Minimally Invasive Ultrasound-Guided Carpal Tunnel Release

Preliminary Clinical Results

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Ultrasound-guided carpal tunnel release was performed on 14 patients (18 wrists) using dynamic expansion of the transverse safe zone. Our patient population included able-bodied patients and those with impairments. The first 8 cases (12 wrists) underwent the procedure in an operating room, the remainder in an outpatient setting. No complications occurred, and all patients were able to immediately resume use of their hands without therapy. Improvements in the Quick Form of the Disabilities of the Arm, Shoulder, and Hand Index and Boston Carpal Tunnel Questionnaire at 3 months were comparable to results reported with mini-open and endoscopic release. Our results show that ultrasound-guided carpal tunnel release can be safely and effectively performed in an outpatient setting.

Key Words—carpal tunnel release; median nerve; musculoskeletal (interventional); ultrasound

Abbreviations
BCTQ, Boston Carpal Tunnel Questionnaire; CTR, carpal tunnel release; CTS, carpal tunnel syndrome; QDASH, Quick Form of the Disabilities of the Arm, Shoulder, and Hand Index; TCL, transverse carpal ligament; US, ultrasound

Carpal tunnel syndrome (CTS) is the most common peripheral entrapment neuropathy and has an incidence of 3.5% to 6.2%, leading to 450,000 surgical releases annually at a total cost of more than 2 billion dollars.[1–3] Greater than 90% of patients report clinical improvement after release.[4–6] Although initially performed via a large (3–5 cm) palmar incision, carpal tunnel release (CTR) techniques have continually evolved to reduce surgical trauma, with the goal of improving cosmesis, reducing postoperative pain, and promoting faster recovery.[7] Currently available CTR techniques include mini-open CTR via a single 1- to 3-cm palmar incision, endoscopic CTR via 1 (wrist) or 2 (wrist and palm) 1- to 2-cm incisions, and ultrasound (US)-guided CTR via a single cm wrist or palmar incision of less than 1 cm.[8–10]

Regardless of the technique, the primary goal of CTR is to transect the transverse carpal ligament (TCL) while avoiding injury to nearby neurovascular structures.[11] Although endoscopic CTR may promote a faster recovery compared to mini-open CTR, concerns have been raised regarding the potential for increased complications due to limited visualization of surrounding structures during TCL transection.[10–12] Ultrasound-guided CTR techniques combine a single small incision with direct US visualization of at-risk structures, such as the median nerve and its thenar motor branch/recurrent motor branch, ulnar vessels, and superficial palmar arterial arch.[13–20] To date, more than 620 cases of US-guided CTR have been reported in the peer-reviewed literature, with a clinical success rate of greater

than 98% and no documented neurovascular injuries.[7,21–26] Furthermore, a recently published single-surgeon prospective randomized clinical trial comparing mini-open CTR to US-guided CTR reported that patients treated with US-guided CTR had substantially faster functional recovery, pain reduction, and pain medication discontinuation.[7]

To transect the TCL, endoscopic CTR techniques and most US-guided CTR techniques place the surgical device within the transverse safe zone, a region bordered radially by the median nerve and ulnarly by the hook of the hamate or ulnar vessels, whichever lies more radially.[7,21,23,24,27,28] The transverse safe zone width can range from 4 to 8 mm but has considerable interindividual variability and in some individuals can be less than 3 or even 0 mm.[21] Transection of the TCL through a small skin incision while establishing an acceptable transverse safe zone is a technical challenge with both endoscopic and US-guided CTR. During endoscopic CTR, both the minimal incision size and the maximally available transverse safe zone are determined by the size of the introducer sheath and endoscopic cannula. In contrast, previously described US-guided CTR techniques require only a very small (<1 cm) skin incision but can challenge the operator to establish and maintain an acceptable transverse safe zone.[7,21,23,24,27]

A single-use disposable device (SX-One Micro-Knife; Sonex Health LLC, Rochester, MN) has recently become commercially available. The device allows the user to establish and maintain an acceptable transverse safe zone, via the use of expandable protective balloons. The device is inserted through a single distal forearm skin incision of less than 5 mm and into the carpal tunnel transverse safe zone under direct US guidance. The protective balloons allow for a consistent transverse safe zone of approximately 8 mm while a retractable microknife cuts the TCL 4 to 6 mm radial to the hook of the hamate. A recently performed cadaveric investigation using the same device to perform US-guided CTR in 34 unembalmed cadaveric specimens documented a 100% rate of TCL release and no neurovascular injuries as assessed by independent observers.[29]

The primary purpose of this article is to document our initial intermediate-term (3-month) clinical results performing US-guided CTR using enhanced transverse safe zone control in a consecutive group of 14 patients (18 wrists). We hypothesized that US-guided CTR using enhanced transverse safe zone control can be performed safely and effectively in an office or procedure room setting and will allow patients to rapidly recover, including those patients dependent on their upper limbs for ambulation.

Methods

Patients and Study Protocol

A total of 16 patients (22 wrists) with CTS were recruited for US-guided CTR from the Physical Medicine and Rehabilitation Clinic at the lead author's institution at the University of Michigan. Two patients (4 wrists) were lost to follow-up 4 weeks after release and are therefore not included in this report. As of their last follow-up point 4 weeks after release, these 2 patients had reported no complications and were recovering uneventfully. Therefore, 14 patients (18 wrists) were followed for 12 weeks after release. Patients included able-bodied individuals and those with functional impairments: specifically, 1 patient with postpolio syndrome who ambulated with forearm crutches, 1 with multiple sclerosis who did not use assistive devices, and 2 with paraplegia who ambulated with a manual wheelchair. Selection criteria included a history and examination findings consistent with CTS, electrodiagnostic testing confirming median neuropathy at the wrist and persistent, functionally limiting symptoms for greater than 3 months despite nonsurgical treatment, including activity modification, splinting, and/or corticosteroid injections. All procedures were performed by a single fellowship-trained physiatrist (P.T.H.) with more than 8 years of clinical experience in diagnostic and interventional musculoskeletal US. The initial 8 cases (12 wrists, 4 bilateral and 4 unilateral) were performed in the University of Michigan Hospital operating room in conjunction with a fellowship-trained neurosurgeon (L.Y.; not scrubbed in but present for supervision). While in the operating room, all standard protocols were followed with respect to sterile preparation and anesthesia, including the use of conscious sedation with appropriate monitoring. The subsequent 8 cases (10 wrists, 2 bilateral and 6 unilateral) underwent the procedure in an outpatient setting solely by the primary author, following standard protocols for outpatient local anesthesia (ie, no conscious sedation). This article presents the prospective 3-month results of a 12-month study investigating the safety and clinical outcomes of the procedure. All patients were followed with the use of validated outcome measures (the

Boston Carpal Tunnel Questionnaire [BCTQ] and Quick Form of the Disabilities of the Arm, Shoulder, and Hand Index [QDASH]). The preprocedure results were collected on the day of the release. One- and 3-month postprocedure data were collected via mailed questionnaires or follow-up phone calls by office staff. One set of scores was collected at each interval regardless if the patient underwent unilateral or bilateral releases.

The BCTQ and QDASH are measures of pain and function commonly used in the evaluation of interventions related to CTS.[30] The BCTQ has a calculated symptom score and a functional status score, which range from 1 to 5. The QDASH score ranges from 0 to 100. Higher scores for both instruments indicate worse symptoms and a poorer functional status. In addition, 2 nonvalidated global outcome measures were used at the 3-month follow-up, assessing whether symptoms improved (yes/no) and how satisfied patients were with the results of the procedure (5-point ordinal scale: 1, very dissatisfied; 2, dissatisfied; 3, neither satisfied nor dissatisfied; 4, satisfied; and 5, very satisfied). This study was performed in accordance with the Declaration of Helsinki and was approved by Institutional Review Board of the University of Michigan Medical School (approval No. HUM00127628). All adult participants provided written informed consent to participate in this study.

Before US-guided CTR, all wrists were evaluated with high-frequency transducers on US equipment available in the University of Michigan's Department of Physical Medicine and Rehabilitation (15–6-MHz linear array transducer on an X-Porte system; Fujifilm SonoSite, Bothell, WA; or 18–5-MHz linear array Affinity system; Philips Healthcare, Bothell WA). This evaluation used standardized protocols, including identification of the thenar motor/recurrent motor and palmar cutaneous branches of the median nerve, and any communicating branches between the median and ulnar common digital nerves (so-called Berrettini branches).[17,31] The purpose of this evaluation was not only to assess the median nerve but also to identify contraindications to proceeding with US-guided CTR, which included the following: (1) inability to adequately visualize at-risk structures, including the thenar motor branch/recurrent motor branch of the median nerve, palmar cutaneous branch of the median nerve, ulnar vessels, superficial palmar arterial arch, and median and ulnar palmar digital nerves; (2) distorted or variant anatomy that would preclude

establishment of a safe transverse safe zone; and (3) presence of a mass lesion or other process that would require treatment beyond transection of the TCL. No patients were excluded on the basis of US findings.

Procedure Description

All US-guided CTR procedures were performed by the primary author using the MicroKnife device in accordance with the manufacturer's instructions and the high-frequency linear array transducers previously described in accordance with the manufacturer's instructions. All patients received a US-guided local anesthetic injection of approximately 8 mL of 1% lidocaine without epinephrine via a 25-gauge, 50-mm needle. Care was taken to generously infiltrate the planned incision site at the proximal wrist crease (Figure 1) and the palmar fascia

Figure 1. Preprocedural anatomic markings and skin incision. Image shows incision placement along the distal forearm and device direction of insertion (arrow). Skin markings highlight the anatomic landmarks to assist during the procedure. Blue line represents the place for incision. Black dashed and solid red lines mark the location of the median nerve and ulnar artery, respectively; a indicates superficial palmar arch; H, hook of the hamate; Mn, median nerve; P, pisiform; S, scaphoid; T, trapezium; and U, ulnar nerve.
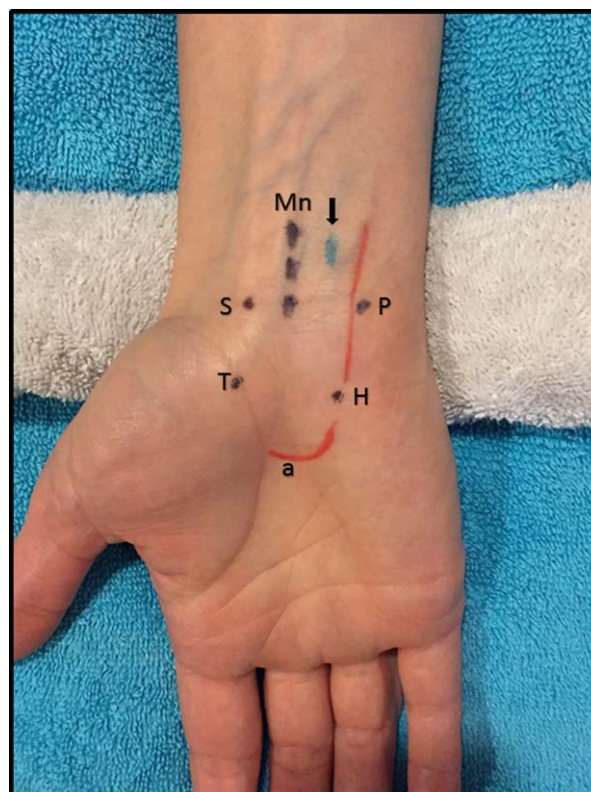
superficial to the TCL. This needle was then withdrawn, and a second 25-gauge, 50-mm needle was used to hydrodissect the median nerve away from the flexor tendons and TCL using 10 mL of sterile 0.9% normal saline under direct US guidance. This process allowed for better delineation of the boundaries of the TCL. Then under US guidance, a No. 15 blade scalpel was used to make a vertical stab incision through the preanesthetized skin wheal down to and through the antebrachial fascia. After this step, US guidance was used to accurately place the device into the carpal tunnel, within the transverse safe zone, and position the tip just distal to the distal aspect of the TCL. The tip of the device was positioned superficial to the midpalmar fat pad and proximal and superficial to the superficial palmar arterial arch, approximately 1 cm distal to the hook of the hamate. An evaluation of the device's position in and out of plane relative to the transducer was performed to ensure proper positioning of the device immediately deep to the TCL and radial to the pisiform and hamate (Figure 2, A–C). The handle on the device was then depressed and locked, filling the balloons to expand and maintain the transverse safe zone (Figure 2D and Video 1). The device was manipulated slightly ulnarly or radially to optimally position the cutting knife (once activated) away from the path of the median nerve and the ulnar neurovascular structures. Once appropriate positioning in the transverse safe zone was again confirmed by US, the knife

Figure 2. Placement of device and balloon inflation. **A**, External intraoperative image shows device placement. The device is initially inserted vertically until penetrating the antebrachial fascia, after which it is advanced distally oblique and parallel to the forearm. **B**, In-plane US view shows the device within the carpal tunnel, with proximal (PROX) to the left of the image. The device is placed approximately 1 cm distal to the TCL (arrows) to ensure complete release. **C**, Out-of-plane US view shows the device (open arrow) within the transverse safe zone (dotted double arrow) at the level of the distal carpal tunnel (solid arrows). The protective balloons (curved arrows) are deflated, as shown in the inset. The transverse safe zone in this patient is bordered by the ulnar artery, which encroaches in the tunnel. Therefore, the ulnar (ULN) side of the arrow spans from the median nerve (dotted ellipse) to the ulnar artery (a) and not the hook of the hamate (H). **D**, Out-of-plane US view shows the device with protective balloons (curved arrows) inflated, as shown in the insert. Note expansion of the transverse safe zone (dotted double arrow) and the radial displacement of the median nerve (dotted ellipse). FT indicates flexor tendons; solid ellipse, ulnar nerve; and ThM, thenar muscles.
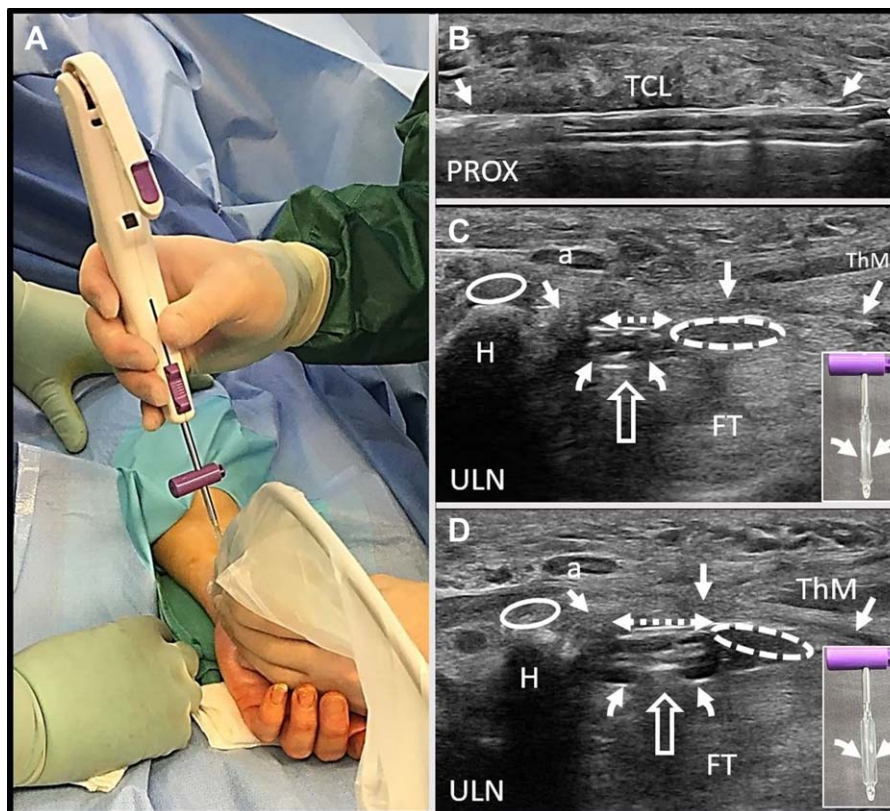
was deployed and translated in a distal-to-proximal direction under direct US guidance to transect the TCL (Figure 3 and Video 2). The knife was then advanced back to its distal location; the regional anatomy was rechecked with US; and a second pass was completed with the knife to ensure complete TCL release. After complete release, the knife was recessed into its protected position, and the protective balloons were deflated. The position of the device was evaluated via US to confirm a now superficial location relative to the TCL and osseous boundaries of the carpal tunnel. The TCL was then probed with the device through the area of transection to ensure that no remaining intact fibers persisted

Figure 3. Ultrasound-guided release of the TCL. **A**, External image shows the device with protective balloons inflated and the retrograde cutting knife (open arrow) deployed. **B**, Correlative in-plane US view shows the device with distal (DIST) to the right of the knife (open arrow) cutting the TCL (solid arrows). [Color figure can be viewed at wileyonlinelibrary.com]
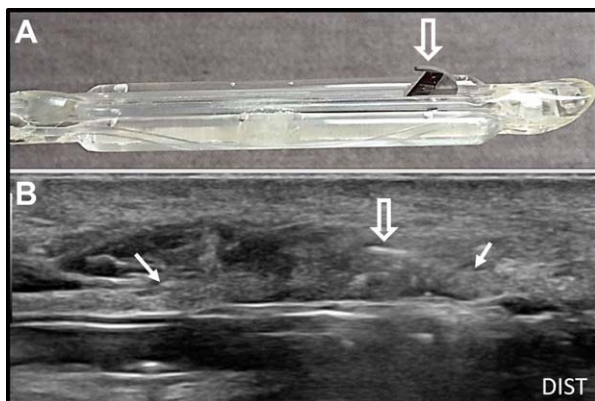

Figure 4. Ultrasound confirmation of complete release of the TCL. Out-of-plane view shows the device (open arrow) with the protective balloons (curved arrows) deflated, showing the device superficial to the boundaries of the transected TCL (solid arrows); a indicates ulnar artery; FCR, flexor carpi radialis; FT, flexor tendons; Rad, radial; S, scaphoid; solid ellipse, ulnar nerve; ThM, thenar muscles; and ULN, ulnar.
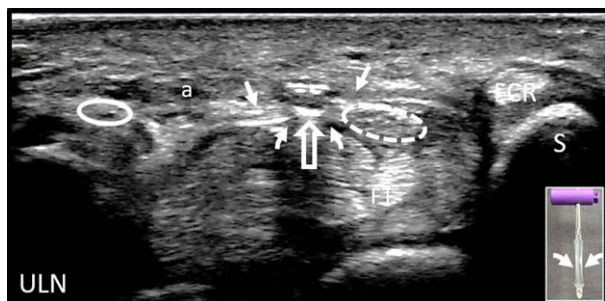
(Figure 4 and Video 3). Probing confirmed complete TCL transection in all cases, and no additional passes were required. The device was then removed from the incision, and excess fluid and blood were expressed through the wound, followed by adhesive bandages (Nexcare Steri-Strips; 3M, Minneapolis, MN) or 4-0 nylon suture closure (Figure 5). A sterile gauze pad and occlusive dressing were applied. The average total times for the procedure and balloon inflation were 7 and 2 minutes, respectively, and the incision length was less than 5 mm.

Postprocedure neurologic and physical examinations were performed to ensure that no neurologic or tendon injuries had occurred. All patients were discharged home under their own power at the same level of preprocedure function. No activity limitations were imposed, and none of the patients required a therapy referral after release. One patient who used bilateral forearm crutches and 2 who used manual wheelchairs were able to immediately resume the use of these ambulatory aides after release.

Results

The mean age of the 16 patients was 64 years (range, 62–90 years). All 16 patients (22 wrists) were evaluated in person by the operator 1 week after the procedure. There were no complications, and all wounds had

Figure 5. Postprocedure wound closure. Intraoperative image shows the closed incision with a single suture.

healed by the first postoperative visit. All patients had reported full use of their hands since the day of the procedure. As previously stated, 2 patients (4 wrists) were lost to follow-up thereafter and were not included in the formal data analysis. Patients were then mailed the BCTQ and QDASH forms and the 2 patient-oriented outcome measures to collect the 3-month interval data. Those who did not respond by mail were contacted by office staff and completed the surveys over the phone. At 1 and 3 months, the average BCTQ symptom scores improved from 2.96 before release to 1.75 and 1.54, respectively (difference, 1.42), and the average BCTQ functional status scores improved from 2.64 before release to 1.75 at 1 and 3 months (difference, 0.89; Table 1). The average QDASH scores improved from 45 to 19 (1 month) and 18 (3 months; difference, 27; Table 2). All patients reported improvements in symptoms, and the average global satisfaction rating was 4. Importantly, all of the patients with impairments retained their preprocedure level of independence throughout this initial follow-up period.

Although not formally collected, we did solicit feedback from patients regarding their experience with US-guided CTR. In general, patients described minimal postoperative pain. Most patients reported adequate pain relief with ice, limb elevation, and over-the-counter analgesic/anti-inflammatory medications. Additionally, patients who received US-guided CTR in the office setting using only local anesthesia generally reported little

Table 1. Mean BCTQ Scores (n = 14)

Period	Symptom Severity (Range)	Functional Status (Range)
Prerelease	2.96 (1.82–4.18)	2.64 (1.12–3.5)
1 mo post	1.75 (1–3.36)	1.75 (1–3.12)
3 mo post	1.54 (1.09–2.54)	1.75 (1–3.12)
3-mo change	1.42	0.89
MCID at 3 mo[27]	1.14	0.74

MCID indicates minimal clinically important difference.

Table 2. Mean QDASH Scores (n = 14)

Period	Score (Range)
Prerelease	45 (16–72)
1 mo post	19 (0–55)
3 mo post	18 (0–39)
3-mo change	27

Minimal clinically important difference score of 34 or change in score of greater than 20.

discomfort throughout the procedure. In this setting, many patients also volunteered their satisfaction with the convenience of the procedure with regard to having the procedure done in the outpatient setting, the ease of scheduling, the lack of a need to modify medications or dietary intake on the day of the procedure, and the ability to immediately resume use of affected limb.

Discussion

The most important finding in this report is that US-guided CTR using enhanced transverse safe zone control can be safely implemented in both the operating room and outpatient settings with excellent intermediate-term results in a diverse patient population. In our initial group of 14 patients (18 wrists), there were no complications, and clinical improvement was similar to that previously reported for mini-open CTR, endoscopic CTR, and US-guided CTR.[5,7] More specifically, the 3-month improvements in BCTQ symptom and functional status scores in our cohort were 1.42 and 0.89, respectively, which exceed the minimally clinically important differences of 1.14 and 0.74 previously reported by Kim and Jeon[32] after limited open CTR. Similarly, it was also reported by Clement et al[30] that patient satisfaction 3 months after OCTR highly correlated with a postrelease QDASH score of 34 or less or a post-CTR reduction of greater than 20 points. In the cohort presented in this article, the mean 3-month QDASH score was 18, and the mean reduction was 27, reflecting high patient satisfaction.

Currently, most CTRs are performed by the mini-open approach with predictably good results and a low complication rate.[11,12] However, the palmar incisions used for mini-open CTR may slow recovery and necessitate substantial alterations in hand and upper limb function during recovery.[7,11,12] These alterations can lead to increased time away from work or a short stay at a skilled nursing facility for those dependent on the use of their upper limbs for transferring and ambulation. Indeed, 3 patients in this study were crutch or wheelchair ambulators and were able to transfer and ambulate immediately after the procedure. Smaller incision sizes and reduced procedural trauma appear to promote faster recovery. Studies have demonstrated that patients treated with endoscopic or US-guided CTR recover faster and may have less postprocedural pain compared to those treated with mini-open CTR, presumably in

part because of reduced surgical trauma.[12] These observations have resulted in the historical trend of using smaller palmar incisions for open CTR (ie, mini-open CTR). However, the smaller palmar incisions used during mini-open CTR may make the procedure more technically challenging and still require temporary avoidance of palmar pressure. Although endoscopic CTR appears to promote a faster recovery and may allow immediate palmar "weight bearing" (in the single-incision technique), endoscopic CTR is more difficult to perform outside the operating room setting. Endoscopic CTR is also more expensive than mini-open CTR and has been associated with a higher risk of neuropraxia, presumably due to the relatively large size of the cannula and lack of complete visualization of surrounding structures.[11,33] Ultrasound-guided CTR provides the advantages of endoscopic CTR while allowing the operator to perform the procedure in an office-based setting using real-time visualization of all relevant structures. Innovations in image-guided procedures (trigger digit release, tenotomies, fasciotomies, and neurolysis) have advanced in parallel with improved US technology, accessibility, and skilled operators.[34,35] Ultrasound-guided CTR has been evolving in the past 2 decades but has primarily relied on instruments borrowed or repurposed from other procedures: for example, the hook knife.[23,27,36] Ultrasound-guided CTR using enhanced transverse safe zone control is the latest advancement in this field and is distinguished by providing the user the ability to access the carpal tunnel via a small forearm incision, control the transverse safe zone via inflatable balloons, and efficiently cut the TCL in a variety of practice settings.

Study strengths included the prospective collection of data using validated patient-reported outcome measures, a high follow-up rate (>87%), and inclusion of patients with physical impairments dependent on upper limb function for mobility. Nonetheless, we acknowledge several limitations of the study. First, neither the patients nor the assessors were blinded to the intervention, and there was no comparative or control group. However, the primary purpose of this investigation was to report our initial experience using US-guided CTR with enhanced transverse safe zone control in a clinically relevant setting, including a diverse patient population and the use of local anesthesia only. Future studies may include direct comparisons to alternative CTR techniques. Second, we are reporting our intermediate results at 3 months after the procedure. Although this follow-up period may be short, it is sufficient to document the safety of US-guided CTR with enhanced transverse safe zone control as used to treat our patients. Furthermore, since 100% of the patients returned to normal activities within the follow-up period, this duration was sufficient to document the efficacy of the treatment, as reflected in previous studies.[7,22] Nonetheless, we will continue to follow our patients for 12 months, as previously stated. Third, our sample size was relatively small and included patients treated by a single operator. Future studies should include larger sample sizes and possibly combine experiences from multiple users.

Our initial experience with US-guided CTR using enhanced transverse safe zone control demonstrates that this procedure can be safely and effectively performed in an outpatient setting by physicians who have expertise in advanced US-guided procedures. Specific advantages of US-guided CTR as implemented in our practice include but are not limited to the following: (1) increased patient convenience of an office/procedure room setting using only local anesthesia, freeing up operating rooms for more complex cases; (2) use of a small forearm incision with the ability to immediately use the upper limbs; (3) improved user and patient confidence given the ability to directly visualize all carpal tunnel structures with US and control the transverse safe zone via the use of the inflatable balloons; and (4) reduced need for support personnel after transition to the clinic, accompanied by potential cost savings. The convenience of the office/procedure room and ability to immediately bear weight on the upper limbs are particularly advantageous to patients with functional limitations, as was the case for 3 of our patients. Further assessment of US-guided CTR using enhanced transverse safe zone control is justified and should include an assessment of societal implications from both the psychosocial and cost-of-care perspectives.

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