

Collins N, Crossley K, et al. Foot orthoses and physiotherapy in the treatment of patellofemoral pain syndrome: randomised clinical trial. BMJ 2008;337:a1735

Design: Randomized clinical trial

Population/sample size/setting:

- 179 patients (100 women, 79 men, mean age 29) treated for anterior knee pain in a university setting in Australia
- Eligibility criteria were age 18-40, anterior knee/retropatellar pain lasting 6 weeks, tenderness on palpation of patella, provoked by at least two of these: prolonged sitting, kneeling, squatting, running, hopping, or stair walking
- Exclusion criteria were concomitant injury or pain from hip, lumbar spine, or other knee structures, previous knee surgery, patellofemoral instability, knee joint effusion, any foot condition that precluded use of orthoses, use of physical therapy or foot orthoses in previous year, or use of anti-inflammatory drugs

Main outcome measures:

- Block randomization to one of four interventions: foot orthoses plus PT (n=44), PT alone (n=45), foot orthoses without PT (n=46), and flat shoe inserts (n=44)
- PT participants attended six sessions of 20-60 minutes over six weeks, then encouraged to continue with self-management program; PT included patellar mobilization, patellar taping, and muscle retraining using biofeedback
- Orthotic group received prefabricated, commercially available inserts which were fitted to shoes with comfort as primary goal
- Orthoses could be customized to some degree through heat molding or adding wedge and heel raises
- Flat inserts were made from same material as orthoses, but were of uniform thickness without inbuilt arch or wedging
- Outcomes were measured at baseline and at 6, 12, and 52 weeks after randomization
- At 52 weeks, majority of patients recorded moderate or marked global improvement from baseline (84% with foot orthoses, 73% with flat inserts, 81% with PT, and 81% with PT plus foot orthoses)
- At six weeks, foot orthoses were superior to flat inserts (85% moderate or marked global improvement vs. 58% for flat inserts; PT alone had 93% and PT plus orthoses had 90% global improvement—not significantly different from foot orthoses alone)
- Foot orthoses produced more side effects (rubbing, blistering, and discomfort) than flat inserts; these responded to making adjustments such as heat molding, and did not preclude wearing of orthoses

Authors' conclusions:

- Prefabricated foot orthoses are superior to flat inserts in short term management of patellofemoral pain syndrome, implying that their contoured shape is beneficial
- Foot orthoses do not improve outcomes of physical therapy
- General practitioners may seek to hasten recovery by prescribing foot orthoses

Comments:

- The main outcome (global improvement) was measured on a five point Likert scale, with “marked improvement” and “marked worsening” at the opposite ends of the scale
- A five point scale that tries to cover this wide a range of possible clinical responses may sacrifice some statistical power, making group differences less likely to be apparent
- For example, Table 2 shows no apparent difference between foot orthoses and flat inserts at 12 weeks (81% vs. 79% improvement); Table 2 shows global improvements of 46.7 and 30.6, which is statistically significant on an independent sample t-test
- Therefore, a finer measuring scale for the main outcome might have given more precise estimates of group differences
- Flat inserts may have produced a beneficial response compared to providing no foot intervention, but a control group to test this was not used

Assessment: For conclusion that prefabricated foot orthoses are superior to flat inserts :
adequate