Sensory Enhancing Insoles Modify Gait during Inclined Treadmill Walking with Load

DANIEL L. MIRANDA[1], WEN-HAO HSU[1], KELSEY PETERSEN[1], STACEY FITZGIBBONS[1], JAMES NIEMI[1], NICHOLAS LESNIEWSKI-LAAS[1], and CONOR J. WALSH[1,2]

[1]Wyss Institute for Biologically Inspired Engineering at Harvard University, Boston, MA; [2]School of Engineering and Applied Sciences, Harvard University, Cambridge, MA

ABSTRACT

MIRANDA, D. L., W.-H. HSU, K. PETERSEN, S. FITZGIBBONS, J. NIEMI, N. LESNIEWSKI-LAAS, and C. J. WALSH. Sensory Enhancing Insoles Modify Gait during Inclined Treadmill Walking with Load. *Med. Sci. Sports Exerc.*, Vol. 48, No. 5, pp. 860–868, 2016. **Introduction**: Inclined walking while carrying a loaded backpack induces fatigue, which may destabilize gait and lead to injury. Stochastic resonance (SR) technology has been used to stabilize spatiotemporal gait characteristics of elderly individuals but has not been tested on healthy recreational athletes. Herein, we determined if sustained vigorous walking on an inclined surface while carrying a load destabilizes gait and if SR has a further effect. **Methods**: Participants were fitted with a backpack weighing 30% of their body weight and asked to walk at a constant self-selected pace while their feet were tracked using an optical motion capture system. Their shoes were fitted with SR insoles that were set at 90% of the participant's sensory threshold. The treadmill incline was increased every 5 min until volitional exhaustion after which the treadmill was returned to a level grade. SR stimulation was turned ON and OFF in a pairwise random fashion throughout the protocol. Spatiotemporal gait characteristics were calculated when SR was ON and OFF for the BASELINE period, the MAX perceived exertion period, and the POST period. **Results**: Vigorous activity increases variability in the rhythmic stepping (stride time and stride length) and balance control (double support time and stride width) mechanisms of gait. Overall, SR increased stride width variability by 9% before, during, and after a fatiguing exercise. **Conclusion**: The increased stride time and stride length variability may compromise the stability of gait during and after vigorous walking. However, participants may compensate by increasing double support time and stride width variability to maintain their stability under these adverse conditions. Furthermore, applying SR resulted in an additional increase of stride width variability and may potentially improve balance before, during, and after adverse walking conditions. **Key Words:** LOAD CARRIAGE, FATIGUE, STOCHASTIC RESONANCE, SOMATOSENSORY SYSTEM, PROPRIOCEPTION, VARIABILITY, SENSATION

Recreational hiking has gained popularity in the United States, with an estimated 73 million Americans hiking each year (6,45). Similar to soldiers, recreational hikers commonly walk vigorously on various terrains and inclines while carrying a loaded backpack ranging in mass from 10% to 60% body weight (BW) (10,45). This vigorous activity causes fatigue, which may have combined effects on gait stability and biomechanics that increase the risk for acute injury. Although no studies have investigated the combined effect of inclined walking, backpack load carriage, and/or fatigue on gait, there is evidence that each of these factors has an isolated effect on the kinematics, kinetics, and/or spatiotemporal gait characteristics of walking.

Gabell and Nayak (13) separate spatiotemporal gait characteristics from those related to the rhythmic stepping mechanism (stride time and stride length) and the balance control mechanism (double support time and stride width). Few studies have quantified these variables during any combination of inclined walking, backpack load carriage, and/or fatigue. For inclined walking, results from two independent studies suggest that spatiotemporal gait characteristics are not altered while walking at an incline (26,29); however, these studies did not incorporate the effects of backpack loading and/or fatigue into their protocols.

Extensive research has been conducted on the effect of load carriage on joint kinematics and kinetics during walking (28); however, few studies have investigated the effect of load carriage on spatiotemporal gait characteristics. A study by Dames and Smith (11) did not report any difference in stride time, stride length, double support time, or stride width between level ground walking with no load and 15% BW. Results published by Mullins et al. (33) showed no changes in spatiotemporal gait characteristics while participants performed a 2-h level ground walking protocol while carrying a 22-kg load distributed between a vest, combat webbing, and a firearm. Furthermore, there is evidence that

---

Address for correspondence: Daniel L. Miranda, Ph.D., Wyss Institute for Biological Engineering at Harvard University, 3 Blackfan Circle, 2nd Floor, Boston, MA; E-mail: daniel.miranda@wyss.harvard.edu.
Submitted for publication September 2015.
Accepted for publication November 2015.

0195-9131/16/4805-0860/0
MEDICINE & SCIENCE IN SPORTS & EXERCISE®

DOI: 10.1249/MSS.0000000000000831

female recreational hikers (40) and soldiers (17) have increased double support time in response to increased load while walking on the level ground. This increase in double support time was also observed in male soldiers carrying a very heavy load and is thought to provide greater control and stability during walking (18,19,21). Although interesting, these findings are less applicable to recreational hikers or soldiers fatigued by prolonged vigorous inclined walking while carrying a common backpack load.

Polcyn et al. (36) has observed an increase in energy expenditure as a result of load carriage. Hasselquist et al. (20) reported additional increases in energy expenditure when walking with a backpack load at a 9% incline grade. These studies also show an increase in double support time as a result of loading and the incline. Despite these findings, no prolonged fatiguing protocol was performed. However, there is evidence that spatiotemporal gait characteristics are affected by muscle fatigue. Barbieri et al. (1) show that muscular fatigue increased both stride time and step width. Work from Qu and Yeo (37) incorporated fatigue into their loaded walking protocol to determine its effect on spatiotemporal gait characteristics with and without a backpack load. Their findings show that step width variability increased after fatigue and while carrying a heavy load, which are in agreement with the Barbieri et al. study. Only Qu and Yeo reported that variability was affected as a result of load and/or fatigue.

Although the spatiotemporal gait characteristics are important for quantifying gait, it is clear that too little or too much variability in these characteristics is a sign of gait instability (2,3,7,42). The combined effect of inclined walking, backpack load carriage, and fatigue on spatiotemporal gait characteristics may compromise walking stability and may increase risk of slip, trip, and fall injuries (4,39). In fact, 68%–82% of recreational hikers who suffer an injury do it during a single hike. Specifically, the main acute injuries are ankle sprains (11%–47% of hikers) and lacerations, abrasions, and/or fractures (5%–59% of hikers) (45).

The human somatosensory system provides important control information about tactile sensation, balance, and proprioception to coordinate foot placement and prevent accidents (9,22,25). These mechanoreceptors provide information about the rhythmic stepping and balance control mechanisms of gait to successfully prevent slipping, tripping, and/or falling while walking (12,35). More importantly, loss of proprioception as a result of extended vigorous activity while carrying a loaded backpack has been identified as an injury risk factor (23,34,46). This loss in proprioception may negatively influence spatiotemporal gait characteristics during hiking, thus increasing an individual's risk of sustaining an injury.

There are few options to restore sensation; however, one potential is using the principle of stochastic resonance (SR). SR refers to a phenomenon in nonlinear biological systems where sensory signal recognition is enhanced by the introduction of low levels of uncorrelated input noise. The mechanism by which SR improves sensitivity is most likely a partial depolarization of the receptor membrane, shifting the receptor closer to the action potential firing threshold (35). Sensory enhancing insoles, using SR technology, target the cutaneous tactile and proprioceptive mechanoreceptors that are abundant on the plantar aspect of the foot (27). When applied to these mechanoreceptors, SR is shown to improve stride time, stride length, double support time, and/or stride width in healthy elderly people, patients with stroke, and patients with diabetic neuropathy (24,25,30,42). Notably, a recent study by Lipsitz et al. (30) has shown that the improvements in spatiotemporal gait characteristics gained when SR is on translate to an improved score in a clinical test assessing fall risk in elderly participants. Although there has been some work on evaluating the effect of SR on younger walkers (14), no study has investigated the effect of SR on the gait characteristics of healthy young recreational athletes during an extended vigorous walking protocol designed to mimic an arduous uphill hike while carrying a loaded backpack.

It should be noted that high variability in the rhythmic stepping mechanism of gait (stride time and stride length) is associated with gait instability (31,44), whereas variability in the balance control mechanism (double support time and stride width) of gait is not always an index of instability (3). As mentioned before, too much or too little step width variability are both a reflection of gait instability (2,7). Healthy young individuals with relatively low baseline variability, compared with the elderly, may demonstrate a different response when their gait is compromised and/or when SR is applied. Therefore, the purposes of this study were to determine 1) if gait characteristics are modified before, during, and after sustained vigorous walking on an inclined surface while carrying a loaded backpack and 2) if mechanical SR applied to the plantar aspect of the feet further changes these gait characteristics. We hypothesized that sustained vigorous walking on an inclined surface while carrying a loaded backpack would increase the gait characteristics related to the balance control (double support time and stride width) mechanism to compensate for the compromised gait characteristics related to the rhythmic stepping (stride time and stride length) mechanism (i.e., increases in the stride time and stride length). Furthermore, we hypothesized that mechanical SR applied to the plantar aspect of the feet would decrease the stride time and stride length gait characteristics although further increase the double support time and step width gait characteristics.

METHODS

Research participants. The Harvard Medical School Institutional Review Board approved all experimental procedures and recruitment materials used for this study. Twenty-seven recreational athletes (10 female, 17 male; 22.4 ± 3.1 yr old; 156.5 ± 22.0 lb; 67.7 ± 3.4 inches; 90.3 ± 9.3 bpm peak hour; 8/14/20 min/med/max percent peak incline; 1.1 ± 0.1 $m \cdot s^{-1}$ treadmill speed) were enrolled in this study. The self-reported inclusion criteria were as follows: 1) 18–30 yr old; 2) no prior medical history of major injuries or pathologies (such as a fracture, ligament tear/sprain, arthritis) to the ankle, knee, or hip that resulted in hospitalization or enrollment in a rehabilitation/therapy program; 3) no chronic disease; 4) no neurological, visual, vestibular, or balance disorders; 5) no systemic infection at the time of the study; 6) not pregnant; 7) no tobacco or recreational drug use; 8) fluent in English (because of language limitations of the research team); 9) exercise at least 3 $h \cdot wk^{-1}$; and 10) with a Tegner activity score of 3 or greater (43). An additional criteria reported by the research team included a vibratory SR perception threshold within 10%–100% of the stimulation amplitude of the insole device. This permitted the device to be set to the stimulation range used successfully in previous studies (42).

Participants were asked to bring their own shoes to the study visit and remove the original insoles. Upon granting his or her informed consent, each participant donned an HR monitor (BioHarness 3 Chest Strap; Zephyr Technology, Annapolis, MD), athletic shirt, shorts, and socks provided by the research team. Next, participant weight was taken to load a standard issue United States Military MOLLE II Backpack to 30% of their BW. This weight was chosen based on studies showing that the optimal backpack load for males (16) and females (40) is 30% BW while still impacting the participants' perceived exertion (38). The backpack was loaded such that the weight was placed in an internal pouch located at shoulder height and close to the backpack frame. The backpack was then fitted to the participant so that the load was comfortably distributed across their torso and waist using the backpack shoulder straps and waist belt. Five retroreflective surface markers were placed on each shoe and ankle in the following locations: first and fifth metatarsal heads, medial and lateral malleoli, and the heel. An additional four markers were rigidly affixed to a contoured plastic plate that was secured to the dorsal aspect of each shoe.

Insole device. Three-quarter-length vibrating insoles were fitted into each participant's shoes before beginning the study procedures. The insole device has been previously described in detail (30). Briefly, two piezoelectric actuators were placed 2 cm apart and embedded within the urethane foam of the insole. These actuators were double insulated to avoid electrical contact with the participant's foot and positioned in the middle arch region of the insole to deliver SR stimulation to the plantar aspect of the foot. The electrical circuit components and control software for each insole were tethered to the participant by a 30-ft cable permitting investigator control and adjustment. These cables were routed along the legs and away from the participant to allow the study task to be conducted safely without the risk of tripping. The vibrating insole devices used in this study are still investigational. All devices were approved by the Harvard Medical School Institutional Review Board and labeled as nonsignificant risk devices.

Determining SR thresholds. The participant's sensory perception threshold was determined for each foot after donning the loaded backpack using the threshold determination method described by Lipsitz et al. (30). A computer tablet running custom LabVIEW software (National Instruments Corporation, Austin, TX) was used to interface with and control the amplitude of the SR being delivered to the insoles. The participant was asked to stand in a neutral position with equal weight on each foot. The computer program set the SR amplitude to maximum and then decreased the amplitude until the participant could no longer feel the stimulation. The amplitude was then increased until the participant could feel the stimulation again. The boundaries of sensation for each foot were iteratively narrowed with input from the participant by repeating this adjustment process until finding a stable threshold stimulation level. This threshold level was determined when the participant could feel the stimulation at the level just above and not feel the stimulation at the level just below but was uncertain at the threshold level. A typical participant would report feeling the SR stimulation approximately half of the time when it was turned on at the threshold level. The ON stimulation level was then set to and maintained at 10% below the sensation threshold determined for each foot. This was done to ensure subsensory stimulation for each participant when the insoles were set at the ON stimulation level. The OFF stimulation (control) level was set to zero. Therefore, the SR stimulation was not felt by the participant during testing, creating a blind condition between OFF and ON. The participants were routinely asked and instructed to inform the investigators if they could feel the SR stimulation from the insole devices during the study procedures. There were no reports by any of the participants.

Experimental environment. All study procedures were performed in the Motion Capture Lab at the Wyss Institute for Biologically Inspired Engineering at Harvard University (Fig. 1). A 10-camera T-Series Vicon (Centennial, CO) optical motion capture system was used to track the retroreflective surface markers (9.5 mm diameter) on each participant's shoes during a single static standing calibration trial and throughout the loaded walking protocol at a capture rate of 120 Hz. HR was monitored and recorded at approximately 1 Hz throughout the protocol using the OmniSense LIVE software (Zephyr Technology).

Loaded walking protocol. Each participant performed the loaded walking protocol on a split belt treadmill (Fully Instrumented Treadmill; Bertec Corporation, Columbus, OH). The backpack was secured to an overhead safety track to minimize the risk of falling. A comfortable walking speed was determined by setting the treadmill belt speed first at 1.1 $m \cdot s^{-1}$ and then allowing the participant to adjust the speed up or down. A speed of 1.1 $m \cdot s^{-1}$ was chosen based on a study by Caron et al. (8), where the preferred treadmill walking speed was 1.11 ± 0.12 $m \cdot s^{-1}$ while participants carried a backpack load. This speed was maintained throughout the loaded walking protocol (Fig. 2). First, the

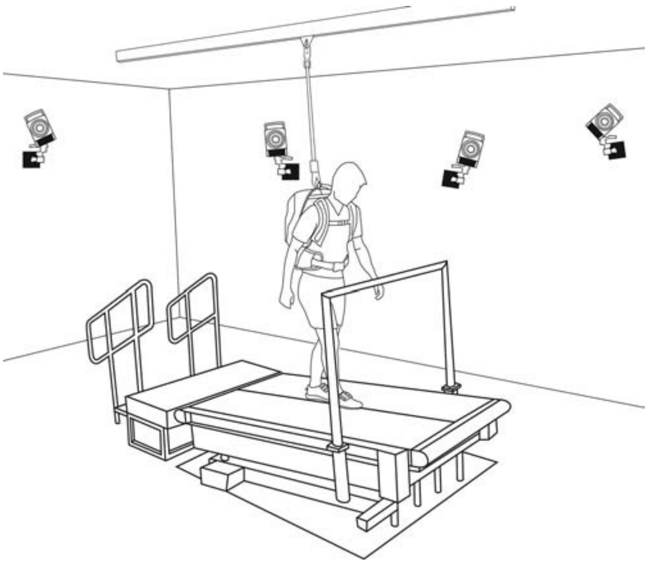

FIGURE 1—Experimental environment including optical motion capture cameras, treadmill, overhead harness, and a participant wearing a loaded backpack while walking. The retroreflective markers used for tracking the feet are located on the heels and the dorsal aspect of the feet.

participant performed a 5-min warm-up at a 0% grade. Next, the participant performed a series of 5-min walking periods starting at a 0% grade (BASELINE). The treadmill grade was increased by 2% after every 5-min period until the participant reached a level of volitional exhaustion (MAX) evidenced by a self-reported score of 18 on the Borg Perceived Exertion Scale (5). The participant was asked at regular intervals to indicate their perceived exertion over the course of the walking protocol. Upon reaching volitional exhaustion, the treadmill was lowered to a 0% grade and the participant continued to walk at the same speed for an additional 8 min (POST). Afterward, the loaded backpack was removed, the treadmill speed was lowered, and the participant completed a 5-min cool down.

Each 5-min walking period was separated into two stages. The first stage was a 1-min incline acclimation stage where the SR condition was set to OFF. The second stage was a 4-min trial stage where the SR condition (ON or OFF) was randomly assigned (pairwise) to each minute to obtain two pairs of trials where the SR condition was either ON for 1-min or OFF for 1-min. Optical motion capture and HR data were collected in 1-min segments during the second stage to obtain four trials per each 5-min walking period.

The 8-min POST walking period consisted of eight 1-min trials where the SR condition (ON or OFF) was randomly assigned (pairwise) to each minute to obtain four pairs of trials where the SR condition was either ON for 1 min or OFF for 1 min. There was no acclimation stage during the POST walking period. Optical motion capture and HR data were collected in 1-min segments during the POST walking period to obtain eight trials.

Data processing and analysis. Six of the 27 participants were excluded before data processing and analysis because of an inability to reach and sustain a minimum incline grade and a vigorous intensity level, as defined by Zhu et al. (47). Specifically, a participant was excluded if they could not reach and sustain 77% of their maximum age-predicted HR (equation 1) for 5 min or an incline level of 10% (15).

$$\mathrm{HR}_{\max} = 208 - 0.7 \times \mathrm{age} \qquad [1]$$

The paired (SR ON–SR OFF) trial's optical motion capture and HR data from the BASELINE, MAX, and POST walking periods were processed and analyzed for the remaining 21 participants. All four trials (two pairs) were used for the BASELINE walking period. All four trials (two pairs) were used for the MAX walking period if the participant was able to complete the entire MAX walking period; otherwise, only two trials (one pair) were used. Two trials (one pair) were used for 6 of the 21 analyzed participants. Four of the eight trials (two pairs) were used for the POST walking period. These four trials were determined as the first two pairs of trials where the SD of HR was at or below 1.5 bpm. This was done to eliminate trial pairs where the HR changed by 10–20 bpm between SR conditions, correlating to a difference in intensity level (15). The first four trials were used for one participant, the middle four trials were used for 16 participants, and the final four trials were used for four participants.

The retroreflective marker data from the BASELINE, MAX, and POST trials were labeled using Vicon Nexus 1.8.5 software. Labeled trials were then processed and analyzed using Visual3D v5 software (C-Motion, Germantown,

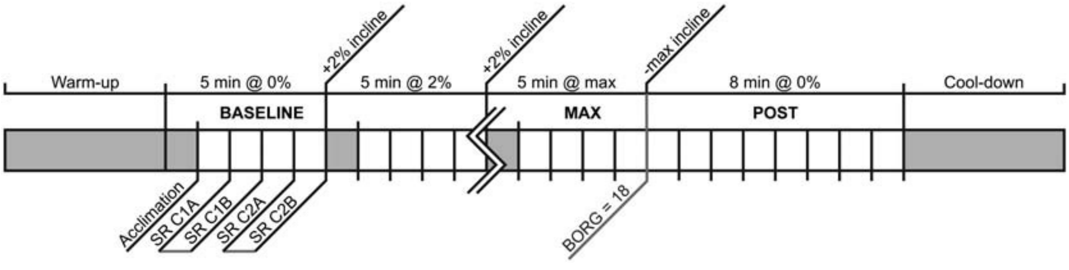

FIGURE 2—Experimental timeline describing the inclined walking protocol. The SR condition (SR ON or SR OFF) was randomized in a pairwise fashion during each trial set. For example, SR C1A and SR C1B make up the first pair of trials in the baseline condition. The SR condition for SR C1A was randomly turned ON or OFF and the SR condition for SR C1B was opposite SR C1A. This same procedure was used for the SR C2 pair and all of the subsequent paired trials.

TABLE 1. Study cohort demographics.

	Total sample *n* = 21
Age (yr, ave. ± SD)	22.8 ± 3.1
Weight (lb, ave. ± SD)	161.1 ± 21.5
Height (inches, ave. ± SD)	68.3 ± 3.3
Female (*n*)	6
Peak HR (% max, ave. ± SD)	94.27 ± 4.73
Peak incline (%, min/med/max)	10/14/20
Treadmill speed ($m \cdot s^{-1}$, ave. ± SD)	1.1 ± 0.1

MD). Retroreflective marker position data were filtered using a fourth-order digital low-pass Butterworth filter with a cutoff frequency of 12 Hz. Right and left foot models were generated for each participant from their static calibration trial. The metatarsal head and malleoli markers were only used to define the anterior and posterior ends of each foot, respectively. The four-marker cluster and calcaneus marker were used as tracking markers (Fig. 1).

The events of heel strike and toe off for the left and right feet were identified as the local maxima of the anterior (global Y) trajectory of the foot's proximal end position (heel) and the local minima of the posterior (global Y) trajectory of the foot's distal end position (toe), respectively (41). Temporal gait characteristics (stride time, stride length, double support time, and stride width) were calculated for the final 30 s of each 1-min trial to obtain approximately 50 steps per trial. Stride time was defined as the time between ipsilateral heel strikes. Stride length was defined as the distance between the proximal end positions of the foot at successive ipsilateral heel strikes. Double support time was defined as the total time one foot was in contact with the ground during the stance phase of the contralateral foot. Stride width was defined as the mediolateral distance between the proximal end position of the foot at ipsilateral heel strike to the proximal end position of the foot at the next contralateral heel strike.

The mean and coefficient of variation (CV) of the stride times, stride lengths, double support times, and stride widths were determined as outcome variables for each trial. For each participant, the average of each outcome variable was taken for each SR condition (SR ON and SR OFF) within each walking period (BASELINE, MAX, and POST). Comparisons between SR condition and walking period were made using a two-way repeated-measures ANOVA on the mean and CV of these outcome variables. These tests were performed with a significance level (alpha) of 0.05.

RESULTS

The demographics for the 21 participants who successfully completed the walking protocol are provided in Table 1. Box plots (min/25th percentile, 50th percentile, 75th percentile/max) of the mean and CV for the gait characteristics related to the rhythmic stepping (stride length and stride time) and balance control (step width and double support time) mechanisms are provided in Figures 3 and 4, respectively.

There were no changes in stride time between the walking period ($P = 0.983$) and the SR condition ($P = 0.193$). Stride

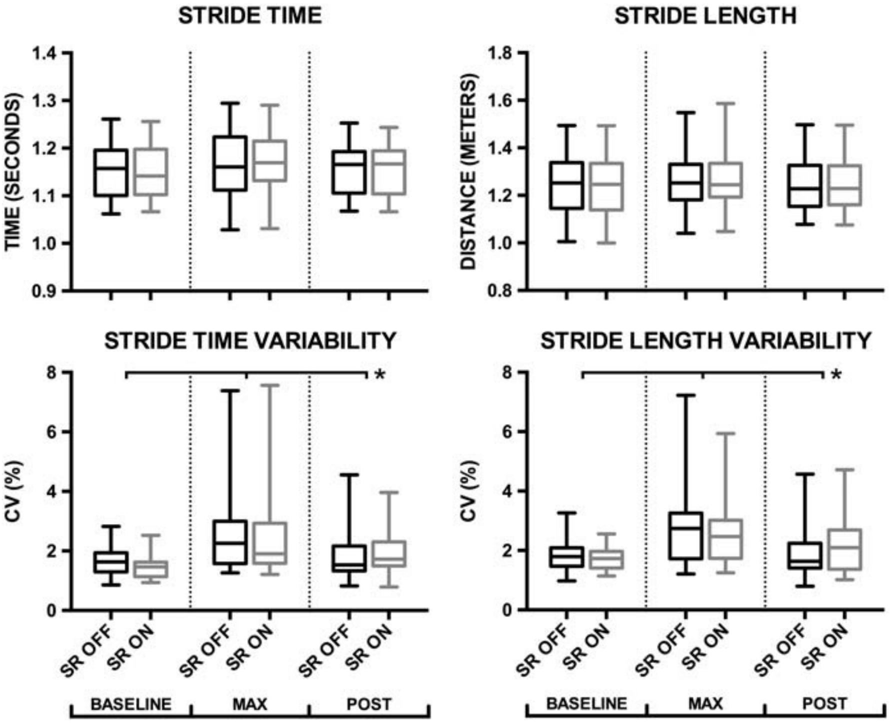

FIGURE 3—Box plots containing the results for the gait parameters related to the rhythmic stepping mechanism. The stride time and stride time variability are on the left, and the stride length and stride length variability are on the right. Each box represents the min, 25th percentile, 50th percentile, 75th percentile, and max of each outcome variable grouped by the walking period (BASELINE, MAX, POST) and SR condition (ON, OFF). *denotes significant differences between the walking period.

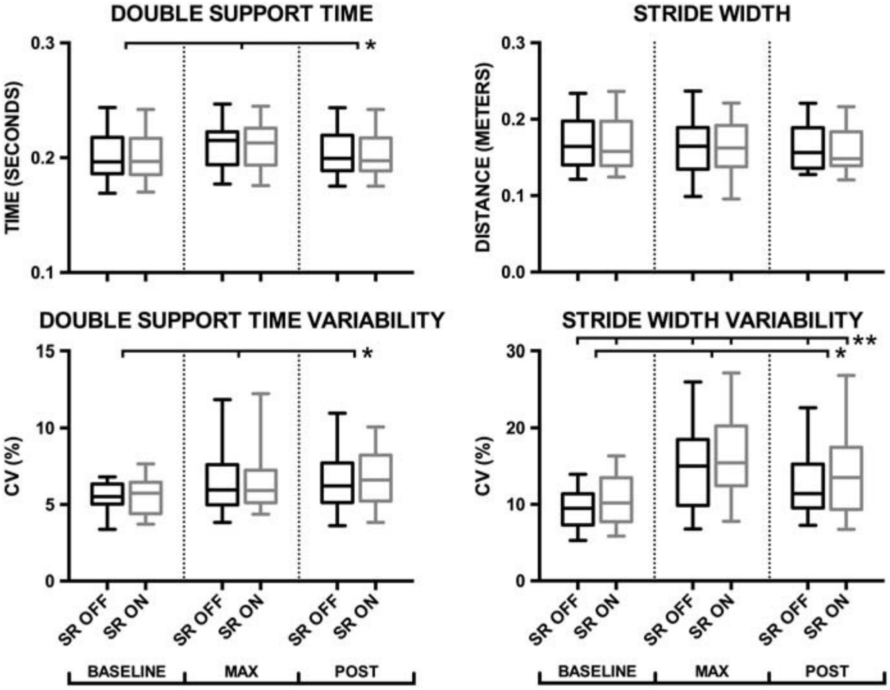

FIGURE 4—Box plots containing the results for the gait parameters related to the balance control mechanism. The double support time and double support variability are on the left, and the stride width and stride width variability are on the right. Each box represents the min, 25th percentile, 50th percentile, 75th percentile, and max of each outcome variable grouped by the walking period (BASELINE, MAX, and POST) and SR condition (ON and OFF). *denotes significant differences between the walking period. **denotes significant differences between SR condition.

time variability was affected by the walking period (*P* < 0.001) but not by the SR condition (*P* = 0.726). Compared with the BASELINE period, the stride time variability was 62% greater during the MAX period and 22% greater during the POST period. Similarly, stride length was not affected by the walking period (*P* = 0.894) or the SR condition (*P* = 0.159); however, stride length variability was affected by the walking period (*P* < 0.001) but not by the SR condition (*P* = 0.820). Compared with the BASELINE period, the stride length variability was 51% greater during the MAX period and 12% greater during the POST period. There was no interaction between the walking period and SR condition for stride time (*P* = 0.707), stride time variability (*P* = 0.608), stride length (*P* = 0.768), and stride length variability (*P* = 0.256).

Double support time was affected by the walking period (*P* < 0.001) but not SR condition (*P* = 0.230). Compared with the BASELINE period, double support time was 6% longer during the MAX period and 1% longer during the POST period. Additionally, double support time variability was affected by the walking period (*P* = 0.004) but not SR condition (*P* = 0.211). Compared with the BASELINE period, the double support time variability was 15% greater during the MAX period and 19% greater during the POST period. Stride width was not affected by the walking period (*P* = 0.457) or SR condition (*P* = 0.257); however, there were changes in stride width variability between the walking period (*P* < 0.001) and the SR condition (*P* = 0.007). Compared with the BASELINE period, the stride width variability was 57% greater during the MAX period and 30% greater during the POST period. Additionally, the variability was 9% greater for the SR ON condition compared with the SR OFF condition. There was no interaction between the walking period and the SR condition for double support time (*P* = 0.517), double support time variability (*P* = 0.886), stride width (*P* = 0.563), and stride width variability (*P* = 0.652).

DISCUSSION

There were two goals to this study: 1) to determine if spatiotemporal gait characteristics are modified before, during, and after sustained vigorous walking on an inclined surface while carrying a loaded backpack, and 2) if mechanical SR applied to the plantar aspect of the feet further changes these gait characteristics. The variability in stride time and stride length (rhythmic stepping mechanism) was increased by 62% and 51% while walking at maximal effort and by 22% and 12% after returning to the level ground compared with the baseline condition, respectively. No changes were observed for these outcomes when SR was applied. The double support time was 1%–6% longer and the variability in double support time and stride width (balance control mechanism) increased while walking at maximal effort (15% and 57%, respectively) and after returning to the level ground (19% and 30%, respectively) compared with the baseline condition. Stride width variability was the only spatiotemporal gait characteristic that was affected by SR condition. Furthermore, the observed 9% increase in stride width variability when the SR insoles were active was independent of the walking period.

This is the first study to investigate the combined effect of a backpack load carriage and incline during a fatiguing exercise on spatiotemporal gait characteristics in healthy recreational athletes. The observed increase in stride time and stride length variability suggests a disruption in the normally consistent gait-patterning process due to vigorous effort during and after a fatiguing exercise. As a result, healthy individuals need to compensate for this disruption by increasing the variability of their double support time and stride width. In fact, a *post hoc* analysis revealed a positive linear relationship (Fig. 5) between the degradation of the rhythmic stepping mechanism (stride time and stride length) and the improvement of the balance control mechanism (double support time and stride width). This analysis suggests that the participants who exhibited the greatest detriments to their rhythmic stepping mechanism compensated the most with their balance control mechanism.

Moreover, the additional increase in the variability of stride width provides evidence that SR applied to the plantar aspect of the feet improves the balance control mechanism of gait in active young individuals. Prior work investigating the effect of SR on gait has focused on elderly participants with slower stride times, shorter stride lengths, longer double support times, and wider step widths, compared with healthy young individuals (7,30,42). Moreover, the variability (as high as 39%) in these metrics for elderly participants is two to four times larger than the values reported herein (7,44).

It is generally accepted that high variability in the rhythmic stepping mechanism of gait (stride time and stride length) is associated with gait instability (31,44). Interestingly, variability in the balance control mechanism of gait is not always an index of instability (3). In fact, too much or too little step width variability is a reflection of gait instability (2,7). Specifically, abnormal step width variability is defined as a CV of less than 7% or greater than 30% (44). We observed step width variability to range between 9.68% and 16.61%, which falls within the normal range.

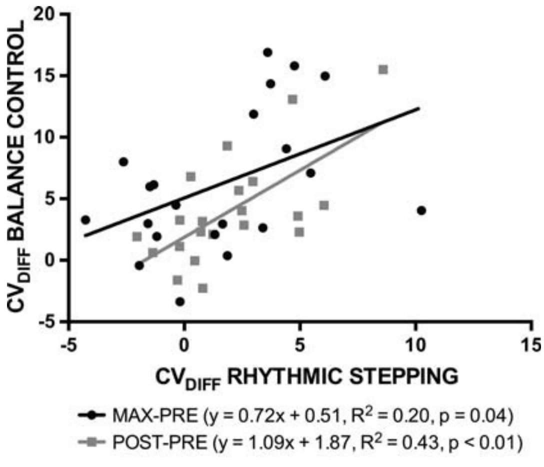

FIGURE 5—The difference in summed variability for the rhythmic stepping mechanism versus the difference in summed variability for the balance control mechanism from the PRE to MAX (*black circles* and *line*) and PRE to POST (*gray squares* and *line*) walking conditions. Linear regression analyses revealed significant positive relationships.

Clinicians consider high baseline variability of both rhythmic stepping and balance control mechanisms in elderly walkers as a risk factor for falling, and therapies have been designed to reduce the variability to levels associated with more stable gait (30,44). For example, SR applied to the plantar aspect of the feet has been shown to reduce the variability in stride time, stride length, double support time, and stride width in elderly patients (14,30,42). Moreover, this reduction in variability translates to significantly improved scoring on a clinical test for fall risk (30). Despite these findings, there may be a baseline-dependent effect of the SR insoles on gait variability. Stephen et al. found that participants with the highest baseline variability (CV of 15%–20%) tended to see reductions with SR on; however, participants with low baseline (CV of 5%–10%) tended to see increases with SR on. Herein, our baseline variability was generally low, which may account for our observed increase with SR on.

Variability of the parameters associated with the rhythmic stepping mechanism of gait increased as a result of inclined walking with a loaded backpack during the MAX and POST periods, as compared with BASELINE. Increases in the normally consistent parameters of step length and stride time may compromise the gait-patterning processes and, at an extreme, increase risk of slipping, tripping, and/or falling during fatiguing conditions (13). In our study, variability in double support time and stride width, which are parameters related to balance control, was almost six times higher than that related to the rhythmic stepping mechanism. Biomechanically, this variability is needed to maintain balance and introduces a certain level of flexibility in limb movements while walking. This flexibility may lead to greater stability, which is required to maintain safe gait during a variety of walking conditions where the balance control mechanisms require a certain level of adaptability (2).

Despite the higher variability observed in the parameters related to the balance control mechanism compared with those related to the rhythmic stepping mechanism, the baseline magnitude is low (~6% for double support time and ~10% for stride width) when compared with the normal spectrum of variability (e.g., 7%–30% for stride width) (44). We hypothesize that the observed increase in variability of both double support time and stride width pushes the balance control system into a more optimal and adaptable state, compensating for the more variable stride times and stride lengths brought on by the vigorous and/or fatigued walking conditions. Similarly, the increased step width variability due to mechanical SR applied to the plantar aspect of the feet is encouraging for the efficacy of SR insoles for improving the balance control mechanisms of gait for young healthy individuals during vigorous hiking activities.

There are some limitations to this study. First, we are limited to conducting experiments in a confined laboratory environment where a treadmill is necessary for tracking gait characteristics during inclined walking. We recognize that harnessed treadmill walking is different than over ground walking and likely influences some of our outcome measures; however, the study was designed in such a way that each participant was able to act as their own control for both the walking period (BASELINE, MAX, and POST) and the SR condition (ON and OFF). Furthermore, our perceived exertion metric indicating maximal exertion is subjective. In fact, six participants reached 18 on the scale (indicating a return to 0% incline) but did not maintain a vigorous HR or only walked for fewer than 30 min. This was likely a result of discomfort with the study equipment (e.g., loaded backpack, treadmill, overhead harness) and protocol causing their perceived exertion to reach the study maximum rather than fatigue resulting from physical exertion. However, we were able to identify these participants and eliminate them from the data analysis by establishing a standard of 5 min for vigorously walking at an incline (15). Additionally, the insole devices used in this study were tethered to a computer, which would not be feasible during an outdoor hiking task. Nevertheless, we were able to successfully route the wires to avoid any interference during the walking protocol. Additional device work is needed to untether these research devices from the computer. Another limitation to the current insole device is the limited discrete range of amplitudes available. This limited our ability to accurately set thresholds for participants with sensory perception thresholds below 10% of the maximum device amplitude. Therefore, we had to exclude one participant with sensory perception thresholds below 10% as noted in our inclusion criteria. Finally, work from Martin and Nelson (32) suggests that females exhibit a sex dimorphism in spatiotemporal gait parameters, which was most pronounced at heavy carry loads (≥45% weight). Despite this, a consistent story is found when viewing the data from all of our study participants compared with each gender group.

In conclusion, our findings show that vigorous activity increases the variability in spatiotemporal gait characteristics related to the rhythmic stepping and balance control mechanisms of walking. It is likely that the increased stride time and stride length variability may compromise the gait-patterning process of walking because of vigorous effort during and after a fatiguing exercise. As a result, the observed increase in double support time and stride width variability are balance compensation mechanisms that allow healthy individuals to maintain their stability under adverse conditions. Additionally, the application of SR to the plantar aspect of the feet further increased, on average, stride width variability by 9%. This may correspond to improved balance control in these participants. Furthermore, the lack of interaction between the walking period and the SR condition suggests that SR is effective before, during, and after vigorous activity. With further development, recreational hikers and soldiers could use an untethered and self-contained insole device during vigorous hikes to improve walking stability. This would allow an SR insole device to be deployed in a much larger study to establish a direct link between SR and injury risk amongst recreational hikers and/or soldiers.

This study was funded by the Defense Advanced Research Projects Agency, Warrior Web Program (contract no. W911QX-12-C-0084), and the Wyss Institute for Biologically Inspired Engineering at Harvard University.

The authors have no professional relationships with companies or manufacturers who will benefit from the results of the present study. The results presented herein do not constitute endorsement by the American College of Sports Medicine.

REFERENCES

1. Barbieri FA, Santos dos PCR, Vitório R, van Dieën JH, Gobbi LTB. Effect of muscle fatigue and physical activity level in motor control of the gait of young adults. *Gait Posture*. 2013;38(4):702–7.
2. Beauchet O, Allali G, Annweiler C, et al. Gait variability among healthy adults: low and high stride-to-stride variability are both a reflection of gait stability. *Gerontology*. 2009;55(6):702–6.
3. Beauchet O, Allali G, Berrut G, Dubost V. Is low lower-limb kinematic variability always an index of stability? *Gait Posture*. 2007;26(2):327–8, author reply 329–30.
4. Bentley TA, Page S, Walker L. The safety experience of New Zealand adventure tourism operators. *J Travel Med*. 2004;11(5):280–6.
5. Borg GA. Psychophysical bases of perceived exertion. *Med Sci Sports Exerc*. 1982;14(5):377–81.
6. Boulware DR, Forgey WW, Martin WJ 2nd. Medical risks of wilderness hiking. *Am J Med*. 2003;114(4):288–93.
7. Brach JS, Berlin JE, VanSwearingen JM, Newman AB, Studenski SA. Too much or too little step width variability is associated with a fall history in older persons who walk at or near normal gait speed. *J Neuroeng Rehabil*. 2005;2(1):21.
8. Caron RR, Lewis CL, Saltzman E, Wagenaar RC, Holt KG. Musculoskeletal stiffness changes linearly in response to increasing load during walking gait. *J Biomech*. 2015;48(6):1165–71.
9. Collins JJ, De Luca CJ. Open-loop and closed-loop control of posture: a random-walk analysis of center-of-pressure trajectories. *Exp Brain Res*. 1993;95(2):308–18.
10. Cox KA, Clark KL, Li Y, Powers TE, Krauss MR. Prior knee injury and risk of future hospitalization and discharge from military service. *Am J Prev Med*. 2000;18(3 Suppl):112–7.
11. Dames KD, Smith JD. Effects of load carriage and footwear on spatiotemporal parameters, kinematics, and metabolic cost of walking. *Gait Posture*. 2015;42(2):122–6.
12. Do MC, Bussel B, Breniere Y. Influence of plantar cutaneous afferents on early compensatory reactions to forward fall. *Exp Brain Res*. 1990;79(2):319–24.
13. Gabell A, Nayak US. The effect of age on variability in gait. *J Gerontol*. 1984;39(6):662–6.
14. Galica AM, Kang HG, Priplata AA, et al. Subsensory vibrations to the feet reduce gait variability in elderly fallers. *Gait Posture*. 2009;30(3):383–7.

15. Garber CE, Blissmer B, Deschenes MR, et al. American College of Sports Medicine Position Stand: quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. *Med Sci Sports Exerc*. 2011;43(7):1334–59.
16. Haisman MF. Determinants of load carrying ability. *Appl Ergon*. 1988;19(2):111–21.
17. Harman E, Frykman P, Pandorf C, Tharion W, Mello R. Physiological, Biomechanical, and Maximal Performance Comparisons of Female Soldiers Carrying Loads Using Prototype U.S. Marine Corps Modular Lightweight Load-Carrying Equipment (MOLLE) with Interceptor Body Armor and U.S. Army All-Purpose Lightweight Individual Carrying Equipment (ALICE) with PASGT Body Armor. Natick (MA): Military Performance Division, US Army Research Institute of Environmental Medicine; 1999. Available from: http://oai.dtic.mil.
18. Harman E, Frykman P, Pandorf C, Tharion W, Mello R. Physiological, Biomechanical, and Maximal Performance Comparisons of Soldiers Carrying Loads Using U.S. Marine Corps Modular Lightweight Load-Carrying Equipment (MOLLE), and U.S. Army Modular Load System (MLS) Prototypes. Natick (MA): Military Performance Division, US Army Research Institute of Environmental Medicine; 1999. Available from: http://oai.dtic.mil.
19. Harman E, Hoon K, Frykman P, Pandorf C. The Effects of backpack weight on the biomechanics of load carriage. Natick (MA): US Army Research Institute of Environmental Medicine; 2000. Available from: http://oai.dtic.mil.
20. Hasselquist L, Bensel CK, Brown ML, et al. Physiological, Biomechanical, and Maximal Performance Evaluation of Medium Rucksack Prototypes. Natick (MA): US Army Natick Soldier Research, Development and Engineering Center; 2013. Available from: http://oai.dtic.mil.
21. Hasselquist L, Bensel CK, Corner B, Gregorczyk KN. An Investigation of Three Extremity Armor Systems: Determination of Physiological, Biomechanical, and Physical Performance Effects and Quantification of Body Area Coverage. Natick (MA): US Army Natick Soldier Research, Development and Engineering Center; 2012. Available from: http://oai.dtic.mil.
22. Horak FB. Postural orientation and equilibrium: what do we need to know about neural control of balance to prevent falls? *Age Ageing*. 2006;35(2 Suppl):ii7–11.
23. Hsiao H, Simeonov P. Preventing falls from roofs: a critical review. *Ergonomics*. 2001;44(5):537–61.
24. Jeka J, Oie K, Schöner G, Dijkstra T, Henson E. Position and velocity coupling of postural sway to somatosensory drive. *J Neurophysiol*. 1998;79(4):1661–74.
25. Kars HJJC, Hijmans JM, Geertzen JHB, Zijlstra W. The effect of reduced somatosensation on standing balance: a systematic review. *J Diabetes Sci Technol*. 2009;3(4):931–43.
26. Kawamura K, Tokuhiro A, Takechi H. Gait analysis of slope walking: a study on step length, stride width, time factors and deviation in the center of pressure. *Acta Med Okayama*. 1991;45(3):179–84.
27. Kennedy PM, Inglis JT. Distribution and behaviour of glabrous cutaneous receptors in the human foot sole. *J Physiol*. 2002;538(Pt3): 995–1002.
28. LaFiandra M, Holt KG, Wagenaar RC, Obusek JP. Transverse plane kinetics during treadmill walking with and without a load. *Clin Biomech (Bristol, Avon)*. 2002;17(2):116–22.
29. Lay AN, Hass CJ, Gregor RJ. The effects of sloped surfaces on locomotion: a kinematic and kinetic analysis. *J Biomech*. 2006; 39(9):1621–8.
30. Lipsitz LA, Lough M, Niemi J, Travison T, Howlett H, Manor B. A shoe insole delivering subsensory vibratory noise improves balance and gait in healthy elderly people. *Arch Phys Med Rehabil*. 2015;96(3):432–9.
31. Maki BE. Gait changes in older adults: predictors of falls or indicators of fear. *J Am Geriatr Soc*. 1997;45(3):313–20.
32. Martin PE, Nelson RC. The effect of carried loads on the walking patterns of men and women. *Ergonomics*. 1986;29(10): 1191–202.
33. Mullins AK, Annett LE, Drain JR, Kemp JG, Clark RA, Whyte DG. Lower limb kinematics and physiological responses to prolonged load carriage in untrained individuals. *Ergonomics*. 2015; 58(5):770–80.
34. Park H, Branson D, Kim S, et al. Effect of armor and carrying load on body balance and leg muscle function. *Gait Posture*. 2014; 39(1):430–5.
35. Perry SD, McIlroy WE, Maki BE. The role of plantar cutaneous mechanoreceptors in the control of compensatory stepping reactions evoked by unpredictable, multi-directional perturbation. *Brain Res*. 2000;877(2):401–6.
36. Polcyn AF, Bensel CK, Harman EA, Obusek JP, Pandorf C. Effects of Weight Carried by Soldiers: Combined Analysis of Four Studies on Maximal Performance, Physiology, and Biomechanics. Natick (MA): US Army Soldier and Biological Chemical Command Soldier Systems Center; 2002. Available from: http://oai.dtic.mil
37. Qu X, Yeo JC. Effects of load carriage and fatigue on gait characteristics. *J Biomech*. 2011;44(7):1259–63.
38. Quesada PM, Mengelkoch LJ, Hale RC, Simon SR. Biomechanical and metabolic effects of varying backpack loading on simulated marching. *Ergonomics*. 2000;43(3):293–309.
39. Simpson KM, Munro BJ, Steele JR. Effect of load mass on posture, heart rate and subjective responses of recreational female hikers to prolonged load carriage. *Appl Ergon*. 2011;42(3):403–10.
40. Simpson KM, Munro BJ, Steele JR. Effects of prolonged load carriage on ground reaction forces, lower limb kinematics and spatio-temporal parameters in female recreational hikers. *Ergonomics*. 2012;55(3):316–26.
41. Stanhope SJ, Kepple TM, McGuire DA, Roman NL. Kinematic-based technique for event time determination during gait. *Med Biol Eng Comput*. 1990;28(4):355–60.
42. Stephen DG, Wilcox BJ, Niemi JB, Franz JR, Kerrigan D, D'Andrea SE. Baseline-dependent effect of noise-enhanced insoles on gait variability in healthy elderly walkers. *Gait Posture*. 2012; 36(3):537–40.
43. Tegner Y, Lysholm J. Rating systems in the evaluation of knee ligament injuries. *Clin Orthop Relat Res*. 1985;198:43–9.
44. VanSwearingen JM, Perera S, Brach JS, Cham R, Rosano C, Studenski SA. A randomized trial of two forms of therapeutic activity to improve walking: effect on the energy cost of walking. *J Gerontol A Biol Sci Med Sci*. 2009;64(11):1190–8.
45. Wannop JW, Worobets JT, Ruiz R, Stefanyshyn DJ. Footwear traction and three-dimensional kinematics of level, downhill, uphill and cross-slope walking. *Gait Posture*. 2014;40(1):118–22.
46. Yen S-C, Ling W, Magill R, McDonough A, Gutierrez GM. Temporal relationship between trunk and thigh contributes to balance control in load carriage walking. *Gait Posture*. 2011; 34(3):402–8.
47. Zhu N, Suarez-Lopez JR, Sidney S, et al. Longitudinal examination of age-predicted symptom-limited exercise maximum HR. *Med Sci Sports Exerc*. 2010;42(8):1519–27.