SX-One MicroKnife® Ultrasound Guided Carpal Tunnel Release: Initial Clinical Experience

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Introduction

Carpal tunnel syndrome is the most common compression neuropathy and affects approximately 12 million Americans and up to 7% of manual labor workers. Over 500,000 carpal tunnel releases (CTR) are performed annually in the United States to treat patients with severe or refractory symptoms. The primary goal of surgical intervention is to cut the transverse carpal ligament to reduce median nerve compression and carpal tunnel pressures and thereby reduce pain, numbness, and tingling and improve function.

Traditional open carpal tunnel release (OCTR) is relatively safe and effective but can be associated with large and sometimes painful scars, pillar pain, and often a relatively prolonged recovery course. Compared to OCTR, endoscopic carpal tunnel release (ECTR) results in improved early post-operative outcomes but is more expensive and incurs a greater risk of transient post-operative nerve symptoms.

Ultrasound guided carpal tunnel release (USCTR) was initially described by Nakamichi in 1997. Since then 621 clinical cases of USCTR have been reported in the peer reviewed literature using a variety of cutting knives or instruments without built in safety or usability features. Despite these limitations, there have been no reported neurovascular complications and the collective clinical success rate of USCTR is over 95%. In addition, a single surgeon, prospective randomized trial comparing USCTR with mini-OCTR demonstrated that patients treated with USCTR recovered faster.

The Sonex Health SX-One MicroKnife® is a surgical tool with a patent pending design featuring integrated safety and usability features that allow users to perform USCTR efficiently and effectively (Figure 1). The SX-One MicroKnife® consists of a hand-piece with an ergonomic grip, thumb slide to activate a retractable retrograde cutting knife (TCL Blade®) and inflatable balloons along the medial and lateral aspects of the tip (Stealth MicroGuards®). Using US guidance, the SX-One MicroKnife® tip is passed through a small distal forearm incision (<5mm) and positioned within the carpal tunnel. Once the position of the device is confirmed relative to the transverse carpal ligament and surrounding neurovascular structures, the balloons are deployed to expand the “safe zone.” The retrograde cutting knife is then activated to transect the ligament using direct US visualization. Following ligament transection, the cutting knife is recessed, the balloons deflated, and the ligament probed to ensure a complete release. The wound is typically closed with SteriStrips (sutures are optional). USCTR using the SX-One MicroKnife® can be performed in a variety of clinical settings, including an office procedural room using only local anesthesia.
Clinical Experience

The first USCTR using the SX-One MicroKnife® was performed February 17, 2017. To date, a total of 531 procedures have been performed in 434 patients, including 97 bilateral procedures.

- 25 different physician users in 14 different states, including Orthopedic Hand Surgeons and Plastic Surgeons.
- 383 procedures performed in the ASC or OR setting and 148 in the office setting.
- 384 procedures performed using only local anesthesia (includes all 148 procedures performed in the office and 236 of the 383 procedures performed in the ASC-OR). Regardless of anesthesia type, all patients have tolerated the procedure well and no procedure had to be discontinued due to patient discomfort.
- Although operative time was not a primary consideration during this initial clinical implementation, total procedural time (from skin incision to device removal) estimated to be 8-15 minutes in most cases.
- Wound size ≤ 5 mm and wounds closed with either SteriStrips or sutures at the operator’s discretion.
- Patients generally allowed to resume activities as tolerated (at operator’s discretion).
Results

- No reported neurovascular complications.

- Clinical results have been excellent and commensurate with the previously published literature for USCTR.
  - Example of 1-month outcomes shown in Figure 2.
  - See Manuscripts and Presentations.

- Compelling patient stories including a patient golfing 5 days post-procedure and a spinal cord injury patient who was able to immediately use their wheelchair for mobility.

![Figure 2](image)

**Figure 2.** Improvements in Quick Form of Disabilities of Arm, Shoulder and Hand Index (QDASH) scores at 1-2 weeks and 1 month in 20 patients treated with USCTR using the SX-One MicroKnife. Changes exceed minimal clinically important differences.
Manuscripts and Presentations – SX-One MicroKnife® Outcomes

- Minimally invasive ultrasound guided carpal tunnel release: preliminary clinical results. Henning et al. (in press, J Ultrasound Medicine). *Clinical experience at the University of Michigan reporting on 18 wrists in 14 patients, including several patients with disabilities who were able to immediately use their crutches and wheelchairs.*

- Sonographic changes following ultrasound guided release of the transverse carpal ligament. Pourcho et al. (accepted for publication, PM&R). *Case report documenting clinical improvement and reduction in median nerve cross-sectional area following USCTR using SX-One MicroKnife®.*

- Ultrasound guided carpal tunnel release using dynamic expansion of the transverse safe zone in a patient with post-polio syndrome: a case report. Henning et al. (accepted for publication, PM&R). *Case report documenting the clinical outcome of a patient with post-polio syndrome who could immediately resume crutch weightbearing following USCTR using the SX-One MicroKnife®.*

- Sonographically detected transligamentous median nerve branch. Beckman et al. (Am J PM&R 2018). *Case report of a transligamentous median nerve branch detected during a cadaveric study of USCTR using the SX-One MicroKnife®. The aberrant branch was detected during “screening” for USCTR and confirmed with dissection.*

- Poster AAHS January 2018 - Abstract #25585 - Ultrasound guided carpal tunnel release using a novel device: early clinical results. Henning et al. (presented). *Combined clinical experience of 38 wrists in 28 patients treated by three different physicians in three different practices, including two Orthopedic Hand Surgeons.*


- Poster AMSSM May 2018 – Novel treatment of a common problem leads to expedited return to golf. Henning et al. (accepted for presentation). *Case report of a golfer who returned to golf 5 days following USCTR using the SX-One MicroKnife® in his dominant hand.*

**Conclusion**

USCTR has an established track record of safety and efficacy in the peer-reviewed literature, including a Level 1 study documenting superior earlier outcomes compared to mini-OCTR. The SX-One MicroKnife® provides a unique combination of integrated safety and usability features to facilitate USCTR. The clinical experience performing USCTR using the SX-One MicroKnife® has been excellent based on over 500 cases performed by a diverse group of operators in multiple practice settings and geographic locations. Peer reviewed outcomes reporting results of USCTR using the SX-One MicroKnife® are already available.
Relevant References (Complete list available upon request):


ABSTRACT: The purpose of this study was to compare the outcomes of 1-mm ultra–minimally invasive ultrasound-guided carpal tunnel release and 2-cm blind mini–open carpal tunnel release. METHODS: We conducted a single-center individual parallel-group controlled-superiority randomized control trial in an ambulatory office-based setting at a third-level referral hospital. Eligible participants had clinical signs of primary carpal tunnel syndrome and positive electrodiagnostic test results and were followed for 12 months. Independent outcome assessors were blinded. Patients were randomized by concealed allocation (1:1) by an independent blocked computer-generated list. The postoperative score on the Quick–Disabilities of the Arm, Shoulder, and Hand (QuickDASH) questionnaire was the primary variable. Grip strength and time for discontinuation of oral analgesics, complete wrist flexion-extension, relief of paresthesia, and return to normal daily activities (including work) were assessed. RESULTS: Ninety-two of 128 eligible patients were randomly allocated and analyzed. QuickDASH scores were 2.2 to 3.3 times significantly lower in the ultra–minimally invasive group for the first 6 months: 23.6 [95% confidence interval (CI), 20.5, 27.4] versus 52.6 [95% CI, 49.4, 57.0] at the first week and 4.09 [95% CI, 1.5, 7.1] versus 13.0 [95% CI, 9.4, 18.9] at 6 months. Return to normal daily activities occurred significantly sooner in the ultra–minimally invasive group: 4.9 [95% CI, 3.2, 6.5] versus 25.4 [95% CI, 18.2, 32.6] days. CONCLUSIONS: Ultra–minimally invasive carpal tunnel release provides earlier functional return and less postoperative morbidity with the same neurologic recovery as mini–open carpal tunnel release for patients with symptomatic primary carpal tunnel syndrome.


PURPOSE: Authors have reported better outcomes, by reducing surgical dissection for carpal tunnel syndromes requiring surgery. Recently, a new sonographically guided technique for ultra-minimally invasive (Ultra-MIS) carpal tunnel release (CTR) through 1mm incision has been described. We hypothesized that a clinical trial for comparing Ultra-MIS versus Mini-open Carpal Tunnel Release (Mini-OCTR) was feasible. METHODS: To test our hypothesis, we conducted a pilot study for studying Ultra-MIS versus Mini-OCTR respectively performed through a 1mm or a 2 cm incision. We defined success if primary feasibility objectives (safety and efficacy) as well as secondary feasibility objectives (recruitment rates, compliance, completion, treatment blinding, personnel resources and sample size calculation for the clinical trial) could be matched. Score for Quick-DASH questionnaire at final follow-up was studied as the primary variable for the clinical trial. Turnover times were studied for assessing learning curve stability. RESULTS: Forty patients were allotted. Primary and secondary feasibility objectives were matched with the following occurrences: 70.2% of eligible patients finally recruited; 4.2% of randomization refusals; 26.6 patients/month recruited; 100% patients receiving a blinded treatment; 97.5% compliance and 100% completion. A sample size of 91 patients was calculated for clinical trial validation. At final follow-up, preliminary results for Quick-Dash substantially favored Ultra-MIS over Mini-OCTR (average 14.54 versus 7.39) and complication rates were lower for Ultra-MIS (5% versus 20%). A stable learning curve was observed for both groups. CONCLUSIONS: The clinical trial is feasible. There is currently no evidence to contraindicate nor withhold the use of Ultra-MIS for CTR.

PURPOSE: To compare the outcomes of percutaneous carpal tunnel release (PCTR) and mini-open carpal tunnel release (mini-OCTR) using ultrasonographic guidance for both techniques. METHODS: We included 74 hands of 65 women with idiopathic carpal tunnel syndrome (age, 52-71 y; mean, 58 y). Thirty-five hands of 29 women had the PCTR (release with a device consisting of an angled blade, guide, and holder, along a line midway between the median nerve and ulnar artery (safe line) under ultrasonography (incision, 4 mm), and 39 hands of 36 women had the mini-OCTR (release along the safe line, distally under direct vision (incision, 1-1.5 cm) and proximally under ultrasonography, using a device consisting of a basket punch and outer tube. RESULTS: Assessments at 3, 6, 13, 26, 52, and 104 weeks showed no significant differences in neurologic recovery between the groups (p > .05). The PCTR group had significantly less pain, greater grip and key-pinches strengths, and better satisfaction scores at 3 and 6 weeks (p < .05), and less scar sensitivity at 3, 6, and 13 weeks (p < .05). There were no complications. CONCLUSIONS: The PCTR provides the same neurologic recovery as does the mini-OCTR. The former leads to less postoperative morbidity and earlier functional return and achievement of satisfaction. LEVEL OF EVIDENCE: Therapeutic III.


ABSTRACT: The aim of this study was to assess the effectiveness and safety profile of a new technique for ultrasonographically assisted percutaneous carpal tunnel release. Experiments were performed on 40 hands in 20 cadavers. We first performed a detailed ultrasonographic examination and correlation study that included surgical dissection of the transverse carpal ligament, the related neurovascular structures and the bony landmarks of the radiocarpal, midcarpal and carpometacarpal joints of the right hand. We then used the measurements we made for percutaneous carpal tunnel release of the transverse carpal ligament using intra-operative ultrasonography for guidance and a hook knife on the left-hand side. The completeness of the release and the potential risks of injury to the flexor tendon and neurovascular bundles were examined. Using real-time intra-operative ultrasonographic monitoring to clearly delineate these targets, we were able to percutaneously release the transverse carpal ligament completely in 18 (90%) of the 20 hands and partially release it in 2 without injuring any neurovascular bundles. We then performed the procedure on 91 consecutive cases of carpal tunnel syndrome and found that the sensory disturbances disappeared in 100% patients 12 mo post-operatively; only 2 hands were graded as unsatisfactory. There were no intra- or post-operative complications. Based on the results from the cadaveric studies and our successful preliminary clinical outcomes, we conclude that this method is tolerable and that its clinical application can be encouraged.


PURPOSE: To present the technique and results of ultrasonographically guided percutaneous carpal tunnel release (PCTR) in a consecutive series of patients with carpal tunnel syndrome (CTS). METHODS: We used previously defined landmarks with the "safe zones," localization, estimated size, and extent of the transverse carpal ligament (TCL) for this prospective clinical study of 91 consecutive cases of carpal tunnel release treated with this technique. The follow-up consisted of 4 time points (1 week and 2, 6, and 12 months) and a final evaluation at an average of 22.5 months. RESULTS: The sensory disturbances disappeared in 76.8%, 93.4%, 100%, and 100% of the patients at 1 week and 2, 6, and 12 months postoperatively, respectively. Moderate pain was experienced in 24.2% of patients within 1 week, in 6.6% of patients within 2 months, and in 1.1% of patients within 12 months after the operation. In the final evaluation, 2 hands were graded as unsatisfactory: one hand had moderate wrist pain without sensory disturbance, and one hand had a recurrence 14 months after the operation. There were no intraoperative or
postoperative complications. **CONCLUSIONS:** Ultrasonographically assisted PCTR is a safe and effective procedure, but it is technically demanding and requires substantial training to be proficient in its use.


**PURPOSE:** The current reference standard for carpal tunnel syndrome is under debate. Recent studies have demonstrated similar diagnostic accuracy between ultrasound and nerve conduction studies. The purpose of the present study was to determine the sensitivity and specificity of ultrasound, nerve conduction studies, and Carpal Tunnel Syndrome 6 (CTS-6) for the diagnosis of carpal tunnel syndrome using latent class analysis. **METHODS:** Latent class analysis is a statistical technique that can be used to estimate the accuracy of diagnosis when there is no universally accepted reference standard. This type of analysis is useful in the setting of carpal tunnel syndrome as there remains substantial controversy with respect to the necessity of nerve conduction studies and other confirmatory testing. CTS-6 is a validated clinical diagnostic tool for the diagnosis of carpal tunnel syndrome that has been shown to have a high sensitivity and specificity. Data from a database on the cases of eighty-five consecutive patients who had had nerve conduction studies, CTS-6, and ultrasound were analyzed using classical latent class analysis, assuming that the three tests were imperfect and conditionally independent. **RESULTS:** The sensitivities of ultrasound, CTS-6, and nerve conduction studies were 91% (95% confidence interval [CI], 81% to 98%), 95% (95% CI, 86% to 99%), and 91% (95% CI, 81% to 97%), respectively. The specificities of ultrasound, CTS-6, and nerve conduction studies were 94% (95% CI, 80% to 100%), 91% (95% CI, 74% to 99%), and 83% (95% CI, 66% to 95%), respectively. **CONCLUSIONS:** Ultrasound, nerve conduction studies, and CTS-6 have similar sensitivity and specificity for the diagnosis of carpal tunnel syndrome. The currently accepted reference standard (nerve conduction studies) had the lowest sensitivity and specificity of the three tests. These findings support previous studies that have suggested that CTS-6 and ultrasound are highly accurate in the diagnosis of carpal tunnel syndrome and that nerve conduction studies are not necessary in most cases.