Scientific/Clinical Article

A clinical trial of tension and compression orthoses for Dupuytren contractures

Annelien Brauns MD *, Maarten Van Nuffel MD, Luc De Smet PhD, Ilse Degroef PhD

Orthopaedic Department, Hand Unit, University Hospitals Leuven, Pellenberg Campus, Pellenberg, Belgium

**Article Info**

**Abstract**

**Study Design:** Randomized clinical trial on 2 patient groups with Dupuytren’s disease.

**Introduction:** Despite an unpredictable outcome, surgery remains an important treatment for Dupuytren’s disease. Orthotic devices are a controversial noninvasive treatment method to influence the myofibroblasts in the nodules.

**Purpose of the Study:** To detect how much improvement 2 types of orthotic device (tension and compression) as only treatment intervention can provide on a Dupuytren’s contracture. Is a compression orthosis better than a tension orthosis?

**Methods:** Thirty patients with measurable flexion contractures of the fingers were identified. Both primary and recurrence cases were included. Patients were randomized in 2 groups of 15 patients. One group had a standard tension orthosis (Levame), the other group a newly designed silicon compression orthotic device. Patients were instructed to wear the orthotic devices 20 hours a day during 3 months. Data were collected at first visit and after 3 months of orthotic treatment. Primary outcomes were active extension deficit of each joint and total active extension (TAE) of the digit. Secondary outcome was patient satisfaction. Visual Analog Scale (VAS) score of function and esthetics (0-10 points) were recorded at the start and after 3 months.

**Results:** Flexion contracture was reduced at least 5 degrees in all patients. After 3 months, TAE was significantly reduced in both groups (both \( P < .001 \)). The mean change in TAE was 32.36° in the tension group and 46.47° in the compression group. Although reduction of TAE deficit was bigger in the compression group, this difference was not statistically significant ( \( P = .39 \)). VAS scale of esthetics and functionality was significantly increased in both treatment groups. The functional VAS scale after 3 months was 11% higher in the compression group than in the tension group ( \( P = .03 \)). A major complication of a tension orthotic is skin ulcers.

**Discussion:** Too much tension may cause myofibroblast stimulation and disease progression, whereas continuous limited tension can improve flexion contractures. The idea of a compression device is based on the treatment concept of hypertrophic burn scars.

**Conclusion:** Tension and compression orthotic devices can be used as a nonoperative treatment of Dupuytren’s disease. Orthotic devices are a controversial noninvasive treatment method to influence the myofibroblasts in the nodules.

**Level of Evidence:** 1 (Randomized controlled trial, Therapeutic study).

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Introduction

Dupuytren’s disease (DD) is a benign fibroproliferative disorder of the hand, characterized by nodules and cords of the palmar fascia. This causes progressive flexion contractures of the metacarpophalangeal (MCP) and/or proximal (PIP) and/or distal interphalangeal (DIP) joints. Despite the high prevalence and extensive research, a definitive cure has not been established.

In the past, the treatment of Dupuytren’s disease has been largely surgical. Surgery is invasive and there are still important intraoperative and postoperative complications (digital neurovascular bundle injury, wound complications, skin necrosis, and so forth). Moreover, recurrence after surgery may be as high as 60 percent. Minimal invasive procedures such as needle fasciotomy and collagenase are a good alternative treatment method to
surgery. Collagenase is injected into the diseased cord. The surgeon can promptly correct extension deficits the following day, but this method has higher recurrence rates than fasciectomy. Recurrence after a good initial correction is unpredictable and may be a result of reappearance of Dupuytren tissue or postoperative scarring. Many approaches of nonoperative treatment have been proposed, but most of them have been abandoned. Nonetheless, the interest in nonoperative methods persists. Although postoperative orthotic treatment is often used, we only found 2 case series presenting the effect of splinting as conservative treatment. Orthoses act on myofibroblasts and the contracted nodules of Dupuytren’s disease consist of myofibroblasts. Myofibroblasts are activated contractile cells similar to those in scar tissue. In vitro experiments report that myofibroblasts are sensitive to mechanical traction but also to compression.

**Purpose of the study**

This pilot study compares the in vivo effect of tension and compression on the range of motion (ROM) in DD. The purpose of this study is to examine the effect of orthoses on the active extension deficit (AED) as an alternative to surgery, in the hope of delaying or obviating surgical treatment. We hypothesize that compression is preferable to tension.

**Materials and methods**

**Study design**

A pilot randomized controlled trial (RCT) was approved by the ethics committee. Between October 2013 and March 2014, 33 patients with Dupuytren’s disease were recruited from the hand clinic of the University Hospital of Leuven, Belgium. Of these patients, 30 patients were included. Patients with flexion contractures of the metacarpophalangeal (MCP), proximal and/or distal interphalangeal (PIP and/or DIP) joints were identified for this study. Inclusion criteria were Dupuytren’s disease with a flexion contracture of minimum 5 degrees of one or more digits, with or without tactile nodules. Both primary and recurrence cases were included. The exclusion criterion was surgery less than 1 year before start of the study. Data were collected at the first visit and after 3 months of orthotic treatment.

Patients were randomized in 2 groups of 15 patients. One group received a standardized tension orthosis (Levame, Fig. 1), the other group, a newly designed compression orthosis with a silicon bed and Velcro strips (Fig. 2). No other therapy intervention was provided. We did not include a control group.

**Intervention**

Patients were instructed to wear the orthosis 20 hours a day during 3 months. During the 4 hours without orthosis, patients had to move the treated digits to avoid stiffness. Nontreated digits could be moved all day long. Patients did not receive any formal hand therapy during orthotic treatment. There was no control of patient compliance.

The hand-based orthoses were designed to increase finger extension and softening of fascial cords and nodules. The cost of an orthosis depends on the number of fingers that are included. Patient fee is 5% of the total cost. The price of a Levame orthosis with 1 or 2 fingers is, respectively, 171.02 EUR (patient fee 8.55 EUR) and 275.35 EUR (patient fee 13.77 EUR). A compression orthotic...
device with 1 or 2 fingers costs, respectively, 122.85 EUR (patient fee 6.14 EUR) and 179.01 EUR (patient fee 8.95 EUR). Fabricating this orthoses takes 1 hour.

**Outcome measures**

Primary outcome was active ROM of the involved digits. AED of each joint was measured at the first visit and after 3 months, using a finger goniometer with 5 degrees graduation for accuracy, following a standardized protocol.16 Measurements were always taken by the same physician to avoid interobserver variability. This physician was blinded to the treatment groups. This means he knew the patient was wearing an orthotic device but not which type of orthosis. Individual joint movement of maximal active extension was summed for each affected digit to calculate the total active extension (TAE).

Secondary outcome was patient satisfaction. Visual Analog Scale (VAS) score of function and aesthetics (0-10 points) were asked at the start of the orthotic treatment plan and afterward. Finally, the patients were asked if the treatment result was “very good,” “good,” or “poor.”

**Randomization and blinding**

Simple randomization was done by a computer-generated random list prepared by an investigator with no clinical involvement in the trial. Patients were enrolled and screened for eligibility by orthopedic surgeons of the Hand Clinic of the University Hospital of Leuven, Belgium. After acceptance of the patient by an orthopedic surgeon, patients were redirected to a researcher. The allocation sequence was concealed from the orthopedic surgeons and the researchers in sequentially numbered envelopes. Informed consent should have been obtained from the participant before opening the appropriate numbered envelope. Patients were assigned in 1 of 2 treatment groups. Figure 3 outlines the flow of the patients through the study. Blinding of participants and orthotic producers were not possible. Outcome assessors and data analysts were kept blind to the allocation.

**Statistical analysis**

An analysis of covariance with the baseline value as covariate was used to compare the outcomes (active extension, TAE, VAS functional, and VAS esthetical) between both groups after 3 months. A transformation (natural logarithm) was applied if model residuals were right skewed. A random patient effect was added in the analyses of goniometry, to take into account the correlation between the clustered measurements (multiple joints or multiple digits of the same patient). The satisfaction was compared between both groups with a Fisher's exact test. Only as-treated analyses are reported because no data were available for the 4 subjects (2 in
traction and 2 in compression group) who stopped treatment (loss to follow-up). No sample size calculation has been performed. All analyses were performed using SAS software, version 9.2, of the SAS System for Windows.

Results

Baseline characteristics

Baseline demographics are presented in Table 1. Thirty patients (21 men and 9 women) were included for this pilot RCT. Sixteen of them (53%) had a positive family history. The mean age at presentation was 63 years (range 44-85 years). The mean age of disease onset was 54 years (range 36-79 years). The left side was involved 16 times, the right on 14 occasions. The little finger was most commonly affected (23 digits), followed by the ring finger (10 digits), the middle finger (6 digits), and index (2 digits). About 40% or 12 patients (5 tension and 7 compression) already had surgery of the treated finger. All but one patient had a regional fasciectomy. The remaining patient underwent a dermofasciectomy with full thickness skin graft. These surgeries took place at least 3 years before initiation of the study protocol. The mean ABE score (median 30, standard deviation 15.03, range 5-57.5) of the compression and tension group were, respectively, 2.2 (range 1-5) and 2.3 (range 0-5). Both groups had comparable baseline characteristics. The MCP joint was affected 6 times in the tension and 5 times in the compression group with a median flexion contracture in both groups of 40° (range 20°-55°). The mean flexion contracture of the PIP joints (17 tension and 15 compression) was 50° (range 15°-65°) in the tension and 57.5° (range 20°-85°) in the compression group. The median baseline contracture of DIP joints (n = 3) was 30° (range 15°-50°). No DIP joints were affected in the tension group. Four patients (13%) were unable to adhere to the treatment protocol: 2 patients of the compression group and 2 patients of the tension group. One patient reported that the orthosis was uncomfortable to do his job. One patient ceased the therapy on advice of his generalist who did not believe in the efficacy of nonoperative treatment in Dupuytren’s disease. The 2 patients with a Levame orthotic device complained of too much pain. Twenty-six patients (36 fingers and 46 joints) completed follow-up at 3 months. The mean ABE score for recurrence risk of Dupuytren’s disease in these patients was 2.27 (range 0-5).

ROM

All patients of both groups had improvement of ROM of each joint. A complete extension (0°) was measured in 4 fingers of the compression group and 3 fingers of the tension group. Figure 4 shows an example of TAE before and after 3 months orthotic treatment.

Tension orthoses improved the TAE from a mean of 52.6° to 20.3°. Mean TAE of the compression group reduced from 65.0° to 18.5°. The mean change in TAE was 32.36° (median 30, standard deviation 15.03, range 5°-60°) in the tension group and 46.47° (median 40, standard deviation 30.56, range 15°-115°) in the compression group (Fig. 5 and Table 2). There was a statistically significant reduction of TAE after 3 months in both the tension (P < .001) and the compression group (P < .001).

Although there was a trend of more reduction of TAE deficit in the compression group, the difference was not statistically significant at 3 months (P = .39). There is no indication that the difference in TAE between both groups depends on baseline characteristics as sex, age, familial history, side, and history of surgery of splinted finger. This has been verified by adding into the regression model the main effect of the potential moderator and its interaction with group (traction vs compression). Subgroup analyses of PIP joints and MCP joints showed no significant difference between both groups (P = .30 and P = .89, respectively).

![Fig. 4. Example of the contracture of a study patient at the time of initial consultation (A) and after 3 months orthotic treatment (B).](image)

Table 1

<table>
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<th>Variable</th>
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<th>Compression</th>
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<td>7/15 (46.67%)</td>
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<tr>
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<td>n/N (%)</td>
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<td>7/15 (46.67%)</td>
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<td>Range</td>
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<td>(20.0-130.0)</td>
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TAE = total active extension.

Variables presented with percentages are analyzed using a Fisher’s exact test. Variables summarized by means, medians are analyzed using a Mann-Whitney U test.

* Percentage of patients who already had surgery of the splinted finger.

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Satisfaction

The VAS scores of esthetics and functionality significantly increased after 3 months in both groups (Figs. 6 and 7). The functional VAS score increased from a mean of 6.3 to 8.0 points in the tension group and from a mean of 6.4 to 8.8 points in the compression group. The functional VAS score after 3 months was 11% higher in the compression group than in the tension group (mean 8.78 vs 7.95, \( P = .03 \), 95% CI: 1.01-1.21). Subgroup analysis of nonoperated patients showed no statistically significant difference between compression and tension orthoses (mean 9.22 vs 8.22, \( P = .13 \)). Subgroup analysis of postoperative patients also showed no statistically significant difference between both groups (mean 8.37 vs 7.60, \( P = .13 \)).

The esthetic VAS score increased from a mean of 4.8 to 7.0 points in the tension group and from a mean of 5.8 to 7.7 points in the compression group. This difference was not statistically significant (\( P = .85 \)).

The compression technique yielded a trend toward higher degree of satisfaction, but this was not significant (\( P = .058 \)). Eighty-five percent (11 of 13) of the patients wearing a compression orthotic device were very satisfied, in comparison to 38% (5 of 13) of the tension group. Seven patients (1 compression and 6 tension) mentioned a good result and only 3 patients, a poor result (1 compression and 2 tension). After 3 months, only 1 patient (tension group) decided to switch to another treatment (collagenase injection). The functional VAS score increased from a mean of 6.3 to 8.0 points in the tension group and from a mean of 5.8 to 7.7 points in the compression group. Seven patients (1 compression and 6 tension) mentioned a good result and only 3 patients, a poor result (1 compression and 2 tension). After 3 months, only 1 patient (tension group) decided to switch to another treatment (collagenase injection). The other patients preferred to continue splinting to maintain the effect, most of them only at nighttime.

Benefits and adverse effects of the orthoses

Subjective outcome parameters were softening and volume loss of nodules and cords. Compression caused softening of nodules and subcutaneous indurations, especially when the silicone layer had good contact with the nodules. This advantage was not seen in the tension group.

Disadvantages of the compression orthotics were the problems to adequately fit the orthotics. It was difficult to have good skin contact, especially at lateral nodules or at the palmar fascia due to concavity and continuous changing of the extension deficit.

Disadvantages of the tension orthoses were pain and ulcers dorsally on the PIP joint (5 patients out of 13).

Discussion

Surgery can promptly correct flexion contractures in DD. However, recurrence remains a problem, especially in patients with aggressive disease.\(^1\)\(^,\)\(^2\)\(^,\)\(^5\)^\(^,\)\(^6\) Forty percent of our patients had prior surgery at least once on the orthotic-treated finger. Ten patients underwent surgery on the contralateral hand but were not satisfied and desired no more surgery. Because of recurrence risk and associated morbidity, there is a lot of research on non-surgical treatment of DD. Collagenase shows promising results, but it has higher recurrence rates than fasciectomy and patients with only nodules without clearly palpable cords are not eligible for this treatment.\(^2\)^\(^,\)\(^4\)^\(^,\)\(^18\) An orthotic device is a low-cost minimal invasive therapy with immediate return to function, mostly used in postoperative rehabilitation.\(^19\) Low-load continuous forces maximize finger extension, maintain correction, and prevent scar contracture. An orthotic intervention as sole treatment is controversial and based on expert opinion.\(^3\)^\(^,\)\(^8\) The results of this pilot RCT demonstrate that a simple orthotic regimen can stabilize and even improve flexion contractures in DD, possibly delaying or preventing surgery. Orthotic treatment can be continued until the finger loses its tendency to flex and can be reapplied in recurrence. After 3

| Table 2 | Mean total active extension |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Variable        | Statistic       | Traction        | Compression     | Difference      | \( P \) value   |
| TAE baseline    | Mean            | 52.6            | 65.0            | .266            |
|                 | Range (15.0-105.0) | (20.0-130.0)  | 18.5            | .923            |
| TAE 3 mo        | Mean            | 20.3            | 18.5            | .346            |
|                 | Range (0.0-60.0) | (0.0-60.0)      | .465            | .346            |
| Change in TAE   | Mean (95% CI)   | \(-32.4 (~39.6 to ~25.1)\) | \(-46.5 (~62.2 to 30.8)\) | .465 (~18.97 to 8.16) | .266            |
|                 | Range           | \(-60.0 to ~5.0\) | \(~115.0 to ~15.0\) | .465 (~18.97 to 8.16) | .266            |
| Change in TAE after correction for the baseline value | Mean (95% CI) | 22.84 (13.3-32.3) | 17.43 (7.8-27.1) | .541 (~18.97 to 8.16) | .266            |

TAE = total active extension.

Overview of the mean total active extension at 0 and 3 months. Result analysis of covariance, comparing the outcome after 3 months between both groups after correction for the baseline value. A random subject effect has been added in the model to take into account the correlation due to the presence of multiple measurements per patient.
months, most patients were used to the orthosis and preferred to continue wearing it at night to maintain the correction.

Myofibroblasts play a primary role in disease progression and recurrence of DD.\textsuperscript{3,20} External mechanical stretch causes upregulation of transforming growth factor β1 (TGF-β1), a potent inducer of myofibroblast differentiation.\textsuperscript{21} Research on TFG-β1 inhibiting drugs has been relatively unsuccessful.\textsuperscript{22,23} Uncontrolled tension may stimulate myofibroblasts by upregulating TFG-β1 and worsen flexion contractures, comparable with scarring.\textsuperscript{19,21,24} Granulation tissue subjected to increased mechanical tension produces hypertrophic scars by inhibiting apoptosis and differentiation of fibroblasts to myofibroblasts.\textsuperscript{15,24} Citron et al\textsuperscript{25} mentioned that application of tension load to Dupuytren’s contractures is counterproductive and may accelerate the progression of deformity.

Too much tension causes inflammation and myofibroblast stimulation, whereas continuous limited tension (within the limits of the fascia’s elasticity) remodelates and softens collagen.\textsuperscript{7,20} The dynamic Levame tension orthosis complies with this theory.\textsuperscript{27} The effect of external applied mechanical stress was already investigated in the 1980s. Messina et al developed a continuous elongation treatment by the continuous extension technique (TEC) device. This study noted a return of contractures in 60% of the patients within 10 days after the removal of the extension device.\textsuperscript{28} Bailey et al and Brandes et al reported the biomechanical effect of continuous extension on Dupuytren’s contracture. Tension forces generate an increased activity of enzymes that depolymerize collagen fibers.\textsuperscript{29,30} For example, increased levels of metalloproteinases in Dupuytren’s disease confirm the positive effect of continuous tension.\textsuperscript{31} Neoformation and reorientation of collagen fibers lead to loss of tensile strength, allowing the fingers to straighten.\textsuperscript{29,30}

Most case studies have used orthoses to prevent recurrence after surgery.\textsuperscript{7-10,32,33} Meinel developed a FixxGlove orthosis with a dorsal insert, similar to our Levame orthosis. He reports a possible effect of long-term nighttime orthotic treatment in preventing recurrence and halting progression. However, this glove orthotic device was only used after percutaneous needle fasciotomy and was worn at night during 6 months.\textsuperscript{32} Mary son Pesco compared the effectiveness of 2 different postoperative extension orthoses, respectively, palmar static and dorsal dynamic, combined with hand therapy. Patients in both groups improved ROM, but dorsal block extension orthoses showed significantly greater improvement. However, this study selected only 6 patients.\textsuperscript{10} Kemler et al and Jerosch-Herold et al found no benefit of night splinting following surgical release of Dupuytren’s contractures.\textsuperscript{7,33} Collis et al also reported no significant differences between an orthotic

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**Fig. 6.** The box plot shows the VAS of esthetic at 0 and 3 months in the tension (A) and the compression group (B). The esthetic VAS score was significantly increased. VAS = Visual Analog Scale.
treated group and a control group in any of the outcome measures (TAE, total active flexion, hand function, and grip strength). This RCT evaluated the effect of postoperative extension orthoses worn for 3 months at night.1

We only found 2 case series presenting the effect of splinting as conservative treatment.1,12 Ball et al presented a preliminary study of only 6 patients treated with night orthoses. Analysis showed reduction in digital contractures without loss of flexion.11 Larocerie-Salgado and Davidson developed a nighttime orthotic regimen of a volar hand-based static extension orthosis together with stretching exercises and massages in PIP joint contractures. Limitation of this study is inclusion of only early contractures of the PIP joint, which is not comparable to our study population.12 Our pilot study recruited more patients, measured the effect on all joints, and asked the participants to wear the orthotic device not only at nighttime. A splinting regimen of 20 hours a day can possibly accelerate the effect on an extension deficit. A visible improvement motivates the patients to wear the orthosis, certainly after previous unsuccessful surgery.

To our knowledge, there are no published studies that investigated the efficacy of compression orthoses in DD. The idea is based on the concept of treating hypertrophic burn scars by compression. Hypertrophic and keloid scars are classified in the same family of fibroproliferative diseases as DD.3 In normal wound healing, granulation tissue disappears after epithelialization due to massive apoptosis of myofibroblasts, which is lacking in fibrotic phenomena.34 Hypercellularity results from underexpression of apoptosis-related genes in fibroblasts and elevated levels of proinflammatory cytokines such as TGF-β.24,35 The activity of myofibroblastic cells depends on the mechanical environment.24 The effect of compression therapy for hypertrophic and keloid scars has been proven clinically and histologically. A prolonged compression can trigger myofibroblast apoptosis and restore cell organization to normal scar tissue.24,36 Reno et al reported about the effect of compression on hypertrophic scars in vitro. Apoptosis of dermal myofibroblasts after compression is 2-fold higher in hypertrophic scars compared with normal scar tissue.25 In combination with a silicon bed, continuous compression could be a good method to manage keloid scarring and DD as well. This silicon layer appears to be an important element and must be worn for at least 12 hours per day for 2-3 months to be effective.27

Both orthoses can be used as nonsurgical treatment in DD with a significant correction of the extension deficit. There is no significant difference in efficacy between compression and tension, but compression orthotic devices seem more comfortable to wear. Continuous limited tension reduces Dupuytren's contractures, but almost 40% of this patients complained of pain and ulceration on the dorsal PIP, which are major complications. The ultimate limitation of compression therapy is the ability to adequately fit the orthosis to the impaired area, which is extremely important to have a good outcome.26 Interface pressure can be used as measurement of contact. There is much discussion about the optimal amount of pressure, a minimum of 25 mmHg is suggested.26 Chang et al reported on the effect of pressure on fibroblasts in vitro. 20 mmHg pressure during 18 hours caused an inhibition of fibroblasts and decrease of TGF-β.1 That is why compression therapy can only be successful when sufficient pressure is applied during a sufficiently long period.20 Our study protocol instructed the patients to wear the orthotic device 20 hours a day. Nonfitting of the orthosis was a particular problem seen at the MCP joint. It is important to see the patient at regular intervals to adjust the orthosis. Possibly, an adjustment of the orthotic design with a counter pressure point on the dorsal MCP joint also can (partially) solve this problem and even increase the treatment effect.

Several limitations have been put forward in this preliminary study for future larger and long-term studies. First, no sample size calculation has been performed. The sample size of 30 may be underpowered and raises the possibility of type II errors, for example, in subgroup analysis of joints and history of surgery. Second, participants and orthotic producers were not blinded. The lack of blinding was due to the nature of the intervention. The physician who took the measurements was only blinded to the type of orthosis, although this may have resulted in a bias. Third, outcome measurements have to be improved in further studies. Patients mentioned no impairment of finger flexion, but we did not include finger flexion as an outcome measurement. Ball et al, Jerosch-Herold et al, and Kemptler et al reported no differences in flexion between an orthotic treated and a control group.21,31 However, some studies indicate that orthoses can compromise finger flexion.30 Future trials better assess flexion measurements as total active flexion and active distal palmar crease.35 As improvement of hand function is an important criterion of success, future research should include a greater variation in the measurement of functional outcomes. We used an easily usable and well-known measure as the VAS score for this pilot study. A definitive trial better uses a Dupuytren's specific functional outcome measure.

Another limitation of our study was loss of follow-up of 4 patients. Because no measurements were available for these participants at 3 months, only as-treated analysis was possible. However, we did not monitor orthotic adherence. All except 2 patients mentioned a good compliance at final appointment, but this was not confirmed with a daily diary. It is questionable whether they really wore the orthotic devices as recommended.

Finally, a follow-up of 3 months is relatively short for a chronic progressive disease as DD. It is justified for a pilot study because the effect of splinting is seen while orthotic devices are being worn.8 We recommend a longer term follow-up of at least 1 year in future trials because it is unknown how the extension deficit would progress the ensuing months. Failure of treatment after 1 year can be a reason to switch to another treatment.

Conclusion

This pilot trial provides a basis for proceeding to a future powered randomized controlled trial. We would not recommend orthoses as the treatment of choice in all patients, but our study justifies the use of orthotic devices as a noninvasive, low-risk, low-cost treatment to delay or avoid surgery in both early proliferative untreated hands and aggressive postsurgery recurrence disease. Both compression and tension seem effective in reducing the AED, but compression therapy is better tolerated and seems more satisfying. Adjustment of the compression orthotic design can possibly optimize the treatment effect. Long-term results of tension and compression on Dupuytren's nodules need more investigation.

References


