

John MM, Kalish SR, et al. Dynamic splinting for hallux limitus: a randomized, controlled trial. J Am Podiatr Med Assoc. 2011;101:285–8.

Design: randomized clinical trial

Purpose of study: in patients with hallux limitus (first metatarsophalangeal joint degenerative arthritis), to compare dynamic splinting plus standard of care versus standard of care alone in active range of motion at the first M-P joint

Reasons not to cite as evidence:

- The descriptions of the patient population is sparse, and does not even give the ages of the participants
- There is no description of the measurement of the main outcome, dorsiflexion range of motion, and no indication that the person doing the measurements was blinded as to group assignment, creating a risk of bias for the main endpoint
- The comparison of the outcomes does not give actual effect sizes in numerical form with confidence intervals, but reports only p values and values of the F statistic (with degrees of freedom) from the analysis of variance (ANOVA) which was used to compare the treatment groups
 - o The only representation of first M-P joint range of motion is in bar graph form in Figure 2
 - o The change in ROM appears to be greater in the dynamic splinting group than in the standard of care group, but the baseline ROM is less in the dynamic splinting group
 - In this situation, the ANOVA should be done in a manner which compares ROM with the baseline ROM as a covariate, to control for regression to the mean, which is a statistical artifact and not a true measure of treatment effectiveness
- No estimate of foot function is given other than ROM; the effects on pain or ability to perform daily activities is nowhere reported, but is of considerable importance to clinical decision-making
- A surrogate treatment outcome, not blinded to treatment group, reported without numerical specification of group differences and confidence intervals, and without information concerning pain and ability to perform daily activities, cannot support an evidence statement regarding the effectiveness of dynamic splinting for first M-P joint degenerative arthritis