Original Article

Novel Carpal Tunnel Release Instrument: A Cadaveric Proof of Concept Study

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Background: Carpal tunnel syndrome is the most common compressive neuropathy of the upper extremity. Standard open carpal tunnel release is the gold standard treatment; however, that procedure can result in scar tenderness and pillar pain. Minimally invasive surgery is less likely to cause these post-surgical complications. The authors invented a newly-designed instrument that facilitates easier placement of the instrument into the carpal tunnel, and that has a more secure holding piece to stabilize the instrument during division of the ligament.

Objective: To investigate the efficacy of our newly-designed instrument using the limited skin incision technique in cadaver model, and to identify potential risks of injury to nearby important structures.

Materials and Methods: Forty unembalmed cadaveric wrists without history or sign of previous injury or surgery were used for carpal tunnel release procedure using limited longitudinal skin incision at palm. To assess the completeness of transverse carpal ligament release, a proximally-extended skin incision was made to evaluate the released ligament. Median nerve, recurrent motor branch of median nerve, palmar cutaneous branch of median nerve, flexor tendons in carpal tunnel, and superficial palmar arterial arch were dissected to identify evidence of injury.

Results: All transverse carpal ligaments of 40 cadaveric wrists were completely released with preservation of fascial coverage between the thenar and hypothenar muscles. All surrounding important structures were identified without evidence of injury.

Conclusion: This newly designed instrument for carpal tunnel release demonstrated precision function and efficacy without injury to surrounding structures, and with preservation of fascial coverage above the ligament. Further investigation for application in clinical use is needed to confirm the safety and efficacy of this newly-designed instrument.

Keywords: Carpal tunnel release, Instrument, Efficacy, Minimally-invasive surgery, Cadaveric study

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Carpal tunnel syndrome (CTS) is the most common compression neuropathy of the upper extremity[1]. The characteristic symptoms and signs of CTS include numbness, paresthesia, and pain along median nerve distribution. Objective changes in sensation and strength of median-innervated muscles in the hand may not be observed in some cases. After unsuccessful conservative treatment, surgical treatment by complete release of transverse carpal ligament should be performed[2].

Carpal tunnel release is the gold standard treatment that was introduced and advocated by Phalen in 1950[3]. Standard open carpal tunnel release is associated with post-surgical complications that include scar tenderness and pillar pain. Endoscopic carpal tunnel release was shown to yield the same result as open method, but with more complications, such as neurovascular injury and incomplete release of the ligament[4-6]. Moreover, the total cost of endoscopic carpal tunnel release was reported to be 43.9% greater than the cost of open carpal tunnel release procedure[7].

Lee WP and Strickland JW (1998) introduced a limited palmar incision technique to preserve fascial convergence between the thenar and the hypothenar muscular fascia, as demonstrated in their study of 28 cadaveric hands[8]. In their study, the palmar aponeurosis was only partially cut to gain access to the carpal tunnel. The muscular fascia and palmar aponeurosis are anatomical structures that play an important role in expediting postoperative recovery. After the administration of adequate local anesthesia, the procedure was started by making a skin incision up to 1.5 cm in length beginning distally at Kaplan's cardinal line and then continuing over the distal part of the carpal ligament. Division of the distal part of the carpal ligament was performed under direct vision, whereas the proximal part of the ligament was blindly divided by a specially-designed "carpal tunnel tome". Their clinical study showed 92.2% highly favorable result, but two cases of median nerve injury. Shapiro S described a microsurgical technique with an incision up to 1 centimeter

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longer that facilitated the division of the entire ligament under direct vision. He preserved fascial coverage of thenar and hypothenar muscle by locating the proximal end of the incision at least 5 millimeters away from the wrist crease to achieve the goals of this minimally invasive technique[9].

However, the minimally-invasive skin incision technique requires a specially-designed instrument that can be inserted into the incision, and that has a secure holding piece that can stabilize the instrument during division of the ligament. Accordingly, the authors of the present study invented a newly designed instrument to satisfy these requirements.

The objectives of the present study were to investigate the efficacy of our newly-designed instrument for carpal tunnel release using limited skin incision technique in cadaver model, and to identify potential risks of injury to nearby important structures.

Materials and Methods

This proof of concept study was performed on 40 unembalmed cadaveric wrists at the Department of Orthopaedic Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand during the year 2017 to 2018 study period. All specimens had no history or sign of injury or previous wrist surgery. The protocol for this study was approved by the Siriraj Institutional Review Board (SIRB) (COA No. 251/2560(EXP)).

Newly-designed instrument

The authors invented a new carpal tunnel release instrument (Petty patent registration number 1603002309) that facilitates easier placement of the instrument into the carpal tunnel, and that has a more secure holding piece to stabilize the instrument during division of the ligament (Figure 1A). This instrument has 4 component parts (Figure 1B), including the holding piece, the angular connecting piece, the blade, and the tip. The holding piece is connected to the angular connecting piece to facilitate convenient insertion of the tip of the instrument under the transverse carpal ligament. The blade was meticulously designed to ensure safe and complete cutting of the ligament. The blade consists of two parts (Figure 1C), including the covered head and a vertical sharp cutting part with expanded wide base that is connecting to a flat-blunt tip (Figure 1D). The flat-blunt tip was designed to protect the median nerve during division of the transverse carpal ligament. The upper slender covered head was designed to protect the fascial convergence between the thenar and hypothenar muscles, which are situated superficial to the transverse carpal ligament.

Surgical technique

A longitudinal 2.5 centimeter skin incision was made from distal to proximal direction starting from the intersection of the following 2 imaginary lines: longitudinal line from the radial border of the ring finger and Kaplan's cardinal line (Figure 2). Palmar aponeurosis was identified and partially separated to identify the distal border of the transverse carpal ligament. The distal border of the transverse carpal ligament was longitudinally divided for 1 centimeter using a No. 15 scalpel blade to expose the area under the median nerve in the carpal tunnel (Figure 3A). A Penfield tissue separator was

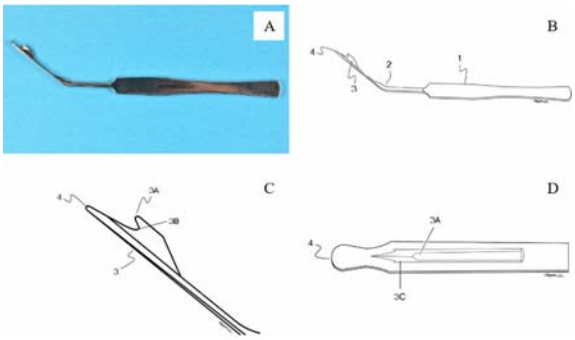

Figure 1. A) Newly designed instrument. B) Shape and parts of instrument: holding piece (1), angular connecting piece (2), blade (3), and tip (4). C) Cutting part with covered head (3A) and vertical sharp cutting part (3B). D) Expanded wide base (3C).

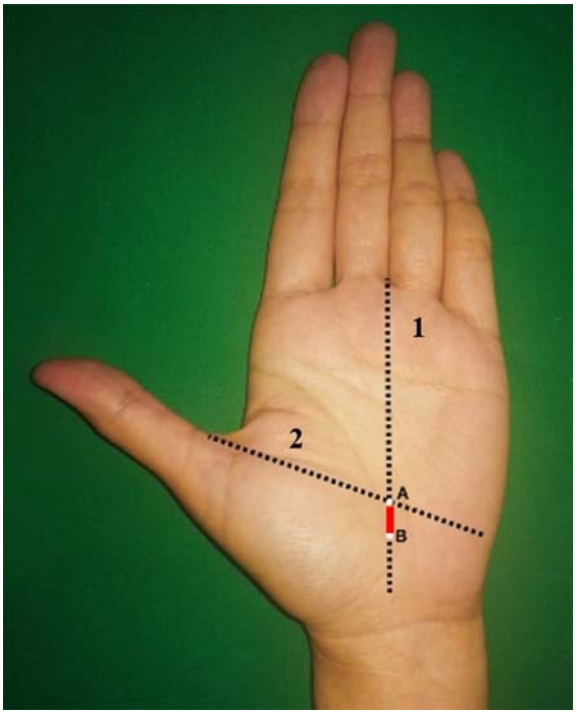

Figure 2. Longitudinal line from radial border of ring finger (1). Kaplan's cardinal line (2). Intersection point between two lines (A). Skin incision 2.5 cm from point A to point B.

inserted underneath the ligament to safely segregate and protect the median nerve during cutting of the remaining ligament. The flat-blunt tip of the instrument was then inserted under the ligament (Figure 3B) with the wrist joint being held in a slightly extended position. The vertical cutting blade of the instrument was gently pushed against the ligament until loss of resistance at the proximal wrist crease was observed.

To ensure the completeness of ligament release, a proximally-extended skin incision to the proximal wrist crease was performed. Median nerve in carpal tunnel, recurrent motor branch of median nerve, palmar cutaneous branch of median nerve, flexor tendons in carpal tunnel, and superficial palmar arterial arch were identified and dissected to examine for evidence of injury.

Results

Carpal tunnel release procedure was performed using the limited skin incision technique in 40 wrists from 20 cadavers. Ten cadavers were male with a mean age of 74.6 years and a standard deviation of 10.1 years. The other 10 cadavers were female with a mean age of 77 years and a standard deviation of 10.1 years. None of the cadaveric wrists had sign of previous injury or surgery. The authors found the transverse carpal ligaments in all cadaveric wrists to be completely cut with preservation of fascial coverage between the thenar and hypothenar muscles (Figure 4). Examination of the median nerve, recurrent motor branch of median nerve, palmar cutaneous branch of median nerve, flexor tendons in carpal tunnel, and superficial palmar arterial arch in each cadaveric wrist revealed no evidence of procedure-related insult to any of these important structures.

Discussion

Open carpal tunnel release has been and continues to be accepted as a standard treatment for cases of carpal tunnel syndrome that are refractory to nonoperative treatments. There are two surgical methods for releasing the carpal tunnel-open and endoscopic. The standard open carpal tunnel release technique is associated with complications that include thenar pain and unsightly scar at the wrist crease that is caused by the long incision and extended soft tissue dissection. Modifications of standard open carpal tunnel release, such as mini-open release, have been advocated to reduce scar formation and thenar pain, and to help expedite an early return to work[10,12]. Mini-open carpal tunnel release (CTR) consists of a longitudinal incision that varies from 1.5 to 3 centimeters that is made in line with the radial border of the ring finger[11,12]. Different tools have been used for mini-open CTR, including Indiana Tome, the KnifeLight, the Safeguard System, and PSU retractor. Epineurotomy was added to minimize median nerve compression after standard open carpal tunnel release[13]. Endoscopic carpal tunnel release developed by Okutsu has been widely used since 1986[14]. Two methods have been used for endoscopic carpal tunnel release, including the single-portal and dual-portal techniques[15]. The single portal technique consists of a single

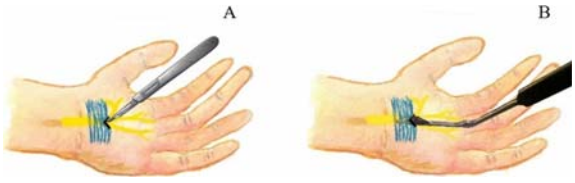

Figure 3. A) Distal border of transverse carpal ligament was partially cut to expose median nerve. B) The flat blunt tip of instrument was inserted under the transverse carpal ligament to begin cutting the remaining part.

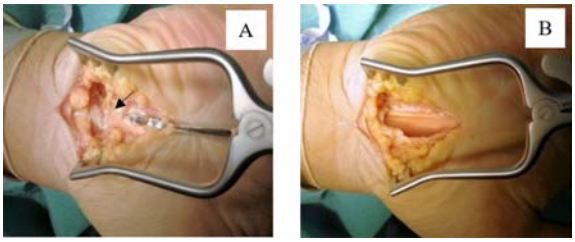

Figure 4. A) Preservation of fascial convergence between thenar and hypothenar muscle was identified (arrow). B) After cutting fascial convergence, complete cut of transverse carpal ligament was identified.

transverse incision for releasing the transverse carpal ligament. The double-portal technique requires two incisions, one transverse incision at the wrist and one longitudinal incision at the palm. A comparison of outcomes between open carpal tunnel release and endoscopic carpal tunnel release revealed no significant superiority between methods[16]. A comparison between mini-open carpal tunnel release and standard open carpal tunnel release also showed no significant difference in outcomes between methods[17]. Mini-open technique showed better functional status and symptom severity outcomes in the earlier stages after surgery, but the differences between groups were not statistically significant[18].

The authors developed a specially designed instrument for carpal tunnel release to avoid complications, such as pillar pain, unsightly scar, and neurovascular injury. This instrument was shown to be safe and convenient to use for carpal tunnel release since the median nerve is protected by the flat-blunt tip. Moreover, the slender covered head part protects the fascial convergence between the thenar and hypothenar muscles above the transverse carpal ligament, and this may reduce pillar pain and promote faster postoperative recovery. However, clinical applications have to be investigated in the next phase of the study.

Conclusion

This newly designed instrument for carpal tunnel release demonstrated precision function and efficacy without injury to surrounding structures, and with preservation of

fascial coverage above the ligament. It also preserves soft tissue convergence between the thenar and hypothenar muscles above the ligament, which may reduce pillar pain and unsightly scarring. Further investigation for application in clinical use is needed to confirm the safety and efficacy of this newly-designed instrument.

Disclosure

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What is already known on this topic?

Carpal tunnel syndrome is the most common compressive neuropathy of the upper extremity. Open carpal tunnel release by separation of the transverse carpal ligament is the standard operative treatment in patients with later-stage disease and in patients with no improvement after conservative treatment. Minimally invasive surgery is increasing in popularity as the treatment of choice due to increased patient satisfaction and reduced complications compared to standard open carpal tunnel release. A specially designed operative instrument is needed to improve the efficacy and outcomes of this minimally invasive operative procedure.

What this study adds?

This newly-designed instrument for carpal tunnel release facilitates instrument insertion into the carpal tunnel via a very small skin incision, and that has a secure holding piece to stabilize the instrument during the ligament cutting procedure. This study demonstrated the unerring efficacy of this instrument for division of the transverse carpal ligament with preservation of fascial coverage between the thenar and hypothenar muscles. The preserved fascial coverage may reduce the incidence of pillar pain in clinical application. This cadaveric study showed good safety with no observed injury to any important surrounding structures.

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Potential conflicts of interest

The authors declare no conflicts of interest.

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