Night Orthosis After Surgical Correction of Dupuytren Contractures: A Systematic Review

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Purpose To determine the role of night orthosis use after surgical correction of Dupuytren contracture.

Methods We searched MEDLINE, EMBASE, CINAHL, AMED, OTSeeker, and CENTRAL for articles published from inception of the databases to August 2015. Assessment was undertaken by 2 independent reviewers (O.A.S. and S.A.). Methodological quality of randomized controlled trials was assessed using the Cochrane risk of bias tool and the Newcastle-Ottawa instrument.

Results Seven studies met the standard for inclusion in this review. A total of 659 patients across these 7 studies were included in the analysis, with follow-up ranging from 3 to 72 months. None of the included studies assessed recurrence. The analysis revealed no significant improvement in range of motion of hand joints for patients who received a static night orthosis after Dupuytren surgery compared with patients without an orthosis. Similarly, no differences were found in patient-reported functional status across the 2 groups.

Conclusions The current literature does not appear to support the use of static night orthosis in addition to hand therapy after surgical correction of Dupuytren contracture. *(J Hand Surg Am. 2017;42(10):839.e1-e10. Copyright © 2017 by the American Society for Surgery of the Hand. All rights reserved.)*

Type of study/level of evidence Therapeutic IV.

Key words Orthosis, Dupuytren contracture, hand, fasciectomy, hand therapy.

Online Exclusive

RECOMMENDATIONS FOR STATIC night orthosis use after surgery for Dupuytren contracture are as old as the literature on this disease. Guillaume Dupuytren himself, in his seminal lecture of 1831, described how his first patient wore a night orthosis after surgery "for another month and an excellent result was achieved."[1] Recently, multidisciplinary treatment guidelines, developed by a European Delphi consensus strategy, concurred with these recommendations; that night orthosis use is to be

commenced as soon as possible after surgery, and to be continued for at least 6 weeks.[2]

However, orthosis use is not an intervention entirely without risk. Reported adverse effects include joint stiffness, edema, pain, and slower return of function.[3] In a single study by Evans et al,[4] the authors hypothesized that mechanical stresses, such as those caused by orthoses, compromise nutrient flow to the involved tissues and may worsen outcomes. Their retrospective cohort study appeared to

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support this idea. A systematic review by Larson and Jerosch-Harold in 2008[5] revealed a paucity of high-quality studies on whether an orthosis should be used after surgery for Dupuytren contracture and recommended that further research is warranted on this topic. This prompted many authors to investigate the clinical effectiveness of orthoses after surgery for Dupuytren contracture, with several randomized controlled trials (RCTs) emerging in this area.[6–8] A recent Cochrane review pooled the results of RCTs and nonrandomized controlled trials and found that night orthoses conferred no benefit to patients.[9]

The aim of this study was to expand the search for studies of night orthosis and synthesize the literature on its effectiveness in patients undergoing elective surgical repair of Dupuytren contracture.

METHODS
Eligibility
The population of interest in this study consisted of patients undergoing elective surgical repair of Dupuytren contracture, irrespective of the surgical techniques used. Studies assessing percutaneous aponeurotomy or collagenase injections were not included. The intervention being considered was unsupervised postoperative static nighttime orthotic use including any brace, cast, or orthotic device initiated immediately after surgery with the aim of maintaining the extension obtained at the time of surgical management. Rates of recurrence were considered the primary outcome, as per the Collegenase Option for Reduction of Dupuytren Long-Term Evaluation of Safety Study (CORDLESS) trial,[10] despite the lack of an agreed definition of recurrence after Dupuytren surgery.[11] The secondary outcomes of interest were the range of movement, as indicated by the total active extension (TAE) of the joint assessed at baseline and final follow-up, and patient-reported functional status. The protocol included orthosis fabrication alone or in combination with therapeutic exercise, patient education, and self-management techniques. Other treatment approaches such as continuous passive motion devices or chiropractic or osteopathic manipulation were excluded from this review. Randomized controlled trials and observational studies were included in this review. The Preferred Reporting Items for Systematic review and Meta-analysis guideline was followed.

Search strategy
The following electronic databases were searched from inception to August 2015 to identify relevant prospective and clinical trials: MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, CINAHL, AMED, and OTSeeker. The search was mapped to MeSH terms and the following terms were used to identify potential articles: "Dupuytren contracture" and "Splints" or "extension orthoses" or "orthotic devices." The search was limited to papers published in English, peer-reviewed journals, dealing with clinical studies on Dupuytren contracture, investigating the use of postoperative orthoses. Two authors (O.A.S. and S.A.) independently screened title and abstract to assess eligibility for inclusion, and then they independently reviewed the potentially eligible studies based on the full text paper, with the senior author (D.T.T.) available for arbitration on inclusion.

Data extraction
The following data were extracted from each article and used for comparisons: author, journal, year of publication, level of evidence, age, sample size, study design, funding, surgical technique, orthosis utilized, outcome measures (TAE and patient-reported functional status), follow-up period, and study results. When included studies did not present results using our *a priori* outcome measure, authors were contacted to provide their results based on the definition of TAE. The same 2 independent reviewers used a data collection spreadsheet to extract data.

Assessment of quality
We appraised the methodological quality of RCTs using a 7-item quality assessment of the Cochrane risk of bias tool.[12] The cohort Newcastle-Ottawa scale was used to score observational studies. The Newcastle-Ottawa instrument has been shown to be 1 of the 2 most useful tools for assessing nonrandomized studies.[1] The instrument evaluates observational studies by allotting stars in terms of selection, comparability, and outcomes. We used the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) tool to assess the strength of the evidence as recommended by the *Cochrane Handbook for Systematic Reviews of Interventions*.[13,14]

RESULTS
Study selection
A total of 685 potentially eligible articles were identified in the literature search (Fig. 1). After reviewing titles, 13 potentially relevant articles were considered for abstract review. After assessment of abstracts, 6 articles had to be excluded. A total of 7 full-text articles were ultimately included. Of these, there were 3 prospective RCTs,[6–8] 1 controlled trial
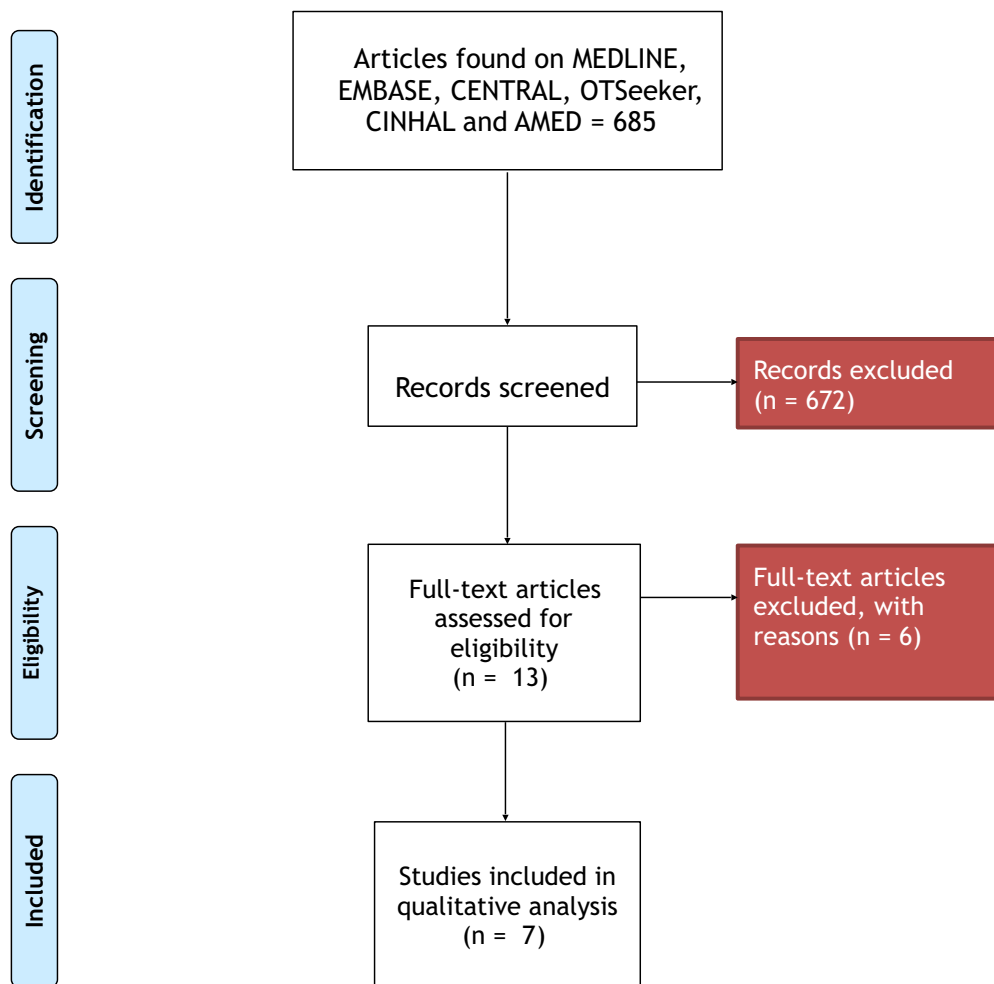
FIGURE 1: Article selection process.

without randomization,[15] 1 prospective noncontrolled observational study without control,[16] and 2 retrospective case series.[4,17] Table 1 summarizes the 3 RCTs that were ultimately included in our synthesis. A total of 264 patients across these 3 trials were included in this review, with follow-up ranging from 3 to 12 months. The characteristics of the included nonrandomized studies are summarized in Table 2. A total of 395 patients across these 4 studies were included in this review, with follow-up ranging from 3 to 72 months.

Primary outcome

Of the randomized studies, Collis et al[6] and Kemler et al[8] did not report recurrence rates. Jerosch-Herold et al[7] intended to report recurrence rates in their original protocol; however, they abandoned the endeavor, citing difficulties in distinguishing a true recurrence from scar contracture and lack of agreement on a definition. Similarly, none of the included nonrandomized studies explicitly assessed recurrence.

Secondary outcome—TAE

In the Jerosch-Herold et al study,[7] TAE was used an outcome measure of range of motion (ROM). Similarly, Collis et al[6] reported TAE for each finger but reported only on TAE of the little finger at the longest follow-up. In contrast, Kemler et al[8] presented ROM by the mean extension deficit of the proximal interphalangeal (PIP) and metacarpophalangeal joints and reduction of extension deficit of the PIP joint in degrees. Therefore, the authors of the Kemler et al[8] study were contacted and data on the TAE of their study subjects that was not reported in their original publication was obtained to maintain consistency of data analysis in this review. Of the nonrandomized studies, both articles by Rives et al[16] and Evans et al[4] found an improvement with orthoses in compliant patients. The other nonrandomized articles, by Glassey[17] and Ebskov et al,[15] did not detect an improvement in ROM. However, both studies had follow-up durations less than a year (3 and 9 months, respectively).

TABLE 1.   Characteristics of Randomized Studies Included in the Systematic Review

Reference	Study Design (LOE)	Sample Size	Age (y)	Outcomes	Intervention	Hand Therapy	Funding	Follow-Up (mo)	Surgery	Results (At final Follow-Up)
Collis et al, 2013[6]	RCT, single-center (II)	56 patients	Mean, 63	TAE of operated fingers, total active flexion of operated fingers, DASH score	Night thermoplastic dorsal extension orthoses protocol with hand therapy	Any or all of the following treatments: active tendon gliding range of motion exercises, education, wound and scar therapy, passive stretch with or without heat to increase finger extension and/or flexion, intermittent use of daytime finger-based dynamic PIP joint extension orthoses, and grip strengthening	None declared	3	Surgical release (no details)	No statistically significant differences were found on • TTAE (little) (95% CI, −20 to < 1; $P = .07$) • TTAE (ring) (95% CI, −12 to 13; $P = .92$) • TTAE (middle) (95% CI, −24 to 7; $P = .23$) • T DASH questionnaire (95% CI, −5 to 3; $P = .59$)
Kemler et al, 2012[8]	RCT, 2-center. (II)	54 patients	Mean, 67	The mean extension deficit, patients-rated global perceived effect, and VAS for pain and comfort	Thermoplastic dorsal static finger extension orthosis protocol with hand therapy (day and night for 4 wk, followed by night only up to 3 mo)	Standardized program of graded exercises (no further details).	None declared.	12	Standard limited fasciectomy	No statistically significant differences were found on • Orthosis group extension deficit mean reduction (21°) in flexion contracture compared with control group (29°) in ($P = .1$) • Global perceived effect ($P = .5$)

(Continued)

TABLE 1. Characteristics of Randomized Studies Included in the Systematic Review (Continued)

Reference	Study Design (LOE)	Sample Size	Age (y)	Outcomes	Intervention	Hand Therapy	Funding	Follow-Up (mo)	Surgery	Results (At final Follow-Up)
Jerosch-Herold et al, 2011[7]	RCT, multicenter (II)	154 patients	Mean, 67.2	TAE of operated fingers, total active flexion of operated fingers, DASH score	Static night orthosis with concomitant hand therapy (for 6 mo)	No detail provided	Nonindustrial funding was received	12	Fasciectomy or dermofasciectomy	No statistically significant differences were found on • TAE (mean all finger) 95% CI, −2.33 to 12.55; P = .1). • DASH questionnaire (95% CI, −2.79 to 4.11; P = .7)

CI, confidence interval; LOE, level of evidence; VAS, visual analog scale.

Secondary outcome—function

Two of the 3 included studies used the Disabilities of the Arm, Shoulder, and Hand (DASH) for assessing patient-reported functional status.[6,7] Kemler et al[8] asked patients "How would you rate the change in limitations caused by Dupuytren's disease since the start of treatment?" and had them grade their answer on a 7-point scale, ranging from worst ever to immense improvement. They interpreted responses as the patient-rated global perceived effect to measure hand function.[8] This scale has shown excellent reliability and been advocated to increase the relevance of information from clinical trials to clinical practice.[18,19] A summary of the extracted data of the outcomes is illustrated in Table 3. Patient-reported outcomes were not measured in the majority of the nonrandomized studies, but Glassey[17] found that patients without orthoses had higher DASH scores at 3 months after fasciectomy.

Overall results

The highest-quality studies included in the review did not report on our primary outcome, flexion contracture recurrence. The studies did not independently show differences in the change in TAE between baseline and final follow-up across the orthosis and the control groups. No difference was observed in DASH scores between the orthosis and the control groups. The study by Rives et al,[16] although older, scored perfectly on the Newcastle-Ottawa risk of bias scale and did show improvement in patients with orthoses. Evans et al[4] also found an improvement with applied tension. In contrast, Glassey[17] found an improvement in TAE in the group with the orthosis, along with lower scores on the DASH. However, unlike the randomized trials, there was significant potential for bias by indication—the surgeon may have selected the suitable and compliant candidates to receive the orthosis.

Risk of bias

In general, the overall methodological quality of studies was moderate to low (Table 4; Fig. 2). Two studies had applied randomization. However, there was a high risk of bias in Collis et al study.[6] Concealed allocation was unclear in Collis et al[6] and Kemler et al.[8] In all studies, patients and care providers were not blinded. Moreover, it was unclear whether outcome assessors were blinded to the intervention.

The overall quality of methodology in the nonrandomized studies was moderate to high (Table 5). The scores on the Newcastle-Ottawa scale ranged from 6 stars[4,15] to a perfect 9 stars.[16] Generally, studies did well in terms of patient selection, but lost stars in the comparability or the outcomes domains.

TABLE 2. Characteristics of Included Nonrandomized Studies

Reference	Study Design	Sample Size	Age (y)	Outcomes	Intervention	Follow-Up (mo)	Result
Evans et al, 2002[4]	Retrospective cohort study	268 participants	Mean, 67.15	Digital ROM, inflammation, flare, hypertrophic scar, and therapy visits.	Day and night tension and nontension orthosis with exercise	72	Improvement in ROM in flexion with tension applied
Glassey, 2001[17]	Retrospective cohort study	31 participants	Mean age, not reported	ROM (joint flexion), pain, grip strength, and hand function	Night extension orthosis	3	Joint range of extension was not maintained by applying orthosis
Ebskov et al, 2000[15]	Prospective, nonrandomized controlled study	76 participants	Mean age, not reported	ROM, recurrence, adherence to orthosis	Dorsal dynamic extension orthosis (timing not specified)	9	Orthosis did not influence the outcome of disease after operation
Rives et al, 1992[16]	Prospective, not controlled study	20 participants	Mean, 60 (range, 44–76)	Percent improvement in PIP joint—measurement of joint angle tool	Dorsal dynamic orthosis with extension force (daytime and overnight)	24	Improvement in outcome in compliant patients

Quality of the evidence

As mentioned, the methodological quality of each of the RCTs reviewed was moderate to low. All the included studies are at risk of both performance and selection bias. Owing to the nature of the intervention, it was difficult to eliminate the performance bias. The Kelmer et al[8] and Jerosch-Herold et al[7] studies have the longest follow-up of 12 months, whereas Collis et al[6] conducted an RCT with only 3 months follow-up. The short follow-up periods in their study introduces the possibility that some of the patients were still recovering, and therefore, effectiveness of any treatment cannot be comprehensively assessed. However, there was also no observed benefit even after a 1-year follow-up in other studies.[8] Based on the GRADE approach, we found that for 2 outcomes (TAE and DASH), the evidence for most of the findings described previously is of moderate quality.

Synthesis of results

The outcomes of the included studies were extracted and are summarized in Table 3. These 3 studies were variable in terms of the length of the intervention and the length of follow-up. In addition, the Kemler et al[8] and Collis et al[6] studies recruited patients to their studies who had much more severe contractures before surgery than the Jerosch-Herold et al study.[7] Hence, a meta-analysis of the extracted outcomes was not appropriate owing to the clinical heterogeneity of the study patient populations.

DISCUSSION

Previous studies have investigated the role of orthoses after surgery for Dupuytren contracture. However, these studies have been vulnerable to various sources of bias and, therefore, the results of these studies do not constitute high-quality evidence. Our study expands on a previous systematic review that examined whether static night orthosis wearing after surgical correction of Dupuytren contracture is effective in preventing recurrence of contracture and improving hand function.[7] Our updated systematic review, which included 3 new RCTs in this field and 4 observational studies, demonstrates that the most critical outcome, recurrence rates, is not being reported. There were no significant differences in our secondary outcomes, TAE and DASH scores, whether night orthotics were used or not. Nonrandomized trials showed contrasting results, or no difference at all, and were susceptible to bias by indication.

Range of movement of digital joints was presented using the TAE, across the studies included in this

TABLE 3. Summary of the Extracted Outcomes of the Included Randomized Studies

|	Collis et al, 2013[6]		Jerosh-Herold et al, 2011[7]		Kemler et al, 2012[8]	
	Orthosis Group (n = 26)	No-Orthosis Group (n = 30)	Orthosis Group (n = 77)	No-Orthosis Group (n = 77)	Orthosis Group (n = 28)	No-Orthosis Group (n = 26)
Preoperative TAE, mean ° (SD)	70.7 (10.7)	75.7 (14.6)	50.7 (22.2)	51.1 (18.8)	70.7 (31.2)	72.1 (22.5)
Three-mo follow-up TAE, mean ° (SD)	30.7 (6.42)	29 (4.6)	32.9 (19.6)	30.9 (20.7)	NA	NA
Six-mo follow-up TAE, mean ° (SD)	NA	NA	31.0 (23.3)	28.4 (21.1)	NA	NA
Twelve-mo follow-up TAE, mean ° (SD)	NA	NA	32.9 (27.4)	29.6 (23.3)	40.3 (20.6)	25.4 (24)
Preoperative DASH, mean (SD)	14 (12)	13 (14)	16.4 (15.1)	15.4 (13.2)	NA	NA
Three-mo postoperative DASH, mean (SD)	10 (9)	11 (16)	9.6 (12.8)	10.8 (12.5)	NA	NA

review. Given that the differences in the TAE between the different studies groups were nonsignificant in the randomized studies with small and narrow confidence intervals, our results further substantiate the findings of the previous review that alluded to the inconsistent trajectory of results of orthosis use in this patient group.[5] Two of the nonrandomized studies showed worsening with night orthoses following fasciectomy for Dupuytren. The study by Evans et al[4] showed that patients with tension applied had worse ROM and extensor lag following a complete follow-up. Glassey[17] had similar findings in terms of ROM, and also found a higher DASH score in patients with an orthosis applied. However, his follow-up was relatively short at 3 months, and he noted that these results are probably not externally valid. Rives et al[16] scored the highest on the Newcastle-Ottawa scale and showed an improvement with an orthosis. Notably, they considered compliance among patients and the positive effect was seen only with patients they considered compliant.

Two of the 3 randomized studies included in this review used the DASH to examine the changes in disability. The DASH score is a well-validated outcome measure for assessing patient-reported disability.[20] However, several items on the 30-item DASH scale inquire about problems with movements that involve the shoulder complex. Therefore, questions can arise regarding its ability to comprehensively capture disability in individuals with hand problems. Although the DASH questionnaire is the most commonly used function outcome measure for Dupuytren disease,[21] it may lack the sensitivity to detect significant improvement following Dupuytren surgery secondary to a ceiling effect. This refers to the relatively good pretreatment scores, which leave less room for improvement. No studies reviewed by Ball et al[21] achieved a DASH score difference equal to, or more than, 15 points, which is considered to be the minimally clinically important difference. The validity of the DASH questionnaire as an outcome measure for Dupuytren disease was further questioned by Jerosch-Herold et al,[7] who showed a weak association between the flexion contracture in Dupuytren disease and functional disability as measured by the DASH questionnaire. This finding is supported by another study that demonstrated that a change in the *Quick*-DASH score did not correlate with the change in extension deficit in Dupuytren disease.[22]

A possible reason for a lack of difference could be dilution bias, especially through nonadherence in the orthosis group. One weakness is that adherence rates relied on patient-completed diaries. Independent

TABLE 4.   Risk of Bias of the Included Randomized Trials Using the Cochrane Collaboration's Tool for Assessing Risk of Bias

	Collis et al, 2013[6]	Kemler et al, 2012[8]	Jerosh-Herold et al, 2011[7]
1. Random sequence generation (selection bias)	Unclear risk	Low risk	High risk
2. Allocation concealment (selection bias)	Unclear risk	Unclear risk	Low risk
3. Blinding of participants and personnel (performance bias)	High risk	High risk	High risk
4. Blinding of outcome assessment (detection bias)	High risk	High risk	High risk
5. Incomplete outcome data (attrition bias)	Low risk	Low risk	Low risk
6. Selective reporting (reporting bias)	Low risk	High risk	High risk
7. Other bias			
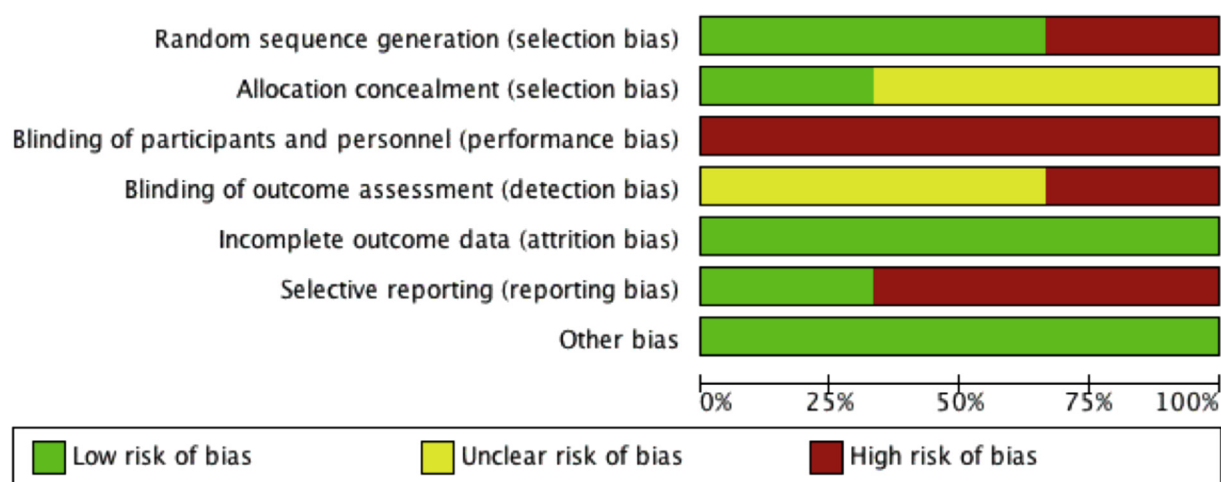
FIGURE 2: Risk of bias graph.

verification of actual orthosis wear was not possible. A major issue that both the Collis et al[6] and the Jerosch-Herold et al[7] studies report is that patients from the nonorthosis group in their studies were given an orthosis if they met certain criteria because it was deemed unethical to withhold an orthosis from a patient developing an early recurrence of the disease (3 and 8 patients, respectively). Hence, the results from those studies actually show that there was no difference in outcome between patients who received hand therapy and an orthosis immediately after surgery compared with patients who received hand therapy alone and were only given an orthosis when a contracture occurred.

Another plausible reason for the lack of effect could be that the amount of tension provided through a static night orthosis is not sufficient to remodel scar tissue.[17] Improvement in PIP flexion contracture with full-time casting is possibly related to the total time immobilized. However, it is unknown if the same principle applies to an intermittent application of force, such as the use of a static night orthosis in postoperative Dupuytren contracture patients.

Future research that focuses on evaluating the effect of different types of orthosis, duration and timing of orthosis wear, and force vectors is required. In addition, a consensus must be reached on standardizing the outcome measures for Dupuytren research. A systematic review of outcomes measures in Dupuytren research recommended a combination of physical measures and questionnaires.[21] More specifically, the Michigan Hand Outcomes Questionnaire[23] and Unité Rhumatologique des Affections de la Main scale[24] were recommended for patient-reported outcomes and measurements of active flexion and extension of each joint, grip strength, and sensibility for physical measures. Attempts at measuring recurrence rates should be made according to the definition used in the CORDLESS trial.[10] Although there are limitations with this, inaccuracies should theoretically be equal between groups in RCTs. A minimum of 1-year follow-up should be completed to allow for the

TABLE 5. Risk of Bias of the Included Nonrandomized Trials Using the Newcastle-Ottawa Tool for Assessing Risk of Bias

Study	Selection				Comparability	Outcome			Total
	Representativeness of the Exposed Cohort	Selection of the Nonexposed Cohort	Ascertainment of Exposure	Outcome of Interest not Present at Start of Study	Comparability of Cohorts on the Basis of the Design or Analysis	Assessment of Outcome	Was Follow-Up Long Enough for Outcomes to Occur	Adequate Follow-Up of Cohorts	
Ebskov et al, 2000[15]	★	★	★	★			★	★	6
Evans et al, 2002[4]	★	★	★		★★	★			6
Rives et al, 1992[16]	★	★	★	★	★★	★	★	★	9
Glassey, 2001[17]	★	★	★	★	★★	★		★	8

healing process to occur and potentially capture recurrences.

This review is subject to limitations. The surgical and physiotherapy literature remain challenging areas to search, with numerous bibliographic databases and nonindexed journals. Whereas we made every attempt to identify relevant studies, we limited ourselves to English language only, and other studies might exist that would have contributed to the review. Although there are minor potential threats to validity, we believe that this review remains the most comprehensive to date.

Based on moderate quality evidence, we can conclude that the routine use of a static night orthosis combined with hand therapy after surgical correction of Dupuytren contracture does not clearly improve DASH scores or hand ROM. In compliant patients, in whom the hand surgeon anticipates potential benefit, it may be worth trying because the cost is low and there is minimal potential harm. No studies showed worsening in any of the assessed outcomes. Importantly, the primary goal of wearing a hand orthosis overnight is to reduce the risk of disease recurrence and prevent flexion contracture due to scarring, which is not being explicitly measured by researchers. Future studies should attempt to compare recurrence rates to more accurately represent outcomes of interest in this patient population.

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