CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

For a 29-year-old male distance runner with unilateral patellofemoral pain, are hip strengthening exercises more effective than corrective foot orthotics in improving knee pain

AUTHOR

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CLINICAL SCENARIO

I have had left knee pain whenever I run for the past 2 years. I have had a history of meniscal injury of my right knee, but not of the left. I also demonstrate decreased hip extension bilaterally during the propulsion phase of the running cycle, as well as bilateral quad dominance during a squat.

During a literature search, most of the studies I found were conducted with female subjects and is therefore not applicable to the entire population of runners. I think it is important to locate the best existing evidence there is regarding patellofemoral pain syndrome (PFPS) in male distance runners, so that clinicians can make a sound evidence based decision on treating male runners who present with PFPS. Additionally, with the prevalence of the condition, identifying a protocol or a gold standard of treatment is ideal in getting these athletes back on their feet doing what they love to do. The purpose of the CAT is to determine whether hip strengthening exercises or orthotics are more effective in managing the condition of PFPS.

SUMMARY OF SEARCH

- There were ten studies that met the inclusion/exclusion criteria. They include 4 systematic reviews, 3 RCTs, and 3 low quality studies including a cohort study, a case control study, and across-sectional experimental study. Three studies were deemed "best evidence" and selected for this review.
- Evidence was found for the use of foot orthoses in early management of patellofemoral pain, but the treatment effects were not sustained at one year follow up.
- Among four different interventions, no statistically significant differences were found at one year follow up, suggesting that foot orthoses, flat inserts, and physical therapy could all be potential treatments for individuals with patellofemoral pain.
- There is conflicting evidence regarding the predictive value of gluteal muscle activity in diagnosing patellofemoral pain.
- Future studies investigating the effects of foot orthoses vs. physical therapy for patellofemoral pain may benefit from including a group that receives no treatment. This could possibly take the form of a randomised controlled crossover trial, in order to not withhold treatment from any of the participants.
- Further research is warranted with improved methodological rigor for studies including EMG of gluteal muscle activity to determine their role in patellofemoral pain.

CLINICAL BOTTOM LINE

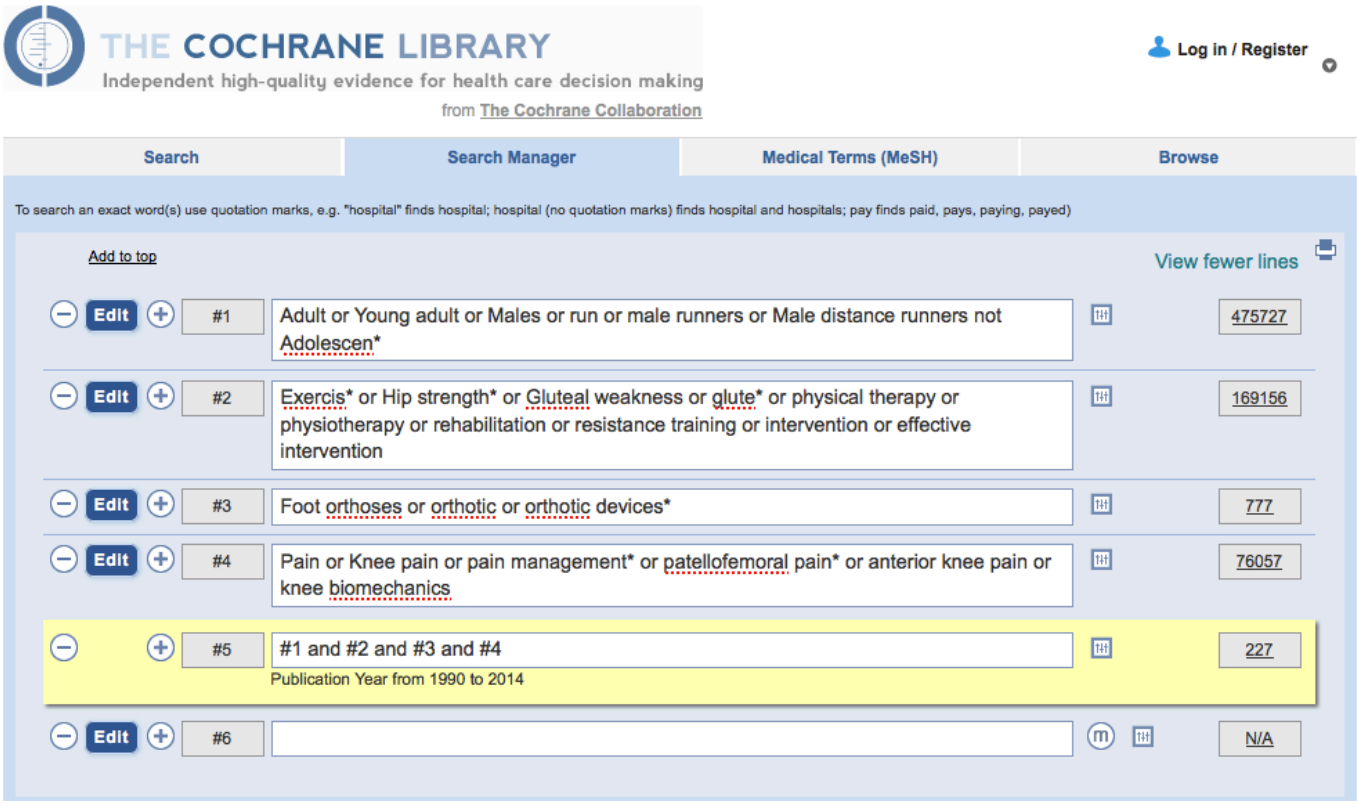
There is some evidence that suggest that foot orthoses can be used as an early intervention in the management of patellofemoral pain. Individuals given this intervention saw a statistically significant improvement at 6-weeks follow up, but not at 52 weeks when compared to flat inserts. The combination of physical therapy with foot orthoses was not more effective than physical therapy alone, and a physical therapy intervention was not superior to the use of foot orthoses as an intervention. Further research is needed suggested before it can be determined if gluteal muscle activity plays a role in predicting patellofemoral pain. Additionally, with the mixed results seen in the literature, clinicians my need to rely on their clinical judgement and experience as well as patient preferences to inform clinical decisions when working with and individual with PFPS.

SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)
Adult Young adult Males Run Male runners Male distance runners Adolescen*	Exercis* Hip strength* Gluteal Weakness Glute* Physical therapy Physiotherapy Rehabilitation Resistance training Intervention Effective intervention	Foot orthoses Orthotics Orthotic Devices*	Pain Knee pain Pain management* Patellofemoral pain* Anterior knee pain Knee biomechanics

Final search strategy:

1. Adult OR Young adult OR Males OR run OR male runners OR Male distance runners NOT Adolescen*
2. Exercis* OR Hip strength* OR Gluteal weakness OR glute* OR physical therapy OR physiotherapy OR rehabilitation OR resistance training OR intervention OR effective intervention
3. Foot orthoses OR orthotic OR orthotic devices*
4. Pain OR Knee pain OR pain management* OR patellofemoral pain* OR anterior lateral knee pain OR anterior knee pain OR knee biomechanics
5. #1 AND #2 AND #3 AND #4



Databases and Sites Searched	Number of results	Limits applied, revised number of results (if applicable)
Cochrane Library	**227**	**Publications Dates:** 1990 – 2014
CINHAL	**78**	**Publication dates:** 1990 – 2014 **Age:** 19-44 **Sex:** Male **Subject:** Major Heading – Foot orthoses, orthoses, physical therapy, pain, foot patellofemoral pain syndrome, biomechanics, shoes, athletic injuries, therapeutic exercise, treatment outcomes, functional status lower extremity, running, running injuries, knee joint, knee, muscle strengthening, othoses design, rehabilitation
PubMed	**6**	**Publication dates:** 1990 – 2014 **Species:** Humans **Sex:** Males **Ages:** 19+ years **Language:** English

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
• Systematic Reviews, Randomized Controlled Trials, Randomized Case-Control Trials, Crossover Studies, Comparative Studies • Study population includes males • Study population consists of young adults (ages 20 – 40) • Study population consists of distance runners with a diagnoses of patellofemoral pain • Study contains a physical therapy or strengthening program intervention • Study contains a foot orthotic intervention • Measures pain as an outcome • Published after 1990 • Published in English
Exclusion Criteria
• Studies that included females only • Studies that include teenagers/adolescence • Studies where subjects have other known patellofemoral pathology • Abstracts, Case reports, interviews, opinion papers

RESULTS OF SEARCH

A total of 6 relevant studies were located and categorised as shown in the following table (based on Levels of Evidence, Centre for Evidence Based Medicine, 2011) and PEDro Scale.

A total of 4 relevant systematic reviews were located and categorised as shown in the following table (based on Levels of Evidence, Centre for Evidence Based Medicine, 2011) and AMSTAR Checklist.

Summary of articles retrieved that met inclusion and exclusion criteria

Author (Year)	Study quality score	Level of Evidence	Study design
Hossain, Munier (2011)	**11/11**	**1a**	Systematic Review
Barton, C (2010)	**10/11**	**1a**	Systematic Review
Barton, C (2013)	**10/11**	**1a**	Systematic Review
Swart, N (2012)	**9/11**	**1a**	Systematic Review
Nakagawa, T (2008)	**10/10**	**1b**	RCT
Mills, K (2012)	**8/10**	**1b**	RCT
Collins, N (2009)	**8/10**	**1b**	RCT
Ferber, R (2011)	**3/10**	**2b**	Cohort Study
Pedro Rodriguesa (2013)	**4/10**	**3a**	Case Control
Dierks, T (2008)	**2/10**	**5**	Cross-sectional experimental

BEST EVIDENCE

The following 3 studies were identified as the 'best' evidence and selected for critical appraisal. Reasons for selecting these studies were:

During my search, I did not find many studies that compared the interventions directly. In fact, I only found one randomized controlled trial that did so. As a result, I selected two systematic reviews (Hossain, 2011 that reviewed foot orthoses for patellofemoral syndrome and Barton 2013, that reviewed studies on patellofemoral syndrome and gluteal activity). For the third study, I chose the RCT that compared both interventions. I would have liked to select the Barton, 2010 systematic review, which also reviewed foot orthoses and patellofemoral syndrome, or the Nakagawa, 2008 RCT, which investigated the relationship between strengthening of hip abductor and lateral rotator muscles in patellofemoral pain syndrome, but since there was an RCT that actually compared both interventions, I went with the RCT even though it was of a lower quality.

- **Hossain, M (2011)**
- **Barton, C (2013)**
- **Collins, N (2009)**

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of Foot orthoses and physiotherapy in the treatment of patellofemoral pain syndrome: randomised clinical trial by Collins, N Crossley, K Beller, E Darnell, R McPoil, T Vicenzino, B, (2009).

Aim/Objective of the Study/Systematic Review:
The aim of this study was to compare the effects of foot orthoses as a treatment for patellofemoral pain syndrome with a physical therapy intervention or an intervention that consisted of only flat inserts, and to assess the value of a physical therapy intervention with foot orthoses. For this study, the authors hypothesized that foot orthoses would be more effective than flat inserts in treating patellofemoral pain while being comparable to physical therapy, and that combining physical therapy with foot orthoses would be more effective than an intervention that consisted of just physical therapy.

Study Design

- This study was a pragmatic (designed to evaluate the effectiveness of an intervention in real-live routine practice conditions) single blinded randomised clinical trial. Using a clinically meaningful improvement of 15 mm on a 100 mm visual analogue pain scale, an assumed power of 0.80 and a significance level of 0.01, 160 participants were required to sufficiently power the study. The authors increased the sample size to 179 to account for a 10% drop out rate.

- Allocation concealment was achieved through blocked randomization. A number generator was used to select random permuted, non-stratified blocks with a block size of eight.

- Prior to randomization, baseline measurements were taken. They were repeated at 6, 12, and 52 weeks after randomization and were acquired through global improvement, severity and worst pain over the last week, anterior knee pain scale, and the functional index questionnaire.

Setting

- Participants from the greater Brisbane, Gold Coast, and Toowoomba regions of Queensland, Australia were recruited and received treatment at the community setting in Brisbane, Australia (Collins et al., 2009, p 2).

Participants

- A power analysis was used to determine the number of participants needed for the study. Consequently, a convenience sample of 179 individuals (100 females and 79 males) aged 18 to 40 participated in the study. All participants were diagnosed with patellofemoral pain syndrome with symptoms existing for at least 6 weeks and, within the most recent 12 months, did not receive treatment in the form of physical therapy or foot orthoses.

- Intervention Groups:
    1. Foot Orthoses (n=46): mean age 27.9 years; mean height 172.8 cm; mean BMI 26.1 kg/m^2
    2. Flat Inserts (n=44): mean age 29 years; mean height 174.9 cm; mean BMI 23.9 kg/m^2
    3. Physical Therapy (n=45): mean age 30.9; mean height 170.9 cm; mean BMI 24.2 kg/m^2
    4. Foot Orthoses & Physical Therapy (n=44): mean age 29.6; mean height 173.3 cm, mean BMI 24.8 kg/m^2

- Follow Up Data:
    1. For the foot orthoses group, follow up at 6 weeks was n=42, 12 weeks n=40, and at 52 weeks n=43.
    2. Follow up for the flat inserts at 6 weeks was n=41, 12 weeks n=41, and at 52 weeks n=42.
    3. The physical therapy group's follow up at 6 weeks was n=41, 12 weeks n=43, and 52 weeks n=45.
    4. The combined physical therapy and foot orthoses group's follow up at six weeks was n=40, at 12 weeks, it was n=38, and at 52 weeks, n=41.

- For all groups, follow up at 6 weeks was 97%, at 12 weeks 90%, and 52 weeks 96% (171). Of the 179 participants, the overall drop out rate was 4.5%.

- There were no significant differences between groups at baseline.

Intervention Investigated

Control

The authors used the flat inserts group as a control for the foot orthoses only. However, they did not have a group that received no treatment with which any of the interventions were compared.

- Flat Inserts Group
  Participants in this group were issued flat, even inserts with no arch support or heel wedge.

Experimental

One of 17 physical therapists, all trained in the treatment protocol, provided the treatment. All treatments were provided at the same institution for six weeks over six sessions. Additional sessions were added if needed for the participants in the orthoses & physical therapy group. Each of the six treatment sessions was between 20 minutes and an hour. At the end of 6 weeks, participants returned to self-management.

Interventions rendered are as follows:

- Foot Orthoses Group
  Each participant in this group was fitted with prefabricated orthoses to the participant's comfort.

- Physical Therapy Group
  Participants in this group received an intervention that consisted of previously tested methods of treating patellofemoral pain. They include patellar mobilisation, patellar taping, as well as retraining of the hip musculature, and a strengthening program mainly focused on the quads with EMG feedback. They also performed hamstring and hip stretches and were issued an exercise program to perform at home.

- Orthoses & Physical Therapy Group
  The intervention for the participants in this group was a combination of the prefabricated orthoses, fitted to the participants' comfort as well as the same interventions for the physical therapy group.

Throughout the trial, participants were advised to continue exercise and activities that did not cause their concordant sign. Participants were asked to avoid other interventions to manage their symptoms, but were allowed to use over the counter medications. Participants kept record of and reported any other interventions used as well as any side effects experienced from the study interventions

Outcome Measures

The blinded assessor that performed baseline measures performed subsequent measures at 6 weeks, 12 weeks, and 52 weeks. Outcome measures included the following:

- Global improvement was measured using a 5-point Likert scale where a score of 1 indicated marked improvement, a score of 3 indicated the same (or no improvement), while a score of 5 indicated marked worsening.
- Visual Analogue Scale was used to report severity of usual and worst pain over the past week. It ranged from -100 to 100 with a score of -100 indicating much worse, a score of 0 indicating the same, and a score of 100 indicating completely better.
- The anterior knee pain scale was used to assess participants' pain function on a scale of 0 to 100 with a higher a score of 100 indicating no pain or disability.
- The functional index questionnaire was used to assess participants' pain and function. It ranges from 0 to 16 points with a score of 16 indicating no pain or disability.

Main Findings

All 171 participants at the 52-week follow up were included in the statistical analysis. General findings are listed here, with interpretation of these findings under the critical appraisal section.

- At 6 weeks follow up, a between group difference of 19.8 was found when foot orthoses when compared with flat inserts, with the true value falling between 4.0 and 35.6. This was a significant difference at CI=99% (P=0.01). Additionally, with a NNT = 4, the data suggests that relative risk reduction for the foot orthoses was 0.66.

- On the global improvement scale at 6, 12, and 52 weeks, no significant differences were found between any of the other groups. At 6 and 12 weeks follow up, physical therapy vs. foot orthoses had an between group differences of 7.8 and 6.7 respectively with CI =99%, with the true values falling between -7.8 to 23.5 and -12.1 to 25.5 respectively. Similarly for the foot orthoses plus physical therapy vs. physical therapy group, at 6 and 12 weeks, the between group differences were 3.2 and 8.4 at CI=99%, with the true values falling between -12.3 to 18.8 and -10.7 to 23.0 respectively and were sustained at 52 weeks. These trends were sustained at 52 weeks follow up for all between group comparisons across all outcome measures.

- When each intervention was examined by itself, all groups except the flat inserts group saw clinically meaningful improvement in all outcome measures at the end of 52 weeks. The flat insert group saw clinically meaningful improvements in worse pain severity, anterior knee pain scale, and functional index questionnaire but not usual pain severity.

- No between group differences were found at baseline or at 52 weeks follow up (99% CI, P = 0.01).

- Participants in all groups reported use of co-interventions during the trial; however, No significant differences were found between any of the a priori group comparisons (foot orthoses vs. flat inserts, physical therapy vs. foot orthoses, and Foot orthoses & physical therapy vs. physical therapy).

- Participants in all groups experienced minor side effects throughout the trial. Those whose interventions included the foot orthoses or the flat insert reported minor discomfort that was resolved with adjustments to the orthoses or insert. Participants whose interventions involved physical therapy had minor skin irritations to the patellar taping as well as back pain.

Original Authors' Conclusions

- Foot orthoses provide a short-term therapeutic effect and was found to be more effective than flat inserts.
- No differences were found between interventions that included foot orthoses only, physical therapy only, or combining the two interventions.
- Since foot orthoses were effective, prescribing them as a short-term intervention may aid in the recovery process.

Critical Appraisal

Validity

PEDro Scale: 8/10 based on Eligibility Criteria: Yes; Random Allocation: Yes; Concealed Allocation: Yes; Baseline Comparison: Yes; Blind Subjects: No; Blind Therapist: No; Blind Assessors: Yes; Adequate Follow-up: Yes; Intention-to-treat analysis: Yes; Between Group Comparison: Yes; Point Estimates and Variability: Yes. (Eligibility score does not contribute to total score.)

Strengths

- This study receives credit for randomly allocating the subjects to intervention groups by using a randomization sequence that was kept off-site.
- The authors were transparent about the study protocol, as they were published before the study was conducted. Additionally, recommendations from standards of reporting trial were incorporated into the methodology of the study, which increases the validity of the findings.
- There was also baseline comparison of intervention groups and the authors indicated that there were no significant differences between the groups. The randomization of subjects ensured that any differences found between the groups at baseline were totally due to chance.
- The follow up periods of 6 and 52 weeks were adequate enough to track short and long-term effects of the interventions, and the data analyst as well as the assessor of the outcome measures was blinded. The blinding of this assessor made it more objective in collecting the data at follow up.
- Intention to treat (ITT) analysis was performed. This is a positive because everyone was included in the analysis regardless of dropout, retaining the original sample size. Between groups comparisons were performed at follow up as well.
- The authors reported adverse effects associated with the interventions examined. Additionally, all primary outcomes were reported in this study, which reduces the possibility of selective reporting bias.
- With no differences between the groups at baseline, this makes the findings of the study generalizable to bigger population of individuals with PFPS.

Weaknesses

- There was no blinding when it comes to the subjects or the therapists administering the intervention, which presents some potential for bias.
- The authors performed several comparisons with the collected data, as a result, the significant difference found between foot orthoses and flat inserts at 6 weeks could be a false positive (a type I error).
- The study did not include a group that received no treatment. As a result, it cannot be determined if individuals with PFPS could have had similar results over time with no treatment.

Interpretation of Results

The following bulleted list of interpretations corresponds with the main findings mentioned above.

- At 6 weeks follow up; foot orthoses vs. flat inserts had a relative risk reduction of 0.66. This means that the risk of bad outcomes is reduced by the use of foot orthoses by 34% (1-0.66 = 0.34 or 34%) relative to the use of flat inserts.
- For the global improvement scale at 6, 12, and 52 weeks follow up for all other between group comparisons (physical therapy vs. foot orthoses and foot orthoses plus physical therapy vs. physical therapy); the width of the CI included zero (for example, -7.8 to 23.5 for physical therapy vs. foot orthoses at 6 weeks). If the authors are 99% confident that this range captures the true mean of the population, there is a possibility that the true mean is, in fact, zero, indicating no difference. Consequently, the interpretation of this is that there were no differences in outcomes between groups that received physical therapy, foot orthoses, or a combination of both.

  All groups had clinically meaningful improvements where pain and severity of pain are concerned; which could suggest all interventions could be used to treat patellofemoral pain syndrome.

- The foot orthoses group saw statistically significant difference when compared to the control at 6 weeks. This suggests that foot orthoses could be used as an early, short-term intervention in a clinical scenario, which could be followed with other interventions as necessary (based on the patient case) for long-term benefits.

- Use of over-the-counter pain medicines does not have an effect on the type of intervention used.

(2) Description and appraisal of gluteal muscle activity and patellofemoral pain syndrome: a systematic review by Barton, C; Lack, S; Malliaras, P; and Morrissey D (2013)

Aim/Objective of the Study/Systematic Review:

The aim of this systematic review was to synthesize the available evidence in an effort to help clinicians better comprehend the correlation between gluteal muscle activity and patellofemoral syndrome (PFPS). In addition, the reviewers aimed to provide guidelines in the management of the condition as well as to identify possible research opportunities.

Study Design

Study Type

- This study was a systematic review with meta analysis that sought prospective and case-control studies that evaluated gluteal EMG activity and its connection to PFPS. However, no prospective studies were identified.
    - Prospective studies would have followed subjects over a period of time to see which were more likely to develop the condition; in this case PFPS.
    - The case-control studies evaluated two groups, one with PFPS and one without, which were compared to determine which group have a greater proportion of individuals with the risk factor, in this case, gluteal weakness.

METHODS

Search Strategy

- The authors included 5 databases in their search including MEDLINE, EMBASE, CINHAL, Web of Knowledge and Google Scholar.

- A strategy outlined by a previously performed systematic review on exercise therapy and PFPS was used for diagnosis search terms, which was combined with keyword including EMG or muscle and gluteal or hip or trunk or proximal. Once the studies to be included in the review were determined, the authors screened the reference lists and completed a search in Google Scholar for other potential studies to be included. The authors did not include unpublished studies as it was deemed impractical to gather all the unpublished studies that exist on this topic.

Selection Criteria

- Studies that evaluated gluteal EMG activity were selected. The studies that were sought included prospective and case-control studies. However, no prospective studies were included.

- Additionally, only studies where subjects experienced patellofemoral pain, anterior knee pain, or chondromalacia patellae were included.

- Any study that included subjects with other knee pathology were not considered for this review.

- Of the original 572 titles and abstracts screened, the full text of 13 studies were reviewed, after which, 10 were selected.

Review Process

- Titles and abstracts were downloaded into a reference management software.
- Two independent reviewers assessed each abstract for inclusion. Full text articles were obtained if inclusion could not be determined from the abstracts.
- Inconsistencies between the reviewers were resolved during a consensus meeting with a third reviewer on hand if needed.

Study Analysis

- Two independent reviewers used two methodological quality assessment tools to evaluate each study. Inconsistencies between the reviewers were resolved during a consensus meeting with a third reviewer on hand if needed.
- Assessment tools used include the modified Downs and Black Quality Index and the PFPS diagnosis checklist.

- The Downs and black Quality Index evaluates studies on a 16-point scale with scores of 10 or more indicating a higher quality (HQ) and those scoring less than 10 being considered low quality (LQ).
- The PFPS diagnosis checklist summarizes the criteria for inclusion and exclusion of the diagnosis of PFPS measured on a 7-point scale.

- Data were extracted from the study in order to calculate effect size. Any missing data were obtained by contacting the original authors.
- Effect sizes were determined as: small ≤ 0.59, medium 0.60 – 1.19, and large ≥1.20.
- Studies that evaluated the same EMG variable and functional activity were pooled.
- Heterogeneity was established using χ^2 and I^2 statistics with $P<0.05$ defining heterogeneity.
- Levels of evidence were determined by a previous study and are as follows:
  - Strong Evidence – pooled results from at least 2 statistically homogeneous HQ studies ($p>0.05$) to indicate significant results or non-significant results if data are pooled.
  - Moderate Evidence – pooled results from multiple studies, which must include one or more statistically heterogeneous HQ studies ($p<0.05$), or several statistically homogeneous studies ($p>0.05$).
  - Limited Evidence – results from several statistically heterogeneous LQ studies ($p<0.05$) or just one study that is considered HQ.
  - Very Limited Evidence – results derived from only one study that is considered LQ.
  - Conflicting Evidence – insignificant results from several statistically heterogeneous studies ($p<0.05$) of varying quality.

Quality Assessment

- The authors used the Modified Downs and Black scale as well as a PFPS diagnosis checklist to determine study inclusion. From the Modified Downs and Black scale, 6 studies rated high quality (≥ 11/16) while 4 rated low quality (≤ 10/16). The PFPS checklist indicated that the studies had large heterogeneity with scores ranging from 1 to 7 on the scale.
- Only one study had a blinded outcomes assessor and three studies reported the validity and reliability of the methodology used.
- Studies that were rated low in methodological quality did not report confounding factors or where, if any, inappropriate matching between cases and controls occurred.

Setting

Three studies did not report their settings. The remaining studies were conducted in university labs, university clinics, physical therapy clinics, as well as sports medicine and orthopaedic clinics.

Participants

- Ten case-control studies of varying quality that evaluated EMG activity of gluteus medius were selected for this review. Two of these evaluated gluteus maximus. Only one used a sample size calculation, and only one had a blinded outcome assessor. Nine studies used surface electrodes to evaluate EMG activity, while one study used intramuscular electrodes.

- Three studies did not report how their subjects were recruited. For the remaining studies, their study population was one of convenience and came from a variety of sources including university population, surrounding community, university clinic, local physical therapy, sports medicine, and orthopaedic clinics, as well as community fitness centres.

- Participants across all 10 studies totalled 335. Three studies did not report age ranges; however, for those that did report, adults over 18, not including the geriatric population, were recruited. The number of males vs. females could not be determined, as two studies did not report the gender ratio for their studies. One study did not report anthropometric data for their subjects. The average height and weight across the remaining 9 studies ranged from 1.60 m to 1.90 m and weight raged from 53 kg to 77 kg. Three studies had all female subjects.

- The studies had a low number of participants with subjects in the control groups averaging 18 (174 total) and the experimental group 16 (161 total).

Intervention Investigated

Control

The control groups consisted of individuals who were pain free and age-matched to those in the experimental groups. EMG levels (onset, duration, and activation level) of gluteus maximus (GMed) and gluteus medius (GMax) were measured during various functional tasks. Activities included overground running, stair ascent/descent, lateral step down, walking, drop jump landing, single leg jump, as well as a single leg anterior reach task.

Experimental

The experimental groups consisted of individuals who had a diagnosis of PSPS, anterior knee pain, or chondromalacia patellae. EMG levels (onset, duration, and activation level) of gluteus maximus and gluteus medius were measured during various functional tasks. Activities included overground running, stair ascent/descent, lateral step down, walking, drop jump landing, single leg jump, as well as a single leg anterior reach task.

Outcome Measures

The outcome measures of interest in this review included the onset, the duration, and the activation levels of gluteal musculature with the use of EMG. All studies measured gluteus medius activity while two studies measured gluteus maximus activities.

Main Findings

Onset of Muscle Activity

- Four studies found a strong relationship with delayed onset of GMed during stair descent in individuals with PFPS p=0.10. Pooled ES (−0.53, −0.91 to −0.15).
- Four studies found a moderate relationship with delayed onset of GMed during stair ascent in individuals with PFPS p=0.02. Pooled ES (−0.52, −0.85 to −0.19).
- One study found a weak relationship with delayed onset of GMed during running in individuals with PSPF. ES (−0.74, −1.38 to −0.10).
- One study found no difference in GMed activation between the two groups with lateral step-downs. No difference was found with GMax during running.
- One study found no difference between the groups in GMed activity during single leg jump.

Duration of Muscle Activation

- Three studies found a strong relationship with a shorter duration of GMed activity individuals with PFPS during stair ascent p=0.23. Pooled ES (−0.43, −0.84 to −0.02).
- Three studies found a moderate relationship with a shorter duration of GMed activity in individuals with PSPF during stair descent p=0.04. Pooled ES (−0.91, −1.34 to −0.47).
- One study found a weak relationship with a shorter GMed activity duration in individuals with PSPF during running. ES (−0.85, −1.50 to −0.20).
- One study found a no difference between the two groups in GMax activity during running.

Muscle Activation Levels

- One study found very weak relationship with increased GMax activity and stair descent in the PSPF group. ES (0.80, 0.16 to 1.44).
- Two studies found no differences in GMed activity during running between the two groups p=0.31.
- One study found no difference between the two groups in peak GMed or GMax activity during running or drop jump landing.
- Three studies found no differences between the two groups in average GMed activity during walking, stair ascent, single leg jump, or single leg reach task.
- Three studies found conflicting evidence between the experimental and control groups regarding GMed activity during stair descent p=0.009. Additionally, two studies found conflicting evidence regarding GMax activity during running when both groups were compared p=0.02.

Original Authors' Conclusions

- The evidence found through available studies is not sufficient to draw a clear conclusion regarding the link between gluteal muscle activity and a diagnosis of PFPS due to a number of limitations in the available studies.
- Delayed and shorter duration GMed muscle activity during stair ascent has a moderate-to-strong link with PFPS.
- GMax activity increases with stair descent, while evidence is limited when it comes to a delay or shorter duration of GMed activity during running.
- Further research is warranted to determine if screening of gluteal muscle activity should be a part of an evaluation of individuals at risk of developing PFPS.

Critical Appraisal

Validity

- This review was thorough and receives a 10/11 on the AMSTAR checklist for assessing the methodological quality of systematic reviews.
- One weakness that causes this review to lose credibility is the fact that the authors' search was not as

comprehensive as it could be, as they did not search or grey literature (unpublished studies) increasing the potential for publication bias.
- The authors provided tabulated data of all included studies and their characteristics as well as participant demographics.
- The authors were transparent regarding the methods used to assess the included studies as well as the use of independent reviewers with the plan for a third reviewer to resolve disputes.
- Heterogeneity for pooled data was determined using the χ^2 test, and I^2 statistic. Being able to assess heterogeneity can be considered a major strength of the review.
- The authors identified that there were no conflict of interest

Despite the lack of including grey literature, this paper receives a score of 10/11 on the AMSTAR. The methodological rigor of this review puts it at low bias. Additionally, the authors were able to pool results, which shows strong heterogeneity between the studies included.

Interpretation of Results

[Favourable or unfavourable, specific outcomes of interest, size of treatment effect, statistical and clinical significance, minimal clinically important difference. You may calculate effect size or confidence intervals yourself from the data provided in the article.] Describe in your own words what the results mean.

Onset of Muscle Activity

- During stair descent, individuals in the experimental group had a significant delay in gluteus medius activity, which could indicate a link between timing of the gluteus medius muscle and PFPS.
- While ascending stairs, individuals with PFPS had a moderate delay in the gluteus medius muscle. This could also indicate a link between timing for the gluteus medius muscle and PFPS.
- While there is a delay in when the gluteus medius turns on during running and lateral step-downs, this information may not be applicable to the diagnosis of PFPS. As a result, on timing of this muscle group with this delay in activity may have little or no relationship to PFPS.
- The results indicate there may not be a link between gluteus medius muscle timing and single jumping.

Duration of Muscle Activation

- During stair ascent, individuals with PFPS had a significantly shorter delay in gluteus medius activity when compared to the control group. This could indicate a link between gluteus medius weakness and PFPS.
- Gluteus medius also had a shorter duration in EMG activity with stair descent indicating possible weakness being linked to PFPS.
- The link between a shorter duration of muscle activity in gluteus medius is weak during running, and there is no link with gluteus maximus activity during running. This means there is a possibility that there is no link between the activities of these muscles and PFPS during running.

Muscle Activation Levels

- The link between gluteus maximus activity and increased levels of muscle activation while ascending stairs is weak. As a result, increased activity levels in this muscle group may not have an effect on PFPS.
- With running, drop jump landing, walking, and single leg reach task, the activity levels in gluteus medius and gluteus maximus may play a role in PFPS.

From what the authors found, the evidence seems inconclusive regarding a connection between delayed onset, muscle activity duration, and peak muscle activity of gluteal musculature during functional activities and patellofemoral pain. While some strong relationships were found, the pooled effect sizes were so small that these results cannot be considered meaningful.

(2) Description and appraisal of foot orthoses for patellofemoral pain in adults by Hossain, M; Alexander, P; Burls, A; and Jobanputra, P (2011)

Aim/Objective of the Study/Systematic Review:

The aim of this systematic review was to evaluate the efficacy of foot orthoses compared with knee orthoses, analgesic agent, placebo, or no treatment in the management of patellofemoral joint (PFJ) pain in adults as well as to identify gaps in the literature.

Study Design

Study Type

- This study was a systematic review of randomized controlled trials to evaluate the effects of foot orthoses on knee pain in adults.

METHODS

Search Strategy

- Electronic searches were performed through the Cochrane Bone, Joint and Muscle Trauma Group Specialized Register, the Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, CINHAL, Turning Research into Practice (TRIP), and PEDro.
- The authors also search the WHO International Clinical Trials Registry Platform and Current Controlled Trials for studies that were currently in progress. No language or publication status restrictions were made.
- Searches were also performed for unpublished studies by means of contacting orthotic manufacturing companies. Authors and experts were also contacted for assistance tin identifying additional publications.
- The authors searched British Library's Zetoc table of contents database in an effort to locate conference proceedings. Additionally, ProQuest and Opensigle databases were searched for unpublished studies.

Selection Criteria

- To be considered for this review, studies had to be randomized or quasi-randomized and compared foot orthoses with flat insoles or a physical therapy intervention. Additionally, studies were included if their primary outcomes were knee pain and function.

Review Process

- In reviewing the search results, two independent reviewers screened the results through reviewing of titles and abstracts, after which, the full text versions were screened for inclusion.
- Disagreements between these two reviewers were resolved by a third.
- Two independent reviewers used a data extraction form to extract data, and a third was on hand to resolve disagreements.
- Missing information was accounted for by contacting authors.

Study Analysis

- Using The Cochrane Collaboration's 'Risk of bias' tool, two independent reviewers carried out an assessment of risk of bias of included studies. Among the sources of bias assessed included adequate sequence generation, allocation of concealment, blinding, incomplete outcome data, and selective reporting.
- Disagreements between these two reviewers were resolved by a third.
- Trials' authors were contacted for clarification of methodology if needed.
- Mean difference (and 95% CI) was used as effect size for continuous outcomes, and for dichotomous outcomes, risk ratios and 95% CI were calculated.
- Authors performed intention-to-treat analyses for all subjects that were randomized to an intervention group. The authors used denominators reported in the study when they were not able to obtain missing data from the trial authors.
- With only 2 studies in this review, the authors did not perform an assessment of heterogeneity.
- Assessment of reporting biases were not possible through funnel plots due to the small amount of data available, but the authors were ale to locate unpublished and ongoing studies.
- With only 2 studies being reviewed, the authors were able to perform limited pooling. There was no statistical heterogeneity, and the authors could not perform a meta-analysis to allow meaningful summary.
- There were not enough data to perform subgroup analysis based on gender, activity level, or type of orthoses.
- A sensitivity analysis was not performed as planned due to lack of sufficient data, though the authors intend to perform a sensitivity analysis to determine if missing data had an effect.

Quality Assessment

- The authors determined that both studies satisfied randomization criteria. The Collins study used a randomization sequence that was kept at an off-site facility, while Wiener-Ogilvie allocated participants to groups through use of sealed envelopes containing group numbers, from which participants chose one envelope.
- Participants from neither study were blinded. However, Collins used a blinded outcome assessor and data analyst, while outcome assessors for Wiener-Ogilvie were not blinded.
- The authors consider the Collins article low risk of bias, as efforts to gather incomplete data were exhausted (one person passed away, and 7 could not be contacted).
- Differences between treatment groups were noted at baseline in the Collins article; however, these differences were not statistically significant. Similarly, Wiener-Ogilvie had differences at baseline, but they did not report whether these differences were statistically significant.
- A risk of performance bias exist in both trials as those who received foot orthoses had much more contact with the health professionals during the course of the fitting of the orthoses. No attempts were made to control such different levels of care by the trial authors.
- Overall, risk of bias was deemed low as a result of allocation concealment.

Setting

- Only two publications were selected for this review. Both were single centre clinical trials, and neither had a group that received no intervention. One was in Australia and the other in the UK.
- Risk of bias for Wiener-Ogilvie was unclear, as 27 out of 31 participants completed the trial. Those lost to follow-up included individuals who were hospitalized, had accidental knee injuries, or discontinued for personal reasons. The remaining participants, who were randomized were analysed on an intention-to-treat basis.
- Regarding selective reporting, the protocol used in the Collins article was previously published, and all primary outcomes were reported including adverse effects. However, secondary outcomes were not reported. The protocol used by Wiener-Ogilvie was not available.

Participants

There were 210 participants across both trials and data for 198 were included in final analyses.

Collins

- There were 179 participants (100 women, 79 men), age range 18-40 years.
- One person passed away, and 7 did not complete the trial.
- Participants were adults recruited from the local community through the use of media advertisements.

Wiener-Ogilvie

- There were 31 subjects (22 women, 9 men). This article did not report age ranges, but average age for all participants were 38.7 years for those in the orthoses group, 51.0 years for participants in the exercise group, while the average age for those in the combined group was 61.8.
- Four participants dropped out of the trial.
- Participants for this study came through referral by a general practitioner. There were no age restrictions and all had excessive foot pronation.

Intervention Investigated

Control

- For the Collins study, insoles (flat inserts) were used as a control that would act as a placebo against the foot orthoses. There was not a group that received no treatment.

Experimental

- The Collins study compared foot orthoses vs. insole (flat inserts)
- Both studies compared foot orthoses plus physical therapy vs. physical therapy alone
- Both studies compared orthoses vs. physical therapy
- Orthoses used in both studies were made of ethylene-vinyl acetate.
- Physical therapy differed between the two studies; where Collins included patellar mobilization and taping, Wiener-Ogilvie did not.

Outcome Measures

Primary Measures

Primary outcome measures for both studies include pain and function, assessed through a number of different scales.

- **Collins**
  - Outcome measurements were assessed at 6, 12, and 52 weeks post intervention.
  - A number of scales were used to report pain. They include Visual Analogue Scale, which is a 100 mm scale where 100 mm indicates worst pain. The global improvement scale was also used. This was a 5-point Likert scale where 1 indicated marked improvement, 3 indicated the same or no improvement, and 5 indicated marked worsening. A VAS on a 20cm scale was also used to report global improvement where -100mm indicated much worse, 0mm indicated the same, and 100 cm indicated completely better.
  - Function was reported using the Functional Independence Questionnaire (FIQ). This is a 16-point scale where 16 indicate no disability, and 0 indicates 100% disability.

- **Wiener-Ogilvie**
  - Outcome measures were assessed at 4 and 8 weeks.
  - Pain was reported through the 100 mm Visual Analogue Scale where 100 mm indicated worse pain. The global improvement scale was also used to report pain on a 5-point Likert scale. The trial authors did not give any distinction regarding the definition of 1 vs. 5 on this scale. The Knee Pain Scale (KPS) was also used. This is a 6-point Likert scale where 1 indicates no pain and 6 indicates maximum pain. A final measure used to report pain was the Short-Form 36 (SF-36). The SF-36 pain scale had two questions, one with 5 options and the other with 6. This scale ranged from 0 to 100 with a score of 100 being equivalent to less pain.
  - Function was not measured in this study.

Secondary Measures

- **Collins**
  - The use of over-the-counter analgesics were reported, no other information was given.
  - Adverse effects of interventions were reported. No other information was given.

- **Wiener-Ogilvie**
  - Patient satisfaction regarding foot orthoses was reported. No information was given regarding how these data were reported.
  - Quality of Life was reported through the SF-36 functional scale. This scale had 10 questions with a best possible score of 100 being equivalent to best health.

Main Findings

The authors of this review presented data for 6 and 52 weeks for the Collins article, and for Wiener-Ogilvie, 4 and 8 weeks. Pooled data are representative of those taken from week 6 of the Collins article and week 8 of Wiener-Ogilvie. General findings are reported here with interpretations of these findings reported under the critical appraisal section.

Orthoses vs. Insole (Collins only):

- For knee pain at 6 weeks, reports on the global improvement scale favoured foot orthoses over insoles with Risk Ratio (RR) 1.48 95% CI (1.11 to 1.99). These results were not sustained at 52 weeks RR 1.15, 95% CI (0.92 to 1.44). The authors of this review reported a similar finding for VAS where no statistically or clinical important differences were found at 6 or 52 weeks mean difference (MD) -8.20, 95% CI (-17.67 to 1.27) for 6 weeks and MD 1.50, 95% CI (-8.57 to 11.57).

- For knee function, no statistically significant differences were found using the FIQ. At six weeks, MD 0.70, 95% CI (-0.30 to 1.70), while at 52 weeks MD -0.40, 95% CI (-1.50 to 0.70). For the Anterior Knee Pain Scale, results were slightly better MD 4.30, 95% CI (0.34 to 8.26), but were not sustained at 52 weeks MD -1.40, 95% CI (-5.50 to 2.70).
- No reports of patient satisfaction or quality of live life were taken. No differences were found regarding analgesic use RR 0.89, 95% CI (0.45 to 1.78). Participants who received foot orthoses reported more adverse effects. These results were significant RR 1.87, 95% CI (1.21 to 2.91).

Orthoses plus Physical Therapy vs. Physical Therapy

- For knee pain in the Collins trial, no significant differences were found in the short-term RR 1.00, 95% CI (0.86 to 1.17) or long-term RR 1.01, 95% CI (0.82 to 1.23) with pooled results for global improvement sale. Additionally, no differences were found regarding pain on the VAS at 6 or 52 weeks MD -3.70, 95% CI (-12.99 to 5.59) and MD -3.40, 95% CI (-13.52 to 6.72) respectively.
- For knee pain in the Wiener-Ogilvie trial, differences were not statistically significant after 8 weeks for the SF-36 pain scale MD 9.60, 95% CI (-8.99 to 28.19).
- For knee function, the Collins study found no differences between the groups at 6 or 52 weeks MD 0.40 95% CI (-0.59 to 1.39) and MD -0.40, 95% CI (-1.51 to 0.71). There were also no significant differences at 6 and 52 weeks for the anterior knee pain scale MD 0.20, 95% CI (-3.72 to 4.12) and MD 3.60, 95% CI (-0.52 to 7.72) respectively.
- Wiener-Ogilvie also found no differences at8 weeks for the SF-36 function scale MD -4.50, 95% CI (-17.36 to 8.36), and no differences with concurrent use of analgesics RR 0.56, 95% CI (0.28 to 1.13). The authors of the Collins article did not report data for adverse effects in the physical therapy group.

Orthoses vs. Physical therapy

- Regarding knee pain in the Collins study, no significant differences were found between the group on the global improvement scale or VAS at 6 or 52 weeks. For the global improvement scale RR 0.99, 95% CI (0.80 to 1.21) and RR 1.04, 95% CI (0.86 to 1.27) respectively and for VAS MD 7.60, 95% CI (-1.77 to 16.97) and MD 5.40, 95% CI (-4.57 to 15.37) respectively.
- Wiener-Ogilvie had similar findings for the SF-36 pain scale after 8 weeks MD 13.30, 95% CI (-9.19 to 35.79).
- For Collins, knee function in the physical therapy group was statistically more significant on the FIQ at 6 MD -1.10, 95% CI (-2.10 to -0.10) and again at 52 weeks MD -1.20, 95% CI (-2.29 to -0.11). However, no significant differences were found with the anterior knee pain scale at either interval: 6 weeks MD -3.70, 95% CI (-7.64 to 0.24) and 52 weeks MD -2.40, 95% CI (-6.48 to 1.68).
- Knee function as reported by Wiener-Ogilvie had no significant differences at 8 weeks for the SF-36 function scale MD 0.24, 95% CI (-0.68 to 1.17). Similarly, no significant differences were found regarding the use of concurrent analgesics RR 0.81, 95% CI (0.44 to 1.49). The authors of the Collins study did not report data for adverse effects.

Original Authors' Conclusions

- While there are short-term improvements in outcomes for the use of foot orthoses in the treatment of patellofemoral pain, there are no long-term benefits.
- The use of foot orthoses produces significantly more adverse effects than those who used insoles.
- The use of foot orthoses while receiving physical therapy does not have better outcomes compared to physical therapy alone.
- Patients treated with orthoses vs. those treated with physical therapy are not likely to have better outcomes.

Critical Appraisal

Validity

[Methodology, rigour, selection, sources of bias, quality score on methodology quality rating scale (indicate the quality assessment tool used and the maximum possible score on that scale, e.g., 7/10 on PEDro scale), appropriateness of analytical approach (e.g., adjustments for confounding variables, management of missing data).]

Comment on missing information in original paper.

- This review was very detailed and receives a score of 11/11 on the AMSTAR checklist for assessing the methodological quality of systematic reviews.
- The reviewers performed a thorough search for studies of varying quality including studies in different languages, and grey literature such as unpublished studies, and studies that were currently being conducted. Additionally, they were very transparent with their search strategy. This points to low risk of publication bias.
- The reviewers contact trial authors for missing information or for clarity on methodology prior to deciding on inclusion/exclusion. They also stated reasons for which studies were excluded from the review, and provided a list of these studies that were excluded. This indicates low risk of selection bias.
- Reviewers provided detailed characteristics of the included studies as well as demographic characteristic of the participants of each study.
- The authors were clear about the methods of assessment used including sensitivity analysis, quality assessment tool, assessment of risk of bias (including allocation concealment and blinding) and utilized multiple reviewers with a plan of a third reviewer to resolve disputes.
- Although they were not able to perform much pooling of data due to insufficient number of studies, the reviewers reported the strategies they had planned to use to assess heterogeneity. As a result, funnel plots, χ^2 test, and I^2 statistic could not be computed. A weakness of the review.
- Finally, the authors made an effort to disclose any form of support received; there were no conflict of interest.

Overall, a rigorous search and analysis were performed, and a thorough report regarding this review. It can be considered low risk of bias and of high methodical quality.

Interpretation of Results

[Favourable or unfavourable, specific outcomes of interest, size of treatment effect, statistical and clinical significance, minimal clinically important difference. You may calculate effect size or confidence intervals yourself from the data provided in the article.] Describe in your own words what the results mean.

Orthoses vs. Insoles (Collins only)

- The results at 6-weeks follow up show short-term improvement in pain with the use of foot orthoses vs. insoles. With a risk ratio of 1.48, this indicates that individuals treated with foot orthoses over a 6-week period are 1.48 times more likely to see improvements over those treated with insoles. At 52 weeks:

however, this was not sustained, as the 95% CI range (0.92 to 1.44) contains 1.0. With a possible RR of 1.0, this indicates no difference between the two treatments at 52 weeks.

- No improvement in function was seen at 6-weeks or at 52-weeks follow up in this intervention on the FIQ. With the mean difference (MD) having a 92% CI range of -0.30 to 1.07, there is a possibility that the MD is 0.0, which would indicate improvement with this treatment.

Orthoses plus Physical Therapy vs. Physical Therapy

- With both studies finding no differences between these two groups, this means that both interventions could be efficacious treatments in individuals with patellofemoral pain. Additionally, the argument could be made that adding orthoses to a physical therapy intervention would not yield better results.

Orthoses vs. Physical Therapy

- No significant difference in knee pain was found with either intervention. This indicates that either could be an effective method of treating the condition.
- Clinically important improvement in knee function was found at 6 and 52 weeks in the Collins study favouring physical therapy on the FIQ. However, with MD being -1.10 and -1.20 at each follow-up respectively, this information must be used with caution, as it indicates that the difference between the treatments is barely significant.
- The use of over-the-counter pain medications did not have an effect on the intervention used.

IMPLICATIONS FOR PRACTICE and FUTURE RESEARCH

- This review focused on studies that investigated a number of different interventions for patellofemoral syndrome (PFPS), as well as the possible link between gluteal activation and PFPS in an effort to identify strategies for rehab. Studies included traditional physical therapy, foot orthoses, and flat inserts. These reviews were of high quality, demonstrating high validity and low chance of publication, selection, or information biases.

- Diminished hip abductor and hip extensor strength has been credited for patellofemoral pain syndrome (PFPS). [4,5,6,7] Additionally, many studies have focused on a hip-strengthening regimen as a rehabilitation intervention for the condition. Lower extremity kinematics have also been linked to PFPS.[8, 9, 10] A possible etiology that could be corrected with foot orthoses. A great deal of the studies regarding interventions for PFPS has been conducted with female subjects only or very few males. [4,5,6,7,9,10]

Implications for Clinical Practice

The evidence from one high quality (PEDro 8/10) randomised clinical trial investigated the efficacy of several treatment methods in the management of PFPS.[1] The findings suggest that short-term improvement could be attained with the use of foot orthoses in individuals with PFPS, which indicate that additional interventions may be warranted for long-term benefits. Additionally, the authors found no difference between the use of foot orthoses, traditional physical therapy, or a combination of both. This addition to the body of literature regarding the management of PFPS provides some understanding of the condition to practicing clinicians, as well as a tool for which they could use to direct the plan of care for a patient with PFPS.

- A high quality systematic review (AMSTAR 10/11) synthesized the available evidence regarding the relationship between gluteal muscle activity and PFPS.[2] The authors concluded that there is a link between and suggests, biofeedback or gait training should be considered in managing the condition."[2] However, clinicians must interpret these results with caution as the effect sizes were weak, and the methodological design of the studies reviewed may have had several systematic errors due to lack of blinding, lack of power from too few participants, as well as possible confounding factors.

Implications for Future Research

- The studies reviewed provide a better understanding of PFPS, how it responds to different treatments, and its possible link to gluteal muscle activity. It also adds to the literature great information regarding the management of the condition. However, several things could be improved upon for future studies. In the Collins study, for example, participants receiving the foot orthoses intervention were not screened for excessive foot pronation or other abnormalities in lower extremity kinematics during functional tasks.[1] As a result, it is possible that foot orthoses may not have been appropriate for the individuals who received that intervention. Therefore, screening individuals for excessive foot pronation is warranted for future studies.

- The studies reviewed by Barton and colleagues have great potential for isolating a possible etiology for PFPS. However, the methods used by the studies reviewed could be improved in the future. These include a blinded assessor as well as blinded participants, longer follow up period, as well as a set guideline to increase methodological rigor, [11] thereby decreasing the opportunity for bias and increasing validity. A sample size calculation could also be used to reduce the chance for finding results that aren't significant.

- The current body of literature that exist seem to have mostly female participants, and the results may not be generalizable to the population of individuals with PFPS. A prospective study by Leetun and colleagues concluded that, "Males had stronger hip external rotator and abductor strength and greater quadratus lumborum endurance compared with females,"[12] which could be a postulate for the dearth of studies with few or no males. However, future studies regarding the management of PFPS, regardless of the intervention, should include more males due to the biomechanical differences in lower limb kinematics between males and females.

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