

Carpal Tunnel Release with UltraGuideCTR™ and Real-time Ultrasound Guidance: Clinical Summary

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Note: SX-One MicroKnife® has been renamed UltraGuideCTR. The device, intended use, indications for use, and clinical data regarding safety and effectiveness are the same.

Introduction

Carpal tunnel syndrome is the most common compression neuropathy and affects approximately 13 million adults and up to 7% of manual labor workers.^{1,2} Over 580,000 carpal tunnel releases (CTR) are performed annually in the United States to treat patients with severe or refractory symptoms.³ The primary goal of surgical intervention is to transect or divide the transverse carpal ligament (TCL) to reduce median nerve compression and thereby reduce symptoms and improve function.^{4,5}

Traditional open carpal tunnel release (OCTR) using a blade, knife and/or scissors to transect the TCL is relatively safe and effective but can be associated with large and sometimes painful scars, pillar pain, and often a prolonged recovery course.⁶⁻⁹ During endoscopic carpal tunnel release (ECTR) the TCL is transected using small internal cameras in combination with blades, knives or instruments incorporating them.^{6,7,10-12} ECTR improves early post-operative outcomes but utilizes significant operating room equipment, limits visualization of the carpal tunnel contents, incurs a greater risk of transient post-operative nerve symptoms, and cannot be easily performed outside of the operating room.^{7,10-12}

Carpal tunnel release using ultrasound (US) guidance was initially described by Nakamichi in 1997.^{13,14} Since then over 20 peer reviewed publications have reported clinical results on over 2100 hands (>1600 patients) treated with CTR using US guidance and blades, knives or instruments incorporating them.^{9,14-21} These publications have documented the safety and effectiveness of CTR using US guidance, including a collective clinical success rate of >95% and an excellent safety profile.^{9,14-21} In addition, a single surgeon, prospective randomized trial (Level 1 study) comparing CTR with US guidance to traditional mini-OCTR without US guidance demonstrated that patients treated with CTR using US guidance recovered significantly faster.⁹

Sonex Health's patented UltraGuideCTR was specifically designed to provide physicians with a simple, elegant, safe, and effective tool to perform CTR with or without US guidance (Figure 1). Please see the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions. UltraGuideCTR consists of an ergonomic handpiece and a working tip containing a retractable retrograde cutting knife (TCL Blade®) and inflatable balloons along both sides of the tip (Stealth MicroGuards®). When using US guidance, the UltraGuideCTR tip is passed through a small wrist incision in the proximal carpal tunnel region 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 create space in the carpal tunnel. This is achieved by increasing the diameter of the device as well as the distance between the balloon edges and centrally located cutting knife. The retrograde cutting knife is then activated to divide 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 fascia and skin are typically closed with adhesive strips (e.g., Steri-Strip™) and/or sutures. CTR with UltraGuideCTR and real-time US guidance can be performed in a variety of clinical settings, including an office procedural room using only local anesthesia.^{17,21}



Figure 1. UltraGuideCTR (Sonex Health, Inc., Eagan, MN).

Clinical Experience

The first CTR with UltraGuideCTR and real-time US guidance was performed 2/17/2017.

- Over 16,000 procedures completed, including many simultaneous bilateral releases.¹⁵⁻²¹
- 112 physician users in 35 different states.
- Procedures performed in the ASC, OR and clinic office setting – most procedures performed using only local anesthesia/WALANT technique.¹⁵⁻²¹
- Post-operative discomfort typically managed with acetaminophen or NSAIDs as necessary: no opioids required.^{15,17-21}
- Patients are generally allowed to resume activities as tolerated (at physician's discretion).
- 9 peer reviewed clinical publications, including a multicenter study (see Manuscripts):
 - 774 hands/609 patients performed by over 25 different physicians.
 - Statistically and clinically significant improvements in PROMs (e.g., QDASH, BCTQ) as early as 1-2 weeks post-procedure and sustained at long-term follow-up (≥ 1 year).
 - Median return to normal activity of 3 days and return to work of 5 days in a multicenter, pragmatic study.
 - Reduction in median nerve swelling (cross-sectional area).
- 20 scientific presentations (see Presentations).

- Sonex Health APEX-CTR Database: >20 different physicians, 300 patients (341 hands) with 12 month follow-up:
 - Intra-operative pain (0-10): median 1.0 (78% identified needle stick as most painful part) (n=226).
 - 62% of patients returned to normal daily activities within 3 days, increasing to 83% within 7 days (n=294).
 - 54% of patients returned to work within 3 days, increasing to 77% within 7 days (n=191 patients).
 - Would recommend to a friend (0-10, 10=extremely likely): median 10.0 at 12 months (n=300 patients).
 - Global Satisfaction (1-5, 5=very satisfied): median 5.0 at 12 months (n=341 hands).
 - Significant improvements in BCTQ and QDASH scores (Figures 2 and 3).

*Unpublished data from APEX-CTR Database (APEX-CTR = Assessment of the Patient Experience-Carpal Tunnel Release). Real world data measuring the short-term and long-term patient experience following carpal tunnel release with UltraGuideCTR and real-time US guidance. Data represent the cohort of patients with 12 month follow-up as of 14-November-2022. Not all patients provided data at every time point.

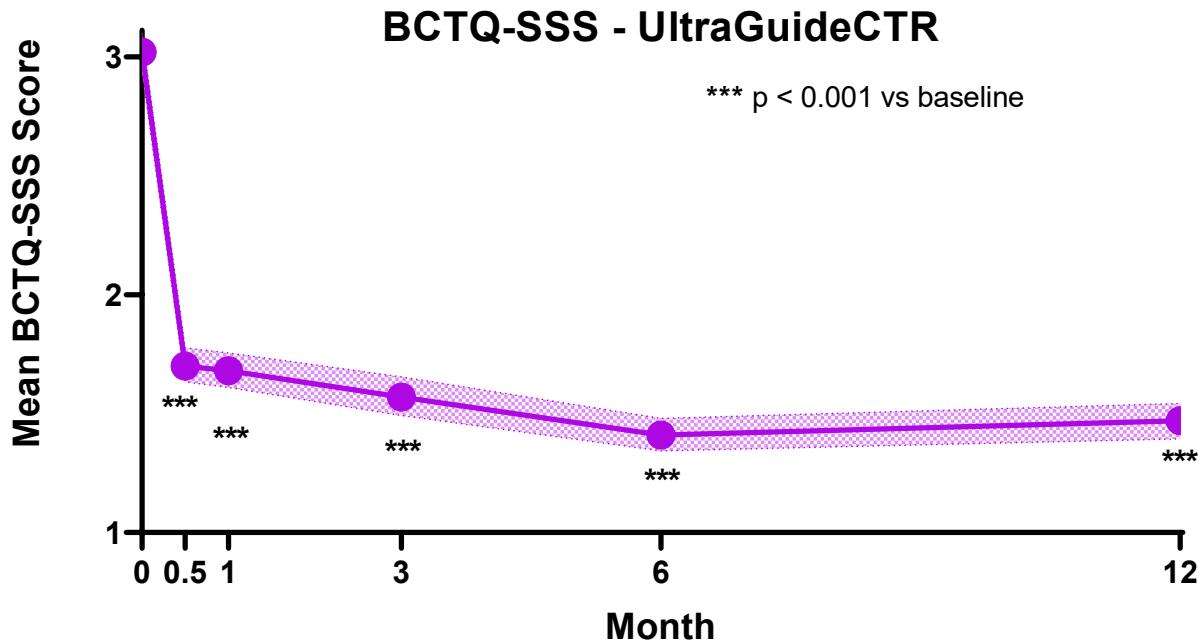


Figure 2. Mean Boston Carpal Tunnel Questionnaire Symptom Severity Scale (BCTQ-SSS) scores for 341 hands with up to 12 month follow-up following CTR with UltraGuideCTR and real-time US guidance. Data also shown for those patients who provided follow-up data at 0.5, 1, 3, and/or 6 months following the procedure (not all patients provided data at every intermediate time point and). Results show statistically significant reductions in BCTQ-SSS scores that exceed minimal clinically important differences at each time point compared to pre-op ($p < .001$; lower scores = better outcome).

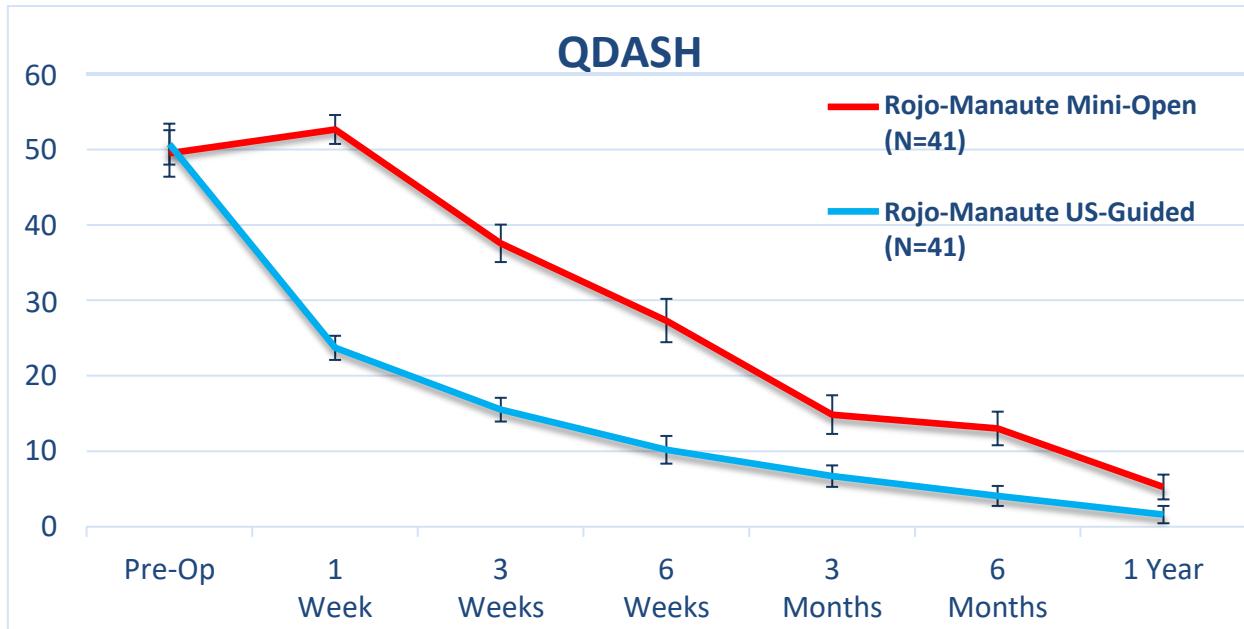


Figure 3a. QDASH scores following traditional mini-open CTR without US guidance (red line) and CTR with US guidance (lower scores = better outcome). Data reproduced from a prospective, randomized trial (Level I) comparing the two techniques. Patients treated with CTR using US guidance recovered significantly faster during the first 3-6 weeks compared to traditional mOCTR.⁹

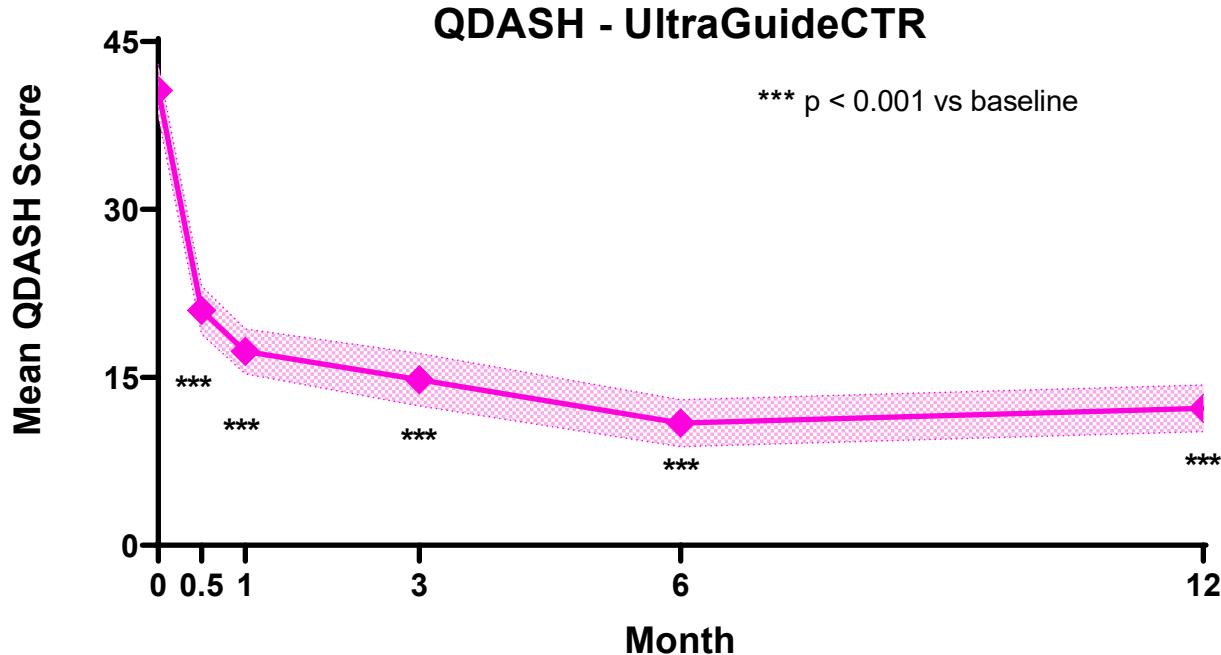


Figure 3b. Mean QDASH scores for 300 patients with up to 12 month follow-up after CTR with UltraGuideCTR and real-time US guidance. Data also shown for those patients who provided follow-up data at 0.5, 1, 3, and/or 6 months following the procedure (not all patients provided data at every intermediate time point and 12-month QDASH results were not available for 1 patient). Results are comparable to US guided group in Figure 3a and show statistically significant reductions in QDASH scores that exceed minimally clinically important differences at each time point compared to pre-op (p < .001; lower scores = better outcome).

Manuscripts Reporting Clinical Results

Note: SX-One MicroKnife has been renamed UltraGuideCTR. The device, intended use, indications for use, and clinical data regarding safety and effectiveness are the same.

- Bergum RA, Ciota MR. Office-based carpal tunnel release using ultrasound guidance in a community setting: long-term results. *Cureus*. 2022 Jul 23;14(7):e27169. doi: [10.7759/cureus.27169](https://doi.org/10.7759/cureus.27169). PMID: 35898805; PMCID: PMC9308387. *Prospective case series of 88 patients (123 hands) with minimum 1-year follow-up. All cases were confirmed by electrodiagnostic studies, and 2/3 of hands were moderately-severe or severe. All procedures were performed in an office-based procedure room using only local anesthesia and 46% of hands were treated as simultaneous bilateral procedures. Patients experienced statistically and clinically significant improvements in BCTQ-SSS, BCTQ-FSS and QDASH scores by 1-2 weeks post-procedure that persisted at 1 year. No intra-operative complications occurred; no conversions or supplementary analgesic medications were required. There were no neurovascular injuries, infections, or recurrences. One patient developed complex regional pain syndrome in the early post-operative period which was successfully treated; the patient subsequently had the contralateral hand treated with CTR using ultrasound guidance without complication.*
- Fowler JR, Chung KC, Miller LE. Multicenter pragmatic study of carpal tunnel release with ultrasound guidance. *Expert Rev Med Devices*. 2022 Mar;19(3):273-280. doi: [10.1080/17434440.2022.2048816](https://doi.org/10.1080/17434440.2022.2048816). Epub 2022 Mar 10. PMID: 35236202. *Multicenter pragmatic study of 373 patients/427 hands with 6-month follow-up. Procedures were performed at 24 different sites, 88% were performed using only local anesthesia and 25% of hands were performed as simultaneous bilateral procedures. Nearly 2/3 of physicians has performed <20 procedures prior to first patients enrolling in the database. QDASH, BCTQ-SSS and BCTQ-FSS scores were significantly improved by 2 weeks, continued to improve throughout the 6-month follow-up, and exceeded minimal clinically important differences. Median return to normal activities was 3 days, and median return to work was 5 days (48% of working patients were manual laborers), both of which compared favorably to historical controls for OCTR/mOCTR. No neurovascular complications occurred. One patient had revision surgery due to persistent symptoms attributed to an incomplete release.*
- Leiby BM, Beckman JP, Joseph AE. Long-term clinical results of carpal tunnel release using ultrasound guidance. *Hand (N Y)*. 2021 Jan 29;1558944720988080. doi: [10.1177/1558944720988080](https://doi.org/10.1177/1558944720988080). Online ahead of print. PMID: 33511873. *Prospective case series of 47 patients (76 hands) with minimum 1-year follow-up. Nearly 1/3 of all hands with preoperative electrodiagnostic testing were graded as severe and over 70% of patients had one or more co-morbidities. 25 patients (50 hands) had bilateral simultaneous releases. Patients experienced statistically and clinically significant improvements in BCTQ-SSS, BCTQ-FSS and QDASH scores by 1-2 weeks post-procedure that persisted at 1 year. No complications occurred and there were no recurrences.*
- Kamel SI, Fried B, Pomeranz C, Halpern EJ, Nazarian LN. Minimally invasive ultrasound-guided carpal tunnel release improves long-term clinical outcomes in carpal tunnel syndrome. *AJR Am J Roentgenol*. 2021 Aug;217(2):460-468. doi:

10.2214/AJR.20.24383. Epub 2020 Sep 2. PMID: 32876476. Case series of 61 wrists in 46 patients for which ≥ 1-year follow-up was available on 55 wrists/40 patients. All cases were performed using local anesthesia in a clinic procedure room. Patients experienced statistically and clinically significant improvements in QDASH and BCTQ scores by 2-weeks post-procedure, which persisted at a median follow-up of 1.7 years (1.0-2.8 years). Two patients lost to follow up at 1 year had re-operations, one for post-traumatic wound dehiscence with subsequent infection and one for possible compartment syndrome following racquet sport participation. In the latter case, surgical exploration revealed compression of the median nerve by the distal forearm fascia.

- **Chappell CD, Beckman JP, Baird BC, Takke AV. Sonographic changes in median nerve cross sectional area following microinvasive ultrasound guided carpal tunnel release. J Ultrasound Med 2020;39: 693-702.** Report of 37 wrists in 23 consecutive patients treated with CTR using the SX-One MicroKnife® and ultrasound guidance. All procedures were performed in an office procedure room using only local anesthesia (WALANT). No complications occurred. The authors reported statistically significant reductions in median nerve cross-sectional area, as well as statistically and clinically significant improvements in BCTQ scores at 6-10 weeks post-release. Although the primary endpoint of the study was the change in median nerve cross sectional area at 6-10 weeks, statistically significant reductions in nerve CSA and BCTQ scores were also observed as early as 2-4 weeks post-release.
- **Joseph AE, Leiby BM, Beckman JP. Clinical results of ultrasound guided carpal tunnel release performed by a primary care sports medicine physician. J Ultrasound Med 2020;39: 441-52.** Three-month follow-up on 35 wrists in 22 consecutive patients treated with CTR using the SX-One MicroKnife® and ultrasound guidance, including 11 patients treated with bilateral simultaneous releases. The authors reported no complications and there were statistically and clinically significant improvements in QDASH and BCTQ scores within 1-2 weeks post-release.
- **Henning PT, Yang L, Awan T, Lueders D, Pourcho AM. Minimally invasive ultrasound-guided carpal tunnel release: preliminary clinical results. J Ultrasound Med 2018; 37: 2699-706.** 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. Multiple cases were performed in the office setting using only local anesthesia. The authors reported no neurovascular complications and excellent clinical outcomes.
- **Latzka EW, Henning PT, Pourcho AM. Sonographic changes following ultrasound- guided release of the transverse carpal ligament: a case report. PM&R 2018; 10: 1125-9.** Case report documenting clinical improvement and reduction in median nerve cross- sectional area following CTR using the SX-One MicroKnife® with ultrasound guidance.
- **Henning PT, Lueders D, Chang K, Yang L. Ultrasound-guided carpal tunnel release using dynamic expansion of the transverse safe zone in a patient with post-polio syndrome:a case report. PM&R 2018; 10(10): 1115-8. Case report**

documenting the clinical outcome of a patient with post-polio syndrome who could immediately resume crutch weightbearing following CTR using the SX- One MicroKnife® and ultrasound guidance.

Presentations Reporting Clinical or Cadaveric Results

Note: SX-One MicroKnife has been renamed UltraGuideCTR. The device, intended use, indications for use, and clinical data regarding the safety and effectiveness are the same.

- Oral presentation at the American Association for Hand Surgery (AAHS) Annual Meeting, January 2022. Kirsch M, Pohl L, Walters M. Clinical results and return to work following carpal tunnel release with ultrasound guidance (CTR-US) performed in an office procedure room. *Ninety-nine wrists in 81 patients treated by a single surgeon in an office-procedure room using only local anesthesia. No complications occurred. Median intra-op pain score was 0. Significant reductions in QDASH, BCTQ-SSS and BCTQ-FSS occurred by 2 weeks, were maintained during the 6-month follow-up, and exceeded minimal clinically important differences. Sixty-two patients provided return to work data, with 48% returning to work within 1-3 days and 79% within 7 days. Among the 10 heavy manual laborers, 50% returned within 3 days and 90% within 7 days.*
- Oral presentation at the American Association for Hand Surgery (AAHS) Annual Meeting, January 2022. Nichols GE, McGinley JC, Galloway J, Hawley J. Carpal tunnel release with ultrasound guidance (CTR-US): intermediate term results with MRI correlation. *Prospective study of 95 wrists in 65 patients with up to 6-months follow-up and pre- versus post-operative MRI scans on 17 wrists at a mean of 3-months post-op. No complications occurred and QDASH, BCTQ-SSS and BCTQ-FSS scores significantly improved at all time points from 2 weeks to 6 months. MRI scans demonstrated complete TCL transection, palmar shifting of the median nerve, and reduced median nerve compression.*
- Poster presentation at the American Association for Hand Surgery (AAHS) Annual Meeting, January 2022. Smith J, Beckman J. Creating space: can the transverse safe zone be increased for carpal tunnel release with ultrasound guidance. *Cadaveric study of 52 unembalmed wrists demonstrating significantly increased TSZ size (mean increase 4.0 mm) and a reduction in ulnar artery encroachment from 54% to 13% with placement of UltraGuide CTR and balloon deployment.*
- Oral presentation at the American Society for Surgery of the Hand (ASSH) Annual Meeting September-October 2021. Bergum R, Ciota M. Office-based carpal tunnel release using ultrasound guidance: long-term results. *Case series of 109 wrists in 76 patients at 1-year post-CTR with ultrasound guidance. All cases were performed by a surgeon-non-surgeon team in an office-based procedure room using only local anesthesia (WALANT). All patients tolerated the procedure, no intra-operative complications occurred, and 1 wrist developed CRPS at 2 weeks which resolved with treatment. BCTQ and QDASH scores significantly improved versus pre-op at all time points from 2-weeks to 1-year and results were similar for the 28 patients treated with simultaneous bilateral procedures compared to those treated with unilateral procedures.*

- Poster presentation at the American Society for Surgery of the Hand (ASSH) Annual Meeting September-October 2021. Andrews S, Chen S, Lawton D. Long-term outcomes of carpal tunnel release using ultrasound guidance: experience of a fellowship-trained hand surgeon. *Case series of 69 patients treated by a single, fellowship-trained hand surgeon and for whom 1-year follow-up was available. All cases were unilateral releases. No intra-operative or significant post-operative complications occurred. Compared to pre-operative values, BCTQ-SSS, BCTQ-FSS, and PROMIS GPH scores were significantly reduced at 1-year, with changes exceeding minimally clinically important differences. Mean global satisfaction was 4.4 (4= satisfied, 5 = very satisfied) for the 67 patients responding to this question at 1-year.*
- Poster presentation at the American Society for Surgery of the Hand (ASSH) Annual Meeting, October 2020 (virtual). Beckman JP, Kirsch SF, Miller TC, Paterson PD. Ultrasound guided carpal tunnel release: one-year results following implementation by a fellowship trained hand surgeon. *Case series of 68 wrists in 51 patients at a minimum 1-year post-CTR, including 16 patients (32 hands) treated with bilateral simultaneous releases and multiple patients treated with as part of a same day surgery clinic.*
- Poster presentation at the American Society for Surgery of the Hand (ASSH) Annual Meeting, October 2020 (virtual). Long-term clinical results of ultrasound-guided carpal tunnel release. Joseph A, Leiby B, Beckman B. *Prospective case series of 38 patients/64 wrists at minimum 1-year follow-up, including 44 wrists treated as simultaneous bilateral releases. No complications or recurrences occurred, and patients experienced statistically and clinically significant improvements in BCTQ-SSS, BCTQ-FSS and QDASH scores by 1-2 weeks that persisted through the 1-year follow-up.*
- Poster presentation at the American Medical Society for Sports Medicine (AMSSM) Annual Meeting (virtual), April 2020. Ultrasound guided carpal tunnel release performed in an office setting: preliminary results. Bergum R, Ciota M. *Case series reporting 3-month follow-up on 32 wrists in 23 patients. There were no intraoperative complications and patients experienced statistically significant improvements in QDASH, BCTQ-SS and BCTQ-FS scores by 2 weeks which persisted at 3 months. Most patients returned to normal daily/work activities within 3-7 days. One patient developed complex regional pain syndrome at 2 weeks without evidence of anatomic injury, responding to treatment at 1 month.*
- Poster presentation American Association for Hand Surgery (AAHS), January 2020. Ultrasound guided carpal tunnel release: Clinical results of 45 wrists at 6 months. Kindle B, Beckman J, Hubbard R. *Case series reporting 6-month follow-up on 45 wrists in 32 patients treated with CTR using the SX-One MicroKnife® and ultrasound guidance with local anesthesia, plus diazepam anxiolysis based on patient preference. The authors reported no intra-operative complications; one patient had pillar pain that spontaneously resolved by 3-months post-release. Statistically and clinically significant improvements in BCTQ and QDASH scores were observed at 2-weeks post-release and were maintained at the final 6-month follow-up.*
- Podium presentation at the American Medical Society for Sports Medicine (AMSSM)

Annual Meeting, April 2019. Sonographic changes in median nerve cross sectional area following ultrasound guided carpal tunnel release. Chappell CD, et al. *Case series of 37 wrists in 23 patients treated by a single physician with pre- and post-operative nerve cross-sectional area measurements and clinical results. No neurovascular complications occurred. The authors reported significant reductions in nerve cross-sectional area post-CTR with the SX-One MicroKnife using ultrasound guidance as well as statistically and clinically significant improvements in BCTQ scores.*

- Poster presentation at the American Medical Society for Sports Medicine (AMSSM) Annual Meeting, April 2019. Novel treatment leads to rapid return to work. Bergum R, Ciota M. *Case report of nurse treated with CTR using ultrasound guidance and the SX-One MicroKnife who was able to return to work the day following the procedure and ultimately had the contralateral wrist treated.*
- Podium presentation at the American Institute of Ultrasound in Medicine (AIUM) Annual Meeting, April 2019. Ultrasound guided carpal tunnel release: hand surgeon experience including implementation of a same day evaluation and surgery clinic. Beckman J, et al. *Case series of single fellowship trained hand surgeon experience performing CTR under the guidance of ultrasound using only local anesthesia, including patients treated as part of a same day evaluation and surgery clinic.*
- Podium presentation at American Association for Hand Surgery (AAHS), January-February 2019. Ultrasound guided carpal tunnel release: initial results. Chen S, Yamazaki K. *Case series reporting 3-month follow up on 65 wrists in 61 patients performed by a hand surgeon- non-surgeon team, including 26 cases performed using WALANT technique. The authors reported no complications and significant improvements in patient reported outcomes.*
- Poster at Eastern Orthopaedic Association Meeting October 2018. Ultrasound guided carpal tunnel release in a procedural room setting: early clinical results. Miller T, et al. *Case series reporting 3-month follow-up on 66 wrists in 52 patients, including 36 wrists in 28 patients treated as part of a same-day surgery clinic. The authors reported no complications, median patient satisfaction of 5 (1-5 scale) and statistically and clinically significant reductions in QDASH and BCTQ scores. No difference in outcomes or satisfaction between same-day surgery group and non-same day surgery group.*
- Video Theater presented at American Society for Surgery of the Hand (ASSH) Annual Meeting, September 2018. Ultrasound guided carpal tunnel release: technique and integration into a hand surgeon's practice. Paterson P. *Video demonstration of carpal tunnel release performed under ultrasound guidance using the SX-One MicroKnife®.*
- Podium presentation at Cleveland Clinic 18th Annual Meeting - New Technology in Upper Extremity Surgery: The Cutting Edge, May 2018. Ultrasound guided carpal tunnel release and implementation of a same day surgery clinic. Paterson P. *Case series of 53 patients treated by a single surgeon, including 31 patients treated in a same day surgery clinic ("Release and Relief" program). The author reported no neurovascular complications and clinically and statistically significant improvements in QDASH and BCTQ scores. The author also reported significant improvements in practice efficiency due to implementation of*

CTR using the SX-One MicroKnife® and ultrasound guidance.

- Podium presentation at the American Medical Society for Sports Medicine (AMSSM) Annual Meeting, April 2018. Ultrasound guided carpal tunnel release performed by a primary care physician: preliminary results. Joseph AE, Leiby BM. *Case series of 11 wrists in 9 patients treated by a single physician. The authors reported no neurovascular complications, statistically and clinically significant improvements in QDASH and BCTQ scores, and excellent patient satisfaction. Abstract published in Clin J Sports Med 2018;28:225.*
- Poster presented at the AMSSM Annual Meeting, April 2018. Novel treatment of a common problem leads to expedited return to golf. Henning PT, et al. *Case report of a golfer who returned to golf 5 days following CTR using the SX-One MicroKnife® and ultrasound guidance in his dominant hand.*
- Poster presented at the American Association for Hand Surgery (AAHS), January 2018. Ultrasound guided carpal tunnel release using a novel device: early clinical results. Henning PT, et al. *Combined clinical experience of 38 wrists in 28 patients treated by three different physicians in three different practices, including two Orthopedic Hand Surgeons. The authors reported no complications and excellent clinical outcomes.*
- Poster presented at the AMSSM Annual Meeting, May 2017. Ultrasound guided carpal tunnel release using dynamic safe zone expansion: a cadaveric validation study. Presley JC, et al. *Cadaveric validation study of CTR using the SX-One MicroKnife® and ultrasound guidance in 34 unembalmed cadaveric wrist specimens. Dissection revealed complete releases without neurovascular injury in all specimens.*

Conclusion

CTR performed using US guidance has an established track record of safety and effectiveness in the peer-reviewed literature, including a Level 1 study documenting superior earlier outcomes compared to traditional mini-OCTR without US guidance. UltraGuideCTR provides a unique combination of safety and usability features to facilitate CTR with US guidance. The clinical experience performing CTR with UltraGuideCTR and real-time US guidance has been excellent based on over 16,000 cases performed by a diverse group of operators in multiple practice settings, including the office setting. Peer reviewed publications reporting clinical results of CTR with UltraGuideCTR and real-time US guidance are already available, including a multicenter pragmatic study.

References

Note: SX-One MicroKnife has been renamed UltraGuideCTR. The device, intended use, indications for use, and clinical data regarding safety and effectiveness are the same.

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