ABSTRACT: We developed a hand brace and studied its efficacy and tolerability in patients with carpal tunnel syndrome (CTS). We randomized 83 subjects into a treated group, which wore the hand brace at night for 4 weeks, and a control group, which received no treatment. The primary efficacy measure was change in the Boston Carpal Tunnel Questionnaire (BCTQ) score. Secondary measures were Subjects' Global Impression of Change Questionnaire (SGICQ), median distal motor latency, sensory conduction velocity and amplitude, and neurophysiological class of severity. The treated group showed a reduction in BCTQ symptomatic score (from 2.75 to 1.54 at 4 weeks; $P < 0.001$) and functional score (from 1.89 to 1.48; $P < 0.001$). There were no significant changes in the control subjects. SGICQ documented improvement in all treated subjects ($P = 0.006$). No significant difference was found in electrophysiological measurements, but overall neurophysiological classification shifted to less severe classes in the treated group ($P < 0.05$). Thus, the study demonstrates that this hand brace is highly efficient in relieving symptoms and functional loss in CTS.
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AN INNOVATIVE HAND BRACE FOR CARPAL TUNNEL SYNDROME: A RANDOMIZED CONTROLLED TRIAL

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Carpal tunnel syndrome (CTS) is the most frequent entrapment neuropathy, with an incidence from 88 to 125 cases/100,000,[22] a prevalence of 9.2% in women and 0.6% in men in The Netherlands,[9] an overall prevalence of 3.8% in Sweden, and a 10% lifetime risk.[1,3] About half of the cases are related to repetitive and cumulative trauma in the workplace, making CTS the occupational epidemic syndrome of our time.[5] Considering lost work time, medical fees, and legal expenses for workers' compensation, the cost for individual cases was estimated to have reached $100,000 in the USA at the end of the 1980s, and the associated direct medical costs have been estimated to be more than $1 billion per year in that country.[15,21]

Conservative treatment is attempted first unless there is a progressive motor and sensory deficit or severe electrophysiological abnormalities.[1] Conservative treatments include modification of daily activities, immobilization by wrist splint, nonsteroidal antiinflammatory drugs, diuretics, and intracarpal and oral steroids.[1,6] Splinting is used and has been recommended by several investigators but there have been no randomized controlled studies of its efficacy.[4,11,14,20] The rationale for splinting comes from the observation that CTS symptoms become manifest or worsen after a period of hand overuse and can be relieved by prolonged inactivity,[20] is based on the finding in CTS of elevated resting intracarpal tunnel pressure that further increases with wrist flexion and extension, and the pathophysiological hypotheses that symptoms are pressure-related.[12,23] Therefore, immobilizing the wrist in a neutral position maximizes available carpal tunnel space, minimizes nerve compression, and provides symptomatic relief.[4]

Abbreviations: BCTQ, Boston Carpal Tunnel Questionnaire; BCTQ FUNCT, Boston Carpal Tunnel Questionnaire for functions; BCTQ SYMPT, Boston Carpal Tunnel Questionnaire for symptoms; CTS, carpal tunnel syndrome; DML, distal motor latency; SGICQ, Subjects' Global Impression of Change Questionnaire; SCV, sensory conduction velocity; SNAP, sensory nerve action potential

Key words: Boston Carpal Tunnel Questionnaire; carpal tunnel syndrome; hand brace; neurophysiological classification

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Recently, we noticed that gently squeezing the distal heads of the metacarpal bones (excluding the first) and stretching the third and fourth fingers relieved, in few seconds, the paresthesias and pain of CTS.[16] This maneuver provided the rationale to design and develop an innovative hand brace for conservative treatment of CTS. In this study we report the results of a randomized, controlled trial examining its efficacy and tolerability.

MATERIALS AND METHODS

Hand Brace. The hand brace, which we have called Manu (patent pending; Fig. 1), is made of soft tissue without rigid components and consists of: (1) a palmar strap with a Velcro adjustable fastening to tighten the distal heads of the second and fifth metacarpal bones; (2) a triangular prism-shaped pad positioned dorsal to digits II and V, producing mild stretching of digits III and IV; (3) a dorsal strap connected to a wrist band with a Velcro adjustable fastening to avoid displacement of the brace; and (4) a component that connects and stabilizes the other components. The hand brace does not impede thumb–index finger pinch, thumb–little finger opposition, and wrist flexion and extension. However, hand function is somewhat reduced and we recommend the use of the brace only during rest at night. In this setting, the user is able to carry out most common actions such as turning the light switch on and off, taking a tablet from its container, holding a glass, or using a portable telephone.

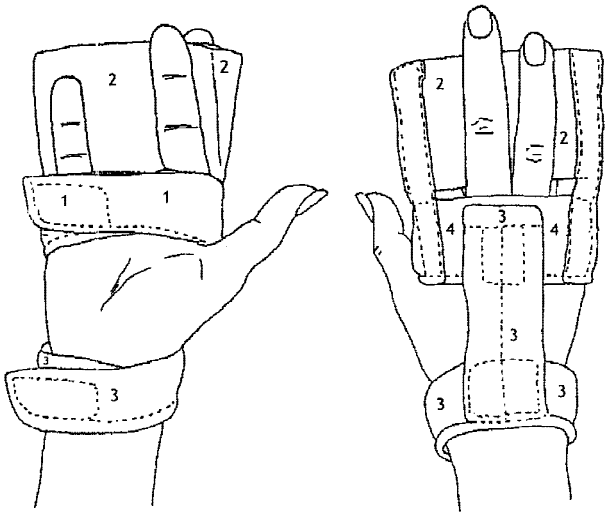

FIGURE 1. The hand brace: palmar and dorsal view. 1: palmar strap; 2: triangular prism-shaped pad; 3: dorsal strap connected to a wrist band; 4: component that connects and stabilizes the brace.

Study Design and Subject. We considered all subjects referred for possible CTS to the EMG laboratory in the period January–June 1999. Entry criteria included CTS symptoms (pain, numbness, and paresthesias in the median nerve distribution) and signs (hypesthesia in a median nerve distribution, thenar atrophy, positive Phalen test) exclusively or predominantly in one hand and at least one abnormal median nerve electrophysiological study. Exclusion criteria were previous CTS surgery, rheumatoid arthritis, CTS related to systemic diseases, pregnancy, or clinical and electrophysiological signs of polyneuropathy.

Electrodiagnostic studies were performed according to published recommendations by determination of median sensory conduction velocity (SCV) from wrist to digit II (normal $\geq$ 47 m/s) and median distal motor latency (DML) (normal $\leq$ 4.2 ms).[2] When these studies were normal, a median-to-ulnar comparison on stimulating the ring finger (normal median-to-ulnar latency difference $\leq$ 0.5 ms) or a segmental (wrist-to-palm) sensory conduction (normal $\geq$ 45 m/s) were performed.[10,24] On the basis of the electrophysiological results, hands were classified according to the following neurophysiological classification: *extreme CTS,* absence of median motor and sensory response; *severe CTS,* absence of median sensory response and prolonged DML; *moderate CTS,* slowed digit II–wrist SCV and abnormal DML; *mild CTS,* slowed median digit II–wrist SCV and normal DML; *minimal CTS,* normal digit II–wrist SCV and DML, but abnormal segmental or comparison tests; and *negative,* normality of all tests.[18]

Subjects meeting the study criteria were informed about the aims of the study and, if willing to participate, signed an informed consent. All subjects were required to agree not to receive other treatments, or change work duties or medications during the study, or otherwise report it. Subjects were randomized into two groups by having them select sealed envelopes containing a group assignment. Subjects in the treated group were instructed to wear the hand brace in the symptomatic or more symptomatic hand every night for 4 weeks. Subjects in the control group were asked to wait for an observational period of 4 weeks before beginning any treatment. The protocol and informed consent were approved by the institutional ethics committee.

Measurements. The primary efficacy parameter was a patient-oriented validated measurement, the Italian version of the Boston Carpal Tunnel Questionnaire (BCTQ).[15,19] The BCTQ evaluates two domains of CTS: symptoms (BCTQ SYMPT), assessed

with an 11-item scale; and functional status (BCTQ FUNCT), assessed with an 8-item scale (each item has five possible responses). The symptomatic and functional score is calculated as the mean of the responses of the individual items. The change from baseline value was evaluated at 2 and 4 weeks. A secondary parameter was the Subjects' Global Impression of Change Questionnaire (SGICQ), which is rated in four categories (moderate or much improvement, minimal improvement, no change, worsening) and was administered at 4 weeks. Other secondary parameters were: (1) changes of median nerve distal motor latency, median sensory conduction velocity, and sensory nerve action potential amplitude from wrist to digit II from baseline to week 4; and (2) changes of electrophysiological class of severity from baseline to week 4.

Compliance and Tolerability. Compliance and tolerability was assessed by a questionnaire asking how many nights in 4 weeks the subject wore the hand brace: all 28 nights; most (at least 21) nights; half (about 14) of the nights; and some (less than 7) nights, and whether there were adverse effects.

Statistical Analysis. Data on demographic and clinical characteristics in the two groups were compared by an independent-sample *t*-test for continuous variables and the chi-square or Fisher's exact test (when any expected cell count in a 2 × 2 table was <5) for a dichotomous variable. Comparisons between the groups regarding the BCTQ and neurophysiological endpoints for all the changes from baseline were accomplished by an analysis of covariance (ANCOVA) model including gender, age, and baseline scoring as covariate. Comparisons for the neurophysiological classification score and the SGICQ between the treated and the control group were accomplished by using ordered logistic regression including in the model gender, age, and baseline score. A calculation on the power of the study was performed using the mean values and SDs of the primary outcome measures (BCTQ SYMPT and BCTQ FUNCT). In all statistical analyses, significance was assessed using two-tailed tests with an $\alpha = 0.05$.

Statistical calculations were carried out using the statistical software Stata (release 5, Stata Co., Santa Monica, CA).

RESULTS

From a total of 151 subjects screened for CTS, 83 patients with exclusively or predominantly unilateral CTS symptoms and/or signs and abnormal median nerve electrophysiological studies were recruited and randomized. Three patients did not complete the study. One patient in the treated group was lost to follow-up and two patients in the control group underwent surgery. Final data were analyzed for 80 subjects, including 40 treated with the hand brace and 40 in the control group. Demographic and baseline clinical characteristics at randomization are reported in Table 1. There were no statistically significant differences between the treated and control group in gender, age, SYMPT and FUNCT score of the BCTQ, electrophysiological parameters (Table 1), and neurophysiological classes of severity (Fisher's exact test, $P = 0.325$).

Primary Outcome. The average SYMPT and FUNCT scores of the BCTQ were significantly reduced in the treated group compared with the control group at 2 weeks and further improved at 4 weeks (Table 2). The result of the power calculation using SYMPT and FUNCT BCTQ means and SDs showed that a sample size of 40 patients in each group conferred on the study a power of detecting a significant difference using a two-tailed test with a significance level = 0.05 of 100% for SYMPT BCTQ and 98% for FUNCT BCTQ (with an α level of 0.05 and β level of 0.1).

Secondary Efficacy Parameters. The Subjects' Global Impression Change Questionnaire at 4 weeks indicated that the hand brace produced relief of CTS symptoms in all 40 patients, as 32 were moderately or much improved and 8 minimally improved. Most patients reported improvement after the very first night of treatment. The majority of controls reported no change (23 of 40) or worsening (7 of 40), but 10 patients reported some improvement. The difference between the two groups was highly significant ($P = 0.006$). Regarding the neurophysiological endpoints, median motor distal latency and median

Table 1. Demographic and clinical characteristics at baseline.

Characteristics	Treated	Controls
Gender (F/M)	36/4	33/7
Age*	46.10 ± 12.94	50.0 ± 12.65
BCTQ SYMP*	2.75 ± 0.65	2.77 ± 0.68
BCTQ FUNCT*	1.89 ± 0.70	2.02 ± 0.72
Distal motor latency (ms)*	4.63 ± 1.43	4.51 ± 0.95
Sensory conduction velocity (m/s)*	33.3 ± 14.2	35.8 ± 11.5
Sensory nerve action potential (μV)*	14.2 ± 9.90	12.1 ± 9.19

**Values are mean ± SD.*

Table 2. Summary of clinical endpoints at 2 and 4 weeks.

	Baseline mean (SD)	2 weeks mean (SD)	*P**	4 weeks mean (SD)	*P**
BCTQ SYMPT					
Treated	2.75 (0.7)	1.59 (0.4)	<0.001	1.54 (0.4)	<0.001
Controls	2.77 (0.7)	2.62 (0.8)		2.61 (0.6)	
BCTQ FUNCT					
Treated	1.89 (0.7)	1.50 (0.5)	<0.001	1.48 (0.5)	<0.001
Controls	2.02 (0.7)	2.02 (0.7)		2.03 (0.7)	

**Analysis of variance to compare the treated group and the control at 2 and 4 weeks using the baseline score as a covariate and adjusted for gender and age.*

sensory conduction velocity were not significantly different in the two groups at 4 weeks compared with baseline (Table 3). Median sensory nerve action potential amplitude, although not reaching significance, showed a trend to increase among treated subjects (Table 3). In particular, in 3 patients with severe CTS, the sensory nerve action potential was absent at baseline but recordable after 4 weeks of treatment. Comparison of the changes in the distribution of neurophysiological classes of severity from baseline to 4 weeks showed that the hand brace produced a significant shift to the less severe classes in the treated group (Table 4). In particular, a three-class reduction was observed in 1 treated patient and 0 control, a two-class reduction in 1 treated patient and in 1 control, and a one-class reduction in 9 treated and in 3 controls. No change was observed in 29 treated patients and in 35 controls. An increment of one class was observed in 1 control.

Compliance and Tolerability. Of the 40 subjects in the treated group, 38 wore the hand brace for all or most of the nights. The brace was well tolerated, and only 3 subjects reported some difficulty in falling asleep and 4 subjects transient paresthesias after the hand brace was removed.

DISCUSSION

This study demonstrates that the innovative hand brace we developed is not only fast and highly effective in reducing CTS symptoms but can also improve functional score as assessed by the BCTQ (Table 2), a validated patient-oriented measure. The SGICQ confirmed the results of the primary outcome measurement. The BCTQ and SGICQ showed a correlation trend in the treated patients. Interestingly, 25% of controls reported some improvement of symptoms at 4 weeks by SGICQ. This improvement, although not sufficient to reach statistical significance in a more detailed and quantified measurement such as the mean BCTQ SYMPT, suggests that the natural history of CTS is not necessarily one of deterioration. Median distal motor latency and median sensory conduction velocity did not change in either the treated or control group (Table 3). In 3 subjects from the treated group, the median sensory nerve action potential was absent at baseline but recordable at 4 weeks, and in the treated group the mean amplitude of the median sensory nerve potential amplitude showed a trend toward improvement without reaching statistical significance (Table 3). These findings suggest that nerve conduction was blocked in some sensory fibers (neurapraxia) at study entry

Table 3. Summary of neurophysiological endpoints.

	Baseline mean (SD)	4 weeks mean (SD)	Baseline variation mean (SD)	*P**
Distal motor latency (ms)				
Treated	4.63 (1.4)	4.45 (1.3)	–0.18 (0.4)	0.238
Controls	4.51 (1.0)	4.47 (0.8)	–0.04 (0.4)	
Sensory conduction velocity (m/s)				
Treated	33.34 (14.2)	37.20 (11.7)	3.86 (8.6)	0.550
Controls	35.83 (11.5)	37.92 (11.7)	2.09 (5.0)	
Sensory nerve action potential (μV)				
Treated	14.19 (9.9)	18.74 (15.8)	4.55 (11.7)	0.051
Controls	12.15 (9.2)	12.44 (9.4)	0.29 (5.1)	

**Analysis of variance using the baseline value as a covariate and adjusted for gender and age.*

Table 4. Neurophysiological classification endpoint.

Neurophysiological classification	Baseline		4 weeks		
	Treated N (%)	Controls N (%)	Treated N (%)	Controls N (%)	*P**
Negative	0 (0.0)	0 (0.0)	3 (7.5)	3 (7.5)	
Minimal	1 (2.5)	2 (5.0)	1 (2.5)	0 (0.0)	
Mild	10 (25)	14 (35)	12 (30)	13 (32.5)	0.043
Moderate	24 (60)	20 (50)	22 (55)	20 (50)	
Severe	5 (12.5)	2 (5.0)	2 (5.0)	2 (5.0)	
Extreme	0 (0.0)	2 (5.0)	0 (0.0)	2 (5.0)	

**Ordered logistic regression to compare the neurophysiological class between the treated group and the comparison group after 4 weeks of treatment, adjusted for baseline neurophysiological class, gender, and age.*

but recovered after 4 weeks of treatment. Overall, the electrophysiological modifications, individually considered, allowed a significant shift of the treated subjects to less severe classes in the neurophysiological classification (Table 4). The brace was very well tolerated and patients were highly compliant.

A possible concern is whether the lack of a placebo intervention in the nonsplinted group could have influenced the results. Two recent placebo-controlled studies showed no significant reduction in subjective and electrophysiological measures in placebo groups.[6,17] Moreover, in a study on 105 adults with CTS, the investigators found rates of symptom relief in the splinted group substantially lower than those observed in our study.[14] These studies thus provide circumstantial evidence supporting our belief that the effect observed with the use of the hand brace in our study is not attributable to a placebo effect.

It is generally agreed that CTS symptoms and signs are due to chronic compression and ischemia of the median nerve as it passes through the carpal tunnel.[23] Wrist splinting has been reported to improve CTS in 38–76% of patients, but such splinting was often associated with other treatments, and the studies were not controlled and were mostly retrospective.[4,11,13,14] We developed the Manu hand brace on the basis of a relief maneuver that rapidly relieves positive symptoms in CTS.[16] It is conceptually very different from the currently available types of splint that work by immobilizing the wrist. We believe that the relief maneuver and the hand brace may reduce nerve compression and ischemia of the median nerve by: (1) modifying the shape, dimensions of the carpal tunnel, and the spatial relationship between the median nerve and the surrounding structures; and (2) holding digits III and IV in extension, pulling the lumbrical muscle bellies away from carpal tunnel, and reducing the bulk of structures in the carpal tunnel and the intracarpal pressure.[7,8,25]

In conclusion, this short-term, randomized, controlled study demonstrates the high efficacy of our hand brace in CTS. Magnetic resonance imaging and intracarpal pressure studies are in progress to elucidate how the brace improves CTS symptoms and functional loss. Further studies are necessary to evaluate its long-term effects and for comparing its efficacy with the traditional wrist splint and other conservative treatments.

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