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AN ADVANCED STAGE OF CARPAL TUNNEL SYNDROME – IS NIGHT-TIME SPLINTING STILL EFFECTIVE?

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Abstract
Objectives: There is no consensus on whether conservative treatment with night splints is indicated also in moderate and severe stages of carpal tunnel syndrome (CTS). The goal of this study was to compare the efficacy of night-time splinting at different stages of CTS. **Material and Methods:** Forty-five patients with electrodiagnostic (EDX) features of CTS included in the study were divided into 2 groups based on nerve conduction studies. The patients in the first group had only median nerve sensory fiber involvement, whereas the patients in the second group had also motor fiber involvement. The custom-made volar night splint was the only treatment for all of the included patients. The patients were assessed before the fabrication of orthosis and after 12 weeks of its use. The parameters measured were hand grip strength and the *Visual Analogue Scale* for pain and paraesthesia. The patients further completed the *Boston Carpal Tunnel Syndrome Questionnaire* (BCTQ) and a shorter version of the *Disabilities of the Arm, Shoulder and Hand Questionnaire* (QuickDASH). **Results:** In the first group, a statistically significant improvement was established in paraesthesia and hand grip strength ($p = 0.019$, $p = 0.024$, respectively), but there was no statistically significant improvement in pain, and the results of both BCTQ and QuickDASH. In the second group, a statistically significant improvement was found in paraesthesia, the *BCTQ Symptom Severity Scale* and QuickDASH results ($p = 0.008$, $p < 0.001$, $p = 0.011$, respectively), whereas no statistically significant improvement was established in pain, hand grip strength and the *BCTQ Functional Status Scale*. However, when comparing the change in the outcome measures between the 2 groups, no statistically significant differences were found. **Conclusions:** This study has shown that 12-week night-time splinting is beneficial not only for patients with mild CTS but also for those with advanced CTS, and those awaiting surgical treatment. Therefore, splinting is recommended for all patients with CTS. Int J Occup Med Environ Health. 2020;33(6):771–80

Key words:
carpal tunnel syndrome, hand function, conservative treatment, median nerve, outcome measures, splinting

INTRODUCTION

Carpal tunnel syndrome (CTS) is one of the most common entrapment neuropathies caused by the compression of the median nerve (MN) as it passes through the carpal tunnel. Its prevalence established in a population-based study is 5.3% in women and 2.1% in men [1]. Age distribution differs according to gender. A study investigating the incidence of CTS in a general population showed the highest incidence in women aged 50–59 years and, after that, a decline with age [2]. The highest incidence in men was shown to have 2 peaks, the first between the age of 50–59 years, and the second in those aged ≥70 years [2].

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Carpal tunnel syndrome is common among people of working age, and a clear association between the development of CTS and workplace activities has been established [1,3]. Predisposing factors for focal MN damage other than age and gender are vocational activities that involve excessive and repetitive hand movement, and also a variety of medical conditions, of which hypothyroidism, diabetes mellitus, previous wrist trauma, amyloidosis, sarcoidosis and rheumatoid arthritis are the most common [4].

The most common symptoms caused by CTS are numbness and tingling of the hand in the thumb, index and middle finger, and the radial half of the ring finger. These problems are usually more pronounced at night when they tend to wake the patients up during the sleep. Long-standing CTS may cause atrophy of the thenar muscles and decreased hand grip strength.

Diagnosis is usually clinical by identifying the symptoms and can be confirmed with electrodiagnostic (EDX) testing. Carpal tunnel syndrome can further be divided into subgroups based on the severity of compression shown in nerve conduction studies (NCSs) [5]. In diagnosing CTS, electromyography is an extension of the patient's medical history and physical examination [6]. The fundamental problem of diagnosing CTS is the lack of the gold standard, as there are 3 diagnostic measures that could be a standard (clinical symptoms and signs, neurophysiological testing, and surgical outcome) but none of them is perfect and they all have false negatives and false positives [7]. Some authors suggest dividing the patients into 6 groups based on neurophysiological findings: negative, minimal CTS, mild CTS, moderate CTS, severe CTS and extreme CTS [8–10]. However, the most commonly used grading system for CTS, based on neurophysiological tests, divides the patients into 3 groups: mild, moderate and severe CTS [11]. In mild CTS, there is only prolongation of distal sensory latency (DSL); in moderate CTS, there is prolongation of DSL and distal motor latency (DML); and in severe CTS, there is also low amplitude or absent compound muscle action potential (CMAP) [11].

Treatment methods can be divided into 2 groups: surgical and non-surgical or conservative. There are numerous conservative methods for treating CTS, but there is still no consensus as to which conservative treatment method is the best [12].

The guidelines of the American Academy of Orthopaedic Surgeons (AAOS) for CTS suggest that there is strong evidence supporting the use of immobilization (brace/splint/orthosis) for improving patient-reported outcomes [13–15].

It has been previously shown that the resting intracanal pressure in patients with CTS is elevated and that wrist positions away from neutral can increase the pressure [16,17]. Wearing wrist splints in a neutral position can increase the carpal tunnel space, decrease compression of MN and, therefore, alleviate the symptoms [18].

To the best of the authors' knowledge, there are no studies investigating whether the stage of nerve entrapment based on EDX findings influences the patient-reported outcome measures and functional improvement after 12 weeks of conservative treatment with night splints. The main goal of this study was to find out whether the efficacy of night-time splinting differs regarding the different stages of CTS. The authors' goal was to determine whether the conservative treatment with night-time splinting is reasonable also in the advanced stages of CTS where the motor fiber damage of MN is already present.

MATERIAL AND METHODS

This study was a prospective interventional study conducted at the University Medical Centre Maribor (UMC Maribor), Slovenia, in May 2015–June 2018. Patients with EDX features of CTS, referred to the Institute of Physical and Rehabilitation Medicine (IPRM) in order to be treated with a custom-made volar night splint, were included in the study. The diagnosis was based on the pa-

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b)

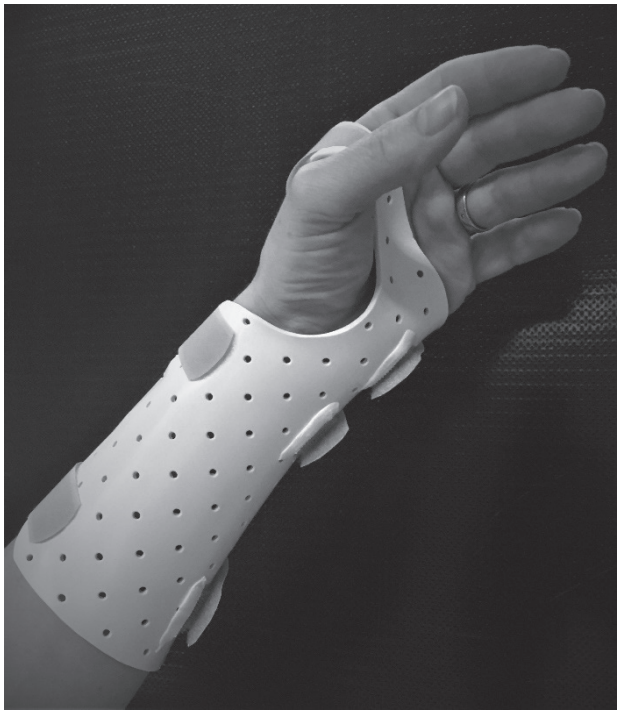

Figure 1. Custom-made volar night splint

tient's medical history, clinical examination, and EDX testing. Clinical confirmation was made by the presence of at least 3 of the most common criteria defined by AAOS: numbness and tingling in the distal MN sensory distribution, night paraesthesia, hypoesthesia in the MN sensory distribution, positive Tinel's sign, positive Phalen's test, or atrophy of the thenar muscle group. The inclusion criteria were the following: age ≥18 years, day-time or night-time paraesthesia in the distal MN sensory distribution, hand clumsiness, grasp weakness, sleep disturbances, and EDX confirmation of CTS.

The exclusion criteria were:

- traumatic injury to the upper limb;
- corticosteroid injection in the carpal tunnel region in the last 6 months;
- systemic causes of CTS (hypothyroidism, diabetes and pregnancy), previous stroke, rheumatoid arthritis;
- primary arthrosis affecting any joint of the upper limb;
- previous surgical treatment of CTS;
- previous treatment with splints for CTS;
- Dupuytren's contracture and EDX signs of radiculopathy or polyneuropathy.

The custom-made volar night splint was the only treatment for CTS introduced to the included patients. The volar wrist splint made from the low temperature thermoplastic material Orfit Eco® (Orfit Industries, Antwerp, Belgium) did not include fingers and was made by occupational therapists experienced in the field of custom-made orthoses. The splint is shown in Figure 1. The patients were instructed to use the splints mainly at night for 12 weeks. If CTS was bilateral, the splints were used on both hands. The patients were examined twice – before the orthoses were made and 12–14 weeks after the orthosis use, on average after 12.8 weeks. If both hands were affected, the hand that the patient identified as having worse symptoms was evaluated. The patients evaluated the severity of pain and

paraesthesia on a 10-cm *Visual Analogue Scale* (0 – total absence of symptoms, 10 – the worst possible symptoms that the patient can imagine). The hand grip strength was measured with the Jamar hydraulic hand dynamometer (Jamar® Hand Dynamometer, Sammons Preston Rolyan, Chicago, Illinois, USA) in a standardized position (the arm adducted, the elbow flexed to 90°, and the hand and forearm in a neutral position). The mean value of the 3 successive measurements expressed in kilograms (kg) was used in statistical analysis.

Phalen's test, Tinnel's sign and flexion, and nerve compression tests were carried out and marked as positive or negative. Phalen's test was performed by asking the patient to oppose the back of their hands by fully flexing their wrists, and to maintain this position for 60 s. The test was recorded as positive if the patient reported paraesthesia in the distal MN sensory distribution. The meta-analysis by MacDermid and Wessel [19] reported test's sensitivity of 68% and specificity of 73%. Tinnel's test was performed with the patient seated with their arm in a fully supinated position as the examiner tapped above the carpal tunnel with a percussion hammer. The test was reported positive when the patient complained of temporary paraesthesia in the distal MN sensory distribution. The reported test's sensitivity is 50% and specificity 77% [19]. The wrist flexion compression test was performed with the patient seated, their elbow extended, and their wrist in forced full flexion as the examiner compressed the carpal tunnel manually for 30 s. The test was reported positive if the patient complained of tingling in MN sensory distribution. The reported test's sensitivity is 82% and specificity 99% [20].

The patient-reported outcome measures used were the following: the *Boston Carpal Tunnel Syndrome Questionnaire* (BCTQ) and a shorter version of the *Disabilities of the Arm, Shoulder and Hand Questionnaire* (QuickDASH). Notably, BCTQ is a disease-specific questionnaire that measures patient-reported symptom severity and functional status [21]. It is divided into the *Symptom Severity Scale* (SSS) and the *Functional Status Scale* (FSS).

The *Symptom Severity Scale* consists of 11 questions referring to the patient's symptoms in a typical 24-h period during the past 2 weeks with answers on a 5-pt Likert scale (5 being the most severe) while FSS contains 8 questions assessing the activities of daily living. The patients rate their level of difficulty in performing the tasks on a 5-pt Likert scale (5 again being the most severe). Mean values for both scales are calculated so that for each scale a final score of 1–5 is generated, with a higher score indicating greater disability. Finally, BCTQ is a recommended measuring tool for patients with CTS with good psychometric properties regarding the validity, reliability and responsiveness [21].

Consisting of 11 items, QuickDASH is used to measure physical function and symptoms on a 5-pt Likert scale. From the item scores, the scale score ranging 0–100 is calculated, with a higher number indicating greater disability. A study by Yücel and Seyithanoğlu [22] showed a good correlation between QuickDASH and BCTQ, and QuickDASH was also shown as reliable and valid for patients with CTS. As QuickDASH is not a disease-specific questionnaire and it evaluates the impairment of the whole upper limb, the authors excluded the patients with CTS that had concomitant primary arthrosis or recent traumatic injury in their upper limbs, since this could affect the results of the questionnaire.

The evaluation of compliance for the prescribed treatment was made by asking the patients about how many nights a week on average they used the orthosis in the first, second and third month. Based on a study by Chesterton et al. [23] dated 2018, adherence to night-time splinting for at least 4–6 nights/week was required.

Before inclusion in the study, EDX testing was performed on the Medelec Synergy device by an experienced neurophysiologist. The testing was conducted in a room with the temperature of ≥25°C and with the minimum

temperature of 34°C of the examined hand. An antidromic sensory NCS across the wrist with the conduction distance of 14 cm was performed for the median and ulnar nerve (UN) on the ring finger. The difference between the nerve latencies for MN and UN on the ring finger was calculated (the difference was considered significant if >0.4 ms). A motor NCS of MN was recorded from the thenar muscle (it was considered pathological if >4.3 ms), and for UN from the hypothenar muscle at the distance of 8 cm. Based on the obtained DSL, DML, CMAP, sensory nerve action potential, sensory conduction velocity, and the difference between MN and UN latencies on the ring finger, the patients were divided into 2 groups.

The sensory fibers of MN in patients with CTS are usually damaged in early stages, and the motor fibers get damaged in longer-standing CTS [24]. For this reason, the patients were divided according to the results of EDX testing regarding the sensory or motor nerve fiber involvement. The first group had only sensory nerve conduction slowing across the carpal tunnel. The second group had sensory nerve conduction slowing and also prolonged DML.

The sample size estimation was based on a pilot study and the primary outcome measure chosen was BCTQ SSS. The standard deviation was calculated at 0.6 and the expected change in scores with treatment was 0.5. Based on the significance level of 5% and the power of 80%, 23 participants were required in each group. Statistical analysis was performed using IBM SPSS Statistics version 22. The Wilcoxon signed-rank test was used to compare the differences between the outcome measures before and after treatment in the whole sample and also in both groups. The Mann-Whitney U test was used to compare differences in the change of outcome measures between the 2 groups. The data is presented with the median, interquartile range and the p-value (significance $p < 0.05$). The study was approved by the human research ethics committee of the University Medical Centre Maribor, Slovenia. Each participant provided informed consent and could withdraw from the study at any time.

RESULTS

The initial sample consisted of 70 individuals in whom unilateral or bilateral CTS was confirmed by EDX testing. Overall, 55 of these 70 patients returned for the second evaluation. At the second evaluation, 3 patients had to be excluded due to surgical treatment of CTS. The remaining 7 excluded patients presented new relevant medical documentation that was not known to the authors at the time of the inclusion in the study (1 had De Quervain's tenosynovitis, 1 had polyneuropathy, 4 had diabetes, and 1 had radiculopathy). The complete data of 45 participants who had received night splints was included in the analysis; 42 of them were women (93.3%). All of the patients were right-handed. The mean age of the participants was 50.1 years.

The patients were divided into 2 groups. According to the EDX findings, 19 patients (42.2%) had a difference in MN and UN sensory latency measured on the ring finger higher than 0.4 ms and were classified in the first group; 18 of them were women (94.7%). Twenty-six (57.8%) patients with MN motor fiber involvement were pooled in the second group. They presented with the following EDX findings: 23 (88.5%) had only prolonged median DML (DML >4.3), 2 (7.7%) had prolonged median DML (DML >4.3) and lower amplitude of CMAP (<3.5 mV), and in 1 (3.8%) patient CMAP was absent; 24 of them were women (92.3%).

The demographic information and baseline EDX data for the participants are shown in Table 1 and Table 2, respectively.

In the first group, 14 patients (73.7%) reported the right hand, and 5 patients (26.3%) reported the left hand, as having worse symptoms. In that group, 15 patients (78.9%)

Table 1. Characteristics of the participants with carpal tunnel syndrome (CTS) in the study conducted at the University Medical Centre Maribor, Maribor, Slovenia, in 2015–2018

Variable	Participants (N = 45)	
	group 1 (N = 19)	group 2 (N = 26)
Gender [n (%)]		
male	1 (5.3)	2 (7.7)
female	18 (94.7)	24 (92.3)
Age [years] (M)	47.0	52.4
CTS symptoms [n (%)]		
right	3 (15.8)	5 (19.2)
left	1 (5.3)	2 (7.7)
bilateral	15 (78.9)	19 (73.1)
right hand used for study	14 (73.7)	19 (73.1)
Dominance [% R:L]	100:0	100:0

Group 1 – patients with only median nerve sensory fiber involvement; group 2 – patients with median nerve sensory and motor fiber involvement.

Table 2. Baseline electrodiagnostic (EDX) data for the median nerve (MN) of the more symptomatic hand which was included in the statistical analysis in the study conducted at the University Medical Centre Maribor, Maribor, Slovenia, in 2015–2018

Parameter	Participants (N = 45) (M±SD)	
	group 1 (N = 19)	group 2 (N = 26)
DSL [ms]		
MN	3.1±0.4	3.6±2.0
UN	2.3±0.3	2.3±0.3
SNAP MN [μV]	26.4±10.9	11.6±11.2
SCV MN [m/s]	45.0±5.8	25.7±14.1
DML MN [ms]	3.6±0.4	5.2±1.5
CMAP MN [mV]	12.1±3.2	9.8±5.1
MCV MN [m/s]	60.6±5.2	57.4±9.3

CMAP – compound muscle action potential; DML – distal motor latency; DSL – distal sensory latency; MN – median nerve; MCV – motor nerve conduction velocity; SNAP – Sensory nerve action potential median nerve; SCV – sensory nerve conduction velocity; UN – ulnar nerve.
Other explanations as in Table 1.

received splints for both hands, 3 patients (15.8%) for the right hand only, and 1 patient (5.3%) for the left hand only.

In the second group, 19 patients (73.1%) reported the right hand, and 7 patients (26.9%) reported the left hand, as having worse symptoms. In that group, 19 patients (73.1%) received splints for both hands, 5 patients (19.2%) for the right hand only, and 2 patients (7.7%) for the left hand only.

The compliance rate for wearing the splints was excellent in both groups, and the most common reason for non-compliance was the improvement of symptoms. Discomfort while wearing the splints was only reported by 1 patient and the splints had to be corrected by occupational therapists. All of the patients used the splints for ≥4 nights/week during the 12-week period.

The statistical analysis showed that there was a statistically significant improvement in all the parameters measured, except for pain and hand grip strength, in the whole sample, by comparing the results between the first and the second evaluation. The results showed that the patients reported less paraesthesia, and the results of both BCTQ and QuickDASH were better after 12 weeks of treatment with night splints. The results are shown in Table 3.

The authors also compared the parameters for the 2 groups before and after treatment. The results showed a statistically significant improvement of paraesthesia and hand grip strength in the first group. In the second group, there was a statistically significant change in paraesthesia, BCTQ SSS and QuickDASH results before and after treatment. When comparing the changes of outcome measures between the 2 groups, the statistical analysis showed no statistically significant differences for either of the parameters. All of these results are shown in Table 3.

Table 3. The results of the outcome measures for the included patients in the study conducted at the University Medical Centre Maribor, Maribor, Slovenia, in 2015–2018

Participants	*Visual Analogue Scale*		Hand grip strength	*Boston Carpal Tunnel Questionnaire*		QuickDASH
	pain	paraesthesia		*Symptom Severity Scale*	*Functional Status Scale*	
Total (N = 45) (Me (IQR))						
before treatment	4.7 (2.7–6.9)	6.5 (5.0–7.7)	18.7 (13.7–23.7)	3.0 (2.6–3.4)	2.6 (2.1–3.4)	50.0 (31.8–59.1)
after treatment	4.0 (0.9–6.5)	3.8 (1.1–6.8)	20.7 (13.8–25.5)	2.5 (1.8–3.1)	2.3 (1.7–3.2)	43.2 (22.7–58.0)
p[a]	0.060	<0.001*	0.105	<0.001*	0.007*	0.029*
Group 1 (N = 19) (Me (IQR))						
before treatment	4.0 (2.5–6.8)	6.2 (3.2–8.2)	18.0 (10.7–24.3)	3.0 (2.6–3.4)	2.5 (1.8–3.4)	45.5 (34.1–59.1)
after treatment	4.0 (1.5–6.7)	2.1 (0.7–7.8)	22.0 (14.3–26.7)	2.6 (1.8–3.4)	2.3 (1.5–3.4)	45.5 (20.5–61.4)
p[a]	0.239	0.019*	0.024*	0.131	0.055	0.554
Group 2 (N = 26) (Me (IQR))						
before treatment	4.8 (3.7–6.9)	7.1 (5.3–7.6)	18.9 (14.5–23.4)	3.0 (2.6–3.5)	2.8 (2.1–3.4)	50.0 (29.0–57.4)
after treatment	4.0 (0.8–5.8)	4.7 (2.1–6.6)	20.3 (13.1–25.3)	2.4 (1.8–2.9)	2.5 (1.9–3.2)	43.2 (24.4–51.1)
p[a]	0.137	0.008*	0.790	<0.001*	0.055	0.011*
Change of outcome measures before and after treatment (Me (IQR))						
group 1 (N = 19)	0.3 (–0.5–2.2)	0.8 (0.0–4.0)	2.0 (0.4–2.0)	0.4 (–0.4–0.8)	0.3 (0.0–0.4)	0.0 (–9.1–18.2)
group 2 (N = 26)	1.3 (–0.7–3.7)	2.4 (–0.6–3.7)	1.4 (–2.8–3.1)	0.9 (0.1–1.1)	0.3 (–0.1–0.7)	4.6 (–0.5–12.5)
p[b]	0.401	0.991	0.329	0.078	0.557	0.317

[a] Mann-Whitney U test.
[b] Wilcoxon signed-rank test.
* $p < 0.05$.
Other explanations as in Table 1.

DISCUSSION

The aim of this study was to compare the effectiveness of night-time splinting in patients with only sensory fiber involvement to those with motor fiber involvement, and to evaluate the reasonableness of splint prescription in advanced CTS. The results of this study showed that in patients with only sensory fiber involvement, the level of paraesthesia and hand grip strength improved after treatment, whereas in the group with sensory and motor fiber involvement, the improvement was shown in the domain of paraesthesia and also in the results of BCTQ SSS and QuickDASH. The results clearly show that the patients with advanced CTS also benefit from night-time splinting even if they are already waiting for surgical decompression of MN, if they refuse surgical treatment or are not eligible for surgery. Based on experience, a significant number of patients with CTS that meet the EDX criteria for surgical treatment refuse the surgical intervention. The reasons can be a fear of surgery, the loss of income, a fear of pain, transient weakness etc. [25]. Also, some of the patients have general contraindications for the surgery, so night-time splinting can be a possibility for symptom relief and functional improvement in those patients.

Earlier studies mostly showed good results of conservative treatment in reducing symptoms of mild CTS in its early phases but newer research has shown that patients with long-lasting symptoms can also experience relief [14,26]. Comparably, this study also showed good results of night-time splinting even in patients with motor fiber involvement of MN, which is one of the EDX criteria for advanced CTS. While the study by Hall et al. [14] investigated the effects of 8-week full-time splinting and performing nerve gliding exercises, this study investigated only night-time wrist splinting during a 12-week period. Its results suggest that night-time splinting only is enough to alleviate symptoms in patients with CTS, as wearing splints during the day may be impairing the patients in their activities of daily living and workplace activities. Also, wearing splints during the day could discourage the patients to participate in social life activities. The results of this study suggest that splinting already improves the patient's outcome measures and brings relief of symptoms, so that no additional costly physical therapy would be necessary.

As this study showed that night-splinting is effective also in patients with advanced CTS, it is questionable if EDX testing is necessary before introducing splints. In the authors' opinion, treatment with splints can be introduced even before CTS is confirmed by EDX testing, based only on a careful history and clinical confirmation of CTS. Some studies investigating conservative treatment went even further by investigating changes in MN edema using MRI studies [27]. Although the study showed a correlation in symptom relief and a reduction of MN edema after splinting and exercise in patients with CTS, performing an MRI is too expensive solely for the purpose of MN edema observation. Symptom relief and functional improvement in patients could be enough for evaluating the effectiveness of splinting.

One of the flaws of this study was that there was no control group without treatment, because that was not approved by the human research ethics committee. There was also no comparison to placebo, as placebo treatment would be almost impossible to implement. To the best of the authors' knowledge, to this date there have been no published studies investigating splinting in patients with CTS that were placebo-controlled. One that came closest was published by De Angelis et al. [28] and compared a conventional rigid splint with a soft splint. Currently, Atroshi et al. [29] are performing a study which will be placebo-controlled by using a soft (neoprene) bandage as placebo treatment. In the authors' opinion, a soft splint cannot be considered as true placebo because soft splints could also have a direct effect on MN compression.

The grouping of the patients may seem another limitation of this study. Even though the AAEM classifies CTS in 3 stages (mild, moderate and severe), the authors decided to divide patients into 2 groups only, considering the differentiation between sensory and motor nerve fiber involvement. The hallmark of the advanced stages of CTS is motor nerve fiber involvement which is the case in moderate and severe stages.

Another flaw of the study was the subjective nature of the outcome measures in evaluating the results of 12-week night-time splinting. None of the outcome measures are objective as only EDX testing or MRI studies would provide a truly objective insight into the grade of MN damage. However, the diagnosis of CTS is by definition clinical. The study by Manente et al. [15] conducted in 2001 showed that even though splinting improved both the symptoms and functional score, there was no change in median DML and median sensory conduction velocity detected by EDX studies, so the reasonableness of control EDX testing is questionable.

Previous studies already showed that night-time splinting was more effective than no treatment in patients with CTS, but the superiority of splinting over other non-surgical interventions was not shown [30]. It is also known that splinting improves the outcome measures in patients with mild CTS and also in long-lasting CTS. This study, by comparing the improvement in mild and advanced CTS,

showed an improvement in outcome measures in both groups, but no statistically significant differences in the improvement between both groups were established. Night-time splinting is, therefore, recommended not only in mild and advanced CTS, but also in patients awaiting surgical treatment.

CONCLUSIONS

This study showed that night-time splinting lasting ≥12 weeks was beneficial not only for patients with mild CTS but also for those with advanced CTS. Night-time splinting showed symptom relief in the mild and advanced CTS groups, and there were no statistically significant differences in the improvement of outcome measures between both groups. This study, therefore, provides additional evidence that night-time splinting is beneficial also in patients with advanced stages of CTS that are awaiting surgical treatment or have subjective or objective reasons for not being eligible for the surgery.

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