Application of Osborne's Ligament Suspension and Ulnar Nerve Anterior Transposition in Conjunction with Transcutaneous Electrical Nerve Stimulation for Managing Cubital Tunnel Syndrome: A Retrospective Study

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AIM: To explore the effectiveness and safety of Osborne's ligament suspension and ulnar nerve anterior transposition (OLSUNAT) in conjunction with transcutaneous electrical nerve stimulation (TENS) for managing cubital tunnel syndrome (CTS).

METHODS: A total of 116 individuals diagnosed with CTS who underwent OLSUNAT in our hospital between October 2020 and December 2023 were retrospectively selected. They were divided into a treatment group (62 cases) and a control group (54 cases) based on whether they received subsequent TENS. Observation indicators included pain level, numbness, ulnar nerve conduction velocity, strength of the abductor of the little finger, two-point discrimination, elbow range of motion, fine motor activities of the upper limb and hand, SF-36 scores, and incidence of complications.

RESULTS: No significant differences in baseline characteristics were identified between the treatment and control groups (p > 0.05). After treatment, both groups showed remarkable improvements in pain level, numbness, motor nerve conduction velocity (MCV), sensory nerve conduction velocity (SCV), strength of the abductor of the little finger, two-point discrimination, elbow range of motion, Simple Test for Evaluating Hand Function (STEF) score, and SF-36 scores compared to before treatment (p < 0.05). However, the treatment group showed greater progress than the control group (p < 0.05). Although the overall incidence of complications in the treatment group was slightly lower than in the control group, this difference did not reach statistical significance (p > 0.05).

CONCLUSIONS: OLSUNAT combined with TENS offers significant advantages in managing CTS, effectively alleviating symptoms, promoting nerve and elbow function recovery, and improving patients' quality of life while demonstrating high safety. However, further extensive and long-term studies are needed to confirm its sustained efficacy and safety.

Keywords: cubital tunnel syndrome; Osborne's ligament suspension and ulnar nerve anterior transposition; transcutaneous electrical nerve stimulation; nerve function; elbow function; complications

Introduction

Cubital tunnel syndrome (CTS) is a common peripheral nerve compression disorder, primarily caused by the compression of the ulnar nerve at the elbow. It leads to symptoms such as numbness, pain, and weakness on the ulnar side of the hand, significantly affecting patients' quality of life and work capacity [1, 2, 3]. In recent years, its incidence has been steadily rising, placing an increasing burden on both patients and society [4].

Currently, various treatment methods exist for CTS, but their effectiveness varies. Traditional approaches, such as conservative treatments (e.g., physical therapy, drug therapy), may have some success in mild cases, but achieving optimal outcomes in moderate to severe cases is often challenging [5, 6]. Surgical intervention is essential for treating moderate to severe CTS, though various surgical techniques present distinct advantages and disadvantages [7, 8, 9].

Osborne's ligament suspension and ulnar nerve anterior transposition (OLSUNAT) is a relatively new surgical technique designed to alleviate ulnar nerve compression by altering its position [10, 11]. Additionally, transcutaneous electrical nerve stimulation (TENS), an adjunct therapy, is considered beneficial for promoting nerve function recovery [12, 13, 14]. However, there remains a lack of sufficient research and definitive conclusions on the efficacy of combining OLSUNAT with TENS for treating CTS.

This study aims to evaluate the efficacy and safety of this combined treatment approach for CTS and to provide a stronger clinical reference for its use.

Materials and Methods

General Information

This study retrospectively selected 116 patients diagnosed with CTS who underwent OLSUNAT at our hospital between October 2020 and December 2023. Patients were di-

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vided into two groups based on whether they received subsequent TENS: 62 cases in the treatment group and 54 cases in the control group. The study adhered to the guidelines outlined in the Declaration of Helsinki and received ethical approval from the Ethics Committee of the First Hospital of Qinhuangdao (Approval Number: 2020D011). All patients provided signed informed consent after being informed of the study's purpose.

Inclusion and Exclusion Criteria

Inclusion criteria: ① Patients with a clear diagnosis of CTS, with typical symptoms such as numbness, pain, and weakness on the ulnar side of the little finger and ring finger, atrophy of the intrinsic muscles of the hand, and weakness, and confirmed ulnar nerve injury by neuroelectrophysiological examination; ② Aged between 18 and 65 years; ③ Disease duration between 3 months and 2 years; ④ Patients who had received OLSUNAT combined with TENS in The First Hospital of Qinhuangdao, with complete treatment records, including the surgical process and relevant parameters of electrical stimulation treatment; ⑤ Medical records containing detailed descriptions of symptoms, physical sign records, and necessary imaging and neuroelectrophysiological examination results before and after treatment.

Exclusion criteria: ① Cases with incomplete medical records that cannot accurately assess the treatment effect and the patient's condition; ② Cases with other diseases that may affect the recovery of nerve function, such as severe diabetic peripheral neuropathy, upper limb nerve compression caused by cervical spondylosis, etc.; ③ Patients who received other related treatments that may affect the research results during the treatment period, such as additional nerve repair drug treatment or other physical therapy methods.

Treatment Methods

OLSUNAT: Brachial plexus block anesthesia was administered, and a tourniquet was applied to the upper arm. Once the anesthesia took effect, an arc-shaped incision approximately 10 to 12 centimeters in length was made behind the medial epicondyle of the humerus. The skin, subcutaneous tissue, and deep fascia were sequentially incised to expose Osborne ligament. The ulnar olecranon end of the ligament was cut and turned towards the palmar side to relieve the ulnar nerve compression caused by Osborne's ligament. The ulnar nerve was then freed, and any other compression points were relieved. During this process, care was taken to preserve the blood supply to the nerve's epineurium. The ulnar nerve was repositioned anterior to the medial epicondyle of the humerus. Osborne's ligament was flipped to cover the ulnar nerve, and its free edge was sutured to the flexor fascia. The elbow joint was passively flexed and extended to ensure smooth ulnar nerve gliding without compression or sharp angle formation. Routine hemostasis, irrigation, and suturing were performed. Postoperatively, standard treatments such as anti-infection measures, nerve nutrition, and detumescence were administered, and the wound was regularly monitored (the detailed surgical procedure is shown in Fig. 1A–F).

The instrument used for TENS treatment was the QL/T-III type transcutaneous electrical nerve stimulator from Beoka Company (Chengdu, China). TENS treatment began on the second day post-operation. First, the location of the ulnar nerve on the affected side was identified. The positive electrode was positioned 6 centimeters above the elbow, and the negative electrode was placed 6 centimeters below the elbow. The current range was set from 0 to 100 mA, the voltage range from 0 to 100 V, the stimulation frequency at 2 Hz, and the pulse width at 10 ms. Stimulation intensity started at 0 and was gradually increased until the muscles on the affected side twitched and the patient could tolerate the sensation (the treatment instrument and the patient's condition during treatment are shown in Fig. 1G,H). Each treatment session lasted for 20 minutes, occurring once a day for 4 consecutive weeks.

Observation Indicators

① In this study, we collected the baseline characteristics of patients, including age, gender, body mass index (BMI), disease location, disease severity, and duration.

⁽²⁾ Pain Degree: The Visual Analog Scale (VAS) is a simple and effective tool for pain assessment [15]. Before the operation and 6 months post-operation, patients were asked to indicate their pain intensity on a straight line marked with a scale from 0 to 10. A score of 0 represents no pain, while a score of 10 represents unbearable severe pain. For example, if a patient experiences slight pain that is still tolerable, they might mark their pain at 3 or 4; if the pain is very severe and affects normal activities and sleep, they might mark it at 8 or 9.

③ Numbness Symptom Assessment: Given the subjective nature of numbness, the assessment score for this study was developed using a Likert scale questionnaire, modeled after the FJS-12 questionnaire [16]. Before the operation and 6 months post-operation, patients were asked, "Do you notice any troublesome numbness around the surgical scar?" They were then instructed to choose one answer from the following options: "Never", "Almost never", "Rarely", "Sometimes", or "Most of the time", corresponding to scores of 4, 3, 2, 1, and 0 points, respectively. Thus, a higher numbness score indicates a lower degree of numbness.

④ Ulnar Nerve Conduction Velocity: Electromyography examination of the ulnar nerve was conducted to record both the motor nerve conduction velocity (MCV) [17] and sensory nerve conduction velocity (SCV) [18] from the elbow to the elbow at 6 months before and after the operation. MCV and SCV were both detected by electromyography (Sierra Summit, Cadwell Industries, Seattle, WA, USA).

⁽⁵⁾ Strength Level Determination of the Abductor of the Little Finger: Before and 6 months after the operation, a spe-

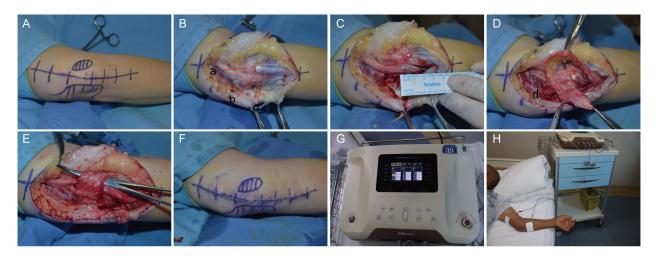


Fig. 1. Surgical steps of Osborne's ligament suspension and ulnar nerve anterior transposition (OLSUNAT) and the method of transcutaneous electrical nerve stimulation (TENS) treatment. (A) Design of the surgical incision. (B) Identification of the ulnar nerve, Osborne's ligament, and Osborne's fascia, followed by the design of a fascial ligament flap approximately 1.5 cm long and 1.0 cm wide. In the figure, a represents the ulnar nerve, b represents Osborne's fascia, and c represents Osborne's ligament. (C) Cutting Osborne's fascial ligament from the olecranon end of the ulna, lifting the fascial ligament towards the medial epicondyle of the humerus, and releasing the ulnar nerve while preserving its nutrient blood vessels. (D) After fully releasing the ulnar nerve, repositioning it anterior to the medial epicondyle of the humerus. In the figure, d represents the nutrient blood vessel. (E) Suturing one end of the fascial ligament to the fascia, creating a new nerve tunnel capable of accommodating approximately one finger. (F) Wound closure. (G) The instrument used for TENS treatment is the QL/T-III type transcutaneous electrical nerve stimulator from Beoka Company (Chengdu, China). (H) A patient undergoing TENS treatment.

cialized muscle strength measurement device was used to evaluate strength levels, which were categorized from 0 (complete paralysis) to 5 (normal strength). Specific test movements were performed on the abductor of the little finger to assess the muscle's ability to resist resistance, thereby determining its strength level. For example, at level 0, the little finger cannot be abducted at all, while at level 5, the little finger can be easily abducted against strong resistance. The strength levels of the abductor of the little finger in both patient groups were converted into numerical values for comparison. The numerical values obtained from the muscle strength measurement device (ranging from 0 to 5 points) were used to calculate the average strength for each group. A higher average value typically indicates relatively stronger strength in the abductor of the little finger.

(6) Two-Point Discrimination: Before and 6 months after the operation, the two-point discrimination threshold of a specific area of the patient's hand was measured, defined as the minimum distance at which two stimulation points can be distinguished [19]. Normally, the two-point discrimination of the skin on the hand is quite sensitive. However, when the ulnar nerve is damaged, two-point discrimination may deteriorate, leading to an increased threshold.

© Elbow Range of Motion: Before and 6 months after the operation, the maximum angles of flexion and extension of the elbow joint were measured, including the limit angles for both movements. The normal flexion angle of the elbow typically ranges from 135 to 150 degrees, while the extension angle approaches 0 degrees. Limited range of motion

in the elbow may be caused by factors such as pain, muscle weakness, or joint adhesion, and is significant for evaluating the impact of CTS on elbow function [20].

(8) Fine Motor Activities of the Upper Limb and Hand: The Simple Test for Evaluating Hand Function (STEF) was used to assess the fine motor activities of the upper limb and hand before and 6 months after the operation [21]. The scale consists of 10 test items, with movements progressing from simple to difficult, coarse to fine, and from the healthy side to the affected side. Each item is scored from 1 to 10 points, with a maximum total score of 100 points. A higher total score indicates better fine motor activities of the patient's upper limb and hand.

(9) Quality of Life Assessment: The SF-36 (36-Item Short Form Survey) is a self-reported measurement tool for health-related quality of life [22]. It includes 36 questions that cover eight different dimensions of health, encompassing both physical and mental components: limitations in physical activities due to health problems, limitations in social activities due to physical or emotional issues, limitations in usual role activities due to physical health problems, bodily pain, general mental health, limitations in usual activities due to emotional distress, vitality, and general health perceptions. The scores are converted into a scale ranging from a minimum value of 0 (the worst condition) to a maximum value of 100 (the best condition). The total SF-36 score is calculated at the beginning of the study and again 6 months after the surgery.

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Table 1. Baseline characteristics.						
Characters	Treatment (62)	Control (54)	t/χ^2	р		
Age (years, $\bar{x} \pm s$)	39.35 ± 8.62	40.65 ± 6.91	-0.883	0.379		
Sex (n)			0.111	0.739		
Male	36	33				
Female	26	21				
BMI ($\bar{x} \pm s$)	21.97 ± 2.70	21.61 ± 2.88	0.688	0.493		
Diseased site (n)			0.011	0.917		
Left	27	23				
Right	35	31				
Severity (n)			0.075	0.784		
Moderate	41	37				
Severe	21	17				
Course of disease (months, $\bar{x} \pm s$)	11.31 ± 4.24	10.83 ± 3.65	0.639	0.524		

BMI, body mass index.

Incidence of Complications: The surgical complications of patients were compared, and the occurrences of infection, local hematoma compression, poor nerve recovery due to inadequate rehabilitation, atrophy, claw-shaped deformity of the ring and little fingers, and inflexible finger extension and flexion were carefully recorded during the postoperative and discharge follow-up periods.

Statistical Analysis

For the software used for statistical analysis, we adopted SPSS 25.0 (SPSS Statistics Inc., Chicago, IL, USA) for data analytics.

First, for continuous variables, such as age, course of disease, and specific values of various examination indicators (e.g., ulnar nerve conduction velocity, elbow range of motion measurements), a normality test was performed using the Shapiro-Wilk test to determine whether the data conform to a normal distribution. Continuous variables were presented as mean \pm standard deviation ($\bar{x} \pm s$). If the data followed a normal distribution, an independent sample ttest was employed to compare the disparities between the two groups. For categorical variables, such as gender and disease location, frequency and percentage were used for representation, and the chi-square test was applied to determine whether notable disparities existed in the distribution between groups. When comparing changes in indicators before and after treatment between the two groups, a paired t-test was used. All statistical analyses were conducted at a preset significance level (p < 0.05) to ascertain whether the results were statistically significant.

Results

Baseline Characteristics

No significant differences were found between the two groups in terms of age, gender, BMI, disease location, severity of the condition, and course of the disease (p > 0.05) (Table 1).

Symptom Assessment

Following treatment, the pain levels (VAS scores) and numbress symptoms (numbress scores) in both groups were significantly improved compared to before treatment (p < 0.05). Additionally, the reductions in pain level and numbress symptoms in the treatment group were greater than those in the control group (p < 0.001) (Table 2).

Nerve Function Related Indicators

After treatment, the MCV and SCV in both groups were significantly increased compared to before treatment (p < 0.05). Additionally, the improvements in MCV and SCV in the treatment group were greater than those in the control group (p < 0.01) (Table 3).

After treatment, the strength of the abductor of the little finger and the two-point discrimination in both groups were significantly improved compared to before treatment (p < 0.05). Furthermore, the improvements in the strength of the abductor of the little finger and the two-point discrimination in the treatment group were greater than those in the control group (p < 0.05) (Table 4).

Elbow Function Related Indicators

After treatment, both the elbow range of motion and the STEF scores in both groups were significantly increased compared to before treatment (p < 0.05). Additionally, the increases in elbow range of motion and STEF scores in the treatment group were greater than those in the control group (p < 0.001) (Table 5).

Quality of Life Assessment

Prior to treatment, no significant difference in SF-36 scores were identified between groups (p > 0.05); Following treatment, the SF-36 scores of both groups were significantly increased, and the degree of increase in the treatment group was more significant (p < 0.001) (Table 6).

Table 2. Level of	pain and numbness	$(\bar{x} \pm s, \text{ points}).$
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Group (n)	VAS		Numbness score		
Gloup (II)	Before	After	Before	After	
Treatment (62)	5.19 ± 1.55	$1.63\pm0.58^*$	2.90 ± 0.78	$0.76\pm0.43^*$	
Control (54)	4.91 ± 1.52	$2.24\pm0.70^{\ast}$	2.76 ± 0.91	$1.26\pm0.62^{\ast}$	
t	1.002	-5.155	0.916	-5.103	
р	0.318	< 0.001	0.362	< 0.001	

*signifies a notable disparity (p < 0.05) when comparing post-treatment with pretreatment. VAS, Visual Analog Scale.

Table 3. Nerve conduction velocity ($\bar{x} \pm s$, m/s).

Group (n)	MCV		SCV		
	Before	After	Before	After	
Treatment (62)	32.04 ± 7.64	60.60 ± 13.89*	32.03 ± 7.42	$55.08\pm6.49*$	
Control (54)	32.51 ± 6.82	$53.12\pm9.65^*$	31.67 ± 7.29	$48.23\pm6.16^{\ast}$	
t	-0.353	3.322	0.261	5.803	
р	0.725	0.001	0.794	< 0.001	

*signifies a notable disparity (p < 0.05) when comparing post-treatment with pretreatment. MCV, motor nerve conduction velocity; SCV, sensory nerve conduction velocity.

Incidence of Complications

The overall rate of complications in the treatment group was 3.23%, a trifle lower than the 9.26% in the control group, but the disparity was not statistically significant (p > 0.05) (Table 7).

Discussion

This study aims to explore the effectiveness and safety of OLSUNAT in conjunction with TENS in treating CTS. Through the retrospective analysis of 116 individuals, we have obtained meaningful results.

In terms of general information, no remarkable discrepancies were identified between the two groups in age, gender, BMI, disease location, severity of the condition, and course of the disease. This ensures the comparability of the two groups and provides a reliable basis for the subsequent research results.

Symptom assessment in this study primarily included the evaluation of pain levels and numbness symptoms, while nerve function-related indicators covered ulnar nerve conduction velocity, strength of the abductor of the little finger, and two-point discrimination. After treatment, the pain levels and numbness symptoms in both groups were substantially improved compared to pre-treatment. Simultaneously, the MCV and SCV in both groups significantly increased, and the strength of the abductor of the little finger and two-point discrimination also improved. These findings indicate that OLSUNAT effectively alleviates CTS symptoms and promotes nerve function recovery.

However, the treatment group demonstrated better improvement in pain levels, numbress symptoms, MCV, SCV, strength of the abductor of the little finger, and twopoint discrimination compared to the control group. This suggests that the combined treatment method of OLSUNAT and TENS offers significant advantages.

Several factors may contribute to this advantage. On one hand, OLSUNAT reduces the compression of the ulnar nerve by changing its position, which alleviates symptoms and facilitates nerve function recovery. On the other hand, TENS may promote nerve regeneration and repair by stimulating the nerves, further enhancing their function. This stimulation can regulate the nerve conduction pathway, improve the transmission of nerve signals, and reduce the patient's perception of pain and numbness [23]. Additionally, TENS may positively impact local blood circulation, improving the nutritional supply to the nerves, and aiding in recovery.

In a study considering TENS as a pain treatment, researchers have found that the endogenous opioid system plays a role in the neuromodulation of anti-nociception [24]. These findings suggest that TENS may induce the release of endogenous opioid peptides by stimulating nerve fibers, leading to vasodilation and improved blood circulation.

While the treatment group exhibited greater improvements in symptoms and nerve function, the differences between the two groups may also be influenced by other factors, such as individual variability. Different patients may experience varying degrees of nerve damage, recovery abilities, and responses to treatment, all of which can affect symptom improvement and nerve function.

Compared with other studies, our research demonstrated that the combination of OLSUNAT and TENS has more significant advantages in improving the symptoms and nerve

Table 4. Strength of the abductor of the little finger and two-point recognition ($\bar{x} \pm s$, points).

Group (n)	Strength of the abductor of the little finger		Two-point recognition		
	Before After		Before	After	
Treatment (62)	1.87 ± 1.05	$4.16\pm0.73^{\ast}$	7.68 ± 1.35	3.80 ± 1.31*	
Control (54)	2.09 ± 0.94	$3.81\pm0.73^{\ast}$	7.32 ± 1.40	$4.60\pm1.07*$	
t	-1.193	2.554	1.399	-3.608	
р	0.235 0.012		0.164	< 0.001	

*signifies a notable disparity (p < 0.05) when comparing post-treatment with pre-treatment.

Table 5. Elbow motion and STEF scores ($\bar{x} \pm s$, points).

Group (n)	Elbow motion		STEF score		
	Before	After	Before	After	
Treatment (62)	79.16 ± 17.13	$123.08 \pm 17.96*$	32.18 ± 4.16	$69.35\pm8.70^{\ast}$	
Control (54)	83.87 ± 17.90	$105.93 \pm 18.97 *$	32.48 ± 3.73	$60.13\pm7.27*$	
t	-1.446	4.998	-0.412	6.146	
р	0.151	< 0.001	0.681	< 0.001	

*signifies a notable disparity (p < 0.05) when comparing post-treatment with pre-treatment. STEF, Simple Test for Evaluating Hand Function.

Table 6. SF-36 scores ($\bar{x} \pm s$, points).

Group (n)	SF	-36	t	p	
Group (II)	Before After		ι	P	
Treatment (62)	48.27 ± 4.94	80.34 ± 8.09	-26.632	< 0.001	
Control (54)	49.48 ± 5.72	74.50 ± 8.92	-17.344	< 0.001	
t	-1.220	3.695			
р	0.225	< 0.001			

function of patients. For instance, a study by Balevi [25] utilized modified simple decompression (MSD) of the ulnar nerve for treating CTS; however, the improvements in nerve conduction velocity and symptom relief were not as pronounced as those observed in our study [25]. Additionally, we found that TENS positively influences local blood circulation, aligning with the findings of Vieira *et al.* [26], which further supports the efficacy of this combined treatment approach.

The outcome of the elbow function-related indicators revealed that both the elbow range of motion and the STEF scores significantly improved after treatment, with the treatment group demonstrating superior improvement compared to the control group. This finding suggests that this treatment method effectively enhances elbow function and the fine motor activities of the upper limb and hand in patients. These results align with conclusions from other related study [27]. In the treatment group, the combination of TENS further facilitated the recovery of nerve function, allowing the muscles around the elbow to receive nerve signals more effectively, which in turn improved muscle strength and coordination, thereby enhancing elbow range of motion and fine motor activities. Additionally, TENS may positively influence blood circulation in the elbow [28]. Enhanced blood circulation provides essential nutrients and oxygen, promotes tissue repair and regeneration, and reduces the risk of joint adhesions and related issues, ultimately contributing to improved elbow function and range of motion.

The results indicate that the treatment method of OL-SUNAT combined with TENS not only has advantages in alleviating symptoms and enhancing nerve and elbow function in patients, but also significantly improves their quality of life. A key reason for this improvement in quality of life in the treatment group is likely due to OLSUNAT's effectiveness in reducing compression and relieving symptoms by repositioning the ulnar nerve, positively impacting patients' daily lives. Additionally, TENS further enhances nerve function by stimulating the nerve, promoting its regeneration and repair, which in turn diminishes the interference of pain and numbness on patients' everyday activities.

However, the surgery may carry certain complications, including infection, local hematoma compression, and poor nerve recovery. TENS can aid in the regeneration and repair of nerves through stimulation, which improves nerve function. This stimulation may help mitigate the inflammatory response of the nerves, thereby reducing the risk of further nerve damage and associated complications. Additionally, TENS may positively influence local blood circulation, promoting wound healing and decreasing the likelihood of infection and hematoma. It is important to note that the difference in complication rates between groups in this study was not statistically significant, which could be related to factors such as the limited sample size and short follow-up duration. Future large-scale and long-term stud-

Table 7. Complications n (%).

Group (n)	Ulnar nerve injury	Local hematoma compression	Infection	Ulnar nerve slipped	Postoperative recurrence	Overall incidence
Treatment (62)	0 (0.00)	1 (1.61)	1 (1.61)	0 (0.00)	0 (0.00)	2 (3.23)
Control (54)	1 (1.85)	1 (1.85)	0 (0.00)	2 (3.70)	1 (1.85)	5 (9.26)
χ^2						0.942
р						0.332

ies are necessary to more accurately evaluate the impact of TENS on complications.

Conclusions

In conclusion, OLSUNAT combined with TENS offers significant advantages in the treatment of CTS, effectively alleviating patients' symptoms, enhancing the recovery of nerve and elbow function, and demonstrating a high safety profile.

Availability of Data and Materials

All experimental data included in this study can be obtained by contacting the first author if needed.

Author Contributions

WW designed and performed the research and wrote the paper; YT designed the research and supervised the report; GGZ designed the research and contributed to the analysis; JFD designed the experimental protocol; WYL and RW collected the experimental data. All authors contributed to important editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

The study adhered to the guidelines outlined in the Declaration of Helsinki and received ethical approval from the Ethics Committee of the First Hospital of Qinhuangdao (Approval Number: 2020D011). All patients provided signed informed consent after being informed of the study's purpose.

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Conflict of Interest

The authors declare no conflict of interest.

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