Clinical Practice Guideline: **Inserts and Other Shoe Modifications for Individuals without Diabetes**

Date of Implementation: **May 21, 2015**

Product: **Specialty**

GUIDELINES

For plans that have limited coverage:

American Specialty Health – Specialty (ASH) considers shoe inserts and other shoe modifications described by CPT Codes L3000, L3001, L3002, L3003, L3010, L3020, L3030, L3031, L3040, L3050, L3060, L3070, L3080, and L3090 (as described below) to be medically necessary when the following is met:

1. If they are on a shoe that is an integral part of a medically necessary brace and if they are medically necessary for the proper functioning of the brace.

The above criteria are consistent with CMS policy. Refer to the *Diabetic Shoes/Inserts (CPG 259 – S)* clinical practice guideline for orthopedic footwear criteria for patients with diabetes.

For plans that do not exclude foot orthotics:

ASH considers shoe inserts and other shoe modifications described by HCPCS Codes L3000, L3001, L3002, L3003, L3010, L3020, L3030, L3031, L3040, L3050, L3060, L3070, L3080, and L3090 (as described below) to be medically necessary when prescribed by a physician for the below criteria:

1. For Adults and Children (any one condition)
   a. Chronic plantar fasciitis
   b. Chronic calcaneal bursitis
   c. Calcaneal spurs
   d. Inflammatory conditions of the foot/ankle
   e. Medial osteoarthritis of the knee (lateral wedge insole)
   f. Musculoskeletal/arthropathic deformities (e.g., bunions, hallux valgus, talipes deformities, tendonitis, pes cavus deformities, hammertoes, anomalies of toes)
   g. Neurologically impaired feet (e.g., neuroma, tarsal tunnel syndrome)
   h. Vascular conditions (e.g., Buerger's disease, peripheral vascular disease)

NOTE: Both adults and children must have symptoms associated with the particular foot condition (foot orthotics are NOT medically necessary when the foot condition does not cause symptoms) and have failed to respond to a course of appropriate conservative

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treatment (e.g., physical therapy, injections, strapping, anti-inflammatory medications, over-the-counter/pre-fabricated foot inserts/orthotics). Orthotics should not be the first line of treatment.

Foot orthotics are considered not medically necessary when these criteria are not met such as for back or knee pain (other than medial osteoarthritis), corns and calluses, and lower leg injuries as there is insufficient evidence to support a conclusion supporting the health outcomes or benefit.

ASH considers CPT code L3260 medically necessary when prescribed as rehabilitative foot orthotics following foot surgery or trauma when the rehabilitative foot orthotics are medically necessary as part of their post-surgical or casting care. In these instances, foot orthotics are considered an integral part of the covered surgical procedure or foot trauma repair.

ASH considers CPT codes L3332, L3334, and L3350 not medically necessary for any condition. Evidence is insufficient to support their use.

HCPCS CODES AND DESCRIPTIONS

HCPCS Code	HCPCS Code Description
L3000	Foot insert, removable, molded to patient model, UCB type, Berkeley shell, each
L3001	Foot, insert, removable, molded to patient model, Spenco, each
L3002	Foot insert, removable, molded to patient model, Plastazote or equal, each
L3003	Foot, insert, removable, molded to patient model, silicone gel, each
L3010	Foot insert, removable, molded to patient model, longitudinal arch support, each
L3020	Foot insert, removable, molded to patient model, longitudinal/metatarsal support, each
L3030	Foot insert, removable, formed to patient foot, each
L3031	Foot insert/plate, removable, addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, each
L3040	Foot, arch support, removable, premolded, longitudinal, each
L3050	Foot, arch support, removable, premolded, metatarsal, each
L3060	Foot, arch support, removable, premolded, longitudinal/metatarsal, each

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HCPCS Code	HCPCS Code Description
L3070	Foot, arch support, nonremovable, attached to shoe, longitudinal, each
L3080	Foot, arch support, nonremovable, attached to shoe, metatarsal, each
L3090	Foot, arch support, nonremovable, attached to shoe, longitudinal/metatarsal, each
L3260	Surgical boot/shoe, each
L3332	Lift, elevation, inside shoe, tapered, up to one-half inch
L3334	Lift, elevation, heel, per inch
L3350	Heel wedge

DESCRIPTION/BACKGROUND

Orthotics are usually rigid or semi-rigid devices that provide stability or restrict motion, prevent deformity, protect against injury, assist with function, or support weak or injured body parts. When speaking of foot orthotics specifically, they function to protect fixed or long-term malalignment or biomechanical faults, cushion exposed bones or protect skin at risk of breakdown due to disease or other conditions that result from disease. The scope of this guideline is foot orthotics or inserts. A foot orthotic is a type of shoe insert that does not extend beyond the ankle and may include heel wedges and arch supports. The goal of treating conditions with foot orthotics is to decrease pain and increase function. They may also correct some foot deformities and provide shock absorption to the foot. A custom-fitted or custom-molded foot orthosis may be used as a replacement or substitute for missing parts of the foot (e.g., due to amputation) and when it is necessary for the alleviation or correction of illness, injury or congenital defect. The major foot-related conditions that increase the risk of ulcers and amputations in those with diabetes and other conditions that impair peripheral circulation, are peripheral neuropathy, altered biomechanics (caused by increased plantar pressure, bone deformities, limited joint mobility), peripheral vascular disease, skin pathology and a history of prior ulcers. When properly fitted, footwear can reduce abnormal pressures, reduce formation of calluses and ulcers and protect the foot from external trauma. Foot orthotics can either be over-the-counter/prefabricated/premolded orthotics or a custom device derived from a three-dimensional representation of the member's foot. Most patients with these conditions can safely wear properly fitted commercial shoes. Prefabricated shoe inserts may also be used. The use of custom-fitted or custom-molded orthotic inserts are typically reserved for those patients with neuropathy and/or altered circulation who also have severe foot deformities such as Charcot arthropathy, severe arthritis, large bunions or prior amputation.

A prefabricated orthosis is one that is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated (custom-made) orthosis is considered prefabricated.

A custom foot orthotic is a shoe insert that is made directly from an Anatomical Volumetric Foot Model (AVFM). The AVFM is modified with the appropriate medial and/or lateral arch fill, lateral column expansion, heel expansion, and intrinsic forefoot and/or rearfoot corrections as defined by the prescribing physician (PFOLA, 2006). Custom orthotics can be divided into two categories: 1) functional or 2) accommodative. Functional orthotics are designed to control abnormal motion. They may be used to treat foot pain caused by abnormal motion; they can also be used to treat injuries such as shin splints or tendinitis. Functional orthotics are typically crafted of a semi-rigid material such as plastic or graphite; whereas accommodative orthotics are softer and are designed to provide additional cushioning and support. They can be used to treat diabetic foot ulcers, painful calluses on the bottom of the foot, and other uncomfortable conditions.

CPT Codes L3000 and L3010 are two commonly used custom foot orthoses codes. CPT Code L3000 is the traditional UCBL (University of California-Berkeley Lab) type; a rigid device with high heel cups, high medial flanges, a sustentaculum tali shelf, and aggressive cast corrections to provide maximal control. The L3010 is seen as a “Levy Mold”, the removable, longitudinal arch support that is molded to the cast of the patient’s foot but has little or no heel cup.

The Pedorthic Footcare Association classifies custom foot orthoses within the following categories: rigid, semi-rigid, and soft. Rigid shells are constructed with base materials such as plastics, fiberglass, and carbon fiber or similar. Semi-rigid shells would be made with base materials from cork, or dense foams with a durometer, or hardness, of 45 and higher. Soft shells would be shells made with base materials from soft materials, generally with a durometer of less than 45.

Conservative treatment of foot pain may include adjustment of activities and patient education, anti-inflammatory medications (if the patient is able to tolerate), night splints, physical therapy interventions, and/or prefabricated orthotics and taping.

EVIDENCE REVIEW

Overall, the evidence base with respect to the clinical effectiveness of foot orthoses is limited. Many studies have used heterogeneous combinations of treatments and materials, making it difficult to draw conclusions from reviews of the clinical trials. There is some evidence in the literature to suggest that custom made orthoses are as effective as prefabricated orthoses for the treatment of heel pain syndromes and related conditions.

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Low Back Pain and Orthotics

Kelaher et al. (2000) looked at the effects of semi-rigid orthotics on asymptomatic workers who stand all day. Ten subjects wore prefabricated semi-rigid orthotics for two months while a control group wore flexible Sorbothane shoe inserts for two months. No significant changes were noted for strength, posture or stability measures after two months for either group. Subjects did report reduced low back discomfort and increased foot discomfort during a tiring exertion task while using the semi-rigid orthotics vs. the control condition. Many limitations exist for this study.

Defrin et al. (2005) looked at whether the correction of a small leg length inequality (LLI) (i.e., 10mm or less) can help relieve chronic low back pain. Thirty-three (33) patients from a physical therapy clinic participated in the RCT. In 22 patients, LLI was corrected using shoe inserts and in 11 patients, no correction was made. Pain and disability were measured and a significant reduction in both was noted. Further studies are needed to confirm these outcomes. In another study looking at chronic low back pain and LLI, Zhang (2005) performed a study looking at the impact of chiropractic adjustments and orthotics to reduce symptoms in the feet and other parts of the body, including the low back, for standing workers. Thirty-two subjects were split into three study groups; 10 subjects in the chiropractic care (Activator technique and home exercises) plus orthotics group (and home exercises), 8 in the control group, and 14 subjects in the orthotics group. Foot orthotic information was captured and sent to Foot Level-ers, Inc. for fabrication. Outcomes showed that the combination of chiropractic care and orthotics significantly improved symptoms, function, and quality of life. For the orthotics group, trends in improvements were noted, except for pain, where no trend or significance was noted. The control group did not experience any changes during this time. Authors suggested that orthotics and chiropractic care may improve symptoms for workers who stand longer than 6 hours. However, several limitations were noted; orthotic compliance was unknown, and pain levels for low back and other pain were rated very low. Golightly et al. (2007) wanted to determine the changes in pain and disability after shoe lift intervention for subjects with chronic LBP who have LLI. Only 11 subjects participated in this study. Subjects were tested pre and post treatment intervention. Lift height was determined by subjects based on reduction of pain. Subjects did experience pain relief and less disability following the intervention. Further well-designed studies are needed to confirm these findings.

Cambron et al. (2011) completed a pilot study on shoe orthotics and their effect on chronic low back pain. The main purpose of this study was to pilot a randomized controlled trial (RCT) design for the use of shoe orthotics for patients with chronic low back pain. Fifty (50) subjects were randomized into either a treatment group who received customized orthotics, or a wait-list control group. After 6 weeks, the wait-listed group received customized orthotics as well. Pain levels and function were measured using the Visual Analog Scale (VAS) and Oswestry Disability Index at the end of the 6-week period. Data suggested that orthotics reduced pain and improved function relative to the control group after 6 weeks. Improvements were maintained at 12 weeks, but no additional improvements were gained during this time. Further studies are needed to confirm these results, keeping in mind controlling for external influences.

Ferrari (2012) noted that while customized foot orthotics are prescribed often for patients with chronic low back pain (LBP) and lower limb pain, there are few trials to demonstrate the effectiveness. For fibromyalgia, there are none. Thus, Ferrari (2012) completed a cohort-controlled trial of the addition of customized orthotics to the standard care of patients diagnosed with fibromyalgia. Thirty-two (32) subjects were given back exercises and analgesics and were considered the control group. The remaining 35 subjects received the same therapy and also customized foot orthotics. After 8 weeks, the orthotics group had an improvement in function over the control group. The author suggested that adding orthotics to 'usual care' for patients with fibromyalgia may help in the short term. Consideration of what really is 'usual care' for patients with fibromyalgia should be attended to when deciphering results. Additionally, Ferrari (2013) compared reported disability due to chronic low back pain following a motor vehicle accident in groups of patients receiving usual care and usual care plus customized foot orthotics. 66 patients completed treatment (34 received orthotics). At 8 week follow up, both groups improved however the orthotic group had a lower Oswestry disability score and used fewer analgesics than the usual care group. He concluded that orthotics improved short term outcomes compared with usual care alone. He found the same results in patients with chronic low back pain following work-related injury (Ferrari, 2013).

Cabron et al. (2017) investigated the efficacy of shoe orthotics with and without chiropractic treatment for chronic low back pain compared with no treatment. Adult subjects (N=225) with symptomatic low back pain of ≥3 months were recruited from a volunteer sample. Subjects were randomized into 1 of 3 treatment groups (shoe orthotic, plus, and waitlist groups). The shoe orthotic group received custom-made shoe orthotics. The plus group received custom-made orthotics plus chiropractic manipulation, hot or cold packs, and manual soft tissue massage. The waitlist group received no care. The primary outcome measures were change in perceived back pain (numerical pain rating scale) and functional health status (Oswestry Disability Index) after 6 weeks of study participation. Outcomes were also assessed after 12 weeks and then after an additional 3, 6, and 12 months. After 6 weeks, all 3 groups demonstrated significant within-group improvement in average back pain, but only the shoe orthotic and plus groups had significant within-group improvement in function. When compared with the waitlist group, the shoe orthotic group demonstrated significantly greater improvements in pain (P<.0001) and function (P=.0068). The addition of chiropractic to orthotics treatment demonstrated significantly greater improvements in function (P=.0278) when compared with orthotics alone, but no significant difference in pain (P=.3431). Group differences at 12 weeks and later were not significant. Authors concluded that six weeks of prescription shoe orthotics significantly improved back pain and dysfunction compared with no treatment. The addition of chiropractic care led to higher improvements in function.

Menez et al. (2023) examined the effects of foot orthoses on gait kinematics and low back pain (LBP) in individuals with leg length inequality (LLI) in a systematic review. Inclusion criteria were the analysis of kinematic parameters during walking or LBP before and after foot orthosis use in patients with LLI. Ultimately, five studies were retained. The results showed that insoles seem to reduce pelvic drop and active compensations of the spine when LLI is moderate/severe. However, insoles do not always seem to be efficient in improving gait kinematics in patients with low LLI. All of the studies noted a significant reduction of LBP with use of insoles. Consequently, although these studies revealed no consensus on whether and how insoles affect gait kinematics, the orthoses seemed helpful in relieving LBP.

Orthotic Management in Knee Osteoarthritis (OA)

In 2002, Toda and Segal assessed the effectiveness of an insole with subtalar taping on patients with medial compartment OA. Prior to this several authors reported that inserted insoles were effective for patients with mild OA versus severe OA. In the cases of severe OA, it is very difficult to change the femorotibial angle (FTA) where the varus angle of the knee has already changed due to degeneration of the medial compartment of the knee. Subtalar taping has also shown some potential in affecting pain and function in patients with knee OA. Eighty-eight (88) females diagnosed with knee OA were treated with wedged insoles for 8 weeks. Two types of wedged insoles were used. One had the lateral wedge fixed to an ankle strap (subtalar strapping insole) and the other was a sock type ankle support with lateral rubber heel wedge insert. Participants were randomized into one of the two groups. Results indicate that the subtalar strapping insole was more effective than the sock type insole for increasing maximum ambulation and pain. They postulate that the subtalar strapping insole may regulate medial compartment loading, however not all participants demonstrated a changed FTA. It is also notable that those with subtalar strapping complained of more pain with ambulation on uneven surfaces.

Given that the medial compartment is the most commonly affected in osteoarthritis, different means of reducing the adduction moment at the knee was evaluated by Reeves and Bowling (2011) as it is regarded as an indication of medial knee joint compression. They examined evidence for the following: walking barefoot, lateral wedges, thin soled shoes, toe out gait, cane use, lateral trunk sway, and bracing to unload the knee. Results indicated that despite the discomfort with lateral wedges in shoes, they are effective for those with early-stage OA, yet not for severe cases of OA. Barefoot walking or using thin soled shoes reduces the knee adduction moment relative to thick soled shoes. Walking with a toe-out gait reduces the second peak of the adduction moment but not the first peak. Cane use in the opposite hand and lateral trunk sway both effectively reduce the adduction moment. Unloading braces reduce the net adduction moment and unload the medial compartment of the knee. Thus, these biomechanically related interventions may effectively delay the onset or severity of OA.

Raj and Dewan (2011) reviewed the efficacy of knee braces and foot orthoses in the management of knee OA. Twenty-five (25) studies met the inclusion criteria. In focusing on the evidence for foot orthoses, lateral wedged insoles with subtalar strapping, medial-wedged insoles and specialized footwear were discussed. Results showed that foot orthoses are effective in decreasing pain, joint stiffness, and drug dosage for those with OA. Improvement in proprioception, balance and physical function were also noted. Results should be taken with some skepticism given the poor quality of studies and heterogeneity of interventions.

Hinman et al. (2012) evaluated the effects of lateral wedges on frontal plane biomechanics in patients with medial knee osteoarthritis. Seventy-three (73) participants with knee osteoarthritis completed gain analysis with and without a lateral wedge in their shoe. The purpose behind lateral wedges for those with osteoarthritis is to reduce the adduction moment that promotes degeneration of the medial knee joint. Frontal plane kinetics were evaluated. Results demonstrated that lateral wedges did reduce the peak knee adduction moment and angular impulse. Other analysis suggested that a reduced knee ground reaction force lever arm with lateral wedges may be the central reason why loading is reduced in the medial compartment.

Sacco et al. (2012) confirmed that joint loading was decreased not only in gait, but also in functional activities like walking downstairs when wearing flexible and minimalistic footwear in patients with knee OA. Thirty-four (34) elderly women were split into two groups: OA and a control. Stair descent was evaluated with heeled shoes, barefoot and with the minimalistic shoe. They found that the reduced load was equivalent in the barefoot and minimalist shoe trials vs. the heeled shoe.

In a 2015 Cochrane review on braces and orthoses for treating osteoarthritis of the knee by Duivenvoorden et al. Randomized and controlled clinical trials investigating all types of braces and foot/ankle orthoses for OA of the knee compared with an active control or no treatment were selected for review. For the comparison of laterally wedged insole versus no insole, one study (n = 40, low-quality evidence) showed a lower VAS pain score in the laterally wedged insole group (absolute percent change 16%) after nine months. For the comparison of laterally wedged versus neutral insole after pooling of three studies (n = 358, moderate-quality evidence), little evidence was found of an effect on numerical rating scale (NRS) pain scores (absolute percent change 1.0%), Western Ontario-McMaster Osteoarthritis Scale (WOMAC) stiffness scores (absolute percent change 0.1%) and WOMAC function scores (absolute percent change 0.9%) after 12 months. Evidence of an effect on health-related quality of life scores (absolute percent change 1.0%) was lacking in one study (n = 179, moderate-quality evidence). Data for the comparison of laterally wedged insole versus valgus knee brace could not be pooled. After six months' follow-up, no statistically significant difference was noted in VAS pain scores (absolute percent change -2.0%) and WOMAC function scores (absolute percent change 0.1%) in one study (n = 91, low-quality evidence); however, both groups showed improvement. Authors conclude that the optimal choice for an orthotic remains unclear and long-term results are lacking.

Wagner and Luna (2018) investigated the effects of footwear, including shoe inserts, in reducing lower extremity joint pain and improving gait, mobility, and quality of life in older adults with OA. Participants who were 50 years or older and those who had OA in at least one lower extremity joint narrowed the results. The initial search resulted in a total of 417 citations. Eleven articles met inclusion criteria. Authors conclude that because of the limited number of randomized control trials, it is not possible to make a definitive conclusion about the long-term effects of footwear on lower extremity joint pain caused by OA. There is mounting evidence that shock-absorbing insoles, subtalar strapping, and avoidance of high heels and sandals early in life may prevent lower extremity joint pain in older adults, but no conclusive evidence exists to show that lateral wedge insoles will provide long-term relief from knee joint pain and improved mobility in older adults with OA. More high-quality randomized control trials are needed to study the effectiveness of footwear and shoe inserts on joint pain and function in older adults with OA.

Zafar et al. (2020) investigated the effectiveness of insoles for knee osteoarthritis and provide future areas of research to help better define treatment guidelines. Foot orthoses are an example of non-pharmacological conservative treatments mentioned in National Institute for Health and Care Excellence (NICE) guidelines to treat knee osteoarthritis (OA). These include lateral wedge insoles (LWI), developed with the intention of load reduction of the knee. Different footwear has also been shown to affect pain, biomechanical and functional outcomes in knee OA patients. Thirty-four out of 226 papers were included after application of inclusion and exclusion criteria. Results also showed that insoles work in correcting the position of the knee, but it may or may not affect patients' pain and function. Ferreira et al. (2021) sought to determine if lateral wedge insoles adjusted by biomechanical analysis improve the condition of patients with medial knee osteoarthritis. A total of 38 patients with medial knee osteoarthritis were allocated to either an experimental group (lateral wedge insoles) or a control group (neutral insoles). The experimental group (n = 20) received an adjusted lateral wedge insole of 2, 4, 6, 8, or 10 degrees, after previous biomechanical analysis. The control group (n = 18) received a neutral insole (0 degrees). All patients used the insoles for 12 weeks. After 12 weeks, between-group differences did not differ significantly for pain intensity, biomechanical parameters, Knee Injury and Osteoarthritis Outcome Score, and physical performance tests, except on the Knee Injury and Osteoarthritis Outcome Score subscale Authors concluded tailored wedge insoles were no more effective at improving biomechanical or clinically meaningful outcomes than neutral insoles, except on symptoms. More participants from the experimental group reported they felt some improvement. However, these effects were minimal and without clinical significance.

Bartsch et al. (2022) investigated the impact of varus malalignment of the knee on pain reduction achieved by an ankle-foot orthosis and a laterally wedged insole in patients with medial knee osteoarthritis. Twenty-eight participants with medial knee osteoarthritis. All participants wore a 5-mm laterally wedged insole and an ankle-foot orthosis for a period of 6 weeks each in a randomized order. Pain was reported on a numerical rating scale and was correlated with limb alignment, as defined by the mechanical axis deviation in full-leg standing radiographs. Insole and orthosis use reduced pain compared with baseline. A higher mechanical axis deviation (greater varus) correlated significantly with smaller pain reduction for both aids (insole $p = 0.003$, orthosis $p < 0.001$). A cut-off to predict pain response was found at a mechanical axis deviation of 14-15 mm for both aids, i.e. > 3° knee varus. Authors concluded that there is a correlation between varus malalignment and pain reduction. There seems to be a mechanical axis deviation cut-off that predicts the response to treatment with the aids with good sensitivity.

<u>Patellofemoral Pain Syndrome (PFPS) and Anterior Knee Pain and Orthotic Use</u>

A Cochrane Review by Hossain et al. (2011) assessed the effects of foot orthoses for managing PFPS in adults. RCTs and quasi-randomized clinical studies comparing foot orthoses with flat insoles or other physical therapy intervention were included. Primary outcomes were knee pain and knee function. Two trials with a total of 210 participants were included. One trial found that foot orthoses had reduced pain at 6 weeks but not at one year follow up. The orthoses group also complained of more minor adverse events as well. The evidence did not provide compelling support for the use of orthotics for management of PFPS over other interventions.

Barton et al. (2011) conducted an interesting study attempting to define preliminary clinical predictors for when foot orthoses would be efficacious for patients with PFPS. Sixty (60) individuals with PFPS were given non-custom, prefabricated foot orthoses with a 4° rearfoot varus wedge. At 12 weeks, levels of improvement were documented along with other measures. Fourteen (14) patients (25%) reported marked improvement. When the following were included, 78% of all patients reported marked improvement: footwear motion control property score of <5.0 (meaning they wear less supportive footwear), usual pain <22.0 mm, dorsiflexion ROM with knee flexed <41°, and reduced single leg squat pain when wearing orthoses. Thus, it appears that by identification of these four (4) factors, a stronger prediction of the helpfulness of orthotics can be assumed.

Collins et al. (2012) conducted a systematic review and meta-analysis evaluating the evidence for conservative management of PFPS. Of the 48 studies identified, 27 had low to moderate risk of bias and were included. Meta-analysis of the highest quality of studies demonstrated that a multi-modal approach, without biofeedback, for 6 weeks is appropriate for management of PFPS. Individual intervention data supported the use of foot orthoses with and without multi-modal physical therapy vs. flat inserts. They suggest that practitioners begin with a multi-modal approach and add foot orthotics if improvement is not noted.

Mills et al. (2012) performed an RCT of the short-term efficacy of in-shoe orthotics. They also evaluated the impact of foot mobility on results. Forty (40) patients diagnosed with anterior knee pain of greater than 6 weeks who had never used orthotics in the previous 5 years participated in the study. Subjects were able to choose between orthotics of 3 different firmness values based on comfort. At 6 weeks foot orthoses produced a significant global improvement compared with the control group. Measures of function also showed significant improvement over the control group as well. When analyzing foot mobility, patients with noted changes in midfoot width from non-weight bearing to weight bearing were more likely to report a successful outcome.

Collins et al. (2018) developed consensus statements using best practice methods. This consensus statement, from the 5th International Patellofemoral Research Retreat held in Australia in July 2017, focuses on exercise therapy and physical interventions (e.g., orthoses, taping and manual therapy) for patellofemoral pain. Recommendations from the expert panel support the use of exercise therapy (especially the combination of hip-focused and knee-focused exercises), combined interventions and foot orthoses to improve pain and/or function in people with patellofemoral pain. The use of patellofemoral, knee or lumbar mobilisations in isolation, or electrophysical agents, is not recommended. There is uncertainty regarding the use of patellar taping/bracing, acupuncture/dry needling, manual soft tissue techniques, blood flow restriction training and gait retraining in patients with patellofemoral pain. Callaghan et al. (2021) investigated what treatments impacted patellofemoral joint osteoarthritis (PFJOA). Eleven studies were identified which included assessment of either patellar taping, or foot orthotics, knee bracing or combined physiotherapy treatments. A randomized trial of a foot orthotic showed a non-significant improvement in pain after 6 weeks with a between groups adjusted mean difference for maximum VAS of 21.9 mm and 8.1 for KOOS pain. Long-term effects of all interventions are still unknown, which indicates the need for further research to determine the longer-term impact of all biomechanical devices on outcomes in symptomatic PFJOA.

Kayll et al. (2023) evaluated the effects of biomechanical foot-based interventions (e.g., footwear, insoles, taping and bracing on the foot) on patellofemoral loads during walking, running or walking and running combined in adults with and without patellofemoral pain or osteoarthritis. Authors identified 22 footwear and 11 insole studies (participant n=578). Pooled analyses indicated low-certainty evidence that minimalist footwear leads to a small reduction in peak patellofemoral joint loads compared with conventional footwear during running only. Low-certainty evidence indicated that medial support insoles do not alter patellofemoral joint loads during walking or running. Very low-certainty evidence indicated rocker-soled shoes have no effect on patellofemoral joint loads during walking and running combined. Authors concluded that minimalist footwear may reduce peak patellofemoral joint loads slightly compared with conventional footwear during running only. Medial support insoles may not alter patellofemoral joint loads during walking or running and the evidence is very uncertain about the effect of rocker-soled shoes during walking and running combined. Clinicians aiming to reduce patellofemoral joint loads during running in people with patellofemoral pain or osteoarthritis may consider minimalist footwear. Alexander et al. (2023) evaluated the effectiveness of interventions to prevent and manage knee injuries in runners in a systematic review and meta-analysis. Thirty RCTs (18 prevention, 12 management) analyzed multiple interventions in novice and recreational running populations. Low-certainty evidence indicated that running technique retraining (to land softer) reduced the risk of knee injury compared with control treadmill running. Very low-certainty to low-certainty evidence from 17 other prevention trials indicated that various footwear options, multicomponent exercise therapy, graduated running programs and online and in person injury prevention education programs did not influence knee injury risk. In runners with patellofemoral pain, very low-certainty to low-certainty evidence indicated that running technique retraining strategies, medial-wedged foot orthoses, multicomponent exercise therapy and osteopathic manipulation can reduce knee pain in the short-term. Authors concluded that there was low-certainty evidence that running technique retraining to land softer may reduce knee injury risk by two-thirds. Very low-certainty to low-certainty evidence suggests that running-related patellofemoral pain may be effectively managed through a variety of active (e.g., running technique retraining, multicomponent exercise therapy) and passive interventions (e.g., foot orthoses, osteopathic manipulation).

Knee Ligament Injury and Orthotics

In a study by Jenkins et al. (2008), the relationship of foot orthoses uses, and anterior cruciate ligament (ACL) injury was explored in women basketball players. Given the high prevalence of ACL injury in women athletes, any potential influences for prevention of injury should be explored. One hundred and fifty-five (155) players were observed for ACL and other ligament injury from 1992-2005. Certain groups of athletes (based on years of participation) did not receive foot orthoses and served as a control group. The treatment group included athletes who participated in the remaining years. These athletes received orthotics to wear during the basketball season. Data analysis included knee ligament injury rates and comparison of rates among groups. Athletes in the control group had three collateral injuries and three ACL injuries. Athletes in the treatment group had four collateral injuries and one ACL injury. Thus, athletes in the control group were 1.72 times more likely to sustain a collateral injury and 7.14 times more likely to experience an ACL injury than the treatment group. Thus, foot orthotics may play a role in preventing ACL injury in female collegiate basketball players.

Jenkins and Raedeke (2006) also studied the use of foot orthotics in women's basketball and their effect on lower extremity (LE) injury. One hundred and thirty-two (132) female athletes were observed for LE injury between 1993 and 2004. Groups were established based on the same methodology as the previous study. Data analysis included LE overuse injury rates and effect of foot orthotics on these rates. The control group had a LE injury rate of 5.37 per 1,000 exposures and the orthotic group had a rate of 6.44 per 1,000 exposures. The incidence ratio was not significantly different between groups. This study rejected the idea that foot orthotics can assist with prevention of LE injury in female basketball players.

Plantar Fasciitis (PF) and Orthotics

Gross et al. (2002) studied the impact of semi-rigid customized orthotics on pain and disability for patients with plantar fasciitis. Fifteen (15) subjects with PF participated in the study. Pre and post measures suggest that semi-rigid custom orthotics may significantly reduce pain with walking and also reduce more global measures of pain and disability for patients with PF. Cole et al. (2005) reviewed the literature and determined that of all interventions for plantar fasciitis, shoe inserts, stretching exercises, steroid injections, and custom-made night splints may all be beneficial. In a study by Roos et al. (2006), 43 patients (34 women and nine men) diagnosed with PF were randomized to receive foot orthoses and night splints, or just night splints alone. Some patients were lost to drop out, but results for 34 subjects indicated that at 12 weeks, pain reduction was 30-50% improved from baseline. All outcome measures improved significantly as well. At 52 weeks, 38 subjects indicated continued improved outcomes and pain reduction of 62% for the orthotic group compared to 48% for the night splint only group. At 12 months, the majority of subjects were still using the orthotics, while only one subject was using the night splint. Authors suggested that both interventions are effective in the short and long term, but that compliance is better with fewer side effects for the orthotic group. Thus, orthotics may be the better initial treatment method for patients with PF.

In another study looking at the effectiveness of foot orthoses to treat PF, Landorf et al. (2006) attempted to improve study design by performing an RCT of 135 subjects with PF. Subjects were allocated to one of three groups; sham orthoses, prefabricated orthoses, or customized orthoses. After 3 months of treatment, pain and function were more positively improved with the prefabricated and custom orthotics; however only pain reduction was significantly improved. At 12 months, there were no significant differences between groups. Thus, orthotics may provide short term pain relief and small benefits in function. It also appears that customized and prefabricated orthoses have similar results.

Chia et al. (2009) wanted to look at differences in foot pressure patterns between orthotics, bone spur pads and flat insoles in patients with chronic plantar fasciitis. Thirty (30) subjects with unilateral plantar fasciitis (PF) participated in this study. Both feet were examined for contact pressures and pressure distribution patterns while standing in shoes, customized and prefabricated orthotics, bone spur pads and with flat insoles. The asymptomatic foot was used as a control. Contact pressures were higher for the asymptomatic side due to unequal weight bearing. Bone spur pads were ineffective in reducing rearfoot pressure, while prefabricated and customized orthotics reduced peak rearfoot pressures significantly and may be useful in distributing pressure uniformly over the rearfoot region.

Drake et al. (2011) sought to identify the short-term effectiveness of custom orthotics and stretching for the treatment of plantar fasciitis. Fifteen (15) patients with PF received a custom orthotic and were instructed to wear it for 2 weeks while weight bearing. After two weeks, they were weaned off it. Primary outcome measures were assessed at 2, 4, and 12 weeks. They concluded that use of a custom orthotic in the short term followed by stretching can improve function in patients with PF.

Crawford and Thomson (2003) updated a 2000 Cochrane Review on interventions for plantar heel pain. RCTs and quasi-randomized trials were included. Nineteen (19) trials were included which corresponded to 1626 subjects. Overall, trial quality was poor, and pooling of data was impossible due to heterogeneity. Heel pain was the primary outcome measured. Only 7 trials evaluated the interventions against a control group (placebo or no treatment). Results showed that limited evidence existed for iontophoresis, more evidence existed for cortisone injections. For chronic pain, evidence existed for the use of dorsiflexion night splints for reducing pain. Limited evidence did support the use of orthotics as well and when comparing orthotics to cortisone injections, the evidence was too limited to draw any conclusions. It does appear that there is limited evidence that stretching exercises and heel pads produce better results than custom orthotics for patients who stand longer than 8 hours a day. An important consensus of this review is that well designed RCTs are required to confirm results and state which interventions are most effective. A meta-analysis and comparative trial examined the effectiveness of foot orthotics in patients with plantar fasciitis and found that prefabricated and custom foot orthotics can decrease rear foot pain and improve foot function. (Lee et al., 2009; Chia et al., 2009) Lee et al. (2009) performed a meta-analysis examining the effects of foot orthoses on self-reported pain and function in patients with plantar fasciitis. The meta-analysis results showed significant reductions in pain and significant increases in function after orthotic intervention. The authors concluded that the use of foot orthoses in patients with plantar fasciitis appears to be associated with reduced pain and increased function. A Cochrane review found that custom foot orthotics may not reduce foot pain any more than prefabricated foot orthotics, but that when custom foot orthotics are used in conjunction with a night splint, patients may get heel pain relief. (Hawke et al., 2008).

A cross-over study design by Van Lunen et al. (2011) studied the immediate effects of heel-pain orthosis and augmented low-dye taping on plantar pressures and pain in subjects with PF while walking and jogging. Seventeen (17) subjects with PF participated in the study. Plantar pressures and pain were assessed in three conditions; control, taping, and orthosis after 45 seconds of walking and jogging. Both taping and orthosis use reduced pressures and pain significantly during walking and jogging compared to the control group. Further research is needed to determine long term effect of these interventions.

Coheña-Jiménez et al. (2021) sought to determine the clinical results of custom-made foot orthoses versus placebo flat cushioning insoles combined with an extracorporeal shock wave therapy on pain and foot functionality in patients with plantar fasciitis. Patients with plantar fasciitis were randomly assigned to either group A (n = 42), which received custom-made foot orthoses, or group B (n = 41), which received placebo insoles. All the participants received active extracorporeal shock wave therapy including stretching exercises. The main outcome was foot pain, measured by visual analogue scale and the secondary outcome measures were recorded by Roles and Maudsley scores respectively, at the beginning and at one week, one month and six months. Eighty-eight patients were assessed for eligibility. Eighty-three patients were recruited and randomized. This study showed significant differences between both groups according to the visual analogue scale at one and six months. Authors concluded that wearing a custom-made foot orthosis leads to an improvement in patients with plantar fasciitis; it reduced foot pain and improved foot functionality.

Heel Pain and Inserts

Bonanno et al. (2011) wanted to determine the mechanism behind the effectiveness of heel inserts for treatment of plantar heel pain in the older population. The purpose of their study was to investigate whether foot orthoses and heel inserts affect plantar pressures in older adults with heel pain. Thirty-six (36) older adults were subjects for the study. Five different conditions were tested during walking: wearing a standardized shoe, shoe with silicon heel cup, shoe with soft foam heel pad, shoe with heel lift, and shoe with prefabricated orthotic. Statistically significant reductions of heel pressures occurred in 3 of the 4 conditions with shoe inserts. The largest reduction was noted in the prefabricated orthotic (fivefold reduction in heel pressure), with an increase in midfoot contact area, which resulted in a greater distribution of forces. Thus, this was considered the most effective insert for this population. McGinnis and Stubbs (2011) completed a recent Cochrane Review on the treatment of heel pressure ulcers with various pressure relieving devices. Heel pressure ulcers can develop readily in patients with vascular compromise, and these ulcers require special attention due to the impact on function. Only one study met criteria for inclusion. This study, with 141 patients, compared two mattress systems and no heel devices. Too many losses to-follow-up occurred, thus no conclusions could be gained. Authors concluded more research is needed in this area. In a dated paper by Nichols (1989), heel lifts are discussed as a conservative intervention for Achilles tendinitis, along with relative rest, gastrocnemius-soleus rehabilitation, cryotherapy, nonsteroidal anti-inflammatory drugs, and correction of biomechanical abnormalities. No newer studies were found to support this summary.

Whittaker et al. (2018) investigated the effectiveness of foot orthoses for pain and function in adults with plantar heel pain. A total of 19 trials (1660 participants) were included. In the short term, there was very low-quality evidence that foot orthoses do not reduce pain or improve function. In the medium term, there was moderate-quality evidence that foot orthoses were more effective than sham foot orthoses at reducing pain. There was no improvement in function in the medium term. In the longer term, there was very low-quality evidence that foot orthoses do not reduce pain or improve function. A comparison of customized and prefabricated foot orthoses showed no difference at any time point. Authors concluded that there is moderate-quality evidence that foot orthoses are effective at reducing pain in the medium term, however it is uncertain whether this is a clinically important change. Rasenberg et al. (2018) investigated the effects of different orthoses on pain, function, and self-reported recovery in patients with PHP and compare them with other conservative interventions. Twenty studies investigating eight different types of foot orthoses were included in the review. Most studies were of high quality. Authors concluded that foot orthoses are not superior for improving pain and function compared with sham or other conservative treatment in patients with PHP.

Tran and Spyr (2019) reviewed the comparative clinical and cost effectiveness of custom-made foot orthoses versus prefabricated foot orthoses for patients requiring a foot orthotics. The evidence showed no difference between custom-made and prefabricated foot orthoses for pain reduction or functional improvement after short-term (6 weeks), medium-term (12 weeks) and long-term (12 months) treatment in adult patients with plantar heel pain. There was also no difference between interventions for short-term self-reported recovery and patient satisfaction. Evidence on comfort was mixed. Morrissey et al. (2021) developed a best practice guide for managing people with plantar heel pain (PHP). Fifty-one eligible trials enrolled 4351 participants, with 9 RCTs suitable to determine proof of efficacy for 10 interventions. Forty people with PHP completed the online survey and 14 experts were interviewed resulting in 7 themes and 38 subthemes. Authors concluded that best practice from a mixed-methods study synthesizing systematic review with expert opinion and patient feedback suggests core treatment for people with PHP should include taping, stretching and individualized education. Patients who do not optimally improve may be offered shockwave therapy, followed by custom orthoses.

Harutaichun et al. (2023) aimed to determine the effects of heat molded custom foot orthoses (CFOs) on foot and lower limb kinematics when compared with prefabricated foot orthoses (PFOs) and wearing no orthoses (shod condition), and to determine the short-term effects of CFOs on pain intensity and foot function. The immediate effects of CFOs on the lower limb and multi-segment foot motion were assessed. Participants were then asked to use the CFOs for one month and foot pain, function, and temporal-spatial parameters were assessed at baseline and at one month follow up. Thirty-five participants (22 females), aged 40.1 (10.5) years, with a mean duration of symptoms of 12.59 months were recruited. The symptomatic limbs showed a higher forefoot varus angle and greater rearfoot and forefoot corrections were required compared to the non-symptomatic limbs. When compared with PFOs and shod conditions, CFOs provided the least forefoot and knee motion in the transverse plane during contact phase, least rearfoot motion in the coronal plane during midstance, and least forefoot motion in the frontal plane, knee motion in the transverse plane, and hallux motion during the propulsive phase. Significant improvements were seen for foot pain and function with significant increases in cadence and walking velocity after one month of CFO use, and those most likely to respond had greater pain and less ankle eversion. Authors concluded that CFOs appear to improve pathological biomechanics associated with plantar heel pain. After one month follow up, the CFOs decreased pain intensity and increased foot function, and showed significant improvements in temporal and spatial parameters of gait.

Pes Planus and Inserts

In a study by Wenger et al. (1989) the use of corrective shoes and inserts for flexible flatfoot in infants and children was evaluated. One hundred and twenty-nine (129) children were randomly assigned to four groups: control, corrective orthopedic shoes, heel cup, and custom molded inserts. After three years of treatment, 98 patients remained compliant, and their data was used in analysis. Radiographic analysis showed no significant differences between groups, including the control group. Thus, it appears that the course of flexible flatfoot in infants is not affected by use of corrective shoes or inserts. A Cochrane review by Evans and Rome (2011) identified the evidence for non-surgical interventions for flexible pediatric flat feet. Flat feet typically reduce as a child ages and few have been found to be symptomatic. No standardized framework has been identified to evaluate the pediatric flat foot and it is often unnecessarily treated. Currently management is determined according to age, flexibility, pain, gender, weight and joint hypermobility. When foot orthoses are indicated, inexpensive generic, over the counter inserts will work. Customized orthotics should be reserved for children with foot pain and arthritis, deformity or for those who are unresponsive. Authors suggest that there is a need for standardized assessment and management with focus on the best available evidence. Further research on the effects of shoes and inserts is warranted. Dars et al. (2017) updated the current evidence base for the effectiveness of foot orthotics (FOs) for paediatric flexible pes planus. Out of 606 articles identified, 11 studies (three RCTs; two case-controls; five case-series and one single case study) met the inclusion criteria. A diverse range of pre-fabricated and customised FOs were utilised and effectiveness measured through a plethora of outcomes. Summarised findings from the heterogeneous evidence base indicated that FOs may have a positive impact across a range of outcomes including pain, foot posture, gait, function and structural and kinetic measures. Despite these consistent positive outcomes reported in several studies, the current evidence base lacks clarity and uniformity in terms of diagnostic criteria, interventions delivered and outcomes measured for paediatric flexible pes planus. Authors concluded that there continues to remain uncertainty on the effectiveness of FOs for paediatric flexible pes planus. Despite a number of methodological limitations, FOs show potential as a treatment method for children with flexible pes planus. Herchenröder et al. (2021) synthesized the evidence of foot orthoses for adults with flatfoot. A total of 110 studies were identified through the database search. 12 studies met the inclusion criteria and were included in the review. These studies investigated prefabricated and custom-made foot orthoses, evaluating stance and plantar pressure during gait. The sample sizes of the identified studies ranged from 8 to 80. In most of the studies, the methodological quality was low and a lack of information was frequently detected. Authors concluded there is a lack of evidence on the effect of foot orthoses for flatfoot in adults. This review illustrates the importance of conducting randomized controlled trials and the comprehensive development of guidelines for the prescription of foot orthoses. Given the weak evidence available, the common prescription of foot orthoses is somewhat surprising.

Evans et al. (2022) assessed the benefits and harms of foot orthoses for treating paediatric flat feet. Authors identified all randomised controlled trials (RCTs) of FOs as an intervention for paediatric flat feet. The outcomes included in this review were pain, function, quality of life, treatment success, and adverse events. Intended comparisons were: any FOs versus sham, any FOs versus shoes, customised FOs (CFOs) versus prefabricated FOs (PFOs). They included 16 trials with 1058 children, aged 11 months to 19 years, with flexible flat feet. Distinct flat foot presentations included asymptomatic, juvenile idiopathic arthritis (JIA), symptomatic and developmental co-ordination disorder (DCD). The trial interventions were FOs, footwear, foot and rehabilitative exercises, and neuromuscular electrical stimulation (NMES). Due to heterogeneity, we did not pool the data. Most trials had potential for selection, performance, detection, and selective reporting bias. No trial blinded participants. The certainty of evidence was very low to low, downgraded for bias, imprecision, and indirectness. Three comparisons were evaluated across trials: CFO versus shoes; PFO versus shoes; CFO versus PFO. Asymptomatic flat feet 1. CFOs versus shoes (1 trial, 106 participants): low-quality evidence showed that CFOs result in little or no difference in the proportion without pain (10-point visual analogue scale (VAS)) at one year; absolute decrease; or on withdrawals due to adverse events; absolute effect. 2. PFOs versus shoes (1 trial, 106 participants): low to very-low quality evidence showed that PFOs result in little or no difference in the proportion without pain (10-point VAS) at one year; absolute effect; or on withdrawals due to adverse events. 3. CFOs versus PFOs (1 trial, 108 participants): low-quality evidence found no difference in the proportion without pain at one year; absolute effect; or on withdrawal due to adverse events. Function and quality of life (QoL) were not assessed. Symptomatic (JIA) flat feet 1. CFOs versus shoes (1 trial, 28 participants, 3-month follow-up): very low-quality evidence showed little or no difference in pain (0 to 10 scale, 0 no pain) between groups (MD -1.5, 95% CI -2.78 to -0.22). Low-quality evidence showed improvements in function with CFOs (Foot Function Index - FFI disability, 0 to 100, 0 best function; MD -18.55, 95% CI -34.42 to -2.68), child-rated QoL (PedsQL, 0 to 100, 100 best quality; MD 12.1, 95% CI -1.6 to 25.8) and parent-rated QoL

(PedsQL MD 9, 95% CI -4.1 to 22.1) and little or no difference between groups in treatment success (timed walking; MD -1.33 seconds, 95% CI -2.77 to 0.11), or withdrawals due to adverse events (RR 0.58, 95% CI 0.11 to 2.94); absolute difference (9.7% fewer, 20.5 % fewer to 44.8% more). 2. PFOs versus shoes (1 trial, 25 participants, 3-month follow-up): very low-quality evidence showed little or no difference in pain between groups (MD 0.02, 95% CI -1.94 to 1.98). Low-quality evidence showed no difference between groups in function, child-rated QoL, or parent-rated QoL. 3. CFOs versus PFsO (2 trials, 87 participants): low-quality evidence showed little or no difference between groups in pain (0 to scale, 0 no pain) at 3 months, function, child-rated QoL, or parent-rated QoL. Authors concluded that low to very low-certainty evidence shows that the effect of CFOs (high cost) or PFOs (low cost) versus shoes, and CFOs versus PFOs on pain, function and HRQoL is uncertain. This is pertinent for clinical practice, given the economic disparity between CFOs and PFOs. FOs may improve pain and function, versus shoes in children with JIA, with minimal delineation between costly CFOs and generic PFOs. This review updates that from 2010, confirming that in the absence of pain, the use of high-cost CFOs for healthy children with flexible flat feet has no supporting evidence, and draws very limited conclusions about FOs for treating paediatric flat feet. The availability of normative and prospective foot development data, dismisses most flat foot concerns, and negates continued attention to this topic.

According to Barry and Pille (2023) customized or prefabricated foot orthoses do not result in significant improvements in pain, function, or parent and child quality-of-life scores. Importantly, quality-of-life scores were not reported in patients who were asymptomatic. There is a need for further targeted studies to identify the clinical utility of foot orthoses in children with flat feet that are associated with underlying conditions; however, asymptomatic flat feet in children should not be routinely treated.1 (Strength of Recommendation: C, consensus, disease-oriented evidence, usual practice, expert opinion, or case series.) Oerlemans et al. (2023) examined the effectiveness of orthoses for flexible flatfeet in terms of patient-reported outcomes in children and adults in a systematic review and meta-analysis. In total nine studies were included: four RCT in children (N = 353) and four RCT and one prospective study in adults (N = 268) were included. There was considerable heterogeneity between studies. A meta-analysis demonstrated that pain reduction between baseline and follow-up was significantly larger in the orthoses (N = 167) than in the control groups in adults. Authors concluded that due to heterogeneity in study designs, we cannot conclude that foot orthoses are useful for flexible flatfoot in children and adults. However, based on the meta-analysis orthoses might be useful in decreasing pain in adults. The authors did not receive support from any organization for the submitted work.

<u>Rheumatic Arthritis (RA)/Juvenile Idiopathic Arthritis (JIA)</u>

JIA is a condition that can affect the gait and function of children. Powell et al. (2005) examined the efficacy of different orthotics, shoe inserts and shoes for this condition. Forty children with JIA and foot pain were randomized into one of three groups: custom made semi-rigid orthotics with shock absorbers, off-the-shelf flat neoprene shoe inserts, and supportive athletic shoes with arch support and shock absorption qualities. Subjects were assessed by blinded personnel for pain, timed walking, foot function index, and physical functioning subscale of the Pediatric Quality of Life Inventory. Results demonstrated that children in the orthotics group showed a significantly greater improvement in pain, ambulation speed, activity limitations, and level of disability when compared to the two other groups. Parents and children also reported clinically meaningful improvement in quality of life, though not statistically significant. Supportive athletic shoes or off-the-shelf shoe inserts did not report significant changes in measures except for pain. The authors concluded that children with JIA with foot pain may benefit from customized semi-rigid foot orthotics to improve pain, increase gait speed, and improve activity and functional levels compared to prefabricated orthotics, shoe inserts, and athletic shoes.

Foot orthoses have been prescribed for patients with RA who experience foot pain. Given the limited evidence to support this intervention, Clark et al. (2006) sought to review the present state of the literature to determine efficacy of foot orthoses for these patients. Authors suggest there is no consensus of opinion on the type of foot orthoses for management of foot pain in the patient with RA. However, the literature does provide high evidence for a reduction of pain and improvement of functional ability when orthoses are used. Overall, given the small sample sizes and lack of valid or reliable outcomes, further research is necessary to confirm results and determine efficacy.

A Cochrane Review by Hawke et al. (2008) discussed the use of custom foot orthoses for the treatment of foot pain. Because customized orthotics are often prescribed for patients with foot pain, it is important to synthesize the evidence of their effectiveness for different types of foot pain. As is typical for Cochrane Reviews, RCTs and controlled clinical trials were evaluated. Outcomes included foot pain, function, disability, quality of life, satisfaction, adverse events, and compliance. Eleven (11) trials consisting of 1,332 subjects were included. Foot pain conditions included plantar fasciitis (PF) (691 participants), rheumatoid arthritis (RA) foot pain (231 participants), pes cavus (154 participants), juvenile idiopathic arthritis (JIA) (147 participants), and hallux valgus (209 participants). Comparisons to customized orthoses were made against sham orthoses, no intervention, standard intervention, prefabricated orthoses, manipulation/mobilization and stretching, night splints and surgery. Follow up periods ranged from one week to three years. Results demonstrated that customized foot orthotics were effective for pes cavus, rearfoot pain RA, JIA foot pain, and painful hallux valgus. Surgery was more effective for hallux valgus. Prefabricated orthotics appeared to be as effective for JIA as customized orthotics, but study quality was lacking. No conclusions could be made about whether custom orthoses were effective for PF of metatarsophalangeal joint pain in RA. Overall, customized orthoses were safe to use.

Chang et al. (2012) suggest that use of materials that have memory properties can be effective for reducing the pain of metatarsalgia in patients with RA. Insoles are used to redistribute forces under the heads of the metatarsals, which can relieve pain. Often, typical insoles are not effective due to the deformities that are present in patients with RA. Chang and his team developed dynamic insoles that use sequential foam padding and are customized under successive walking, which causes impressions. Seventeen (17) patients participated in the study. Pain and plantar pressures were evaluated. Results demonstrated that peak and mean pressures across the metatarsal heads were reduced significantly in the dynamic insoles. Heel pressures were not reduced significantly. Pain scores were also reduced for the dynamic insole group.

In a review of custom foot orthoses for RA, Hennessy et al. (2012) critically appraised the evidence regarding the effectiveness of custom foot and ankle orthoses for patients with RA. Meta-analyses were conducted for outcome domains with multiple RCTs. The inclusion criteria were met by 17 studies. Two studies had high quality for internal validity and 3 studies had high quality for external validity. No study had high quality for both internal and external validity. There was weak evidence for custom orthoses reducing pain and forefoot plantar pressures. Evidence was inconclusive for foot function, walking speed, gait parameters, and reducing hallux abductovalgus angle progression. Authors concluded that custom orthoses may be beneficial in reducing pain and elevated forefoot plantar pressures in the rheumatoid foot and ankle. However, more definitive research is needed in this area. Conceição et al. (2015) completed a systematic review and meta-analysis of effects of foot orthoses (FO) on pain and disability in rheumatoid arthritis patients. Three studies, involving 110 patients who received FO and 108 control patients, met the study criteria. Relative to controls, FO had a positive impact on pain. Between group differences in disability were not statistically significant. Authors concluded that FO may improve pain in RA patients, but their impact on disability remains undetermined. Additional large RCTs are needed to investigate the effects of these devices in RA patients.

Frecklington et al. (2017) conducted a literature review on the effectiveness of footwear on foot pain, function, impairment and disability for people with foot and ankle arthritis. 1440 studies were identified for screening with 11 studies included in the review. Mean (range) quality scores were 67% (39-96%). The majority of studies investigated rheumatoid arthritis (n = 7), but also included gout (n = 2), and 1st metatarsophalangeal joint osteoarthritis (n = 2). Meta-analysis and GRADE assessment were not deemed appropriate based on methodological variation. Footwear interventions included off-the-shelf footwear, therapeutic footwear and therapeutic footwear with foot orthoses. Key footwear characteristics included cushioning and a wide toe box for rheumatoid arthritis; cushioning, midsole stability and a rocker-sole for gout; and a rocker-sole for 1st metatarsophalangeal joint osteoarthritis. Footwear interventions were associated with reductions in foot pain, impairment and disability for people with rheumatoid arthritis. Between group differences were more likely to be observed in studies with shorter follow-up periods in people with rheumatoid arthritis (12 weeks). Footwear interventions improved foot pain, function and disability in people with gout and foot pain and function in 1st metatarsophalangeal joint osteoarthritis. Footwear interventions were associated with changes to plantar pressure in people with rheumatoid arthritis, gout and 1st metatarsophalangeal joint osteoarthritis and walking velocity in people with rheumatoid arthritis and gout. Authors concluded that footwear interventions are associated with reductions in foot pain, impairment and disability in people with rheumatoid arthritis, improvements to foot pain, function and disability in people with gout and improvements to foot pain and function in people with 1st metatarsophalangeal joint osteoarthritis. Footwear interventions have been shown to reduce plantar pressure rheumatoid arthritis, gout and 1st metatarsophalangeal joint osteoarthritis and improve walking velocity in rheumatoid arthritis and gout.

Gijon-Nogueron et al. (2018) sought to determine the effectiveness of foot orthoses in patients with rheumatoid arthritis (RA), in comparison with other treatments, in terms of enhanced disability and reduced pain. A systematic review and meta-analysis was conducted of a number of randomised controlled trials focusing on patients with RA. Of the initial 118 studies considered, 5 were included in the final systematic review and meta-analysis. These five studies had enrolled a total of 301 participants, with follow-up periods ranging from 4 to 36 months. Although the use of orthoses seems to alleviate foot pain, our meta-analysis did not reveal statistically significant differences between control and intervention groups regarding long- and short-term pain relief and/or reduced disability. Authors concluded that foot orthoses can relieve pain and disability and enhance patients, but no significant differences were found between control and intervention groups.

Tenten-Diepenmaat et al. (2019) summarized the comparative effectiveness of FOs in the treatment of various foot problems in patients with rheumatoid arthritis, on the primary outcomes foot function and foot pain, and the secondary outcomes physical functioning, health related quality of life, compliance, adverse events, the costs of FOs and patient satisfaction. Studies comparing different kinds of FOs, with a presumed therapeutic effect, in the treatment of foot problems related to rheumatoid arthritis were included. Ten studies were identified, with a total number of 235 patients. These studies made a comparison between different materials used (soft versus semi-rigid), types of FOs (custom-made versus ready-made; total-contact versus non-total contact), or modifications applied (metatarsal bars versus domes). Also, different techniques to construct custom-made FOs were compared (standard custom-molding techniques versus more sophisticated techniques). A medium effect for (immediate) reduction of forefoot plantar pressure was found in favor of treatment with soft FOs compared to semi-rigid FOs. Other comparisons between FOs resulted in non-significant effects or inconclusive evidence for one kind of FOs over the other. Authors concluded that foot orthoses made of soft materials may lead to more (immediate) forefoot plantar pressure reduction compared to foot orthoses constructed of semi-rigid materials. Definitive high quality RCTs, with adequate sample sizes and long-term follow-up, are needed to investigate the comparative (cost-) effectiveness of different kinds of foot orthoses for the treatment of foot problems related to rheumatoid arthritis. Reina-Bueno et al. (2019) sought to determine the effect of custom-made foot orthoses versus placebo insoles on pain, disability, foot functionality, and quality of life. Patients were randomly assigned to either group A, which received custom-made foot orthoses, or group B, which received placebo, flat cushioning insoles, for three months. The primary outcome was foot pain, measured by visual analog scale. Foot functionality, foot-related disability, and quality of life were measured using the Foot Function Index, the Manchester Foot Pain and Disability Index, and 12-Item Short Form Health Survey (SF-12) questionnaires, respectively, at the beginning and at days 30, 60, and 90. A total of 53 patients, aged 59.21 ± 11.38 years, received either the custom-made foot orthoses (N = 28) or the placebo (N = 25). For the analysis of the data, only participants who had been measured at the four time points (0, 30, 60, and 90 days) were included. In group A, all variables showed statistically significant differences when comparing the initial and final measurements. Pain showed 6.61 ± 2.33 and 4.11 ± 2.66 in group A, at baseline and at 90 days, respectively, and Group B showed 6.16 ± 1.77 and 5.60 ± 2.71 at baseline and at 90 days, respectively. This was the only variable that showed statistically significant difference between groups (P = 0.048). Authors concluded that the custom-made foot orthoses significantly reduced the participants' foot pain, although they did not have positive effects on disability, foot functionality, and quality of life compared with only cushioning.

Gaino et al. (2021) compared balance, foot function and mobility in patients with rheumatoid arthritis with and without foot orthoses. A total of 94 subjects with rheumatoid arthritis were randomized; of these, 81 were included in the analyses (Intervention group: 40; Control group: 41). The Intervention Group received custom-made foot orthoses while the Control Group received no intervention. Measures assessed at baseline and after 4 weeks included the "Foot Function Index," the "Berg Balance Scale," and the "Timed-up-and-go Test". Authors concluded that foot orthoses improved foot function and balance in patients with rheumatoid arthritis.

Brosseau et al. (2016) created evidence-based guidelines evaluating foot care interventions for the management of juvenile idiopathic arthritis (JIA). The Ottawa Panel selection criteria targeted studies that assessed foot care or foot orthotic interventions for the management of JIA in those aged 0 to ≤18 years. Authors concluded that the use of customized foot orthotics and prefabricated shoe inserts seems to be a good choice for managing foot pain and function in JIA. Fellas et al. (2022) investigated the effect of customized preformed foot orthoses on pain, quality of life, swollen and tender lower joints and foot and ankle disability in children with JIA. Pain was the primary outcome and was followed up to 12 months post intervention. Secondary outcomes include quality of life, foot and ankle disability and swollen and tender joints. A linear mixed model was used to assess the impact of the intervention at each time point. Sixty-six participants were recruited. Child-reported pain was reduced statistically and clinically significant at 4 weeks and 3 months post intervention in favour of the trial group. Statistical significance was not reached at 6 and 12-month follow-ups. Quality of life and foot and ankle disability were not statistically significant at any follow-up; however, tender midfoot and ankle joints were significantly reduced 6 months post intervention. Authors concluded that results of this clinical trial indicate customized preformed foot orthoses can be effective in reducing pain and tender joints in children with JIA exhibiting foot and ankle symptoms. Long-term efficacy of foot orthoses remains unclear. Overall, the trial intervention was safe, inexpensive and well tolerated by paediatric patients. Fellas et al. (2022) also sought to understand whether customised preformed FOs are effective in improving gait parameters in children with JIA. A multicentre, parallel design, single-blinded randomised clinical trial was used to assess the gait impacts of customised preformed FOs on children with JIA. Children with a diagnosis of JIA, exhibiting lower limb symptoms and aged 5-18 were eligible. The trial group received a low-density full length, Slimflex Simple device which was customised chair side and the control group received a sham device. Peak pressure and pressure time integrals were used as the main gait outcomes and were measured using portable Tekscan gait analysis technology at baseline, 3 and 6 months. Differences at each follow-up were assessed using the Wilcoxon rank sum test. 66 participants were recruited. Customised preformed FOs were effective in altering plantar pressures in children with JIA versus a control device. Reductions of peak pressures and pressure time integrals in the heel, forefoot and 5th metatarsophalangeal joint were statistically significant in favour of the trial group. This was associated with statistically significant increased midfoot contact with the trial device at baseline, 3 and 6-month data collections. The trial intervention was safe and well accepted by participants, which is reflected in the high retention rate (92%).

Chronic Non-Cancer Pain (includes many of the conditions above)

Banerjee and Butcher (2020) reviewed the clinical effectiveness of customized or prefabricated shoe inserts for chronic, non-cancer pain. There are a variety of chronic pain conditions such as chronic back pain, chronic neck pain, chronic tension headache, and chronic arthritic pain. Chronic pain can affect various parts of the body such as the lower back, upper back, knee, leg, feet, shoulder, neck, and hip. Lower back pain appears to be the most predominant type, accounting for more than one-third of those suffering from chronic pain. There are several non-pharmacological treatment options available for chronic pain such as exercise, multidisciplinary rehabilitation, psychological therapies, and physical modalities. Foot orthotics are one example of a non-pharmacological treatment option for chronic pain and include custom-made shoe inserts or prefabricated shoe inserts (with a treatment intent). These inserts are intended to support or align foot structures or to prevent or correct foot deformities, and can be of various types such as soft, semi-rigid, and rigid. Foot orthotics have been used for the management of chronic pain, in individuals with various conditions such as rheumatoid arthritis and low back pain., However, there appears to be some uncertainty with respect to its effectiveness in improving pain and disability. This report is an upgrade from a recent (published in 2020) CADTH Reference List report and with additional restrictions with respect to inclusion criteria. The purpose of the current report was to summarize and critically appraise the relevant evidence identified in the previous report regarding the clinical effectiveness of customized foot orthotics or prefabricated shoe inserts (with a therapeutic intent) for chronic non-cancer pain. Key findings included the following:

- There were inconsistencies regarding the effectiveness of foot orthoses compared with control (standard insole, placebo, or none) in alleviating pain in adult patients with foot pain based on findings from three systematic reviews and two randomized controlled trials (RCTs); reported results from these studies included statistically significant improvements in pain with foot orthoses compared to control (one systematic review, and two RCTs), no statistically significant between group difference (one systematic review) and inconsistent findings for between group differences (one systematic review describing studies individually).
- There were inconsistencies regarding the effectiveness of foot orthoses compared with control (standard insole, placebo, or none) in improving function in adult patients with foot pain based on findings from two systematic reviews and one RCT; reported results from these studies included a statistically significant improvement with foot orthoses compared to control (one RCT) and no statistically significant between group differences (two systematic reviews and one RCT).
- Limited evidence (one RCT) showed improvement in pain and function with foot orthoses compared to no foot orthoses, in adult patients with chronic low back pain.

Findings need to be interpreted with caution considering the limitations (such as unclear or variable quality of included studies, small sample size and overlap of studies included in the systematic reviews). No studies were identified that compared treatments with foot orthoses with pharmacological treatments for non-cancer pain in adults.

Hurn et al. (2022) conducted a systematic review and meta-analysis investigating the effectiveness of nonsurgical interventions for hallux valgus (HV). Eighteen included studies investigated a wide range of nonsurgical interventions for HV. Most studies had small sample sizes and concerns regarding risk of bias. Five separate meta-analyses for foot orthoses, splints, manual therapy, and taping added to foot exercises showed no significant effects on primary outcomes. However, results from 8 studies showed a significant pain reduction with the use of foot orthoses, night splints, dynamic splints, manual therapy, taping added to foot exercises, a multifaceted physical therapy program, and Botox injections. Four studies reported a clinically significant reduction in HV angle with night splints, foot exercises, multifaceted physical therapy, and Botox injections. Authors concluded that there is a low level of certainty surrounding the effectiveness of nonsurgical interventions for HV, but a reduction in pain appears more likely than improvement in HV angle.

Pires Neves et al. (2022) performed a systematic review to investigate the effects of foot orthoses on pain and the prevention of lower limb injuries in runners. Twelve studies (5321 runners) met our review criteria. The control and the foot orthoses group sustained 721 (37%) and 238 (24%) injuries, respectively. Compared with the control group, the use of foot orthoses resulted in a significant reduction in lower limb injury risk. Moreover, the foot orthoses group corresponded to a 40% reduction in the risk of developing lower limb injuries. Authors concluded that the use of foot orthoses may help reduce the incidence of lower limb injuries and pain in runners.

Hunter et al. (2023) aimed to determine if medially-posted foot orthoses immediately reduce hip abduction moment (HAM) and pain in females with Greater trochanteric pain syndrome (GTPS), including gluteal tendinopathy and bursitis during walking gait. A double-blind, repeated-measures trial with randomized intervention order compared three conditions in 53 women with GTPS. Participants acted as their own control during baseline (everyday-shoe insole), medially-posted (active) orthosis, or flat insert (sham orthosis) walking. Data were collected via three-dimensional gait analysis for HAM, hip, pelvic, and thorax kinematics; as well as ground reaction force; and pain via the numerical rating scale. Subgroup analysis was performed based on a pronated foot-posture defined by the Foot Posture Index. A small pain reduction was found between the active orthosis and flat insert. No difference was detected for pain between other condition comparisons. Thoracic lateral flexion increased at second-peak HAM between the baseline and active conditions. No differences were detected for HAM, remaining kinematic or kinetic variables, or ground reaction force data across the three conditions. No significant differences were detected between any of the three conditions for biomechanical or pain data in the pronated-foot subgroup. Authors concluded that a medially-posted foot orthosis did not immediately alter gait biomechanics or provide a clinically meaningful pain reduction in women with GTPS. There is uncertainty regarding the clinical benefit of orthoses in the management of GTPS. Longer-term follow-up or the use of customized orthoses may produce different outcomes and should be explored in future research.

Diabetic Foot Ulcers and Orthotics

Diabetic foot ulcers are a serious issue and have many functional implications. Spencer (2000) completed a Cochrane Systematic Review on the pressure-relieving interventions used for preventing or treating these foot ulcers. Five (5) total RCTs met the inclusion criteria: 4 for prevention and 1 for treatment. The studies for prevention of foot ulcers suggested that in-shoe orthotics are beneficial as a sole intervention when comparing different types of orthotics, and as compared to removal of the callus. They could not conclude whether it was the cushioning or the pressure re-distribution that provided the positive outcomes, as the data indicated equality of the two. Many other pressure-relieving methods (e.g., removable casts or foam inlays) have not been investigated adequately. For the one study on treatment of ulcers, contact casting indicated positive results, but evidence was limited. More research is needed to effectively demonstrate appropriate treatment interventions for the diabetic foot ulcer. Chevalier and Chockalingam (2012) examined the role of the practitioner in foot orthoses effectiveness. They emphasize that while foot orthoses have been shown to have positive effects in the literature for various lower extremity issues, the literature is of variable quality and outcomes. The exact mechanisms of orthotic use are not fully understood but seem to relate to reducing plantar pressure and changing biomechanics of the foot and knee. Added into this is practitioner variability in the assessment of orthoses performance. Eleven practitioners participated in this study. Each completed a clinical assessment of one subject and then created custom orthotics based on that assessment and casting in a neutral non-weight bearing position. Each subject completed ten trials (i.e., ten walks over force plates wearing each of the custom orthotics made by each of the eleven practitioners). Kinetic and kinematic data were recorded for each trial. Results demonstrated that systematic kinematic effects could be observed for the kinematic data in the sagittal plane for forefoot to hindfoot and hindfoot to tibia peak angles. This confirmed for the authors that inter-practitioner variability is a major factor in orthotic intervention for patients with various conditions. They suggest that caution be taken when considering the literature where customized orthotics are used as an intervention based on the practitioner variability noted in this study, where clinical assessments vastly differ for the same patient. Evidence in the published scientific literature does not demonstrate a clear advantage of one treatment over another. Experts generally recommend that conservative therapy should be tried first, and over-the-counter arch supports, and heel pads should be tried for most patients prior to the use of custom-fabricated devices.

Bus et al. (2015) systematically reviewed footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in patients with diabetes. Authors reviewed both controlled and non-controlled studies. They included two systematic reviews and meta-analyses, 32 randomized controlled trials, 15 other controlled studies, and another 127 non-controlled studies. Sufficient evidence of good quality supports the use of non-removable offloading to heal plantar neuropathic forefoot ulcers and therapeutic footwear with demonstrated pressure relief that is worn by the patient to prevent plantar foot ulcer recurrence. The evidence base to support the use of other offloading interventions is still limited and of variable quality. The evidence for the use of interventions to prevent a first foot ulcer or heal ischemic, infected, non-plantar, or proximal foot ulcers is basically non-existent. High-quality controlled studies are needed in these areas.

Ahmed et al. (2020) aimed to summarize and evaluate the evidence for footwear and insole features that reduce pathological plantar pressures and the occurrence of diabetic neuropathy ulceration at the plantar forefoot in people with diabetic neuropathy.Twenty-five studies were reviewed. This involved a total of 2063 participants. Eleven studies investigated footwear, and 14 studies investigated insoles as an intervention. Six studies investigated ulcer recurrence; no study investigated the first occurrence of ulceration. The most commonly examined outcome measures were peak plantar pressure, pressure-time integral and total contact area. Methodological quality varied. Strong evidence existed for rocker soles to reduce peak plantar pressure. Moderate evidence existed for custom insoles to offload forefoot plantar pressure. There was weak evidence that insole contact area influenced plantar pressure. Authors concluded that rocker soles, custom-made insoles with metatarsal additions and a high degree of contact between the insole and foot reduce plantar pressures in a manner that may reduce ulcer occurrence. Most studies rely on reduction in plantar pressure measures as an outcome, rather than the occurrence of ulceration. There is limited evidence to inform footwear and insole interventions and prescription in this population. Further high-quality studies in this field are required.

Kaminski et al. (2022) aimed to systematically identify and adapt suitable international guidelines to the Australian context to create new Australian evidence-based guidelines on prevention of first-ever and/or recurrent diabetes-related foot ulceration (DFU). Relative to these guidelines, Recommendation 8 was adopted and states: Consider prescribing orthotic interventions, such as toe silicone or (semi-)rigid orthotic devices, to help reduce abundant callus in a person with diabetes who is at risk for foot ulceration. Moon et al. (2023) concluded that, based on the literature, to prevent diabetic foot ulcers, practitioners should regularly screen patients for the presence of neuropathy as well as neuroarthropathies and prescribe the appropriate shoes and orthotics based on the best available clinical evidence. Although not widely available, there is potential for data-driven customization of orthotics and shoe wear based on plantar pressure data to prevent the development of diabetic foot ulcers more effectively, and ultimately prevent lower limb amputations.

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education, training, and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

It is best practice for the practitioner to appropriately render services to a member only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the member to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* policy for information.

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