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Evidence Table

**PICO:** For active individuals, would the use of orthoses alone or with physical therapy be better than no treatment for common overuse injuries.

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| **Author, Name of Journal, Year** | **Title** | **Purpose and Design of Study** | **Number and Type of Subjects** | **Orthotic Intervention and Time Frame** | **Outcome Measures** | **Statistically Significant Results**  **(p<0.05)** | **Conclusion/**  **Recommendations** |
| Landorf KB, Keenan AM, Herbert RD.  Arch Intern Med  2006 | Effectiveness of foot orthoses to treat plantar fasciitis: a randomized trial. | To determine short and long term benefits of orthoses for treatment of plantar fasciitis.  Randomized trial | 136 patients with plantar faciitis (>4 weeks)  N= 46 sham, 44 prefabricated, and 46 customized  Similar demographics between groups except weight in prefabricated group | Three interventions: sham, prefabricated, and custom (semi-rigid)  Custom orthoses made from neutral position plaster casts  Not allowed to receive any other intervention  3 and 12 month follow-up | Intention to Treat Analysis:  Foot Health Status Questionnaire  Pain score  Function score | 3 months:  Mean pain score  Prefabricated: 8.7 points better (p=.05)  Custom: 7.4 points better (p=.10)  Mean function score  Prefabricated: 8.4 points better (p=.03)  Custom: 7.5 points better (p=.04)  12 months:  No significant effects | The authors concluded that prefabricated and custom orthoses provide small short term benefits for function and may help decrease pain (although not considered significant). The use of prefabricated orthoses seems to provide the same benefits as custom orthoses in this population.  Using prefabricated orthoses are a less expensive method of providing orthotic intervention than custom with similar effects. The use of other interventions and modalities may augment the effects of orthoses. |
| Burns J, Crosbie J, Ouvrier R, Hunt A.  J Am Podiatr Med Assoc  2006 | Effective Orthotic Therapy for the Painful Cavus Foot: A Randomized Controlled Trial. | To determine effects of custom orthotics for people with pes cavus.  RCT | 154 patients with bilateral pes cavus (Foot Posture Index ≤ -2) and chronic foot pain (>1 year)  N= 75 customized, and 79 sham  Included both idiopathic and neuromuscular origins | Two interventions:  Sham and custom (semi-rigid)  Custom orthoses made from neutral-suspension plaster casts  Allowed to continue medication, physical therapy, and other interventions  3 month follow-up | Intention to Treat Analysis:  Foot Health Status Questionnaire  Pain Score  Function Score  SF-36 Health Survey  Physical functioning  General health  Vitality  Social functioning  Plantar Pressure  Pedar-mobile in-shoe system and Novel software | 3 months:  Mean pain score  Custom: 8.3 points better (p=.022)  Mean function score  Custom: 9.5 points better (p=.005)  QoL (physical function)  Custom: 7.0 points better (p=.008)  Plantar Pressure  Difference: -3.0 N⋅s/cm2 (p<.001) | The authors concluded that custom orthotics shaped to the patients specific foot type reduced pain and improved function compared to the control. Reduction in plantar pressure was seen across the whole foot, rearfoot, and forefoot while increasing at the midfoot. This supports the theory of pain reduction through redistribution of plantar pressure loading.  The results of this study could be limited due to concurrent interventions being preformed and wide range of condition severity. Patients reported a few adverse effects including foot pain and ankle instability. |
| Loudon JK, Dolphino MR.  Foot Ankle Spec  2009 | Use of Foot Orthoses and Calf Stretching for Individuals With Medial Tibial Stress Syndrome. | To determine if patients with medial tibial stress syndrome respond to orthoses and stretching.  Prospective Cohort Study | 23 patients (11 women and 12 men) with symptoms of medial tibial stress syndrome  Included avid runners, walkers who ran, and those who walked at least 10 miles/week  Demographics (age, height, weight, duration of symptoms, and alignment measures) collected on all patients | Interventions:  Prefabricated orthoses along with calf stretching  Gastrocnemius and soleus stretching against wall, 3 repetitions x 30 seconds each, twice per day  Not allowed to receive any other intervention  3 week follow-up | Numerical Pain Rating Scale  50% improvement was considered a success  Global Rating of Change questionnaire | 3 weeks:  Women: 44% successful  Men: 83% successful  Overall: 65.2% successful (15 patients)  Change in pain level successful group: 3.4 points better (p< .00)  GRC score between groups: successful group 4.3 points better, unsuccessful group 0.8 points better (p<.0001) | The authors concluded that men appeared to respond better to orthoses and stretching than women although many patients still had some pain symptoms at three weeks. Duration of symptoms was shown to be a poor indicator for improvement.  The study had several design flaws including no control group and a small sample size therefore application might be limited. The use of orthoses seem to aid in reduction of pain symptoms in the short term but other interventions or activity modification may be necessary. |
| Dananberg HJ, Guiliano M.  J Am Podiatr Med Assoc  1999 | Chronic Low-Back Pain and  Its Response to Custom-Made  Foot Orthoses. | To determine if addressing sagittal plane blockage with custom orthoses reduces back pain.  Prospective study | 32 patients with chronic low back pain and possible gait abnormalities  Examined for hallux limitus, functional hallux limitus, and ankle equinus  Included all different types of long standing back pain (SI pain, mechanical, spinal stenosis) for which other interventions failed | Interventions:  Custom orthoses and manipulations when appropriate  Custom orthoses made from semi-weight bearing impression with modifications based on gait analysis  Manipulations were performed on 1st MTP joint, ankle, and fibular head to increase ROM  1 and 6 month follow-ups | Quebec Back Pain Disability Scale questionnaire  Converted to mean pain score | 1 month (time 1):  Mean reduction  Orthoses: 0.66 ± 0.78 (p= .0025)  6 month (time 2):  Mean reduction  Orthoses: 0.66 ± 0.92 (p= .01) | The authors concluded that orthoses used to correct gait has both short and long term benefits for those suffering from chronic low back pain. They believe that patients don’t limp because they hurt but actually hurt because of limping.  Although there were significant differences the changes in pain were actually very small. These small improvements may not transfer to clinically significant differences. There are also several problems with this study such as small sample size and low follow-up. |
| Collins N, Crossley K, Beller E, Damell R, McPoil T, Vicenzino B.  BR J Sports Med  2009 | Foot orthoses and physiotherapy in the treatment of  patellofemoral pain syndrome: randomised clinical trial. | To determine effectiveness of orthoses, physical therapy, or a combination for treatment of patellofemoral pain syndrome.  Randomized clinical trial | 179 patients (79 male and 100 female) with patellofemoral pain syndrome (>6 weeks)  N= 44 sham, 46 orthoses, 45 physical therapy, and 44 physical therapy plus orthoses  Similar demographics between groups except duration | Four Interventions:  Sham, physical therapy, orthoses, and physical therapy plus orthoses  Prefabricated orthoses were customized by heat molding and wedge/heel raises  Physical therapy included patellofemoral joint mobilization, patellar taping, quadriceps muscle training, and education (20-60 minutes for 6 sessions)  Allowed to continue over the counter medication  6, 12, and 52 week follow-up | Intention to Treat Analysis:  Global Improvement  Likert Scale  Visual analogue scale  Usual Pain  Visual analogue scale  Worst Pain  Visual analogue scale  Anterior knee pain scale  Functional index questionnaire | 6 weeks:  Relative Risk Ratio  Orthoses vs Sham: 0.66 (p= .01)  Number Needed to Treat  Orthoses vs Sham: 4 (p= .01)  12 weeks:  No significant differences  52 weeks:  No significant differences | The authors concluded that orthoses provided similar benefits as physical therapy in the short term. Also that orthoses did not augment pain reduction in combination with physical therapy. Lastly orthoses provided earlier and larger improvements than the sham.  The use of orthoses may hasten recovery in patients suffering from patellofemoral pain syndrome and could be more cost effective in some cases. Orthoses and/or physical therapy were shown to control pain better than the sham at the long term therefore favoring intervention. |
| Kulig K, Reischl SF, Pomrantz AB, Burnfield JM, Mais-Requejo S, Thordarson DB, Smith RW.  Physical Therapy  2009 | Nonsurgical Management of Posterior Tibial Tendon Dysfunction With Orthoses and Resistive Exercise: A Randomized Controlled Trial. | To determine effectiveness of orthoses and resistance exercise for tibialis posterior tendinopathy.  Prospective study | 36 patients with stage I or II tibialis posterior tendinopathy (>3 months) | Three Interventions:  Orthoses-stretching, orthoses-stretching-concentric exercise, and orthoses-stretching-eccentric exercise  Gastrocnemius and soleus stretching, 3 repetitions x 30 seconds each, twice per day  Exercise tibialis posterior musculotendinous unit (horizontal adduction with plantarflexion), 15 repetitions x 3 sets  Discontinued athletic activities or increasing activity  12 week follow-up | Foot function index  Total  Pain  Disability  Activity limitation  5-Minute walk test  Pain after 5-MWT | 12 weeks:  Foot Function Index  Total: all groups (p< .0001); between groups (p< .042)  Pain: all groups (p< .0001); between groups (p< .048)  Disability: all groups (p< .0001); between groups (p< .036)  Pain after 5-MWT  VAS: all groups (p= .0001) | The authors concluded that for early stages of tibialis posterior tendinopathy the use of stretching and orthoses provided benefits in functioning and pain reduction. The addition of either concentric or eccentric strengthening of the tibialis posterior tendon augments these effects.  The investigation had no control group so the affects of rest and activity modification on the natural course of the condition cannot be determined. The use of orthoses and activity modification appears to be beneficial for these patients. |
| Mayer F, Hirshmuller A, Muller S, Schuberth M, Baur H.  Br J Sports Med  2007 | Effects of short-term treatment strategies over 4 weeks in  Achilles tendinopathy | To determine short term effectiveness of physical therapy or orthoses on patients with Achilles Tendinopathy.  RCT | 31 male runners (>32 km/week) with untreated, unilateral Achilles tendinopathy (>6 months)  N= 11physical therapy, 10 insoles, and 10 control | Three Interventions:  Physical therapy, custom semi-rigid orthoses, or no treatment  Physical therapy included deep friction massage, local pulsed ultrasound, ice, and sensory motor training (balance and eccentric exercises); 30 minutes, 10 sessions  Custom semi-rigid orthoses were produced by dynamic plantar pressure distribution (longitudinal arch support and bowl shaped heel); worn at all times  4 week follow-up | Before treadmill Test:  Subjective Pain  Pain disability index  Pain experience scale  After Treadmill Test:  Subjective Pain  Pain disability index  Pain experience scale  Strength performance capacity  Peak torque of plantar flexors  Lido-Active Isokinetic System | 4 weeks:  Pain Disability Index  Physical therapy: (p< .05)  Orthoses: (p<.05) | The authors concluded that both physical therapy and orthoses improved pain reduction in the short term compared to controls. Both treatment groups demonstrated no increase in pain with treadmill testing after the intervention unlike the controls. Similarly both treatments increase eccentric plantar flexion torque by 10%.  Physical therapy and orthoses seem to reduce pain without activity modification. These interventions could be beneficial for people with active lifestyles. The orthoses group showed greater reduction in pain during the short term but this could be in part to the small sample size. |
| Hirschmuller A, Baur H, Muller S, Helwig P, Dickhuth H-H, Mayer F.  Br J Sports Med  2011 | Clinical effectiveness of customised sport shoe  orthoses for overuse injuries in runners: a randomised  controlled study | To determine effectiveness of custom orthoses for reducing pain and impairment of overuse injuries in runners.  RCT | 99 runners (>32 km/week) with unilateral overuse running injury (>3 months)  N= 51 custom orthoses, and 48 control  Included lower extremity overuse injuries (patello femoral pain syndrome, iliotibial band syndrome, shin splints, plantar fasciitis and tendinopathies) | Two Interventions:  Custom orthoses (semi-rigid) and control  Custom semi-rigid orthoses were produced by dynamic plantar pressure distribution (longitudinal arch support and bowl shaped heel); worn at all times  Patients were advised to wear neutral running shoes  8 week follow-up | Subjective Pain Experience Scale  Pain Disability Index  Comfort Index | 8 weeks:  Subjective Pain Experience Scale  Orthoses: (p<.05)  Pain Disability Index  Orthoses: (p<.05) | The authors concluded that orthoses decreased pain and reduced impairment in runners. Comfort scores for orthoses were high for most runners (score of about 80%). Authors noted that there was an increase in pain the first week of orthoses use that resolved.  Orthoses produced meaningful differences without activity modification. These effects may not generalize to less active populations. Tendinopathies were the most common overuse conditions within the investigation therefore results may be limited to other conditions. |