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A Prospective, Randomized Trial Comparing Open and Endoscopic Carpal Tunnel Release Within the Same Patient

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Abstract

Background: Surgical management of carpal tunnel syndrome includes performing an endoscopic (ECTR) or open (OCTR) carpal tunnel release. Several studies have shown less postoperative pain and improvement in grip and pinch strength with the endoscopic technique. The goal of this study was to prospectively examine outcomes, patient satisfaction, and complications after both ECTR and OCTR in the opposite hands of the same patient. **Methods:** This was a prospective study in which patients with bilateral carpal tunnel syndrome underwent surgical release with both techniques, with initial operative approach randomized in the more symptomatic hand. Demographic data and functional outcomes were recorded, including the pain score, 2-point discrimination, Semmes-Weinstein monofilament testing, thenar strength testing, grip strength, carpal tunnel syndrome functional status score, carpal tunnel syndrome symptom severity score, and overall satisfaction. **Results:** Thirty patients completed the study; there were no significant differences in any measure at any of the postoperative time points. Symptom severity and functional status scores were not significantly different between groups at any evaluation. Subjectively, 24 of 30 patients did state they preferred the ECTR, mostly citing less pain as their primary reason, although pain scores were not significantly different. Differences in overall satisfaction were also not significant. **Conclusions:** Both techniques are well tolerated with no differences in outcomes. With the added cost and equipment associated with ECTR, and no added benefit, the usefulness of ECTR is questionable.

Keywords: carpal tunnel, open, endoscopic, patient satisfaction, internal control

Introduction

Carpal tunnel syndrome is the most common peripheral nerve entrapment of the upper extremity, and median nerve decompression is the most common hand operation performed in the United States.[1] The diagnosis is clinical, but often electrophysiological testing with electromyography (EMG) and nerve conduction velocity is obtained to help confirm findings or assist patients in discussion of severity and prognosis. Initial management includes splinting, nonsteroidal anti-inflammatories, corticosteroid injections, and therapy.[2] For cases that fail conservative management, surgical release of the transverse carpal ligament is recommended.

The open approach utilizes an incision directly over the transverse carpal ligament, which has been proven to be safe and effective. Several modifications and specific instruments have been developed to help improve this procedure. Most notably, an endoscopic technique was developed as a minimally invasive approach. The initial endoscopic approach included a 2-portal technique,[3] but after several reported complications, the single portal technique developed by Agee et al[4,5] became popularized. Some randomized trials comparing the open and endoscopic techniques have suggested less postoperative pain, faster improvement in grip and pinch strength, as well as earlier return to work and preoperative levels of activities of daily living with the endoscopic technique.[6]

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Results from randomized controlled trials comparing the 2 approaches have been mixed. Some studies have suggested that despite no differences in symptom relief or return to work, the endoscopic technique was favored due to less scar tenderness and improved grip and pinch strength.[7] Another meta-analysis performed by Sanati et al showed that there is earlier return to work with the use of the endoscopic approach.[8] A separate study by Cowan et al showed that job type was the most important predictor of return to work for patients who underwent a release using a minimally invasive approach. Other factors included preoperative counseling and psychological factors such as anxiety in response to pain.[9]

The goal of this study was to examine postoperative quantitative outcomes, such as pain and functional status, in addition to patient satisfaction with the procedure technique. This would be done in a prospective manner in patients who have bilateral symptoms requiring surgical release so that both procedures can be performed on the same patient, serving as their own control.

Materials and Methods

This was a prospective, randomized study that included patients diagnosed with bilateral carpal tunnel syndrome. The study was approved by the institutional review board. Inclusion criteria were patients aged 18 to 75 years from the senior author's practice with clinical and electrodiagnostic testing confirmation of bilateral carpal tunnel syndrome. Patients also met criteria for surgical release by failing nonsurgical management for each side. The exclusion criteria omitted patients who were pregnant or diagnosed with peripheral neuropathy, inflammatory arthropathy, or recurrent carpal tunnel.

The original power study calculated at 90% power and 5% significance level for 0.2 effect size would have required 59 patients for enrollment. During study recruitment, however, a change occurred in the senior author's practice pattern. Patients were more likely to choose having their procedure done wide awake in the clinic setting under local anesthesia, which precluded the use of endoscopic release. Therefore, after obtaining complete data for 30 patients within the study, recruitment was terminated. A power analysis looking at the symptom severity scale using an effect size of 0.5 and paired 1-sided *t* tests shows that 30 subjects provide 85% power at the .5 significance level.

Patients provided written informed consent. Demographic data were collected and included age, sex, hand dominance, duration of symptoms, occupation, previous treatments (splinting, corticosteroid injection), workman's compensation claim, and medical comorbidities. Surgical preoperative planning included pregnancy testing for women of child-bearing age, as well as an electrocardiogram or chest radiography if indicated. Carpal tunnel syndrome diagnosis was performed using clinical assessment of symptoms such as history, evaluation of distribution of numbness in the hand, Phalen's and Durkan's provocative testing, and EMG testing.

The primary outcome measures in this study were results from the carpal tunnel syndrome functional status score (CTS-FSS) and the carpal tunnel syndrome symptom severity score (CTS-SSS). These were recorded at the time of study enrollment preoperatively and during postoperative weeks 2, 4, 8, 12, and 24. The secondary outcome measures that were recorded included Visual Analog Pain Scale reports, 2-point discrimination of the thumb, Semmes-Weinstein monofilament testing of the thumb, abductor pollicis brevis (APB) thenar strength testing, and overall grip strength testing. Patients reported overall satisfaction with the procedure on a scale of 0% to 100% at the conclusion of the study with comments for technique preference. The data were normally distributed and paired sample *t* tests were performed on the study data between the 2 techniques. Operative and postoperative visit notes were reviewed for any evidence of complications or need for procedure conversion.

The patient selected the hand that was most symptomatic on which the first surgery occurred. The type of procedure technique that was performed was randomly assigned by a computer-generated schedule. The patients were informed of the procedure technique during the consent process prior to the day of surgery. The patient's contralateral procedure was performed with the opposite technique approximately 1 month later.

The surgeries were performed in an outpatient surgery center or hospital operating room. Both techniques included the use of infiltrated local anesthesia and intravenous sedation with benzodiazepines and propofol. A tourniquet was also utilized in both techniques. The open technique used an approximately 3-cm incision placed in line with the radial border of the ring finger, over the transverse carpal ligament in the proximal palm. Dissection was taken through the palmar fascia to the transverse carpal ligament which was divided under direct visualization. The endoscopic technique originally described by Agee et al was performed.[4] This technique utilizes a 1.5- to 2-cm transverse incision in the distal wrist crease between the flexor carpi radialis and flexi carpi ulnaris tendons. After the skin incision, the forearm fascia is exposed and a distally based, U-shaped flap is created, entering a course following the ring finger ray. A probe is inserted that scrapes any adhesions off the deep surface of the carpal tunnel, creates a passageway for the endoscope, and determines the distal extent of the ligament.

A video camera and fiberoptic light source are coupled with the endoscope and this is inserted into the window. Clear visualization of the transverse carpal ligament without interference of tendons, the median nerve, or the superficial palmar arch is required prior to release. The trigger

elevates the blade and the ligament is released in a distal-to-proximal direction using upward pressure with the device and downward pressure from fingers externally on the palm.[4-6] The cut edges of the ligament and an intact median nerve can be visualized before removal of the device. The proximal forearm fascia is cleared bluntly on its superficial and deep surface and this too is released several centimeters into the forearm with the use of scissors. The incision is then closed and a dressing is applied.

In both techniques, the antebrachial fascia was released several centimeters proximal to the incision. Postoperative protocols were the same for both techniques with removal of dressings in 3 to 5 days and immediate initiation of hand range of motion exercises.

Results

A total of 30 patients completed the study. There were 25 women (83%) and 5 men (17%). The average age of all patients was 54 years. Most patients reported a low-demand office or clerical-type job, while 7 patients (23%) were reported to be either retired or disabled. Twenty-six patients (86%) were right hand dominant, and 13 endoscopic releases (43%) were performed on a patient's right hand, while 17 (57%) were performed on a patient's left hand (Supplemental Table S1). There were no instances in which the endoscopic technique was converted to the open procedure.

The primary outcomes included the CTS-FSS and CTS-SSS. For the endoscopic technique, the CTS-SSS had a preoperative value of 2.74, and at the 24-week visit, the average score was 1.28. For the open technique, the preoperative average was 2.63 and at the 24-week visit, 1.23. There were no significant differences seen between matched endoscopic and open CTS-SSS values at any time point (Table 1). Further analysis was performed and differences were calculated between each postoperative and preoperative CTS-SSS value. There was improvement seen in scores compared with preoperative values in both the endoscopic and open techniques, but when these 2 cohorts were compared, there was no significant difference seen in the amount of improvement achieved at each time point (Supplemental Table S2).

For the CTS-FSS, the average preoperative values for the endoscopic and open techniques were 2.32 and 2.24, respectively. The endoscopic group showed an improvement in the score, with an average of 1.18 at 24 weeks, and the open group also showed an improvement, with an average score of 1.16. These were not found to be significantly different (Table 1). Differences between scores at postoperative visits and the preoperative value were also not significantly different between the 2 groups (Supplemental Table S3).

Using the Visual Analog Pain Scale, patients reported an average pain scale rating of 1.73 for the limb that underwent endoscopic release and 1.52 for the limb that underwent open release. At 24 weeks, there was an improvement in pain in both groups, with values of 0.35 and 0.30, respectively (Table 1). In addition, over half of the patients reported no pain by the 8-week visit for both procedure types.

Table 1. Average CTS-SSS, CTS-FSS, and VAS.

	Preoperative	2 wk	4 wk	8 wk	12 wk	24 wk
SSS-O	2.63	1.91	1.58	1.50	1.39	1.23
SSS-E	2.74	1.73	1.59	1.35	1.31	1.28
P value	.53	.11	.48	.11	.29	.71
FSS-O	2.24	1.95	1.48	1.32	1.28	1.16
FSS-E	2.32	1.77	1.40	1.22	1.21	1.18
P value	.69	.11	.25	.15	.26	.80
VAS-O	1.52	1.79	1.46	0.85	0.65	0.30
VAS-E	1.73	1.70	1.05	0.77	0.45	0.35
P value	.74	.44	.20	.44	.28	.42

Note. CTS = carpal tunnel syndrome; SSS = syndrome symptom severity score; FSS = functional status score; VAS = Visual Analog Pain Score; O = open; E = endoscopic.

Table 2. Average Values of 2PD and SW Monofilament Testing.

	Preoperative	2 wk	4 wk	8 wk	12 wk	24 wk
2PD-O	6.63	6.28	5.96	5.11	4.85	4.69
2PD-E	6.77	6.00	5.28	5.00	5.07	5.04
P value	.85	.35	.14	.38	.30	.21
SW-O	3.80	3.53	3.39	3.39	3.24	3.17
SW-E	3.67	3.59	3.28	3.18	3.11	3.12
P value	.33	.33	.22	.11	.19	.37

Note. 2PD = 2-point discrimination; SW = Semmes-Weinstein; O = open; E = endoscopic.

Two-point discrimination values for the thumb were recorded bilaterally. Both groups had preoperative values that were above 6.5. The endoscopic group improved to an average of 5.04 and the open group improved to an average of 4.69, but this too was not significant (Table 2). Preoperative Semmes-Weinstein monofilament testing was performed on all fingers, but the thumb value was compared between groups for statistical analysis. Both groups had improvement in sensibility, but the postoperative values were not significantly different compared with the preoperative values (Table 2).

The APB strength testing showed an average of 4.48 in the endoscopic group and 4.52 in the open group preoperatively. There was improvement in strength without significance, with both groups having an average final value of 4.9 (Table 3). Recordings of grip strength using a dynamometer did not show any significant differences either. Strength values were shown to decrease in the early postoperative

Table 3. Averages Values of APB Strength and GS.

	Preoperative	2 wk	4 wk	8 wk	12 wk	24 wk
APB-O	4.52	4.07	4.57	4.74	4.85	4.90
APB-E	4.48	4.23	4.61	4.78	4.89	4.90
P value	.83	.15	.41	.36	.32	.48
GS-O	17.93	10.14	14.07	15.70	15.70	17.69
GS-E	16.53	11.93	14.57	16.17	16.76	17.58
P value	.61	.20	.41	.42	.32	.48

Note. APB = abductor pollicis brevis; GS = grip strength; O = open; E = endoscopic.

Table 4. Patient Satisfaction.

	Score (maximum 100)
O-Avg	90.33
E-Avg	94.93
P value	.10

Note. O = open; E = endoscopic.

period, but then approached preoperative grip in the open cohort or exceeded preoperative grip in the endoscopic group (Table 3).

Finally, overall satisfaction with the procedure, on a scale of 0 to 100, was reported by the patients at the study conclusion. During the previously reported interim analysis, there was an initial significant difference in satisfaction scores between the 2 groups. After the enrollment of more patients into the study, however, no significant difference remained. The endoscopic group had an average satisfaction score of 94.9 and the open group, 90.3 ($P = .1$; Table 4). Seventeen patients reported equal satisfaction scores for both procedures. Despite this, 24 patients (80%) still subjectively listed that they preferred the endoscopic technique; 5 (17%) patients preferred the open technique and 1 patient (3%) had no preference. The most common reason for citing the endoscopic technique as the preferred technique was "less pain." Objectively, however, pain scores, as reported earlier, did not show a significant difference. Other reasons included the following: "healed faster," "less scar," "less numbness," and "able to use faster." For those preferring the open procedure, they too cited "less pain," "able to work sooner," and "healed quicker." There were no intraoperative or postoperative complications reported for either group.

Discussion

A previously reported interim analysis of our study showed no differences in objective outcomes; however, there was a significant difference in patients' preferences toward the endoscopic approach with higher satisfaction scores.[10] After enrollment of additional patients, final study results showed the same conclusion in terms of objective outcomes. For patient satisfaction, however, comparison of final satisfaction scores did not show a significant difference between the endoscopic and open techniques.

A recent meta-analysis of good-quality randomized controlled clinical trials comparing the 2 techniques has found similar results. The study by Sayegh and Strauch concluded that symptom relief, severity, functional status, and pillar pain values were similar for both techniques, and patients underwent just one procedure type. They found that patients who underwent endoscopic release had earlier return of grip and pinch strength as well as return to work and less scar tenderness, but the early differences were lost with longer follow-up. However, the return to work data lacked reliability as each study had a different recording method and often patients returned when cleared by their physician regardless of the procedure type. Of note, the study also found a 3-fold increase in reversible neuropraxia with the endoscopic release.[2] Our trial minimized bias by having a single surgeon who was already experienced in the endoscopic technique (RMH) perform all procedures. This reduced the opportunity for adverse events, incomplete release, or failure of symptom relief. Having the patient serve as an internal control also improved the strength of our study. This reduced the bias of reporting the more subjective outcomes measured, such as satisfaction and procedure preference, as both decompression techniques were performed on opposite hands of the same patient. The first procedure, although performed on the patient's most symptomatic hand, was also randomly assigned. Due to this study design, we were unable to include return to work data because patients underwent their second operation within a month following their first. Most patients also reported that they were housewives or retired from their jobs.

In 2016, Hu et al published a meta-analysis of randomized clinical trials that included patients with bilateral carpal tunnel syndrome who underwent both procedures. Our previously reported interim analysis was one of 5 studies included in this analysis, with our study being the first from the United States, and our current updated data include more patients than 2 other reported studies. The pooled study data indicated that there was no significant difference seen in complications, pain scores, static 2-point discrimination, or hand grip strength.[11] Only 2 studies reported symptom severity and functional status scores, our analysis and the one performed by Kang et al.[12] With the addition of current data, symptom severity scores were not different, but there was a significant difference seen in CTS-FSS improvement from preoperative values with the endoscopic technique.

During the study collection period, a change occurred in the senior author's practice pattern. Wide-awake surgery with the use of local anesthesia as pioneered by Lalonde has allowed many hand procedures to be moved into the clinic setting, precluding the need for a tourniquet or other anesthetics.[13] Several procedures including carpal tunnel release, A1 pulley release, flexor tendon repair, and even some fractures have been shown to be safe and effectively performed with this anesthetic technique.[13-18] As a result, the senior author's clinical practice included discussing and offering patients the ability to have their surgical release performed open under local anesthesia. More patients ultimately began to choose the local anesthetic option. This limited recruitment into our study, so enrollment was terminated when data for 30 patients were collected despite the lower power.

This study did not find a benefit to the use of one technique over the other when endoscopic and open procedures were compared for patients with carpal tunnel syndrome requiring surgical release. Both techniques are well tolerated with no significant differences in measurable objective outcomes, notably pain scores, 2-point discrimination, Semmes-Weinstein monofilament testing, thenar and grip strength, and CTS-SS and CTS-FS scores. There was also no significant difference found in the comparison of patient satisfaction scores at the conclusion of the study even though most patients still cited that they preferred the endoscopic technique. The ability to perform open carpal tunnel releases wide awake in the clinic setting has led the senior author to revert to the open carpal tunnel release as the preferred technique in most patients.

Ethical Approval

This study was approved by our institutional review board.

Statement of Human and Animal Rights

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

Statement of Informed Consent

Informed consent was obtained from all individual participants included in the study.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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