**Clinical assessment and management of foot and ankle osteoarthritis: a review of current evidence and focus on pharmacological treatment**

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**Abstract**

Foot and ankle osteoarthritis (OA) is a common and disabling problem that adversely affects physical function and significantly reduces quality of life. Although the knee was considered to be the lower limb site most often affected by OA, recent population data showed foot OA is as prevalent as knee OA, and rates increase with advancing years. The most common foot OA sites include the first metatarsophalangeal joint and the midfoot, with the ankle affected less often. Despite the high prevalence and disabling nature of foot and ankle OA, the condition has been neglected by clinical researchers, and there are very few trials investigating non-surgical foot or ankle OA treatment options. There are no accepted clinical diagnostic criteria for foot or ankle OA so imaging remains common. Clinical guidelines based on knee and hip OA research recommend education, exercise, and weight loss in the first instance. Topical non-steroidal anti-inflammatory drugs (NSAIDs) or capsaicin may be used as an adjunct. Failing these approaches, paracetamol should be recommended, however if there is inadequate symptomatic relief, then clinicians should trial an oral NSAID or a cyclooxygenase-2 inhibitor. Given adverse events and co-morbidities are common in the elderly, older patients should be closely monitored. Some studies have investigated intra-articular injections for foot and ankle OA, and there is some evidence to suggest hyaluronic acid may be effective in the short term for ankle OA. With the lack of research on foot or ankle OA treatments however, robust clinical trials are urgently needed.

**Key points:**

* Foot osteoarthritis is very common, particularly in older adults, and there is a growing body of evidence that it is highly disabling
* There is little research on management strategies for foot and ankle OA, however it is possible that pharmacological approaches recommended for knee and hip OA are effective, including paracetamol and/or topical non-steroidal anti-inflammatory drugs (NSAIDs) or capsaicin
* Oral NSAIDs (including a cyclooxygenase-2 inhibitor) or intra-articular hyaluronic acid injections may be considered if initial pharmacological approaches are ineffective, especially for ankle OA, but further high quality clinical trials are necessary

1. **Introduction**

Osteoarthritis (OA) is a major global public health problem, with a worldwide prevalence of 23.9% [1]. The condition causes significant pain and disability, and adversely affects quality-of-life. Disability associated with OA also results in a substantial economic burden. The economic burden of OA is due to direct treatment-related costs, particularly joint replacement surgery, in addition to indirect costs such as lost productivity [2, 3]. Rates of OA are projected to rapidly increase over the coming decades as the population ages and rates of obesity rise [4]. As a consequence, it is anticipated that there will be a large increase in demand for health services for the symptoms and disability associated with OA in the coming years.

Foot OA has recently been found to be highly prevalent and disabling, yet in contrast to hand, knee and hip OA, there is little research in the field to guide clinical management. The following paper provides a review of the assessment and non-surgical treatment of foot and ankle OA for clinical practice. Where evidence-based information specifically related to the foot, ankle, or individual foot joints is lacking, relevant clinical research from other joints that may be generalized to the foot/ankle will be provided.

1. **Epidemiology and impact of foot and ankle osteoarthritis**

Historically, the knee has been considered to be the most commonly affected weight bearing region, with a reported prevalence of 7.6-16.4% [1]. However, recent research revealed the population prevalence of symptomatic radiographic foot OA was 16.7% [5], suggesting it may be as common as knee OA. Within the foot, the first metatarsophalangeal (MTP) joint is the most commonly affected joint, with a prevalence rate slightly higher than hip OA at 7.8% [5]. Midfoot joints are also commonly affected, including the 2nd cuneiform-metatarsal joint (6.8%), the talo-navicular joint (5.8%), the naviculo-cunieform joint (5.2%), and the 1st cuneiform-metatarsal joint (3.9%) [5]. If these individual joints are considered as a single midfoot complex, as they typically are for clinical management [6], the prevalence of symptomatic radiographic midfoot OA is reported to be 12.0% [7]. The prevalence of symptomatic radiographic OA of the ankle has also been reported to be 3.4% [8], and it has been suggested that the majority of these are post traumatic [9].

Foot and ankle OA are highly debilitating. An overwhelming 69% of people with symptomatic radiographic foot OA report experiencing disabling foot pain [5], and this pain has been shown to result in functional limitations and significant impairments in measures of balance, strength and locomotor ability [10]. Disabling foot pain is a significant and independent risk factor for falls [11], and foot OA, particularly of the first MTP joint, also leads to significant reductions in all domains of the foot health status questionnaire, and the physical and social function subscales of the Short Form 36 questionnaire [12]. It has also been shown to worsen symptoms at other joints, and to increase the risk of developing OA more proximally in people aged over 45 years. Specifically, a recent large cohort study found that the presence of foot/ankle pain significantly reduced health and physical function in people with knee OA [13]. Subsequent analyses from this cohort found that foot/ankle pain substantially increased the risk of developing symptomatic radiographic knee OA within the subsequent four years [14], and increased the risk of worsening knee pain in those with existing knee OA [15].

Foot and ankle problems are a common cause for consulting a general practitioner [16]. In fact, up to 32% of people with foot pain report consulting their general practitioner, more than those suffering from musculoskeletal pain at any other site [17]. The adverse effects upon health, physical function and quality of life from foot and ankle OA have also been shown to impact on working ability, with foot OA reported to be the only OA site significantly associated with employment reduction in males [18]. This is important given half of people with OA are of working age [19].

1. **Foot and ankle OA phenotypes**

The median number of foot joints affected by OA in people aged over 65 is four [20], suggesting that the typical presentation of foot OA is as a multi-joint disease pattern. This was confirmed in a recent population-based study which used latent class analysis to investigate potential foot OA phenotypes. Outcomes showed two distinct foot OA phenotypes; a polyarticular form of foot OA that included a clustering of midfoot joints, and isolated OA of the first MTP joint [21]. Both subgroups were significantly older than people with no or minimal OA, whilst the polyarticular group were also more likely to be female, and to have more persistent and severe pain, greater functional limitation, a higher BMI, and increased presence of nodal hand OA. The study also found that the disease was more prevalent in one foot only, however when foot OA was bilateral, there was a strong association for a symmetrical distribution [21]. A high level of symmetry is also common in the polyarticular form of hand OA [22].

1. **Assessment**
   1. **Clinical assessment**

Evidence based recommendations for the clinical diagnosis of OA currently exist for the knee [23], with a diagnosis made by three signs on examination (crepitus, restricted movement and bony enlargement) and symptoms (knee pain, short-lived morning stiffness and functional limitation). Despite the comparable prevalence, there are currently very few agreed guidelines for the clinical diagnosis of foot or ankle OA, which limits our ability to advance the development of interventions and provide targeted treatment.

A variety of foot and ankle assessment measures have been adopted by a number of OA-linked prospective cohort studies. The Johnston County Osteoarthritis Project and the Framingham Foot Study included a pictorial atlas of common foot disorders, foot structure (measured with the Arch Index) and assessment of hallux valgus and hallux rigidus [24, 25], whilst Chingford 1000 Women Study used the International Musculoskeletal Foot and Ankle Assessment [26]. Although a number of measures have been validated against foot disorders [27], all have yet to be validated against OA-related outcomes.

The Clinical Assessment Study of the Foot (CASF) derived a brief collection of static assessments from pre-study consensus work, including measures of foot posture, range of motion, observation, and palpation [28]. None of these were able to discriminate between individuals with and without structural radiographic midfoot changes [29]. However, assessments including dorsal hallux and first MTP joint pain, [hallux valgus](https://www.sciencedirect.com/topics/medicine-and-dentistry/hallux-valgus), first interphalangeal joint hyperextension, keratotic lesions of the hallux and first MTP joint, decreased first MTP joint dorsiflexion, ankle/subtalar joint eversion, and [ankle joint](https://www.sciencedirect.com/topics/medicine-and-dentistry/ankle-joint) dorsiflexion range of motion, were all significantly associated with radiographic first MTP joint OA severity [30]. Findings from a smaller elderly population have shown that older people with radiographic OA of the talo-navicular joint and navicular-first cuneiform joint exhibit flatter feet represented by the arch index [31].

A diagnostic rule developed for first MTPJ OA suggests five clinical observations can accurately identify the presence or absence of radiographic first MTPJ OA in patients with first MTPJ pain [32]. These include pain duration greater than 25 months, the presence of a dorsal exostosis, hard-end feel, crepitus and less than 64° of first MTPJ dorsiflexion. More recently, a consensus study provided five recommended assessment components for first MTP joint OA, including pain on walking over the past week, first MTP joint and ankle joint range of motion, foot posture (foot posture index), resting calcaneal stance position, and palpation to determine pain location [33].

Findings suggest that some of these physical examinations may be of limited use for discriminating the presence or absence of symptomatic midfoot OA, but a number may hold some value in diagnosing first MTP joint OA. Further work would be beneficial to determine if these and other clinical measures may be useful in discriminating between the presence or absence of symptomatic OA in all identifiable foot joints.

* 1. **Imaging assessment**

The latest recommendations from the European League Against Rheumatism is that imaging is not required to make a diagnosis of OA in patients with a typical presentation of the disease [34]. Routine follow up imaging to monitor disease progression or treatment response is also not recommended. The exceptions to these include cases where the patient’s presentation is atypical and thus imaging may be needed to confirm a diagnosis of OA or make a differentiation diagnosis, or if there is a rapid and unexpected progression of symptoms, and imaging may be used to see if progression is related to symptoms or an additional diagnosis. In such cases, the guidelines recommend plain-film radiography in the first instance prior to other modalities. The vast majority of the recommendations were made based on studies from other sites given there is very little research in to imaging for foot and ankle OA. One exception was a small study which found that when ultrasound imaging was added to clinical assessment findings, the diagnostic confidence of rheumatologists in differentiating OA from inflammatory arthritis of the hands or feet was significantly increased [35].

Notwithstanding these recommendations, radiography is routinely used in the primary care setting [36], and in clinical research, to confirm diagnosis and/or grade OA severity. Regarding grading, a systematic review [37] of the radiographic prevalence of foot OA from 27 studies found that most (70%) used the Kellgren and Lawrence (KL) system [38]. This system classifies OA based on the presence or absence of osteophytes and joint space narrowing, using a scale of 1 (doubtful OA) to 4 (severe OA). The majority of studies (95%) in the review classified OA as being at least grade 2 (minimal) changes [37].

Whilst the use of the KL system allows comparison between studies of radiographic OA at more proximal joints such as the knee, it has been argued that it places too much dependence on the presence of osteophytes, which are implied to precede joint space narrowing in a chronological progression of OA [39, 40]. Furthermore, another review reported a large variation on the definition and grading of OA using the KL system [41]. In response to these limitations, Menz and colleagues developed a foot-specific atlas which classifies radiographic OA of the first MTP joint, 1st cuneiform-metatarsal joint, the 2nd cuneiform-metatarsal joint, the talo-navicular joint, and the naviculo-cunieform joint [42]. The atlas overcomes the major disadvantages highlighted in previous radiographic foot OA studies by (i) obtaining dorsoplantar and lateral views, (ii) requiring x-rays to be taken while weightbearing, and (iii) grading both osteophytes and joint space narrowing separately on a scale of 0 (absent) to 3 (severe osteophyte; or joint fusion). As an example, figure 1 is a dorsal view of the first MTP joint showing the grades for joint space narrowing. Radiographic OA is defined as present at any of the five foot joints if there is a score of 2 or greater for either osteophytes (indicating a moderate or severe osteophyte) or joint space narrowing (indicating severe joint space narrowing or joint fusion at at least one point) on either the dorsoplantar or lateral view [42].  The authors reported that the atlas had moderate to excellent within-rater reliability, and mostly fair to excellent between-rater reliability. The overall foot OA score was also found to possess moderate to excellent within- and between-rater reliability [42].

Insert Figure 1 near here

Figure 1. Dorsal projection of the first metatarsophalangeal joint showing the grades for joint space narrowing based on the Atlas developed by Menz et al [42]. A grade of 0 indicates no joint space narrowing, 1 indicates definite joint space narrowing, 2 indicates severe joint space narrowing, and 3 indicates joint fusion at at least one point.

An additional atlas has been recently developed to grade radiographic OA at the ankle (tibiofibular and tibiotalar) and subtalar (talocalcaneal) joints [43]. The ankle and hindfoot atlas grades osteophytes and joint space narrowing from 0 (normal) to 3 (severe) from weightbearing mortise and lateral views. Osteophytes are graded in the medial and lateral compartments from the mortise view, and anterior and posterior from the lateral view, whilst joint space narrowing is graded in each joint in both views. The KL system is used to provide an overall OA grade as described above [38]. Using x-rays from 30 participants, the study found the atlas to possess good to excellent reliability for most radiographic features from most views.

1. **Treatments**

Although there are no clinical guidelines for the management of foot or ankle OA, it is reasonable to suggest that recommendations pertaining to the management of OA at other sites may be appropriately applied to the foot and ankle. The National Institute for Health and Care Excellence (NICE) guidelines for peripheral joint OA, developed largely from hip and knee OA trials, advise that core management strategies should include (i) advice and education regarding the disease and its prognosis, (ii) strengthening and aerobic exercise, and (iii) weight loss, where appropriate [44]. These recommendations are largely consistent with those from the Osteoarthritis Research Society International [45], the most recent guidelines from the Royal Australian College of General Practitioners (RACGP) [46], and the European League Against Rheumatism [47]. It is probable however that many people with OA will experience symptoms that cannot be effectively managed by these non-pharmacological treatments. The following section outlines the use of pharmacological, injectable, and conservative treatment strategies for foot and ankle OA.

* 1. **Pharmacological management**

Paracetamol/acetaminophen or topical NSAIDs are generally recommended following first line strategies. To date, there are no clinical trials of paracetamol/acetaminophen in foot or ankle OA. In knee OA, dosages from seven RCTs (N=2491 participants) included in a systematic review and meta-analyses comparing paracetamol/acetaminophen with placebo, ranged from around 1000mg/day to nearly 4000mg/day, with no clear benefit of one over the other [44]. The NICE guidelines advise clinicians to consider regular dosing of paracetamol/acetaminophen [44], however it should also be highlighted that the most recent RACGP guidelines were unable to recommend either for or against paracetamol/acetaminophen, and cautioned against regular dosing [46]. This was largely based on findings from a recent systematic review of eight observational studies on adverse events (AEs) from standard analgesic doses, which found paracetamol/ acetaminophen was associated with potential for some harms due to both short-term excess doses and longer-term regular dosing [48]. Furthermore, a large systematic review also showed paracetamol/acetaminophen provided only minimal short-term OA-related pain reductions that were unlikely to be clinically relevant [49]. However, depending on the foot and/or ankle joint(s) affected, it is reasonable to suggest that lower doses in the order of 1000mg/day may be trialled initially, and gradually increased in case of ineffectiveness and the absence of AEs. Use should be discontinued if paracetamol/ acetaminophen is not effective.

Topical NSAIDs are both safe and effective and should be considered as an adjunct to non-pharmacological strategies. There are no clinical trials on the use of topical NSAIDs for the treatment of foot/ankle OA. The most recent systematic review and network meta-analysis of 36 RCTs in predominantly hip and knee OA found that topical NSAIDs were superior to placebo for OA-related pain relief, and significantly improved physical function [50]. Diclofenac patches, followed by ibuprofen cream, were found to be the most effective for pain. Topical salicylate gel was the only topical NSAID to be associated with AEs, with users of all other topical NSAIDs not experiencing a higher rate of AEs compared to non-users or placebo [50].

Likewise, application of topical capsaicin should also be considered as adjunct to either core non-pharmacological treatments, or in place of topical NSAIDs [44]. A recent systematic review and network meta-analysis concluded that capsaicin prescribed at the recommended British National Formulary dosage (0.025% four times per day) is superior to placebo for pain relief [51]. Although no RCT has directly compared capsaicin to topical NSAIDs, the analysis showed capsaicin resulted in clinically meaningful improvements in pain that were similar to topical NSAIDs, suggesting the cream could be used in its place.

When paracetamol/acetaminophen and/or topical NSAIDs or capsaicin are ineffective for managing the symptoms of foot or ankle OA, clinicians should consider prescribing oral NSAIDs, including COX-2 inhibitors [44]. The clinical improvement in OA-related symptoms from NSAIDs is small, but greater than that of paracetamol/acetaminophen for most patients, and is clinically meaningful [46]. We recommend trialling an oral NSAID or COX-2 inhibitor at lowest effective dose, such as 1000mg/day of ibuprofen or naproxen, or 100mg/day of celecoxib, for the shortest possible period. This is consistent with the only published clinical trials of NSAIDs in foot OA. The first of these found similarly effective pain reductions with 800mg of etodolac and 1000mg of naproxen at 5 weeks [52], whilst the second found similar results at 8-weeks with 20mg/day of piroxicam and 1000mg/day of naproxen [53]. There is also good evidence that 150mg/day diclofenac results in clinically meaningful improvements in pain for knee OA [54], however it may be prudent to trial doses of around 100mg in the first instance for foot or ankle OA. Patients should be carefully monitored, and dosage may be gradually and slightly increased in the absence of symptomatic improvements and lack of AEs. Indeed, the potential for harms with NSAIDs are well-recognised, particularly in older persons, thus the co-prescription of a proton-pump inhibitor may also be considered, or alternatively, clinicians may consider not prescribing oral NSAIDs in this population [45].

Evidence concerning opioid use is poor, and toxicity-related AEs (particularly in the elderly), in addition to dependence, remain serious concerns [44]. As such, the most recent guidelines recommend that both oral and trans-dermal opioids are not indicated for OA [46]. Additional pharmacological strategies that are either not recommended for peripheral joint OA, or lack evidence, include chondroitin, avocado soybean unsaponfiables, vitamin D, turmeric, tricyclic agents, glucosamine, and risedronate [44-46].

* 1. **Intra-articular injections**

Intra-articular (IA) injections have been investigated more than any other non-surgical approach for foot and ankle OA. Although the ankle OA has a lower prevalence than first MTP joint or midfoot OA, the majority of studies used participants with ankle OA. A 2018 systematic review [55] found 22 studies that evaluated the effects of IA injections in people with ankle OA, however only five of these were RCTs [56-60]. Of the five RCTs, three compared hyaluronic acid (HA) to saline [56, 57, 59], one compared HA to exercise therapy [58], and one compared HA and rehabilitation exercise to an injection of Botulinum toxin type A. Pooled RCT results from the systematic review showed HA significantly improved ankle OA symptoms over saline at 6-months [55]. However, no trial blinded the administering physician, all were generally small (n=20 to 75), and most had inadequate or unclear randomisation and/or allocation concealment. Case series on the effects of platelet-rich plasma, corticosteroid, and mesenchymal stem cell injections also suggest symptomatic improvements however these trials are all small and lack a control group which limits interpretations [55]. Larger studies with adequate randomisation, control, and blinding are needed before firm conclusions regarding the efficacy of IA injections for ankle OA can be made.

In the first MTP joint, there has been one RCT comparing an IA injection of HA to saline [61] and one comparing HA to a corticosteroid injection [62], however only the former was adequately powered and reported randomisation and blinding information. Clinically meaningful reductions in first MTP joint pain were observed in both the HA and saline groups over 6-months [61], and in the HA and corticosteroid group over 3-months [62]. However, there were no statistically significant between-group differences in change in pain in either study. There have only been two uncontrolled studies comparing IA injections for midfoot OA, both of which used a corticosteroid [63, 64]. Results from both studies showed symptomatic improvements in the short term (3-4 months) however these positive clinical responses were generally not maintained in the longer term (12 months).

* 1. **Conservative treatments**

There is little research on conservative treatment options for OA of the foot and ankle. In fact, there are no randomised controlled trials (RCT) investigating management strategies for multi-joint foot OA, and high-quality trials investigating single-joint foot or ankle OA are also lacking. To date, there have only been two non-pharmacological non-surgical RCTs published on OA of the first MTP joint [65, 66], three small pilot studies for midfoot OA [6, 67, 68], and no clinical trials for conservative treatment for ankle OA. Notably, no study has investigated the effects of core OA management strategies (derived from hip and knee OA trials) recommended by international OA clinical guidelines [44-46], with the exception of one small trial [65]. This study assessed the addition of a single foot strengthening exercise, as well as sesamoid mobilisation and gait training, to a range of other physical interventions, and reported significant improvements in strength and function for the intervention group. However, the small sample size (n=20), use of multiple interventions, and lack of adequate control precludes an understanding of the effects of strength exercise on foot-OA related pain. Although no study has investigated the effects of aerobic exercise on foot or ankle OA symptoms, one cohort study of 221 participants aged between 40 and 91 years reported that regular exercise did not increase the risk for progression of foot OA [69]. The only other non-pharmacological non-surgical foot OA RCT compared the effects of rocker-soled footwear with prefabricated foot orthoses in 102 participants with OA of the first MTP joint [66]. The results showed that there were clinically meaningful symptomatic improvements in both groups, however there were no between-groups differences. It is worth noting that there were fewer AEs and greater adherence in the foot orthoses group.

Of the three small studies to assess a conservative intervention for midfoot OA, all used a foot orthosis/insert. The first investigated the effects of a full-length flat carbon graphite insert in 20 female patients with midfoot OA, and found symptomatic improvements with the intervention, albeit the study lacked adequate control [68]. Another non-randomised study compared the addition of a rigid carbon fibre footplate (insert) to custom semi-rigid foot orthoses in 57 participants with midfoot OA and found similar clinical improvements in pain, function, and walking ability in both groups [67]. The final trial was a feasibility study in which 37 participants with symptomatic radiographic midfoot OA were randomised to receive a pair of semi-custom foot orthoses or a sham device [6]. Both groups reported improvements in pain, function, and global impression of change over 12-weeks, however benefits were greater in the intervention group.

1. **Gaps in our knowledge and key areas for clinical focus**

The burden of foot and ankle OA has not been well understood until recently, and the condition has been neglected in clinical research. Consequently, there are a plethora of questions regarding the impact of foot and ankle OA in the community, and its optimal management in the clinical setting. Perhaps most pressing is the urgent need for clinical trials investigating core management strategies recommended by international OA clinical guidelines, such as education and advice, exercise, and weight loss where appropriate. The condition is a leading cause for consulting a general practitioner [70], and general practitioners largely manage the condition using medication, including for new presentations [36]. Thus, more clinical trials on the efficacy and safety of analgesic and anti-inflammatory medications for foot and ankle OA are also needed. Indeed, dosing is inferred based mainly on the larger knee and hip joints, and while these may be appropriate, it would be useful for clinicians to be able to recommend evidence-based dosing specifically for foot and ankle OA. Likewise, given the strong association between foot and ankle OA and advancing age [5] and co-morbidities [7, 36] (as for most OA), clinical research on the short- and long-term benefits and harms of pharmacological treatments for older people (e.g. >70 years), and those with concomitant chronic disease such as diabetes, is needed. Finally, there are no adequately powered and controlled clinical trials of any intervention for midfoot OA, despite the region being the most commonly affected foot site [7], with a prevalence higher than hip OA [1]. Thus, research on management strategies for midfoot OA are also urgently needed.

1. **Conclusion**

Foot and ankle OA is highly prevalent, especially in older populations. Surprisingly however, there has been very little clinical research in to the impact and treatment of foot and ankle OA, and much of the existing literature is based on small samples and with a number of methodological limitations such as a lack of blinding and/or controls. Knowledge of how to manage foot and ankle OA is extrapolated largely from OA studies at other lower limb sites. Generally, OA guidelines advise advice and education, exercise, and weight loss, where appropriate, as first-line strategies [44]. Low-dose paracetamol/acetaminophen, topical NSAIDs, or topical capsaicin may also be considered as an adjunct to first-line treatments, or in the case of inadequate pain relief. If these approaches remain insufficient, then either an oral NSAID or COX-2 inhibitor may be substituted or added. Patients should be carefully monitored for symptomatic response and for any AEs, particularly the elderly and those with co-morbidities. There is limited evidence to suggest that HA injections may be useful up to 6-months in people with ankle OA, however evidence for other IA injections and in other foot joints is limited. Overall, further well-designed large RCTs are needed to provide evidence-based management options for this common and painful problem.

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**The authors Kade Paterson and Lucy Gates declare they have no conflicts of interest**

**COMPETING INTERESTS**

The authors declare there are no competing interests.

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