

SURGICAL TREATMENT OF CARPAL TUNNEL SYNDROME: A RANDOMIZED STUDY

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SUMMARY

This paper aims to evaluate, by means of a randomized prospective clinical study, two distinct groups divided according to the surgical methodology applied. The first group (group A) was treated by endoscopic operation and the second (group B) one by open access. We evaluated 55 patients (57 wrists), 32 (56.0%) females and 25 (44.0%) males. The sample was composed by 36 (65.5%) Caucasian, 17 (30.9%) black and 2 (3.63%) Asian patients. The mean age was 34.75 years (minimum of 24 y.o. and maximum of 76 y.o.). Group A was composed by 30 (52.63%) wrists and group B by 27 (47.36%). All the patients were pre- and postoperatively evaluated at 1, 2, 4, 6 and 12 weeks after surgery and the following parameters were considered: thenar muscle

trophism, pain (analogical scale), sensibility with Semmes-Weinstein monofilament, grip strength and finger pinch (with Jamar dynamometer). We did not find significant statistical differences regarding side, dominance, hypotrophy, pain and strength. The non-parametric Mann-Whitney's test ($p = 0.0178$) showed that the group of patients submitted to endoscopic operation were able to resume professional the activities. Our study did not evidence, at the end of statistical analysis, statistically significant differences comparing the both methods of surgical treatment.

Keywords: *Carpal tunnel syndrome; Prospective studies; Postoperative care.*

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INTRODUCTION

Statistical data evidence that carpal tunnel release is the surgical procedure most frequently performed by Hand Surgery experts in the USA, and this nosologic entity affects about 1% of the American population⁽¹⁾.

Surgical treatment is usually indicated to patients with affections rated as moderate or severe, and consists of sectioning carpal cross-sectional ligament (CCSL), which may be performed by endoscopy or open surgery, promoting volume increase of the carpal channel and reducing pressure over median nerve.

Several surgical techniques have been described, determining a number of discussions about which method is the most effective one.

As there is no consensus so far about the best method of surgical decompression refused by a scarce amount of research based on results of randomized clinical trials, the best therapeutic option still remains unclear.

As a result of the observation of different and contradictory opinions about the therapeutic approach to CTS, we decided to prospectively study and compare surgical outcomes with the use of two different techniques aiming to clarify, by means of statistical analysis of pre- and postoperative clinical variables (thenar muscle trophism, pain, tactile sensitivity, grip strength and finger pinch) which surgical treatment technique provides the best results.

MATERIALS AND METHODS

First of all, this study was submitted to the Committee on Medical and Research Ethics for appreciation and approval.

Subsequently, informed consent terms were prepared for each patient enrolled.

This was a Randomized Prospective Clinical Trial. Fifty-five patients (57 wrists) were assessed, being 32 (56.0%) females and 25 (44.0%) males. Sample was constituted of 36 (65.5%) Caucasian, 17 (30.90%) African-American, and 2 (3.63%) Asian patients. Mean age was 34.75 years (range: 24 - 76 years).

Patients with clinical and electroneuromyographic diagnosis of CTS have been enrolled in the study, and were initially submitted to conservative treatment, either with the use of orthosis or plastered immobilization, and with the use of non-steroidal anti-inflammatory drugs and physical therapy for at least two months, ultimately presenting no favorable outcome. All patients complained about nighttime pain and dropping things off hands, and they also presented with positive Tinel's and Phalen's tests. Patients with vascular-nervous changes at the affected limb (resulting from trauma or secondary to systemic disease) or those previously submitted to surgical procedures on the area to be addressed at the region corresponding to carpal tunnel.

Randomization process was performed by assessing the last hospital general registration number on each patient's medical files. Those showing EVEN numbers at the last digit were included in group A and those with an ODD number were grouped in group B (Table 1). Differentiation by groups was determined by surgical methodology employed, being the first group composed by 30 (52.63%) wrists of patients aged in average 35.6 years (range: 24 - 76 years) and those were submitted to surgical treatment by endoscopic ap-

Study conducted at the Fractures, Orthopaedics and Rehabilitation Institute (IFOR).

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proach. Group B was composed by 27 (47.36%) wrists of patients aged 33.9 in average (range: 26 - 59 years) and the treatment provided was open surgery.

Patients from both groups were assessed at baseline and after 1, 2, 4, 6 and 12 weeks postoperatively, with the following parameters being investigated: thenar muscle trophism, pain scale, sensitivity with Semmes-Weinstein's monofilament, grip strength and finger pinch strength.

Concerning thenar muscles trophism, the patients were classified into two groups (with and without hypotrophy) (Table 2), and submitted to pain evaluation, using an analogous scale, hand grip and finger pinch strength assessment (as kgf) with the aid of a Jamar dynamometer. Sensitivity was tested using Semmes-Weinstein's monofilaments applied on forefinger's pulp.

Distribution of Patients

Kind of Surgery	Ferquency	Percentage
Arthroscopic	30	52.6%
Open	27	47.4%

Table 1 - Distribution of patients according to employed surgical methodology.

Distribution by thenar hypotrophy presence

Thenar hypotrophy	Frequency	Percentage
Yes	6	10.5%
No	51	89.5%

Table 2 - Distribution by thenar hypotrophy presence or absence.

ENDOSCOPIC SURGERY TECHNIQUE

Under Bier's regional blockage's effect, we performed a cross-sectional incision of approximately 2 cm at volar region of the wrist, at fourth chirodactyl's axis in extension, between ulnar flexor tendon of the carpus and the long palmar. A dissection by planes was performed up to the antebrachial palmar fascia, with "U"-shaped distal opening followed by the introduction of a retractor, hamate probe, and, lastly, the cannula containing an optical system and the blade for releasing the carpal cross-sectional ligament. Finally, tissues were closed by planes and an antebrachio-palmar immobilization was applied to the wrist, which was kept for a period of two days, when physical therapy sessions could be initiated.

SURGICAL TECHNIQUE THROUGH OPEN VIEW (MINI-OPEN)

A palmar longitudinal incision and in parallel to thenar fold, of about 5 mm, ulnar to interthenar hollow, without reaching into wrist's flexion fold and Kaplan's line distally is performed, followed by tissue dissection by planes and introduction of tentacannula under carpal cross-sectional ligament and by its section. The following steps were: skin closure, immobilization with anterobrachiopalmar device at 20° of extension, also for two days. Postoperative follow-up followed the same procedures applied to patients from Group A.

STATISTICAL METHOD

Initially, all variables were descriptively analyzed by a professional Medical Statistician. For quantitative variables, this analysis was made by observing minimum and maximum values and by calculating averages, standard devia-

tions and medians. For qualitative variables, we calculated absolute and relative frequencies.

For comparing both groups for averages, the Student's t test was employed⁽²⁾. When data normality hypothesis was ruled out, the Mann-Whitney's non-parametric test was used⁽²⁾.

In order to test groups homogeneity against proportions, the chi-squared test⁽²⁾ or the Fisher's exact test (recommended when occurring expected frequencies below 5) were employed⁽²⁾.

In order to check for groups behavior, considering the conditions studied, we applied the Variance Analysis with repeated measurements technique⁽³⁾ which consists of adjusting a multivariate linear model from which the following hypotheses were tested:

H_{01} : the average response profiles corresponding to the groups are parallel, meaning that there is no interaction between group factor (Open or Endoscopic surgery) and evaluation condition factor (baseline, 1, 2, 4, 6 and 12 weeks). H_{02} : the average response profiles are coincident, meaning that there is no group factor effect. H_{03} : the average response profiles are parallel to the abscissas' axis, meaning that there is no evaluation condition factor effect. Hypotheses H_{02} and H_{03} were only tested when H_{01} was not ruled out, and the Wilks' statistics with approximation to F statistics was used when testing these hypotheses.

For all analyses, the significance level adopted was 5%.

RESULTS

Tables 3 and 4 show the distributions for operated and dominant limbs.

Table 5 shows the distribution of patients according to preoperative sensitivity and after 1, 2, 3, 4, 6 and 12 weeks postoperatively.

Distribution by dominant side

Dominant limb	Frequency	Percentage
Right	49	89.1%
Left	6	10.9%

Table 3 - Distribution of limbs regarding side and dominance.

Distribution according to operated side

Operated limb	Frequency	Percentage
Right	30	52.6%
Left	27	47.4%

Table 4 - Distribution of limbs according to side and dominance.

All variables above were compared to the kind of surgery performed; however, none presented a significant statistical difference.

Table 6 was provided intending to demonstrate the distribution of patients according to the kind of surgery and time to resume professional activities. The Mann-Whitney's non-parametric test ($p = 0.0178$) evidenced that the group of patients operated on by open approach showed significantly higher values than those treated by endoscopic approach. That is, the latter could resume their professional activities earlier.

Graph 1 shows the results for preoperative and postoperative grip strength assessments. Regarding grip strength,

Postoperative Sensitivity Distribution

Sensitivity	Group 1	Group 2	Percentage
1st week			
Red	16	14	52.6%
Violet	8	7	26.3%
Blue	6	6	21.1%
2nd week			
Red	7	4	19.3%
Violet	10	11	36.8%
Blue	13	12	43.9%
4th week			
Red	1	1	3.5%
Violet	9	7	28.1%
Blue	14	14	49.1%
Green	6	5	19.3%
6th week			
Violet	8	6	24.6%
Blue	15	14	50.9%
Green	7	7	24.6%
12th week			
Violet	3	4	12.3%
Blue	9	8	57.9%
Green	18	15	276.8%

Table 5 - Distribution of patients according to preoperative sensitivity and after 1, 2, 3, 4, 6 and 12 weeks postoperatively.

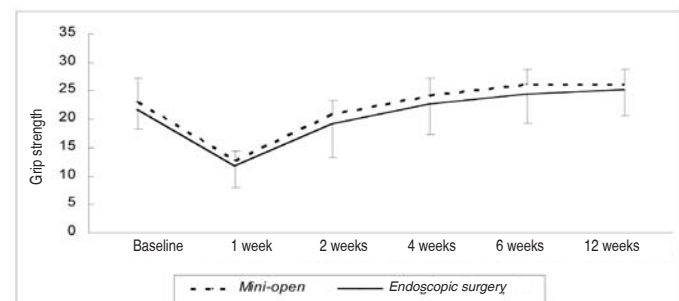
we noticed an important and expected decrease between baseline and the first postoperative assessment (1st week). In the following assessments, strength improvement was noticeable, reaching to values that are equivalent to the existent ones before the surgery at around the 4th and 6th week (3rd and 4th assessments). However, there was no significant difference between groups A and B.

Graph 2 shows the results for pre-and postoperative grip strength assessments. The pinch strength showed a similar evolution. The results for the first postoperative assessment were inferior to baseline. However, from the second postoperative assessment on, the results were found to be close to baseline, and being superior to those as early as the third postoperative assessment. We noticed that group B showed significantly higher averages than those of group A in all time points.

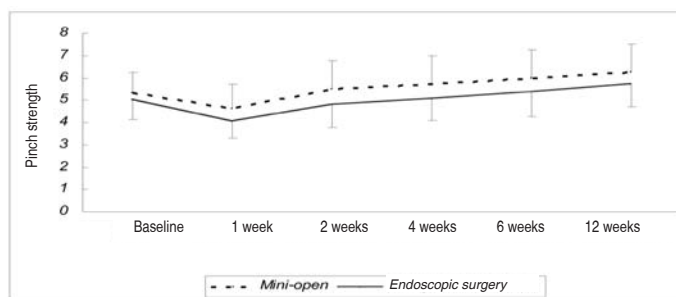
Distribution of Postoperative Complications

Complications	Frequency	Percentage
Neuropraxis	07	12.3%
None	47	82.5%
Re-operated	03	5.2%

Table 6 - Distribution of patients according to surgical complications.



Graph 1 - Pre- and postoperative grip strength assessments.



Graph 2 - Pre- and postoperative pinch strength assessments.

DISCUSSION

This study called our interests due to the existence of a number of studies in literature reporting authors' experiences; however, we noticed that there is no consensus yet regarding the best method for surgical decompression, which, today, exalt endoscopic techniques.

Treating CTS represents a challenge for healthcare professionals who are still searching for an efficient solution to this problem. Several therapeutic methodologies have been suggested when we refer to various authors in literature.

Concerning surgical treatment, there is a consensus towards recommending it only when conservative therapies lead to no efficient outcomes, being saved, most of the times, for moderate and severe cases⁽⁴⁾.

The attempt to find a safe and efficient method for patients with CTS may be established by statistical data confirming that carpal tunnel release is the most frequently performed surgery in the United States. It is estimated that two thirds of the costs incurred to Hand Surgery specialty are associated to the length of time in which patients remain as functionally disabled, according to Kelsey⁽⁵⁾. In Brazil, there are no available statistical data that could reflect our reality.

The approach to be adopted for CTS treatment should be fixing the causative agent of nerve compression. It is important to emphasize that the selection of the kind of treatment may be influenced by many factors, such as age, symptoms duration, occupation, severity of clinical and electromyographic signs, previous treatments provided, and opportunity to switch from a professional activity⁽⁶⁾.

The diagnostic criteria used in our research were similar for both groups. All patients in the study showed classical clinical symptoms, and condition confirmation and grading was performed with the aid of electroneuromyography, which in terms of therapy approach selected, is the best diagnostic option, involving the study of median nerve conduction by carpal cross-sectional ligament. The characteristic abnormality found is the local reduction of speed conduction on distal, motor and sensitive fibers, with or without reduction of the action potential range of the median nerve.

Aiming to compare the various existing surgical techniques, many authors conducted researches intending to elucidate polemics reporting the benefits and drawbacks of each approach⁽⁷⁾. Many of them simply described particular modifications on instruments or access ports⁽⁸⁾.

Due to the different and contradictory opinions about the best therapeutic approach to CTS, we decided to study two specific surgical techniques in a prospective and random-

ized way, comparatively assessing its outcomes. Initially, in our case series, we didn't find statistically significant differences preoperatively, namely: age, gender, pathology duration, pain analogous scale, grip and pinch strength, sensitivity and postoperative follow-up time. Therefore, both studied groups were regarded as similar and appropriate for comparison.

We selected as endoscopic technique the decompression method by means of a proximal port, as recommended by Agee⁽⁹⁾, as described in our methodology, especially because of the factors related to this method's safety, reinforced by other authors' precepts. In our opinion, methods addressing the carpal cross-sectional ligament from proximal to distal determine a considerable risk of damage to the anatomical structures distal to that one.

The fast resolution of paresthesia as a symptom in all patients from both groups soon after surgical release is, in our opinion, consistent to the statement by Lundborg⁽¹⁰⁾, who correlates this complaint to median nerve ischemia, which is solved by surgery. We also found the same results in our study.

For pain assessment, we applied the visual analogous scale at baseline and on the 12th week postoperatively for all patients. Although this is a subjective method, we noticed a significant lower level of pain in patients operated on by endoscopy, verifying a higher level of satisfaction among these patients at therapy completion. Nevertheless, during the early postoperative period, we found a considerable reduction of pain in individuals from both groups.

Performing repeated movements of wrist flexion and extension, combined with limiting CT space and reduced elasticity of the carpal cross-sectional ligament produce higher pressure to this region, resulting in a stronger compression on median nerve. A normal carpal tunnel pressure is approximately 2 mmHg with wrist at neutral position⁽¹¹⁾. However, there are other factors that may cause its raise, such as the recognition of: trauma, synovial cyst, rheumatoid arthritis, gutta, thumb abductor hypertrophy, pregnancy, hypothyroidism and acromegalia, infections, amyloidosis.

This condition is most prevalent in individuals whose occupations involve frequent manual daily tasks, with a trend towards relating it to the work environment. It is estimated that its prevalence reaches approximately 1% of the overall population and between 5% and 15% among employees of high-risk industries because of the repeated use of wrist flexion and extension, strong hand grip and incorrect wrist flexion at heavy-duty machinery or hand-held tools handling. This prevalence is 9.2% for women and 0.6% for men⁽⁶⁾. A similar rate was found in our study.

All the exposed factors must be considered, and they are very important, because a successfully applied therapy also depends on understanding and controlling these variables. The resulting grip and pinch strength loss after CTS decompression is a common finding. This can be explained by several factors, such as: pain at surgical wound, adherence secondary to hematoma, volar sub-dislocation of the flexor tendons⁽¹²⁾. Our study constituted of observing the time to resume professional activities, at least to preoperative levels, and above. We found that the group submitted to endoscopic surgery showed a significantly early recovery of these levels of strength. We believe that the reduced dissection of subcutaneous cell tissue and the avoidance of palmar fascia opening (which is performed in open surgeries) may have contributed to the early recovery of grip and pinch strength levels. These parameters are more frequently analyzed when we want patients to return to their professional activities. Our research did not evidence statistically significant difference between both surgical treatment methods after a long period of outpatient-based follow-up.

With the aid of Semmes-Weinstein's monofilaments, we found that, at baseline, the patients from both groups presented with a reduced protective sensitivity, but they did recover later in time, although remaining with a subtle reduction of tactile sensitivity.

Zumiotti⁽¹³⁾ had already warned that although CTS treatment seems to be easy to perform, median nerve decompression can lead to difficult-to-solve complications. In our study, no peroperative complication was reported. Neuropraxis was reported for 4 patients in endoscopy group and 3 patients developed this complication in the group of open surgery. Two patients were submitted to a new surgical procedure due to recurrence of symptoms during the first postoperative year when operated by open surgery and only one when endoscopy was used.

In general, medical-scientific literature reports endoscopic surgery's superiority over open surgery in terms of complications and early return to professional activities. Patients operated on by endoscopy resumed their activities 14 days following surgery, and the patients submitted to the open surgery took 28 days to resume activities postoperatively. In this very study, we emphasized some drawbacks of the endoscopic treatment, especially highlighting its high cost compared to open procedures⁽¹⁴⁾. Overall, in our research, we did not find statistically significant difference at the end of the analysis of the variables when we compared both treatment methodologies, except for return to professional activities, which, for patients operated on with the endoscopic technique, was earlier.

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