

Premoselli S, Sioli P, et al. Neutral wrist splinting in carpal tunnel syndrome: a 3- and 6- month clinical and neurophysiologic follow-up evaluation of night-only splint therapy. *Eura Medicophys* 2006;42:121-6.

Design: Randomized clinical trial

Brief summary of results:

- 50 patients (45 women, 5 men, mean age 50) referred for treatment of carpal tunnel syndrome to a rehabilitation medicine department at the University of Milan
- Eligibility based on electrodiagnostic studies: compound motor action potential of median nerve distal latency <4.7 ms, and difference between median and ulnar sensory action potential latencies >0.4 ms
- Patients with diabetes and with “clear CTS” were excluded
- Randomized by odd/even visit booking number to nocturnal splint (n=25) or observation only (n=25)
- Nocturnal splint was made from custom-molded thermoplastic resin without laces or fasteners to increase ease of use and better compliance
- Splint was to be worn for 6 months during the night, but not during the day
- Outcome measurements were done at entry, at 3 months, and at 6 months
- Symptom and function scores improved in the splint group at 3 and 6 months, but not in the control group
- Median sensory and motor conduction showed improvements in the splint group but not in the control group at 3 and 6 months
- Pressure-provocative test improved in the splint group but not in the control group at 3 and 6 months

Authors' conclusions:

- Long-term splint use produces symptomatic, functional, and neurophysiologic improvements in carpal tunnel syndrome

Comments:

- Inclusion/exclusion criteria are not well defined: patients with “clear CTS” were excluded, but the definition of “clear CTS” is lacking; presumably, the nerve conduction criteria were intended to exclude patients with motor denervation, but other criteria are not specified
- Randomization by odd/even booking number is not satisfactory, since lack of allocation concealment is a known source of bias in randomized trials
- Blinding of follow-up measurements is not specified, and could also be a source of bias
- Patients who failed to comply with the assigned treatment or who had surgical intervention were excluded from the follow-up analyses; since these are outcomes of relevance in an effectiveness study, their exclusion from analysis is unacceptable

Assessment: Inadequate for an evidence statement (several sources of bias not controlled)