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Original Research

Long-Term Clinical Results of Carpal Tunnel Release Using Ultrasound Guidance: A Multicenter Pragmatic Study

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Purpose: The purpose of this study was to report the 1-year clinical outcomes of carpal tunnel release using ultrasound guidance (CTR-US) performed in a large, real-world population of patients enrolled in a multicenter registry.

Methods: All patients who participated in a postmarket registry study of CTR-US outcomes and provided both preoperative and 1-year postoperative data were included. Main outcomes were the Quick Disabilities of the Arm, Shoulder, and Hand Questionnaire (QDASH), Boston Carpal Tunnel Questionnaire Symptom Severity Scale (BCTQ-SSS), and Boston Carpal Tunnel Functional Status Scale (BCTQ-FSS) scores at 1 year. Subgroup analysis was performed to assess the effect of patient and procedural factors on 1-year outcomes.

Results: A total of 300 patients (341 hands) were treated by 25 different physicians, including 41 (13.7%) treated with simultaneous bilateral procedures. Mean patient age was 54.2 years, 63% were women, 24% had ≥2 comorbidities, and 54% had symptoms for >2 years. Mean QDASH scores decreased from 40.6 ± 20.6 to 12.2 ± 18.3 at 1 year, BCTQ-SSS scores decreased from 3.0 ± 0.7 to 1.5 ± 0.7 at 1 year, and BCTQ-FSS scores decreased from 2.4 ± 0.8 to 1.4 ± 0.6 at 1 year. Women improved more than men at 1 year for QDASH, BCTQ-SSS, and BCTQ-FSS. Patients treated with simultaneous bilateral procedures had similar 1-year outcomes to those treated with unilateral procedures. Multiple other factors including high body mass index, diabetes status, current tobacco use, rheumatoid/inflammatory arthritis, operation in the dominant hand, higher comorbidity burden, and concurrent ipsilateral procedures did not significantly affect 1-year outcomes. Two patients had revision surgeries in addition to one patient with an infection, and one with a suspected small finger tendon injury.

Conclusions: Patients treated with CTR-US in real-world conditions report significant and clinically meaningful improvements in symptoms and function that are maintained at 1 year. The results are consistent across broad patient demographics and are not affected by performing simultaneous bilateral procedures.

Type of study/level of evidence: Therapeutic IV.

Carpal tunnel syndrome (CTS) is the most common compression neuropathy with a reported prevalence of 3%–8% in the United States.[1–4] Carpal tunnel release (CTR) is one of the most frequent procedures in the upper limb, with more than 600,000 procedures performed annually.[5,6] Although CTR outcomes are generally positive with high patient satisfaction and low complication rates, over time, a trend to reduce surgical morbidity by reducing incision size or changing incision location has been observed.[6–9] Historically, most CTR procedures have been performed using traditional open, mini-open, or endoscopic techniques.[8,10–13] However, CTR using ultrasound guidance (CTR-US) is a more recently developed CTR technique in which the transverse carpal ligament (TCL) is released through a small incision while visualizing critical structures using

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Table 1
CTR-US Studies Reporting Clinical Results at a Minimum of 1-Year Follow-Up*

Study	Location	Number of Sites/Providers	Technique	Patients	Hands
Nakamichi and Tachibana[14], 1997	Japan	NR	Basket punch with blade	50	50
Nakamichi et al[21], 2010	Japan	1 provider	Angled blade	29	35
Chern et al[22], 2015	Taiwan	1 site	Hook knife	80	91
Rojo-Manaute et al[15], 2016	Spain	1 provider	Hook knife	46	46
Wang et al[23], 2019	Taiwan	NR	Hook knife	84	113
Wang et al[20], 2021	Taiwan	NR	Hook knife	376	661
de la Fuente et al[24], 2021	Spain	1 provider	V-shaped knife	47	47
Kamel et al[25], 2021	United States	1 provider	UltraGuideCTR†	46	61
Leiby et al[7], 2022	United States	1 provider	UltraGuideCTR	47	76
Bergum and Ciota[19], 2022	United States	2 providers/1 site	UltraGuideCTR	88	123
Wang et al[26], 2022	Taiwan	NR	Hook knife	37	37
Krogh et al[27], 2023	Denmark	1 provider/1 site	Hook knife	10	10
Aguila, 2023 (current study)	*United States*	*25 providers/25 sites*	*UltraGuideCTR*	*300*	*341*
13 studies				**1,240**	**1,691**

NR, not reported.
* See text for explanation of included studies.
† Sonex Health, Inc.

ultrasound.[7,14–17] Previous studies have shown the safety and effectiveness of CTR-US techniques using blades or blade-containing devices, as well as the potential for these procedures to accelerate recovery.[7,15,16,18,19] However, among the 12 studies reporting minimum 1-year results, only one included over 100 patients,[20] and none were multicenter designs including physicians from diverse practices (Table 1).[7,14,15,19–27] Additional, larger-scale, long-term studies are necessary to document the durability of the results and help further define the role of CTR-US in the surgical treatment of patients with CTS.

A previously published study using data from a 1-year, multicenter registry documented the short and intermediate-term safety and effectiveness of CTR-US up to 6 months postprocedure in 373 patients/427 hands.[16] The primary purpose of the current study was to report the final, long-term (minimum 1-year) results of CTR-US from the same registry. The secondary purpose was to determine whether baseline patient or procedural factors affected 1-year outcomes.

Methods

A full description of the study design and methods can be found in a previously published study reporting the 6-month patient outcomes from this registry.[16]

Study design

Patients undergoing CTR-US enrolled in a 1-year, multicenter, observational postmarket registry in the United States. This registry was launched to collect postmarket safety and effectiveness data on CTR-US using a commercially available hand-held device (UltraGuideCTR, Sonex Health, Inc.). The study was conducted per the Declaration of Helsinki and STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines[28] and was granted a waiver of consent exemption from WCG IRB (Puyallup) under 45 CFR §46.104(d)(4) because subjects would not be identifiable with this method of data collection.

Eligibility criteria

The eligibility criteria for this study were previously described.[16] Briefly, eligible patients were adults (age ≥18 years) treated with CTR-US who were willing to participate in the registry and provided both preoperative and 1-year postoperative data. Participating physicians diagnosed CTS as per their usual practices and decisions for CTR-US were based on physician and patient preferences through a shared decision-making process. No patients were excluded based on old age, medical/surgical history, concomitant procedures, or clinical presentation in this real-world registry.

CTR with ultrasound guidance

All patients were treated with CTR-US using a single-use, commercially available, hand-held device (Fig. 1) (UltraGuideCTR) that creates space in the carpal tunnel using two inflatable balloons. At the time of the study, physicians had performed fewer than 10 to over 100 procedures using CTR-US. Details of the CTR-US technique have been previously described.[16] In brief, after sterile field preparation and hand positioning, US was used to identify relevant landmarks. After local anesthesia, a small longitudinal wrist incision was created, and the device was positioned in the tunnel using US. After the confirmation of device position, the balloons were expanded to create space within the tunnel, followed by deployment of the retrograde cutting blade to release the TCL from distal to proximal under continuous US guidance. The blade was recessed, balloons were deflated, and the TCL probed under US guidance to ensure a complete release. Physician and practice preferences dictated patient selection, anesthesia choice, and postprocedure care. Postoperative data were collected by text message, email, or chart review.

Outcome measures

We asked the registry patients to complete a preoperative questionnaire, daily text message questions for 14 days postprocedure, and emailed questionnaires at 2 weeks, 1, 3, 6 months, and 1-year after surgery. The preoperative questionnaire included demographic data, work status, and baseline patient-reported outcome measures such as the Quick Disabilities of the Arm, Shoulder, and Hand Questionnaire (QDASH), and the Boston Carpal Tunnel Questionnaire Symptom Severity Scale (BCTQ-SSS), and Functional Status Scale (BCTQ-FSS). Postoperative outcomes were collected by text message or email and included QDASH, BCTQ-SSS, BCTQ-FSS, and patient satisfaction measures.

QDASH is a patient-reported questionnaire with a total score ranging from 0 (no disability) to 100 (severe disability).[29] The BCTQ is a CTS-specific questionnaire with questions on symptom severity and functional status. Scoring for BCTQ-SSS and BCTQ-FSS range from 1 to 5, with higher scores indicating more severe symptoms.[30] BCTQ-SSS score was obtained independently for each hand for

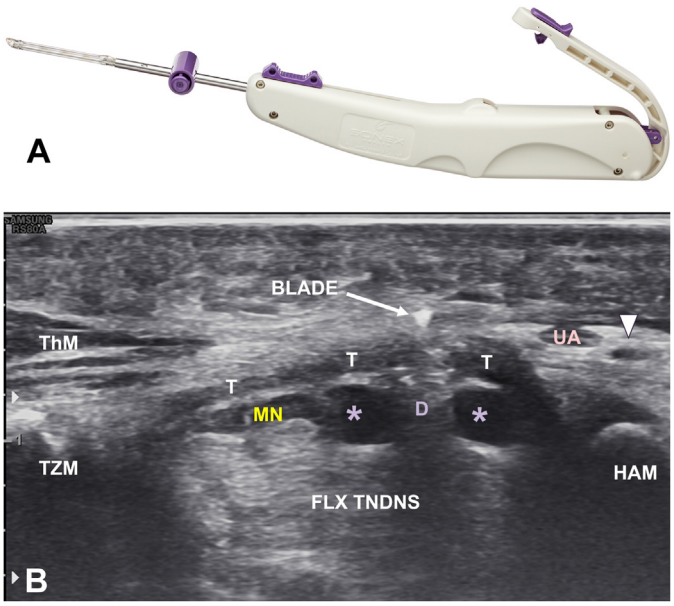

Figure 1. UltraGuideCTR device. **A** UltraGuideCTR device tip with hidden blade and inflatable balloons is inserted through a small incision. **B** Transverse view of the distal carpal tunnel at the level of the hamate (HAM) and trapezium (TZM). The device (D) has been placed into the transverse safe zone of the carpal tunnel just deep to the TCL (T), and the balloons (asterisks) are deployed to create space. The ulnar balloon is next to the hamate, and the radial balloon separates the median nerve (MN) from the centrally located cutting blade. The blade tip is visualized in the cross-section above the ligament. In this view, the relative positions of the device tip, balloons, blade, MN, and ulnar artery (UA) can be clearly seen. Thm = thenar muscles, arrowheads = superficial and deep branches of the ulnar nerve. Top = superficial, Left = radial.

patients treated with simultaneous bilateral releases. QDASH and BCTQ-FSS scores were collected per patient. Minimal clinically important differences (MCIDs) for postoperative change in patient-reported outcomes were considered to be 15 points for QDASH,[31] 1.14 points for BCTQ-SSS,[32] and 0.74 points for BCTQ-FSS.[32] Patient satisfaction was reported on a 5-point Likert scale ranging from 1 (very dissatisfied) to 5 (very satisfied). We also asked patients if they would recommend CTR-US to a friend or colleague, reporting on a scale from 0 (low) to 10 (high). Treating physicians reviewed patient charts for specific complications including superficial and deep infection, arterial laceration, permanent nerve injury, and reoperation for incomplete release.

Statistical analysis

The current analysis included all patients from the registry who provided both preoperative data and any 1-year postoperative data. However, not all patients completed all questions at 1 year, resulting in fewer patients/hands in some subgroup analyses than the total number of patients/hands in the study. We calculated means, standard deviations, and percentages for patient characteristics and baseline measures and used a repeated measures linear mixed model to analyze the changes in QDASH and BCTQ over time due to the presence of missing values. We used the same model for the subgroup analysis with adjustment for baseline values and used Dunnett's multiple comparison test to compare each time point with baseline. *P* values of $< .05$ were considered statistically significant in all cases except subgroup analysis in which *P* values of $< .008$ were considered statistically significant after Bonferroni's correction. We conducted these analyses on an individual patient level; we calculated patient satisfaction as the percentage of patients answering 4 (satisfied) or 5 (very satisfied) and calculated mean and median procedure recommendation scores.

Table 2
Patient Characteristics

Characteristic	Patients (N = 300)	
	n	(%)
Age (y)		
Mean (SD)	54.2	(13.7)
18–34	23	(8)
35–64	203	(68)
≥65	73	(24)
Sex		
Women	188	(63)
Men	112	(37)
BMI (kg/m^2)		
Mean (SD)	32.6	(8.5)
BMI ≥30	166	(55)
Comorbidities		
Anxiety	70	(24)
Depression	62	(21)
Diabetes	31	(11)
Thyroid disease	42	(14)
Arthritis	27	(9)
Tobacco use (current)	39	(13)
Chronic pain syndrome	22	(7)
Polyneuropathy or other nerve disorder	9	(3)
Current opioid use	10	(3)
Renal failure	1	(<1)
CTS symptom duration		
≤6 mo	32	(11)
>6 mo to 1 y	61	(20)
>1–2 y	47	(16)
>2 y	163	(54)
Operative hand		
Dominant	147	(49.0)
Nondominant	112	(37.3)
Bilateral	41	(13.7)
Current employment	191	(64)
Desk*	101	(53)†
Light manual activity‡	48	(25)†
Heavy manual activity§	42	(22)†
Baseline Symptoms and Function	**Mean (SD)**	
QDASH (0–100 scale)	40.6	(20.6)
BCTQ-SSS (1–5 scale)	3.0	(0.7)
BCTQ-FSS (1–5 scale)	2.4	(0.8)

BMI, body mass index.
* For example, keyboard, mouse, writing, telephone, and supervisory/managerial.
† Among currently employed patients.
‡ For example, driving (trucking, taxi), delivery, stacking, and cleaning.
§ For example, construction, farming, trade work (plumbing, carpentry), heavy lifting, pushing, or pulling.

Results

Among the 959 patients who enrolled in the registry by November 2022 and were at least 1-year post-CTR-US, 300 patients (341 hands) provided both preoperative and 1-year postoperative data (31%). We analyzed this group for the current study. Data were available on 236 (79%) of these patients at 2 weeks, 251 (84%) at 1 month, 233 (78%) at 3 months, 258 (86%) at 6 months, and 300 (100%) at 1 year. All patients were treated with CTR-US between November 2019 and November 2021 by 25 different providers (9 surgeons and 16 nonsurgeons) at 25 sites in the United States. Before participating in this registry, 64% of the physicians had experience with fewer than 20 CTR-US procedures. Among the 300 patients, 163 (54%) had symptoms for >2 years and 72 (24%) had two or more comorbidities (most commonly anxiety and

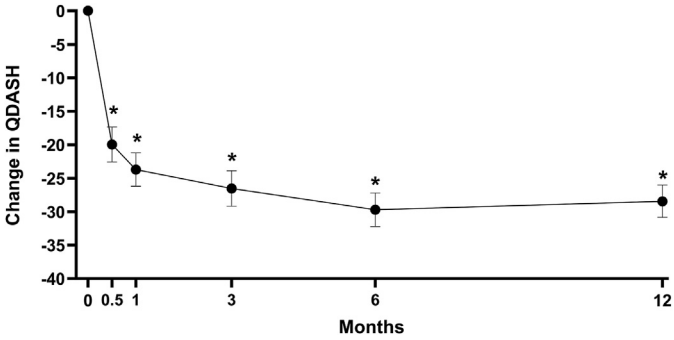

Figure 2. QDASH over time. Mean change and 95% CI in QDASH score over 1-year post-CTR-US. Statistically significant improvements in QDASH scores are maintained at 1 year and exceed the MCID of 15. *P < .0001 compared with preoperative baseline score.

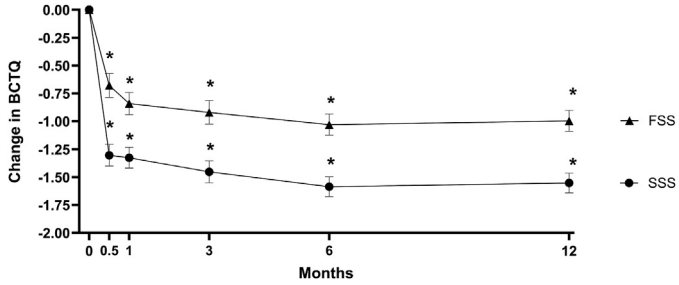

Figure 3. BCTQ-SSS and BCTQ-FSS over time. Mean change and 95% CI in BCTQ scores over 1-year post-CTR-US. Statistically significant improvements in both BCTQ-SSS and BCTQ-FSS scores are maintained at 1-year and exceed the MCID of 1.14 for BCTQ-SSS and 0.74 for BCTQ-FSS. *P < .0001 compared with preoperative baseline score.

depression; Table 2). Forty-one patients (13.7%) had simultaneous bilateral procedures, 62.7% had CTR-US on their dominant hand, and 7% had concurrent ipsilateral procedures at the time of surgery (eg, trigger finger release, release for De Quervain's tenosynovitis, cubital tunnel release, and cyst removal).

The mean QDASH score was 40.6 ± 20.6 before surgery, decreased to 21.0 ± 16.7 at 2 weeks, and remained low through 1 year at 12.2 ± 18.3 (P < .001 vs pre-op; Fig. 2). Mean BCTQ-SSS score decreased from 3.0 ± 0.7 before surgery to 1.7 ± 0.6 at 2 weeks, and 1.5 ± 0.7 at 1 year (P < .001 vs pre-op; Fig. 3). Mean BCTQ-FSS score was 2.4 ± 0.8 before surgery, 1.7 ± 0.6 at 2 weeks, and 1.4 ± 0.6 by 1 year (P < .001 vs pre-op; Fig. 3). All changes exceeded respective MCIDs at 1 year. At 1 year, 87.7% of the patients were satisfied with the procedure, and the mean procedure recommendation score (0–10) was 8.9.

Patient subgroups were analyzed to determine whether differences in baseline patient characteristics or procedural factors affected QDASH, BCTQ-SSS, or BCTQ-FSS scores at 1-year post-CTR-US (Table 3). All outcome measures more improved significantly for women than men (P < .008). No other factors, including simultaneous bilateral procedures, concomitant ipsilateral procedures, and comorbidities, significantly affected 1-year outcomes.

Complication data were available for 290 (96.7%) patients and included two revision surgeries for incomplete releases (0.67%, one of which was reported in a previous publication), 1 deep infection (0.33%), and one suspected small finger tendon injury (0.33%) lost to follow-up.[16]

Discussion

The main finding of this study was that diverse patients treated with CTR-US reported statistically significant and clinically meaningful improvements in symptoms and function that persist long term and are accompanied by high satisfaction. This extends previous short-term results from the same registry[16] and shows the durability of improvement. Additionally, this study evaluated the effect of patient and procedural factors on long-term outcomes, revealing that only sex significantly affected 1-year results, with women improving in QDASH and BCTQ more than men.

Since Nakamichi and Tachibana first described an ultrasound-assisted CTR using a basket punch,[14] 12 articles (>900 patients/1,300 hands) have reported 1-year clinical results of CTR-US using devices incorporating blades to release the TCL, similar to open, mini-open, and endoscopic CTR techniques (Table 1).[7,12–15,19–25] Despite various outcome measures, these studies report the same pattern of recovery: rapid improvement within the first weeks to months, slowing of improvement between 3 and 12 months, and durability of improvement over 1–2.8 years. However, only one study included more than 100 patients[20]; most studies excluded patients with specific comorbidities, and the procedures were generally performed by highly experienced physicians at a single institution. The current study expands this literature by reproducing these findings in a real-world, multicenter registry including 25 physicians and 300 patients, reporting rapid improvements in symptoms and function that persisted long term.

The results reported here are similar to the outcomes reported for both open and endoscopic CTR.[33,34] Although there are no directly comparable large-scale registry studies reporting 1-year results, Jansen et al[35] reported similar improvements in BCTQ scores at 6 months after open CTR in a multicenter registry.

The inclusion of patients with diverse backgrounds and comorbidities provided the opportunity to analyze baseline factors that might influence outcomes. Among previous long-term CTR-US studies, only Kamel et al[25] examined potential prognostic variables at a mean of 1.7 years post-CTR-US. They limited their analysis to age, sex, body mass index, and baseline median nerve cross-sectional area. The authors reported no statistical association of these variables with QDASH or BCTQ scores at follow-up. Our subgroup analysis revealed that sex was the only factor to be associated with improvements in QDASH and BCTQ scores, despite examining a range of patient and procedural factors that could influence the outcomes. In the existing literature, the relationship between sex and CTR outcomes is inconsistent. Some shorter-term studies have associated female sex with better outcomes, whereas most long-term studies have found no relationship.[35–40] A mechanism for sex-related effects on CTR outcomes has not been identified. Despite the statistical relationship between sex and 1-year outcomes in the current study, the quantitative differences are small and below the MCID threshold. In summary, the findings of our subgroup analysis support those of previous studies, indicating that CTR- US is a safe and effective technique with good long-term results, including patients with comorbidities (eg, anxiety, depression, diabetes, and thyroid disease) and those having concomitant ipsilateral procedures.[7,19]

Many patients with CTS present with bilateral symptoms and are candidates for simultaneous bilateral procedures, which are beneficial by shortening the overall episode of care.[7,19,41] Only three of the aforementioned long-term CTR-US studies differentiate patients treated with simultaneous bilateral release,[7,19,20] and two examined whether this influenced outcomes.[7,19] These two studies found that patients treated with simultaneous bilateral releases had similar QDASH and BCTQ outcomes compared with those not treated with simultaneous release. The current study similarly found no significant effect on QDASH and BCTQ outcomes. Taken

Table 3
Subgroup Analysis of Change Over Time at 1-Year Follow-Up

Baseline Characteristic	QDASH			BCTQ-SSS			BCTQ-FSS		
	n	Mean	95% CI	n	Mean	95% CI	n	Mean	95% CI
Age (y)									
18–34	22	−31.3	−40.87, −21.73	23	−1.6	−1.94, −1.32	22	−1.1	−1.46, −0.78
35–64	197	−28.1	−31.09, −25.07	226	−1.6	−1.66, −1.44	197	−1.0	−1.09, −0.86
≥65	72	−28.8	−33.67, −23.9	80	−1.5	−1.69, −1.33	72	−1.0	−1.21, −0.84
P value		.795			.833			.705	
Sex									
Woman	188	−31.6	−34.82, −28.41	210	−1.7	−1.77, −1.54	188	−1.1	−1.26, −1.03
Man	111	−23.1	−26.45, −19.66	129	−1.4	−1.52, −1.25	111	−0.7	−0.89, −0.61
P value		**<.008***			**<.008***			**<.008***	
Body mass index (kg/m^2)									
<30	132	−26.4	−30.32, −22.4	149	−1.5	−1.64, −1.37	132	−0.9	−1.07, −0.77
≥30	166	−30.2	−33.15, −27.17	189	−1.6	−1.71, −1.48	166	−1.1	−1.18, −0.94
P value		.134			.313			.138	
Diabetes									
Yes	31	−28.2	−30.84, −25.54	33	−1.6	−1.66, −1.47	31	−1.0	−1.09, −0.89
No	262	−30.8	−37.03, −24.56	298	−1.5	−1.8, −1.21	262	−1.1	−1.34, −0.82
P value		.522			.698			.522	
Tobacco use†									
Yes	39	−28.7	−31.3, −26.2	46	−1.6	−1.66, −1.47	39	−1.0	−1.1, −0.9
No	254	−25.8	−33.62, −17.89	287	−1.5	−1.72, −1.19	254	−0.9	−1.24, −0.65
P value		.482			.425			.731	
Rheumatoid or inflammatory arthritis									
Yes	27	−28.0	−30.53, −25.38	31	−1.5	−1.62, −1.44	27	−1.0	−1.07, −0.87
No	266	−33.5	−41.74, −25.26	300	−1.8	−2.12, −1.55	266	−1.3	−1.63, −1
P value		.217			.052			.046	
Simultaneous bilateral procedures									
Yes	40	−30.2	−35.66, −24.79	80	−1.6	−1.75, −1.41	40	−1.1	−1.33, −0.92
No	259	−28.2	−30.82, −25.5	259	−1.5	−1.65, −1.44	259	−1.0	−1.08, −0.87
P value		.506			.763			.110	
Worker compensation cases									
Yes	7	−24.0	−33.39, −14.66	7	−1.3	−1.8, −0.87	7	−0.7	−1.28, −0.14
No	287	−28.8	−31.24, −26.27	327	−1.6	−1.66, −1.48	287	−1.0	−1.11, −0.92
P value		.371			.379			.344	
Dominant hand operated									
Yes	147	−30.4	−33.89, −26.9	147	−1.6	−1.76, −1.5	147	−1.1	−1.19, −0.94
No	112	−25.2	−29.29, −21.15	112	−1.4	−1.6, −1.27	112	−0.9	−1.03, −0.69
P value		.060			.064			.057	
Concurrent procedure(s) on ipsilateral upper extremity‡									
Yes	21	−31.1	−39.38, −22.74	25	−1.6	−1.96, −1.31	21	−1.1	−1.4, −0.79
No	278	−28.2	−30.76, −25.71	314	−1.6	−1.64, −1.46	278	−1.0	−1.09, −0.89
P value		.531			.602			.527	
Number of comorbidities§									
0	140	−28.7	−32.15, −25.28	161	−1.6	−1.7, −1.47	140	−0.93	−1.07, −0.8
≥2	72	−28.5	−33.73, −23.21	79	−1.6	−1.77, −1.36	72	−1.1	−1.28, −0.91
P value		.939			.890			.168	

* Statistically significant ($P < .008$) after correcting for multiple comparisons.
† Question specifically asked whether the patient was currently smoking or using nicotine products.
‡ Concurrent procedures included trigger finger/thumb release, release for De Quervain's tenosynovitis, cubital tunnel release, and cyst removal.
§ Comorbidities included diabetes, nerve disorders, arthritis, depression, anxiety, chronic pain syndromes, thyroid conditions, and kidney failure (see also Table 2).

together, these studies suggest that when compared with unilateral procedures, patients treated with simultaneous bilateral CTR-US would have similar clinical improvements.

Of the 300 patients in the current study, two had revision surgeries for incomplete release during follow-up. One of these revisions was previously reported in an earlier publication from this registry.[16] Revision rates for open and endoscopic CTR vary widely in the literature, from <1% to 5%, with the most common reason being incomplete release.[42,43] Two previous studies reported revisions for persistent or recurrent symptoms after CTR-US using blade techniques. In a case series of 80 patients/91 hands, Chern et al[22] reported late symptom recurrence (>1 year) in one hand, which was then successfully re-treated using CTR-US. More recently, de la Fuente et al[24] reported two early revisions at <1-year follow-up of the 47 patients. Overall, revision due to incomplete release after CTR-US is uncommon, commensurate with MRI studies documenting successful decompression after CTR-US.[44–47]

Strengths of this study include the large sample size, demographics typical of CTR patients, and long-term follow-up with analysis of prognostic indicators. The patients in this study were predominantly women, with an average age of 54 years and mostly high body mass index, and more than 50% had long-term symptoms (>2 years) before CTR-US. Additionally, we collected these real-world data from a diverse patient group with multiple comorbidities treated by 25 different providers of varied procedural experience and included a high number of patients treated with simultaneous bilateral releases.

This study also has several limitations. First, the study included patients only with both preoperative and 1-year postoperative data (31% of the total registry), and postoperative data were collected via text and email as opposed to in-person visits. Both of these factors may contribute to selection bias. Reassuringly, the results are similar to those previously reported using similar CTR-US techniques within multiple study designs.[14,15,18,20–23] Second, although demographically representative of CTS patients, the group was not

racially diverse (89% white). Third, these procedures were performed using a single blade-based technique, and thus appropriate caution should be used when comparing these findings with other CTR-US techniques. Additionally, all physicians in this study used the same general CTR-US technique; however, other factors, such as patient selection, specific procedural decisions, and postprocedural care, were determined by the treating physician. Although this lack of standardization could be seen as a limitation, we consider this a strength because it supports the broad applicability of the findings.

In conclusion, the results of this study indicate that patients treated with CTR report significant and clinically meaningful improvements in symptoms and function that are maintained at the 1-year follow-up. The results are consistent across patient demographics and are not affected by performing simultaneous bilateral procedures or concurrent ipsilateral procedures.

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References

1. Sevy JO, Varacallo M. *Carpal Tunnel Syndrome*. StatPearls Publishing [Internet]; 2022.
2. Atroshi I, Englund M, Turkiewicz A, Tagil M, Petersson IF. Incidence of physician-diagnosed carpal tunnel syndrome in the general population. *Arch Intern Med*. 2011;171(10):943–944.
3. Luckhaupt SE, Dahlhamer JM, Ward BW, Sweeney MH, Sestito JP, Calvert GM. Prevalence and work-relatedness of carpal tunnel syndrome in the working population, United States, 2010 National Health Interview Survey. *Am J Ind Med*. Jun 2013;56(6):615–624.
4. Dale AM, Harris-Adamson C, Rempel D, et al. Prevalence and incidence of carpal tunnel syndrome in US working populations: pooled analysis of six prospective studies. *Scand J Work Environ Health*. 2013;39(5):495–505.
5. Atroshi I, Gummesson C, Johnsson R, Ornstein E, Ranstam J, Rosen I. Prevalence of carpal tunnel syndrome in a general population. *JAMA*. 1999;282(2):153–158.
6. Fajardo M, Kim SH, Szabo RM. Incidence of carpal tunnel release: trends and implications within the United States ambulatory care setting. *J Hand Surg Am*. 2012;37(8):1599–1605.
7. Leiby BM, Beckman JP, Joseph AE. Long-term clinical results of carpal tunnel release using ultrasound guidance. *Hand (N Y)*. 2022;17(6):1074–1081.
8. Li Y, Luo W, Wu G, Cui S, Zhang Z, Gu X. Open versus endoscopic carpal tunnel release: a systematic review and meta-analysis of randomized controlled trials. *BMC Musculoskelet Disord*. 2020;21(1):272.
9. Michelotti BM, Vakharia KT, Romanowsky D, Hauck RM. A prospective, randomized trial comparing open and endoscopic carpal tunnel release within the same patient. *Hand (N Y)*. 2020;15(3):322–326.
10. Munns JJ, Awan HM. Trends in carpal tunnel surgery: an online survey of members of the American Society for Surgery of the Hand. *J Hand Surg Am*. 2015;40(4):767–771 e2.
11. Leinberry CF, Rivlin M, Maltenfort M, et al. Treatment of carpal tunnel syndrome by members of the American Society for Surgery of the Hand: a 25-year perspective. *J Hand Surg Am*. 2012;37(10):1997–2003 e3.
12. Schwarz AM, Lipnik G, Hohenberger GM, Krauss A, Plecko M. Mini-open carpal tunnel release: technique, feasibility and clinical outcome compared to the conventional procedure in a long-term follow-up. *Sci Rep*. 2022;12(1):9122.
13. Hacquebord JH, Chen JS, Rettig ME. Endoscopic carpal tunnel release: techniques, controversies, and comparison to open techniques. *J Am Acad Orthop Surg*. 2022;30(7):292–301.
14. Nakamichi K, Tachibana S. Ultrasonographically assisted carpal tunnel release. *J Hand Surg Am*. 1997;22(5):853–862.
15. Rojo-Manaute JM, Capa-Grasa A, Chana-Rodriguez F, et al. Ultra-minimally invasive ultrasound-guided carpal tunnel release: a randomized clinical trial. *J Ultrasound Med*. 2016;35(6):1149–1157.
16. Fowler JR, Chung KC, Miller LE. Multicenter pragmatic study of carpal tunnel release with ultrasound guidance. *Expert Rev Med Devices*. 2022;19(3):273–280.
17. Eberlin KR, Amis BP, Berkbigler TP, et al. Multicenter randomized trial of carpal tunnel release with ultrasound guidance versus mini-open technique. *Expert Rev Med Devices*. 2023;20(7):597–605.
18. Capa-Grasa A, Rojo-Manaute JM, Rodriguez FC, Martin JV. Ultra minimally invasive sonographically guided carpal tunnel release: an external pilot study. *Orthop Traumatol Surg Res*. 2014;100(3):287–292.
19. Bergum RA, Ciota MR. Office-based carpal tunnel release using ultrasound guidance in a community setting: long-term results. *Cureus*. 2022;14(7):e27169.
20. Wang PH, Wu PT, Jou IM. Ultrasound-guided percutaneous carpal tunnel release: 2-year follow-up of 641 hands. *J Hand Surg Eur Vol*. 2021;46(3):305–307.
21. Nakamichi K, Tachibana S, Yamamoto S, Ida M. Percutaneous carpal tunnel release compared with mini-open release using ultrasonographic guidance for both techniques. *J Hand Surg Am*. 2010;35(3):437–445.
22. Chern TC, Kuo LC, Shao CJ, Wu TT, Wu KC, Jou IM. Ultrasonographically guided percutaneous carpal tunnel release: early clinical experiences and outcomes. *Arthroscopy*. 2015;31(12):2400–2410.
23. Wang PH, Li CL, Shao CJ, Wu KC, Chern TC, Jou IM. Ultrasound-guided percutaneous carpal tunnel release in patients on hemodialysis: early experiences and clinical outcomes. *Ther Clin Risk Manag*. 2019;15:711–717.
24. de la Fuente J, Aramendi JF, Ibanez JM, et al. Minimally invasive ultrasound-guided vs open release for carpal tunnel syndrome in working population: a randomized controlled trial. *J Clin Ultrasound*. 2021;49(7):693–703.
25. 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 Am J Roentgenol*. 2021;217(2):460–468.
26. Wang JC, Li CY, Ko PY, et al. The correlation of carpal tunnel pressure with clinical outcomes following ultrasonographically-guided percutaneous carpal tunnel release. *J Pers Med*. 2022;12(7):1045.
27. Krogh TP, Isaksen C, Rojo-Manaute JM, et al. Implementation of ultrasound-guided carpal tunnel release. *Dan Med J*. 2023;70(9):A11220689.
28. von Elm E, Altman DG, Egger M, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Lancet*. 2007;370(9596):1453–1457.
29. Beaton DE, Wright JG, Katz JN, Upper Extremity Collaborative G. Development of the QuickDASH: comparison of three item-reduction approaches. *J Bone Joint Surg Am*. 2005;87(5):1038–1046.
30. Levine DW, Simmons BP, Koris MJ, et al. A self-administered questionnaire for the assessment of severity of symptoms and functional status in carpal tunnel syndrome. *J Bone Joint Surg Am*. 1993;75(11):1585–1592.
31. Franchignoni F, Vercelli S, Giordano A, Sartorio F, Bravini E, Ferriero G. Minimal clinically important difference of the disabilities of the arm, shoulder and hand outcome measure (DASH) and its shortened version (QuickDASH). *J Orthop Sports Phys Ther*. 2014;44(1):30–39.
32. Kim JK, Jeon SH. Minimal clinically important differences in the Carpal Tunnel Questionnaire after carpal tunnel release. *J Hand Surg Eur Vol*. 2013;38(1):75–79.
33. Trumble TE, Diao E, Abrams RA, Gilbert-Anderson MM. Single-portal endoscopic carpal tunnel release compared with open release : a prospective, randomized trial. *J Bone Joint Surg Am*. 2002;84(7):1107–1115.
34. Atroshi I, Larsson GU, 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;332(7556):1473.
35. Jansen MC, Evers S, Slijper HP, et al. Predicting clinical outcome after surgical treatment in patients with carpal tunnel syndrome. *J Hand Surg Am*. 2018;43(12):1098–1106 e1.
36. De Kleermaeker F, Meulstee J, Bartels R, Verhagen WIM. Long-term outcome after carpal tunnel release and identification of prognostic factors. *Acta Neurochir (Wien)*. 2019;161(4):663–671.
37. Rivlin M, Kachooei AR, Wang ML, Ilyas AM. Electrodiagnostic grade and carpal tunnel release outcomes: a prospective analysis. *J Hand Surg Am*. May 2018;43(5):425–431.
38. Louie DL, Earp BE, Collins JE, et al. Outcomes of open carpal tunnel release at a minimum of ten years. *J Bone Joint Surg Am*. Jun 19 2013;95(12):1067–1073.
39. Hobby JL, Venkatesh R, Motkur P. The effect of age and gender upon symptoms and surgical outcomes in carpal tunnel syndrome. *J Hand Surg Br*. 2005;30(6):599–604.
40. Bowman A, Rudolfer S, Weller P, Bland JDP. A prognostic model for the patient-reported outcome of surgical treatment of carpal tunnel syndrome. *Muscle Nerve*. 2018;58(6):784–789.
41. Osei DA, Calfee RP, Stepan JG, Boyer MI, Goldfarb CA, Gelberman RH. Simultaneous bilateral or unilateral carpal tunnel release? A prospective cohort study of early outcomes and limitations. *J Bone Joint Surg Am*. 2014;96(11):889–896.
42. Wessel LE, Gu A, Asadourian PA, Stepan JG, Fufa DT, Osei DA. The epidemiology of carpal tunnel revision over a 1-year follow-up period. *J Hand Surg Am*. 2021;46(9):758–764.
43. Carroll TJ, Dussik CM, Clary Z, Hoffman S, Hammert W, Mahmood B. Endoscopic versus open carpal tunnel surgery: risk factors and rates of revision surgery. *J Hand Surg Am*. 2023;48(8):757–763.
44. Petrover D, Hakime A, Silvera J, Richette P, Nizard R. Ultrasound-guided surgery for carpal tunnel syndrome: a new interventional procedure. *Semin Intervent Radiol*. 2018;35(4):248–254.
45. Petrover D, Silvera J, De Baere T, Vigan M, Hakime A. Percutaneous ultrasound-guided carpal tunnel release: study upon clinical efficacy and safety. *Cardiovasc Intervent Radiol*. 2017;40(4):568–575.
46. Chou RC, Robinson DM, Homer S. *Ultrasound-guided percutaneous carpal tunnel release: a systematic review*. PM R; 2022.
47. Nicholas GE, Galloway J, Hawley J, McGinley JC. Carpal tunnel release with ultrasound guidance: intermediate-term clinical outcomes and magnetic resonance imaging findings. *J Hand Surg Glob Online*. 2023;5(5):595–600.