Clinical Practice Guideline: **Lower Extremity Orthoses (Knee, Ankle and Foot Orthotics)**

Date of Implementation: **December 20, 2012**

Product: **Specialty**

POLICY

American Specialty Health – Specialty (ASH) clinical committees have determined that the following uses of lower extremity orthoses are professionally recognized, safe and established as clinically effective:

- Foot orthotics in the management of plantar fasciitis; [Note: see the *Custom-Fabricated Foot Orthotics* **(***CPG 186 – S)* clinical practice guideline for medical necessity criteria]
- The use of Ankle-Foot-Orthoses (AFOs) for improvement of gait function in support of the management of patients with foot drop or spasticity;
- Ankle orthotics for the treatment of acute ankle injuries, for rehabilitation after the initial injury, and to prevent re-injury.

The following uses of lower extremity orthoses are professionally recognized and safe, however, additional studies are needed before the clinical effectiveness can be established. A trial period using lower extremity orthoses for patients unresponsive to other established treatments may be clinically appropriate for:

- Foot orthotics for the treatment and management of patellofemoral pain syndrome;
- Foot orthotics for the treatment and management of osteoarthritis;
- Foot orthotics for the treatment and management of patients with foot pain in juvenile idiopathic arthritis; [Note: see the *Custom-Fabricated Foot Orthotics* **(***CPG 186 – S)* clinical practice guideline for medical necessity criteria]
- Knee braces for patellofemoral pain;

Although professionally recognized and safe, the scientific literature is inconclusive regarding the clinical efficacy for the following uses and a trial of care is not supported by the available evidence:

- Foot orthotics in asymptomatic persons for the prevention of musculoskeletal pain syndrome;
- Knee braces for the prevention of injury.
- Foot orthotics for the treatment of low back pain.

The use of knee braces in post surgical rehabilitation lacks scientific literature to establish clinical efficacy. However, their use is safe and the current standard of care as supported by the American Academy of Orthopedic Surgeons (AAOS).

To CQT for review 10/17/16
CQT reviewed 10/16/17
To QIC for review and approval 11/01/16
QIC reviewed and approved 11/01/16
To QOC for review and approval 11/17/16
QOC reviewed and approved 11/17/16

Other supporting resources and documentation include the following:

- *Orthotic Training and Evaluation – CPG 152 – S*
- *Strapping and Taping – CPG 143 – S*
- *Custom-Fabricated Foot Orthotics – CPG 186 - S*

PROCESS AND DEFINITIONS

When developing, reviewing, and approving clinical policy, ASH peer-review committees consider whether the technique/procedure:

- Is established as clinically effective by:
    - Scientific information published in an acceptable peer-reviewed clinical science resource, and
    - The consensus opinion of the Evidence Evaluation Committee (EEC) when available;
- Is professionally recognized by:
    - Inclusion in the educational standards accepted by the majority of the professions' educational institutions,
    - Wide acceptance and use of the practice, and
    - Recommendations for use made by healthcare practitioners practicing in the relevant clinical area;
- Poses a health and safety risk; and
- Is plausible or implausible
    - A belief, theory, or mechanism of health and disease that can be explained within the existing framework of scientific methods, reasoning, and available knowledge is considered plausible.
    - A treatment intervention or diagnostic procedure that requires the existence of forces, mechanisms, or biological processes that are not known to exist within the current framework of scientific methods, reasoning and available knowledge is considered implausible.

Substitution harm (indirect harm): Compromised clinical outcomes caused by:

- Utilizing a specific diagnostic or therapeutic procedure when the safety, clinical effectiveness, or diagnostic utility is either unknown or is known to be unsafe, ineffective, or of no diagnostic utility, *instead of* a diagnostic or therapeutic procedure known to be safe, be clinically effective, or to have diagnostic utility; or
- The utilization of a diagnostic or therapeutic procedure that is substantially less effective or safe than another procedure with established safety, and clinical effectiveness or utility.

Labeling effects (non-specific harm): The harm that results from identifying in a patient a condition or a finding that is not clinically valid.

Safe: The terms "safe" and "safety," are used only with specific reference to the absence of direct harm. Direct harm would include any injury to a patient caused by the mechanical, thermal, biological, chemical, pharmacological, electrical, electromagnetic, or psycho-dynamic properties of a diagnostic or therapeutic procedure, and as such, the procedure would be considered unsafe.

Direct harm: Any injury to a patient caused by the mechanical, thermal, biological, chemical, pharmacological, electrical, electromagnetic, or psycho-dynamic properties of a diagnostic or therapeutic procedure.

Benefit versus risk profile: The relative effectiveness or utility of a therapeutic intervention or diagnostic procedure versus its potential for direct harm.

- Positive (benefits outweigh risks),
- Negative (risks outweigh benefits), or
- Equivocal (available information is inconclusive).

INTRODUCTION

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. Functional devices realign or assist the neuromuscular system by providing dynamic or static support. Static orthoses are rigid and are used to support severe weakness or paralysis of a body part or parts [e.g., ankle-foot orthosis (AFO) for a patient with hemiplegia]. Dynamic orthoses are used to facilitate movement to allow function.

Orthoses are typically named by anatomic region, such as foot, ankle, ankle-foot, and knee-foot-ankle orthoses. Foot orthoses refer to devices that are placed in shoes. Ankle orthoses are supportive in nature, and may be used to provide immobilization. AFOs have a shoe insert component as well as an ankle component. The knee-foot-ankle orthoses (KAFO) add a knee component to the AFO. AFOs and KAFOs are for neurologic patients that have weakness or paralysis of lower extremity musculature.

Other terms that may be used relative to orthoses are splints and braces. A splint is defined as an appliance for preventing movement of joints. A brace is defined as a rigid or semi-rigid device, orthosis or appliance that supports or holds a joint in a corrected position and/or restricts motion in certain directions. It can be used to allow function while restricting movement in directions that could potentially re-injure aspects of the joint.

Some orthoses are pre-fabricated but can be trimmed or molded to accommodate the patient. Other orthoses are custom-fabricated and are made specifically for the individual and their special biomechanical issues. Development of these custom products requires considerable labor. Typically, an unmodified, pre-fabricated orthosis is used initially and if results are poor, a pre-fabricated, modified or custom type is selected.

Foot Orthotics

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. Most patients with these conditions can safely wear properly-fitted commercial shoes. Pre-fabricated 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.

Ankle Orthotics

An ankle orthotic is a type of orthotic used in treating acute ankle injuries such as a sprain, for rehabilitation after the initial injury and to prevent re-injury of the ankle. They are also used to treat chronically unstable ankles although the literature has not supported the efficacy of ankle orthotics in this area. Ankle orthotic options include lightweight sports plastics/Velcro models, hinged devices, lace-up devices, neoprene sleeves, ankle wraps and taping, braces, various types of casts, stabilizing shoes and air stirrups.

Ankle-Foot Orthotics

An AFO extends well above the ankle to the top of the calf. It requires fastening at the lower leg, just above the ankle. This device may be used for ambulatory patients with weakness or deformity of the foot and ankle, which also require stabilization for medical reasons and when the patient has the potential to benefit functionally from use of the device. Commonly, AFOs are used to treat disorders including but not limited to ankle dorsiflexion, plantar flexion, inversion and eversion, spastic displegia due to cerebral palsy, lower motor neuron weakness due to poliomyelitis and spastic hemiplegia in cerebral infarction. Certain neurologic and muscle control conditions such as stroke, neoplasms, hemiplegia, cerebral palsy, myelomeningocele and atrophic or dystrophic conditions may produce lower extremity spasticity or hyperactivity of muscles, hypotonicity of certain muscles and neuromuscular imbalances. Gait functioning, balance and foot/ankle positioning may be impacted. Custom-fitted and custom-molded foot orthoses and ankle-foot orthoses (AFOs) are used in ambulatory patients to control or correct foot joints, counteract internal deforming forces, compensate for weakness, correct or eliminate pathologic positioning, improve balance, improve gait functioning and reduce excessive plantar flexion.

Knee Orthoses

Knee braces are designed to resist abnormal motions, augment the mechanical stability of the knee, and assist in the recovery and rehabilitation of an injured knee (France & Paulos, 1994). Knee braces may also be indicated to prevent future injury in an unstable knee. The braces are rigid or semi-rigid to provide support for the injured knee, or restrict or eliminate motion from the injured knee. A variety of materials are used in knee braces, along with the implementation of hinges and straps.

There are four types of knee braces that have been referenced in the literature. Prophylactic knee braces are designed to prevent or reduce the severity of an injury. This type of brace is often used to protect the medial collateral ligament (MCL) from valgus stresses, and the anterior cruciate ligament (ACL) from rotational stresses. Functional knee braces are often referred to as derotational braces. Their main function is to reduce risk of injury by preventing excessive loading, while maintaining normal range of motion (ROM). Rehabilitative knee braces are designed to control flexion-extension during the initial healing period after ligament or meniscal surgery, or reconstruction surgery. They are designed to allow controlled motion, and the ROM can be adjusted as the healing process progresses. Unloading/Offloading knee braces are used in the treatment of moderate to severe osteoarthritis of the knee, to decrease pain and disability.

Another type of brace is the patellofemoral knee brace, or knee sleeve. These braces are used for patellar subluxation, dislocation, or patellar hypermobility. Plan knee sleeves are also used to treat postoperative knee swelling, and patellofemoral pain syndrome.

REVIEW OF THE LITERATURE

Healthy Runners and Orthotics

It is important to have an understanding of the actual influence orthotics may have on healthy subject's lower extremity kinematics and kinetics to fully understand how they may help with injured individuals. MacLean et al. (2006) used three-dimensional analysis to collect kinetic and kinematic data while running in shoes alone or shoes plus custom foot orthotics. Fifteen (15) female runners participated in the study. Kinematic and kinetic data from the lower extremity were analyzed for each of the above two conditions as subjects performed five over-the-ground running trials. Results demonstrated that while wearing the custom orthotics, subjects significantly reduced their peak rearfoot eversion angles and velocity, as well as their internal moment for ankle inversion. It is unknown whether these biomechanical changes actually equate to something positive or negative from a clinical standpoint. Further research is needed to elucidate these findings.

Thus, MacLean et al. (2008) performed another study looking at the short and long term influences of custom foot orthotics on lower extremity dynamics of a group of female runners with a history of overuse injury in the previous 6 months. Each subject was fit for custom orthotics and wore them for all running activities for 6 weeks. Three-dimensional kinematic and kinetic data were collected while subjects ran over-ground with and without orthotics. Data were collected before and after the 6 week intervention. Immediate changes were noted in ankle dynamics. Significant decreases in peak values were noted for rearfoot eversion angle and velocity (as previously noted), impact peak and loading rate. Ankle inversion impulse was also significantly reduced during loading. At the knee, maximum external rotation moment significantly increased with orthotics. At 6 weeks, subjects noted a significant decrease in pain and an improvement in symptoms. Thus, authors conclude that orthotics have the potential to change kinematics and kinetics of the ankle but how these relate to reduction of symptoms is unclear and needs further study.

There is also some data demonstrating that orthotics help coordinate intralimb joint coupling variability of the lower extremity during running, which may influence injury. MacLean et al. (2010) analyzed the influence of custom foot orthotics on lower extremity intralimb coupling during running in injured runners with shoes only and shoes plus orthotics compared to healthy runners using only shoes. Three-dimensional kinematics data was collected during a 30 minute run. Results demonstrated that coordination variability and coupling patterns were impacted by history of injury, orthotics, and run duration. Authors concluded that injured runners may benefit from orthotics to improve or maintain coordination variability of the tibia and calcaneus during early stance phase. However, similar to other results, more studies are needed to confirm this and to understand the mechanism behind the relationship between injury and changes in kinematics due to orthotics.

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 pre-fabricated 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.

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.

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).

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, 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.

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 down stairs 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.

Patellofemoral Pain Syndrome (PFPS) and Anterior Knee Pain and Orthotic Use
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, pre-fabricated 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 a 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.

Knee Ligament Injury and Orthotics

In a study by Jenkins et al. (2008), the relationship of foot orthoses use 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 a RCT of 135 subjects with PF. Subjects were allocated to one of three groups; sham orthoses, pre-fabricated orthoses, or customized orthoses. After 3 months of treatment, pain and function were more positively improved with the pre-fabricated 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 pre-fabricated 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 pre-fabricated 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 pre-fabricated 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) 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.

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 pre-fabricated orthotic. Statistically significant reductions of heel pressures occurred in 3 of the 4 conditions with shoe inserts. The largest reduction was noted in the pre-fabricated 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.

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.

Rheumatic Arthritis (RA)/Juvenile Idiopathic Arthritis (JIA)

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 pre-fabricated 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, pre-fabricated 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. Pre-fabricated 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.

Stroke and Ankle-Foot Orthoses (AFO)

AFO braces are used for patients with foot drop due to hemiplegia or other neurologic issues. Determination of whether an AFO is the best treatment option has yet to be determined. Van Swigchem et al. (2012) looked at use of an AFO compared to peroneal muscle stimulation during gait with and without an orthotic device. During activities of daily living, often individuals encounter obstacles during walking. For someone with foot drop, these can be dangerous experiences that can lead to falls. This study aimed to identify which intervention is more beneficial with respect to the ability to negotiate a sudden obstacle. Twenty-four (24) community dwelling individuals with hemiplegia post stroke participated in the study. These subjects used AFO bracing consistently. All twenty-four (24) were fitted with a functional electrical stimulation (FES) device. Obstacle avoidance ability was tested after 2 and 8 weeks. Thirty (30) obstacles needed to be avoided during a treadmill walk. These objects were dropped in front of the affected foot while walking on the treadmill with the AFO and then repeated with the FES. Obstacle avoidance rates were calculated for each device. Success rates for avoidance were significantly higher among the twenty-four (24) participants when they used FES compared to when they were wearing the AFO; this was emphasized further when normalized for muscle strength of the lower extremity.

Another study looked at the effects of dynamic AFOs in chronic stroke patients. Erel et al. (2011) completed a RCT with 3 month follow up looking at the long and short term effects of AFO use on function of patients with hemiparesis. Twenty-eight (28) patients with chronic hemiparesis were randomly assigned to a study or control group. The control group wore tennis shoes and the study group wore the dynamic AFO after an initial assessment with tennis shoes. For the initial assessment both groups had no differences between outcome measures. After 3 months of AFO use, the subjects were retested. Timed Up Stairs, gait velocity and physiologic cost index (measure of effort), showed significant differences in favor of the study group. Functional reach and Timed Up and Go and Timed Down Stairs did not show differences. Thus, patients with chronic hemiparesis may benefit from using a dynamic AFO.

Tyson and Kent (2013) sought to determine the effectiveness of an AFO on mobility, walking and balance in people with stroke. Randomized controlled trials of AFOs in people with stroke, which measured balance, walking impairments, or mobility and were reported in English, were selected. Thirteen trials with 334 participants were selected. The effect of an AFO on walking activity (P=.000-.001), walking impairment (P=.02), and balance (weight distribution) (P=.003) was significant and beneficial. The effect on postural sway (P=.10) and timed mobility tests (P=.07-.09) was non-significant, and the effect on functional balance was mixed. The selected trials were all crossover trials of the immediate effects; long-term effects are unexplored. Authors concluded that an AFO can improve walking and balance after stroke, but only the immediate effects have been examined. The effects and acceptability of long-term usage need to be evaluated. Tyson et al.(2013) systematically reviewed the evidence on the effects of an AFO on gait biomechanics after stroke. Controlled trials of an ankle-foot orthosis on gait biomechanics in stroke survivors were identified. Twenty trials involving 314 participants were selected. An ankle-foot orthosis had a positive effect on ankle kinematics ($P < 0.00001$-0.0002); knee kinematics in stance phase ($P < 0.0001$-0.01); kinetics ($P = 0.0001$) and energy cost ($P = 0.004$), but not on knee kinematics in swing phase ($P = 0.84$), hip kinematics ($P < 0.18$-0.89) or energy expenditure ($P = 0.43$). There were insufficient data for pooled analysis of individual joint moments, muscle activity or spasticity. All trials, except one, evaluated immediate effects only. Authors concluded that an ankle-foot orthosis can improve the ankle and knee kinematics, kinetics and energy cost of walking in stroke survivors.

Orthotic Management in Cerebral Palsy (CP)

AFOs have long been used for children with spastic CP to assist with gait and function. Taking this a step further, Bahramizadeh et al. (2012) studied whether a specific floor reaction type AFO (FRATO) would actually assist postural control in children with spastic CP. A quasi-experimental design was used to test eight children with spastic CP against eight matched control subjects. Posture control was assessed with and without the brace in a standing position. Centers of pressure (CoP) were measured; standard deviations (SDs) were included as an indication of excursion from center. The greater the lack of postural control, the higher the standard deviation. Velocities of these SDs were also analyzed. It appeared from the data that postural control was not significantly different between groups and therefore the FRATOs did not affect postural control. The authors did note that maximum knee extension was affected by the brace and could potentially positively affect alignment of the knee.

Morris et al. (2011) published a result from an international consensus conference with regards to orthotic management of cerebral palsy. Participants reviewed the evidence and considered how these patients are treated on a day to day basis. They determined that many of the papers were of low quality. Of interest is that substantial evidence suggests AFOs which control the ankle and foot within the gait pattern allow for a more efficient gait in those children who are ambulatory. Minimal evidence exists for the use of hip, spine, or upper limb orthoses. Overall the extent to which orthoses may prevent further deformity was not established. Sees and Miller (2013) reviewed foot deformities and in children with CP and treatments. Authors state that treatment for the young children should be primarily with orthotics and manual therapy. Equinus is the most common deformity, with orthotics augmented with botulinum toxin being the primary management in young children. Varus deformity of the feet is often associated with equinus, and can almost always be managed with orthotics until 8 or 10 years of age. Planovalgus is the most common deformity in children with bilateral lower extremity spasticity. The primary management is orthotics until the child no longer tolerates the orthotic; then surgical management needs to consider all the deformities and all should be corrected.

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. 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.

Achilles Rupture and AFO

Given changes and advances in the care and immediate weight bearing status of Achilles tendon rupture, Kearney et al. (2011) wanted to investigate the effects of an AFO with varying heel wedges and how the results may impact management of these injuries. AFOs and heel wedges are now being used for these immediate weight bearing protocols. Researchers evaluated the plantar pressures and gait parameters on 15 healthy participants using 3 different AFOs with 4 different levels of heel wedges inserted into the AFO. Therefore, a total of 12 conditions were evaluated (randomly sequenced). Results demonstrated that AFOs with a higher number of inserted heel wedges reduced forefoot pressures, increased heel pressures, and also the time spent in terminal stance pre-swing phases of the gait cycle. These results should be considered when determining weight bearing and loading of an Achilles tendon rupture and use of an AFO with heel wedges.

Lastly, related to many of the previous studies, 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.

Knee Orthoses

Pietrosimone et al. (2008) looked at the relative risk reduction with the use of prophylactic knee braces in the prevention of knee injuries in collegiate football players. They were able to identify seven studies that met their criteria. The number of participants and frequency of knee injuries were used to calculate the relative risk reduction or increase. They found a relative risk reduction in 3 studies, but a relative increased risk of injury in 4 studies. Their findings were inconsistent due to the flaws in methodology of many of the studies. Due to the nature of the study, it is not possible to blind the participant of the athletic trainer from the intervention. Most of the studies did not assign the players randomly, and players with previous injuries were assigned the prophylactic brace. The braces used also varied, sometimes using different models within the same study. The authors concluded that they could not recommend or discourage the use of prophylactic knee braces. They also acknowledged the possibility that the knee braces may increase the risk of injury. Rishiraj et al. (2009) reviewed the literature and also concluded that the research on the prophylactic brace is limited. This is due to the lack of non-injured athletes using the brace for fear of decreased performance.

McDevitt et al. (2004) conducted a prospective, randomized, multicenter clinical trial to determine whether postoperative functional knee bracing is effective. They assigned one hundred volunteers from the 3 US service academies with ACL injuries into the braced or non-braced groups. Surgical procedures and postoperative physical therapy were identical. There were no statistically significant differences between groups in the different outcome measures at a minimum 2 year follow-up. Two braced subjects had re-injuries and three non-braced subjects had re-injuries. Bodendorfer et al. (2013) reviewed the literature on anterior cruciate ligament bracing in providing stability and preventing injury or graft re-rupture. Despite widespread use of prophylactic and functional knee braces, the evidence supporting their efficacy in reducing and/or preventing injury remains limited. Knee braces have been shown to be more effective in preventing medial collateral ligament injuries than anterior cruciate ligament injuries in both cadaveric and clinical studies. The use of functional braces after anterior cruciate ligament reconstruction has been supported and refuted in both postoperative and long-term studies.

Rishiraj et al. (2012) studied single leg peak vertical ground reaction forces (PVGRF) in 23 healthy male students while wearing a functional knee brace during a drop jump, as compared to not wearing the knee brace. There was a significant decrease in the PVGRF in the braced group. The authors concluded that the brace could keep GRF low enough from reaching the ACL and causing a tear.

There is little published data supporting the use of rehabilitative braces but they are accepted clinically, and avoid the risks associated with casting. The American Academy of Orthopedic Surgeons (AAOS) has noted in its position statement that rehabilitative braces used in the early post-surgical phase following ACL reconstruction may provide some benefit (2003).

Rannou et al. (2010) reviewed the literature on unloading knee braces and recommended their use for decreasing pain and improving function. The AAOS also concludes that some unloading knee braces may provide significant reduction in pain for patients if they are fitted correctly. Steadman et al. (2014) reviewed the current state of unloading braces on knee mechanics, clinical impact and long term disease progression. Authors concluded that despite the significant research that has been done to show improvement in OA symptoms with unloading brace use, current literature shows an existing debate on the effectiveness of these braces to change biomechanics of the knee and thus affect disease progression.

However, clinical findings show overall improvements in pain, function, instability and quality of life.

.Duivenvoorden et al. (2015) updated an earlier Cochrane review on braces and orthoses for treating osteoarthritis of the knee. Authors concluded that evidence was inconclusive for the benefits of bracing for pain, stiffness, function and quality of life in the treatment of patients with medial compartment knee OA. Low-quality evidence shows lack of an effect on improvement in pain, stiffness and function between patients treated with a valgus knee brace. Moyer et al. (2015) completed a meta-analysis of randomized trials on the effects of valgus knee bracing on pain and function, and compliance and complications, in patients with medial knee osteoarthritis (OA). Six studies met criteria and were included in the meta-analysis. Overall, there was a statistically significant difference favoring the valgus brace group for improvement in pain. When compared to a control group that did not use an orthosis, the effect size was moderate for pain and function. When compared to a control group that used a control orthosis, only a small, statistically significant effect for pain remained Compliance ranged from 45% to 100%. Up to 25% of patients reported minor complications with brace use. Meta-analysis of randomized trials suggests valgus bracing for medial knee OA results in small-to-moderate improvements in pain.

A Cochrane Review by D'hondt et al. (2002) on orthotic devices for treating patellofemoral pain found the evidence too limited to draw any definite conclusions. One trial did show that a Protonics orthosis was significantly more effective at decreasing pain at six weeks when compared to no treatment. Dixit et al. (2007) reported that there was little evidence to support the use of knee braces in patellofemoral pain, and better outcomes were produced with physical therapy.

SUMMARY

In general, pre-fabricated and customized orthotics demonstrate some effectiveness for reduction of PFPS, ACL injury, mild to moderate OA, JIA and RA metatarsalgia, and PF. The mechanism behind their effectiveness is not completely understood but reduction of plantar pressures and biomechanical changes may be implicated. Heel lifts do not appear to be effective for treatment of heel pain or ulcers but are still used for conservative treatment of achilles tendinitis. AFOs are helpful for improving gait and function for patients with hemiplegia post stroke and for children with spastic CP.

Prophylactic knee braces are often recommended for athletes but there is no clear supporting evidence. There may be a risk of increased injury. There is little evidence to support the use of functional knee braces to prevent re-injury. There is little evidence supporting the use of rehabilitative knee braces but they have been clinically accepted. While there is limited evidence on the benefit of unloading knee braces, they also have been clinically accepted. Lastly, there is limited evidence in support of patellofemoral knee braces, or knee sleeves, in the treatment of patellar subluxation, postsurgical knee effusion, and patellofemoral pain syndrome.

Lower Extremity Orthoses Conclusions

- The use of foot orthotics is effective for the treatment and management of plantar fasciitis.
- The use of AFOs is effective for improvement of gait function in support of the management of patients with foot drop or spasticity.
- The scientific literature supports the use of ankle orthotics for the treatment of acute ankle injuries, for rehabilitation after the initial injury, and to prevent re-injury
- The scientific literature supports the use of foot orthotics for the treatment and management of patellofemoral pain syndrome and for osteoarthritis.
- The scientific literature supports the use of foot orthotics for the treatment and management of patients with foot pain in juvenile idiopathic arthritis.
- The scientific literature is inconclusive regarding the use of foot orthotics in healthy runners with a history of injury.
- The scientific literature is inconclusive regarding the use of foot orthotics in the treatment of low back pain.
- The scientific literature is inconclusive regarding the use of foot orthotics in asymptomatic persons for the prevention of musculoskeletal pain syndrome.
- The literature is inconclusive regarding the relative effectiveness of customized vs. prefabricated foot orthotics but suggests no difference.
- The scientific literature is inconclusive regarding the use of prophylactic knee braces.
- The scientific literature provides limited support for the use of knee braces for patellofemoral pain syndrome.
- There is no scientific literature for the use of rehabilitative knee braces used in the early post-surgical stage but it is the current standard of care based on the AAOS position statement.

Documentation Requirements to Substantiate Medical Necessity

"Medically necessary" or "medical necessity" shall mean health care services that a healthcare practitioner/provider, exercising prudent clinical judgment, would provide to a patient for the purpose of evaluating, diagnosing, or treating an illness, injury, disease or its symptoms, and that are (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and considered effective for the patient's illness, injury, or disease; and (c) not primarily for the convenience of the patient or healthcare provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury, or disease.

The patient's medical records should document the practitioner's clinical rationale for using the specific orthoses, as well as the patient's response.

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.

It is best practice for the practitioner to appropriately render services to a patient 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 expert training, it would be best practice to refer the patient 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, 2013).

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 policy *Managing Medical Emergencies in a Health Care Facility (CPG 159 – S)* for information.

References

American Academy of Orthopedic Surgeons (AAOS). Position statement on the use of knee braces. Rosemont, IL:1997 Oct. Revised 2003 Dec.

Bahramizadeh M, Mousavi ME, Rassafiani M, Aminian G, Ebrahimi I, Karimlou M, Toole GO. The effect of floor reaction ankle foot orthosis on postural control in children with spastic cerebral palsy. Prosthet Orthot Int. 2012 Mar;36(1):71-6.

Barton CJ, Menz HB, Crossley KM. Clinical predictors of foot orthoses efficacy in individuals with patellofemoralpain.Med Sci Sports Exerc. 2011 Sep;43(9):1603-10.

Bodendorfer BM, Anoushiravani AA, Feeley BT, Gallo RA. Anterior cruciate ligament bracing: evidence in providing stability and preventing injury or graft re-rupture. Phys Sportsmed. 2013;41(3):92-102.

Bonanno DR, Landorf KB, Menz HB. Pressure-relieving properties of various shoe inserts in older people with plantar heel pain. Gait Posture. 2011 Mar;33(3):385-9.

Bus SA, van Deursen RW, Armstrong DG, Lewis J, Caravaggi CF, Cavanagh PR; International Working Group on the Diabetic Foot (IWGDF). Footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in patients with diabetes: a systematic review. Diabetes Metab Res Rev. 2015 Sep 5.

Cambron JA, Duarte M, Dexheimer J, Solecki T. Shoe orthotics for the treatment of chronic low back pain: a randomized controlled pilot study.J Manipulative Physiol Ther. 2011 May;34(4):254-60.

Chang BC, Wang JY, Huang BS, Lin HY, Lee WC. Dynamic impression insole in rheumatoid foot with metatarsal pain. Clin Biomech (Bristol, Avon). 2012 Feb;27(2):196-201.

Chevalier TL, Chockalingam N. Effects of foot orthoses: How important is the practitioner? Gait Posture. 2012 Mar;35(3):383-8.

Chia KK, Suresh S, Kuah A, Ong JL, Phua JM, Seah AL. Comparative trial of the foot pressure patterns between corrective orthotics, formthotics, bone spur pads and flat insoles in patients with chronic plantar fasciitis. Ann Acad Med Singapore. 2009 Oct;38(10):869-75.

Clark H, Rome K, Plant M, O'Hare K, Gray J. A critical review of foot orthoses in the rheumatoid arthritic foot. Rheumatology (Oxford). 2006 Feb;45(2):139-45.

Cole C, Seto C, Gazewood J. Plantar fasciitis: evidence-based review of diagnosis and therapy. Am Fam Physician. 2005 Dec 1;72(11):2237-42.

Collins NJ, Bisset LM, Crossley KM, Vicenzino B. Efficacy of nonsurgical interventions for anterior knee pain: systematic review and meta-analysis of randomized trials. Sports Med. 2012 Jan 1;42(1):31-49.

Conceição CS, Gomes Neto M, Mendes SM, Sá KN, Baptista AF. Systematic review and meta-analysis of effects of foot orthoses on pain and disability in rheumatoid arthritis patients. Disabil Rehabil. 2015;37(14):1209-13.

Crawford F, Thomson C. Interventions for treating plantar heel pain. Cochrane Database Syst Rev. 2003;(3):CD000416.

Defrin R, Ben Benyamin S, Aldubi RD, Pick CG. Conservative correction of leg-length discrepancies of 10mm or less for the relief of chronic low back pain. Arch Phys Med Rehabil. 2005 Nov;86(11):2075-80.

D'hondt NE, Stuijs PA, Kerkhoffs GM, Verheul C, Lysens R, Aufdemkampe G, Van Dijk CN. Orthotic devices for treating patellofemoral pain syndrome. Cochrane Database Syst Rev. 2002;(2):CD002267.

Dixit S, DiFiori JP, Burton M, Mines B. Management of patellofemoral pain syndrome. Am Fam Physician. 2007 Jan 15;75(2):194-202.

Duivenvoorden T, Brouwer RW, van Raaij TM, Verhagen AP, Verhaar JA, Bierma-Zeinstra SM. Braces and orthoses for treating osteoarthritis of the knee. Cochrane Database Syst Rev. 2015 Mar 16;3:CD004020.

Drake M, Bittenbender C, Boyles RE. The short-term effects of treating plantar fasciitis with a temporary custom foot orthosis and stretching. J Orthop Sports Phys Ther. 2011 Apr;41(4):221-31.

Erel S, Uygur F, Engin Simsek I, Yakut Y. The effects of dynamic ankle-foot orthoses in chronic stroke patients at three-month follow-up: a randomized controlled trial. Clin Rehabil. 2011 Jun;25(6):515-23.

Evans AM, Rome K. A Cochrane review of the evidence for non-surgical interventions for flexible pediatric flat feet. Eur J Phys Rehabil Med. 2011;47(1):69-89.

Ferrari R. A cohort-controlled trial of the addition of customized foot orthotics to standard care in fibromyalgia. Clin Rheumatol. 2012 Jul;31(7):1041-5.

Ferrari R. Effects of customized foot orthotics on reported disability and analgesic use in patients with chronic low back pain associated with motor vehicle collisions. J Chiropr Med. 2013 Mar;12(1):15-9.

Ferrari R. Effect of customized foot orthotics in addition to usual care for the management of chronic low back pain following work-related low back injury. J Manipulative Physiol Ther. 2013;36(6):359-63.

France EP, Paulos LE. Knee bracing. J Am Acad Orthop Surg. 1994 Oct;2(5):281-7. Cigna Medical Policy on Knee Braces. Online. May 15, 2012.

Golightly YM, Tate JJ, Burns CB, Gross MT. Changes in pain and disability secondary to shoe lift intervention in subjects with limb length inequality and chronic low back pain: a preliminary report. J Orthop Sports Phys Ther. 2007 Jul;37(7):380-8.

Gross MT, Byers JM, Krafft JL, Lackey EJ, Melton KM. The impact of custom semirigid foot orthotics on pain and disability for individuals with plantar fasciitis. J Orthop Sports Phys Ther. 2002 Apr;32(4):149-57.

Hawke F, Burns J, Radford JA, du Toit V. Custom-made foot orthoses for the treatment of foot pain. Cochrane Database Syst Rev. 2008 Jul 16;(3):CD006801.

Hennessy K, Woodburn J, Steultjens MP. Custom foot orthoses for rheumatoid arthritis: A systematic review. Arthritis Care Res (Hoboken). 2012 Mar;64(3):311-20.

Hinman RS, Bowles KA, Metcalf BB, Wrigley TV, Bennell KL. Lateral wedge insoles for medial knee osteoarthritis: effects on lower limb frontal plane biomechanics. Clin Biomech (Bristol, Avon). 2012 Jan;27(1):27-33.

Hossain M, Alexander P, Burls A, Jobanputra P. Foot orthoses for patellofemoral pain in adults. Cochrane Database Syst Rev. 2011 Jan 19;(1):CD008402.

Janisse DJ, Janisse E. Shoe modification and the use of orthoses in the treatment of foot and ankle pathology. J Am Acad Orthop Surg. 2008 Mar;16(3):152-8.

Jenkins WL, Raedeke SG, Williams DS 3rd. The relationship between the use of foot orthoses and knee ligament injury in female collegiate basketball players. J Am Podiatr Med Assoc. 2008 May-Jun;98(3):207-11.

Jenkins WL, Raedeke SG. Lower-extremity overuse injury and use of foot orthotic devices in women's basketball. J Am Podiatr Med Assoc. 2006 Sep-Oct;96(5):408-12.

Joint Commission International. (2013). Joint Commission International Accreditation Standards for Hospitals (5th ed., pp. 264): Joint Commission Resources.

Kearney RS, Lamb SE, Achten J, Parsons NR, Costa ML. In-shoe plantar pressures within ankle-foot orthoses: implications for the management of achilles tendon ruptures. Am J Sports Med. 2011 Dec;39(12):2679-85.

Kelaher D, Mirka GA, Dudziak KQ. Effects of semi-rigid arch-support orthotics: an investigation with potential ergonomic implications. Appl Ergon. 2000 Oct;31(5):515-22.

Landorf KB, Keenan AM, Herbert RD. Effectiveness of foot orthoses to treat plantar fasciitis: a randomized trial.Arch Intern Med. 2006 Jun 26;166(12):1305-10.

Lee SY, McKeon P, Hertel J. Does the use of orthoses improve self-reported pain and function measures in patients with plantar fasciitis? A meta-analysis. Phys Ther Sport. 2009;10(1):12–18.

Lowry CD, Cleland JA, Dyke K. Management of patients with patellofemoral pain syndrome using a multimodal approach: a case series. J Orthop Sports Phys Ther. 2008 Nov;38(11):691-702.

Maas JC, Dallmeijer AJ, Huijing PA, Brunstrom-Hernandez JE, van Kampen PJ, Jaspers RT, Becher JG Splint: the efficacy of orthotic management in rest to prevent equinus in children with cerebral palsy, a randomised controlled trial. BMC Pediatr. 2012 Mar 26;12:38.

MacLean C, Davis IM, Hamill J. Influence of a custom foot orthotic intervention on lower extremity dynamics in healthy runners. Clin Biomech (Bristol, Avon). 2006 Jul;21(6):623-30.

MacLean CL, Davis IS, Hamill J. Short- and long-term influences of a custom foot orthotic intervention on lower extremity dynamics. Clin J Sport Med. 2008 Jul;18(4):338-43.

MacLean CL, van Emmerik R, Hamill J. Influence of custom foot orthotic intervention on lower extremity intralimb coupling during a 30-minute run. J Appl Biomech. 2010 Nov;26(4):390-9.

McDevitt ER, Taylor DC, Miller MD, Gerber JP, Ziemke G, Hinkin D, Uhorchak JM, Arciero RA, Pierre PS. Functional bracing after anterior cruciate ligament reconstruction: a prospective, randomized, multicenter study. 2004.

McGinnis E, Stubbs N. Pressure-relieving devices for treating heel pressure ulcers. Cochrane Database Syst Rev. 2011 Sep 7;(9):CD005485.

Mills K, Blanch P, Dev P, Martin M, Vicenzino B. A randomised control trial of short term efficacy of in-shoe foot orthoses compared with a wait and see policy for anterior knee pain and the role of foot mobility. Br J Sports Med. 2012 Mar;46(4):247-52.

Morris C, Bowers R, Ross K, Stevens P, Phillips D. Orthotic management of cerebral palsy: recommendations from a consensus conference. NeuroRehabilitation. 2011;28(1):37-46.

Moyer RF, Birmingham TB, Bryant DM, Giffin JR, Marriott KA, Leitch KM. Valgus bracing for knee osteoarthritis: a meta-analysis of randomized trials. Arthritis Care Res (Hoboken). 2015;67(4):493-501.

Nichols AW. Achilles tendinitis in running athletes. J Am Board Fam Pract. 1989 Jul-Sep;2(3):196-203.

Pietrosimone BG, Grindstaf TL, Linens SW, Uczekaj E, Hertel J. A systematic review of prophylactic braces in the prevention of knee ligament injuries in collegiate football players.J Athl Train. 2008 Jul-Aug;43(4):409-15.

Powell M, Seid M, Szer IS. Efficacy of custom foot orthotics in improving pain and functional status in children with juvenile idiopathic arthritis: a randomized trial. J Rheumatol. 2005 May;32(5):943-50.

Raja K, Dewan N. Efficacy of knee braces and foot orthoses in conservative management of knee osteoarthritis: a systematic review.Am J Phys Med Rehabil. 2011 Mar;90(3):247-62.

Rannou F, PoiraudeauS, Beaudreuil J. Role of bracing in the management of knee osteoarthritis. Curr Opin Rheumatol. 2010 Mar;22(2):218-22.

Reeves ND, Bowling FL. Conservative biomechanical strategies for knee osteoarthritis. Nat Rev Rheumatol. 2011 Feb;7(2):113-22.

Rishiraj N, Taunton JE, Lloyd-Smith R, Woollard R, Regan W, Clement DB. The potential role of prophylactic/functional knee bracing in preventing knee ligament injury. Sports Med. 2009;39(11):937-60.

Rishiraj N, Taunton JE, Lloyd-Smith R, Woollard R, Regan W, Niven B. Functional knee brace use effect on peak vertical ground reaction force during drop jump landing. Knee Surg SportsTraumatol Arthroscop. 2012 Feb 1. (Epub ahead of print).

Roos E, Engström M, Söderberg B. Foot orthoses for the treatment of plantar fasciitis.Foot Ankle Int. 2006 Aug;27(8):606-11.

Sacco IC, Trombini-Souza F, Butugan MK, Pássaro AC, Arnone AC, Fuller R. Joint loading decreased by inexpensive and minimalist footwear in elderly women with knee osteoarthritis during stair descent. Arthritis Care Res (Hoboken). 2012 Mar;64(3):368-74.

Sees JP, Miller F. Overview of foot deformity management in children with cerebral palsy. J Child Orthop. 2013 Nov;7(5):373-7.

Spencer S. Pressure relieving interventions for preventing and treating diabetic foot ulcers. Cochrane Database Syst Rev. 2000;(3):CD002302.

Toda Y, Segal N. Usefulness of an insole with subtalar strapping for analgesia in patients with medial compartment osteoarthritis of the knee. Arthritis Rheum. 2002 Oct 15;47(5):468-73.

Tyson SF, Kent RM. Effects of an ankle-foot orthosis on balance and walking after stroke: a systematic review and pooled meta-analysis. Arch Phys Med Rehabil. 2013l;94(7):1377-85.

Tyson SF, Sadeghi-Demneh E, Nester CJ. A systematic review and meta-analysis of the effect of an ankle-foot orthosis on gait biomechanics after stroke. Clin Rehabil. 2013;27(10):879-91.

Van Lunen B, Cortes N, Andrus T, Walker M, Pasquale M, Onate J. Immediate effects of a heel-pain orthosis and an augmented low-dye taping on plantar pressures and pain in subjects with plantar fasciitis. Clin J Sport Med. 2011 Nov;21(6):474-9.

van Swigchem R, van Duijnhoven HJ, den Boer J, Geurts AC, Weerdesteyn V. Effect of peroneal electrical stimulation versus an ankle-foot orthosis on obstacle avoidance ability in people with stroke-related foot drop. Phys Ther. 2012 Mar;92(3):398-406.

Wenger DR, Mauldin D, Speck G, Morgan D, Lieber RL. Corrective shoes and inserts as treatment for flexible flatfoot in infants and children. J Bone Joint Surg Am. 1989 Jul;71(6):800-10.

Zhang J. Chiropractic adjustments and orthotics reduced symptoms for standing workers. J Chiropr Med. 2005 Winter;4(4):177-81.