

1 **Effects of a 4-week intervention using semi-custom insoles on perceived pain and**
2 **patellofemoral loading in targeted subgroups of recreational runners with**
3 **patellofemoral pain.**

4 **Abstract**

5 **OBJECTIVE:** Explore the effects of a 4-week intervention using semi-custom insoles in
6 recreational runners with patellofemoral pain.

7 **DESIGN:** Mixed methods

8 **PARTICIPANTS:** Seventeen (10 males and 7 females) recreational runners.

9 **SETTING:** Laboratory

10 **OUTCOME MEASUREMENTS:** Participants were separated into specific subgroups, then
11 provided with a pair of semi-custom insoles, for a period of 4-weeks. Lower extremity
12 kinetics/kinematics during running at 4.0 m/s were obtained. In addition, knee pain was
13 examined using the Knee injury and Osteoarthritis Outcome Score-Patellofemoral scale
14 (KOOS-PF). Data were collected before and after wearing the insoles for 4-weeks.

15 **RESULTS:** Significant improvements were shown for KOOS-PF in both subgroups (strong:
16 (pre)=63.84 & (post)=71.49 and weak and tight: (pre)=53.03 & (post)=72.73), although only
17 improvements in the weak and tight group exceeded the minimum clinically important
18 difference (MCID). **In addition, significant reductions in peak patellofemoral stress were**
19 **shown in both subgroups (strong: (pre)=6.82 & (post)=6.39KPa/BW and weak and tight:**
20 **(pre)=7.66 & (post)=6.28KPa/BW), although only reductions in the weak and tight group**
21 **exceeded the MCID.**

22 **CONCLUSIONS:** Semi-custom insoles may be a mechanism to reduce patellofemoral pain
23 symptoms in recreational runners from the weak and tight subgroup. **It is proposed that this**
24 **improvement was mediated through reductions in patellofemoral loading in this subgroup.**

26 **Keywords:** patellofemoral pain; patellofemoral loading; subgrouping; insoles

27

28 **Introduction**

29 Recreational running is an extremely popular physical and leisure modality, known to
30 provide a plethora of physiological and psychological benefits (Lee et al., 2014). Over 2-
31 million people in the UK utilize running as a regular mode of exercise (Sport England, 2014).
32 However, despite the clear physical benefits mediated by running, it is also known to be
33 associated with a high incidence of chronic pathologies. Over the course of one-year as many
34 as 80 % of runners will experience an overuse injury as a consequence of their training (Van
35 Gent et al., 2007).

36

37 Patellofemoral pain is the most common chronic pathology in runners (Taunton et al., 2002),
38 which typically manifests as retropatellar or diffuse peripatellar pain, aggravated by activities
39 such as running that frequently load the joint (Crossley et al., 2016). Elevated patellofemoral
40 joint stress, which is a reflection of the patellofemoral joint reaction force divided by the
41 patellofemoral contact area, is commonly accepted as a key aetiological factor in the
42 development of patellofemoral pain syndrome (Farrokhi et al., 2011).

43

44 The long term prognosis for those who present with patellofemoral pain is poor, with
45 between 71-91 % all patients experiencing ongoing symptoms up to 20 years following
46 diagnosis (Nimon et al., 1998). Female recreational runners are 2-3 times more likely to
47 suffer from patellofemoral pain in comparison to males (Robinson & Nee, 2007), owing to
48 increased dynamic knee abduction (Malinzak et al., 2001; Ford et al., 2003; Sakaguchi et al.,
49 2014), hip internal rotation (Lephart et al., 2002; Decker et al., 2003), hip adduction
50 (Sakaguchi et al., 2014), knee valgus moment (Sigward & Powers, 2005) and patellofemoral

51 stress (Sinclair & Selfe, 2015), as well as decreased dynamic measures of knee flexion angle
52 (Malinzak et al., 2001; Lephart et al., 2002), hip abductor (Sugimoto et al., 2014) and
53 quadriceps strength (Lephart et al., 2002). Importantly, those who experience patellofemoral
54 symptoms may later present with radiographic evidence of osteoarthritis at this joint (Thomas
55 et al., 2010). Pain symptoms force many runners to reduce or even end their participation in
56 running activities (Blond & Hansen, 1998), and many individuals with patellofemoral pain
57 develop associated psychological disorders including mental distress and self-perceived
58 health (Jensen et al., 2005); pain-related fear, low self-efficacy and fear of the future (Smith
59 et al., 2018); kinesiophobia, depression and catastrophizing (Maclachlan et al., 2018).

60

61 As a consequence of the high incidence of patellofemoral pain, a significant range of
62 conservative treatment modalities have been explored in biomechanical and clinical
63 literature; including exercise therapy, taping, bracing, insoles, soft tissue manipulation and
64 acupuncture (Smith et al., 2017). Pain is the key clinical symptom associated with
65 patellofemoral syndrome, thus the attenuation of pain through conservative modalities is of
66 considerable interest to both clinicians and researchers alike. Insoles utilized by runners
67 typically feature a contoured medial arch profile, and offer a mechanism by which lower
68 extremity joint loading can be altered.

69

70 The acute effects of foot insoles on the kinetics and kinematics of running are well
71 documented, but there is currently a paucity of research investigating biomechanical
72 adaptations over time, or the effectiveness of insoles for the treatment of patellofemoral pain
73 symptoms. Two studies are however of note. Collins et al., (2008) examined the efficacy of
74 foot orthoses, flat inserts and multimodal physiotherapy in patients with clinically diagnosed
75 patellofemoral pain. Their results showed that all three treatments mediated significant and

76 clinically meaningful improvements in pain symptoms. Eng and Pierrynowski, (1993)
77 assigned a group of adolescent female patients with patellofemoral pain to either: a control
78 who undertook an exercise program, or a treatment group who were provided with soft
79 insoles in addition to participating in the exercise program. Their findings showed that both
80 the treatment and control groups exhibited significant reductions in pain, but that
81 improvements in the treatment group were significantly greater than those in the control
82 group. Both studies indicate that soft insoles may be beneficial in the treatment of
83 patellofemoral pain symptoms for patients, but whether these findings also apply to
84 recreational runners with patellofemoral pain symptoms is unknown.

85

86 Different factors may predispose recreational runners compared to patients to the
87 development and therefore treatment of patellofemoral pain symptoms, due to their
88 physiological differences. Selfe et al., (2016) recently identified three subgroups of patients
89 with patellofemoral pain ('strong', 'weak and tight' and 'weak and pronated foot') using six
90 low cost, simple clinical assessment tests that can be applied in routine practice. This initial
91 study suggested that developing a strategy to target specific interventions for each subgroup
92 may ultimately lead to improved patient outcomes. The current study aimed to explore the
93 effects of a 4-week intervention using semi-custom foot insoles on pain symptoms and
94 patellofemoral loading in subgroups of recreational runners.

95

96 **Methods**

97 *Participants*

98 Seventeen participants (10 male and 7 female), volunteered to take part. Participants were
99 invited to attend the laboratory if they suffered from self-reported knee pain exacerbated by
100 their running training. Specific diagnosis of patellofemoral was made in accordance with the

101 recommendations of Crossley et al., (2002). Participants were excluded from the study if
102 there was evidence of any other knee pathology or they had previously undergone surgery on
103 the patellofemoral joint. Furthermore, participants who had exhibited symptoms for less than
104 3 months were also excluded, as were those aged 50 or above to reduce the likelihood of pain
105 being caused by degenerative joint disease. Written informed consent was provided in
106 accordance with the declaration of Helsinki. The procedure was approved by the Universities
107 Science, Technology, Engineering, Medicine and Health ethics committee, with the reference
108 STEMH 424.

109

110 *Procedure*

111 Participants attended the laboratory on two occasions. On the first occasion the participants
112 were assessed using the six clinical tests described by Selfe et al. (2016) on their affected
113 limb only. These assessments involved two muscle strength tests (quadriceps and hip
114 abductors), two muscle length tests (m. gastrocnemius and m. rectus femoris), one patellar
115 mobility test, and one foot posture index test (Redmond et al., 2006). Based on this
116 information participants were sub-grouped in accordance with Selfe et al. (2016) which
117 revealed that participants belonged to either the ‘strong’ (N=11) or weak and tight (N=6)
118 groups (Table 1). All other tests were completed on both occasions.

119

120 @@@ **TABLE 1 NEAR HERE** @@@

121

122 *Clinical tests*

123 Initially participants completed the Knee injury and Osteoarthritis Outcome Score-
124 Patellofemoral subscale (KOOS-PF) (Crossley et al., 2017) and Coop-Wonca questionnaires
125 (Jensen et al., 2015), in order to assess self-reported knee pain and psychological wellbeing.

126 Biomechanical data was then collected from the participants during running trials in their
127 own footwear, as described below.

128

129 *Intervention*

130 Once the biomechanical and KOOS-PF data were obtained, participants were then provided
131 with a pair of off-the-shelf insoles (Sole Control, Sole, Milton Keynes, UK) in their size. The
132 insoles were made from ethylene-vinyl acetate and had a shore A 30 hardness rating. Because
133 the participants from both subgroups did not exhibit an everted foot posture, the insoles did
134 not feature any rearfoot posting. Participants were asked to wear the insoles for all of their
135 running training for 4-weeks (Bolgla & Boling, 2011). To mould the insoles they were placed
136 into a pre-heated oven (90 °C) for a duration of two minutes. The heated insoles were then
137 placed inside the participants shoes. Participants were asked to stand upright without moving
138 for two minutes to allow the process of moulding the insoles to the longitudinal arch profile
139 of each participant, in accordance with manufacturer instructions. Insoles were placed inside
140 both shoes although only the pathological side was examined. Participants were instructed to
141 maintain their habitual training regime. They recorded the number of completed kilometers
142 during the 4-week period prior to the intervention and again during the 4-week intervention
143 period. Following the 4-week intervention participants returned to the laboratory where the
144 complete protocol was repeated whilst wearing their insoles.

145

146 *Biomechanical tests*

147 Participants ran at a velocity of 4.0 m/s \pm 5%, striking an embedded piezoelectric force
148 platform (Kistler, Kistler Instruments Ltd., Alton, Hampshire; length, width, height = 0.6 x
149 0.4 x 0 m) with their affected limb. The force platform sampled at 1000 Hz. Running velocity
150 was quantified using infrared timing gates, which were positioned 4 m apart. The stance

151 phase of running was delineated as the duration over which > 20 N of vertical force was
152 applied to the force platform. A successful trial was defined as one within the specified
153 velocity range, where the foot made full contact with the force platform and where no
154 evidence of gait modifications due to the experimental conditions were evident.

155

156 Kinematics and ground reaction force (GRF) information were synchronously collected.
157 Kinematic data were captured at 250 Hz via an eight camera motion analysis system
158 (Qualisys Medical AB, Goteburg, Sweden). Dynamic calibration of the motion capture
159 system was performed before each data collection session.

160

161 Lower extremity segments were modelled in 6 degrees of freedom using the calibrated
162 anatomical systems technique (Cappozzo et al., 1995), using a marker configuration utilized
163 previously to quantify the effects of orthoses patellofemoral joint kinetics (Sinclair, 2018). To
164 define the anatomical frames of the pelvis, thigh, shank and foot retroreflective markers were
165 positioned onto the iliac crest, anterior superior iliac spine (ASIS), and posterior super iliac
166 spine (PSIS). In addition, further markers were placed unilaterally onto the medial and lateral
167 malleoli, greater trochanter, medial and lateral femoral epicondyles, calcaneus, first
168 metatarsal and fifth metatarsal heads of the affected limb. Foot markers were positioned onto
169 the upper of the participants' shoes. Carbon-fiber tracking clusters comprising of four non-
170 linear retroreflective markers were positioned onto the thigh and shank segments. In addition
171 to these the foot segments were tracked via the calcaneus, first metatarsal and fifth metatarsal,
172 and the pelvic segment was tracked using the PSIS and ASIS markers. Static calibration trials
173 were obtained with the participant in the anatomical position in order for the positions of the
174 anatomical markers to be referenced in relation to the tracking clusters/markers. A static trial
175 was conducted with the participant in the anatomical position in order for the anatomical

176 positions to be referenced in relation to the tracking markers, following which those not
177 required for dynamic data were removed.

178

179 *Processing*

180 Dynamic trials were digitized using Qualisys Track Manager in order to identify anatomical
181 and tracking markers then exported as C3D files to Visual 3D (C-Motion, Germantown, MD,
182 USA). All data were normalized to 100 % of the stance phase. GRF and kinematic data were
183 smoothed using cut-off frequencies of 50 and 12 Hz with a low-pass Butterworth 4th order
184 zero lag filter (Sinclair, 2014). Three dimensional kinematics of the knee and ankle were
185 calculated using an XYZ cardan sequence of rotations (where X = sagittal plane; Y = coronal
186 plane and Z = transverse plane). Three dimensional angular kinematic measures from the
187 knee, ankle and tibia which were extracted for statistical analysis were 1) angle at footstrike,
188 2) peak angle and 3) angular joint range of motion (ROM) from footstrike to peak angle. In
189 addition the eversion/tibial internal rotation (EV/ TIR) ratio was calculated by dividing the
190 eversion ROM by the tibial internal rotation ROM. Knee joint kinetics were computed using
191 Newton-Euler inverse-dynamics and normalized to body mass. The peak knee adduction
192 moment, knee adduction moment load rate (the peak increase in the adduction moment
193 between adjacent data points) and knee adduction moment integral during the stance phase
194 (using a trapezoidal function) were extracted.

195

196 Patellofemoral loading during the stance phase of running was quantified using a model
197 adapted from van Eijden et al., (1986), in accordance with the protocol of Wilson et al.,
198 (2015). The hamstring force was calculated using the hip extensor moment, hamstrings and
199 gluteus maximus cross-sectional areas (Ward et al., 2009) and by fitting a 2nd order
200 polynomial curve to the data of Nemeth & Ohlsen, (1985) who provided muscle moment

201 arms at the hip as a function of hip flexion angle. The gastrocnemius force was calculated
202 firstly by quantifying the ankle plantarflexor force, which was resolved by dividing the
203 plantarflexion moment by the Achilles tendon moment arm. The Achilles tendon moment
204 arm was calculated by fitting a 2nd order polynomial curve to the ankle plantarflexion angle
205 in accordance with Self & Paine (2001). Plantarflexion force accredited to the gastrocnemius
206 muscles was calculated via the cross-sectional area of this muscle relative to the triceps surae
207 (Ward et al., 2009).

208

209 The hamstring and gastrocnemius forces were multiplied by their estimated muscle moment
210 arms to the knee joint in relation to the knee flexion angle (Spoor & van Leeuwen, 1992), and
211 then added together to estimate the knee flexor moment. The derived knee flexor moment
212 was added to the net knee extensor moment quantified using inverse dynamics were then
213 summed and subsequently divided by the quadriceps muscle moment arm (van Eijden et al.,
214 1986), to obtain quadriceps force adjusted for co-contraction of the knee flexor musculature.
215 Patellofemoral force was then quantified by multiplying the adjusted quadriceps force by a
216 constant which was obtained by using the data of van Eijden et al., (1986).

217

218 Finally, patellofemoral joint stress was quantified by dividing the patellofemoral force by the
219 patellofemoral contact area. Patellofemoral contact areas were obtained by fitting a
220 polynomial curve to the sex specific data of Besier et al., (2005), who estimated
221 patellofemoral contact areas as a function of the knee flexion angle using MRI. All
222 patellofemoral forces were normalized by dividing the net values by bodyweight (BW). From
223 the above processing, peak patellofemoral force, and peak patellofemoral stress (KPa/BW)

224 were extracted. Patellofemoral instantaneous load rate (BW/s) was also extracted by
225 obtaining the peak increase in force between adjacent data points.

226

227 The patellofemoral integral during the stance phase (quantified using a trapezoidal function)
228 was also calculated and the total patellofemoral force per mile (BW·mile) was obtained by
229 multiplying this parameter by the number of steps required to run a mile. The number of steps
230 required to complete one mile was quantified using the step length (m), which was
231 determined by taking the difference in the horizontal position of the foot centre of mass
232 between the right and left legs at footstrike.

233

234 *Statistical analyses*

235 Descriptive statistics of means and standard deviations were obtained for each outcome
236 measure. Shapiro-Wilk tests were used to screen the data for normality. Differences in
237 running distance prior to and during the intervention were examined using a paired t-test.
238 Differences in biomechanical and knee pain parameters were examined using 2 (PRE-POST
239 INTERVENTION) x 2 (SUBGROUP) mixed ANOVA's. Statistical significance was
240 accepted at the $P \leq 0.05$ level. Effect sizes for all significant findings were calculated using
241 partial Eta² (η^2). Effect sizes were contextualized using the following guidelines; small =
242 0.01, medium = 0.06 and large = 0.14 (Cohen, 1988). All statistical actions were conducted
243 using SPSS v24.0 (SPSS Inc, Chicago, USA). In accordance with the recommendations of
244 Crossley et al., (2017), the minimal clinically important difference (MCID) for the KOOS-PF
245 scale was considered to be 16.4 points. For all of the other variables the MCID was
246 considered to be 2.3 * the pooled standard error of measurement (Sinclair et al., 2018).

247

248 **Results**

249 Tables 2-5 present the knee pain, psychological wellbeing, patellofemoral loading and
250 kinematic parameters obtained before and after the 4-week intervention.

251

252 *Running distance*

253 No significant difference ($P>0.05$) in running distance was observed. Participants completed
254 17.26 ± 8.43 km of running training prior to the intervention and 17.19 ± 6.92 km during the
255 intervention.

256

257 *Knee pain*

258 A significant PRE-POST INTERVENTION main effect ($P<0.05$, $p\eta^2 = 0.65$) was observed
259 for KOOS-PF pain symptoms with participants reporting significant improvements following
260 the 4-week period. Importantly, the magnitude of the improvements exceeded the MCID in
261 only the weak and tight sub-group (Table 2). **There was no significant ($P>0.05$) main effect**
262 **as a function of SUBGROUP (Table 2).**

263

264 *Psychological wellbeing*

265 The Coop-Wonga questionnaire showed a significant PRE-POST INTERVENTION main
266 effect of ($P<0.05$, $p\eta^2 = 0.48$), with participants exhibiting significant improvements
267 following the 4-week period. **Importantly, the improvements in both subgroups exceeded the**
268 **MCID. There was no significant ($P>0.05$) main effect as a function of SUBGROUP (Table**
269 **2).**

270

271 **@@@ TABLE 2 NEAR HERE @@@**

272

273 *Patellofemoral loading and knee moments*

274 Significant PRE-POST INTERVENTION main effects were observed for both peak
275 patellofemoral force ($P < 0.05$, $\eta^2 = 0.41$) and peak patellofemoral stress ($P < 0.05$, $\eta^2 = 0.42$)
276 with significant reductions being present following the 4-week period. Finally, a significant
277 PRE-POST INTERVENTION main effect ($P < 0.05$, $\eta^2 = 0.37$) was observed for
278 patellofemoral force per mile, with significant reductions being present following the 4-week
279 period. **Importantly, in each of the aforementioned patellofemoral loading variables, the**
280 **reductions exceeded the MCID in only the weak and tight sub-group (Table 3). There were**
281 **no significant ($P > 0.05$) main effects as a function of SUBGROUP for any of the**
282 **patellofemoral loading variables (Table 3).**

283

284 Finally, for the knee adduction moment integral, a significant PRE-POST INTERVENTION
285 main effect ($P < 0.05$, $\eta^2 = 0.32$) was shown, with significant increases being present
286 following the 4-week period (Table 3). **Importantly, the increase in the knee adduction**
287 **moment integral exceeded the MCID in only the weak and tight sub-group (Table 3). There**
288 **was no significant ($P > 0.05$) main effect as a function of SUBGROUP (Table 3).**

289

290 **@@@ TABLE 3 NEAR HERE @@@**

291

292 *Joint kinematics*

293 For the knee sagittal angle at footstrike a significant PRE-POST INTERVENTION main
294 effect ($P < 0.05$, $\eta^2 = 0.51$) was shown, with the flexion angle being significantly reduced
295 following the 4-week intervention. In addition, a significant PRE-POST INTERVENTION
296 main effect ($P < 0.05$, $\eta^2 = 0.28$) was shown for the magnitude of peak knee flexion, with
297 peak flexion being significantly reduced following the 4-week period. **Importantly, in each of**
298 **the aforementioned joint kinematic variables, the reductions exceeded the MCID in only the**

299 weak and tight sub-group (Table 4). There were no significant ($P>0.05$) main effects as a
300 function of SUBGROUP for any of the joint kinematic variables (Table 4).

301

302 @@@ *TABLE 4 NEAR HERE* @@@

303 @@@ *TABLE 5 NEAR HERE* @@@

304

305 **Discussion**

306 This study explored the efficacy of semi-custom foot insoles in recreational runners with
307 patellofemoral pain. The runners were categorized into previously identified subgroups (Selfe
308 et al., 2016), which allowed the effects of the insoles to be considered by subgroup. To the
309 authors knowledge this represents the first intervention study to explore the efficacy of
310 insoles in recreational runners with patellofemoral pain using these targeted subgroups. Given
311 the extremely high incidence of patellofemoral pain amongst runners, analyses of this nature
312 may generate essential clinical information regarding conservative management of
313 patellofemoral pain.

314

315 The first key finding from the current investigation is that both patellofemoral pain symptoms
316 and psychological wellbeing parameters were significantly improved in both subgroups as a
317 function of the 4-week intervention using foot insoles. This observation concurs with those of
318 Collins et al., (2008), who showed that insoles without medial posting produced significant
319 and clinically meaningful improvements in pain symptoms in patients with patellofemoral
320 pain. However, it should be noted that although a large effect size was revealed, the
321 magnitude of the improvements in pain symptoms quantified via the KOOS-PF questionnaire
322 only exceeded the MCID in the weak and tight group (Crossley et al., 2017). Of further
323 importance is that participants average weekly running mileage remained consistent prior to

324 and during the intervention period, indicating that improvements in pain symptoms did not
325 appear to be mediated through reductions in training volume. The findings indicate that
326 insoles have the potential to provide clinically meaningful improvements in self-reported pain
327 symptoms in runners with patellofemoral pain classified into the weak and tight subgroup
328 according to Selfe et al., (2016). However, it should be stressed that the findings from the
329 current study are specific to the insoles utilized in this investigation and further exploration is
330 needed using additional insoles before substantial claims can be fully corroborated.

331

332 Of further importance to the current investigation is the observation that peak patellofemoral
333 force/ stress and the patellofemoral force per mile were significantly attenuated in both
334 subgroups as a function of the 4-week intervention. Contextualization of these patellofemoral
335 loading variables showed that whilst large effect sizes were found; much like the alterations
336 in pain symptoms the reductions only exceeded the MCID in the weak and tight group.
337 Specifically, excessive patellofemoral joint stress is considered a key mechanism linked to
338 the aetiology of pain symptoms in active individuals (Ho et al., 2012). Therefore, it is
339 proposed that the improvements in pain symptoms in the weak and tight subgroup as a
340 function of the 4-week intervention, may have been mediated as a direct consequence of the
341 corresponding statistical reductions in patellofemoral loading.

342

343 Further to the above, it is likely that the reductions in patellofemoral loading in the weak and
344 tight subgroup, were mediated by the corresponding reductions in knee flexion in this group
345 which also exceeded the MCID. The alterations in knee flexion may be caused by a
346 proprioceptive effect, facilitated by the shock attenuating properties of the insoles. This
347 notion is supported by the observations of Sinclair et al., (2015) who found that shock
348 absorbing insoles produced significant reductions in both knee flexion and patellofemoral

349 joint loading during running. Furthermore, insoles have also been shown previously to
350 enhance proprioception through stimulation of cutaneous mechanoreceptors (Yalla et al.,
351 2014). The central nervous system uses ascending motor pathways that receive information
352 from the feet to control the position of the lower extremities and coordinate movement
353 (Christovao et al., 2013). However, because proprioception was not examined as part of this
354 study, further confirmatory analyses are required before this can be substantiated.
355 Nonetheless, a reduced knee flexion angle may lead to a reduction in the demands on the
356 knee extensors during the landing phase, thus the loads imposed on the patellofemoral joint
357 are attenuated (Thomee et al., 1999).

358

359 A further important consideration in relation to the current investigation is the observation
360 that the integral of the knee adduction moment increased significantly as a function of the 4-
361 week intervention. However, the increases in knee adduction moment integral as a function
362 of the 4-week intervention showed that only the weak and tight subgroup exceeded the MCID
363 threshold. This observation supports those of Franz et al., (2008), who found that insoles
364 significantly increased the knee adduction moment during walking and running. Although the
365 experimental insoles did not feature any posting, the medial arch support may have
366 sufficiently shifted the position of the centre of pressure medially across the entirety of the
367 stance phase to produce a consistent change in the moment arm of the GRF vector relative to
368 the knee joint centre (Franz et al., 2008). This increases the knee adduction moment integral,
369 and consequently compressive loading at the medial aspect of the tibiofemoral joint (Kean et
370 al., (2012). As the medial tibiofemoral compartment is considerably more susceptible to
371 injury than the lateral aspect (Wise et al., 2012) and tibiofemoral pathologies account for up
372 to 16.8 % of all knee injuries (Taunton et al., 2002) an increase in knee adduction moment is
373 an undesirable outcome. Kean et al., (2012) also demonstrated that the integral of the knee

374 adduction moment was a clinically important predictor of medial radiographic knee
375 osteoarthritis. Therefore, whilst insoles were effective in reducing patellofemoral symptoms
376 in the weak and tight subgroup; over time they may increase the risk of medial compartment
377 knee osteoarthritis in this group. This is a clear and essential avenue for further longitudinal
378 analyses to investigate the long term efficacy of insoles in runners with knee pathologies.

379

380 A potential drawback to this investigation is that patellofemoral joint kinetics were quantified
381 via a musculoskeletal modelling approach. This process was necessary due to the
382 impracticalities and invasive nature of obtaining in vivo measurements of joint kinetics.
383 However, although the approach utilized in this study represents expansion compared to
384 preceding mechanisms, in that the model accounted for co-contraction of the knee flexor
385 musculature, further work is required to improve the efficacy of subject specific knee joint
386 musculoskeletal models which will make further developments in clinical biomechanics
387 possible.

388

389 In conclusion, this is the first study to examine pain symptoms, psychological wellbeing and
390 biomechanical parameters following an intervention using insoles with recreational runners
391 subgrouped in accordance with Selfe et al. (2016). The findings showed significant
392 improvements in self-reported pain, psychological wellbeing and patellofemoral loading as a
393 function of the 4-week intervention. The recreational runners in the study fell into two
394 subgroups; strong and weak and tight. Although improvements in pain were found in both
395 groups, only the weak and tight subgroup results were associated with reductions in pain
396 symptoms that exceeded the MCID. It is proposed that this improvement was mediated
397 through reductions in patellofemoral stress in this subgroup. The key implication from this
398 study is that using semi-custom insoles as a conservative management strategy can reduce

399 pain symptoms in male and female runners associated with the weak and tight subgroup.
400 Further research including a control group and also runners from the weak and pronated
401 group is important for advancements in the treatment of patellofemoral pain.

402

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<i>Overall</i>	<i>Strong</i>	<i>Weak and tight</i>
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	Mean	SD	Mean	SD	Mean	SD
N	17		11		6	
Age	34.06	10.41	33.64	9.68	34.83	12.59
Body mass (kg)	72.28	13.02	73.75	13.69	71.03	13.71
Stature (m)	1.74	0.08	1.75	0.09	1.72	0.07
BMI (kg/m²)	23.80	2.44	23.74	2.47	23.90	2.61
10 km time (min: seconds)	47:24	4:16	46:26	4:09	47:19	4:10
Muscle length Rectus Femoris (°)	135.83	9.60	134.23	10.29	138.78	8.17
Muscle Length Gastrocnemius (°)	66.06	4.19	65.12	4.52	67.78	3.14
Muscle strength Quadriceps (Nm/kg)	1.38	0.31	1.55	0.20	1.06	0.17
Muscle strength hip abductors (Nm/kg)	1.41	0.41	1.61	0.35	1.04	0.20
Patellar mobility (mm)	11.18	1.91	11.73	2.00	10.17	1.33
Foot posture index	3.12	2.03	3.18	2.14	3.00	2.00

556 Table 1: Demographic variables overall and for each subgroup.

557

558 Table 2: Knee pain and psychological wellbeing parameters as a function of the foot orthoses intervention and subgroup.

	Strong				Weak & Tight				MCID	
	Pre		Post		Pre		Post			
	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
KOOS-PT	63.84	9.88	71.49	10.92	53.03	16.86	72.73	7.74	16.40	A
COOP-WONCA	1.91	0.29	1.55	0.30	2.08	0.23	1.83	0.24	0.16	A

559 Key: A = PRE-POST INTERVENTION main effect

560

561 Table 3: Musculoskeletal loading and temporal parameters as a function of the foot orthoses intervention and subgroup.

	Strong				Weak & Tight				MCID	
	Pre		Post		Pre		Post			
	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
Peak Patellofemoral force (BW)	3.40	0.75	3.08	0.77	3.68	1.30	2.85	1.11	0.54	A
Patellofemoral load rate (BW/s)	83.59	18.74	88.63	22.52	103.13	30.18	95.45	35.70	14.83	
Peak patellofemoral Stress (KPa/BW)	6.82	1.66	6.39	1.51	7.66	2.64	6.28	2.59	1.16	A
Step length (m)	1.31	0.13	1.33	0.10	1.36	0.19	1.38	0.23	0.09	
Patellofemoral force per mile (BW·mile)	183.07	42.25	155.15	46.84	189.44	81.54	138.24	63.03	32.44	A
Peak knee adduction moment (Nm/kg)	0.89	0.32	1.02	0.35	1.02	0.16	1.11	0.28	0.18	
Knee adduction moment integral (Nm/kg·ms)	78.57	35.96	89.97	38.16	76.67	23.50	97.73	28.11	19.69	A
Knee adduction moment load rate (Nm/kg/s)	54.50	16.80	65.85	25.92	67.85	19.87	76.73	24.09	12.61	

562 Key: A = PRE-POST INTERVENTION main effect

563

564 Table 4: Knee joint kinematics parameters as a function of the foot orthoses intervention and subgroup.

Strong	Weak & Tight	MCID
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	Pre		Post		Pre		Post			
	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
Sagittal plane (+ = flexion)										
Angle at footstrike (°)	11.70	3.18	9.25	3.59	16.69	7.96	9.93	7.96	3.13	A
Peak flexion (°)	38.86	4.44	36.62	4.99	41.54	10.59	37.64	9.99	3.78	A
Range of motion (°)	27.15	3.14	27.37	3.39	24.85	7.00	27.71	8.46	3.04	
Coronal plane (+ = adduction)										
Angle at footstrike (°)	-3.89	2.79	-3.27	3.12	-2.35	5.16	-2.17	2.94	1.99	
Peak abduction (°)	-9.69	4.94	-9.48	4.98	-7.94	4.63	-9.11	3.75	2.76	
Range of motion (°)	5.80	3.43	6.21	3.49	5.59	3.58	6.94	2.13	1.92	
Transverse plane (+ = internal)										
Angle at footstrike (°)	-5.22	10.95	-1.33	6.94	-4.79	9.29	-0.87	6.62	5.04	
Peak internal rotation (°)	9.71	7.23	11.68	5.18	12.47	6.71	16.26	4.36	3.80	
Range of motion (°)	14.92	8.48	13.01	4.51	17.26	5.82	17.13	5.31	3.64	

565 Key: A = PRE-POST INTERVENTION main effect

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567

568 Table 5: Ankle and tibial kinematics as a function of the foot orthoses intervention and subgroup.

	Strong				Weak & Tight				MCID	
	Pre		Post		Pre		Post			
	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
<i>Ankle</i>										
Sagittal plane (+ = dorsiflexion)										
Angle at footstrike (°)	7.55	6.93	6.55	6.31	6.72	6.98	7.53	8.54	4.11	
Peak dorsiflexion (°)	16.86	4.49	16.80	4.33	19.49	5.90	19.57	6.32	2.94	
Range of motion (°)	11.29	5.57	11.88	5.31	13.45	4.17	12.74	3.72	2.91	

Coronal plane (+ = inversion)										
Angle at footstrike (°)	-2.55	5.99	-2.14	5.32	-2.88	9.66	1.14	10.88	4.39	
Peak eversion (°)	-11.79	6.65	-11.21	7.30	-15.55	10.49	-12.49	9.28	4.71	
Range of motion (°)	9.24	2.08	9.06	3.35	12.67	4.18	13.62	4.35	1.95	
Transverse plane (+ = external)										
Angle at footstrike (°)	-13.96	3.93	-13.60	3.37	-16.97	5.86	-13.46	5.16	3.54	
Peak external rotation (°)	-4.84	4.80	-5.03	5.37	-6.38	4.83	-1.12	6.24	5.13	
Range of motion (°)	9.12	2.59	8.57	2.74	10.59	3.42	12.34	3.20	1.79	
Tibial internal rotation (+ = internal)										
Transverse plane										
Angle at footstrike (°)	6.50	5.86	6.33	4.86	7.96	8.79	3.46	9.98	4.08	
Peak tibial internal rotation (°)	13.11	7.11	12.55	7.18	17.20	11.04	12.89	9.54	4.86	
Range of motion (°)	6.61	2.34	6.22	3.81	9.24	4.74	9.42	3.94	2.10	
EV/TIR ratio	1.49	0.43	1.74	0.59	1.48	0.28	1.52	0.34	0.27	

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