the flexor tendons and the neurovascular bundles. In case ultrasound showed a superficial flexor tendon or neurovascular bundle, the needle was inserted with extra caution. Since the introduction of ultrasound tendon rupture has not occurred anymore, which may indicate that pre-operative ultrasound enhances safety of the procedure. Sakellariou *et al.* recently published a paper in which they describe their positive experience with ultrasound-guided PNF (23). However, the hypothesis that ultrasound reduces the peri-operative complication rate of PNF is in need of further research.

Minimum pre-operative TPED as an inclusion criterion varies in previous studies. Some studies do not report a minimum TPED (7,10), but most studies use a minimum TPED of 20 to 30 degrees (8,11,12,20). In this study we included patients with a minimum TPED of 15 degrees. At this point patients frequently present with a positive tabletop test and start having complaints during daily activities (24). Furthermore, a recent study by Broekstra *et al.* showed that measurements of TPED have a maximum dispersion of 15 degrees (25). By excluding patients with a pre-operative TPED below 15 degrees from the data-set, we excluded the possibility that TPED correction was based on a measurement error. For example, a few patients had a pre-operative TPED of 2 to 6 degrees. In our opinion it is likely that these values were subjected to data-entry or measurement errors. We decided not to exclude patients with a *TPED correction* below 15 degrees. Note that this variable (TPED correction) is different from the preoperative TPED. If we excluded the cases with a TPED correction below 15 degrees, we would have overestimated the treatment effect.

Our main limitation is the retrospective nature of our study. The data of 246 rays had to be excluded because of missing data regarding pre- and postoperative PED's. Furthermore we do not have detailed information regarding follow-up and recurrence. As previous research has shown us that the longevity of PNF is limited when comparing it to limited fasciectomy, this would have been valuable information (12). However, this is subject of future investigation.

Thanks to the great amount of patients that were treated during several years, we were able to show the results of PNF in a large population. To ensure reliable results, we have taken the multi-level structure of our data into account. The fact that data of hands, rays and joints in patients with Dupuytren's disease are correlated is underestimated by many researchers. Therefore we strongly recommend to carefully select a correct statistical method when starting a new study regarding a disease that affects bilateral or multiple structures in one patient.

We can conclude that PNF is an effective treatment modality for patients with mild to moderate Dupuytren's disease. Furthermore, our results show that the procedure is significantly more effective for MCP-contractures, than for PIP- and DIP-contractures. The complication rate is low and PNF is also effective for patients with recurrent disease. It is therefore an excellent treatment modality for patients who wish to postpone more aggressive procedures.

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