

# Percutaneous Aponeurotomy and Lipofilling versus Limited Fasciectomy for Dupuytren's Contracture: 5-Year Results from a Randomized Clinical Trial

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**Background:** In the Dupuytren Rotterdam randomized controlled trial, percutaneous aponeurotomy with lipofilling (PALF) was as effective as limited fasciectomy in correcting primary Dupuytren's contracture after 1 year. The authors report the 5-year results of this trial, with a special focus on recurrence of contractures.

**Methods:** The authors invited all patients who had undergone PALF or limited fasciectomy to participate in a posttrial follow-up assessment. Thirty-one PALF patients and 21 limited fasciectomy patients were assessed by an independent examiner for the degree of contracture and whether patients had undergone a secondary procedure. The primary composite endpoint was recurrence rate, defined as either 20 degrees or greater worsening in contracture (relative to week 3) or as having undergone a secondary procedure for a new or worsening contracture.

**Results:** At 5 years, more joints in the PALF group than in the limited fasciectomy group had a recurrence (74 percent versus 39 percent;  $p = 0.002$ ). When redefining recurrence as a worsening in total extension deficit of at least 30 degrees for treated digits as often reported, this was 77 percent versus 32 percent ( $p = 0.001$ ). Total extension deficit was also worse for PALF-treated digits (53 degrees versus 31 degrees;  $p < 0.010$ ).

**Conclusions:** Although the authors previously reported that PALF offers a shorter convalescence and fewer long-term complications but a similar degree of contracture correction at 1-year follow-up, at 5 years, the corrections were less durable than those for limited fasciectomy. This again highlights that limited fasciectomy and different types of needle aponeurotomy have specific advantages and disadvantages to weigh by patients and clinicians. (*Plast. Reconstr. Surg.* 142: 1523, 2018.)

**CLINICAL QUESTION/LEVEL OF EVIDENCE:** Therapeutic, II.

The standard of care for Dupuytren's disease remains the more open limited fasciectomy that removes the diseased tissue, and the

more minimally invasive percutaneous needle fasciotomy surgery that mechanically divides the cord to straighten the finger.<sup>1</sup> In comparison, percutaneous needle fasciotomy offers benefits because it is less invasive,<sup>2</sup> may be performed at the outpatient clinic, and is associated with a lower mild complication

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rate<sup>3</sup> and a more rapid return to normal use of the hand.<sup>3,4</sup> The largest drawback of percutaneous needle fasciotomy, however, is that its results may be less durable over time than for limited fasciectomy, with reported recurrence rates ranging from 50 to 85 percent,<sup>4,5</sup> whereas rates for limited fasciectomy range from 12 to 39 percent.<sup>4,5</sup> Although collagenase has become very popular in many countries, it is not considered in this article, as it is not always reimbursed and is beyond the scope of this study. In an attempt to improve the durability of the results of percutaneous needle fasciotomy, we developed an alternative treatment approach that relies on a more extensive percutaneous release than classic percutaneous needle fasciotomy, followed by subdermal autologous lipografting (percutaneous aponeurotomy with lipofilling, or PALF).<sup>6,7</sup> Pre-clinical studies have demonstrated that the grafted lipoaspirate contains adipose-derived stem cells that may inhibit contractile myofibroblasts,<sup>8</sup> which are the cells primarily responsible for fibrosis and the pathogenesis of the contractures in Dupuytren's disease. Although these studies imply a potential, long-term benefit of lipofilling in concurrence with aponeurotomy for Dupuytren's disease, data from clinical studies are sparse.<sup>1,7</sup>

The Dupuytren Rotterdam trial was originally designed to compare the efficacy and safety of PALF and limited fasciectomy in patients with primary disease.<sup>9</sup> We found that during the first postoperative year, PALF corrected contractures as effective as limited fasciectomy, whereas no significant difference in recurrence was found between both groups. In the current study, we report results after an extended follow-up period of 5 years in patients who previously participated in the Dupuytren Rotterdam trial.

## PATIENTS AND METHODS

### Study Design

The design of the Dupuytren Rotterdam trial and the 1-year follow-up data have been described previously (Dutch Trial Register NTR1692).<sup>9</sup> In short, the study was a prospective, randomized, single-blind, clinical trial designed to compare PALF with limited fasciectomy at 1 year after treatment. Patients with primary Dupuytren's disease and a flexion contracture of at least 20 degrees at the metacarpophalangeal joint and/or 30 degrees at the proximal interphalangeal joint were eligible, whereas patients with contractures affecting the thumb or patients using anticoagulant therapy were excluded.

Although we previously reported the data collected preoperatively and at 2 and 3 weeks, 6 months, and 1 year after treatment, this study compared the 5-year results between both groups. All surviving patients originally assessed at baseline in the Dupuytren Rotterdam trial were considered eligible.

### Treatments

PALF and limited fasciectomy were performed under exsanguination by tourniquet and under regional or general anesthesia. Detailed descriptions of the techniques have been previously reported and a video demonstrating the PALF technique can be found in the Supplemental Digital Content.<sup>6,7</sup> All patients were offered a comparable rehabilitation program under supervision of hand therapists and were instructed to use an extension splint at night for 6 months.

### Follow-Up Examinations

The 5-year follow-up examination was performed by a single examiner (R.M.W.) who was not involved in the previous trial and, before assessment, was unaware of the treatment allocation. The examiner was an experienced hand therapist with several years of experience in measuring goniometry of the hand. The goniometry measurements were performed following the guidelines of the American Society of Hand Therapists. The degree of contracture was assessed using a goniometer after reaching a firm endpoint during passive extension of the digits at the metacarpophalangeal, proximal interphalangeal, and distal interphalangeal joint levels. Total extension deficit was defined as the sum of the degree of extension deficit of the metacarpophalangeal, proximal interphalangeal, and distal interphalangeal joints, and hyperextension at the joint level was defined as 0 degrees to prevent underestimation of the total extension deficit. To increase comparability between patients who underwent treatment for a single digit and those treated for multiple digits, we analyzed the digit most severely affected in patients with more than one affected digit.

### Primary and Secondary Outcome Measures

The primary endpoint was a composite measure of recurrence assessed at the level of affected joints. Recurrence was defined as either having undergone a secondary procedure for a new or worsening contracture, or as an increase in extension deficit of more than 20 degrees relative to week 3 after treatment. The latter was based on

a recent Delphi-based definition for recurrence of contracture that used a similar definition, although using 1 year as follow-up.<sup>10</sup> To facilitate comparison with the randomized trial by van Rijssen et al. comparing limited fasciectomy with percutaneous needle fasciotomy (without lipofilling), we also defined recurrence as an increase in total passive extension deficit of at least 30 degrees at the level of treated digits (relative to week 3).<sup>11</sup> To assess the patient perspective,<sup>12</sup> we asked patients who had not undergone a secondary procedure at the time of follow-up to complete the Disabilities of the Arm, Shoulder and Hand questionnaire and a number of ad hoc visual analogue scale questions pertaining to satisfaction with the overall treatment result, restoration of hand function, position of the fingers, appearance of the area of the hand treated, and whether patients' expectations were met concerning the overall treatment result.

### Statistical Analysis

Descriptive statistics were applied on demographic and clinical characteristics and groups were compared using *t* tests, chi-square tests, and Fisher's exact test as appropriate. Continuous variables were reported as means and standard deviations, and categorical variables were summarized with the use of frequencies.

To assess the possible risk of bias because of loss to follow-up, we compared patient characteristics, disease-specific characteristics at baseline, and 1-year outcomes including the degree of extension deficit and Disabilities of the Arm, Shoulder and Hand questionnaire scores using two-sided *t* tests and chi-square tests as appropriate between respondents and nonrespondents. The primary outcome analysis, assessing recurrence of contracture, was performed at the level of individual joints. The proportion of affected joints meeting this primary endpoint was compared between groups using chi-square tests. We did not perform multivariable analyses to facilitate interpretation of the results and because we felt we had adequately adjusted for possible selection bias between the two treatment groups through randomization.

To compare the degree of extension deficit between treatment groups, we used two-sided *t* tests after assessment for normality. Because 5-year extension deficit was unavailable for patients who had undergone a secondary procedure at the time of follow-up, and because excluding these patients may underestimate the degree

of total extension deficit, we imputed the degree of extension deficit at 5 years using the pretreatment degree of extension deficit in these patients. Because of the relatively small sample size, we added a comparison of the median extension deficit, testing with a nonparametric Mann-Whitney *U* comparison on our primary outcome measurement as a control.

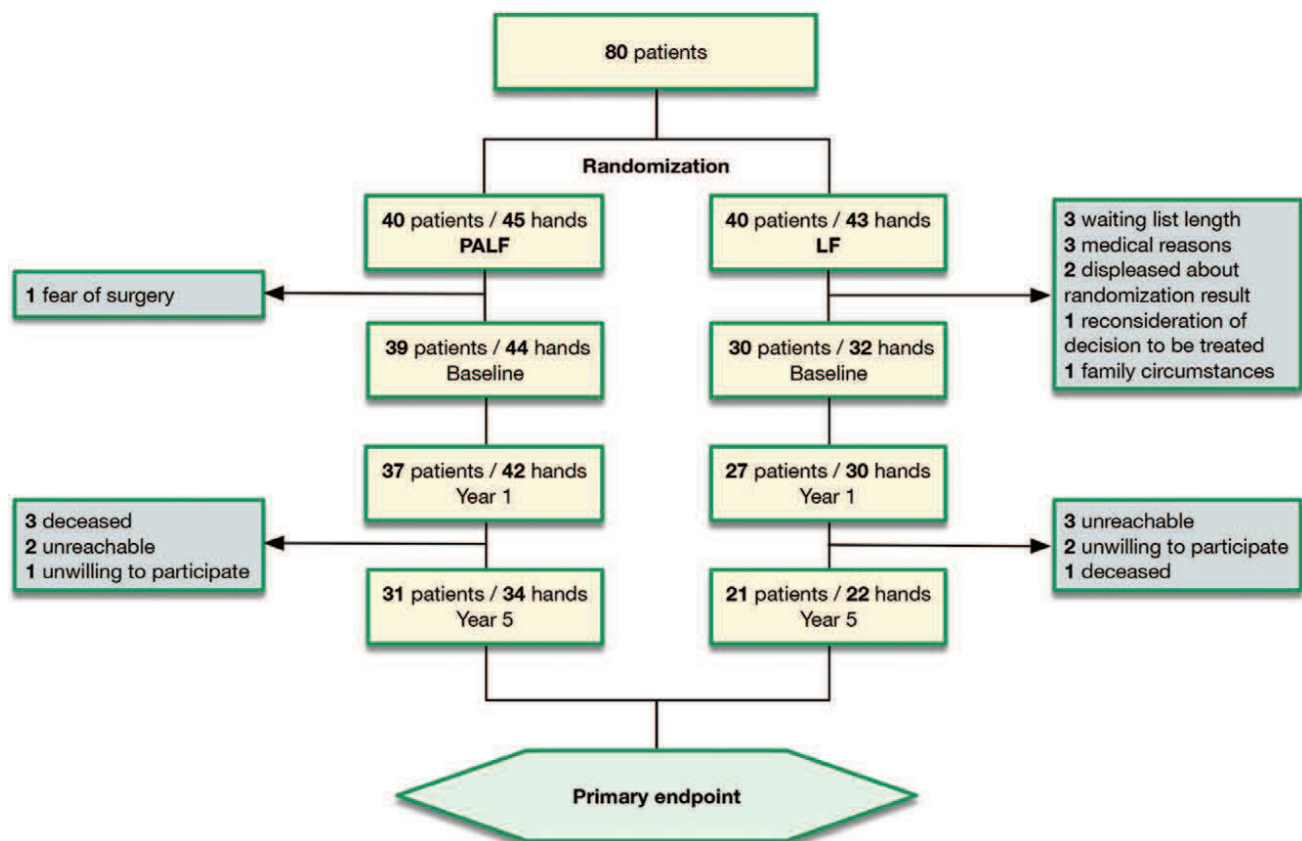
Exploratory univariable and multivariable logistic regression modeling was finally used to identify factors predicting recurrence at the level of treated digits. All baseline clinical factors showing evidence for an association ( $p < 0.100$ ) in univariable analyses were included in multivariable models using a stepwise backward elimination approach. Significance thresholds were set at  $p < 0.05$ , and all statistical analyses were performed using IBM SPSS Version 20.0 (IBM Corp., Armonk, N.Y.).

## RESULTS

### Study Sample

Between October of 2015 and February of 2016, 52 of the 80 patients that were originally randomized (65 percent) agreed to participate in the present 5-year study, of whom four were bilaterally treated and assessed, resulting in a total of 56 treated hands (Fig. 1). Baseline characteristics were not significantly different between the treatment groups (Table 1). Respondents and nonrespondents also did not differ in baseline characteristics, including diathesis factors, with the exception that respondents more often had a family member with Dupuytren's disease. [See Table, Supplemental Digital Content 1, which shows baseline characteristics, divided by patients who were able and willing to participate (respondents) with the present study and those who were unable or unwilling to participate (nonrespondents), <http://links.lww.com/PRS/D110>.] There were also no clinically meaningful differences between respondents and nonrespondents in extension deficit and Disabilities of the Arm, Shoulder and Hand questionnaire scores at 1-year follow-up, further indicating that the loss to follow-up was not selective. The average follow-up duration for both treatment groups was similar (PALF, 5.4 years; limited fasciectomy, 5.5 years;  $p = 0.685$ ).

The mean age of the patients was 62 years in the overall group, and 82 percent were men. The majority of the digits analyzed were Tubiana grade I (36 percent) or II (46 percent) before surgery.



**Fig. 1.** Flow diagram of the complete study, for which we now report the 5-year results. *PALF*, extensive percutaneous needle aponeurotomy with lipofilling; *LF*, limited fasciectomy.

**Table 1. Baseline Characteristics of the Study Sample, Divided by Treatment Group**

	PALF	LF	<i>p</i>
No. of patients	31	21	
No. of hands	34	22	
Patient characteristics			
Mean age $\pm$ SD, yr	62 $\pm$ 9	62 $\pm$ 7	0.103
Male gender	82%	82%	0.959
Diabetes	9%	9%	0.973
Alcohol, units/wk	2	2	0.741
Disease-specific variables			
Positive family history	59%	67%	0.561
Ectopic disease	29%	19%	0.391
Ledderhose disease	21%	14%	0.556
Peyronie disease	12%	10%	0.796
No. of rays treated			0.253
1	52%	69%	
>1	48%	31%	
Extension deficit, degrees			
Total flexion deformity	61 $\pm$ 34	58 $\pm$ 35	0.772
MP joints	21 $\pm$ 26	26 $\pm$ 25	0.488
No. of affected MP joints	18	15	0.258
PIP joints, degrees	39 $\pm$ 28	31 $\pm$ 29	0.311
No. of affected PIP joints	28	16	0.391

PALF, extensive percutaneous needle aponeurotomy with lipofilling; LF, limited fasciectomy; MP, metacarpophalangeal; PIP, proximal interphalangeal; DASH, Disabilities of the Arm, Shoulder and Hand questionnaire.

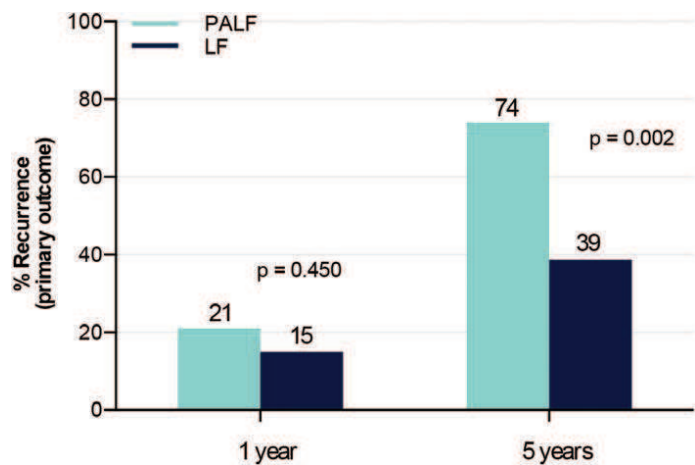
Our primary outcome analyses were based on 77 affected joints; 46 in the PALF group and 31 in the limited fasciectomy group.

### Recurrence Rate and Residual Contracture

Although at 1 year after surgery the recurrence rate was not significantly different between groups, more affected joints in the PALF group (74 percent) than in the limited fasciectomy group (39 percent) had a recurrence at 5 years ( $p = 0.002$ ), based on our composite outcome endpoint analysis of either having undergone a secondary procedure or having an increase in extension deficit of more than 20 degrees relative to week 3 after treatment (Fig. 2). Among the subgroup of patients with Ledderhose and/or Peyronie disease [i.e. systemic involvement (72 affected joints; 94 percent of all included joints)], we also found more affected joints in the PALF group than in the limited fasciectomy group (73 percent versus 37 percent;  $p = 0.002$ ).

When defining recurrence as an increase in total passive extension deficit of at least



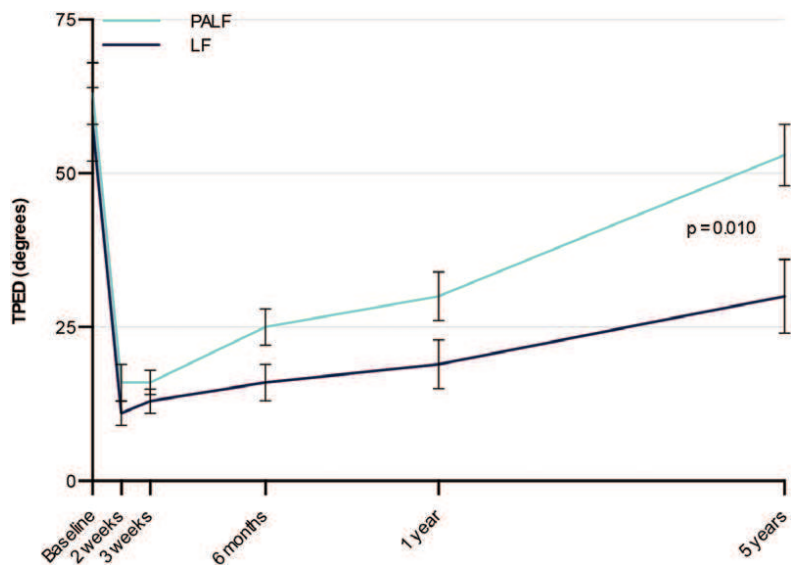


**Fig. 2.** Recurrence rates in the percutaneous aponeurotomy with lipofilling (PALF) and the limited fasciectomy (LF) groups based on the composite endpoints at 1 and 5 years after surgery.

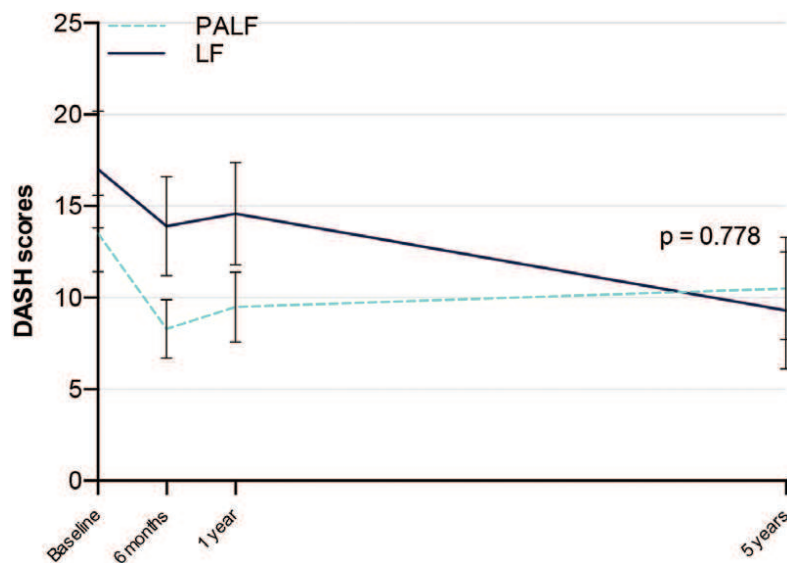
30 degrees (relative to week 3) for treated digits, following van Rijssen et al., we also find that more digits in the PALF group (77 percent) met the definition for recurrence at 5 years than in the limited fasciectomy group (32 percent;  $p = 0.001$ ). At 5 years postoperatively, the estimated mean degree of total passive extension deficit was also significantly worse for digits treated with PALF than with limited fasciectomy (53 degrees versus 31 degrees) (Fig. 3). When comparing the median degree of total extension deficit between both treatment groups, we also found that PALF-treated digits had significantly worse extension

deficit (PALF, 33 degrees; limited fasciectomy, 21 degrees;  $p = 0.007$ ).

When analyzing metacarpophalangeal and proximal interphalangeal joints separately, for metacarpophalangeal joints, the proportion of joints with a recurrence based on the composite endpoint analysis at 5 years in the percutaneous aponeurotomy with lipofilling group was higher than in the limited fasciectomy group but was not significant (61 percent versus 33 percent;  $p = 0.166$ ). The degree of extension deficit was also higher for affected metacarpophalangeal joints after PALF than after limited fasciectomy (24 degrees versus



**Fig. 3.** Estimated total passive extension deficit (TPED) in both groups preoperatively and at all recorded follow-up visits. The  $p$  value corresponds to the difference between both groups at 5 years after surgery. PALF, percutaneous aponeurotomy with lipofilling; LF, limited fasciectomy.



**Fig. 4.** Disabilities of the Arm, Shoulder and Hand questionnaire (DASH) scores in both groups preoperatively and at all recorded follow-up visits. The  $p$  value corresponds to the difference between both groups at 5 years after surgery. PALF, percutaneous aponeurotomy with lipofilling; LF, limited fasciectomy.

11 degrees) (Fig. 4). For proximal interphalangeal joints, however, more affected joints in the PALF group met the primary endpoint than in the limited fasciectomy group (82 percent versus 44 percent;  $p = 0.017$ ). The estimated degree of extension deficit was also higher for affected proximal interphalangeal joints after PALF than after limited fasciectomy (47 degrees versus 28 degrees) (Fig. 4).

#### Patient-Reported Outcomes

A total of 18 PALF-treated patients and 17 limited fasciectomy-treated patients (i.e., the patients who had not yet undergone a revision procedure) completed the study questionnaires at 5 years after surgery. Among this subset of patients, 5-year Disabilities of the Arm, Shoulder and Hand questionnaire scores were not significantly different between groups (PALF, 10.5 points; limited fasciectomy, 9.3 points) (Fig. 5). Satisfaction was also not significantly different between groups (Table 2).

#### Risk Factors for Recurrence

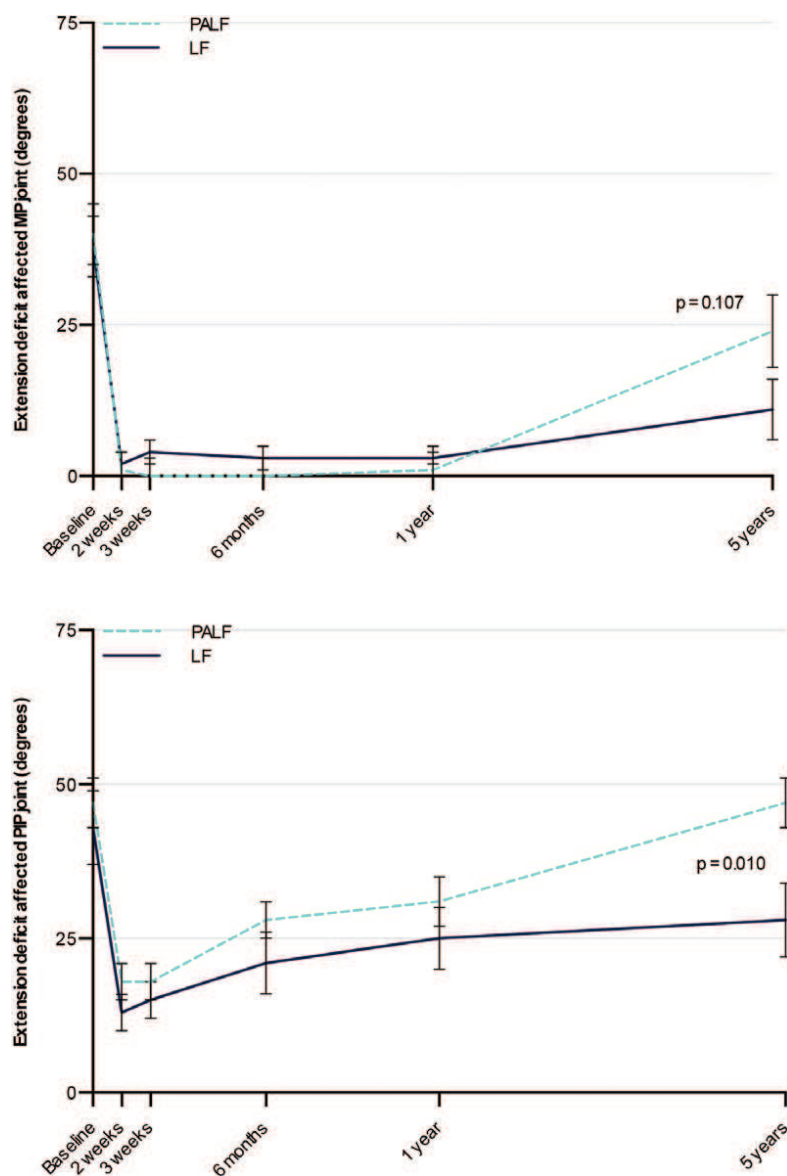
Significantly more patients with an affected proximal interphalangeal joint had a recurrence at 5 years. All other baseline characteristics, including ectopic disease, family history of the disease, diabetes, and epilepsy were unrelated.

In multivariable analysis (Table 3), we found that the presence of an affected proximal interphalangeal joint remained to show a trend for an independent association with a higher likelihood of developing a recurrence. These analyses again

confirmed, as indicated by the significantly lower odds, less recurrence after limited fasciectomy than after PALF at 5 years postoperatively.

## DISCUSSION

Long-term results of treatments are highly relevant to patients with Dupuytren's disease, as recurrence rate was recently found to be among the most important attributes for patients in making treatment choices.<sup>13</sup> Attempting to reduce the relatively high recurrence rate of traditional needle aponeurotomy for Dupuytren's contracture, we developed an alternative approach using an extensive and fundamentally different percutaneous release technique and subsequent autologous lipografting (PALF). The purpose of the present study was to assess the 5-year results of a randomized controlled trial comparing this treatment with standard limited fasciectomy for primary Dupuytren's contracture. We found that at 5-year follow-up, significantly more joints in the PALF group than in the limited fasciectomy group had a recurrence (74 percent versus 39 percent;  $p < 0.001$ ), based on either having undergone a secondary procedure or having an increase in extension deficit of more than 20 degrees. In line with this finding, the degree of total extension deficit was significantly worse after PALF than after limited fasciectomy. Extension deficit was worse for proximal interphalangeal joints compared with metacarpophalangeal joints, and for proximal



**Fig. 5.** Estimated extension deficit for affected metacarpophalangeal (MP) (above) and proximal interphalangeal (PIP) joints (below) in both treatment groups preoperatively and at all recorded follow-up visits. The  $p$  values correspond to the differences between both groups at 5 years after surgery. PALF, percutaneous aponeurotomy with lipofilling; LF, limited fasciectomy.

interphalangeal joints the difference in extension deficit between both treatment groups was also larger than for metacarpophalangeal joints. No differences were found in patient-reported outcomes.

In this study, PALF-treated digits had a recurrence rate that was 35 percent higher than that of limited fasciectomy-treated digits at 5 years after treatment (74 percent versus 39 percent). This finding is in line with the previously reported higher rate for conventional needle aponeurotomy. A question that remains is whether the recurrence of PALF is better than for conventional

needle fasciotomy. Comparisons with previous literature cannot be made directly because differences in definitions can importantly influence recurrence rate and<sup>14,15</sup> because factors such as patient selection can influence outcome in different studies. Until today, the only other randomized study<sup>11</sup> comparing fasciectomy and needle fasciotomy for Dupuytren's disease to date reported a 64 percent higher recurrence rate of traditional needle aponeurotomy (percutaneous needle fasciotomy) as compared with limited fasciectomy at 5 years (21 percent versus 85 percent)

**Table 2. Satisfaction Scores Using a Visual Analogue Scale from 0 to 10 in the PALF and Limited Fasciectomy Subgroups at 5 Years after Surgery**

Question	PALF (n = 18)	LF (n = 17)	p
Are you satisfied about the overall result of the surgical procedure?	7.1 ± 3.1	8.5 ± 2.1	0.138
Does the overall result of the surgical procedure meet your expectations?	7.3 ± 3.1	8.0 ± 2.8	0.495
How satisfied are you about the position of your fingers?	6.5 ± 3.3	7.6 ± 2.8	0.316
How satisfied are you about the extent to which your hand function was restored?	7.0 ± 3.1	8.4 ± 2.2	0.130
How satisfied are you about the way your hand/operated area looks?	7.8 ± 2.8	8.2 ± 2.5	0.643
Would you choose the same surgical procedure again?	83%	77%	0.691
Would you recommend the same surgical procedure to friends, family, and acquaintances?	89%	88%	0.952

PALF, percutaneous needle aponeurotomy with lipofilling; LF, limited fasciectomy; MP, metacarpophalangeal; PIP, proximal interphalangeal; DASH, Disabilities of the Arm, Shoulder and Hand questionnaire.

**Table 3. Baseline Independent Risk Factors for 5-Year Recurrence at the Level of Treated Digits from the Final Multivariable Logistic Regression Model**

Risk Factor	OR	95% CI	p
Treatment type*	0.16	0.04–0.54	0.002
Affected PIP joint	4.08	0.92–18.2	0.065

PIP, proximal interphalangeal.

\*Values are reported for limited fasciectomy, with percutaneous aponeurotomy with lipofilling as the reference group.

using a comparable total passive extension deficit-based definition for recurrence, which is smaller than the 45 percent difference found in the present study (32 percent versus 77 percent). Without a direct head-to-head comparison of traditional needle aponeurotomy and PALF, accounting for baseline differences and using similar outcome measurements, however, it cannot be concluded whether this difference is statistically significant or clinically relevant. In addition, a direct comparison of an aponeurotomy technique with and without fat grafting would be needed to conclude on the specific effect of fat grafting for reducing recurrence; a conclusion on the specific fat grafting effect cannot be directly derived from the present study.

The inferior recurrence rate of PALF is particularly evident at the proximal interphalangeal joint level, as indicated by the larger between-treatment group differences in 5-year recurrence rates and extension deficit for affected proximal interphalangeal joints (38 percent and 19 degrees) than for metacarpophalangeal joints (28 percent and 14 degrees). This finding confirms the general observation that proximal interphalangeal joint contractures are more difficult to treat and, as a result, have comparatively poorer results. It also suggests that PALF may be more valuable for patients with affected metacarpophalangeal joints than for proximal interphalangeal joints, because

metacarpophalangeal joints generally have a smaller change of a recurrent contracture.

This study has a number of limitations. A first limitation is the loss to follow-up. Reasons for this were diverse and are inherent in this Dupuytren population, such as a number of patients who died or who were not in sufficiently good health to participate in the long-term follow-up. Despite this, baseline characteristics were similar between the treatment groups included in the 5-year follow-up. A second limitation is that our study included a relatively high proportion of patients with diathesis factors, which limits the generalizability of the results. This may also have contributed to the relatively high recurrence rates of limited fasciectomy (i.e., 21 percent in the study by van Rijssen et al. compared to 32 percent when applying a similar definition in our study). A third limitation is that we estimated the degree of extension deficit for those patients who had undergone a secondary procedure at the 5-year follow-up examination using their preoperative contracture. This assumed that patients' threshold for undergoing treatment remains unchanged over time, which may not always be correct. Nevertheless, this allowed us to estimate extension deficits for patients, whereas without this analysis, only patients with limited recurrence would have been included. Fourth, we used a composite endpoint of recurrence that does not take into account when in time patients who had undergone a revision procedure reached this endpoint. Future studies may take this individual variation into consideration to allow for time-to-event type analyses to predict longer term outcomes, such as risk of recurrence, at the individual patient level. Finally, we had limited power to assess the long-term outcomes separately for affected metacarpophalangeal and proximal interphalangeal joints because of the small sample size, which may have



precluded us from finding significant differences at the metacarpophalangeal joint level.

## CONCLUSIONS

We found that among patients with primary Dupuytren's disease, PALF provided less durable corrections compared with limited fasciectomy at 5-year follow-up, although the 35 percent higher rate may be lower than has previously been reported for traditional percutaneous needle fasciotomy. After limited fasciectomy, convalescence is typically longer, impeding an early return to work or daily manual activities.<sup>16,17</sup> In contrast, patients treated with PALF returned to normal use of the hand after an average of 9 days as compared with an average 17 days for limited fasciectomy patients in our previous study.<sup>9</sup> This highlights the less-invasive nature of the technique. In addition, both contracture correction and recurrence after PALF is better for metacarpophalangeal joints than for proximal interphalangeal joints. Considered together, when comparing both techniques in primary disease, PALF provides good short-term outcome with quick convalescence and fewer complications compared with limited fasciectomy, whereas limited fasciectomy offers straighter fingers at 5-year follow-up.

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