

Neutral wrist splint for mild to moderate carpal tunnel syndrome

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- Background** : *Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy. Neutral wrist splint has been recommended for mild to moderate symptoms CTS. There is insufficient evidence regarding the effectiveness of splinting in longer periods of time (at least 3 months).*
- Objective** : *To evaluate the effects of 3 months neutral wrist splint on neurophysiologic condition, symptoms and functions for mild to moderate carpal tunnel syndrome (CTS).*
- Methods** : *Fifty-four patients with clinical symptoms, nerve conduction study (NCS), and diagnosed as mild to moderate CTS. During the 3-month duration of the study, the treatment group received day and night time, neutral wrist splints combined with condition-related patient instructions and the control group received only condition-related patient instructions. Neurophysiologic condition was evaluated by nerve conduction study including distal sensory latency (DSL) and distal motor latency (DML). Symptoms and functional status were assessed by Boston Carpal Tunnel Questionnaire (SYMPT BCTQ and FUNCT BCTQ).*

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Results : *The treatment group demonstrated improvement in all measured outcomes (DSL, DML, SYMPT BCTQ, and FUNCT BCTQ). The treatment group also showed significantly more improvement than the control group in decreasing DSL and DML values. In linear regression analysis, the decrease in DSL was significantly associated with splint treatment (RR = 4.79, 95% CI = 1.35 - 17.11; P = 0.02).*

Conclusions : *Three-month daytime and nighttime neutral wrist splinting was more effective than patient instructions alone in improving neurophysiologic condition in mild to moderate CTS. This splinting modality shows good patient compliance and no serious side effects.*

Keywords : *Carpal tunnel syndrome, splint, Boston carpal tunnel questionnaire.*

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เหตุผลการทำวิจัย : ภาวะเส้นประสาทมีเดียนถูกกดรัดที่อุโมงค์หรือ CTS พบบ่อยสุดในกลุ่มเส้นประสาทถูกกดรัด มีคำแนะนำให้ใช้ที่ประคองข้อมือในท่าเหยียดตรงในผู้ป่วยที่มีอาการระดับน้อยถึงปานกลาง ในขณะนี้อยังขาดข้อมูลผลจากการใช้ที่ประคองข้อมือในระยะยาว ที่นานอย่างน้อย 3 เดือน

วัตถุประสงค์ : เพื่อประเมินผลของที่ประคองข้อมือที่จัดข้อมืออยู่ในท่าตรง ในการรักษาภาวะเส้นประสาทมีเดียนถูกกดรัดบริเวณอุโมงค์ข้อมือที่มีความรุนแรงระดับน้อยถึงปานกลาง ในด้านประสาทสรีระ อาการทางคลินิก และการใช้งานมือ

วิธีการศึกษา : ผู้ที่มีอาการทางคลินิกและผลตรวจการเหนี่ยวนำกระแสประสาทด้วยไฟฟ้าวินิจฉัยเข้าได้กับภาวะเส้นประสาทมีเดียนถูกกดรัดบริเวณอุโมงค์ข้อมือระดับน้อยถึงปานกลาง, กลุ่มทดลองและกลุ่มควบคุมได้รับการรักษาเป็นเวลา 3 เดือน โดยกลุ่มทดลองได้รับที่ประคองข้อมือที่จัดข้อมืออยู่ในท่าตรงซึ่งแนะนำให้ใส่ทั้งกลางวันและกลางคืน ร่วมกับการให้ความรู้ในการใช้ข้อมือที่ถูกต้อง ขณะที่กลุ่มควบคุมจะได้รับเฉพาะความรู้เพียงอย่างเดียว, การวัดด้านประสาทสรีระใช้ไฟฟ้าวินิจฉัยเพื่อวัดค่าการเหนี่ยวนำกระแสประสาท คือ ค่า distal sensory latency (DSL) และ distal motor latency (DML) และใช้คะแนนแบบสอบถาม Boston carpal tunnel questionnaire ในการประเมินอาการทางคลินิกและการใช้งานมือ

ผลการศึกษา : กลุ่มทดลองให้ผลหลังรักษาดีขึ้นทุกตัวชี้วัด คือ ทั้งค่าการเหนี่ยวนำกระแสประสาทและค่าคะแนนแบบสอบถาม และเมื่อเปรียบเทียบกับกลุ่มควบคุมพบว่าค่าความเร็วของการเหนี่ยวนำกระแสประสาทของกลุ่มทดลองดีขึ้นมากกว่ากลุ่มควบคุมอย่างมีนัยสำคัญ และการวิเคราะห์ความถดถอยเชิงเส้นตรงพบว่าการใช้ที่ประคองข้อมือให้ค่าการตรวจ DSL ดีขึ้นกว่าอย่างมีนัยสำคัญ ($RR = 4.79, P = .02$)

สรุป : การใช้ที่ประคองข้อมือทั้งวันโดยจัดข้อมืออยู่ในท่าตรง ให้ผลการรักษาที่ดีกว่าอย่างมีนัยสำคัญในการคืนกลับของการทำงานด้านประสาทสรีระของเส้นประสาทมีเดียน ในผู้ที่ มีภาวะเส้นประสาทมีเดียนถูกกดรัดบริเวณอุโมงค์ข้อมือที่มีความรุนแรงระดับน้อยถึงปานกลาง การยอมรับของผู้ป่วยต่อการใช้ได้รับการตอบรับที่ดี ไม่พบปัญหาารายแรงใด ๆ จากการใช้ที่ประคองข้อมือ

คำสำคัญ : เส้นประสาทมีเดียนถูกกดรัดอุโมงค์ข้อมือ, ประคองข้อมือ, แบบสอบถามบอสตัน.

Carpal tunnel syndrome (CTS) is one of the most common entrapment neuropathies. Patients with CTS may experience symptoms of numbness, tingling, or pain in the thumb, index, and long finger, and/or loss of hand function. Prevalence of CTS among the general population was reported to be about 5%, affecting people from 40 to 60 years of age and more commonly found in women than men.⁽¹⁾ CTS has been reported to occur more frequently in certain professions that require frequent grasping, forceful grasping with flexed wrist postures, and exposure to vibration from hand-held tools.⁽²⁾

Splinting has been recommended for cases of CTS with mild to moderate symptoms.⁽³⁾ Pressure in the carpal tunnel increases with flexion and extension of the wrist.⁽⁴⁾ Splinting is used to fix the wrist in a neutral position in order to lower the pressure inside the canal.

Consensus was reached (Delphi technique) on a multidisciplinary treatment guideline for carpal tunnel syndrome⁽⁵⁾ that recommended many suitable treatment options for CTS, including patient instructions alone or patient instructions combined with splinting and/or other interventions. The treatment guideline for splinting describes splinting of the wrist in a neutral position with the fingers free. Regarding duration, the guideline suggests nighttime or both daytime and nighttime splinting.

In 2012, a systematic review⁽⁶⁾ in the treatment of CTS concluded that there is insufficient evidence regarding the effectiveness and safety of one splint design over another and of splinting over other non-surgical interventions. That study found that treatments varied in duration, type, and routine of splint wear. Duration of splint use ranged from two

weeks of nocturnal use to one year of nocturnal use. The most common time durations were between two and four weeks. Accordingly, the study of the effects of splinting in longer periods of time (at least 3 months) would be of value in identifying and defining a more effective CTS treatment protocol.

In many settings, including our clinic, commercially available adjustable wrist splints are available and convenient. Our patients are advised to wear a splint during their active use of the hand or as often as they could during the daytime or nighttime. Patient instructions regarding the improper positions and/or activities to avoid are also normally provided to patients. Based on our review of the literature, there is no study that compares splinting combined with patient instructions vs. patient instructions alone in the treatment of CTS. As previously noted, it was also observed in our literature review that longer-term (at least 3 months) splint effectiveness studies in CTS are insufficient.

The aim of this study was to evaluate the effect of 3-month neutral wrist splint on neuro-physiologic condition, symptoms and function in mild to moderate carpal tunnel syndrome (CTS).

Methods

The protocol for this study has been approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand. Written informed consent was obtained from all study participants.

Participants

Study participants were recruited from the Out-patient Unit and electrodiagnostic lab of the

Department of Rehabilitation Medicine, King Chulalongkorn Memorial Hospital, Bangkok, Thailand. Patients who had symptoms associated with CTS, physical examination and unilateral or bilateral electrodiagnostic study, mild to moderate CTS, and who were willing to join the study were enrolled. Patients with one or more of the following conditions were excluded: 1) CTS previously treated with steroid injection or surgery; 2) history of hand or wrist injury; 3) diagnosed as cervical radiculopathy or peripheral neuropathy; 4) underlying disorders resulting from poorly controlled diabetes mellitus; 5) pregnancy; and 6) other metabolic diseases.

Study design and randomization

This 3-month randomized, single-blind, controlled trial randomly allocated enrolled patients into splinting or non-splinting treatment groups. The randomized sequence was computer-generated with results sealed in opaque, tamper-proof, numbered envelopes.

Treatment procedures

The patients who was diagnosed of CTS on both hands, only one side would be recruited into the study. The side that showed more prolongation of distal sensory latency (DSL) on pre-treatment testing would be selected.

Control group

Patients were given instruction regarding the nature of CTS and advised to avoid full extension and flexion of the wrist, reduce heavy work activities, and avoid repetitive movements. An education pamphlet was given to each member of the control group to learn more by themselves.

Splinting group

Patients were given a commercially available adjustable wrist splint^(a) that was properly fitted and that immobilized the wrist in the neutral position. Patients were advised to wear the splint as often as possible during the day time as well as night time and at night in order to achieve the maximum effectiveness. If they were unable to wear the splint during the day, they were also advised to do so at during the night time and to record the hours of use on the recording card. Patients were told that there would be no negative repercussions or effect if they were unable to use the splint. Subjects in the splint group were given other similar treatments as received by those in the control group including instructions and education pamphlet.

Electrodiagnostic testing

Nerve conduction study by electrodiagnostic testing, including sensory nerve conduction study (SNCS) and motor nerve conduction study (MNCS) is commonly reported outcome that evaluates neurophysiologic function. The SNCS and MNCS were performed at baseline and at 3 months after the start of treatment. The objectives of the initial baseline study were, as follows: 1) to provide comparable baseline data; 2) to confirm the diagnosis of mild to moderate CTS; and, 3) to exclude severe cases of CTS (CMAP amplitude less than 5.0 mV) and other neurological conditions.

The testing was done according to the guidelines of AAEM.⁽⁷⁾ Before recruiting subjects into the study, sensory and motor nerve distal latencies (DSL and DML) and forearm NCSs of both the median and ulnar nerves were performed for

excluding peripheral neuropathy and cueing C8 or T1 radiculopathy or another non-focal neuropathy.⁽⁷⁾ The cases that were suspected to have double crush syndrome (CTS with cervical radiculopathy), needle EMG would be performed and the subject would be excluded if there was denervation of the ulnar or radial innervated muscle and/or paracervical muscles.

All electrodiagnostic studies were conducted by an examiner who was blinded to the patient treatment groups. Studies were performed using a Medelec Synergy EMG/EP System (software version 11, Oxford Instruments plc, Abingdon, United Kingdom). All patients received done electrodiagnostic testing at the same room and the hand was warmed if the palm temperature was below 32°C. Sensory nerve conduction studies were performed using antidromic technique on the median nerve at the wrist 13 cm from the ring-electrode at the second digit. Distal sensory latency (DSL) that was measured at the initial deflection from baseline was considered abnormal if greater than 3.2 ms. In cases where in the DSL value was between 2.8 and 3.2 ms⁽⁸⁾, the combined sensory index (CSI)⁽⁹⁾ was used to confirm the diagnosis. A CSI score greater than 0.9 ms was considered abnormal. Motor nerve conduction study was performed by stimulations at the wrist 8 cm from an active electrode that was placed into the abductor pollicisbrevis (APB) muscle. Distal motor latency (DML) greater than 4.2 ms was defined as abnormal. Change in DSL and DML values from baseline to 3 months after the start of treatment was used as a primary outcome indicating improvement in the neurophysiology of the median nerve. A decrease in DSL or DML values indicated that the conductivity of the patient's nerve

impulse was improved.

The severity grading of CTS was done according to the electrodiagnostic criteria as follows: Mild CTS, prolonged DSL and normal DML; Moderate CTS, prolongation of both DSL and DML; Severe CTS, abnormal DSL and DML, with either an absent SNAP or low or absent CMAP amplitude (<5.0 mV).⁽⁷⁾

Symptom and function questionnaire

Boston carpal tunnel syndrome (BCTS) questionnaire, which was developed by Levine⁽¹⁰⁾, was used for assessing symptom severity and functional status in CTS. It was found to be highly reproducible (Pearson correlation coefficient, $r = 0.91$ and $r = 0.93$ for symptoms and functional status, respectively) and internally consistent (Cronbach's alpha, 0.89 and 0.91, respectively). A well-trained assistant who was blinded to the patient treatments and was not involved in patients' treatment, explained the questionnaire to the participants without any guide and let them answer independently. The questionnaire consists of two subscales: a symptom severity scale (SYMPT BCTQ) consisting of 11 questions and a functional status scale (FUNCT BCTQ) consisting of 8 questions. Each question was rated using 5-point Likert scale scoring, with 1 point indicating (mildest pain or no difficulty with activity) and 5 points indicating (most severe pain or cannot perform activity at all). The score for each subscale was calculated as a mean and then divided by the number of questions in the subscale. The full score for each subscale was 5. This instrument has been reported as being more responsive to clinical change than traditional physical examination measures.⁽¹¹⁾

Statistical analysis

Data were analyzed using SPSS Statistics version 17 (SPSS, Inc., Chicago, IL, USA) Baseline characteristics between groups were compared using unpaired *t*-test for continuous variables and chi-square test for categorical data. Within-group changes between pretreatment and post-treatment for DSL, DML and BCTS scores were analyzed by repeated measures ANOVA. Between-group comparison of pretreatment and to post treatment changes in DSL, DML and BCTS scores were analyzed by the analysis of covariance (ANCOVA) to adjust the baseline or pre-treatment value. The ratios of patients who had improvement in DSL, DML, and/or BCTS score were compared using chi-square test. Multivariate logistic regression was used to determine whether the treatment effect was significant when controlling for possible confounders. A *P* - value of less than 0.05 was considered statistically significant. Ninety-five percent confidence intervals (CIs) were calculated for all comparisons. A

sample size of 26 patients per group was calculated based the mean differences \pm SD of sensory latency and motor latency at 3-month follow-up and the mean \pm SD of BCTQ SYMPT and BCTQ FUNCT at the 6-week follow-up from the two previous studies^(12,13) with 80% power and 5% significance level.

Results

The baseline demographic data, the number of patients with CTS in their dominant hand, severity, and CTS symptom duration were compared and no significant differences were observed between the groups (Table 1). Patients in the present study were predominately women. The splinted group had a higher percentage of moderate CTS than the control.

Of the 128 patient candidates who were screened for participation in this study, 54 were recruited (Figure 1). All the subjects completed the protocol of their respective study group, without any drop outs at the 3-month follow-up.

Table 1. Demographics and clinical characteristics at baseline.

	Controls group (n = 26)	Splint group (n = 28)	<i>P</i> value (Between group)
Mean age (y) (SD)	53.6 (12.2)	53.0 (12.4)	0.99*
Female/male	23/3	27/1	0.26†
Dominant hand CTS (hand) (%)	19 (73.1)	20 (71.4)	0.89†
Severity; mild: moderate (hand) (%)	14:12 (54:46)	9:19 (32:68)	0.11†
Symptom duration (months)	6.1	6.7	0.74*

* Independent *t*- test for between groups analysis; *P* value is not significant.

† Chi-square test for between groups analysis; *P* value is not significant.

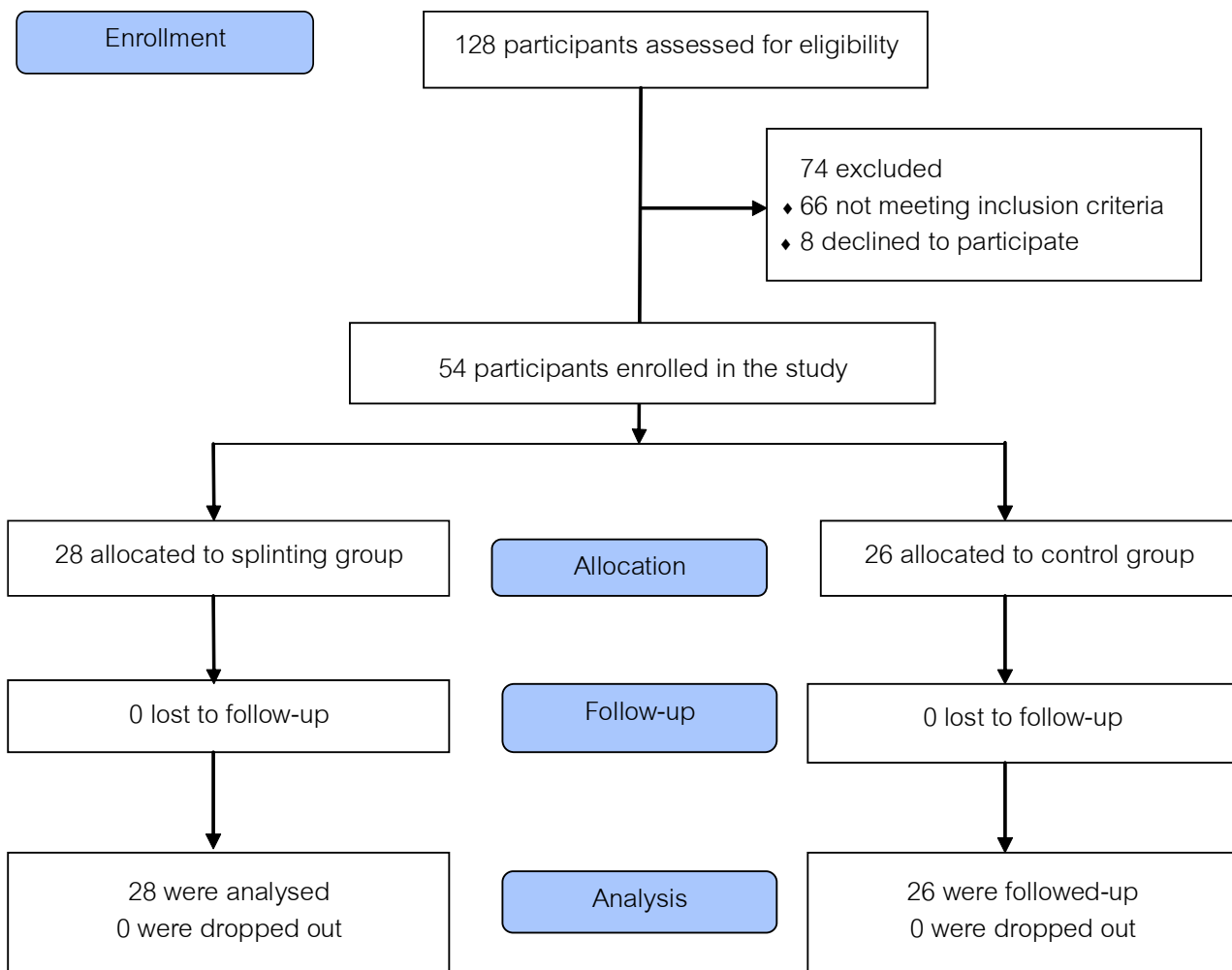


Figure 1. Flow diagram of enrolled participants.

A comparison of measured outcomes between the baseline and the 3-month follow-up are shown in Table 2. Baseline values for DSL, DML and SYMPT BCTQ were slightly more severe in the splinted group. The splinted group had greater improvement in all measured outcomes (DSL, DML, SYMPT BCTQ, and FUNCT BCTS). Pre- and post-treatment comparison, the splinted group showed significant improvement in all measured outcomes while the control group showed significant improvement only in SYMPT BCTQ and FUNCT BCTS scores, but not in DSL and DML values. Regarding the between group comparisons, the splinted group demonstrated

significantly more improvement in DSL and DML values than the control.

Multivariate logistic regression analysis showed that treatment of mild to moderate CTS with splint was significantly associated with improvement in DSL value when controlling for confounders, including baseline severity grading, duration of symptoms, and baseline DSL (Table 3).

All subjects in the splinting group reported being able to use their splint during both daytime and nighttime. Mean duration of splint wear was 6.2 ± 2.5 hour/day (min = 2 hrs, max = 11hrs) and 8.0 ± 2.0 hour/day (min = 4 hr, max = 11hr) for daytime

and nighttime, respectively. No serious adverse events were reported from splint usage. Some minor adverse outcomes of splint treatment including itching

and feelings of discomfort were reported however.

There is no other medication was allowed to use such as analgesic drugs or NSAIDs in all subjects.

Table 2. Outcomes at pre-treatment and post-treatment at 3 months.

	Control group (n = 26)	Splint group (n = 28)	P value*	95% CI of between-group mean difference
Pre-treatment				
Sensory DL (msec)	3.29 (0.59)	3.40 (0.62)		
Motor DL (msec)	4.46 (0.98)	4.71 (1.05)		
Symptom severity	1.64 [1.27,1.97]	1.68 [1.45,2.32]		
Functional deficits	1.25 [1.09,1.50]	1.25 [1.00,1.72]		
Post-treatment at 3 months				
Sensory DL (msec)	3.26 (0.61)	3.17 (0.57)		
Motor DL (msec)	4.42 (0.95)	4.36 (0.98)		
Symptom severity	1.32[1.18,1.82]	1.27 [1.09,1.64]		
Functional deficits	1.13 [1.00,1.25]	1.06 [1.00,1.38]		
Differences (Post - Pre)				
Sensory DL (msec)	-0.03 (0.36)	-0.23 (0.33)	0.04*	0.02, 0.40
P value†	.70	.001†		
Motor DL(msec)	-0.04 (0.42)	-0.35 (0.57)	0.04*	0.04, 0.58
P value†	.64	.003†		
Symptom severity	-0.27 [-0.48,0.09]	-0.45 [-0.70, -0.11]	0.17	-0.05, 0.39
P value†	.004†	<.001†		
Functional deficits	-0.06 [-0.25, 0.00]	-0.13 [-0.34, 0.00]	0.37	-0.16, 0.43
P value†	.01†	.03†		

NOTE: Values are means (SD) for sensory DL and motor DL and median [IQL25, IQL75] for symptom severity and functional deficits. Minus value mean decreasing after the treatment.

Abbreviation: DL, distal latency, n = total number of subjects in each group

* ANCOVA (adjusted by pre-treatment value) for between-group analysis; p value is significant.

† Repeated measures ANOVA for within- group analysis; p value is significant.

Table 3. Univariate and multivariate logistic regression analyses for shortening the sensory distal latency at 3-month follow-up.

Characteristic	Univariate			Multivariate		
	RR	95% CI	P	RR	95% CI	P
Splint treatment	4.80	1.50 - 15.38	0.008*	4.79	1.35 - 17.11	0.02*
Severity (ref.= mild degree)	2.73	0.89 - 8.34	0.08	1.32	0.26 - 6.73	0.74
Symptom duration	1.08	0.98 - 1.20	0.15	1.11	0.98 - 1.26	0.10
Pre-treatment DSL	2.26	0.77 - 6.63	0.26	2.21	0.48 - 10.27	0.31

*P values are significant

Discussion

The splinting group showed significant changes in DSL, DML, SYMPT BCTQ and FUNCT BCTQ score at the conclusion of 3 months of treatment (Table 2). The control group demonstrated significant changes in BCTQ score compared between baseline and 3 months, but the changes in DSL and DML were not significant (Table 2).

The results of this study show that wrist splint has a better result in improvement of neurophysiologic conditions or electrophysiological parameters but not the clinical symptoms. This disagreement has also been reported in previous studies^(14 - 17) that there was weak or no correlation between clinical and electrodiagnostic assessment in during treatment of patients with CTS and most authors suggested to consider both of them. Further more, there was a report⁽¹⁸⁾ concluded that 3-months splint using could improve both symptoms and electrodiagnostic study.

The improvement of clinical symptoms and function (BCTS score) in the control group may result from the effect of the patient instructions, which cautioned patients against heavy lifting activities, repetitive movements, and poor wrist positions.⁽⁵⁾ Even

though there was a statistical improvement of BCTQ score in both groups, the change ranging from 0.06 to 0.45 (Table 2) did not reach the minimally clinically significant difference (MCID).⁽¹⁹⁾

A systematic review⁽⁶⁾ concluded that there is limited evidence regarding splint-wearing regimen and full-time splinting vs. nighttime splinting. This study was designed to investigate the effectiveness of full-time splinting for a period of 3 months in the treatment of CTS. All patients were advised to wear their splint both day and night, as far as they could tolerate. The mean time of splint use for daytime and night time was 6.2 ± 2.5 hours and 8.0 ± 2.0 hours, respectively. All splint group patients reported being able to wear their splints full-time (both day and night) for three months, with no adverse events being reported. Overall protocol compliance in the splint group was considered to be good. A commercially available splint was used that supported the patient's wrist in the neutral position. The splint was made from soft and breathable materials, easy to apply and adjust, and left the fingers and thumb free to move.

There was significant improvement in the neurophysiologic parameters in the splinted group. At the end of three months of treatment, splinted patients had decreases in DSL and DML of 0.23 ms and 0.35 ms, respectively. After 3 months of treatment, Premoselli S.⁽¹²⁾ reported decreases in DSL and DML of 0.15 ms and 0.27 ms, respectively. The decreases in DSL and DML in that study were less than the DSL and DML decreases that were observed in the present study. Premoselli S.⁽¹²⁾ protocol involved nighttime-only splinting, while the protocol in this study called for both daytime and nighttime splint use. Walker WC.⁽¹³⁾ compared the effects of night-only to full-time splinting and concluded that physiologic improvement is best with full-time splint wearing.

The control group in the study by Premoselli S.⁽¹²⁾ received no treatment, whereas the control group in our study received patient instructions. Control group patients in the Premoselli S.⁽¹²⁾ study had a worsening of SYMPT BCTQ score, FUNCT BCTQ score, DSL value, and DML value, while the patients in our study had an improvement in each of the measured outcomes. This may imply that patient instructions were beneficial and should be provided to CTS patients as a part of any CTS treatment protocol. As for the control of confounding factors (baseline severity, duration of symptoms, and baseline DSL) we found that splinting therapy had an increased chance of decreasing DSL value when compared with non-splinting therapy (RR 4.79, 95% CI 1.35 to 17.11) (Table 3).

The findings of this study suggest that 3-month neutral wrist splinting produces more improvement in neurophysiological condition or electrodiagnostic parameters than patient instructions alone. This splinting modality has good patient

compliance without serious side effects.

Study limitations

The results of this study reflect the findings and outcomes of a specific splint design (commercially adjustable neutral wrist splint) and treatment regimen (both daytime and nighttime or full-time) in three months of treatment only. It may not be transferrable to other splint designs or treatment regimens.

Conclusions

Three-month day time and night time neutral wrist splinting was more effective than patient instructions alone regarding improvement of neurophysiologic conditions in mild to moderate CTS. This splinting modality has good patient compliance with no serious side effects.

Suppliers

FuturoTM, 3M Australia Pty. Ltd. 950 Pacific Highway Pymble, NSW 2073.

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Conflict of interest declaration

No commercial party having a direct financial interest in the results of this research supports the writing of this article or will confer any benefit to the authors or on any organization with which the authors are associated. We have no conflict of interest to declare.

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