Original Article

Effects of Focused ESWT in Moderate Degree Carpal Tunnel Syndrome: A Preliminary, Randomized Double-Blinded Controlled Trial

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ABSTRACT

Objectives: To study the effects of focused extracorporeal shockwave therapy (f ESWT) combined with night splint and compare 4 and 10 treatment sessions in patients with moderate carpal tunnel syndrome (CTS)

Study design: A randomized, double-blinded, controlled trial

Setting: An outpatient rehabilitation clinic in King Chulalongkorn Memorial Hospital, Bangkok, Thailand

Subjects: Patients with a diagnosis of moderate CTS

Methods: Patients were randomly assigned to one of the two groups. The intervention group received ESWT once a week for ten consecutive weeks, while the comparison group received sham ESWT for the first four weeks and real ESWT for the subsequent six weeks. All patients were advised to wear a night splint. The Boston Carpal Tunnel Syndrome Questionnaire (BCTQ) and the electrodiagnostic study were evaluated at baseline, 4, and 10 weeks.

Results: The f ESWT group improved significantly in both BCTQ symptoms (p = 0.022) and BCTQ function (p-value 0.025), whereas the comparison group improved only in BCTQ symptoms (p = 0.028). At 4 weeks, the f ESWT group showed statistically significant improvement in distal sensory latency (p = 0.019) and sensory nerve conduction velocity across the wrist (p = 0.028) compared to the comparison group. Over the course of ten sessions of ESWT, clinical outcomes and neurophysiologic parameters continued to improve. However, the number of patients exceeding the minimal clinically important difference in BCTQ did not change after the first 4 sessions.

Conclusions: This preliminary study shows that adding f ESWT to a night splint is safe and effective for improving symptoms, function, and neurophysiologic parameters in moderate CTS. In terms of cost-effectiveness, four sessions may be more appropriate.

Keywords: carpal tunnel syndrome, extracorporeal shockwave therapy, Boston carpal tunnel syndrome questionnaire, electrodiagnosis

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Introduction

Carpal tunnel syndrome (CTS) is the most common type of entrapment neuropathy worldwide. It is caused by a compression of the median nerve at the wrist as it passes through the carpal tunnel. Patients may present with intermittent nocturnal paresthesia and dysesthesia in the median innervated territory. Later in the disease, sensory loss and thenar muscle atrophy emerge.[1] CTS is considered to have a complex etiology involving ischemic changes caused by increased intracarpal canal pressure. Nonsurgical treatments, including patient education, wrist orthosis, and oral medication, should be considered first-line treatment for mild to moderate CTS. Despite limited evidence, physical modalities are routinely employed in clinical practice for treating CTS.[2]

Extracorporeal shock wave therapy (ESWT) is a non-invasive therapy that uses an acoustic wave with a high peak pressure (100 megapascals), rapid pressure increase (10 nanoseconds), short duration (10 milliseconds), and an energy density of 0.003–0.89 megajoules/millimeter^2 (mJ/mm^2)[2,3] There are several types of shockwave generators currently available, including the piezoelectric approach, which produces shockwaves that are focused on a specific tissue area. The focused ESWT (f ESWT) concentrates acoustic energy on a specific point on the target. Applying f ESWT necessitates precise identification of the area to be treated.[4] This allows for the most favorable therapeutic effect while avoiding damage to the surrounding tissue. Furthermore, ESWT can be divided into three energy levels: low, moderate, and high.[5] There have been reports of the therapeutic effects of low-energy ESWT on peripheral nerve regeneration in animal models.[6,7] In recent years, ESWT has received significant attention as a novel and non-invasive method for treating CTS. Seok et al. in 2013 were the first to report the efficacy of ESWT in treating CTS. They concluded that ESWT can be as helpful as corticosteroid injection in relieving CTS symptoms.[8] A systemic

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review and meta-analysis in 2023 by Zhang et al. reported that ESWT can improve symptoms, functional outcomes, and electrophysiologic parameters in patients with mild-to-moderate CTS.[9] However, the mechanism by which ESWT affects entrapment neuropathy remains unclear. Moreover, no treatment protocol for ESWT has been established. Previous studies have used protocols ranging from 4 to 6 sessions, with one study extending up to 12 sessions.[9] Clinical services in our institution typically provide 10-session treatments which include using other physical modalities. The present study aimed to investigate the effect of f ESWT and compare the dose-related therapeutic effect of ten-sessions versus four-sessions of f ESWT on symptoms, function, and neurophysiologic condition in patients with moderate CTS.

Methods

Study design

This prospective, double-blinded (patients and assessors), randomized controlled trial was conducted between November 2018 and October 2019. The study was approved by the Institutional Review Board, Faculty of Medicine, Chulalongkorn University with approval number IRB174/61 on July 12, 2018 and followed the Code of Ethics (Declaration of Helsinki). It was registered with the clinical trials registry on August 25, 2018. (TCTR20180825002) This study was reported following the CONSORT 2010 guidelines for randomized controlled trials.

Participants

Patients with moderate CTS were recruited from a university hospital's outpatient rehabilitation clinic and electrodiagnostic lab based on criteria established by the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) guidelines.[10] Patients with comorbidities such as diabetes, rheumatoid arthritis, or cervical radiculopathy; prior carpal tunnel surgical release or corticosteroid injection; or prior treatment of f ESWT were excluded from the study.

In the present study, the cut-off points for normal electrophysiological values were as follows: 1) The upper limit of onset median distal sensory latency (DSL) was < 3.2 ms at a distance approximately 13 cm proximal to the active ring electrode at the second digit. 2) In cases of DSL between 2.8 and 3.2 ms, the combined sensory index was applied, and a value > 0.9 was considered abnormal.[11] 3) The upper limit of median motor latency was < 4.2 ms at approximately 8 cm from the active recording electrode at the abductor pollicis brevis muscle. 4) The sensory nerve action potential (SNAP) amplitude was also measured. Following AANEM guidelines, we recruited individuals with moderate CTS for our study. Mild: only prolonged DSL; Moderate: both prolonged DSL and DML; Severe: no SNAP response or a low or absent compound motor action potential (CMAP) amplitude.

The experiment protocol was thoroughly explained to all eligible individuals. Each participant provided written informed consent prior to treatment allocation. The side of the wrist with a higher BCTQ score was recruited for each patient. An independent researcher used a computer-generated randomization with a 1:1 ratio to allocate the patients into two groups. The group assignment was not blinded to the physiatrist performing the f ESWT. Patients were unaware whether they were in the intervention or comparison group.

The sample size was calculated using the Boston Carpal Tunnel Questionnaire (BCTQ) results from a study by Vahdatpour et al.[12] with a 90% power and a 5% significance level. In addition, for the magnitude of difference (X1-X2), we used the minimal clinically important difference (MCID) of the BCTQ symptom severity subscale (0.8) and the BCTQ functional status subscale (0.5).[13] Based on this calculation, we aimed to enroll approximately 20 patients for each group.

Interventions

The patients in the intervention group received one session of f ESWT each week for ten weeks. The patients sat in a comfortable position with the hand of interest on a pillow. The size of the f ESWT gel pad applicator was chosen based on the patient's body mass index (BMI) (BMI ≤ 25 kg/m^2: size 10, BMI > 25: size 15 kg/m^2). The f ESWT probe was positioned perpendicularly on the patient's palm, over the median nerve at the carpal tunnel. Anatomic landmarks on the wrist were used to locate the median nerve (between the flexor carpi-radialis and palmaris longus tendons). Shockwaves were delivered without anesthesia using a piezoelectric generator (Swiss PiezoClast®, EMS, Dallas, USA) or a total of 1,000 shocks given at a rate of eight pulses per second. The intensity level was gradually increased to the highest level tolerated by the patient, but the energy flux density did not exceed 0.08 mJ/mm^2.

The comparison group was given sham ESWT for the first four weeks and real ESWT for the remaining six weeks, for a total of ten weeks. An identical handpiece was utilized in the sham ESWT and in the real ESWT, but a plastic sheet was placed between the gel pad and the handpiece applicator to block the wave in the comparison group. Patients in that group could hear the sound but could not feel the wave striking during treatment.

The investigator gave all subjects a commercial wrist splint to maintain basic CTS care. The wrist splint was firmly fixed in a neutral position to immobilize the affected wrist, and patients were recommended to wear it at night. The total number of nights they wore the splint throughout the 10 weeks was recorded. The average nights per week of splint wear for each patient was calculated. Patients were encouraged to avoid repetitive flexion and extension of the wrist and any other treatments from the initial screening through the duration of the trial, including analgesic drugs, acupuncture therapy, manual therapy, ultrasound, laser therapy, or any CTS treatment.

Outcome measurements

Investigators blinded to the trial evaluated the clinical outcomes, and all measurements were taken before and after the fourth and tenth treatment sessions. The Boston Carpal Tunnel Questionnaire (BCTQ), which includes a symptom severity and functional status subscales, was used as the primary outcome measure. It is widely used for clinical studies in individuals with CTS, with high internal consistency and validity.[14] The BCTQ is divided into two sections: the symptom severity subscale (BCTQ SYMPT) which consists of 11 questions with scores ranging from 1 (mildest) to 5 (most severe), and the functional status subscale (BTCQ FUNCT) consisting of eight questions with scores ranging from 1 (no difficulty with the activity) to 5 (unable to perform the activity at all). The secondary outcome measure was electrodiagnostic testing, which was carried out according to AANEM recommendations. We measured the sensory nerve action potential, distal sensory latency (DSL), distal motor delay (DML), and sensory conduction velocity across the wrist. All nerve conduction examinations were performed in the same room by the same physiatrist, who was blinded to the treatment allocation. The skin temperature of the tested limb was kept at 32°C. The median sensory nerve conduction study was performed antiheroically by stimulating the median nerve between the palmaris longus and the flexor carpi radialis tendon, approximately 13 cm proximal to the active ring electrode at the proximal phalange of the second digit. The motor nerve conduction study was performed by maximally stimulating the median nerve 8 cm proximal to the surface electrode recording at the abductor pollicis brevis muscle.

Data analysis

SPSS version 22.0 software for Windows was used for statistical analysis. A descriptive analysis was performed for the baseline characteristics of all measurements. The Fisher's exact test was used for categorical data in the between-group comparison. For continuous data, the Mann-Whitney U test was used. For within-group comparisons, the Wilcoxon signed-rank test was used. Missing data were handled using the last observation carried forward. Statistically significance was set at $p < 0.05$.

Results

Figure 1 shows the study flowchart. Ninety-four patients were assessed for eligibility, and twenty patients were recruited. Table 1 shows that the baseline characteristics are comparable between groups.

The baseline BCTQ was comparable between the two groups. Both the BCTQ severity and function subscales improved significantly from baseline in the intervention group at 4 and 10 weeks. The BCTQ SYMPT showed significant improvement in the comparison group only at 4 weeks, whereas BCTQ FUNCT showed a significant improvement at both 4 and 10 weeks. (Table 2)

Although neither group showed a significant within-group improvement in the DSL, DML, SNAP amplitude, or SNCV across in the wrist in the nerve conduction study, when the two groups were compared, only the intervention group showed a significant difference in DSL and SNCV across the wrist. We then compared the treatment sessions in the intervention group between four-session and ten-session f ESWT. After the

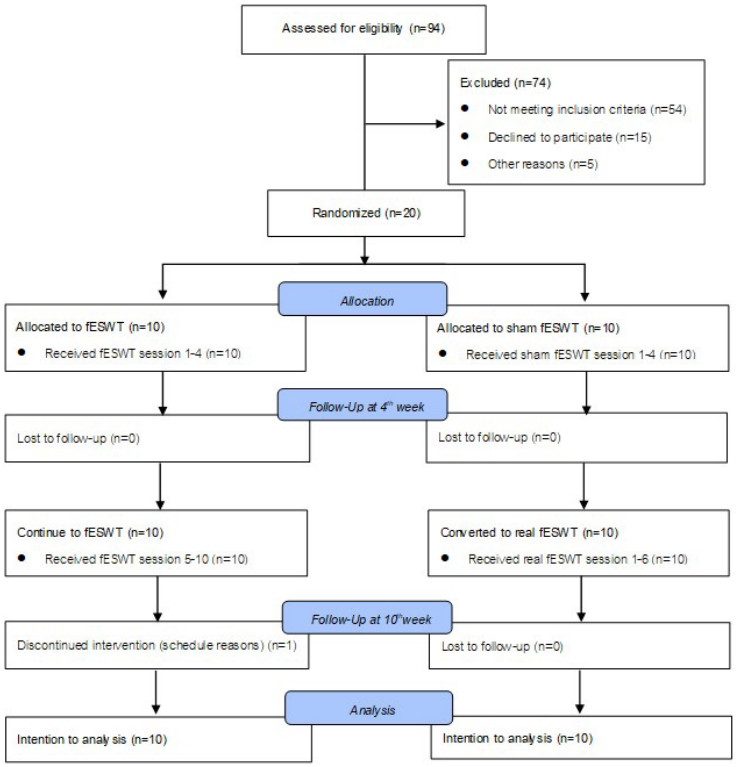


Figure 1. Flow of participants

Table 1. Baseline demographic and clinical characteristics of patients in the study

	Intervention group (n = 10)	Comparison group (n = 10)	*p*-value
Age (years)[1]	54 (15)	61 (9)	0.063
Gender (female)[1]	10 (100)	10 (100)	1.000
BMI (kg/m^2)[1]	26 (13)	22.5 (3)	0.123
Symptom duration (months)[1]	12 (21)	21 (26)	0.874
Dominant hand studied[2]	6 (60)	9 (90)	0.280
Repetitive work (hand function activity > 8 hours/day)[2]	6 (60)	6 (60)	1.000
BCTQ SYMPT[1]	2.1 (1.1)	2.0 (0.9)	0.323
BCTQ FUNCT[1]	1.6 (1.9)	1.6 (0.7)	0.311
DSL, (ms)[1]	3.8 (0.7)	3.5 (0.8)	0.063
DML, (ms)[1]	5.2 (1.5)	5.1 (2.4)	0.851
SNCV across wrists, (m/s)[1]	34.0 (6.7)	36.9 (8.5)	0.063
SNAP amplitude, (μV)[1]	22.4 (21.0)	40.8 (30.4)	0.123

[1]Median (IQR), [2]number (%)

BMI, Body mass index; BCTQ, The Boston Carpal Tunnel Questionnaire; SYMPT, symptoms; FUNCT, function; DSL, distal sensory latency; DML, distal motor latency; SNCV, sensory nerve conduction velocity; SNAP, Sensory nerve action potential

Table 2. Outcome variables at pre-treatment and post-treatment in each group

	Intervention group (n = 10)		Comparison group (n = 10)		between group *p*-value
	Median (IQR)	*p*-value	Median (IQR)	*p*-value	
BCTQ SYMPT					
Baseline	2.1 (1.6-2.8)		2.0 (1.3-2.2)		
4 weeks	1.6 (1.3-1.9)	0.022*	1.6 (1.1-1.9)	0.038*	0.949
10 weeks	1.5 (1.0-1.9)	0.001*	1.4 (1.0-2.0)	0.034*	-
BCTQ FUNCT					
Baseline	1.6 (1.3-2.8)		1.6 (1.2-1.9)		
4 weeks	1.4 (1.2-1.7)	0.025*	1.4 (1.1-1.7)	0.147	0.273
10 weeks	1.4 (1.2-1.6)	0.021*	1.2 (1.1-1.3)	0.025*	-
DSL (ms)					
Baseline	3.8 (3.4-4.2)		3.5 (2.9-3.8)		
4 weeks	3.6 (3.3-3.8)	0.184	3.8 (2.9-4.0)	0.041*	0.007†
10 weeks	3.4 (3.0-3.8)	0.053	3.6 (3.1-4.1)	0.066	-
DML (ms)					
Baseline	5.2 (4.7-6.2)		5.1 (4.3-6.7)		
4 weeks	5.2 (4.4-4.9)	0.100	5.2 (3.9-6.7)	0.995	0.280
10 weeks	5.0 (4.4-5.9)	0.193	4.6 (4.1-6.4)	0.251	-
SNCV across wrists (m/s)					
Baseline	34.0 (30.8-37.5)		36.9 (34.5-43.9)		
4 weeks	35.4 (34.2-39.2)	0.146	34.0 (32.1-43.4)	0.093	0.007†
10 weeks	37.6 (33.7-42.9)	0.059	36.2 (31.6-41.2)	0.043*	-
SNAP amplitude (μV)					
Baseline	22.4 (13.4-34.3)		40.8 (18.7-49.2)		
4 weeks	31.4 (25.7-49.1)	0.147	36.9 (18.7-49.2)	0.338	0.410
10 weeks	28.8 (17.7-41.7)	0.318	37.5 (24.8-47.5)	0.689	-

*Wilcoxon signed-rank test for within-group analysis; *p*-value is significant; †Mann-Whitney U test for between-group analysis of change from baseline to 4 weeks; p-value is significant

IQR, Interquartile Range; BCTQ, The Boston Carpal Tunnel Questionnaire; SYMPT, symptoms; FUNCT, function; DSL, distal sensory latency; DML, distal motor latency; SNCV, sensory nerve conduction velocity; SNAP, Sensory nerve action potential

fourth session, there was continued improvement in BCTQ and neurophysiologic parameters, but the improvement did not statistically significantly exceed the improvement from baseline to 4 weeks. (Table 3) Although improvement in BCQT, DSL was significantly prolonged in the comparison group, electrodiagnostic parameters improved after six sessions of real ESWT. (Table 4)

Regarding the MCID of BCTQ, there were more patients in the intervention group whose BCTQ SYMPT and FUNCT improved more than the MCID at 4 weeks, but that number of patients remained unchanged at week 10. In the comparison group, no patients exceeded the MCID of BCTQ, either

Table 3. Changes in the outcome variables from baseline to 4 weeks and 4 to 10 weeks in the intervention group

	Baseline to 4 weeks Mean (SD)	4 weeks to 10 weeks Mean (SD)	*p*-value[a]
BCTQ SYMPT	0.7 (0.8)	0.0 (0.6)	0.435
BCTQ FUNCT	0.5 (0.6)	0.0 (0.6)	0.846
DSL (ms)	0.2 (0.4)	0.2 (0.3)	0.176
DML (ms)	0.3 (0.5)	0.0 (0.6)	0.886
SNCV across wrists (m/s)	-2.3 (4.7)	-1.6 (3.5)	0.135

[a]Paired t-test for within-group analysis.

The minus value indicates increasing after treatment

SD, standard deviation; BCTQ, The Boston Carpal Tunnel Questionnaire; SYMPT, symptoms; FUNCT, function; DSL, distal sensory latency; DML, distal motor latency; SNCV, sensory nerve conduction velocity

Table 4. Changes in the outcome variables from baseline to 4 weeks and week 4 to week 10 in the comparison group

	Baseline to 4 weeks Mean (SD)	4 weeks to 10 weeks Mean (SD)	*p*-value[a]
BCTQ SYMPT	0.2 (0.3)	0.0 (0.6)	0.435
BCTQ FUNCT	0.2 (0.4)	0.0 (0.6)	0.846
DSL (ms)	-0.2 (0.3)	0.2 (0.3)	0.176
DML (ms)	-0.0 (0.5)	0.0 (0.6)	0.886
SNCV across wrists (m/s)	2.0 (3.4)	-1.6 (3.5)	0.135

[a]Paired t-test for within-group analysis.

SD, standard deviation; BCTQ, The Boston Carpal Tunnel Questionnaire; SYMPT, symptoms; FUNCT, function; DSL, distal sensory latency; DML, distal motor latency; SNCV, sensory nerve conduction velocity

Table 5. The number and percentage of patients who have BCTQ scores improved above the MCID in each group (n = 10)

	Intervention group n (%)	Comparison group n (%)
Improvement of BCTQ SYMPT at the 4th week	5 (50)	1 (10)
Improvement of BCTQ FUNCT at the 4th week	4 (40)	1 (10)
Improvement of BCTQ SYMPT at the 10th week	5 (50)	4 (40)
Improvement of BCTQ FUNCT at the 10th week	4 (40)	5 (50)

Data are presented as number (%), MCID of BCTQ SYMPT = 0.8, MCID of BCTQ FUNCT = 0.5

BCTQ, The Boston Carpal Tunnel Questionnaire; SYMPT, symptoms; FUNCT

SYMPT or FUNCT, while at week 10, 40% and 50% of the patients exceeded the MCID of BCTQ SYMPT and FUCT, respectively. (Table 5)

The average duration of wearing wrist orthoses at night was comparable in both groups: 4.8 (SD = 1.5) hours per day in the intervention groups and 4.7 (SD = 1.6) hours per day in the comparison group. There were no complications in either group, and no additional medicine was required.

Discussion

This randomized, double-blind, controlled trial investigated the effect of f ESWT combined with night splints in moderate CTS patients. Beyond the fourth session of f ESWT, we discovered that the intervention group improved significantly more than the comparison group in median nerve DSL and SNCV across the wrist. These findings are consistent with recent meta-analyses indicating that ESWT exerts an excitatory effect on peripheral nerves, particularly sensory nerves.[15] Electrophysiological findings should be interpreted with caution due to the modest level of change. However, the significantly higher proportion of patients in the intervention group achieving BCTQ scores above the MCID indicates meaningful improvement in functional capacity and symptom severity. When we extended the f ESWT sessions to 10, the improvement was maintained, but the change was less than the first four sessions. Furthermore, the number of patients whose BCTQ exceeded the MCID in the intervention group remained unchanged from the previous four weeks. In contrast, in the comparison group, the number increased after sixth sessions of real f ESWT. Our results support the therapeutic effect of ESWT reported in previous studies.[8,9,12,16-18] To date, there are no clear guidelines for using ESWT in CTS patients. Few studies have investigated the effect of f ESWT using different protocols.[8,9,12] Most research, including

the present study, have employed low energy flux density, which has been proven to enhance the mechanism that promotes axonal regeneration following axotomy.[6] However, the number of shots and sessions, as well as the adjuvant treatments, in those studies have varied. Seok et al. reported that a single session of f ESWT could be as effective as a local corticosteroid injection for CTS.[8] Similarly, Aramrussameekul et al. found no significant difference in clinical efficacy between the two treatments.[19] Notably, Atthakomol et al. found that a single session of radial ESWT provided long-lasting benefits.[20] Vahdatpour et al. demonstrated that four sessions of f ESWT led to significant reductions in VAS scores and improved BCTQ and electrodiagnostic parameters.[12] Paoloni et al. reported that three sessions of f ESWT in patients with mild to moderate CTS resulted in more significant improvements compared to ultrasound and cryo-ultrasound treatments.[18]

To our knowledge, the present study is the first randomized double-blinded study to evaluate the effect of and compare the therapeutic outcomes of ESWT sessions combined with a night wrist splint. Only one clinical study conducted by Ke et al. in 2016 comparing the number of sessions of ESWT showed that three sessions of radial ESWT had a cumulative clinical effect. In contrast, a single session showed only an insignificant effect.[17] A 2019 animal model by Sagir et al. found ESWT applied to an injured nerve enhances myelin sheath thickness and promotes regeneration. That study also reported that focused ESWT performed better than radial ESWT and did significantly better when applied at lower impulses.[21] This may explain why four sessions yielded more improvement per session than 10 sessions. So far, no research has been conducted on the ceiling effect of ESWT. According to our findings, four sessions may be more cost-effective in clinical practice.

In our study, the comparison group also improved in BCQT, which may be attributed to the application of wrist splinting, a plausible mechanism of edema reduction. Manente et al. found a significant reduction in BCQT in CTS patients wearing a night wrist splint compared to a control group, but no significant difference in electrophysiologic evidence.[22] However, a meta-analysis provided inadequate data to substantiate the clinical usefulness of splints.[23] Despite BCQT improvement, in the present study we observed electrophysiologic parameter progression in the comparison group while wearing only a night splint. However, the electrophysiologic parameters were reversible after six sessions of ESWT. Park et al. showed that ESWT could inhibit the progression of CTS in an animal model. Hence, early administration of ESWT is suggested for a better outcome.[24]

Study limitations

There are several limitations in our study. First, we were able to include only about 50% of all the eligible patients, and all the participants were female both of which could limit the results' generalizability. Second, it would have been desirable to follow up for a more extended period. According to previous studies, the effect of ESWT lasts longer than 3 months and is still apparent after 6 months.[12,18] Third, imaging studies such as diagnostic ultrasonography were not performed in our study. Lastly, we used the original BCTQ and verbally translated it into Thai, but that translation was not validated for psychometric properties. Future studies should include a larger number of patients with more extended follow-up periods as well as imaging studies such as ultrasonography which might be helpful in assessing the effects of ESWT on median nerve morphological change and validating the Thai version of the BCTQ to ensure accurate and reliable outcome measurement.

Conclusion

Our preliminary findings indicate that up to ten sessions of f ESWT combined with a night splint are safe and effective for improving function and electrophysiologic parameters in patients with moderate CTS although four sessions may be more cost-effective.

Conflict of interest disclosure

The authors have no conflict of interest to report.

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Data availability

The datasets generated and analyzed during the present study are not publicly available due to ethical approval limitations involving patient data and anonymity. However, they are available from the corresponding author upon reasonable request.

Author contribution

Cherdpong Pimubol: conceptualization, investigation, formal analysis, writing- original draft,

Jirapa Champaiboon: conceptualization, investigation, writing - review & editing,

Jariya Boonhong: conceptualization, methodology, funding acquisition, supervision.

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