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SHORT-TERM RESULTS OF ENDOSCOPIC (OKUTSU METHOD) VERSUS PALMAR INCISION OPEN CARPAL TUNNEL RELEASE: A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL

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Abstract:
Purpose: The surgical techniques widely used in Japan for idiopathic carpal tunnel syndrome (CTS) are the Okutsu method of endoscopic carpal tunnel release (ECTR) and palmar incision for open carpal tunnel release (OCTR). However, no prospective randomized controlled trials (RCTs) have compared treatment outcomes between these two procedures. This RCT compared short-term outcomes between ECTR and OCTR for CTS.

Materials and Methods: Subjects were 101 hands (79 patients) treated in the department. ECTR was performed on 51 hands (40 patients), and OCTR was performed on 50 hands (39 patients). For assessment items, the following patient-based outcomes were evaluated: 1) changes in subjective symptoms; and 2) impairment in activities of daily living. The following items were also evaluated by physicians: 3) abductor pollicis brevis-distal latency (APB-DL); 4) sensation; and 5) muscle strength. All these assessments were made in postoperative weeks 4 and 12.

Results: Recovery of muscle strength at postoperative week 4 was significantly better with ECTR (p<0.05), but no significant differences were identified between groups in any of the other items. The ECTR group showed transient postoperative exacerbation of subjective symptoms in two hands (4%) and of APB-DL in three hands (6%). Comparison of hands with improved and exacerbated postoperative APB-DL in the ECTR group revealed significantly greater preoperative electrophysiological severity in exacerbated hands (p<0.05). The cause of postoperative exacerbation with ECTR was considered to be transient nerve dysfunction resulting from the unique aspects of the ECTR procedure.

Conclusions: Compared with OCTR, ECTR offers superior recovery of muscle strength in the early postoperative period. At the same time, ECTR may carry a risk of transient nerve dysfunction in the early postoperative period. Caution must therefore be exercised when using ECTR for patients with severe electrophysiological findings.

Key words: carpal tunnel syndrome, endoscopic carpal tunnel release, Okutsu procedure, prospective randomized controlled trial, therapeutic results

INTRODUCTION
Minimally invasive techniques have been developed for surgery to treat idiopathic carpal tunnel syndrome (CTS), with the aim of avoiding painful postoperative scarring, transient decreases in mus-
ble strength, and pillar pain, and to help patients return quickly to regular daily activities and work. Since the report by Okutsu et al.\(^1\), endoscopic carpal tunnel release (ECTR) has been widely performed and has become one of the standard minimally invasive techniques in Japan. Open carpal tunnel release (OCTR), involves placing a skin incision only in the palm (palmar incision technique\(^2\)\(^−\)\(^4\)), and has also been widely performed\(^5\). Studies have shown favorable therapeutic results for both of these techniques\(^2\)\(^−\)\(^4\),\(^21\).

A number of prospective randomized controlled trials (RCTs) have been undertaken to compare treatment outcomes between ECTR and OCTR, but most such studies have used the Chow\(^6\) and Agee\(^7\) techniques for ECTR, as these are the most widespread forms of ECTR\(^8\)\(^−\)\(^17\). The results have suggested that, while no differences exist in CTS treatment outcomes with these two ECTR techniques compared with OCTR, the ECTR techniques have the advantage of allowing patients to return to regular daily activities and the workplace within a shorter period, as wound pain and loss of muscle strength are reduced. Those ECTR techniques also have a disadvantage of higher rates of complications, including permanent nerve damage and temporary nerve dysfunction.

No evidence has been presented regarding treatment outcomes with the Okutsu method, which is a commonly used method in Japan, despite this being the first ECTR technique developed in the world. The Okutsu method reportedly offers the advantages of good treatment outcomes with little wound pain\(^21\). In addition, because a good visual field can be ensured with the Okutsu method using a clear outer tube, the advantages of reduced nerve and blood vessel damage compared with the Agee and Chow techniques, both of which use opaque outer tubes, have been emphasized\(^21\). However, occasional reports are also seen of complications from nerve or arterial arch damage from the hook knife used in the Okutsu method\(^22\). Those reports, however, are from studies of the Okutsu method only, or poor-quality retrospective case-control studies, so the level of evidence for the procedure is low. We have found no RCTs comparing treatment outcomes between the Okutsu method and the palmar incision technique that is the current standard for open surgical procedures, so the relative merits of these two surgical procedures remain unclear. The present RCT therefore aimed to compare treatment outcomes with the Okutsu method and a palmar incision technique using a high level of evidence.

**MATERIALS AND METHODS**

**Approval of ethics committee**

We obtained approval for all study protocols from the ethics committee of Fukushima Medical University (approval No. 1151).

**Subjects**

Subjects were 79 patients (101 hands) with CTS treated surgically in our hospital. Patients were selected for CTS according to symptoms such as numbness or nighttime pain, clinical findings such as sensory impairment or muscle weakness, and whether positive results were obtained for Phalen’s test and Tinel’s sign. Nerve conduction velocity tests were used in definitive diagnosis, and CTS was diagnosed in a patient if distal motor latency to the abductor pollicis brevis (APD-DL) was ≥4.5 ms. Patients with injury such as past fracture of the distal radius, inflammatory diseases such as rheumatism, diabetes, cervical radiculopathy, thoracic outlet syndrome, or other peripheral nerve diseases, or who were receiving dialysis, were excluded. Surgery was indicated in patients who had: subjective symptoms; impairment in daily living and work; abductor pollicis brevis-distal latency (APB-DL) ≥6 ms, or APB-DL < 6 ms; and ≥3 months of ineffective conservative therapy, such as oral vitamin B12 and wrist splint. The reasons for and methods of the study were explained to patients, including that selection of the operative procedure would be random. Study subjects were those who provided informed consent to participate after receiving this explanation.

Subjects were assigned to either the ECTR or OCTR group using a random number table in the order in which surgeries were performed. When both hands were affected, each hand was assigned separately. Patients with bilateral CTS who did not agree to undergo a different procedure performed on each hand were excluded from the study. The ECTR group included 40 patients and 51 hands (3 hands in 3 men, 48 hands in 37 women). By age, the largest group was in their 50s (range, 41-82 years; mean age, 59 years). The OCTR group included 39 patients and 50 hands (7 hands in 5 men, 43 hands in 34 women). Again, the largest age group was in their 50 s (range, 28-78 years; mean age, 58 years). No significant differences were identified between groups in terms of age, sex, dis-
ease duration, or preoperative APB-DL (Table 1).

Surgical procedures and postoperative protocol

In both groups, surgery was performed under local anesthesia. In the ECTR group, surgery was performed without a tourniquet according to the methods of Okutsu et al. In the OCTR group, tourniquets were used with all patients and a 3-cm vertical incision was made in the palm (Fig. 1). Surgeries in the ECTR group were performed by two handsurgeons with more than 8 years of clinical experience. The two hand surgeons had performed at least 20 ECTR operations at the start of the RCT. In the OCTR group, surgeries were performed by five residents. They performed the surgeries under the guidance of the two surgeons who operated on the ECTR group. The same protocol for postoperative care was used in both groups. At the completion of surgery, a compression dressing was applied from the palm to the wrist in all patients to stop the bleeding. The compression dressing was removed the following day and an adhesive film was applied to the wound. No wound treatment was performed until the sutures were removed. At 1 week after surgery, the patient came to the hospital and the sutures were removed. All patients took oral anti-inflammatory analgesics for 1 week after surgery. No restrictions were placed on hand use in daily activities or work throughout the entire postoperative period.

Assessment methods

The following five items were assessed to evaluate treatment outcomes. Indicators for patient-based outcomes were: 1) changes in subjective symptoms; and 2) level of impairment in activities of daily living (ADL) (chopstick use, writing, buttoning clothes, holding a book, and holding a telephone receiver). Assessment items used by the physicians were: 3) APB-DL; 4) sensation (according to the Semmes-Weinstein monofilament (SW) test and static two-point discrimination (2PD)); and 5) muscle strength (grip strength, tip pinch strength, and side pinch strength). The following methods were used to assess patient-based outcomes. With regard to outcome assessments, changes in subjective symptoms, such as the severity of numbness and nighttime pain, were classified in three grades (improved, unchanged, and exacerbated) in relation to preoperative condition. Second, to evaluate impairment of ADL, a visual analogue scale (VAS) was used, with the worst condition of inability to perform various ADL rated as 0, and the best condition of feeling no impairment in ADL rated as 100. Patients made a mark on the 100-mm line corresponding to their perceived level of ADL function, and the distance from 0 to their mark was taken.

ECTR group | OCTR group
---|---
Case count | 51 hands in 40 patients | 50 hands in 39 patients
Sex | Men: 3 hands in 3 patients | 7 hands in 5 patients
Women: 48 hands in 37 patients | 43 hands in 34 patients
Age (years) | Youngest: 41 | Youngest: 28
| Oldest: 82 | Oldest: 78
Most common age group | Fifth decade | Fifth decade
Average age (years) | 59 | 58
Average disease duration (months) | 40 | 35
Average APB-DL (ms) | 7.5 | 8.0

No significant difference were identified between two groups in terms of gender, age, disease duration, or preoperative APB-DL.
as the level of ADL impairment. Third, a Nicolet Viking IV electromyograph (Nicolet Biomedical Inc, Madison, WI) was used for measuring APB-DL. The stimulating electrodes were negative electrodes placed 2 cm medial to the distal carpal joint crease of the palmar forearm, and between the flexor carpi radialis muscle and palmaris longus tendon. For recording electrodes, a negative surface electrode was placed in the center of the belly of the abductor pollicis brevis (APB) muscle and a positive electrode was placed at the attachment of the APB tendon to the proximal phalanx. A supramaximal stimulus was used when making measurements. When a waveform could not be detected with the surface recording electrode, a needle electrode was used. In assessing APB-DL, mean values for all cases were used for comparisons between groups. In addition, cases with improved APB-DL compared with the preoperative level were taken to be improved, and those with deterioration of APB-DL were taken to be exacerbated. The proportion of improved and exacerbated cases was compared between groups. Fourth, in assessing sensation, a SW tester (Touch-Test® sensory evaluators; North Coast Medical Inc, San Jose, CA) was used for the SW test, and a 2-point discriminator (Kono Seisakusho, Chiba, Japan) was used for static-2PD. The pad of the middle finger was taken as the measurement site in both groups. Fifth, to assess muscle strength, grip strength was measured using a digital dynamometer (TL110; Toei Light, Saitama, Japan), and tip pinch strength and side pinch strength were measured using a pinch meter (Sakai Medical, Tokyo, Japan). Sensation and muscle strength were measured three times, and the mean value was recorded as the measured value. Of the above assessments, degrees of improvement in ADL impairment, sensation, and muscle strength were defined as the value obtained when the value measured preoperatively was subtracted from the value measured at the time of assessment. Improvement was then compared between groups.

For the assessment of patient-based outcomes, the patients themselves completed the assessment forms. For physician assessments, three physicians who were not involved in the treatment served as examiners and made all measurements. Examiners were not blinded to surgical technique. Postoperative assessments were performed at week 4 and week 12.

Of the outcome indicators, changes in subjective symptoms were determined and APB-DL was measured in all cases. Because ADL impairment, sensation and muscle strength were measured starting in the second half of the study, these values were measured for 58 hands in 47 patients. In the ECTR group, surgery was performed on 27 hands in 22 patients (1 hand in 1 man and 26 hands in 21 women; range, 43–78 years; mean, 63 years). In the OCTR group, surgery was performed on 31 hands in 25 patients (6 hands in 4 men and 25 hands in 21 women; range, 28–78 years; mean, 60 years). Between these two groups, no significant differences were seen in age, sex, disease duration or preoperative APB-DL.

Furthermore, the ratios of patients in whom subjective symptoms and electrophysiological findings exacerbated postoperatively were compared between groups. In exacerbated cases, assessments were performed in postoperative months 6 and 12 to observe postoperative courses and determine the clinical course of postoperative complications.

Statistical analysis

The Mann-Whitney test, Student’s t-test, and $\chi^2$ test were used for statistical analyses. The level of significance was set at $p<0.05$.

RESULTS

Withdrawal rate and intention-to-treat (ITT) analysis

Endoscopic surgery could not be performed on 1 hand in 1 patient from the ECTR group, and this patient was withdrawn. The withdrawal rate for the study was thus 1% (1/101 hands). At the time
of data assessment, each of the two groups thus included 50 hands. In the patient for whom ECTR could not be performed, the muscle belly of the flexor digitorum superficialis was inside the carpal tunnel, rendering insertion of the outer tube impossible. The withdrawn case was excluded from the ECTR group for assessment purposes and was excluded from ITT analysis (initial grouping).

Assessments of outcome indicators

1) Changes in subjective symptoms (Fig. 2)

At postoperative week 12, the rate of improved cases tended to be higher for the OCTR group than for the ECTR group ($p=0.08$), but no significant difference was seen between groups at any time points. In other words, within 12 weeks of surgery, no significant differences were evident in terms of
improvement in subjective symptoms between ECTR and OCTR. However, for the ECTR group, subjective symptoms were exacerbated in 2 hands (4%) at postoperative week 4 and in 1 hand (2%) at postoperative week 12. For the OCTR group, subjective symptoms were not exacerbated in any patients.

2) Degree of improvement in ADL impairment (Figs. 3a, b)

No significant differences were seen between groups in the degree of improvement in chopstick usage, writing, buttoning clothes, holding a book or holding a telephone receiver in postoperative weeks 4 or 12. In other words, within 12 weeks of surgery, no marked differences were seen in the degree of improvement in ADL impairment between ECTR and OCTR.

3) APB-DL

Cases in which APB-DL could not be assessed because waveforms could not be detected either pre- or postoperatively because of high-level atrophy were excluded from analysis. At postoperative week 4, 4 hands in the ECTR group and 3 hands in the OCTR group were unassessable. At postoperative week 12, 3 hands in both groups were unassessable. No significant difference in the percentage of unassessable cases was seen between groups.

No significant differences were seen in mean APB-DL at postoperative weeks 4 and 12 (Fig. 4a). In the ratios of improved and exacerbated APB-DL cases (Fig. 4b), at postoperative week 4, the ratio of improved cases for the OCTR group tended to be higher when compared to the ECTR group (p=0.08), but no significant differences were seen between the two groups at any time points after surgery. In other words, no marked differences were identified in short-term therapeutic results between ECTR and OCTR in terms of electrophysiological findings. However, exacerbation of APB-DL was seen in 3 hands (6%) at postoperative week 4 and in 1 hand (2%) at postoperative week 12.

<table>
<thead>
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<th>Table 2. APB-DL : comparison of improved and exacerbated cases</th>
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<td>Surgery</td>
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<tr>
<td>-------------------------</td>
</tr>
<tr>
<td>ECTR</td>
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<tr>
<td></td>
</tr>
<tr>
<td>Total (46)</td>
</tr>
<tr>
<td>OCTR</td>
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*p=0.08, **p=0.14, †p=0.004

APB-DL : Motor nerve distal latency of the abductor pollicis brevis.

Cases in whom waveforms could not be measured before and after surgery were excluded. Among the exacerbated cases in the ECTR group, the preoperative APB-DL for the exacerbated cases was significantly greater when compared to the improved cases(†).
week 12 in the ECTR group. When comparing improved and exacerbated APB-DL cases in the ECTR group (Table 2), preoperative APB-DL for the exacerbated cases was significantly greater ($p<0.05$). In addition, mean age for the exacerbated cases tended to be high ($p=0.08$), but no significant differences were apparent. In other words, ECTR on electrophysiologically severe cases was associated with an elevated risk of exacerbating nerve function postoperatively.

4) Degree of improvement in sensation

No significant difference was seen in the two sensation tests, the SW test (Fig. 5a) and static-2PD (Fig. 5b), at postoperative weeks 4 and 12. In other words, within 12 weeks of surgery, no marked differences were evident in the degree of improvement in sensation between ECTR and OCTR.

5) Degree of improvement in muscle strength

With regard to grip strength (Fig. 6a), the degree of decrease in postoperative grip strength at postoperative week 4 was significantly lower for the ECTR group than for the OCTR group ($p<0.05$). However, at postoperative week 12, no significant differences were seen between groups. With regard to tip pinch strength (Fig. 6b), the degree of improvement at postoperative week 12 tended to be higher for the ECTR group than for the OCTR group ($p=0.09$), but no significant differences were seen at any postoperative time points. With regard to side pinch strength (Fig. 6c), the degree of improvement at postoperative week 4 was significantly higher for the ECTR group than for the OCTR group ($p<0.05$). In addition, the degree of improvement at postoperative week 12 tended to be higher for the ECTR group than for the OCTR group ($p=0.07$). In other words, the degree of improvement in grip strength and side pinch strength during the early postoperative period was greater for the ECTR group than for the OCTR group.

6) Long-term course of postoperatively exacerbated cases for the ECTR group (Tables 3a, b)

Subjective symptoms and APB-DL exacerbated only for the ECTR group, and the long-term clinical course was analyzed for exacerbated cases. In one of the 2 patients in whom subjective symptoms were exacerbated, numbness and desensitization persisted on the ulnar side of the middle finger and the radial side of the ring finger at postoperative month 12 (Table 3a ; Case 1). These exacerbations were thought to represent common digital nerve injury caused by a hook knife. In the other patient in whom subjective symptoms and APB-DL were exacerbated (Table 3a ; Case 2) or in the 2 patients in whom only APB-DL was exacerbated (Table 3b ; Cases 3 and 4), subjective symptoms and APB-DL were improved at postoperative month 6 when compared to before surgery. These findings suggest that the cause of exacerbation was transient nerve dysfunction.
The Okutsu method is an ECTR technique developed in Japan, and the treatment outcomes are reportedly exceptional\(^{21}\). However, no RCTs have compared outcomes between the Okutsu method and OCTR, although a number of RCTs have compared outcomes between the Chow\(^7\) or Agee\(^7\) techniques and open-release methods\(^8\). Among these are nine reports comparing these techniques with OCTR performed without using special instruments, with short incisions using palmar or palm and forearm incisions\(^9\text{−}17\). Of these nine RTCs, only one\(^14\) reported significantly better improvements in subjective symptoms of numbness, nighttime pain, and skilled activity with ECTR. The other eight studies found no difference between groups\(^9\text{−}13,15\text{−}17\). Five of the reports\(^9,13,14,16,17\) described improvements in sensation, but no significant differences were seen in any of the studies. Three reports\(^9,10,16\) described electrophysiological findings, also without any significant difference. With regard to improvements in muscle strength, four\(^10\text{−}12,14\) of nine reports on grip strength, two\(^10,14\) of four reports on tip pinch strength, and four\(^9,10,12,14\) of six reports on side pinch strength reported greater improvements with

Fig. 6. Degree of improvement in muscle strength.

\textbf{a)} Degree of improvement in grip strength

Degree of improvement = postoperative grip strength − preoperative grip strength

At postoperative week 4, the degree of decrease in grip strength was significantly lower for the ECTR group \((p<0.05)\).

\textbf{b)} Degree of improvement in tip pinch strength

Degree of improvement = postoperative tip pinch strength − preoperative tip pinch strength

No significant differences were seen between groups.

\textbf{c)} Degree of improvement in side pinch strength

Degree of improvement = postoperative side pinch strength − preoperative side pinch strength

At postoperative week 4, the degree of improvement was significantly greater for the ECTR group than for the OCTR group \((p<0.05)\).
ECTR. These results suggest that while no difference exists between ECTR and small incision methods in terms of improved subjective symptoms, sensation, or electrophysiological findings, recovery of muscle strength is superior with ECTR. The present study showed no difference in changes for subjective symptoms, improvement in ADL impairment, APB-DL, or improvement in sensation, but results of muscle strength tests for grip strength and side pinch strength were superior at postoperative week 4 in the ECTR group. Treatment outcomes with the Okutsu method may be considered very similar to those with the Chow and Agee methods, with no difference in short incision methods for subjective symptoms, ADL, electrophysiological findings, or level of improvement in sensation. However, muscle strength improvements in the early postoperative period appear superior to those with short incision methods.

Better muscle strength recovery in the early postoperative period with ECTR appears attributable, first, to the influence of wound pain with OCTR. Among RCTS comparing ECTR and small incision methods, four of seven studies describing wound pain reported significantly milder wound pain with ECTR. A second factor is the influence of the surgical procedure in OCTR on the thenar muscle. Trumble et al. suggested that the reason for the superior recovery of muscle strength with ECTR compared with OCTR is that less damage is incurred from the spread of soft tissue near the origin of the thenar muscle. In our OCTR procedure, all shallow tissue starting with the flexor retinaculum was cut, including subcutaneous tissue and the palmar aponeurosis. Therefore, in the short period up to 12 weeks postoperatively, movement of the thenar muscle attachment, surrounding hematoma, and inflammatory changes strongly affect outcomes, and the thenar muscle is very likely to be weaker than with ECTR.

The transient postoperative nerve dysfunction seen in the ECTR group was attributed to surgical manipulation when inserting the outer tube into the carpal tunnel, within which pressure is already elevated from the CTS. This procedure during ECTR increases pressure in the carpal tunnel tremendously compared with OCTR, and is thought to be a cause of the postoperative transient nerve dysfunction. Lundborg et al. reported electrophysiological findings for the median nerve when pressure was applied continuously to the carpal tunnel in healthy people. They indicated that both time and pressure are involved in the onset of nerve dysfunction. In median nerves impaired by CTS, the time and pressure needed to exacerbate nerve dysfunction is unclear. However, the present study demonstrated that ECTR cases in which APB-DL was exacerbated showed significantly poorer preoperative electrophysiological findings than cases in which APB-DL was improved. This suggests that

Table 3. Long-term course of postoperatively exacerbated cases for the ECTR group

<table>
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<tr>
<th>Case</th>
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<th>Week 4</th>
<th>Week 12</th>
<th>Month 6</th>
<th>Month 12</th>
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<tbody>
<tr>
<td>1</td>
<td>Exacerbated</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Exacerbated</td>
<td></td>
<td>Improved</td>
<td>Improved</td>
<td>Improved</td>
</tr>
</tbody>
</table>

The cause of exacerbation in Case 1 was thought to be common digital nerve injury by a hook knife.
In Case 2, improvements were seen after postoperative week 12.

b) Shifts in APB-DL for the exacerbated APB-DL cases

<table>
<thead>
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<th>Case</th>
<th>Preoperative</th>
<th>Postoperative assessment period</th>
<th>Week 4</th>
<th>Week 12</th>
<th>Month 6</th>
<th>Month 12</th>
</tr>
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<tbody>
<tr>
<td>2</td>
<td>9.7 no response</td>
<td>10.3</td>
<td>5.6</td>
<td>4.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>14.7 no response</td>
<td>9.7</td>
<td>6.1</td>
<td>5.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>10.3 no response</td>
<td>8.1</td>
<td>5.6</td>
<td>5.0</td>
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</tr>
</tbody>
</table>

APB-DL: Motor nerve distal latency of the abductor pollicis brevis.
In all cases, APB-DL improved over preoperative values from 12 weeks to 6 months after surgery.
in severe CTS, the median nerve is more vulnerable, and that compared with healthy people, nerve dysfunction may increase even with low pressure and a relatively short duration of compression. Based on the above results, as a general rule, we currently perform OCTR on patients with preoperative APB-DL ≥10 ms.

This study demonstrates that exacerbation with the Okutsu method takes the form of transient nerve dysfunction that resolves within 6 months postoperatively. However, such damage does not occur in palmar incision methods. As CTS is frequently seen in routine care, all orthopedic surgeons need to be able to safely and reliably treat CTS. Furthermore, the ultimate objective of carpal tunnel release is to improve median nerve damage, and it is imperative to avoid exacerbating nerve damage by concentrating too much on minimizing surgical invasiveness. Based on the results of our RCT, caution must be exercised when performing ECTR on patients with severe CTS.

REFERENCES