Keele UNIVERSITY
Impact Accelerator Unit

# Keele Critically Appraised Topic (CAT Form)

## Clinical Question

In patients with 1st metatarsal phalangeal joint (MTPJ) osteoarthritis (OA)is the addition of an orthotic more effective than providing footwear and lifestyle advice in improving pain and quality of life?

## Clinical bottom line

There is limited evidence that the addition of a specified orthotic (Welsh et al protocol) is better than footwear and lifestyle in improving pain.

Based on two randomised controlled trials (RCTs), evidence suggests similar benefit for 1st MTPJ pain using either MBT footwear or Vasyli custom orthotics using the Welsh at al protocol. The evidence should be treated with caution due to the studies having small numbers.

More adverse events occurred in the MBT footwear intervention which may make the Vasyli orthotic the preferred intervention of choice due to greater adherence and fewer adverse events.

One of the two papers tested a contoured Formorthotic product. No evidence of benefit.

## Lay Summary

Some people can experience pain in their big toe joint because of a condition called osteoarthritis (OA). This happens more often to older people and can make their big toe stiff and painful.

Clinicians can try different ways to help, like special shoes or inserts you put inside your shoes, called orthotics. Studies show that both special shoes (called MBT) and custom-made inserts (called Vasyli orthotics) can help with the pain.

However, people using the special MBT shoes experienced some problems or side effects, so the custom-made inserts might be a better choice as they cause fewer problems and people are more likely to feel more comfortable using them.

Another type of insert that fits the shape of the foot did not seem to be any better in helping with the pain.

Louise Smith-Williams l.smith-williams@nhs.net May 2025

At the moment there are no clear rules for clinicians on the best way to treat this toe problem, so more research is needed to help people experiencing this condition.

## Why is this important?

Osteoarthritis (OA) of the 1st metatarsal phalangeal joint (MTPJ) is the most common form of foot OA and affects 8% of people aged 50 years and over (Roddy et al, 2015). The condition is characterised by pain and stiffness.

There are no clinical guidelines to inform the management of 1st MTPJ OA. NICE Interventional Procedures Guidance (IPG727 01.06.22) references non-conservative management including exercise, physiotherapy, orthotics, analgesia, non-steroidal anti-inflammatories and cream and corticosteroid injection.

The provision of orthotics, as an intervention for MTPJ OA, is varied in clinical practice. This may be footwear with a stiffened sole and/or tapered toe box to orthotic inserts such as carbon fibre inlays, extension under the hallux (Morton's extension) to foot posture control with 1st ray cut outs. The cost of these items varies.

The group wished to explore the current evidence to determine the best current evidence to help guide future practice.

## Search timeframe

March 2014 – March 2024

### Search criteria

| **Population Intervention Comparison Outcomes (PICO) themes** | **Description** | **Search terms** |
|---|---|---|
| Population and Setting | Patients with 1st Metatarsophalangeal joint OA (MTPJ)<br><br>Inclusions<br><br>➢ 18 years old<br>➢ 1st MTPJ OA<br>➢ Hallux arthritis<br>➢ Hallux limitus<br>➢ Hallux rigidus<br><br>Exclusions:- | |

| | | |
|---|---|---|
| | HAV<br>Hallux abductovalgus<br>Hallux interphalangeus<br>Turf toe<br>Sesamoiditis<br>Gout<br>Rheumatoid Arthritis<br>Fracture<br>Previous surgery<br>Arthrodesis | |
| Intervention or Exposure<br>(i.e. what is being tested)<br>e.g. manual therapy | Mortons extension<br>Carbon fibre insole<br>Rigid orthotic<br>Metatarsal bar<br>Lifestyle advice with orthotic +/- mortons extension +/- carbon fibre | ➢ 1st MTPJ OA<br>➢ Hallux arthritis<br>➢ Hallux limitus<br>➢ Hallux rigidus<br>Mortons extension<br>Carbon fibre insole<br>Rigid orthotic<br>Metatarsal bar<br>Lifestyle advice with orthotic +/- mortons extension +/- carbon fibre |
| Comparison, if any | Lifestyle advice<br>Rocker footwear<br>Rigid footwear<br>Tapered toe box<br>Walking boots/shoes | |
| Outcomes of interest | Pain<br>QoL | |
| Types of studies<br>e.g. Randomised Controlled Trials, Systematic Reviews | RCT<br>SR | |

## Databases searched

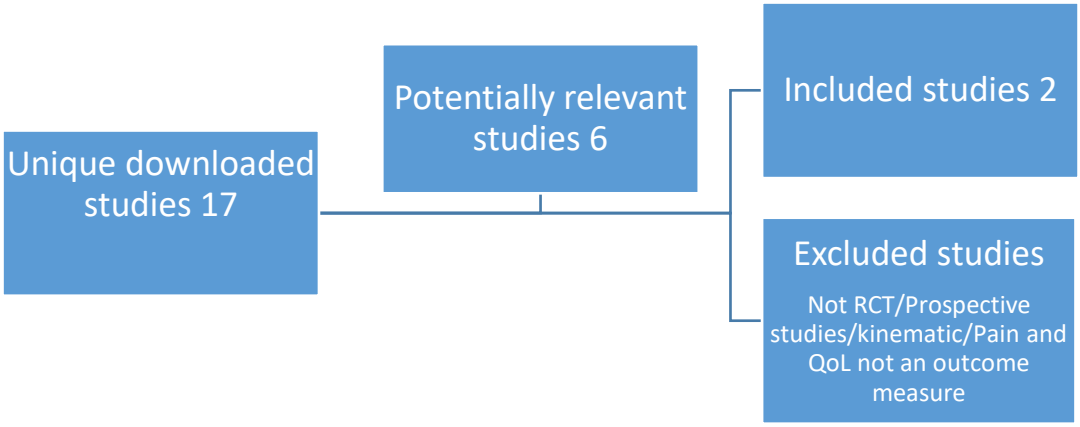
MEDLINE

CINAHL

## Date of search

22nd March 2024

## Results of the search: include the number in each box




There were 17 unique downloaded studies. There were two relevant studies. The two included studies and their critical appraisal is in Table 1. There were 15 excluded studies.

## Table 1- Detail of included studies

| First author, year and type of study | Population and setting | Intervention or exposure tested | Study results | Assessment of quality and comments |
|---|---|---|---|---|
| Menz et al, 2016<br><br>RCT | >18 years old, 1st MTPJ pain > 12 weeks, Pain minimum 20 mm on 100 mm visual analogue scale (VAS), <64 degrees 1st MTPT range of motion, pain palpating dorsal aspect of joint<br><br>La Trobe, Melbourne Victoria Australia | Rocker sole shoes (MBT, Mahuta or Matwa models)<br><br><u>Versus</u><br><br>Vasyli Customs Medium density, Vasyli Medical modified as described by Welsh et al – full length, modified by adding a cut out section beneath the first metatarsal and trimming the distal edge to the level of the second to fifth toe sulcus. Participants with pronated feet defined as a FPI score > 7, full length 4-degree varus wedge added until there was a reduction in the FPI score of at least 2 points. | 2 groups compared (orthotic) n= 52 v (footwear) n= 46 via randomisation, intention to treat. Follow up assessments of outcome was via self-completion questionnaires returned by mail and staff entering outcome measure data and conducting statistical analysis were blinded.<br><br>Primary outcome measure was Pain via the Foot Health Status Questionnaire (FHSQ)<br><br>What results were found for each outcome? Improved FHSQ for but no | Good quality trial addressed a clearly focused issue 'Pain'. Parallel group randomised trial, groups similar at start of trial and treated similarly with exception of intervention, CI 95%, patients covered in the trial similar to those treated in clinic. |

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| | | | statistical difference.<br><br>Conclusion: Prefabricated foot orthoses and rocker-sole footwear are similarly effective at reducing foot pain in people with first MTP joint OA. However, prefabricated foot orthoses may be the intervention of choice due to greater adherence and fewer associated adverse events.<br><br>Adverse events being new episode of back pain or lower extremity pain, blisters, discomfort from the intervention or impaired balance. Participants in the footwear group were more likely to report one adverse event (39% v 16%) | |

| | | | | |
|---|---|---|---|---|
| Paterson et al, 2022<br><br>RCT | Aged 45 years and above, activity related joint pain and morning stiffness > 30 minutes, 1st MTPJ pain most days of the last month and for >/= to 12 weeks, VAS 1st MTPJ pain > or = to 3 on an 11 point numerical rating scale (NRS), radiographic evidence of 1st MTPJ OA > or equal to 2 using a radiographic atlas.<br><br>3 departments across 2 locations – The University of Melbourne, Melbourne, Australia, La Trobe University, Melbourne, Australia | Blue medium density prefabricated contoured orthoses<br><br>Versus<br><br>3 mm prefabricated flat insole of the same colour, density and branding as the foot orthoses<br><br>Formorthotics | 2 groups compared n = 41 (sham group) and n = 47 intervention group.<br><br>Parallel group, randomized, multi-centre, participant- and assessor-blind, sham-controlled trial<br><br>Primary outcome measure was Pain via change in first MTP joint walking pain (11-point numerical rating scale (NRS), 0 -10) over 12 weeks<br><br>What result was found for each outcome? Contoured foot orthoses are no more effective than flat insoles for the clinical management of 1st MTPJ OA at 12 weeks.<br><br>Adverse events – the authors make no comment regarding the presence or absence of adverse events | Good quality trial addressed a clearly focused issue 'Pain'. Parallel-group randomised trial, multi-centre, participant and assessor-blind, sham-controlled trial. Groups similar at start of trial and treated similarly with exception of intervention, CI 95%, patients covered in the trial similar to those treated in clinic. |

## Summary

Both RCTs are good quality, but have small sample size, therefore results should be treated with caution.

Rocker sole footwear (MBT) and Vasyli custom medium density orthoses modified using the Welsh et al protocol infers no statistical difference between the two. In this study, the Vasyli are favoured over the footwear group due to greater adherence and the greater incidence of adverse effects in the footwear group.

There is no benefit in the use of a Blue medium density prefabricated Formorthotics for 1st MTPJ OA.

## Implications for practice

The appraisal of the literature suggests some evidence behind MBT footwear and Vasyli custom orthotics using Welsh et al protocol. There are cost implications as MBT footwear are more expensive than Vasyli and MBT footwear associated with more adverse events..

Further research is needed though practitioners may wish to review their current prescribing practises and patient advice recommendations.

## What would you post on social media?

Results should be viewed with caution, however some but limited evidence exists that both MBT footwear and Vasyli custom orthoses modified using the Welsh et al protocol provide benefit for improving pain for 1st MTPJ OA.

## References


Effectiveness of Foot Orthoses Versus Rocker-Sole Footwear for First Metatarsophalangeal Joint Osteoarthritis: Randomized Trial - PubMed

Effect of foot orthoses vs sham insoles on first metatarsophalangeal joint osteoarthritis symptoms: a randomized controlled trial - PubMed

Welsh BJ, Redmond AC, Chockalingam N, Keenan AM. A case-series study to explore the efficacy of foot orthoses in treating first metatarsophalangeal joint pain. J Foot Ankle Res 2010;3:17.



Louise Smith-Williams l.smith-williams@nhs.net May 2025

Please tick the box that best reflects your clinical bottom line and include the picture on page 1

| CAT image | Evidence quality | Checkbox |
|---|---|---|
|  | Good quality evidence to support use…. | ☐ |
|  | Insufficient or poor-quality evidence OR substantial harms suggest intervention used with caution after discussion with patient… | ☑ |
|  | No good quality evidence, do not use until further research is conducted OR<br>Good quality evidence to indicate that harms outweigh the benefits…. | ☐ |

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