Randomized Controlled Trial Comparing the Outcome of a Modified Mini-Incision

Approach versus the Conventional Approach for Carpal Tunnel Release

Mohamed Mostafa Mahmoud*1, Mohamed Shukri Abdelgawad2,

Mohamed Abd Allah Abd Elhady¹, Ahmed Hamdy³, Amr Sameer¹

Departments ¹General Surgery, ²Vascular Surgery and ³Neurology, Faculty of Medicine, Mansoura University, Egypt

*Corresponding author: Mohamed Mostafa Mahmoud, Mobile: (+20) 01063566019,

Email: mohamedmostafa85@mans.edu.eg

ABSTRACT

Background: Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy that is best managed by surgical carpal tunnel release (CTR). CTR via the open approach remains the gold standard management of that condition. However, it has some complications like postoperative scar and pillar pain. Performing the procedure through mini-incision would be beneficial to decrease these complications.

Objective: The purpose of this study was to compare the outcome of the modified mini-incision approach to the conventional one for carpal tunnel release.

Patients and Methods: 68 patients were enrolled in our randomized prospective trial and were divided into two groups; Group A included patients who had the mini-incision approach, and Group B included patients who had the traditional approach.

Results: The incision length was significantly shorter in Group A at the expense of operative time that was significantly prolonged in the same group. The time for wound healing and return to daily activities was significantly shorter in the same group. Both approaches led to a significant improvement in median nerve function manifested in the decline in latency period, increase in amplitude, and decrease in pain along the median nerve distribution. Nonetheless, the incidence of wound-related pain and pillar pain increased with the conventional approach.

Conclusion: The mini-incision approach offers several advantages over the conventional approach. It is associated with less postoperative pain, fewer wound-related complications, faster recovery, and less incidence of recurrent symptoms. Nonetheless, the two approaches offer comparable effects on median nerve function.

Keywords: Carpal tunnel syndrome; Conventional incision; Mini-incision.

INTRODUCTION

Carpal tunnel syndrome (CTS) is a clinical entity that describes the entrapment of the median nerve as it passes through the carpal tunnel ^[1], which is a fibro-osseous tunnel located in the ventral aspect of the wrist ^[2]. It is the most common nerve entrapment syndrome affecting humans, as it represents about 90% of all entrapment neuropathies ^[3], with a prevalence of 3.8% in the general population ^[4].

CTS patients typically present with pain, tingling, or paraesthesia affecting the median nerve distribution in the hand ^[5]. Its pathogenesis is multifactorial, with multiple incriminated personal and occupational factors. Physical workload over the wrist joint could increase the risk of that problem. Additionally, other risk factors include diabetes mellitus, pregnancy, rheumatoid arthritis, obesity, and hypothyroidism ^[6,7].

The management of CTS includes conservative options or surgical carpal tunnel release (CTR), with a documented superiority of the surgical approaches regarding the improvement of symptoms and improvement of hand functions ^[6]. CTR could be achieved via open, mini-incision, or endoscopic approaches ^[4].

The former is the standard surgical management of CTS, as it provides a clear and wide surgical field, identification of anatomical variations, and complete division of the flexor retinaculum ^[8]. Nonetheless, it has some disadvantages, including scar

tenderness, chronic wound pain, broadening of the carpal arch, and entrapment of the flexor tendons ^[8,9]. These drawbacks would definitely have a negative impact on patient recovery and satisfaction. Hence, it is crucial to seek alternative approaches to minimize the risk of these complications, like mini-incision approaches ^[8].

Although creating mini-incisions is associated with less wound pain, less scar tenderness, and better cosmetic outcomes, the smaller incision could negatively affect field exposure, leading to incomplete division of the retinaculum and incomplete resolution of preoperative manifestations ^[9, 10].

After intensive research in the current literature, there is a paucity of studies evaluating the efficacy and safety of mini-incision approaches in achieving CTR in Egyptian patients. That is why we conducted the present study to present our experience with the modified mini-incision technique and compare its outcomes to the conventional open approach.

PATIENTS AND METHODS

The current randomized prospective trial with two parallel groups with a 1:1 allocation, was conducted at Mansoura University General Surgery Department over a one-year period, from November 2021 to November 2022. Our trial was designed for adult patients diagnosed with unilateral CTS based on nerve conduction velocity (NCV) study ^[11,12], who reported failure of conservative treatment.

The patients were collected from our outpatient clinic after proper preoperative preparation. History taking focused on the patient's name, age, gender, comorbidities, special habits, complaint, and duration. The patients were asked to express their pain along the median nerve distribution using the "visual analogue scale" (VAS), with increasing numbers indicating more pain severity ^[13]. The clinical examination focused on the neurosensory assessment of the median nerve, performing Tinel sign, and assessment of two-point discrimination via the Disk-Criminator. The degree of sensory nerve affection was subjectively measured using the VAS, with lower values indicating less sensory affection and vice versa.

NCV studies were ordered for all patients via Summit 12 Ch. Amplifier Sierra (Cadwell Laboratories, Inc., Kennewick, WA, USA). We placed the surface electrode on the abductor pollicis muscle, and the median nerve was stimulated at the wrist and the elbow. The following motor parameters were collected for the median nerve: latency, amplitude, and conduction velocity. Regarding sensory parameters, we placed the surface electrode on the second finger, and the nerve was stimulated at the wrist region. The latency of the nerve was classified as absent or present sensory response. The latency period was measured and recorded in patients with present responses. Additionally, the sensory amplitude was measured and recorded. Furthermore, the severity of nerve compression was classified according to the criteria published by the "American Association of Neuromuscular and Electrodiagnostic Medicine" as mild, moderate, or severe ^[12].

After careful patient assessment, we excluded patients with either of the following criteria: bilateral affection, the presence of concomitant hand or wrist pathology, cervical spine disorders (spondylosis), proximal radiculopathy, combined nerve compression manifestations, inflammatory joint disorders (gout or rheumatoid arthritis), major psychiatric illness, previous hand or upper limb surgery, or lost at followup.

Sixty-eight patients were found eligible for our study. Patients were randomly assigned following

simple randomization procedures, the allocation sequence was concealed through sequentially numbered, opaque, sealed and stapled envelopes. Sequence generation and allocation concealment was done by the 1st author; while patients' enrolment and assignment to any of the 2 adopted interventions were done by the last author. We adopted non-blinded randomization in this study. Group A (n = 34) included patients who had CTR via the mini-incision approach, and Group B (n = 34) included the remaining patients who had the same procedure via the conventional open approach. All procedures were performed under local infiltration anesthesia when the patient was supine.

All cases were operated by the same 2 consultant surgeons in our institute (the 1^{st} and 2^{nd} authors) who possess experience and expertise to do such surgeries in a meticulous and scientific manner ensuring the best possible outcomes for our patients.

In Group A, we used a special metal guide (McDonald Dissector). Our longitudinal mini-incision started just above the proximal flexor wrist crease and then extended for 1.5 - 2 cm in a proximal direction. The superficial fascia was opened, and blunt dissection was performed till identification of the median nerve. The metal guide was inserted into the carpal tunnel, and a scissor was inserted into its grove to cut the transverse carpal ligament proximally and distally (Figure 1). In this approach the median nerve is often not dissected directly; instead, the incision is made over the flexor carpi radialis (FCR) tendon, which lies near the median nerve without the need for direct dissection.

In Group B, a longitudinal incision was created in the palm between the thenar and hypothenar eminences along the longitudinal axis of the ring finger. Then, it was extended to the proximal flexor wrist crease. The transverse carpal ligament was identified, and its ulnar side was divided after protection of the underlying median nerve. The incision might be extended to provide adequate exposure to the ligament. Once the ligament was released, the surgeon carefully explored the area to identify and examine the median nerve. Any adhesions or connective tissue compressing the nerve were freed, allowing the nerve to regain its normal mobility.



Figure (1): (A) Design of the incision for the mini approach. (B) Dissection of the subcutaneous tissue till reaching flexor retinaculum and exposure of the median nerve. (C) The MacDonald dissector was used to protect median nerve while dividing the flexor retinaculum. (D) Introduction of the MacDonald dissector for division of the flexor retinaculum distally. (E) Introduction of the MacDonald dissector for division of the flexor retinaculum proximally. (F) The median nerve after complete division of the flexor retinaculum. (G) After closure of skin incision by nonabsorbable sutures. (H) The shape of the scar 3 months postoperative. -----

We used the same method for wound closure in all cases of both groups (closing the wound in layers, suturing the subcutaneous tissue with interrupted absorbable Vicryl 2/0 sutures followed by skin closure by simple interrupted proline 3/0 sutures). The incision length and operative time were recorded in all cases. All patients were discharged on the same day of the operation, and follow-up visits were scheduled after two weeks, then after 1, 3, and 6 months. The incidence of early postoperative complications like hematoma, infection, and wound dehiscence was noticed at the initial follow-up visit (after two weeks). The time to complete wound healing and the duration needed to return to normal daily activities were recorded in each group. Complete wound healing was defined as when the wound was completely epithelized with no drainage or defects ^[14]. Patients were asked if they expressed any scar or pillar pain after 1, 3, and 6 months. The scars were examined also to elucidate the keloid formation rate.

At the six-month follow-up, the patients were asked to express their pain compared to their preoperative sensation (via the same VAS score). Additionally, the degree of sensory affection was subjectively assessed using the same scale. NCV was also ordered for all patients and its results were compared between the two groups postoperatively and compared to their baseline preoperative values. The

incidence of recurrent symptoms was also recorded in the two groups. The patients were also asked to express their satisfaction with the surgical intervention on a five-point Likert scale (from excellent to very poor)^[2]. Our main outcome was the safety and efficacy of the new mini-incision approach in CTS patients. Safety was measured by the incidence of postoperative complications, while efficacy was measured by the improvement of CTS-associated pain and NCV parameters. Secondary outcomes included operative time, incision length, incidence of recurrent symptoms, and patient satisfaction.

Sample size calculation:

We estimated the proper sample size for the study using online software current (http://powerandsamplesize.com). In order to detect a significant improvement in CTS-associated pain, we needed to enrol 34 patients in each study group to achieve an 80% study power and a 0.05 significance level. Consequently, we enrolled a total of 68 CTS patients in our study.

Ethical approval:

This trial was approved by the Institutional Review **Board of Faculty of Medicine, Mansoura University** (IRB code: R.21.11.1511). The patients were informed about the nature and the aim of the study, with the potential advantages and disadvantages of each approach. Their approval to participate in the study was documented by written consent. The Helsinki Declaration was observed throughout the study's duration.

Statistical analysis

We used the SPSS software for data tabulation and analysis. Categorical data were presented as frequencies and percentage and compared between the two groups using the Chi-Square test. The same data category was compared within the same group at different time points via the marginal homogeneity or McNamar's test. For numerical data, we expressed it as means and standard deviations (if not skewed) or as medians and ranges (if skewed). The two groups were compared using the student-t or Mann-Whitney tests, respectively. To compare variables within the same group at two-time points, we applied the paired samplet test or Wilcoxon-signed rank test, respectively. Any pvalue was considered significant if it was less than 0.05.

RESULTS

79 cases were assessed for eligibility; of whom 11 cases were excluded. Then 68 cases were randomly assigned into the 2 study groups and were analysed for the primary outcome (Figure 2).



Figure (2): Flowchart of included patients.

Our statistical analysis revealed no significant difference between the two groups regarding baseline parameters (Table 1).

Table (1): Baseline data of the included patients.

	Group A (n = 34)	Group B (n = 34)	Р
Age (years)	31.44 ± 5.24	31.35 ± 5.77	0.948
Gender			
Male	13(38.2%)	11 (32.4%)	0.612
Female	21 (61.8%)	23 (67.6%)	0.012
Smoking	10 (29.4%)	8 (23.5%)	0.582
Diabetes	11 (32.4%)	11 (32.4%)	1
Affected side			
Right	24 (70.6%)	27 (79.4%)	0.401
Left	10 (29.4%)	7 (20.6%)	0.401
Duration of symptoms (months)	12.44 ± 3.59	11.62 ± 3.57	0.346
~			

Data are presented as mean \pm standard deviation or as frequency (%)

As shown in table 2, incision length was significantly shorter in Group A. However, the duration of the procedure showed a significant prolongation with the mini-incision approach. Although the incidence of hematoma or infection did not differ between the two groups, more patients with wound dehiscence were encountered in Group B. The mini-incision approach was associated with significantly better postoperative recovery, manifested in the decreased time needed for wound healing and decreased time to return to normal daily activities. No patients developed hypertrophic or keloid scars in Group A, compared to 8.8% of Group B patients.

Table	(2):	Operative	data	and	early	postoperative
outcom	nes in	the two gro	oups.			

	Group A (n = 34)	Group B (n = 34)	Р
Operative time (min)	27.50 ± 3.82	23.97 ± 3.26	< 0.001*
Incision length (mm)	17.35 ± 2.16	$\begin{array}{r} 39.32 \pm \\ 4.08 \end{array}$	< 0.001*
Hematoma/infection	0 (0%)	1 (2.9%)	0.314
Wound dehiscence	0 (0%)	5 (14.7%)	0.020*
Time to heal (days)	7.97 ± 1.06	13.59 ± 2.44	< 0.001*
Return to normal activity (days)	8.62 ± 1.92	17.15 ± 3.59	< 0.001*
Scar effect (hypertrophic/ keloid)	0 (0%)	3 (8.8%)	0.076

Data are presented as mean \pm standard deviation or as frequency (%), *: Significant

The incidence of wound pain showed a significant increase in association with the conventional approach at both one- and three-month

follow-up visits. Moreover, the same approach led to a significant rise in the incidence of pillar pain at the scheduled three follow-up visits (Table 3).

 Table (3): Incidence of scar-related pain at follow-up in both groups.

	Group A (n = 34)	Group B (n = 34)	Р
Wound pain at one month	2 (5.9%)	9 (26.5%)	0.021*
Wound pain at three months	0 (0%)	5 (14.7%)	0.020*
Wound pain at six months	0 (0%)	3 (8.8%)	0.076
Pillar pain at one month	3 (8.8%)	10 (29.4%)	0.031*
Pillar pain at three months	1 (2.9%)	7 (20.6%)	0.024*
Pillar pain at six months	0 (0%)	4 (11.8%)	0.039*

Data are presented as frequency (%), *: Significant

Preoperative pain scores were comparable between the two groups. Although both approaches showed a significant decline regarding pain severity. the decline was more pronounced in Group A, indicating less postoperative pain in association with the mini-incision. Regarding sensory nerve affection and NCV parameters, most of them expressed no significant differences between the two groups prior to the procedure. Both approaches led to a significant improvement of these variables at follow-up, and that was manifested in improved sensory affection, decreased nerve latency, and increased amplitude. One should also notice that all of these improvements were statistically comparable between the two approaches, indicating equal efficacy of the two approaches in improving median nerve function (Table 4).

Table (4): Changes in pain, sens	ory affection, and NCV	parameters in the two groups.
----------------------------------	------------------------	-------------------------------

	Group A	Group B	P between
	(n = 34)	(n = 34)	both groups
Preoperative VAS	7 (6 - 10)	8 (6 -10)	0.069
Follow-up VAS	1(0-3)	2 (0 – 3)	< 0.001*
P within the same group	< 0.001*	< 0.001*	
Preoperative median nerve distribution sensory affection	8 (6 - 10)	8 (6 - 10)	0.292
Follow-up median nerve distribution sensory affection	2(0-5)	2(0-6)	0.783
P within the same group	< 0.001*	< 0.001*	
Preoperative median nerve motor latency (ms)	5.5(3.8-9.9)	6.1 (4.2 – 13.8)	0.189
Follow-up median nerve motor latency (ms)	3.3(2.1-5.5)	3.4 (2.1 – 6.5)	0.854
P within the same group	< 0.001*	< 0.001*	
Preoperative median nerve motor amplitude (mv)	5.85 (0.10 - 12.4)	4.45 (0.10 - 10.8)	0.222
Follow-up median nerve motor amplitude (mv)	8.65 (2 - 15)	7.6 (1.1 – 12.3)	0.155
P within the same group	< 0.001*	< 0.001*	
Preoperative median nerve motor conduction velocity (m/s)	67.21 ± 11.74	63.32 ± 9.18	0.134
Follow-up median nerve motor conduction velocity (m/s)	$68.21{\pm}7.92$	62.56 ± 7.32	0.003*
P within the same group	0.878	0.693	
Preoperative median nerve sensory latency (ms) in patients with sensory response	6.74 ± 1.42	6.11 ± 1.71	0.169
Follow-up median nerve sensory latency (ms)	2.64 ± 0.82	2.57 ± 0.55	0.729
P within the same group	< 0.001*	< 0.001*	
Preoperative median nerve sensory amplitude (mv) in patients with sensory response	3.4 (0.4 – 20)	8.05 (0.3–13.1)	0.040*
Follow-up median nerve sensory amplitude (mv)	18.5 (9.5 - 30.2)	19 (12.2 – 27.2)	0.570
P within the same group	< 0.001*	< 0.001*	

Data are presented as median (Range) or as mean \pm standard deviation, *: Significant

The degree of median nerve compression improved significantly with the two approaches. Additionally, the sensory response of the median nerve increased significantly with the two approaches. As shown in table 5, both approaches had comparable effects on the sensory response and nerve compression improvement. **Table (5):** Changes in the degree of nerve compression and sensory response in both groups.

	Group A (n = 34)	Group B (n = 34)	P between both groups
Preoperative degree of nerve con	npression		
Mild	3 (8.8%)	0 (0%)	
Moderate	18 (52.9%)	20 (58.8%)	0.208
Severe	13 (38.2%)	14 (41.2%)	
Follow-up degree of nerve comp	ression		
Mild	5 (14.7%)	2 (5.9%)	
Moderate	2 (5.9%)	1 (2.9%)	0.575
Severe	2 (5.9%)	3 (8.8%)	0.575
Normal	25 (73.5%)	28 (82.4%)	
P within the same group	< 0.001*	< 0.001*	
Preoperative median sensory ner	rve latency (ms)		
No sensory response	9 (26.5%)	10 (29.4%)	- 0.787
Sensory response	25 (73.5%)	24 (70.6%)	0.787
Follow-up median sensory nerve	latency		
No sensory response	3(8.8%)	4(11.8%)	- 0.60
Sensory response	31(91.2%)	30(88.2%)	0.03
P within the same group	0.031*	0.039*	
Preoperative median nerve sense	ory amplitude		
No sensory response	9 (26.5%)	10 (29.4%)	0.787
Sensory response	25 (73.5%)	24 (70.6%)	0.787
Follow-up median nerve sensory	amplitude		
No sensory response	3(8.8%)	4(11.8%)	- 0.69
Sensory response	31(91.2%)	30(88.2%)	0.09
P within the same group	0.031*	0.039*	

Data are presented as frequency (%), *: Significant

Patient satisfaction with the surgical procedure showed no significant difference between the two approaches (Table 6).

Table (6): Patient satisfaction with the surgicalprocedure.

	Group A (n = 34)	Group B (n = 34)	Р
Patients' satisf	action		
Very poor	0 (0%)	1 (2.9%)	
Poor	2 (5.9%)	2 (5.9%)	
Fair	4 (11.8%)	2 (5.9%)	0.132
Good	7 (20%)	16 (47.1%)	•
Excellent	21 (61.8%)	13 (38.2%)	

Data are presented as frequency (%)

DISCUSSION

The primary aim of any research in the field of medicine or surgery is mainly to improve patient outcomes. Although the open conventional approach is still the standard management of CTS after failed conservative methods, it has some undesirable outcomes, including pillar pain, scar pain, delayed recovery, and poor cosmoses ^[15].

That is why surgeons tended to seek alternative approaches to minimize the risk of these complications. Limited incisions have become popular since their introduction in 1993 as two limited incisions that were modified into a single incision ^[16,17]. Although these limited incisions could decrease the risk of scar-related complications, they offer less exposure during the operation, which could increase the risk of nerve damage, especially in the presence of anatomical variations. Nonetheless, if performed by an experienced surgeon, that risk could be minimized.

Herein, we compared the perioperative and short-term outcomes of the mini-incision approach with the conventional open approach in our tertiary care surgical setting. Our study was randomized in nature, and that was reflected in our preoperative and baseline characteristics, which showed almost no significant difference between our two groups. That should reduce the risk of any bias that could skew our results in favor of one group over the other.

We noted significant prolongation in the operative time in association with the mini-incision approach. This is a reasonable consequence as the mini-incision allows relatively smaller operative field exposure compared to the conventional approach. Hence, the surgeon must perform the operative steps with caution to decrease the risk of injuring nearby nerves or blood vessels, which could reach up to 4.3% using mini-incisions, as reported by **Zyluk and Strychar** ^[18]. We did not encounter any of these complications with the mini-incision approach in our trial, and that could reflect its safety, along with our surgical expertise in performing it without an increased risk of complications. Additionally, the reader should notice that the difference between the two operative

times was about four minutes between the two approaches, which is clinically irrelevant despite its statistical significance. **Bai** *et al.* ^[9] reported that operative time had mean values of 25.1 in the miniincision group, compared to 23.5 minutes in the conventional approach. Yet, the difference turned out to be insignificant in the statistical analysis (p = 0.13).

The reader should notice that we performed our mini-incisions proximal to the palmar crease rather than the mini palmar incisions described in previous studies [2,3,9], as we think that creating the incision in that area provides better direct access to the flexor retinaculum, and thus, easy nerve release. Although the previous papers using the palmar mini-incisions did not report the healing time, we think that performing the incision proximal to the palmar crease would take less time to heal. That could be explained by many factors; (1) constant use and movement of the hand, (2) limited blood supply of the palm, (3) higher risk of infection secondary to environmental contaminants exposed to the palmar wound, and (4) the presence of thick and tough skin in the palmar area, which may hinder new tissue growth and wound healing.

For our main outcome we used both subjective and objective evaluation. The later included NCS, which is an excellent tool to measure nerve function and its changes. We should also highlight that the previous papers handled comparison between the standard and other mini-approaches did not use NCS like us. Instead, they used hand grip strength only. In our opinion, although both tests are objective methods to assess nerve function, hand grip does not directly assess nerve conduction or identify specific nerve pathology. Moreover, NCS is widely accepted and used in clinical practice than the hand grip test.

In the current study, the incidence of wound hematoma, dehiscence, and hypertrophic scars increased with the conventional approach, although it does not reach statistical significance in some parameters. Another study noted a decline in woundrelated complications like hematoma formation with the mini-incision approaches ^[19]. While, **Bal** *et al.* ^[20] reported a decline in the incidence of hypertrophic scars when the mini-incision was used. The previous two studies confirm our findings.

Our findings revealed an earlier return to daily activities when the mini-incision was used, and that coincides with **Ji** *et al.* ^[21], who reported an average period of 59 days to return to work with the conventional open approach, compared to only 23.7 days with the mini-incision approach. Additionally, **Khoshnevis** *et al.* ^[2] reported that return to work occurred after 9.37 days in the mini-incision group, compared to 24.07 days in the conventional group (p < 0.001). The decreased postoperative pain, earlier wound healing, and decreased wound complication rate could explain the previous findings.

In our study, we noted a significant improvement in CTS-related manifestations via

subjective and objective assessment. The former was manifested in the decline in preoperative pain, while the latter was manifested by improvement in NCV. In line with our findings, Gaba et al. [15] reported significant improvement in sensory symptoms, key pinch, grip pinch, palmar pinch, and NCV parameters after using mini-incision in 27 CTS patients compared to their baseline findings. Additionally, Chen et al. [8] also highlighted the efficacy of the mini-incision approach in improving median nerve function at 13follow-up. month They noted а significant improvement in sensation, pinch strength, and grip strength after using the mini-incision (p < 0.001).

Moreover, **Saaiq** reported symptomatic relief of most patient symptoms in the majority of patients who underwent mini-incision (96.1%). The nonresponders who had persistent symptoms were diabetics of five years duration or more. The author also reported a significant improvement in the "Boston Carpal Tunnel Syndrome Questionnaire" after the procedure ^[3]. **Mardanpour** *et al.* ^[22] also reported similar outcomes after performing the mini-incision approach in 300 CTS patients.

We noted a significant decline in the incidence of both scar-related and pillar pain in association with the mini-incision approach during follow-up. This is in accordance with **Ji and his co-workers**^[21], who reported an incidence of 34.6% and 23.1% for the same problems, respectively, with the conventional open approach, compared to only 8.1% and 18.4%, respectively, when a mini-incision was used.

Scar-related pain could be explained by the formation of subcutaneous neuromas secondary to injury to the palmar cutaneous branches of median or ulnar nerves ^[9]. However, the exact pathophysiology of pillar pain is still undetermined. Multiple theories have been proposed, including muscular and tendon changes, carpal tunnel structural alternations, postoperative edema, and neurological effects ^[23-25].

Although the conventional open approach would theoretically offer a better operative field that allows better exposure and division of the flexor retinaculum, it was associated with a higher recurrence rate at the six-month follow-up (11.8% vs. 0% with the mini-incision). Other studies also reported a 0% recurrence rate one year after using the mini-incision approach ^[3,15].

We think that the larger scar would yield more fibrosis and adherence to the underlying released nerve, leading to the recurrence of the preoperative manifestations. Previous studies have supported that concept ^[26-28]. This is in contrast to the study conducted by **Castillo and Yao**^[29], who reported an increased risk of incomplete CTR using mini-incisions.

Although our statistical analysis revealed no difference between the two approaches regarding patient satisfaction, the percentage of patients with excellent satisfaction was higher in the mini-incision group (61.8% vs. 38.2% in the conventional group).

However, another similar study reported a significant improvement in patient satisfaction in the miniincision group $(p < 0.001)^{[2]}$.

Being randomized, and comparing the results of NCV results preoperatively and postoperatively in the studied cases not relying only on the subjective findings of pain improvement after decompression; the results of our trial can be reliably and effectively validated.

Our study handled a unique surgical perspective. However, it has some limitations. The small patient sample collected from a single surgical institution and the lack of long-term follow-up are the main limitations. Also not assessing how many of the patients were left-handed or ambidextrous and if the intervention performed on the "working" hand, was another limitation. These should be addressed in upcoming studies.

CONCLUSION

Based on the preceding findings, the miniincision approach offers several advantages over the conventional open approach. It is associated with less postoperative pain, fewer wound-related complications, faster recovery, and less incidence of recurrent symptoms. Nonetheless, the two approaches offer comparable effects on median nerve function measured by NCV.

- **Conflicts of interest:** Nil.
- **Funding:** No funding.
- **Registration:** Our study registered at ClinicalTrials.gov by this identifying number NCT06114823 (last public release 28/10/2023 and last update posted 2/11/2023).

REFERENCES

- 1. Balcerzak A, Ruzik K, Tubbs R *et al.* (2022): How to differentiate pronator syndrome from carpal tunnel syndrome: A comprehensive clinical comparison. Diagnostics, 12(10): 2433. https://doi.org/10.3390/diagnostics12102433.
- 2. Khoshnevis J, Layegh H, Yavari N *et al.* (2020): Comparing open conventional carpal tunnel release with mini-incision technique in the treatment of carpal tunnel syndrome: A non-randomized clinical trial. Ann Med Surg., 55:119-23.
- 3. Saaiq M (2021): Presentation and outcome of carpal tunnel syndrome with mini incision open carpal tunnel release. Med J Islam Repub Iran, 35: 67.https://doi.org/10.47176/mjiri.35.67.
- 4. Wipperman J, Goerl K (2016): Carpal tunnel syndrome: Diagnosis and management. Am Fam Physician, 94(12):993-99.
- 5. Wright A, Atkinson R (2019): Carpal tunnel syndrome: An update for the primary care physician. Hawaii J Health Soc Welf., 78(11): 6-10.
- 6. Pourmemari M, Heliövaara M, Viikari-Juntura E *et al.* (2018): Carpal tunnel release: Lifetime prevalence, annual incidence, and risk factors. Muscle Nerve, 58(4):497-502.

- Tang H, Cheng Y, Guo H (2022): Association between hormone replacement therapy and carpal tunnel syndrome: a nationwide population-based study. BMJ Open, 12(1): e055139. https://doi.org/10.1136/bmjopen-2021-055139.
- Chen Y, Ji W, Li T *et al.* (2017): The mini-incision technique for carpal tunnel release using nasal instruments in Chinese patients. Medicine, 96(31): e7677. https://doi.org/10.1097/md.000000000007677.
- **9. Bai J, Kong L, Zhao H** *et al.* **(2018): Carpal tunnel release with a new mini-incision approach versus a conventional approach, a retrospective cohort study. Int J Surg., 52:105-9.**
- **10.** Keser N, Dortcan N, Cikla U *et al.* (2017): Semivertical incision: An aesthetically and electrophysiologically effective mini-incision technique for carpal tunnel decompression. Med Sci Monit., 23:2993-3000.
- **11. Graham B, Regehr G, Naglie G** *et al.* (2006): Development and validation of diagnostic criteria for carpal tunnel syndrome. J Hand Surg Am., 31(6):919-24.
- 12. Werner R, Andary M (2011): Electrodiagnostic evaluation of carpal tunnel syndrome. Muscle Nerve, 44(4):597-607.
- **13.** Hawker G, Mian S, Kendzerska T *et al.* (2011): Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). Arthritis Care Res., 63 (11): 240-52.
- **14. Pastar I, Stojadinovic O, Yin N** *et al.* (2014): Epithelialization in wound healing: A comprehensive review. Adv Wound Care, 3(7):445-64.
- **15.** Gaba S, Bhogesha S, Singh O (2017): Limited incision carpal tunnel release. Indian J Orthop., 51(2):192-8.
- **16. Bromley G (1994):** Minimal-incision open carpal tunnel decompression. J Hand Surg Am., 19(1):119-20.

- 17. Abouzahr M, Patsis M, Chiu D (1995): Carpal tunnel release using limited direct vision. Plast Reconstr Surg., 95(3):534-8.
- **18.** Zyluk A, Strychar J (2006): A comparison of two limited open techniques for carpal tunnel release. J Hand Surg Br., 31(5):466-72.
- **19.** Corlobé P (2004): L'électromyogramme des syndromes canalaires. Chirurgie de la Main., 23: 4-14.
- **20.** Bal E, Pişkin A, Ada S *et al.* (2008): Comparison between two mini incision techniques utilized in carpal tunnel release. Acta Orthop Traumatol Turc., 42(4):234-37.
- **21.** Ji W, Chen Z, Huang Q (2014): Subjective outcome evaluations following open carpal tunnel release [in Chinese]. J Chinese Hand Surg., 30: 118-20.
- 22. Mardanpour K, Rahbar M, Mardanpour S (2019): Functional outcomes of 300 carpal tunnel release: 1.5 cm longitudinal mini-incision. Asian J Neurosurg., 14(3):693-97.
- **23.** Santosa K, Chung K, Waljee J (2015): Complications of compressive neuropathy: prevention and management strategies. Hand Clin., 31(2):139-49.
- 24. Morrell N, Harris A, Skjong C *et al.* (2014): Carpal tunnel release: do we understand the biomechanical consequences? J Wrist Surg., 3(4):235-38.
- **25.** Brooks J, Schiller J, Allen S *et al.* (2003): Biomechanical and anatomical consequences of carpal tunnel release. Clin Biomech., 18(8):685-93.
- 26. Tung T, Mackinnon S (2001): Secondary carpal tunnel surgery. Plast Reconstr Surg., 107(7): 1830-43.
- 27. Zieske L, Ebersole G, Davidge K *et al.* (2013): Revision carpal tunnel surgery: a 10-year review of intraoperative findings and outcomes. J Hand Surg Am., 38(8):1530-39.
- 28. Jones N, Ahn H, Eo S (2012): Revision surgery for persistent and recurrent carpal tunnel syndrome and for failed carpal tunnel release. Plast Reconstr Surg., 129(3):683-92.
- **29.** Castillo T, Yao J (2014): Prospective randomized comparison of single-incision and two-incision carpal tunnel release outcomes. Hand, 9(1):36-42.