## **Randomized Controlled Trial**



## Comparison of Ultrasound-guided Transverse **Carpal Ligament Release via Different Approaches in Carpal Tunnel Syndrome: A Prospective, Randomized, Controlled Trial**

Xiaochen Shi, PhD1, Jiaan Zhu, PhD2, Guicheng Li, MD1, Xuesong Gu, MD3, and Hailin Xu, PhD1

From: Department of Orthopedics and Trauma, Peking University People's Hospital, Peking University, Beijing, China; <sup>2</sup>Department of Ultrasound, Peking University People's Hospital, Peking University, Beijing, China; 3Department of Vascular Ultrasound, Jilin City Central Hospital, Jilin Province, China

Address Correspondence: Hailin Xu, PhD Department of Orthopedics and Trauma, Peking University People's Hospital, Peking University No.11 Xizhimen South Street Beijing, 100044, China E-mail: xuhailinsu@sina.com

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Free full article: www.painphysicianjournal.com Background: Ultrasound-guided transverse carpal ligament (TCL) needle release has been demonstrated to be an effective treatment for carpal tunnel syndrome (CTS). However, no existing evidence has investigated the comparative efficacy of different release approaches.

Objective: To compare the efficacy of ultrasound-guided TCL needle release via different approaches for patients with mild to moderate CTS over a 12-month follow-up.

Study Design: A prospective, randomized, controlled trial.

Setting: Outpatient clinic at a university hospital.

Methods: Sixty-four patients with mild to moderate CTS (> 3 months' duration) were randomly assigned to either the long-axis group (one session of ultrasound-guided corticosteroid injection plus long-axis TCL needle release) or the short-axis group (one session of ultrasound-guided corticosteroid injection plus short-axis TCL needle release) in a one-to-one ratio. The primary outcomes were the symptom severity scale (SSS) and functional severity scale (FSS) scores of the Boston Carpal Tunnel Questionnaire (BCTO). The secondary outcomes were electrophysiological studies, including distal motor latency (DML) and sensory nerve conduction velocity (SNCV), crosssectional area (CSA) of the median nerve (MN), and patient-reported successful clinical response. Assessments were performed before treatment and at one, 3, 6, and 12 months after treatment.

Results: A total of 60 patients (30 per group) completed the trial. Compared to the baseline, both groups exhibited improvement in SSS, FSS, SNCV, DML, and CSA at all follow-up time points, with statistical differences for SSS, FSS, and SNCV at 3, 6, and 12 months (P < 0.05), DML at 6 and 12 months (P < 0.05), and CSA at each follow-up time point (P < 0.05). Compared to the shortaxis group, the long-axis group exhibited more improvement in SSS and FSS at all follow-up time points, with statistical differences at 3, 6, and 12 months (P < 0.05), and in SNCV and DML at 6 and 12 months (P < 0.05). Although the long-axis patients exhibited more improvement in their wrists' CSAs, the intergroup differences were nonsignificant at all follow-up time points (P > 0.05). Four patients in the short-axis group experienced recurrent symptoms and underwent surgery at 12 months, whereas no recurrence was observed in the long-axis group.

Limitations: A relevant future trial with a longer follow-up period than this one used is still necessary.

**Conclusions:** Ultrasound-guided TCL needle release via the long-axis approach appears to be more effective than the short-axis approach for treating mild to moderate CTS.

Key words: Carpal tunnel syndrome, transverse carpal ligament, needle release, 12-month efficacy, corticosteroid, comparison, ultrasound, different approaches

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arpal tunnel syndrome (CTS), one of the most frequent entrapment neuropathies, is characterized by pain, numbness, tingling, and weakness in the regions innervated by the median nerve (MN) (1). Generally, CTS is believed to result from compression of the MN as it passes through a restricted, narrowed carpal tunnel due to gradual ischemia and fibrosis (2). A systematic review published in 2023 demonstrated that impaired MN excursion featured significantly patients with CTS (3).

To manage CTS, conservative therapy (oral medication, exercises, splints, physical therapy, etc.) is attempted initially (4). However, conservative treatment is typically effective only for patients with early-stage or mild CTS (5). Surgical intervention is usually recommended for patients with late-stage or severe CTS due to the surgery's possible complications and long recovery period (6-8). To minimize the risk of surgical complications, a technique known as ultrasound-guided transverse carpal ligament (TCL) transection, involving a sharp-bladed knife, was introduced (9,10). However, the specific training required to perform a TCL transection and the sharp blade's potential to damage the nerve the limit the procedure's use. Recently, a combination of ultrasound-guided TCL needle release and corticosteroid injections has been reported to be associated with favorable outcomes (11-16). Moreover, this procedure can be performed in the outpatient clinic under local anesthesia, leaves no scars on the patient's skin, and has a shorter recovery period.

Currently, there are 2 main approaches of the ultrasound-guided TCL needle release: the long-axis approach and the short-axis approach. The long-axis approach can decompress the carpal tunnel more extensively. In contrast, the short-axis approach can release the subsynovial connective tissue (SSCT) simultaneously. Operators select the release approach based on their own preferences. The evidence of the approaches' comparative efficacy is limited; and the long-term efficacy of the TCL needle release remains unclear. Assessing the options for the release approach based on evidence is important. Hence, this trial aimed to assess the 12-month efficacy of the combination of ultrasound-guided corticosteroid injections and TCL needle release. The trial's other purpose was to investigate the comparative therapeutic effectiveness of the long- and short-axis approaches in patients with mild to moderate CTS.

## **M**ETHODS

This prospective, randomized, controlled trial was conducted at Peking University People's Hospital with

the approval of a local ethical committee (2024PHB019-001) and officially registered at ClinicalTrials.gov (NCT06251674). All enrolled patients provided written informed consent. The trial was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

From September 2021 to December 2022, a total of 68 consecutive patients with mild to moderate CTS visiting the outpatient clinic of the Department of Ultrasound were eligible, and 64 of them were enrolled in the trial. The patients were randomized to either the long- or short-axis group in a one-to-one ratio using random number table method. The inclusion criteria were as follows: (I) unilateral CTS; (II) age between 18 and 80 years; (III) typical clinical symptoms of CTS that persisted for more than 3 months; (IV) electrophysiological parameters supportive of mild to moderate CTS (mild: abnormal sensory nerve conduction velocity [SNCV] with normal distal motor latency [DML]; moderate: abnormal DML and SNCV) (17,18); (V) CTS confirmed by high-resolution ultrasound (19). The exclusion criteria were: (I) pregnancy; (II) concurrence with rheumatic diseases, chronic renal failure, hypothyroidism, or diabetes mellitus; (III) a known history of corticosteroid or lidocaine allergy; (IV) polyneuropathy or cervical radiculopathy; (V) previous surgery or injection for CTS; (VI) CTS caused by trauma, surgery, intracarpal lesions, or MN lesions; (VII) malignant tumors or severe cardiorespiratory diseases; (VIII) withdrawal from the trial or refusal to participate.

## **Ultrasound-guided Procedures**

All procedures were conducted by a physician (with 8 years experience in administering of ultrasound-guided musculoskeletal injections) using the Aplio i800 (Canon Medical Systems Corporation) with an 18 MHz high-frequency transducer.

The patients were seated on a chair with their affected wrists up in a slight dorsiflexion position. Under rigorous sterile antisepsis, a transducer was scanned transversely from the proximal to the distal end of each affected wrist to assess the overall situation of the carpal tunnel. Then, the transducer was rotated 90° and placed at about the level of the proximal flexor crease of the wrist and maintained perpendicular to the longitudinal axis of the MN.

Under continuous ultrasound guidance, a 22-gauge needle on a 1 mL syringe containing 1% lidocaine was introduced into the carpal tunnel from the proximal end using an in-plane approach, and about 5 mL of 1% lidocaine was injected layer by layer as the needle was

guided down into the carpal tunnel. Once the needle tip reached the surface of the MN, a 5 mL solution (one mL of compound betamethasone [Schering Pharmaceutical Co., Ltd.], 2 mL of 2% lidocaine, and 2 mL of 0.9% saline) was injected. TCL needle release was then performed by moving the needle forward and backward through the TCL and gradually adjusting the tip from proximal to distal to ensure the carpal tunnel was fully decompressed (Fig. 1). The needle tip was also verified in the transverse plane. TCL needle release was considered adequate when the needle could easily pass through the ligament, with 10-15 perforations on average.

In the short-axis approach, the procedures were similar to those in the long-axis group, except that the release was performed via an in-plane ulnar approach. To eliminate the confounding effect of hydrodissection, we adopted the same procedure and volume for the corticosteroid injections as we did for the long-axis group. After the injection, the transducer was placed transversely at the scaphoid-pisiform bone level, and the TCL and MN were observed in the short-axis plane. The needle was introduced from the ulnar end using an in-plane approach. The TCL and SSCT were perforated 10-15 times, respectively (Fig. 2A and 2B), until the needle could easily pass through.

During the whole procedure, continuous ultrasound guidance was provided to avoid injury to the nerve, the vascular channel, or any other structure. All patients were monitored for 30 minutes after the procedure for any possible complication, such as pain, ecchymosis, nerve trauma, or bleeding. The puncture site was covered with a bandage for 24 hours, and the wrist was immobilized for 3 days. An assistant researcher followed up on all the patients to prohibit any alternative treatment during the trial period.

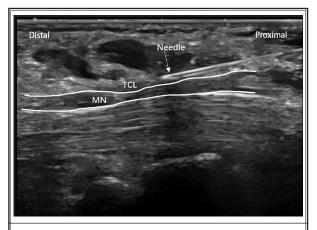
#### **Outcome Measurements**

An independent investigator, blinded to the randomization and treatment, conducted all the evaluations. The evaluations were performed at the baseline and one, 3, 6 and 12 months after the treatment. The investigator also recorded any evidence of complications at each follow-up time point.

## **Primary Outcome**

# **Boston Carpal Tunnel Syndrome Questionnaire** (BCTQ)

BCTQ is the tool used most often for evaluating CTS symptoms. It contains 11 items on a symptom severity



 $\label{eq:condition} \begin{tabular}{ll} Fig.~1.~Ultrasound-guided~TCL~needle~release~via~long-axis~approach. \end{tabular}$ 

TCL: transverse carpal ligament; MN: median nerve; Arrow: needle

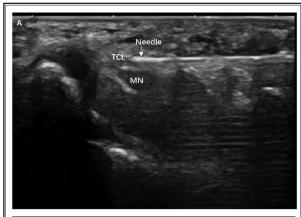




Fig. 2. A) Ultrasound-guided TCL needle release via short-axis approach. B) Ultrasound-guided SSCT release via short-axis approach.

TCL: transverse carpal ligament; MN: median nerve; Arrow: needle; SSCT: subsynovial connective tissue

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scale (SSS) and 8 items on a function status scale (FSS). Each item is scored from one to 5, with higher scores indicating greater severity and dysfunction. The minimal clinically important difference (MCID) is an improvement of 0.8 and 0.5 in the SSS and FSS scores, respectively (20).

## **Secondary Outcomes**

#### **Electrophysiological Measurements**

The DML and SNCV were measured according to the recommendations of the American Academy of Orthopedic Surgeons (17,18). To measure the SNCV, a stimulator was positioned 14 cm proximal to the active electrode over the second interphalangeal joint. To measure the DML, the active electrode was placed on the abductor pollicis brevis muscle with a stimulator 8 cm proximal to the active electrode.

#### Cross-Sectional Area (CSA) of the MN

Patients were seated in a neutral position with the affected palms up and the fingers semi-extended. The CSA was measured at the level of the scaphoid-pisiform bone in the transverse axis. Measurements were performed manually by tracing a continuous line on the inner hyperechoic rim using an electronic caliper. The average value of 3 repeated measurements was used for statistical analysis.

## **Global Improvements**

Patients were asked to report the therapeutic effects at each follow-up time point on one of 5 levels: excellent, good, fair, no change, worsened (21). The estimation of excellent or good was considered a successful clinical response.

## Sample Size

G\*Power version 3.1.9.2 (University of California—Los Angeles, PRID: SCR 013762) was utilized to calculate the sample size (22). A preliminary power analysis was performed using an independent t-test to compare intergroup differences in SSS and FSS scores at the baseline and 12 months after the treatment. We used a large effect size due to absence of preliminary data. The results suggested that at least 54 patients were required to achieve sufficient power ( $[1 - \beta] = 0.80$ ,  $\alpha = 0.05$ , effect size = 0.85).

#### **Statistical Analyses**

Statistical analyses were conducted using SPSS<sup>TM</sup> 26.0 version (IBM<sup>TM</sup> Corporation). P < 0.05 was con-

sidered statistically significant (2-tailed). Normal distribution data were presented as mean ± SE (standard error). Categorical data were presented as numbers (%). Baseline characteristics between the groups were compared using the chi-squared test or Fisher's exact test for categorical data and the independent t-test for continuous data. The chi-squared test was used to compare the successful clinical response of the 2 groups at all follow-up time-points. The independent t-test was used for intergroup comparisons of the SSS and FSS scores, CSA, SNCV, and DML. The repeated measures Friedman test, followed by the post hoc Bonferroni test, was used to compare continuous data within the same group at different time points.

## RESULTS

Thirty patients in each group completed the trial. Two patients in each group were lost to the follow-up, as shown in the flow chart (Fig. 3). There were no statistical differences in baseline clinical or demographic characteristics between the 2 groups (Table 1).

Compared with the baseline, both groups exhibited improvements in SSS, FSS, SNCV and DML at all follow-up assessments, with significant statistical differences in SSS, FSS, and SNCV at 3, 6, and 12 months (P < 0.05) and DML at 6 and 12 months (P < 0.05) (Tables 2 and 3). At all follow-up time points, both groups' MNs also exhibited improvement in their CSAs from the baseline (P < 0.05). The long-axis group showed greater improvements in their SSS and FSS scores than did the short-axis group at all follow-up time points, with significant statistical differences at 3, 6, and 12 months (P < 0.05) (Tables 2 and 3) (Fig. 4A and 4B); SNCV and DML were also more improved in the long-axis group, with statistical differences at 6 and 12 months (P < 0.05) (Table 3). Although the long-axis group showed more improvements in the CSAs than did the shortaxis group, the differences were nonsignificant at all follow-up time points (P > 0.05) (Table 3).

A respective total of 50.0% (15/30) vs. 43.3% (13/30), 80.0% (24/30) vs.70.0% (21/30), 93.3% (28/30) vs. 83.3% (25/30), and 93.3% (28/30) vs. 70.0% (21/30) of patients reported successful clinical response at one, 3, 6, and 12 months after treatment in the long-axis and short-axis groups (P = 0.796, 0.552, 0.121, 0.042) (data not shown). Four patients in the short-axis group reported recurrent symptoms and underwent surgery 12 months after the procedure, whereas no recurrence was reported in the long-axis group.

No pain was reported by patients during the pro-

cedure after they received a local anesthetic. A few hours after the procedure, 3 patients in each group reported localized pain, which resolved spontaneously 2 days later. All patients denied receiving alternative treatments during the trial period. No procedural complications were observed in either group.

#### **D**ISCUSSION

Our trial is the first prospective, randomized, controlled trial to compare the efficacy of the long- and short-axis approaches in ultrasound-guided TCL needle release in patients with mild to moderate CTS. The main findings suggested that the long-axis approach was more beneficial than the short-axis approach in terms of improvements in symptom severity, functional ability, and nerve function at 12 months after treatment.

Combinations of ultrasound-guided percutaneous TCL needle release with corticosteroid injections are increasingly used in

clinical practice (11-16). Overall, the combined therapy has proven to be more effective than corticosteroid injections or TCL needle release alone (12-14). A study by Zeng et al (11) concluded that the combined therapy was more beneficial than mini-open surgery in its improvements to pain, disability, and electrophysiological test results at 3 months after treatment. Despite the well-recognized efficacy of the combined therapy, the comparative efficacy of different approaches is still unknown. A conclusion cannot be drawn from previous studies because of differences in patient selection. Additionally, the long-term efficacy of this procedure remains nebulous.

A thickened TCL that directly compresses the MN induces CTS, which in turn exacerbates intracarpal inflammation. This condition causes a cycle of intracarpal swelling and further MN compression (23-25). Ultrasound-guided corticosteroid injection reduces intracarpal in-

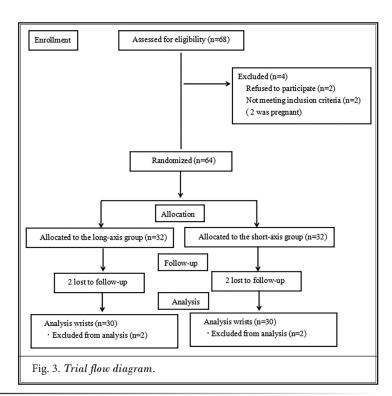


Table 1. Patients' baseline demographic and clinical characteristics.

Characteristics	Long-Axis Group (n = 30)	Short-Axis Group (n = 30)	<sup>a</sup> P-value
Age (year) ± SE (range)	51.9 ± 1.4 (42-69)	51.7 ± 1.3 (44-66)	0.919
Gender, n (%)	-	-	0.761
male	8 (26.7)	6 (20.0)	
female	22 (73.3)	24 (80.0)	
Body height (cm) ± SE (range) Body weight (kg) ± SE (range)	165 ± 14 (158-176) 64.7 ± 1.5	$167 \pm 13 (156-183)  64.6 \pm 1.6$	0.442 0.944
Duration (month) ± SE (range)	27.8 ± 3.0 (3-66)	26.7 ± 3.7 (3-72)	0.811
Lesion site, n (%)	-	-	0.596
left	10 (33.3)	13 (43.3)	
right	20 (66.7)	17 (56.7)	
Grading, n (%)	-	-	0.605
Mild	11 (36.7)	12 (40.0)	
Moderate	19 (63.3)	18 (60.0)	
SSS (SE)	2.55 ± 0.10	$2.49 \pm 0.10$	0.712
FSS (SE)	$2.50 \pm 0.10$	$2.46 \pm 0.10$	0.737
SNCV (m/s) (SE)	33.13 ± 1.51	33.27 ± 1.41	0.936
DML (ms) (SE)	$4.76 \pm 0.18$	$4.73 \pm 0.18$	0.925
CSA (mm²) (SE)	$14.2 \pm 0.3$	$14.0 \pm 0.4$	0.885

Continuous data were presented as mean  $\pm$  standard error.

SNCV, sensory nerve conduction velocity; DML, distal motor latency; CSA, cross-sectional area; SE, standard error; SSS, symptom severity scale; FSS, functional status scale.

www.painphysicianjournal.com E681

<sup>&</sup>lt;sup>a</sup>Independent t-test, Chi-square test, or Fisher exact test.

P < 0.05 is considered statistically significant.

 $Table\ 2.\ Both\ groups'\ SSS\ and\ FSS\ scores\ before\ and\ after\ treatment.$ 

	Long-Axis Group (n = 30)	Mean Difference (95% CI)	<sup>a</sup> P-value	Short-Axis Group (n = 30)	Mean Difference (95% CI)	<sup>a</sup> P-value	Intergroup Difference (95% CI)	<sup>b</sup> P-value
SSS Baseline	$2.55 \pm 0.10$	-	-	$2.49 \pm 0.10$	-	-	-	0.712
Month 1	$2.08 \pm 0.10$	-0.48 (-0.44 to -0.53)	0.143	$2.17 \pm 0.10$	-0.32 (-0.29 to -0.53)	0.071	-0.16 (-0.22 to 0.02)	0.466
Month 3	1.41 ± 0.10	-1.14 (-0.94 to -1.21)	<0.001	1.58 ± 0.10	-0.91 (-0.80 to -0.99)	< 0.001	-0.23 (-0.31 to -0.09)	0.024
Month 6	1.09 ± 0.10	-1.46 (-1.21 to -1.61)	<0.001	1.25 ± 0.10	-1.24 (-1.16 to -1.29)	< 0.001	-0.23 (-0.35 to -0.05)	< 0.001
Month 12	1.09 ± 0.10	-1.46 (-1.22 to -1.65)	<0.001	$1.34 \pm 0.10$	-1.16 (-0.88 to -1.17)	< 0.001	-0.29 (-0.50 to -0.02)	< 0.001
FSS Baseline	$2.50 \pm 0.10$	-	-	$2.46 \pm 0.10$	-	-	-	0.737
Month 1	1.92 ± 0.10	-0.60 (-0.53 to -0.70)	0.128	$2.00 \pm 0.10$	-0.46 (-0.53 to -0.64)	0.055	-0.14 (-0.33 to 0.00)	0.498
Month 3	1.43 ± 0.10	-1.08 (-0.97 to -1.19)	<0.001	1.67 ± 0.10	-0.80 (-0.75 to -0.85)	< 0.001	-0.28 (-0.10 to -0.30)	0.021
Month 6	$1.08 \pm 0.10$	-1.42 (-1.28 to -1.60)	<0.001	1.29 ± 0.10	-1.16 (-1.09 to -1.24)	< 0.001	-0.28 (-0.10 to -0.40)	0.003
Month 12	1.09 ± 0.10	-1.41 (-1.30 to -1.63)	<0.001	1.42 ± 0.12	-1.04 (-0.93 to -1.12)	< 0.001	-0.40 (-0.52 to -0.19)	0.004

Data were presented as mean  $\pm$  standard error.

Table 3. Both groups' SNCV, DML and CSA before and after treatment.

	Long-Axis Group (n = 30)	Mean Difference (95% CI)	<sup>a</sup> P-value	Short-Axis Group (n = 30)	Mean Difference (95% CI)	<sup>a</sup> P-value	<sup>b</sup> P-value
SNCV Baseline	33.13 ± 1.51	-	-	33.27 ± 1.41	-	-	0.936
Month 1	35.03 ± 1.56	-1.90 (-2.00 to -0.60)	0.305	$35.00 \pm 1.48$	-1.83 (-2.09 to -1.57)	0.160	0.975
Month 3	40.13 ± 1.38	-6.90 (-7.35 to -6.05)	< 0.001	38.17 ± 1.39	- 4.9 (-5.26 to -4.54)	< 0.001	0.318
Month 6	44.67 ± 1.16	-11.24 (-11.80 to -9.40)	< 0.001	40.83 ± 1.41	-7.56 (-9.00 to -5.88)	< 0.001	0.040
Month 12	44.67 ± 1.16	-11.24 (-12.24 to -8.76)	< 0.001	38.89 ± 1.47	-5.60 (-10.34 to -0.86)	0.008	0.006
DML Baseline	$4.76 \pm 0.18$	-	-	$4.73 \pm 0.18$	-	-	0.925
Month 1	$4.70 \pm 0.18$	-0.06 (-0.12 to -0.00)	1.000	$4.72 \pm 0.17$	-0.01 (-0.02 to 0.00)	1.000	0.957
Month 3	$4.47 \pm 0.15$	-0.30 (-0.10 to -0.60)	0.062	$4.56 \pm 0.15$	-0.18 (-0.10 to -0.30)	0.062	0.766
Month 6	$4.09 \pm 0.10$	-0.68 (-0.30 to -1.00)	< 0.001	4.42 ± 0.15	-0.31 (-0.10 to -0.65)	< 0.001	0.049
Month 12	$4.09 \pm 0.10$	-0.68 (-0.50 to -1.30)	< 0.001	$4.46 \pm 0.15$	-0.27 (-0.20 to -0.59)	0.001	0.031
CSA Baseline	14.2 ± 0.3	-	-	$14.0 \pm 0.4$	-	-	0.885
Month 1	12.3 ± 0.3	-1.8 (-1.9 to -1.7)	0.037	$12.8 \pm 0.3$	-1.2 (-1.3 to -1.1)	0.015	0.238
Month 3	$12.0 \pm 0.3$	-2.1 (-2.2 to -2.0)	< 0.001	$12.4 \pm 0.3$	-1.6 (-1.8 to -1.5)	< 0.001	0.335
Month 6	$11.8 \pm 0.3$	-2.2 (-2.4 to -2.1)	< 0.001	$12.2 \pm 0.3$	-1.8 (-2.0 to -1.6)	< 0.001	0.336
Month 12	11.8 ± 0.3	-2.2 (-2.4 to -2.0)	< 0.001	12.5 ± 0.4	-1.5 (-1.7 to -1.2)	< 0.001	0.144

Data were presented as mean  $\pm$  standard error.

SSS, symptom severity scale; FSS, functional status scale; CI, confidence intervals.

<sup>&</sup>lt;sup>a</sup>*P*-value obtained from Friedman test with subsequent post hoc Bonferroni test.

<sup>&</sup>lt;sup>b</sup>Independent t-test (change from baseline [mean difference] between groups).

P < 0.05 is considered statistically significant.

SNCV, sensory nerve conduction velocity; DML, distal motor latency; CSA, cross-sectional area; CI, confidence intervals.

<sup>&</sup>lt;sup>a</sup>P-value obtained from Friedman test with subsequent post hoc Bonferroni test.

<sup>&</sup>lt;sup>b</sup>Independent t-test (change from baseline [mean difference] between groups).

P < 0.05 is considered statistically significant.

flammation rapidly (26-28); TCL needle release relieves compression of the MN and reduces tension of the intracarpal structures (12,13). In the present trial, both groups showed significant improvements in all the measured parameters at 12 months after treatment. Therefore, we believe that this combined therapy may yield long-term efficacy.

Adhesion of the MN with the TCL may induce impaired nerve excursion (3). In our trial, the long-axis approach released the TCL from the proximal to the distal end, resulting in more extensive decompression of the carpal tunnel. By this approach, we could decrease the MN gliding resistance more sufficiently. In contrast, the short-axis approach released the TCL only at the inlet of the carpal tunnel. The residual adhesion after insufficient release might induce recurrent CTS (29). Although the short-axis approach can release the SSCT simultaneously, SSCT is a pathological change that follows MN compression and may occur in severe cases or late stage of CTS (30,31). Thus, patients with SSCT should seek surgical intervention (32-34).

Compared to the short-axis group, the longaxis group exhibited more significant improvements in BCTQ scores and results of electrophysiological studies, except at the first month after treatment. The absence of intergroup differences in the initial month might have occurred because the corticosteroid had already exerted its anti-inflammatory function and overlapped the effect of the needle release. From the third to the sixth month, the long-axis group showed more significant improvements in pain and disability than did the short-axis group; from the sixth to the twelfth month, the clinical and neurophysiological parameters remained stable in the long-axis group, whereas those parameters in the short-axis group exhibited slight deterioration on average; 4 patients in the short-axis group required surgery at 12 months due to recurrent symptoms, whereas no recurrence was reported in the long-axis group. Since we adopted the same injection procedure for both groups, the intergroup differences were due to the different approaches of the TCL needle release. Therefore, we believe the long-axis approach had superior efficacy to the short-axis approach in the long term. Although the intergroup differences in SSS and FSS scores were statistically significant, the differences did not reach the point of the MCID. Thus, their clinical significance is still uncertain.

Ultrasound-guided TCL needle release provides lower cost, faster recovery, and fewer complications than does surgical treatment; and it is less traumatic

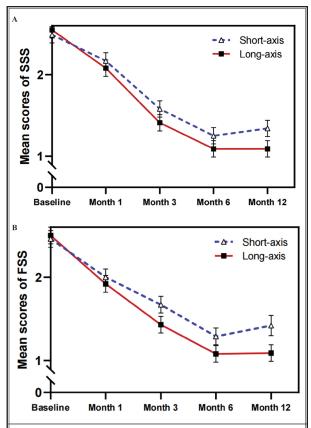


Fig. 4. A) The mean scores of SSS in both groups at each follow-up time point (mean  $\pm$  standard error). B) The mean scores of FSS in both groups at each follow-up time point (mean  $\pm$  standard error). SSS: symptom severity scale; FSS: functional status scale.

and technically demanding than ultrasound-guided TCL transection. Among the patients in the long-axis group, 93.3% (28/30) reported successful clinical response at the twelfth month, and no cases reported recurrence or any complications during the trial period. Additionally, the long-axis approach may result in a lower risk of damage to the surrounding structures of the MN. Hence, we recommend this procedure as the primary method for treating mild to moderate CTS.

To ensure procedural success, the following rules should be observed: (I) during needle release, the needle tip should always be visible to avoid damaging the MN, vascular channels, tendons or other structures; (II) the space of the carpal tunnel is limited, so slight wrist extension is necessary to increase the puncture area; and (III) the TCL is stiffer in patients with CTS, so there will be a sense of resistance during needle release. The needle should not be withdrawn until it can easily pass

though the TCL, or else the release may be inadequate. Lastly, (IV) the corticosteroid HD must be performed after the needle tip has reached the surface of the MN. If the position of the needle tip is not clear, the clinician must use normal saline to confirm its position.

#### Limitations

Our trial has some limitations. First, we did not address the effect of spontaneous remission. However, the mean durations of symptom onset for both groups were 28 and 27 months, respectively. The possibility of spontaneous remission was relatively small. Although we did not include a sham group, our results indicated substantial efficacy of needle release for patients with mild to moderate CTS. Second, although the long-axis group showed greater improvement in the CSA than the short-axis group at all the follow-up time points, the differences did not reach statistical significance. Therefore, other ultrasound parameters, such as superb microvascular and shear-wave elastography, may

be needed to help clarify the sonographic differences between the 2 approaches. Third, a trial with a longer follow-up period is still necessary.

## **C**ONCLUSION

Our trial demonstrated that ultrasound-guided percutaneous TCL needle release via the long-axis approach was more effective than the short-axis approach in improving pain, disability, and nerve function during a 12-month follow-up.

#### **Author Contributions**

Xiaochen Shi and Hailin Xu were responsible for conception and design. Xiaochen drafted the article; Hailin Xu revised the manuscript critically for important intellectual content. Jiaan Zhu provided administrative support. Guicheng Li acquired and interpreted the data. Xuesong Gu was responsible for the data collection and assembly. All authors were responsible for the final approval of the manuscript.

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