

# 1 Lateral wedging of the foot: A scoping review

## 2 Abstract

3 **Background:** Lateral wedges are a common intervention used to alter biomechanical  
4 function of the lower limb. Although there is evidence investigating the use and impact of  
5 lateral wedges in individuals with medial knee osteoarthritis, knowledge of how these  
6 wedges affect foot function in healthy adults is limited. Therefore, this study intends to  
7 investigate how lateral wedging affects foot function in healthy adults and furthermore, how  
8 wedge design influences the outcome.

9 **Methods:** The framework outlined by Arksey and O'Malley was used for this scoping review.  
10 To ensure methodological quality and transparent reporting, the study adheres to the  
11 PRISMA-ScR preferred reporting guidelines. A systematic search was conducted using  
12 Medline via EBSCO; SPORT Discuss; CINAHL; AMED via OVID; and Scopus.

13 **Results:** The initial search yielded 252 articles in total; 21 studies were included in the final  
14 analysis. Significant incongruence exists in descriptions of wedge length among the 21  
15 included studies. Thirteen studies (61%) reported using full length wedges, five studies did  
16 not report wedge length, and only one study analyzed more than one wedge length.  
17 Ethylene vinyl acetate was the most common material although reporting of hardness was  
18 inconsistent. A broad range of inclination angles were used, with limited explanation for why  
19 these values were selected. All but one study that analyzed ankle/subtalar joint frontal plane  
20 moments, reported an increase in the external eversion moment.

21 **Conclusion:** The review identified significant variation in the design of wedges used within  
22 this body of work, and a lack of investigation into the influence of wedge design. Wedge  
23 design appears to be a secondary consideration with very few studies examining multiple  
24 material types or wedge placements. All but one of the included studies reported a

25 significant change in ankle/STJ joint moments with lateral wedging. Unfortunately, further  
26 generalization was not possible due to the inconsistency and variation.

27 **Keywords:** Valgus wedge, kinematics, kinetics, foot biomechanics, orthotic devices,  
28 orthoses, healthy adults, footwear modification

29

## 30 **Background**

31 Lateral wedging, also known as valgus wedging, is a common conservative intervention  
32 used by health professionals as part of a management plan aimed at altering biomechanical  
33 function in the lower limb. Lateral wedges are created by sloping material so that the lateral  
34 side is thicker than the medial side and the gradient between is a uniform incline. These are  
35 typically added to an orthotic, an otherwise flat insole, or on occasion to the midsole of a  
36 shoe<sup>1</sup>, the goal being to change foot function. The biomechanical effect of lateral wedges  
37 has been most frequently examined by research investigating medial knee osteoarthritis  
38 (OA)<sup>2,3</sup> and lateral ankle instability.<sup>4,5</sup>

39

40 The seminal work from Merton Root and his colleagues, now known as Root theory, appears  
41 to have been the first theoretical explanation for lateral wedging.<sup>6</sup> According to Root et al<sup>6</sup>  
42 abnormal alignment of the foot, such as forefoot valgus, leads to compensatory movement  
43 which may increase an individual's risk of injury. In this example, Root theory would  
44 recommend clinicians build a wedge of equal size to the structural imbalance, and place this  
45 under the lateral aspect of the forefoot, thus "balancing" the rearfoot and forefoot and  
46 preventing compensation. Recently however, the concept of subtalar joint (STJ) neutral, a  
47 central theme discussed in Root theory, has been challenged.<sup>7,8</sup> Many of the assessments  
48 within Root theory, including forefoot position, are static and non-weightbearing. Concerns  
49 have been raised over the value of these assessments when it comes to designing orthoses  
50 to be used dynamically.<sup>7,8</sup> Given the paucity of other theoretical explanations, this leads us  
51 to question the conceptual reasons behind lateral wedge prescription in practice.

52

53 When designing and fabricating underfoot interventions such as orthoses or insole  
54 modifications, the materials used may impact kinematic and kinetic outcomes.<sup>9-12</sup> In healthy  
55 populations, material selection has been shown to effect plantar pressure, modify contact  
56 areas, and elicit mechanical change.<sup>9,10,12</sup> Therefore, appropriate choice of materials

57 appears to be important in order for clinical interventions to be effective. In a recent  
58 systematic review on the effect of different orthotic materials on plantar pressures, Gerrard  
59 et al<sup>10</sup> suggested that it is essential that all clinicians who prescribe orthoses have access to  
60 robust evidence examining the effects of material selection.

61

62 Despite evidence reporting the effects of lateral wedging in individuals with medial knee OA,  
63 a systematic understanding of how lateral wedging affects foot function in healthy adults is  
64 lacking. Therefore, the purpose of this study was to investigate how lateral wedging affects  
65 foot function in healthy adults and furthermore, how wedge design influences the outcome.  
66 Based on a precursory assessment of the evidence, a scoping review has been deemed the  
67 most suitable way to answer this question.

68

## 69 **Methods**

70 The framework outlined by Arksey et al<sup>13</sup> was used for this scoping review: step 1, identify  
71 the research question; step 2, identify relevant studies; step 3, study selection; step 4,  
72 charting the data; and step 5, collating, summarizing and reporting the results. To ensure  
73 methodological quality and transparent reporting, the PRISMA-ScR preferred reporting  
74 guidelines were adhered to (see Appendix 1).<sup>14</sup> A comprehensive search was formulated  
75 and conducted by the first author (AJ) in April 2021 using Medline via EBSCO; SPORT  
76 Discuss; CINAHL; AMED via OVID; and Scopus. Search strategy terms displayed in Table 1  
77 were truncated using wildcard symbols to broaden the search and modified for each  
78 database. No limitation was placed on the date of publication.

79

80 ***INSERT TABLE 1 NEAR HERE***

81

82 At the outset of this review process, inclusion and exclusion criteria were developed to  
83 ensure that only relevant studies were included for analysis. As the search was developing

84 and familiarity with the literature increased, these criteria were reviewed and refined. Studies  
85 were included if they measured kinetic or kinematic variables in the foot when a lateral  
86 wedge is placed under the foot, assessed the effect of lateral wedging during walking or  
87 running gait, used live human participants and were published in English. Studies were  
88 excluded if they had no extractable data for “healthy” participants, involved participants  
89 under 18 years of age, measured the effect of lateral wedging during a sporting activity other  
90 than walking or running, or measured the effect of lateral wedging following a surgical  
91 intervention.

92

93 Reference management software EndNote version X9.3.1 (Clarivate Analytics, PA, USA)  
94 was used for the screening and analysis phase of this review. Before screening, all  
95 duplicates were removed by EndNote and then checked, and manually completed by the  
96 principal investigator (AJ). Two reviewers (AJ and PM) independently screened all titles and  
97 abstracts against eligibility criteria. In cases of non-consensus, a third author’s opinion was  
98 planned for consultation (MC); however, this was not required. Reference lists of retrieved  
99 articles were searched for further potentially relevant studies. Following title and abstract  
100 screening, two reviewers (AJ and PM) screened the full text of all remaining studies to  
101 compile a final list of included articles.

102

103 Data were charted using Microsoft Excel (Microsoft Corporation, WA, USA) to extract key  
104 information from the selected studies. This information included author(s), year of  
105 publication, study location, study population, wedge specifications (material, length,  
106 placement, and inclination), footwear conditions, gait type, outcome measures and relevant  
107 findings. In some cases, studies compared a pathological group to a healthy population. In  
108 these instances, only the relevant findings relating to the healthy group were extracted and  
109 charted.

110

111 **Results**

112 ***Selection and characteristics of studies***

113 A total of 252 articles were retrieved for abstract review, with 21 studies satisfying the  
114 inclusion criteria included for final analysis (Figure 1). Characteristics of these 21 included  
115 studies are presented in Table 2. Participant numbers ranged from eight to fifty, with a mean  
116 age of 30.2 years old. The date range of publications spanned from 2003 to 2021 with 12  
117 (57%) of the included studies published since 2013. Four of the included studies used a  
118 comparator group with two comparing healthy individuals to a pathological cohort (medial  
119 knee OA and lateral ankle instability)<sup>5, 15</sup>, while the other two compared groups with differing  
120 foot postures.<sup>16, 17</sup>

121

122 Figure 1: Flowchart diagram of literature search, screening, and selection. ***INSERT FIGURE***

123 ***1 HERE***

124

125 ***INSERT TABLE 2 NEAR HERE***

126

127 ***Wedge Length***

128 Specifications of wedges used in the included studies are detailed in Table 3. Eight studies  
129 reported using full length wedges.<sup>5, 15, 18-23</sup> Of these, two included pictures which show the  
130 wedge extending to the end of the insole.<sup>19, 21</sup> Also included in the eight studies to report full  
131 length wedging were the Fukuchi et al<sup>18</sup> and Lewinson et al<sup>20</sup> studies, both of whom included  
132 a picture showing wedges that extend just beyond the metatarsal heads to the sulcus of the  
133 foot. The remaining four studies in this group did not include a picture of their wedge length,  
134 and as such it was not possible to determine accuracy of the description “full length”.<sup>5, 15, 22, 23</sup>

135

136 Five studies added wedges extending to the sulcus of the foot.<sup>16, 17, 24-26</sup> Only the Sawada et  
137 al<sup>25</sup> article included a picture to provide visual clarification. The language used to describe

138 length in this group was varied with descriptions including: “3/4 length”<sup>16</sup>, “graded to zero at  
139 the base of the 5<sup>th</sup> metatarsal”<sup>24</sup>, “the lateral wedge insoles had base heights equal to that of  
140 the fifth metatarsal”<sup>25</sup>, “just distal of the fifth metatarsal”<sup>26</sup>, and “sulcus length”.<sup>17</sup>

141

142 Studies by Weinhandl et al<sup>27</sup> and Pascual Huerta et al<sup>28</sup> were the only two to report looking  
143 solely at rearfoot wedges, however neither included a picture to confirm placement. The  
144 Pascual Huerta et al<sup>28</sup> study stated that the wedges used in their study were 14cm long and  
145 4cm wide. The Van Gheluwe et al<sup>29</sup> study was the only one to examine differences in wedge  
146 length. This was also the only study to use a forefoot wedge, which in this case was  
147 compared to a rearfoot wedge. This study utilised six different insole conditions with a range  
148 of rearfoot (4° valgus to 8° varus) and forefoot (3° valgus to 6° varus) wedges, all compared  
149 to a neutral, flat insole. No details regarding wedge length were reported by five studies.<sup>30-34</sup>  
150 Despite not reporting length in the manuscript, three of these five provided pictures which  
151 showed wedges running the complete length of the insole or midsole.<sup>30, 32, 34</sup>

152

### 153 ***Wedge material type and hardness***

154 There were a range of materials used with the most common being ethylene vinyl acetate  
155 (EVA), used in ten studies (47%).<sup>5, 15, 17, 18, 20, 23, 26-29</sup> Other materials used included vinyl  
156 acetate<sup>24</sup>, polyvinyl acetate<sup>31</sup>, high intensity silicon<sup>25</sup>, polylactide<sup>16</sup>, cork<sup>19</sup> and wood.<sup>33</sup>

157

158 The reporting of material used and the hardness of the material was inconsistent. Five  
159 studies did not define the type of wedge material used<sup>21, 22, 30, 32, 34</sup> and nine studies provided  
160 no detail relating to material hardness of the wedge.<sup>16, 18-22, 31, 33, 34</sup> Within those studies that  
161 did report durometer (measure of hardness), there was variation in terminology. Scales used  
162 included Shore A<sup>17, 25, 27-29, 32</sup>, which ranged from 40-70, Asker C<sup>30</sup> and kilogram per square  
163 millimeter (kg/mm<sup>2</sup>).<sup>5, 15, 23</sup> Two studies recorded the wedges simply as “high density”.<sup>24, 26</sup>  
164 Three studies provided no detail of both the material type and hardness or density.<sup>21, 22, 34</sup>

165

166 ***Inclination angle***

167 A broad range of wedge inclination angles were used, ranging from 3° to 14° laterally  
168 wedged ( $6.21 \pm 2.51^\circ$ ). The highest inclination angle of 14°, was in the study by Schmalz et  
169 al<sup>34</sup>, where the wedge was placed in the midsole of a shoe. Considering only insole based  
170 wedges, the range of inclinations were 3° to 10° laterally wedged ( $5.94 \pm 2.10^\circ$ ). All studies in  
171 this review included an unwedged control condition as a comparison. Six studies compared  
172 more than one lateral wedge inclination.<sup>16, 18, 20, 21, 24, 30</sup> Telfer et al<sup>16</sup> included the most  
173 comprehensive range of inclinations, extending from 6° laterally wedged through to 10°  
174 medially wedged, in 2° increments. Although laterally wedged conditions were of interest to  
175 the current review, it was noted that seven studies additionally examined medial wedges.<sup>16,</sup>  
176 <sup>18, 20, 21, 26, 28, 29</sup>

177

178 Nineteen studies (90%) reported inclination in degrees whilst two studies reported millimeter  
179 thickness of the lateral border. Kluge et al<sup>19</sup> reported that using a 4mm wedge is  
180 approximately equivalent to a 4-5° angle. Sawada et al<sup>25</sup> used a 7mm wedge and noted that  
181 this was comparable to a 5.3° inclination angle. Neither study provided any further details  
182 about wedge dimensions such as foot or insole width.

183

184 ***INSERT TABLE 3 NEAR HERE***

185

186 ***Kinematic, centre of pressure and kinetic effect***

187 Kinematic and kinetic outcomes of the included studies are displayed in appendix 2.  
188 Interpretation of kinematic and kinetic variables was difficult due to the varied terminology  
189 used across all studies.

190

191 ***Subtalar joint moments***

192 Eleven studies reported on ankle/STJ inversion, eversion, or valgus moments.<sup>5, 15, 17, 18, 20, 23,</sup>  
193 <sup>28, 30-32, 34</sup> A mix of internal and external joint moments were measured which, when not

194 clearly outlined can make results appear contradictory. The external moment includes the  
195 impact of ground reaction force and inertial forces, and therefore is equal and opposite to the  
196 internal joint moment.<sup>35</sup> There are consistent findings amongst all but one study in this  
197 review that lateral wedging effects the ankle/STJ by increasing the external eversion  
198 moment<sup>17, 30, 32</sup>, increasing the internal inversion moment<sup>18, 20</sup>, increasing the external  
199 valgus moment<sup>5, 15, 23, 34</sup> or decreasing the internal valgus moment.<sup>31</sup> These findings were all  
200 statistically significant ( $p < 0.05$ ). The only study included that did not reach statistical  
201 significance was the work of Pascual Huerta et al<sup>28</sup>. In this study the authors compared a 7°  
202 lateral rearfoot wedge to a flat condition and found no significant change in net ankle  
203 inversion moments.

204

#### 205 ***Ankle abduction moment***

206 The Møller Mølgaard et al<sup>22</sup> study was the only study to report ankle abduction moment.  
207 Looking at the effect of lateral wedging when used within three different types of footwear,  
208 the authors found a reduction in ankle abduction moment, across all conditions. Schmalz et  
209 al<sup>34</sup> used the steepest wedge included in this review (14°) and did not find statistically  
210 significant results. The insignificant findings are supported by Nester et al<sup>26</sup> who analyzed a  
211 10° insole based lateral wedge, and also found no change with respect to rearfoot  
212 plantarflexion moments.

213

#### 214 ***Centre of pressure***

215 Centre of pressure (COP) was investigated by eight studies.<sup>5, 15, 18-20, 25, 29, 32</sup> Seven of these  
216 studies (87.5%) reported that COP was shifted laterally with the use of lateral wedges.<sup>5, 15, 18,  
217 20, 25, 29, 32</sup> Lewinson et al<sup>20</sup> noted that this effect was more pronounced as wedge inclination  
218 increased from 3° to 6° and 9°. Of these eight studies, the Kluge et al<sup>19</sup> study was the only  
219 one to report insignificant findings.

220

#### 221 ***Kinematics***

222 Kinematics were reported by twelve of the included studies.<sup>5, 15, 17, 19, 21, 23-27, 32, 33</sup> Nine studies  
223 discussed ankle/STJ eversion and of these, five reported a significant increase.<sup>17, 19, 24, 25, 32</sup>  
224 Of these 12 studies, only Forghany et al<sup>24</sup> analyzed multiple inclinations, reporting a  
225 significantly larger effect from their steeper wedge (8.5°) when compared to their less steep  
226 (5°) condition. Kluge et al<sup>19</sup> who assessed a range of walking speeds, reported that speed  
227 did influence the effect of lateral wedging on ankle eversion, with wedges making less of a  
228 difference at faster speeds. Three studies in this review showed insignificant effects of lateral  
229 wedging on ankle eversion. All three compared a single inclination to the control condition.<sup>5,</sup>  
230 <sup>15, 27</sup> Two studies reported rearfoot eversion, both finding that lateral wedging did not induce  
231 a significant change.<sup>21, 25</sup> Rabiei et al<sup>33</sup> analyzed “foot pronation” (measured as the combined  
232 movement in all three planes, frontal, sagittal, and transverse) in healthy female runners  
233 using a rearfoot lateral wedge. These findings indicated a significant increase in foot  
234 pronation, from 5% to 35% of stance phase ( $p = 0.012$ ), compared to the control condition.

235

## 236 **Discussion**

237 Understanding of the effect exerted by lateral wedging on foot function is limited by  
238 inconsistency in reporting of lateral wedge length, minimal reporting of specific wedge  
239 properties, a wide variation in wedge inclination angles, and an array of kinematic and kinetic  
240 outcome variables used to assess their biomechanical effect. Interpretation of the kinematic  
241 and kinetic effect of wedging is also restricted by the use of inconsistent terminology.

242 This review found that full length or sulcus length wedges were used in the majority of  
243 included studies, rather than rearfoot or forefoot wedges. This finding may be explained by a  
244 dominance of literature that has investigated the relationship between lateral foot wedging  
245 and knee adduction moments (KAM).<sup>2, 36-41</sup> Sixteen studies (80%) included in this review  
246 analyzed frontal plane knee kinetics such as KAM. With the preposition that full length

247 wedges are considered optimal to reduce KAM, it is perhaps not surprising that this was the  
248 dominant design.<sup>42, 43</sup> Hinman et al<sup>43</sup> were the first authors to identify the impact of wedge  
249 length on KAM. Prior to this work, researchers interchangeably used rearfoot or full-length  
250 wedges. Initially Hinman et al<sup>43</sup>, and more recently Fischer et al<sup>42</sup>, have compared multiple  
251 lengths of lateral wedge, both studies concluding that longer wedges (full length or sulcus  
252 length) elicited a larger reduction in KAM than a rearfoot only wedge. Despite some  
253 evidence surrounding alteration to KAM with full length lateral wedges, there is currently very  
254 limited research indicating what is the optimal length and positioning of lateral wedging to  
255 elicit functional changes in foot biomechanics.

256 Kogler et al<sup>44</sup> have shown that lateral wedging under the forefoot is the most effective way to  
257 reduce strain in the plantar aponeurosis. This in vitro study analyzed nine different test  
258 conditions, considering all possible combinations of rearfoot lateral, forefoot lateral, rearfoot  
259 medial, and forefoot medial wedging. Results of this work showed that all configurations with  
260 a forefoot lateral wedge induced a greater reduction in plantar aponeurosis strain than those  
261 without, including a lateral rearfoot wedge. As the only study included in the current review to  
262 compare different wedge placements, Van Gheluwe et al<sup>29</sup> found that whilst rearfoot  
263 wedging had no impact on forefoot plantar pressures, lateral forefoot wedging shifted the  
264 COP laterally at the forefoot.

265 There has been limited investigation into the impact of material properties on lateral wedge  
266 function. A multitude of different materials were used in the included studies, the hardness of  
267 these were inconsistently reported. A recent systematic review has indicated some orthotic  
268 materials can reduce peak plantar pressures during walking.<sup>10</sup> Whilst Gerrard et al<sup>10</sup> reported  
269 no clear consensus about the effects of EVA hardness on force modulation, they did note  
270 that softer EVA deforms to the shape of the foot thus increasing the contact area with the  
271 foot and impacting plantar pressures. Soft materials are generally thought to be more  
272 suitable when cushioning or shock attenuation is the desired outcome, whereas firm

273 materials are better suited to redistribution of load.<sup>12</sup> Gerrard et al<sup>10</sup> suggested that the ability  
274 of a material to conform to the foot is a key factor in altering plantar pressures. Extrapolating  
275 Gerrard et al<sup>10</sup> results to lateral wedging it may be postulated that lateral wedges constructed  
276 from more firm material may induce a larger change in joint moments and kinematics due to  
277 their reduced compressibility. Conversely, wedges manufactured from softer materials may  
278 exert less kinetic and kinematic effect. Unfortunately, although a range of materials were  
279 used across all included studies, no studies analyzed more than one material type or  
280 hardness therefore limiting our ability to draw conclusions or make recommendations  
281 relating to optimal material selection.

282 Lateral wedge inclination angles applied in the included studies ranged from 3° to 14°, with  
283 no clear rationale provided as to why particular inclination angles were selected. Previous  
284 research has highlighted comfort as a factor that may determine the degree of wedge  
285 inclination to be investigated.<sup>45-47</sup> Research has postulated that a threshold of between 5°  
286 and 7° exists and beyond this level comfort is adversely affected.<sup>45-47</sup> Erhart et al<sup>30</sup> and  
287 Lewinson et al<sup>20</sup> were the only studies in the current review to discuss comfort, both  
288 reporting higher discomfort levels with their largest inclination angles (8° and 9°,  
289 respectively). All studies in the current review that compared multiple inclination angles  
290 reported an increase in angulation is associated with a larger biomechanical change.<sup>16, 18, 20,</sup>  
291 <sup>21, 24, 30</sup> Beyond the concept of comfort, the basis for using a particular material thickness or  
292 inclination angle appears to be guided by a limited evidence-base. In light of this finding, we  
293 postulate that inclination angles used in lateral wedge research may relate to the properties  
294 of commercially available prefabricated materials (such as thickness), rather than what is  
295 known to be optimal. That is, convenience of available material may be a significant factor  
296 that determines inclination angle selection.

297 Despite significant variance in wedge design, as well as the mix of internal and external joint  
298 moments reported, lateral wedges were reported to modify frontal plane moments of the

299 ankle/STJ, in all but one included study. Although analyzed by a smaller number of studies,  
300 several reported that lateral wedging shifts the COP laterally thereby lengthening the ankle  
301 joint eversion moment arm. This lateralization of COP and change in moment arm appear to  
302 explain the increase in external eversion (valgus) moment at the ankle/STJ. With respect to  
303 other outcome measures analyzed by the included studies, there is insufficient consistency  
304 to make generalisations or draw conclusions.

305 Inconsistent terminology in the description of lateral wedges was a major finding of this  
306 review. Consequently, based on definitions drawn from included studies, we propose the  
307 following standard definitions for lateral wedge length and placement which can be adopted  
308 in future work.

- 309 • Full length lateral wedge: Beginning from the most proximal aspect of the insole,  
310 under the calcaneus. Extending to the distal end of the insole, past the apex of the  
311 digits.
- 312 • Sulcus length (3/4 length) lateral wedge: Beginning from the most proximal aspect of  
313 the insole, under the calcaneus. Extending to the sulcus of the foot, just distal to the  
314 metatarsal heads and tapering to nothing at this point.
- 315 • Rearfoot lateral wedge: Beginning from the most proximal aspect of the insole, under  
316 the calcaneus. Extending to the styloid process full thickness and tapering to nothing  
317 prior to the midshaft of the 5<sup>th</sup> metatarsal.
- 318 • Forefoot lateral wedge: Beginning from the calcaneo-cuboid joint and extending  
319 distally to the sulcus of the foot.

## 320 **Conclusion**

321 The review has identified significant variation in the design of wedges used within this body  
322 of work and a lack of investigation into the influence of wedge design. Wedge design  
323 appears to be a secondary consideration with very few studies examining multiple material

324 types or wedge placements. All but one of the included studies reported a significant change  
325 in ankle/STJ joint moments with lateral wedging. Unfortunately, further generalization was  
326 not possible due to the inconsistency and variation. This dearth of evidence suggests that  
327 clinicians using lateral wedges in practice are most likely fabricating these without robust  
328 evidence-based guidance. We recommend that future work should seek to provide clinicians  
329 with an understanding of how best to manufacture and prescribe lateral wedges that will  
330 achieve their desired clinical and biomechanical outcomes.

331

332 **Abbreviations**

333 OA, osteo-arthritis

334 EVA, ethylene vinyl acetate

335 STJ, subtalar joint

336 COP, centre of pressure

337 KAM, knee adduction moment

338 **Declarations**

339 ***Ethics approval***

340 Not applicable.

341 ***Consent for publication***

342 Not applicable.

343 ***Availability of data and material***

344 All data generated or analyzed during this study are included in this published article [and its  
345 supplementary information files].

346 ***Competing interests***

347 The authors declare that they have no competing interests.

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349 Not applicable.

350 ***Authors' contributions***

351 AJ and MC conceived the study. AJ, MC, KS and DR designed the study. AJ and PM  
352 conducted the literature search and extracted data. AJ, MC, KS, DR and PM drafted the  
353 manuscript. All authors approved the final manuscript.

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