Physical Therapy in Sport 12 (2011) 70–75

Contents lists available at ScienceDirect

Physical Therapy in Sport

journal homepage: www.elsevier.com/ptsp

Original research

Effects of prefabricated foot orthoses on pain and function in individuals with patellofemoral pain syndrome: A cohort study

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ARTICLE INFO

Article history:
Received 1 July 2010
Received in revised form
2 August 2010
Accepted 10 September 2010

Keywords:
Foot orthoses
Patellofemoral pain syndrome
Functional performance
Knee pain

ABSTRACT

Objectives: This study evaluated the effects of unmodified prefabricated foot orthoses over a 12-week period on functional performance; and subjective pain and function in individuals with patellofemoral pain syndrome (PFPS).
Design: Prospective cohort study over 12 weeks. Each participant was prescribed prefabricated foot orthoses at baseline.
Participants: Sixty individuals with PFPS (18–35 years).
Main outcome measures: : Change in pain and ease of completing a single leg squat; change in the number of pain free step downs and single leg rises from sitting; usual and worst pain in the previous week; the anterior knee pain scale (AKPS); and the lower extremity functional scale (LEFS).
Results: At 12 weeks, significant improvements in single leg squat pain and ease, and the number of pain free step downs and single leg rises from sitting were found. Additionally, significant reductions in usual and worst pain, and improvements on the AKPS and LEFS were observed.
Conclusions: Functional performance improvements following unmodified prefabricated foot orthoses were greater at 12 weeks that those achieved immediately. Enhanced functional performance over time may have significant implications for osteoarthritis prevention in some individuals with PFPS. Improvements in subjective pain and function appear to plateau over time.

1. Introduction

Patellofemoral pain syndrome (PFPS) is the most common presentation of knee pain to sports medicine and orthopaedic clinics among adolescents and young adults (Taunton, Ryan, Clement, McKenzie, Lloyd-Smith, & Zumbo, 2002). Symptoms resulting from PFPS often reduce functional performance (Barton, Menz, & Crossley, in press; Devereaux & Lachman, 1984; Sandow & Goodfellow, 1985), and have been linked to osteoarthritis development over time (Thorstensson, Petersson, Jacobsson, Boegard, & Roos, 2004). One commonly advocated intervention for PFPS with growing evidence is foot orthoses. In a recent systematic review (Barton, Munteanu, Menz, & Crossley, 2010) we identified a number of studies supporting foot orthoses efficacy in individuals with PFPS. Specifically, one high quality randomised controlled trial (RCT) reported that a greater number of participants receiving prefabricated foot orthoses reported improvement at six weeks compared to those receiving flat inserts (Collins, Crossley, Beller, Darnell, McPoil, & Vicenzino, 2008). The prescription approach used in this study included the provision of four pairs of prefabricated foot orthoses, with each pair modified (using heat moulding and the addition of posting) over a six week period to enhance comfort (Collins et al., 2008).

After identifying a paucity of research evaluating the effects of foot orthoses on functional performance in individuals with PFPS (Barton et al., 2010), we completed a study evaluating the immediate effects of unmodified prefabricated foot orthoses on functional performance in a group of 52 PFPS participants (Barton et al., in press). Results showed foot orthoses to reduce pain and enhance ease when completing a single leg squat in 42 and 69% of participants, respectively, and increase the number of pain free step downs and single leg rises from sitting in 57 and 38% of participants, respectively (Barton et al., in press). The longer term effects of these orthoses now need to be evaluated. If immediate functional improvements are sustained or improved over time with the same unmodified prefabricated foot orthoses, they may have capacity to improve long term outcomes from PFPS and potentially reduce the

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1466-853X/$ – see front matter © 2010 Elsevier Ltd. All rights reserved.
doi:10.1016/j.ptsp.2010.09.002

Fig. 1. Prefabricated foot orthoses (Vasyli Pro, Vasyli International) prescribed to each participant.

risk of osteoarthritis development. Additionally, if similar subjective outcomes to those produced by the more resource dependent (i.e. time and cost to customise multiple pairs) prescription approach evaluated by Collins et al can be achieved, prescribing unmodified prefabricated foot orthoses may be an alternative approach.

The aims of this study were to evaluate the intermediate term (6–12 weeks) effects of unmodified prefabricated foot orthoses on (i) functional performance after 12 weeks; and (ii) subjective pain and function after six and 12 weeks in individuals with PFPS.

2. Methods

2.1. Participants

Sixty individuals with PFPS (16 males and 44 females) were recruited via advertisements placed at universities, hospitals, and community notice boards in the greater Melbourne area. Mean age, height and weight of participants was 26 (±5) years, 1.70 (±0.08) m, and 68 (±12) kg, respectively. The study was approved by La Trobe University's Faculty of Health Sciences Human Ethics Committee and each participant gave written informed consent prior to participation. Inclusion and exclusion criteria were based on definitions used in previous RCTs (Collins et al., 2008; Crossley, Bennell, Green, Cowan, & McConnell, 2002). Inclusion criteria were: aged 18–35 years old; insidious onset of peripatellar or retropatellar knee pain of at least 6 weeks duration; worst pain in the previous week of at least 30 mm on a 100 mm visual analogue scale; pain provoked by at least two activities from running, walking, hopping, squatting, stair negotiation, kneeling, or prolonged sitting; pain elicited by patellar palpation, PFJ compression or resisted isometric quadriceps contraction. Exclusion criteria were: use of foot orthoses in the previous five years, physiotherapy treatment in the previous six months, concomitant injury or pain arising from the lumbar spine or hip; knee internal derangement; knee ligament insufficiency; previous knee surgery; PFJ instability; or patellar tendinopathy.

2.2. Intervention

Each participant attended a single treatment session (15 min) where they were issued with a pair of prefabricated foot orthoses. The orthoses were unmodified, commercially available three-quarter length devices with lateral cut-outs (Vasyli Pro, Vasyli International), made of ethylene-vinyl acetate (EVA) of medium (Shore A 55) density, containing built-in arch supports and 4° varus wedging (see Fig. 1).

Participants were asked to wear suitable footwear to allow foot orthoses compliance whenever possible through the 12 week study period. To assist with compliance, each participant was provided with a diary, in which they entered the physical activity they completed daily, the footwear they wore and whether they used the foot orthoses.

2.3. Functional performance measures

The effects of prefabricated foot orthoses on functional performance were evaluated using four previously described clinical tests (Barton et al., in press). All functional performance measures were performed at baseline and following 12 weeks of wearing the foot orthoses. Between-days reliability for each measurement has been previously established (intraclass correlation coefficients = 0.65–0.74; $\kappa = 0.79$) (Barton et al., in press).

2.3.1. Change in number of pain free step downs (20 cm step)

Each participant stood on a 20 cm step and moved from a position of bipedal stance to tap the foot of their non-testing limb below and return to bipedal stance repeatedly at a rate of 48 steps per minute until pain onset (or increase from resting), or until they completed 25 repetitions (Barton et al., in press). Each participant completed this test without foot orthoses at baseline, with foot orthoses following a 3 min rest at baseline, and then with foot orthoses after the 12-week period.

2.3.2. Change in number of pain free single leg rises from sitting (45 cm stool)

Each participant crossed their arms and repeatedly rose from sitting on one leg and then returned to sitting at a rate of 20 repetitions per minute until pain onset (or increase from resting), or until they completed 20 repetitions (Barton et al., in press). Each participant completed this test without foot orthoses at baseline, with foot orthoses following a 3 min rest at baseline, and then with foot orthoses after the 12-week period.

2.3.3. Change in pain and ease of completing a single leg squat

At baseline, participants were asked to complete five single leg squats with and without the foot orthoses, with conditions alternated (at least twice per condition) until the participant was confident of their decision. Participants rated change in pain and ease of task completion on a five point Likert scale. The five options given for 'ease' were markedly harder, somewhat harder, same, somewhat easier, and markedly easier. The five options given for 'pain' were markedly more, somewhat more, same, somewhat less, and markedly less (Barton et al., in press). Following 12 weeks of wearing the foot orthoses each participant underwent the same evaluation. If participants reported pain at baseline without the foot orthoses but then no pain at 12 weeks with the foot orthoses, the decision at 12 weeks was documented as markedly less pain.

2.4. Subjective pain and function outcome measures

Four continuous subjective measures of pain and function were taken at baseline, 6 weeks and 12 weeks. These included usual and worst pain in the previous week measured on a 100 mm visual analogue scale (VAS) (Collins et al., 2008; Crossley et al., 2002), the Anterior Knee Pain Scale (AKPS) (Kujala, Jaakkola, Koskinen, Taimela, Hurme, & Nelimarkka, 1993), and the Lower Extremity Functional Scale (LEFS) (Binkley, Stratford, Lott, & Riddle, 1999).