



Research article

The effect of foot orthoses for patients with patellofemoral pain syndrome: A systematic review and meta-analysis

Ziyan Chen^{a,1}, Jinlong Wu^{a,b,1}, Xiaodong Wang^a, Zhanbing Ren^{a,*}^a College of Physical Education, Shenzhen University, Shenzhen, 518060, China^b College of Physical Education, Southwest University, Chongqing, 400715, China

ARTICLE INFO

Keywords:

Foot orthoses
Patellofemoral pain syndrome
Knee function
Pain intensity
Systematic review
Meta-analysis

ABSTRACT

Objective: This research quantitatively studied the benefits of foot orthoses for patients with patellofemoral pain syndrome (PFPS) from five aspects: pain intensity, knee function, sport and recreation function, knee symptoms, and knee related quality of life.**Data sources:** Potential articles were retrieved using five electronic databases (Web of Science, PubMed, Scopus, China National Knowledge Infrastructure, and Wanfang). The search period was from inception to October 17, 2021.**Review methods:** Two researchers independently completed record retrieval and selection, data extraction, and methodological quality assessment. Pooled effect sizes were calculated using a random-effects model or fixed-effect model and a 95% confidence interval (95% CI). Data from six randomized controlled trials (RCT) meeting the inclusion criteria were extracted for meta-analysis with methodological quality assessment scores ranging from seven to ten.**Results:** Results showed that compared to the control group, foot orthoses can significantly improve knee function (SMD = -0.45[-0.74, -0.16], $P = 0.002$, $I^2 = 0\%$), and improve sport and recreation function (SMD = -0.54[-1.04, -0.03], $P = 0.04$, $I^2 = 0\%$). But the foot orthoses had no significant effect in pain intensity (SMD = -0.01[-0.32, 0.30], $P = 0.95$, $I^2 = 64\%$), knee injury symptoms (SMD = -0.36[-0.86, 0.14], $P = 0.16$, $I^2 = 0\%$), and knee related quality of life (SMD = -0.45[-0.95, 0.05], $P = 0.08$, $I^2 = 0\%$).Subgroup analysis of pain intensity showed that foot orthoses had some effect compared to flat/soft inserts (SMD = -0.28[-0.57, 0.00], $P = 0.05$, $I^2 = 0\%$). The effect of other treatments (physiotherapy and gait retraining) was significantly better than that of foot orthoses (SMD = 0.45[0.09, 0.80], $P = 0.01$, $I^2 = 46\%$). Compared with exercise alone, the effect of foot orthoses combined with exercise was more significant (SMD = -0.98[-1.64, -0.32], $P = 0.004$).**Conclusion:** The findings suggested that foot orthoses significantly improved knee function and sport and recreation function in patients with PFPS, but had no significant effect on pain intensity, knee injury symptoms, and knee related quality of life. This study supported the positive therapeutic effect of foot orthoses on PFPS.

1. Introduction

Patellofemoral Pain Syndrome (PFPS), also known as runner's knee and anterior knee pain syndrome, is defined as increased pain in the area behind or around the patella when the knee is bent and loaded with weight [1]. In orthopedics and sports medicine, PFPS is considered to be one of the important causes of knee pain [2]. Due to limited knee function, PFPS harms the patient's sports ability [3]. The study found that a quarter of PFPS patients experience persistent symptoms for an average

of 16 years after the initial symptoms [4]. The disease has a high recurrence rate [4]. When the patients had patellofemoral pain repeatedly for a long time, it may eventually develop into osteoarthritis [5, 6]. Therefore, it is important to actively explore treatment strategies for PFPS and effectively solve the actual problems of patients.

The occurrence of PFPS has both external and internal factors [2]. External factors include overtraining and inappropriate shoes, and internal factors are due to abnormal foot movement [2]. That is to say, excessive foot pronation may result in increased internal rotation of the tibia and

* Corresponding author.

E-mail address: rzbi@szu.edu.cn (Z. Ren).¹ These authors contributed equally to this work.

femur and lateral displacement of the patella [7, 8, 9, 10], resulting in the lower extremity in a dynamic valgus position [11, 12, 13, 14, 15]. Subsequently, the knee valgus and quadriceps angle (Q angle) increase, which leads to increased lateral stress of the patellofemoral joint (PFJ) [2].

At present, foot orthoses are a common method for the clinical treatment of PFPS. It can improve the patient's foot movement and activate the lower extremity muscles, thereby improving the symptoms of PFPS. In the expert consensus on patellofemoral pain, foot orthoses are recommended for short-term use to relieve pain [16]. Previous studies have proposed two mechanisms for the treatment of PFPS with foot orthoses [17, 18]. The first is that the foot orthoses can reduce foot pronation, correct the movement trajectory of the PFJ, and improve compensatory internal rotation of the lower extremity [17]. In the second, the foot orthoses activate the lower extremity muscles, and the enhanced vastus medialis muscle and gluteus medius reduce excessive lateral movement of the patella [18].

In recent years, some studies have used foot orthoses to treat patients with PFPS [17, 19, 20, 21, 22]. Some studies have used foot orthoses as a single treatment, and others have chosen foot orthoses combined with physical therapy or exercise therapy. Because of the differences in the various intervention programs, the comprehensive effect of foot orthoses cannot be determined. Bonacci et al. found that compared to foot orthoses, a 6-week gait retraining program has a clinically meaningful effect on runners with patellofemoral pain [21]. Shih et al. showed that the incidence of pain decreased in the experimental group of runners wearing foot orthotics, while there was no significant change in the control group wearing regular insole [23]. The foot targeted exercises combined with foot orthoses for 12 weeks were more effective than knee targeted exercises alone in individuals with patellofemoral pain [19]. Thus, it is necessary to conduct a systematic evaluation of the role of foot orthoses, provide valuable guidance and suggestions to physical therapists and clinicians, and thereby provide better medical services for patients with PFPS. Based on previous experimental and theoretical studies on the treatment of PFPS by foot orthoses, the objectives of this study were: (1) to investigate the benefits of foot orthoses on PFPS from five aspects: pain intensity, knee function, sport and recreation function, knee injury symptoms and knee related quality of life; (2) to provide suggestions for the clinical application of foot orthoses in the future.

2. Methodology

This study complied with the Preferred Reporting Items for Systematic Review and Meta-analyses Statement (PRISMA) [24] to ensure study transparency. The protocol was registered with the trial registration number CRD42021283945 under the International Prospective Register of Systematic Reviews (PROSPERO).

2.1. Search strategy

We searched five electronic databases (PubMed, Web of Science, Scopus, The Chinese National Knowledge Infrastructure (CNKI), and Wanfang from inception through October 17, 2021, to identify all relevant published articles about the effect of foot orthoses for patients with PFPS. The search terms are as follows: (1) "Foot orthoses" OR "Foot orthosis" OR "Foot orthotics" OR "Shoe orthotics" OR "Footwear" OR "Shoe insert" OR "Insole"; and (2) "Anterior knee pain" OR "Patellofemoral pain" OR "Patellofemoral pain syndrome" OR "Patellofemoral osteoarthritis" OR "Chondromalacia patellae". The two sets of terms are connected by AND, and the Chinese translations of these terms are used in the Chinese database. In addition, additional publications were manually identified by searching the reference lists of related studies to further identify relevant studies.

2.2. Eligibility criteria

2.2.1. Types of studies

Only peer-reviewed articles were considered in this study, and included articles must be published in journals. The study included only a

Randomized Controlled Trial (RCT). Some studies assign patients by hospital number or date of birth, which does not meet RCT criteria. Studies that did not involve any control group were excluded. Cross-sectional studies, pre - and post-control designs with only one group, and qualitative studies were all excluded. In addition, reviews, comments, conference abstracts, and book chapters were excluded. Included studies must be published in Chinese or English.

2.2.2. Types of participants

Inclusion criteria were as follows: (1) the participants were 18 years old and above; (2) Participants were diagnosed with patellofemoral pain, anterior knee pain, patellofemoral osteoarthritis, or chondromalacia patellae; (3) Pain occurs in the behind or around the area of the patella during tasks that increase the load of the PFJ (running, squatting, jumping, kneeling, or sitting for a long time, etc.); (4) Patella tenderness on palpation, or pain when stepping down or squatting on lower limbs.

2.2.3. Types of intervention

Interventions in the experimental group could be divided into: (1) foot orthoses only; (2) Comprehensive treatment including foot orthoses (foot orthoses combined with physiotherapy, exercise, and manual therapy). The interventions in the control group were other than foot orthoses. Studies in which both the experimental and control groups used foot orthoses were excluded.

2.2.4. Types of outcome measures

Outcome measures of this study include pain intensity, knee function, sports and recreation function, knee injury symptoms, and knee related quality of life. The results of the included studies must include at least one outcome measure mentioned above. Pain intensity was measured using a visual analog scale (VAS), anterior knee pain scale (AKPS), and pain subscales in the Knee injury and Osteoarthritis Outcome Score (KOOS). Knee function was measured using the Kujala patellofemoral score (KPS), the functional index questionnaire (FIQ), and the Activities of daily living function subscales in the KOOS. Sport and recreation function, knee injury symptoms, and knee related quality of life were measured by the sport and recreation function, symptoms, and quality of life subscales in KOOS respectively. To avoid selection bias, in addition to the above scales, if there are studies that use other scales to measure the same outcome, they will also be included in the analysis. Study data reported sample size, mean, standard deviation or standard error, and 95% confidence interval.

2.2.5. Study selection and data extraction

One researcher (Z.Y.C) performed the electronic searches, and two researchers (Z.Y.C and J.L.W) independently screened the studies based on the titles and abstracts after the removal of duplicate studies. For the sake of comprehensively identifying relevant studies, the remaining studies were examined in full text, and studies that did not meet the inclusion criteria were eliminated. Discrepancies between the two researchers (Z.Y.C and J.L.W) were discussed until a consensus was reached. A third researcher (Z.B.R) made the final decision after group discussion if consensus could not be reached. Standardized information tables were developed to extract basic features from each study. The information extracted from each study was as follows: first author, year of publication, age of participants, sample size, intervention protocol and period, and outcome measures. Besides, numerical data (sample sizes, mean, standard deviation, median and interquartile range) were extracted from each included study for pooled analysis. Two researchers independently extract data from each study and resolve differences through discussion.

2.3. Quality assessment

The methodological assessment was independently conducted by two researchers (Z.Y.C and J.L.W) using the Physiotherapy Evidence

Database (PEDro) scale [25]. PEDro scale is a validated tool for methodological assessment of the study and is commonly used to assess physiotherapeutic interventions [25]. The assessment criteria were as follows: eligibility criteria (unscored), random allocation, concealed allocation, similar measures between groups at baseline, instructor blinding, assessor blinding, participant blinding, more than 85% retention rate, intention-to-treat analysis, between-group statistical comparisons, and point estimates of at least one set of outcome data. One point was awarded for a study that meets each item. According to the scores, the quality of these studies can be divided into four grades: excellent (9–10 points), good (6–8 points), fair (4–5 points), and poor (less than 4 points) quality.

2.4. Case report

In all the studies we included, all patients were informed about the content of the experiments and provided the written informed consent prior to inclusion.

3. Data analysis

We analyzed the effect sizes of all data using Review Manager 5.3. When different instruments were used to measure outcome variables, the effect sizes (ES) in each study were computed using standardized mean differences (SMDs) with a 95% confidence interval (CI) between groups [26]. The included studies were estimated to be heterogeneous due to differences in the characteristics of the participants and the experimental protocol in each study. To explain the potential heterogeneity, a random-effects model was used in most data synthesis processes. The random-effects model assumes that the included studies were tested in different populations, with different effect sizes calculated for each study

[27]. When the number of studies in the meta-analysis was very small, we used a fixed-effects model to conduct the data synthesis process, because in this case, it may be impossible to estimate the between-studies variance (tau-squared) with any precision [27]. The fixed-effects model assumes that all studies had a common true effect size, and therefore the effect size was the same in all the study populations [27]. Heterogeneity was assessed using the I^2 statistic. Studies with an I^2 statistic of >75% were considered to have a high degree of heterogeneity; studies with an I^2 statistic of 50–75% were considered to have a moderate degree of heterogeneity; and studies with an I^2 statistic of <50% were considered to have a low degree of heterogeneity [28]. When heterogeneity >50%, subgroup analysis was performed to explore the source of heterogeneity. Because fewer than 10 studies were included, publication bias was not discussed in this study.

4. Results

4.1. Study identification

We searched a total of three English and two Chinese electronic databases and initially retrieved 537 relevant studies. Since then, 258 duplicate studies have been deleted. The remaining studies were screened by title, excluding 216 studies unrelated to the study topic and the remaining 63 studies. After screening according to abstracts and full texts, the six studies were included in this meta-analysis (Figure 1). The two researchers reached an agreement during the independent screening process.

4.2. Study characteristics

The characteristics of the included studies are shown in Table 1. A total of six peer-review articles in English were included [19, 20, 21, 22,

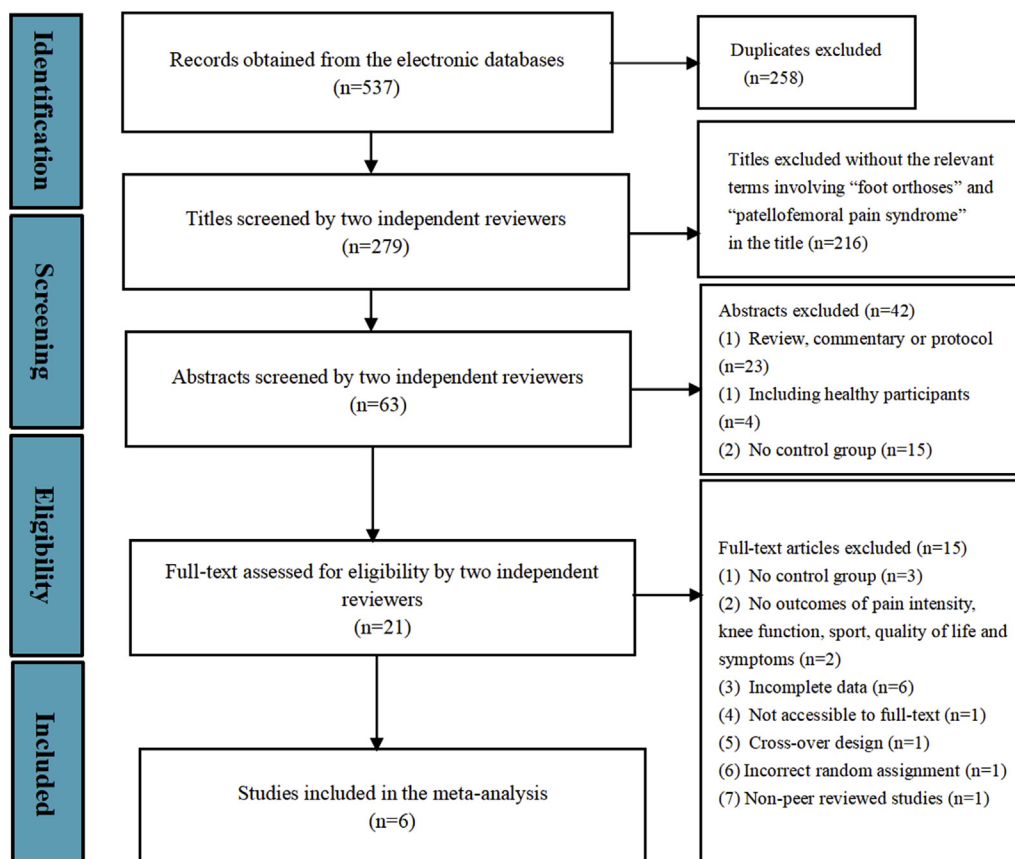


Figure 1. Selection process for included studies.

Table 1. Characteristics of RCT in the meta-analysis.

Study	Type of participants	Sample size (Mean age \pm SD)	Experiment	Control	Period	Outcome measures
Bonacci, 2017 [21]	Patellofemoral pain	EG:8(34.0 \pm 9.5) loss to follow-up:1 CG:8(31.5 \pm 9.7) loss to follow-up:1	Foot orthoses	Gait retraining	6-weeks	AKPS, VAS
Collins, 2008 [20]	Patellofemoral pain syndrome	Foot orthoses + physiotherapy:44(29.6 \pm 5.6) loss to follow-up:1 Physiotherapy:45(30.9 \pm 5.8) loss to follow-up:3; Foot orthoses:46(27.9 \pm 5.3) loss to follow-up:1	Group1: Foot orthoses; Group2: Physiotherapy Group3:Foot orthoses + physiotherapy		6-weeks	AKPS, VAS, FIQ
Mølgaard, 2018 [19]	Patellofemoral pain	EG:20 loss to follow-up:3 CG:20 (31.2 \pm 10.8) loss to follow-up:5	Standard knee targeted exercises combined with foot targeted exercises and foot orthoses	Standard knee targeted exercises	12-weeks	KOOS (pain, ADL, Sport, QoL and Symptoms)
Mills, 2012 [29]	Anterior knee pain	EG:20(30.4 \pm 5.47) loss to follow-up:1 CG:20(28.5 \pm 5.89)	Wearing orthoses	Wearing usual shoes	6-weeks	VAS, KPS
Shih, 2011 [23]	Runners who had pronated foot along with patellofemoral pain or foot pain during running	EG:12(31.3 \pm 8.3) CG:12(34.4 \pm 9.8)	A soft insole with a semi-rigid rearfoot medial wedge	A soft insole without corrective posting	60-minute running test	VAS
Tan, 2019 [22]	Patellofemoral osteoarthritis	EG:13(55 \pm 4) loss to follow-up:1 CG:13(65 \pm 8) loss to follow-up:2	Full-length foot orthoses\three-quarter length foot orthoses	Flat inserts	6-weeks	VAS, AKPS, KOOS (pain, ADL, Sport, QoL and Symptoms)

Note: EG = Experiment Group; CG = Control Group; VAS = Visual Analog Scale; FIQ = functional index questionnaire; KPS = Kujala Patellofemoral Score; JOA = Japanese Orthopaedic Association score; KOOS = Knee injury and Osteoarthritis Outcome Score; AKPS = Anterior knee pain scale; ADL = Activity Daily Life; QOL = Quality of life. Physiotherapy include patellar mobilisation, patellartaping, vasti muscle retraining exercises with electromyographic biofeedback, hamstring and anterior hip stretches, hip external rotator retraining.

23, 29]. Patients included in the study were diagnosed with patellofemoral pain, anterior knee pain, and patellofemoral osteoarthritis. Intervention types include (1) foot orthoses only; (2) Comprehensive treatments (foot orthoses combined with manual therapy, exercise, and physiotherapy). One study compared foot orthoses with three types of treatments (foot orthoses plus physiotherapy, physiotherapy, and flat inserts) [20]. we extracted data for foot orthoses, flat inserts, and foot orthoses plus physiotherapy respectively in different analysis groups. Intervention durations ranged from 2 weeks to 12 weeks. The time of outcome measures included immediate measures and follow-up: four studies measured immediate effects after the intervention [20, 22, 23, 29], one at 4 and 12 months follow-up [19], and one at 12 weeks follow-up [21]. These two studies did not take measurements immediately after the intervention, and we extracted the first follow-up measurement data [19, 21]. Pain intensity was assessed in all studies, knee function was measured in four studies [19, 20, 22, 29], and sport and recreation function, knee injury symptoms, and knee related quality of life were assessed in two studies [19, 22].

4.3. Quality assessment

The methodological quality of each study was assessed by two researchers independently according to the criteria of the PEDro scale [25]. Details of the quality assessment for each study are summarized in Table 2. A total of six studies were included in this meta-analysis, of which four reached a good level [19, 21, 22, 23], and two reached an excellent level [20, 29]. Five studies reported the source of recruitment and inclusion criteria, and one study did not report the source of recruitment [23]. All studies were RCT, and five reported allocation concealment. Four studies used participant blinding [20, 22, 23, 29], none used therapist blinding (due to design limitations), and three used assessor blinding [19, 20, 29]. Except for one study [19], the remaining five studies measured at least one main outcome for more than 85% of the participants. Two studies reported that participants with

measurement outcomes received treatment according to protocol or control conditions [21, 23], and two used intention-to-treat analysis [19, 20]. All studies reported between-group statistical comparison and point estimates of at least one set of outcome data.

4.4. The effect of foot orthoses on pain intensity

All studies evaluated the impact of foot orthoses on the pain intensity of patients with PFPs. To be specific, five studies measured pain intensity using VAS scale [20, 21, 22, 23, 29], 3 using AKPS scale [20, 21, 22], and two studies using the "pain" subscale in the KOOS [19, 22]. Three studies used both VAS and AKPS scales [20, 21, 22]. One study used VAS, AKPS, and the "pain" subscale in the KOOS to measure [22]. In the Collins, 2009, we extracted the data of the foot orthoses (experimental group) and physiotherapy (control group) to compare the difference between the foot orthoses and other treatments [20]. To combine discrepancies in outcome measures, the random-effects model was conducted. Results of the meta-analysis showed that foot orthoses had no significant effect on pain intensity and there was large heterogeneity between studies (SMD = -0.01[-0.32, 0.30], $P = 0.95$, $I^2 = 64\%$). To explore the source of heterogeneity, we conducted a subgroup analysis of different intervention methods. The results showed that foot orthoses had some effect compared to flat/soft inserts (SMD = -0.28[-0.57, 0.00], $P = 0.05$, $I^2 = 0\%$); Other treatments (physiotherapy and gait retraining) are significantly better than foot orthoses (SMD = 0.45[0.09, 0.80], $P = 0.01$, $I^2 = 46\%$); Compared with exercise alone, foot orthoses combined with exercise therapy have a significant effect (SMD = -0.98[-1.64, -0.32], $P = 0.004$) (Figure 2).

4.5. The effect of foot orthoses on knee function

Four studies assessed the impact of foot orthoses on knee function. Of these studies, one used the FIQ scale [20], one used the KPS scale [29], and two used the "activities of daily living" subscale in KOOS to measure

Table 2. The methodological quality of the included studies (PEDro assessment).

Study	PEDro Items Number											Methodological Quality	Score
	1	2	3	4	5	6	7	8	9	10	11		
Bonacci, 2017 [21]	√	√	√	√	×	unclear	unclear	√	√	√	√	Good	8
Collins, 2008 [20]	√	√	√	√	√	×	√	√	√	√	√	Excellent	10
Mølgaard, 2018 [19]	√	√	√	√	×	×	√	×	unclear	√	√	Good	7
Mills, 2012 [29]	√	√	√	√	√	×	√	√	unclear	√	√	Excellent	9
Shih, 2011 [23]	×	√	unclear	√	√	unclear	unclear	√	√	√	√	Good	7
Tan, 2019 [22]	√	√	√	√	√	×	unclear	√	unclear	√	√	Good	7

Note: 1. eligibility criteria were specified; 2. subjects were randomly allocated to groups; 3. allocation was concealed; 4. the groups were similar at baseline regarding the most important outcome indicators; 5. there was blinding of all subjects; 6. there was blinding of all therapists; 7. there was blinding of all assessors; 8. measures of at least one key outcome was obtained from more than 85% of the subjects initially allocated to groups; 9. all subjects for whom outcome measures were available received the treatment or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”; 10. the results of between-group statistical comparisons were reported for at least one key outcome; 11. the study provided both point measures and measures of variability for at least one key outcome.

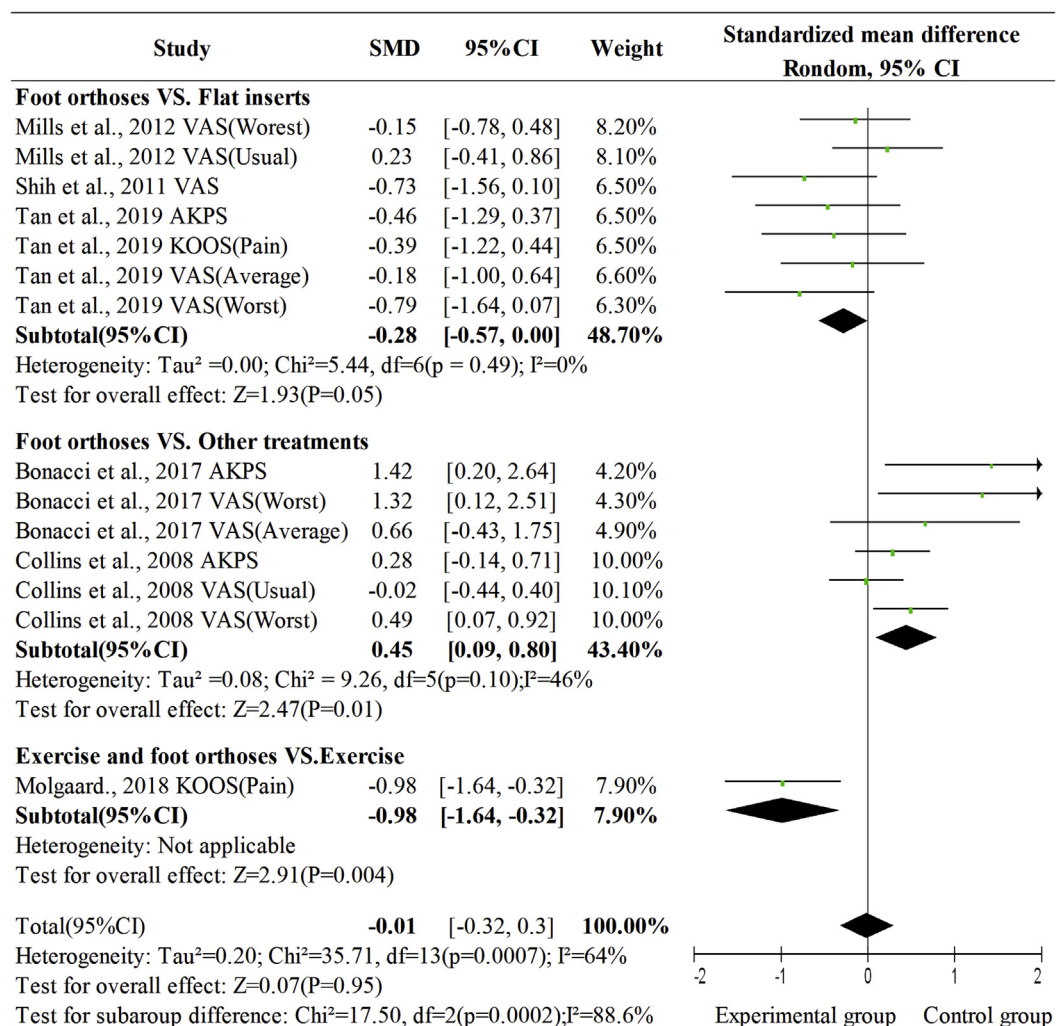


Figure 2. Effect of Foot orthoses on the pain intensity.

knee function [19, 22]. In Collins,2009, we extracted the data on foot orthose combined with physiotherapy (experimental group) and physiotherapy (control group), because in this case, the foot orthoses were a single variable, which could prove the effectiveness of this treatment [20]. To combine discrepancies in outcome measures, the random-effects model was conducted. The results of the meta-analysis showed that foot orthoses significantly improved knee function and there was little heterogeneity between studies, indicating that the results of this study were stable (SMD = -0.45[-0.74, -0.16], P = 0.002, I² = 0%) (Figure 3).

4.6. The effect of foot orthoses on sport and recreation function

Mølgaard, 2018 and Tan, 2019 used the “sport and recreation function” subscale in KOOS to measure changes in patients' exercise and recreation ability before and after treatment [19, 22]. Since there was almost no heterogeneity between the two studies (I² = 0), the fixed-effect model was selected for analysis. Meta-analysis found that foot orthoses significantly improved sport and recreation performance in patients with PFPS (SMD = -0.54[-1.04, -0.03], P = 0.04, I² = 0%) (Figure 4).

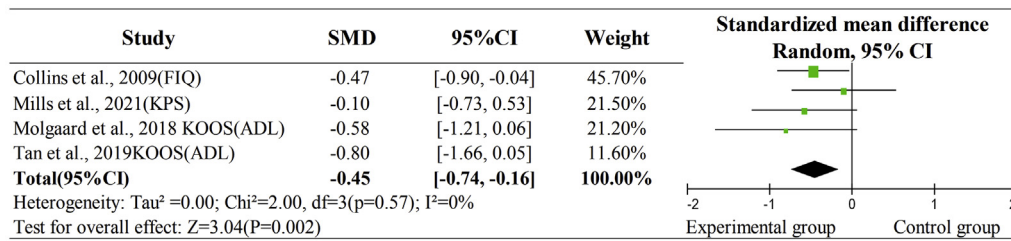


Figure 3. Effect of Foot orthoses on the knee function.

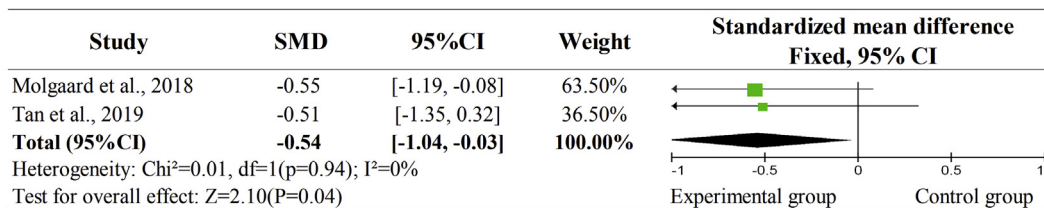


Figure 4. Effect of Foot orthoses on the sport and recreation function.

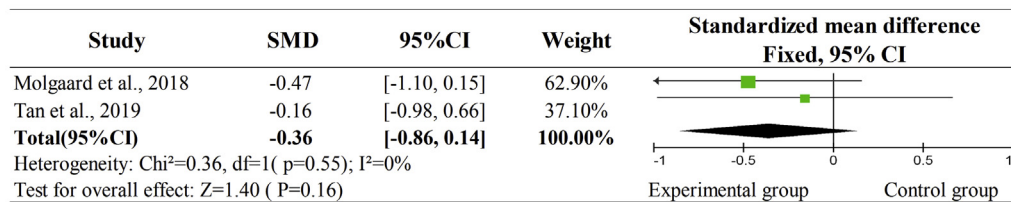


Figure 5. Effect of Foot orthoses on the knee injury symptom.

4.7. The effect of foot orthoses on knee injury symptoms

Similarly, Mølgaard, 2018 and Tan, 2019 used “symptoms” subscale of KOOS scale to evaluate the change in patients’ knee injury symptoms before and after treatment [19, 22]. Since there was almost no heterogeneity between the two studies ($I^2 = 0$), the fixed-effect model was selected for analysis. The meta-analysis found that the use of foot orthoses did not significantly improve the symptoms of PFPS patients (SMD = -0.36[-0.86, 0.14], $P = 0.16$, $I^2 = 0\%$) (Figure 5).

4.8. The effect of foot orthoses on knee-related quality of life

Finally, to assess the changes in the knee related quality of life before and after treatment, the two studies also used “quality of life” subscale in the KOOS scale to value [19, 22]. Since there was almost no heterogeneity between the two studies ($I^2 = 0$), the fixed-effect model was selected for analysis. The meta-analysis found no significant change in the quality of life of patients with PFPS after they used foot orthoses (SMD = -0.45[-0.95, 0.05], $P = 0.08$, $I^2 = 0\%$) (Figure 6).

5. Discussion

The results of the study showed that the knee function and sport and recreation function of patients with PFPS were significantly improved after the use of foot orthoses. However, in terms of pain intensity, knee injury symptoms, and knee related quality of life, the foot orthoses did not show a better therapeutic effect than the control group. The main results will be discussed in detail in the following discussion.

All six studies evaluated changes in pain intensity after the use of foot orthoses. Due to high heterogeneity among studies and large differences among interventions, subgroups were set and analyzed according to the intervention methods. Compared with flat inserts/soft insoles, foot

orthoses had some effect, which shows that the foot orthose is a feasible treatment for PFPS patients. After wearing foot orthoses, the pain intensity of PFPS patients was relieved and they gained a more comfortable sports experience [23]. In the subgroup of foot orthoses compared with other treatments, we combined Bonacci et al. [21] and Collins et al. [20] studies. Collins et al. compared physiotherapy (patellar taping and electromyographic biofeedback training, etc.) with foot orthoses, and Bonacci et al. compared gait retraining with foot orthoses. The results showed that the combination of physiotherapy and gait retraining was superior to foot orthoses. This demonstrates that patellar taping, electromyographic biofeedback training, and gait retraining all contribute to the improvement of PFPS. Patellar taping can correct abnormal patellofemoral trajectory and relieve pain. Electromyographic biofeedback training allows patients to control muscles according to the electromyography signal, thereby strengthening muscles contraction. Gait retraining can reduce the hip motion in the frontal plane and improve the hip mechanics [30, 31]. Therefore, gait retraining can help patients with PFPS to reduce pain and improve lower-extremity function [30]. However, foot orthoses do not directly affect the knee joint, and wearing foot orthoses for a short period of time can neither correct the patella trajectory nor strengthen the muscles around the knee joint, so it can only play an auxiliary effect. In the subgroup of foot orthoses combined with exercise therapy versus exercise therapy alone, we found that foot orthoses combined with exercise therapy were more effective than exercise alone. Therefore, in future research, foot orthoses can be combined with exercise therapy to reduce the pain intensity of patients and shorten the treatment period. The therapist can prescribe exercises based on the patient’s specific situation and provide them with better intervention programs.

This study demonstrated that the use of foot orthoses helped improve knee function. Collins et al. reported that foot orthoses combined with physiotherapy had no obvious advantage over physiotherapy, but we found that comprehensive therapy had a more significant effect [20].

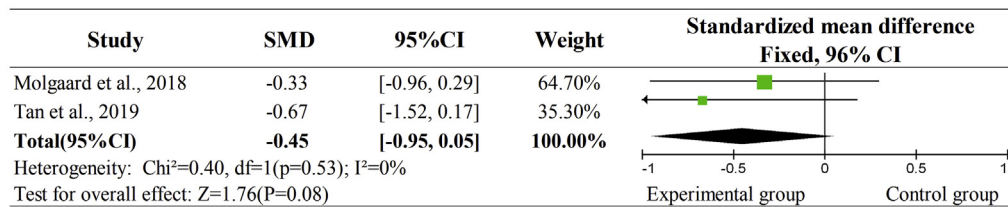


Figure 6. Effect of Foot orthoses on the knee related quality of life.

Molgaard et al. showed that compared with the knee targeted exercises group, foot orthoses combined with knee and foot targeted exercise were more beneficial in improving the knee joint function of patients with PFPS, although there was no statistical significance [19]. These results were consistent with the above subgroup analysis of pain intensity, as the subgroup analysis also showed that foot orthoses combined with exercise therapy were superior to exercise therapy alone. It further illustrates that foot orthoses can be used as an auxiliary means of physical therapy or sports training. Mills et al. compared the foot orthoses group with the wait-and-see policy group, and the results showed that the use of foot orthoses alone did not significantly improve knee function. The study reported that the foot orthoses group was significantly better than the control group in terms of global improvement, indicating that patients were able to perceive their health improvements after using the foot orthoses [29]. This study also reported that compared with the wait-and-see policy group, patients in the foot orthoses group had moderate improvements in specific functions, indicating that after treatment, patients can more easily complete activities that were considered difficult before treatment [29]. Although the study has no significant difference in knee function between the foot orthoses group and the wait-and-see policy group, the statistical results are more favorable for the foot orthoses group.

In terms of sports and recreation function, knee injury symptoms, and knee related quality of life, the results of the study showed that the foot orthoses significantly improved the exercise and entertainment capacity of PFPS patients, but did not significantly improve the knee injury symptoms and quality of life. The sport and recreation function were improved because patients wearing foot orthoses can improve the contact pattern of the PFJ and reduce the load on the knee joint [32, 33]. Accompanied by the decrease in pain, the patient's exercise capacity strengthened. However, in the short term, no significant changes in knee injury symptoms and quality of life were seen with foot orthoses [19, 22]. Although the two included studies both showed that as the treatment duration extended, patients in the experimental group had a trend of improvement in knee injury symptoms and quality of life, there was no statistical difference between the experimental and control groups [19, 22]. This may be because the foot orthoses indirectly act on the knee joint by changing the biomechanics of the foot. It is not the most effective way to relieve the symptoms of knee injury [34]. In addition, the knee related quality of life is affected by a combination of physiological and psychological factors and cannot be significantly changed by foot orthoses alone.

5.1. Limitations

This study has the following limitations: (1) the number of included studies is limited, and more high-quality RCT should be included in the future to verify the therapeutic effect of foot orthoses on patellofemoral pain, to increase the reliability of the analysis. (2) This study included a pilot study, which may affect the accuracy of the results to a certain extent. (3) This study included long-term and short-term interventions of foot orthoses on PFPS, where structural findings related to PFPS are difficult to obtain in the short term. Future studies could conduct subgroup analyses of different intervention durations to investigate the optimal durations for foot orthoses. (4) There are many reasons for PFPS, and this study did not group and analyze different types of patients. (5) In addition, this study did not investigate the sports background of the included patients, which may also affect the results of the study. (6)

Finally, this study did not summarize the information on foot orthoses, and future studies can supplement the models of foot orthoses.

6. Conclusions

The results of this meta-analysis showed that the foot orthoses had a significant effect on knee function and sport and recreation function of patients with PFPS, but it had no obvious effect on pain intensity, knee injury symptoms, and knee related quality of life. This study supported the positive impact of foot orthoses on the treatment of PFPS.

Declarations

Author contribution statement

Ziyan Chen: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

JinLong Wu: Performed the experiments; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Zhanbing Ren: Performed the experiments; Wrote the paper.

Xiaodong Wang: Performed the experiments.

Funding statement

This work was supported by Humanities and Social Science of Shenzhen University(17QNFC59); Research Foundation for Young Teacher of Shenzhen University (QNJS0274); High-level Scientific Research Foundation for the Introduction of Talent of Shenzhen University (RC00228); Natural Science Featured Innovation Projects in Ordinary Universities in Guangdong Province (2021KTSCX297); Characteristic Innovation Project (Social Science) of the Education Department of Guangdong Province (2017WTSCX104).

Data availability statement

Data included in article/supplementary material/referenced in article.

Declaration of interests statement

The authors declare no conflict of interest.

Additional information

No additional information is available for this paper.

References

- [1] K.M. Crossley, J.J. Stefanik, J. Selfe, N.J. Collins, I.S. Da Vis, C.M. Powers, J. McConnell, B. Vicenzino, D.M. Bazett-Jones, J.F. Esclier, Patellofemoral pain consensus statement from the 4th International Patellofemoral Pain Research Retreat, Manchester. Part 1: terminology, definitions, clinical examination, natural history, patellofemoral osteoarthritis and patient-reported outcome measure, *Br. J. Sports Med.* 50 (14) (2016) 839–843.
- [2] C.J. Barton, S.E. Munteanu, H.B. Menz, K.M. Crossley, The efficacy of foot orthoses in the treatment of individuals with patellofemoral pain syndrome: a systematic review, *Sports Med.* 40 (5) (2010) 377–395.

- [3] D.Y. Gaitonde, A. Ericksen, R.C. Robbins, Patellofemoral pain syndrome, *Am. Fam. Phys.* 99 (2) (2019) 88–94.
- [4] G. Nimon, D. Murray, M. Sandow, J. Goodfellow, Natural history of anterior knee pain: a 14- to 20-year follow-up of nonoperative management, *J. Pediatr. Orthop.* 18 (1) (1998) 118–122.
- [5] C.A. Thorstensson, M.L. Andersson, H. Jönsson, T. Saxne, I.F. Petersson, Natural course of knee osteoarthritis in middle-aged subjects with knee pain: 12-year follow-up using clinical and radiographic criteria, *Ann. Rheumat. Diseases* 68 (12) (2009) 1890–1893.
- [6] C.A. Thorstensson, I.F. Petersson, L.T. Jacobsson, T.L. Boegård, E.M. Roos, Reduced functional performance in the lower extremity predicted radiographic knee osteoarthritis five years later, *Ann. Rheumat. Diseases* 63 (4) (2004) 402–407.
- [7] J.F. Eggold, Orthotics in the prevention of runners' overuse injuries, *Phys. Sportsmed.* 9 (3) (1981) 124–131.
- [8] J.J. Eng, M.R. Pierrynowski, Evaluation of soft foot orthotics in the treatment of patellofemoral pain syndrome, *Phys. Ther.* 73 (2) (1993) 62–68, discussion 68–70.
- [9] R.E. Klingman, S.M. Liaos, K.M. Hardin, The effect of subtalar joint posting on patellar glide position in subjects with excessive rearfoot pronation, *J. Orthop. Sports Phys. Ther.* 25 (3) (1997) 185–191.
- [10] D.A. Nawoczenski, T.M. Cook, C.L. Saltzman, The effect of foot orthotics on three-dimensional kinematics of the leg and rearfoot during running, *J. Orthop. Sports Phys. Ther.* 21 (6) (1995) 317–327.
- [11] C.J. Barton, P. Levinger, K.M. Crossley, K.E. Webster, H.B. Menz, The relationship between rearfoot, tibial and hip kinematics in individuals with patellofemoral pain syndrome, *Clin. Biomech. (Bristol, Avon)* 27 (7) (2012) 702–705.
- [12] C.J. Barton, P. Levinger, H.B. Menz, K.E. Webster, Kinematic gait characteristics associated with patellofemoral pain syndrome: a systematic review, *Gait Posture* 30 (4) (2009) 405–416.
- [13] A.R. Boldt, J.D. Willson, J.A. Barrios, T.W. Kernozek, Effects of medially wedged foot orthoses on knee and hip joint running mechanics in females with and without patellofemoral pain syndrome, *J. Appl. Biomech.* 29 (1) (2013) 68–77.
- [14] C. Mølgaard, M.S. Rathleff, O. Simonsen, Patellofemoral pain syndrome and its association with hip, ankle, and foot function in 16- to 18-year-old high school students: a single-blind case-control study, *J. Am. Podiatr. Med. Assoc.* 101 (3) (2011) 215–222.
- [15] C.J. Barton, P. Levinger, K.E. Webster, H.B. Menz, Walking kinematics in individuals with patellofemoral pain syndrome: a case-control study, *Gait Posture* 33 (2) (2011) 286–291.
- [16] K.M. Crossley, M. van Middelkoop, M.J. Callaghan, N.J. Collins, M.S. Rathleff, C.J. Barton, Patellofemoral pain consensus statement from the 4th International Patellofemoral Pain Research Retreat, Manchester. Part 2: recommended physical interventions (exercise, taping, bracing, foot orthoses and combined interventions), *Br. J. Sports Med.* 50 (14) (2016) 844–852.
- [17] L.B. Johnston, M.T. Gross, Effects of foot orthoses on quality of life for individuals with patellofemoral pain syndrome, *J. Orthop. Sports Phys. Ther.* 34 (8) (2004) 440–448.
- [18] J. Hertel, B.R. Sloss, J.E. Earl, Effect of foot orthotics on quadriceps and gluteus medius electromyographic activity during selected exercises, *Arch. Phys. Med. Rehabil.* 86 (1) (2005) 26–30.
- [19] C.M. Mølgaard, M.S. Rathleff, J. Andreassen, M. Christensen, S. Lundbye-Christensen, O. Simonsen, S. Kaalund, Foot exercises and foot orthoses are more effective than knee focused exercises in individuals with patellofemoral pain, *J. Sci. Med. Sport* 21 (1) (2018) 10–15.
- [20] N. Collins, K. Crossley, E. Beller, R. Darnell, T. McPoil, B. Vicenzino, Foot orthoses and physiotherapy in the treatment of patellofemoral pain syndrome: randomised clinical trial, *BMJ (Clin. Res. Ed)* 337 (2008) a1735.
- [21] J. Bonacci, M. Hall, N. Saunders, B. Vicenzino, Gait retraining versus foot orthoses for patellofemoral pain: a pilot randomised clinical trial, *J. Sci. Med. Sport* 21 (5) (2017).
- [22] J.M. Tan, H.B. Menz, K.M. Crossley, S.E. Munteanu, H.F. Hart, K.J. Middleton, A.J. Smith, N.J. Collins, The efficacy of foot orthoses in individuals with patellofemoral osteoarthritis: a randomised feasibility trial, *Pilot Feasibil. Stud.* 5 (2019) 90.
- [23] Y.F. Shih, Y.K. Wen, W.Y. Chen, Application of wedged foot orthosis effectively reduces pain in runners with pronated foot: a randomized clinical study, *Clin. Rehabil.* 25 (10) (2011) 913–923.
- [24] D. Moher, A. Liberati, J. Tetzlaff, D.G. Altman, Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement, *PLoS Med.* 6 (7) (2009), e1000097.
- [25] C.G. Maher, C. Sherrington, R.D. Herbert, A.M. Moseley, M. Elkins, Reliability of the PEDro scale for rating quality of randomized controlled trials, *Phys. Ther.* 83 (8) (2003) 713–721.
- [26] J.J. Deeks, J.P. Higgins, D.G. Altman, *Analysing Data and Undertaking Meta-Analyses: Cochrane Handbook for Systematic Reviews of Interventions*, 2008.
- [27] M. Borenstein, L. Hedges, H. Rothstein, *Meta-Analysis Fixed Effect vs. Random Effects*, 2007.
- [28] M. Borenstein, L. Hedges, J. Higgins, H. Rothstein, *Effect Sizes Based on Means. Introduction to Meta-Analysis*, 2009.
- [29] K. Mills, P. Blanch, P. Dev, M. Martin, B. Vicenzino, 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.* 46 (4) (2012) 247–252.
- [30] B. Noehren, J. Scholz, I. Davis, The effect of real-time gait retraining on hip kinematics, pain and function in subjects with patellofemoral pain syndrome, *Br. J. Sports Med.* 45 (9) (2011) 691–696.
- [31] R.W. Willy, J.P. Scholz, I.S. Davis, Mirror gait retraining for the treatment of patellofemoral pain in female runners, *Clin. Biomech.* 27 (10) (2012) 1045–1051.
- [32] J.C. D'Amico, M. Rubin, The influence of foot orthoses on the quadriceps angle, *J. Am. Podiatr. Med. Assoc.* 76 (6) (1986) 337–340.
- [33] H.H. Huberti, W.C. Hayes, Patellofemoral contact pressures. The influence of q-angle and tendofemoral contact, *J. Bone Jt. Surg. Am.* 66 (5) (1984) 715–724.
- [34] M.T. Gross, J.L. Foxworth, The role of foot orthoses as an intervention for patellofemoral pain, *J. Orthop. Sports Phys. Ther.* 33 (11) (2003) 661–670.