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Five-Year Results of a Randomized Clinical Trial on Treatment in Dupuytren's Disease: Percutaneous Needle Fasciotomy versus Limited Fasciectomy

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Background: The increasing number of methods for treating Dupuytren's disease indicates a need for comparative studies. In this article, the 5-year follow-up results of a randomized controlled study that compared percutaneous needle fasciotomy and limited fasciectomy are presented.

Methods: One hundred eleven patients with 115 affected hands with a minimal passive extension deficit of 30 degrees were assigned randomly to the two groups. Follow-up examinations were performed at 1 and 6 weeks; 6 months; and 1, 2, 3, 4, and 5 years. Outcome parameters were total passive extension deficit, patient satisfaction, flexion, and sensibility. Furthermore, disease extension was recorded. The primary endpoint was recurrence, defined as an increase of total passive extension deficit of greater than 30 degrees. Ninety-three patients reached this endpoint.

Results: The recurrence rate after 5 years in the needle fasciotomy group (84.9 percent) was significantly higher than in the limited fasciectomy group (20.9 percent) ($p < 0.001$), and occurred significantly sooner in the needle fasciotomy group ($p = 0.001$). Older age at the time of treatment decreased the recurrence rate ($p = 0.005$). No other diathesis characteristics influenced recurrence. Patient satisfaction was high in both groups but was significantly higher in the limited fasciectomy group. Nevertheless, many patients (53 percent) preferred percutaneous needle fasciotomy in case of recurrence.

Conclusions: Percutaneous needle fasciotomy is the preferred treatment for elderly patients with Dupuytren's disease and for those willing to accept a possible early recurrence in the context of the advantages, such as fast recovery, a low complication rate, and minimal invasiveness. (*Plast. Reconstr. Surg.* 129: 469, 2012.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, II.

Percutaneous needle fasciotomy is a treatment for Dupuytren's disease that was reinvented by French rheumatologists in the late 1970s, and is essentially a modification of the treatment that was first suggested by Sir Henry Cline in 1777: aponeurotomy or fasciotomy.[1,2] Percutaneous needle fasciotomy is gaining popularity because of the growing demand for fast recovery, a low complication rate, and minimal invasiveness.[1] In a previous report on our randomized clinical trial, we have shown that functional recovery during the first 6 weeks was significantly faster following percutaneous needle fasciotomy than after

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limited fasciectomy.[3] We also found that percutaneous needle fasciotomy is not as effective as limited fasciectomy for moderately severe and severe forms of the disease (Tubiana stages III and IV).[3] As a major drawback, the reported recurrence rates after percutaneous needle fasciotomy have been relatively high.[4–6] Worldwide, hand surgeons most frequently use limited fasciectomy, despite its relatively longer recovery period and high complication rates, especially in recurrent cases.[7–13]

To date, a randomized controlled trial comparing the two treatments with long-term follow-up had not been performed. The purpose of the present study is to fill this gap and to report on our 5-year recurrence rates. This study also allowed us to analyze whether preoperative disease factors predispose patients to recurrence. Our primary outcome measure was total passive extension deficit of each treated ray. Patient satisfaction with results of treatment and treatment preference in case of recurrence were also studied.

PATIENTS AND METHODS

Study Design

This study was designed according to, and approved by, the local medical ethics committee in January of 2002. From August of 2002 to January of 2005, every patient with Dupuytren's disease who presented at our department was assessed for enrollment in the study. Inclusion criteria were total passive extension deficit of at least 30 degrees in any ray (excluding the thumb), the existence of a clearly defined palmar cord, and willingness to participate in the trial. Written consent was obtained from all patients at study entry. Excluded were patients with postsurgical recurrence or extension of the disease after earlier treatment, patients who were not allowed to stop their anticoagulants, patients generally unfit for surgery, and patients with a specific treatment preference. Patients were asked to fill out a questionnaire about their health status and demographic characteristics, and these data have been published before.[3] The Abe diathesis scoring system was applied at the end of the study to evaluate its influence on recurrence and extension in our study.[14] The diathesis score (D) is calculated as follows: D = a + b + c + d + e + f, where "a" is bilateral hand involvement (with = 1, without = 0), "b" is little finger surgery (with = 1, without = 0), "c" is early onset of disease (with = 1, without = 0), "d" is plantar fibrosis (with = 2, without = 0), "e" is presence of knuckle pads (with = 2, without = 0), and "f" is radial side involvement (with = 2, without = 0).

Randomization

Randomization was performed through the pulling of sealed envelopes by a secretary.[3]

Surgical Technique

Percutaneous needle fasciotomy was performed as an outpatient procedure using local anesthesia for the skin only.[2] Cords were divided using a 25-gauge needle at as many places as necessary to achieve maximal passive extension. A small dressing was applied for 24 hours. Patients were encouraged to start using the hand immediately after the procedure. All hands were treated only once.

Limited fasciectomy was performed under regional or general anesthesia using a palmar Skoog incision in combination with a Bruner-type incision in the digits. All diseased fascias were removed and the skin was closed following flap transposition as indicated. A light compressive bandage was applied; the patient was instructed to wear the bandage for 7 days until the first visit to the outpatient clinic. Patients were encouraged to practice extension and flexion of the fingers immediately after the anesthesia had worn off.

Follow-Up

After the 6-week interval,[3] patients were seen at 6 months and at 1, 2, 3, 4, and 5 years after treatment. Follow-up investigation consisted of goniometry to assess extension deficit, sensibility, and satisfaction. For the latter, the following two questions were asked:

1. How satisfied are you with the results of your treatment (1 = not at all, 10 = excellent)?
2. How likely is it that you would choose this treatment modality again (1 = no, 10 = yes, definitely)?

At the start of the study, recurrence was defined as an increase of total passive extension deficit of at least 30 degrees compared with the 6-week follow-up values in the ray treated previously. Extension was defined as disease activity outside the area treated previously. Recently, a number of studies have been published using a definition of recurrence by joint.[15–18] To enable comparison of our data with these studies, their definition, that a return of contracture (20 degrees) in successfully treated joints, in which successfully treated joints had reached a total passive extension deficit of 0 to 5 degrees, was also applied.

Statistical Analysis

Statistical analysis was performed using SPSS version 15.0 (SPSS, Inc., Chicago, Ill.). The chi-square test was used for categorical data. The *t* test was used for recurrence and patient satisfaction. Linear regression analyses were performed to study age versus recurrence differences. Correlation regression analyses were applied to calculate the influence of demographics on recurrence rate. Significance was set at a value of $p \leq 0.05$.

RESULTS

In total, 93 patients (84 percent) reached the primary endpoint or could be followed for 5 years. The demographic details of these patients are summarized in Table 1. In these 93 patients, 125 joints were treated with limited fasciectomy and 167 joints were treated with percutaneous needle fasciotomy. There were no statistically significant differences in various characteristics between the percutaneous needle fasciotomy and limited fasciectomy groups. The mean passive extension deficits of the study population at the start of the study and the outcome figures at 6 weeks are summarized in Table 2.

Table 1. Demographics and Patient Characteristics

	LF ($n = 41$)	PNF ($n = 52$)	p
Sex			
Male	32	44	0.42
Female	9	8	
Knuckle pads	6	9	0.77
Lederhosen	7	3	0.07
Dupuytren's in family	20	18	0.15
Epilepsy	0	2	0.21
Diabetes	4	7	0.61
Early-onset disease before 50 yr	14	19	0.88
Abe score > 4	5	6	0.97
Mean age (yr)	63.1	62.8	0.86

LF, limited fasciectomy; PNF, percutaneous needle fasciotomy.

Recurrence after Limited Fasciectomy and Percutaneous Needle Fasciotomy

During 5-year follow-up, 33 hands in 31 patients treated with limited fasciectomy did not develop recurrence (76.8 percent), whereas nine hands did (20.9 percent). One hand showed extension (2.3 percent) (Figs. 1 and 2). After 5 years, only eight hands treated with percutaneous needle fasciotomy showed no signs of recurrence (15.1 percent). The other 45 hands (84.9 percent) had reached the primary endpoint of the study. Clinical examples of percutaneous needle fasciotomy are shown in Figure 3. The recurrence rate in the limited fasciectomy group was significantly smaller, ($p < 0.001$; 95 percent confidence interval, 1.597 to 2.628), and recurrence occurred significantly later after limited fasciectomy than after percutaneous needle fasciotomy ($p = 0.001$). Figure 4 shows the Kaplan-Meier survival estimates of the study groups. For both procedures, the distribution of recurrences appeared to be distributed normally. For limited fasciectomy, there were two recurrences at 2 years, two at 3 years, three at 4 years, and three at 5 years. For percutaneous needle fasciotomy, there were six recurrences at 6 months, 10 at 1 year, 13 at 2 years, seven at 3 years, eight at 4 years, and one at 5 years.

Age and Recurrence

Although not statistically significant in the limited fasciectomy group, because of the small number of recurrences, a higher age at the time of treatment seemed to predict a delay of recurrence ($p = 0.07$). In the percutaneous needle fasciotomy group, the age-recurrence correlation was statistically significant at $p = 0.04$. When the limited fasciectomy and percutaneous needle fasciotomy groups were considered together, the older age group showed less recurrent disease than the younger patients ($p = 0.005$) (Fig. 5). No factors

Table 2. Mean Passive Extension Deficits by Joint, of That Part of the Study Population That Reached the Primary Endpoint or Completed the 5-Year Follow-Up at the Start of the Study and the Outcome Figures at 6 Weeks by Joint*

	PNF-Treated Joints ($n = 167$)			LF-Treated Joints ($n = 125$)		
Joint	Mean Pretreatment PED (degrees)	Mean 6-Week Results (degrees)	Successfully Treated Joints (%)†	Mean Pretreatment PED (degrees)	Mean 6-Week Results (degrees)	Successfully Treated Joints (%)†
MCP	43	9	55	41	1	94
PIP	35	21	26	32	9	47

PNF, percutaneous needle fasciotomy; LF, limited fasciectomy; PED, passive extension deficit; MCP, metacarpophalangeal joint; PIP, proximal interphalangeal.
*$n = 93$ patients.
†Reduction to passive extension deficit of 0–5degrees.

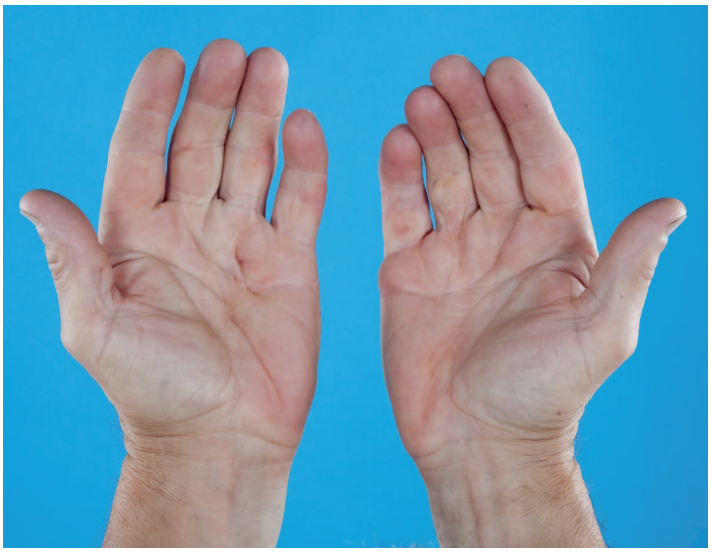

Fig. 1. Anteroposterior view of a 61-year-old man who was treated with limited fasciectomy in the fourth digit but suffered from extension in the fifth digit after 5 years.

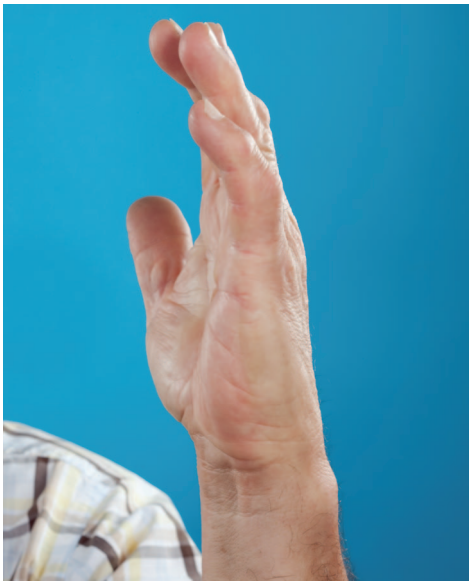

Fig. 2. Lateral view of the patient shown in Figure 1.

correlating with recurrent disease were found other than age at the time of treatment (Table 3).

Abe Scoring System for Predicting Recurrence and Extension

Abe scores for both treatment groups were calculated. Four of 10 patients with recurrence or extension in the limited fasciectomy group had an Abe score higher than 4; in the percutaneous needle fasciotomy group, nine of 45 had an Abe score higher than 4. These scores did not influence the chances of recurrence (limited fasciectomy group, $p = 0.23$; percutaneous needle fasciotomy group, $p = 0.19$). Therefore, our study does not support the Abe hypothesis; a higher score did not correlate with recurrence in our study.

Choice of Treatment for Recurrent Disease

In the limited fasciectomy group, four of nine patients chose to have their recurrences treated with percutaneous needle fasciotomy. Six patients (five with recurrences and one with extension) chose not to be treated. None of the patients in the limited fasciectomy group who presented with recurrent disease chose limited fasciectomy again.

Twenty-six of 45 patients with recurrent disease in the percutaneous needle fasciotomy group chose to undergo a second treatment with percutaneous needle fasciotomy. Seven patients preferred limited fasciectomy. The remaining 12 patients did not opt for treatment of recurrent disease.

Satisfaction

The average patient satisfaction score was significantly higher in the limited fasciectomy group (8.3), as compared with the percutaneous needle fasciotomy group (6.2; $p < 0.001$). The score for choosing the same procedure as preferred future treatment was 8.7 in the limited fasciectomy group, which was significantly higher than the score of 7.0 in the percutaneous needle fasciotomy group ($p = 0.008$). The scores for both questions were strongly correlated to recurrent disease. In patients with re-

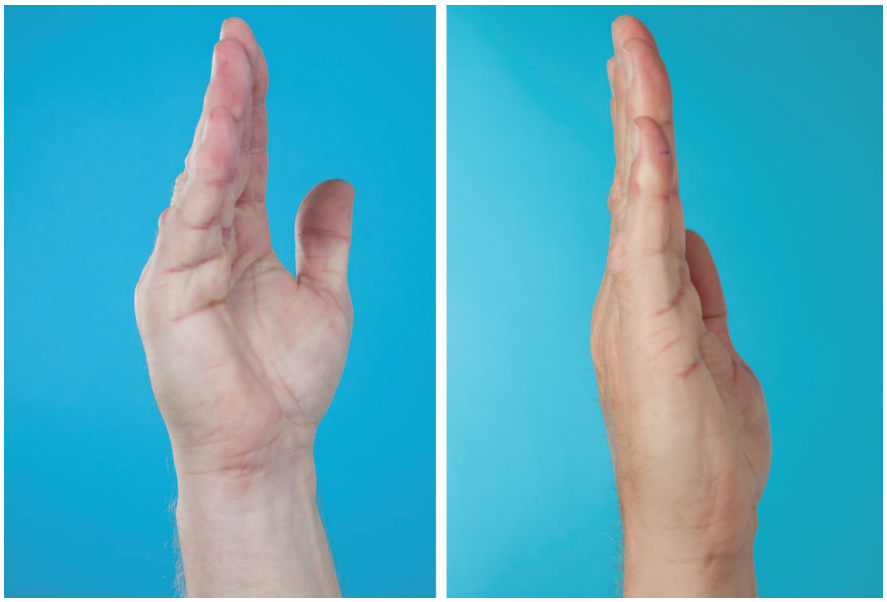

Fig. 3. Preoperative (*left*) and postoperative (*right*) views of a 63-year-old man who underwent percutaneous needle fasciotomy of the fifth digit of the right hand.

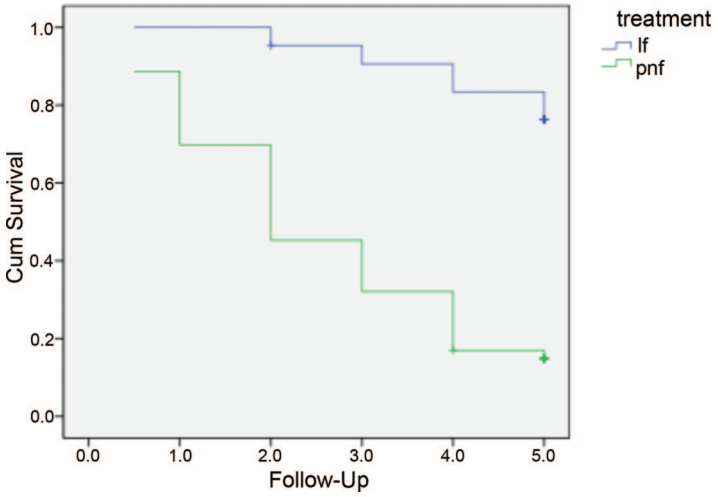

Fig. 4. Kaplan-Meier survival estimates for both treatment modalities. A decreased rate of patients in the study (*y* axis) with time (*x* axis, in years of follow-up) as the result of reaching the primary endpoint of the study (increase of total passive extension deficit of greater than 30 degrees) is shown. *Cum*, cumulative; *lf*, limited fasciectomy; *pnf*, percutaneous needle fasciotomy.

currence, satisfaction with treatment results was significantly less ($p < 0.001$) as compared with the patients without recurrence (odds ratio, 0.61). These patients also expressed less preference for the same treatment ($p = 0.02$; odds ratio, 0.83).

DISCUSSION

This study focused on Dupuytren's disease recurrence rates that occurred during a 5-year follow-up period after treatment by percutaneous needle fasciotomy or limited fasciectomy. A number of definitions can be found in the literature for recurrence after treatment for Dupuytren's disease. For example, McFarlane and McGrouther used the definition "recurrent joint contracture sufficient to require further operation.[8] Hueston used "appearance of new Dupuytren's tissue within the area cleared at operation," and this definition is the most widely used one.[20] Some authors, such as Mäkelä et al. and Badois et al. did not define recurrence.[8,21–23]

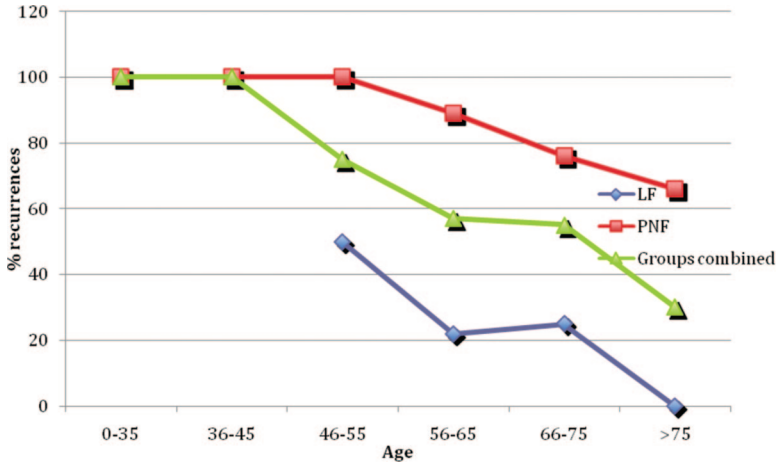

Fig. 5. Recurrence rates in different age groups. On the *x* axis, different age groups are shown in years at the time of treatment. On the *y* axis, the percentage of these patients who developed recurrence is shown (limited fasciectomy, percutaneous needle fasciotomy, and combined). *LF*, limited fasciectomy; *PNF*, percutaneous needle fasciotomy.

Table 3. Influence of Risk Factors on Recurrence

Feature	*p*	Odds Ratio
Sex	0.29	1.84
Knuckle pads	0.25	1.44
Lederhosen	0.98	1.01
Diabetes	0.78	1.20
Epilepsy	0.99	1E + 009
Fifth digit involvement	0.06	3.10
Radial side involvement	0.39	1.29
Early-onset disease	0.06	2.41
Family members with Dupuytren's disease	0.58	1.27

Hueston's definition of recurrence could not be used because, in percutaneous needle fasciotomy, no tissue is removed. Therefore, recurrence was defined indirectly, as an increase of the total passive extension deficit of 30 degrees or more in a ray compared with the result at 6 weeks after treatment. This measure is reproducible and clinically more relevant than the other definitions. A worsening of digital extension of 30 degrees was chosen because it corresponds to the Hueston tabletop test and is considered the minimal contracture with which to qualify for surgery at our center.

Recurrence after Limited Fasciectomy

In a previous study on the 3-year results of the same cohort of patients, we found a recurrence rate of 9 percent.[6] At 5 years, the recurrence rate had increased to 20.9 percent. This figure compares favorably with other studies, although comparison is hampered because of varying definitions and a lack of 5-year follow-up data from other studies. We found only two studies with long-term data that we consider to some extent relevant for comparison. Jurisić et al. retrospectively studied the population of Primorsko-Goranska County in Croatia and found a 73 percent recurrence rate after limited fasciectomy and a mean follow-up of 7 years.[13] However, they had defined recurrence as the development of new Dupuytren's disease lesions in the area where fasciectomy had been performed, including the smallest palpable nodule irrespective of a presenting contracture. Thirty-four percent of these recurrences required further surgery. Foucher described his results on the open palm technique in 54 patients in 1992 with a 5.6-year follow-up period. Recurrence was not clearly defined. The recurrence rate in his study was 41 percent.

Recurrence after Percutaneous Needle Fasciotomy

In our study, 85 percent of the patients developed recurrence over the 5-year follow-up period. This recurrence rate is the highest ever published for percutaneous needle fasciotomy. Nevertheless, we believe that the results of others would have been similar if their cohorts had been followed for 5 years and had a comparable definition been used. In our analysis at 3 years, the recurrence rate was 63 percent. This figure is very similar to that of previously published series with the same follow-up period. In our pilot, we found a 65 percent recurrence rate after a mean of 33 months,[5] whereas Foucher et al. reviewed 100 rays after a mean of 3.2 years and found a recurrence rate of 58 percent.[4] The only study that reported

5-year results was from the group of Badois et al.[23] They reported a recurrence rate of only 50 percent, but their definition of recurrence is unclear.

Recurrence after Limited Fasciectomy and Percutaneous Needle Fasciotomy Compared with Those after Treatment with Collagenase

In the past decade, the results of various studies on the application of collagenase for Dupuytren's disease have been published.[15–19] The results of these studies have been presented in a manner different from ours. All collagenase studies looked at the effect of treatment at each joint individually. The treatment is defined as "clinically successful" when correction of the deformity decreases to within 0 to 5 degrees of full extension.

If we reanalyze our data accordingly, 94 percent of the treated metacarpophalangeal joints in the limited fasciectomy group and 55 percent of those in the percutaneous needle fasciotomy group reached this endpoint. In the proximal interphalangeal joint, the corresponding figures are 47 percent following limited fasciectomy and 26 percent following percutaneous needle fasciotomy. Our results were achieved with only one treatment, whereas patients treated with collagenase often needed multiple treatment sessions. In the study by Hurst et al., 76 percent of metacarpophalangeal joints and 40 percent of proximal interphalangeal joints reached the primary endpoints.[18] A comparison with our data shows that the results we achieved with limited fasciectomy were better than those obtained by Hurst et al. with collagenase. A single treatment with percutaneous needle fasciotomy, however, seems to be somewhat inferior to up to three injections with collagenase.

At present, there are only two long-term follow-up studies available in which collagenase was used, one with 8 years' follow-up and the other with 2 years' follow-up.[18,19] One of the studies[19] also used another definition of recurrence (i.e., it was defined as any degree of loss of extension as compared with full extension). If we apply this definition in our study, the recurrence rate for the metacarpophalangeal joint would be 21 percent in the limited fasciectomy group and 57 percent in the percutaneous needle fasciotomy group ($p = 0.00$). For the proximal interphalangeal joint, rates are 21 percent for the limited fasciectomy group and 70 percent for the percutaneous needle fasciotomy group ($p = 0.00$). In Watt's study, recurrence rates were 68 percent in the metacarpophalangeal joint and 100 percent in the proximal interphalangeal joint after 8 years. Recurrence rates of collagenase therapy at 8 years are therefore comparable to, if not worse than, our percutaneous needle fasciotomy results after 5 years.

In a study conducted by Hurst and Badalamente in 2007, the recurrence rate, defined as a return of contracture of at least 20 degrees in successfully treated joints, was 19 percent after 2 years. If we would apply this in our study, recurrence rates would be as follows. In the metacarpophalangeal joint, we reached "success" in 72.1 percent (132 of 183 joints). The recurrence rate would be 5.3 percent (four of 76 joints) in the limited fasciectomy group and 21.8 percent (12 of 55 joints) in the percutaneous needle fasciotomy group after 5 years. In the proximal interphalangeal joint, we reached success in 34.3 percent. The recurrence rate would be 5.3 percent (one of 19 joints showed recurrence) in the limited fasciectomy group and 23.5 percent (four of 17 joints) in the percutaneous needle fasciotomy group. These results indicate that the recurrence rate after collagenase is considerably higher than after limited fasciectomy and percutaneous needle fasciotomy, even after a considerably shorter follow-up period.

Age versus Recurrence

As Hindocha et al. pointed out in their study, age of onset younger than 50 years increases the chances for recurrent disease.[24] To our knowledge, our study is the first to show a general correlation between age and disease recurrence.

Dupuytren's Diathesis

Our findings do not corroborate those of many authors supporting the view that Dupuytren's diathesis is a risk factor for recurrence or extension. We were unable to find a statistically significant influence of fifth digit involvement, early onset, radial disease, familial predisposition, ectopic lesions, sex, or comorbidities such as diabetes and epilepsy on the appearance of recurrence.

McFarlane and McGrouther reported 5-year results on limited fasciectomy with the open-palm technique and were also unable to prove the effect of Hueston's diathesis. This finding, along with the establishment of an effect of age on recurrence, suggests that their findings are consistent with ours.[8]

Patient Satisfaction

Patient satisfaction was high for both percutaneous needle fasciotomy and limited fasciectomy treatments. Patients who had received limited fasciectomy were significantly more satisfied at 5 years with their treatment than those with percutaneous needle fasciotomy. The outcomes were influenced in a negative way when recur-

rence took place. However, many patients who suffered recurrent disease chose to undergo percutaneous needle fasciotomy again. This indicates that many patients are likely to prefer a minor procedure with fast recovery at the expense of a higher chance of an early recurrence.

CONCLUSIONS

Although percutaneous needle fasciotomy is equally effective for mild to moderate Dupuytren's disease (Tubiana stages I and II), as we have shown in previous studies, recurrence rates are significantly higher than after limited fasciectomy. A higher age at disease presentation correlates with a lower tendency for recurrence. For this reason, we believe that percutaneous needle fasciotomy treatment is best suited for well-informed elderly patients with relatively mild contractures (Tubiana stages I and II) and for those who are willing to accept a higher recurrence risk in the context of a lower complication rate, a faster recovery, and minimal invasiveness.

CODING PERSPECTIVE

This information prepared by Dr. Raymond Janevicius is intended to provide coding guidance.

26040	Percutaneous needle fasciotomy
26121	Fasciectomy, palm only
26123	Fasciectomy, palm with release of single digit
+26125	Each additional digit

- A percutaneous fasciotomy is reported with code 26040. If an open fasciotomy is performed, use code 26045.
- Fasciectomy for Dupuytren's contracture is reported with codes 26121, 26123, and 26125.
- If disease is limited to the palm, with no finger involvement, use code 26121.
- If disease involves the palm and a single digit, report code 26123. Codes 26121 and 26123 are not used together, as code 26123 *includes* what is done in code 26121.
- Each additional digit fasciectomy is reported with code 26125. This is an add-on code and will never stand alone. Code 26125 must always used with code 26123.

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Evidence-Based Medicine: Questions and Answers

Q: What papers are amenable to Level of Evidence grading? What if my paper is not amenable to grading? Will *PRS* consider it for publication?

A: A good rule of thumb is as follows (these papers are not amenable to LOE grading):

- Animal studies
- Cadaver studies
- Basic science studies
- Review articles
- Instructional course lectures
- CME courses
- Editorials
- Correspondence

As far as what is or is not ratable, the standard is to exclude basic science, bench work, animal, and cadaveric studies because the information gained from these studies is not something that can be applied directly to patient treatment decisions.

PRS definitely welcomes such papers, and such papers will be considered for publication. As indicated above, the LOE grade is a number, a quantitative designation for data. Papers that cannot be graded for Level of Evidence grade are not "worse" than those that can be graded.