

Rannou F, Dimet J, et al. Splint for Base-of-Thumb Osteoarthritis. Ann Intern Med 2009;150:661-669.

Design: Randomized clinical trial

Population/sample size/setting:

- 112 patients (101 women, 11 men, mean age 63) referred for thumb osteoarthritis to a rehabilitation medicine service in Paris
- Eligibility criteria were base of thumb pain at least 30 mm on a 100 mm VAS, age 45 to 75, at least 2 radiographic changes (osteophytes, joint space narrowing, subchondral bone sclerosis, subchondral cysts), and at least 1 clinical change (trapeziometacarpal joint enlargement or closure of the first web space)
- Exclusion criteria included trauma, crystalline or inflammatory arthritis, previous hand surgery, hand or wrist injection in past 2 months, bilateral thumb OA, or skin disease interfering with wearing of a splint

Main outcome measures:

- Randomized to nighttime use of a custom-fitted splint (n=57) or usual care (analgesics and other medications, n=55)
- Splint was made of neoprene covering the base of the thumb but not the wrist; splints were made by 3 occupational therapists and fitted to ensure that the first web could be opened and the thumb and index finger could be placed in opposition
- Primary outcome was pain level on a 100 mm VAS measured 1 month after the study began; both groups had a 10 mm improvement in VAS at 1 month, with no difference between the groups
- Repeated VAS measurements were recorded at 6 and 12 months; at the end of 12 months, the splint group had a 22-point improvement in pain VAS, significantly more than the control group, which had only an 8 point reduction
- Several secondary outcomes were assessed, including the Cochin Hand Function Scale, which asks about 18 common hand tasks on a 5 point scale: 0 represents no difficulty and 90 represents impossible to do on all 18 tasks
- For the splint group, the Cochin scale improved 1.9 points from baseline to 12 months, but worsened by 4.3 points in the control group; the baseline mean Cochin scores were 19.4 and 17.7
- Radiographic scores were similar in both groups at baseline and at 12 months
- Treatment adherence was high for the splint group; 63% of the splint patients needed a splint adjustment during the 12 months of the study; 68% expressed satisfaction with the splint after 1 month of use, 83% were satisfied at 6 months, and 90% were satisfied at 12 months
- The use of medication for symptom relief was greater in the control group than in the splint group after 12 months

Authors' conclusions:

- Splinting at night did not differ from usual care at 1 month, but at 12 months, it showed a clinically significant advantage over usual care
- Splints were inexpensive well tolerated
- Blinding of patients, health care providers, and outcome assessors was not practical and was not done; however, the number of visits was equal for both groups and the use of co-interventions was greater in the control group, so that the effect of non-blinding was probably marginal

Comments:

- Study was generally well-planned and well-executed, with statistical analyses which are appropriate for situations with missing data, and which do not impose linear relationships where they are not present
- The assessment of clinical and radiographic status was stated to have been done by “two independent, trained physicians” who were “not involved in patients’ treatment,” implying blinded assessment, but the discussion states that the assessment was not blinded; the meaning of “independent” is not clear
- The text states that the control group used more co-interventions; this may be because 35% of the splint group and 20% of the control group used no medications at 12 months; however, acetaminophen plus opioids was used by 5 splint patients and only 1 control patient at 12 months

Assessment: High quality for an evidence statement that a custom-made splint used only at night may reduce pain and increase function if used for 12 months