Annals of Internal Medicine | ARTICLE

Splint for Base-of-Thumb Osteoarthritis

A Randomized Trial

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Background: Some guidelines recommend splinting for base-of-thumb osteoarthritis, despite lack of evidence of efficacy.

Objective: To assess the efficacy and acceptability of a splint for base-of-thumb osteoarthritis.

Design: Multicenter, randomized trial. Randomization was computer-generated, and allocation was concealed by faxing centralized treatment assignment to investigators at the time of enrollment. Patients and investigators were not blinded to assignment, and patients self-reported outcomes.

Setting: 2 tertiary care hospitals in France.

Patients: 112 patients (101 women) with base-of-thumb osteoarthritis.

Intervention: Custom-made neoprene splint ($n = 57$) or usual care ($n = 55$).

Measurements: Primary outcome was change in pain level assessed on a visual analogue scale (VAS) (range, 0 to 100 mm) from baseline to 1 month. Secondary outcomes were change in measures of hand disability at 1 month and change in pain level and measures of disability at 12 months. Tolerance and adherence with the splint were recorded.

Results: At 1 month, no difference in change occurred in pain level from baseline in the intervention and control groups (adjusted mean change, −10.1 vs. −10.7; between-group difference, 0.6 [95% CI, −7.9 to 9.1]; $P = 0.89$). Disability was assessed by the Cochin Hand Function Scale score (range, 0 to 90) or patient-perceived disability (VAS, 0 to 100 mm). At 12 months, change in pain from baseline was greater in the intervention group than in the control group (adjusted mean change, −22.2 vs. −7.9; between-group difference, −14.3 [CI, −23.4 to −5.2]; $P = 0.002$). The Cochin Hand Function Scale score was −1.9 versus 4.3 (between-group difference, −6.3 [CI, −10.9 to −1.7]; $P = 0.008$) and patient-perceived disability was −11.6 versus 1.5 (between-group difference, −13.1 [CI, −21.8 to −4.4]; $P = 0.003$). At 12 months, 86% of the intervention group had worn the splint for more than 5 nights a week, and no adverse effects were observed.

Limitation: Patients, health care providers, and outcome assessors were not blinded.

Conclusion: For patients with base-of-thumb osteoarthritis, wearing a splint had no effect on pain at 1 month but improved pain and disability at 12 months.

Primary Funding Source: Programme Hospitalier de Recherche Clinique National.

Ann Intern Med. 2009;150:661-669. www.annals.org
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ClinicalTrials.gov registration number: NCT00350896.

Base-of-thumb osteoarthritis (BTOA) is a relatively common condition affecting middle-age and older persons (1). Base-of-thumb osteoarthritis induces pain and closure of the first web, which in turn causes an alteration of the thumb–index pinch and, therefore, limitation in hand function (1). The consequences of BTOA have been specifically evaluated and compared with osteoarthritis of digits 2 to 5 of the interphalangeal joints (2). Substantial pain and similar pain and disability levels were observed in both osteoarthritis locations, and results suggested that hand osteoarthritis (base of thumb or interphalangeal joints) is as cumbersome as a rheumatoid arthritis of the hand for some people (3, 4).

Few treatments have been specifically assessed in BTOA. The European League Against Rheumatism recently proposed 11 evidence-based recommendations for the management of hand osteoarthritis (5). Among these, 3 specifically concern BTOA: intra-articular corticosteroid injections for painful flares, surgery when conservative treatments have failed, and splints to prevent or correct lateral angulation and flexion deformity. However, no randomized trials with placebo or nonsplint comparison have been done to support this recommendation. Two small (26 and 21 participants each) head-to-head, randomized, controlled trials (RCTs) found better pain relief with a full splint (covering the thumb base and wrist) than with a half splint (covering only the thumb base) (6, 7). However, these studies did not examine the effect on disability or closure of the first web. More recently, a small RCT compared 2 splints and exercise regimens and found no short-term differences (8). The conclusions of the European League Against Rheumatism standing committee on splints for BTOA was that "apart from expert opinion, placebo-controlled or nonsplint-controlled research evidence [is] required" (5).

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Context

Some guidelines recommend splinting for symptomatic treatment of base-of-thumb osteoarthritis.

Contribution

In this randomized trial, nighttime splinting had no effect compared with usual care after 1 month, but it clinically significantly reduced patients' pain and disability after 12 months.

Caution

The study was not blinded, and the splints were custom-made.

Implication

Nighttime splinting is an effective treatment of base-of-thumb osteoarthritis.

—The Editors

We conducted an RCT to assess the efficacy of splinting for BTOA on pain at 1 month. Secondary objectives were to assess the efficacy of splinting for BTOA on pain and disability at 12 months and safety and adherence with splinting for BTOA.

METHODS

Design

We conducted a 12-month, open-label, parallel-group, multicenter RCT in 2 tertiary care hospitals (Cochin Hospital and Lariboisière Hospital, Paris, France) after methodological and reporting guidelines (9, 10).

Participants

We screened all patients who consulted with physicians (mostly rheumatologists) for disabling BTOA during outpatient visits at tertiary care hospitals or at private practices for inclusion in the trial and invited them to participate. Inclusion criteria were pain at the base of the thumb 30 mm or greater on a visual analogue scale (VAS) (range, 0 to 100 mm), age 45 to 75 years, radiographic evidence of at least 2 of 4 radiographic items (osteophytes, joint space narrowing, subchondral bone sclerosis, or subchondral cysts), and at least 1 of 2 clinical items (trapeziometacarpal joint enlargement or closure of the first web) at the trapeziometacarpal joint. Other hand joints could be affected. Exclusion criteria were posttraumatic osteoarthritis, crystal arthritis, inflammatory arthritis, neurologic disorder involving the upper limb, hand or wrist trauma within the past 2 months, previous hand surgery, collagen diseases (the Dupuytren syndrome, the Marfan syndrome, or the Ehlers–Danlos syndrome), hand or wrist infiltration within 2 months, skin disease interfering with wearing the splint, having already worn a splint for BTOA (that is, splinting had been previously proposed), having bilateral BTOA with no predominant symptomatic side, psychiatric disorder needing treatment adaptation in the past 3 months, inability to speak or write French, and pregnancy.

Ethics Approval

The local ethics committee approved the study protocol, and all patients gave written informed consent to participate.

Intervention

Patients were randomly assigned to receive a custom-made neoprene splint to be worn at night or to usual care. The splint was a rigid rest orthosis recommended for use only at night. It covered the base of the thumb and the thenar eminence but not the wrist (**Figure 1**). Splints were made by 3 trained occupational therapists, who adjusted the splint for each patient so that the first web could be opened and the thumb placed in opposition with the first long finger. Patients were encouraged to contact the occupational therapist if they felt that the splint needed adjustment, pain increased while wearing the splint, or they had adverse effects (such as skin erosion).

Because no treatment can be considered the gold standard in this situation, patients in the control and intervention groups received usual care at the discretion of their physician (general practitioner or rheumatologist). We decided not to use a placebo because, to our knowledge, no placebo for splinting has achieved successful blinding of patients, as recommended (11). Furthermore, use of a placebo could underestimate the treatment effect (12).

Randomization and Allocation Concealment

We randomly assigned patients who met the inclusion criteria and agreed to participate. The randomization process was centralized at the coordinating office (Clinical Research Unit, Cochin Hospital), which had no involvement in enrollment, follow-up, or assessment of participants. A statistician made a computer-generated randomization list (with a block size of 6 and stratified by center) at the coordinating office. Once the screening process was complete, the investigator sent a fax to the coordinating office. The coordinating office randomly assigned the patient to a treatment and faxed the investigator the allocated treatment. Patients randomly assigned to wear the custom-made neoprene splint were sent information on an appointment time to meet with 1 of the 3 trained occupational therapists to adjust the splint within 1 week after inclusion.

Outcome Measures

Our primary outcome was change in pain level assessed on a VAS (0 to 100 mm) from baseline to 1 month. Secondary outcomes were change in measures of hand disability at 1 month, as well as change in pain level and measures of disability at 12 months.

Two independent, trained physicians of physical medicine and rehabilitation (who were not involved in patients' treatment) assessed several clinical and radiographic (structural) variables at enrollment (baseline) and at 1, 6, and 12 months.

Clinical Variables

We assessed several clinical variables at each visit. We assessed pain during the previous 48 hours (VAS, 0 to 100 mm). A clinically relevant success at the individual level was defined by the following improvement thresholds: greater than 10, 15, and 20 mm on a 0- to 100-mm VAS for pain (13). Hand disability was assessed by using the Cochin Hand Functional Scale score (0 = low level of disability; 90 = high level of disability) (3, 4, 14). We also assessed patient global perceived disability (VAS, 0 to 100 mm) and patient global assessment (semiquantitative scale of 6 points: worse, the same, weakly improved, fairly improved, much improved, or totally improved) at 1, 6, and 12 months. We considered patients who responded at least fairly as having improved. We assessed pinch strength by using an electronic dynamometer (Amplifier HDM, Société Biometrics France, Parc Club Orsay Université, Orsay, France) (15, 16). We tested pinch strength 3 times (1 minute apart) and recorded the highest value, and we also assessed pain during pinch (VAS, 0 to 100 mm). Thumb mobility, evaluated by the Kapandji index thumb opposition (0 to 10 for each side) and counter-opposition subscales (0 to 4 for each side) (0 = impossible to do), was also assessed (17–19). Closure of the first web (at baseline and 12 months) was examined. A photograph of both hands was taken with the patient sitting on a chair, palms of the hands and wrists resting on a table in front. We asked patients to put the thumb in maximal abduction (**Figure 2**). One physician calculated the angle between the line measured along the medial side of the thumb after the axis of the first and second phalanges and the line measured along the lateral side of the index after the axis of the first and second phalanges by using a goniometer. We assessed intrarater reliability on the 40 first measures as good, with an intraclass correlation coefficient of 0.96.

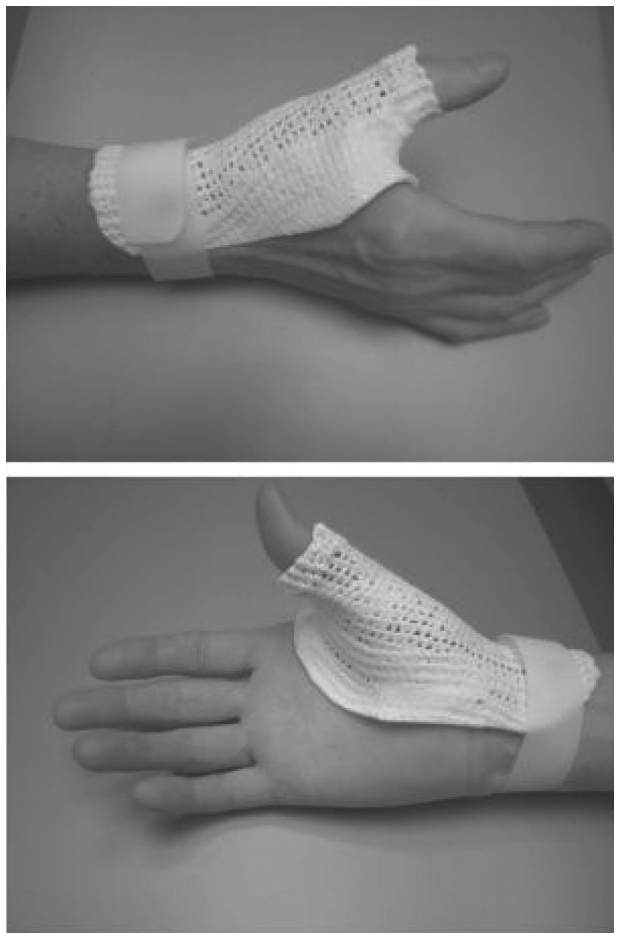
Radiographic Variables

Patients had standardized radiography of the hand at baseline and 12 months. Images of both hands, palm down, were taken on the same film. To obtain optimal positioning, we asked patients to sit in front of the radiography table and rest their palms comfortably on the table. One experienced reader (blinded to treatment allocation and any order of patients undergoing radiography) assessed the radiographs. We blinded films for dates and names, and baseline and follow-up films were mixed. We assessed radiographic evidence of progression of BTOA by the trapeziometacarpal and scaphotrapezial subscores of the Kallman scale (range, 0 to 10) (20). The Kallman scale is a method sensitive to change, and results suggest that structural changes can be detected in hand osteoarthritis during 1 year (21).

Co-interventions

We also assessed the use of co-interventions at each visit: analgesics (acetaminophen or acetaminophen plus opioids), nonsteroidal anti-inflammatory drugs, symptomatic slow-acting drugs for osteoarthritis (that is, the nutraceuticals chondroitin sulfate and avocado and soybean unsaponifiable extracts and diacerein, which is believed to have anti–interleukin-1 effects on cartilage), intra-articular corticosteroid injections, and surgery.

Figure 1. **Dorsal view (*top*) and palmar view (*bottom*) of a custom-made neoprene splint for base-of-thumb osteoarthritis.**



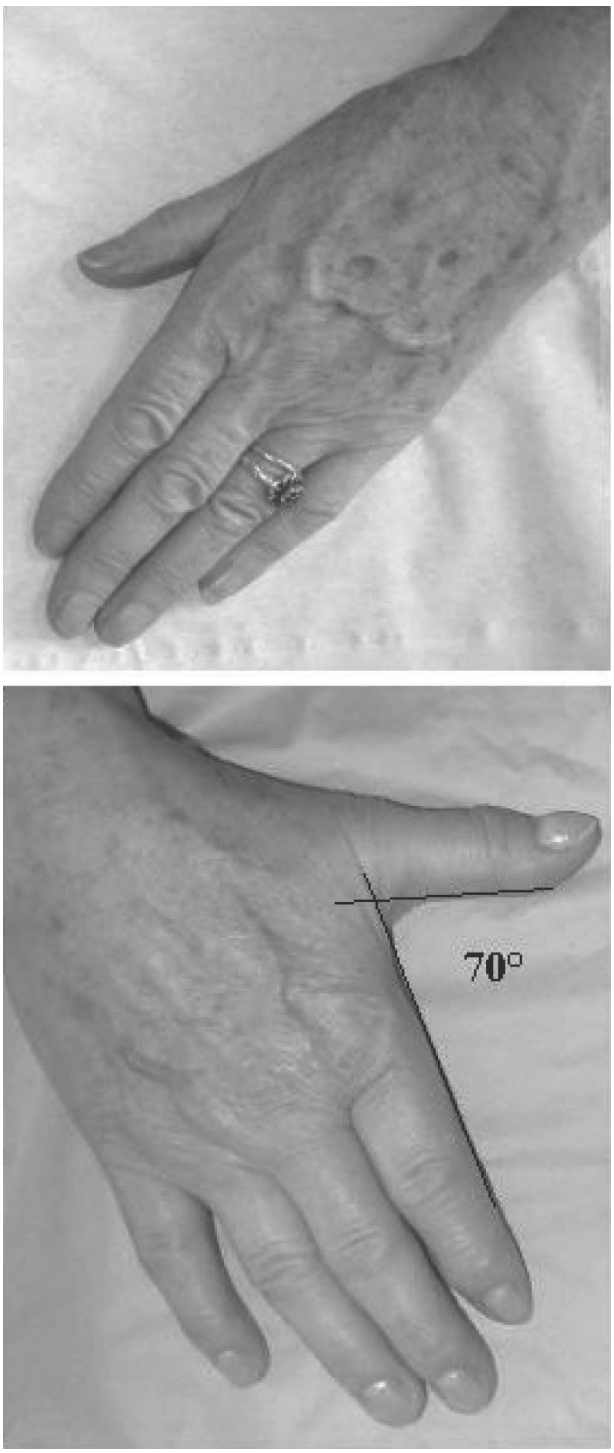
Adherence

Patients recorded adherence to wearing the splint in a weekly diary. The investigator checked the diary at the 1-, 6-, and 12-month follow-up visits. We considered adherence to be good if the splint was worn 5 to 7 nights a week, fair if worn 3 or 4 nights a week, weak if worn 1 or 2 nights a week, and absent if worn less than 1 night a week.

Tolerance

Adverse effects, such as skin erosions, allergy to the splint, or increased pain were self-reported in a weekly diary, which investigators checked at the 1-, 6-, and 12-month visits.

Figure 2. **First web closure and measurement of maximal abduction.**



Top. Example of a closure of the first web in base-of-thumb osteoarthritis. **Bottom.** Measurement of the angle in maximal abduction. The angle between the line measured along the medial side of the thumb after the axis of the first and second phalanges and the line measured along the lateral side of the index after the axis of the first and second phalanges was calculated by using a goniometer.

Blinding

Because no credible placebo exists for splinting, patients and care providers could not be blinded to treatment assignment. As well, the primary outcome (that is, pain at 1 month) was a patient-reported outcome, so a prospective open blinded end point study was not possible (22). To limit and evaluate the risk for bias, we systematically assessed co-interventions administered to patients and whether patients crossed over by using another splint. Furthermore, data collectors responsible for follow-up assessment were independent (that is, they were not involved in patients' care).

Sample Size

To achieve a 15-mm clinical difference in VAS score between control and intervention groups, with a slightly overestimated SD of 26, an α risk for 0.05, and power $(1 - \beta)$ of 0.80, the number of participants needed in each group was 54. With an estimated 10% of patients lost to follow-up, we sought to include 120 patients but recruited only 112.

Statistical Analysis

A blinded statistician did the statistical analyses at an independent center (Bichat Hospital, Paris, France). All analyses were done on an intention-to-treat basis, in that all patients were considered in the analysis and were analyzed in the group to which they had been assigned.

For each outcome, we used both a random-effects regression model (23, 24) and a mixed-effects repeated measurements model (25, 26) in our analysis. Both models are likelihood-based, use all available data, and provide valid results under the assumption that missing data are missing at random. The random-effects regression models model repeated measurements over time under the hypothesis that outcomes evolve linearly with time, whereas the mixed-effects repeated measurements model do not impose a linear relationship between outcome and time. We used the random-effects regression model to compare the slopes between treatment groups; that is, the test of difference of the treatment effect is based on the test of the nullity of the coefficient associated with the treatment-by-time interaction, representing the average difference in slopes between treatment A and treatment B. We used the mixed-effects repeated measurements model to estimate and compare adjusted mean change from baseline to follow-up visits. Fixed effects included baseline value of the outcome, center, treatment, time, and treatment-by-time interaction. An unstructured correlation matrix was used to model the within-subject error correlation structure.

For secondary outcomes, we did a sensitivity analyses adjusted on several comparisons by the Hochberg method to mean change at 1 month, mean change at 12 months, and estimated slope at 12 months (27).

We calculated the proportion of patients with clinically relevant success at 12 months by using 3 improvement thresholds: more than 10 mm, 15 mm, and 20 mm

on a 0- to 100-mm VAS for pain (13). We compared qualitative secondary outcome measures by chi-square test. Data analysis involved use of SAS, version 9.1 (SAS Institute, Cary, North Carolina).

Role of the Funding Source

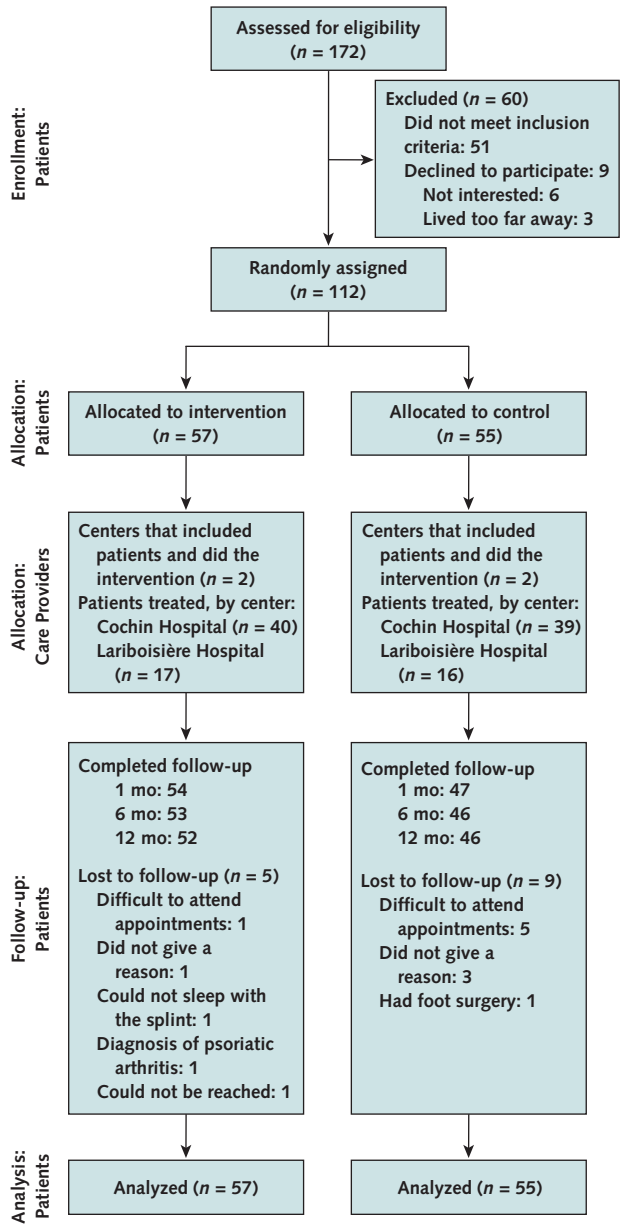
The Programme Hospitalier de Recherche Clinique National funded the study. The funding source was not involved in the design and conduct of the study and collection, management, and analysis of the data. It was not involved in the writing and final approval of the manuscript. Authors did not receive compensation or funding for conducting independent data analyses. The corresponding author had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

RESULTS

Participant Flow and Baseline Characteristics

Figure 3 shows the flow of participants through the trial. We screened 172 patients; 121 met inclusion criteria and 112 were randomly assigned from January 2004 to January 2006. Fourteen patients (13%) were lost to follow-up at 12 months. We assigned 5 patients to the intervention group and 9 to the control group. Eleven patients withdrew in the first month (for difficulties keeping appointments [$n = 6$]; no known reason [$n = 4$]; and sleep difficulties with the splint [$n = 1$]), and 3 patients withdrew between 1 and 12 months (psoriatic arthritis [1 in the intervention group at 1 to 6 months], could not be reached [1 in the intervention group at 6 to 12 months], and foot surgery [1 in the control group at 1 to 6 months]). Patients in the intervention and control groups did not differ in baseline characteristics (**Table 1**).

Figure 3. **Study flow diagram.**



Short-Term Clinical Outcomes

No between-group differences in primary or secondary outcomes were observed at 1 month (**Table 2**). Change in pain was similar between the groups (adjusted mean change, −10.1 vs. −10.7; between-group difference, 0.6 [95% CI, −7.9 to 9.1]; $P = 0.89$), as was change in disability by Cochin Hand Function Scale score (1.3 vs. −0.3; between-group difference, 1.6 [CI, −2.3 to 5.5]; $P = 0.42$) and patient-perceived disability (0.2 vs. −0.7; between-group difference, 0.9 [CI, −8.7 to 10.6]; $P = 0.85$). At 1 month, 29% of patients in the intervention group and 21% in the control group reported that they had improved ($P = 0.53$).

Long-Term Outcomes

Reduction in pain at 12 months was greater in the intervention group than in the control group (adjusted mean change, −22.2 vs. −7.9; between-group difference, −14.3 [CI, −23.4 to −5.2]; $P = 0.002$), as was reduction in disability by Cochin Hand Function Scale score (−1.9 vs. 4.3; between-group difference, −6.3 [CI, −10.9 to −1.7]; $P = 0.008$) and patient-perceived disability (−11.6 vs. 1.5; between-group difference, −13.1 [CI, −21.8 to −4.4]; $P = 0.003$) (**Table 2**). No between-group differences in other secondary clinical outcomes were observed. Sensitivity analyses that accounted for several comparisons confirmed the 12-month reductions in pain, Cochin Hand Function Scale score, and patient-perceived disability. All results were confirmed with comparisons of estimated slopes by random coefficient models. At 12 months, 54% of patients in the intervention group and 11% in the control group reported that they had improved ($P = 0.001$), and the differences

Table 1. **Baseline Patient Characteristics and Use of a Splint for Base-of-Thumb Osteoarthritis***

Characteristic	Intervention Group (*n* = 57)	Control Group (*n* = 55)
Mean age (SD), *y*	63.0 (7.9)	63.5 (7.6)
Women, *n (%)*	53 (93)	48 (85)
Intense manual work, *n (%)*	14 (25)	17 (31)
Regular manual work, *n (%)*	33 (61)	29 (54)
Dominant side affected, *n (%)*	34 (61)	27 (49)
Family history of base-of-thumb osteoarthritis, *n (%)*	33 (58)	29 (53)
Mean pain duration (SD), *wk*	66.7 (93.1)	80.4 (121.6)
Mean VAS score for pain (SD)†	45.5 (19.9)	47.6 (19.2)
Mean CHFS score (SD)†	19.7 (12.4)	17.7 (12.9)
Mean VAS score for perceived disability (SD)†	38.2 (25.2)	38.5 (21.5)
Mean closure of the first web (SD)†	65.7° (13.3°)	65.6° (12.0°)
Mean pinch strength (SD), *N*†	181.9 (71.1)	171.0 (83.3)
Mean VAS score for pain level during pinch strength (SD)	30.7 (26.0)	33.7 (27.4)
Mean Kapandji score for index thumb opposition (SD)	9.5 (1.0)	9.6 (0.7)
Mean Kapandji score for index thumb counter-opposition (SD)†	2.2 (0.7)	2.2 (0.8)
Current treatment, *n (%)*		
Acetaminophen	19 (33)	16 (29)
Acetaminophen plus opioids	5 (9)	7 (13)
NSAIDs	19 (33)	15 (27)
SYSADOA	23 (40)	21 (38)
No treatment	12 (21)	12 (22)
Mean Kallman score (scaphotrapezal)	1.7 (2.0)	1.5 (1.9)
Mean Kallman score (trapeziometacarpal)	5.0 (2.6)	4.6 (2.5)

CHFS = Cochin Hand Function Scale; NSAID = nonsteroidal anti-inflammatory drug; SYSADOA = symptomatic slow-acting drug for osteoarthritis; VAS = visual analogue scale.
* Score ranges: VAS, 0–100 mm; CHFS, 0–90; Kapandji for index thumb opposition and counteropposition, 0–10 and 0–4, respectively; and Kallman, 0–10.
† Results are estimated by using several imputation methods to handle missing data.

were statistically significant at varying clinically significant definitions of improvement (61% vs. 38% reported >10-mm improvement [$P = 0.014$]; 56% vs. 31% reported >15-mm improvement [$P = 0.007$]; and 54% vs. 25% reported >20-mm improvement [$P = 0.002$]).

No between-group differences were observed in radiologic evidence of BTOA progression (adjusted difference in Kallman scaphotrapezial subscale score [favoring intervention], −0.08 [CI, −0.53 to 0.35; $P = 0.68$]; and adjusted difference in trapeziometacarpal subscale score [favoring control], 0.07 [CI, −0.71 to 0.85; $P = 0.86$]).

Co-interventions

The proportion of patients using co-interventions was similar at baseline, but more patients in the control group used them during the trial (**Table 3**). No patient in the control group reported wearing a splint, and no patient in either group required hand surgery.

Treatment Adherence and Adverse Events

Treatment adherence in the intervention group was high: 93% reported wearing the splint 5 to 7 nights a week at 1 month, 81% at 6 months, 86% at 12 months, and 75% during the whole year of follow-up. No patient reported wearing the splint less than 1 night a week or during the day. At 12-month follow-up, 33 (63%) patients who wore splints needed a splint adjustment, and 30 patients had it adjusted. The proportion of patients very satisfied or satisfied with the splint was 68% at 1 month, 83% at 6 months, and 90% at 12 months. No adverse effect directly attributable to the splint was reported.

DISCUSSION

In this trial of splinting for BTOA, we found no effects on the trial's primary outcome of pain and disability at 1 month, but use of the splint significantly decreased pain and hand disability compared with usual care at 1 year. The splint had no effect on the radiographic progression of osteoarthritis or on other secondary outcomes, including web closure, a common effect of BTOA (**Figure 2**). We believe that these findings are clinically as well as statistically significant because BTOA is extremely common (28) and the splints were inexpensive and were well-tolerated by participants. We searched MEDLINE and EMBASE from 1966 to 2008 using the search terms *osteoarthritis*, *base of thumb*, *trapeziometacarpal joint*, *splint*, *orthosis*, and *randomized clinical trial* to identify previous trials of splinting for BTOA and found no such RCT. Therefore, we believe that this is the first RCT assessing the benefit of splinting. The findings justify the European League Against Rheumatism recommendations to consider use of splints for treating BTOA (5), but they also challenge the claim made in the recommendations that the reason to use the splints is to prevent or correct lateral angulation and flexion deformation (that is, first web closure), at least in the first year of use.

The trial has several methodological and clinical limitations. We did not blind patients, health care providers, or outcome assessors to the study intervention, and we did not blind patients to study hypotheses (29), because the success of such methods has not been demonstrated and they increase the complexity of the organization and cost of the trial. Consequently, we cannot exclude the possibility that usual care participants' awareness of their treatment assignment contributed to their worse outcomes. However, BTOA evolved similarly in the 2 trial groups during the first month; no patients in the control group crossed over to wearing a splint; and patients in each group had the same number of visits—so we believe these effects were probably marginal. Use of co-interventions was higher in

Table 2. **Estimates of Mean Change in Outcomes From Baseline to 1 or 12 Months and Estimates of Slope With Intervention and Control Treatment**

Outcome	Intervention Group	Patients Available, *n*	Control Group	Patients Available, *n*	Difference (95% CI)*	*P* Value
Pain level (VAS score [range, 0–100 mm])						
Mean at baseline (SD)	45.5 (19.9)	57	47.7 (19.8)	54	–	–
Mean change from baseline to 1 mo (±SE)†	−10.1 ± 3.0	55	−10.7 ± 3.3	46	0.6 (−7.9 to 9.1)	0.89
Mean change from baseline to 12 mo (±SE)†	−22.2 ± 3.2	52	−7.9 ± 3.5	45	−14.3 (−23.4 to −5.2)	0.002
Estimate of slope at 12 mo (±SE)‡	−19.3 ± 3.1	–	−4.3 ± 3.3	–	−15.0 (−24.0 to −5.9)	0.001
CHFS score (range, 0–90)						
Mean at baseline (SD)	19.4 (12.2)	56	17.7 (12.9)	55	–	–
Mean change from baseline to 1 mo (±SE)†	1.3 ± 1.4	54	−0.3 ± 1.5	47	1.6 (−2.3 to 5.5)	0.42
Mean change from baseline to 12 mo (±SE)†	−1.9 ± 1.6	49	4.3 ± 1.7	46	−6.3 (−10.9 to −1.7)	0.008
Estimate of slope at 12 mo (±SE)‡	−2.3 ± 1.5	–	3.8 ± 1.6	–	−6.1 (−10.4 to −1.8)	0.006
Patient-perceived disability (VAS score [range, 0–100 mm])						
Mean at baseline (SD)	38.2 (25.2)	57	38.6 (21.5)	55	–	–
Mean change from baseline to 1 mo (±SE)†	0.2 ± 3.4	56	−0.7 ± 3.8	47	0.9 (−8.7 to 10.6)	0.85
Mean change from baseline to 12 mo (±SE)†	−11.6 ± 3.1	51	1.5 ± 3.4	46	−13.1 (−21.8 to −4.4)	0.003
Estimate of slope at 12 mo (±SE)‡	−13.6 ± 2.7	–	1.5 ± 2.8	–	−15.1 (−22.8 to −7.4)	0.001
Closure of the first web						
Mean at baseline (SD)	66.3° (13.2°)	54	66.0° (12.0°)	48	–	–
Mean change from baseline to 12 mo (±SE)†	4.4° ± 1.6°	48	3.5° ± 1.7°	45	0.9° (−3.5° to 5.3°)	0.68
Pinch strength, *N*						
Mean at baseline (SD)	181.9 (71.1)	57	171.0 (83.3)	55	–	–
Mean change from baseline to 1 mo (±SE)†	5.1 ± 5.5	56	−0.2 ± 6.3	46	5.3 (−10.5 to 21.2)	0.50
Mean change from baseline to 12 mo (±SE)†	−5.4 ± 7.1	50	−14.4 ± 7.7	46	9.0 (−11.3 to 29.2)	0.38
Estimate of slope after 12 mo (±SE)‡	−3.0 ± 6.5	–	−11.0 ± 6.8	–	8.0 (−10.6 to 26.5)	0.40
Pain level during pinch strength (VAS score [range, 0–100 mm])						
Mean at baseline (SD)	30.7 (26.0)	57	33.7 (27.4)	55	–	–
Mean change from baseline to 1 mo (±SE)†	−7.9 ± 3.4	56	−7.0 ± 3.8	46	−0.9 (−10.6 to 8.8)	0.85
Mean change from baseline to 12 mo (±SE)†	−10.3 ± 3.9	50	−3.7 ± 4.2	46	−6.6 (−17.5 to 4.4)	0.24
Estimate of slope at 12 mo (±SE)‡	−7.9 ± 3.3	–	−0.3 ± 3.5	–	−7.6 (−17.2 to 2.0)	0.12
Kallman score (scaphotrapezal [range, 0–10])						
Mean at baseline (SD)	1.7 (2.0)	54	1.5 (1.9)	49	–	–
Mean change from baseline to 12 mo (±SE)†	0.22 ± 0.16	48	0.30 ± 0.17	46	−0.08 (−0.53 to 0.35)	0.70
Kallman score (trapeziometacarpal [range, 0–10])						
Mean at baseline (SD)	5.1 (2.6)	54	4.4 (2.4)	49	–	–
Mean change from baseline to 12 mo (±SE)†	0.40 ± 0.29	48	0.33 ± 0.30	46	0.07 (−0.71 to 0.85)	0.86
Kapandji index thumb opposition score (range, 0–10)						
Mean at baseline (SD)	9.5 (1.0)	57	9.6 (0.7)	55	–	–
Mean change from baseline to 1 mo (±SE)†	−0.09 ± 0.09	56	−0.05 ± 0.10	47	−0.04 (−0.30 to 0.22)	0.74
Mean change from baseline to 12 mo (±SE)†	0.14 ± 0.09	51	−0.16 ± 0.09	46	0.30 (0.06 to 0.55)	0.016
Estimate of slope at 12 mo (±SE)‡	0.19 ± 0.09	–	−0.13 ± 0.09	–	0.32 (0.06 to 0.57)	0.015
Kapandji index thumb counter-opposition score (range, 0–4)						
Mean at baseline (SD)	2.2 (0.7)	57	2.2 (0.8)	55	–	–
Mean change from baseline to 1 mo (±SE)†	−0.07 ± 0.06	56	0.09 ± 0.07	47	−0.15 (−0.34 to 0.03)	0.10
Mean change from baseline to 12 mo (±SE)†	0.10 ± 0.07	51	−0.06 ± 0.08	46	0.16 (−0.05 to 0.37)	0.13
Estimate of slope at 12 mo (±SE)‡	0.15 ± 0.07	–	−0.09 ± 0.08	–	0.24 (0.04 to 0.45)	0.022

CHFS = Cochin Hand Function Scale; VAS = visual analogue scale.
* Intervention minus control.
† Results from mixed-effects repeated measurements model.
‡ Results from random-effects regression model.

Table 3. **Co-interventions Administered***

Drug Treatment, *n* (%)	1 Month		6 Months		12 Months	
	Intervention Group (*n* = 54)	Control Group (*n* = 47)	Intervention Group (*n* = 53)	Control Group (*n* = 46)	Intervention Group (*n* = 52)	Control Group (*n* = 46)
Acetaminophen	13 (24)	16 (34)	10 (19)	15 (33)	10 (19)	16 (35)
Acetaminophen plus opioids	4 (7)	4 (8)	5 (9)	2 (4)	5 (10)	1 (2)
NSAIDs	13 (24)	12 (25)	13 (24)	16 (35)	12 (23)	13 (28)
SYSADOA	23 (43)	21 (45)	17 (32)	20 (43)	18 (35)	17 (37)
Corticoid injection	0	3 (6)	0	1 (2)	0	1 (2)
None	9 (17)	2 (4)	13 (24)	1 (2)	18 (35)	9 (20)

NSAID = nonsteroidal anti-inflammatory drug; SYSADOA = symptomatic slow-acting drug for osteoarthritis.
* Row numbers may exceed the total because patients may have had >1 co-intervention.

the control group, however, which could have reduced the apparent treatment effect attributable to the splint alone.

We did not adjust for clustering of trial patients by provider, which could inflate the standard error and reduce the effective sample size (10). Also, the trial was conducted in 2 tertiary care teaching hospitals, and splints were custom-made by trained occupational therapists. Therefore, our findings may not be generalizable to other settings. However, we hope this study provides the basis for further investigations of efficacy of splints, both custom-made and prefabricated, for patients with BTOA in other settings.

Splints were worn only at night, and we cannot exclude that the effect of splinting took longer than 1 month to detect because of this nighttime-only use. However, common adverse effects of continual splinting, or continual passive muscle support more generally, are muscle disuse, atrophy, and weakness. We considered the possibility that the high long-term adherence we documented might reflect increased reliance on the splint by some participants because of muscle weakness and decreased hand function, but the results do not support this hypothesis because pinch strength decreased more in the control group than in the intervention group, although the 2 decreases did not seem to differ statistically.

Adherence was self-reported, and we cannot exclude the possibility that patients overstated their adherence. Osteoarthritis pain is often very cyclical in nature, and we did not consider that cyclical nature in our study design; but we assumed successful randomization so that osteoarthritis flares at baseline were equally distributed between groups.

Finally, we did not assess symptomatic osteoarthritis in the same hand or ipsilateral wrist. Splinting could alter movements throughout the hand and wrist so that subjective changes in pain and function could be attributable to changes in osteoarthritis symptoms in joints other than those at the base of the thumb. However, the splint covered only the base of the thumb and the thenar eminence (not the wrist), and it was a rest orthosis instead of a functional orthosis designed only for nighttime wear. Therefore, we believe the splint was unlikely to have had any substantial effect on pain and function of other joints in the ipsilateral hand.

In summary, these trial findings suggest that, for patients with BTOA, use of splints has no effect on pain at 1 month but leads to a clinically significant reduction in pain and disability at 12 months. The intervention was well tolerated. Additional studies of splints in other settings, especially primary care settings, are now needed to confirm the value of splinting for treatment of osteoarthritis at the base of the thumb.

From Assistance Publique–Hôpitaux de Paris, Hôpital Cochin, Hôpital Bichat, and Hôpital Lariboisière; Université Paris Descartes; Université Paris 7 Denis Diderot; Institut National de la Santé et de la Recherche Médicale; and Institut Fédératif de Recherche sur le Handicap, Paris, France, and Unité de Recherche Clinique, Centre Hospitalier Régional, La Roche-sur-Yon, France.

Acknowledgment: Laura Heraty participated as a medical editor in the elaboration of the final version of the manuscript.

Grant Support: By the Programme Hospitalier de Recherche Clinique National (PHRC AOM grant 02038).

Potential Financial Conflicts of Interest: None disclosed.

Reproducible Research Statement: *Study protocol, statistical code, and data set*: Available (in French) from Dr. Poiraudeau (e-mail, serge.poiraudeau@cch.aphp.fr).

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References

1. **Poole JU, Pellegrini VD Jr.** Arthritis of the thumb basal joint complex. J Hand Ther. 2000;13:91-107. [PMID: 10855745]

2. **Spacek E, Poiraudeau S, Fayad F, Lefèvre-Colau MM, Beaudreuil J, Rannou F, et al.** Disability induced by hand osteoarthritis: are patients with more symptoms at digits 2-5 interphalangeal joints different from those with more symp-

toms at the base of the thumb? Osteoarthritis Cartilage. 2004;12:366-73. [PMID: 15094135]
3. **Duruöz MT, Poiraudeau S, Fermanian J, Menkes CJ, Amor B, Dougados M, et al.** Development and validation of a rheumatoid hand functional disability scale that assesses functional handicap. J Rheumatol. 1996;23:1167-72. [PMID: 8823687]
4. **Poiraudeau S, Lefevre-Colau MM, Fermanian J, Revel M.** The ability of the Cochin rheumatoid arthritis hand functional scale to detect change during the course of disease. Arthritis Care Res. 2000;13:296-303. [PMID: 14635299]
5. **Zhang W, Doherty M, Leeb BF, Alekseeva L, Arden NK, Bijlsma JW, et al.** EULAR evidence based recommendations for the management of hand osteoarthritis: report of a Task Force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT). Ann Rheum Dis. 2007;66:377-88. [PMID: 17046965]
6. **Weiss S, LaStayo P, Mills A, Bramlet D.** Prospective analysis of splinting the first carpometacarpal joint: an objective, subjective, and radiographic assessment. J Hand Ther. 2000;13:218-26. [PMID: 10966142]
7. **Weiss S, Lastayo P, Mills A, Bramlet D.** Splinting the degenerative basal joint: custom-made or prefabricated neoprene? J Hand Ther. 2004;17:401-6. [PMID: 15538680]
8. **Wajon A, Ada L.** No difference between two splint and exercise regimens for people with osteoarthritis of the thumb: a randomised controlled trial. Aust J Physiother. 2005;51:245-9. [PMID: 16321131]
9. **Boutron I, Moher D, Tugwell P, Giraudeau B, Poiraudeau S, Nizard R, et al.** A checklist to evaluate a report of a nonpharmacological trial (CLEAR NPT) was developed using consensus. J Clin Epidemiol. 2005;58:1233-40. [PMID: 16291467]
10. **Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P; CONSORT Group.** Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. Ann Intern Med. 2008;148:295-309. [PMID: 18283207]
11. **Boutron I, Estellat C, Ravaud P.** A review of blinding in randomized controlled trials found results inconsistent and questionable. J Clin Epidemiol. 2005;58:1220-6. [PMID: 16291465]
12. **Paterson C, Dieppe P.** Characteristic and incidental (placebo) effects in complex interventions such as acupuncture. BMJ. 2005;330:1202-5. [PMID: 15905259]
13. **Tubach F, Ravaud P, Beaton D, Boers M, Bombardier C, Felson DT, et al.** Minimal clinically important improvement and patient acceptable symptom state for subjective outcome measures in rheumatic disorders. J Rheumatol. 2007;34:1188-93. [PMID: 17477485]
14. **Poiraudeau S, Chevalier X, Conrozier T, Flippo RM, Lioté F, Noël E, et al.** Reliability, validity, and sensitivity to change of the Cochin hand functional disability scale in hand osteoarthritis. Osteoarthritis Cartilage. 2001;9:570-7. [PMID: 11520171]
15. **Hochberg MC, Vignon E, Maheu E.** Session 2: clinical aspects. Clinical assessment of hand OA. Osteoarthritis Cartilage. 2000;8 Suppl A:S38-40. [PMID: 11156493]
16. **Chevalier X, Mejjad O, Babini S.** Methodology for the assessment of treatments in hand osteoarthritis. Osteoarthritis Cartilage. 2000;8 Suppl A:S70-2. [PMID: 11156499]
17. **Kapandji A.** [Clinical test of apposition and counter-apposition of the thumb]. Ann Chir Main. 1986;5:67-73. [PMID: 3963909]
18. **Kapandji A.** [Proposal for a clinical score for flexion-extension of the long fingers]. Ann Chir Main. 1987;6:288-94. [PMID: 3448998]
19. **Lefevre-Colau MM, Poiraudeau S, Oberlin C, Demaille S, Fermanian J, Rannou F, et al.** Reliability, validity, and responsiveness of the modified Kapandji index for assessment of functional mobility of the rheumatoid hand. Arch Phys Med Rehabil. 2003;84:1032-8. [PMID: 12881830]
20. **Kallman DA, Wigley FM, Scott WW Jr, Hochberg MC, Tobin JD.** New radiographic grading scales for osteoarthritis of the hand. Reliability for determining prevalence and progression. Arthritis Rheum. 1989;32:1584-91. [PMID: 2490851]
21. **Maheu E, Cadet C, Gueneugues S, Ravaud P, Dougados M.** Reproducibility and sensitivity to change of four scoring methods for the radiological assessment of osteoarthritis of the hand. Ann Rheum Dis. 2007;66:464-9. [PMID: 17107982]
22. **Hansson L, Hedner T, Dahlöf B.** Prospective randomized open blinded end-point (PROBE) study. A novel design for intervention trials. Prospective Randomized Open Blinded End-Point. Blood Press. 1992;1:113-9. [PMID: 1366259]
23. **Diggle PJ, Liang KY, Zeger SL.** Analysis of Longitudinal Data. Oxford: Clarendon Pr; 1994.
24. **Laird NM, Ware JH.** Random-effects models for longitudinal data. Biometrics. 1982;38:963-74. [PMID: 7168798]
25. **Molenberghs G, Thijs H, Jansen I, Beunckens C, Kenward MG, Mallinckrodt C, et al.** Analyzing incomplete longitudinal clinical trial data. Biostatistics. 2004;5:445-64. [PMID: 15208205]
26. **Mallinckrodt CH, Clark SW, Carroll RJ, Molenbergh G.** Assessing response profiles from incomplete longitudinal clinical trial data under regulatory considerations. J Biopharm Stat. 2003;13:179-90. [PMID: 12729388]
27. **Hochberg Y.** A sharper Bonferroni procedure for multiple tests of significance. Biometrika. 1988;75:800-802.
28. **Wilder FV, Barrett JP, Farina EJ.** Joint-specific prevalence of osteoarthritis of the hand. Osteoarthritis Cartilage. 2006;14:953-7. [PMID: 16759885]
29. **Boutron I, Guittet L, Estellat C, Moher D, Hróbjartsson A, Ravaud P.** Reporting methods of blinding in randomized trials assessing nonpharmacological treatments. PLoS Med. 2007;4:e61. [PMID: 17311468]

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