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1 **The effect of different types of insoles or shoe modifications on medial**
2 **loading of the knee in persons with medial knee osteoarthritis: a**
3 **randomised trial**

4
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19 the final manuscript.

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40 **ABSTRACT**

41 Many conservative treatments exist for medial knee osteoarthritis (OA) which aims to reduce
42 the external knee adduction moment (EKAM). The objective of this study was to determine
43 the difference between different shoes and lateral wedge insoles on EKAM, knee adduction
44 angular impulse (KAAI), external knee flexion moment, pain and comfort when walking in
45 individuals with medial knee OA.

46 Seventy individuals with medial knee OA underwent three-dimensional walking gait analysis
47 in five conditions (barefoot, control shoe, typical wedge, supported wedge and mobility shoe)
48 with pain and comfort recorded concurrently. The change in EKAM, KAAI, external knee
49 flexion moment, pain and comfort were assessed using multiple linear regressions and
50 pairwise comparisons.

51 Compared with the control shoe, lateral wedge insoles and barefoot walking significantly
52 reduced early stance EKAM and KAAI. The mobility shoe showed no effect. A significant
53 reduction in latter stance EKAM was seen in the lateral wedge insoles compared to the other
54 conditions, with only the barefoot condition reducing the external knee flexion moment.
55 However, the mobility shoe showed significant immediate knee pain reduction and improved
56 comfort scores. Different lateral wedge insoles show comparable reductions in medial knee
57 loading and in our study, the mobility shoe did not affect medial loading.

58

59 Keywords: Knee Osteoarthritis, footwear, lateral wedge insoles, adduction moment, walking

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65 **INTRODUCTION:**

66 Knee osteoarthritis (OA) is the most common form of OA and is the leading cause of pain and
67 disability in older adults (1). At the current time, there is no cure for knee OA and therefore
68 non-surgical conservative management is at the forefront of the treatment for the disease. In
69 the UK, National Institute of Clinical Excellence (NICE) guidelines recommend conservative
70 management techniques such as footwear and insoles to be part of the management of the
71 condition (2). The medial compartment of the knee joint is more often affected than the lateral
72 compartment (3).

73

74 Dynamic joint loading has been implicated both in the development of knee pain associated
75 with OA (4) and the progression of the disease (5). During walking the ground reaction force
76 passes medial to the knee in the frontal plane, this creates a moment that adducts the tibia
77 relative to the femur, with the peak load on the medial compartment almost 2.5 times more
78 than that on the lateral compartment (6). The external knee adduction moment (EKAM),
79 captured from three dimensional motion analysis and inverse dynamics, is a valid and reliable
80 proxy representing dynamic load distribution and is the primary mechanism, along with the
81 external knee flexion moment, for the majority of compressive load in the joint (6, 7, 8). The
82 EKAM typically has an early stance peak (first) and a late stance peak (second) with the first
83 peak always higher than healthy controls regardless of severity, whereas the second peak is
84 only higher in the more severe individuals (9). Therefore, given the target population for
85 conservative management (mild and moderate knee OA), the primary parameters of interest
86 are the first peak in the EKAM and also the knee adduction angular impulse (KAAI), which
87 is the area under the adduction curve (10). These two parameters have been demonstrated to
88 be related to severity (11) to structural features of OA and to progression (12, 13). Therefore,

89 reducing the EKAM during walking and other activities could be effective in delaying
90 progression in medial knee OA.

91 Many unloading strategies are available including proximal and distal gait adaptations, direct
92 orthotic management at the knee such as valgus knee braces (14, 15), or indirectly at the foot
93 and ankle interface such as shoes/footwear and foot orthoses such as lateral wedge insoles (16,
94 17, 18). The latter are popular as they are typically inexpensive with good adherence to
95 treatment. Different types of shoes and orthotics have been shown to reduce the EKAM in
96 knee OA trials (16, 18, 19) but these have not been directly compared in terms of their effects
97 on medial knee loading and clinical responses. Further, in recent studies directly measured
98 medial compressive loads have been shown to be affected by the magnitude of the external
99 knee flexion moment (20) in that a reduction in EKAM may not correspond with a true
100 reduction in medial loads if a corresponding increase in knee flexion moment was seen. The
101 literature on the different effects of lateral wedge insoles and shoe modifications on the knee
102 flexion moment has also not been fully described.

103

104 There is also not one type of lateral wedge insole, but rather several types such as heel only,
105 full length and full length insoles with medial support, also with different angulations of
106 lateral incline. In this study we chose to investigate a full length lateral wedge insole (typical)
107 as these have been found to be better than heel only wedges (21) and also one with a medial
108 arch support (supported), as this was previously found to be better functionally for the foot
109 and ankle and more comfortable (22). We have demonstrated in a previous paper the effects
110 on early stance peak EKAM and external knee flexion moment of these two different types of
111 lateral wedge insole (18). In addition, other footwear based approaches to lowering medial
112 load have been proposed. One such shoe treatment which aims to mimic barefoot walking
113 during gait (16), which is perceived as the best walking style for reducing medial loading, has

114 been developed and recommended as efficacious for medial knee OA. These shoes have not
115 been directly compared with traditional lateral wedge insoles in terms of their effects on
116 medial knee load.

117

118 Understanding which treatment reduces medial loading and reduces pain may provide
119 guidance in terms of which, if any, of these treatments is most likely to be efficacious for
120 medial knee OA. The objectives of this study were to determine which of several different
121 conservative treatments (barefoot, shoes and insoles) most lowers the EKAM during walking,
122 to determine if any concurrent changes occur in the external knee flexion moment and to
123 compare the degree of immediate knee pain reduction and comfort during usage.

124

125 **METHODS:**

126 The study is a Level 1 evidence randomised clinical trial (ISCRTN 83706683) whereby
127 ethical approval was obtained from the North West Research Ethics Committee
128 (09/H1013/51).

129 **Participants.** Participants with knee pain were recruited from the following sources:
130 orthopaedic/physiotherapy clinics and advertisements in local media. The eligibility criteria
131 for participation in the study were aged 45 years and above, medial tibiofemoral OA with
132 radiographs demonstrating Kellgren and Lawrence grade 2 or 3 in the affected painful knee
133 with medial greater than lateral joint space narrowing, and at least mild pain during walking
134 on a flat surface during the last week assessed by the KOOS pain subscale (P5) (23).
135 Radiographs were generally acquired as part of the patient's routine care and were read by an
136 experienced academically-based musculoskeletal radiologist according to the OARSI atlas
137 (24). When no radiographs were available, we accepted evidence from recent arthroscopies or
138 knee MRI's as providing sufficient information to evaluate eligibility. Patients were excluded

139 if they presented with pain more localised to the patellofemoral joint on examination than
140 medial joint (wedge inserts are not appropriate for disease in this compartment and lowering
141 the EKAM may make them worse), had tricompartmental knee OA or grade 1 or grade 4
142 tibiofemoral OA on the Kellgren and Lawrence scale. Other exclusions included a history of
143 high tibial osteotomy or other realignment surgery, total knee replacement on the affected
144 side, or any foot and ankle problems, such as painful hallux valgus; plantar fasciitis;
145 peripheral neuropathy or any foot and ankle pain, that contraindicated the use of the load
146 modifying footwear interventions. In addition, participants were excluded if they had severe
147 coexisting medical morbidities or used orthoses prescribed by a podiatrist or orthotist. Eligible
148 participants were invited to attend the gait laboratory where informed consent was obtained.

149 .

150 **Interventions.** The analyses were conducted in the context of a single visit randomised trial.
151 We tested five conditions: barefoot, a flat soled shoe (Ecco Zen) (control), two different
152 lateral wedge insoles each which have been shown to reduce EKAM in patients with medial
153 knee OA (18, 25) and a mobility shoe (16) meant to mimic barefoot walking. Both lateral
154 wedge insoles consisted of a 5 degree lateral wedge. The major difference between the lateral
155 wedge insoles was that one had medial support (referred to hereafter as the ‘supported’
156 wedge (18) whereas the other had no medial support (the ‘typical’ wedge) (25). During the
157 trial, these lateral wedges were inserted into the flat-soled control shoe with participants
158 having a minimum of 5 minutes familiarisation period to the condition. The mobility shoe
159 was a flexible grooved shoe (16) (see figure 1).

160 **Protocol.** All participants underwent gait analysis in all of the conditions. The order of
161 presentation of the different conditions was randomised prior to participants’ enrolment using
162 computer-generated permutations (using <http://www.randomization.com/>). Patients walked at
163 their self-selected speed in all conditions. Upon completing each treatment, participants were

164 asked to compare the knee pain experienced under that treatment while walking to pain when
165 wearing their own shoes by scoring this pain on a 5-point Likert scale ranging from -2
166 (indicating much better pain compared to the participants' normal shoes) to +2, (indicating
167 much worse pain compared to the participant's normal shoes). Additionally, we asked
168 participants to rate each condition's comfort, in comparison to their normal everyday shoes. This
169 was measured on a 10cm VAS, with scores ranging from -5 (much less comfortable than the
170 participants' normal shoes), to +5 (much more comfortable than the participant's normal shoes).
171 All outcomes were measured in all five study conditions (control shoe, typical lateral wedge,
172 supported lateral wedge, mobility shoe, and barefoot.)

173 A 16 camera Qualisys OQUS3 motion analysis system operating at 100 Hz and four AMTI
174 force plates operating at 200 Hz were used to measure kinematics and kinetics during the
175 trials. Each participant completed a minimum of three successful trials at a self-selected
176 walking speed. The CAST marker set technique (26) was employed whereby rigid clusters of
177 four non-orthogonal markers were positioned over the lateral shank, lateral thigh and sacrum
178 to track the movements of the limbs. Retroreflective markers were glued securely to the
179 control shoes with the foot modelled as a rigid segment. A reference trial was conducted
180 where retroreflective markers were placed on bony landmarks specifying their location in
181 relation to the clusters and to approximate joint centre. Ankle and knee joint centres were
182 calculated as midpoints between the malleoli and femoral epicondyles respectively. The hip
183 joint centre was calculated using the regression model of Bell et al. (27) based on the anterior
184 and posterior superior iliac spine markers. Using an inverse dynamic approach Visual 3D (C-
185 Motion, Rockville, Maryland) we calculated the EKAM and sagittal plane external knee
186 flexion moment (KFM) during stance phase for all of the trials and conditions. A custom
187 Matlab (Matlab, USA) programme was used to extract the peak EKAM and KFM during
188 early stance (up to 50% of stance phase) and the peak latter stance EKAM (from 50% of

189 stance phase) and to calculate the knee adduction angular impulse (KAAI) (9), which is the
190 area under the adduction moment curve during the entire stance phase of gait. EKAMs and
191 KFMs were normalised to participant's mass (Nm/kg) with the KAAI normalised to
192 participant's mass and stance time (Nm/kg*s).

193 **Data analysis.** Multiple linear regression was used to test for differences in continuous
194 outcomes of interest, between the 5 different experimental conditions. We created four
195 models, one for each of the gait outcomes of interest (EKAM (first and second peak) KAAI,
196 and KFM). In each model, the predictor variable was the orthotic intervention, coded as
197 'dummy variables' – giving 5 predictor variables in total, one for each condition). The control
198 shoe condition was used as the reference group. The model also accounted for the repeated-
199 measures design of the study by including the participant ID as a panel variable. We used a
200 Hausman specification test to check for the validity of using a random-effects model, in
201 preference to a fixed-effects model of the same specification. The test did not show statistical
202 significance and consequently, a random-effects model was used. We checked for model fit
203 by investigating residuals against fitted plots. Since model residuals appeared heteroskedastic,
204 robust standard errors (using sandwich estimators) were used to improve estimates of standard
205 errors. Post-hoc pairwise contrasts were produced, using linear combinations of the beta
206 coefficients from the model to test for differences in all possible comparisons of the orthotics
207 conditions, with ten pairwise tests for each of the three outcomes considered (EKAM, KAAI,
208 and maximum external flexion moment). To counter issues of multiple testing, confidence
209 intervals and p-values from these pairwise tests were adjusted using the Benjamini-Hochberg
210 procedure (28, 29), using a false discovery rate (FDR) of 0.05 (see supplementary material).

211

212 Because patient perceived change in knee pain was not normally distributed, we used
213 Wilcoxon Sign Rank tests to investigate whether the distribution of patient-perceived pain
214 change ranks were equal to zero, in each orthotic condition separately.

215

216 Finally, for each condition, we measured if the patient-perceived change in comfort was
217 different from zero. To test this, we used a random-effects linear regression model, with the
218 participants' comfort ratings as the outcome variable. The predictor variable again was the
219 orthotic intervention condition, coded as 'dummy variables', as in the EKAM/KAAI
220 regression. We then combined the model intercept with the beta coefficients of each condition
221 in turn. This tests if the mean comfort rating in each is equal to zero. Additionally, as both
222 walking speed and knee flexion moment were considered potential confounding variables, we
223 repeated the above models, with walking speed and external knee flexion moment added as
224 additional covariates.

225 All statistical analysis was performed using the statistical software package Stata (version
226 13.1; Stata Corporation, College Station, TX, USA), with an alpha level of 0.05 (two-sided)
227 for the assessment of statistical significance.

228

229 **RESULTS**

230 The flow of participants into the study is shown in figure 2. The characteristics of the 70
231 participants were: a mean age of 60.3 years (SD 9.6), mean BMI of 30.5 kg/m² (SD 4.9), and 27
232 (38.6%) were female. Data on Kellgren-Lawrence (K-L) grades were available for 62 of the 70
233 study participants, and of these, the mean K-L grade was 2.6 (SD 0.5). We reviewed recent knee
234 arthroscopy reports or MRIs for 8 participants who did not have x-rays prior to the study to
235 ensure that these subjects also had medial > lateral cartilage loss and other features of OA.

236

237 When we examined the effects of the conditions on measures of medial loading (tables 1, 2,
238 Figure 3), we found that barefoot walking had the greatest effect on early stance peak EKAM,
239 lowering it by -7.6% ($p < 0.001$ vs. control shoe). Both lateral wedges reduced the early stance
240 peak EKAM by -5.9 and -5.6% ($p = 0.001$ vs. control shoe) for typical and supported
241 respectively as we have previously reported (18). However, the mobility shoe did not produce a
242 significant reduction in the early stance peak EKAM compared with the control shoe (-1.6%, $p =$
243 0.38).

244 For the second peak in EKAM during late stance, both of the lateral wedge insoles significantly
245 reduced the magnitude of this peak in comparison to the control condition. There was no
246 difference in the mobility or barefoot conditions in comparison to the control condition. For the
247 knee adduction angular impulse (KAAI), the barefoot condition and the two lateral wedge
248 conditions were significantly different in comparison to the control condition (barefoot -4.3%,
249 $p = 0.023$; typical wedge -7.95%, $p < 0.001$; supported wedge -5.5%, $p < 0.001$).

250 Pairwise comparisons (see supplementary material eTables 1, 2 and 3) showed that there were no
251 significant differences in the effects on the early stance peak in EKAM between each of the two
252 lateral wedge conditions and barefoot walking. However, the early stance peak in EKAM in the
253 barefoot condition was reduced significantly more than the mobility shoe (mean difference -
254 0.024 Nm/kg, $p = 0.004$).

255 For the second peak in EKAM, both of the lateral wedge insoles had significantly greater
256 reductions than the barefoot (typical wedge mean difference -0.029 Nm/kg, $p < 0.01$; supported
257 wedge mean difference -0.019 Nm/kg, $p = 0.004$) and mobility (typical wedge mean difference -
258 0.023 Nm/kg, $p < 0.01$; supported wedge mean difference -0.013 Nm/kg, $p = 0.024$) conditions. A
259 larger second peak reduction in the typical wedge resulted in a significant reduction in KAAI in
260 comparison to the mobility shoe (mean difference 0.008 Nm/kg*s, $p = 0.011$).

261 In comparison with the control shoe and all other conditions, the barefoot condition had
262 significant reductions in the maximum external knee flexion moment (KFM) (etable 3) during
263 early stance. No other changes in external knee flexion moment were seen.

264

265 Compared with the control shoe, walking speed increased by 0.03m/s with the mobility shoe
266 (95% CI 0.02 to 0.04, $p < 0.001$) and slowed by 0.04m/s with barefoot walking (95% CI -0.05 to
267 -0.03, $p < 0.001$), but with adjustment for walking speed, this did not affect the overall findings or
268 their significance. Additional adjustment for external knee flexion moment changes also did not
269 affect the differences seen between conditions in medial load measures.

270

271 In contrast with the findings with regard to medial loading, immediate reductions in knee pain
272 were seen in two conditions: the supported (but not the typical) wedge (as reported previously
273 (17)) and the mobility shoe (both $p < .001$) (see figure 4). A significant worsening of knee pain
274 was reported by patients for the control shoe (not the subject's own shoe) ($p = .015$) and barefoot
275 walking ($p=.054$).

276 In terms of comfort, the control shoe was rated as less comfortable than the participant's
277 everyday shoes (see table 3). Even though the wedges were placed inside these control shoes,
278 both lateral wedges were rated as more comfortable than everyday shoes as were the mobility
279 shoes.

280

281 **DISCUSSION**

282 To examine the effects of shoes and orthotics suggested as effective in unloading the medial
283 knee compartment, we carried out a randomised trial, comparing these treatments. We found
284 that barefoot walking and lateral wedge insoles all significantly reduced medial loading in the
285 first part of stance phase with both of the lateral wedge insoles reducing medial loading during

286 latter periods of stance. The two types of lateral wedge insoles showed roughly comparable
287 effects on the knee adduction moment and impulse with only the barefoot walking
288 significantly altering the sagittal moment. Although the mobility shoe did not reduce medial
289 knee loading, participants reported that it diminished knee pain more than the typical wedge,
290 control shoe and barefoot, and was rated as more comfortable than the other treatments.

291

292 While lateral wedge inserts have not been shown to decrease knee pain in knee osteoarthritis
293 (30), they do reduce medial loading. Since excess loading in the medial compartment
294 contributes to knee pain and disease progression and since knee OA treatments that alter this
295 are likely to be popular and inexpensive, further exploration of their possible effects is
296 desirable. In that vein, our work suggests two important findings. First, they suggest that
297 lateral wedge insoles reduce medial knee loading more than a control shoe throughout the
298 whole of stance phase and significantly better than both barefoot walking and the mobility
299 shoe during latter stance where the supported insole reduces immediate knee pain better than
300 the typical device with increased comfort. Secondly, whilst the mobility shoes did not reduce
301 medial loading significantly, they were rated highly by participants for reductions in knee pain
302 and comfort.

303

304 Barefoot walking was found to have the greatest reduction in EKAM in comparison to the
305 control shoe and is in agreement with a previous study by Shakoor and Block (31). However,
306 they found a greater reduction (-11.9%) in the peak EKAM (KAAI was not assessed in that
307 study). Differences between our study and that of Shakoor and Block could have accounted
308 for the difference in the magnitude of effect. We focused on the early stance first peak EKAM
309 and not the peak EKAM (which is sometimes different) and we used one control shoe whereas
310 they compared barefoot to a person's individual shoes. We found importantly that barefoot

311 walking reduced medial loading during latter stance in comparison to the control shoe, but had
312 increased medial loading in the latter period of stance in comparison to the lateral wedge
313 insoles. This reduced latter stance reduction in EKAM in the lateral wedge insoles, whilst not
314 directly related to severity or progression, would contribute to a greater reduction in the
315 overall loading during stance phase (KAAI) which has been related to cartilage loss (13).
316 Different shoes may differ in their effect on medial knee loading and our control shoe may
317 have been more effective than some personal shoes in reducing knee medial loads. An
318 exploration of types of personal shoes and their effects on knee loading was beyond the scope
319 of this trial but this is an important next step to determine what role different footwear has on
320 medial knee loading.

321

322 In agreement with Jones et al. (22), there was no change in the reduction of EKAM or KAAI
323 with the two different lateral wedge insoles. This is in contrast to the work by Nakijima et al.
324 (32) who reported that a lateral wedge insole with an arch support reduced medial knee
325 loading more than a standard lateral wedge. One reason for this difference is that the lateral
326 wedge insole with the medial support used in this study is an off-the-shelf device and not
327 custom made as in the study by Nakajima et al. It is noteworthy that the medial support
328 incorporated into our lateral insole was not hard and could readily be compressed with weight-
329 bearing and this may underlie the similar effects of both insoles we studied. Both insoles were
330 deemed to be comfortable (table 3) but the supported lateral wedge received a greater overall
331 comfort score and significantly reduced pain immediately in comparison to the typical wedge.

332

333 The mechanism for these reductions in EKAM and KAAI are perceived to be related to the
334 change in the centre of pressure location for the lateral wedge insoles (33) which leads to a
335 greater reduction in moment arm. The barefoot walking had a slightly slower speed but this

336 was not associated with changes in EKAM or KAAI. Therefore, the mechanism for this is
337 potentially due to altered foot mechanics but this was not the remit of this paper and further
338 research is needed.

339

340 External knee flexion moments also contribute to medial knee loading and effects of shoe
341 inserts or shoes on flexion moments could affect medial loading independently of EKAM or
342 KAAI. We found no significant effects of shoe inserts or shoes on external knee flexion
343 moment (20). Only barefoot walking reduced flexion moments and this may have been a
344 consequence of a slower overall walking speed but this needs to be further explored. Further,
345 recent work by Trepczynski and colleagues (8) using instrumented knee prostheses suggests
346 that the external knee flexion moment contributes importantly to medial knee loading only
347 during activities when the knee is overly-flexed, such as stair climbing and squatting or
348 kneeling. Our participants were only required to walk on level ground and our findings on
349 flexion moments suggest that with this activity, most of the variance in medial loading is
350 readily explained by the EKAM and KAAI.

351

352 Our results on the effects of the mobility shoe contrast with earlier studies in that we found a
353 reduction of just greater than 1% in medial knee loading during early stance. One possible
354 reason could have been the choice of control shoe. As noted earlier Shakoor and colleagues
355 (16) tested mobility shoes against the individuals' own shoes. Those authors comment that the
356 choice of shoe worn by the patient has an effect on reduction in medial knee loads compared
357 with the mobility shoe. It is also possible that medial loading reductions occur over time with
358 the mobility shoe (34). While the mobility shoe did not show expected reductions in medial
359 loading, the participant's immediate knee pain scores were significantly improved in
360 comparison to the control shoe with a favourable comfort rating. This suggests that patient

361 adherence would be high and if medial loading were reduced significantly over time, this
362 could be an effective intervention.

363

364 The reductions in pain seen in the mobility shoe and the lateral wedge insoles disagree with
365 some longitudinal studies and the full reason behind why there were these changes is not
366 known. However, one of the potential reasons could be due to an increased comfort in both
367 the supported insole and the mobility shoe which reflected better perceived pain scores.

368

369 As with any study there are limitations other than the ones described earlier. The pain and
370 comfort responses were assessed immediately and it is possible that these may change over
371 time. However, previous work (35) has suggested that immediate pain response and longer
372 term pain response with wedges are highly correlated.

373

374 In conclusion, different lateral wedge insoles show comparable reductions in medial knee
375 loading with the supported insole reducing pain more. In our study, the mobility shoe did not
376 affect medial loading. While we confirmed findings of other studies in demonstrating a
377 clearcut reduction in early stance medial loading when walking barefoot, barefoot walking
378 increased medial loading during the latter period of stance and may not be the best for medial
379 loading reduction.

380

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479 **Table and Figure Legends**

480 Figure 1: Lateral wedge insoles and mobility shoes

481 Figure 2: Consort Figure: those eligible/enrolled/randomised/studied

482 Figure 3: EKAM time series plots for the different conditions (N=70)
483 Figure 4: Participant rating of knee pain during use of each condition compared with knee
484 pain using their own shoe.
485 Table 1: EKAM, KAAI, Knee flexion moment, Comfort Rating (VAS), and walking speed
486 Table 2: Effects of each condition on moments and walking speed compared with control
487 shoe.
488 Table 3: Participants report of shoe/condition comfort
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