Newly Developed Operative Instrument for Carpal Tunnel Release: A Cadaveric Study

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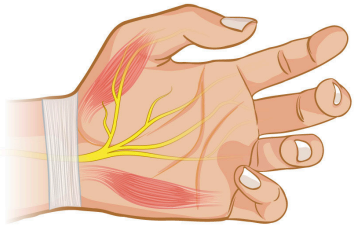
CTR knives mark 2 and 3 for carpal tunnel release

CTR Knives 2 and 3 effectively transected the TCL without causing injury to surrounding structures and preserved, the overlying fascial coverage of the ligament.



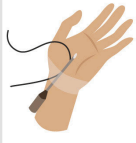
18 fresh cadavers (36 wrists) for CTR Knife 2

12 fresh cadavers (24 wrists) for CTR Knife 3

All cadavers had no history of previous injury or surgical interventions at their wrists.

CTR knife 2 with a disposable blade no. 15 installed

CTR knife 3 with disposable blade no. 11 installed



Carpal tunnel release operation using limited longitudinal palmar incision

Assess the completeness of transverse carpal ligament (TCL) transection and identify any potential injuries

- CTR Knife 2 achieved a complete cut of TCL for 35 of 36 cadaveric wrists
- CTR Knife 3 had 21 of 24 complete TCL cuts
- No identifiable injury to the neurovascular structures or tendons in the surrounding area.

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SMJ SIRIRAJ MEDICAL JOURNAL | Pichaisak, et al. *Siriraj Med J* 2025;77(3):233-238.

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Received 2 July 2024 Revised 23 August 2024 Accepted 23 August 2024
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https://doi.org/10.33192/smj.v77i3.270013

ABSTRACT

Objective: This study aims to assess the effectiveness and safety of the newly designed instruments, Carpal tunnel release (CTR) Knives 2 and 3, which use a limited skin incision technique in cadavers.

Materials and Methods: The study utilized 36 wrists from 18 fresh cadavers for CTR Knife 22 and 24 wrists from 12 fresh cadavers for CTR Knife 3. None of the cadavers had a history of previous injury or surgical interventions. A limited longitudinal palmar incision was made for the carpal tunnel release, conducted with the newly developed CTR Knives, which are equipped with a disposable blade number 15 (for CTR Knife 2) or 11 (for CTR Knife 3). To assess the completeness of transverse carpal ligament (TCL) transection, the skin incision was extended proximally to expose and evaluate the released ligament. Meticulous dissection was performed to identify any potential injuries to the neurovascular structures around the surgical area.

Results: CTR Knife 2 achieved a complete cut of TCL for 35 of 36 cadaveric wrists, with only one incomplete cut, while CTR Knife 3 achieved 21 out of 24 complete TCL cuts. The incomplete cuts were likely due to severe thickening of the ligament. Subsequent exploration after the procedure revealed no identifiable injury to the neurovascular structures or tendons in the surrounding area.

Conclusion: The newly developed CTR Knives 2 and 3 effectively transected the TCL without causing injury to surrounding structures and preserved, the overlying fascial coverage of the ligament.

Keywords: Carpal tunnel release; limited incision; instrument; safety; effectiveness; cadaveric study (Siriraj Med J 2025; 77: 233-238)

INTRODUCTION

Carpal tunnel syndrome (CTS), the most prevalent compression neuropathy of the upper extremity,[1] is characterized by numbness, tingling, and weakness in the hand and arm resulting from the compression of the median nerve within the carpal tunnel at the wrist. When conservative treatments such as magnetic stimulation,[2] splinting, medication, and therapy fail to provide relief, surgical interventions are necessary. The standard surgical treatment for CTS is a procedure known as carpal tunnel release (CTR), which involves severing the ligament that forms the roof of the carpal tunnel to relieve pressure on the median nerve. This procedure can be performed using traditional open incisions or minimally invasive techniques such as endoscopic or arthroscopic methods. By releasing pressure on the median nerve, CTR aims to alleviate symptoms and improve hand function.

Carpal tunnel release (CTR) can be performed traditional open incisions or minimally invasive techniques such as endoscopic or arthroscopic approaches. Traditional open CTR often leads to higher post-operative complications, including pillar pain and scar tenderness compared to minimally invasive techniques,[3,4] which are associated with a higher incidence of nerve injury, incomplete release of the carpal ligament, and vascular injury.[5-8] Additionally, there is often a learning curve for surgeons adopting these newer techniques, which can potentially affect surgical outcomes.

A technique using a limited palmar incision has been developed to reduce complications associated with both traditional and minimally invasive carpal tunnel release (CTR), such as pillar pain, painful scarring, and the learning curve for surgeons. Despite these improvements, instances of serious median nerve injury have still been reported.[9] In response, the CTR Knife 1 was developed and has shown promising results in reducing nerve injury complications.[10,11] However, a limitation of this tool is its manufacturing process, particularly the sharpening of the blade, which requires skilled technicians. Additionally, frequent use can dull the blade, leading to ineffective cutting. Therefore, this study aimed to assess the effectiveness of CTR knives 2 and 3 for carpal tunnel releases using a limited incision technique on fresh cadavers.

MATERIALS AND METHODS

Subjects

This proof-of-concept study was carried out at the Department of Orthopaedic Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand, between 2020 and 2021. All fresh cadavers aged 18 years or older at the time of death. No specimens showed any signs of previous injuries, wrist surgeries, or congenital defects. The study protocols received approval from the Siriraj Institutional Review Board (SIRB) (Protocol no. 447/2563 (Exempt) for CTR Knife 2 and Protocol no. 890/2563 (Exempt) for CTR Knife 3.

Sample size calculation

This calculation was based on the sample size formula used for estimating the proportion of an infinite population.[12] With an alpha error set at 0.05, $Z_{0.975}$ =1.96, the researcher anticipated that the complete severance of the transverse carpal ligament (TCL) would be at least 90% (P=0.9), with an allowable margin of error at 10% (d=0.1). To maintain a 95% confidence level, a minimum sample size of 35 hands was necessary. Therefore, the study involved the examination of 35 fresh cadaveric wrists (sourced from 18 bodies) for each version of the CTR knives.

CTR Knife 2 and CTR Knife 3

The CTR Knife 2 and 3 (Fig 1) were modified from the original CTR Knife 1.[10,11] The alterations involved replacing the cutting component of CTR Knife 1 with a commercially available blade, specifically blade number 15 for CTR Knife 2 (Fig 1a, 1b) and blade number 11 for CTR Knife 3 (Fig 1c, 1d), with each featuring a locking mechanism. These enhancements facilitate the swift replacement of blades during operations, addressing issues related to decreased sharpness and the necessity for frequent sharpening of the cutting element. Additionally, a protective bar was added to the design to safeguard soft tissues during the removal of the CTR Knives 2 and 3 following the incision of the TCL.

Surgical technique

For consistency, a single orthopaedic surgeon (WP) carried out all carpal tunnel release operations in the present study. A detailed version of the surgical technique used in this procedure has been described in a previous study.[11] In brief, a longitudinal incision of 1.5-2.0 centimeters was made at the intersection of two imaginary lines: one extending from the radial border of the ring finger and the other from Kaplan's cardinal line (Fig 2a). Following this, the palmar aponeurosis was longitudinally incised and retracted to expose the distal border of the TCL. Subsequently, a 0.5-centimeter longitudinal incision was then made on the distal border of the TCL using a No. 15 scalpel blade to expose the median nerve within the carpal tunnel. Penfield dissectors were employed to detach the median nerve from the ligament. Subsequently, the flat blunt tip of the CTR Knife 2 or 3 was carefully inserted under the remaining TCL (Fig 2b), while the wrist was kept slightly extended. Gentle pressure was applied to advance the blade against the ligament until it met resistance at the proximal wrist crease, after which the knife was retracted. Throughout this process, a protective bar was utilized to prevent soft tissue damage, particularly to the fascial layer between the thenar and hypothenar muscles.

Effectiveness and safety of CTR Knife 2 evaluation

After finishing the procedure, the surgeon departed from the operative site to maintain the integrity of the blinding process. Following the procedure, a skin incision was made extending proximally to the proximal wrist crease (Fig 2c) by the hand surgeon to assess the adequacy of the ligament release and to check for potential injuries to structures within the carpal tunnel, including the median

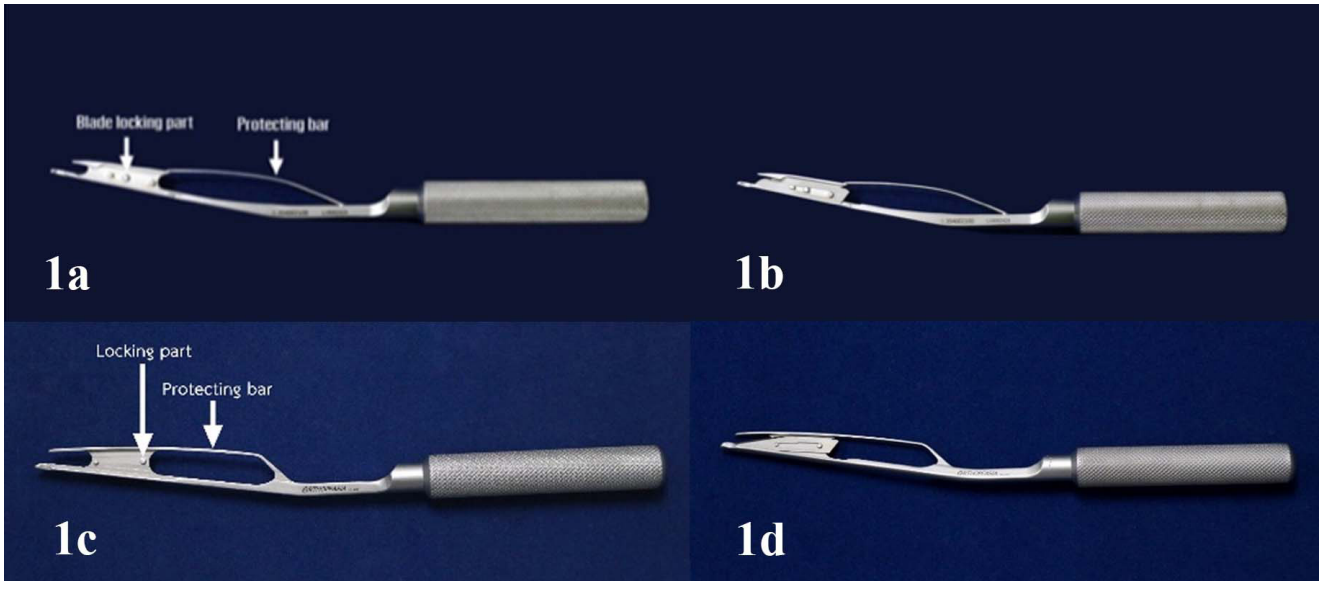

Fig 1. CTR Knives 2 and 3. CTR Knife 2 shows the blade locking part and the protecting bar (1a), and CTR Knife 2 with a disposable blade no. 15 installed (1b). CTR Knife 3 shows the blade locking part and the protecting bar (1c), and CTR Knife 3 with disposable blade no. 11 installed (1d).

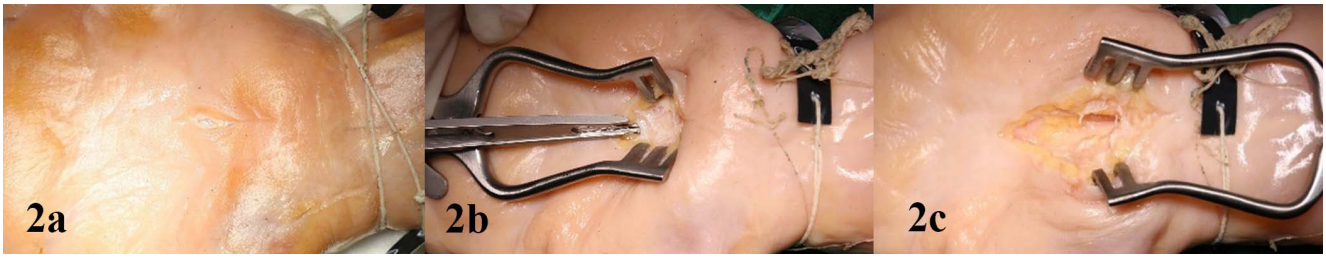

Fig 2. Surgical technique. The incision was made at the convergence point of two theoretical lines: one originating from the radial edge of the ring finger and the other originating from Kaplan's cardinal line. (2a); the insertion of CTR Knife 2 (with blade no.15 installed) to the distal border of the transverse carpal ligament (2b); An extended incision after the procedure to evaluate the effectiveness and safety of CTR Knives (2c).

nerve, the recurrent motor branch of the median nerve, the palmar cutaneous branch of the median nerve, flexor tendons, and the superficial palmar arterial arch. These structures were carefully examined and evaluated under direct visualization from two independent assessors, a hand surgeon, and an experienced research assistant who was trained and involved in CTR knives studies since 2019.

RESULTS

Following a minimally invasive carpal tunnel release surgery using the CTR Knife 2, equipped with blade number 15, a complete transection of the TCL was achieved in 34 out of 35 cadaveric wrists, constituting a success rate of 97.1%. Notably, in one case, incomplete cutting was observed due to pronounced TCL thickening (Fig 2c). When using CTR Knife 3 (equipped with disposable blade number 11), a complete transection of the transverse carpal ligament was achieved in 21 out of 24 cadaveric wrists (87.5%). However, in some cases, obstructions caused by the catching or snagging of the transverse carpal ligament within the narrow, acute-angled niche between the protective bar and the blade, were encountered during the cutting process. During the decompression maneuver, a tactile sensation of obstruction was perceived. Upon further inspection, it was evident that obstructions occurred at this specific niche area and required the application of increased force pressure against the transverse carpal ligament to overcome the impediment. However, no obstructive sensation was observed within the gap between the protective bar and blade number 15.

Throughout the procedure, the integrity of the fascia between the thenar and hypothenar muscles were preserved. Subsequent exploration encompassed assessment of the median nerve, its motor branch, the palmar cutaneous branch of the median nerve, tendons, and associated vessels, revealing no indications of neurovascular injury from both CTR Knife 2 and 3.

DISCUSSION

The effectiveness and safety of CTR Knives 2 and 3 in performing carpal tunnel release procedures using a limited incision surgical technique was demonstrated in our study. The rate of incomplete cutting of the transverse carpal retinaculum (TCR) was comparable between the previously studied CTR Knives 1,[10] 2 and 3 (current study). There were no incomplete cuts in 36 attempts with Knife 1, one incomplete cut in 35 attempts with CTR Knife 2, and three incomplete cuts in 24 attempts with CTR Knife 3. However, no model of CTR knives could detect potential injuries to the surrounding neurovascular structures adjacent to the operative field.

Several instruments, including the retinaculotome,[13] carpal tunnel tome,[9] and Knifelight,[14] have been developed and used for limited incision carpal tunnel release procedures. A major concern with these approaches is the increased risk of nerve and blood vessels injuries due to limited visibility and anatomical variations in the TCL among patients. Studies have shown that the Paine retinaculotome effectively releases the TCL through a limited incision approach, yielding satisfactory results.[13,15,16] However, both the Paine retinaculotome and CTR Knife 1 have experienced issues with blade dullness of the cutting edge after multiple uses, which affects sharpness and cutting ability.

The carpal tunnel tome, while effective, has a high cost which is a significant drawback. It requires the use of several specialized and complex instruments, including an elevator for the TCL, a nerve protection instrument, and a disposable carpal tunnel tome, which can be expensive. Additionally, there have been reports of complications where the median nerve was lacerated during the procedure.[9]

One issue with the Knifelight device is with the plastic skids that sandwich the cutting blade, which are prone to breaking under the increased force required to transect the TCL. Furthermore, the Knifelight is a costly disposable device, and its technical complexity poses challenges for surgeons during its use.

Given the successful application of CTR Knife 1 in both cadaveric studies and clinical patients,[10,11] we strongly recommend adopting a similar surgical technique. This approach enables a complete transection of the TCL with a single cut while preserving the fascial integrity between the thenar and hypothenar muscular fasciae. Ongoing clinical trials evaluating CTR Knives 2 and 3 should demonstrate reduced tissue trauma and an absence of neurovascular injuries when compared to existing techniques or instruments used in TCR.

Our study, conducted using fresh cadaveric specimens, has certain limitations inherent to its design. First, certain procedural aspects may deviate from those encountered in live patient scenarios. For instance, the administration of local anesthesia could potentially induce anatomical alterations around the injection site, and employing a tourniquet might lead to vascular congestion in the hand. Consequently, these factors could result in variations in the incidence of neurovascular injuries in living patients. Second, this study did not explore common complications associated with open carpal tunnel release, such as pillar pain, painful scarring, or postoperative infection rates. These complications are intended to be addressed in future research involving patients diagnosed with carpal tunnel syndrome who undergo future carpal tunnel release procedures. The third limitation of this study was our inability to achieve the initially planned sample size of 35 cadavers for CTR Knife 3. Despite calculations indicating this number would suffice, logistical constraints resulted in the inclusion of only 24 cadavers in the study. The primary reason for this limitation was the unavailability of additional cadavers during the designated study period. While efforts were made to adhere to the predetermined sample size, practical constraints necessitated adjustment of the sample size. Consequently, the reduced sample size may impact the generalizability of our findings. Future studies with larger sample sizes are required to validate the results obtained in this study.

CONCLUSION

The recently developed CTR Knife 2, a specialized tool for limited incision carpal tunnel release procedures, has proven to be both effective and safe. Nonetheless, further investigation through clinical trials is necessary to assess its suitability for widespread clinical application.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request. The data are not publicly available due to privacy or ethical restrictions.

ACKNOWLEDGMENTS

The authors gratefully acknowledge Assist. Prof. Dr. Yuwarat Montreerarat of the Hand and Microsurgery Division of the Department of Orthopaedic Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University for her assistance in the evaluation of CTR knives effectiveness and safety, and Ms. Suchitphon Chanchoo of the Research Division of the Department of Orthopaedic Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University for her assistance with data collection and figures preparation.

DECLARATION

Grants and Funding Information

This project is not funded by any external sources.

Conflict of Interest

WP is the patent owner of the CTR knives 2 and 3. Other authors have no relationships, conditions, or circumstances that present a potential conflict of interest.

Registration Number of Clinical Trial

This study utilized cadaver for research. As it does not involve living human participants, clinical trial registration was not required.

Author Contributions

W.P. : conceptualisation, project administration, methodology, funding acquisition, supervision, investigation, data curation, formal analysis, visualisation, validation, writing-original draft preparation, review & editing. N.P. : conceptualisation, methodology, investigation, writing – review & editing. P.C. : conceptualisation, methodology, investigation, formal analysis, writing –review and editing, corresponding author.

Use of Artificial Intelligence

Artificial Intelligence tool was not used in this manuscript.

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