Chapter

Impact of Self-Selected Customized Orthotics on Lower Limbs Biomechanics

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Abstract

Customized insoles are commonly prescribed to prevent or treat a variety of foot pathologies and to reduce foot and lower limb fatigue. Due to the patient-specific design and production of such orthotics, the concept of self-selected customized orthotics (SSCO) has recently been developed. The goal of this study was to assess the impact of SSCO technology on several physiological and biomechanical variables during uphill power walking. Thirty male participants underwent an uphill power walking intervention at constant speed in two insoles conditions (control and SSCO). The electromyographic (EMG) activity of their right gastrocnemii and vastii muscles was measured. Perceived fatigue was assessed every 5 minutes and the intervention stopped when the targeted fatigue level was reached. Baseline and post-intervention assessments were also performed. Sixty-three percent of the participants experienced an improvement in foot fatigue while wearing the SSCO. The foot arch seemed to collapse less when participants wore the SSCO, but statistical significance was not reached. The changes in mean EMG activity was not consistent between the 50% isometric contraction and the walking trial. In conclusion, while some interesting trends were observed when wearing SSCO, further investigations should be performed to try and reach statistical significance.

Keywords: orthopedics, custom orthotics, orthotics, lower limbs, insoles, walking, fatigue, neuromuscular, biomechanics

1. Introduction

Customized insoles have been shown to reduce pain [1], improve static balance [2] and redistribute pressure [3, 4]. As a result, they are commonly prescribed to prevent or treat a variety of foot pathologies [5]. For instance, wearing custom-made foot orthoses has been reported to reduce medial foot loading and/or improve the condition of people with patellofemoral pain [6]. Research has also shown that the use of custom-made laterally wedged insoles can reduce pain, enhance joint function and improve quality of life in older adults affected by medial knee osteoarthritis [7]. Customized insoles have also demonstrated the ability to prevent deformations and necrosis of the foot by decreasing forefoot pressure [8–12], hence reducing the risks of ulceration for patients with diabetes and neuropathy [13, 14]. Custom-made inserts can also be prescribed to reduce areas of peak pressure in individuals with high medial longitudinal arches, leading to a lower risk of developing pes cavus deformities [15].

Besides their ability to improve people's health, comfort and quality of life, customized insoles are also designed to reduce the sensation of foot and lower limbs fatigue. For example, see [16], investigated the effect of custom-made orthotics in healthy participants undergoing long periods of standing and walking at work. The results reported a significant reduction in foot fatigue reflected by 68% of the population experiencing less foot discomfort at the end of the day, and by 60% of the participants reporting more comfort at work when wearing customized orthotics. Another study by, see [15], studied the impact of customized insoles on a population of females with idiopathic pes cavus during gait. They reported that the integrated electromyography (EMG) activity of four leg muscles (i.e. tibialis anterior, gastrocnemius medialis, rectus femoris and biceps femoris) decreased after wearing the custom-made orthotics. Also, see [17], studied the impact of insoles with custom arch support during uphill and downhill walking for individuals with flatfoot conditions. Their findings showed that added arch support led to a significant decrease in peak oxygen uptake (VO_2), as well as a potential reduction in the activity of the rectus femoris. This indicates that wearing insoles with customized arch support could potentially improve motor control efficiency, and hence reduce fatigue in the lower extremities during gait.

In summary, multiple scientific evidence has demonstrated that custom-made insoles can positively impact people's health and quality of life. Yet, the patient specific design and production of such orthotics remains a potential limitation. Due to the known deformability of the foot [18–20], customized orthotics were originally molded based on a foot cast taken under different weight-bearing conditions [3]. With the constant advancements in 3D scanning and 3D printing technologies, the development of customized insoles is now being facilitated by the combined use of computer-aided design and computer-aided manufacturing (CAD-CAM). Nevertheless, the design and production of custom-made orthotics still require an in-depth examination with a specialist involving a variety of measurements, which can be time-consuming and potentially costly.

As a result, the concept of self-selected customized orthotics (SSCO) has recently been developed and introduced in stores and pharmacies. This concept is based on the use of an automated kiosk (Dr. Scholl's®, Bayer Healthcare, LLC, Whippany, NJ, USA) with embedded plantar pressure scan that can measure foot size, arch type and weight. Using the corresponding measures, the kiosk's recommendation engine can pre-select a specific insole design among a finite set of prefabricated orthotics with different arch and heel support characteristics. Such a system could represent an interesting opportunity to extend the accessibility of customized insole technology. However, conversely to traditional custom-made insoles, no investigation has yet measured the potential benefits of wearing SSCO. This study was designed to assess the impact of this new insole technology on several physiological and biomechanical variables during gait. More specifically, this study focuses on how SSCO can potentially reduce the perception of fatigue during uphill power walking.

2. Methods

2.1 Recruitment and testing conditions

This study was approved by the Conjoint Health Research Ethics Board of the University of Calgary (Ref: REB17-0875_MOD5). A total of 30 male participants (mean age: 26 years SD 5; mean BMI: 23.9 SD 2.7; shoe size: US 9–11) with no history of insole related condition/disorder, were tested on two separate days with a minimum of 48 hours between sessions to allow full recovery from the walking intervention. Participants were consistently scheduled at the same day time to reduce the risk of impacting their energy level and were asked to wear the same pair of running shoes during each session. Prior to testing, each participant read and signed a consent form.

Two different insole conditions were evaluated in a randomized order, including a control (i.e. no insole added, CTRL) and a SSCO with custom arch support (Custom Fit®, Dr. Scholl's®, Bayer Healthcare, LLC, Whippany, NJ, USA). The selected SSCO were built off three layers: a soft top cloth for comfort and durability, a cushion layer to disperse foot pressure and reduce shocks, and a 3D arch support dual layer to best fit the morphology of each individual's arch. For each shoe size, four different SSCOs were available with different arch support characteristics. For every participant, the best SSCO fit was selected based on weight (i.e. more or less than 170 lbs) and arch type (i.e. low, medium or high arch).

2.2 Anthropometrics and subjective evaluations

Upon the participant's arrival, an anthropometric evaluation was performed where variables such as height, weight, foot width and arch height were measured.

2.3 Baseline assessments

Prior to testing, participants were asked to fill out a questionnaire to assess the intensity of their baseline fatigue using a 0–5 Likert scale (**Table 1**).

Surface bipolar Ag-AgCI EMG electrodes (Norotrode Myotronics-Noromed Inc., Kent, WA, USA) with a diameter of 10 mm and an inter electrode spacing of 22 mm were positioned on the muscle bellies of the gastrocnemius lateralis (GL) and medialis (GM) of the right leg (**Figure 1**). To enhance signal conductivity, the corresponding skin surfaces were shaved and cleaned using abrasive tape and isopropyl wipe prior to electrode positioning. According to the SENIAM guidelines [21], each electrode was placed in the direction of the underlying muscle fibers.

Following electrode placements, each participant was placed lying prone in a horizontal position on an isokinetic dynamometer (Biodex System 4, Biodex Medical Systems, USA) with the right foot fixed to a plantarflexion attachment and the lateral malleolus aligned with the centre of rotation of the dynamometer. The EMG activity of the GL and GM muscles was recorded at 2400 Hz during two

Fatigue Level	Description
0 – No fatigue	No fatigue.
1 – Very slightly noticeable	Legs and feet feel active but no pain.
2 – Slightly noticeable	Slight fatigue and pain in legs and/or feet, but not enough to cause you to change your walking pattern.
3 – Noticeable	Legs and/or feet start to feel heavy and in moderate pain, to a level where you think about changing your walking pattern to help relieve your muscles.
4 – Very noticeable	Heavy legs and/or feet, and in enough pain to make you change your walking pattern because you need to relieve your muscles.
5 – Extremely noticeable	Legs and feet very hard to move and in a lot of pain, to the point where you immediately want to stop walking and sit down.

Table 1.
Likert scale (0–5) used to define the level of perceived fatigue for each participant.

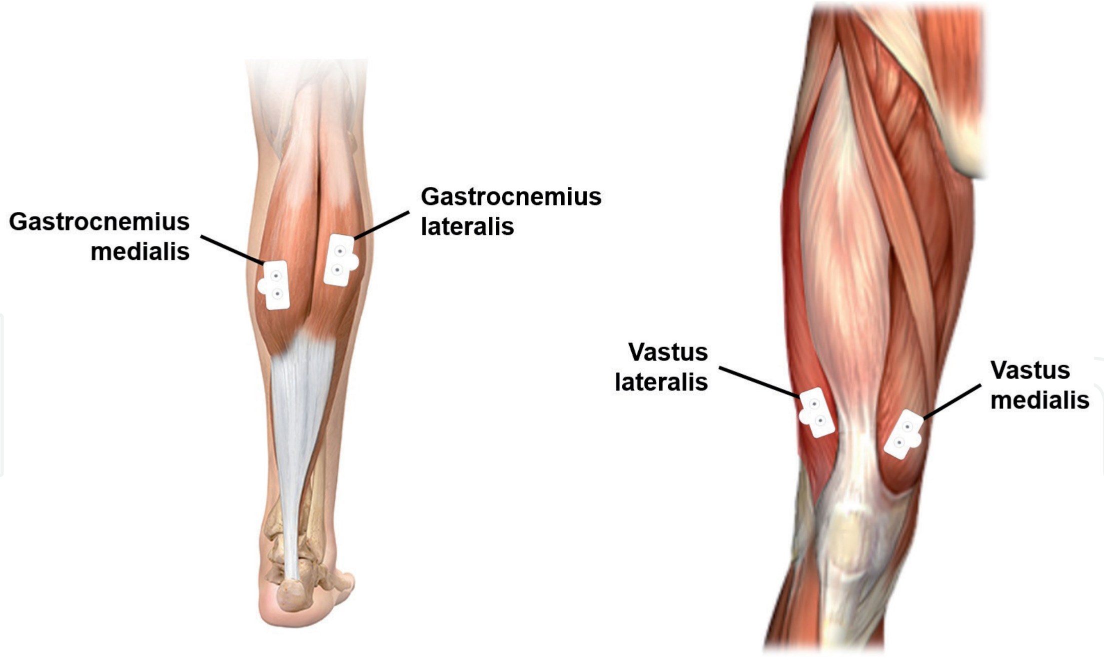

Figure 1.
Left: EMG electrodes placement on the gastrocnemius lateralis (GL) and medialis (GM) - right: EMG electrodes placement on the vastus lateralis (VL) and medialis (VM).

15-second isometric plantarflexion trials performed at 50% of the participant's maximal strength. To ensure a consistent torque output between trials and testing sessions, the maximal torque output of each subject was measured during the first day using two maximal voluntary contractions (MVC) trials. The corresponding value was then used to provide torque visual feedback during each 50% sustained contraction trials.

Participants were then asked to remove their shoes and socks and perform three 10-second standing trials and six walking trials (three steps per foot) on a foot pressure scan (Currex Footplate, Currex GmbH, Germany).

2.4 Walking intervention

The walking intervention was defined as a power walking trial on a 4° inclined treadmill at a constant speed of 4mph. Such settings were deemed sufficient - based on preliminary testing performed on seven volunteers - to induce fatigue in the feet and legs within a period of 30 to 60 minutes.

Prior to the intervention, additional EMG electrodes were placed on the vastus lateralis (VL) and vastus medialis (VM) (**Figure 1**). To detect heel strike, a one-dimensional (1D) accelerometer (sampling rate: 2400 Hz, encapsulated in a 20/12/5 mm plastic shell, measuring range: ± 50 g, frequency response: 0–400 Hz, mass: < 5 grams, ADXL 78, Analog Devices, Inc., Norwood, USA) was taped on the participant's right heel and synchronized with the EMG recordings.

Prior to the intervention, a 6-minute warm-up trial was performed with increasing walking speed and inclination angle (i.e. 2 minutes at 3mph and 1° incline, 2 minutes at 3.5 mph and 2.5° incline, and 2 minutes at 4mph and 4° incline). After warm-up, EMG activity of the GL, GM, VL and VM were recorded at 2400 Hz respectively for segments of 5 minutes. At the end of each segment, the participant was asked to rate his level of perceived fatigue using the same 0–5 Likert scale as the one used during the baseline assessments (**Table 1**). During the first testing session, the intervention stopped when the subject reached a fatigue level of 4 (described as heavy/sore legs and/or feet leading to voluntary changes in walking pattern to relieve muscles) on the perceived fatigue scale. The corresponding time was used to define the duration of the intervention during the second testing session. If a participant was not able to reach a fatigue level of 4 after a duration of 60 minutes or reached a fatigue level of 5 (i.e. extremely sore legs and feet very leading to the immediate need to stop the intervention), prior to 30 minutes, the intervention was stopped, and the corresponding data was not used in the analysis.

2.5 Post-intervention assessments

Immediately following completion of the intervention, each participant performed the same tests as describe in the baseline assessments section, starting with the foot pressure scans (standing and walking), followed by one isometric contraction trial. At the end of each session, participants were asked to rate their post-intervention perceived fatigue, as well as the comfort of the tested insoles (overall, heel, arch, forefoot).

2.6 Data processing

Data were all processed using custom-written Matlab codes (R2017a, MathWorks, Inc.).

2.6.1 Foot pressure scans

For each standing and walking trial performed on the foot pressure scan, the corresponding static and dynamic arch indices were calculated using the method described by, see [22], which defines the arch index as the ratio between the midfoot area (i.e. middle third of the entire footprint excluding the toes) and the area of the whole foot (toes excluded).

2.6.2 EMG

A wavelet transform using 20 non-linearly scaled wavelets (centre frequencies: 1.38, 3.86, 7.54, 12.42, 18.47, 25.69, 34.08, 43.61, 54.30, 66.12, 79.09, 93.19, 108.41, 124.76, 142.24, 160.83, 180.55, 201.37, 223.31, 246.35 Hz) was applied to the raw EMG signals recorded during each isometric contraction trials. The mean EMG frequency of each muscle was calculated using the power spectrum of the corresponding wavelet transformed signal and compared between baseline and post-intervention.

A custom-written heel-strike detection algorithm was applied to the walking EMG data to isolate each step within a defined window (i.e. 300 ms before and 600 ms after heel strike). For each step and muscle, the active portion of the EMG signal was selected using fixed time windows (i.e. from 75 ms before to 150 ms after heel strike for the GL and GM, and from 195 ms to 555 ms after heel strike for the VL and VM). The resulting active portions were then wavelet transformed using the method described above, and the corresponding power spectra were averaged for the first (non-fatigued) and last (fatigued) minute of recording.

2.7 Data analysis

The impact of fatigue was assessed for each variable as the relative change from non-fatigued to fatigued stages (i.e. baseline to post-intervention, first to last minute) and expressed as a percentage. A one-tailed paired T-test with alpha = 0.05 was performed to compare between insole conditions.

3. Results

3.1 Subjective fatigue assessment

A total of 21 participants reached the targeted fatigue level within 30 to 60 minutes. The remaining subjects fatigued either too quickly (N = 3) or not sufficiently (N = 6) during the intervention, and hence were not included in the analysis.

The mean absolute gain in perceived muscle fatigue was the slightly lower for the SSCO compared to the CTRL (**Table 2**). Regarding the perceived impact of each insole condition, 63% of the participants experienced improvements in foot fatigue while wearing the SSCO, and 40% experienced the same effect while wearing the CTRL.

3.2 Static and dynamic arch indices

The SSCO condition resulted in a slightly smaller increase in static arch index for the left foot compared to CTRL, and in a slight decrease in static and dynamic arch indices for the right foot (**Figure 2**). A strong variability was observed among subjects (i.e. large standard error) and none of the arch index results reached statistical significance (P-values >0.05, **Table 3**).

		CTRL	SSCO
Mean absolute gain in perceived muscle fatigue during intervention		3.30	2.98
Mean intensity of perceived muscle fatigue	Baseline	0.40	0.42
from 0 (no fatigue) to 5 (exhaustion)	Post-intervention	3.70	3.40
Percentage of the population experiencing improvements in foot fatigue		40%	63%

Table 2.
Mean absolute gain in perceived muscle fatigue (i.e. difference between baseline and post-intervention mean intensity of perceived muscle fatigue) and impact of each insole condition with respect to foot fatigue perception (N = 21).

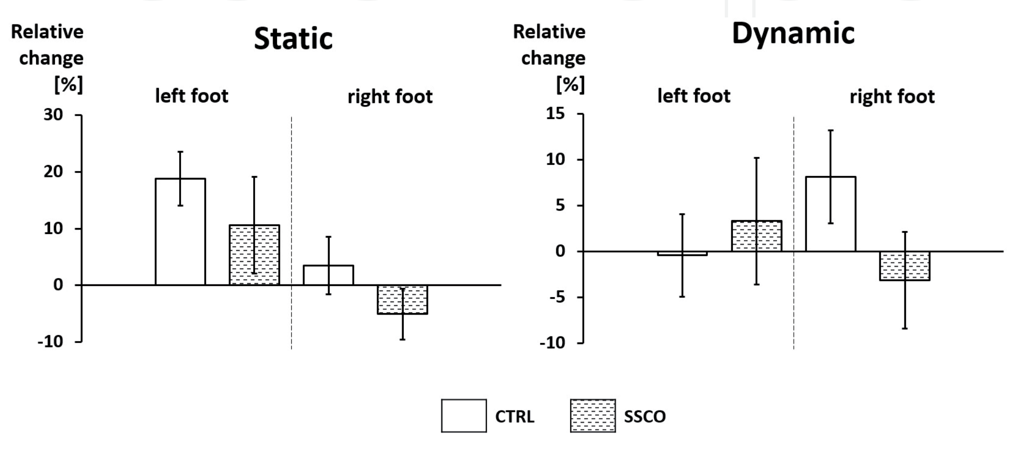

Figure 2.
Mean relative change in static (left) and dynamic (right) arch index from baseline to post-intervention. The error bars represent the standard error resulting from the data of all fatigued subjects (N = 21).

3.3 Mean EMG activity and frequency

3.3.1 50% isometric contraction

An increase in mean EMG activity was observed in the GL and GM muscles for both insole conditions (**Figure 3**). The corresponding increases were smaller for the GL compared to the GM in the CTRL condition, while the mean EMG activity of these two muscles increased similarly when participants were wearing the SSCO. For both conditions and both muscles, the relative changes in mean EMG frequency were negligible (~1%). None of these changes reached statistical significance when comparing across conditions (**Table 3**).

			CTRL	SSCO	P-value
Foot pressure scan	Static arch index	L	+19% (SE 5%)	+11% (SE 9%)	0.14
		R	+3% (SE 5%)	−5% (SE 4%)	0.13
	Dynamic arch index	L	−0.5% (SE 5%)	+3% (SE 7%)	0.39
		R	+8% (SE 5%)	−3% (SE 5%)	0.10
50% isometric contraction	Mean EMG activity	GL	+13% (SE 6%)	+20% (SE 9%)	0.29
		GM	+30% (SE 16%)	+23% (SE 9%)	0.38
	Mean EMG frequency	GL	+1% (SE 1%)	+0% (SE 1%)	0.33
		GM	+0% (SE 1%)	+1% (SE 1%)	0.20
Uphill power walking intervention	Mean EMG activity	GL	−6% (SE 3%)	−8% (SE 2%)	0.24
		GM	+0% (SE 2%)	−4% (SE 2%)	0.08
		VL	+8% (SE 4%)	+5% (SE 3%)	0.17
		VM	+1% (SE 5%)	+2% (SE 4%)	0.45
	Mean EMG frequency	GL	+6% (SE 1%)	+6% (SE 1%)	0.39
		GM	+5% (SE 0%)	+4% (SE 1%)	0.33
		VL	+0% (SE 2%)	+1% (SE 0%)	0.28
		VM	+3% (SE 2%)	+1% (SE 1%)	0.23

Table 3.
Mean relative change in arch index (static and dynamic) and mean EMG activity and frequency (for GL and GM during 50% isometric contraction and for GL, GM, VL, VM during the uphill power walking intervention) from non-fatigued to fatigued (SE: Standard error) (N = 21).

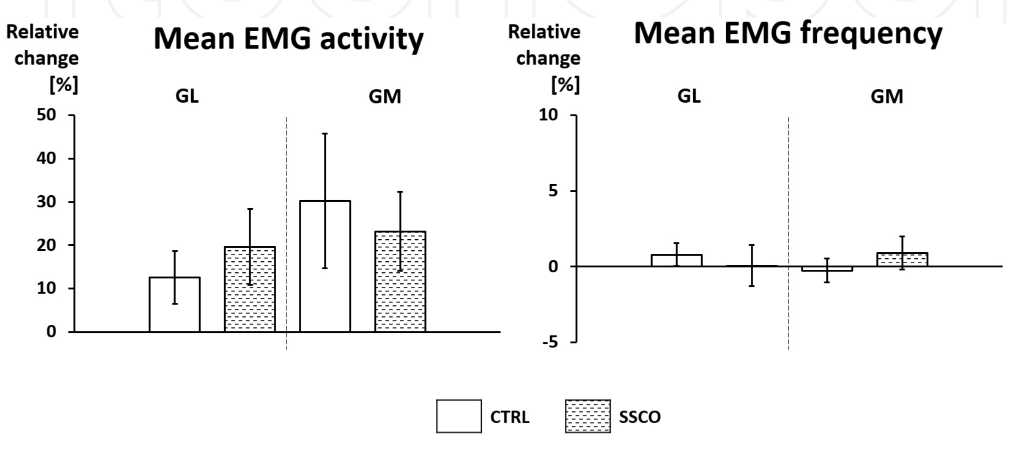

Figure 3.
Mean relative change in mean EMG activity (left) and frequency (right) of the GL and GM muscles from baseline to post-intervention. The error bars represent the standard error resulting from the data of all fatigued subjects (N = 21).

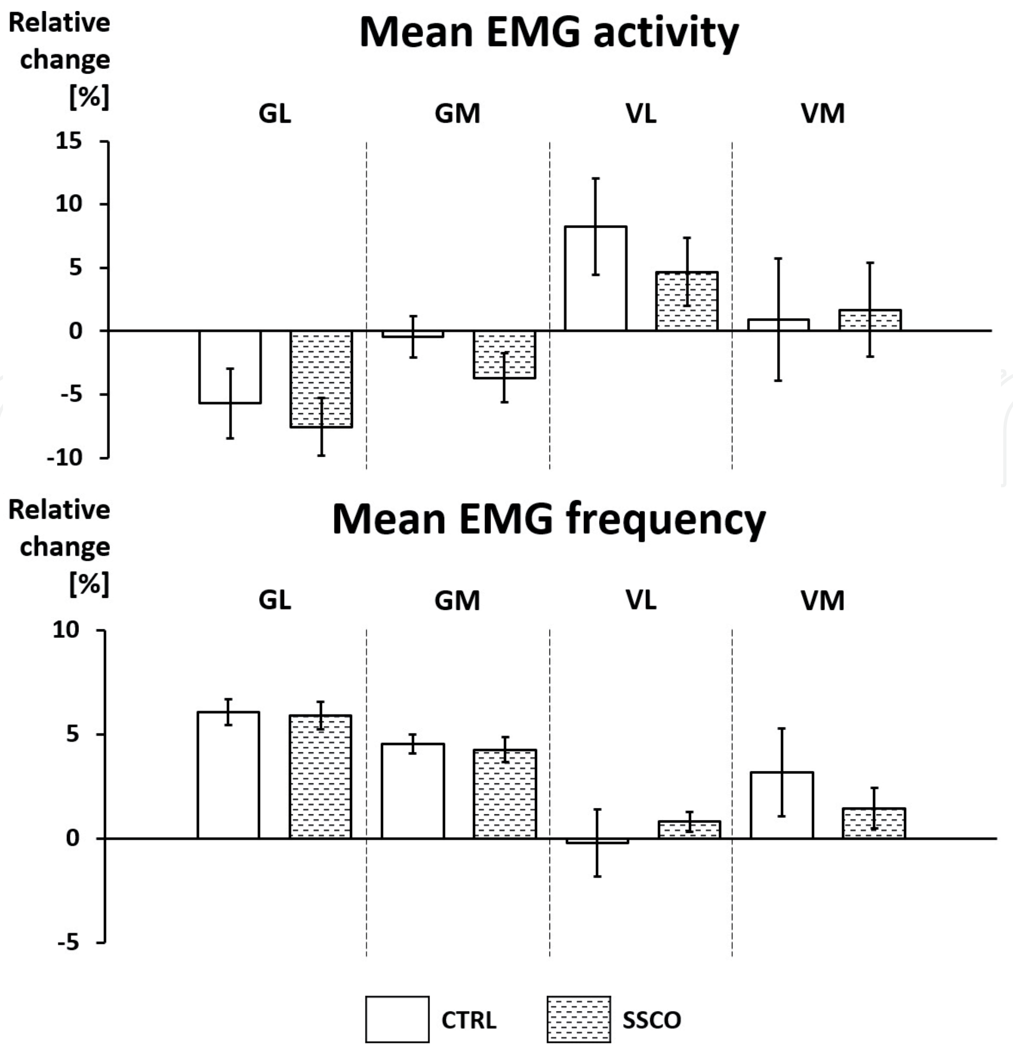

Figure 4.
Mean relative change in mean EMG activity (top) and frequency (bottom) of the GL, GM, VL and VM muscles from first to last minute of the intervention. The error bars represent the standard error resulting from the data of all fatigued subjects (N = 21).

3.3.2 Uphill power walking intervention

For both conditions, the mean EMG activity of the GL and GM decreased between the first and last minute of the intervention, while the opposite trend was observed for the VL and GM (**Figure 4** top). The decrease observed in mean EMG activity for the GL and GM was slightly stronger, and the increase in mean EMG activity of the VL was slightly less for the SSCO condition compared to CTRL. No specific difference could be observed when comparing the changes in mean EMG frequency between conditions (**Figure 4** bottom). None of the results reached statistical significance when comparing across conditions (**Table 3**).

4. Discussion

In this study, a protocol was designed to induce perceived fatigue in the lower limbs of healthy male volunteers. A variety of qualitative and quantitative variables were collected at baseline and post-intervention to assess the impact of perceived fatigue on different metrics. Two insole conditions were assessed and compared including one control (CTRL) and one self-selected customized orthotics (SSCO). The purpose of this comparison was to evaluate the impact of short-term exposure to SSCO on the perception of lower limbs fatigue. This study was motivated by the fact that, to our knowledge, no investigation had yet presented the potential effect that this new semi-custom insole design may have on the physiology and biomechanical behavior of the lower extremities. In comparison, many reports have highlighted the benefits of customized orthotics, especially regarding their positive impact on balance [2] and pressure distribution [3, 4], which appear to reduce foot pain [1] and improve the quality of life of people with specific lower limb conditions [5–14]. As a result, this study aimed at providing new insights regarding the potential impact of wearing SSCO over a short period of time (sub-hour) on selected variables associated with foot morphology, lower limb muscle activity and perceived fatigue.

In terms of subjective assessment, most of the participants (N = 21) reached the targeted perceived fatigue level within the limited time window defined by the protocol. Among these 21 participants, the mean absolute gain in perceived muscle fatigue was slightly lower when the SSCO were worn. Considering that participants started both trials with the same level of baseline fatigue and that the duration of the intervention was constant across conditions, this indicates that the SSCO helped to slightly reduce the sensation of muscle fatigue during the intervention. In addition, 63% of these participants reported experiencing improvements in foot fatigue when wearing the SSCO. Such insights agree with, see [16], who reported that 68% of their tested population experienced improved foot fatigue after wearing customized orthotics during long periods of standing and walking.

Regarding the relative change in arch index, for both conditions, small differences were observed between left and right foot, as well as between static and dynamic trials. The largest change was found statically on the left foot, where the increase in arch index was slightly lower for the SSCO compared to CTRL. Considering that an increase in arch index indicates a flattening of the arch, such insight may indicate that the integrity of the arch of the left foot was slightly less impacted while wearing the SSCO. Knowing that SSCO were designed to provide additional arch support and if we hypothesize that a flattening of the arch is associated with fatigue (i.e. loss of muscle integrity over time), this result could potentially be linked to the findings of, see [17], who reported that insoles with custom arch support help reduce the impact of fatigue during up- and downhill walking. However, none of the results presented in the current study reached statistical significance. This could be explained by the large standard errors, which is expected to result from the morphological differences between participants (i.e. low vs. high arch). As a result, these results appear challenging to interpret and further investigations should focus on populations with similar arch types to assess whether these standard errors would be decreased.

The mean EMG activity of the GL and GM muscles calculated during the 50% isometric contraction increased between baseline and post-intervention for both conditions. If we hypothesize that the mean EMG activity reflects the number of motor units that is required to perform a certain task, this observation could indicate that, when fatigue occurs, groups of motor units lose their ability to generate a consistent amount of force, therefore leading to more motor units being recruited [23, 24]. The comparison between conditions showed a slightly lower increase in EMG activity for the GM while wearing the SSCO, indicating a potential smaller impact of fatigue on the corresponding muscle. However, the opposite trend was found for the GL during the same task. In addition, the mean EMG activity of these two muscles decreased for both conditions between the first and the last minute of the walking trial, while the opposite trend was found for the VL and VM. Considering the large standard errors and the lack of statistical significance, these findings remain challenging to interpret.

Almost no change was observed with respect to mean EMG frequency during the 50% isometric contraction. However, the mean EMG frequency of the GL and GM muscles increased between the first and last minute of the walking intervention. This indicates that the firing rate of the corresponding motor units increased with fatigue, which is the opposite of the expected behavior reported in the literature [23]. No significant change was observed in terms of mean EMG frequency for the VL and VM muscles throughout the intervention.

These results reflect the complexity of measuring and interpreting long dynamic EMG signals, which can easily be impacted by several external factors such as excessive sweating or skin motion artifacts. In addition, it should be noted that the use of EMG for fatigue assessment has been severely debated in the last few decades, mostly due to the constantly changing definition of the actual fatigue phenomenon. Fatigue was originally broadly defined as the inability to maintain a specific force [25], which became more specific later as the decrease in the force production ability of the neuromuscular system during sustained contractions [26]. Due to the limitations of such definitions with respect to protocol design (i.e. purely static [27]), the definition of fatigue has been evolving throughout the year in order to allow dynamic measurements [28]. However, the scientific community has still not settled on a standard definition of this very subjective concept and its potential assessment, which shows that further research is still needed to elaborate a reliable definition of fatigue and to design consistent protocols to measure it. Nevertheless, this study still resulted in 70% of the individuals experiencing fatigue, with many of those individuals demonstrating less perceived fatigue while wearing SSCO. As a result, the data from this study could be re-evaluated once a more reliable definition of fatigue using EMG is established.

Several limitations should be noted with respect to the design of this study. First, none of the results reached statistical significance, and therefore, every conclusion should be interpreted with care. This may be due to the fact that the sample size was small and included people with slightly different morphologies and physical condition. While all attempts were made to control for such population characteristics, they remain challenging to assess prior to recruitment (i.e. arch type, physical condition with respect to uphill power walking). As a result, large standard errors were observed, which may have been reduced if the sample size had been a bit larger. A large sample size would also have allowed the potential classification of participants based on their morphological characteristics, which should be further explored in future studies.

The short time exposure to the new insole condition (i.e. less than one hour wearing the SSCO) was also a limitation that may not have given enough time for some morphological changes to occur. Future work should inspect the potential long-term impact of wearing such orthotics on the physiological and biomechanical behavior of the lower limbs. It should also be noted that the experiment was not blinded. While participants were unaware of the design and purpose of the SSCO, it was impossible to blind them to the fact that the insoles in their shoes had been changed. To try and limit the potential testing order impact, the session order was randomized among participants.

The very subjective aspect of fatigue and the way it is defined should also be included as an important limitation. In this study, participants were given a specific definition of perceived fatigue (**Table 1**) which was designed to be as intuitive as possible but remains a purely qualitative measure. Finally, the lack of literature regarding the potential impact of SSCO on the physiological and biomechanical behavior of the lower extremities made the direct comparisons with previous studies impossible.

5. Conclusion

In conclusion, this study provided a preliminary framework that aimed at better understanding the physiological and biomechanical consequences of wearing SSCO. Some of the preliminary findings presented in this study indicated that wearing SSCO may have some benefits with respect to perceived fatigue, arch support, and lower limb muscle fatigue. Nevertheless, additional work should be accomplished to fully understand how this new insole design impacts the lower extremities during a more diversified range of physical activities (i.e. standing, running, etc.). In addition, future work should focus on measuring the potential long-term impact (i.e. several days, weeks, months) of such orthotics by investigating potential morphological, perceptual or biomechanical changes around multiple body segments, such as the lower back, the knees and feet.

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Conflict of interest

The authors declare no conflict of interest.

Notes/thanks/other declarations

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