Results: 40 individuals were randomized to the TO group, while 39 were randomized to the PW group. 35 individuals in the TO group, and 32 individuals in the PW group provided data at all testing sessions. The TO group exhibited an average change in their self-selected foot progression angle of −8.87° and −6.96° (indicating more toe-out) at follow-up and retention, respectively. No changes were observed in the PW group, and between-group differences were significant at both time points (−9.04°, 95% CI: −11.22°, −6.86° at follow-up, p<0.001; (−6.78°, 95% CI: −8.82°, −4.75° at retention, p<0.001). This translated into significantly larger improvements at follow-up in the TO group for the late stance KAM (−0.34 %BW*ht, 95% CI: −0.51 %BW*ht, −0.16 % BW*ht, p<0.001) as well as the KAM impulse (−0.06 %BW*ht*s, 95% CI: −0.11 %BW*ht*s, −0.01 %BW*ht*s, p = 0.031). While improvements, based on confidence interval assessment, in these two variables were maintained in the TO group at retention, no statistically significant between-group differences remained (p = 0.063 and p = 0.058). No other statistically-significant between-group differences were observed in any other biomechanical variable (p>0.103). Both groups experienced improvements in self-reported pain and function (95% confidence intervals of change did not cross zero), and while these improvements were larger in the TO group, no differences were statistically significant (p>0.079). Finally, self-reported adverse events in both groups were minor, and not appreciably different between groups (n = 4 for PW, n = 8 for TO).

Conclusions: These findings indicate that a 4-month walking program that involved toe-out gait modification produced statistically significant larger improvements in knee joint loading, and greater, but statistically non-significant, improvements in pain and function compared to a similar walking program that did not involve toe-out gait modification. Future research identifying methods to improve the feasibility and effectiveness of delivering gait modification in the clinical setting, as well as an assessment of the potential economic benefits, is needed.

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THE EFFICACY OF LATERAL WEDGE INSOLES FOR PAINFUL MEDIAL KNEE OSTEOARTHRITIS AFTER PATIENT SCREENING: A RANDOMISED TRIAL

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Purpose: New treatments for OA, especially safe and inexpensive ones, are badly needed. Lateral wedge insoles placed inside shoes, by moving the center of pressure laterally during walking, reduce the load across the medial knee. Motion analysis studies suggest that, on average, they reduce the knee adduction moment (KAM) by 5–6%. Unfortunately, in trials comparing these lateral wedge insoles to neutral ones, the insoles have not reduced knee pain. In a recent meta-analysis, all of eight controlled trials were null and the effect size on pain reduction was 0.03 (95% CI −0.18, 0.22). However, the wedge's effect on KAM is extremely inconsistent and, for roughly 25%, the wedge can lead to no change or even increasing medial load. Furthermore, OA in the patella may get worse if load is shifted laterally. We therefore hypothesized that if we selected persons with painful medial compartment knee OA who showed a biomechanical response to wedge insoles and did not have painful lateral patellofemoral OA, that they would experience a reduction in knee pain compared with neutral insoles.

Methods: We carried out a randomized controlled cross-over trial of persons with painful medial knee OA (global knee pain in last week >=4 [0–10 NRS]) age 40–85 years who had knee x-rays showing Kellgren and Lawrence grade 2–4 OA and definite medial without lateral joint space narrowing. On examination by an experienced physiotherapist, they had to have medial joint line tenderness but were excluded if they had pain at the patellar facets, a positive patellar compression test. Other exclusions included inflammatory arthritis. Subjects then underwent motion analysis screening and those whose KAM values did not decrease by at least 2% compared with neutral insoles and their own shoe were also excluded. Those who remained were then randomized to wedge or neutral insoles for 8 weeks, had an 8 week washout after which they were crossed over to the other treatment for 8 weeks. Both insoles had a density of 70 Shore A, and we used a 5 degree wedge. The primary outcome was global knee pain over the last week using a 0–10 NRS and secondary outcomes were NRS knee pain for a nominated activity and KOOS pain scale. Analyses tested for carryover effects and if absent, used an ANCOVA approach to compare the efficacy of the 2 treatments, testing for differences between treatments after 8 weeks of use, controlling for baseline values.

Results: Of 192 potential subjects screened for the study, we excluded 109 who didn't meet inclusion criteria (60 did not meet x-ray criteria; 28 were ineligible based mostly on patellofemoral findings on physical examination, the remainder for other reasons). Of the remaining 83, 21 did not have at least 2% lower KAM using the wedge insole and were therefore classified as 'non-responders' to lateral wedges. The mean percentage reduction of KAM in those 62 subjects randomized, compared to their own shoe, was −7.54% (95% CI −8.73 to −6.67%), and mean age was 64.2 yrs (SD 9.1) and BMI 28.2 (SD 3.4). 23 (37.1%) were women. The mean global knee pain score was 5.1 (SD 1.7) at baseline. There were no significant carryover effects for pain outcomes. We found that lateral wedge insoles reduced knee pain more than neutral insoles (treatment difference: 0.6pts on a 0–10 scale; 95% CI 0.1 to 1.2pt; p = 0.03) (see table). 7 subjects experienced side effects leading to treatment discontinuation; 4 during lateral wedge and 3 during neutral insole treatment.

Conclusions: Unlike previous studies which reported no effect in medial compartment knee OA patients, we found that lateral wedge insoles were effective in reducing pain in medial OA patients, especially if patients are prescreened to select those likely to respond. Our results suggest that stratified approaches to OA treatments may yield new opportunities to identify effective treatments in subgroups of patients.

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ANALYSIS OF PROTEINS IN THE SYNOVIAL FLUID DURING JOINT DISTRACTION: UNRAVELLING MECHANO-SENSITIVE PATHWAYS THAT DRIVE INTRINSIC CARTILAGE REPAIR?

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Purpose: Surgical knee joint distraction is reported to deliver sustained clinical improvement for up to 5 years in individuals with late stage osteoarthritis (OA). The procedure, in which the joint is fixed and distracted (≈5mm) by an externally placed frame for 6 weeks, also leads to apparent cartilage regeneration by magnetic resonance imaging (MRI). We have previously identified several mechanosensitive pathways in murine joints after induction of OA and have shown that these pathways are reflected in the synovial fluid (SF) protein response of individuals following joint injury. We hypothesised that alteration of the

Pain Levels After 8 Weeks Use of Lateral Wedge/Neutral Insoles, After Controlling for Baseline Level

	Lateral Wedge Insole	Neutral Insole	Difference between groups	
	Post-treatment least squares mean (95% CI)	*Post-treatment least squares mean (95% CI)*	*Post-Least squares mean (95% CI)*	*P value*
Global knee pain (0–10) (1^0 outcome)	4.2 (3.8 to 4.7)	4.9 (4.4 to 5.3)	0.6 (0.1 to 1.2)	0.03
Nominated aggravating activity pain(0–10)*	4.9 (4.4 to 5.4)	5.9 (5.4 to 6.4)	1.0 (0.4 to 1.6)	0.001
KOOS pain (100–0)	60.5 (57.3 to 63.7)	59.3 (56.1 to 62.5)	−1.2 (−5.6 to 3.2)†	0.58

*Majority of activities nominated as pain-aggravating including stair/incline use (41.9%) and walking (29.0%). 'Least squares means' are predicted means, taken from the ANCOVA model, controlling for baseline value.

†negative value means lateral wedge had greater reduction in pain than neutral.