

TITLE: Splinting versus Early Mobilization following Carpal Tunnel Release: A Prospective Randomized Study

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INTRODUCTION: Annually, over 300,000 carpal tunnel releases are performed in the US. Aspects of postoperative hand management remain poorly defined, particularly the question of whether to splint or permit early mobilization. A review of current literature reveals a limited number of studies to provide guidance. Finsen V, Andersen, K, and Russwurm, H (1999) concluded that there was no advantage from splinting the wrist after open carpal tunnel release and Huemer, GM et al (2007) concluded that postoperative splinting does not improve functional outcome. Despite these findings, splinting following carpal tunnel release is still widely practiced. This was our rationale for launching another randomized controlled trial to corroborate and expand upon the results of these studies. In our efforts to enroll the required sample size of 88 patients, 221 patients have been approached. We have observed an enrollment rate of 47%. To date, 103 patients have been randomized to either the splinting or mobilization arm of the study.

OBJECTIVE: To evaluate differences in patients splinted for 3 weeks with those with early mobilization with regards to the following: date of return to activities of daily living, date of return to work at light and full duty, scar tenderness, pillar pain, grip strength, key pinch strength, and occurrence of complications.

- 1). Patients with early mobilization following carpal tunnel release will have significantly less early post-operative pain and pillar pain and will return to work at light and regular duty sooner than patients splinted for three weeks.
- 2). There will be no difference between early mobilization patients and splinted patients at 6 months with regard to symptom, function, work status or complication rate.

METHODS: Subjects will be selected from a pool of patients with idiopathic carpal tunnel syndrome undergoing carpal tunnel release at both Hand Surgical Associates in Boston, MA and Hand Surgery Center in Greenville, SC. The target sample size is 88. Once a patient is identified as having idiopathic carpal tunnel syndrome the patient will be pre-screened. If the patient does not need a second procedure, the surgeon will discuss the study and if the patient agrees to participate, informed consent will be obtained by the operating surgeon. The clinical research coordinator will provide the clinic with the randomization envelope, which will be placed in the subjects' clinical record. The operating surgeon will be blinded to the treatment arm until after the carpal tunnel release has been performed. After the carpal tunnel release has been performed the circulating nurse will open the envelope and reveal the treatment arm to the surgeon. Subjects will be seen at 2 week, 6 week, 3 month and 6 month post-operative dates. At these dates the subjects will fill out a modified version of the Maine Carpal Tunnel Outcome Questionnaire. Primary outcomes will be return to work (yes/no), pillar and scar tenderness (yes/no) and number of days at work/out of work. Clinical outcomes include atrophy, pinch and key grip strength, two point discrimination, and Semmes and Weinstein monofilaments. Occurrence of complications will also be documented.

RESULTS: To date the study is still in the enrollment phase. As of May 2008, 74 subjects have completed the study and 12 are active on the study for a total of 86 subjects. Five patients have been lost to follow-up, while ten patients withdrew their consent to participate and two patients were removed from the study. A total of 118 patients have been missed with, 28 patients preferring to be splinted after surgery, 11 preferred mobilization, and 78 patients refused to participate for reasons ranging from the number of follow up appointments, the distance of their home from the hospital, and lack of available time.

CONCLUSION: To date the study is still in the data collection phase, therefore, no conclusions can be drawn. However, conclusions will be drawn from the analyses of the principal outcome measures between splinted and non-splinted groups by using a variety of bio-statistical methods including logistic regression.

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