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ARTICLE INFO	A B S T R A C T
<i>Keywords:</i> Design Footwear Intervention OA Rehabilitation Shoe	Background: Lateral wedge insoles (LWI) were proposed to treat medial knee osteoarthritis through reductions of the ambulatory knee adduction moment (KAM). Limited attention was however paid to the LWI length, resulting in unclear understanding of its effect on KAM reductions. The knee flexion moment (KFM) was also shown to be important in knee osteoarthritis, but little is known about the effect of LWI length on it. <i>Research question</i> : This study aimed to compare the KAM and KFM of healthy subjects walking with four dif- ferent lengths of LWI, explicitly without LWI and with LWI below the hindfoot (HF), below the hindfoot and forefoot (HF + FF) and below the hindfoot, forefoot and hallux (HF + FF + HX) segments. <i>Methods</i> : Nineteen healthy participants (63% male; 24 ± 3 years old) walked in an instrumented gait lab with LWI of four different lengths. Repeated one-way ANOVAs and post-hoc <i>t</i> -tests were used to compare knee ki- netics among LWI lengths. <i>Results</i> : The peak value of the KAM during the first half of stance and the KAM impulse differed with respect to the LWI length (p < 0.001). A length of at least HF + FF, but not necessarily longer, was needed to decrease both KAM parameters compared to walking without LWI. The LWI length had no effect on the peak value of the KFM during the first half of stance (p = 0.86). <i>Significance</i> : The results in this study could contribute to better selections of LWI for medial knee osteoarthritis and suggested that the length of the LWI could be a critical factor that should be considered in future research.

1. Introduction

Knee osteoarthritis (OA) is a disease causing pain and functional disability in approximatively 8% of men and 16% of women [1]. Since no cure has been found for it, there is a critical need for therapeutic options to slow disease progression. Walking mechanics was shown to play an important role in OA development [2,3]. Specifically, for medial compartment knee OA, the most frequent form of the disease [4], the maximum value of the knee adduction moment (KAM) during the first half of stance (1st peak) and the KAM impulse have been consistently associated with pain as well as disease severity and progression [5–7]. Therefore, gait interventions reducing these kinetic parameters are sought as a means to treat medial knee OA patients.

Lateral wedged insoles (LWI) have been proposed to decrease the KAM, with studies reporting reduced 1st peak in healthy subjects and OA patients walking with LWI running from the heel until the tip of the metatarsals to the tip of the toes [8,9]. On the other hand, some studies have reported no significant decrease with rearfoot LWI [10,11].

Although comparing studies is difficult due to the large variations in KAM results, certainly related to varying methodology among studies, prior works suggest that the length of the LWI influences the modifications in KAM. Interestingly, while the effect of the wedging amplitude has been well described [12,13], little is known about the effect of LWI length. To the authors' knowledge, there has been one study comparing LWI of different lengths [14]. It reported reduction in the 1st peak with full-length but not with rearfoot LWI, confirming an effect of the LWI length on the KAM modifications. Additional research considering different LWI lengths is however necessary. Indeed, during walking, the foot functions primarily as three segments, the hindfoot (HF), forefoot (FF) and hallux (HX) [15-17], and the effect of LWI should be determined with respect to these segments. In comparison, the rearfoot LWI used in the prior study assessing the effect of LWI length included the HF and half of the FF. Determining the effect of LWI relative to the three primary segments would notably help selecting LWI for medial knee OA patients among the devices in the market. It would also provide a basis to interpret previous studies testing LWI of

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Full length article





no LWI HF LWI HF+FF LWI HF+FF+HX LWI

Fig. 1. Bottom view of the comfort insole with the four lengths of LWI used in this study.

varying lengths. Prior research put little focus on the KAM impulse, and a better description of the effect of LWI length on this parameter could likewise facilitate the selection among commercially available LWI and enhance the interpretation of LWI literature.

Better understanding the length of LWI, necessary to reduce the KAM 1st peak and impulse, could also have implications on the design of new footwear for medial knee OA (e.g., orthotics or shoes). In fact, normal walking includes a roll of the foot during stance phase, consisting in a succession of three rockers [18]. The third rocker, between FF and HX, requires a large dorsi-flexion of the toes which could be altered if the amount and/or stiffness of the footwear components below the HX segment are too high [19,20]. Disturbing the dorsiflexion of the lesser digits could have important negative clinical implications. Therefore, there is a need to determine whether the LWI should run until the tip of the toes, or if LWI below the HF and FF segments are enough to reduce the KAM. This is important because LWI running until the tip of the toes are common in knee OA literature [8,9] and the only study assessing LWI length so far did not consider a LWI running below the HF and FF [14]. The possibility to shorten the LWI could also enhance comfort, notably regarding blisters [21], and thus improve compliance. The possibility of limiting the LWI to the HF and FF segments is particularly motivated by the fact that the toes are loaded late during stance compared to the occurrence of the KAM 1st peak and impulse [22].

Since the maximum value of the knee flexion moment (KFM) during the first half of stance (1st peak) has been shown to complement the KAM parameters in the assessment of the mechanical load acting on the knee during walking [23], it has been receiving a growing interest in the study of OA. Particularly, a larger KFM 1st peak was recently associated with faster progression of medial knee OA [7], suggesting that gait interventions, such as LWI, should not increase this parameter [24]. Data in literature seem to indicate no effect of LWI on KFM 1st peak [25,26], but a study describing the effect of LWI length on this kinetic parameter is missing.

The present work aimed to compare the KAM and KFM of healthy subjects walking with four different lengths of LWI, explicitly without LWI and with LWI below the HF, HF + FF and HF + FF + HX segments. This study specifically tested the hypothesizes that: 1) a minimum length of HF + FF is necessary for LWI to reduce the KAM 1st peak and

impulse; 2) there are no differences in KAM parameters between LWI of lengths HF + FF and HF + FF + HX; 3) there are no differences in KFM 1st peak among the four LWI lengths.

2. Methods

2.1. Participants

Nineteen healthy subjects (12 males) without history of serious lower extremity injury took part in this study. Mean (\pm standard deviation) age, height and weight of the participants were 24 \pm 3 years old, 1.76 \pm 0.10 m and 71 \pm 12.2 kg, respectively. A sample size calculation was performed using the effect sizes of LWI on KAM parameters in healthy subjects (Cohen's d > 1.2) reported in a prior review study [8]. To be conservative and consistent with preexisting data, the sample size calculation was based on multiple paired *t*-tests and lower effect size (Cohen's d = 1.0). With a power of 80% and an effective alpha level of 0.8%, a minimum of 16 participants was required for this study (G*Power, DE). This research was approved by the local ethics committee, and informed consent was obtained from all participants before data collection.

2.2. Gait analysis

Participants performed a series of gait trials at normal self-selected speed with LWI of four different lengths. Specifically, they walked with (1) neutral frontal plane stability shoes (gel-beyond, Asics, JP) as a control (i.e., with LWI length of zero) and with the same shoes when custom LWI were added below the (2) HF, (3) HF + FF and (4) HF + FF + HX segments. After reviewing multi-segment foot models [15–17], it was decided to separate the HF and FF at the basis of the metatarsals, and separate the FF and HX at the top of the metatarsals (Fig. 1). LWI were made of high density ethylene vinyl acetate (EVA) with a durometer of 60 (Shore C) and wedged at 5° following literature recommendations [12,13]. They were inserted between the comfort insole and the midsole in both, the left and right, shoes.

The kinetics of the right knee was measured during walking trials across a 10 m long walkway instrumented with a motion capture system (Vicon, Oxford, UK) and two ground-embedded force plates (Kistler AG, Winterthur, CH), recording synchronously at 120 and 1200 Hz, respectively. Data were first collected without LWI and then the LWI of lengths HF, HF + FF and HF + FF + HX were tested in a random order. For each LWI length, participants were given practice time and when they felt used to the footwear, three successful trials were recorded. A trial was considered successful when the right foot fully stepped on a force plate.

The kinetic parameters were obtained following a standard procedure [7,24]. Briefly, technical clusters of reflective markers were fixed on participants' foot, shank, thigh and pelvis segments. Then, anatomical landmarks were identified by palpation during a standing reference pose (fifth metatarsal, lateral calcaneus, medial and lateral malleolus, medial and lateral tibial condyle, medial and lateral femoral condyle, anterior and posterior superior iliac spine). These landmarks were used to define the anatomical frame of the lower-limb segments and the transformations between the technical and anatomical frames. During gait, an optimization algorithm was used to calculate the position and orientation of the technical frames and then the technical-toanatomical transformations were used to calculate the position and orientation of the anatomical frames. Knee moments were calculated using a classical inverse dynamics approach based on the position and orientation of the anatomical frames, force plate data and inertia property of the segments. The KAM 1st peak, KAM impulse and KFM 1st peak of the right knee were extracted for each trial. Similarly, the maximum value of the KAM during the second half of stance (KAM 2nd peak), the maximum value of the knee extension moment during the first half of stance (KEM 1st peak) and gait speed were extracted for sake of completeness. Moments were normalized to bodyweight and height (%BW*Ht). Finally, the measures were averaged over the three trials with the same footwear to have one value per parameter, LWI length and participant. All biomechanical processing was done using the software application BioMove (Stanford, CA).

2.3. Statistical analysis

For each gait parameter, a repeated one-way ANOVA was performed to determine if the length of the LWI (none, HF, HF + FF and HF + FF + HX) had an effect on the parameter. When necessary, posthoc paired *t*-tests were done to compare the four lengths and Cohen's d effect sizes (ES) were calculated to report the magnitude of the differences. The normality of the data was assessed using Lilliefors tests before analyzing the data with parametric statistics. Statistical significance level was set *a priori* at p < 0.05, with a Bonferroni correction for multiple comparisons in post-hoc analyses (effective p < 0.008). All statistics were done with SPSS version 23 (IBM, NY).

3. Results

The ANOVA indicated a significant effect of LWI length on the KAM 1st peak (p < 0.001) and impulse (p < 0.001), but not on the KFM 1st peak (p = 0.86) (Fig. 2). Furthermore, the length of the LWI significantly affected the KAM 2nd peak (p < 0.001) and had no significant effect on the KEM 1st peak (p = 0.32) and on walking speed (p = 0.41).

Post-hoc analyses showed that walking with HF + FF (p = 0.002; ES = 0.824) or HF + FF + HX (p = 0.002; ES = 0.817) LWI significantly reduced the KAM 1st peak compared to walking without LWI (Fig. 3A). A significant decrease in KAM 1st peak was also observed between HF and HF + FF LWI (p = 0.008; ES = 0.69). The KAM impulse was significantly reduced with HF (p = 0.007; ES = 0.70), HF + FF (p < 0.001; ES = 1.53) or HF + FF + HX (p < 0.001; ES = 1.60) LWI compared to no LWI (Fig. 3B). There was also a significant decrease in KAM impulse between HF and HF + FF LWI (p = 0.004; ES = 0.76). Finally, walking with HF + FF or HF + FF + HX LWI significantly reduced the KAM 2nd peak compared to walking without LWI (p < 0.001; ES of 1.10 and 1.18, respectively)



Fig. 2. Average knee adduction moment (KAM) and knee flexion moment (KFM) curves of the 19 healthy subjects walking with lateral wedge insoles (LWI) of four different lengths. Stars (*) indicate significant effect of the LWI length on the kinetic parameters (repeated ANOVA with p < 0.001).

or walking with HF LWI (p < 0.001 with ES = 1.08 for HF + FF, and p = 0.004 and ES = 0.77 for HF + FF + HX) (Fig. 3C).

4. Discussion

The results supported the first hypothesis as, compared to walking without LWI, LWI of at least HF + FF length were necessary to reduce both the KAM 1st peak and impulse. Shorter LWI, running only below the HF, decreased the impulse but not the 1st peak. Furthermore, decrease in KAM impulse was smaller with HF than HF+ FF LWI. Although the KAM 2nd peak has not been directly related to medial compartment knee OA [3], comparing this parameter led to consistent observations, with the need of LWI of at least HF + FF length for KAM 2nd peak reductions compared to no LWI and smaller KAM 2nd peak with HF + FF and HF + FF + HX than with HF LWI. These results extended prior literature [8-11,14] by describing the dependence of KAM modifications to LWI length and suggesting the top of the metatarsals as the limit to differentiate LWI that reduce both KAM parameters from those that only decrease KAM impulse. This limit could be explained by an increased moment arm in rearfoot eversion induced by a lateral tilting of the metatarsal heads [27]. Particularly, an increased rearfoot eversion lever arm has been associated with KAM reductions through a lateral shift of the center of pressure. The present findings could have important clinical implications because they question the suitability of LWI shorter than HF + FF. Furthermore, highlighting that all LWI are not equal regarding reductions in KAM parameters suggests that future review studies should take into account the length of the LWI as different KAM reductions could lead to different clinical outcomes [28].

The second hypothesis was also verified as KAM parameters were not different between HF + FF and HF + FF + HX LWI. These results, suggesting that it is sufficient having LWI running from the heel to the top of the metatarsals, could reveal useful for the design of footwear interventions for medial knee OA. Indeed, building orthotics or shoes with stiff material below the toes is challenging because this material could alter the normal walking patterns, specifically the third rocker



Fig. 3. Mean (\pm standard deviation) of the kinetic parameters over the 19 healthy subjects with respect to the length of the lateral wedges insoles (LWI). Results are reported for the three parameters affected by the LWI length. KAM refers to knee adduction moment. Stars (*) indicate significant differences between LWI lengths (p < 0.008).

[18]. Therefore, for comparable KAM reductions, it might be interesting limiting the LWI at the top of the metatarsals. In addition to facilitating the design and helping maintaining normal walking patterns, suppressing the LWI below the toes could enhance comfort, specifically regarding blisters due to the reduction of the volume available for the toes when full-length LWI are added in narrow shoes. Helping maintaining normal walking patterns and enhancing comfort could also augment compliance, which is another factor that could improve clinical outcomes of LWI [29,30].

As hypothesized, the KFM 1st peak did not differ with the length of the LWI. The present results therefore extend prior literature by showing that there are no changes in KFM 1st peak whatever the length of the LWI [25,26]. Consequently, the need for LWI of at least HF + FF length, but not necessarily of HF + FF + HX length, discussed in the paragraphs above remains unchanged when the KFM is considered. While it is clear that it is preferable not to increase the KFM 1st peak in patients with medial knee OA, there is not enough data in the literature yet to determine if gait interventions for medial knee OA should reduce the KFM 1st peak [3]. Therefore, LWI do not appear to induce detrimental changes in KFM 1st peak. This observation is particularly relevant to the interpretation of prior LWI studies that did not analyze the KFM. On the other hand, it is possible that the uncertain clinical benefits reported for LWI could be related to an absence of reduction in KFM 1st peak [29,30]. If future research recommend that gait modifications for medial knee OA should reduce the KFM 1st peak, in addition to the KAM 1st peak and impulse, then interventions based on LWI will need to be upgraded, for example by changing the characteristics of the LWI or by complementing the LWI with physical exercises.

This study tested a population of young healthy subjects and, while similar observations are expected in older individuals with medial knee OA, additional studies are required to actually characterize the effect of LWI length on KAM and KFM parameters in this pathological population. The present study focused on the immediate modifications in KAM and KFM. Since a biomechanical adaptation over time is possible, further research will need to determine if the conclusions remain the same after a period of wear. There is no consensus on multi-segment modeling of the foot, with different models assigning the bones (particularly the navicular, cuneiform and cuboid) differently between the HF and FF segments [15–17]. It is thus worth noting that the decision to separate the HF and FF at the basis of the metatarsals should have no impact on the conclusions as the important limit in regards to KAM 1st peak reduction is at the top of the metatarsals. The small population tested in this study could appear as another limitation. Nevertheless, the repeated within-subject design provided adequate statistical power. Indeed, even if additional significant differences in KAM parameters could possibly be detected with a larger sample size, LWI of length HF + FF should remain the most suitable. Finally, like in any gait study, some measurement errors, notably due to soft-tissue artifact, could not be excluded. These errors should however have little effect on the conclusions of the study thanks to the within-subject design.

5. Conclusion

This study provided new insights regarding LWI that could have an impact on gait rehabilitation of patients with medial knee OA. Specifically, it suggested that a length of at least HF + FF, but not necessarily longer, is required for a decrease in both KAM 1st peak and impulse. It also indicated that the KFM 1st peak is not affected by LWI, whatever the length of the LWI. In the future, literature reviews analyzing clinical outcomes of LWI trials, with considerations for the LWI length, could improve our understanding of this simple gait intervention and contribute to better uses with medial knee OA patients.

Conflict of interest statement

None.

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