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Final 1-Year Results of the TUTOR Randomized Trial Comparing Carpal Tunnel Release with Ultrasound Guidance to Mini-open Technique

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Background: Studies comparing carpal tunnel release with ultrasound guidance (CTR-US) to mini-open CTR (mOCTR) are limited. This randomized trial compared the efficacy and safety of these techniques.
Methods: In this multicenter randomized trial, patients were randomized (2:1) to unilateral CTR-US or mOCTR. Outcomes included Boston Carpal Tunnel Questionnaire Symptom Severity Scale (BCTQ-SSS) and Functional Status Scale (BCTQ-FSS), numeric pain scale (0–10), EuroQoL-5 Dimension 5-Level (EQ-5D-5L), scar outcomes, and complications over 1 year.
Results: Patients received CTR-US (n = 94) via wrist incision (mean 6 mm) or mOCTR (n = 28) via palmar incision (mean 22 mm). Comparing CTR-US with mOCTR, the mean changes in BCTQ-SSS (−1.8 versus -1.8; P = 0.96), BCTQ-FSS (−1.0 versus −1.0; P = 0.75), numeric pain scale (−3.9 versus −3.8; P = 0.74), and EQ-5D-5L (0.13 versus 0.12; P = 0.79) over 1 year were comparable between groups. Freedom from scar sensitivity or pain favored CTR-US (95% versus 74%; P = 0.005). Complications occurred in 2.1% versus 3.6% of patients (P = 0.55), all within 3 weeks postprocedure. There was one revision surgery in the CTR-US group, and no revisions for persistent or recurrent symptoms in either group.
Conclusions: CTR-US and mOCTR demonstrated similar improvement in carpal tunnel syndrome symptoms and quality of life with comparable low complication rates over 1 year of follow-up. CTR-US was performed with a smaller incision and associated with less scar discomfort. *(Plast Reconstr Surg Glob Open 2024; 12:e5665; doi: 10.1097/GOX.0000000000005665; Published online 4 March 2024.)*

INTRODUCTION

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy, estimated to impact 5% of the adult population.[1] Carpal tunnel release (CTR) is a definitive CTS treatment indicated in patients with severe or persistent symptoms. Approximately 3% of individuals will undergo CTR at some point during their lifetime to manage their CTS symptoms.[2] Because the various CTR techniques aim to divide the transverse carpal ligament, the effectiveness among techniques is generally equivalent.[3,4] Each technique has advantages and disadvantages that should be discussed with patients through a shared decision-making process to determine the optimal approach based on individual factors.

The mini-open approach (mOCTR) is the most common CTR technique,[5] using a 1–3 cm palmar incision to directly visualize the transverse carpal ligament, median nerve, and other critical structures. The effectiveness and safety of mOCTR are well established, with patients experiencing significant improvements in function and pain postoperatively, and a low risk of mainly temporary complications.[6] However, survey results suggest that patients with CTS prefer less-invasive surgical options using smaller incisions and allowing for rapid recovery.[7] This suggests a role for and interest in smaller-incision CTR techniques

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that provide an expeditious return to daily activities with an acceptable cosmetic result.

Carpal tunnel release with ultrasound guidance (CTR-US) uses a small (<1 cm) wrist incision with real-time ultrasonography to visualize the relevant anatomy during the procedure. While numerous case series have reported favorable outcomes with CTR-US,[8–11] randomized trials provide higher-quality evidence to inform clinical decision-making. Two previous single-center randomized trials evaluated patient-reported outcomes and complication rates with CTR-US and mOCTR.[4,12] Based on the favorable results with CTR-US in these trials, the multicenter randomized TUTOR trial was designed to compare CTR-US to mOCTR in patients with CTS. The 3-month TUTOR results were previously reported, in which the efficacy and safety of the techniques were comparable overall, with less postoperative scar discomfort reported in the CTR-US group.[13] The current article presents the final 1-year results from the TUTOR trial, providing long-term comparative evidence on these two surgical approaches for CTR.

Takeaways

Question: In patients with carpal tunnel syndrome, what are the 1-year comparative outcomes of carpal tunnel release with ultrasound guidance (CTR-US) versus the mini-open technique (mOCTR)?

Findings: This multicenter randomized trial demonstrated that CTR-US and mOCTR resulted in comparable low complication rates with similar improvements in symptoms, function, pain, and quality of life over 1 year. CTR-US was performed through a smaller wrist incision with less postoperative scar discomfort than mOCTR.

Meaning: While CTR-US and mOCTR provide durable relief from carpal tunnel syndrome symptoms, CTR-US utilizes a smaller incision with less postoperative scar discomfort.

METHODS

Trial Design

TUTOR is a multicenter randomized controlled trial with a 1-year follow-up designed to compare outcomes of patients after unilateral CTR-US or mOCTR. The 3-month outcomes of this trial were previously published.[13] The trial was approved by a central institutional review board (WCG IRB, Puyallup, Wash.) and prospectively registered at ClinicalTrials.gov (NCT05405218). All patients provided written informed consent before enrollment, including confirmation of their willingness to receive either procedure.

Patients

Trial eligibility was determined after a clinical examination and diagnostic ultrasound of the median nerve. All patients had persistent CTS symptoms despite prior nonsurgical treatment. A CTS diagnosis required meeting all three of the following criteria: (1) a clinical diagnosis of idiopathic CTS by the treating physician based on history and physical exam; (2) CTS-6 score greater than or equal to 12, indicating greater than 80% probability of CTS;[14] and (3) median nerve cross-sectional area greater than or equal to 10 mm^2 at the proximal carpal tunnel on diagnostic ultrasound, which is a validated threshold for median nerve enlargement supporting a CTS diagnosis.[15] Patients with bilateral CTS were eligible for enrollment if the symptoms on the contralateral hand did not interfere with daily activities or work. Patients were ineligible if they received previous treatments that could confound trial outcomes or the response to surgery, including recent corticosteroid injections or previous surgery on the affected hand, recent CTR or planned procedures on the contralateral hand, or the need for concomitant procedures during CTR. Patients meeting all criteria were randomized to CTR-US or mOCTR.

Trial Procedures

Patients were randomized in a 2:1 ratio to either unilateral CTR-US or mOCTR at each site using a permuted block design with random block sizes. Trial investigators were experienced hand surgeons with a median of 14 years' experience in performing mOCTR. Each surgeon investigator completed cadaver training and at least 10 CTR-US procedures before treating patients in the study. The median prior surgical experience was 1000 mOCTR procedures and 12 CTR-US procedures per surgeon.

CTR-US was performed using a commercially available device (UltraGuideCTR, Sonex Health, Inc., Eagan, Minn.) inserted into the carpal tunnel through an incision proximal to the wrist under real-time ultrasound guidance. Detailed procedural steps are available elsewhere.[9,16] The mOCTR technique used a standard longitudinal palmar incision without ultrasound guidance. Each surgeon individually determined the site of service, anesthesia type, wound closure method, and wound care recommendations.

Outcome Measures

In-person patient follow-up occurred according to the standard of care at each site. A validated, regulatory-compliant remote data collection system (Viedoc, Uppsala, Sweden) was used to collect data daily for the first 14 days and then at 1, 3, 6, and 12 months thereafter. Study outcomes included the Boston Carpal Tunnel Questionnaire Symptom Severity Scale (BCTQ-SSS) and Functional Status Scale (BCTQ-FSS) scores, numeric pain scale (0–10 scale) scores, EuroQoL-5 Dimension 5-Level (EQ-5D-5L) scores, patient-reported scar assessments (cosmesis, discomfort, satisfaction), and device- or procedure-related complications. The minimal clinically important difference for patient-reported outcomes were a change of −1.14 points for BCTQ-SSS,[17] −0.74 points for BCTQ-FSS,[17] −2.0 points for numeric pain scale,[18] and 0.09 points for EQ-5D-5L.[19] Complications were recorded through one of four reporting mechanisms involving (1) the treating physician during the procedure, (2) the patient or study site personnel during an in-person follow-up visit, (3) the patient via phone, or (4) site review of wound healing images. An independent medical reviewer evaluated all complications reported during the trial to determine

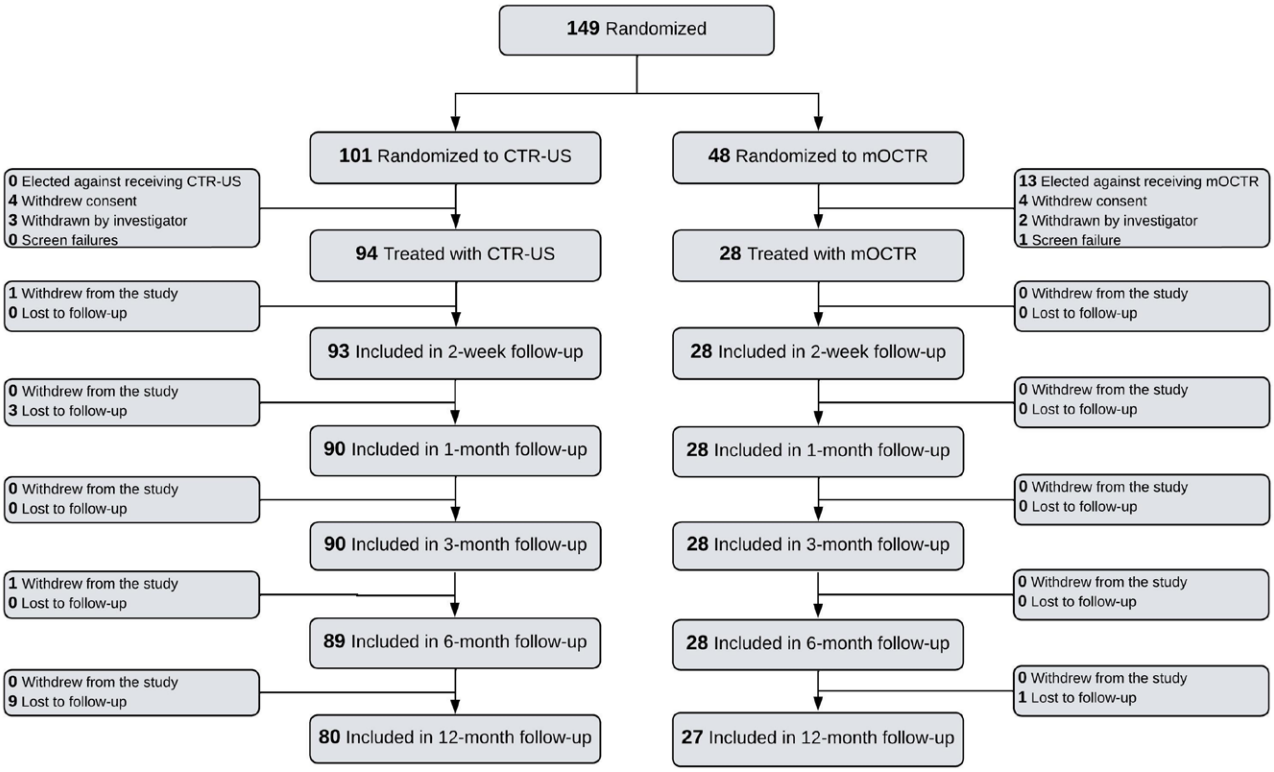

Fig. 1. CONSORT patient flow diagram.

their classification. Safety oversight was provided by an independent data safety and monitoring board.

Statistical Analysis

A power analysis indicated that 102 patients would provide 80% power to detect a moderate effect size (Cohen $d = 0.6$) between groups with 2:1 randomization, two-tailed $\alpha = 0.05$, and an equal variance t test. To account for patient attrition during the trial, the enrollment target was 120 patients. The analysis population was composed of randomized patients who underwent their assigned treatment. Baseline patient characteristics were summarized using means and SDs for continuous variables after a normal distribution, medians, and interquartile ranges (IQR) for continuous variables following a nonnormal distribution, and counts and percentages for categorical variables. The 1-year change in patient-reported outcomes was analyzed using a linear mixed model, reported as the baseline-adjusted least squares mean and 95% confidence interval (95% CI). Postoperative scar assessments and complications occurring through 1 year were compared between the groups using Fisher exact test. All significance testing was two-sided, and the results were considered statistically significant if the P value was less than 0.05.

RESULTS

Between July 2022 and January 2023, 149 participants from 11 centers were randomized (2:1) to CTR-US (n = 101) or mOCTR (n = 48). After randomization, seven patients assigned to CTR-US withdrew (none explicitly refusing CTR-US) and 20 patients assigned to mOCTR withdrew (13 explicitly refusing mOCTR) before surgery. Overall, 122 received their assigned treatment (94 CTR-US; 28 mOCTR). Patient follow-up compliance through 1 year was 88% overall (85% CTR-US; 96% mOCTR; Fig. 1). There were no statistical differences in baseline patient characteristics between groups. All procedures were completed as planned, and no CTR-US procedures were converted to OCTR/mOCTR. Most procedures used only local anesthesia (83% CTR-US; 71% mOCTR). The surgical incision in the wrist was shorter with CTR-US than the palmar incision with mOCTR (6 ± 2 versus 22 ± 7 mm; $P < 0.001$). Sutureless closure was performed in 81% of CTR-US cases and 0% of mOCTR cases ($P < 0.001$; Table 1).

A rapid improvement in CTS symptoms was noted in both groups over the first 2 postoperative weeks, with gradual continued improvement throughout the 1-year follow-up period. Over 1 year, the mean change in BCTQ-SSS was −1.8 after CTR-US and −1.8 after mOCTR (both $P < 0.001$ compared with baseline), which was comparable between groups ($P = 0.96$). Similar trends were noted in BCTQ-FSS, with statistically significant changes in each group over 1 year (−1.0 versus −1.0; both $P < 0.001$ compared with baseline) that were not different between groups ($P = 0.75$) (Fig. 2). The mean values for BCTQ-SSS and BCTQ-FSS at 1 year ranged from 1.2 to 1.3 in both groups, indicating near maximal improvement. The change in the numeric pain scale over 1 year was statistically significant

Table 1. Patient and Procedure Characteristics with CTR-US versus mOCTR*

Variable	CTR-US (n = 94)	mOCTR (n = 28)
Patients		
Age (y)	57 ± 14	57 ± 14
Female sex	63.8% (60/94)	75.0% (21/28)
Symptom duration > 2 years	59.6% (56/94)	50.0% (14/28)
Bilateral CTS	29.8% (28/94)	46.4% (13/28)
CTS-6 total score	18.8 ± 4.2	19.6 ± 4.3
Median nerve cross-sectional area (mm^2)	15.6 ± 3.9	14.8 ± 3.2
BCTQ-SSS	3.05 ± 0.66	3.06 ± 0.75
BCTQ-FSS	2.24 ± 0.75	2.31 ± 0.79
Hand/wrist pain severity	4.5 ± 2.8	4.5 ± 3.0
EQ-5D-5L	0.77 ± 0.18	0.75 ± 0.23
Procedures		
Local anesthesia only	83.0% (78/94)	71.4% (20/28)
Incision length (mm)	6 ± 2†	22 ± 7
Suture-free closure	80.9% (76/94)†	0% (0/28)

*Values are mean ± SD or percent (n/N).
†Statistically significant difference between groups ($P < 0.001$).

(−3.9 versus −3.8; both $P < 0.001$ compared with baseline) and comparable between groups ($P = 0.74$; Fig. 3), with mean values at 1 year less than 1 in both groups. Health-related quality of life improved considerably over 1 year in each group (0.13 versus 0.12; both $P < 0.001$ compared with baseline), with no group differences ($P = 0.79$; Fig. 4), and mean EQ-5D-5L values of more than 0.88 in both groups at 1 year. The mean improvement in BCTQ-SSS, BCTQ-FSS, numeric pain scale, and EQ-5D-5L scores exceeded the minimal clinically important difference in both groups over 1 year. Patient-reported satisfaction with both procedures at 1 year was high (95.0% CTR-US versus 92.6% mOCTR; $P = 0.64$). Scar appearance (92.5% versus 85.2%; $P = 0.27$), scar satisfaction (100% versus 92.6%; $P = 0.06$) and freedom from sensitivity/pain (95.0% versus 74.1%; $P = 0.005$) at 1 year favored CTR-US (Fig. 5).

There was no difference in the risk of complications with CTR-US and mOCTR (2.1% versus 3.6%; $P = 0.55$). Three complications were reported during the trial, all occurring during the first 3 postoperative weeks and previously described.[13] They included a partial third common

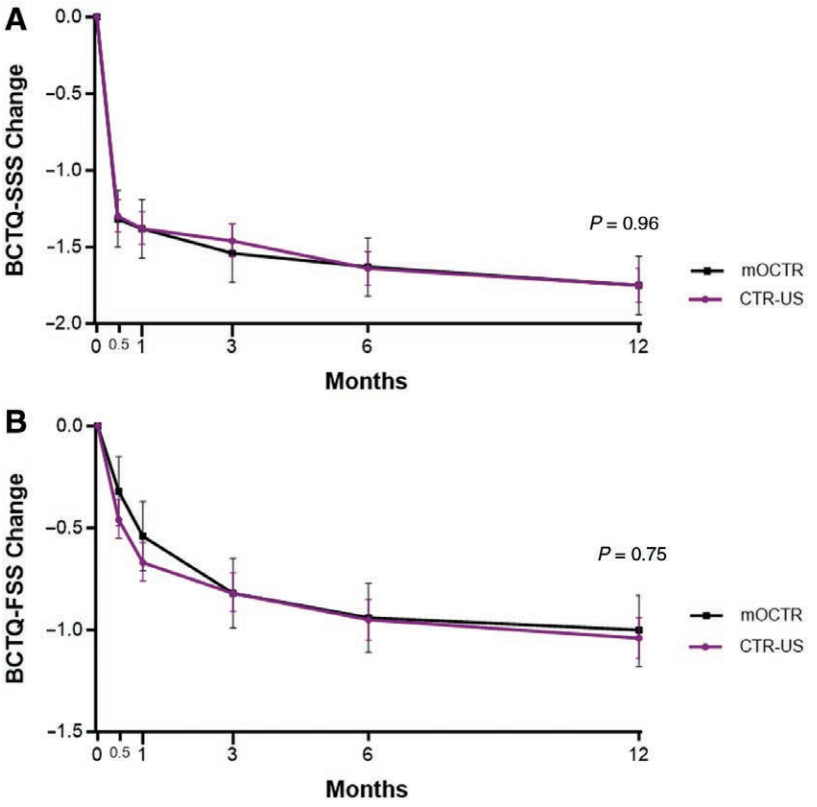

Fig. 2. BCTQ-SSS and BCTQ-FSS changes over 1 year with CTR-US and mOCTR. Plotted values are baseline-adjusted least squares mean change and 95% confidence interval. Over 1-year follow-up, the mean change for BCTQ-SSS (A) was −1.8 for CTR-US and −1.8 for mOCTR. The mean change for BCTQ-FSS (B) was −1.0 for CTR-US and −1.0 for mOCTR. All changes were statistically significant ($P < 0.001$) compared with baseline, and there was no statistical difference between groups for BCTQ-SSS ($P = 0.96$) or BCTQ-FSS ($P = 0.75$).

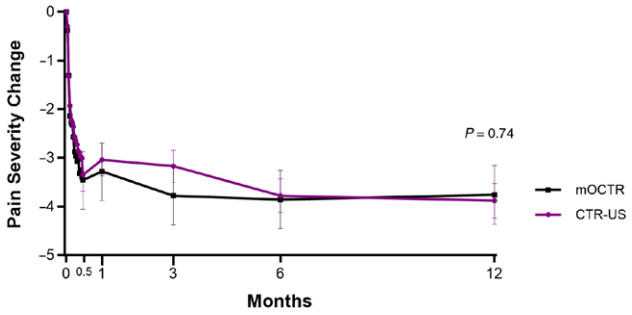

Fig. 3. Numeric pain scale scores over 1 year after CTR-US and mOCTR. Plotted values are baseline-adjusted least squares mean change and 95% confidence interval. At 1 year, the mean change was −3.9 for CTR-US and −3.8 for mOCTR, both statistically significant ($P < 0.001$) compared with baseline. There was no statistical difference between groups ($P = 0.74$).

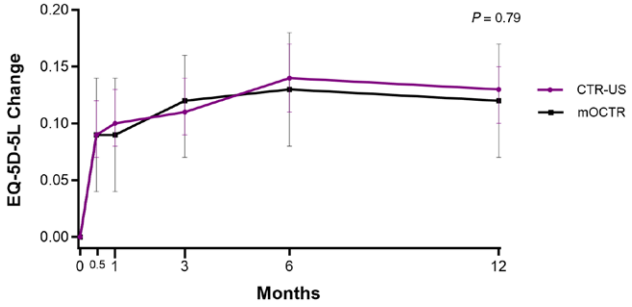

Fig. 4. EQ-5D-5L scores over 1 year after CTR-US and mOCTR. Plotted values are baseline-adjusted least squares mean change and 95% confidence interval. At 1 year, the mean change was 0.13 for CTR-US and 0.12 for mOCTR, both statistically significant ($P < 0.001$) compared with baseline. There was no statistical difference between groups ($P = 0.79$).

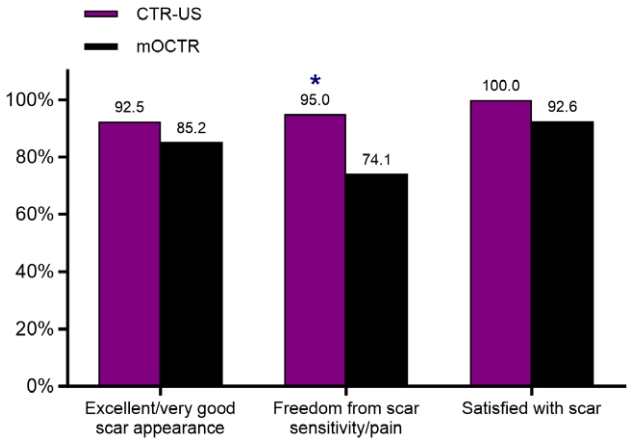

Fig. 5. Patient-reported scar assessment 1 year after CTR-US and mOCTR. Plotted values are the percentage of patients reporting outcomes. *$P = 0.005$ for group difference.

palmar digital nerve injury treated with a nerve wrap during reexploration in the CTR-US group, neurapraxia after CTR-US treated with a corticosteroid injection, and wound dehiscence after mOCTR requiring additional sutures. All three patients who experienced these early complications reported satisfaction with their procedure at the 1-year follow-up. There were no revisions for persistent or recurrent symptoms during the 1-year follow-up in either group.

DISCUSSION

The 1-year outcomes from the multicenter randomized TUTOR trial demonstrate that CTR-US and mOCTR each relieve CTS symptoms that are durably maintained. Although self-reported satisfaction with the procedure was high (>90%) in both groups, patients treated with CTR-US reported less discomfort related to their surgical scar. Overall, CTR-US and mOCTR are safe procedures that provide comparable relief from CTS symptoms over long-term follow-up.

The 1-year results with CTR-US in this trial corroborate the long-term results reported in single-arm CTR-US studies[8–11] that reported sustained and clinically important improvements in CTS symptoms with a low rate of complications (Table 2). In this trial, more than one in four patients assigned to mOCTR withdrew before treatment because they did not desire mOCTR despite initially consenting to randomization. This highlights an important consideration regarding patient preferences and values that should be assessed when determining the surgical technique. Prior studies have identified areas of concern that influence patient decision-making, including surgical risks, cost, surgical options, and postoperative pain.[20] Although previous sensitivity analyses confirmed that these patient withdrawals did not alter the trial conclusions,[13] they highlight a broader need for shared decision-making that incorporates patient values and preferences when determining the optimal approach for CTR.

Scars in the hand can negatively impact patient function, underscoring the need to report the scar outcomes most important to patients.[21] The location and smaller size of the incision used for CTR-US may explain its advantages over mOCTR for scar-related endpoints. Most (61.1%) CTR-US patients were free from scar discomfort by 3 months, yet only 17.9% treated with mOCTR achieved this milestone. At 1 year, 95.0% of CTR-US patients reported no scar symptoms compared with 74.1% of mOCTR patients. This suggests that a longer palmar incision may be more prone to symptomatic scarring than the smaller wrist incision used in CTR-US. This finding is supported by a meta-analysis where the primary risk factor for postoperative complications after mOCTR (mainly scar discomfort) was a longer incision length.[6] Given their anatomic location, palmar incisions may be more susceptible to irritation from repetitive manual activity than incisions proximal to the wrist crease. One theorized reason for scar discomfort after mOCTR is incisional trauma to small cutaneous nerves, resulting in injury or entrapment of regenerating nerve endings within the fibrous scar tissue.[22] Over time, scar sensitivity typically decreases, although resolution of discomfort may take 9 or more months.[22] The wrist incision used for CTR-US may result in fewer symptoms due to its different location, shorter length, cutaneous nerve anatomy, and

Table 2. Studies Reporting Long-term Results of CTR-US*

Study	Patients	Hands	Follow-up (y)	BCTQ-SSS	BCTQ-FSS	Q-DASH	Complications
TUTOR	**94**	**94**	**1.0**	**−1.7**	**-1.0**	**—**	**2.1%**
Aguila[10]	300	341	1.0	−1.5	−1.0	−28	1.4%
Bergum[9]	88	123	1.0	−1.7	−1.2	−32	0.8%
Leiby[8]	47	76	1.0	−2.1	−1.7	−45	0%
Kamel[11]	46	61	1.7	−2.0	−1.4	−43	3.3%

*Long-term defined as mean follow-up duration of 1 year or longer.
Q-DASH, Quick Disabilities of the Arm, Shoulder and Hand.

reduced mobility requirements compared with a longer palmar incision. Overall, these findings demonstrate that surgical approach, location of incision, and scar length significantly influence patient-reported scar discomfort after CTR, and should be carefully considered when determining the appropriate surgical technique for this procedure.

The investigators in this trial were substantially more experienced with mOCTR than CTR-US. This experience gap may have resulted in outcomes that favored mOCTR. Thus, the comparable CTR-US results, achieved with less experience, are notable and suggest proficiency with ultrasound may be attained quickly. All investigators completed a cadaver-based training program and at least 10 CTR-US procedures (median 12) before treating patients in this trial. This learning curve with CTR-US is consistent with previous studies demonstrating proficiency by providers with a wide range of prior experience in ultrasound and CTR.[10,23] While the substantial difference in surgeon experience precluded statistically analyzing its impact on trial results, comparing CTR-US and mOCTR outcomes among similarly experienced surgeons would be informative.

This study has several limitations. First, it was not feasible to blind patients or investigators to treatment allocation. Consequently, performance and expectation bias may have influenced the trial outcomes. Second, patient preferences were not collected in the trial. In future studies, it would be helpful to determine if specific patient subgroups are more likely to choose one CTR technique over another, since understanding the drivers of patient preference is critical for optimizing shared decision-making. Third, the investigators in this study had substantial experience performing mOCTR but comparably less experience with CTR-US. Thus, the trial results may have been influenced by surgeon experience. Fourth, a disproportionate number of patients randomized to mOCTR withdrew before treatment. The potential impact of this limitation was previously explored in an as-randomized sensitivity analysis confirming this did not influence the trial conclusions.[13] Finally, the comparative performance of CTR-US reported here is specific to mOCTR only. Comparisons between CTR-US and other techniques such as endoscopic CTR warrant additional investigation.

CONCLUSIONS

In this multicenter randomized trial, CTR-US and mOCTR demonstrated similar improvement in CTS symptoms and quality of life with comparable low complication rates over 1 year of follow-up. Compared with mOCTR, CTR-US was performed with a smaller incision and associated with less scar discomfort. Given the comparable efficacy and safety between these CTR techniques, the decision about technique should be made jointly between patient and surgeon after discussing individual factors such as preferences, activity level, and scar concerns.

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DISCLOSURES

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