Mini-open double-incision technique versus limited-open technique for carpal tunnel release: a prospective double-cohort study

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Background
There is no universal agreement on the effectiveness and safety of various methods for carpal tunnel release, and their numerous modifications. Multiple minimally invasive techniques have been proposed to decrease postoperative morbidity. However, there are concerns regarding the risk for neurovascular injury and incomplete decompression.

Patients and methods
To evaluate the safety and efficacy of carpal tunnel release using a mini-open, blind, double-incision technique (group I) versus the limited-open technique (group II), a prospective double-cohort study on a total of 90 consecutive patients presenting with idiopathic carpal tunnel syndrome resistant to conservative treatment was conducted. Safety was measured by the prevalence of complications and revision surgery, whereas efficacy was measured by the Boston Carpal Tunnel Syndrome Questionnaire, pinch grip strength, the static 2-point discrimination test, and patient satisfaction with the cosmetic result of the procedure.

Results
All parameters (except the median pinch strength at 1 month) showed progressive postoperative improvement, with no significance difference between the two groups. The mini-open, blind, double-incision technique resulted in a higher degree of postoperative patient satisfaction with the cosmetic result, fewer surgical site complications and less painful scar, shorter operative time, and earlier restoration of pinch grip strength. This, however, did not translate directly into Levine functional and symptom scores that differed significantly between the two groups.

Conclusion
Both techniques described in the study led to good, comparable clinical results. However, experience with the mini-open double-incision technique is encouraging as it represents a safe and effective line of management for idiopathic carpal tunnel syndrome.

Keywords:
carpal tunnel, flexor retinaculum, transverse carpal ligament

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Introduction

Carpal tunnel syndrome (CTS) accounts for about 90% of all entrapment neuropathies, with prevalence varying from 0.6% in men to 5.8% in women. It is caused by entrapment of the median nerve in the carpal tunnel and increased intracarpal pressure resulting in numbness, tingling, and burning pain in at least two of the three digits supplied by the median nerve, loss of dexterity, muscle wasting, and decreased functional ability [1–3].

The most effective treatment for CTS is surgical division of the transverse carpal ligament (TCL). Controversy persists regarding the effectiveness and safety of various methods for carpal tunnel release (CTR) and their numerous modifications. Moreover, there is no universal agreement on the terms used to describe these methods. The 'short-incision open' or 'limited-open' technique is the most frequent surgical procedure performed as it allows direct visualization of the whole TCL [4,5]. However, pain in the scar or in the palm was reported in up to 82% of patients [6,7].

Multiple minimally invasive and endoscopic surgical approaches [6–20] have been proposed to decrease the postoperative morbidity and to promote faster recovery and return to work. However, there are concerns regarding the risk for neurovascular injury and incomplete decompression. Also, there is no robust evidence that recommends one surgical technique over others [20–23].

The aim of this study was to evaluate the safety and efficacy of CTR using a mini-open, blind, double-incision technique against the limited-open technique.

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Safety is measured by the prevalence of complications and requirement for revision surgery, whereas efficacy is measured by the Symptom Severity Scale (SSS) (11 items) and the Functional Status Scale (FSS) (eight items) of the Boston Carpal Tunnel Syndrome Questionnaire (BCTQ) [24], pinch grip strength, the static 2-point discrimination (2PD) test, and patient satisfaction with the cosmetic result of the procedure.

Patients and methods

A total of 90 consecutive patients presenting with idiopathic CTS resistant to conservative treatment for at least 6 months were enrolled in a prospective double-cohort study from January 2009 to December 2011. Diagnosis of CTS was established clinically according to the American Academy of Neurology diagnostic criteria [25]. Cases were classified according to neurophysiological studies into three grades [26,27]: mild CTS, characterized by prolonged sensory latencies with normal motor studies and no evidence of axon loss; moderate CTS, characterized by prolonged sensory and distal motor latencies with no evidence of axon loss; and severe CTS, characterized by any of the aforementioned nerve conduction studies (NCS) abnormalities with evidence of axon loss.

Exclusion criteria were presence of rheumatoid arthritis, diabetes mellitus, having suffered trauma in the preceding year, presence of neuromuscular disorders, thyroid disorder, pregnancy, failed previous surgery, bilateral cases, and CTR in the contralateral hand during the previous year.

Patients were assigned to one of two groups according to surgeon preference (each author managed or supervised all cases managed in one of the two groups) as follows: group I comprised patients subjected to CTR using the mini-open, blind, double-incision technique (45 patients), and group II comprised patients subjected to CTR using the limited-open technique (45 patients). The baseline characteristics of the two groups are presented in Table 1.

Table 1 The baseline characteristics of the patients included in group I and group II

Points of comparison	Group I (45 patients)	Group II (45 patients)	*P* value
Age (years)	40 ± 10	42 ± 9	0.27
Sex (female/male)[a]	30/15	26/19	0.51
Side involved (dominant/nondominant)[a]	27/18	33/12	0.26
Duration to operation (months)	9 (7–15)	12 (8–15)	0.39
Electrophysiological grades			
Mild	9	11	0.69
Moderate	29	25	
Severe	7	9	
Symptom Severity Scale	3.18 (3.1–3.36)	3.18 (3–3.36)	0.55
Functional Status Scale	3 (2.75–3.06)	3 (2.88–3.13)	0.19
Sensory Index	1.83 (1.67–2.0)	2 (1.67–2.33)	0.84
Tip-pinch strength (kg)	2 (1.8–2.3)	2.2 (1.9–2.3)	0.31
Wasting of thenar muscles[a]	10/45 (22.2)	14/45 (31.1)	0.48
Mean operative time (min)	17.5 ± 5	19.3 ± 3	0.03

Data are mean ± SD or median (percentile), [a]Fisher's exact test was used.

Preoperative evaluation

The patients were evaluated with the BCTQ [24], which consists of two parts: the SSS (11 items) and the FSS (eight items). Each item was scored from 1 to 5, with a higher score indicating greater disability. Each scale generated a final score equal to the sum of individual scores divided by the number of items. The static 2PD test was conducted using the 2PD esthesiometer. The results were expressed in ranks:

(i) 2PD less than 6 mm,
(ii) 2PD 6–10 mm,
(iii) 2PD 10–15 mm, and
(iv) 2PD more than 15 mm.

Measurements were taken on the thumb, index, and middle fingers, and the mean result was recorded as the 'Sensory Index'. The tip-pinch strength of both hands was assessed using a pinch gauge. Patients were asked to squeeze the pinch gauge with maximum strength with the shoulder adducted and in neutral rotation, elbow flexed to 90°, forearm in neutral rotation, and wrist in 0–30° extension and 0–15° ulnar deviation. Measurements were recorded three consecutive times to obtain a mean result.

Operative technique

A pneumatic tourniquet was maintained on the arm throughout the procedure, and the operative time was recorded. The wrist was placed in moderate extension over a towel roll without radial or ulnar deviation. Neither tenosynovectomy nor neurolysis was performed in either group.

Group I: mini-open, blind, double-incision technique (45 patients)

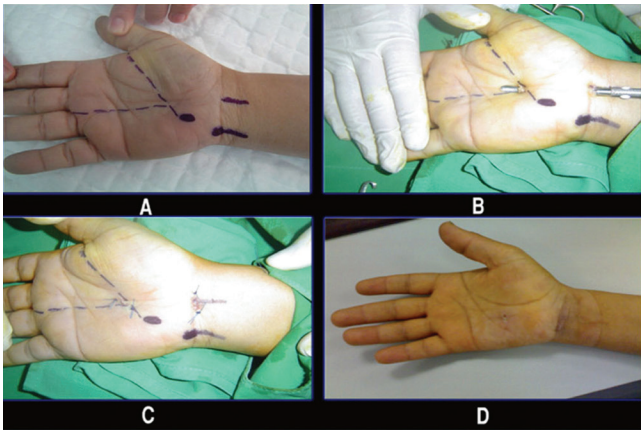
The technique used (Fig. 1) was a modification of the technique described by Wilson [8]. Before starting the operation, landmarks were identified and marked on the palm of the patient: the flexor carpi ulnaris tendon, the palmaris longus tendon, the pisiform, the hook

of hamate, Kaplan's cardinal line [28], and the radial border of the ring finger. A 1.5–2-cm transverse incision was made just proximal to the distal wrist crease in the center of the volar aspect of the wrist between the flexor carpi ulnaris and palmaris longus tendons. The distal antebrachial fascia was opened with a mosquito clamp to directly visualize the proximal edge of the TCL. A blunt-tipped dissector was inserted deep into the TCL into the carpal tunnel in line with the radial border of the ring finger, taking care not to damage the median nerve. If the space was found to be too tight, a 1-cm longitudinal snip was made with scissors on the proximal edge of the TCL to widen the space. The tip of the dissector was then felt at the level of Kaplan's cardinal line, and a second 1-cm transverse incision was made on its tip. Using the same dissector, a subcutaneous tunnel was formed between the two incisions superficial to the TCL. The TCL was then divided from proximal to distal with blunt-tipped strong scissors of adequate length. One blade of the scissors was inserted into the carpal tunnel, whereas the other was inserted into the subcutaneous tunnel. Cutting should continue until the scissor tip was retrieved in the distal incision. A probe was then inserted into the carpal tunnel to ensure that the carpal tunnel was decompressed completely.

Group II: limited-open technique (45 patients)

This technique was executed through an ~3–4-cm incision between Kaplan's cardinal line and the distal wrist crease, parallel to the thenar crease in line with the radial border of the ring finger (Fig. 2). The middle zone of the TCL was divided with a scalpel under vision while using a dissector to protect the median nerve. The proximal and distal edges of the TCL were then divided with blunt-tipped scissors.

Figure 1



(a) Intraoperative photograph of one patient from group I showing the anatomical landmarks drawn on the palm of the patient. (b) Intraoperative photograph of one patient from group I showing a dissector inserted into the proximal incision, passing deep in the transverse carpal ligament, and its tip pointing out of the distal incision. (c) Intraoperative photograph of one patient from group I after skin closure. (d) Photograph of one patient from group I after wound healing.

Postoperative management

Postoperative management was the same for both groups. A postoperative compression dressing and elastic bandage were applied before release of the tourniquet to prevent hematoma formation, and they were kept in place until suture removal after 2 weeks. Thereafter, active and passive range-of-motion exercises were initiated as tolerated for a period of 2–4 weeks.

Postoperative evaluation

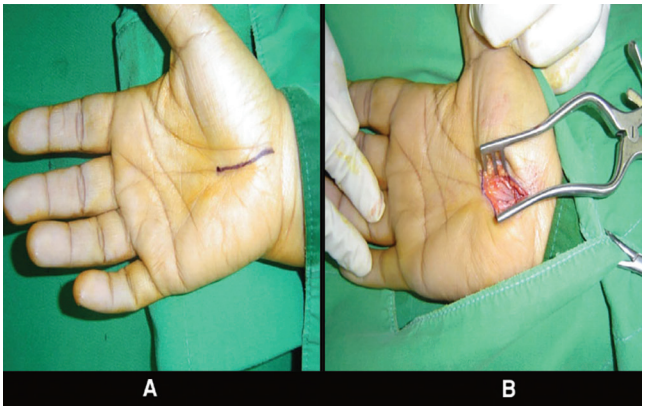
The patients were evaluated postoperatively using the same preoperative parameters at the end of the first month and then after 3 months, 6 months, and finally at 12 months postoperatively. We also compared the prevalence of complications, the need for revision surgery, and patient satisfaction regarding the cosmetic result of the procedure.

Statistical analyses

Power Analysis Software (PASW) and power analysis sample size (PASS) were used for sample size calculation and statistical analysis. Assuming a SD of 15%, the required sample size after setting the power to 90% to detect a mean difference of 0.5 points (10%) between groups on the five-point BCTQ score (primary end-point) as statistically significant at the 5% level was 74. Each group had to have at least 37 participants. To allow for attrition, we increased the sample size by 20%, and thus each group included 45 participants.

Continuous variables were tested for normality. The baseline information, duration of surgical procedure,

Figure 2



Intraoperative photograph of one patient from group II showing the site of the skin incision (a) and after release of the transverse carpal ligament (b).

operative time, and baseline scores were analyzed using two-tailed unpaired *t*-tests or the Mann–Whitney *U*-test as appropriate. Fisher's exact test was used to compare the number of patients who were satisfied with their cosmetic results, the number of patients with thenar muscle wasting, side involvement, and gender distribution. The χ^2-test was used for neurophysiological grades. The difference was considered statistically significant if *P* value was less than 0.05. To compare the different SSS, FSS, pinch grip strength, and static 2PD across the different time periods, Friedman's analyses were carried out. Post-hoc tests were used to compare the scores between a given time period and the one that preceded it. As post-hoc tests were used several times, the significance level was divided by the number of planned comparisons, and each two-sample test was accordingly performed at the reduced level. The Kruskal–Wallis test was used to compare the different scores between the two intervention groups at the different time periods, with Cochran's *Q*-test for success (categorical data).

Results

The average patient age at the time of operation was 40 ± 10 years for group I versus 42 ± 9 years for group II. The median duration of symptoms before surgery was 9 months in group I and 12 months in group II. The median preoperative SSS was 3.18 points in group I and 3.18 points in group II, whereas the mean preoperative FSS was 3 points in group I and 3 points in group II. Wasting of thenar muscles was present in 10 (22.2%) patients in group I and in 14 (31.1%) patients in group II. No statistically significant difference was found between the two groups regarding patient demographics and baseline characteristics ($P > 0.05$), as shown in Table 1. The mean operative time was significantly shorter in group I than in group II (17.5 ± 5 vs. 19.3 ± 3 min; $P = 0.03$). Shifting to open CTR during the primary procedure was not needed in any case in group I.

All patients were available for follow-up from 6 months postoperatively. At 1 year, three patients in group I and two patients in group II were lost to follow-up. All parameters (except the median pinch strength at 1 month) showed progressive postoperative improvement. Significant differences between the median preoperative and 3-month follow-up results were observed in all parameters. Statistical comparison of the median Sensory Index, median SSS, and median FSS showed no significant difference between the groups at any stage of follow-up (Table 2). At 1 month postoperatively, the median pinch strength in group I was significantly better than that in group II ($P = 0.02$).

Table 2 Results of patients included in group I and group II

Points of comparison	Group I	Group II	*P* value
Symptom Severity Scale			
Preoperative	3.18 (3.1–3.36)	3.18 (3–3.36)	0.55
1 month	2.72 (2.5–2.8)*	2.7 (2.6–2.9)*	0.29
3 months	1.55 (1.45–1.68)*	1.54 (1.36–1.72)*	0.79
6 months	1.36 (1.27–1.45)*	1.45 (1.36–1.54)*	0.16
1 year[a]	1.36 (1.27–1.45)	1.36 (1.27–1.45)	0.33
P value	<0.0125	<0.0125	
Functional Status Scale			
Preoperative	3 (2.75–3.06)	3 (2.88–3.13)	0.19
1 month	2.75 (2.63–2.88)	2.75 (2.63–2.88)	0.42
3 months	1.63 (1.5–1.75)	1.5 (1.5–1.75)	0.06
6 months	1.5 (1.31–1.63)	1.5 (1.38–1.63)	0.97
1 year[a]	1.25 (1.25–1.5)	1.38 (1.25–1.5)	0.13
P value	<0.0125	<0.0125	
Sensory Index			
Preoperative	1.83 (1.67–2.0)	2 (1.67–2.33)	0.84
1 month	1.67 (1.33–1.67)*	1.33 (1.33–1.67)*	0.77
3 months	1.33 (1.33–1.33)*	1.33 (1.33–1.33)*	0.54
6 months	1.33 (1–1.33)*	1.33 (1–1.33)*	0.87
1 year[a]	1.17 (1–133)	1.33 (1–1.33)	0.49
P value	<0.0125	<0.0125	
Tip-pinch strength (kg)			
Preoperative	2 (1.8–2.3)	2 (1.8–2.2)	0.31
1 month	2.1 (2–2.35)	1.9 (1.7–2.1)	0.002[§]
3 months	2.3 (2–2.75)*	2.5 (2.28–2.8)*	0.12
6 months	2.7 (2.6–3.1)*	2.9 (2.78–3.15)*	0.07
1 year[a]	2.8 (2.6–3)	3 (2.7–3.2)	0.06
P value	<0.0125	<0.0125	
Patients' satisfaction regarding the cosmetic result	38/45 (86%)	26/45 (58%)	0.009[§]

[a]Three missing patients in group I, and two missing patients in group II, *Significantly different from the preceding time value, [§]Significant difference between the two intervention groups.

At 3 months postoperatively, 38/45 (86%) patients in group I and 26/45 (58%) patients in group II were satisfied with the cosmetic result of the procedure (Fisher's exact test $P = 0.009$, RR = 2.21, 95% CI = 1.13–4.29).

Complications

Surgical site complications were more pronounced in patients in group II (12/45) than in patients in group I (3/45). One patient in group I and five patients in group II complained of tender scars, and one patient in group I and two patients in group II had pillar pain, but all these cases resolved spontaneously within 6 months. Minor wound dehiscence was reported in three patients in group II, which healed on repeated dressings. One superficial wound infection occurred in group I and in two cases in group II, which healed on repeated

dressings. Deep infection was not reported in either group. No complications in the form of neurovascular injury, reflex sympathetic dystrophy, or tendon injury were observed in either group. One case in group I presented with persistent pain due to incomplete CTR. The condition was confirmed by neurophysiological studies, and the patient was successfully treated by open release after 6 months postoperatively (Table 3).

Discussion

In the absence of a gold standard, we used as a control group one of the most commonly used techniques for CTR, which is the 'limited-open' technique. Analysis of the outcomes of the current double-cohort study demonstrates that the mini-open, blind, double-incision technique is as safe and effective as the limited-open method for CTR. It yields good relief from symptoms and improvement in function. It offers several advantages over the open technique, including higher degree of postoperative patient satisfaction with the cosmetic result, fewer surgical site complications and less painful scar, shorter operative time, and earlier restoration of pinch grip strength. This, however, did not translate directly into Levine functional and symptom scores that, at each assessment, differed significantly between the two groups.

Mini-open and endoscopic techniques [6–20] were invented to address the potential complications of open release by using smaller incisions placed, as much as possible, away from the middle of the palm. They provide the same neurologic recovery as does the open technique, plus lower postoperative pain and quicker functional recovery time, making it more helpful to resume normal life activities. Endoscopic techniques are more resource intensive. They need special instruments and require higher degree of surgical skill. Comparative studies showed no significant advantage for endoscopic techniques compared with the more simple and less-expensive mini-open techniques [19–23].

Table 3 Recorded complications in patients included in group I and group II

Complications	Group I	Group II	*P* value[a]
Tender scar	1	5	0.34
Pillar pain	1	2	
Neurovascular injuries	0	0	
Reflex sympathetic dystrophy	0	0	
Minor wound dehiscence	0	3	
superficial wound infection	1	2	
Deep infection	0	0	
Recurrence	0	0	
Revision surgery	1	0	

[a]χ^2-Test was used.

The procedure described in the current study is very simple, not technically demanding, and does not require special equipments. It was executed through two small incisions with minimal soft tissue dissection that led to a smooth postoperative period and minimal morbidity. Two incisions were used to avoid incomplete decompression, which was not reported except in one case in group I (2.2%). The proximal incision allowed the surgeon to directly visualize the proximal edge of the TCL in order to divide its entire thickness. The distal incision lay along the Kaplan's cardinal line, which is a line from the apex of the interdigital fold between the thumb and index finger to the hook of hamate. It represents a landmark for the distal edge of the TCL, and it lies in a safe area about 18 mm proximal to the superficial palmar arch (SPA) [28,29]. The distal incision allowed the surgeon to divide the whole length of the ligament, including the distal holdfast fibers of the TCL, which are found volar to the distal TCL connecting the thenar and hypothenar muscles [30,31]. Moreover, a probe was used to verify complete CTR. A subcutaneous tunnel was formed superficial to the TCL.

It is assumed that preservation of the superficial fascia and adipose tissue over the flexor retinaculum allows faster recovery, less scar tenderness, and less pillar pain. This may be due to preservation of the unmyelinated nervous fibers at the interthenar crease, avoiding formation of microscopic neuromas and subsequent pain after standard CTR [9,10]. However, this assumption does not appear to affect the results of the current study. The exact etiology of pillar pain is not clear. It may be secondary to alteration of the carpal arch structures, edema of the tissues superficial to TCL, injury to the cutaneous branches of the palm, or relaxation of the muscles originating from the TCL [32,33].

No case of neurovascular injury was reported in either group. The technique used in group I does not allow the surgeon to fully visualize all important structures and thus it is expected to carry an increased risk for neurovascular injuries. Structures liable to injury are the palmar cutaneous branch of the median nerve, the SPA, the recurrent motor branches of the median nerve, Berrettini branch, and the ulnar neurovascular structures [34–39]. Although anatomical variations in the vicinity of the carpal tunnel are encountered in about 6% of cases, they are rarely the primary cause for serious injuries [40,41]. In the current study, fixed anatomical landmarks were used to define a safe zone for division of the TCL. The mean distance from the site of ligamentous division to the recurrent motor branches of the median nerve, the SPA, and the palmar cutaneous branch of the median nerve is 5.7, 8.7, and

7.2 mm, respectively [42]. Also, it lies more than 4-mm radial to the radial margin of the hook of the hamate to avoid injury of the ulnar neurovascular structures. Also, ulnar deviation of the wrist was avoided, because it was found to be associated with progressive radial migration of the ulnar neurovascular structures making them prone to injury [43,44].

Although its scope for improvement is limited, the tip-pinch strength assessed by dynamometry using a standardized protocol is considered the most sensitive measure for early motor recovery [45]. It targets the thenar musculature and is therefore more specific to median nerve pathology. Earlier recovery of tip-pinch strength was reported in group I, compared with group II, 1 month postoperatively. This may be due to faster healing and less scar tenderness. Contraction of muscles originating from the TCL would cause pain if tissue healing is incomplete. Also, if the patient had pillar or scar pain or tenderness, the dynamometer handle may produce discomfort. On the other hand, the usefulness of power grip as an indicator of early recovery is questionable. Most of the muscles required for power grip are supplied by the median nerve proximal to the carpal tunnel, the ulnar or radial nerve. Weakness of the muscles affected by CTS may be masked by compensatory action of other synergistic muscles. As with power grip, the key pinch is a complex motor task that may be compensated for by synergistic muscle action or 'trick' movements. Subjective rating of weakness is also included in the SSS of the BCTQ [30].

No consensus exists regarding the best way for neurophysiological diagnosis of CTS. Numerous nerve conduction tests with a wide range of sensitivity and specificity are used. It is recommended that each neurophysiological laboratory should have its own reference values [46]. Median ulnar sensory latency difference appears to have the highest diagnostic accuracy as sensory fibers have a larger proportion of large myelinated fibers, which have a higher energy requirement and are thus more susceptible to ischemic damage [47]. Although neurophysiological studies are not warranted either as a diagnostic test or as a predictive indicator of surgical outcome in cases of clear-cut clinical CTS [48–51], they were used in the current study for medico-legal reasons to preoperatively document the degree of sensory and motor involvement. They were not used for postoperative evaluation except in failed cases (one case in group I). On the basis of the neurophysiological studies, cases were classified into three grades. We used this grading scale to verify the absence of selection bias. No statistically significant difference was found between the two groups regarding the distribution of cases in relation to the neurophysiological grade.

In the current study, a standard follow-up program for a fixed period of time was applied on all patients in both groups. Diabetic patients were excluded because their functional outcome is expected to be worse than the functional outcome of patients with idiopathic CTS, although they have the same probability of positive surgical outcome [52]. Patient-reported measures of health status are crucial to evaluation of different surgical techniques. The use of multiple outcome measures in the literature reflects the lack of consensus regarding the best method of assessment. In the current study, we used the BCTQ [24], which is the most popular outcome measure used in the literature to assess the disability associated with CTS. It is a standardized, disease-specific, patient-based outcome measure that has shown reproducibility, validity, reliability, and responsiveness [53–56]. The SSS concerns severity and frequency of symptoms, whereas the FSS concerns difficulties in performing specified activities.

Although we conducted an a priori power analysis for this study to have an adequate sample size for our primary objective (BCTQ), this study has some limitations. First, being nonrandomized it could have some bias in patient selection, although we tried to avoid this bias by assigning one surgeon to be responsible for one cohort. Second, we are aware that this study concerns only short-term follow-up. Further long-term studies are recommended for assessment of recurrence rate. Also, the sample size was too small to assess the effect of the procedure on pillar pain, which was not one of our primary intentions. Finally, one of the indicators of the success of the procedure is the duration of return to work. It was not measured because most of the female patients were housewives.

Conclusion

Both techniques described in the study led to good, comparable clinical results. However, experience with the mini-open double-incision technique is encouraging. It represents a safe and effective line of management for idiopathic CTS. It yields good relief from pain with improved function and minimal complications. It offers a higher degree of postoperative patient satisfaction regarding the cosmetic result, fewer surgical site complications and less painful scar, shorter operative time, and earlier restoration of strength.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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