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A pilot study assessing the effectiveness of postoperative splinting after limited fasciectomy for Dupuytren's disease

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Abstract
Before surgery for Dupuytren's contracture, 54 patients with a proximal interphalangeal (PIP) joint flexion contractures of at least 30° were randomized to receive either a 3-month splinting protocol together with hand therapy under the direct supervision of hand therapists, or the same hand therapy alone. Extension deficit of the PIP joint (primary outcome measure), global perceived effect, pain intensity, comfort and complications were assessed at baseline and 1 year after surgery. In an intention-to-treat analysis, the group assigned to splint-plus-hand therapy had a mean reduction of 21° in flexion contracture after 1 year, compared with 29° in the group receiving hand therapy alone ($p = 0.1$). There was no difference between the groups regarding other parameters. After operative release of a Dupuytren's contracture, a postoperative protocol using a splint and hand therapy was no better than hand therapy alone in minimizing postoperative flexion contractures.

Keywords
Dupuytren's disease, splint

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Introduction

Dupuytren's disease (DD) is characterized by irreversible and progressive fibrosis of the palmar fascia (Townley et al., 2006). Surgical treatment by limited or complete palmar fasciectomy is frequently followed by a recurrence of flexion contractures. After surgery, 80% of the patients will develop a recurrence of a flexion contracture (Hueston, 1982).

To prevent, or slow down recurrence and optimize results, many surgeons choose to splint digits postoperatively. Splinting is used during the wound healing phase until the collagen has matured. However, some are of the opinion that the use of a splint is valueless as they regard recurrence as an extension of the disease. Some even think that the tissue stress caused by splinting itself may result in collagen production by myofibroblasts and thus in recurrence, and therefore deliberately do not use splints (Brandes et al., 1994). As a result, postoperative management of DD is characterized by many different protocols and guidelines, and studies have not clarified the approach to be preferred. In two UK studies surgeons and hand therapists were questioned about their postoperative management of DD (Abbott et al., 1987; Au-Yong et al., 2005). Both studies reported, not only a great variety in the indication for using a splint, but also a great diversity in the type and duration of splinting.

Although many surgeons use splints, this practice has not been proven to be beneficial. There is only one randomized controlled study measuring the effectiveness of postoperative splinting in DD, which

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reported no differences between a group of patients who were all routinely splinted and a group of patients receiving hand therapy and only splinted if and when contractures occurred (Jerosch-Herold et al., 2011). Retrospective controlled studies and prospective cohort studies indicate no, or minimal, advantage in postoperative splintage compared with postoperative conservative therapy (Ebskov et al., 2000; Rives et al., 1992). Static splints seem to be more effective than dynamic splints (Evans et al., 2002). In addition, the static splint is also more commonly used (Abbott et al., 1987; Au-Yong et al., 2005).

The aim of this randomized controlled trial was to assess the clinical effectiveness and possible adverse effects of splinting after release of a Dupuytren's contracture.

Patients and methods

Patient recruitment and characteristics

The study was conducted in two Dutch hand clinics. We included 54 patients with DD and a proximal interphalangeal (PIP) joint flexion contracture of at least 30° treated in both clinics in the period from 15 February 2007 to 1 June 2008. Five patients were excluded from the study. They were either below 18 years of age, had undergone partial amputation or arthrodesis of a digit, or were patients with insufficient knowledge of the Dutch language. In each patient, only the most affected finger was studied. Patients were requested to continue hand therapy with or without splint use for at least 3 months. Not applying this exact protocol was not a reason to exclude patients. The study complied with the Declaration of Helsinki and was approved by the Medical Ethics Committee of both institutions. All patients gave written informed consent.

Randomization and concealment

Immediately before operative release of the contracture, the patients were randomized and assigned to receive either a 3-month splinting protocol together with hand therapy, or hand therapy alone. In both groups, therapy started 10 days after limited fasciectomy when the wounds had healed and sutures had been removed. A table of random numbers was used to make the treatment assignments. By using separate tables for patients with either primary DD or recurrence/extension of the disease, stratification according to primary or recurrent/extended disease was obtained. The assignments were made by a research assistant and were concealed from the outcome assessor who performed the 1 year analysis. The operating surgeon was also blinded to the treatment allocation.

Interventions

Operative procedure. The operative procedure in all cases was a standard limited fasciectomy as a day patient procedure to obtain full (passive) extension of all finger joints. Surgeons were allowed to carry out a capsuloligamentous release to achieve full PIP joint extension. Skin closure was always possible, either primarily or by using transposition flaps, and no full thickness skin grafts had to be applied. Wounds were closed with nylon sutures and a bandage was applied that kept the fingers in an extended position. After 10 days the bandage and sutures were removed.

Splint and therapy protocol. The hand therapy received by both groups consisted of a standardized programme of graded exercises designed to improve the strength, mobility and function of the affected hand. Hand therapy took place for 30 minutes twice a week, with a minimum of 2 days between sessions. The total duration of hand therapy was 3 months, starting 10 days after surgery. To ensure standardization, hand therapy was only given by selected hand therapists in the two institutions.

The thermoplastic dorsal static finger extension splint was produced and adjusted by a hand therapist. In the case of a simple contracture of one or two fingers, a small splint was applied. When more fingers were involved or when full (active) extension was not reached during surgery, a dorsal splint covering more than two-thirds of the lower arm was applied. The splint aimed to keep the wrist and metacarpophalangeal (MCP), PIP and distal interphalangeal (DIP) joints in 0° of flexion. Using Velcro tape, the splint was fixed and the fingers were kept extended passively.

Patients were instructed to apply the splint day and night during the first 4 weeks, while adapting the Velcro tape as firmly as pain permitted until full extension was achieved. Flexion of MCP, PIP and DIP joints was practised without the splint at least five times a day for 15 min. From week 6 to 3 months postoperatively, patients gradually began to use their hands normally in the daytime and the night splintage was continued.

Outcome assessment

The patients were assessed before randomization and 1 year after the operation. In one centre, the patients (n = 36) were also assessed at 6 weeks and 3 months after the operation. All assessments were carried out by the same independent third party, a resident who had no part in the operative procedure or postoperative treatment. Outcome measures were

Table 1. Baseline characteristics of the patients according to the assigned treatment. Values given as mean (SD) where appropriate.

Characteristic	Splint plus hand therapy (n = 28)	Hand therapy alone (n = 26)	p-value
Age (years)	63 (9)	64 (11)	0.7
Male sex	23	23	0.5
Operated side L/R	12/16	15/11	0.3
Age of onset (years)	49 (8)	49 (11)	0.1
Residual disease	14	8	0.2
Bilateral disease	18	21	0.2
Extension deficit MCP joint (°)	12 (20)	17 (20)	0.3
Extension deficit PIP joint (°)	59 (19)	55 (15)	0.4
Number of digits operated	1.3 (0.5)	1.6 (0.7)	0.1

L: left; R: right.

grouped into five categories. First, extension deficit of the PIP joint (primary outcome measure) was measured using goniometry. Second, patients rated global perceived effect. Patients answered the question "How would you rate the change in limitations caused by Dupuytren's disease since the start of treatment?" on a seven-point scale, indicating: 1 = worst ever; 2 = much worse; 3 = worse; 4 = not improved/not worse; 5 = improved; 6 = much improved; and 7 = immense improvement. Third, the intensity of pain was assessed using a 10 cm visual analogue scale (VAS) where 0 meant no pain and 10 meant excruciating pain. Fourth, comfort related to the splint was scored after 6 weeks using a non-validated VAS where 0 meant that the splint was extremely uncomfortable and 10 meant that it was completely comfortable. Compliance was measured by asking patients at each visit whether the splint was used as instructed. Fifth, we listed technical and surgical complications and side effects.

Statistical analysis. When designing this study, no randomized controlled trials studying the effect of postoperative splinting in DD had been reported. Previous non-randomized studies had reported conflicting results. Therefore, we were unable to calculate the required sample size and alternatively chose to include a minimum of 25 patients in each group. The statistical analysis was conducted according to the "intention to treat" principle. For all outcome measures, differences between the baseline and 12 month values for each individual were calculated and compared between both groups using independent samples t-tests or, if the results were not normally distributed, nonparametric tests. Fisher's exact test was used to compare proportions. For global perceived effect (dichotomized in ≥ "much improved" and in ≤ "improved"), differences between the two groups were calculated. Two-tailed p-values less than 0.05 were considered to indicate statistical significance.

Results

The splint-plus-hand therapy group (n = 28) and the hand therapy alone group (n = 26) were statistically comparable at baseline regarding all prognostic variables and outcome measures (Table 1).

After 1 year, all patients were available for follow-up. The intention-to-treat analysis revealed that the mean extension deficit of the PIP joint, with splint-plus-hand therapy was reduced by 21° and 29° with hand therapy alone (p = 0.1; Table 2). Concerning global perceived effect, of the 28 splint-plus-hand therapy patients, 18 (64%) reported not less than "much improved", compared with 19 (73%) of the 26 hand therapy alone patients (p = 0.5). Scores observed in the intensity of pain at 6 weeks did not differ statistically significantly between the treatment groups. Generally, comfort related to the splint was rated unfavourably (score of 4.4 on a 10 cm VAS where 10 means completely comfortable). Compliance was variable with a mean period of use of 3 months and a SD of 1.5 months. The only technical and surgical complications and side effects were the occurrence of haematomas and residual flexion deficits. The frequency of their occurrence did not differ between the treatment groups. Pressure ulcers did not occur. Table 3 presents the interval analysis of the subgroup (n = 36) at baseline and 6 weeks, 3 months and 12 months after the operation. Differences between the groups were not statistically significant at any of the intervals. In both groups, the greatest gain in extension of the PIP joint occurred after the operation (between baseline and 6 weeks), whereas the greatest loss in extension of the PIP joint occurred between 3 and 12 months.

Table 2. Outcomes of treatment after 1 year. Values given as mean (SD) where appropriate.

Characteristic	Splint plus hand therapy (*n* = 28)	Hand therapy alone (*n* = 26)	*p*-value
Reduction of extension deficit PIP joint (°)	21 (22)	29 (21)	0.1
Global perceived effect*	18	19	0.5
Pain at 6 weeks (VAS)	1.9 (2.0)	2.1 (2.4)	0.7
Splint comfort at 6 weeks (VAS)	4.4 (3.4)		
Duration of splint use (months)	3.0 (1.5)		
Haematoma	5	4	0.8
Flexion deficit	8	4	0.2

* Number of patients reporting at least "much improved" on global perceived effect after 1 year.

Table 3. Interval analysis of the subgroup (*n* = 36). Values given as mean (SD) where appropriate.

	Baseline	6 weeks	3 months	12 months
Extension deficit PIP joint				
Splint group	56 (15)	22 (10)	26 (14)	37 (18)
Control group	51 (11)	18 (19)	17 (19)	24 (26)
Extension deficit MCP joint				
Splint group	14 (20)	3 (10)	4 (8)	4 (10)
Control group	18 (18)	2 (9)	0 (0)	0 (0)
Global perceived effect				
Splint group	n/a	5.2 (1.8)	5.6 (1.5)	5.4 (1.9)
Control group	n/a	5.9 (1.5)	6.0 (1.4)	5.7 (1.7)
Pain intensity (VAS)				
Splint group	0 (0)	2.4 (2.1)	1.4 (1.2)	1.3 (2.1)
Control group	0 (0)	2.9 (2.5)	1.6 (2.4)	0.7 (1.3)
Splint comfort (VAS)				
Splint group	n/a	5.3 (3.3)	5.7 (2.7)	5.7 (2.7)
Control group	n/a	n/a	n/a	n/a

Splint group (*n* = 18), Control group (*n* = 18).
Differences between the groups were not statistically significant at any of the intervals.

Discussion

This randomized controlled trial studied the effectiveness of splinting after surgery for DD. In summary, we found no evidence to support the idea that postoperative splinting is clinically effective in preventing recurrent flexion contracture of fingers after surgical release of a Dupuytren's contracture, whereas the adverse effects of splinting were limited to discomfort. The higher percentage of flexion deficit after splinting was not statistically significant. The interval analysis of a subgroup revealed similar results at 6 weeks and 3 months after surgery.

Wearing a splint limits hand mobility after surgery, which can result in loss of finger flexion. We attempted to prevent loss of flexion by having participants in the splint group flex their finger joints for 15 min at least five times a day and then change to night-time only splinting after 6 weeks. Nevertheless, 29% of splint patients and 15% of control patients demonstrated a flexion deficit at 1-year follow-up. Glassey (2001), in a retrospective case review, found that those without a splint had 20° more total flexion than the splint group at 3 months. Although neither our findings or those of Glassey were statistically significant, they raise concern that splinting is not harmless.

A recent systematic review evaluated splinting after surgery for DD (Larson and Jerosch-Herold, 2008). Four studies, with sample sizes ranging from 23 to 268, met the inclusion criteria (Ebskov et al., 2000; Evans et al., 2002; Glassey, 2001; Rives et al., 1992). The quality of the reporting was found to be

poor and the heterogeneity in splint types, duration of wear, outcomes and follow-up prevented pooling of the results. Despite these limitations, the study concluded that the clinical effectiveness of splinting on finger movement and hand function remains unproven. A recently published randomized controlled trial observed no differences between a group of patients who were all routinely splinted and a group of patients receiving hand therapy who were only splinted if and when contractures occurred (Jerosch-Herold et al., 2011). Although the study generated strong evidence against the clinical effectiveness of postoperative splinting, it is weakened by the fact that it was limited to night-time splinting starting 2 weeks after surgery, and by a protocol in which it was deemed unethical to withhold the application of a splint in patients who developed contractures and which did not respond to hand therapy only (21 of 77 patients allocated to the non-splint group were in fact splinted). Our pilot study is the next step to answering the question of the efficacy of splinting. We also did not find any statistical differences and we plan to use these negative results to design a larger and adequately powered study to detect any clinically meaningful differences.

In this study we made a first attempt to measure comfort with a non-validated instrument but, because of the importance of the subject of comfort in splint use, the validation of a comfort score should be the subject of a future study.

Because pilot data were lacking, we could not perform a power analysis and this is a limitation of our study. Nevertheless, we have no doubt about the ineffectiveness of postoperative splinting after the release of Dupuytren's contracture since previous studies, as well as our own, have found no evidence that it is beneficial. The range of motion of the PIP joint has been used as the primary outcome measure, since that is exactly what splints are intended to influence. Jerosch-Herold et al. (2008) suggested the use of the Disabilities of Arm, Shoulder and Hand Questionnaire as the primary outcome measure and based their power analysis on the presumption that a difference of 15 points is a clinically important difference. Using this, a total of 51 patients would be needed in each group for a power of 90% (Jerosch-Herold et al., 2008).

Conflict of interests

None declared.

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