# Effects of Foot Orthotics on Running Economy: Methodological Considerations

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## Abstract

**Objective:** The purpose of the study was to collect preliminary data to address methodological considerations that may impact subject-specific reactions to foot orthotics during running.

**Methods:** Six endurance-trained recreational runners recruited from a chiropractic college campus wore their preferred running shoes and then inserted either their custom-made orthotics during 1 testing session or their shoe-fitted insoles during the other testing session. Comfort perception was measured for each footwear condition. Measurements of oxygen consumption ($VO_2$) at several moderate exercise intensities, to mimic recreational running, generated an individual's economy-of-running line. Predicted running velocity at $VO_{2max}$ ($vVO_{2max}$) was calculated as an index of endurance performance. Lower extremity muscle activity was recorded. Descriptive statistics, a repeated-measures analysis of variance model, and a paired *t* test were used to document any systematic changes in running economy, lower extremity muscle activities, and $vVO_{2max}$ within and across subjects as a function of footwear conditions.

**Results:** Decreases in $VO_2$ at several moderate exercise intensities ($F_{(1,5)footwear} = 10.37$, $P = .023$) and increases in $vVO_{2max}$ ($t_5 = 4.20$, $P = .008$) occurred in all 6 subjects while wearing their orthotic intervention vs their shoe-fitted insoles. There were no consistent changes in lower extremity muscle activity.

**Conclusions:** Methodological decisions to use a sustained incremental exercise protocol at several moderate exercise intensities and to measure comfort perception of a custom-molded foot orthosis were effective at documenting systematic improvements in running economy among the 6 recreational runners tested. The development of a less physically demanding sustained exercise protocol is necessary to determine underlying neuromuscular mechanisms and/or clinical effectiveness of orthotic interventions. (J Manipulative Physiol Ther 2012;35:327-336)

**Key Indexing Terms:** *Running; Oxygen Consumption; Electromyography; Orthotic Device; Chiropractic*

Running economy is defined as the steady-state oxygen consumption for a given running velocity. Previous data indicate that foot orthoses may influence oxygen consumption during steady-state treadmill running protocols at workloads between slightly above aerobic threshold to slightly below anaerobic threshold.[1,2] Subject-specific changes in steady-state oxygen consumption occurred as a function of the heel material characteristics of the running shoes; however, the maximal change for any 1 subject was 2%.[1] Approximately a 1% improvement in steady-state oxygen consumption occurred by increasing midsole longitudinal bending stiffness, with 11 of the 13 subjects showing this experimental effect.[2] These subtle but consistent changes in running economy as a function of shoe material characteristics provide an experimental model to identify systematic changes in neuromuscular efficiency with orthotics interventions.

However, given subject-specific reactions and subtle physiologic changes during steady-state treadmill runs at 1 exercise intensity,[1,2] measurement of running economy during sustained incremental exercise protocols at several moderate exercise intensities may be more effective at revealing experimental changes in running economy as described previously.[3-7] Sustained incremental exercise protocols mimic recreational running activities and may be used to predict endurance performance. Measurements of oxygen consumption ($VO_2$) at several moderate exercise intensities generate an individual's economy-of-running line.[3,4,6,8] An individual's economy-of-running line is a reliable and valid index of neuromuscular efficiency.[6,9] Using linear extrapolation of an individual's economy-of-running line to $VO_{2max}$, the predicted running velocity at $VO_{2max}$ ($vVO_{2max}$) may be calculated as a primary predictor of endurance performance.[3,4,6,8,10,11] Physiologic

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adaptations to high-intensity and aerobic interval training programs substantiate a relationship among running economy, $vVO_{2max}$, and middle- and long-distance running performances.[8,12-15]

Reduction of muscle activities of the lower extremities is another index of improvements in neuromuscular efficiency during running.[16,17] Recordings of surface electromyography (EMG) signals from muscles in the lower extremities are processed using root-mean square algorithms to explain changes in motor unit recruitment and rate coding during gait cycles. Electromyographic root mean square values reflect the amount of muscle activation within a given period of time. The effects of orthotic interventions on reducing muscle activities of the lower extremities during steady-state treadmill running protocols remain inconclusive. To date, most of the evidence only revealed subject- and muscle-specific changes in EMG root mean square values as a function of footwear conditions.[1,2,18]

The concept of comfort perception was proposed as a critical component that may explain subject-specific reactions to foot orthotics and any possible neuromuscular benefits of orthotic interventions.[16,17,19-21] Accordingly, an orthotic intervention that supports the preferred movement path will be perceived as more comfortable and enhance neuromuscular efficiency; whereas orthotic intervention that counteracts the preferred movement path will be perceived as less comfortable and decrease neuromuscular efficiency.[16,17,21] Further insights on neuromuscular mechanisms underlying any beneficial effects of orthotic interventions may require that subjects positively adapt to a preferred foot orthosis condition as determined by improved comfort perception.[16,17,19,20] The importance of custom or subject-specific orthotic design on neuromuscular efficiency is also emerging in the literature as evidenced by minor improvements in rear foot motion control and vertical impact loading with a custom orthotic intervention.[22-24]

The study was preliminary in nature to determine if using methodologies that mimic recreational running activities and measure comfort perception would provide systematic and more robust changes in running economy as function of footwear conditions. A 30-minute incremental treadmill protocol was deemed necessary to allow for a reliable and valid assessment of an individual's economy-of-running line as shown previously in the literature.[3,4,6,8] Measurement of comfort perception of a custom-designed orthotic intervention was used to document that subjects adapted to a preferred foot orthosis condition. Subject-specific reactions to foot orthotics may be a confounder to identifying systematic effects of orthotic interventions.[16,17,21,22] However, our proposed methodological considerations limited the sampling frame of recreational runners because of the demanding nature of the sustained running protocol and the availability of many high-quality commercial brand running shoes, that is, no perceived need for an orthotic intervention by recreational runners.

The purpose of the study was to collect preliminary data to address methodological considerations that may impact subject-specific reactions to foot orthotics during running. The preliminary data should reveal systematic and physiologic meaningful changes in an individual's economy-of-running line. Specifically, deceases in submaximal $VO_2$ at several moderate exercise intensities should occur for all subjects when performing the sustained running protocol while wearing their preferred foot orthosis as compared with their shoe-fitted insoles. Secondary outcomes were EMG activities of lower extremity muscles during the sustained running protocol and the calculation of $vVO_{2max}$. If our preliminary running economy data align with the proposed theoretical relationship between improvements in footwear comfort perception and improvements in neuromuscular efficiency, then objective and generalizability gait tests that measure movement economy and mimic sustained physical activities of daily life, for example, exercise and work-related walking, shopping, hiking, and others, may be developed to address subject-specific reactions to foot orthotics and any possible neuromuscular or clinical benefits of orthotics interventions.

## Methods

### Participants

A convenience sample of 6 endurance-trained recreational runners (3 males, 3 females; 32.3 ± 10.07 years) was recruited from a chiropractic college campus community. Their endurance training status is documented by their cardiopulmonary response to the exercise protocols as a function of their sex and age (Tables 1-6). The recruitment strategy consisted of general announcements posted throughout campus from October 2005 through September 2007 with all 6 subjects recruited enrolling in the study. The inclusion criteria were healthy, endurance-trained individuals with a self-reported preference for running while wearing their orthotic intervention as compared with wearing their shoe-fitted insert. The endurance training criteria for 30 minutes of running were the self-reported abilities of male subjects to sustain a mile pace of at least 7:00 minutes and female subjects to sustain a mile pace of at least 8:00 minutes. These endurance training criteria were approximately 50% above the 2004-2008 Olympic qualifying pace set by the United States Track and Field Association for the 10-km race.[25,26] Participants received their prescribed orthotic intervention from a qualified health care professional at the campus health center. The orthotic intervention was complimentary because of their membership as part of the college campus community. Exclusion criteria were self-reported musculoskeletal conditions involving the lower extremities, for example, hip, knee,

**Table 1.** *Treadmill testing protocols for male endurance-trained runners*

| Testing protocols | Testing parameters | | | |
|---|---|---|---|---|
| | Stage | Pace (mph[a,b]) | % Grade | Duration (min) |
| Warm up | 1 | 6.7 (9:00) | 0 | 5 |
| Submaximal treadmill run | | | | |
| | 1 | 7.1 (8:30) | 0 | 5 |
| | 2 | 7.5 (8:00) | 0 | 5 |
| | 3 | 8.0 (7:30) | 0 | 5 |
| | 4 | 8.6 (7:00) | 0 | 5 |
| | 5 | 9.2 (6:30) | 0 | 5 |
| Recovery | | | | |
| | 1 | 3.5 | 0 | 3 |
| | 2 | 0 (rest) | 0 | 10 |
| | 3 | 6.7 | 0 | 2 |
| Maximal treadmill run [c] | | | | |
| | 1 | 7.1 (8:30) | 0 | 1 |
| | 2 | 7.5 (8:00) | 0 | 1 |
| | 3 | 8.0 (7:30) | 0 | 1 |
| | 4 | 8.3 (7:15) | 0 | 1 |
| | 5 | 8.6 (7:00) | 0 | 1 |
| | 6 | 8.6 (7:00) | 2 | 1 |
| | 7 | 8.6 (7:00) | 4 | 1 |
| | 8 | 8.6 (7:00) | 6 | 1 |
| | 9 | 8.6 (7:00) | 8 | 1 |
| | 10 | 8.6 (7:00) | 10 | 1 |

[a] mph range corresponds to a range of approximately 3.2 to 4.1 m/s.
[b] Minutes per mile pace in parentheses.
[c] The maximal treadmill run was terminated at volitional exhaustion.

**Table 2.** *Treadmill testing protocols for female endurance-trained runners*

| Testing protocols | Testing parameters | | | |
|---|---|---|---|---|
| | Stage | Pace (mph[a,b]) | % Grade | Duration (min) |
| Warm up | 1 | 6.0 (10:00) | 0 | 5 |
| Submaximal treadmill run | | | | |
| | 1 | 6.3 (9:30) | 0 | 5 |
| | 2 | 6.7 (9:00) | 0 | 5 |
| | 3 | 7.1 (8:30) | 0 | 5 |
| | 4 | 7.5 (8:00) | 0 | 5 |
| | 5 | 8.0 (7:30) | 0 | 5 |
| Recovery | | | | |
| | 1 | 3.5 | 0 | 3 |
| | 2 | 0 (rest) | 0 | 10 |
| | 3 | 6.0 | 0 | 2 |
| Maximal treadmill run [c] | | | | |
| | 1 | 6.3 (9:30) | 0 | 1 |
| | 2 | 6.7 (9:00) | 0 | 1 |
| | 3 | 7.1 (8:30) | 0 | 1 |
| | 4 | 7.3 (8:15) | 0 | 1 |
| | 5 | 7.5 (8:00) | 0 | 1 |
| | 6 | 7.5 (8:00) | 2 | 1 |
| | 7 | 7.5 (8:00) | 4 | 1 |
| | 8 | 7.5 (8:00) | 6 | 1 |
| | 9 | 7.5 (8:00) | 8 | 1 |
| | 10 | 7.5 (8:00) | 10 | 1 |

[a] mph range corresponds to a range of approximately 2.8 to 3.6 m/s.
[b] Minutes per mile pace in parentheses.
[c] The maximal treadmill run was terminated at volitional exhaustion.

ankle or foot, and self-reported cardiovascular disease or any other medical conditions that interfered with their ability to perform sustained submaximal exercise for 30 minutes or strenuous high-intensity exercise. The New York Chiropractic College institutional review board reviewed and approved all experimental procedures. All subjects signed an informed consent form.

## Experimental Design

Running economy and lower extremity muscle activity during human gait were assessed as a function of footwear conditions using a repeated-measures experimental design in a controlled laboratory environment. The endurance-trained runners participated in submaximal and maximal treadmill protocols, heel-toe running, in 2 testing sessions (Tables 1 and 2). The testing sessions were 1-week apart, and the subjects received compensation of $40.00 per testing session. The subjects wore their preferred running shoes and then inserted either their custom-made orthotics during 1 testing session or their shoe-fitted insoles during the other testing session. The order for each footwear condition was randomized. Although we did not control for the commercial brand of running shoes worn by our subjects, there is evidence that the effects of a custom orthotic design are beneficial regardless of the running shoe itself[24] and the preferred footwear of all of subjects was their self-selected commercial brand of running shoes with the orthotic intervention. Theoretically, subject-specific reactions to footwear appear to reflect the concept that the neuromechanical system of an individual has a preferred movement pattern for a motor task that is preprogrammed and subjects self-select comfortable running shoes that support their preferred movement path.[16,17,21]

Body weight, without shoes, was recorded at the beginning of each testing session. To help ensure metabolic conditions were similar before each trial, subjects were instructed to maintain similar dietary intakes and physical activities during the week before the first and second testing sessions. In the 24 hours before each trial, subjects were asked to avoid unaccustomed or strenuous exercise and to refrain from alcohol consumption. The first and second testing sessions were conducted at the same time of day. There was no control for menstrual cycle phase among the female runners because most studies do not report an impact of menstrual cycle phase on exercise cardiorespiratory variables and oxygen uptake kinetics.[27-29]

**Table 3.** *Cardiopulmonary variables during submaximal running protocol*

| | | Weight (kg) | | $VO_2$ (mL/kg/min) | | % | $V_E$ (L/min) | | Correlation ($R^2$) | |
|---|---|---|---|---|---|---|---|---|---|---|
| Subject | Sex | Orthotic | Insole | Orthotic | Insole | Change | Orthotic | Insole | Orthotic | Insole |
| 1 | Male | 64.1 | 64.1 | 41.7 ± 5.18 (37.2-46.2) | 43.0 ± 5.10 (38.5-47.5) | 3.02 | 63.3 ± 11.49 (53.2-73.4) | 64.3 ± 11.16 (54.4-74. 1) | 0.98 | 0.99 |
| 2 | Male | 79.1 | 78.6 | 40.1 ± 3.00 (37.5-42.7) | 41.8 ± 3.87 (38.4-45.2) | 4.07 | 83.7 ± 14.42 (71.1-96.3) | 93.1 ± 16.09 (79.0-107.2) | 0.99 | 0.98 |
| 3 | Male | 100.0 | 98.6 | 39.4 ± 3.74 (36.1-42.7) | 41.2 ± 4.16 (37.6-44.8) | 4.37 | 88.8 ± 12.79 (77.6-100.0) | 92.2 ± 15.25 (78.8-105.6) | 0.99 | 0.99 |
| 4 | Female | 52.9 | 52.1 | 36.3 ± 4.06 (32.7-39.9) | 39.0 ± 5.41 (34.3-43.7) | 6.92 | 49.8 ± 4.51 (45.8-53.8) | 53.5 ± 6.84 (47.5-59.5) | 0.99 | 0.99 |
| 5 | Female | 59.1 | 59.1 | 35.7 ± 2.93 (33.1-38.3) | 39.2 ± 3.52 (36.1-42.3) | 8.93 | 65.6 ± 10.07 (56.8-74.4) | 72.5 ± 13.05 (61.1-83.9) | 0.96 | 0.98 |
| 6 | Female | 57.3 | 57.7 | 32.7 ± 2.41 (30.6-34.8) | 40.2 ± 2.91 (37.6-42.8) | 18.66 | 68. 1 ± 10.30 (59.1-77.1) | 88.8 ± 12.06 (78.2-99.4) | 0.97 | 0.95 |
| | Mean | 68.7 | 68.4 | 37.7 | 40.7 | 7.66 | 69.9 | 77.4 | – | – |
| | SD | 17.78 | 17.34 | 3.33 | 1.56 | – | 14.26 | 16.51 | – | – |
| | 95th CI | – | – | 34.2-41. 2 | 39.1-42.4 | – | 54.9-84.9 | 60.1-94.7 | | |

Mean ± SD with 95th CI in parentheses for $VO_2$ and $V_E$ of each subject across the 5 submaximal treadmill stages. Percent improvement (% Change) in submaximal $VO_2$ for each subject when the subjects were wearing their orthotic intervention as compared with when they were wearing the shoe-fitted insoles. Correlations between $VO_2$ and $V_E$ across the 5 submaximal treadmill stages for each subject. Mean, SD and 95th CI for $VO_2$ and $V_E$, per footwear condition.

**Table 4.** *Energy expenditure during submaximal running protocol*

| | | RER | | Energy expenditure (joule/min) | |
|---|---|---|---|---|---|
| Subject | Sex | Orthotic | Insole | Orthotic | Insole |
| 1 | Male | 0.94 ± 0.021 (0.92-0.96) | 0.93 ± 0.019 (0.91-0.95) | 13,565 | 13,942 |
| 2 | Male | 0.96 ± 0.012 (0.95-0.97) | 0.95 ± 0.21 (0.93-0.97) | 10,593 | 11,095 |
| 3 | Male | 0.96 ± 0.035 (0.93-0.99) | 0.97 ± 0.027 (0.95-0.99) | 8,248 | 8,750 |
| 4 | Female | 0.88 ± 0.005 (0.876-0.884) | 0.87 ± 0.007 (0.86-0.88) | 14,068 | 15,325 |
| 5 | Female | 0.91 ± 0.011 (0.90-0.92) | 0.92 ± 0.005 (0.916-0.924) | 12,477 | 13,732 |
| 6 | Female | 0.96 ± 0.011 (0.95-0.97) | 0.97 ± 0.013 (0.96-0.98) | 11,932 | 14,612 |
| | Mean | 0.94 | 0.94 | 11,814 | 12,909 |
| | SD | 0.033 | 0.038 | 2,135.8 | 2,492.6 |
| | 95th CI | 0.903-0.971 | 0.896-0.974 | 10,105-13,523 | 10,915-14,904 |

Mean ± SD with 95th CI for the RER for each subject across the 5 submaximal treadmill stages. Based the subject's mean RER and $VO_2$ (L/min) values across the 5 submaximal treadmill stages, the average number of kilocalories (kcal) burned per minute was calculated for the submaximal running protocol by multiplying number of kcal per liter $O_2$ consumed by liters of $O_2$ consumed per minute. The Zuntz table provided the number of kcal per liter $O_2$ consumed based on substrate utilization (RER value). Calculated values in kcal/min were converted to joule/min.

The orthotic intervention was the flexible, custom-made orthotics, UltraStep by Foot Levelers, Inc (Roanoke, VA). The insertion of the custom-made orthotics into our subjects' preferred running shoes was used to alter comfort perception between the 2 footwear conditions. Greater comfort perception by our subjects when running with the orthotic intervention as compared with running with the shoe-fitted insoles allowed us to address the theoretical relationship between increased comfort perception and improvements in neuromuscular efficiency. The duration of orthotic intervention was not controlled because the experimentally manipulated criterion for the orthotic intervention was comfort perception, that is, preferred footwear condition, after an adequate adaptation or "wear-in" period.[16,17,19] In addition, recent evidence indicates that short- and long-term influences of foot orthotics on biomechanics of musculoskeletal systems are dependent on the patient wearing the orthotic intervention after an adequate "wear-in" period as opposed to correcting any underlying musculoskeletal condition.[23]

**Table 5.** *Ratings of footwear comfort*

| | | VAS by subjects | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Characteristics | Footwear | 1 | 2 | 3 | 4 | 5 | 6 | Mean ± SD |
| Overall | Orthotic | 124 | 83 | 102 | 114 | 135 | 115 | 112.1 ± 18.04 |
| | Insole | 117 | 85 | 73 | 93 | 89 | 77 | 89.0 ± 15.59 |
| Heel cushioning | Orthotic | 131 | 70 | 104 | 121 | 132 | 115 | 112.2 ± 23.15 |
| | Insole | 117 | 48 | 73 | 104 | 90 | 77 | 84.8 ± 24.44 |
| Forefoot cushioning | Orthotic | 132 | 103 | 107 | 122 | 110 | 115 | 114.8 ± 10.68 |
| | Insole | 117 | 110 | 58 | 107 | 83 | 77 | 92.0 ± 22.96 |
| Medial-lateral control | Orthotic | 130 | 38 | 118 | 131 | 95 | 115 | 104.5 ± 35.09 |
| | Insole | 117 | 82 | 58 | 94 | 67 | 77 | 82.5 ± 20.95 |
| Arch height | Orthotic | 88 | 21 | 125 | 140 | 131 | 115 | 103.3 ± 44.11 |
| | Insole | 117 | 30 | 53 | 93 | 92 | 77 | 77.0 ± 31.20 |
| Heel cup | Orthotic | 130 | 36 | 92 | 133 | 138 | 118 | 107.8 ± 38.87 |
| | Insole | 115 | 37 | 58 | 97 | 111 | 78 | 82.7 ± 30.88 |
| Heel width | Orthotic | 130 | 115 | 90 | 113 | 138 | 118 | 117.3 ± 16.49 |
| | Insole | 115 | 112 | 78 | 104 | 112 | 78 | 99.8 ± 17.30 |
| Forefoot width | Orthotic | 130 | 112 | 91 | 110 | 123 | 118 | 114.0 ± 13.43 |
| | Insole | 115 | 108 | 81 | 106 | 112 | 78 | 100.0 ± 16.21 |
| Length | Orthotic | 130 | 70 | 95 | 132 | 147 | 118 | 115.3 ± 28.18 |
| | Insole | 115 | 69 | 90 | 94 | 133 | 78 | 96.5 ± 23.76 |

Ratings of footwear comfort: 150 mm VAS from not comfortable at all (0 mm) to the most comfortable imaginable (150 mm).

**Table 6.** *Maximal running performance*

| | | | $VO_{2max}$ (ml/kg/min) | | $vVO_2$ (mph) | |
|---|---|---|---|---|---|---|
| Subjects | Sex | Age | Orthotic | Insole | Orthotic | Insole |
| 1 | Male | 43 | 61.7 | 60.4 | 11.32 | 10.97 |
| 2 | Male | 24 | 53.6 | 53.5 | 11.87 | 10.64 |
| 3 | Male | 23 | 50.4 | 51.1 | 10.56 | 10.08 |
| 4 | Female | 24 | 60.3 | 60.7 | 11.15 | 9.84 |
| 5 | Female | 35 | 48.8 | 48.3 | 10.09 | 8.89 |
| 6 | Female | 45 | 45.1 | 46.0 | 10.62 | 8.46 |
| | | Mean ± SD | 53.3 ± 6.57 | 53.3 ± 6.14 | 10.94 ± 0.636 | 9.81 ± 0.977 |

### Measurement Protocols

***Measurement of Oxygen Consumption During Submaximal ($VO_2$) and Maximal ($VO_{2max}$) Treadmill Runs.*** Cardiorespiratory-metabolic variables were measured using the $V_{max29}$ automated metabolic cart (Sensorimedics, Yorba Linda, CA). According to the manufacturer's instructions, the metabolic cart was calibrated before the submaximal treadmill run and again before the maximal treadmill run within each testing session (mass flow sensor, oxygen analyzer and, carbon dioxide analyzer). $VO_2$ was measured continuously, breath-by-breath method, using the exercise/indirect calorimetry test program throughout the submaximal testing protocol. Steady-state values of $VO_2$, ventilation ($V_E$) and the respiratory exchange ratio (RER) were calculated using the steady-state graphic editing program, which averaged the breath-by-breath measurements during the final 2 minutes of each treadmill stage.

After a 15-minute recovery period, the subjects performed a graded exercise run to volitional exhaustion to determine $VO_{2max.}$ $VO_2$ was measured continuously, breath-by-breath method, using the exercise/indirect calorimetry test program throughout the maximal testing protocol. Using the exercise summary graphic edit program, $VO_{2max}$ was the average of peak values from breath-by-breath measurements during a 20-second interval, at volitional exhaustion. According to technical specifications, the accuracy of test-retest values of $VO_{2max}$ are within 2% using the $V_{max29}$ automated metabolic cart.

***Measurement of Lower Extremity Muscle Activity During Submaximal Treadmill Runs.*** Surface EMG responses were recorded from the mid-bellies of the following muscles of the right leg: vastus lateralis, biceps femoris (hamstrings), medial gastrocnemius (MG), and tibialis anterior. Self-adhesive, pregelled, surface disposable Ag-AgCl electrodes (10 mm in diameter) were aligned in parallel with the muscle fibers in a bipolar arrangement. The interelectrode distance was 10 mm. A ground electrode for each muscle site was placed nearby (within 10 mm) in such a manner so as to form an apex of a triangle with respect to the bipolar recording electrodes. The EMG signals were preamplified at the electrode site, bandpass filtered (10-500 Hz), and amplified × 1000. The EMG signals were collected with an analog-to-digital converter at a sampling rate of 1000 Hz. The EMG data were stored on the hard drive for off-line analyses.

Using an 8-camera motion analysis system (Peak Motus, Denver, CO) and the event timing algorithms of Hreljac et al,[30] the running cycle was defined from right heel strike to right heel strike. For each muscle, rectified EMG signals from 30 running cycles during the last 2 minutes of each treadmill stage were smoothed with linear processing algorithms to generate an envelope of EMG activity for each running cycle, and then, the 30 EMG envelopes were ensemble averaged.[31,32] The peaks of the ensemble averages of the 4 muscles were normalized to the peak of the ensemble average of treadmill stage 5, with treadmill stage 5 being expressed as 100%.[32-35]

***Comfort Perception.*** A visual analog scale (VAS) is a reliable indicator of footwear comfort when orthotic conditions are compared with a control condition during a physical activity such as running.[36,37] Using the VAS methodology of Mundermann et al,[36] subjects rated footwear comfort of their preferred shoes for performing endurance running with their orthotic intervention and with the shoe-fitted insoles on a scale from 0 mm "not comfortable at all" to 150 mm "most comfortable imaginable". A minimal meaningful difference for comfort perception ratings may be estimated to be from 20 to 25 mm.[19,36,37]

### Statistical Analyses

Descriptive statistics (mean, SD, 95th confidence interval [CI]) were used to report changes in running economy and muscle activity within and across subjects as a function of footwear conditions. In addition, a repeated-measures analysis of variance model with repeated measures on treadmill stages and footwear conditions was used to reveal the effects of custom-made orthotics on $V\text{O}_2$ during submaximal running. A paired *t* test was used to detect the effect of footwear conditions on $vV\text{O}_{2max}$. The test-retest accuracy of $V\text{O}_{2max}$ measurements was 2% or less. A paired *t* test was used to test the null hypothesis that the slight variations in $V\text{O}_{2max}$ between the testing days, that is, footwear conditions, were not different. Secondary analyses tested for the presence of order effects in the measurements of $V\text{O}_2$ and examined $V_E$ and RER during submaximal and maximal running protocols to address other potential confounding influences on the measurement of $V\text{O}_2$. Multiple paired *t* tests were used to detect differences for the various aspects of footwear comfort between conditions. The actual *P* values obtained from statistical tests were reported because there were no corrections for the experimentwise error rate or multiple comparisons due to the preliminary nature of the study design.

## Results

### Descriptive Statistics

Tables 3 and 4 summarize subject characteristics and their submaximal running performance as a function of footwear conditions. For all subjects, submaximal $V\text{O}_2$ was less when the subjects were wearing their orthotic intervention as compared with when they were wearing the shoe-fitted insoles. The mean improvement in submaximal $V\text{O}_2$ with the orthotic intervention was 7.66% with a range from 3.02% to 18.66%. For all subjects, $V_E$ was proportional to $V\text{O}_2$ across the 5 submaximal treadmill stages, and the correlations were similar between footwear conditions. For all subjects, RER's were similar between footwear conditions. Given that the subjects were metabolizing a similar mixture of foods to perform the submaximal running protocol, regardless of footwear condition, their energy expenditures were less when they were wearing their orthotic intervention as compared with when they were wearing the shoe-fitted insoles.

With respect to subject6, it was assumed that other factors beyond footwear were contributing to the approximately 19% improvement in running economy when the subject was wearing the orthotic intervention. $V_E$ and $V\text{O}_2$ were proportional across the 2 testing sessions for subject 6 ($R^2$ = .95). Although the subject was a trained distance runner and self-reported that activities of daily living, recreational activities, work-related activities, and sleep patterns were similar in the week preceding each testing session, the subject reported a greater perceived exertion when performing the submaximal running protocol, that is, same amount of work, wearing the shoe-fitted insoles as compared with the orthotic intervention. Maximal running performance was the same, $V\text{O}_{2max}$ and anaerobic threshold estimate, regardless of footwear condition. On average, subject 6 was exercising at 73% of $V\text{O}_{2max}$ while wearing her orthotic intervention and at 87% of $V\text{O}_{2max}$ while wearing her shoe-fitted insole with this latter value approaching her anaerobic threshold (93% of $V\text{O}_{2max}$) that was estimated during the maximal running protocol (anaerobic threshold algorithm, visual detection of "break point" in $V\text{CO}_2$ vs $V\text{O}_2$ slope).

### Footwear Comfort

Table 5 summarizes the ratings of footwear comfort. Subjects rated their preferred running shoes with their orthotic intervention as more comfortable than without their orthotic intervention, 112 vs 89 mm (*P* = .027). The orthotic intervention improved heel cushioning (*P* = .002), forefoot cushioning (*P* = .036), heel cup fit (*P* = .011), heel width (*P* = .024), and length (*P* = .038) of subjects' preferred running shoes with no reported improvements in medial-lateral stability (*P* = .192), arch height support (*P* = .148), and forefoot width (*P* = .051). When examining the

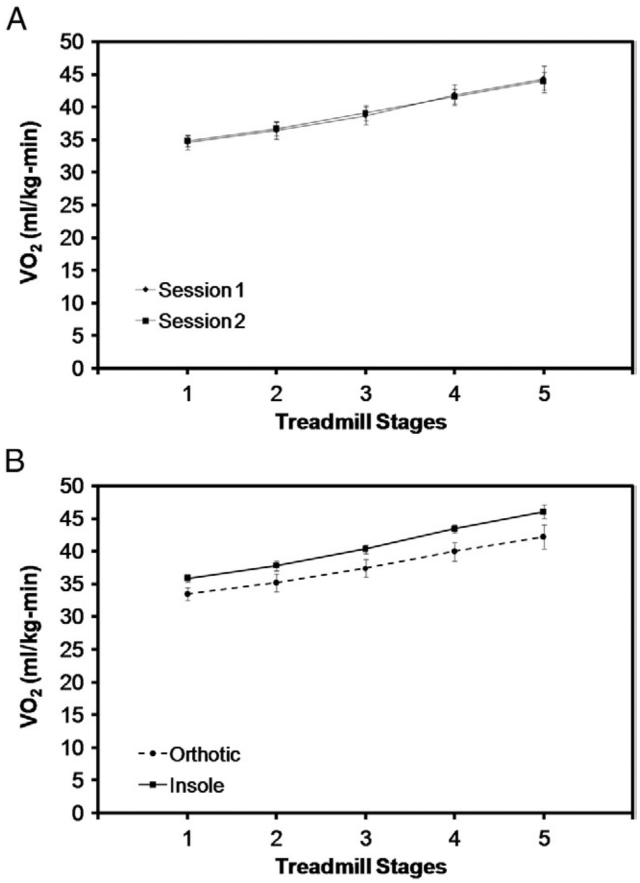


**Fig 1.** *A, Superimposed data lines with error bars for testing sessions 1 and 2 indicate that the order of testing the footwear conditions did not impact submaximal $Vo_2$ values at each treadmill stage (n = 6). B, Changes in submaximal $Vo_2$ values at each treadmill stage (n = 6) as a function of footwear conditions. Refer to Tables 1 and 2 for treadmill speeds at each stage as a function of sex. The error bars are the standard errors of the means.*

relationships between improvement in submaximal $Vo_2$ with the orthotic intervention and changes in footwear comfort characteristics with the orthotic intervention, moderate correlations ($0.40 \leq r \leq 0.69$) were observed for overall comfort ($r = 0.64$), heel cushioning ($r = 0.64$), heel cup fit ($r = 0.60$) with low correlations ($r < 0.40$) for medial-lateral stability ($r = 0.31$) and arch height support ($r = 0.33$). Improvements in submaximal $Vo_2$ and the overall fit of the running shoe with the orthotic intervention were evidence by high correlations ($r \geq 0.70$) for heel width ($r = 0.89$), forefoot width ($r = 0.86$), and length ($r = 0.71$).

### Submaximal Running Performance

There were no order effects of footwear condition on submaximal $Vo_2$ ($F_{(1,5)\text{session}} = 0.13$, $P = .913$, Fig 1A). Submaximal $Vo_2$ was significantly less across the 5 treadmill stages when the subjects were wearing their orthotic intervention as compared with when they were wearing the shoe-fitted insoles ($F_{(1,5)\text{footwear}} = 10.37$, $P = .023$; Fig 1B). Submaximal $V_E$ was significantly less across the 5 treadmill stages when the subjects were wearing their orthotic intervention as compared with when they were wearing the shoe-fitted insoles ($F_{(1,5)\text{footwear}} = 6.69$, $P = .049$). Footwear accounted for 68% of the variance in $Vo_2$ (partial $\eta^2 = 0.675$) at an observed power of 0.731 and for 57% of the variance in $V_E$ (partial $\eta^2 = .572$) at an observed power of 0.550. During submaximal running, RERs were similar for both footwear conditions ($F_{(1,5)\text{footwear}} = 0.122$, $P = .741$).

### Maximal Running Performance

Table 6 summarizes $Vo_{2max}$ and $vVo_{2max}$ for each subject. $Vo_{2max}$ values were similar for both footwear conditions ($t_5 = 0.049$, $P = .962$). $vVo_{2max}$ was greater when the subjects were wearing their orthotic intervention as compared with when they were wearing the shoe-fitted insoles ($t_5 = 4.20$, $P = .008$).

### Electromyographic Responses

There were no consistent changes in EMG activity as a function of increasing treadmill speeds or between footwear conditions.

## Discussion

Methodological decisions to use a sustained incremental treadmill protocol and to measure comfort perception of a custom-molded foot orthosis were effective at documenting systematic improvements in running economy of at least 3% in the 6 recreational runners tested. Footwear accounted for 68% of the variance in submaximal $Vo_2$. Increases in $vVo_{2max}$ are a statistical artifact of decreases in $Vo_2$ at several moderate exercise intensities for a given $Vo_{2max}$. In light of this statistical artifact, $vVo_{2max}$ estimated that a custom orthotic design improved endurance running performance of our 6 recreational runners by at least 3% with an average effect of approximately 12%. In summary, meaningful physiologic effects of the foot orthotic on the cardiopulmonary response to exercise (Tables 3-6) were at least 3%, with average effects ranging from approximately 5% to approximately 12%. In previous research studies, subtle physiologic effects of orthotic interventions on running economy were 1% to 2% during steady-state treadmill runs at 1 exercise intensity.[1,2]

Sustained incremental exercise protocols that are designed to generate an individual's economy-of-running line and predict endurance performance are very effective at revealing meaningful physiologic and functional changes in running economy as described previously.[3-8,12-15] Previous research documented relationships among shoe material characteristics, custom orthotic designs, running, and comfort perception.[1,2,19,22,24,36,37] All of our recreational runners rated meaningful improvements for heel cushioning with the custom-molded foot orthosis vs the shoe-fitted insoles. Heel cushioning is related to both injury prevention and comfort perception.[19,36,37] The relationships between improvement in submaximal $\dot{V}O_2$ with the orthotic intervention and changes in overall comfort ($r$ = 0.64) and heel cushioning ($r$ = 0.64) were similar.

Subject- and muscle-specific changes in EMG activity of the lower extremities were not observed between footwear conditions during the stance phase of running. Similar to our findings, Roy and Stefanyshyn[2] previously reported that decreases in EMG root mean square values analyzed during the stance phase of running did not accompany decreases in oxygen consumption as a function of footwear conditions. Detecting reduction of muscle activities of the lower extremities may depend on detailed analyses of EMG signals as a function of distinct events within the running cycle. In agreement with this recommendation, previous research reported that subject- and muscle-specific decreases in EMG root mean square values occurred during the preactivation phase[1] and weight acceptance phase[18] of the running cycle. As compared with EMG root mean square values, wavelet analyses for EMG of lower extremity muscles during gait activities may provide greater insights on the effects of orthotic interventions on muscle activation patterns.[20]

### Limitations

The inherent limitation of a preliminary study is the small sample size. The sampling frame of recreational runners and our ability to address the test-retest reliability of the effects of orthotic interventions on running economy were limited by the demanding nature of sustained running protocol. The economy-of-running lines for all of our subjects were linear with similar RER values for both testing session. However, RER values greater than 0.90 for 5 of the 6 subjects substantiated the demanding nature of our exercise protocol. Testing of recreational runners who already perceived their orthotic intervention as being their preferred footwear was subject selection bias. In addition, the availability of many high-quality commercial brand running shoes limited the sampling frame of recreation runners and contributed to subject selection bias. The generalizability of the data findings is limited by subject selection bias and an inadequate sample size; as such, insights on clinical effectiveness and decisive neuromechanical mechanisms of orthotic interventions are not addressed by this research.

Although the subjects did not report any major dietary or training modifications between testing sessions, a diet diary and training log may more accurately address any potential confounding effects of short-term dietary modifications or muscle fatigue on cardiopulmonary responses to exercise. Menstrual cycle phases were not documented. A limited number of studies on endurance performance documented higher heart rates, greater ratings of perceived exertion, and increases in $\dot{V}O_2$ from 2% to 8% when females were exercising at workloads greater than 65% of their $\dot{V}O_{2max}$ during the mid-luteal phase of their menstrual cycle.[28,38-40] The confounding effects of interdian variation on the time-based parameters of oxygen uptake kinetics during treadmill running and/or menstrual cycle phase may have contributed to the 19% difference in submaximal $\dot{V}O_2$ as function of footwear for subject 6.[27,28,41,42]

Future research needs to address intraday and interday reliability of measuring the effects of orthotic interventions on movement economy, adequate sample sizes, and the potential confounders of diet, previous exercise, menstrual cycle phase, and oxygen uptake kinetics on cardiopulmonary responses to exercise. Developing controlled laboratory protocols to determine movement economy by varying exercise intensities from walking to jogging to running will decrease the physical demand of the sustained incremental exercise protocol and allow us to address the limitations of the current research.

## Conclusion

Methodological decisions to use a sustained incremental exercise protocol at several moderate exercise intensities and to measure comfort perception of a custom-molded foot orthosis were effective at documenting systematic improvements in running economy among the 6 recreational runners tested. However, the development of a less physically demanding sustained exercise protocol that is reliable and mimics physical activities of daily living is necessary to determine underlying neuromuscular mechanisms and/or clinical effectiveness of orthotic interventions.

### Practical Applications

- Ratings of comfort perception of custom orthotic designs with an adequate adaptation or "wear-in" period may be important to detect physiologic meaningful changes in running economy.
- Development of laboratory-controlled protocols on movement economy that more closely mimic recreational and daily living physical activities is necessary to determine underlying neuromuscular mechanisms and/or clinical effectiveness of orthotic interventions.
- The research data provide some evidence base for recommending orthotic interventions to recreational athletes who are seeking chiropractic health care for musculoskeletal complaints related to their participation in physical activities.

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# Erratum

In the article "Thank You to JMPT Peer Reviewers for 2011" by Johnson C in the February 2012 issue (2012;35(2):74-5; doi:10.1016/j.jmpt.2012.01.003), the following name was accidentally omitted and should be included on the list of 2011 peer reviewers: James Brantingham, DC, PhD.