

# Osteoarthritis and Cartilage



## Associations between changes in knee pain location and clinical symptoms in people with medial knee osteoarthritis using footwear for self-management: an exploratory study

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### SUMMARY

**Objective:** To examine whether change in pain location is associated with clinically-relevant improvements in walking pain severity and physical dysfunction in people with medial tibiofemoral osteoarthritis (OA) using footwear for self-management.

**Design:** We analysed a sub-set of 91 participants pooled from both arms of a 6-month randomised controlled trial of footwear for knee OA. The Photographic Knee Pain Map was self-administered to generate changes in the number of painful zones ('unchanged', 'increased', 'decreased') and anatomical patterns of pain ('unchanged', 'no longer diffuse', 'becoming diffuse', 'other pattern changes'). Improvement in symptoms was determined using the minimum clinically important differences (MCIDs) in pain severity on a numeric rating scale, and function with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Fisher's exact tests examined differences in symptom improvement across categories of change and odds ratios (ORs, 95% CI) were calculated (adjusted for treatment allocation).

**Results:** Seventy-four percent ( $n = 67$ ) of participants reported a change in pain location, and 46–50% ( $n = 42$ –45) reported clinically-relevant improvements in pain and function respectively. Fewer participants 'becoming diffuse' reported improved pain ( $n = 0$ , 0%) when compared to the other pattern change categories ( $P = 0.012$ ). Participants with 'no longer diffuse' (OR (95% CI) = 0.3 (0.1–0.9) or 'becoming diffuse' (OR (95% CI) = 0.0 (0.0–0.4) pain patterns had significantly lower odds of improved function than those with 'other pattern changes'.

**Conclusion:** Participants either developing into, or changing from, diffuse pain patterns were less likely to experience improvement in pain and/or function when self-managing with footwear.

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### Introduction

Osteoarthritis (OA) is a prevalent chronic musculoskeletal condition and the knee is commonly affected<sup>1</sup>. Afflicted individuals suffer considerable pain and experience difficulty in

performing activities of daily living. As a result, OA imposes a substantial burden on society and significant costs to the healthcare system<sup>2</sup>. As there is no cure for OA, management focusses on non-surgical strategies that aim to alleviate pain and improve physical function<sup>3–5</sup>. In practice, clinicians typically monitor patient outcomes to therapy via changes in both pain severity and pain location around the knee joint. Despite increasing awareness that anatomical location and/or area of pain may influence pain severity and physical dysfunction in people with knee OA<sup>6–8</sup>, it is unknown if changes in pain location are related to improvements in pain severity and/or function over time.

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The location of knee pain in people with knee OA is highly variable, both in terms of the anatomical location of pain (e.g., anterior, isolated medial, anterior-medial etc.) and the breadth of the area where pain is felt (e.g., local, regional or more generalised in nature)<sup>6,8–12</sup>. In people with mixed compartmental knee OA, the most common anatomical locations of pain are anterior-medial and/or isolated medial knee pain<sup>6,11–13</sup>. The severity of clinical symptoms appears to be associated with pain location<sup>6,8</sup>. In a large cohort of older adults with chronic knee pain, Farrokhi *et al.*<sup>8</sup> reported that individuals with pain over the patellar region combined with at least one painful location elsewhere in the medial or lateral knee had greater odds of reporting pain, other symptoms, sports or recreational activity limitations and lower knee-related quality of life when compared to people suffering knee pain isolated to either location alone. Diffuse knee pain (i.e., pain indicated ‘all over’ the knee and/or affecting more than two anatomical regions of pain) is reported by 10–52% of people with symptomatic knee OA<sup>6,7,11,12</sup>. Cross-sectional studies show that people with more diffuse pain tend to experience more severe and frequent pain, greater physical dysfunction, higher levels of anxiety, and widespread hyperalgesia or neuropathic-like pain, when compared to those with more localized OA pain<sup>6,8–11,14</sup>.

It is possible that changes in knee location may be related to changes in the severity of symptoms in people with knee OA. Insight into the relationship between changes in pain location and clinical outcomes may yield useful information, helping to increase our understanding of why some patients with knee OA achieve greater clinical improvement than others. However, there have been no longitudinal studies mapping changes in knee pain location in people with knee OA, neither investigating how changes in pain location may be related to clinical status over time. The aim of this study was to utilise data from a recently completed clinical trial to examine whether changes in knee pain location were associated with clinically important improvements in pain severity and/or physical function in a cohort with symptomatic medial tibiofemoral OA who self-managed their condition with footwear.

## Patients and methods

This study is an exploratory analysis of data from a sub-sample of participants from a 6-month randomised controlled trial (ACTRN12613000851763) that compared the effects of unloading shoes to conventional walking shoes in people with symptomatic medial tibiofemoral OA<sup>15</sup>. Trial findings showed both types of footwear improved pain and physical function by clinically-relevant amounts, with no superiority of one shoe over the other<sup>16</sup>. Accordingly, data across both intervention arms were pooled for the present analyses. Although knee pain location was assessed at baseline in all trial participants for descriptive purposes, the decision to conduct the present study and thus evaluate pain location also at follow-up, was made half-way through the trial. All participants who provided data on knee pain location at both baseline and 6-month follow-up ( $n = 91$  (55% of the 164 enrolled in the trial)) were included in this analysis.

### Participants

Volunteers were recruited from the community and enrolled in the trial if they had knee OA according to American College of Rheumatology criteria<sup>17</sup>. Inclusion criteria were (1) aged  $\geq 50$  years, (2) knee pain on most days of the past month, (3) average pain score of  $\geq 4$  on an 11-point numerical rating scale (NRS, terminal descriptors ‘no pain’ and ‘worst pain possible’) over the past week and (4) definite X-ray evidence of medial tibiofemoral OA (Kellgren–Lawrence grade of  $\geq 2$ <sup>18</sup>, at least grade 1 medial osteophytes

and medial  $\geq$  lateral osteophytes, and at least grade 1 medial joint space narrowing and medial  $>$  lateral joint space narrowing<sup>19</sup>). People were excluded if they reported (1) intra-articular corticosteroid injections or knee surgery to either knee in the past 3 months, (2) a history of knee joint replacement or high tibial osteotomy, (3) systemic arthritic conditions, (4) any other muscular, joint or neurological condition affecting lower limb function, (5) a body mass index  $\geq 36$  kg/m<sup>2</sup>, and/or (6) ankle/foot pathology or pain that was either perceived as worse than knee pain and/or required treatment in the past 6 months.

For bilaterally eligible knees, only the most symptomatic knee was evaluated. If both knees were eligible and equally painful, the right knee was deemed the study knee by default. Ethics approval was obtained from The University's Human Research Ethics Committee and all participants provided written informed consent.

### Intervention

Participants were randomized to receive one pair of either unloading walking shoes (Gel-Melbourne OA, Asics) or conventional neutral walking shoes (Gel-Odyssey, Asics)<sup>16</sup>. Shoes were appropriately sized and participants were asked to wear them as much as possible every day ( $\geq 4$  h/day) for 6 months and to avoid changing shoes. The unloading shoe contained a triple-density midsole (stiffer laterally than medially) and mild lateral wedge insole. The conventional shoes did not contain these specific design features<sup>16</sup>.

### Descriptive characteristics

Participant demographics were collected by questionnaire and included age, sex and duration of symptoms. Height and weight were measured to calculate body mass index. Radiographic severity of OA was assessed from semi-flexed posterior-anterior weight-bearing X-rays. Using the Kellgren–Lawrence grading system<sup>18</sup>, grades of  $\geq 2$  were considered evidence of OA where a grade 2 was defined as ‘definite osteophytes and possible joint space narrowing’, grade 3 represented ‘moderate multiple osteophytes, definite joint space narrowing and possible bone deformity’ and grade 4 ‘large osteophytes, marked joint space narrowing, severe sclerosis and definite bone deformity’. Use of co-interventions was collected using monthly logbooks and at the 6-month assessment.

### Location of knee pain

The Photographic Knee Pain Map [Fig. 1(A)] was used to determine location of knee pain at baseline and 6 months<sup>20</sup>. It is a patient-administered instrument with good to excellent intra-rater and inter-rater reliability, and has demonstrated convergent validity against an interviewer-administered knee pain map in patients with knee pathology<sup>20</sup>. The map consists of a photographic representation of the anterior view of a pair of knees. Participants were instructed to mark all painful locations in their study knee (“Please use small crosses to mark where you feel your knee pain on this diagram. (You can use several crosses if needed)”). Additionally, a tick box below the photograph enabled participants to report pain in the posterior knee as either present or absent. Subsequently, a template transparency that divided the knee into nine anterior zones based upon anatomic landmarks [Fig. 1(B)] was overlaid on the photograph by a researcher (PKC). For each zone, pain was recorded as present if one or more marks were located in the zone as per the bordering lines on the transparency. Marks located on bordering lines indicated pain in both adjacent zones. Thus, for each participant, pain was recorded as either present or absent in each of the 10 zones (nine anterior and one posterior zone)<sup>6,20</sup>. In

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