CLINICAL ARTICLE

A Retrospective Clinical Study of Endoscopic Treatment of Carpal Tunnel Syndrome using the Modified Soft Tissue Release kit

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Objective: Carpal tunnel syndrome (CTS) is the most common peripheral entrapment neuropathy, and endoscopic carpal tunnel release (ECTR) is one of the minimally invasive procedures for the treatment of CTS. Based on the shortcomings of ECTR, we designed the "Modified Soft Tissue Release Kit" to assist the endoscopic operation. This study aimed to evaluate the effectiveness and safety of endoscopic treatment of CTS using this kit.

Methods: This retrospective review included 57 patients (86 wrists) who underwent ECTR using the "Modified Soft Tissue Release Kit" at our department between January 2017 and August 2019. Three scale scores (i.e., Quick–Disabilities of the Arm, Shoulder, and Hand [QDASH]; Boston Carpal Tunnel Syndrome Questionnaire [BCTSQ]: symptom severity [BCTSQ-SS] and functional status [BCTSQ-FS]) were recorded to assess hand function and symptoms preoperatively, 1 month postoperatively, 3 months postoperatively, and at the last follow-up. We also asked patients to answer a satisfaction question during follow-up. Pre- and post-operation scores were compared using paired Wilcoxon signed-rank test. Spearman's rank-order correlation was used to evaluate the relationship between scale scores and patient satisfaction.

Results: A total of 55 patients (83 wrists) were followed up, with an average follow-up of 27.2 ± 9.3 months. The median preoperative QDASH score was 45.5; the scores at 1 month postoperatively, 3 months postoperatively, and the last follow-up were 4.5, 0, and 0, respectively, with a significant decrease noted compared with the preoperative scores ($P < 0.001$). The median preoperative BCTSQ-SS and BCTSQ-FS scores were 3.3 and 2.8, respectively; the scores at 1 month postoperatively, 3 months postoperatively, and the last follow-up were 1.2, 1.0, and 1.0, and 1.1, 1.0, and 1.0, respectively, all of which decreased significantly compared with the preoperative scores ($P < 0.001$). The incidence of nerve injury was 0. The incidence of pillar pain was 0 at the last follow-up. One patient showed no improvement in hand symptoms and function postoperatively, and two patients showed long-term recurrence despite postoperative symptom remission. Approximately 94.5% (52/55) of the patients were satisfied or very satisfied with the outcome.

Conclusions: ECTR with the "Modified Soft Tissue Release Kit" can significantly relieve symptoms and improve function in patients with CTS, with significant short- and mid-term efficacy and high safety.

Key words: Carpal tunnel syndrome; Endoscopy; Minimal invasion; Modified soft tissue release kit; Safety

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Introduction

Carpal tunnel syndrome (CTS) is caused by compression of the median nerve in the carpal tunnel (Fig. 1), which is the most common peripheral entrapment neuropathy, accounting for 3%–5% of the general population. Of this, 73% show bilateral symptoms, and the incidence in females is three times that in males, especially in middle-aged and older adult women.[1–3] Patients usually present with numbness, pain, or paresthesia in the median nerve innervation area of the thumb, index finger, and middle finger. Symptoms are pronounced at night. Patients with severe condition present with thenar muscle atrophy, grip strength decline, and limited thumb abduction.[4]

Except those caused by increased carpal tunnel contents, such as lipomas, ganglion cysts, and nerve sheath tumors, CTS patients are recommended to be treated with surgeries when conservative treatments fail.[5] Recently, with the rapid development of endoscopic techniques, endoscopic carpal tunnel release (ECTR) has been favored by scholars due to its advantages of a small incision, minor trauma, small scar, and fast recovery. However, during clinical application, the shortcomings of this surgical method have gradually emerged. Due to its small surgical field and narrow operating space, the absence of a suitable auxiliary device for cooperation during operation can lead to incomplete release of the transverse carpal ligament and complications such as nerve injury.[6] Based on these shortcomings, CONMED Corporation (Utica, NY, USA) developed a carpal tunnel release kit named "CTS Relief Kit" to assist in ECTR. However, two limitations were found in our clinical use of the "CTS Relief Kit." First, the cannula may rotate after insertion into the carpal tunnel, causing the median nerve to slip into the operating area. Combined with a limited local visual field, there is a risk of nerve injury. Second, the only knife in the "CTS Relief Kit" is the spade knife, which is not safe in single-incision surgery.

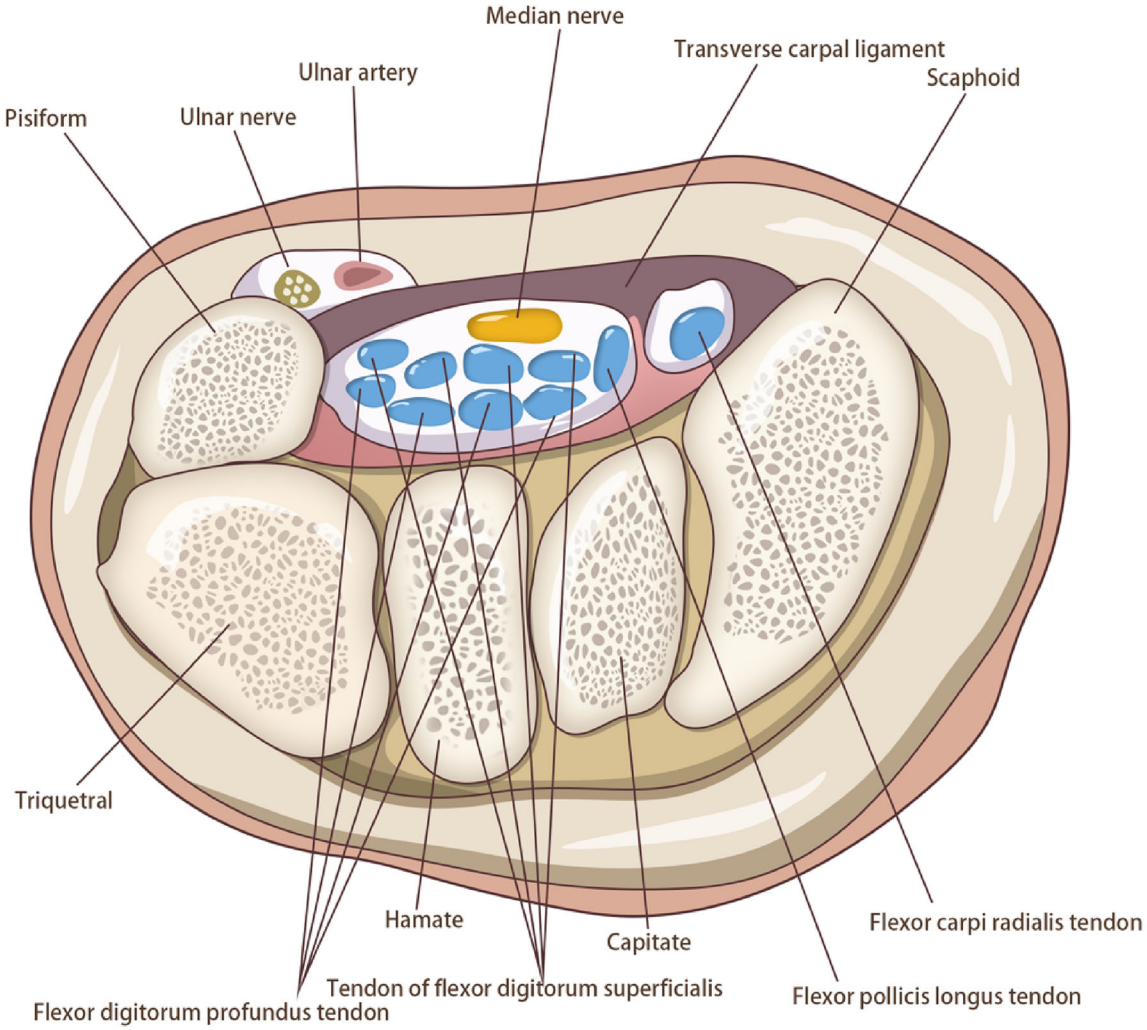

Fig. 1 Diagram of preoperative carpal tunnel anatomy

Therefore, we have improved the kit by adding a pair of balance blades to the cannula, deepening the sliding groove on the cannula, and adding a hook knife to improve the safety and stability of the endoscopic operation. We have named the new kit as the "Modified Soft Tissue Release Kit." The operation with this kit is easy and safe. If its efficacy and safety are verified, it will be helpful to promote the application of endoscopic treatment of CTS. Hence, the aims of the study were: (i) to explore the clinical efficacy of ECTR using the "Modified Soft Tissue Release Kit" and (ii) to evaluate the safety of this kit.

Methods

This study was approved by the Ethics Committee of Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine (approval number SH9H-2020-T397-1), and the patient's privacy was strictly protected during the study. In this retrospective study, we included 57 patients (86 wrists) who received ECTR using the "Modified Soft Tissue Release Kit" between January 2017 and August 2019. A total of 55 patients (83 wrists) were followed up.

Inclusion and Exclusion Criteria

Inclusion criteria: (i) Patients diagnosed with CTS by symptoms, signs, electromyography (EMG), and imaging findings. Diagnostic criteria: patients had numbness, pain, and sensory disturbances in the thumb, index finger, middle finger, and the radial side of the ring finger, with or without grip and pinch weakness, and EMG showed median nerve entrapment;[7] (ii) all patients enrolled in the study showed no improvement during conservative treatment with wrist splinting for more than 3 months; (iii) patients were treated with ECTR using the "Modified Soft Tissue Release Kit"; and (iv) all patients were followed up for at least 12 months.

Exclusion criteria: (i) CTS caused by increased carpal tunnel contents, such as lipomas, ganglion cysts, and nerve sheath tumors; (ii) patients with peripheral neuropathy of the upper extremity; (iii) patients with rheumatoid arthritis and gout, causing pain and deformities in the hand joints; and (iv) patients with a history of surgery or trauma to the hand or upper limb.

Design of Modified Soft Tissue Release Kit

This kit was composed of a thin (6 mm) cannula with lining core, thin (6 mm) expander, spade knife, hook knife, detacher, thick (7 mm) expander, and thick (7 mm) cannula with lining core (Fig. 2). First, we designed the cannula and expander into two models to facilitate the surgeon to select the appropriate model according to the actual situation. Then, we added a pair of balance blades and a deep sliding groove to the cannula to make the operation safer. Finally, we added a hook knife, which can make endoscopic release of the transverse carpal ligament relatively more convenient and safer.

Surgical Procedure

After successful anesthesia, the patient was placed in the supine position. The surgeon disinfected and draped the patient. The blood of the upper limb was evacuated using a dispersed blood bandage, and a tourniquet was used to prevent blood return. The superficial palmar arch was then marked. After fully abducting the thumb, the surgeon drew a horizontal line along the thumb, forming an angle with a vertical line drawn between the middle and ring fingers. The surgeon then made the angle bisector and extended it backward by approximately 1 cm, marking the distal outlet of the carpal tunnel. The pisiform was marked, and the inlet of endoscopy was marked 1 cm radial and 0.5 cm proximal to it (Fig. 3). A transverse incision of approximately 0.8 cm was made at the inlet; the skin and subcutaneous tissue were incised. Under the deep fascia, the expander was used to expand under the transverse carpal ligament toward the distal outlet of the carpal tunnel. The cannula was inserted, and the balance blade on the cannula was clamped with a hemostat to avoid the median nerve straying into the operating area due to cannula rotation. After the median nerve was observed with 2.7 or 2.9 mm 30° endoscope, the surgeon rotated the cannula to ensure that the median nerve was outside the operating area. Then, the transverse carpal ligament was completely incised using a hook knife under direct endoscopic vision (Fig. 4). After rinsing the incision, it was sutured with 5–0 absorbable suture. The tourniquet was released after pressure dressing.

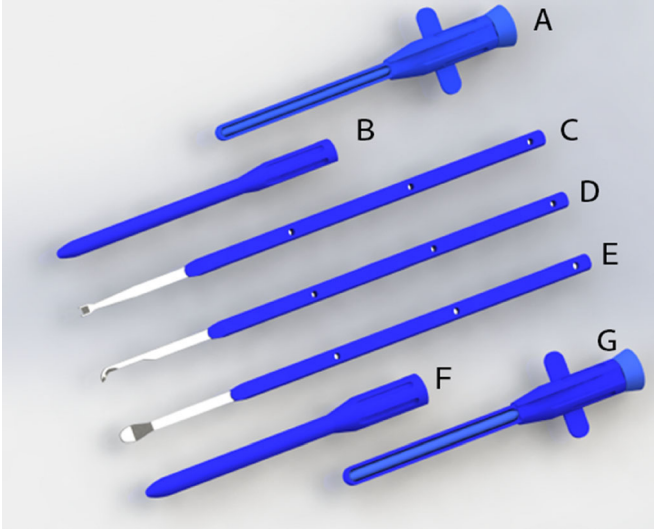

Fig. 2 Modified soft tissue release kit. (A) Thin (6 mm) cannula with lining core; (B) Thin (6 mm) expander; (C) Spade knife; (D) Hook knife; (E) Detacher; (F) Thick (7 mm) expander; (G) Thick (7 mm) cannula with lining core

Outcome Measures

Quick–Disabilities of the Arm, Shoulder, and Hand (QDASH)

QDASH consisting of 11 questions was used to analyze the ability to use the upper limbs to perform certain functions.

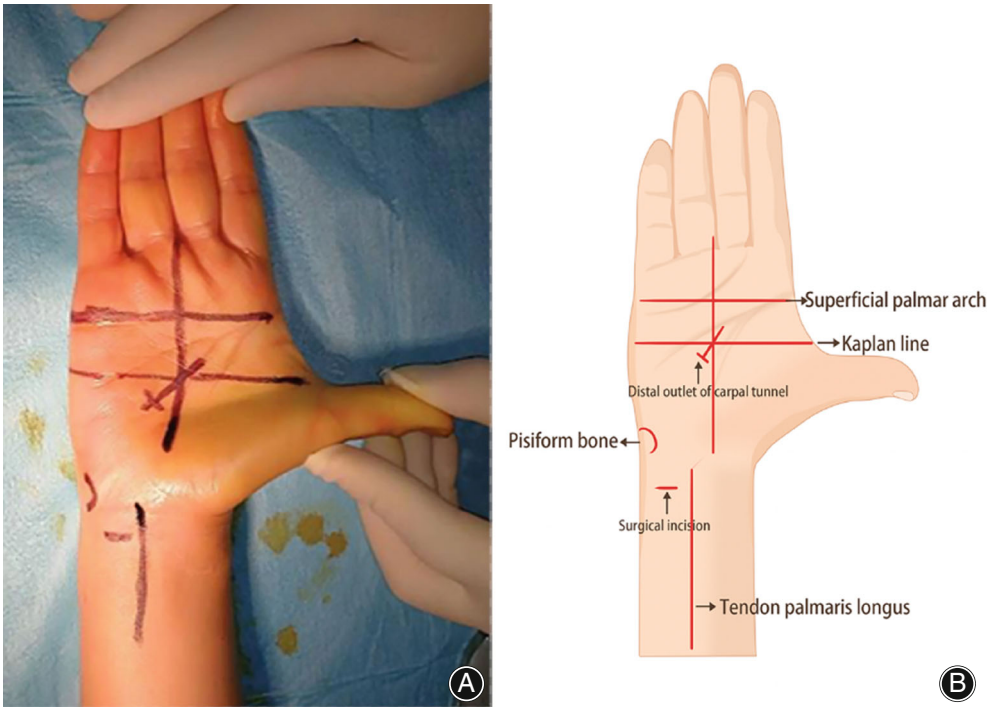

Fig. 3 Preoperative marking. (A) Surgical incision and essential anatomical structures were marked preoperatively; (B) Diagram of preoperative marking

The score was calculated on a scale of 0 to 100, with 0 being completely normal and 100 being completely disabled. Patients were assessed preoperatively, 1 month postoperatively, 3 months postoperatively, and lastly, follow-up using the QDASH scale.

Two parts of the Boston Carpal Tunnel Syndrome Questionnaire

Symptom severity (BCTSQ-SS) and functional status (BCTSQ-FS) scales: BCTSQ-SS and BCTSQ-FS scales were specifically designed for symptoms and function related to CTS, which contained 11 and 8 questions, respectively. Each scale score was the average calculated after answering all the questions. Each question was scored according to a five-point scale (1–5), the higher the score, the higher the degree of hand sensory disorders and dysfunction. Patients were assessed preoperatively, 1 month postoperatively, 3 months postoperatively, and at the last follow-up using the BCTSQ-SS and BCTSQ-FS scales.

Patient Satisfaction

The Global Satisfaction Questionnaire was used on a five-point scale from 1 (very dissatisfied) to 5 (very satisfied). Patients were questioned at 1 month postoperatively and at the last follow-up.

Statistical Analysis

SPSS 26.0 software (IBM, Armonk, NY, USA) was used for data processing. The Shapiro–Wilk test was used for the normal distribution test for the quantitative data. Patient ages and follow-up durations were normally distributed and were represented as mean ± standard deviation. Similarly, the remaining quantitative data were non-normal distributions and were represented as median (interquartile range). Preoperative and postoperative quantitative data were compared using Wilcoxon signed-rank test. $P < 0.05$ was considered statistically significant. Spearman's correlation was used to determine the relationship between scale scores and patient satisfaction. Qualitative variables were presented as frequency and constituent ratio.

Results

General Results

A total of 55 patients (83 wrists) were followed up: 9 males (16.4%) and 46 females (83.6%). 28 cases (50.9%) were bilateral. A total of 39 wrists (47%) were on the left side and 44 (53%) on the right side. The mean age was 58.6 ± 9.4 years, ranging from 35 to 83 years (Table 1).

Clinical Outcomes

A total of 55 patients (83 wrists) were followed up for an average of 27.2 ± 9.3 months (12–44 months). The follow-up outcomes for median scores on QDASH, BCTSQ-SS, and BCTSQ-FS scales were listed in Table 2. The above scale scores at 1 month postoperatively, 3 months postoperatively, and the last follow-up were significantly lower than those preoperatively, and the differences were statistically significant ($P < 0.001$). Similarly, the scale scores at 3 months postoperatively and the last follow-up also changed compared with scores at 1 month postoperatively; the differences were statistically significant ($P < 0.001$). At 1 month

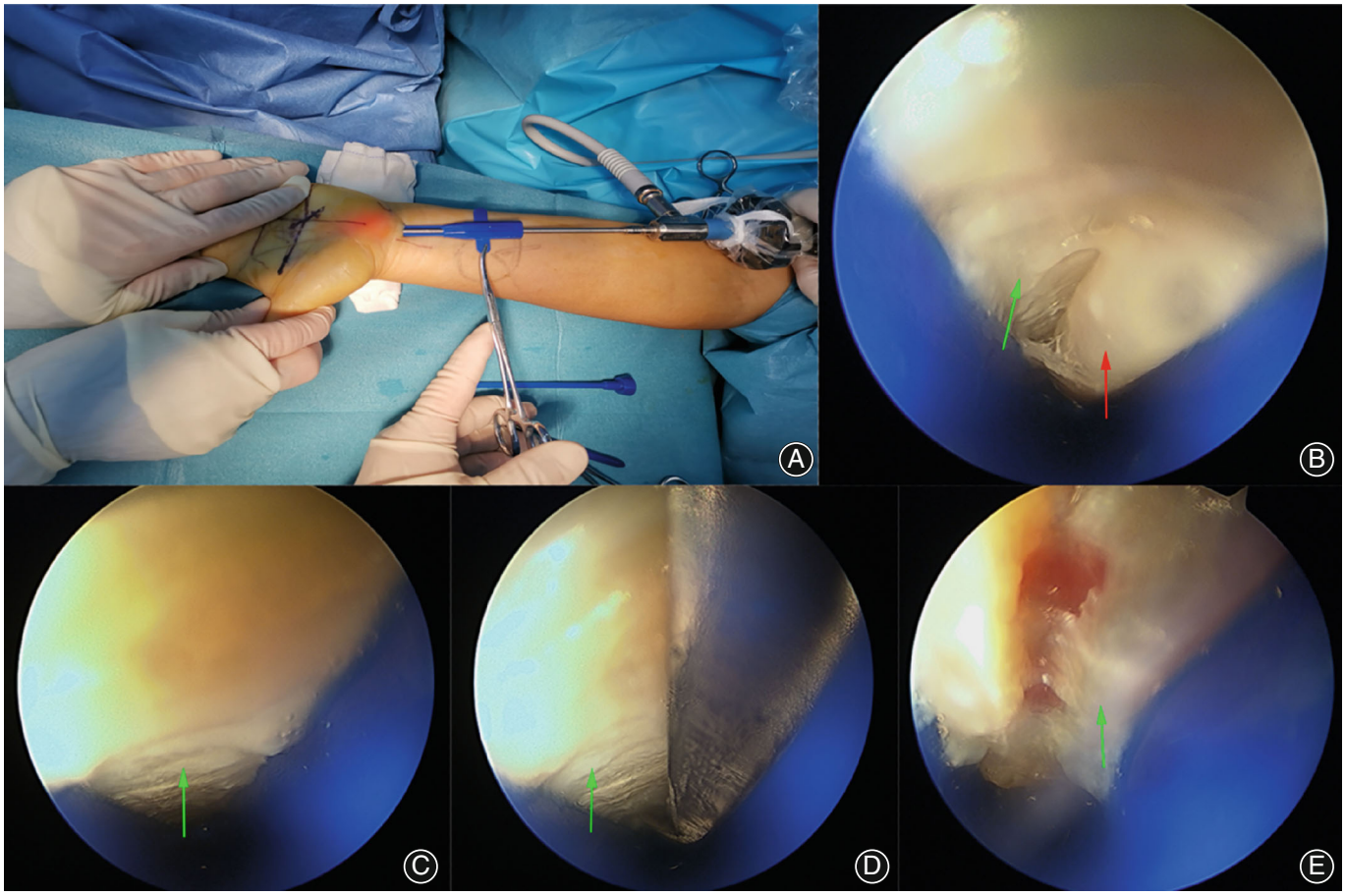

Fig. 4 Surgical images of endoscopic carpal tunnel release (ECTR) using the Modified Soft Tissue Release Kit. Green arrow: transverse carpal ligament; Red arrow: median nerve. (A) Using endoscopy to explore the carpal tunnel; (B) Median nerve can be observed under direct vision; (C) Cannula was rotated to ensure that the median nerve was outside the surgical area while exposing the transverse carpal ligament to the surgical area; (D) Incising the transverse carpal ligament with the hook knife; (E) The transverse carpal ligament was completely released

TABLE 1 Baseline patient characteristics

Patient features	
Case (number)	55
Wrist (number)	83
Age (years)	58.6 ± 9.4 (35–83)
Sex	
Male	9 (16.4%)
Female	46 (83.6%)
Hand	
Left	39 (47%)
Right	44 (53%)
Affected side	
Unilateral	27 (49.1%)
Bilateral	28 (50.9%)

Note: Data are presented as number (%).

postoperatively, the neural symptoms disappeared completely and the hand function returned to normal in 22.9% (19/83) of the wrists (the QDASH score was 0, and both the BCTSQ-SS and BCTSQ-FS scores were 1). Approximately 66.3% (55/83) of the wrists recovered completely 3 months postoperatively, and 68.7% (57/83) of the wrists had recovered completely at the last follow-up (Table 3). At the last follow-up, 95.2% (79/83) of the wrists had lower QDASH scores and 96.4% (80/83) of the wrists had lower BCTSQ scores than those before surgery (Table 4).

During the 1-month and the last follow-ups, 89.1% (49/55) and 94.5% (52/55), respectively, of the patients were satisfied or very satisfied with the outcome. At the 1-month follow-up, BCTSQ ($r = -0.58$, $P < 0.001$) and QDASH scores ($r = -0.56$, $P < 0.001$) were moderately negatively correlated with patient satisfaction. Patient satisfaction was strongly negatively correlated with BCTSQ scores ($r = -0.74$, $P < 0.001$) and QDASH scores ($r = -0.72$, $P < 0.001$) at the last follow-up.

Complications

The incidence of complications at the last follow-up was 3.6% (3/83). One patient had no obvious improvement in hand symptoms postoperatively. This patient was later found

TABLE 2 Results of preoperative and postoperative outcome measures

Scale Score	Preoperative	Postoperative			*P* value
		1 month	3 months	Last follow-up	
QDASH	45.5 (6.8)	4.5 (6.7)	0 (4.5)	0 (4.5)	<0.001
BCTSQ-SS	3.3 (0.2)	1.2 (0.3)	1.0 (0.1)	1.0 (0.1)	<0.001
BCTSQ-FS	2.8 (0.3)	1.1 (0.3)	1.0 (0.1)	1.0 (0.1)	<0.001

Abbreviations: BCTSQ-FS, Boston Carpal Tunnel Syndrome Questionnaire: functional status; QDASH, Quick–Disabilities of the Arm, Shoulder, and Hand; BCTSQ-SS, Boston Carpal Tunnel Syndrome Questionnaire: symptom severity.

TABLE 3 Complete recovery rate of affected wrists postoperatively

Complete Recovery Rate	1 month	3 months	Last follow-up
Number of completely recovered wrists	19	55	57
Number of wrists that have not completely recovered	64	28	26
Total number of wrists	83	83	83
Percentage of wrists that are completely recovered	22.9%	66.3%	68.7%

TABLE 4 Middle-term (the last follow-up) remission of wrist function and symptoms

Changes of Scale Scores	QDASH	BCTSQ
Scores decreased	79	80
Scores unchanged or increased	4	3
Total number of wrists	83	83
Remission rate	95.2%	96.4%

Abbreviations: BCTSQ, Boston Carpal Tunnel Syndrome Questionnaire; QDASH, Quick–Disabilities of the Arm, Shoulder, and Hand.

to have concurrent cervical spondylosis; therefore, we referred him to the spinal surgery department for further treatment. Two patients showed improvements in hand symptoms and function postoperatively; however, symptoms, such as numbness and tingling, relapsed months later. After examination and judgment, we believed that the reappearance of symptoms was due to diabetic peripheral neuropathy. Therefore, both patients were advised to visit the endocrinology department for appropriate glycemic control. The incidence of pillar pain was 18.1% (15/83) at 1 month postoperatively. We suggested that these patients could use neurotrophic drugs or physical therapy to relieve symptoms and continue to follow up. Then, the incidence of pillar pain decreased to 2.4% (2/83) at 3 months postoperatively and 0 at the last follow-up. No patient reported wound pain postoperatively. The incidence of median nerve injury was 0.

Discussion

In this study, we introduced a new kit named the "Modified Soft Tissue Release Kit" for endoscopic treatment of CTS. This kit showed excellent clinical efficacy, with significant improvement in QDASH, BCTSQ-SS, and BCTSQ-FS scores postoperatively. Moreover, ECTR with this kit could ensure that the transverse carpal ligament was incised under direct endoscopic vision and that the median nerve was outside the operating area, ensuring high surgical safety.

Current Status of ECTR

With the rapid development of endoscopic surgery, ECTR is highly praised for its advantages, such as small incisions, minor trauma, fast recovery, and a small scar.[8] However, complex operation, small surgical field, and narrow operating space of traditional endoscopic surgery can cause incomplete release of the transverse carpal ligament and nerve injury.[9,10] Atroshi *et al.* followed up 63 patients (63 wrists) who received ECTR. The BCTSQ-SS and BCTSQ-FS scores were 1.8 and 2.0 at the 3-week follow-up, 1.5 and 1.3 at the 3-month follow-up, and 1.4 and 1.3 at the 1-year follow-up, respectively. The incidence of scar or palm pain was 52% (33/63) at 3 months postoperatively, and no obvious relief was noted postoperatively in three cases (4.8%).[11] Sayegh *and* Strauch found that compared with open carpal tunnel release, ECTR had no significant difference in long-term efficacy; however, the incidence of nerve injury was higher.[12]

Innovative Designs of Modified Soft Tissue Release Kit

To facilitate endoscopic operation and improve the safety of ECTR, we designed a new kit, "Modified Soft Tissue Release Kit," which had many optimizations and innovations compared with the "CTS Relief Kit." First, we added a pair of balance blades to the cannula. During the operation, the assistant gripped the balance blade with a hemostat to avoid

cannula rotation, making the operation safer. Second, we added a hook knife to the kit. In single incision surgery, the transverse carpal ligament could be released from the distal to the proximal end. This operation method was consistent with most surgeons' habits, making the operation more convenient. Similarly, we designed the blade of the hook knife to be straight and at an obtuse angle to the handle to ensure that the tissue with stronger tension was easier to incise. The transverse carpal ligament had high tension and, therefore, was easy to incise. The median nerve was soft and, therefore, was not easily injured. Finally, a deep sliding groove was designed on the cannula to prevent the knife from accidentally straying from the operating area, further increasing the safety of the surgery.

Advantages and Clinical Application of the New Technique

This technique has the following advantages: (i) it is easy to operate; (ii) the surgical incision is only approximately 0.8 cm and coincides with the transverse wrist crease, making the scar smaller and less obvious, while avoiding the scar of the palm; and (iii) the innovative designs of the new kit make the knife always in the operating area, ensuring that the transverse carpal ligament is incised under direct endoscopic vision and that the median nerve is always outside the operating area, with higher stability and safety.

Next, we would like to share some experience on the clinical application of this new technology (i)The inlet of endoscopy was on the ulnar side of the tendon palmaris longus. A transverse incision of approximately 0.8 cm, which coincided with the transverse wrist crease, was made at the inlet. The expander was used to expand under the transverse carpal ligament toward the outlet of the carpal tunnel. It was relatively safe to establish the operating area in this way. The specific preoperative localizations of the inlet of endoscopy and the outlet of the carpal tunnel are shown in the surgical procedure section and Fig. 3. (ii) The surgeon could choose the appropriate model of cannula and expander based on the size of the patient's hand. (iii) A 2.7-mm or 2.9-mm endoscope was recommended to ensure adequate operating space. (iv) After the cannula was inserted, the median nerve was observed with endoscopy. Then, the surgeon could rotate the cannula to ensure that the median nerve was outside the operating area. After that, the balance blade on the cannula was clamped with a hemostat by an assistant to ensure the stabilization of the cannula. Finally, under the protection of the deep sliding groove, the transverse carpal ligament was incised under direct endoscopic vision with the hook knife. This operational method not only ensures the complete release of the transverse carpal ligament, but also does not easily injure the median nerve.

In this study, the median preoperative scores were 45.5 (6.8) for QDASH, 3.3 (0.2) for BCTSQ-SS, and 2.8 (0.3) for BCTSQ-FS. The median 1-month postoperative scores were 4.5 (6.7) for QDASH, 1.2 (0.3) for BCTSQ-SS, and 1.1 (0.3) for BCTSQ-FS. Previous literature indicated that the minimum clinically significant difference included an eight-point change in the QDASH score, 0.8 points in the BCTSQ-SS score, and 0.5 points in the BCTSQ-FS score.[13–15] Therefore, the median scores changed at the 1-month follow-up, surpassing the minimum clinically significant difference criteria compared with the preoperative scores. At the last follow-up, the median scores of QDASH, BCTSQ-SS, and BCTSQ-FS were 0 (4.5), 1.0 (0.1), and 1.0 (0.1), respectively. The incidence of median nerve injury was 0. The incidence of wound pain was 0. At the last follow-up, the incidence of pillar pain was 0 and that of other complications was 3.6% (3/83). Therefore, the kit has high operational safety while ensuring efficacy.

Complications

A total of three patients had complications. One patient had no improvement in hand symptoms postoperatively and was diagnosed with concurrent cervical spondylosis thereafter. Therefore, attention should be paid to the differential diagnosis of diseases with similar manifestations to CTS, especially the possibility of multiple co-existing diseases. The other two patients had diabetes; their symptoms were relieved postoperatively but relapsed months later. Zimmerman *et al.* conducted a retrospective study on the relationship between the postoperative efficacy of CTS and diabetes using a large sample size (10,770 wrists in 9049 patients). They concluded that the prognosis of CTS patients with diabetes was worse than that in patients without diabetes; it was easy to cause residual symptoms or long-term recurrence of symptoms postoperatively.[16] Therefore, attention should be paid to glycemic control in patients with diabetes in the future.

Strengths and Limitations of the Study

In this study, we conducted an initial investigation on ECTR using the Modified Soft Tissue Release Kit. The effectiveness and safety of this technique were verified by a small sample retrospective study, which was an economical and convenient method. However, there were still several limitations to this study. First, there were no controlled studies on patients who underwent traditional ECTR or were treated using a "CTS Relief Kit." Second, this study was a retrospective study in a single center. Therefore, we plan to conduct a multicenter randomized controlled study in the future to obtain clinical research data with more substantial evidence.

Conclusion

In conclusion, ECTR using the Modified Soft Tissue Release Kit is convenient and safe and can quickly improve hand symptoms and restore hand function, with significant short- and middle-term efficacy. In the future, randomized controlled trials with large samples are needed to provide more robust data for the promotion and application of the kit.

Author Contributions

Yiming Li and Xin Jiao contributed equally to this manuscript and should be considered the co-first authors.

Yaokai Gan designed the "Modified Soft Tissue Release Kit," conceived the study and performed all surgeries. Yiming Li followed up the patients and wrote this manuscript. Yiming Li and Xin Jiao collected and analyzed the data. Dingwei Shi assisted to during surgeries. Zengguang Wang helped to analyze the data. Yifei Yao assisted in conceiving the study. Kerong Dai was the leader of our research team and supervised the performance of all surgeries. All authors read and approved the final manuscript.

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Authorship Declaration

We acknowledged that all authors listed meet the authorship criteria according to the latest guidelines of the International Committee of Medical Journal Editors, and that all authors agreed with the manuscript.

Conflicts of Interest

The authors declare that no conflicts of interest.

Ethics Statement

This study was approved by the Ethics Committee of Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine (approval number SH9H-2020-T397-1); patient privacy was strictly protected during the study. I declared that all methods were performed per the relevant guidelines and regulations. The requirement of informed consent was waived due to the study's retrospective nature. I declared that the informed consent was waived by the Ethics Committee of Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine.

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