

# INFLUENCE OF FOOT ORTHOTICS UPON DURATION OF EFFECTS OF SPINAL MANIPULATION IN CHRONIC BACK PAIN PATIENTS: A RANDOMIZED CLINICAL TRIAL

Anthony L. Rosner, PhD,<sup>a</sup> Katharine M. Conable, DC,<sup>b</sup> and Tracy Edelmann, DC<sup>c</sup>

## ABSTRACT

**Objective:** The purpose of this study was to investigate the effects of 4 weeks of custom foot orthotics on pain, disability, recurrence of spinal fixation, and muscle dysfunction in adult low back pain patients receiving limited chiropractic care.

**Methods:** Adult volunteers with low back pain of greater than or equal to 1 month's duration were randomized to receive custom orthotics (group A) or a flat insole sham (group B) with limited chiropractic care in 5 visits over 4 weeks. Primary outcome measures are as follows: Quadruple Numerical Pain Rating Scale (for back), the Roland-Morris Disability Questionnaire, the number of muscles grade 4 or lower on manual muscle testing, and the number of spinal fixations detected by motion palpation and vertebral challenge at intake (B1), 2 weeks later before treatment began and orthotic use was initiated (B2) and before each subsequent treatment at approximately days 3, 10, 17, and 24 after B2. Secondary outcome measures are correlations of all primary outcomes.

**Results:** Both groups improved on all Numerical Pain Rating Scale, Roland-Morris Disability Questionnaire, and the number of muscles from intake (B1) to final visit. Only group B yielded significant improvements in the number of spinal fixations. No outcome measures showed statistical difference between groups at any time point; however, those who wore custom orthotics longer each day showed trends toward greater improvements in some outcome measures.

**Conclusions:** Both groups improved with chiropractic care including spinal manipulation; however, there were no statistical differences shown between sham and custom orthotic groups. Future studies should formally measure the time that orthotics or shams are worn in a weight-bearing capacity each day. (*J Manipulative Physiol Ther* 2014;37:124-140)

**Key Indexing Terms:** *Orthotic Devices Manipulation; Spinal Manipulation; Kinesiology; Applied Back Pain; Pain Assessment; Outcomes Assessment (Health Care); Chiropractic*

The joints at the lower extremities and the pelvis are considered to be fundamental to posture and biomechanical function. These include the feet and ankles, which support the entirety of the body, and the sacral base. Irwin<sup>1</sup> identified 4 elements, which are capable

of reducing more than two-thirds of common pain occurrences: (1) manual manipulation to reduce somatic dysfunction; (2) foot orthotics to optimize the amplitude of the arches of the feet as well as vertically aligning the ankle; (3) a heel lift to level the sacral base; and (4) a set of therapeutic postures, which are designed to minimize the restrictions of peripheral soft tissue reflective of the earlier posture. To these elements has been added the finding that electromyographic changes occur with the use of foot orthotics, documenting the importance of studying muscle activity as a reaction to shoe inserts and foot orthoses.<sup>2</sup>

These observations suggest a rationale for including the following 3 elements in an investigation of chronic back pain:

## SPINAL FUNCTION

As assessed and managed by chiropractic, the condition and response of the spine to treatment have been widely described, the most robust research having been reported over the past 20 years.<sup>3-5</sup>

<sup>a</sup> Research Director, International College of Applied Kinesiology, Shawnee Mission, KS.

<sup>b</sup> Associate Professor, Chiropractic Division, Logan University/College of Chiropractic, Chesterfield, MO.

<sup>c</sup> Private Practice, Wildwood, MO.

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Submit requests for reprints to: Anthony L. Rosner, PhD, LLD [Hon], 1330 Beacon St, Suite 315, Brookline, MA 02446-3202 (e-mail: [arosner66@aol.com](mailto:arosner66@aol.com)).

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## ACTIVITY OF THE FOOT AND ITS MANAGEMENT

Foot orthotics may successfully modify selected aspects of lower extremity mechanics and enhance foot stability. Recent investigations have demonstrated that custom-fit orthotics may restrict undesirable motion at the foot and ankle, enhancing detection of perturbations by joint mechanoreceptors and providing structural support for controlling postural sway in ankle-injured subjects.<sup>6</sup> A recent systematic review concluded that foot orthotics increased activation of the tibialis anterior and peroneus longus and might have altered lower limb and back muscle activation. Changes in electromyographic activation were reported as well, although standards for reporting these were found wanting when confidence intervals were calculated.<sup>7</sup>

The effectiveness of custom-fit foot orthotics in promoting ankle stability and alleviating foot, ankle, and leg pain has been reported in 35 clinical trials, case series, and case studies involving patients with foot and lower limb pain, juvenile idiopathic arthritis, rheumatoid arthritis, plantar fasciitis, cavus (high arch pain), inversion ankle sprain, Morton neuroma, hallux valgus, and patellofemoral pain.<sup>8-39</sup> In some instances, orthotics were used in combination with other conservative, noninvasive therapies,<sup>8,11,17,20,24,32,36,38,39</sup> often involving spinal manipulation.<sup>9,11,17,24,32,39-42</sup>

Studies suggested that pain and disability scales associated with low back pain (LBP) resolved with the use of orthotics.<sup>9,11,12,40-42</sup> A case series reported that orthotics produced a 2-fold extension of the duration of improvements produced by orthopedic manipulation for back pain.<sup>9</sup> A crossover randomized trial feasibility study demonstrated that comparable improvements in pain and disability occurred during the first 6 weeks of wearing orthotics, regardless of whether orthotics were used immediately after randomization or after a 6-week waiting period. However, further improvements after the initial 6 weeks were not found.<sup>12</sup>

Shoe inserts may be used as a preventive measure. The incidence of stress fractures and pain at different locations was reduced by 1.5% to 13.4% with the use of shoe inserts.<sup>43</sup> Furthermore, differences in comfort ratings were found to be significantly related to foot arch height, foot and leg alignment, and foot sensitivity concerning the use of insoles<sup>43</sup> as well as possibly influencing fatigue and the development of injuries as far as shoes were concerned.<sup>44</sup>

## MANUAL MUSCLE TESTING

Before the 1980s, manual muscle testing (MMT) as a method for diagnosing spinal dysfunction was seldom recognized in orthodox medical circles. However, the reliability and validity of MMT as originally envisioned by Goodheart<sup>45</sup> with elaborations by Walther<sup>46</sup> and designat-

ed as applied kinesiology (AK) have recently reported in the literature,<sup>47</sup> together with assessments of its strengths, weaknesses, distinctions in practice, and criticisms.<sup>48</sup>

Manual muscle testing is a commonly used method for documenting impairments in muscle strength and may be an adjunct for assessing spinal function. A 2003 survey of doctors of chiropractic by the National Board of Chiropractic Examiners indicated that 37.6% of respondents in the United States used AK in 2003,<sup>49</sup> with similar numbers having been reported in the past from Australia<sup>50</sup> and other reports.<sup>51</sup>

Kendall and Kendall<sup>52</sup> described "break testing," where a muscle tested from a contracted position against increasing applied pressure by the examiner could either maintain its position or "break away." They discussed a variety of numerical grading systems.<sup>52</sup> In AK, muscles that maintain their position are graded as facilitated or "strong (5/5)," whereas those that break away are classified as inhibited or "weak (4/5 or less)."<sup>45</sup> For AK evaluation, muscle strength per se is not regarded to be a notable issue with clinical syndromes and is not considered to be a factor in back pain or the onset of chronicity.<sup>53-57</sup> Rather, AK uses MMT to identify an imbalance of muscles in which one set of muscles tends to become overactivated while another group becomes inhibited.<sup>58</sup> Janda<sup>59</sup> argued that this phenomenon was not readily explainable by anatomical, histologic, biochemical, or physiologic attributes of the muscle itself. Instead, the terms *facilitated* or *overactive* referred to the neurologic state of the muscle in its response to MMT.<sup>59</sup>

Inhibition of muscles, especially those that have a stabilization role, has been identified in some persons with spinal complaints.<sup>60-63</sup> The theory in AK is that, if the central nervous system does not activate muscles at the right moment to the correct magnitude and in harmony with other muscles involved in the activity, dysfunction and microtrauma may result. Added to the tenets of contemporary AK is that multiple muscle tests are performed in a series or parallel manner before any diagnosis is ever made.

At present, no randomized clinical trials exist that evaluate the use of foot orthotics to support and/or extend the beneficial effects of spinal manipulation. The only reports that designate the combination of spinal manipulation with foot orthotics to manage back pain are a single case study<sup>11</sup> and 1 clinical trial, which witnessed improvements in 2 cohorts subjected to spinal manipulation with or without orthotics. The latter, however, lacked an assessment between the groups.<sup>8</sup>

There have been no studies involving the use of muscle testing in combination with foot orthotics to test the hypothesis that muscle activity appears to change with the use of shoe inserts<sup>2</sup> and to evaluate MMT to serve as an accurate transcript of neural dysfunction.<sup>47,48</sup> Our hypotheses were as follows:

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