SCIENTIFIC ARTICLE

A Prospective, Randomized Trial of Splinting After Minicarpal Tunnel Release

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Purpose To determine if any significant differences exist in patient-reported or clinical outcomes among 3 different postoperative orthotic regimens: no orthosis, removable orthosis, and plaster nonremovable orthosis—following miniopen carpal tunnel release (CTR) surgery for symptomatic isolated carpal tunnel syndrome.

Methods A total of 249 patients received a miniopen CTR and were subsequently randomized into 1 of 3 orthotic regimens: 80, no orthosis; 83, removable orthosis; and 86, nonremovable orthosis—to be removed at the first postoperative visit 10 to 14 days later. Patient-reported outcomes included the quick Disabilities of the Arm, Shoulder, and Hand (*Quick*DASH) surveys, Levine-Katz Symptom Severity and Functional Status Scales, and Pain at Rest and in Action using the Numerical Pain Rating Scale. Clinical outcomes included wrist range of motion, grip, and lateral pinch strengths. All outcomes were evaluated bilaterally at 10 to 14 days, 6 weeks, and 3, 6, and 12 months after surgery by evaluators blinded to the assigned regimen. Demographic information was obtained before surgery, and complications were recorded throughout the study.

Results There were no statistically significant differences in any patient-reported or clinical outcomes at any follow-up period except at 6 and 12 months: the lateral pinch strength of the nonremovable orthosis group with CTR in the dominant hand was weaker than both of the other groups. Patient demographic characteristics did not significantly influence the outcomes at any time. Scar tenderness was the most commonly observed complication followed by stiffness. There were 2 cases each of complex regional pain syndrome and superficial wound dehiscence and 1 case of wound infection that resolved with oral antibiotics.

Conclusions The postoperative orthotic regimen does not change any patient-reported outcome up to at least 12 months following miniopen CTR. Lateral pinch strength was weaker in the nonremovable orthosis group at 6 and 12 months. Our data do not support the use of any postoperative orthosis following routine miniopen CTR. *(J Hand Surg Am. 2018;■(■):■−■.*

Type of study/level of evidence Therapeutic I.

Key words Carpal tunnel syndrome (CTS), carpal tunnel release (CTR), postoperative orthosis, postoperative dressing.

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Carpal tunnel syndrome (CTS) is the most frequently encountered compressive neuropathy. Decompression of the carpal tunnel is 1 of the most commonly performed procedures in the United States, currently being performed over 300,000 times per year and increasing.[1,2] Open release of the carpal tunnel is a well-accepted treatment for this condition.[3] Following surgical decompression, the use of a postoperative orthosis was once commonplace.[4] Although the number of operating hand surgeons who routinely apply some form of postoperative orthosis is declining, there is some evidence to suggest that this practice still exists to a considerable degree.[5,6]

Advocates of postoperative orthotics propose theoretical advantages including prevention of flexor tendon bowstringing, prevention of nerve subluxation and prolapse into the healing wound, reduction of immediate postoperative pain, and lower rates of wound-healing complications and symptom recurrence.[7–10] Those who do not use orthotics believe they cause unnecessary morbidity and slow recovery and can increase time to return to work.[11]

Randomized controlled studies comparing orthosis fabrication to the use of no orthosis after surgery have been performed before and have failed to show any benefit to orthotics.[8,9,11–14] Three English-language systematic reviews published in the last 6 years address postoperative management of carpal tunnel release (CTR).[15–18] The most recent and comprehensive review, performed by Peters et al in 2013,[18] concluded that more high-quality trials were needed to assess the effectiveness and safety of postoperative interventions, including orthotics.

Given the degree of variability that still exists among surgeons and the call for more high-quality trials, we endeavored to provide further data on the issue through a prospective, randomized controlled trial of substantial size and follow-up and that directly compares 3 of the most common orthotic regimens used today. The purpose of this study was to determine if any significant differences exist in patient-reported or clinical outcomes among these 3 different orthotic regimens—no orthosis, removable orthosis, and plaster nonremovable orthosis—at various follow-up periods in the short and long term. Our hypothesis was that there is no benefit to orthosis usage at any follow-up period, including at 1 year after surgery.

METHODS

This study was conducted at a single center. Patients were continuously enrolled from December 2010 to January 2015. Patients were required to have failed at least 6 months of nonsurgical treatment for symptomatic, isolated CTS. The CTS was confirmed by electrodiagnostic testing. A total of 251 patients met the inclusion criteria. Patients who presented with acute-onset CTS, concomitant peripheral neuropathy, a history of metabolic disease, postoperative recurring CTS, symptoms of ipsilateral basilar joint arthritis, or who required another operation during CTR were excluded. No patients had nerve conduction or electromyography evidence of peripheral neuropathy, cervical radiculopathy, proximal areas of median nerve compression, or cubital or ulnar tunnel syndrome. Two patients identified for the study did not proceed with CTR, leaving 249 patients enrolled.

Patients were treated by 1 of 4 fellowship-trained hand surgeons (B.J.B., E.G.S., K.J.K., B.J.F.). An *a priori* power analysis using the Quick Disabilities of the Arm, Shoulder, and Hand (*Quick*DASH) score 1 year after surgery as the primary outcome was performed using a minimal clinically important difference (MCID) score of 15.9 as previously described in the literature.[19,20] A minimum sample size of 45 subjects per group was proposed to give the study statistical power of 80% and the ability to detect both an MCID in the primary outcome and an effect size of 0.6 SDs for secondary outcomes when using a 2-tailed test with P value of less than .05. The study proceeded well beyond the target number of subjects to account for an unpredictable number of patients lost to follow-up at 1-year time. The study was ultimately discontinued owing to resource constraints after 4 years. All institutional review board–approved protocols were followed; all patients signed appropriate consent forms. This study was carried out in accordance with the World Medical Association Declaration of Helsinki (2008 revision) and the guidelines of the Consolidated Standards of Reporting Trials.

Description of patient-reported outcome measures

Scores for the *Quick*DASH range from 0 (least disability) to 100 (most disability). The Levine-Katz Symptom Severity Scale (SSS) assesses pain, weakness, and sensation through 11 questions the patient rates on a 5-point scale with 5 being the most difficult. The Levine-Katz Functional Status Scale (FSS) has 8 questions self-rated on a 5-point scale of difficulty with 5 indicating a difficulty so great that the patient is unable to perform a given function. The averages of these surveys are reported. The Pain at Rest and Pain in Action scores were taken using the Numerical Pain Rating Scale (NPRS). The NPRS is a 10-point scale with a 0 indicating no pain and a 10 indicating the highest imaginable level of pain.