Changes in Gait Economy Between Full-Contact Custom-made Foot Orthoses and Prefabricated Inserts in Patients with Musculoskeletal Pain

A Randomized Clinical Trial

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Background: Specific kinematic and kinetic outcomes have been used to detect biomechanical change while wearing foot orthoses; however, few studies demonstrate consistent effects. We sought to observe changes in walking economy in patients with musculoskeletal pain across 10 weeks while wearing custom-made foot orthoses and prefabricated shoe inserts.

Methods: In this crossover randomized controlled trial, 40 participants wore custom-made orthoses and prefabricated inserts for 4 weeks each, consecutively. The path length ratio was used to quantify walking economy by comparing the undulating path of a point in the pelvis with its direct path averaged across multiple strides.

Results: For the prefab-custom group (n = 27), significant decreases in path length ratio (improved economy of gait) were noted at the initial introduction of prefabricated inserts ($P = .02$) and custom orthoses ($P = .02$) but maintained a trend toward improved economy only while wearing custom orthoses ($P = .08$). For the custom-prefab group (n = 13), there was worsening of the path length ratio that was significant after removing the custom-made orthoses for 4 weeks ($P = .01$).

Conclusion: For patients with lower-extremity musculoskeletal pain, immediate improvements in economy of gait can be expected with both interventions. It seems, however, that only the custom-made orthoses maintain economy of gait for 4 weeks. Patients who begin wearing custom-made orthoses and then wear prefabricated insoles can expect a decrease in economy of gait. (J Am Podiatr Med Assoc 98(6): 429-435, 2008)

Despite the generally accepted notion that foot orthoses offer symptomatic improvement for common musculoskeletal conditions of the lower limb,[1, 2] the exact mechanism by which foot orthoses offer improvement is still unclear. The theory that foot orthoses serve to "realign the skeleton" is unsubstantiated[3, 4] because numerous kinematic studies[4-6] show small, nonsystematic, and patient-specific change with and without the use of orthoses. A main challenge in evaluating the kinematic effects of foot orthoses has been the selection of a sensitive objective method of measurement. Detailed biomechanical examination of specific lower-extremity joints, such as the rearfoot, knee, and hip, yield patient-specific changes but universal trends.[3, 4, 7] A biomechanical outcome measure that is reliable, valid, and sensitive to change is required to objectively determine the influence of foot orthoses on gait. Foot orthoses, theoretically, alter the kinematic, kinetic, and neural control patterns a person uses in gait to reduce or avoid pain. In addition, it could be argued that improved gait (walking) economy is desired. *Gait economy* might be defined as the amount of work required to walk using a particular style of walking. Increased gait economy implies less work. Gait, or the style of walking, is unique to an individual and may include qualities associated with biomechanical or neurologic alterations. One goal of efficient walking is to move forward expending the least amount of energy. Energy

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consumption measurements, such as the use of oxygen during walking, are a fundamental component of gait analysis, yet alone they do not explain how one gait pattern may require more or less effort than another.[8] In addition, measurement of oxygen consumption is impractical in a clinical setting.

The biomechanical efficiency quotient, first reported by Kerrigan et al[9] in 1996, uses average stride length, vertical displacement of the trunk during walking, and sacral height during standing to quantify biomechanical walking economy. The biomechanical efficiency quotient assumes that energy is conserved if the vertical excursion of the body's center of mass is minimized.[10] The biomechanical efficiency quotient is expressed as the measured vertical displacement divided by the predicted vertical sacral displacement, where increasing values indicate increasingly less economical gait. The mathematical model designed to predict actual vertical sacral displacement correlated strongly with predicted displacement (r = 0.94),[11] and the biomechanical efficiency quotient has been shown to be associated with energy cost.[9, 12] Although the biomechanical efficiency quotient seems to be a valid tool for measuring walking economy, its reliability and sensitivity to change are unknown. Given that the biomechanical efficiency quotient uses stride length and sacral vertical displacement, both of which can be independently controlled during constant-speed gait, the biomechanical efficiency quotient may have poor measurement properties and is, therefore, poorly suited to detecting small changes in walking economy, such as those induced by foot orthoses. In 1996, Kerrigan et al[9] determined that the biomechanical efficiency quotient was sensitive enough to detect changes with and without ankle-foot orthoses in participants with significant neurologically based gait disabilities. However, for intervention investigations where subtle changes are expected, it was thought that a more sensitive and reliable objective measure of gait effort was required.

A recent investigation suggested that other outcomes may be better able to discriminate small changes in gait.[13] One outcome that seems to effectively detect changes in gait economy is the path length ratio. It uses the length of the curved trajectory of a fixed point in the pelvis (approximates the person's center of mass) as a person walks one stride. The length of the curved path is compared with the direct path. The ratio of these two lengths (curved over direct) provides a measure of walking economy. The median value of multiple curved and direct path ratios obtained from a set of strides is used to calculate the path length ratio. The value of the path length ratio is always greater than 1.0, and larger values imply impaired walking economy because increasingly undulating gaits are less economical. The path length ratio has a 95% upper confidence limit standard error of measurement of 0.001 U and is approximately 22 times more sensitive than the biomechanical efficiency quotient at detecting changes in walking speed.[13] We propose that the path length ratio is sensitive at detecting differences in walking economy in participants wearing custom-made foot orthoses versus prefabricated shoe inserts. Because it is still unclear whether custom-made foot orthoses offer any benefit over inexpensive prefabricated devices,[14] we hope to show that this tool is sensitive enough to detect objective differences between these devices. A limitation of this outcome is that interpreting a change in the path length ratio, at present, is challenging. Absolute changes cannot be converted to change in metabolic cost, and the minimal clinically important difference is not known.

This study determined the pattern of change in walking economy measured across 10 weeks using the path length ratio in participants with common musculoskeletal complaints who were using prefabricated inserts and custom-made orthoses. We hypothesize that there are statistically significant decreases in the path length ratio (improved economy) using custom-made orthoses compared with prefabricated inserts. This hypothesis is supported by a study[15] using the same participants whereby they rated their pain by using the numerical pain rating scale while wearing the custom and prefabricated interventions. A statistically significant decrease in the numerical pain rating scale score was noted after 3 and 4 weeks in the group that started wearing the custom-made orthoses. There was also a statistically significant increase in pain when the custom-made orthoses were removed from this group.

Methods

Design

Forty-two participants were randomly assigned to receive custom-made orthoses for 4 weeks and then prefabricated inserts for 4 weeks (custom-prefab group) or prefabricated inserts for 4 weeks and then custom-made orthoses for 4 weeks (prefab-custom group). Gait analysis was performed at McMaster University's Human Movement Laboratory. Participants were fitted with a belted sensor pack containing three markers that was tightened over the pelvis and across the sacrum. The Optotrak (Northern Digital

Inc, Waterloo, Ontario, Canada), a highly accurate three-dimensional motion measurement device, was used to measure movement of the markers. Participants were asked to walk on a treadmill at a standard speed of 0.89 m/sec (2.0 mph) for 3 min. Path length ratio values for two groups of participants (custom-prefab, n = 13 and prefab-custom, n = 27; two nonadherent individuals) were measured at weeks 0, 2, 6, and 10. Each group wore their first assigned intervention from weeks 2 to 6 and the second intervention from weeks 6 to 10. The intervention crossover occurred at week 6. Note that no washout period was provided between the two foot orthosis conditions. A path length ratio value was obtained while wearing each intervention at the crossover point. Changes in the path length ratio during the first intervention period were compared with those at the first baseline at week 0. Changes in the path length ratio during the second intervention period were compared with those at the second baseline at week 6.

Participants

A convenience sample of participants was recruited via electronic mail postings on the McMaster University intranet. Individuals came from the medical, teaching, and administrative staff and their spouses and from the undergraduate and graduate student population. Participants were at least 18 years of age with an active lifestyle (participated in planned activity three times per week or more for ≥ 30 min). They presented with one (primary) or several (secondary) current musculoskeletal complaints of the lower extremity during activity, including plantar fasciitis, metatarsalgia, tibialis anterior/posterior tendonitis, and patellofemoral tracking dysfunction. Exclusion criteria included systemic disease (eg, rheumatoid arthritis), having worn foot orthoses during the past 6 months, pain as a result of traumatic injury (eg, fracture or sprain), a hereditary condition (eg, Charcot-Marie-Tooth disease), or a fixed deformity (eg, rigid forefoot equinus). Sex, ethnicity, and body weight were not part of the exclusion criteria. The participants also had to be available for a continuous 10 weeks. During this time, they had to attend a testing facility during weeks 0, 2, 6, and 10. Last, the participants had to be willing to wear prescribed foot orthoses in a comfort-style shoe for a continuous 8 weeks.

Outcome Measure

The primary outcome measure used in this study was the path length ratio. It has been suggested that the path length ratio can be reliably measured (ρ^2 = 0.972) and that 0.001-U changes can be confidently (95% confidence interval) detected.[13]

Interventions

Each of the 42 participants was cast during week 0 for a pair of custom-made foot orthoses. Prefabricated shoe inserts were ordered for each participant according to shoe size. The interventions were accurately trimmed and fitted into each participant's footwear by the primary researcher. The participants were not told any details about the intervention itself. The participants were instructed to wear the combination of intervention and footwear for a single hour the first day, adding an hour or two each day (within tolerance) until they could wear the combination for the entire day. Each participant was instructed to wear the first intervention for 4 weeks (weeks 2–6) and the second intervention for 4 weeks (weeks 6–10). It was not possible to blind the primary researcher to the intervention assignment. In addition, although the participants were not told which intervention they were receiving, significant differences in the "feel" and appearance of the interventions made complete concealment impossible.

Full-Contact Custom-made Foot Orthoses. For the purpose of standardization, a single practitioner (L.C.T.) cast each participant and used the method of a single orthotic laboratory (Sole Supports Inc, Lyles, Tennessee). A previous investigation[16] determined the intracaster forefoot to rearfoot frontal plane angle reliability of ρ^2 = 0.94 using this casting method. This foam casting box method uses the ground as the solid frame of reference, ensuring that the heel and the fifth and first metatarsal heads are on the plane of the ground while maintaining maximal attainable arch height. The idealized contours of the foot are captured in a functional posture called *maximal arch subtalar stability*.[17] The custom-made foot orthoses were cast in a functional posture to maximize the longitudinal arch height at midstance with the heel and the fifth and first metatarsal heads on the ground. The orthoses were created from a non–cast-corrected (no plaster fill was added) three-dimensional plaster of Paris model of each participant's foot. They were made from a thermoplastic (high-molecular-weight high-density polyethylene) matched in thickness to participant characteristics (body weight, arch shape, and arch flexibility rating) and were fabricated to fully contact the sole of the participant's foot from the heel to just proximal to the metatarsal heads.

Prefabricated Shoe Inserts. The prefabricated insert was a low-density, open-celled, 4-mm foam insert (Tana Sport, a division of Sara Lee Household & Body Care Canada, Cambridge, Ontario, Canada) sized to each participant's foot. This type of inexpensive cushioning-style shoe insert is representative of those that are readily available in many retail outlets.

Data Analysis

This study was originally designed to detect an effect size greater than 1.0 (a change in path length ratio group mean greater than 1 SD), with type I and type II errors at 0.05 and 0.2, respectively. These values were used to calculate a minimum sample size of 16 participants per group.[18] In addition, we assumed a 25% participant dropout rate, which required that we enroll 20 patients per study group.

A between- and within-group two-way analysis of variance was used to determine whether the participants' path length ratio scores differed. An independent-samples *t* test was used to determine whether the two groups had different path length ratio values at baselines 1 and 2. Analyses were performed with a software program (SPSS version 15; SPSS Inc, Chicago, Illinois), with $\alpha = 0.05$ indicating significant statistical differences. Sphericity tests determined that the variances were equally distributed in the two groups across time. Post hoc tests to determine within-group differences across time used least significant differences and were adjusted for multiple comparisons.

Results

Descriptive Characteristics

Two of the 42 participants withdrew from the study before the second- and sixth-week visits to the testing facility due to scheduling conflicts. This represents an attrition rate of approximately 5%, much better than the anticipated 25%. The remaining 40 participants completed the entire 10 weeks of the study. Most of the participants were women (27 versus 13) who were also older than the men (35.7 versus 32.5 years). The overall mean (SD) age was 34.6 (11.3) years. The primary regions of musculoskeletal discomfort were classified into four categories: arch/foot (n = 12), heel (n = 10), metatarsal (n = 8), and shin/knee (n = 10). There was no significant difference in the frequency of regions ($\chi^2_3 = 0.80$, $P > .05$). A shipping delay of the custom orthoses required that seven participants who were randomized to receive the custom orthoses first instead received the prefabricated insert first and the custom product second.

Effect of Foot Orthoses on Walking Economy

Baseline 1 was the path length ratio measurement at week 0, when the participants had not yet been introduced to an intervention. Baseline 2 corresponds to the path length ratio measurement after the participants had worn their first intervention for 4 weeks (week 6 of the study). The prefab-custom and custom-prefab groups had significantly different path length ratio scores at the first baseline (1.015 and 1.011, respectively, $t_{38} = 4.030$, $P < .001$) and at the second baseline (1.015 and 1.011, respectively, $t_{38} = 4.349$, $P < .001$) (Fig. 1). Post hoc power analysis determined that the prefab-custom group was powered at 0.822 and the custom-prefab group at 0.442.

For the prefab-custom group, there was a significant improvement in path length ratio between baseline 1 (week 0) and the introduction of the prefabricated insert at week 2 ($P = .02$). This effect however, was not maintained for the 4 weeks of wearing the prefabricated insert ($P = .32$). This group also showed a significant improvement on first wearing the custom-made orthoses compared with the first baseline ($P = .01$), and this effect was maintained for the 4 weeks of custom orthoses use ($P = .01$). A significant improvement in path length ratio was found at baseline 2 (week 6 initial intervention) and week 6, initial introduction of custom orthoses ($P = .02$), that did not remain significant throughout the 4-week course of wear compared with the second baseline. There was, however, a trend toward maintenance of gait economy while the custom-made orthoses were being worn ($P = .07$). A trend was considered if $P \leq .075$ but did not reach a significance of $P \leq .05$.

For the custom-prefab group, there was no effect at the introduction of the custom orthoses ($P = .17$) or at the end of the 4 weeks of wear ($P = .26$). Likewise, there was no effect on the immediate introduction to the prefabricated insert at week 6 ($P = .90$). There was, however, a significant decrease in the path length ratio (worsening of economy of gait) at week 10, 4 weeks after the custom-made orthoses had been removed ($P = .01$).

Discussion

The aim of this study was to determine whether the use of custom-made foot orthoses by participants with musculoskeletal pain of the lower limb resulted in improved economy of gait. These findings show that those patients may experience improved economy of gait while wearing custom-made foot orthoses for 4 weeks. The prefab-custom group saw improved economy of gait, which met statistical significance,

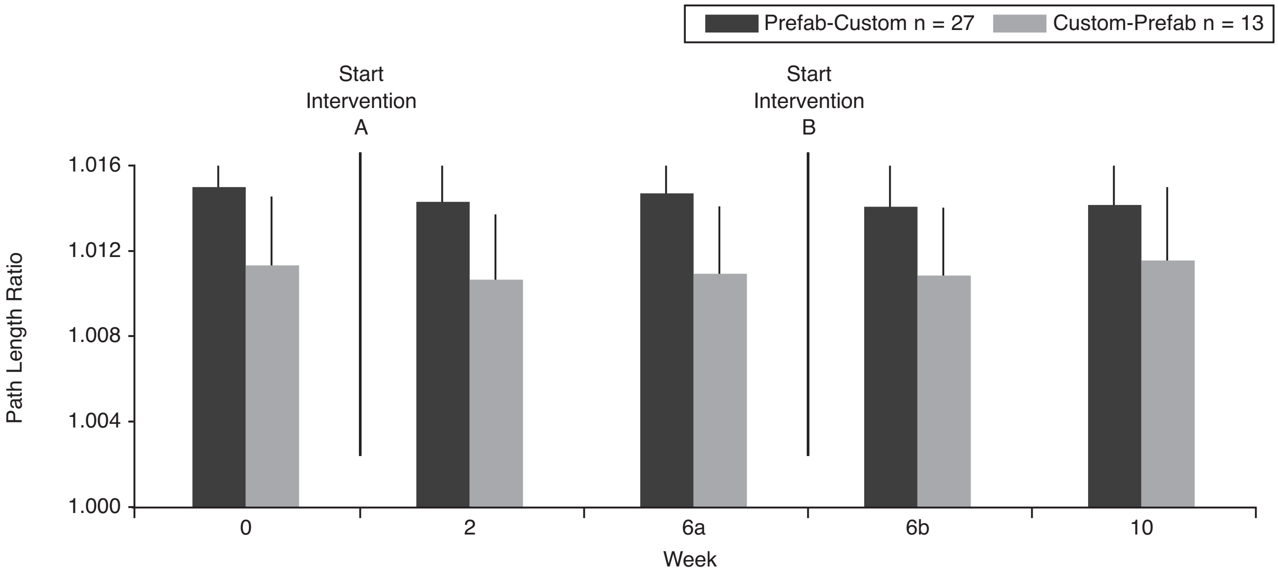

Figure 1. Changes in gait economy, measured using the mean path length ratio, across 10 weeks for 27 participants wearing shoes with a prefabricated shoe insert for 4 weeks and then full-contact custom-made orthoses for 4 weeks (prefab-custom group) and for 13 participants wearing shoes and the devices in the reverse order (custom-prefab group). Error bars represent SD.

on immediately using the prefabricated insert and the custom-made orthoses. It seems that both interventions resulted in a perturbation of the gait toward improved economy. Only the custom-made orthoses, however, sustained the effect across time. These results had some parallel findings to a previous study[15] with this same group of participants when asked to report their changes in pain. The introduction of either intervention saw a slight increase in reporting of pain, which may relate to the "perturbation effect," but only use of the custom-made orthoses saw a sustained reporting of decreased pain, which was maintained for weeks. Because these changes in path length ratio mimicked the pain response in the same participants, there is support for construct validity of the measurement.

For the custom-prefab group, there was a significant decrease in walking economy, as measured using the path length ratio, at week 10 that corresponds to wearing the prefabricated insert 4 weeks after wearing the custom-made orthoses for 4 weeks. This result mirrors the reporting of increased pain in this patient sample when the custom-made foot orthoses were removed after 4 weeks.[15]

One limitation of this study was the unbalanced group size. The custom-prefab group had 13 participants compared with 27 in the prefab-custom group. Accordingly, the group with 13 participants was poorly powered at 0.442, which allowed less certainty to claim that there was no effect of either of the interventions before the statistically significant week 10 effect. It is possible that there was an immediate effect due to the prescription of the custom-made foot orthosis, but the small sample size limited statistical inference. Adequate power of 0.822 was achieved in the prefab-custom group such that there is greater certainty in claiming that the observed nonchanges were in fact true. The sample size calculations of 16 participants per group were optimistic. Future studies should use a minimum of 25 participants per group to achieve a power similar to that of the group with 27 participants in this study.

This study also used a nonstandard crossover statistical design. Typically, a pause (washout period) between the two consecutive interventions is introduced to minimize the effects of the first intervention on the second's influence.[18] This then allows one to analyze the two group's data as if they received both interventions in the same order (crossover one group's data). We did not have the practical ability to introduce a washout period. This design then suggested the time-series analysis reported in this article. Our design also had the added benefit of mimicking clinical scenarios in which a patient is prescribed very conservative orthoses for 4 weeks and is then introduced to a more aggressive intervention (the prefab-custom group herein). Alternatively, a patient initially given aggressive orthoses for 4 weeks then switches to a conservative insert (the custom-prefab group herein) is also modeled. Further implications of these scenarios are discussed by Trotter and Pierrynowski.[15]

This study used a less common method for fabricating the foot orthoses. The custom-made full-contact foot orthoses used in this study used the Sole Supports Inc protocol.[17] This particular casting and fabrication method considers the maximum natural arch and body mass characteristics of each patient. This product might be classified as a more aggressive form of functional foot orthosis because there is no addition of medial arch fill during cast preparation. Accordingly, the generalizability of these results is limited to these foot orthoses.

The overall attrition rate in this study was small (< 5%) compared with similar prospective foot orthoses studies,[19] with rates of 27% to 41%. This could be attributed to the fact that this study was conducted in a university hospital environment, where the general understanding and attitudes toward research are very positive.

Much of the research attempting to determine how foot orthoses improve clinical symptoms uses biomechanical models to measure specific changes in lower-extremity kinematics. Several studies[20] have indicated that orthoses reduce the amount of foot pronation in the flatfoot condition. Medially wedged orthoses have also been reported to decrease frontal and transverse motion at the knee, but the effects were very small (1° and 2°).[21] We propose that the path length ratio may be of more clinical interest when measuring the effects of foot orthoses due to its use of "global" walking economy in lieu of isolating a single kinematic variable. The sustained improvement in economy of gait in participants wearing full-contact custom-made foot orthoses may be due to increased medial longitudinal arch contact. The study by Nurse and Nigg[22] suggests that varied sensory input to the sole of the foot affects coordination and adjustment of gait. Nigg[23] theorizes that optimal plantar sensory input allows lower-limb musculature adaptation to a preferred gait pathway with the result of decreasing muscle activity. Nigg's neuromuscular model may help explain why immediate changes (perturbations) in the path length ratio are seen when placing either the prefabricated or the custom-made intervention into participants' shoes.

There have been suggestions that custom-made foot orthoses are no more efficacious than are inexpensive prefabricated devices in the prevention of injuries.[14] Others, however, noted that custom-made devices are better across time.[24] The present results seem to support the notion that custom-made foot orthoses are better than prefabricated shoe inserts and result in immediate and longer-term improvements in walking economy.

Conclusion

For patients with lower-extremity musculoskeletal pain, immediate improvements in economy of gait can be expected on wearing prefabricated inserts and full-contact custom-made foot orthoses. It seems, however, that this effect is maintained for at least 1 month for only the custom-made foot orthoses. Patients who begin wearing full-contact custom-made foot orthoses and then cease to wear them may expect a decrease in walking economy within 4 weeks. Future work exploring longer periods of orthotic wear and changes in gait economy may be valuable in determining at what point participants reach maximum gait economy. In addition, investigations that use different types of foot orthoses are required to determine the generalizability of these findings.

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