The Effect of Foot Orthoses on the Reduction of Knee Pain in People with Patellofemoral Pain Syndrome

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Clinical Question: Do foot orthoses reduce knee pain in people with patellofemoral pain syndrome compared to other conservative methods of treatment?

Background: Patellofemoral pain syndrome (PFPS) is a common cause of knee pain for adolescents and adults younger than the age of 60, with women presenting disproportionately more often than men.[1,2] PFPS is defined as pain around or behind the patella that is aggravated during weight bearing activities on a flexed knee.[1,3] Evidence shows that patellofemoral pain syndrome development is likely multifactorial, including functional disorders of the lower extremity such as patellar maltracking and dynamic valgus of the knee.[2] Alignment factors such as femoral neck anteversion, knee hyperextension, genu valgum, Q angle, tibia varum and excessive rearfoot pronation have also been associated with PFPS.[3] Additionally, other accompanying issues of the knee with PFPS include crepitus and functional deficit.[2] Treatment of PFPS is generally conservative, including NSAIDs, physical therapy, taping, and foot orthoses.[1,2,4]

Foot orthoses (FOs) can be used for the management of a variety of conditions involving the foot and ankle. FOs can be classified as prefabricated, semi-custom, or custom. Prefabricated FOs come in a range of sizes, are typically chosen based on the user's shoe size, and require little to no adjustment for fitting. Semi-custom FOs require expertise to mold to the user's foot. This can be done by heating the device and molding it to the user's foot, or adding a wedge/post to the device. Custom foot orthoses require a mold or impression to be made of the user's foot with a foam impression, a 3D scan, or a plaster cast.[5] These devices are unique to the user's foot, and have a multitude of design options for top covers, base materials, and modifications.

Posting and wedges at the heel, midfoot, or forefoot of the FO allow the foot orthosis to change the coronal angle of the ankle, which in turn can impact the knee. In the case of PFPS, creating a neutral coronal plane knee angle and foot alignment can potentially decrease pain in the knee by resolving malalignment factors such as genu valgum and excessive rearfoot pronation.[2,5]

Search Strategy:
Databases Searched: PubMed, Google Scholar, JPO
Search Terms: (patellofemoral pain) AND (foot orthotics OR foot orthoses OR foot orthosis OR insert)
Inclusion/Exclusion Criteria: Include articles written 2007-present, English, free full-text, Clinical trial, randomized controlled trial. Excluding adolescent participants.

Synthesis of Results: Three studies were identified that matched inclusion criteria).[4,6-8] All three studies included participants who were diagnosed with patellofemoral pain syndrome. Two of the studies used custom foot orthoses[4,6], while one study used prefabricated foot orthoses.[7-8] Two studies compared foot orthoses to an exercise program[4,7,8], and one study compared pain score at different time points during the intervention. [6] All of the studies were attempting to see if there was a reduction in pain with the various interventions. Two studies used a visual analogue scale to determine outcome measures[6-8], and one study used the pain subscale of the Knee Injury and Osteoarthritis Outcomes Score (KOOS).[4] All three studies found that foot orthoses decreased pain in patients with patellofemoral pain syndrome, however two studies[4,7,8] noted no difference in pain at the one year follow up. Only one of the studies had a control group.[4] Two of the studies[4,6] had relatively small sample sizes compared to the Collins[7,8] study. Finally, one study limited their participant diagnosis to calcaneal eversion, thus limiting the global applicability of the study.[4]

Clinical Message: The results of these studies indicate that using foot orthoses may lead to successful management of PFPS. Participation in physical therapy on its own or in combination with the use of foot orthoses may promote successful management of PFPS, but these studies showed varying results. Further studies are needed to determine how physical therapy may factor into orthotic management of PFPS. Future

studies with larger sample sizes and control groups would help further this topic. Additionally, future studies could investigate the difference between custom and prefabricated orthoses in their impact on PFPS.

Evidence Table

	Mølgaard, 2017[4]	Munuera, 2011[6]	Collins, 2014[7,8]
Population	40 adults diagnosed with patellofemoral pain and screened for excessive calcaneal eversion, Age 18-58.	21 subjects with patellofemoral pain, age 15-36, with retro/peripatellar pain during certain activities for longer than 6 weeks.	179 participants age 18-40, with insidious onset of anterior knee or retropatellar pain greater than 6 weeks duration and provoked by at least two weight bearing activities.
Study Design	Randomized assessor-blinded controlled superiority trial.	Clinical trial without control group.	Pragmatic, single blind, randomized clinical trial in a community setting for 12 months.
Intervention	Knee targeted exercises, foot targeted exercises and custom foot orthoses made of EVA. FOs had posting/wedging under medial longitudinal arch and/or heel.	Custom foot orthoses made of 2-mm thick polypropylene and 4-mm thick polyethylene foam liner of 4 shore A hardness. Varus forefoot wedge was added after two weeks.	All study groups received 6 weeks of physeiotherapy pre-treatment. There were four intervention groups: prefabricated FOs, physiotherapy, physiotherapy with preabricated FOs, and flat inserts (placebo intervention). Prefabricated orthoses from Vasyli International, made of EVA, high/medium/low density with in-built arch support and 6 degree rearfoot varus wedge.
Comparison	Knee targeted exercises only.	Initial pain, pain at two-week check-up, and pain at four-week check-up.	Flat inserts vs FOs, physiotherapy vs FOs, and physiotherapy & FOs vs physiotherapy.
Methodology	Determine if there is a decrease in pain at 4 month and 12 month follow-ups.	Patellofemoral pain was evaluated with a visual analogue scale before treatment, two weeks into treatment, and four weeks into treatment.	Determine the clinical efficacy of foot orthoses in the management of PFPS compared to previously stated comparisons over a 12 month period.
Outcomes	Primary Outcome: Knee Injury and Osteoarthritis Outcomes Score (KOOS) self-reported questionnaire Pain subscale. Secondary outcomes: KOOS subscales for ADL, Sport, QoL and Symptoms.	Visual Analogue Scale for patellofemoral pain.	Usual and Worst pain Visual Analogue Scale, Anterior Knee Pain Scale, Functional Index Questionnaire, Patient Perceived Treatment Effect Score and Perceived Global Effect Visual Analogue Scale.
Key Findings	Targeted exercises and foot orthosis intervention group had a larger improvement in KOOS pain than the knee exercises only control group at 4 month follow up. At 12 month follow up, the intervention and control groups had no significant difference.	Custom foot orthoses significantly decreased patellofemoral pain over the course of four weeks. Participants with PFP tended to present with forefoot varus and addressing this with forefoot posting assisted even more in reducing pain, as evidenced by increasing forefoot posting after two weeks of wearing the FO.	Global improvement was greater in the prefabricated FO group compared to the flat insert group at 6 and 12 weeks post intervention, though there was no significant difference at 52 weeks. There was no significant difference between the physiotherapy and FO groups or the physiotherapy and phyiostherapy combined with FO groups. All groups had clinically meaningful improvements in pain at 52 weeks. Some

	Mølgaard, 2017[4]	Munuera, 2011[6]	Collins, 2014[7,8]
			foot orthoses users reported mild side effects: rubbing and blistering, discomfort, and pain. These did not impact their ability to continue FO use after adjustment.
Study Limitations	Selected population with excessive calcaneal eversion limits the generalizability of the study. Intervention group received additional foot specific exercises that the control group did not.	There was no control group.	Did not assess hindfoot, midfoot or forefoot positioning.

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