Prospective randomized comparison of single-incision and two-incision carpal tunnel release outcomes

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Abstract

Background This study analyzes both the subjective and objective symptom and functional outcomes of patients who underwent either traditional single-incision or two-incision carpal tunnel release (CTR).

Methods From 2008 to 2009, patients with isolated carpal tunnel syndrome were randomized to undergo either single-incision or two-incision CTR by a single surgeon at a university medical center. Pre-operatively, participants completed a Disabilities of the Arm, Shoulder, and Hand (DASH) Questionnaire, Bringham and Women's Carpal Tunnel Questionnaire (BWCTQ), as well as grip and pinch strength and Semmes–Weinstein monofilament sensation testing. At 2 weeks, 6 weeks and at least 6 months post-operatively, these measurements were repeated along with assessment of scar tenderness and pillar pain. Data were analyzed using SPSS version 20 software to perform non-parametric tests and Pearson's correlations. Significance was set at $p=0.05$.

Results There was no statistically significant difference between the single- and two-incision CTR groups with respect to pre- and post-operative DASH scores, BWCTQ scores, grip strength, pinch strength, scar tenderness, or pillar pain. The only statistically significant difference was improved sensation by Semmes–Weinstein in the single-incision group in the second finger at 6 weeks post-operatively and in the third finger at 6 months post-operatively.

Conclusions The preservation of the superficial nerves and subcutaneous tissue between the thenar and hypothenar

eminences may account for reports of less scar tenderness and pillar pain among recipients of two-incision CTR compared to single-incision CTR in the early post-operative period. However, there is similar post-operative recovery and improvement in grip and pinch strength and sensation after 6+ months post-operatively.

Keywords Carpal tunnel syndrome · Carpal tunnel release · DASH Questionnaire · Bringham and Women's Carpal Tunnel Questionnaire · Two-incision carpal tunnel release · Minimally-invasive carpal tunnel release

Introduction

The surgical treatment of carpal tunnel syndrome (CTS) with carpal tunnel release (CTR) remains one of the most common surgical procedures performed in the United States. While the current American Academy of Orthopaedic Surgery (AAOS) clinical practice guideline summary recommends "complete division of the flexor retinaculum" for the surgical treatment of CTS, it does not recommend a specific CTR technique. This is likely due to the lack of level 1 evidence demonstrating that one technique is superior to another [8].

There are essentially four unique CTR techniques that utilize different approaches and instrumentation for transecting the transverse carpal ligament (TCL). The oldest and most widely studied is the traditional single-incision technique, which utilizes a 2–4-cm single longitudinal incision between the thenar and hypothenar creases at the base of the palm extending from Kaplan's cardinal line to the distal wrist flexion crease [9, 12]. There is also a "limited single-incision" technique which utilizes the same approach and landmarks, but with smaller (1.5–2 cm) single incisions [7, 13]. "Two-incision," [4, 5] or "twin-incision" [2], has also been used to describe a technique that utilizes two small approximately 1-cm incisions — one transverse incision at the distal wrist crease and one longitudinal incision at the

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distal site of the TCL — and direct visualization to incise the TCL. Lastly, there are single and two-portal endoscopic CTR techniques that rely on the use of an endoscope [1, 11].

As reviewed in our previous single- versus two-incision CTR study, a number of researchers have shown the efficacy of each of these techniques; however, few have compared and investigated the outcome differences between any two techniques in a prospective randomized fashion [3]. Since CTR is already such a successful operation, demonstrating clinically significant improvements in new CTR techniques is a challenge. Nonetheless, it remains an important task in order to adequately inform patients about the potential risks and benefits of different CTR techniques. Given the senior author's experience with the single-incision and two-incision techniques, our focus is on comparing these two techniques. Our clinical experience of two-incision patients seemingly experiencing quicker post-operative recovery and less long-term pillar pain and scar sensitivity prompted our initial comparison of these two techniques. Our previous retrospective study utilized the AAOS-recommended instruments for assessing CTR outcomes in research — the Brigham and Women's Carpal Tunnel Questionnaire (BWCTQ) and the Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire [6]—and found statistically significantly fewer post-operative symptoms and improved function among the two-incision patients compared to the single-incision CTR patients.

The purpose of this current study is to prospectively compare the qualitative and quantitative differences in post-operative outcomes of patients who underwent either traditional single-incision (single-incision) or two-incision CTR. Given that our previous retrospective study of CTR outcomes in these groups found improved outcomes in the two-incision group, our hypothesis is that this prospective study will also support this finding as well as provide quantitative hand function data to explain any qualitative patient-reported differences in post-operative symptoms and function.

Materials and Methods

Eligibility and Randomization

IRB approval was obtained prior to performing this prospective study. Beginning in late 2008, consecutive patients of a single surgeon at an academic medical center were assessed for eligibility and invited to participate in the study. Inclusion criteria were the presence of electrodiagnostically confirmed isolated CTS, willingness to proceed with CTR, and ability to complete post-operative follow-up. Patients with a history of hand trauma or confounding co-morbidities (e.g., conversion disorder, CRPS, hypothyroidism, pregnancy, diabetes) were excluded. All participants who met these criteria and agreed to participate gave informed consent and were given a unique

identifier for use on study questionnaires and documentation. All returned consents and documentation was stored in a secured location as it was collected until the final data analysis. Participants were randomized to receive either single- or two-incision CTR using a coin toss randomization strategy to ensure equal distribution between the two groups. Only one patient was not randomized in this fashion, since she had previously undergone CTR on the contralateral hand and desired the same surgical procedure on her affected hand.

Subjective Assessment of Pre- and Post-operative Symptoms and Function

A single trained research assistant performed all of the pre- and post-operative assessments of participant symptoms and function independent of the surgeon's evaluation. A Disabilities of the Arm, Shoulder, and Hand (DASH) Questionnaire [6], a BWCTQ [10] were completed immediately prior to CTR and then at 2 weeks, 6 weeks and at least 6 months post-operatively. Post-operative scar tenderness was assessed at these time points by patient self-report using a 5-point Likert scale (none, mild, moderate, severe, very severe). Post-operative pillar pain was also assessed at these time points by the researcher applying pressure on the radial pillar and then the ulnar pillar with the patient rating the pain at each of these sites using a 0 to 10 scale (0=no pain, 10=excruciating pain).

Objective Assessment of Pre- and Post-operative Symptoms and Function

Concurrently with the pre-operative administration of the DASH and BWCTQ, pre-operative grip strength was measured using a hydraulic hand dynamometer (North Coast Medical Precision Instruments, Morgan Hill, CA, USA) with the participant instructed to hold their arm adducted, elbow flexed at 90 degrees and wrist in neutral while applying maximal force in gripping the dynamometer. Pre-operative pinch strength was measured using a pinch gauge (North Coast Medical Precision Instruments) with the participant instructed to apply maximal force in pinching the gauge between their index finger and thumb. Pre-operative sensation was assessed using a five-piece (sizes 2.83, 3.61, 4.31, 4.56, 6.65) Semmes–Weinstein Monofilament (SWM) kit (Touch–Test Sensory Evaluator; North Coast Medical, Inc.) according to the manufacturer's protocol. These measurements were then repeated at 2 weeks, 6 weeks and at least 6 months post-operatively.

Surgical Techniques

A single orthopaedic hand surgeon performed all of the single- and two-incision CTR procedures. The two-incision CTR technique used in this study utilizes a 1-cm transverse incision in the distal wrist flexion crease, just ulnar to the palmaris

longus tendon, to protect the palmar cutaneous nerve. A small incision is then made into the antebrachial fascia overlying the median nerve. A BD Beaver™ Arthro-Lok™ blade (Catalog # 379081; Becton, Dickinson and Company, Franklin Lakes, NJ, USA) is then used under direct vision with loupe magnification and with the assistance of a head lamp to incise 80 % of the TCL in an antegrade fashion. A 1-cm longitudinal incision is then made at Kaplan's cardinal line along the radial aspect of the fourth digit. The subcutaneous tissues are dissected down to the palmar fascia and the superficial palmar arch is identified and protected. The Beaver blade is then used to transect the remaining 20 % of the TCL in a retrograde fashion. Complete release of the TCL is confirmed when the limbs of the ligament are parallel with a clear gap between them. The tissues superficial to the TCL are left intact.

The single-incision CTR technique used in this study utilizes a 2-cm longitudinal incision limited proximally by the distal wrist flexion crease and distally by Kaplan's cardinal line along the radial aspect of the fourth ray [2]. The subcutaneous tissues are dissected down to the level of the palmar

fascia, which is then incised sharply to allow visualization of the TCL, which is then incised under direct vision.

Statistical Analysis

Power analysis was performed and an N of 28 has power of 80.7 % to detect an effect size of ~15 % with respect to mean BWCTQ function or symptom scores and ~10 % with respect to mean DASH scores. Data from the completed questionnaires and strength and sensation measurements were analyzed using SPSS software version 20 (IBM Corporation, Armonk, NY, USA) to perform non-parametric tests and Pearson's correlation. Significance was set at $p=0.05$.

Results

A total of 34 hands were assessed for eligibility and 30 (88 %) met criteria for inclusion in the study and agreed to randomization (Fig. 1). The four patients excluded from

Fig. 1 Consolidated Standards of Reporting Trials (CONSORT) diagram of participants. *N* refers to the number of hands

Table 1 Study participants included in analysis

	Open	Two-incision	Total
Number of participants	13	11	24
Men	4	3	7
Women	9	8	17
Number of hands	16	13	29
Men	4	4	8
Women	12	9	21
Mean age (years) [†]	62.94 (17.17)	62.00 (14.14)	62.52 (15.61)
Men	73.50 (9.26)	66.75 (13.20)	70.12 (11.15)
Women	59.42 (18.01)	59.62 (14.77)	59.62 (16.30)
Mean 6+-month follow-up [‡] (months)	12.00 (2.94)	11.70 (3.09) ^a	11.88 (2.94)
Hand dominance			
Right	13	12	25
Left	3	1	4
Affected hand			
Right only	5	11	16
Left only	8	0	8
Both	3	2	5

Number of participants, hands, mean (SD) age and duration of 6+-month follow-up, hand dominance, and affected hand(s) by surgery technique (open vs. two-incision CTR)

^a Three participants in this group were lost to follow-up at 6+ months

[†] $p=0.95$

[‡] $p=0.99$

randomization cited refusal to commit to completion of the necessary study follow-up. Only one patient was excluded from the final statistical analysis, since she did not complete any post-operative follow-up. Seven patients included in the analysis missed one of the follow-up visits.

There were no statistically significant differences between the two groups with respect to mean age or duration of follow-up (Table 1). There was also no statistically significant electrodiagnostic difference between groups. The two-incision group mean motor latency (6.91 ± 2.60 [mean $\pm$ SD]) and sensory latency (9.74 ± 7.32) was slightly longer than

the single-incision group mean motor (5.81 ± 2.09) and sensory (8.48 ± 6.37) latencies ($p=0.28$ and $p=0.67$, respectively).

There was no statistically significant difference between the single-incision and two-incision CTR groups with respect to pre- and post-operative BWCTQ Symptom Severity Scale (SSS) and Functional Status Scale (FSS) or DASH scores (Table 2). At 6+ months post-operatively, the mean SSS scores were identical (1.33, SD 0.36 and 0.53) and the mean FSS scores were similar (1.57 ± 0.88 and 1.60 ± 0.87) between the single-incision and two-incision CTR groups, respectively.

Table 2 Mean (SD) pre- and post-operative scores from the Brigham and Women's Carpal Tunnel Questionnaire (BWCTQ) Symptom Severity Scale (SSS), BWCTQ Functional Status Scale (FSS), and the Disabilities of the Arm Shoulder and Hand (DASH) Questionnaire

	Open	Two-incision	<i>p</i> values
BWCTQ SSS			
Pre-operatively	2.84 (0.77)	2.91 (0.59)	0.58
2 weeks post-operatively	1.70 (0.44)	1.80 (0.71)	0.85
6 weeks post-operatively	2.27 (1.58)	1.89 (0.77)	0.61
6+ months post-operatively	1.33 (0.36)	1.33 (0.53)	0.09
BWCTQ FSS			
Pre-operatively	2.39 (0.97)	2.54 (0.75)	0.72
2 weeks post-operatively	2.57 (1.23)	2.50 (1.12)	0.61
6 weeks post-operatively	2.08 (0.79)	2.10 (1.06)	0.69
6+ months post-operatively	1.57 (0.88)	1.60 (0.87)	0.35
DASH			
Pre-operatively	41.96 (24.10)	35.80 (14.23)	0.61
2 weeks post-operatively	38.04 (21.61)	39.51 (19.87)	0.77
6 weeks post-operatively	26.68 (18.83)	30.48 (25.49)	0.83
6+ months post-operatively	13.22 (20.63)	13.50 (22.46)	0.11

Table 3 Mean post-operative scar tenderness and pillar pain scores

	Open	Two-incision	<i>p</i> values
Scar tenderness			
2 weeks post-operatively	0.93 (1.1)	0.31 (0.86)	0.10
6 weeks post-operatively	0.42 (0.90)	0.45 (0.93)	0.92
6+ months post-operatively	0.13 (0.50)	0.0	0.33
Radial pillar pain			
2 weeks post-operatively	0.93 (1.79)	0.46 (0.78)	0.84
6 weeks post-operatively	0.25 (0.87)	1.18 (2.44)	0.35
6+ months post-operatively	0.56 (1.55)	0.0	0.65
Ulnar pillar pain			
2 weeks post-operatively	0.33 (0.90)	0.38 (0.96)	0.84
6 weeks post-operatively	0.83 (1.40)	0.36 (0.67)	0.55
6+ months post-operatively	0.94 (2.05)	0.0	0.49

Mean (SD) post-operative scores from scar tenderness scale (0=none, 1=mild, 2=moderate, 3=severe, 4=very severe) and pillar pain scales (0=no pain, 10=excruciating pain)

There was a consistent trend toward less post-operative scar tenderness and less post-operative pillar pain among the two-incision group, but this did not reach statistical significance (Table 3). Of note, at 6+ months post-operatively, the two-incision group reported no scar tenderness and no pillar pain.

The pre- and post-operative strength and sensation measurements are summarized in Table 4. There was no

statistically significant difference in mean pre-operative and post-operative grip strength measurements between groups; however, there was a greater absolute and relative increase in grip strength among the single-incision group compared to the two-incision group. In contrast, pinch strength was more improved in the two-incision group at 6+ months post-operatively. While both groups had improved post-operative sensation, Semmes–Weinstein scores were significantly

Table 4 Mean pre- and post-operative grip and pinch strength and change in Semmes–Weinstein monofilament scores

	Open	Two-incision	<i>p</i> values
Grip strength (lb), % of pre-operative strength			
Pre-operatively	36.16 (21.20)	44.53 (23.13)	0.45
2 weeks post-operatively	21.00 (19.45), 109 %	15.62 (14.83), 35 %	0.41
6 weeks post-operatively	37.46 (21.84), 132 %	26.18 (13.12), 72 %	0.28
6+ months post-operatively	42.81 (22.15), 137 %	43.60 (14.15), 118 %	1.00
Pinch strength (lb), % of pre-operative strength			
Pre-operatively	12.00 (5.83)	17.85 (12.68)	0.34
2 weeks post-operatively	9.60 (5.30), 81 %	15.23 (12.53), 92 %	0.31
6 weeks post-operatively	12.08 (5.23), 114 %	13.64 (4.27), 92 %	0.55
6+ months post-operatively	12.25 (6.04), 102 %	16.60 (3.27), 128 %	0.07
Change in Semmes–Weinstein monofilament scores			
2 weeks post-operatively			
Thumb	0.0 (0.38)	0.08 (0.76)	0.72
Second finger	−0.53 (0.74)	−0.31 (0.48)	0.54
Third finger	−0.53 (0.64)	−0.31 (0.75)	0.36
6 weeks post-operatively			
Thumb	−0.17 (0.83)	−0.18 (0.60)	0.75
Second finger	−0.67 (0.49)	−0.18 (0.40)	0.03
Third finger	−0.67 (0.49)	−0.36 (0.50)	0.22
6+ months post-op			
Thumb	−0.38 (0.72)	−0.20 (0.63)	0.53
Second finger	−0.56 (0.51)	−0.10 (0.32)	0.09
Third finger	−0.69 (0.60)	0.0 (0.50)	0.04

Mean (SD) pre- and post-operative grip and pinch strength and mean percentage of pre-operative strength and mean change in Semmes–Weinstein Monofilament score (−1 for every size filament decrease, +1 for every size filament increase)

improved among the single-incision group in the second finger at 6 weeks ($p=0.02$) and in the third finger at 6 weeks and 6 months post-operatively ($p=0.01$).

Lastly, although there was a statistically significant negative correlation between overall age and pre-operative grip strength ($R=-0.40$, $p=0.03$), there were no statistically significant correlations between age and pre- or post-operative DASH, FSS, SSS scores, post-operative scar tenderness, pillar pain, grip and pinch strength, or sensation measurements. However, there were statistically significant positive correlations between pre- and post-operative FSS and DASH scores in both groups (Table 5). Both the single-incision and two-incision CTR groups had statistically significant negative correlations between pre-operative and 2 weeks post-operative grip and pinch strength and DASH scores, with increased strength associated with lower DASH scores. Yet the majority of these correlations lost strength and statistical significance at the 6-week and 6+ month time points with the exception of grip and pinch strength and DASH scores in the single-incision group at 6+ months ($R=-0.80$, $p<0.0001$ and $R=-0.83$, $p<0.0001$, respectively).

Discussion

Our previous findings from a retrospective study revealed a statistically significant difference in improved BWCTQ and DASH scores among participants who underwent two-incision versus single-incision CTR [3]. Consequently, we were somewhat surprised not to find the same result in this study. In comparing the mean 6+ month BWCTQ and DASH scores to those from our previous study, the scores are lower in the single-incision group and higher in the two-incision group, which explains the attenuation of any statistically significant difference between groups. The reason for this difference is

unclear, since the study groups had comparable demographics, inclusion criteria, and treatment by the same surgeon. However, in reviewing the outliers in both groups, one two-incision participant who had both hands treated stands out as having substantially worse outcomes that could have been secondary to his development of bilateral ring finger trigger fingers during the course of post-operative follow-up. It is possible that his trigger finger symptoms influenced his responses and also negatively affected his grip and pinch strength scores. While exclusion of his outcomes results in two-incision group mean data that is comparable to that found in our retrospective study, the differences between groups still does not reach statistical significance. Furthermore, the difference between the results found during the prospective and retrospective arms of this study may represent a case of recall bias, and highlight a fundamental weakness of a retrospective study.

As expected, pre- and post-operative grip and pinch strength had an inverse correlation with DASH scores in both groups, with increased strength associated with lower DASH scores. Although all patients had improved post-operative strength, there was no statistically significant difference between groups. The fact that there was less improvement in Semmes–Weinstein scores in the two-incision group could indicate that the median nerve neuropathies were more severe in the two-incision group; a hypothesis which is also supported by the slightly worse pre-operative electrodiagnostics in this group.

It was interesting to find that none of the two-incision participants complained of scar tenderness or pillar pain at the last follow-up, whereas one single-incision group participant complained of moderate scar tenderness and three complained of pillar pain. This difference in scar tenderness is likely due to the fact that the two-incision CTR technique preserves the soft tissues and small subcutaneous nerve branches between the thenar and hypothenar eminences.

Table 5 Correlations between pre- and post-operative FSS scores, grip and pinch strength and DASH scores

	Pre-operatively	2 weeks post-operatively	6 weeks post-operatively	6+ months post-operatively
FSS and DASH				
Overall	0.77, $p<0.0001$	0.92, $p<0.0001$	0.87, $p<0.0001$	0.96, $p<0.0001$
Open	0.83, $p<0.001$	0.92, $p<0.0001$	0.85, $p<0.0001$	0.98, $p<0.0001$
Two-incision	0.71, $p=0.007$	0.91, $p<0.0001$	0.89, $p<0.0001$	0.92, $p<0.0001$
Grip strength and DASH				
Overall	-0.55, $p=0.001$	-0.59, $p=0.001$	-0.48, $p=0.023$	-0.64, $p<0.0001$
Open	-0.54, $p=0.03$	-0.51, $p=0.064$	-0.58, $p=0.048$	-0.80, $p<0.0001$
Two-incision	-0.59, $p=0.03$	-0.74, $p=0.004$	-0.45, $p=0.19$	-0.30, $p=0.40$
Pinch strength and DASH				
Overall	-0.60, $p=0.001$	-0.62, $p=0.001$	-0.31, $p=0.155$	-0.60, $p=0.002$
Open	-0.60, $p=0.014$	-0.69, $p=0.006$	-0.35, $p=0.26$	-0.83, $p<0.0001$
Two-incision	-0.58, $p=0.037$	-0.59, $p=0.033$	-0.32, $p=0.36$	-0.22, $p=0.55$

Since this is an area of the palm used frequently in daily activities (e.g., gripping, single-incisioning doors or jars), disruption of these tissues and nerves may lead to post-operative hypersensitivity and or pain that affect hand function and patient quality of life. Thus it is reasonable to assume that preservation of the tissues in this area contributed to the lack of scar tenderness in the two-incision group.

The prospective randomized design of this study is a strength, which enabled us to draw temporal associations between the single-incision and two-incision CTR interventions and their post-operative outcomes. Nonetheless, this study has several limitations. First, although only one patient was completely lost to follow-up after surgery, 31 % of our participants were lost to follow-up at one time point and had incomplete data sets, which makes it difficult to draw conclusions that most accurately reflect the true post-operative outcomes at these points in time. Not having the 6+-month follow-up data on three two-incision participants is also limitation that makes it difficult to compare the outcomes between the two groups. Lastly, although this study was adequately powered to detect what has been previously established to be clinically significant differences in BWCTQ scores, it is possible that it was still underpowered to detect statistically significant differences in the other outcome variables. Moreover, it is possible that our current outcome measures may have lacked the sensitivity and responsiveness to detect smaller differences between CTR techniques in the early post-operative period.

In conclusion, in this prospective randomized study, there was decreased scar sensitivity and pillar pain following the two-incision CTR when compared to single-incision CTR, although this failed to reach statistical significance. For this reason, we continue to offer this technique to patients as an alternative to the traditional single-incision CTR. Perhaps another study of a larger cohort will determine if there is indeed a significant difference between the two techniques. However, at this time, the results of this study indicate that there is no consistent statistically significant difference in post-operative symptoms or functional outcomes between the single-incision and two-incision CTR procedures that would merit definite recommendation of one procedure over the other. Therefore, both single-incision and two-incision CTR procedures may be offered as equally efficacious surgical treatments for CTS.

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Compliance with ethics requirements 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. Informed consent was obtained from all patients for being included in the study.

Conflicts of Interest Tiffany N. Castillo, MD declares that she has no conflict of interest.

Jeffrey Yao, MD declares that he has no conflict of interest in relation to this study; however, he has been a paid consultant for Arthrex, Trimed, Smith and Nephew Endoscopy, and Axogen. He has a grant from the American Foundation for Surgery of the Hand and has had honoraria and paid travel for educational speaking engagements for Arthrex and Trimed, and has patents and royalties from work with Arthrex as disclosed on his COI form.

There is no identifying patient information contained in this manuscript and all patients provided informed consent prior to participation in the study.

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