AJR Online First Accepted Manuscript

Minimally Invasive Ultrasound-Guided Carpal Tunnel Release Improves Long-Term Clinical Outcomes in Carpal Tunnel Syndrome

Sarah I Kamel, MD, Bradley Freid, BS, Corbin Pomeranz, MD, Ethan J Halpern, MD, Levon N Nazarian, MD

doi:10.2214/AJR.20.24383
Accepted: August 25, 2020

The complete title page, as provided by the authors, is available at the end of this article.

Abstract

Background: Ultrasound guidance allows carpal tunnel release to be performed with smaller incisions and quicker recovery than traditional open or endoscopic surgery.

Objective: To evaluate the long-term effectiveness of ultrasound-guided carpal tunnel release in improving function and discomfort in patients with carpal tunnel syndrome.

Methods: Retrospective review was conducted of 61 ultrasound-guided carpal tunnel release procedures performed in 46 patients (15 bilateral procedures) with clinically diagnosed carpal tunnel syndrome. These were performed under local anesthetic at an outpatient radiology office using the SX-One MicroKnife® (Sonex Health). Patients answered three questionnaires (Quick–Disabilities of the Arm, Shoulder, and Hand [QDASH] and two parts of the Boston Carpal Tunnel Syndrome Questionnaire: symptom severity [BCTSQ-SS] and functional status [BCTSQ-FS] scales) assessing the affected wrist's function and discomfort immediately pre-procedure, 2 weeks post-procedure, and at least one year post-procedure. Higher scores indicated increasing disability. Patients also answered a global satisfaction question at follow-up. Pre- and post-procedure scores were compared using paired Wilcoxon signed-rank tests.

Results: The 46 patients included 25 women and 21 men. Mean age was 60.6 years (range 21-80). Median pre-procedure scores were 45.4 for QDASH, 3.2 for BCTSQ-SS, and 2.5 for BCTSQ-FS. Median 2 week post-procedure scores were 22.5 for QDASH, 1.7 for BCTSQ-SS, and 1.9 for BCTSQ-FS, all decreased ($p<0.001$) from preprocedure scores and surpassing reference standards for clinically important difference in scores. Follow-up questionnaires were obtained for 90% (55/61) of wrists, a median of 1.7 (1.0-2.8) years post-procedure, with further declines ($p<0.001$) in median scores: 2.3 for QDASH, 1.2 for BCTSQ-SS, and 1.1 for BCTSQ-FS. At long-term follow-up, 96% (52/54) of wrists demonstrated lower QDASH, and 98% (53/54) lower BCTSQ (average of BCTSQ-SS and BCTSQ-FS), vs. pre-procedure scores. 93% (37/40) of surveyed patients were satisfied/very satisfied with long-term outcomes. No immediate postoperative complications occurred. Two patients required surgical intervention 8-10 days postoperatively, one for infection following injury and one for post-traumatic compartment syndrome.

Conclusion: Ultrasound-guided carpal tunnel release quickly improves hand function and reduces hand discomfort; improvement persisted beyond one year.

Clinical Impact: Ultrasound-guided carpal tunnel release may be a safe, effective, and less invasive alternative to traditional surgery.

Recommended citation:
Kamel SI, Freid B, Pomeranz C, Halpern EJ, Nazarian LN. Minimally Invasive Ultrasound-Guided Carpal Tunnel Release Improves Long-Term Clinical Outcomes in Carpal Tunnel Syndrome. *AJR* September 2, 2020. Accepted manuscript. doi:10.2214/AJR.20.24383

Highlights:

Key Finding: Patients undergoing ultrasound-guided carpal tunnel release experienced quick and persistent improvements in function and discomfort (baseline, 2 week, and >1 year post-procedure questionnaire scores for QDASH: 45.4, 22.5, and 1.2; BCTSQ-SS: 3.2, 2.5, and 1.2; BCTSQ-FS: 2.5, 1.9, and 1.1). No immediate and two peri-operative complications occurred in 46 patients.

Importance: Ultrasound-guided carpal tunnel release may be a safe, effective, and less invasive alternative to traditional open or endoscopic surgery.

Introduction

Carpal tunnel syndrome (CTS) is the most common peripheral entrapment neuropathy, affecting approximately 3-5% of the general population, with 65% having bilateral symptoms.(1–3) Patients typically present with numbness, paresthesias and/or pain in the distribution of the median nerve, with nocturnal worsening of symptoms. Diagnosis of CTS is made primarily by clinical examination, but electrodiagnostic testing can be confirmatory, and imaging assessment by ultrasound or MRI can be helpful in confirming median nerve enlargement or excluding structural abnormality contributing to symptoms of CTS.(4)

Patients with CTS have a significant loss of income compared to those with other upper extremity conditions, with longer periods away from work due to disability.(5) The economic burden in the United States as a result of carpal tunnel syndrome is reported as $2.7-4.8 billion per year, with surgical management resulting in a yearly $1.6 billion economic benefit.(6) Surgical management involves transection of the transverse carpal ligament to decrease compression of the median nerve within the carpal tunnel, either by an open or endoscopic technique. While trials demonstrate no difference in >10 year outcomes regardless of surgical technique, studies suggest earlier resolution of postoperative pain and return to work with the endoscopic method.(7–9) However, one randomized control trial found that over half of patients

treated either endoscopically or with open surgery still had postoperative pain at three month follow-up, associated with an incision that can range from 1 to 3 cm.(10) To attempt to decrease postoperative pain and disability, multiple investigators have developed ultrasound-guided techniques for carpal tunnel release that are even less invasive than endoscopic techniques, and have shown an earlier return to hand function.(11–15) Early reports have shown short-term benefit of this procedure in small patient groups. Our purpose was to evaluate the long-term clinical success of ultrasound-guided carpal tunnel release in a larger patient cohort than in earlier studies evaluating short-term endpoints.

Methods

Review board approval

Institutional Review Board (IRB) approval was granted for this retrospective, HIPAA compliant study. All patients were at least one year following their procedure at the time that this study was conducted. Questionnaires regarding pain and function levels were administered as part of routine clinical care at pre-procedural baseline and at 2 weeks post-procedure. Both written and oral consent were waived for the retrospective review of these questionnaies. IRB approval was obtained to contact patients to administer the same questionnaire at greater than 1-year follow-up; patients who could be contacted were asked to give oral consent for this long-term follow-up questionnaire.

Ultrasound evaluation and patient selection

From July 2017 to April 2019, 51 patients were referred to our outpatient ultrasound clinic from a variety of medical and surgical specialists who made a clinical diagnosis of CTS. A total of 55% (n=28) were referred from physiatrists, sports medicine physicians and primary care physicians; 16% (n=8) from orthopedic surgeons; 18% (n=9) from internal medicine subspecialists, predominantly rheumatologists; and 12% (n=6) from other referrer groups. In all referred patients, the CTS was refractory to conservative management including activity modification, splinting or glucocorticoid injection for at least 6 months following initiation of therapy; patients were therefore deeped appropriate clinical candidates for percutaneous intervention by their referring clinician.

In our clinic, patients underwent diagnostic ultrasound evaluation of the carpal tunnel to exclude structural abnormality contributing to CTS, evaluate the degree of median nerve enlargement and compression by the transverse carpal ligament (**Figure 1**), and confirm anatomic eligibility for the procedure. Documentation of the median nerve cross-sectional area (by drawing a freehand region of interest around the nerve cross-section in short axis as seen in **Figure 1**) was obtained in two locations, proximally at the level of the pronator quadratus muscle and at the distal wrist crease at the entrance to the carpal tunnel. Difference between the two cross-sectional area measurements (ΔCSA) was calculated by subtracting the former measurement from the latter, with ΔCSA greater than 0.02 cm^2 deemed consistent with an imaging diagnosis in support of CTS.(16,17) ΔCSA was also classified as mild (<0.06 cm^2), moderate (0.06-0.09 cm^2) or severe (>0.09 cm^2) based on literature correlating sonographic evaluation of nerve enlargement with nerve conduction studies.(18)

Sonographic identification of relevant anatomic landmarks was performed, including confirmation of orientation of the recurrent motor and palmar cutaneous branches arising from the radial side of the median nerve. Assessment of the transverse and longitudinal safe zones was necessary for procedure planning. The transverse safe zone was defined as the shortest distance between the ulnar border of the median nerve and radial border of either the hook of the hamate or the ulnar artery, using whichever structure is closer to the median nerve (**Figure 2)**. The longitudinal safe zone was defined as the distance between the distal extent of the transverse carpal ligament and the superficial palmar arch (**Figure 3B)**. Patients were excluded from the study if the transverse safe zone was 0 mm, indicating that the ulnar artery was immediately superficial to (or radial to) the ulnar edge of the median nerve, or if the longitudinal safe zone was < 2 mm. Additionally, variant anatomy within the transverse safe zone, such as an ulnar path of the recurrent motor or palmar cutaneous branch, excluded patients from safely undergoing the procedure. Other anatomic variations such as a bifid median nerve or persistent median artery did not preclude the patient from undergoing the procedure, as long as the critera relating to the transverse and longitudinal safe zones were satisfied. A structural abnormality contributing to CTS, such as a mass or accessory muscle, was an additional imaging exclusion criterion. Clinical exclusion criteria beyond the referral diagnosis of CTS refractory to conservative treatment were willingness to undergo the procedure, inability to give informed consent, inability to return for two-week follow-up, and uncorrectable coagulopathy.

Ultrasound-guided carpal tunnel release procedure

The senior author (LNN), a board-certified radiologist with 25 years of experience in ultrasound-guided musculoskeletal interventions, performed all carpal tunnel release procedures

following training on 6 cadaver wrists. All procedures were performed under local anesthetic only, in an outpatient ultrasound radiology clinic using a 15 MHz linear transducer (Sonosite XPorte, FUJIFILM Sonosite, Bothell, WA) or a 14 MHz linear transducer (Canon Aplio i800, Canon Medical Systems, Tustin, CA) and the SX-One MicroKnife® device (Sonex Health, Eagan, MN). The patient was placed in a supine position with the arm and hand resting on a side table with the forearm in supination. Standard sterile technique was utilized to prep the wrist and forearm with ChloraPrep (Becton, Dickinson, and Co., Franklin Lakes, NJ). Sterile surgical drapes were applied to the wrist and forearm, and a sterile cover was placed over the ultrasound probe (CIVCO Medical Solutions, Coralville, IA). Sterile gel was used as an acoustic coupling agent (Aquasonic, Parker Laboratories, Fairfield, NJ). A sterile marker was used to mark the skin over the relevant anatomy and safe zones.

A 25-gauge, 1 ½-inch needle was used to create a small skin wheal at the anticipated site of device insertion at the ulnar aspect of the median nerve at the level of the proximal wrist crease using 2 ml of 2% lidocaine, for subcutaneous anesthesia. Following this, a 21-gauge, 2-inch needle administered 5-10 ml of 1% lidocaine mixed with 1:100,000 epinephrine under continuous ultrasound guidance deep to the transverse carpal ligament, to hydrodissect along the deep aspect of the ligament, to create a clear passage for the dilator and radially shift the median nerve, expanding the transverse safe zone. The needle was then redirected to administer local anesthetic superficial to the ligament.

A #15 scalpel blade was used to create a 4-5 mm longitudinal incision at the proximal wrist crease, penetrating the antebrachial fascia. Continuous ultrasound guidance was used to insert a uterine dilator within the transverse safe zone to loosen any remaining adhesions deep to the transverse carpal ligament (**Supplemental Video 1**). After the dilator was removed, the

transverse carpal ligament transection device **(Figure 4)** was advanced through the same path under continuous ultrasound guidance. Satisfactory device position was documented by ultrasound with respect to the transverse carpal ligament and surrounding neurovascular structures. The device balloon was deployed to increase the size of the transverse safe zone (**Figure 3A**). Next, the cutting knife was activated and the transverse carpal ligament transected in a retrograde manner, under continuous ultrasound guidance (**Figure 3B, Supplemental video 2)**. Following transection, the cutting knife was placed in a recessed position and the uterine dilator reinserted to probe the transverse carpal ligament to ensure complete ligament transection (**Figure 3C, Supplemental video 3 and 4**). If the ligament was not transected completely, the device was reinserted and a second pass was performed in 39% (24/61) of wrists; this was seen in cases of longstanding CTS where the transverse carpal ligament was markedly thickened.

Following removal of the device and post-procedure survey ultrasound scanning to look for bleeding complications, the incision was closed with Nexcare Steri-Strip™ wound closure adhesive (3M Company, St. Paul, MN) and a cling dressing applied. Average incision to closure time was 16 ± 5 minutes. Patients were discharged to home within several minutes after procedure completion and instructed to leave the dressing on for 24 hours and allow the Steri-Strips to fall off on their own. The night following the procedure, patients were instructed to ice the area and use acetaminophen as needed. None of the patients required stronger analgesics. Patients were instructed to limit use of the hand for 3 days and advance function as tolerated.

Clinical follow-up and power analysis

Patients returned to our department for initial follow-up two weeks following the procedure. The wound was examined for healing and signs of infection, and the patient was queried regarding their symptoms. Patients answered three questionnaires assessing the function and pain of the affected hand at each of three time points: immediately prior to the procedure, at two week follow-up, and at greater than one year follow-up. The questionnaires were the Quick–Disabilities of the Arm, Shoulder, and Hand (QDASH), and two components of the Boston Carpal Tunnel Syndrome Questionnaire (BCTSQ): the symptom severity scale (BCTSQ-SS) and functional status scale (BCTSQ-FS). QDASH, a previously validated questionnaire, consists of 11 questions addressing ability to perform certain functions using the upper extremity, with a calculated score reported on a scale of 0 to 100, with 100 representing complete disability.(19) BCTSQ-SS and BCTSQ-FS questionnaires specifically address symptoms associated with CTS and have been validated in assessing response to treatment.(20) The calculated score for each questionnaire is the average response to questions that are answered on a five point scale (1 through 5), with higher scores indicating increasing disability. At follow-up, patients also answered a five-point global satisfaction survey from 1 (very dissatisfied) to 5 (very satisfied).

Prior literature demonstrates that the minimum clinically important difference in QDASH scores is a change of 8 points.(21) The minimum clinically important difference for the BCTSQ, based on an average of both subscales (BCTSQ-SS and BCTSQ-FS), is 0.74, with reports of changes of 0.8 and 0.5 as clinically important in BCTSQ-SS and BCTSQ-FS respectively.(20,22) Our data from pre-procedure surveys demonstrated a median BCTSQ score of 2.9 (interquartile range 1). For the purpose of power and sample size calculations, we used a parametric approximation. Assuming our carpal tunnel release would result in a clinically important

reduction in BCTSQ score, the sample size needed to show a statistically significant reduction in score (alpha = 0.05) is n=10 for a power of 0.80. Our sample size of 61 wrists provides a power of nearly 1.00 to show a statistically significant difference in clinical response to ultrasound-guided carpal tunnel release.

Statistical Analysis

Descriptive statistics were determined for the study cohort. A paired Wilcoxon signed-rank test was used to evaluate pre- and post-procedure questionnaire scores as well as to evaluate for change between subsequent follow-ups. Spearman's rank-order correlation was used to determine associations of survey scores and patient reported satisfaction. It was also used to test associations between change in follow-up questionnaire score (between long-term follow-up and pre-operative score) and severity of median nerve neuropathy as assessed by ΔCSA. Multinomial logistic regression was performed to determine factors associated with patient satisfaction at long-term follow-up using the following variables: age, sex, body mass index (BMI), median nerve cross sectional area in the carpal tunnel and ΔCSA. For this regression, satisfaction was categorized as any dissatisfaction or neutral survey response versus a satisfied or very satisfied response. Finally, multiple linear regression was performed to predict change in BCTSQ and QDASH survey scores between long-term follow-up and pre-procedure score using the following variables: age, sex, BMI, median nerve cross sectional area in the carpal tunnel and ΔCSA. For all analyses, *P* values <0.05 were considered statistically significant. Statistical analysis was performed using IBM SPSS (version 23).

Results

Among the 51 patients (69 wrists) meeting clinical criteria for CTS who presented to our ultrasound clinic for carpal tunnel release evaluation, three patients (5 wrists) did not meet ultrasound criteria for the procedure. In these 5 wrists, the transverse safe zone was unacceptable, with the ulnar artery crossing over the median nerve superficial to the transverse carpal ligament. No patients were excluded for variant anatomy or structural abnormality in the carpal tunnel. Two patients (3 wrists) elected not to undergo the procedure during the study duration; otherwise no additional referred patient met clinical exclusion critera. Thus, a total of 46 patients (61 wrists) met clinical and imaging criteria and elected to undergo carpal tunnel release. These 46 patients included 25 (54%) women and 21 (46%) men. Mean patient age at the time of procedure was 60.7 years (range 21 to 80 years), with a mean BMI of 28.3 (SD=7.0). Mean pre-operative median nerve cross sectional area at the carpal tunnel was 0.16 cm^2 (SD = 0.04) and the mean ΔCSA was 0.08 cm^2 (SD=0.04). According to ΔCSA, the imaging findings of CTS were moderate in 28% (17/61) and severe in 28% (17/61). A total of 33% (15/46) of patients had the carpal tunnel release performed bilaterally, with a median time interval of 35 days (range 14-287 days) between procedures. 44% (27/61) of carpal tunnel release procedures were performed on the patient's dominant side. Demographic and ultrasound features are summarized in **Table 1.**

A total of 87% (40/46) of patients, representing 90% (55/61) of wrists, were successfully contacted a median of 1.7 years (range 1.0-2.8 years, interquartile range 0.45 years) following the procedure to complete the long-term follow-up questionnaires. **Figure 5** demonstrates the median questionnaire scores for QDASH, BCTSQ-SS and BCTSQ-FS pre-procedure as well as at two week and long-term follow-up post-procedure. Median score for each questionnaire at

two-week and long-term follow-up demonstrated a statistically significant decline (all p<0.001) compared with the pre-procedure score, (QDASH: 45.4, 22.5, and 2.3, at pre-operative, 2-week, and long-term follow-up respectively; BCTSQ-SS: 3.2, 1.7, and 1.2, at pre-operative, 2-week, and long-term follow-up respectively; BCTSQ-FS: 2.5, 1.9, and 1.1, at pre-operative, 2-week, and long-term follow-up respectively). Change in median score between pre-procedure and 2-week follow-up surpassed minimum clinically important difference criteria reference standards. Scores also showed a statistically significant decline between 2-week and long-term follow up (p=0.001 for QDASH with median difference of -14.3, p=0.001 for BCTSQ [average of BCTSQ-SS and BCTSQ-FS subscales] with median difference of -0.4). At long-term follow-up, 96% (52/54) and 98% (53/54) of wrists demonstrated lower scores for QDASH and BCTSQ (average of BCTSQ-SS and BCTSQ-FS subscales), respectively, compared with the pre-procedure score.

At two-week and long-term follow-up, 83% (38/46) and 93% (37/40) respectively of surveyed patients reported feeling satisfied or very satisfied with the procedure. Patient satisfaction was not significantly different between the two follow-up points (p=0.16, z=1.4). At long-term follow-up, patient satisfaction showed a statistically significant moderate inverse correlation with BCTSQ score (r=-0.6, p <0.001) and QDASH score (r=-0.5, p<0.001).

Multinomial logistic regression evaluating age, sex, BMI, and nerve cross sectional area measurements, generated a statistically significant model [$\chi^2(10)=24$, p=0.003] indicating that with decreasing age (years), patients were more likely to be satisfied about outcomes at long-term follow-up (p<0.001, odds ratio 5.2, 95% CI 4.4 to 6.3]. Ultrasound severity of median nerve neuropathy (categorized by ΔCSA) showed a moderate positive correlation with decline in QDASH (r_s= 0.3, p=0.03) and BCTSQ scores (r_s=0.3, p=0.04) at long-term follow-up.

Multiple linear regression did not identify any statistically significant predictors ($p>0.5$) of change in BCTSQ or QDASH questionnaire scores at long-term follow-up compared to preoperative scores among the demographic variables and median nerve cross sectional area measurements.

Among the three patients reporting dissatisfaction (n=1) or neutral (n=2) feelings regarding the procedure at long-term follow-up, all had initially presented with mixed symptoms of clinically diagnosed CTS in addition to underlying systemic conditions (Parsonage Turner syndrome [n=1], chemotherapy induced neuropathy [n=1], and myasthenia gravis [n=1]). None demonstrate a change in questionnaire score meeting minimum clinically significant improvement at two-week follow-up or at long term follow-up. All underwent the procedure with the understanding that full recovery of median nerve function may not be attainable.

Among the six patients not included in long-term follow-up, four could not be successfully contacted. These four patients demonstrated functional improvement at two weeks (mean QDASH and BCTSQ differences of -26.6 and -1.1 respectively from pre-procedure scores) and were either satisfied or very satisfied with the procedure at that time. The remaining two patients required referral to surgery following post-procedure follow up. One suffered from a mechanical fall eight days postoperatively (following removal of Steri-Strips) that resulted in an open wound at the site of incision; the patient subsequently developed clinical signs of infection and eventually required open surgical washout for methicillin-resistant *Staphylococcus aureus*. Given the timing of the infection, this was considered a periprocedural infection. The other patient reported improvement in CTS symptoms until postoperative day 10, on which prolonged use and an injury to the wrist while playing racquetball resulted in acute onset of wrist pain, paresthesias and swelling concerning for compartment syndrome. Surgical exploration

demonstrated compression of the median nerve by fascia in the distal forearm; this fascia was resected.

No patient in the study cohort experienced an immediate postoperative neurovascular complication.

Discussion

Our study demonstrates that ultrasound-guided carpal tunnel release can be performed safely, with high patient satisfaction and significant long-term relief of CTS. Patients had marked clinical improvement as early as two weeks postoperatively. Further, a total of 93% of patients surveyed after 1 year were satisfied or very satisfied. In the three patients who were not satisfied at long-term follow-up, multifactorial pathologies may have contributed to their ongoing discomfort. The rapid postoperative recovery and longstanding relief of symptoms suggests that ultrasound-guided carpal tunnel release may be advantageous to traditional surgical methods of transverse carpal ligament transection. The rapid recovery times in part relate to incision size, which was 4-5 mm in our cohort (**Figure 7**), compared with 5-40 mm in endoscopic or open surgery.(23)

The greatest functional improvements were observed in patients with the most severe imaging findings on ultrasound evaluation, as determined by ΔCSA. This finding suggests that such patients may stand to benefit the most from ultrasound-guided carpal tunnel release. Also, given the limited functional improvement in patients with mixed symptoms of CTS and systemic contributions to upper extremity neuropathy, we recommend careful consideration in performing this procedure in patients in whom the diagnosis may be multifactorial.

Several alternative ultrasound-guided carpal tunnel release devices have been described in clinical practice mostly outside of the United States, which are summarized in **Table 2**. The thread technique involves two puncture sites in the skin proximally and distally to the transverse carpal ligament which allow surgical thread to loop around the ligament and transect it when pulled, with studies demonstrating technical and clinical success in small patient cohorts with up to 6 months follow-up .(24,25) However, there is limited visualization of the cutting thread under ultrasound, and confirmation of positioning prior to transection is determined by movement of critical structures while tugging on the thread. Use of a medical device MANOS (MANOS CTR™, Thayer Intellectual Property, Inc., San Francisco, CA) also involves two puncture sites in the skin proximal and distal to the transverse carpal ligament through which a cutting device is inserted deep to the ligament and a sawing maneuver is used to transect the ligament. Ultrasound guidance or nerve conduction can be used to position the probe. However, the transection is performed by feel or palpation rather than by continuous ultrasound guidance.(26,27) Additionally, use of a second more distal puncture site increases potential risk of injury to the superficial palmar arch or to digital nerve branches. Several hook-knife devices have also been described for use in carpal tunnel release, placed superficial or deep to the transverse carpal ligament allowing for manual transection of the ligament when the knife is retracted.(28,29) While this has not been directly studied, a theoretical advantage of the device used in our study is the protective balloon that when inflated allows for a larger safe zone and protection of the neurovascular structures. Further, the ability to disengage the blade of the device used in this study minimizes risk of iatrogenic injury during blade manipulation (**Supplemental video 5 and 6**). Table 2 summarizes clinical outcomes at various post-operative time intervals as measured by BCTSQ-SS and BCTSQ-FS in studies using these various ultrasound-guided techniques. Table 2

also provides for reference one year outcomes from a prospective trial comparing endoscopic and surgical technques. (30) While long-term outcomes between surgical and minimally invasive techniques may not be substantially different, the main advantage of the latter is quicker postoperative recovery and return of function.

Since the time of this study, we have made several modifications to our operations in response to the two patients who required surgery for complications experienced 8-10 days postoperatively. The procedure now includes more extensive preprocedural cleaning that extends to the forearm circumferentially prior to draping. A Tegaderm™ (3M Company, St. Paul, MN) is now placed at the distal third of the forearm to act as an additional sterile barrier at the edge of the sterile field. In addition, two passes of the ligament transection are performed routinely on all patients to potentially decrease the risk of remnant tissue that may contribute to incomplete release. Future studies are warranted to evaluate outcomes following these procedural modifications.

A primary limitation of this study is that it does not account for operator variability given that all procedures were performed by a single physician with experience in musculoskeletal intervention. However, the results of our questionnaire scores at two-week follow-up are consistent with the data in another study that used this ultrasound-guided technique.(14) Additionally, previous work has demonstrated no difference in technical success of ultrasound-guided transverse carpal ligament resection in two operators with different levels of experience.(31) A second limitation is that long-term follow-up was performed over the phone, rather than by an in-person assessment with physical exam correlation and imaging evaluation. Finally, we did not perform a direct comparison with patients who underwent open or endoscopic carpal tunnel release. Further studies are needed with longitudinal follow up and cost

analysis to determine if this procedure should be integrated into the standard treatment for CTS refractory to conservative management.

In conclusion, ultrasound-guided carpal tunnel release quickly improves hand function and reduces hand discomfort, with persistent improvement at one year. Ultrasound-guided carpal tunnel release may be a safe, effective and less invasive alternative to traditional open or endoscopic surgery, particularly in patients for whom traditional surgery may be high-risk or contraindicated.

References

1. Atroshi I, Gummesson C, Johnsson R, Ornstein E, Ranstam J, Rosén I. Prevalence of carpal tunnel syndrome in a general population. JAMA. 1999 Jul 14;282(2):153–8.

2. Pourmemari M-H, Heliövaara M, Viikari-Juntura E, Shiri R. Carpal tunnel release: Lifetime prevalence, annual incidence, and risk factors. Muscle Nerve. 2018;58(4):497–502.

3. Bland JDP, Rudolfer SM. Clinical surveillance of carpal tunnel syndrome in two areas of the United Kingdom, 1991-2001. J Neurol Neurosurg Psychiatry. 2003 Dec;74(12):1674–9.

4. Kleopa KA. In the Clinic. Carpal Tunnel Syndrome. Ann Intern Med. 2015 Sep 1;163(5):ITC1.

5. Foley M, Silverstein B, Polissar N. The economic burden of carpal tunnel syndrome: long-term earnings of CTS claimants in Washington State. Am J Ind Med. 2007 Mar;50(3):155–72.

6. Hubbard ZS, Law TY, Rosas S, Jernigan SC, Chim H. Economic benefit of carpal tunnel release in the Medicare patient population. Neurosurg Focus. 2018 May 1;44(5):E16.

7. Atroshi I, Hofer M, Larsson G-U, Ranstam J. Extended Follow-up of a Randomized Clinical Trial of Open vs Endoscopic Release Surgery for Carpal Tunnel Syndrome. JAMA. 2015 Oct 6;314(13):1399–401.

8. Brown RA, Gelberman RH, Seiler JG 3rd, et al. Carpal tunnel release. A prospective, randomized assessment of open and endoscopic methods. JBJS. 1993 Sep;75(9):1265–1275.

9. Saw NLB, Jones S, Shepstone L, Meyer M, Chapman PG, Logan AM. Early Outcome and Cost-effectiveness of Endoscopic versus Open Carpal Tunnel Release: a Randomized Prospective Trial. J Hand Surg Br Eur Vol. 2003 Oct 1;28(5):444–9.

10. Atroshi I, Larsson G-U, Ornstein E, Hofer M, Johnsson R, Ranstam J. Outcomes of endoscopic surgery compared with open surgery for carpal tunnel syndrome among employed patients: randomised controlled trial. BMJ. 2006 Jun 22;332(7556):1473.

11. Rojo-Manaute JM, Capa-Grasa A, Chana-Rodríguez F, et al. Ultra-Minimally Invasive Ultrasound-Guided Carpal Tunnel Release. J Ultrasound Med. 2016;35(6):1149–57.

12. Chappell CD, Beckman JP, Baird BC, Takke AV. Ultrasound (US) Changes in the Median Nerve Cross-Sectional Area After Microinvasive US-Guided Carpal Tunnel Release. J Ultrasound Med Off J Am Inst Ultrasound Med. 2020 Apr;39(4):693–702.

13. Hebbard PD, Hebbard AIT, Tomka J, Appleyard R. Ultrasound-Guided Microinvasive Carpal Tunnel Release Using a Novel Retractable Needle-Mounted Blade: A Cadaveric Study. J Ultrasound Med Off J Am Inst Ultrasound Med. 2018 Aug;37(8):2075–81.

14. 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 Off J Am Inst Ultrasound Med. 2020 Mar;39(3):441–52.

15. Henning PT, Yang L, Awan T, Lueders D, Pourcho AM. Minimally Invasive Ultrasound-Guided Carpal Tunnel Release: Preliminary Clinical Results. J Ultrasound Med Off J Am Inst Ultrasound Med. 2018 Nov;37(11):2699–706.

16. Elnady B, Rageh EM, Ekhouly T, et al. Diagnostic potential of ultrasound in carpal tunnel syndrome with different etiologies: correlation of sonographic median nerve measures with electrodiagnostic severity. BMC Musculoskelet Disord [Internet]. 2019 Dec 29 [cited 2020 May 18];20. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6935486/

17. Klauser AS, Halpern EJ, De Zordo T, et al. Carpal Tunnel Syndrome Assessment with US: Value of Additional Cross-sectional Area Measurements of the Median Nerve in Patients versus Healthy Volunteers. Radiology. 2009 Jan 1;250(1):171–7.

18. Klauser AS, Abd Ellah MMH, Halpern EJ, et al. Sonographic cross-sectional area measurement in carpal tunnel syndrome patients: can delta and ratio calculations predict severity compared to nerve conduction studies? Eur Radiol. 2015 Aug 1;25(8):2419–27.

19. Gummesson C, Ward MM, Atroshi I. The shortened disabilities of the arm, shoulder and hand questionnaire (QuickDASH): validity and reliability based on responses within the full-length DASH. BMC Musculoskelet Disord. 2006 May 18;7:44.

20. Leite JC de C, Jerosch-Herold C, Song F. A systematic review of the psychometric properties of the Boston Carpal Tunnel Questionnaire. BMC Musculoskelet Disord. 2006 Oct 20;7:78.

21. Mintken P, Glynn P, Cleland J. Psychometric properties of the shortened disabilities of the Arm, Shoulder, and Hand Questionnaire (QuickDASH) and Numeric Pain Rating Scale in patients with shoulder pain. J Shoulder Elb Surg Am Shoulder Elb Surg Al. 2009 Apr 1;18:920–6.

22. Atroshi I, Johnsson R, Sprinchorn A. Self-administered outcome instrument in carpal tunnel syndrome. Reliability, validity and responsiveness evaluated in 102 patients. Acta Orthop Scand. 1998 Feb;69(1):82–8.

23. Cellocco P, Rossi C, Bizzarri F, Patrizio L, Costanzo G. Mini-Open Blind Procedure Versus Limited Open Technique for Carpal Tunnel Release: A 30-Month Follow-Up Study. J Hand Surg. 2005 May 1;30(3):493–9.

24. Guo D, Yu T, Ji Y, Sun T, Guo J, Guo D. A Non-Scalpel Technique for Minimally Invasive Surgery: Percutaneously Looped Thread Transection of the Transverse Carpal Ligament. HAND. 2015 Mar 1;10(1):40–8.

25. Burnham RS, Loh EY, Rambaransingh B, Roberts SL, Agur AM, Playfair LD. A Controlled Trial Evaluating the Safety and Effectiveness of Ultrasound-Guided Looped Thread Carpal Tunnel Release. HAND. 2019 Apr 15;1558944719842199.

26. Markison RE. Percutaneous ultrasound-guided MANOS carpal tunnel release technique. Hand N Y N. 2013 Dec;8(4):445–9.

27. McCormack B, Bowen W, Gunther S, Linthicum J, Kaplan M, Eyster E. Carpal Tunnel Release Using the MANOS CTR System: Preliminary Results in 52 Patients. J Hand Surg. 2012 Apr 1;37(4):689–94.

28. Chern T-C, Kuo L-C, Shao C-J, Wu T-T, Wu K-C, Jou I-M. Ultrasonographically Guided Percutaneous Carpal Tunnel Release: Early Clinical Experiences and Outcomes. Arthrosc J Arthrosc Relat Surg. 2015 Dec 1;31(12):2400–10.

29. Petrover D, Silvera J, De Baere T, Vigan M, Hakimé A. Percutaneous Ultrasound-Guided Carpal Tunnel Release: Study Upon Clinical Efficacy and Safety. Cardiovasc Intervent Radiol. 2017 Apr 1;40(4):568–75.

30. Trumble TE, Diao E, Abrams RA, Gilbert-Anderson MM. Single-Portal Endoscopic Carpal Tunnel Release Compared with Open Release : A Prospective, Randomized Trial. JBJS. 2002 Jul;84(7):1107–1115.

31. Burnham R, Playfair L, Loh E, Roberts S, Agur A. Evaluation of the Effectiveness and Safety of Ultrasound-Guided Percutaneous Carpal Tunnel Release: A Cadaveric Study. Am J Phys Med Rehabil. 2017 Jul;96(7):457–463.

TABLES:

Table 1: Demographic and ultrasound features of 46 patients undergoing carpal tunnel release in total of 61 wrists

Participant Features	Value
Demographics	
Age (years)	60.7 (21-80)
Sex	
Female	25 (54%)*
Male	21 (46%)
BMI	28.3 (7)
Ultrasound findings	
Median nerve CSA at the carpal tunnel (cm^2)	0.16 (0.04)
Median nerve CSA at the pronator quadratus (cm^2)	0.08 (0.03)
ΔCSA (cm^2)	0.08 (0.04)

CSA = Cross sectional area

ΔCSA = CSA at the carpal tunnel – CSA at the pronator quadratus

All continuous variables reported as mean with standard deviation in parentheses.

*Number of participants with percent in parentheses

Table 2: Clinical outcomes reported in the present and prior studies for alternative ultrasound-guided carpal tunnel release procedures and for a prospective study that compared outcomes between endoscopic and traditional open surgical techniques.

Technique		First author and reference	Number of wrists	Mean patient age (range if available)	Length of follow-up	BCTS-SS	BCTS-FS
Ultrasound-guided technique	Present Study		61	60 (21-80)	20 months	1.2 (1)*	1.1 (0.7)*
	MANOS technique	McCormack et al[27]	52	65 (41-101)	6 months	1.9±0.9	1.9±0.9
	Threaded loop technique	Guo et al[24]	34	52 (22-94)	3 months	1.4±0.5	1.2±0.3
	Manual hook-knife technique	Petrover et al[28]	129	61.5	6 months	1.3±0.3	1.3±0.5
Comparative study	Endoscopic surgical technique	Trumble et al[30]	97	56	12 months	1.8±0.15	1.7±0.1
	Open surgical technique	Trumble et al[30]	95	56	12 months	1.8±0.1	1.7±0.11

*Median score and interquartile range in parentheses are reported for the present study given that the data was not normally distributed. All other studies report mean ± standard deviation

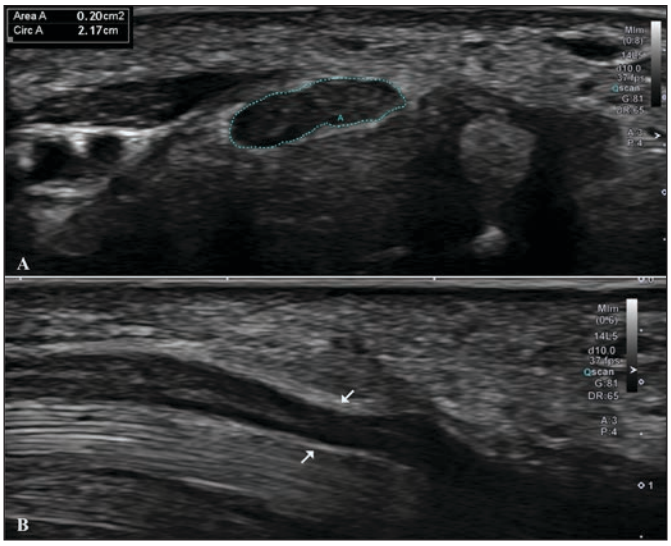

Fig. 1- 64-year-old man with clinical symptoms of carpal tunnel and a preoperative QDASH score of 78. (A) demonstrates the median nerve at the carpal tunnel in short axis, with a cross sectional area of 0.2 cm2 and ΔCSA of 0.09 cm2 (B) Long axis view of the median nerve in the same patient demonstrates compression of the nerve (arrows) by a thickened flexor retinaculum. This patient underwent ultrasound-guided carpal tunnel release, with complete resolution of symptoms at two-week follow up. The patient remains symptom free at follow-up one year later.

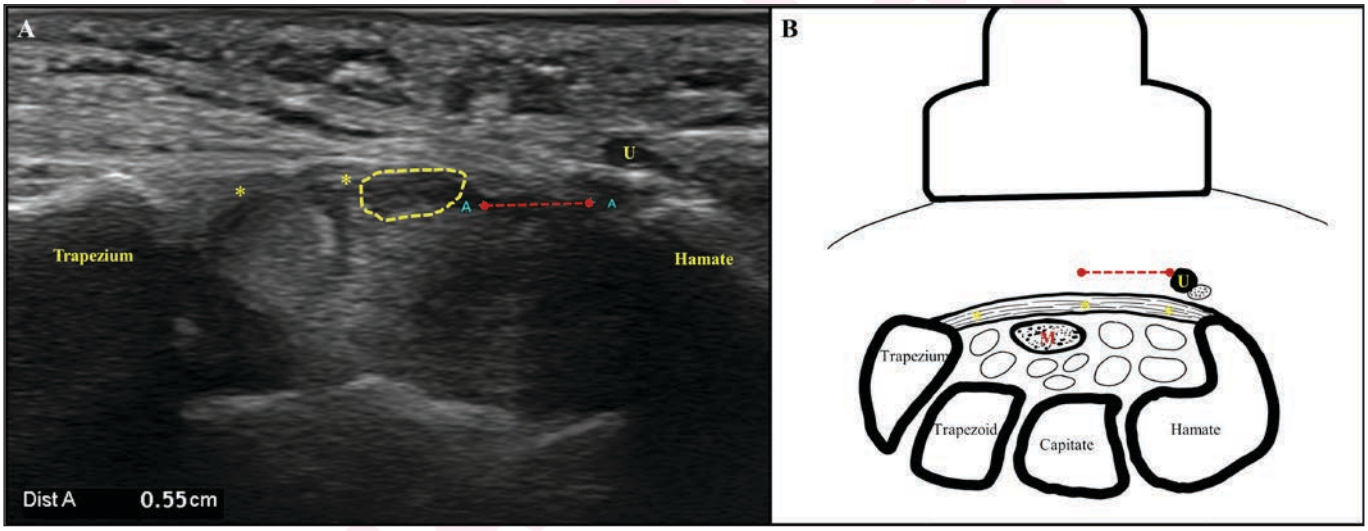

Fig. 2- Preprocedural anatomy of the carpal tunnel. (A) Grayscale transverse image of the carpal tunnel at the level of the hook of the hamate, where the transverse safe zone (red dashed line) is measured. It is defined as the distance between the ulnar border of the median nerve (dotted circle) to the closer structure, either the hook of the hamate or the ulnar neurovascular bundle (U). In this case, the transverse safe zone was 0.55 cm. (B) Schematic detailing sonographic transverse view of the carpal tunnel to determine the transverse safe zone (red dashed line) from the median nerve (M) to the ulnar neurovascular bundle (U), which in this case was closer to the median nerve than the hook of the hamate. * = transverse carpal ligament.

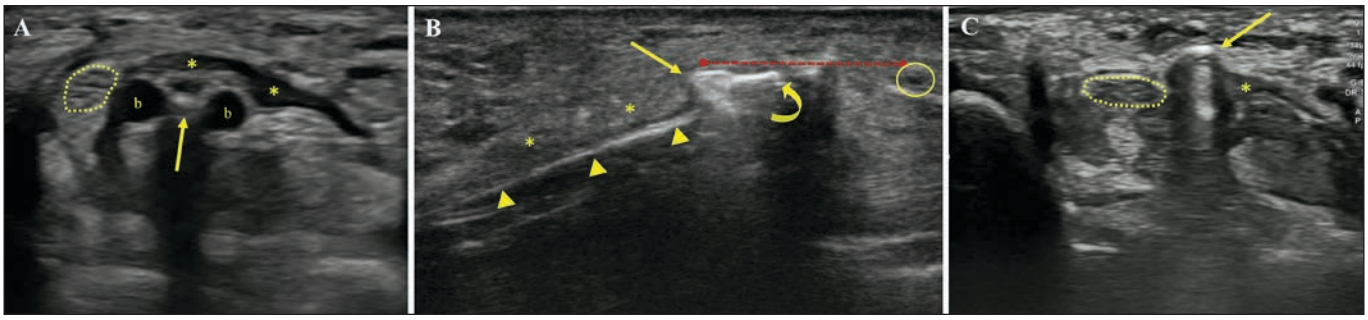

Fig. 3- Intraprocedural ultrasound images during transverse ligament transection (A) Transverse grayscale image of the carpal tunnel following insertion of the transection device and inflation of the protective balloon (b) on both sides of the cutting edge (arrow). The device is positioned in transverse safe zone, ulnar to the median nerve (dotted circle) and deep to the transverse carpal ligament (*). Inflation of the balloon displaces the median nerve radially and protects the components of the carpal tunnel from iatrogenic injury during transverse carpal ligament resection. (B) Longitudinal grayscale image (distal is to the right of image) of the device (arrowhead) positioned within the safe zones. The longitudinal safe zone (dotted red line) is annotated as the distance from the edge of the transverse carpal ligament (*) to the superficial palmar arch (circle). The distal tip of the device (curved arrow) is well within the longitudinal safe zone, and there is no risk of injury to the superficial palmar arch. The hook of the device is deployed (arrow) and can now transect the transverse carpal ligament. (C) Transverse grayscale image of the carpal tunnel following transection of the transverse carpal ligament (*). The uterine dilator (arrow) is re-inserted into the safe zone ulnar to the median nerve (dotted circle) to probe the ligament and verify transection. In this image, the dilator is superficial to the level of the ligament, confirming successful transection.

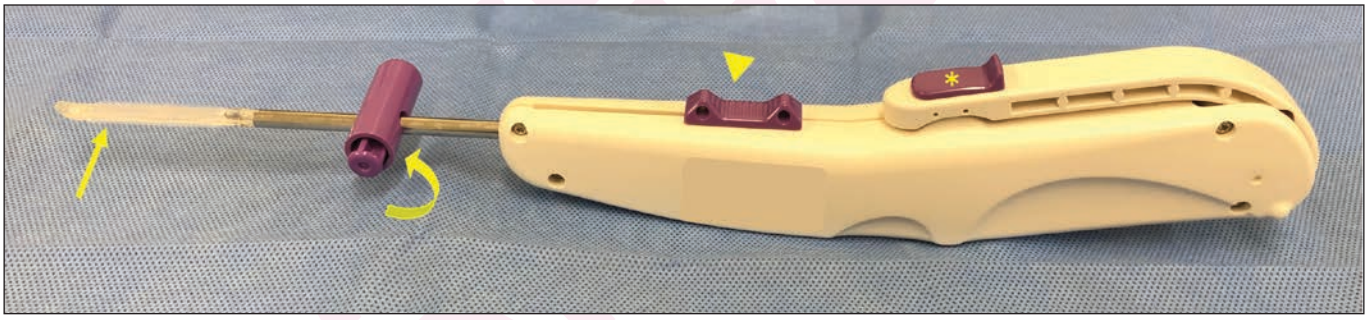

Fig. 4- The SX-One MicroKnife® device (Sonex Health) used to transect the transvere carpal ligament. To prevent iatrogenic injury during manipulation, the device features a retractable hook blade housed within an inflatable balloon (arrow). The balloon is inflated with saline by compressing the lever in the handle (asterisk) and increases the space within the transverse safe zone. The hook blade is deployed and retracted to transect the transverse carpal ligament using the lever denoted by the arrowhead. A stopper (curved arrowhead) is available to prevent inadvertent advancement of the device beyond the longitudinal safe zone.

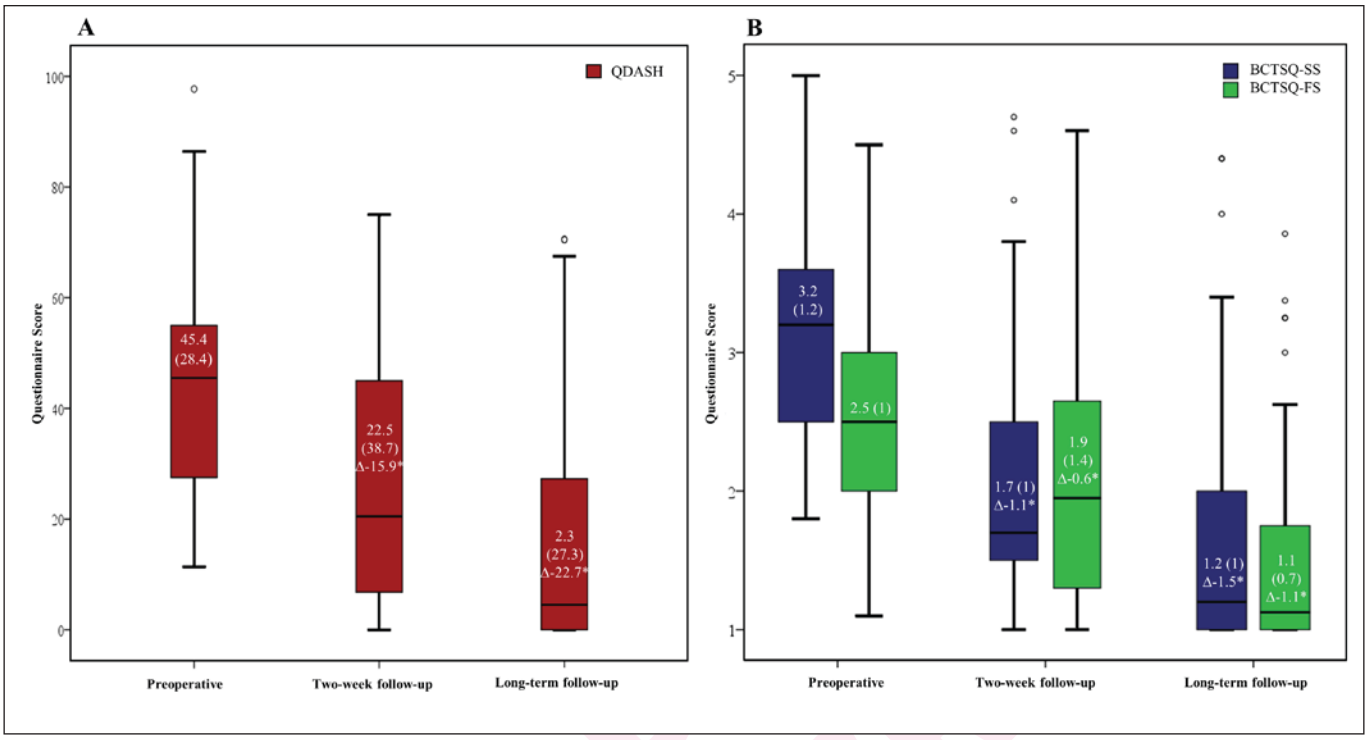

Fig. 5- Box and whisker plots demonstrating trend in QDASH scores (A) and BCTSQ-SS/BCTSQ-FS scores (B) preoperatively and at follow-up obtained two weeks and one year postoperatively. For all questionnaire scores, median value is reported with interquartile range in parentheses. Δ = median difference from pre-procedure score. *indicates that the median difference meets criterial for minimum clinically important difference in score.

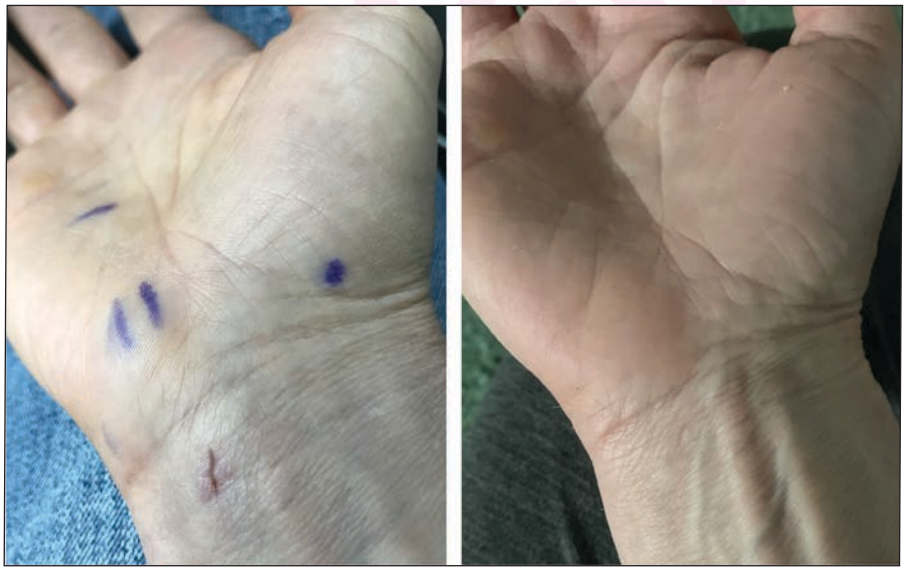

Fig. 6- 52 year old female with long-standing persistent symptoms of carpal tunnel syndrome. Postoperative photos submitted by a patient at 3 days postoperatively (left) and at long-term follow-up (right), demonstrate excellent healing of the 4 mm incision utilized for ultrasound-guided carpal tunnel release.

AJR

Minimally Invasive Ultrasound-Guided Carpal Tunnel Release Improves Long-Term Clinical Outcomes in Carpal Tunnel Syndrome

Original Research Article

Sarah I Kamel, MD[1] sarah.kamel@jefferson.edu

Bradley Freid, BS[2] bradley.freid@jefferson.edu

Corbin Pomeranz, MD[1] corbin.pomeranz@jefferson.edu

Ethan J Halpern, MD[1] ethan.halpern@jefferson.edu

Levon N Nazarian, MD[1] levon.nazarian@jefferson.edu

[1]Department of Radiology, Thomas Jefferson University Hospital. 132 S 10th Street Philadelphia, PA 19107. (215) 955-6752

[2]Sidney Kimmel Medical College, Thomas Jefferson University Hospital. 1025 Walnut St #100, Philadelphia, PA 19107. (215) 955-6983

Corresponding Author:

Sarah I Kamel, MD

Thomas Jefferson University Hospital

132 S 10th Street

Philadelphia, PA 19107

215-955-6752

@sarahkamelmd

No funding was obtained for this study

The author LNN discloses his role on the Medical Advisory Board of Tenex Health, Inc. LNN was not involved in data collection or data analysis portions of the study. Otherwise, the remaining authors have no disclosures.