

A Foot Orthotics Study: Commentary

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Introduction

A recent study was designed to assess the effect of orthotics upon both manual muscle testing and the duration of effects produced by the chiropractic manipulation of the spine [1]. It accomplished this by challenging the manipulation with daily activities (including walking and standing) and determining whether the use of custom foot orthotics prolongs the effects of manipulation which are presumably diminished over time by these activities. Using a means of testing several muscles bilaterally (gluteus maximus, popliteus, lower trapezius, middle deltoid, and neck extensors) in what is known as an applied kinesiology technique, it followed the natural history of indicator muscles of back pain upon their testing with or without orthotics and correlated these results with those of pain and disability, determining whether manual muscle testing results might be predictive indicators of pain and disability as well. The design of the investigation was a randomized controlled trial, in which one group received a custom fitted orthotic sole and the other a contoured sham device. The effects of manipulation were assessed by two primary outcome measures: (1) the Quadruple Visual Analog Scale (VAS) and (2) the Roland-Morris Disability Scale (RMS), and two secondary measures: (1) the determination of the number and location of vertebral fixations [FIX] as determined by palpation and challenge, (2) the determination of the number of weak muscles [WkMus] by a qualified AK clinician, the muscles having been considered relevant by the tenets of applied kinesiology (AK).

The conclusions were the following:

1. Both groups improved on all VAS, RMS and WkMus from intake to the final visit.
2. Only the sham group yielded significant improvements in FIX.
3. No outcome measures registered statistical difference between the groups at any time point.
4. Those who wore custom orthotics longer each day showed trends toward greater improvements in measures the number of weak muscles tested, quadruple numerical pain rating scale, and the Roland-Morris questionnaire.
5. Correlations between all outcome measures (primary and secondary) were both strong and striking, particularly between WkMus and FIX).
6. Improvements in WkMus and FIX with each visit returned to within 10% of baseline values immediately prior to each subsequent visit.

These results uncovered several previously unreported phenomena that bear scrutiny and further research:

1. First and foremost, the orthotic devices that were provided were not truly custom-fitted to the 3-dimensional aspects of each patient's foot. Instead, they were fabricated from the 2-dimensional patterns afforded by the use of the Associate scanning device. In addition, the actual orthotic devices were not

truly custom fitted but rather came from a series of stock items which provided the closest match to the data obtained from the Associate. Furthermore, the sham insoles were puckered rather than flat and in many aspects bore a resemblance to the custom fitted devices, confounding the results. Although we polled our patients in both groups as to roughly what portion of the day they wore their orthotics, we did not match the groups as to how much time during their waking hours that they were actually on their feet with the orthotics in a load-bearing situation. Comparisons with a group not wearing insoles might have displayed differences not seen in this investigation.

2. Time constraints limited our sample size to 19 patients for each cohort, such that this investigation was only preliminary in nature and falling short of the 55 needed to obtain the 80% power needed to detect the minimal clinically significant effect of 6 points on the disability index.
3. We found a disturbing pattern of reversals of secondary outcome measures (the improvements in FIX and WkMus) produced by our manipulative treatments when patients returned for a subsequent treatment. These reversals immediately disappeared with the treatment, producing a sawtooth pattern. Overall, there was gradual improvement over the course of 5 treatments. What was not investigated was whether the primary outcome measures (VAS and RMS) decayed in a similar manner prior to each subsequent treatment.
4. We were unable to obtain high-resolution data on the foot scans produced on an earlier version of the Associate device from Foot Levelers. This meant that individuals with severe pronation problems, for example, were not detected or matched between groups. The previous trial was conducted for about a month to coincide with the availability of research personnel; however, the trends toward superiority of the custom fitted orthotic devices suggested that a more significant result would have been delivered with a longer study period.
5. Subjects in this trial were sometimes confused by the VAS scale, and sensitivity issues regarding the Roland-Morris Scale may have obscured some of the outcomes sought. Although our efforts at blinding patients as to whether they received the sham or custom fitted orthotics were shown to be successful, the price we may have paid was to have provided a contoured sham device that provided some comfort and satisfaction—as

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shown by the positive outcome measures in the sham cohort in the previous investigation.

6. The strong correlations in the outcome measures that we observed were dramatic and bear further study.

Reference

1. Rosner AL, Conable KM, Edelman T (2014) Influence of foot orthotics upon duration of effects of spinal manipulation in chronic back pain patients: A randomized clinical trial. J Manipulative Physiol Ther 37:124-40.