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Effects of a 10-week toe-out gait modification intervention in people with medial knee osteoarthritis: a pilot, feasibility study

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SUMMARY

Objective: To examine the feasibility of a 10-week gait modification program in people with medial tibiofemoral knee osteoarthritis (OA), and to assess changes in clinical and biomechanical outcomes.
Design: Fifteen people with medial knee OA completed 10 weeks of gait modification focusing on increasing toe-out angle during stance 10° compared to their self-selected angle measured at baseline. In addition to adherence and performance difficulty outcomes, knee joint symptoms (Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale and total score, numerical rating scale (NRS) of pain), and knee joint loading during gait (late stance peak knee adduction moment (KAM)) were assessed.
Results: Participants were able to perform the toe-out gait modification program with minimal to moderate difficulty, and exhibited significant increases in self-selected toe-out angle during walking ($P < 0.001$). Joint discomfort was reported by five participants (33%) in the hip or knee joints, though none lasted longer than 2 weeks. Participants reported statistically significant reductions in WOMAC pain ($P = 0.02$), NRS pain ($P < 0.001$), WOMAC total score ($P = 0.02$), and late stance KAM ($P = 0.04$).
Conclusions: These preliminary findings suggest that toe-out gait modification is feasible in people with medial compartment knee OA. Preliminary changes in clinical and biomechanical outcomes provide the impetus for conducting larger scale studies of gait modification in people with knee OA to confirm these findings.

Introduction

Osteoarthritis (OA) is one of the most common musculoskeletal impairments and is currently one of the leading causes of chronic physical disability in adults[1]. The knee is the weight-bearing joint most commonly affected with OA. Given that quality of life decreases and the economic burden increases with more severe symptoms, it is imperative to implement treatment approaches that effectively slow disease progression. Excessive loading and alterations in load distribution within the joint are believed to play major roles in the breakdown of articular cartilage indicative of knee OA progression[2–5]. Accordingly, there has been increased interest in the knee OA literature to develop treatments that target abnormal loading patterns within the knee joint.

The knee adduction moment (KAM) is generally regarded as an important proxy for medial tibiofemoral compartment loading during walking[3,6,7]. Further, the overall peak KAM has been shown to be associated with clinical outcomes unique to medial compartment knee OA including lower limb malalignment[8,9], medial compartment disease severity[10,11], and tibial bone mineral density ratios[12]. Importantly, Miyazaki *et al.*[13] showed that an approximate 25% increase in overall peak magnitude of the KAM at baseline was associated with 6.6 times the risk of radiographic medial compartment disease progression over 6 years while Bennell *et al.*[14], showed that the total area under the KAM–time curve (KAM impulse) at baseline was predictive of loss of cartilage volume over 12 months using magnetic resonance imaging. Taken together, these findings point to an important role for quantification of the KAM in knee OA research, and many studies aiming to examine the effectiveness of load-reducing treatments for knee OA have reported the KAM.

One such treatment is gait modification. A recent systematic review has shown consistent changes in KAM magnitudes following single-session gait modifications such as altering toe-out

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angle[15]. These findings are consistent with previous cross-sectional studies that have shown significant inverse correlations between late stance KAM magnitudes and toe-out ($r > -0.26$) magnitudes during walking[16]. Previous studies have examined the effects of changing toe-out (foot progression) angle on late stance KAM magnitudes in young, healthy individuals without knee OA[17–19] or in those with radiographic evidence of knee OA[19,20]. Though the methodologies differed, consistent findings of reductions in the late stance KAM magnitude suggest a beneficial effect on medial compartment load with toe-out gait modification. Though the clinical relevance of the late stance peak KAM is still unclear (most early studies reported the early stance peak KAM only), increases in toe-out angle have been shown to have a protective role against knee OA progression.

Chang *et al.*[21] studied 56 people with radiographic knee OA over the course of 18 months and assessed gait biomechanics as well as radiographic features of knee OA. As a group, each 5° increase in baseline toe-out angle had an associated odds ratio of 0.60 (95% CI: 0.37, 0.98) for medial tibiofemoral progression. These findings are consistent with the known effects of toe-out gait modification on knee joint load parameters – specifically the late stance peak KAM – and suggest that toe-out gait modification may have longer-term biomechanical and clinical benefits for people with knee OA.

Despite the potential treatment benefits of toe-out gait modification, there are no published studies of the effects of longer-term (i.e., more than one session) toe-out modification in people with knee OA. However, Shull *et al.* recently reported significant improvements in biomechanical and clinical outcomes following 6 weeks of *toe-in* gait retraining guided by haptic feedback[22]. Their study provided initial confirmation of the potential benefits of gait retraining for people with knee OA. However, despite their findings, much is still unknown about gait retraining as a treatment strategy for those with knee OA. First, they chose toe-in rather than toe-out for modification in their study. Thus, the effects of a toe-out only modification remain unknown. Further, the effects of any load-reducing gait modification on joints other than the knee have received little interest. Specifically, given that modification of a given gait characteristic will involve changes at more than one joint or body segment (increasing the toe-out angle, for example, will involve external rotations at the ankle, knee, and hip), positive benefits at the knee could be associated with concurrent negative consequences at other joints. Finally, the feasibility of delivering a longer-term toe-out gait modification program to people with knee OA is unknown.

Therefore, the primary objective of this exploratory, pilot study was to evaluate the efficacy, safety, and adherence to a 10-week toe-out gait modification program in a group of individuals with knee OA. Our secondary objective was to obtain pilot data pertaining to the effect of a longer-term toe-out gait modification intervention on clinical and biomechanical outcomes relevant to knee OA. We hypothesized that individuals would adhere to the program and perform the toe-out gait modification with minimal to moderate difficulty. We also hypothesized that changes in knee joint loading and pain could be achieved with minimal reports of pain at adjacent lower limb joints.

Methods

Participants

Community-dwelling individuals with medial tibiofemoral OA were recruited from our laboratory participant database and via advertisements in print media. Inclusion criteria included: (1) definitive medial tibiofemoral osteophytes; (2) joint space narrowing greater in the medial tibiofemoral compartment compared to the lateral compartment; (3) predominance of pain over the medial aspect of the knee; (4) history of knee pain longer than 6 months; and (5) average knee pain of at least 3 out of 10 (using an 11-point numerical rating scale (NRS) with terminal descriptors of 0 = "no pain" and 10 = "worst pain imaginable") over the 1 month prior to initial screening. Exclusion criteria included: (1) knee surgery or intra-articular pain relief injection within 6 months; (2) current or past (within 6 weeks) oral corticosteroid use; (3) history of knee joint replacement or tibial osteotomy; (4) any other condition affecting lower limb function; and (5) participation in a new structured exercise program (defined as at least 45 min of continuous, planned exercise 3 or more days per week) within the past 3 months or planning to commence exercise or other treatment for knee OA in the next 3 months. The study was approved by the Institution's Clinical Research Ethics Board and all participants provided written informed consent.

Study design

Interested participants were initially screened for inclusion and exclusion criteria over the telephone and eligible individuals were referred for radiographic evaluation. Standing, semi-flexed, postero-anterior radiographs were obtained and graded for disease severity using the Kellgren and Lawrence (KL) OA classification system[23]. Individuals who met the radiographic criteria listed above were invited to the laboratory for a baseline (Week 0) testing session where self-report, objective physical function, and biomechanical data were obtained. Participants returned to the laboratory the following week (Week 1) to begin the gait modification program. This program lasted 10 weeks and involved six training visits with the study therapist at Weeks 1, 2, 3, 5, 7, and 9 of the intervention. Follow-up testing occurred upon completion of the intervention (Week 11). 10 weeks was chosen as an appropriate intervention length based on previous exercise studies in the knee OA population (typically lasting approximately 8–12 weeks), and to provide sufficient time to establish motor re-learning of the new gait modification.

Gait modification intervention

Participants were instructed to increase the toe-out angle of their study limb (most painful in the case of bilateral involvement) by 10° over and above the self-selected amount measured at baseline. 10° was chosen based on self-reported difficulty in obtaining 15–20° of toe-out increase by those with knee OA (unpublished data), and previous research indicating an approximate 40% reduction in risk of radiographic disease progression over 18 months for every 5° increase in baseline toe-out angle[21]. Toe-out modification was facilitated through the use of real-time biofeedback of performance[24–26] at each treatment visit. Participants walked on a treadmill in their own walking shoes at a speed similar to their over ground walking speed, and were provided with tracking data pertaining to their toe-out angle (transverse plane angle of line connecting toe and heel with respect to line of forward progression of the body) in real-time. Twenty-two retro-reflective markers were affixed to the participant according to a modified Helen Hayes marker set[27], and their movements were captured using ten high-speed digital cameras (Motion Analysis Corp., Santa Rosa, CA) sampling at 120 Hz. An initial standing static trial was collected using additional markers placed over the medial malleoli and femoral epicondyles to determine segment orientations. During the treadmill walking, toe-out angle was calculated in real-time using the Biofeedtrak option within Cortex software (Motion Analysis Corp., Santa Rosa, CA) and displayed graphically in front of

the participant as a continuous line streamed live via an overhead projector.

Prior to each training session, participants stood on a protractor device at their target toe-out angle (Fig. 1) to ensure that the anatomical toe-out angle matched the calculated toe-out angle obtained from the motion analysis system. While remaining on the protractor device, a vertical target zone was then placed on-screen that corresponded to the target toe-out angle. During each 30-min training session, participants were instructed to match the line corresponding to their actual toe-out angle with the vertical target zone (Fig. 2) during stance. To promote motor learning, a faded feedback paradigm was used[25] with the amount of real-time biofeedback displayed decreasing from Weeks 1 and 2 (30 min) throughout the intervention (Week 3 = 25 min; Week 5 = 20 min; Week 7 = 15 min; Week 9 = 10 min).

Fidelity of the training sessions was assessed by calculating the difference (toe-out error) between the intended target angle and the actual toe-out angle produced during 10 consecutive stance phases at each of four time points during each training session (1 min, 10 min, 20 min, and 30 min) and averaged within the session. Perceived difficulty in achieving the target toe-out angle was also assessed at each training session using an 11-point NRS (0 = "no difficulty", 10 = "unable to perform"), knee joint pain was assessed using an 11-point NRS (0 = "no pain" and 10 = "worst pain imaginable"), while perceived physical exertion was measured during training using the 15-point Borg rating scale of perceived exertion[28]. Participants were instructed to maintain the increased toe-out angle during walking outside the laboratory.

Adherence to the training program was assessed as the total number of supervised walking sessions attended for each participant. Compliance with the gait modification program was assessed

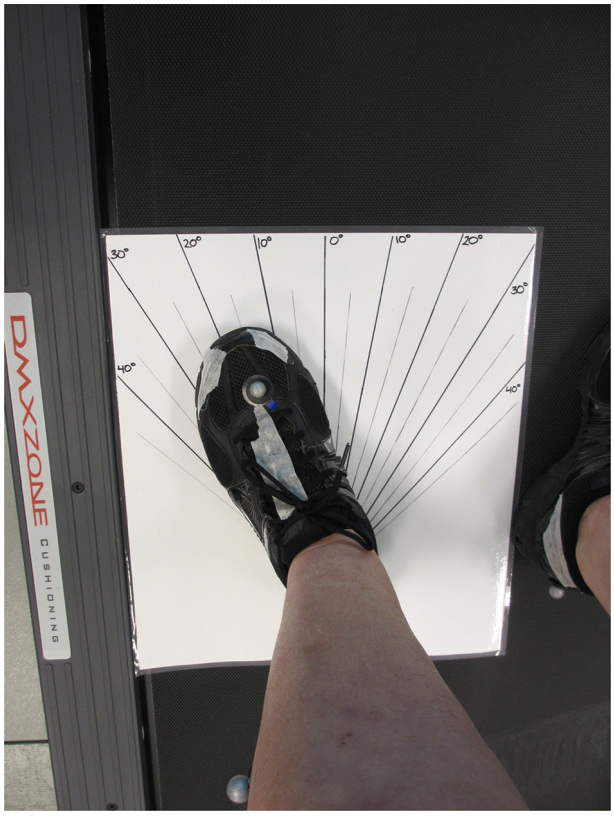

Fig. 1. Protractor device used to calibrate actual toe-out angle with calculated toe-out angle based on motion analysis marker data.

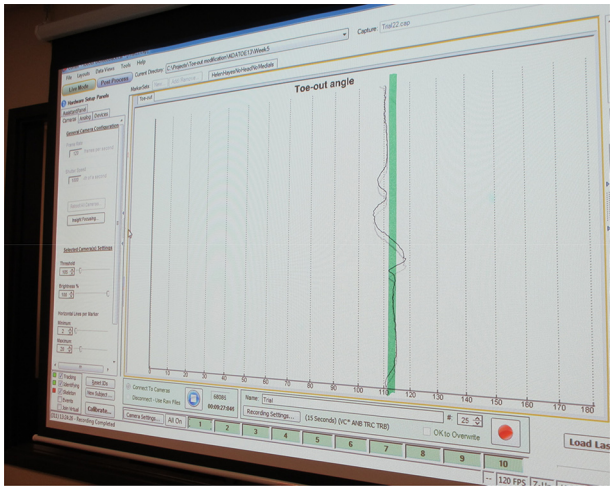

Fig. 2. During training, participants were instructed to match their calculated toe-out angle (solid line) with the target angle corresponding to a 10° increase in toe-out angle (thick vertical line). Specifically, participants were instructed to focus on the straight sections of the real-time toe-out angle – which corresponded to stance phase toe-out angle – rather than the curved portions – which corresponded to swing phase toe-out angle.

weekly via self-report as the perceived confidence in maintenance of the toe-out modification throughout the week outside the laboratory using an 11-point NRS (0 = "not confident at all", 10 = "very confident"). Adverse events were assessed using open-ended questions included in a log book maintained by the participants. Finally, physical activity levels were monitored throughout the intervention using a wearable pedometer device (Fitbit One, Fitbit Inc., San Francisco, CA) that uploaded weekly step count data to a centralized database.

Pain and physical function assessment

At baseline and follow-up, participants completed the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Likert version. Average knee pain over the previous week was assessed using an 11-point NRS with terminal descriptors of 0 = "no pain" and 10 = "worst pain imaginable". Overall perceived change at follow-up compared to baseline was assessed using a 5-point Likert scale (1 = "much worse", 2 = "slightly worse", 3 = "no change", 4 = "slightly better", and 5 = "much better")[29]. Finally, participants completed the timed stair climb test where they were instructed to ascend 12 stairs "as quickly as possible" and the fastest time from two attempts was recorded[30,31].

Gait biomechanics assessment

Gait data were recorded for barefoot over ground (i.e., non-treadmill) walking trials at a self-selected speed using the same marker set and camera system as described above. As in the training sessions, an initial standing static trial with the additional four medial markers was collected. Kinematic data from the cameras were synchronized with two force platforms (OR6-6, Advanced Mechanical Technologies Inc.) visually concealed in the floor of a 10 m walkway and sampling data at 1200 Hz. Walking speed was monitored by using photoelectric timing gates. In instances where the self-selected walking speed at follow-up differed by more than ±5% from baseline, additional trials constrained to this range were conducted and analyzed. Participants were provided no instructions pertaining to walking mechanics during any of the gait assessments. In particular, participants were told to walk

"naturally" and no mention of toe-out angle was made during these assessments.

Inverse dynamics techniques and commercially available software (Orthotrak, Motion Analysis Corp.) were used to calculate gait variables including: KAM (early stance peak, late stance peak, impulse), peak external knee flexion moment (KFM) during stance, and mean toe-out angle (angle between a line connecting the heel and second metatarsal markers with the forward progression of the body) during foot-flat. Trials in which a definitive late stance peak KAM was not identifiable were excluded from analysis of that variable only. The mean value from five trials was calculated for each variable.

Statistical analysis

Differences in outcomes pertaining to the feasibility or completion of the intervention were assessed using either paired *t* tests (weekly step counts) or repeated measures analysis of variance (perceived difficulty, exertion, toe-out error, compliance). All biomechanical and clinical outcomes were assessed for differences between baseline and follow-up using paired *t* tests. The main outcomes included pain (WOMAC and NRS) and overall symptoms (total WOMAC), as well as self-selected toe-out angle, late stance peak KAM, and KAM impulse calculated from raw time (i.e., non-time normalized) values. Other relevant outcomes included the timed stair climb and other biomechanical variables that may increase with toe-out gait modification and influence total knee joint load (peak KFM and early stance peak KAM). All statistical analyses were conducted using the Statistical Package for the Social Sciences (v. 21, SPSS Inc.).

Results

Between October 2012 and February 2013, 43 individuals underwent telephone screening for the study (Fig. 3). Twenty-two of these individuals underwent radiographic screening, and 17 underwent baseline testing. One individual became unable to attend any training sessions and dropped out prior to their first week of training, leaving 16 individuals (7 males; age = 64.8 ± 10.4 years; body mass index = 29.9 ± 6.8 kg/m^2) who began gait modification training. Four participants exhibited mild radiographic signs of OA (KL grade 2), nine participants exhibited moderate OA (KL 3), and three participants exhibited severe knee OA (KL 4). One participant was unable to continue with training after Week 5 due to an acute injury to the contralateral knee unrelated to the intervention.

Attendance at the training sessions was high (85 of 90 sessions attended; 94%) and participants were able to achieve toe-out angles similar to the targeted 10° increase compared to baseline (overall mean toe-out error averaged across all 85 training sessions = 2.6 ± 2.1° below the targeted 10° increase) with moderate perceived difficulty and exertion (Table I). Further, self-confidence in the participants' perceived ability to maintain the increased toe-out angle outside the laboratory was moderate to high (overall mean throughout the intervention = 6.9 ± 2.0) and improved significantly over the duration of the intervention (Week 1 = 5.8 ± 2.5, Week 10 = 7.9 ± 2.3; $P < 0.01$).

Five participants reported an adverse event during training, as measured using open-ended questions asked throughout each training session. These adverse events were all joint discomfort experienced during the first two sessions, and none of which lasted more than two sessions. This included discomfort in the contralateral hip or knee ($n = 1$ each) as well as the ipsilateral ankle, knee, or hip ($n = 1$ each). Outside of the laboratory, there were five reports of increased joint discomfort at the ipsilateral knee ($n = 2$) as well as the ipsilateral ankle or hip ($n = 1$ each) or contralateral knee ($n = 1$). No discomfort lasted longer than 2 weeks. Finally, weekly step counts were consistent across the intervention, with no significant difference between Week 1 (46,393 ± 16,144 steps) and Week 10 (41,735 ± 23,578 steps) ($P = 0.59$).

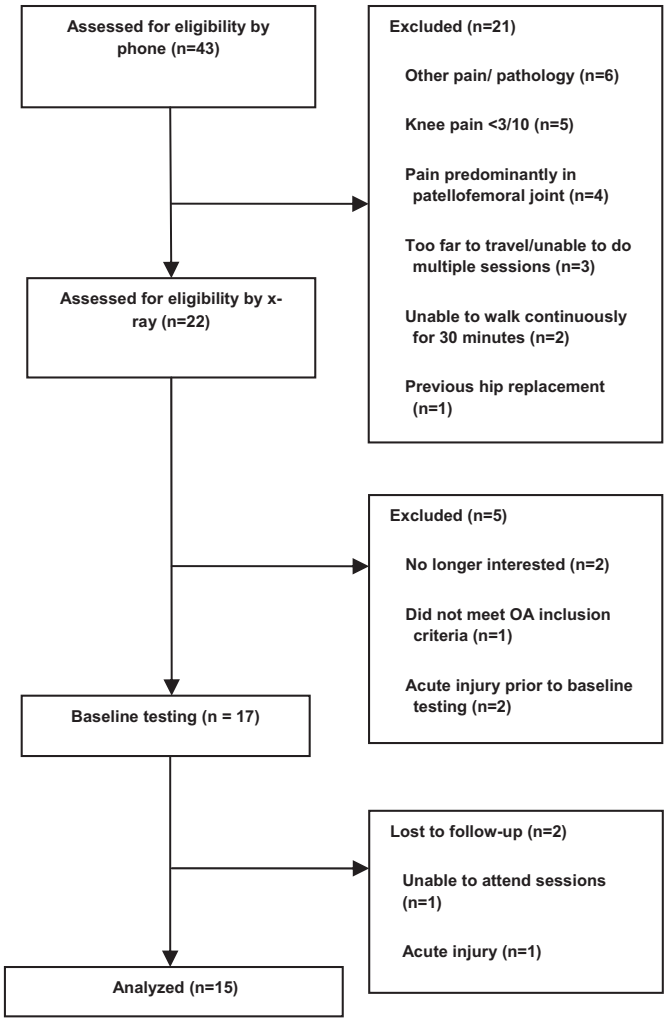

Fig. 3. Flow chart of eligible and recruited participants.

As a group, participants exhibited significant increases in self-selected toe-out angle and significant differences in late stance KAM and self-reported pain following the intervention compared to baseline (Table II). Specifically, significant decreases in the WOMAC pain subscale ($P = 0.02$), total WOMAC score ($P = 0.02$), and average knee pain as measured using the NRS ($P < 0.001$) were observed, as were significant decreases in the late stance peak KAM ($P = 0.04$). Changes at follow-up equated to reductions in excess of 28% for pain (28.4% reduction for WOMAC pain, 44.4% reduction in NRS pain), 28.5% for overall symptoms (WOMAC total score) and 10.5% for the late stance peak KAM. Thirteen of the 15 participants (87 %) reported that their overall symptoms were "slightly better" or "much better" following the intervention compared to baseline, with the same number reporting these responses for change in pain alone, while 11 of 15 (73%) reported that their physical function was "slightly better" or "much better". No gait variable other than the late stance KAM or toe-out angle was significantly altered ($P > 0.05$), and participants completed the timed stair climb test in a similar time at both testing sessions ($P = 0.45$). Of the 75 total trials analyzed for each

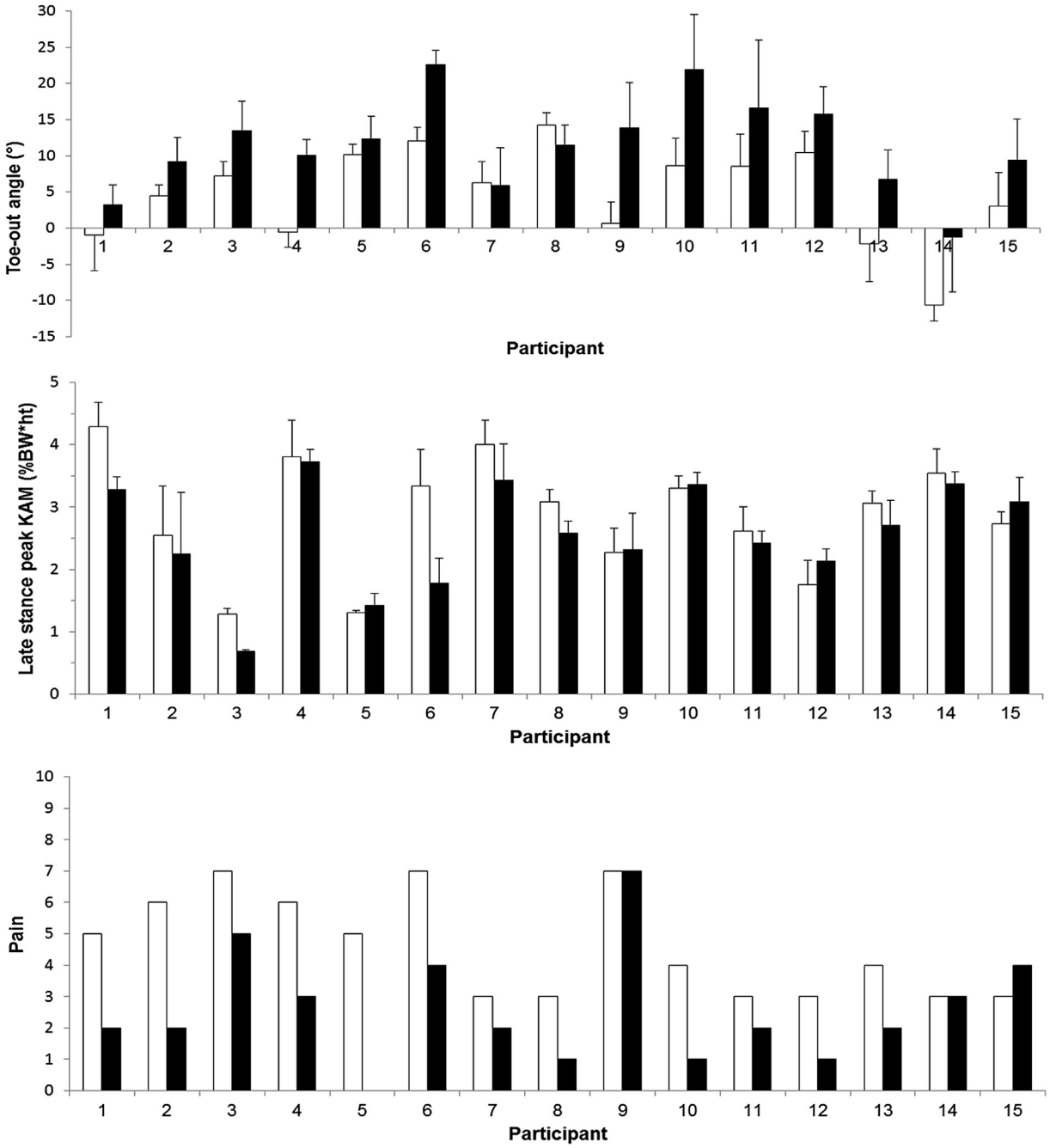

Fig. 4. Individual participant data for self-selected toe-out angle (top panel), late stance peak KAM (middle panel), and knee joint pain as measured using an 11-point NRS (bottom panel). White bars show data from the baseline assessment, while black bars pertain to follow-up data for each participant. Data for toe-out angle and late stance peak KAM pertain to the mean (95% CI) values from the five walking trials at each testing session. Negative toe-out angles denote self-selected toe-in.

testing session, the number of trials without a definitive late stance peak KAM was two and four for the baseline and follow-up assessments, respectively.

Discussion

Results from the current study provide evidence as to the feasibility and initial indications of potential benefits of toe-out gait modification training in individuals with medial knee OA. This study showed that toe-out gait modification performed over 10 weeks can be accurately achieved with minimal difficulty and does not produce any adverse effects at any lower limb joint as reported by the participants in the short-term. Further, these preliminary results suggest that prolonged gait modification focusing on increasing toe-out angle does not have a deleterious effect on symptoms and joint loading parameters relevant to medial knee OA. Since gait modification treatment is part of standard clinical practice for a variety of musculoskeletal pathologies and is commonly delivered with minimal resources and expense (for example, using a mirror), it represents an important treatment strategy with potential implications on the growing personal and economic burdens of knee OA. That said, methods to optimize toe-out gait retraining outside the laboratory setting to people with knee OA must be identified.

Table I
Mean (sd) participant training data over the six training sessions. Toe-out error corresponds to the average difference between the measured toe-out angle and target angle across four time points at each session. Difficulty refers to participants' self-reported difficulty in achieving the target toe-out angle during training (0 = "no difficulty", 10 = "unable to perform"). Pain was assessed using an 11 point NRS (0 = "no pain", 10 = "worst pain imaginable") at four time points during each training session and the mean for each session was calculated. Rating of perceived exertion (RPE) was assessed using the 15-point Borg scale

	Training session					
	Week 1	Week 2	Week 3	Week 5	Week 7	Week 9
Toe-out error (°)	2.9 (2.3)	3.2 (2.1)	2.2 (1.7)	2.6 (2.1)	2.9 (2.1)	2.0 (1.8)
Difficulty (0–10)	5.0 (2.4)	4.2 (2.5)	3.9 (2.4)	3.7 (2.2)	3.4 (2.0)	2.9 (1.9)
Pain (0–10)	3.1 (2.5)	2.3 (2.3)	2.5 (2.2)	2.4 (1.9)	1.6 (1.8)	2.0 (1.5)
RPE (6–20)	11.4 (2.0)	12.1 (2.0)	11.4 (1.9)	11.2 (1.2)	10.6 (1.7)	10.6 (2.1)

This study showed that the uptake of gait modification can be successfully achieved over the short-term (10 weeks) by individuals with knee OA with minimal difficulty, and the changes in self-selected walking parameters can be maintained in the absence of biofeedback of performance. Though participants expectedly reported moderate amounts of difficulty at the first training session (mean of 5.0 out of 10), this improved significantly over the course of the intervention (mean of 2.9 out of 10 by the sixth training session in Week 9). Changes in self-selected toe-out angle observed at the follow-up assessment were similar to those experienced during the training. Specifically, participants exhibited an average of slightly more than 8° of toe-out increase during training (mean error of 2.6° less than the target 10° increase), which translated to an improvement of approximately 7° in the amount of self-selected toe-out during over ground walking. These findings suggest that successful motor learning was achieved, and that practice with some form of feedback of performance was likely beneficial to overall changes in gait. Importantly, this study also showed that the number of adverse events associated with toe-out gait modification was minimal and similar to those expected when commencing a new exercise program. These included muscle and joint discomfort that were experienced for no more than 7–10 days. Future research with longer follow-up periods is needed to better identify any negative consequences of toe-out gait modification in people with knee OA.

Though limited by the small sample size for this pilot study, these findings appear to support the only other published report of repeated gait modification training for those with knee OA[22]. Shull *et al.* found that 6 weeks of toe-in gait modification delivered via haptic feedback based on tibial rotation produced significant changes in pain and function, as well as the overall peak KAM, immediately and 1-month post-intervention in 12 people with knee OA. They found a 20% reduction in the overall peak KAM, which is substantially larger than the 10% reduction observed in the late stance KAM in the present study, despite the shorter intervention length than the current study. This suggests that modest changes in knee OA symptoms may be achieved with small decreases in either the first or second peak KAM. However, our finding of a 1.9/10 reduction in self-reported pain as measured using a NRS is still smaller than the minimal clinically important improvement (2.0/10) for knee OA[32]. Therefore, the overall clinical significance of these findings is unknown and any firm conclusions regarding symptom improvement cannot be made.

Importantly, the small sample size in this pilot study precluded the identification of any definitive trend in the biomechanical and clinical data due to heterogeneity of results. For example, the hypothesized relationship between mechanical loading (i.e., KAM) changes with toe-out and a reduction in knee joint pain was unable to be directly confirmed. Indeed, there was variation in biomechanical and clinical outcomes in this study, despite the finding that all but two participants reported an increase in toe-out angle over the intervention. Only seven participants exhibited a further observable change in late stance KAM combined with self-reported reductions in knee pain (see. Fig. 4). Though we observed a small, inverse relationship ($r = -0.15$) between the change in toe-out angle and change in late stance KAM, this relationship was not statistically significant. Given the complexity between gait characteristics and KAM values (for example, other factors such as lateral trunk lean have been shown to influence KAM values) and the myriad factors known to influence self-reported pain, further research with larger sample sizes and longer intervention times is necessary to best understand the biomechanical and clinical benefits of toe-out gait modification.

Previous studies have shown that decreasing the toe-out angle (or toeing-in) predominantly improves the early stance KAM with minimal effect on the late stance KAM, while increasing the toe-out angle has the opposite effect[18,19,33]. This has been shown to occur due to a lateralization of the center of pressure (COP), and subsequent ground reaction force vector origin, that is more prevalent when the COP is situated anteriorly during late stance compared to under the heel during early stance[34]. Though much of the known clinical validation work on the KAM has focused on the overall peak value or the KAM impulse[10,13,14,35,36], Chang *et al.* showed a decreased risk of OA progression with larger toe-out angles and lower late stance KAM values[21] suggesting important clinical implications related to toe-out angle and late stance knee joint load. Further work to determine the clinical relevance of a reduced late stance KAM is warranted. However, despite the significant decrease in the late stance KAM, we only observed a small, yet not statistically significant reduction in the KAM impulse. Given that the peak KAM is typically smaller in late stance compared to early stance, it is possible that changes in KAM impulse may be linked more closely to the overall peak KAM. Conversely, the lack of significant difference in KAM impulse values may have been limited by the sample size or the magnitude of observed change in self-selected toe-out angle. Finally, as the magnitude of reduction in the KAM that

Table II
Group mean (sd) biomechanical, objective physical function, and self-report data during the intervention. Mean differences (95% confidence intervals (CI)) are also included to compare Baseline and Follow-up values

	Baseline (Week 0)	Follow-up (Week 11)	Mean difference (95% CI)	*P* value
Walking speed (m/s)	1.14 (0.18)	1.14 (0.16)	0.00 (−0.06, 0.05)	0.90
Toe-out angle during foot-flat (°)	4.75 (6.59)	11.41 (6.46)*	6.66 (4.08, 9.23)	<0.001
Early stance peak KAM (%BW × ht)	3.45 (0.82)	3.19 (0.72)	−0.26 (−0.60, 0.07)	0.12
Late stance peak KAM (%BW × ht)	2.87 (0.92)	2.57 (0.84)*	−0.30 (−0.57, −0.02)	0.04
KAM impulse (%BW × ht × sec)	1.33 (0.29)	1.24 (0.34)	−0.08 (−0.20, 0.04)	0.20
Peak KFM (%BW × ht)	1.38 (1.36)	1.51 (1.29)	0.13 (−0.52, 0.79)	0.67
Timed stair climb (seconds)	5.58 (3.10)	5.13 (1.44)	−0.45 (−1.67, 0.77)	0.45
WOMAC pain subscale (0–20)	7.4 (3.4)	5.3 (2.9)*	−2.1 (−3.9, −0.4)	0.02
WOMAC total score (0–96)	36.9 (14.8)	26.4 (13.5)*	−10.5 (−18.9, −2.1)	0.02
NRS pain (0–10)	4.5 (1.7)	2.6 (1.8)*	−1.9 (−2.8, −1.0)	<0.001

BW = body weight; ht = height; sec = second.
* Denotes significant difference ($P < 0.05$) compared to Baseline (Week 0) values.

equates to a clinically-significant amount is unknown, as with the clinical outcomes in this study, conclusions regarding structural improvements must be made with caution.

Though not statistically significant ($P = 0.67$), participants exhibited on average, a 10% increase in the peak KFM. This finding is consistent with previous studies suggesting that decreases in frontal plane moments with toe-out may be associated with increases in sagittal plane moments[34], thus negating any benefits on total knee joint loading. This has been confirmed in a single-subject case study examining a bi-planar gait modification showing that a reduction in the overall peak KAM magnitude did not necessarily result in a reduction in medial tibiofemoral compartment joint loading as measured directly with an instrumented prosthesis[37]. Though results from a single gait analysis session must be interpreted with extreme caution, these findings do point to limitations of relying on a single peak value. Importantly, the benefits of increasing toe-out on late stance KAM values as well as patient-reported outcomes observed in this study must be weighed against the potential consequence to sagittal plane biomechanics and overall knee joint load.

Despite the favourable outcomes found in this study, there are a number of limitations that must be taken into account and should be addressed in future studies. First, the exploratory nature of this pilot study was limited by a small sample size. However, these initial findings do support future studies with larger sample sizes and/or control groups. Indeed, another limitation of the current study was the lack of a control group for purposes of comparison. Though reductions in KAM would not necessarily be expected from a placebo effect or from a walking program alone, aerobic exercise has been shown previously to improve symptoms[31]. Thus, it is unknown whether the changes in symptoms observed in the present study can be attributed solely to the gait modification. However, a lack of increase in weekly step counts over the duration of the intervention suggests that study participants were not more physically active. Further, our changes in pain (effect sizes of 0.7–1.0) are greater than those suggested by Shull *et al.* to be expected due to the placebo effect (effect size of approximately 0.5)[22]. Thus, when combined with similar findings from Shull *et al.*[22], this study provides a rationale for conducting a more resource-intensive randomized controlled trial to best examine the impact of gait modification on those with knee OA. Finally, though participants were asked to subjectively report any adverse effects at other lower limb joints, analysis of joint kinetics at other lower limb joints was not undertaken. As a result, the true consequences of increasing toe-out throughout the lower limb kinetic chain remain unclear.

Though this pilot, feasibility study shows promising findings, it is clear that more research is needed. For example, it is possible that 10 weeks and/or an intended change in toe-out angle of 10° may be insufficient to optimize biomechanical and clinical outcomes. As discussed above, we observed much variability in the biomechanical and clinical outcomes. Longer performance of the gait modification or larger increases in toe-out angle may produce the intended combination of biomechanical and clinical improvement desired in most participants. Future studies in this area should also identify ways to better generalize the results and determine effectiveness. For example, inclusion of a retention testing session after the intervention would permit the examination of any carry-over effects from the intervention, in particular without the use of feedback of performance. Future research should also identify more feasible methods of providing the gait modification training. Though beneficial to best standardize the change in toe-out angle, real-time biofeedback in association with motion capture systems is not widely available clinically. However, as pointed out by Shull *et al.*[22], though it is likely that the use of some form of biofeedback can assist in the training of gait modification, it is not necessarily imperative to achieve changes in gait biomechanics as evidenced by the absence of biofeedback for the vast majority of the time over the course of the 10-week intervention. Identification of accessible methods of delivering gait modification outside the laboratory setting would greatly enhance the clinical applicability of this treatment strategy. As gait modification is already a commonly used component of rehabilitation for a number of different pathologies (e.g., stroke, brain injury, patellofemoral pain syndrome)[38–40], the capacity for gait modification delivery to those with knee OA does exist.

In conclusion, we found that 10 weeks of targeted toe-out gait modification could be safely achieved by older individuals with knee OA and that some statistically significant changes in biomechanics and symptoms may be realized. Though these results are based on an exploratory study with a relatively small sample size, if findings can be improved in future controlled trials and delivered using less resource-intensive modalities (e.g., mirror, raw video), gait modification would represent a new treatment approach that would not only have clinical and biomechanical implications, but could have a significant impact on the growing economic burden of knee OA.

Author contributions

M. Hunt was involved in study design, data analysis; drafting and approval of the manuscript.

J. Takacs was involved in study design, data collection, drafting and approval of the manuscript.

J. Takacs and M. Hunt take responsibility for the integrity of the work as a whole.

Conflict of interest

None.

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