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Journal of Ergonomics

Commentary

Impact of Foot Orthotics upon Duration of Effects of Spinal Manipulation in Chronic Back Pain Patients: A Randomized Clinical Trial

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DESCRIPTION

Our investigation 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. 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 applied kinesiology techniques, 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

Both groups improved on all VAS, RMS, and WkMus from intake to the final visit.

Only the sham group yielded significant improvements in FIX.

No outcome measures registered statistical difference between the groups at any time point.

Those who wore custom orthotics longer each day showed trends toward greater improvements in some outcome measures.

Correlations between all outcome measures (primary and secondary) were both strong and striking, particularly between WkMus and FIX.

Improvements in WkMus and FIX with each visit reversed 90% immediately prior to each subsequent visit.

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

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.

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.

Time constraints limited our sample size to 19 patients for each cohort, such that our 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.

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

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Received: July 09, 2021; **Accepted**: July 23, 2021; **Published**: July 30, 2021

Citation: Rosner AL, Conable KM, Edelmann T (2021) Impact of Foot Orthotics upon Duration of Effects of Spinal Manipulation in Chronic Back Pain Patients: A Randomized Clinical Trial. J Ergonomics. 11: 285.

(VAS and RMS) decayed in a similar manner prior to each subsequent treatment.

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 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.

Subjects in the 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 shown by the positive outcome measures in the sham cohort.

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