

**Plastic and Reconstructive Surgery Advance Online Article**

**DOI: 10.1097/PRS.0000000000002560**

**Comparative Effectiveness of Percutaneous Needle Aponeurotomy and Limited Fasciectomy for Dupuytren's contracture: A Multicenter Observational Study**

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**Financial and conflict of interest disclosure and products**

None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this manuscript.

**Funding**

This research was financially supported by the Esser Foundation, Rotterdam, the Netherlands.

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Portions of this work were presented at the 2014 Annual Meeting of the Dutch Society for Plastic and Reconstructive Surgery, Amsterdam, the Netherlands.

**Acknowledgement**

The authors acknowledge the contribution of the patients, hand therapists and surgeons involved in the collection of data.

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## **Abstract**

**Background:** Percutaneous needle aponeurotomy (PNA) is a less invasive surgical alternative to limited fasciectomy (LF) for Dupuytren's contracture, but appeared less efficacious in a previous randomized clinical trial. This study compared the effectiveness of both techniques in contemporary clinical practice.

**Methods:** We evaluated prospectively gathered data from all patients who were treated with PNA or LF between 2011 and 2014 at 6 hand surgery practice sites in the Netherlands. The degree of total active extension deficit, Michigan Hand Questionnaire (MHQ) subscores, and complications evaluated at 6-12 weeks after treatment were compared after propensity-score based inverse-probability weighting to account for the differences in baseline characteristics between the treatment groups.

**Results:** After inverse-probability weighting, 78 PNA patients and 103 LF patients remained with similar characteristics (88% Tubiana I or II). The degree of total residual extension deficit at follow-up was similar among the weighted groups (PNA 21 degrees vs. LF 18 degrees,  $p=0.330$ ). Furthermore, PNA was associated with a lower mild complication rate (PNA, 5.2% vs. LF, 24.3%,  $p<0.001$ ) and larger increases in the subdomain scores of satisfaction ( $p<0.001$ ), work performance ( $p<0.001$ ), ADL ( $p=0.009$ ), and overall hand function ( $p=0.001$ ).

**Conclusions:** This multicenter observational study found that, among patients with mild to moderately affected digits, PNA reduced contractures as effective as LF does in clinical practice. Furthermore, PNA provided a more rapid functional recovery and had a lower rate of mild complications.

## **Introduction**

Although novel techniques for treating Dupuytren's contracture, such as collagenase injection<sup>1</sup>, have emerged, surgery remains the mainstay of treatment. Two of the most commonly used surgical techniques are Limited Fasciectomy (LF) and Percutaneous Needle Aponeurotomy (PNA). LF continues to be the most established technique for proximal interphalangeal joint (PIP) contractures and advanced cases. PNA is an accepted surgical alternative to LF that seeks to minimize complications and morbidity.

Questions, however, persist regarding the comparative effectiveness of PNA and LF. Numerous studies have described the results for each technique separately but recent reviews of these studies have underscored the complexity of making meaningful comparisons because of differences in study populations and definitions for outcomes.<sup>2-4</sup> To date, there has been one randomized clinical trial comparing PNA and LF.<sup>5</sup> In this study, PNA resulted in 18% less reduction in total passive extension deficit evaluated at 6 weeks postoperatively, primarily due to PNA's inferior efficacy for advanced cases. As a consequence, the authors concluded that PNA seemed particularly useful for treating patients with mild to moderate disease.

As of this writing, nearly a decade has past since the publication of the abovementioned trial, which should have allowed sufficient time to pass for its findings to disseminate into contemporary practice. This study compared the effectiveness of PNA and LF using prospectively gathered data from 6 different hand surgery practice sites in the Netherlands.

## **Methods**

This is a retrospective study of data from a consortium of 6 hand surgery practice sites. Data were gathered in a registry that was developed for research and quality improvement purposes, and included a wide range of patient and treatment characteristics. Patient characteristics included age, gender, comorbidities, bilateral and recurrent disease, and family history. Treatment characteristics included the technique used, digits treated and the joint levels affected. Our institutional review board approved the study protocol and waived the requirement for informed consent due to the retrospective nature of the study.

For this study, all patients who underwent PNA or LF between October 2011 and March 2014 at one of the practice sites were identified. We restricted our analyses to patients with available pre-operative data on the degree of contracture. There were no significant differences in the characteristics of patients with and without data available. In addition, we excluded patients with thumb contractures, isolated MP contractures with less than 20 degrees of contracture who were treated for other purposes than functional disability, and those with a concomitant hand condition or simultaneously undergoing another procedure (e.g. carpal

tunnel release) on the treated side to prevent confounding of outcome assessments. Patients treated for recurrent disease were included if they met all other criteria.

### ***Treatments***

Treatments were performed by one of the 17 hand surgeons of the practice sites through shared decision-making.

LF was performed in an operating theatre with tourniquet exsanguination and loupe magnification under axillary block or general anesthesia. Cords were excised after Bruner type or longitudinal incisions with Z-plasties. Care was taken to prevent injury to the digital neurovascular bundles. Compressive dressings were applied for 2 weeks. All patients were offered a supervised program of hand therapy with instructed use of removable night splints for 3 months.

PNA was performed under local anesthesia. Cords were released using 25 gauge needles at as many levels as possible in the palm and fingers. Patients were instructed to report paresthesias to avoid nerve injury. After release, the treated digit was extended with a progressive force to maximize contracture reduction. Patients were encouraged to flex and extend their fingers immediately following treatment and to restart normal use of their hands after 24 hours. Patients were offered identical rehabilitation and splinting programs as patients undergoing LF.

### ***Outcomes***

The primary outcome was the degree of total residual extension deficit. Certified hand-therapists examined patients before and at visits occurring between 6 and 12 weeks after surgery. The degree of extension deficit was assessed using a finger goniometer by summing up the degree of active extension deficit at the MP, PIP and DIP joint levels for each affected digit. Hyperextension at the individual joints was defined as 0 degrees to prevent underestimation of extension deficit. To increase comparability between patients with single versus multiple digit involvement, we used data from the digit that was most severely affected at baseline (e.g. highest total extension deficit).

The impact of PNA and LF on patient-reported hand function was assessed using the Michigan Hand Questionnaire (MHQ). The MHQ is a self-reported 37-item hand-specific assessment tool evaluating 6 aspects of hand function for each hand separately: overall hand function, ability to perform activities in daily life (ADL), work performance, aesthetics, pain and satisfaction. It is thoroughly developed and well-validated for Dupuytren's disease.<sup>6-8</sup> Scores range from 0(poorest function) to 100(best function). Because functional restoration was considered the primary treatment objective, we excluded all pain outcomes from our analysis. Only the outcomes pertaining to the treated side were considered.

Treatment-related complications were prospectively documented and classified into a mild (neuropraxia, skin fissure, scar and wound healing sequelae) and a serious category

(nerve laceration, uncorrectable contracture, wound infection requiring antibiotic treatment, arterial laceration, tendon rupture, cold intolerance, palmar or digital hematoma).

### ***Statistical analyses***

#### *Sample size*

Sample-size calculations showed that a total number of 144 patients (72 each group) would provide 85% power ( $\beta=0.15$ ,  $\alpha=0.05$ ) to detect a 5° difference in total extension deficit between the treatment groups with the use of two-sided tests.

#### *Adjustment for between-group differences in baseline characteristics*

We anticipated differences in the baseline characteristics between the PNA and LF groups because we expected LF to be the preferred treatment for advanced cases. Such differences in the factors that influence the treatment decision between both treatments threaten the validity of a comparison due to treatment selection bias. Propensity score analyses provide a statistical approach for investigators to minimize this form of bias by accounting for the differences in such factors, given that there are patients who are suitable candidates for both techniques.<sup>9-11</sup> The assumption that there are PNA patients who could have been treated with LF and vice versa is likely met, as decisions often depend on patient preference.<sup>12</sup> In the present study, the propensity score is defined as the probability of undergoing PNA based on factors influencing the decision between LF and PNA, including age, primary or recurrent disease, the number of digits affected, the joint levels affected and the degree of extension deficit at these joints. To calculate this probability (propensity score), we used multivariate logistic regression modeling with the pretreatment factors as independent variables and treatment technique as the dependent variable. To minimize the risk of further bias<sup>13,14</sup>, we also included possible confounders of the relation between treatment and outcomes, including gender<sup>15</sup>, diabetes, smoking status, bilateral and familial history of the disease.

As PNA and LF were the two treatments available, the probability of receiving LF is 1 minus the probability of undergoing PNA (inverse probability) and vice versa. Patients with a high-probability of undergoing LF would therefore have a low-probability of undergoing PNA and vice versa. By weighting patients based on the inverse of their propensity score, patients with a similar probability of undergoing PNA and LF receive more weight while those with a high-probability of undergoing either treatment receive less weight. Consequently, patients with similar baseline characteristics are weighted more than those with dissimilar characteristics, thus resulting in more balanced treatment groups.

Propensity-score based inverse probability weighting was used as the primary method to account for the between-group differences. To verify whether the groups were indeed more balanced afterwards, we compared the groups before and after this approach. As compared

with propensity-score based matching approaches, inverse probability weighting minimizes the exclusion of patients, thereby increasing the ability to generalize from the results.<sup>13,14</sup>

#### *Comparison of outcomes*

Baseline characteristics were compared using Pearson chi-square tests for categorical variables and Student's t-tests for continuous variables. To compare the degree of total residual contracture and MHQ scores at follow-up among the treatment groups, we used repeated measures analyses of variance with the treatment group as a between-subjects factor. To compare complication rates of mild and serious complications, we used using Pearson chi-square or Fisher's exact tests.

To test the robustness of our findings, we performed additional sensitivity analyses using data from patients in the PNA and LF groups who did not have severe PIP contractures (defined as >40 degrees extension deficit).<sup>16</sup> This approach assumes that having a severe PIP contracture is the only factor influencing the decision between NA and LF that should be accounted for.

Descriptive statistics are presented as percentages for categorical variables and as means  $\pm$ SD for continuous variables. Significance thresholds were set at  $p \leq 0.05$ .

#### **Results**

There were a total of 368 patients who underwent PNA (25%) or LF (75%) for Dupuytren's contracture between 2011 and 2014. After applying the eligibility criteria, 293 patients remained to form the study sample. Of these, 78 patients (27%) underwent PNA and 215 patients (73%) underwent LF (Figure 1).

Table 1 shows the baseline characteristics of the study sample before and after inverse probability weighting. Before weighting, PNA patients had, on average, fewer affected digits, 14° less total extension deficit, less advanced PIP joint contractures, and were more likely to have primary disease, demonstrating that LF was the preferred technique for advanced cases. The PNA group also had relatively more women.

After inverse probability weighting, all baseline characteristics were well-balanced among the treatment groups (Table 1). This was in part due to 112 LF patients (52%) with such a high probability of receiving LF that they received a weight of zero in further analyses (Figure 1). These patients, as compared with the other weighted patients, had, on average, 21 degrees more total extension deficit preoperatively, more advanced PIP and DIP contractures, and 8 degrees worse residual contracture postoperatively, further demonstrating that LF was used for patients with advanced disease and the need to account for such differences.

Among the weighted treatment groups, the mean age was 65 years. The majority of digits involved (88%) were Tubiana grade I (<45°) or grade II (45°-90°), 10% grade III (90°-135°) and 2% grade IV (>135°). The majority of digits had isolated MP contractures (42%) or

contractures of both the MP and the PIP joint (37%). Eleven percent of digits had an isolated PIP contracture. The remaining digits had a DIP contracture combined with an affected PIP joint (6%), MP joint (2%) or a contracture spanning all three joints (3%).

All patients in the weighted groups had follow-up data available on the degree of total residual extension deficit and complications. The average follow-up duration was 10 weeks (range, 6–12 weeks) and similar between groups ( $P=0.891$ ). Sixty-seven percent of the PNA patients as compared to 83% of the LF patients completed the MHQ at follow-up with no differences in the baseline characteristics between those who did and did not complete the MHQ.

#### *Residual contracture*

Among the weighted treatment groups, the degree of total residual extension deficit at follow-up was not significantly different (PNA,  $20^\circ$  vs. LF,  $18^\circ$ ; Figure 2A), which corresponded with an improvement from baseline of 66% ( $39^\circ$ ) for PNA and 71% ( $43^\circ$ ) for LF (Figure 2B).

When separately evaluating MP from PIP contractures, the degree of residual extension deficit was not significantly different among the weighted groups for neither the affected MP joints (PNA,  $10^\circ$  vs. LF,  $8^\circ$ ; Figure 3A) nor affected PIP joints (PNA,  $18^\circ$  vs. LF,  $13^\circ$ ; Figure 3B).

#### *Patient-reported outcomes*

Significantly larger improvements in the MHQ subscore of satisfaction, work performance, ADL, and overall hand function were found in the weighted PNA group as compared with the weighted LF group (Figure 4). However, the hand appearance subscore showed a similar improvement.

#### *Complications*

Table 2 compares complication rates among the weighted groups. Although the rate for serious complications did not significantly differ among the groups (PNA, 2.6% vs. LF, 1.7%), mild complications occurred significantly less frequently after PNA than after LF (PNA, 5.2% vs. LF, 24.3%).

#### *Recurrence subgroup*

Comparing only patients who were treated for recurrent disease among the weighted groups, there was no significant difference in the baseline degree of total extension deficit. The degree of total residual extension deficit at follow-up was also not significantly different between the recurrence subgroups (PNA,  $24^\circ$  vs. LF,  $18^\circ$ ;  $P=0.101$ ).

#### *Sensitivity analyses*

Sensitivity analyses performed using data from 65 PNA and 95 LF patients without severe PIP contractures yielded similar results for the outcome comparisons. However, the two groups differed in several baseline characteristics, indicating that inverse probability



weighting achieved more balance and thus more precise inferences about the treatment effects.

## **Discussion**

Interest in comparative effectiveness research has exploded in recent years, because the results from such studies may better reflect real-world practice than those obtained by strictly controlled clinical trials.<sup>17,18</sup> The purpose of this multicenter study was to compare the effectiveness of PNA and LF for treating Dupuytren's contracture in contemporary clinical practice. We found that both techniques provided a similar degree of contracture reduction among patients who have mild to moderately affected digits. These findings were similar when separately evaluating affected MP joints from affected PIP joints. However, PNA was associated with larger improvements in most MHQ subscores and a significantly lower rate of mild complications.

Despite that PNA has become an accepted treatment for Dupuytren's contracture, questions persist regarding its effectiveness as compared with LF. To date, there has been one randomized clinical trial comparing the efficacy of the two treatments.<sup>5</sup> In this trial, PNA achieved 18 percent less reduction in total passive extension deficit than LF assessed at 6 weeks postoperatively. However, subgroup analyses indicated that this difference was primarily due to PNA's inferior results for more advanced cases, while similar results were found for those graded as Tubiana I and II. Hence, the authors concluded that PNA seemed particularly useful as a treatment for patients with mild to moderately severe contractures. The similar degree of contracture reduction achieved among the two treatment groups in this study consisting of primarily (88%) of Tubiana grade I and II patients demonstrates that PNA was indeed used to treat patients with less advanced disease at the practice sites involved, and appeared as effective as LF at reducing contractures in contemporary practice.

The evaluation of changes in MHQ subscores following treatment allowed comparison of the early impact of PNA and LF on different aspects of hand function. Larger improvements in the subscores of overall hand function, satisfaction, work performance and ADL were found in the PNA group, which primarily shows that the technique restores hand function more rapidly than LF does and highlights its less invasive nature. The similar improvement in the subscore of hand appearance among the treatment groups suggests that both treatments help to address concerns patients may have about the appearance of their hand.<sup>19</sup>

The significantly lower rate of mild complications after PNA than after LF is consistent with the findings of previous reports<sup>20</sup> and related to the high rate of neuropraxia found in the LF group. With the exception of neuropraxia, all other complications were unique to each treatment group. Although the low incidence of complications in this study merits

Careful interpretation, this finding is in line with the clinical observation that complications arise as a consequence of the nature of the technique. For example, the reported skin fissures are likely to have occurred because of the percutaneous and blind nature of PNA, whereas the scar and wound healing sequelae found in the LF group can be expected from any open surgical technique. Until sufficiently powered studies are performed directly comparing the risk profile of both techniques among comparable patients, we feel that both the differences in mild complication rates and the type of complications occurring after PNA and LF may be informative for patient counseling.

Strengths of this study include the use of inverse probability weighting to account for the differences in baseline characteristics to minimize bias. This approach allowed comparison of the effectiveness of PNA and LF in actual clinical practice using data from 6 practice sites that were prospectively gathered by therapists who had no knowledge of this study. Although both treatment groups were well-balanced after inverse probability weighting, however, the possibility remains for unobserved confounding factors to have influenced our findings, such as patients' genetic constitution.<sup>21</sup> Another limitation was that a substantial proportion of patients who underwent LF for advanced PIP and DIP joint contractures were not weighted in the analyses, thus our findings do not apply to such patients.

The largest drawback of this study is its short follow-up duration. Although this allowed for a comparison of short-term outcomes, recurrence rates may be just as important to patients when selecting between treatments.<sup>12</sup> Considering that PNA has become the preferred technique for less severe cases in contemporary practice, there is a need for long-term studies assessing whether the previously reported 64% higher recurrence rate at 5 years as compared with LF is still accurate.<sup>22</sup>

The present study provides information that may be used to help Dupuytren's disease patients and clinicians decide between PNA and LF. It shows that PNA, in the short-term, reduces mild to moderately affected digits as effectively as LF does in routine practice, confirming recent recommendations that PNA has most value as a first-line treatment.<sup>23,24</sup> Furthermore, PNA provided a faster functional recovery and had a lower rate of mild complications. Besides an evaluation of treatments, this study highlights inverse probability weighting as a useful and feasible tool in assessing the comparative effectiveness of different treatment techniques for Dupuytren's disease.<sup>25</sup> This approach could be of increasing importance considering the expanding number of treatment strategies for Dupuytren's disease, many of which may never be compared to each other in randomized clinical trials.

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## **Legends**

**Figure 1.** Patient selection flowchart. PNA; Percutaneous needle aponeurotomy, LF; Limited fasciectomy.

**Figure 2.** Degree of total contracture (total active extension deficit) in the weighted PNA and LF groups at baseline and follow-up (A). Means and standard errors are plotted.

Corresponding improvement in contracture expressed in absolute degrees and percentual improvement from baseline (B). PNA; Percutaneous needle aponeurotomy, LF; Limited fasciectomy.

**Figure 3.** Degree of contracture (active extension deficit) for affected MCP (A) and affected PIP (B) joints in weighted PNA and LF groups at baseline and follow-up. Means and standard errors are plotted. MCP; metacarpophalangeal, PIP; proximal interphalangeal, PNA; percutaneous needle aponeurotomy, LF; Limited fasciectomy.

**Figure 4.** Change in MHQ scores in the weighted PNA and LF groups at follow-up from baseline. Asterisks (\*) denote significant differences among the adjusted treatment groups. PNA; percutaneous needle aponeurotomy, LF; Limited fasciectomy.

**Table 1.** Baseline characteristics before and after inverse probability weighting with the use of propensity scores, by treatment group.

**Table 2.** Complications in the weighted PNA and LF groups. PNA; Percutaneous needle aponeurotomy, LF; Limited fasciectomy.

**Table 1.** Baseline characteristics before and after inverse probability weighting, by treatment group.\*

	Not Weighted			Weighted		
	PNA (N=78)	LF (N=215)	p	PNA (N=78)	LF (N=103)	p
<b>Demographics</b>						
Age –yrs.	65±8	63±9	0.103	65±8	65±8	0.837
Male gender –%	68	81	0.014	68	72	0.571
Diabetes –%	18	8	0.014	18	10	0.106
Current smoker –%	14	14	0.974	14	10	0.361
<b>Disease</b>						
<b>Characteristics</b>	47	57	0.157	47	52	0.592
Bilateral disease –%	19	36	0.006	19	28	0.166
Recurrent disease –%	49	47	0.792	49	53	0.533
Positive family history –%	64	45	0.009	64	60	0.600
No. digits affected	23	29		23	28	
1 –%	13	26		13	12	
2 –%						
>2 –%						
<b>Outcomes</b>						
Extension deficit† – degrees	60±28	74±37	0.003	60±28	62±26	0.702
Total	38±29	25±25	<0.001	38±29	40±24	0.740
MP joint level	19±19	41±28	<0.001	19±19	19±22	0.957
PIP joint level	3±8	7±12	0.001	3±8	3±9	0.736
DIP joint level						

\* Plus-minus values are means ±SD.

† Values are reported for all joints.

PNA, Percutaneous Needle Aponeurotomy; LF, Limited Fasciectomy; MP, metacarpophalangeal; PIP, proximal interphalangeal; DIP, distal interphalangeal; SD, standard deviation.

**Table 2.** Complications rates in the inverse probability weighted PNA and LF groups.\*

<b>Complication</b>	<b>PNA (N=78)</b>	<b>LF (N=103)</b>	<b>P value</b>
<b>Serious</b>			0.579
Nerve Laceration	1.3	0.0	
Uncorrectable contracture	1.3	0.0	
Wound infection	0.0	1.3	
Arterial Laceration	0.0	0.0	
Tendon Rupture	0.0	0.0	
Cold Intolerance	0.0	0.0	
Hematoma	0.0	0.0	
Extensive edema	0.0	0.4	
<b>Mild</b>			<0.001
Neuropraxia	2.6	17.4	
Scar sequelae	0.0	4.9	
Skin Fissure	2.6	0.0	
Wound healing	0.0	1.9	

\* Values are percentages.

PNA, Percutaneous Needle Aponeurotomy; LF, Limited Fasciectomy.

Figure 1.

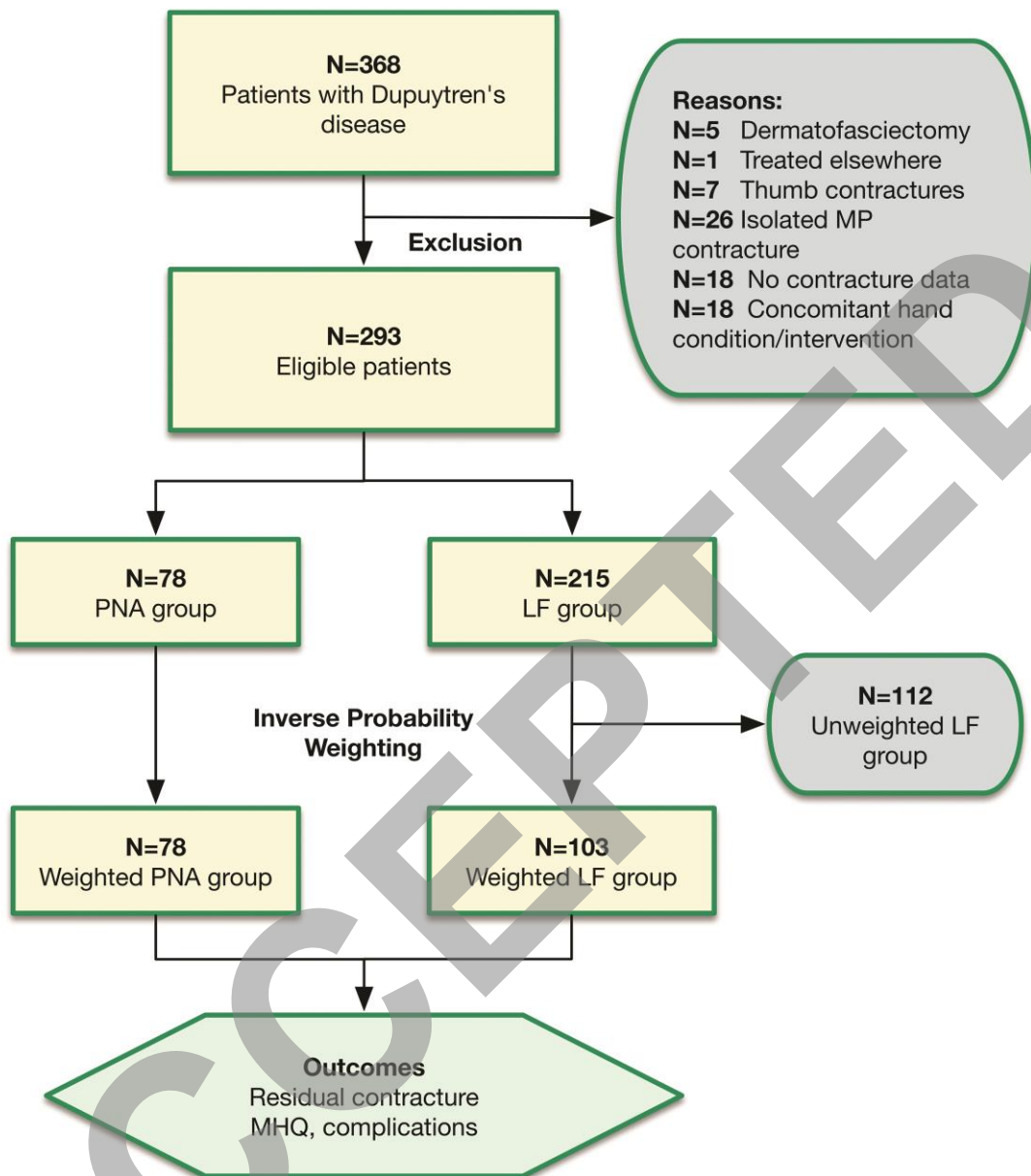




Figure 2.

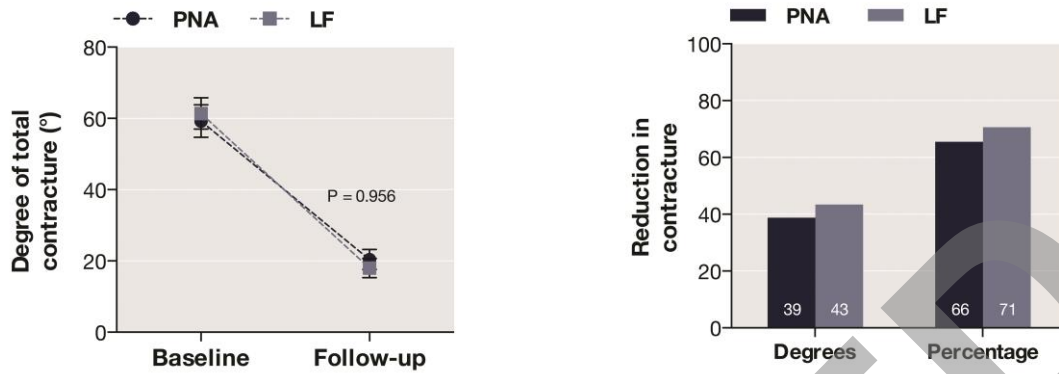


Figure 3.

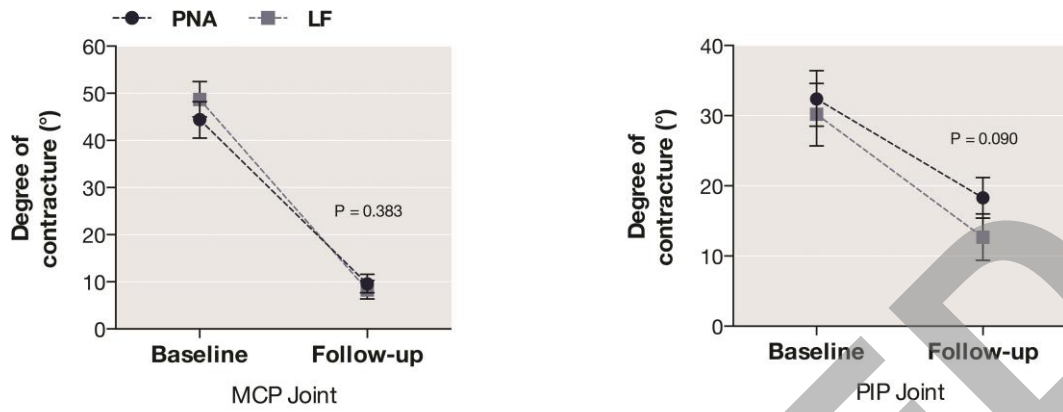


Figure 4.

