Full length article

Unsupervised gait retraining using a wireless pressure-detecting shoe insole

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ARTICLE INFO

ABSTRACT

Background: The knee adduction moment (KAM) is a surrogate measure of mediolateral distribution of loads across the knee joint and is correlated with progression and severity of knee osteoarthritis (OA). Existing biomechanical approaches for unloading the arthritic medial knee compartment vary in their effectiveness in reducing KAM. This study employed a completely wireless, pressure-detecting shoe insole capable of generating auditory feedback via a smartphone. *Research question:* To investigate whether auditory cues from a smartphone can prompt subjects to adjust their gait pattern and reduce KAM. *Methods:* Nineteen healthy subjects underwent gait training inside the lab (*Phase 1*) and received auditory cues during mid- and terminal stance to medialize their foot COP (center-of-pressure). This initial training period was continued unsupervised while walking around campus (*Phase 2*).
Results: After *Phase 1*, subjects reduced their KAM by 20.6% ($p = 0.001$), a finding similar to a previous study that used a wired, lab-based insole system. After further unsupervised training outside the lab during *Phase 2*, subjects were able to execute the newly learned gait pattern without auditory feedback still showing a KAM reduction of 17.2% ($p < 0.001$). Although, speed at *Phase 2* was lower than at baseline ($p = 0.013$), this reduction had little effect on KAM ($r = 0.297$, $p = 0.216$). In addition, the adduction angular impulse was reduced ($p = 0.001$), despite the slower speed.
Significance: Together, these results suggest that the wireless insole is a promising tool for gait retraining to lower the KAM and will be implemented in a home-based clinical trial of gait retraining for subjects with knee OA.

1. Introduction

Osteoarthritis (OA) is a leading cause of years lived with disability, and OA in the knee accounts for 83% of the total OA burden globally [1,2]. The risk of knee OA progression and radiographic severity positively correlate with a greater knee adduction moment (KAM) [3–5], which is a surrogate measure of medial-to-lateral load distribution in the knee joint during level walking [6,7]. In order to unload the medial compartment and slow the progression of medial knee OA, the KAM is a traditional target for biomechanical interventions [8–12]. Orthoses such as lateral wedge [8,9] and gait modifications such as lateral trunk lean [10] and medial thrust gait [11] reduce KAM but have limitations. The load-altering effect of lateral wedges is relatively small and generally inconsistent, in part due to between-subject variability [8,9]. Lateral trunk lean reduces KAM in a dose-dependent manner, but is difficult to execute by some individuals, and may be accompanied by

joint discomfort [13,14]. Medial thrust gait increases knee flexion moment (KFM) [12,15], a sagittal plane knee torque that contributes to overall knee loading thus attenuating the benefits of the reduced KAM [15,16].

To address some of these limitations, we developed a gait modification [12], which stemmed from observations that patients with medial knee OA exhibit a lateralized foot center-of-pressure (COP) [17] and those who execute medial thrust gait showed a medialized COP [18]. Driven by pressure-based auditory feedback, medializing COP without high amplitude gait modifications may lead to a reduced KAM without increasing KFM [12].

The ultimate goal of any therapeutic gait modification is to translate the gait strategy from the gait lab to the clinical setting, and ultimately to the patient's home. Thus, in this study we employed a wireless shoe insole with pressure sensors that communicates wirelessly with a smartphone for the generation of auditory feedback. This setup allows

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Table 1
Subject characteristics.

Characteristics	Mean (SD)
n	19
Sex (M/F)	10/9
Age (yr)	26 (5)
Height (m)	1.71 (0.07)
Mass (kg)	67.0 (8.8)
BMI (kg/m^2)	22.9 (3.0)

individuals to receive pressure-based feedback outside the lab in a clinical setting, within their home, or within their community.

The purpose of this study was to (a) validate this wireless insole against our previously employed lab-based insole [12] and (b) investigate the wireless insole's feasibility for unsupervised gait retraining outside the lab with the goal to learn a modification to reduce the KAM. We hypothesized that medializing COP after gait retraining facilitated by pressure-based auditory feedback, subjects will reduce KAM without changing KFM.

2. Materials and methods

2.1. Subjects

Nineteen healthy subjects participated in the single-day study, which was approved by Rush University's Institutional Review Board. Subjects were recruited by word of mouth from within the university student body, faculty, and staff and informed consents were obtained. All subjects self-reported to be healthy regarding their lower extremities and pain free during the last 48 h, had no history of fracture over the past five years, and never experienced surgery in their lower extremities. Table 1 summarizes subject characteristics.

2.2. Wireless pressure-detecting shoe insole

The insole (OpenGo, Moticon GmbH, Munich, Germany) is completely wireless and capable of measuring plantar pressure distribution within footwear (Fig. 1). Measurements are derived from thirteen capacitive sensors and a three-dimensional accelerometer, which are powered by a coin-cell battery. In the current study, pressure data were wirelessly transmitted in real-time (range: 48–88 ms) to a smartphone. The feedback algorithm is described in more detail elsewhere [12]. In short, pressure readings from two selected lateral sensors were constantly compared with preset thresholds via a customized app (Moticon GmbH, Munich, Germany) on a smartphone. The first sensor was chosen for its position under the anterior aspect of the lateral heel and concurrent activation with the first peak of KAM (KAM1) (range: 18–35% Stance). The second sensor was chosen for its position under the fifth metatarsal head and concurrent activation with the second peak of KAM (KAM2) (range: 64–86% Stance). When the pressure

exceeded the threshold, the smartphone generated an auditory signal. In response to the auditory cue, subjects were to walk with reduced plantar pressure under the lateral side of the foot resulting in COP medialization. Since the feedback design encourages alterations in foot motion in order to modify plantar pressure, the insole is paired with a flexible shoe (FlexOA, Dr. Comfort, Mequon, WI) that allows such changes in foot mechanics. An a priori gait test demonstrated that the KAM of subjects is similar with and without the insole in the shoe (y = 1.005x + 0.015; $r^2 = 0.976$).

2.3. Testing protocol

Fig. 2 provides an overview of the testing and training process. All motion capture occurred in the Rush Motion Analysis Laboratory. The first gait retraining session occurred in the lab and the second occurred outside the lab on campus.
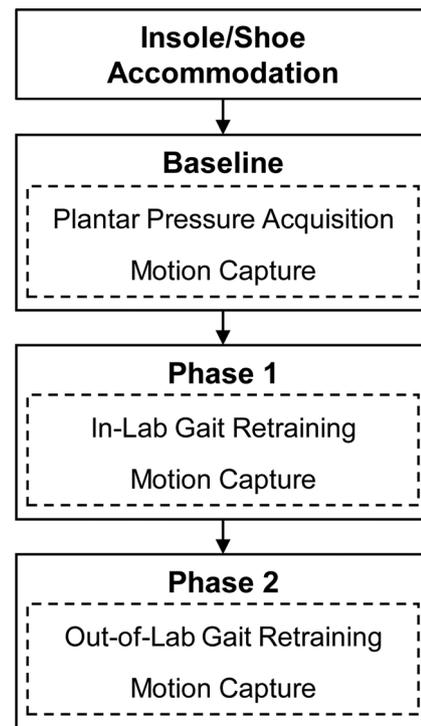

Fig. 2. An overview of the testing and training process of the single-day visit designed for healthy subjects to learn a gait modification using pressure-based auditory feedback generated from a wireless shoe insole.

2.3.1. Baseline plantar pressure acquisition

Prior to gait testing, baseline plantar pressure was acquired. After freely walking in the lab for 10 min to become accustomed to the flexible shoe containing the wireless insole, subjects performed level
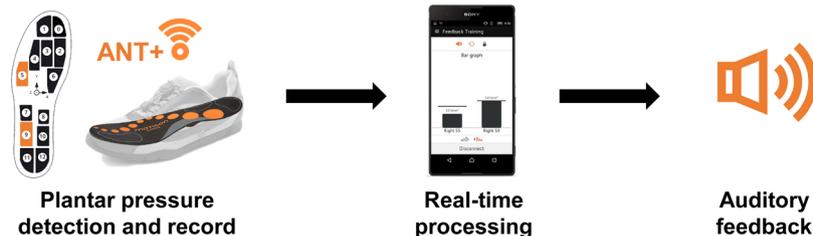

Fig. 1. The wireless shoe insole is capable measuring plantar pressure distribution within footwear and wirelessly transmitting the data in real-time to a smartphone app. Sensors in orange locate in areas that correspond to the time-matched occurrence of the peaks of KAM and are used for generation of feedback.

Table 2

Spatiotemporal variables and knee moments of *Baseline*, *Phase 1* (in-lab), and *Phase 2* (out-of-lab). Subsequent to one-way repeated multivariate analysis of variance for the evaluation of a difference in the combination of all variables of interest, univariate analysis was carried out and *p* is the probability that all three conditions are not different. For pairwise comparisons, $p^†$ is the probability that *Phase 1* or *2* is not different from *Baseline*. $p^‡$ is the probability that *Phase 2* is not different from *Phase 1*.

	One-Way Repeated ANOVA		Baseline	Phase 1			Phase 2		
	F-value	p	Mean (SD)	Mean (SD)	$p†$		Mean (SD)	$p†$	$p‡$
Spatiotemporal Parameters									
Speed (m/sec)	F(2, 36) = 11.446	< **0.001**	1.36 (0.15)	1.22 (0.18)	**0.003**		1.26 (0.15)	**0.013**	0.403
Stride Length (m)	F(2, 36) = 6.867	**0.003**	1.45 (0.11)	1.35 (0.16)	**0.004**		1.38 (0.14)	0.177	0.388
Cadence (strides/min)	F(2, 36) = 5.274	**0.010**	56.54 (3.00)	54.30 (3.79)	**0.040**		55.58 (2.95)	0.492	0.122
Stance Time (sec)	F(2, 36) = 5.174	**0.011**	0.65 (0.04)	0.68 (0.05)	**0.011**		0.66 (0.05)	0.144	0.055
Ground Reaction Force (BW)									
Midstance	F(2, 36) = 17.844	< **0.001**	1.15 (0.08)	1.06 (0.06)	< **0.001**		1.07 (0.05)	< **0.001**	0.306
Terminal Stance	F(2, 36) = 13.522	< **0.001**	1.16 (0.07)	1.09 (0.08)	**0.001**		1.10 (0.08)	**0.001**	0.55
Knee Moments (%BW*HT)									
Flexion	F(2, 36) = 4.551	**0.017**	3.21 (1.22)	2.56 (0.96)	0.094		2.68 (0.95)	0.091	1.000
Extension	F (1.440, 25.919) = 7.903	**0.005**	3.19 (1.03)	2.50 (0.72)	**0.020**		2.68 (0.79)	**0.026**	0.519
Abduction	F(2, 36) = 1.053	0.359	0.47 (0.41)	0.56 (0.38)	–		0.50 (0.31)	–	–
Adduction	F(1.282, 23.078) = 18.085	**0.000**	2.89 (0.52)	2.26 (0.55)	**0.001**		2.37 (0.45)	< **0.001**	0.529
Midstance (KAM1)	F(2, 36) = 19.331	**0.000**	2.56 (0.61)	2.10 (0.54)	**0.001**		2.14 (0.50)	< **0.001**	1.000
Terminal Stance (KAM2)	F(1.473, 26.507) = 9.208	**0.002**	2.45 (0.60)	1.94 (0.56)	**0.018**		1.95 (0.47)	**0.008**	1.000
External Rotation	F(2, 36) = 9.627	**0.000**	1.06 (0.19)	0.89 (0.25)	**0.010**		0.90 (0.25)	**0.009**	1.000
Internal Rotation	F(2, 36) = 1.572	0.222	0.24 (0.09)	0.21 (0.10)	–		0.21 (0.11)	–	–
Knee Angular Impulse (%BW*HT*Sec)									
Adduction (KAI)	F(2, 36) = 10.226	**0.000**	0.93 (0.18)	0.80 (0.18)	**0.018**		0.78 (0.13)	**0.001**	1.000

walking for 20 m at a self-selected, comfortable pace. Plantar pressure on the index side was recorded at 100 Hz and wirelessly transmitted to Moticon SCIENCE software (Moticon GmbH, Munich, Germany) on a laptop computer. Peak pressure recorded in the two lateral sensors of five steps free of turns, accelerations, and decelerations were averaged and later used for calculating training thresholds.

2.3.2. Baseline gait analysis

Following baseline plantar pressure acquisition, five walking trials were acquired. Subjects were asked to walk normally on a 6-meter leveled walkway.

2.3.3. Gait retraining 'phase 1'

After the baseline motion capture of normal gait, subjects were introduced to pressure-based auditory feedback. To generate auditory cues, the insole on the index side was connected through the data transfer protocol ANT+ to a smartphone which generated auditory signals when pressures exceeded 75% of the average peak pressures of *Baseline* (threshold comparable with Ferrigno et al. [12]). Subjects were verbally instructed to subtly alter their walking style to avoid the auditory cues and in a manner that is visually unnoticeable. Subjects then trained with insole-generated feedback, implementing their own gait strategy to maintain plantar pressures below thresholds. A board-certified physical therapist (CF) monitored this introductory training session to ensure that the resulting gait pattern was unnoticeable to a casual observer. *Phase 1* ended when subjects could successfully avoid the auditory cues for the majority of steps while visually demonstrating a normal gait; the average time to accomplish this task was 10 min for all subjects. After the initial in-lab training, subjects performed a second gait test while receiving auditory feedback cues. Only walking trials during which subjects successfully avoided the auditory signal during stance phase on the force plate were accepted.

2.3.4. Gait retraining 'phase 2'

After completing *Phase 1*, subjects performed their training outside the lab. They set out a one-mile predetermined course on campus, while continuously receiving pressure-based auditory feedback through headphones. Subjects were instructed on the course layout and performed training, unsupervised, similar to the in-lab training they had just completed. After returning to the lab, subjects completed their final

gait test with motion capture, this time while executing the newly learned gait modification but with the smartphone turned off and without receiving auditory feedback.

2.4. Motion capture & data analysis

A 24-marker, modified Helen Hayes marker set was applied [12]. Twelve cameras (Qualisys Gothenburg, Sweden) at 120 Hz recorded the position of the reflective markers to reconstruct joint angles and gait kinematics. A force plate (Bertec, Columbus, OH) at 3000 Hz collected ground reaction forces. Data processing was performed using Visual 3D (V3D; C-Motion, Inc., Germantown, MD). A Butterworth filter with a cutoff frequency of 15 Hz was applied to analog force plate data. An average filter with a window size of 15 frames was applied to marker data. The ankle joint was defined as the midpoint between the markers on the lateral and medial malleoli. The knee joint center was defined as the midpoint between the lateral and medial knee joint line markers. The hip joint center was estimated using the method of Bell et al. [19,20]. Position and orientation of segments were computed with six degrees of freedom, and net joint moments were computed using inverse dynamics. The primary variables of interest were the KAM (overall peak, pKAM, KAM1, and KAM2) and KFM. Spatiotemporal measures (speed, stride, and cadence), knee moments in the transverse plane, loading magnitude and duration (ground reaction force GRF magnitude and stance time) were also included to aid understanding difference in the primary variables of interest between study phases. The difference in pKAM (ΔpKAM) between *Baseline* and *Phase 1* was compared with that observed in Ferrigno et al. [12], which followed a similar protocol but employed a lab-based insole to generate pressure-based auditory feedback.

2.5. Statistics

Statistical analyses were performed using IBM SPSS Statistics 22 (SPSS Inc., Chicago, IL). An alpha level of 0.05 indicated statistical significance. To test the first hypothesis that ΔpKAM elicited by the wireless insole from *Phase 1* of the current study is not different from ΔpKAM previously elicited using a lab-based insole [12], we used independent t-test. One-way repeated measures multivariate analysis of variance (MANOVA) was first used to determine if there was a
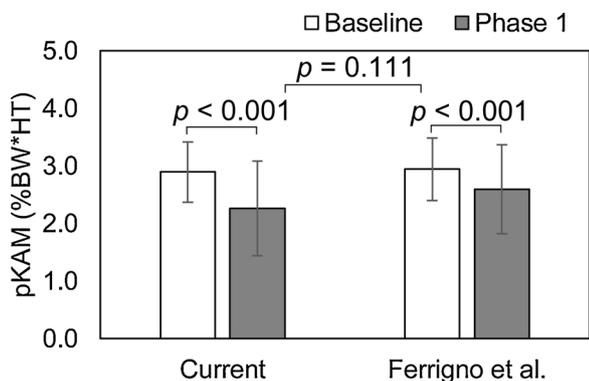
Fig. 3. There was no difference in pKAM reduction between the current study (a wireless insole) and Ferrigno et al. (a lab-based insole). Error bars represent standard deviation.

difference in the combination of all variables of interest when a gait modification was trained using pressure-based feedback. If a significant difference existed, univariate analysis was carried out to understand the difference of each variable between study phases, and subsequent pairwise comparisons were performed. Pearson's correlation coefficients between knee moments and speed [21], stride length [22], and cadence [22] were evaluated since differences in spatiotemporal variables can alter knee moments.

3. Results

Knee moments and spatiotemporal variables at *Baseline*, *Phase 1* (in-lab), and *Phase 2* (out-of-lab) are summarized in Table 2. All knee moments were normalized to body size (percentage body weight*height, %BW*HT).

After gait retraining in *Phase 1*, subjects reduced pKAM by 0.64 ± 0.65%BW*HT ($p = 0.001$; 20.6%). Ferrigno et al. recorded 0.36 ± 0.24%BW*HT pKAM reduction ($p < 0.001$; 12.3%) [12]. There was not a difference in ΔpKAM of the current study and Ferrigno et al. ($p = 0.111$) (Fig. 3).

The one-way repeated measures MANOVA suggested that there was a difference in the combined variables of interest between the three study phases, $F(30, 44) = 2.079$, $p < 0.013$; Wilks' $\Lambda = 0.171$, partial $\eta^2 = 0.586$. Univariate analysis suggested that pKAM, KAM1, KAM2, and KFM were different. Pairwise comparisons revealed differences in the KAMs but not KFM between *Baseline* and *Phase 1* and between *Baseline* and *Phase 2*. After gait retraining in *Phase 2*, subjects reduced
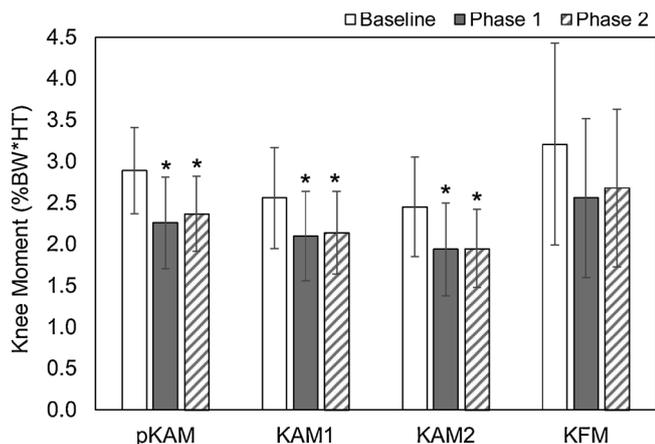

Fig. 4. Knee moments at *Baseline*, *Phase 1* (in-lab), and *Phase 2* (out-of-lab, unsupervised) of gait retraining. * indicates a significant difference found in *Phase 1* or *2* when compared to *Baseline*. Error bars represent standard deviations.

pKAM by 0.52%BW*HT ($p < 0.001$; 17.2%), KAM1 by 0.43%BW*HT ($p < 0.001$; 15.8%), and KAM2 by 0.40%BW*HT ($p = 0.008$; 17.6%) from respective values recorded at *Baseline* (Fig. 4). KAMs of *Phase 1* and *Phase 2* were not different. In other words, the KAM reductions achieved after *Phase 1* were reproduced after *Phase 2* despite the absence of auditory feedback cues. Importantly, the KFM did not increase from *Baseline* during either *Phase 1* or *2*. The GRF reduced 0.074 BW ($p < 0.001$; 6.18%) in midstance and 0.060 BW ($p = 0.001$; 5.10%) in terminal stance, but these differences did not contribute to the difference in KAM1 ($r = 0.015$, $p = 0.953$) and the difference in KAM2 ($r = .393$, $p = 0.096$), respectively.

Differences in speed, stride length, cadence, and stance time were found. After training in the community (*Phase 2*), subjects walked 0.11 m/s slower, which did not significantly correlate with the reduction in KAM ($r = 0.297$, $p = 0.216$). Furthermore, we evaluated the adduction angular impulse (KAI) to examine the loading duration in addition to the magnitude of the KAM [4]. Despite slower speeds after *Phase 1* and *Phase 2* of training, KAI reduced ($p = 0.018$ and 0.001, respectively) (Table 2).

4. Discussion

Addressing the biomechanical contributors to knee OA with a clinically translatable intervention is challenging. Here we took the first step to evaluate a wireless pressure-detecting shoe insole, specifically its validity as a gait retraining tool to re-distribute knee loads and its feasibility for unsupervised training outside the laboratory. Within minutes of training in the lab (*Phase 1*), subjects were able to develop a strategy to avoid the auditory feedback that was relatively unnoticeable to the PT. The extended training period outside the lab (*Phase 2*) demonstrated that subjects were able to train unsupervised with the equipment in the community.

Comparisons between *Phase 1* results and the data of the study by Ferrigno et al. allowed us to validate the new insole. Both studies used the same protocol on healthy individuals within the same lab. While the average pKAM reductions were statistically comparable, the former insole is restricted to in-lab use only and the new insole allows unsupervised training in the community. A recent study showed that as many as eight training sessions in the lab were inadequate for subjects to acquire a modified gait pattern [23]. In this respect, the wireless insole is an important step forward, since it permits unlimited training opportunities throughout the day.

Subjects were able to continue practicing unsupervised during *Phase 2* outside the lab. As subjects returned, they were challenged to execute the gait modification in the absence of the auditory cues. Sixteen of the 19 subjects achieved KAM reduction. The amount of reduction was somewhat lower when compared to *Phase 1* (*Phase 2* < *Phase 1*: 17.2% < 20.6% for pKAM, 15.8% < 17.3% for KAM1, and 17.6% < 18.2% for KAM2). Stride length and cadence were no longer significantly different and approached baseline values. This likely suggests optimization of the newly learned gait pattern rather than training deterioration, since subjects fine-tuned their gait adaptation to a set pressure threshold. In summary, the wireless insole showed to be an appropriate gait retraining tool, ready to be implemented outside the gait lab where more practice can take place but without the supervision of a clinician. There are earlier studies that investigated feedback-prompted gait retraining to modify gait pattern of individuals with medial knee OA, but feedback training was provided only one time per week and confined to the lab [24,25]. The wireless insole and intuitive feedback interface enables continuous training possibilities at home and in the community, promoting retention of the gait modification.

Both KAM1 and KAM2 were reduced in this study. There is a plethora of literature about the importance of reducing KAM1, which has been associated with OA severity [5], progression [16], and pain [26]. More recently, KAM2 has also been implicated in medial compartment loading. A strong correlation between reduction of KAM2 and reduction

of the second peak of medial contact force was recorded in instrumented knees [15]. While the literature is vague about what magnitude of KAM reduction is clinically meaningful, both the KAM1 and KAM2 reductions observed in this study were at the high end and robust relative to more assertive biomechanical interventions. For example, the 15.8% KAM1 reduction in the current study is greater than the 3–6% reductions measured with lateral wedge insoles [8]. Furthermore, most other reduction strategies do not elicit both KAM1 and KAM2 reductions. Toe-in gait reduces KAM1 by 7–20% [25,27] and lateral trunk lean reduces KAM1 by 9.3–14.9% [14]; neither of these gait modifications, however, reduces KAM2 [14,25,27]. Conversely, toe-out gait reduces KAM2 by 12–39%, but is ineffective at targeting KAM1 [28,29].

More recently, the KFM has come under scrutiny as this sagittal plane moment is likely to increase when the frontal plane (KAM) is lowered [12,15]. The KFM normally occurs during the first half of stance before it declines quickly before the ground reaction force shifts its projection anteriorly near midstance to induce an extension moment at the knee. Due to its loading contributions across the lateral and medial knee compartments, the KFM should be assessed when examining the load-induced benefits of biomechanical interventions. In the current study, the gait modification prompted by pressure-based auditory feedback did not alter the KFM.

The study is not without limitations. Training and testing happened on a single-day and the results are only reflective of the initial load redistribution during the early stage of learning (i.e., acquiring) a gait modification. Nevertheless, the data suggest that the training device and regimen can be easily applied to a clinical setting. The training paradigm in the current study is meant to be applied to an older population with knee OA, while we tested it on relatively young healthy subjects. The intended clinical population especially those with co-morbidities and pain might be less capable of changing their gait pattern, demonstrating motor learning deficiencies and less training endurance. Additionally, COP medialization requires a high cognitive effort [30]. Despite this potential drawback in the OA population, the potential value of pressure modulation is great, particularly when paired with a pressure-based feedback insole and is, yet worth future investigation. Ultimately, only a clinical trial can give us the answer, but this pilot data are encouraging to prepare it. Only a single modality of feedback has been tried, while there is a multitude of possibilities. For example, instead of continuous feedback, progressively incremental feedback in the beginning and faded feedback towards the end of gait retraining may be more beneficial. The focus on this study was to test the concept of delivering feedback using a clinically appropriate insole to reduce the KAM. Understanding how COP medialization changes lower limb kinematics would further elucidate the mechanisms behind the changes in kinetics.

In conclusion, this study shows that the wireless insole is a promising tool for gait retraining and may facilitate learning of a gait modification. Since both KAM peaks are reduced simultaneously and other knee moments are unaffected, this technology is clearly capable of enhancing loading conditions in the knee throughout the stance phase and it could be highly translatable to the clinical environment. Future work is now warranted to implement and investigate the use of the wireless insole on individuals with medial knee OA.

Conflict of interests

None.

Acknowledgements

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