Original Article

Safety and Clinical Outcome After Carpal Tunnel Release by a Special Instrument

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Background: Carpal tunnel syndrome (CTS) is the most common compressive neuropathy of the upper extremity. Surgical treatment by carpal tunnel release is needed after unsuccessful conservative treatment. However, complications such as neurovascular injury and incomplete release of the transverse carpal ligament may occur. Therefore, the authors developed a specially designed instrument for carpal tunnel release surgery, called a CTR knife 1, to avoid such complications.

Objective: To demonstrate the safety and clinical outcomes of CTR knife 1.

Materials and Methods: A descriptive study of 36 patients diagnosed with moderate to severe CTS by electrodiagnosis that underwent carpal tunnel release surgery were included in the present study. The technique for carpal tunnel release made use of the CTR knife 1 to cut the transverse carpal ligament by limited palmar incision. The wide-awake local anesthesia with no tourniquet technique was used in all subjects. The Clinical outcomes were evaluated by the symptom severity score and functional severity score of the Thai version of the Boston questionnaire. The outcomes were collected preoperatively and 1, 3, and 6 months postoperatively.

Results: A significant decrease in both the symptom severity score and functional severity score postoperatively was observed. No life-threatening or serious complications such as permanent median nerve injury, tendon rupture, or infection were observed in the present study. Only two patients (5.6%) reported an unaesthetic scar, and one patient (2.8%) reported a painful scar that subsided after one year.

Conclusion: The newly designed CTR knife 1 can be used as a surgical instrument in CTR because it is safe and effective for carpal tunnel release.

Keywords: Carpal tunnel release; CTR knife; Carpal tunnel syndrome; Limited palmar incision; Limited open carpal tunnel release

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The most common compressive neuropathy of the upper extremities is carpal tunnel syndrome (CTS)[1]. Surgical treatment is performed after unsuccessful conservative treatment. There are surgical treatment options such as open or endoscopic carpal tunnel release. Various meta-analyses demonstrate that the traditional open carpal tunnel release resulted in longer recovery of the function[2-6], longer time to return to work[2-4], more wound-related complication[2,3] and higher postoperative hand pain[7], and higher risk of scar tenderness[4] as compared with endoscopic release.

To avoid these complications, endoscopic carpal tunnel release was introduced and showed good results[8-10]. However, a higher rate of complications such as neurovascular injury and incomplete release of the ligament were reported[4,11]. These may result from the introduction of the scope into a narrow space.

The authors' previous cadaveric study using a newly designed CTR knife 1 to cut a transverse carpal ligament (TCL) showed satisfactory results without any visualized neurovascular injury[12]. The purpose of the present study was to demonstrate the clinical outcome of carpal tunnel release in terms of safety and clinical outcomes using the CTR knife 1 with limited palmar skin incision and wide-awake local anesthesia with no tourniquet[13].

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Materials and Methods

Subjects

The study protocol was approved by the Siriraj

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Figure 1. A side view of the newly-designed instrument (A). A side view (B) and top view (C) of the cutting part.

Institutional Review Board (SIRB, COA no. Si 714/2019). Full written consents were obtained from all participants during their initial visit. The present study was conducted at the Department of Orthopedics, Siriraj Hospital, Mahidol University, Bangkok, Thailand between January 2019 and April 2021. The diagnoses were confirmed by electrodiagnosis in all cases. The inclusion criteria were CTS patients aged 18 or older, disease duration of at least three months, and failure of conservative treatment. The severity of CTS patients was determined as moderate or severe by electrodiagnosis. The exclusion criteria were inflammatory joint disease, a history of wrist trauma, malignancy with chemotherapy, and pregnancy or lactation.

Sample size calculation

The sample size was calculated from a formula for estimating the proportion of one population[14].

$$n = \frac{Z^2_{1-\alpha/2}\, P(1-P)}{d^2}$$

where error is 0.05, P is the proportion of success in using CTR knife 1 to cut the transverse carpal ligament, which was estimated that the completion result is not less than 90%, i.e., P=0.9, d is the margin of acceptable error, which is 0.1. Therefore, at the 95% confidence level, a sample size of at least 35 cases is required.

Instruments

The authors invented a new instrument, called a CTR knife 1, Thai patent no. 13276[15], for carpal tunnel release. The major advantages of this CTR knife 1 are a blunt arrow shape tip design (Figure 1C) that can minimize trauma while performing the operation and the base of the cutting part is longer and broader (Figure 1C) to help to protect the median nerve and tendons during operation. The other advantages are the durability of the instrument as it is made from metal (Figure 1A) and it has an ergonomically designed handle that helps surgeons to comfortably perform the surgery. This instrument has one piece that does not require assembly, as compared with other instruments such as Knifelight[16] or carpal tunnel tome[17]. This instrument proved to be safe in cutting TCL and preserving fascial convergence of muscular fascia between the thenar and hypothenar eminence in a previous cadaveric study[12].

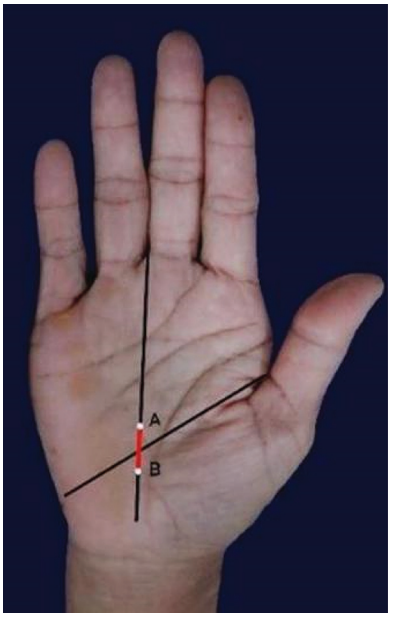

Figure 2. A limited palmar incision. A 1.5 cm to 2 cm incision made over the intersection of two imaginary lines: 1) a longitudinal line from the radial border of ring finger and 2) a Kaplan's cardinal line. The mid-point of the incision was located at the intersection of two lines.

Operative technique

Without a tourniquet, 8 to 10 mL of local anesthesia of 1% lidocaine with adrenaline injection and a 1.5 to 2 cm skin incision was made over the intersection of two imaginary lines, 1) longitudinal line from the radial border of the ring finger and 2) Kaplan's cardinal line. The mid-point of the incision was the intersection of two lines, which was the distal border of TCL. To avoid injury to the palmar cutaneous branch of the median nerve,

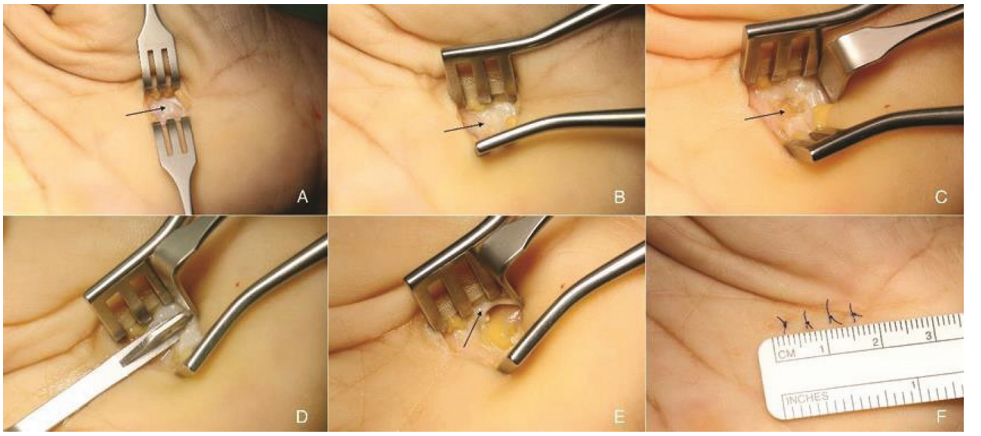

Figure 3. A surgical procedure: exposure of palmar fascia (A) distal border of TCL (B). Fat pad identified after distal border of TCL (C) was cut. Insertion of cutting blade under TCL (D) that was completely divided (E). Skin closure with overall incision length (F).

the incision did not project radially over the interthenar depression (Figure 2). After skin incision, the palmar aponeurosis was cut partially. The distal border of TCL was identified (Figure 3A, B). The vasoconstriction effect caused by adrenaline can cause scanty hemorrhage. Capillary bleeding was easily controlled using bipolar coagulation. The TCL was longitudinally divided into 0.5 to 1 cm at its distal border, starting with the number 15 blade, followed by small blunt-end scissors under direct visualization (Figure 3C). The distal segment of the median nerve was then uncovered. Penfield dissectors were inserted between the TCL and median nerve to isolate the two structures. CTR knife 1 was introduced into the tunnel through the created opening with a safeguarding platform underneath the TCL and the cutting blade confronting the distal undivided edge of the ligament (Figure 3D). The wrist was slightly dorsiflex and the CTR knife 1 was steadily advanced in a proximal direction to divide the remaining TCL until loss of resistance at the proximal wrist crease, which meant a complete cut (Figure 3E). In case of severe thickening of the TCL at the distal segment, cutting more of the TCL was necessary to clearly identify the median nerve and allow a safe cut of the proximal part of the TCL. The split edge of the ligament and median nerve were inspected. Exposure of the fatty tissue distal to the TCL indicated the adequacy of release (Figure 3F). At this time, vascularization over the median nerve could be observed since the tourniquet was not applied. After the bleeding was brought under control using bipolar coagulation, the skin was sutured with 4-0 nylon and compressive dressing was applied. Postoperative pain, numbness, and complications were monitored, and clinical outcome evaluated using the Thai version of the Boston questionnaire[18] at 1, 3, and 6 months postoperatively.

Statistical analysis

Descriptive statistics were presented as median (quartile 1 to quartile 3) for continuous variables after the Kolmogorov-Smirnov test confirmed that the data were not normally distributed, and frequencies and percentages for categorical variables. Differences in clinical characteristics including symptom severity score and functional status score between preoperative and postoperative scores were evaluated using the Friedman test for continuous variables. Post hoc analysis was done comparing preoperative and 1-, 3-, and 6-month postoperative scores using Wilcoxon-signed ranks test. The p-value of less than 0.05 for Friedman test and 0.016 (alpha/3) for post hoc analysis by Wilcoxon-signed ranks test were considered as statistically significant difference. All analyses were performed using PASW Statistics, version 18.0 (SPSS Inc., Chicago, IL, USA).

Results

Thirty-six patients aged 34 to 83, with a median of 57.5 years, were included in the present study. All patients were operated by one surgeon using the CTR knife 1 with limited palmar incision under local anesthesia without tourniquet application. The total operative time was usually less than 15 minutes. The median follow-up period was 12 months with a median period of 12 months and a range of 6 to 15.75 months. Most patient returned to work within two weeks after surgery with a median of 2 months and a range of 2 to 3 months (Table 1).

Clinical evaluation by the Thai version of

Table 1. Demographic data and clinical characteristics of participants

Variables	Overall (n=36)
Female; n (%)	28 (77.8)
Age (years); median (Q1 to Q3)	57.5 (49.25 to 63.25)
Hand dominance: right; n (%)	33 (91.7)
Side of surgery: right; n (%)	23 (63.9)
Return to work (weeks); median (Q1 to Q3)	2 (2 to 3)
Follow up period (months); median (Q1 to Q3)	12 (6 to 15.75)
Complication; n (%)	3 (8.3)
Unaesthetic scar	2 (5.6)
Painful scar	1 (2.8)

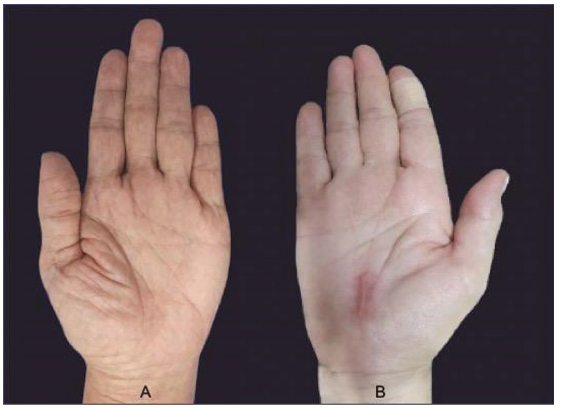

Figure 4. Postoperative scar: Aesthetic scar (A) and unaesthetic scar with insignificant pain (B).

the Boston questionnaire showed that the severity symptoms score dramatically decreased within one month and there were no symptoms after six months postoperatively in most subjects (Table 2). The functional severity score also decreased within one month and patients had normal hand function after six months (Table 2). There were neither neurovascular injuries nor infection observed in the present study. The injury of all nine tendons associated with carpal tunnel was also not observed. A surgical scar of two patients was considered unaesthetic (Figure 4B). A painful scar occurred in one case that decreased to normal levels after one year of follow-ups.

Discussion

Carpal tunnel release using the CTR knife 1 with limited palmar incision[17] and under local anesthesia without tourniquet application[13] technique demonstrated satisfactory clinical outcomes after surgery. Although meta-analysis suggesting that CTS can be effectively managed with endoscopic carpal tunnel release[6], in severe CTS the carpal tunnel itself is narrow and tight, from thick transverse carpal ligament, endoscopic release may injure the median nerve during the procedure. Therefore, the authors preferred open release in that situation. The evolution of special instruments designed for carpal tunnel release have been reported by several groups. Paine and Polyzoidis[19], and Fernandes et al[20] reported carpal tunnel decompression using Paine retinaculotome with the arm tourniquet under either general or regional anesthesia, while Tzaan et al[21] performed under regional block or general mask anesthesia using an accurate midpalmar incision. Those three studies demonstrated satisfactory results. In 1998, Lee and Strickland introduced carpal tunnel tome and performed a release with a limited palmar incision in 1,219 subjects and reporting two cases of median nerve injury[17]. Their 13 years of experience using carpal tunnel tome for carpal tunnel release in 1,332 subjects mentioned 11 complications, such as paresthesia and hypersensitivity of the ulnar side of the middle finger and radial side of the ring finger[22]. The drawback of carpal tunnel tome is the cost as it required using of complicated instruments such as an elevator for transverse carpal ligament, a nerve protection instrument, and a disposable carpal tunnel tome.

The major concern of these limited palmar incisions was the risk of nerve damage due to limited visualization during blind proximal cutting. In 2015, Yoo et al, presented a meticulous anatomical study

Table 2. The symptom severity score and functional severity score from the Thai version of the Boston questionnaire at pre-operation and 1, 3, and 6 months post-operation

Boston carpal tunnel score	Pre-operative	Post-operative			p-value*
		1 month	3 months	6 months	
Symptom severity score	2.1 (1.8 to 2.9)	1.0 (1.0 to 1.3)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	<0.001
p-value post hoc**		<0.001	<0.001	<0.001	
Functional status score	1.9 (1.5 to 2.9)	1.0 (1.0 to 1.1)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	<0.001
p-value post hoc**		<0.001	<0.001	<0.001	

* Friedman test, ** Data compared between pre-operative with post-operative scores by Wilcoxon-signed ranks test

of TCL and showed that the distal was the thickest part of TCL[23]. Therefore, the authors recommended "the preliminary distal-cut-first technique" by cutting the thickest part of TCL until the flat tip of the instrument separated the median nerve and moved freely before advancing the instrument for proximal cutting of the TCL. In 2005, Avci and Sayli developed a special knife, known as Knifelight, to allow for more visualization and reported satisfactory results with few complications[16]. However, the problem with the Knifelight was the easily broken plastic skids that sandwiched the cutting blade. The preliminary distal-cut-first technique may reduce the chance of broken plastic skids of the Knifelight since forceful cutting of distal TCL could be avoided. This thickest part of the TCL might also be the cause of nerve injury from endoscopic carpal tunnel release in both the single and double portal technique, since it involves putting the instrument into the carpal tunnel before dividing TCL, which is difficult.

The present study demonstrated the clinical evaluation of the Thai version of the Boston questionnaire. The symptoms severity and functional severity scores significantly decreased within one month and patients were symptom-free after six months postoperatively (Table 2). Most patients were able to resume daily hand function just a few days after surgery, which is comparable to previous studies[10,20,22,23]. The hand functions that had the most time-consuming recovery were those required grip strength such as opening jars, household chores, and carrying a grocery bag.

This specially designed instrument, CTR knife 1, proved its safety and effectiveness profile in a cadaveric study[12]. It can divide TCL completely in only a single cut while preserving fascial convergence between the thenar and the hypothenar muscular fascia, resulting in less soft tissue injury. The authors' surgical technique demonstrated effectiveness and the safety of the instrument for carpal tunnel release using limited mid-palmar incision under local anesthetic. However, the present study has limitations since it was a case series study. No serious complications were observed in the present study. However, it may pose a problem when the number of patients operated using the CTR knife 1 is increased. A randomized-control study between the CTR knife 1 and the conventional surgical technique is necessary. In addition, the main drawback of the CTR knife 1 is the cutting part as its sharpness will decrease after sterilization and reuse. A replaceable and disposable blade that can be attached to the cutting part should be developed in the future.

What is already known on this topic?

Carpal tunnel release is the treatment option for CTS. However, the complications such as neurovascular injury and incomplete release of the ligament can occurred during the operation. Special surgical instruments for carpal tunnel release have been developed in the past.

What this study adds?

The CTR knife 1, a new patented surgical instrument, in combination with the operative technique has demonstrated its safety and effectiveness for the treatment of CTS.

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Conflicts of interest

WP is the patent owner of the CTR knife 1. Other authors have no relationships, conditions, or circumstances that present a potential conflict of interest.

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