
Prof Bill Vicenzino
Title: Foot Orthoses in the Management of Anterior Knee Pain: An Evidence Informed Pragmatic Clinical Approach

Presenter's Details:
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Professor (Sports Physiotherapy) & Head of Physiotherapy,
University of Queensland
Email: b.vicenzino@uq.edu.au

Overview synopsis:
If you see clients who have overuse injuries such as patellofemoral pain and you are not too confident about the examination of the foot, its role in these conditions and prescribing foot orthoses, then this course is for you. It provides a simple yet effective means of understanding foot function and its role in the treatment of lower limb overuse injuries. More importantly it teaches Vicenzino’s new and efficient way to make a clinical decision on the appropriateness of orthoses in treating overuse injuries. Orthotic prescription is demonstrated and practised. Importantly, integrating the use of foot orthoses with exercises, manual therapy and other physical therapy management (i.e., integration into an overall physical therapy management plan) is covered during the 2-day workshop. Bill is a Prof in Sports Physiotherapy at the University of Queensland (Australia) and leads a productive research team that has a track record in this area with numerous publications and competitive research grants underpinning the workshops and presentations.

Aims and Objectives:
After the course, participants will be able to:

a) Outline the evidence underpinning the use of foot orthoses in the management of anterior knee pain (largely patellofemoral pain) and its role in the decision making process in the physiotherapy treatment plan.
b) Evaluate foot structure and function to identify movement impairments and be able to relate this to the pathomechanics of overuse injuries generally, and patellofemoral pain specifically.
c) Understand the traditional mechanical method of decision-making in selecting foot orthoses and its limitations.
d) Implement a new method of clinical reasoning in the selection of foot orthoses, namely the Treatment Direction Test.
e) Select and fit an orthoses appropriate to the needs of the client.
f) Measure the effectiveness of foot orthosis therapy intervention in patellofemoral pain.
g) Understand orthosis therapy in the broader physiotherapy context in describe how foot orthoses integrate into physical therapy management.

Preliminary program (subject to alteration):

<table>
<thead>
<tr>
<th>Session</th>
<th>Time (hr)</th>
<th>Topic</th>
<th>Handout Part</th>
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<td>1</td>
<td>2</td>
<td>Foot orthoses in patellofemoral pain: evidence based considerations</td>
<td>A, H-J</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>Background overview of ankle and foot structure and function/dysfunction: gait</td>
<td>B</td>
</tr>
<tr>
<td>3</td>
<td>1.5</td>
<td>Orthoses, overuse injuries (PFP) and the treatment direction test (TDT)</td>
<td>C, G</td>
</tr>
<tr>
<td>4</td>
<td>1.5</td>
<td>Orthoses selection reasoning, TDT and fitting lecture</td>
<td>D</td>
</tr>
<tr>
<td>4-5</td>
<td>4</td>
<td>Orthoses fitting and TDT practical</td>
<td>D</td>
</tr>
<tr>
<td>6</td>
<td>2</td>
<td>Integrating orthoses within the physical therapy treatment plan</td>
<td>E, G</td>
</tr>
<tr>
<td>7</td>
<td>1.5</td>
<td>Foot and ankle assessment and treatment practical</td>
<td>F</td>
</tr>
<tr>
<td>8</td>
<td>1.5</td>
<td>Discussion, Q&amp;A and wrap up</td>
<td></td>
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</tbody>
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PART A:

Foot orthoses in patellofemoral pain: evidence based considerations
Inclusion criteria:
1. Non-traumatic AKP >6 weeks, provoked by 2 of the following:
   - Prolonged sitting or kneeling
   - Squatting
   - Jogging or running
   - Hopping or Jumping
   - Stair walking
2. Pain on palpation of peripatellar tissues, or pain on step down (25cm step) or double leg squat
3. Pain over previous week ≥30mm / 100mm VAS
4. Between 18-40 years of age

Exclusion criteria:
1. Other knee injury or pathology: current or past
2. Positive patellar apprehension test
3. Knee joint effusion
4. Foot condition not suitable for orthoses
5. Pain in or referred from hip or lumbar spine
6. Previous treatment with foot orthoses

Idiopathic pain arising from the front of the knee

Common condition; long term impact

Poor prognosis; longer duration & more severe pain

- Of 89 potential candidates only 16 studies met the criteria of RCT
- Physiotherapy evaluated in 8 trials and the remaining other physical interventions
- Braces, PF orthoses, acupuncture, laser, chiropractic, and patellar taping had no evidence supporting them
- Foot orthosis and progressive strengthening exercises were effective, but low quality RCT limiting generalizability


- 20 females (15(1)yr) with PFPS (10(1)mth duration) + excess pronation
- Treatment group = exercise + orthotic
- Control group = exercise (quads & hams)
- 1 therapist session & 3 random calls for compliance!
- 8 week follow up on pain VAS
- Both improved on PVAS but orthotic superior
- Inadequate data provided to derive point estimates of effect


22 RCTs identified:

- 15 were treatment studies
- 2 on PFPS/AKP

Issues with studies of treatment with orthoses:

- Small participant numbers
- Few used adequate placebo controls
- Multitude of outcome measures used
- Usually poor methodological quality

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Age</th>
<th>N</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-fabricated Orthoses</td>
<td>39</td>
<td>17</td>
<td>17.9(17.8)</td>
</tr>
<tr>
<td>Exercise</td>
<td>51</td>
<td>23</td>
<td>10.6(8.2)</td>
</tr>
<tr>
<td>Orthoses + Exercise</td>
<td>62</td>
<td>10</td>
<td>29.8(38)</td>
</tr>
</tbody>
</table>

Main inclusion criteria:
Antero-medial knee pain with pronation (ascertained on clinical exam)

8 week follow up
Orthoses + Exercise (n9) -v- Exercise (n9):
RR: 1.14 (0.75 to 1.74)
pVAS SMD: 0.87* (-0.11 to 1.85) cm

Orthoses (n9) -v- Exercise (n9) :
RR: 0.57 (0.25 to 1.28)
pVAS : 0.8 (-0.17 to 1.77) cm


- 20 females: 14.8 ± 1.2 years PFP
- Excessive pronation
  - nWB Forefoot varus >6°
  - WB Rearfoot valgus >6°
- Randomised to posted or non-posted soft orthosis (spenco)
- All did home exercises general strengthening and stretching
- Outcome: gait, sit, squat at 2, 4, 6 & 8 weeks

• N = 20 females 14.8 ± 1.2 years

http://www.biomedcentral.com/1471-2474/9/27

National Health and Medical Research Council of Australia:
1. Vicenzino: Primary Health Care Project Grant (#301037).
2. Collins: Public Health Scholarship (#351663)

RCT: questions

1. Are foot orthoses more effective than flat inserts?

2. Are foot orthoses more effective than physiotherapy?

3. Does adding foot orthoses to physiotherapy improve outcome?
RCT: methodology

179 participants with AKP (informed consent)
Outcome measures (baseline)

Randomisation
(concealed allocation)

Foot orthoses
(n=46)
Flat inserts
(n=44)
Physiotherapy
(n=45)
Foot orthoses &
Physiotherapy
(n=44)


RCT: interventions

1. Foot orthoses (Vasyli International)

2. Flat inserts

RCT: interventions

3. Physiotherapy

4. Foot orthoses + Physiotherapy

RCT: methodology

179 participants with AKP (informed consent)
   Outcome measures (baseline)
   Randomisation (concealed allocation)

- Foot orthoses (n=44)
- Flat inserts (n=44)
- Physiotherapy (n=45)
- Foot orthoses & Physiotherapy (n=44)

6 appointments with Physiotherapist over 6 weeks

Outcome measures: 6, 12, 52 weeks

RCT: outcome measures

Global improvement

<table>
<thead>
<tr>
<th>Much worse</th>
<th>Same</th>
<th>Completely better</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marked improvement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate improvement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Same</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate worsening</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marked worsening</td>
<td></td>
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</tbody>
</table>


RCT: outcome measures

Global improvement

<table>
<thead>
<tr>
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</tr>
<tr>
<td>Same</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate worsening</td>
<td></td>
<td></td>
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<tr>
<td>Marked worsening</td>
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</tbody>
</table>

SUCCESS

Non-success


RCT: participant characteristics (n=179)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>29.3 ± 5.8 years</td>
</tr>
<tr>
<td>Gender</td>
<td>56% female</td>
</tr>
<tr>
<td>BMI</td>
<td>24.8 ± 5.1 kg/m²</td>
</tr>
<tr>
<td>Bilateral AKP</td>
<td>57% bilateral</td>
</tr>
<tr>
<td>Duration of AKP</td>
<td>28 (12-84) months</td>
</tr>
<tr>
<td>Worst pain VAS</td>
<td>60.5 ± 15.9 mm</td>
</tr>
<tr>
<td>Anterior Knee Pain Scale</td>
<td>71.5 ± 9.8</td>
</tr>
<tr>
<td>Functional Index Questionnaire</td>
<td>9.8 ± 2.1</td>
</tr>
</tbody>
</table>

RCT results: global improvement


An aside: global improvement

NNT 2 (1 to 4) orthoses v wait and see (Mills)

RCT results: global improvement

Foot orthoses

Flat inserts

Physiotherapy

Physiotherapy & Foot orthoses
**RCT: questions**

1. Are foot orthoses more effective than flat inserts?
   - Foot orthoses are more effective than flat inserts in the short term (6 weeks)

2. Are foot orthoses more effective than physiotherapy?
   - Foot orthoses and physiotherapy have similar short and long term effects

3. Does adding foot orthoses to physiotherapy improve outcome?
   - No additional benefits of adding foot orthoses to physiotherapy

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**RCT: observations**

Foot orthoses are more effective than flat inserts in the short term (6 weeks)

NNT 4 (99% CI 2 to 51)

Wide CI suggests heterogeneity of response if patients are treated randomly with foot orthoses

Did not use any specific selection criteria for foot orthoses (e.g., foot posture, motion)

... may underestimate the effect for some patients

Can we improve the success rate?

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**RCT results: global improvement**


- MD 15 (0.68 to 29.52) ; SMD 0.46
- NNT 7; ARR 0.146
- 16.1 (-3.0 to 35.3)
- RRR 0.1 (-0.99 to 1.2)
- NNT 50 (4 to 6)

Can we improve the success rate?

...by predicting who may benefit from an orthosis

Can we predict who will benefit?


Criteria for CPR to predict success @ 12 weeks:
Foot width WB-NWB diff > 1 mm
Age >25 years
Height < 165 cm
Pain severity < 53 mm

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<thead>
<tr>
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<tbody>
<tr>
<td>Foot width</td>
<td>6 (85%)</td>
<td>8 (60%)</td>
<td>1 (50%)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Height</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

+LR [95% CI]: 8.8 [1.1 to 66.9], 2.2 [1.1 to 4.2], 1.6 [1.2 to 2.1]
Plausibility of predictors (foot orthoses):

Foot posture and mobility measures:


Plausibility of predictors:

Mid-foot width difference from NWB to WB:

• Plausible targets for ‘anti-pronation’ orthoses are:
  • increased foot mobility, and/or
  • lower arch
• Foot measures found to be predictors by Sutlive et al (2004) .
  ...though the latter showed lower navicular drop and forefoot valgus to be predictors!

Can we predict who will benefit?

Collins N, Beller E, Darnell R, McPoil T, Vicenzino B., Foot orthotics in the treatment of AKP: A RCT in primary care. NHMRC project#301037

no stratification

for

‘biomechanical foot measures’

Sutlive et al identification of individuals with PFP whose symptoms improved after a combined program of foot orthosis use and modified activity: A preliminary investigation. Phys Ther 2004: 84: 49-61

N = 46, 15 female, 28.1 (6.2) years
Treatment = off the shelf orthoses and activity modification for 3 weeks
Success = 50% improvement in pain VAS

Intrinsic to foot/ankle:
- Great toe extension
- Navicular drop test
- Relaxed calcaneal stance
- Rear foot in subtalar joint neutral position
- Forefoot alignment
- Ankle dorsiflexion with knee flexed
- Ankle dorsiflexion with knee extended

Extrinsic to foot/ankle:
- Leg-length difference
- Tibial varus/valgus
- Q angle
- Tibial torsion
- Craig test for femoral torsion
- Hamstring muscle length
### Physical examination +LR* (95% CI)

<table>
<thead>
<tr>
<th>Examination</th>
<th>+LR* (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forefoot alignment: 2° valgus</td>
<td>4 (0.7 to 21.9)</td>
</tr>
<tr>
<td>Great toe extension: ≤ 78°</td>
<td>4 (0.7 to 21.9)</td>
</tr>
<tr>
<td>Navicular drop: ≤ 3mm</td>
<td>2.3 (1.3 to 4.3)</td>
</tr>
<tr>
<td>RCSP: ≤ 5° valgus and all varus</td>
<td>1.9 (1.0 to 3.6)</td>
</tr>
</tbody>
</table>


*2 to 5 = significant but small shift in probability*
<table>
<thead>
<tr>
<th>Physical examination</th>
<th>( +LR^* ) (95% CI)</th>
</tr>
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<tbody>
<tr>
<td>Forefoot alignment: 2° valgus</td>
<td>4 [0.7 to 21.9]</td>
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Sutlive et al Identification of individuals with PFPS whose symptoms improved after a combined program of foot orthosis use and modified activity: A preliminary investigation. Phys Ther 2004: 84: 49-61

PFPS, mobile feet & foot orthoses: an RCT
Musculoskeletal Pain & Injury Research Unit
Linkage Grant LP0668233
Professor Bill Vicenzino
Kathryn Mills, Peter Blanch, Priya Dev and Professor Michael Martin

1 University of Queensland
2 Australian Institute of Sport
3 Australian National University
Foot orthoses are used in clinical practice

Orthoses are an efficacious treatment option compared with other treatment modalities
(Collins et al 2008, Eng and Pierrynowski 1993)

Orthoses v flat insert @ 6 weeks
NNT 4 (95% CI 2 to 51)

Criteria for preliminary CPR to predict success @ 12 weeks:
- Foot width WB-NWB diff > 11mm
- Age > 25 years
- Height < 165 cm
- Pain severity < 53 mm

(Vicenzino et al., 2010)

Natural history?
Are orthoses more efficacious than wait-and-see?

Investigate the short-term clinical efficacy of orthoses over natural history

Explore if measures of foot posture and mobility are able to predict treatment success

Methodology

Participants: n=40


- Age 18-40 years
- No surgery or injury to the lower limb, pelvis or back
- No orthoses for the past 5 years
- Anterior or retropatella pain
- >6 weeks duration
- Aggravated by stairs, hills, running, jumping/hopping, squats, kneeling/sitting for extended periods
- Pain on palpation of the patella facet, or on deep squat
- No other damage or injury to knee structures
Methodology

Participants n=40

Baseline session

- Kujala Patellofemoral Score
- Usual and worst pain severity
- Patient specific functional scale

Outcome measures (secondary)

Foot Assessment Platform

Foot posture and mobility measures


- Dorsal arch height weight bearing
- Dorsal arch height non-weight bearing
- Midfoot width weight bearing
- Midfoot width non-weight bearing
- Arch height mobility
- Midfoot width mobility
Methodology

Participants n=40
Baseline session

Foot orthoses n=20
Control n=20

Wait-and-see policy

<table>
<thead>
<tr>
<th></th>
<th>Orthosis prescription was based on comfort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shore A</td>
<td>Jog (self-selected constant speed) 3 minutes</td>
</tr>
<tr>
<td>75</td>
<td>Jog (self-selected constant speed) 3 minutes</td>
</tr>
<tr>
<td>60</td>
<td>Most comfortable (highest ranking) orthosis</td>
</tr>
<tr>
<td>52</td>
<td>Orthosis</td>
</tr>
</tbody>
</table>

No of women
15 (75%) 14 (70%)  p=0.731

Age years
30.4 (5.47) 28.5 (5.89)  p=0.285

Height cm
167.3 (16.0) 172.6 (8.9)  p=0.227

Weight kg
78.16 (12.7) 70.5 (10.8)  p=0.709

Worst pain mm
50.3 (20.2) 56.6 (19.4)  p=0.317
Methodology

Randomised n=40

Baseline session

Foot orthoses n=20

Control n=20

Follow-up (6 weeks) n=19

Follow-up (6 weeks) n=20

Primary outcome measures

Secondary outcome measures

• Global improvement scale
• Kujala Patellofemoral Score
• Usual and worst pain severity
• Patient specific functional scale

Global improvement scale

Completely recovered
Much improved
Improved
No change
Worse
Much worse

Success

Completely recovered
Much improved
Improved

No success

No change
Worse
Much worse
Predictive value of foot measures

- Foot length
- Midfoot width in weight bearing
- Midfoot width in non-weight bearing
- Arch height in weight bearing
- Arch height in non-weight bearing
- Difference in arch height
- Foot mobility magnitude ($\sqrt{\text{diff arch height}^2 + \text{diff midfoot width}^2}$)

Midfoot width diff: 11.25 mm (classification tree analysis)
Table 3  Mean (SD) and mean difference (95% CI) between groups for secondary outcome measures adjusted for baseline values

<table>
<thead>
<tr>
<th>Measure</th>
<th>Orthoses (n = 11)</th>
<th>Control (n = 20)</th>
<th>Mean difference</th>
<th>95% CI</th>
<th>Z</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain Numerical</td>
<td>87.01 (15.12)</td>
<td>85.66 (10.81)</td>
<td>1.35 (0.00 to 9.33)</td>
<td>0.44</td>
<td>0.67</td>
<td>0.50</td>
</tr>
<tr>
<td>Visual Analogue</td>
<td>6.60 (2.0)</td>
<td>5.03 (1.2)</td>
<td>1.57 (0.15 to 2.98)</td>
<td>10.74</td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Worst pain</td>
<td>24.4 (22.9)</td>
<td>19.6 (24.2)</td>
<td>-4.82 (15.06 to 5.42)</td>
<td>0.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total point</td>
<td>27.3 (13.9)</td>
<td>26.87 (20.9)</td>
<td>-0.46 (1.91 to 5.02)</td>
<td>0.34</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Significantly lower in orthoses group.

Function not pain most responsive

A randomised control trial of short term efficacy of in-shoe foot orthoses compared to a wait and see policy for anterior knee pain and the role of foot mobility

Kathryn Mills,1 Peter Bland,1 Hyva Dav,2 Michael Martin,2 Bill Vickers1

BJSM
Orthoses are an efficacious treatment option

Comfortable in-shoe foot orthoses produce short-term improvements beyond that of natural history

Improvements appear to be primarily functional and pain may be slower to resolve

Patients with a mobile midfoot are likely to have increased success rate if they are prescribed with an orthosis
PART B:

Background overview of ankle and foot structure and function/dysfunction: gait
Clinical reasoning in gait & Gait analysis

Structure

Function

Dysfunction

Context

• Musculoskeletal practice
• Overuse injuries
• Minor motion imbalances
• Focus on the foot/ankle complex
• Comparative approach: walk-run

Talocrural joint
Dorsiflexion (10°) & plantarflexion (20°)
Normal total range values: 44-70°

Close pack: dorsiflexion

Talar anteroposterior glide - dorsiflexion
Talar posteroanterior glide - plantarflexion
Subtalar Joint

Supination- Pronation tri-planar motion
ROM: 20°-65° (mean = 40°)

Torque conversion: calcaneum-tala-tibia
Axis variation:
  High axis = abd-add > inv-ev
  Low axis = inv-ev > abd-add

Midtarsal Joint

Oblique and Longitudinal axes

Subtalar - mid-tarsal joint relationship

Metatarsal Phalangeal Joints

Ankle & foot motion in gait:

- Sagittal Plane
- Transverse / Frontal Plane

Knee motion during gait:

- Sagittal Plane
- Transverse / Frontal Plane
Hip/pelvic motion during gait:

- Sagittal Plane
- Transverse / Frontal Plane
Clinical implications:

- Lack of hip motion (e.g., extension or internal rotation) impedes hip function - loads back and lower limb
- Lack of control of rotation results in increased range of motion (e.g., excessive internal rotation, tilt) - loads muscles and joints
- Treatment guided by viewing the gait pattern, then evaluating active and passive motion and muscle function in physical examination.


Phase shift as increase speed.

Note foot strike differences between walk and run.
Clinical implications:

• Specificity of muscle contraction type during rehabilitation
• Shock absorption and protective function
• Importance of trunk and hip muscles in sprinting
• Lift off rather than Push off?

Clinical Significance:

• Gait, especially walking, is a basic function necessitating a sound level of knowledge of the motions, muscle activations and mechanisms of gait.
• Important to analyse gait if client presents with an ambulatory problem - make sure that it is relevant to the client.
• Dysfunction will be the focus of next session.
Patient position:
Prone lying in figure 4 position.
Ensure rear surface of heel parallel to floor.

Therapist position:
Seated with foot at about mid section.
Overlooking distal leg.

Procedure:
Identify the medial and lateral extent of calcaneum.
Approximate the mid point (bisector).
Place dots on bone (ie above fat pad and not on tendon).

Indications and notes:
1. Joining the dots defines two vectors by which rearfoot angulation to distal leg is possible.
2. Use white tape under black dot to form markers for video recordings.

Student class notes.
Clinical Gait Analysis: Practical Tips

1. High Sample Rate due to Small Movements & Large Variability
2. Get approximately 10 strides at steady pace
3. Care with Plane of Observation
4. Normal or increased speed not slower
5. Footwear - on/off/compare?
6. Treadmill requires training/familiarisation
7. Video
   - Alignment
   - Lighting
   - Skin Markers
PART C:

Orthoses, overuse injuries (PFP) and the treatment direction test (TDT)
Overuse injury defined:

- Occurs when a structure is exposed to a repetitive force beyond its abilities to withstand such a force (Stanish 1984)
- Intrinsic injury
- Chronic repetitive activity or acute onset repetitive activity

Lower Limb Overuse Injuries

A significant problem
- High Prevalence in fitness activities (e.g., jogging, aerobic gym workouts, cycling, etc)
- Impedes performance
- Interferes with participation

Many lower limb overuse injuries have been putatively associated with abnormal lower limb biomechanics such as excessive pronation

How valid is that association?

Study type

1. Cross sectional
2. Longitudinal (prospective, retrospective)

Prospective longitudinal study of 185 (118 male, 67 female) aged 18.3 ± 0.5 yrs.

Muscle weakness, ligamentous laxity & muscle tightness intensified by large body weight and height, high explosive strength and malalignment of the lower limbs (female>male)

How valid is that association?


1. a significantly more central heel-strike
2. a significantly increased pronation
3. accompanied with more pressure underneath the medial side of the foot
4. a significantly more lateral roll-off

Overuse injuries: classification

Phase I: pain during, may go with warming up, or be present for short while later
Phase II: pain during exercise, not subsiding, present later, but not interfering with ADL
Phase III: pain starting to limit physical activity and in ADL
Phase IV: pain interfering with ADL, consistent if not constant symptoms
Diagnostic based guidelines:

Phase I & II:
- Treat and train while deloading tissues

Phase III & IV:
- Cease activity that produced pain/injury
- Attend to pain ± inflammation as priority
- Deload tissues as a means relieving pain and encouraging normal function

Risk factors:

- Training $^{1,3}$
- Equipment $^{1,3}$
- Environment $^{1,3}$
- Biomechanical $^{2,3}$

1. Extrinsic factors largely checked in interview
2. Intrinsic factor examined physically
3. Must be checked in clinical examination

Multifactorial Mix of Risk Factors (proportional)

Relative Risk of Injury
- Biomechanical Factor
- Environmental Factor
- Equipment Factor
- Training Error

Training Error Increased (e.g., load, heavy weights, less rest)
Training factors

• Too much too soon
• Too much load
• Too little rest
• Poor preparation for heavy work
• Plyometric
• Change in technique

Equipment Factors

• Footwear
  • Heel cup (vertical, firm, snug)
  • Flexibility at MTP joint
  • Fit
  • Age of shoe and amount of wear
• Bike set up for cyclists
Environment Factors

- Camber of surface
- Firmness / compliance of surface
- Temperature and humidity
- Hilly or flat
Biomechanical Factors

- Skill technique
- Bony alignment
- Joint motion
- Muscle
  - Strength (eg. weakness, endurance)
  - Tightness
  - Coordination

LL kinetic chain: foot ...


Clinical biomechanics of PFPS:
Clinical biomechanics of PFPS:

Stresses causing pain

Some Local Causes of valgus vector:
- Bony dysplasia
- Weak VMO
- Tight lateral structures
Clinical biomechanics of PFPS:

Some Distant Causes of Valgus Vector:
- IR & ADD @ Hip
- Bony Irregularity
- Weak Hip ERors
- Tight Hip IRors
- Foot Pronation

Sample:
- 282 physical education students (131 female)
- 18.6 years old (17-21 yr range)
- All enrolled in a similar physical activity program of approximately 12-14 hours sport per week
- All previously asymptomatic and examined at entry into study
1. Explanatory variables:
2. Anthropometric variables (height, weight, body fat%, body composition)
3. Physical fitness (Eurofit test, submaximal ergometer test)
4. General joint laxity (thumb to forearm, elbow, knee, shoulder and little finger hyperextension, patella mediolateral mobility with quads relaxed and knee extended measured in mm)
5. Lower leg alignment (leg length difference, foot alignment - arch height, forefoot and rearfoot alignment)
6. Muscle length and strength (hamstring, quads and gastrocnemius muscle length, isokinetic strength of hamstrings and quads)
7. Static patellofemoral characteristics: Q-angle, genu varum/valgum
8. Dynamic patellofemoral characteristics: tendon reflex response latency
9. Psychological parameters: coping mechanisms, intro/ extroversion, neurotic and psychosomatic lability

Incidence of PFPS = 9% or 24/282
- Female 10%(13)
- Male 7%(11)
- 11/24 had bilateral PFPS

PFPS defined as:
- >6 week duration of symptoms
- Symptoms = retropatellar pain with activities such as jumping, running, squatting, stair climbing
- 2 of the following clinical signs: PF compression in Knee Ext, +ve Clarke’s sign, pain to palpation posterior patella, resisted Knee Ext, and -ve findings for other knee problems (e.g., ligaments, menisci, etc).


Significant contributors to PFPS (logistic regression)
- Reduced quadriceps flexibility (injured:125±13 / control: 132±16; measured with PKB with other hip flexed to 90 degrees)
- Shortened reflex response for VMO
- Reduction in explosive strength, that is, in vertical jump performance (injured:53±4 / control: 56±6cm)

Statistical differences existed in additional variables:
- Gastrocnemius length (injured:33±7 / control: 35±7, weight bearing)
- Thumb-forarm flexibility
- Reflex response of VL as well as VMO above
- Psychological parameter of seeking social support

NOT Q-angle (PFPS 11.5±6.2, Control 13.0±7.7)
Multifactorial Mix of Risk Factors (proportional)

Advice and education

- Training error
- Periodisation
- Cross training
- Consult with coach/athlete

Equipment faults
- What to look for in a shoe
- Shoe rotation
Shoe advice to client:

- Heel cup
  - Firm
  - Vertical
  - Snug
- Extension at MT-P joint
- Fit
- Last shape and foot type?
- Gimmicks, fads and R&D

Advice and education

- Training error
  - Periodisation
  - Cross training
  - Consult with coach/athlete
- Equipment faults
  - What to look for in a shoe
  - Shoe rotation
- Environmental faults
  - Surface compliance and slope
  - Biomechanical faults in skill (e.g., jogging)
- Role for the run coach
PART D:

Orthoses selection reasoning, TDT and fitting lecture
1. Overuse injuries defined, predisposing (risk factors) & treatment

2. Who is likely to need an orthotic

3. How to fit an orthotic

4. What do you do for those who are not likely to need an orthotic

‘Custom’ foot orthoses

measures taken from foot representation of foot

http://www.foothealth.info/orthotics/

Off-the-shelf foot orthoses

‘pre-fabricated’

http://www.vasyli.com/brands/medical.html

Sutlive et al Phys Ther 2004: 84: 49-61

http://www.formthotics.co.nz
Foot orthoses in lower limb overuse injuries:  
Collins et al (2007)

? Quality of current level 1 evidence

Prevention ✓
Foot orthoses over simple insoles
Foot orthoses over control?

Treatment ×
Can’t rely on current evidence base
Need to look at other levels of evidence

No evidence of an effect of custom over prefabricated foot orthoses

How do podiatrists make decisions regarding orthosis use?

Surveyed 1505, with response rate of ~40%.
12% pre-fabricated & 72% customized - majority (73%) were Root-type & majority balanced to Neutral sub-talar position
6 times more likely to prescribe Root-type orthoses


Root ML, Orien WP, Weed JH (1977) Abnormal function of the foot (Volume 2) Los Angeles Ca: Clinical Biomechanics Corp.
Root et al normal foot alignment


Root ML, Orien WP, Weed JH (1977) Abnormal function of the foot (Volume 2) Los Angeles Ca: Clinical Biomechanics Corp.

1. Determine if any intrinsic deformity exists
2. Measure amount of deformity
3. Cast foot to capture degree of deformity
4. Construct functional orthoses (± posts)


- Measurement technique reliability
- Criteria proposed for normal foot alignment
- The position of the rearfoot at midstance during walking = neutral alignment
Challenges the validity of Root et al defined normal alignment during gait. SLS or relaxed stance approximates rearfoot position during walking.

- Questionable validity, due to:
  - Poor reliability of measures
  - Normal foot alignment is not normal
  - Mid-stance rearfoot position is not STJ neutral
- Proposed a tissue-stress model for therapists to use.
1. Identify tissues being stressed (interview)
2. Physical examination (i.e., stress tissues) to confirm tissues as source of symptoms
3. Determine the pathomechanics/etiology of the presenting condition.
4. Institute treatment that:
   a) reduce tissue stress (rest, footwear, orthoses)
   b) modalities to assist healing
   c) restore muscle length and flexibility


- 32 year old male
- Competitive soccer player
- Achilles tendinopathy II*
- 2 year history of the condition
- Aggravated by soccer, jogging & netball

- TOP over Achilles tendon

- Prolonged & excessive pronation determined by clinical observation

- CSOM: Run to pain threshold = 103m

TDT Step 1:
client specific outcome measure

Practitioner

1. Determines that there is some movement abnormality that plausibly relates to symptoms

2. To do this there has to be some modeling of how the abnormal movement leads to excessive stress
TDT Step 2: Physical Manipulation

Mechanical effects

TDT Step 3: Re-evaluate

Effect on pain and function appears to be most critical element in successful management by orthoses, not movement correction.


Are foot orthoses required?

Based on results of TDT?
Modification of McPoil & Hunt Tissue-Stress Model

1. Identify tissues being stressed (interview)
2. (a) Physical examination (i.e., stress tissues) to confirm tissues as source of symptoms
   (b) Treatment Direction Test if orthosis needed
3. Determine the pathomechanics/etiology of the presenting condition.
4. Institute treatment that:
   a) reduce tissue stress (rest, footwear, orthoses)
   b) modalities to assist healing
   c) restore muscle length and flexibility


Physical Manipulation in TDT & Orthotic type is based on gait abnormality:

Excessive pronator or Supinator

Supinator:
Exclude first ray

Proximal to MTP joints

Distal to Cuboid-4/5th rays joint

Supinator TDT/orthotic:

Supinator orthotic:
Excessive pronator or Supinator

Physical Manipulation in TDT & Orthotic type is based on gait abnormality:

Excessive pronation:

loading response: excessive pronation


Sutlive et al Phys Ther 2004: 84: 49-61

http://www.foottomics.com/products.html

http://www.formthotics.co.nz

http://www.vasyli.com/brands/medical.html
External physical devices: Tape

Treatment direction testing
- Pre-requisite to orthotic therapy in most cases
- Only worthwhile with excessive pronation, not lack of pronation

Short term use - usually, some exceptions
- May be used in cases where orthotics not suitable (eg, ballerina, sprinter, gymnast)
- De-load stressed tissues

Tape
- Not good with
  - Bony lack of TC dorsiflexion
  - Forefoot varus
- Adverse effects
  - Skin reactions
    - Allergy or Traction injury of skin
    - Signs and symptoms
  - Skin tests
  - Warnings
Temporary anti-pronation orthotic:

Tape and felt padding have similar effect on arch height

Orthotic therapy options:
Off the shelf mouldable:

Rigid customised fabricated by practitioner:
Guidelines for fitting: background

Biomechanical effects are small, non-systematic and highly variable (Nigg 2007) and should be used with care in fitting.

Nigg review (1999) “…based on this concept, an optimal insert or orthotic would reduce muscle activity, feel comfortable, and should increase performance.”

Main adverse effect is discomfort, which led to discontinuation in most cases (Collins et al 2007)

Guidelines for fitting:
- Comfort
- Performance

“…based on this concept, an optimal insert or orthotic would reduce muscle activity, feel comfortable, and should increase performance.” (Nigg et al 1999)

Guidelines for fitting:
- Comfort
- Performance

- Variables:
  - Volume of orthosis
  - Length of orthosis
  - Density or firmness of orthosis
  - Additions and modifications to orthosis
Length of orthoses

**SIZE & FIT?**

8-10mm proximal to MTP

Guidelines for fitting:

**Comfort First:**
...tested during weight bearing task

1. Appropriate and adequate footwear
2. Select orthoses to footwear (volume)
3. Fit orthoses to foot (length)
4. Heat mold/grinding
5. Additions

Guidelines for fitting:

then **Performance**
...tested during client specific outcome measure / functional task

1. Appropriate and adequate footwear
2. Select orthoses to footwear (volume)
3. Fit orthoses to foot (length)
4. Heat mold/grinding
5. Additions*

* McPoil uses the TDT induced change in dorsal arch height as the guide for orthotic additions
Guidelines for fitting:
No measure of foot form, mechanics, motion or orthosis-paradigmatic related measures

Overarching principle:
EPD = comfortable
EPD = comfortable & pain-free
CSOM

Mechanical effects appear to be 2ndary consideration

Modified McPoil & Hunt Tissue-Stress Model
1. Identify tissues being stressed (interview)
2. (a) Physical examination (i.e., stress tissues) to confirm tissues as source of symptoms & to identify the physical impairments that you may wish to treat
   (b) Treatment Direction Test if orthosis needed
3. Determine the pathomechanics/etiology of the presenting condition.
4. Institute treatment that:
   <reduce tissue stress (rest, footwear, orthoses)
   <modalities to assist healing
   <restore muscle length and flexibility
Treatment options:

• Manual therapy
  • Joint and soft tissue manipulation
  • Talocrural joint
  • Subtalar joint
  • Mid tarsal joint
  • Calf muscles
  • Thigh fascia

• Exercise
  • Control
    • Specific postural sets (A.P.E & A.P.E.D)
    • use of biofeedback such as EMG
  • Endurance
  • Stretching
  • Strength
  • Power
  • Therapeutic exercise course

Treatment options:

- Electro-physical agents
  - Heat soft tissues pre-stretching
    - although exercise is more effective at this
  - Pain gating
    - TENS like electrotherapy
  - Anti-inflammatory
    - only if signs of inflammation remembering that in chronic tendinopathy there are few signs of inflammation so pain is coming from some other source
  - Accelerated healing
    - Dubious claims, little evidence

Some examples of clinical presentations that may not fully respond to the foot orthotic:

Excessive internal rotation of the hip and thigh in mid-stance (eg, as in PFPS):

- tape at the hip joint
- exercises for the external rotators (Brolga)
- stretches for tight internal rotators

Some examples of clinical presentations that may not fully respond to the foot orthotic:

Poor control of patellofemoral joint with weak/poorly activated/delayed onset VMO as in PFPS:

- tape at the patellofemoral joint
- exercises for VMO (EMG, squat)
- stretches for tight lateral structures such as lateral retinaculum or iliotibial band (self, therapist-massage/mobilisation)
Some examples of clinical presentations that may not fully respond to the foot orthotic:

Lack of talocrural dorsiflexion that isn’t bony (which would respond to heel raise):

- Anti-pronation tape at the foot not very effective - especially if reduces in biomechanical effect very quickly
- Specific exercises to stretch calf - foot in supinated position (anti-pronation exercise)
- Manual therapy for calf or ankle joint

Supinated type foot, especially rigid:

- Supinator pad only partly effective
- Manipulative therapy to improve range of motion at the sub-talar joint (± mid tarsal if tight)
- Orthotic with increased shock absorption and possibly motion enhancing?

Hyper-flexible foot:

- Anti-pronation taping only part effective
- Exercises of intrinsic foot muscles
  - Must do in good posture
  - May need some posting/wedging?
PART E:

Integrating orthoses within the physical therapy treatment plan
Should an orthoses be used?

What kind of an orthosis is required?

Where do orthoses fit within the treatment plan (concomitant therapies?)

Evidence in literature:

Are foot orthoses required?

Manual Therapy, 9:185-96

Are foot orthoses required?

What is the likelihood of success?
Case example: anterior knee pain

- 30 yr old chronic AKP
- CSOM 4 stairs to Pain threshold
- TDT 62 steps
- Followed up with orthoses in next 6 weeks

ALD TDT example

Case example:

- Chronic Ankle Instability: mid foot pain - deep and diffuse
- 24 month duration
- Routine rehabilitation not resolve issues completely
- Gait down stairs, uneven surfaces and down slopes/hills (unable to perform latter due to pain and instability)
- Supinator TDT allowed downstairs walking symptom free
- Followed up with supinator pad on innersole (no orthoses was comfortable, so only used pad)

Movement correction is only part of the solution in successful use of foot orthosis, effect on pain and function is possibly most critical.
Treatment Direction Tests Applied:

- Several circumstances encountered:
  - In clinic
    - Standing or Sit to Stand
    - Walking or jogging (approx. < 5 minutes)
  - Runner or long time for onset
    - Apply tape and send out to re-test
    - Send out for run and examine at time of pain
    - Or both?
  - Other
    - BEWARE of client who is unsure of aggravating factor and dysfunction (ie don’t know when pain is a problem)


? Quality of current level 1 evidence

Prevention ✔
- Foot orthoses over simple insoles
- Foot orthoses over control?

Treatment ✗
- Can’t rely on current evidence base
- Need to look at other levels of evidence

*No evidence of an effect of custom over prefabricated foot orthoses*


Root ML, Orien WP, Weed JH (1977) Abnormal function of the foot (Volume 2) Los Angeles Ca: Clinical Biomechanics Corp.

1. Determine if any intrinsic deformity exists
2. Measure amount of deformity
3. Cast foot to capture degree of deformity
4. Construct functional orthoses (± posts)
• Questionable validity, due to:
  • Poor reliability of measures
  • Normal foot alignment is not normal
  • Mid-stance rearfoot position is not STJ neutral

• Proposed a tissue-stress model for therapists to use.

Paradigm of pathomechanics: Tissue-Stress model

Modification of McPoil & Hunt Tissue-Stress Model

1. Identify tissues being stressed (interview)
2. (a) Physical examination (i.e., stress tissues) to confirm tissues as source of symptoms
   (b) Treatment Direction Test for orthosis
3. Determine the pathomechanics/etiology of the presenting condition.
4. Institute treatment that:
   a) reduce tissue stress (rest, footwear, orthoses)
   b) modalities to assist healing
   c) restore muscle length and flexibility
Some key points in fitting:

1. Comfort
2. Treatment Direction Test

Some key points I look out for:

• Size - leading edge of 3/4 device / MTP break area
• Arch area
• Lateral edge

Some challenges with orthoses:

• Adverse effects
• Less than full resolution of the symptoms/condition

Assuming a positive TDT
Adverse or side effects:
Local at foot-orthotic interface
• MTP region, Arch ...

At distance from foot-orthotic interface
• Displacing stress from the site of pain to a new site (eg, lower limb to lumbar spine, foot to knee or hip)

Adverse or side effects:
Distal to foot by displacing stress to new site:
• Perhaps (?) due to:
  • Overcorrection (correction) of abnormal motion/force dissipation at the pain/injury site
  • Unyielding underlying cause of abnormal motion
    • Limb length inequality (functional, structural)
    • Boney faults (torsions, valgus/varus, length)

How determined a-priori? (next slide …)

Adverse or side effects:
How determined a-priori?
• Evaluation:
  • History
    • Physical exam:
      • Observation of CSOM - movement patterns
      • Comparing nwb to wb assessment
      • Assessment of bone, joint and muscle systems
  • Response to TDT; examples
    • Pulling on shin with tape
    • Pain, discomfort or stress elsewhere
    • Observation of abnormal motion pattern
If orthoses:
- 100% improvement then no other treatment
- < 100% improvement then need to look at other treatment

based on data collected on physical evaluation of bone, joint and muscle systems (neural?)

Clinical Reasoning: possible causes of abnormal pronation in Achilles example?
- Lack of talocrural dorsiflexion
  - Calf tightness
  - Joint limitation
  - Bony limitation
- Forefoot varus (yielding or non-yielding)
- Hypermobility midtarsal joint (subtalar)
- Poor muscle control of foot (Int, TP, PL)
- NB: causes extrinsic to the foot, eg:
  - Poor pelvic control (excessive IR)
  - Genu valgum or varum
  - Tibial varum, or torsion

Clinical Reasoning: possible multifactorial causes of Achilles tendon pain?
- Training Error
  - Too much too soon
  - Plyometrics with poor preparations
- Equipmental faults
  - Old shoes
  - Inadequate control
- Environmental faults
  - Too quick an intro into hills
  - Beach sand running (soft, cambered)
  - Biomechanical faults
Clinical Reasoning: what to do when more than 1 factor identified?

- Coaching tenet: change the one factor that most impacts on condition ± influences other factors. To do this, to the following:
  - List the factors that might be at play as elucidated on physical examination ± interview
  - Prioritise in terms of severity while considering the ones most amenable to the interventions available to you
  - Set about systematically modifying factors in ordered, progressive and structured manner.

Plan:

- Physical evaluation & treatment for distal and proximal kinetic chain
- Reasons for choosing distal versus proximal kinetic chain approaches
- Concept of decision making based on end game scenarios: TDT expanded
- The TDT follies ...

Treatment options:

- Advice and education
- External physical devices
  - Tape
  - Orthotics
- Exercise
  - Stretching
  - Control
  - Strength, endurance, power
- Manual therapy
  - Joint and soft tissue manipulation
- Electro-physical agents
Multifactorial Mix of Risk Factors (proportional)

Threshold for injury

- Biomechanical Factors
- Environmental Factors
- Equipment Factors
- Training & Sport Factors

Advice & Education:
- Advice and education
- External physical devices
  - Tape
  - Orthotics
- Exercise
  - Stretching
  - Control
  - Strength, endurance, power
- Manual therapy
  - Joint and soft tissue manipulation
- Electro-physical agents

Treatment options:

Some examples of clinical presentations that may not respond fully to foot orthotic:

Hyper-flexible foot:
- Anti-pronation taping only part effective
- Antipronation Exercises
  - Must do in good posture
  - May need some posting?
Some examples of clinical presentations that may not respond fully to foot orthotic:
Lack of talocrural dorsiflexion that is discerned on basis of response to an anti-pronation TDO:

- Substantial discomfort/pain at the skin-tape interface on the anterior shin
- An obvious limitation of dorsiflexion, e.g., hyperextension of the knee, tibial retardation in mid-stance
- Marked loosening of the tape such that within several gait cycles there is increasing amounts of pronation ...

Some examples of clinical presentations that may not respond fully to foot orthotic:
Treatment is selected on basis of the cause of dorsiflexion limitation:

Bone: heel raise

Calf muscle tightness: specific exercises to stretch calf (controlling pronation)

Joint restriction: manual therapy: ankle joint

Some examples of clinical presentations that may not respond fully to foot orthotic:
Supinated type foot, especially rigid:

- Supinator pad only partly effective
- Manipulative therapy to improve range of motion at the sub-talar joint (± mid tarsal if tight)
- Orthotic with increased shock absorption and possibly motion enhancing?
Patellofemoral pain syndrome:

Management approaches:
- Site of intervention?
  - Foot-leg region
  - Pelvic-hip region
  - Locally at knee
- Where to start?
- TDT?

Some examples of clinical presentations that may not respond to the foot orthotic:
Excessive internal rotation of the hip and thigh in mid-stance (e.g., as in PFPS):
- tape at the hip joint
- exercises for the external rotators (brolga test/manoeuvre)
- stretches for tight internal rotators

Some examples of clinical presentations that may not respond to the foot orthotic:
Poor control of patellofemoral joint with weak/poorly activated/delayed onset VMO as in PFPS:
- tape at the patellofemoral joint
- exercises for VMO (EMG, wall squat)
- stretches for tight lateral structures such as lateral retinaculum or iliotibial band (self, therapist-massage/mobilisation)
PART F:

Foot and ankle assessment and treatment practical
PART F:

Practical Techniques:

Some techniques covered:

1. TDT of foot and ankle (e.g., low Dye, augmented low Dye)

2. TDT of the hip

3. Examination of the foot and ankle:
   Weight bearing:
   - Foot form
   - Big toe extension
   - Ankle dorsiflexion
   - Leg-foot alignment
   - Pelvis-thigh alignment (Brolga)

   Weight bearing versus non-weight bearing:
   - Arch height, width and the difference

   Non-weight bearing:
   - Range of motion and restraints
RISK MANAGEMENT AND SAFETY ISSUES IN TAPPING:

Taping appears to be relatively innocuous in terms of side effects and by and large it is, especially if the therapist considers the following issues. The issues relate to allergic reactions of the skin to the tape and compromise of the neuro-vascular structures coursing through the taped region. To a lesser extent the tendon structures underlying the taped area also need to be considered.

ALLERGIC REACTIONS:
There are 2 types of allergic responses: one brought about by the chemical adhesive used to adhere the tape to the skin and the other is one that is most likely due to a traction stress injury of the skin. The differentiating feature of these two types of adverse event is the skin surface area of the allergic response. In the allergy to the adhesive material, the response is widespread under most of the tape whereas in the traction injury the response is localised to that part of the tape where traction was exerted, usually at the start or end of a technique.

Apart from these differences, which are remedied by two different approaches, the actual allergic response is much the same in symptoms and signs that are witnessed.

Symptoms of allergic reaction:
- Itchiness
- Heat
- Pain
- Irritability

Signs of allergic reaction:
- Redness
- Slight raising
- Blistering (intact)
- Broken blisters and skin
- Broken skin

Precautions to take pre-taping:
If possible always skin test before applying tape. This involves applying a strip of tape to the area to be taped and left on for a comparable period of time to that which the taping technique will be on for. The client then reports any symptoms of allergic response noting the time taken to bring on the response. The tape should then be carefully removed, proximal to distal and inspected for any signs of allergic reaction. Allergic reaction pretty well excludes the use of tape, although there are a number of products on the market that condition and prepare the skin for adhesive tape and tape with hypoallergenic qualities. The use of these products should be tested first in the same manner as the strip test outlined herein before being used for protracted periods of time.

The skin test would only be of benefit in a situation where the clients were a captive audience prior to the need for using tape, for example, pre-season at a sporting club or centre. The use of the skin test is not always possible in clinic as the decision to apply tape and the application of the tape often occur within the space of 30-45 minutes at the most. In these circumstances other strategies are employed.

When a skin test is not possible the following strategies should be used:
• Ask questions about prior experience with adhesive tapes (eg plasters, elastoplast, sports tape) and if there has been allergic responses opt to do a skin test in the first instance.
• Query general allergy tendency of the client, that is, do they have skin allergies often to a variety of stimuli (eg dust, detergents) or do they have eczema or are they sensitive to sun?
• Ascertain the health of the skin and in particular its healing capabilities remembering that healing is compromised in diabetes sufferers, the elderly, those with peripheral vascular disease (smokers), and after the protracted use of steroids to list a few common conditions.
• Observe the skin of the client to ascertain any scars and the extent of the scarring, fairness of skin and presence of eczema and skin irritations.
If there is any reason to suspect compromised skin health or susceptibility to allergic responses and poor healing, then DO NOT proceed with taping.

_Preparation of the skin is also important:_
Clean the skin, remove any hair and dirt and ensure there is no broken skin under and in contact with the tape. Apply skin conditioners if required.

_Precautions to take during taping:_
Do not overly traction or compress the underlying tissues especially where the musculotendinous and neuro-vascular structures are superficial or juxtaposed to bony structures. In short, be technically excellent!

_Precautions to take post-taping:_
• Provide a warning notifying the client what an allergic response will feel and look like and that there is a risk of breaking the skin which makes them susceptible to infections, delayed healing and ongoing problems. Hence they are to be diligent in observing their reactions to tape and reporting them to you.
• Check immediately after taping and before client leaves your rooms that they are not experiencing symptoms suggestive of allergic response or compromise of circulation (blanching, flushness or blueness and fullness of the distal parts of the limb and digits) or neurological impairment (pins and needles, numbness, possibly pain distal to tape in some conditions).
• Check that the tape does not interfere with the functional activities required by the client while still protecting, de-loading or de-stressing the injured structures.
• Removal of taping should be done carefully so as not to traction injure the skin, usually involves pulling the tape back on itself in a proximal to distal direction down the limb.
Tape techniques: Low Dye

Spur:

NOTES:

____________________________________________________________________________________________________________________

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Mini-stirrups

Spur lock off - medially

Spur lock off - laterally
**Anchor & Locks**

**Patient position:**
Supine lying.
Slightly supinated at rearfoot with locked midtarsal

**Therapist position:**
Standing with foot below mid section.

**Procedure:**
For anchors, locks and any tape that course transversely about the leg and ankle, make sure the ankle is maximally dorsiflexed.

**Indications and notes:**
1. Ensure tape goes onto skin without too much tension.
2. Always check for excessive tension by observing and palpating for vascular occlusion.
3. Lay tape on skin (no tension)
4. Note oblique inclination
5. What is the difference between a lock and anchor tape?

---

**Student Class Notes:**
Low Dye

**Patient position:**
Supine lying.
Slightly supinated at rearfoot with locked midtarsal.
If possible, plantarflex first ray and adduct forefoot.

**Therapist position:**
Standing with foot below mid section.

**Procedure:**
1. Spur: start medially and distal, running posteriorly and around to lateral side.
2. Mini-slings: start lateral side of foot, course underneath foot around to anchor on medial side.
3. Start mini-slings distally and lay each subsequent one covering previous by about 1/2 moving in a proximal direction with each mini-sling.
4. Finish with a spur to lock off onto foot

**Indications and notes:**
1. Note that no tape goes circumferentially around the forefoot! Why?
2. May need to put an anchor across dorsum - do this in standing.
Reverse Six

**Patient position:**
Supine lying.
Slightly supinated at rearfoot with locked midtarsal

**Therapist position:**
Standing with foot below mid section.

**Procedure:**
Commence over medial malleolus or proximally course over the anterior ankle region about the cuboid, underneath the foot and importantly then vertically up the leg making sure not to run in a posterior direction.

**Indications and notes:**
1. The longitudinal component needs to reef up the sustentaculum-tali - navicular regions, so that they do not drop (eg pronate) during weight bearing.

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Student Class Notes:
Why is it called a reverse 6?
Calcaneal Slings

Patient position:
Supine lying.
Slightly supinated at rearfoot with locked midtarsal

Therapist position:
Standing with foot below mid section.

Procedure:
Start on medial-anterior shin about 1/3rd way up leg course down obliquely over the Achilles Tendon being very careful not to place too much tension on tape and also to have the ankle dorsiflexed. Pass over the calceneum obliquely before finishing off much like a reverse 6.

Indications and notes:
1. Use about 2 of these.
Augmented low dye

**Patient position:**
Supine lying.
Slightly supinated at rearfoot with locked midtarsal

**Therapist position:**
Standing with foot below mid section.

**Procedure:**
Techniques usually applied in this order:
(i) Low dye (1)
(ii) Anchor (1)
(iii) Reverse 6 (3)
(iv) Calcaneal slings (2)
(v) Locks (3)

**Indications and notes:**
1. Temporary trial of external anti-pronation device.
2. Treatment Direction Test.
3. Deload tissues

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Student Class Notes:
Light anti-pronation tape (example)

**Patient position:**
Supine lying.
Slightly supinated at rearfoot with locked midtarsal

**Therapist position:**
Standing with foot below mid section.

**Procedure:**
Combine anchor, 3 reverse 6s and 3 lock offs.

**Indications and notes:**
1. A low dye technique or just using several calcaneal slings could also be regarded as light anti-pronation taping techniques.

Student Class Notes:
**Weight bearing Dorsiflexion**

**Patient position:**
Standing.
Foot perpendicular to wall with calcaneal bisector and 2nd toe on a line perpendicular to wall.
Mid point of the anterior knee to form the 3rd point on a plane that remains vertical to wall.

**Therapist position:**
Ensuring heel and foot position remain ISQ during test.

**Procedure:**
Lunge forward with knee until anterior knee just touches wall with heel and foot in position above.

**Indications and notes:**
1. Measure ‘d’ directly or take a digital image and measure ‘q’ from image.
2. Do not allow foot or leg in frontal plane to move out of position.
3. This is a reliable technique for measuring DF and should be used as an outcome measure to track change in dorsiflexion.

**Student Class Notes:**
Forefoot Measures: Movements

Patient position:
Prone lying in figure 4 position.
Sub talar in neutral position.

Therapist position:
Seated with foot at about mid section.
Hands pronated.
Fix sub talar joint by holding calcaneum.

Procedure:
Move cuboid for oblique axis motion (a & b) and navicular for longitudinal axis motion ©.

Indications and notes:
1. Do not allow calcaneum to move.

Student Class Notes:
Non-weight Bearing Dorsiflexion Limitation Differentiation

**Patient position:**
Supine lying.
Foot perpendicular to floor.

**Therapist position:**
Seated with foot at about mid section.
Overlooking distal leg.

**Procedure:**
Place rearfoot in sub talar neutral.
While maintaining midtarsal joint in a stable position and subtalar joint in neutral dorsiflex the ankle.

**Indications and notes:**
2. If DF in KE <10°, make a judgement of the end feel: is it soft tissue or hard end feel (ie, muscle, joint versus bone).
3. If DF in KE <10°, flex knee: if now DF = 10° -> gastroc was limiting DF.
4. If DF in KE <10°, flex knee: if now DF < 10° -> not gastroc limiting DF, use end feel to distinguish boney versus soft tissue (joint vs muscle).
5. This test is not a good outcome measure but it is good to help understand what needs to be treated if DF is limited.

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**Student Class Notes:**
PART G:

Foot orthotics in the treatment of lower limb conditions: a musculoskeletal physiotherapy perspective

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Abstract

Orthotic therapy is frequently advocated for the treatment of musculoskeletal pain and injury of the lower limb. The clinical efficacy, mechanical effects, and underlying mechanism of the action of foot orthotics has not been conclusively determined making it difficult for practitioners to agree on a reliable and valid clinical approach to their application and indeed even their fabrication. This problem is compounded by evidence suggesting that the most commonly used approach for orthotic prescription, the (Biomechanical Evaluation of the Foot. Vol. 1. Clinical Biomechanics Corporation, Los Angeles, 1971) approach, has poor validity and many of the associated clinical measurements of that approach lack adequate levels of reliability.

This paper proposes a new approach that is based on two key elements. One is the identification, verification and quantification of physical tasks that serve as client specific outcome measures. The second is the application of specific physical manipulations during the performance of these physical tasks. The physical manipulations are selected on the basis of motion dysfunction and their immediate effects on the client specific outcome measures serve as the basis to making an informed decision on the propriety of using orthotics in individual clients. The motion dysfunction also guides the type of orthotic that is applied. Practical case examples as well as generic and specific guidelines to the application of this clinical assessment process and orthotics are provided in this paper.

1. Introduction

Musculoskeletal pain and injury is a negative consequence of participating in physical activities, such as walking and running, that are frequently prescribed and recommended to aid in preventing or overcoming the diseases of increasingly sedentary lifestyles. Abnormal lower limb biomechanics are often associated with lower limb musculoskeletal conditions (James et al., 1978; Tiberio, 1987, 1988) and the use of orthotics is frequently advocated in their treatment (Sobel et al., 1999). A popular clinical approach to the prescription and fabrication of orthotics is based on the Root et al. (1971) paradigm (McPoil and Hunt, 1995; Lang et al., 1997; Landorf et al., 2001), which in essence is a mechanical approach based on the premise that correct mechanical alignment of the foot and lower limb is required normal function. The clinical corollary of this concept is that the mechanical approach can be used as a basis to prevent or treat musculoskeletal injuries. Interestingly, recent laboratory evidence questions the ability of orthotics to systematically alter mechanical alignment of the rearfoot (Heiderscheit et al., 2001; Nigg et al., 1999; Stacoff et al., 2000), which seriously challenges the validity of the Root et al. (1971) paradigm.

McPoil and Hunt (1995) reviewed the available literature pertaining to the Root et al. (1971) scheme of evaluating and treating foot disorders. They identified serious concerns regarding the ongoing clinical application of this traditional means of prescribing orthotics. Notably, McPoil and Hunt (1995) reported that several underlying suppositions were not reliable or valid. For example, the notion that the subtalar joint neutral position is the position of the rearfoot during mid-stance...
(Root et al., 1971, 1977) was not evident when evaluated in a gait laboratory (McPoil and Cornwall, 1994). In addition, the physical measurements recommended by Root et al. (1977) to evaluate the foot structure and function were found to be unreliable and hence of little utility to the clinician (McPoil and Hunt, 1995). In response to this mounting evidence against the Root et al. (1971) schema for assessment and treatment of foot disorders, McPoil and Hunt (1995) proposed an alternative model for evaluating and managing foot and ankle problems, which they termed the ‘tissue-stress model’. In utilizing this ‘tissue-stress model’ in the assessment and management of foot and ankle problems, they suggested that the objective of the clinical examination was to identify symptomatic tissues that were undergoing excessive stress and then, in a complimentary manner, to include strategies to alleviate this stress in the treatment program. The inclusion of strategies to alleviate the stress in the identified tissues would be in addition to the conventional physical therapy modalities of exercise to treat impaired muscles and electrophysical agents to reduce inflammation and pain. The strategies that are usually used to reduce stress in symptomatic tissues in the lower limb are external physical devices such as orthotics, strapping tape and braces.

A recent survey of podiatrists, a profession that is widely associated with the prescription of foot orthotics, has shown that despite the evidence reported by McPoil and Hunt (1995), the majority of podiatrists still utilize the Root et al. (1971, 1977) schema when prescribing orthotics (Landorf et al., 2001). The recent survey of Landorf et al. (2001) indicates that the ‘tissue-stress model’ has not been widely adopted in clinical practice. Indeed, a 1997 Masterclass on the static biomechanical evaluation of the foot referred to the Root et al. (1971) scheme as the basis of the physical examination (Lang et al., 1997). One possible reason for this apparently low uptake of the ‘tissue-stress model’ is that it may not have provided the practitioner with a conveniently pragmatic approach to the prescription and application of foot orthotics that may be viewed as superior to that proposed by Root et al. (1971, 1977). Furthermore, orthotics often impose an additional significant financial burden onto the client. If for no other reason, it would seem that there is a need for a practical and simple approach to the prescription of orthotics by which both the practitioner and client can readily make an informed decision on their application.

A practical, simple yet seemingly effective approach that we have employed in clinic, termed the treatment direction test (TDT), seeks to overcome the impasse that was highlighted in the preceding section. In brief, the TDT is part of the physical examination that addresses specifically the propriety of prescribing and applying orthotics not only for foot and ankle problems, but also for any lower limb musculoskeletal disorder for which there is a putative biomechanical aetiological basis. It is adjunctive and complimentary to the ‘tissue-stress model’ of McPoil and Hunt (1995), in that it is an additional physical examination procedure. This Masterclass outlines the TDT by describing it in detail and presenting case studies that provide practitioners with exemplars from which to develop and apply the approach in their clinics.

2. Treatment direction test for foot orthotic therapy: generic overview

The TDT consists of a number of iterations of physical activity performed by the client as well as physical manipulations performed on the client by the practitioner. The express aim is to determine the suitability of orthotic devices in the management of the lower limb musculoskeletal condition (Fig. 1). The central feature of the TDT is the identification of physical activities or tasks with which the client has difficulties, particularly tasks that provoke pain and discomfort. Identification of these tasks occurs in the
interview and then verification that the physical activity reproduces symptoms occurs in the physical examination, in most cases at the outset of the physical examination. Following verification that the physical activity is provocative of the client’s symptoms, it is essential that the practitioner quantifies the amount of physical activity that is required to bring about the first onset of pain (i.e. a pain threshold test). While doing this, the practitioner also observes the motion of the foot during the physical activity to identify any aberration from normal or ideal motion patterns. In the event that there are aberrant motion patterns, the practitioner then applies specific physical manipulations, which are based on the observed aberrant motions. The foot is, the area of the lower limb to which the TDT will be applied in this Masterclass (noting that TDT concept can be applied to all motion segments of the lower limb). The physical manipulations usually take the form of adhesive strapping tape or temporary felt orthotics. Then, with the physical manipulations in situ, the client is asked to perform the specific pain-provoking physical activities that were previously identified and verified. The TDT is deemed to be positive if there is an improvement in the motion pattern and more importantly if there is a substantial increase of the quantity of physical activity to the first onset of pain (Fig. 1). A positive TDT implies that there will be a positive outcome to orthotic therapy. If there is no change in the amount of physical activity taken to first bring on the pain with the physical manipulation in place, then the TDT is deemed to be negative, meaning that an orthotic is not likely to be successful in this instance. In a practical sense, anecdotal evidence suggests that the likelihood of success with subsequent application of an orthotic is most probably greatest if the improvement in the quantity of physical activity is in the order of 75% of baseline or higher (i.e. substantial improvements). Certainly it would appear logical that if there was only about a 50% change from baseline level (or lower) during the application of the physical manipulation in the TDT it would be likely that there will be a lower level of success with any subsequent application of orthotics.

3. Treatment direction test for foot orthotic therapy: specific application

In dealing with the specific application of the TDT, the following sections will deal with the assessment of patterns of foot motion during gait. The identification of some commonly seen aberrant foot motion patterns and several physical manipulations specific to these aberrant motion patterns will be outlined. Guidelines for orthotic prescription and application, as well as a description of several case studies that will highlight various aspects of the practical application of the TDT will be presented.

3.1. Assessing quality and quantity of the client specific physical activity

To demonstrate a specific application of the TDT, this paper will restrict the physical activity to a walking task. Quantification of the load to pain threshold could then be distance walked, number of steps taken and/or time taken to the first onset of pain. Thus quantification of the task to pain threshold is reasonably simple. The identification of aberrant foot motion during gait is somewhat more difficult and requires a developed observational skill, and if possible, the assistance of a digital video camera by which the motion may be captured and then observed within a slower timeframe. In cases of lower limb musculoskeletal pain in which abnormal pronation has been suggested as a causative factor (Sobel et al., 1999), it is important to observe gait for any deviation from the ideal pattern of motion. A textbook on gait analysis such as that of Perry (1993) is of considerable help when developing higher-level observational skills of motion during gait.

The use of movement diagrams (e.g. Figs. 2–5), in which the x-axis represents time expressed as a proportion of the total gait cycle and the y-axis represents motion, is of considerable value in communicating concepts regarding the identification of aberrant motions. An ideal pattern of motion of the foot during stance phase is shown in a movement diagram in Fig. 2, in which the foot strikes the floor on the posterolateral heel region in a relative neutral position before
undergoing rapid pronation of approximately 3–5° in the first 5–10% of the gait cycle (Perry, 1993). The foot then remains in this position for another 5–10% of the gait cycle before re-supinating towards the middle and end of stance phase.

For lower limb musculoskeletal conditions with a putative genesis in abnormal foot pronation, the identification of non-ideal gait patterns involves observation of the stance phase of gait for both the quantity of pronation (excessive or lack thereof) and also the timing of pronation (early, late). A commonly described abnormality of pronation is excessive pronation, so labelled because the rearfoot undergoes an increased range of pronation during the first part of the stance phase, notably at contact and weight acceptance (Fig. 3). This may or may not be preceded by pronation occurring in terminal swing phase usually observed as floor contact on the medial aspect of the heel.

Another, not so widely described pattern of abnormal pronation is one in which there is not only a lack of
pronation but also a markedly different pattern of motion during stance phase. This foot motion pattern during gait is termed a supinator pattern (Fig. 4). This pattern involves a slight but rapid supination (inversion) as its first movement on ground contact and loading such that at foot flat, the rearfoot is relatively inverted to the distal leg and also usually to the floor. This position remains for much of the early part of mid-stance. In those who have some flexibility in their foot, the foot then undergoes a rapid and small amount of pronation in the last part of stance phase, usually at around heel off. The reader will recognize that this is almost opposite to the ideal gait pattern described above and normal patterns reported from kinematic studies.

The previously described motion patterns involve both the initial contact and loading part of stance phase as well as mid-stance through to terminal stance phases of gait. There is also a motion aberration that occurs in mid-stance through to terminal stance, known as prolonged pronation or mid-stance pronation. In this gait pattern the foot motion in contact and loading phases were as for the ideal pattern, but instead of undergoing re-supination the foot remains pronated in mid- to late-stance phase of gait (Fig. 5). This pattern of motion is not to be confused with that which occurs in mid- to late-stance phase of gait in the excessive pronator or supinator patterns of motion, in which there will also be a degree of pronated posture observed.

3.2. TDT for excessive pronator motion patterns

There are two basic types of physical manipulations for TDT of excessive pronators, one involving adhesive strapping tape (Hadley et al., 1999; Vicenzino et al., 1997, 2000) and the other utilizing orthopaedic felt (Hadley et al., 1999; Vicenzino et al., 2000). The adhesive strapping tape technique consists of a number of distinct taping techniques that are frequently combined. The most comprehensive form of adhesive strapping tape technique is the augmented low dye (Hadley et al., 1999; Vicenzino et al., 1997, 2000) and the other utilizing orthopaedic felt (Hadley et al., 1999; Vicenzino et al., 2000). The adhesive strapping tape technique consists of a number of distinct taping techniques that are frequently combined. The most comprehensive form of adhesive strapping tape technique is the augmented low dye technique strengthened by addition of reverse sixes and calcaneal slings (Fig. 6 and Table 1). In brief, the augmented low dye is used when there is a requirement to control vertical navicular height (i.e. medial longitudinal arch height), an indirect but reliable and valid measure of pronation (Williams and McClay, 2000), during activities such as jogging for longer than 10 min (Vicenzino et al., 1997). Usually this is restricted to a TDT in the field in which the practitioner has been unable to find an activity that brings on the pain in the clinic (see Table 1: Variations). It is common practice to use as the physical manipulation in the clinical, the minimum amount of tape, such as, 3 reverse sixes or 2 calcaneal slings. Low dye taping may be used where there is localized foot pain, particularly in the arch and heel region where it may be uncomfortable to have the reverse sixes and calcaneal slings passing plantar to the sole of the foot. Full details of this taping technique including indications, contra-indications, research findings summaries and some possible technical variations are shown in Table 1.

The temporary orthotic, constructed of orthopaedic felt or foam, is performed when the taping technique has been shown to relieve pain and improve function. This next stage in the decision making process for orthotic prescription is to evaluate the effectiveness of an in-shoe orthotic device to ascertain if it is as effective as the tape. See Table 2 and Fig. 7 for complete descriptions of the temporary orthotic. In the event that an orthotic, which usually incurs a significant financial burden on the client’s behalf, is required in the physiotherapy management of a musculoskeletal condition, it is advantageous to first have demonstrated to the client’s satisfaction that an in-shoe device will in practice have the same effect as that of the anti-pronation taping technique. This in-shoe device is usually constructed of a relatively inexpensive orthopaedic felt material, which is easy to customize to the individual. As shown in Fig. 7 the orthopaedic felt is attached to the innersole of the shoe. Key technical points of application of the temporary orthotic are that the distal end of the medial padding should end 5–8 mm proximal to the metatarsal phalangeal joint line. All edges of the padding should be bevelled for comfort and the ‘D-shaped’ sustentaculum-tali-navicular support pad should commence just proximal to the level of the medial malleolus and extend well past the navicular. It should not be placed in the arch, as this is not an effective location to control pronation. A laboratory study has demonstrated that an anti-pronation temporary in-shoe device was capable of similar mechanical effects, as measured by changes in vertical navicular height, to that of the augmented low dye taping technique described above (Vicenzino et al., 2000).

There is another circumstance in which the temporary felt orthotics may be used and that is when the taping technique produces discomfort or pain at its point of contact with the skin. For example, it is not uncommon for a person who has limited dorsiflexion or a marked forefoot varus to experience pain at the skin–tape interface on the anterior shin region where the reverse sixes and the calcaneal slings anchor.

3.3. Anti-pronation orthotic application guidelines

In the excessive pronator foot motion type, it is usual practice to use orthotics that are somewhat inverted (i.e. the angle of the superior surface that contacts the plantar foot surface to the inferior surface of the orthotic that sits on the shoe), often referred to as being varus wedged or posted on the medial side of the device.
An example of a pre-fabricated type of an anti-pronation orthotic is the three-quarter length shown in Fig. 8. Pre-fabricated anti-pronation orthotics usually have some degree of varus posting built into the device (e.g. 2–6 degrees) that can be modified by heating (lessen the amount of inversion) or the addition of external rearfoot and forefoot postings (to increase the inversion in the device). The current best level of evidence, which is largely based on laboratory work and not on clinical trials evaluating the efficacy of these types of devices, indicates that it is perhaps the comfort fit of the device and the improvement in performance rather than the effect on the motion that should guide the fitting of the devices (Nigg et al., 1999). Thus, when fitting pre-fabricated orthotics (or custom made orthotics) the practitioner should first fit the orthotic to an acceptable level of comfort and then, once comfortable, the orthotics should be tested in a similar fashion to the TDT explained above. All modifications, whether heating or adding external posts to the device, should be guided by this principle and if it is impossible to make the device comfortable and ameliorate pain and dysfunction, then the client should not be prescribed the orthotic. There are several standard issues to consider in improving the comfort of the device, such as correct sizing (e.g. leading edge ends 5–8 mm proximal to the metatarsophalangeal joint line, lateral border edge) and excessive pressure in the arch areas of the orthotic. The latter is usually remedied by either heat moulding the device and/or by the addition of rearfoot varus or forefoot varus wedges. Once the orthotic is comfortable then the TDT approach of re-evaluating...
Table 1

Anti-pronation taping technique. The augmented low dye technique that may be used as a physical manipulation in the Treatment Direction Test. See Fig. 6 for images of tape.

**Indication:**

Pain and dysfunction that exists in a client with an abnormal pronation, either excessive or prolonged.

**Purpose and Intent:**

To determine if a transient correction of abnormal pronation is associated with a marked amelioration of symptoms and function.

**Positioning:**

**Client** Supine with distal half of lower limb extending off end of treatment table.

**Foot** Moderately supinated at the rearfoot with neutral forefoot–rearfoot alignment. The client actively holds this Position.

**Therapist** Standing at end of foot with head and torso overhanging the foot.

**Taping Techniques and Application Guidelines:**

**Material:**

Rigid adhesive strapping tape 38 mm in width will suit most feet sizes.

**Low Dye:**

1. **Spur:** commences on the medial side of the forefoot just proximal to the metatarsal phalangeal joint line, while maintaining the rearfoot and forefoot position in the frontal plane, the therapist exerts a slight amount of adduction of the forefoot and plantar flexion of the first ray while laying the tape down on the medial side of the foot and around the heel. The spur then concludes by being laid down on the lateral side of the foot, finishing proximal to the metatarsal phalangeal joint.

2. **Mini-stirrups:** commence on the lateral side of the foot over the spur and course underneath the foot, being careful not to wrinkle the plantar skin, before finishing on the medial side of the foot at the level of the spur. The last portion of the mini-stirrup is laid down while the therapist applies an inversion force to the medial side of the foot with the hand that is not holding the tape. The exception to this is the first mini-stirrup, during which the therapist plantar flexes the first ray. A series of some 4–6 mini-stirrups are applied, commencing distally at a level just proximal to the metatarsal phalangeal joints and moving more proximally with successive stirrups overlapping each previous one by about a half tape width.

3. **Spur lock off:** this tape is exactly like the first one but is used to lock in the ends of the mini-stirrups.

**Reverse sixes**

4. Anchor strip applied obliquely to a point on the leg approximately one quarter to one third the way proximal to the ankle.

5. **Reverse six:** starts at the medial malleolus or proximal to it (not distal to it) and runs across the front of the ankle distal to the lateral midfoot, under the plantar aspect of the midfoot before coursing up the medial side of foot, ankle and leg to anchor on the anchor strip. It is important to have the final part of the reverse six cover the navicular and sustentaculum tali areas of the mid and rearfoot.

**Calcaneal sling**

6. Commences on the anterior aspect of the distal leg at the level of the anchor strip, courses distally and posteriorly to wrap obliquely about the Achilles tendon and heel before wrapping underneath the foot (plantarlly).

**Lock off tape**

7. 3–4 lock of tapes that are exactly the same as the anchor strip but overlap each other by approximately half extend from the anchor strip distally.

**Comment:**

- Technical issues—It is very important that the position of the foot and ankle is initially obtained and more importantly maintained during the taping technique as failure to do so often results in an inefficient attempt at correcting pronation during gait.
- Ensure that the forefoot is not abducted but rather slightly adducted throughout the taping technique.
- We have shown in a number of studies that this taping technique is superior to others in its effects on arch height, not only immediately after application but also after jogging for 20 min.
- Risk of either allergic reactions to the tape, or excessive skin stress usually as a result of excessive traction, or compression or injury to underlying soft tissues due to excessive compression must be considered during and after the application of the tape, especially if the taping technique is to be in situ for a protracted period of time.
- Always follow contour of underlying body part and soft tissues such that there is even pressure visible under both sides of the tape (widthwise) as failure to do so increase the risk of compression injury to underlying tissues.
- Do not place excessive traction on the tape during its application as this will result in traction stress and possibly injury to the skin.

**Variations:**

- In some instances, notwithstanding the data in the literature, it appears advantageous to only apply some components of this technique in order to obtain optimal outcomes. For example, is not at all uncommon to use solely reverse sixes or calcaneal slings or low-Dye taping to achieve the desired pain relieving effects.
- If the client is unable to nominate a physical activity that can be reasonably measured in the clinic (e.g., in a runner who runs for 20 min to pain onset), then the anti-pronation taping will need to be applied before the client goes for a run.

**Contra-indications:**

- Allergic reaction to tape.
- Increased pain with tape in situ
the client specific outcome measure is undertaken. Additional, postings may be required at this stage to ensure that the effect is at least the same as for the taping and temporary orthotic.

3.4. Case examples of the excessive pronation TDT applied

Smith et al. (2004) reported a single case of a soccer player with Achilles Tendinopathy in which they demonstrated the application of a TDT. In that case, there was a substantial improvement from 100 m jogging to onset of pain to 1200 m jogging pain free with a single application of several reverse sixes. This improvement was replicated on several occasions and was shown to mirror the improvements gained following the longer-term application of anti-pronation orthotics. This case exemplar was in distinct contrast to an unpublished case study of a triathlete who had a phase III medial tibial stress syndrome of 12 weeks duration (Roy and Irvin,
During jogging this case exhibited excessive pronation and first onset of pain at approximately 400 m of jogging (unpublished case report, Bissett L, O’Meara T, Vicenzino B, 2001). There was no substantial change in the distance jogged to the onset of pain despite a 20% improvement in vertical navicular height with both the application of an augmented low-dye taping technique and pre-fabricated orthotic. That is, there was no improvement following augmented low-dye anti-pronation taping and this was matched by a similar lack of efficacy of a follow up period of protracted use of the anti-pronation orthotic. The improvement in vertical navicular height is commensurate to that reported in several studies of the augmented low-dye technique and temporary orthotic (Vicenzino et al., 1997, 2000), indicating that the lack of effectiveness in influencing jogging distance to pain onset was not due to a lack of mechanical efficacy of the tape or orthotic. These two cases highlight the clinical utility of the TDT to predict the effectiveness (or lack thereof) of orthotic therapy, but do not constitute sufficient level of evidence to be generalized to the broader clinical context. Further work is required to study the clinical utility of the TDT.

Anterior knee pain of patellofemoral joint origin is another example of a condition that has been reported to be strongly associated with abnormal lower limb mechanics (Williams et al., 2001) and treatment of this condition by the correction of abnormal foot motion with orthotics has been advocated (Eng and Pierrynowski, 1993; Gross and Foxworth, 2003; Saxena and Haddad, 2003), including the use of off-the-shelf pre-fabricated orthotics (Eng and Pierrynowski, 1993; Sutlive et al., 2004). The ability to predict the outcome following application of orthotics in patellofemoral pain syndrome is an issue that has recently become the focus of several research groups (Gross and Foxworth, 2003; Sutlive et al., 2004). We recently completed a case study of a 30-year-old female with chronic anterior knee pain that highlights the utility of the TDT to predict orthotic outcomes in patellofemoral pain syndrome. In brief, prior to anti-pronation taping, consisting of three (3) reverse sixes and a low-Dye, the client walked down 4 stairs to the first onset of pain, whereas with taping in situ the client was able to walk 62 stairs. This substantial change in client specific outcome measure of pain and function was replicated with the subsequent application of an anti-pronation orthotic of a longer (6 week) follow up period (unpublished data, Shopka B, Yee B, Costanza A, Al-Marooqi Y, Vicenzino B, 2003). That is, the wearing of an in-shoe orthotic device over a protracted period of time ameliorated the anterior knee pain, and most importantly, this success was predicted by the application of the TDT in the physical examination of this client.
4. TDT for supinator motion pattern

There is one predominant physical manipulation for the supinator pattern of foot motion during gait, termed the supinator pad. The supinator pad consists of a piece of foam or orthopaedic felt that is applied to the plantar surface of the foot such that distally it ends approximately 5–8 mm proximal to the metatarsal phalangeal joints, and proximally just distal to the cuboid-metatarsal articulation. Its lateral extent is to the lateral border of the foot and its medial side covers at least the 3rd through 5th metatarsals but not the 1st and 2nd metatarsals. It is shown in Fig. 9 and details included in Table 3. The orthotic that is frequently used in these cases, that is, in the event of a positive TDT, is one that includes the supinator pad in the orthotic. Frequently the supinator pad made of ethyl vinyl acetate (EVA) is simply attached to an innersole of the client’s shoes. Alternatively, the supinator pad may be attached to a low density EVA off-the-shelf prefabricated orthotic with only little or no built-in rearfoot varus posting.

An example of cases that frequently respond favourably to supinator pads are long term or recurrent foot and ankle pain as a result of severe or recurrent ankle sprains in which there is observed a supinator pattern of foot motion during gait. An exemplar case was a patient with diffuse mid-foot pain following several ankle sprains in a period of approximately 24 months in which the acute phase seemed to settle but resulted in the client experiencing disabling pain when walking down stairs and on uneven or sloped surfaces. Several programs of conventional physiotherapy over the preceding 18 months, consisting of sensori-motor re-training (i.e. ‘proprioceptive’), had limited impact on this pain and dysfunction, despite showing improvement in balance tasks. At the initial physiotherapy session, on using the TDT for supinator gait pattern it was noted that walking down stairs was pain free, where it had been previously disabling. A simple 4° forefoot supinator pad was fashioned from an off the shelf orthotic addition (Vasyli Forefoot Valgus wedge) and applied to the innersole of the client’s shoe with the result being a long lasting improvement in pain and function. This apparently effective management by a simple orthotic was predicted by the application of a TDT in the physical examination. The TDT provides an advantage over other skeletal alignment approaches to orthotic prescription in that it directly assurs the client during the practitioner–client interaction of the propriety of applying an orthotic in this specific situation and also by guiding the practitioner in the management of the client’s problem by providing individualized data to work with from that client.

5. TDT for prolonged pronation motion pattern

The TDT for prolonged pronation is similar to the excessive pronation. However it should be noted that this motion pattern is difficult to differentiate from normal gait and in some cases from mild cases of supinator type motion patterns, requiring the practitioner to first select either the anti-pronation or supinator TDT approach and then if found not to be suitable to swap to the alternative motion dysfunction TDT. Although this does seem to protract the length of the physical examination somewhat, it would leave the client and the practitioner with little doubt about the appropriateness of proceeding with orthotic therapy or not.

6. Integration of orthotic therapy approach into clinical practice

Other findings on physical examination, such as, muscle tightness and weakness (e.g. of the foot, calf, thigh and hip musculature), and reduced motion of the talocrural, sub-talar and metatarsal-phalangeal joints should also be addressed once the effect of the orthotic
has been ascertained. It is sometimes the case that full amelioration of all symptoms occurs only after the selective application of exercises and manual therapy is used in conjunction with orthotic therapy. Clinical examination findings and a clinical reasoning process, that is based on prioritizing physical findings and systematically addressing these findings guide the selection of the exercises and manual therapy.

7. Conclusion

The TDT is a simple pragmatic and practical clinical approach to solving the dilemma that confronts the practitioner who manages clients with lower limb musculoskeletal disorders for which there is a putative aetiological basis in abnormal motion patterns of the foot during gait. It is an adjunctive process to the physical examination that seeks to guide the practitioner in deciding if an orthotic is likely to succeed. Importantly, it does not replace but rather complements the conventional comprehensive clinical examination performed by musculoskeletal physiotherapists.

Acknowledgements

I would like to acknowledge the contribution to the Treatment Direction Test concept of many of my colleagues and students and specifically the following who have directly helped in aligned research in this field: Professor Thomas McPoil, Ms. Leanne Bisset, Ms. Natalie Collins, Ms. Michelle Smith, Ms. Tara O’Meara, Ms. Suzi Brooker, Mr. Bryan Shopka, Ms. Erin Smyth, Mr. Brian Yee, Mr. Adam Costanza, Mr. Yacob Al-Marooqi.

References


Foot Orthoses in Lower Limb Overuse Conditions: A Systematic Review and Meta-Analysis

Natalie Collins, B.Phty. (Hons 1); Leanne Bisset, B.Phty., M.Phty (Sports and Musculoskeletal); Thomas McPoil, P.T., A.T.C., Ph.D; Bill Vicenzino, B.Phty., Grad. Dip. Sports Phty., M.Sc., Ph.D

INTRODUCTION

Foot orthoses have long been advocated in the management of musculoskeletal overuse conditions of the lower limb. As early as 1972, abnormal foot pronation and subsequent overstress on lower limb soft-tissue structures were implicated in running injuries such as chondromalacia of the patella, shin splints, Achilles tendinopathy, heel spurs, and lower-limb stress fractures. Anecdotal reports of successful clinical treatment with foot orthoses often were construed to support the theory that foot orthoses control excessive or prolonged foot pronation during the stance phase of gait, minimizing overstress on soft tissues and alleviating associated symptoms. Current definitions of foot orthoses in the clinical guidelines of the American College of Foot and Ankle Orthopedics and Medicine (ACFAOM) and the Australian Podiatry Council (APC) reflect this concept, making reference to the goal of controlling abnormal foot motion with orthoses. However, debate in recent years on the mechanism underlying the therapeutic effect of foot orthoses questions the role of motion control as a primary mechanism of action. Nevertheless, orthoses currently are defined as in-shoe devices that are either custom fabricated (i.e., based on a three-dimensional representation of the individual's foot) or prefabricated (generically shaped). Prefabricated kits for orthoses may allow some degree of customization to the individual patient through heat molding or add-on posts.

In parallel with this is the evolution of health care towards an evidence-based model in which high quality research evidence is promoted in clinical decision making. Randomized controlled trials (RCT), widely deemed as the gold standard in providing high-quality evidence, are only surpassed by the pooling of several RCT findings in a systematic review and meta-analysis, which represents the highest level in Sackett's hierarchy. The current literature on the clinical efficacy of foot orthoses is reflective of their anecdotal origins, with a predominance of clinical viewpoint and review papers and a lack of experimentally based publications. The lack of higher order synthesis of clinical trials to date makes it difficult for a practitioner who wishes to use evidence-based practice in the prescription of foot orthoses. It is, therefore, timely to conduct a systematic review of the current RCT literature, with the aim to evaluate the clinical efficacy and cost effectiveness of foot orthoses in the management of individuals with, or at risk for, lower limb musculoskeletal overuse conditions.

METHODOLOGY

Literature Search Strategy

A comprehensive search strategy devised using guidelines provided by the Cochrane Reviewer's Handbook, was used by a single reviewer (NC) to search the following databases: MEDLINE, EMBASE, CINAHL and Pre-CINAHL, Physiotherapy Evidence Database (PEDro), PubMed, Sportdiscus, Biological Abstracts, Web of Science, Allied Health and Complimentary Medicine Database, and the full Cochrane Library. All publications listed up until the September 28, 2005, were considered for inclusion, and no restrictions were placed on year of publication, status of publication, or language. Abstracts, then full-text versions of papers were retrieved at successive stages for further evaluation. The same reviewer hand searched reference lists of papers that met the inclusion criteria, as well as systematic reviews on related topics that were identified by the search strategy.
Selection Criteria

To be deemed suitable for inclusion in this systematic review, studies identified by the search strategy had to fulfill key criteria. Clinical trials were selected that randomly allocated participants into intervention groups. Foot orthoses, as defined above, were required to constitute at least one of the interventions used in the management of lower-limb overuse injuries. Overuse conditions were included on the basis of the ACFAOM guidelines, according to which foot orthoses were rated as being medically indicated or essential, useful, or beneficial as an adjunct to other interventions. Finally, at least one clinically relevant outcome measure was required to measure the effect of the intervention over a minimum period of 1 week.

Quality Assessment

Papers identified by the comprehensive search strategy that fulfilled the selection criteria were retrieved for evaluation of their methodological quality. Two independent reviewers (NC and LB), who were blinded to authors, affiliations, and the publishing journal, rated each paper using a modified version of the PEDro rating scale (Appendix A). The original PEDro scale was based largely on the Delphi list of Verhagen et al. Three items that were deemed important in other rating scales were added to the 11 existing PEDro criteria: justification of sample size, use of outcome measures with known validity and reliability, and reporting of adverse or side effects. Specific standardized guidelines were provided for each criterion to minimize rater error. A point was only awarded for a specific criterion when it was clearly satisfied. Points scored by an article across all 14 criteria were then summed to give a final quality rating score. A similar version of this scale has been used recently, with good inter-rater agreement (κ 0.824).6

Final study ratings for each reviewer were collated and examined for discrepancies. Any disagreement between raters was discussed in a consensus meeting (NC and LB), and unresolved items taken to a third reviewer (BV) for resolution.

Data Management and Statistical Analysis

Inter-rater reliability of the modified PEDro scores was evaluated with the kappa (κ) statistic.

Synthesis of quantitative data was conducted using Review Manager (Version 4.2). Data was extracted directly from papers where available, using data provided by intention-to-treat analysis when supplied. A formal written request was made to authors when studies reported insufficient data.

Relative risk (RR) and standardized mean difference (SMD) with 95% confidence intervals (CI) were used to represent the effect size of dichotomous and continuous variables, respectively, for interventions on a random effects model. Based on previous reports, a RR of greater than 1.5 or less than 0.7 was set to represent a clinically beneficial effect in favor of either foot orthoses or the comparison group, respectively; with a RR of 1 signifying a null effect. The SMD was calculated from the mean change score and population standard deviation, using methods of Herbert to extract population standard deviations from pre-standard to post-standard deviations or 95% CI where available. A SMD of greater than or equal to 0.8 was considered to represent a large clinical effect, 0.5 a moderate effect, and 0.2 a weak effect, with a positive value favoring foot orthoses over the comparison intervention. An SMD of 0 represented a null effect. Data pooling was conducted for studies where there was similarity of factors such as the type of foot orthoses, comparator intervention, and timing of outcome measures.

A sensitivity analysis was conducted to determine if the score on the modified PEDro scale would influence the findings of this study, as would be anticipated after the work of Moher et al. who showed that studies with improved quality scores returned findings of reduced efficacy of treatment.

RESULTS

Search Strategy

The comprehensive search strategy identified 3192 publications for further evaluation (Figure 1). Of these, 22 papers met the criteria for inclusion in the systematic review, one of which reported two separate studies. Included studies fell into two categories: those that investigated prevention of onset of a lower limb overuse injury (eight studies reported in seven publications) and those that looked at treatment of injuries (15 studies) (Tables 1 and 2). Within these categories, divisions were made based on the comparison group, that is: foot orthoses versus control or other interventions; or custom versus prefabricated foot orthoses. Of the 23 studies, 14 measured up to 3 months followup, seven up to 6 months followup, and two investigated outcomes up to 12 months.

Methodological Quality

Modified PEDro scores ranged from two to 11 out of 14 (mean score 5.77). As demonstrated in Table 3, a number of criteria were poorly represented. Those reported by less than half of the papers were specification of eligibility criteria (criteria one), allocation concealment (criteria three), blinded (criteria five, six, and seven), intention to treat analysis (criteria nine), justification of sample size (criteria 12), and reporting of adverse or side effects (criteria 14). Of the modified PEDro ratings given independently by the two reviewers, initial disagreement occurred in 41 out of 308 items (κ0.73). Consensus was reached on all but five items on initial discussion between the two reviewers, which were all resolved in discussions with the third reviewer (BV). Inter-rater reliability for individual criteria ranged from weak (κ0.25) for criterion one to 100% agreement for criteria two and 10.

There was no significant correlation between the quality rating score and effect sizes of RR (p = 0.60) and SMD.
Identification of potentially relevant papers via initial screening by title and abstract (where available):

n = 3192

Excluded: n = 2865
- Not lower limb overuse condition
- No foot orthoses used as an intervention
- Not RCT (single group; clinical, literature review, and case study papers)

Retrieval of full papers for more detailed evaluation:

n = 327

Excluded: n = 305
- Not lower limb overuse condition
- No foot orthoses used as an intervention
- No evidence of RCT when full paper evaluated (i.e. when not evident from title/abstract)
- Immediate effects/laboratory studies
- Retrospective studies

RCTs included in the systematic review:

n = 22

Fig. 1: Flow chart of the process and rationale used in selecting papers for inclusion in the review, using a highly sensitive search strategy. RCT, randomized controlled trial.

(\(p = 0.10\)). Thus, all studies were included in the systematic review.

Prevention Studies

All eight studies that investigated the preventative role of foot orthoses used military populations of similar ages that were undergoing basic or regular military training (Table 1). Reasonable sample sizes were available for individual studies, with cohorts ranging from 47 to 451. Intervention periods and timing of final outcome measures were similar for all studies (8 to 16 weeks), reflecting the standard military basic training period. Although other outcome measures were used (Table 4), incidence of injury (number of participants injured compared to noninjured) was consistently used as a primary outcome measure.

Foot orthoses compared to controls

Pooled data from four studies\(^{13,24,29,32}\) that compared foot orthoses to a control group provided evidence of a significant and reasonably sized effect in favor of foot orthoses (RR 1.49; CI 1.07 to 2.08) (Figure 2). A fifth study by Simkin et al.\(^{44}\) for which effect sizes could not be calculated also reported significant results in favor of foot orthoses.
<table>
<thead>
<tr>
<th>Condition</th>
<th>Orthoses vs. Comparison</th>
<th>Sample: total randomized (total analyzed) per group</th>
<th>Mean (SD) age of participants (years)</th>
<th>Intervention &amp; followup (weeks)</th>
<th>Effect size: incidence of injury RR (95% CI)</th>
<th>Notes regarding study. Study conclusions (where effect size = ID)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot orthoses vs. Control</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Esterman, 2005 Lower limb pain or injury</td>
<td>Prefabricated customised$^1$ vs Control</td>
<td>25 (25) vs 22 (22)</td>
<td>ID$\sim$</td>
<td>8</td>
<td>0.23 (0.03 to 1.80)</td>
<td></td>
</tr>
<tr>
<td>Larsen, 2002 Lower limb problems</td>
<td>Custom (casted) vs Control</td>
<td>77 (58) vs 69 (63)</td>
<td>ID</td>
<td>12</td>
<td>1.43 (0.99 to 2.08)</td>
<td></td>
</tr>
<tr>
<td>Milgrom, 1985 Lower limb stress fractures (metatarsal, tibial, femoral)</td>
<td>Prefabricated$^2$ vs Control</td>
<td>143 (113) vs 152 (152)</td>
<td>ID</td>
<td>14</td>
<td>1.58 (1.13 to 2.20)</td>
<td>Participants randomized to orthoses group were assigned to 1 of 6 prefabricated orthoses that they rated highest on a comfort scale. Study conclusions: foot orthoses significantly decreased the incidence of femoral stress fractures in participants with high arches, and metatarsal stress fractures in participants with low arches.</td>
</tr>
<tr>
<td>Mundermann, 2001 Lower limb or back pain/injury</td>
<td>Prefabricated$^3$ vs Control</td>
<td>103 (34) vs 103 (45)</td>
<td>28.5 (6.6)$\sim$</td>
<td>16</td>
<td>2.52 (0.75 to 8.45)</td>
<td></td>
</tr>
<tr>
<td>Simkin, 1989 Lower limb stress fractures</td>
<td>Prefabricated$^2$ vs Control</td>
<td>143 (113) vs 152 (152)</td>
<td>ID</td>
<td>14</td>
<td>ID</td>
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<tr>
<th>Condition</th>
<th>Orthoses vs. Comparison</th>
<th>Sample: total randomized (total analyzed) per group</th>
<th>Mean (SD) age of participants (years)</th>
<th>Intervention &amp; followup (weeks)</th>
<th>Effect size: incidence of injury RR (95% CI)</th>
<th>Notes regarding study. Study conclusions (where effect size = ID)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Foot orthoses vs. Other intervention</strong></td>
<td>Finestone, 1999 Lower limb stress fractures</td>
<td>Custom (semirigid + soft) vs Simple flat insoles</td>
<td>260 (126) vs 126 (53)</td>
<td>18.77 (0.734)</td>
<td>14</td>
<td>1.95 (1.14 to 3.32)</td>
</tr>
<tr>
<td><strong>Custom foot orthoses vs. Prefabricated foot orthoses</strong></td>
<td>Finestone, 2004a Lower limb problems (stress fractures, ankle sprains and foot problems)</td>
<td>Custom (casted, soft) vs Prefabricated (soft)</td>
<td>227 (204) vs 224 (213)</td>
<td>18.74 (0.72)</td>
<td>14</td>
<td>1.06 (0.78 to 1.46)</td>
</tr>
<tr>
<td></td>
<td>Finestone, 2004b Lower limb problems (stress fractures, ankle sprains and foot problems)</td>
<td>Custom (casted, semirigid) vs Prefabricated (semirigid)</td>
<td>215 (180) vs 208 (172)</td>
<td>18.91 (1.1)</td>
<td>14</td>
<td>1.25 (0.88 to 1.77)</td>
</tr>
</tbody>
</table>

ID, inadequate data provided by authors; ~, no significant difference between groups (p = 0.05); ID ~, authors have only reported statistical significance; SD, standard deviation; RR, relative risk; CI, confidence interval.

1 Australian Orthotics Laboratory International, Kirrance, New South Wales, Australia; 2 Military stress orthotics, Langer Biomechanics Group Inc., Deer Park, NY, USA; 3 Marketmall Shoe Repair, Calgary, AB, Canada.
### Table 2: Treatment studies: summary of rated studies

<table>
<thead>
<tr>
<th>Condition</th>
<th>Orthoses vs. Comparison</th>
<th>Sample: total randomized (total analyzed) per group</th>
<th>Mean (SD)/ median # age of participants (years)</th>
<th>Mean (SD)/ median symptom duration (months)</th>
<th>Intervention &amp; followup (weeks)</th>
<th>Patient perceived effect RR (95% CI)</th>
<th>Visual analogue scale SMD (95% CI)</th>
<th>Foot health status questionnaire SMD (95% CI)</th>
<th>Notes regarding study. Study conclusions where effect size = ID</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Foot orthoses vs. Control</strong></td>
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<tr>
<td>Pfeffer, 1999 Plantar fasciitis</td>
<td>Custom (casted) + stretches vs no orthoses + stretches</td>
<td>42 (34) vs 46 (39)</td>
<td>48.5 # vs 47 #</td>
<td>ID~</td>
<td>8</td>
<td>0.87 (0.43 to 1.75)</td>
<td>0.15 (−0.31 to 0.61)</td>
<td>—</td>
<td>Achilles &amp; plantar fascia stretches.</td>
</tr>
<tr>
<td>Wiener-Ogilvie, 2004 Anteromedial knee pain</td>
<td>Prefabricated customised + lower limb exercises vs No orthoses + lower limb exercises</td>
<td>11 (9) vs 10 (9)</td>
<td>61.8 (10.3) vs 51 (22.5)</td>
<td>29.8 (38) vs 10.6 (8.2)</td>
<td>8</td>
<td>1.20 (0.57 to 2.53)</td>
<td>0.87 (−0.11 to 1.85)</td>
<td>—</td>
<td>Lower limb strengthening and stretches.</td>
</tr>
<tr>
<td><strong>Foot orthoses vs. Other intervention</strong></td>
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</tr>
<tr>
<td>Dimou, 2004 Plantar fasciitis</td>
<td>Custom vs Chiropractic adjustments + stretches</td>
<td>10 (10) vs 10 (10)</td>
<td>42.3 (10.3)</td>
<td>21.8 (24.1)</td>
<td>8</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>Achilles stretches. Study conclusions: sample too small to draw firm conclusions; both groups showed significant improvements on final outcome measures.</td>
</tr>
<tr>
<td>Eng, 1993 Anterior knee pain</td>
<td>Soft customised + exercises vs flat insoles + exercises</td>
<td>10 (10) vs 10 (10)</td>
<td>14.8 (1.2)</td>
<td>9.85 (9.85)</td>
<td>8</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>Study conclusions: significantly greater decrease in VAS with running, squatting &amp; stairs in orthoses group (p &lt; 0.05).</td>
</tr>
<tr>
<td>Kelly, 1999 Lesser metatarsalgia</td>
<td>Prefabricated custom vs silicone insole</td>
<td>15 (15) vs 18 (18)</td>
<td>51.25</td>
<td>67 vs 51</td>
<td>8</td>
<td>3.33 (1.15 to 9.66)</td>
<td>0.09 (−0.60 to 0.77)</td>
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Table 2: (Continued)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Orthoses vs. Comparison</th>
<th>Sample: total randomized (total analyzed) per group</th>
<th>Mean (SD)/ median of participants (years)</th>
<th>Mean (SD)/ median symptom duration (months)</th>
<th>Intervention &amp; followup (weeks)</th>
<th>Patient perceived effect RR (95% CI)</th>
<th>Visual analogue scale SMD (95% CI)</th>
<th>Foot health status questionnaire SMD (95% CI)</th>
<th>Notes regarding study, Study conclusions (where effect size = ID)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kilmartin, 1994 Morton’s neuroma</td>
<td>Supination orthoses vs pronation orthoses 10 (10) vs 11 (11)</td>
<td>43 (12)</td>
<td>30 (61.4) vs 13 (7.6)</td>
<td>52</td>
<td>1.09 (0.48 to 2.48)</td>
<td>−0.19 (−1.05 to 0.67)</td>
<td>−0.19</td>
<td></td>
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<tr>
<td>Kriss, 2003 Heel pain</td>
<td>Soft antipronatory pad vs local steroid injection 26 (26) vs 22 (22)</td>
<td>59.33</td>
<td>7.56</td>
<td>12</td>
<td>—</td>
<td>−0.77 (−1.36 to −0.18)</td>
<td>—</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lynch, 1998 Plantar fasciitis</td>
<td>Custom vs viscoelastic heel cups 35 (28) vs 33 (26)</td>
<td>49 ~ (L) 46 (R) 26.5</td>
<td>12</td>
<td>—</td>
<td>0.70 (0.15 to 1.25)</td>
<td>—</td>
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<tr>
<td></td>
<td>Custom vs local steroid injection + NSAIDs 35 (28) vs 35 (31)</td>
<td>49 ~ (L) 46 (R) 26.5</td>
<td>12</td>
<td>—</td>
<td>0.32 (−0.19 to 0.84)</td>
<td>—</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Martin, 2001 Plantar fasciitis</td>
<td>Custom vs tension night splints 85 (71) vs 85 (60)</td>
<td>47 (12) ~ 20 ~ vs 24 ~</td>
<td>12</td>
<td>—</td>
<td>ID</td>
<td>—</td>
<td></td>
<td>Study conclusions: no significant differences between groups at final outcome on pain measures; reported slight differences between groups in VAS (no p value).</td>
<td></td>
</tr>
<tr>
<td>Pfeffer, 1999 Plantar fasciitis</td>
<td>Custom + stretches vs silicone heel pad + stretches 42 (34) vs 51 (42)</td>
<td>48.5 ~ 49.5 ~</td>
<td>ID ~</td>
<td>8</td>
<td>0.15 (0.03 to 0.62)</td>
<td>−0.22 (−0.67 to 0.23)</td>
<td>—</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Custom + stretches vs rubber heel cup 42 (34) vs 50 (43)</td>
<td>48.5 ~ 44 ~</td>
<td>ID ~</td>
<td>8</td>
<td>0.36 (0.14 to 0.94)</td>
<td>−0.42 (−0.87 to 0.04)</td>
<td>—</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postema, 1998 Primary metatarsalgia</td>
<td>Custom moulded vs ready-made insole 41 (41) vs 41 (41)</td>
<td>58.6 (20.4)</td>
<td>ID</td>
<td>2</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
<td>‘Ready made insole’ poorly defined in paper, but appeared to be a flat insole. Participants served as own comparison. Study conclusions: significantly lower pain scores with custom orthoses (p &lt; 0.00).</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Condition</th>
<th>Orthoses vs. Comparison</th>
<th>Sample: total randomized (total analyzed) per group</th>
<th>Mean (SD)/ median age of participants (years)</th>
<th>Mean (SD)/ median symptom duration (months)</th>
<th>Intervention &amp; followup (weeks)</th>
<th>Patient perceived effect RR (95% CI)</th>
<th>Visual analogue scale SMD (95% CI)</th>
<th>Foot health questionnaire SMD (95% CI)</th>
<th>Notes regarding study, Study conclusions (where effect size = ID)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rome, 2004 Plantar heel pain</td>
<td>Functional foot orthoses vs accommodative (cushioning)</td>
<td>26 (22) vs 22 (13)</td>
<td>59.9 (13.5) vs 21.6 (40.5)</td>
<td>12.4 (19.6) vs 21.6 (40.5)</td>
<td>8</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>Reported significant decrease in foot pain &amp; increase in foot function ($p = 0.01$)</td>
</tr>
<tr>
<td>Russell, 2000 Plantar fasciitis</td>
<td>Custom vs night resting splint</td>
<td>26 (14) vs 21 (13)</td>
<td>34.4 (7.6)</td>
<td>8.2 (11.4)</td>
<td>12</td>
<td>ID</td>
<td>ID</td>
<td>—</td>
<td>Pain measured as component of Foot Function Index ($p = 0.9312$). PPE only reported as a correlation with splint wearing time. Study conclusions: no significant difference between groups at final outcome.</td>
</tr>
<tr>
<td>Saggini, 1996 Myofascial pain syndrome of peroneus longus</td>
<td>Custom vs heel lift</td>
<td>6 (6) vs 6 (6)</td>
<td>29.85 (6.9)</td>
<td>ID</td>
<td>4</td>
<td>—</td>
<td>ID</td>
<td>—</td>
<td>Study conclusions: VAS significantly lower in foot orthoses group at 2, 4 &amp; 8 weeks ($p &lt; 0.001$). Nonresponders crossed over at end of 4 weeks (Group C); not considered in this review.</td>
</tr>
<tr>
<td>Turlik, 1999 Heel spur syndrome</td>
<td>Functional foot orthoses vs heel pads (generic)</td>
<td>26 (25) vs 34 (30)</td>
<td>45 ~</td>
<td>12.5 ~</td>
<td>12</td>
<td>ID</td>
<td>ID</td>
<td>—</td>
<td>Study conclusions: significantly greater improvement in morning heel pain and overall symptom relief with custom foot orthoses ($p \leq 0.042$).</td>
</tr>
<tr>
<td>Wiener-Ogilvie, 2004 Anteromedial knee pain</td>
<td>Prefabricated customised vs lower limb exercises</td>
<td>11 (9) vs 10 (9)</td>
<td>38.7 (17.2) vs 51 (22.5)</td>
<td>17.9 (17.8) vs 10.6 (8.2)</td>
<td>8</td>
<td>0.75 (0.45 to 1.26)</td>
<td>0.80 (~0.17 to 1.77)</td>
<td>—</td>
<td>Lower limb strengthening and stretches.</td>
</tr>
</tbody>
</table>

(Continued)
<table>
<thead>
<tr>
<th>Condition</th>
<th>Orthoses vs. Comparison</th>
<th>Sample: mean (SD)/ median (years)</th>
<th>Mean (SD)/ median symptom duration (months)</th>
<th>Intervention &amp; followup (weeks)</th>
<th>Patient perceived effect (95% CI)</th>
<th>Visual analogue scale SMD (95% CI)</th>
<th>Foot health status questionnaire SMD (95% CI)</th>
<th>Effect size</th>
<th>Notes regarding study, Study conclusions (where effect size = ID)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Custom foot orthoses vs. Prefabricated foot orthoses</td>
<td>Landorf, 2004 Plantar fasciitis Custom vs formthotic</td>
<td>46 (45) vs 44 (43)</td>
<td>48.25 (11.8)</td>
<td>11.5</td>
<td>12</td>
<td>1.24 (0.62 to 2.46)</td>
<td>—</td>
<td>0.28 (−0.14 to 0.69)</td>
<td>0.16 (−0.25 to 0.58)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.17 (−0.25 to 0.58)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.14 (−0.27 to 0.56)</td>
<td>0.08 (−0.34 to 0.49)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>—</td>
<td>0.34 (−0.08 to 0.77)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.18 (−0.24 to 0.60)</td>
<td>−0.03 (−0.45 to 0.39)</td>
</tr>
<tr>
<td>Martin 2001 Plantar fasciitis Custom vs prefabricated arch supports</td>
<td>85 (71) vs 85 (62)</td>
<td>47.5 (12)</td>
<td>20</td>
<td>16</td>
<td>12</td>
<td>—</td>
<td>ID</td>
<td>0.77</td>
<td>0.25 (−0.17 to 0.67)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.18 (−0.24 to 0.60)</td>
<td>−0.03 (−0.45 to 0.39)</td>
</tr>
<tr>
<td>Pfeffer, 1999 Plantar fasciitis Custom + stretches vs felt insert</td>
<td>42 (34) vs 47 (42)</td>
<td>48.5</td>
<td>48</td>
<td>ID</td>
<td>8</td>
<td>0.59 (0.27 to 1.30)</td>
<td>0.01 (−0.44 to 0.46)</td>
<td>—</td>
<td>Study conclusions: no significant differences between groups at final outcome on pain measures; reported greater improvement in VAS with custom orthoses of 0.2/10 (no p value).</td>
</tr>
</tbody>
</table>

ID, inadequate data provided by authors; ∼, no significant difference between groups (p = 0.05); ID∼, authors have only reported statistical significance; PPE, patient perceived effect; VAS, visual analog scale; NSAIDS, nonsteroidal anti-inflammatory drug; SMD, standard deviation difference; RR, relative risk; CI, confidence intervals.

Components of FHSQ: 1 Foot pain; 2 Foot function; 3 Footwear; 4 General foot health; 5 Participants only included in study if symptom duration ≥ 6 months; 6 AOL; 2 Spenco Sports Medicine Products, Toronto, Ontario, Canada; 3 Langer Blueline, Langer Biomechanic Group, Inc.; 4 Viscoped, Bauerfiend Gmbh, Hampshire, UK; 5 Bauerfiend, Kennesaw, GA, USA; 6 Tuli International Comfort Products, San Marcos, CA, USA; 7 Footscience International, Christchurch, New Zealand; 8 Hapad, Bethel Park, PA, USA.
Foot orthoses compared to other interventions

Finestone et al.\textsuperscript{14} demonstrated a significant and clinically beneficial effect of foot orthoses over simple insoles (Table 1).

Custom compared to prefabricated foot orthoses

Pooled data from two studies within one publication\textsuperscript{15} comparing custom casted foot orthoses to prefabricated foot orthoses showed no significant effect favoring one type over the other (RR 1.14; CI 0.90 to 1.44) (Table 1; Figure 2).

Treatment Studies

In contrast to the prevention studies, the 15 studies that evaluated the treatment of lower limb overuse conditions with foot orthoses had greater heterogeneity in comparator interventions and the type and timing of outcome measures (Table 2). Consequently, pooling of data was only conducted where similar comparison groups were used, and analysis was divided into three time periods: up to and including 3 months; from 3 months up to and including 6 months; and greater than 6 months. The consistent use of three outcome measures, patient perceived treatment effect (PPE), pain visual analogue scale (VAS) and Foot Health Status Questionnaire (FHS), enabled calculation and comparison of effect sizes and pooling of data for some studies. Table 4 lists other outcome measures used. Studies evaluated the use of foot orthoses predominantly in plantar heel pain or fasciitis (eight studies), but also in anterior knee pain, primary and lesser metatarsalgia, Morton’s neuroma and peroneus longus myofascial pain syndrome.

![Fig. 2: Pooled results from prevention and treatment studies comparing foot orthoses to control, and custom to prefabricated foot orthoses. Solid shapes indicate relative risks (RR); hollow shapes indicate standardized mean differences (SMD). Timing of outcome measures all 0–3 months. * favors orthoses.](image)

Foot orthoses compared to controls

Pooling of data from two studies\textsuperscript{35,50} that compared foot orthoses to no orthoses, with all subjects performing exercises, showed no significant effect in favor of either group for PPE (RR 1.01; CI 0.61 to 1.68) or VAS (SMD 0.38; CI −0.28 to 1.03) (Table 2; Figure 2).

Foot orthoses compared to other interventions

In the intervention period of up to 3 months, data pooling was not conducted because of violation of the assumption of homogeneity of the data (Table 2). Two studies compared foot orthoses to a local steroid injection, with Kriss\textsuperscript{22} finding a significant moderate effect in favor of the injection on VAS, but Lynch et al.\textsuperscript{25} showing no significant difference in VAS between groups (Table 2). Heel inserts were more frequently used as a comparison intervention, with studies reporting conflicting findings. Lynch et al.\textsuperscript{25} showed a significant moderate effect in favor of foot orthoses, whereas Pfeffer et al.\textsuperscript{35} found significant small effects in favor of two different heel inserts on PPE measures, but no significant differences on VAS. Two other studies\textsuperscript{42,48} reported significantly greater improvements in pain measures for foot orthoses than heel inserts, but insufficient data were provided to calculate effect sizes. Different outcomes also arose for studies that compared foot orthoses to a cushioning or flat insole. Kelly and Winson\textsuperscript{20} showed a significant effect in favor of foot orthoses on VAS but not VAS, whereas Rome et al.\textsuperscript{39} showed no significant effect of one group over the other on FHS. Both Eng and Pierrynowski\textsuperscript{11} and Postema et al.\textsuperscript{37} found foot orthoses to be significantly better than flat or ready made insoles on pain measures \((p < 0.05)\) but did not provide sufficient data for effect size calculation. Of the two studies that compared foot orthoses to night splints for plantar fasciitis, Martin et al.\textsuperscript{26} reported slight differences between groups on VAS but did not report statistical significance levels, while Russell\textsuperscript{40} measured pain as a component of the Foot Function Index (which overall showed no significant difference between groups \((p > 0.05)\)) but did not report separate pain data. A single study comparing foot orthoses directly to a lower limb exercise program showed no effect in favor of either intervention on VAS or PPE,\textsuperscript{50} while another study that used chiropractic foot and ankle manipulations as a comparison provided insufficient data for effect size calculation but reported no significant difference on final measures.\textsuperscript{19}

One study that evaluated treatment effects at 6 months found no significant effect of foot orthoses or local steroid injection on VAS\textsuperscript{22} (Table 2). Similarly, PPE and VAS measures from a single study looking at treatment effects beyond 6 months showed no significant effect between pronation and supination foot orthoses.\textsuperscript{21}

Custom compared to prefabricated foot orthoses

Three studies compared custom to prefabricated foot orthoses up to a 3-month period.\textsuperscript{23,26,35} Pooling of data for
Table 3: Quality ratings using Modified PEDro Scale of reviewed papers (n = 22). Listed in descending order of quality rating (see Appendix A for details of Criteria 1–14)

<table>
<thead>
<tr>
<th>Study</th>
<th>Criteria</th>
<th>Score (14) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Landorf, 2004</td>
<td></td>
<td>11 (79)</td>
</tr>
<tr>
<td>Dimou, 2004</td>
<td></td>
<td>9 (64)</td>
</tr>
<tr>
<td>Wiener-Ogilvie, 2004</td>
<td></td>
<td>9 (64)</td>
</tr>
<tr>
<td>Esterman, 2005</td>
<td></td>
<td>9 (64)</td>
</tr>
<tr>
<td>Larsen, 2002</td>
<td></td>
<td>8 (57)</td>
</tr>
<tr>
<td>Kelly, 1998</td>
<td></td>
<td>8 (57)</td>
</tr>
<tr>
<td>Kilmartin, 1994</td>
<td></td>
<td>7 (50)</td>
</tr>
<tr>
<td>Rome, 2004</td>
<td></td>
<td>7 (50)</td>
</tr>
<tr>
<td>Postema, 1998</td>
<td></td>
<td>7 (50)</td>
</tr>
<tr>
<td>Turlik, 1999</td>
<td></td>
<td>6 (43)</td>
</tr>
<tr>
<td>Finestone, 2004*</td>
<td></td>
<td>5 (36)</td>
</tr>
<tr>
<td>Pfeffer, 1999</td>
<td></td>
<td>5 (36)</td>
</tr>
<tr>
<td>Saggini, 1996</td>
<td></td>
<td>5 (36)</td>
</tr>
<tr>
<td>Eng, 1993</td>
<td></td>
<td>4 (29)</td>
</tr>
<tr>
<td>Lynch, 1998</td>
<td></td>
<td>4 (29)</td>
</tr>
<tr>
<td>Martin, 2001</td>
<td></td>
<td>4 (29)</td>
</tr>
<tr>
<td>Milgrom, 1985</td>
<td></td>
<td>4 (29)</td>
</tr>
<tr>
<td>Kriss, 2003</td>
<td></td>
<td>4 (29)</td>
</tr>
<tr>
<td>Mundermann, 2001</td>
<td></td>
<td>4 (29)</td>
</tr>
<tr>
<td>Russell, 2000</td>
<td></td>
<td>3 (21)</td>
</tr>
<tr>
<td>Finestone, 1999</td>
<td></td>
<td>2 (14)</td>
</tr>
<tr>
<td>Simkin, 1989</td>
<td></td>
<td>2 (14)</td>
</tr>
</tbody>
</table>

* Single publication that used consistent methodologies to report results from two separate populations

PPE from two studies showed no significant effect favoring either custom or prefabricated foot orthoses (RR 0.88; CI 0.42 to 1.81) (Figure 2), which also reflected effect sizes calculated for the two individual studies.马丁 et al. did not report statistical analysis to support their findings of greater improvement in VAS in the group receiving custom orthoses, nor did they provide sufficient data for effect size calculation.

Landorf was the only study to measure effect beyond 3 months, with PPE and all subsets of the FHS showing no significant effect for either type of orthoses at both 6 and 12 months.

Cost Effectiveness of Foot Orthoses Intervention

Only two studies evaluated cost effectiveness of interventions. As well as representing both prevention and treatment studies, they used different comparison interventions and inconsistent outcome measures, therefore pooling of data was not possible.

Based on intention-to-treat analysis, Larsen et al. reported that the number of people to be fitted with foot orthoses that are needed to prevent one case of injury was six (95% CI 3–59) at a cost of US $122 (95% CI 58 to 1103). Effect sizes were unable to be calculated; however, the authors did report a nonsignificant relative risk of 0.7 (CI 0.5 to 1.1).

A more extensive cost-effectiveness analysis conducted by Rome et al. provided some data for effect size calculation. The total mean cost per patient for using prefabricated foot orthoses in the treatment of plantar heel pain was significantly greater than using a cushioning insole (SMD −3.31; CI −4.38 to −2.24), as was the total mean cost to the hospital podiatry department (SMD −3.89; CI −5.07 to
Table 4: Summary of measures of outcome used in 23 randomized controlled trials of foot orthoses in lower limb overuse conditions. Includes studies that used components of scales

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>Number of studies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Occurrence of injury</strong></td>
<td></td>
</tr>
<tr>
<td>Presence of lower limb injury (self-report, P/E, radiograph, scintigraphy)</td>
<td>8</td>
</tr>
<tr>
<td>Development of other symptoms</td>
<td>1</td>
</tr>
<tr>
<td>Lower limb pain in the previous 24 hours</td>
<td>1</td>
</tr>
<tr>
<td><strong>Patient perceived treatment effect</strong></td>
<td></td>
</tr>
<tr>
<td>Global/final outcome score; perceived improvement; response rate*</td>
<td>6</td>
</tr>
<tr>
<td>Progression of pain*</td>
<td>1</td>
</tr>
<tr>
<td>Relief with intervention*</td>
<td>1</td>
</tr>
<tr>
<td>Symptom relief VAS</td>
<td>1</td>
</tr>
<tr>
<td>Patient satisfaction questionnaire*</td>
<td>1</td>
</tr>
<tr>
<td>Time to start of improvement</td>
<td>1</td>
</tr>
<tr>
<td><strong>Pain</strong></td>
<td></td>
</tr>
<tr>
<td>Pain VAS (daily; during activities; first-step pain)</td>
<td>7</td>
</tr>
<tr>
<td>Pain*</td>
<td>1</td>
</tr>
<tr>
<td>Numeric Pain Rating Scale 101</td>
<td>1</td>
</tr>
<tr>
<td>First-step pain*</td>
<td>3</td>
</tr>
<tr>
<td>Frequency/severity of morning heel pain*</td>
<td>1</td>
</tr>
<tr>
<td>Change in pain under various specific circumstances</td>
<td>1</td>
</tr>
<tr>
<td>Feelings about life with pain*</td>
<td>1</td>
</tr>
<tr>
<td>Worry about current pain*</td>
<td>1</td>
</tr>
<tr>
<td><strong>Pain and function</strong></td>
<td></td>
</tr>
<tr>
<td>Foot Health Status Questionnaire</td>
<td>3</td>
</tr>
<tr>
<td>Foot Function Index</td>
<td>2</td>
</tr>
<tr>
<td>MACTAR patient specific measure of maximal function</td>
<td>1</td>
</tr>
<tr>
<td>Knee Pain Scale</td>
<td>1</td>
</tr>
<tr>
<td>Effect of heel pain on leisure/work/exercise*</td>
<td>3</td>
</tr>
<tr>
<td><strong>General health</strong></td>
<td></td>
</tr>
<tr>
<td>Short Form 36</td>
<td>2</td>
</tr>
<tr>
<td>EuroQol (EQ5D)Questionnaire</td>
<td>1</td>
</tr>
<tr>
<td>World Health Organization Quality of Life Questionnaire (WHOQOL) Short Form</td>
<td>1</td>
</tr>
<tr>
<td><strong>Activity</strong></td>
<td></td>
</tr>
<tr>
<td>Hours of activity per week</td>
<td>1</td>
</tr>
<tr>
<td>Change in activity</td>
<td>1</td>
</tr>
<tr>
<td>Type &amp; amount of exercise per week; walking distance</td>
<td>2</td>
</tr>
<tr>
<td>Hours on feet per day</td>
<td>1</td>
</tr>
<tr>
<td><strong>Physical measures</strong></td>
<td></td>
</tr>
<tr>
<td>Gait analysis</td>
<td>3</td>
</tr>
<tr>
<td>Surface electromyography (sEMG)</td>
<td>1</td>
</tr>
<tr>
<td>Nerve conduction studies</td>
<td>1</td>
</tr>
<tr>
<td>Pressure pain threshold</td>
<td>2</td>
</tr>
<tr>
<td><strong>Orthoses comfort</strong></td>
<td></td>
</tr>
<tr>
<td>Orthoses comfort*</td>
<td>2</td>
</tr>
<tr>
<td><strong>Compliance</strong></td>
<td></td>
</tr>
<tr>
<td>Compliance with treatment (% wear, daily splint wearing time)</td>
<td>3</td>
</tr>
<tr>
<td><strong>Cost effectiveness</strong></td>
<td></td>
</tr>
<tr>
<td>Cost of treatment</td>
<td>1</td>
</tr>
<tr>
<td>Total off-duty days; subjects with ≥ 1 off-duty days due to lower limb problem</td>
<td>1</td>
</tr>
</tbody>
</table>
There was no significant difference in total mean cost to other National Health Service (NHS) services per patient between the two groups. Rome et al. also reported that, based on mean scores from the EuroQol health status questionnaire, use of the foot orthoses resulted in a quality-adjusted life year gain of 0.0109 compared to the cushioning insert, and an incremental cost per quality-adjusted life year of $3210.

Two studies mentioned costs of materials for different shoe inserts in their discussion of study findings but did not relate these to improvements in outcome measures or consider the total cost of intervention.

**Adverse effects of foot orthoses intervention**

Only eight of the 22 papers that were included in the systematic review analyzed or mentioned the occurrence of adverse events arising from interventions provided. Kilmartin and Wallace was the only study to report an incidence of adverse events, with no significant difference between groups receiving pronation or supination orthoses. Both Dimou et al. and Wiener-Ogilvie and Jones reported no adverse events with any of the interventions.

Overall, the main adverse effect reported was discomfort. This was the primary reason for discontinuing use in reports by Finestone et al. and Esterman and Pilotto and was also reported by participants in the study conducted by Rome et al. Twenty-one percent of participants (30 of 143 recruits) allocated to receive foot orthoses in a preventative role discontinued their use in the first 14 days because of discomfort. Other reported adverse effects of foot orthoses included arch or metatarsal pain, shin splints, and slipping of the orthoses in the boots. Comments about adverse effects of cushioning inserts were slightly different in nature. The silicone insole used in the study by Kelly and Winson was described as being too hot and slippery, while the insole used by Rome et al. tended to go hard and flat and lose its cushioning ability after 4 weeks of wear.

**DISCUSSION**

Two distinct bodies of literature were identified by the comprehensive search strategy: studies that evaluated foot orthoses in a prevention role, and studies investigating foot orthoses in the treatment of lower limb overuse conditions. The systematic review and pooling of data support the use of foot orthoses in preventing lower limb overuse conditions in military populations. However, caution should be exercised in making inferences to populations other than military personnel undergoing basic or standard training. In comparison, there was insufficient evidence to support or refute the use of foot orthoses, either custom or prefabricated, in the treatment of lower limb overuse injuries.

Custom foot orthoses, defined in the ACFAOM guidelines as being derived from a three-dimensional model of the foot, often are regarded to be superior to prefabricated (off-the-shelf) foot orthoses. A particularly interesting finding from this review was the lack of any differential efficacy between custom and prefabricated foot orthoses, both from pooled data and individual study data that could not be pooled. This finding requires followup evaluation. Importantly, this appears to have clinical implications in the management of lower limb overuse conditions, suggesting that the more readily available prefabricated foot orthoses are similar in clinical effect to custom fabricated orthoses. While the cost effectiveness was not directly investigated by the included studies, the custom fabricated orthoses tend to be more resource-intensive (e.g. equipment, material, technical expertise). Another consideration is the wearing-in period often associated with custom foot orthoses and the delay between fitting and supply particularly when prescriptions need to be sent off site. In addition, the lack of differences between custom and prefabricated foot orthoses supports our decision to consider both types of foot orthoses as one group in comparisons with control or other interventions.

Using the best current evidence, it would seem appropriate that clinical guidelines should de-emphasize the difference between custom and prefabricated foot orthoses in the management of overuse conditions. However, this statement should be tempered with consideration of deficits in the studies reviewed and the recognition of the need for further research in this area.

A potential deficiency of this review was that specific overuse conditions being studied in individual papers were generalized, that is, studies were evaluated and pooled across a range of overuse conditions. We considered this to be a legitimate approach, because the findings from previous prevention studies have shown that foot orthoses were effective in preventing a range of overuse conditions, regardless of lower limb site. In addition, the overuse conditions included have a putative association with abnormal foot function, usually ascribed to excessive pronation, and it is frequently recommended that foot orthoses be included in their management. Importantly, the ACFAOM guidelines indicate custom foot orthoses to be either ‘medically indicated and essential’ or ‘useful’ in all of the conditions studied in the reviewed papers, with the exception of Morton’s neuroma and peroneus longus myofascial pain syndrome. When Morton’s neuroma has been diagnosed, ACFAOM have recommended foot orthoses as an adjunct to treatment. Peroneus longus myofascial pain syndrome as described by Saggini et al. was not discussed in the ACFAOM guidelines.

As highlighted in the results, there were a number of criteria from the modified PEDro scale that were reported by less than half of the included studies. Although this has implications for the internal and external validity as well as overall power of the studies, correlation analyses between the modified PEDro score and effect size showed that the deficits in methodological quality did not appear to affect
the overall outcome of the meta-analysis. This differs from previous studies that have reported that the inclusion of low methodological quality studies in a meta-analysis can bias the interpretation of the intervention’s benefit.30

One of the strengths of this systematic review was the minimization of bias through the use of independent reviewers who were blinded to authors, affiliations, and publishing journals. In addition, publication bias was reduced through using a comprehensive search strategy that encompassed all publication forms, including conference presentations and placed emphasis on hand searching of reference lists.

This systematic review has attempted to fill a gap in the literature with respect to Level I evidence but also has identified a number of issues for future research. Not only is more research into the role of foot orthoses in the treatment of lower limb overuse conditions required but it needs to be of higher quality. Overall, greater consensus is necessary in the literature as to what constitutes foot orthoses, perhaps with one consistent set of guidelines that is based on current evidence. Based on evidenced published to date, we would propose the following definition for foot orthoses: in-shoe devices shaped to match the plantar surface of the foot and used in the prevention and treatment of injury, pain, and disability through the optimization of lower extremity function. In addition, the methodology of future RCT research requires more meticulous planning, using the CONSORT statement31 as a guideline to direct high-quality study. Future research should also investigate the long-term efficacy of foot orthoses.

SUMMARY

There is evidence from the meta-analysis to support the use of foot orthoses in the prevention of the first incidence of lower-limb overuse conditions. The inclusion of orthoses in a treatment program for individuals who already have an overuse condition is difficult to support or refute because of the generally poor research base, which has been highlighted by this systematic review.

There is evidence from pooled data that there is no difference between the use of custom and prefabricated foot orthoses, inferring that practitioners may use either in the prevention and treatment of lower-limb overuse injuries.

Focal points for future research conducted in this area include longer intervention durations, greater consistency with reliable measures, and better consensus in definitions of foot orthoses.

REFERENCES


35. Pfeffer, G; Bacchetti, P; Deland, J; et al.: Comparison of custom and prefabricated orthoses in the initial treatment of proximal plantar fasciitis. Foot Ankle Int. 20:214–221, 1999.
40. Russell, BE: Comparison of the plantar fasciitis splint versus the night resting splint in the treatment of plantar fasciitis, Women’s University, Houston, Texas, 1999.
44. Simkin, A; Leichter, I; Giladi, M; Stein, M; Milgrom, C: Combined effect of foot arch structure and an orthotic device on stress fractures. Foot Ankle. 10:25–29, 1989.
### Appendix A: Modified PEDro rating scale

<table>
<thead>
<tr>
<th>All criteria: points are only awarded when a criterion is clearly satisfied. If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Eligibility criteria were specified.</strong> This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.</td>
</tr>
<tr>
<td><strong>2. Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated in order in which treatments were received).</strong> A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomization need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomization allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.</td>
</tr>
<tr>
<td><strong>3. Allocation was concealed.</strong> Concealed allocation means that the person who determined if a subject was eligible for inclusion in the trial was unaware when the decision was made of to which group the subject would be allocated. A point is awarded for this criteria, even if it is not stated that allocation was concealed when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was “off-site.”</td>
</tr>
<tr>
<td><strong>4. The groups were similar at baseline regarding the most important prognostic indicators.</strong> At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups’ outcomes would not be expected to differ on the basis of baseline differences in prognostic variables alone by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.</td>
</tr>
<tr>
<td><strong>4, 7–11. Key outcomes</strong> are those outcomes which provide the primary measure of effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.</td>
</tr>
<tr>
<td><strong>5–7. Blinding</strong> means that the person in question (subject, therapist, or assessor) did not know to which group the subject had been allocated. In addition, subjects and therapists are only considered to be “blind” if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (e.g. visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.</td>
</tr>
<tr>
<td><strong>5. There was blinding of all subjects.</strong></td>
</tr>
<tr>
<td><strong>6. There was blinding of all therapists who administered the therapy.</strong></td>
</tr>
<tr>
<td><strong>7. There was blinding of all assessors who measured at least one key outcome.</strong></td>
</tr>
<tr>
<td><strong>8. Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups.</strong> This criterion is only satisfied if the report explicitly states both the number of subjects initially allocated to groups and the number of subjects from whom key outcome measures were obtained. In trials in which outcomes were measured at several points in time, a key outcome must have been measured in more than 85% of subjects at the time of primary interest.</td>
</tr>
</tbody>
</table>
Appendix A: (Continued)

9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome were analyzed by “intention to treat.” An intention to treat analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and when measures of outcome were available, the analysis was performed as if subjects received the treatment (or control condition) to which they were allocated. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.

10. The results of between-group statistical comparisons are reported for at least one key outcome. A between-group statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyze the data, the latter often is reported as a group x time interaction). The comparison may be in the form hypothesis testing (which provides a “p” value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.

11. The study provides both point measures and measures of variability for at least one key outcome. A point measure is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcome, or as the outcome in (each of) all groups. Measures of variability include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quartile ranges), and ranges. Point measures or measures of variability may be provided graphically (for example, standard deviations may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent standard deviations or standard error). When outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.

12. The sample size is justified. In calculating the sample size, statistical evidence was provided regarding the power of the study and its effect size.

13. The study uses outcome measures that have known validity and reliability. Outcome measures used in the study were referenced for their validity and reliability. If more than one assessor was used for the outcome measures, inter-tester reliability studies were performed, and results of these stated.

14. Adverse or side effects were reported. All adverse events were described and correctly attributed to allocated treatment. If no adverse events occurred, the report explicitly states “no adverse events.” A comparison was made between the beneficial effect of the intervention and the adverse events (i.e. did the benefits of the intervention outweigh the adverse events?).
PART I:

Study protocol

Foot orthoses and physiotherapy in the treatment of patellofemoral pain syndrome: A randomised clinical trial

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Abstract

**Background:** Patellofemoral pain syndrome is a highly prevalent musculoskeletal overuse condition that has a significant impact on participation in daily and physical activities. A recent systematic review highlighted the lack of high quality evidence from randomised controlled trials for the conservative management of patellofemoral pain syndrome. Although foot orthoses are a commonly used intervention for patellofemoral pain syndrome, only two pilot studies with short term follow up have been conducted into their clinical efficacy.

**Methods/design:** A randomised single-blinded clinical trial will be conducted to investigate the clinical efficacy and cost effectiveness of foot orthoses in the management of patellofemoral pain syndrome. One hundred and seventy-six participants aged 18–40 with anterior or retropatellar knee pain of non-traumatic origin and at least six weeks duration will be recruited from the greater Brisbane area in Queensland, Australia through print, radio and television advertising. Suitable participants will be randomly allocated to receive either foot orthoses, flat insoles, physiotherapy or a combined intervention of foot orthoses and physiotherapy, and will attend six visits with a physiotherapist over a 6 week period. Outcome will be measured at 6, 12 and 52 weeks using primary outcome measures of usual and worst pain visual analogue scale, patient perceived treatment effect, perceived global effect, the Functional Index Questionnaire, and the Anterior Knee Pain Scale. Secondary outcome measures will include the Lower Extremity Functional Scale, McGill Pain Questionnaire, 36-Item Short-Form Health Survey, Hospital Anxiety and Depression Scale, Patient-Specific Functional Scale, Physical Activity Level in the Previous Week, pressure pain threshold and physical measures of step and squat tests. Cost-effectiveness analysis will be based on treatment effectiveness against resource usage recorded in treatment logs and self-reported diaries.

**Discussion:** The randomised clinical trial will utilise high-quality methodologies in accordance with CONSORT guidelines, in order to contribute to the limited knowledge base regarding the clinical efficacy of foot orthoses in the management of patellofemoral pain syndrome, and provide practitioners with high-quality evidence upon which to base clinical decisions.

**Trial registration:** Australian Clinical Trials Registry ACTRN012605000463673

ClinicalTrials.gov NCT00118521
**Background**

Patellofemoral pain syndrome (PFP) is a distinct clinical entity defined as "idiopathic pain arising from the anterior knee/patellofemoral region that is of otherwise unknown origin" [1]. Falling within the classification of lower limb musculoskeletal overuse conditions, PFP is highly prevalent among active individuals. A recent retrospective review of running injuries found PFP to be the most common presentation to a sports medicine clinic in both females (19.2% of injuries) and males (13.4% of injuries) [2]. The pain and disability resulting from this condition not only affects short term participation in daily and physical activities, but can have a significant long term impact, with symptoms shown to persist in 1 in 4 sufferers for up to 20 years after initial presentation [3]. As regular physical activity is highly recommended for the prevention of conditions such as cardiovascular disease and type II diabetes, PFP may have important implications for the long term health of affected individuals.

Given the prevalence and impact of this condition and the subsequent demands placed on health care practitioners, the lack of high quality research on the conservative management of PFP is surprising [4,5]. A recent systematic review by Crossley et al [5] concluded that current management of PFP is not based on evidence from randomised controlled trials (RCTs), which are widely deemed to be the gold standard of research design in providing the best evidence for health care interventions [6].

Foot orthoses are a commonly used and frequently recommended intervention in the management of PFP [7]. Preliminary evidence of their clinical efficacy is provided by findings of a pilot study of 20 adolescent females [8]. The addition of soft foot orthoses to an exercise program resulted in significantly greater improvements in pain than treatment with flat insoles and exercises over eight weeks. A more recent study by Wiener-Ogilvie & Jones [9] however found no difference in outcome between 8 weeks of treatment with functional foot orthoses, exercises, or orthoses with exercises. The authors considered the small sample size (N = 31) to have contributed to the inability to detect a significant difference between the three groups. Conversely, a popular physiotherapy program used routinely in Australia does have high quality RCT evidence to support its use in PFP. Crossley et al [10] showed this six week physiotherapy program of quadriceps muscle retraining, patellofemoral joint mobilisation, patellar taping and daily home exercises to be significantly superior to sham ultrasound, non-therapeutic gel application and placebo taping. The short follow up period used in all three studies could be considered to be a downfall, particularly given the condition's demonstrated tendency for chronicity [3].

In order to provide clinicians with high quality evidence upon which to base clinical decision making, it is therefore timely to conduct a RCT to establish the long term clinical efficacy of foot orthoses in the management of PFP.

**Methods**

**Aim**

The primary aim of this study is to determine the clinical efficacy of foot orthoses in the management of PFP, as compared to a flat insole, a proven physiotherapy program, and a combined intervention of foot orthoses and physiotherapy. The cost-effectiveness of foot orthoses compared to the other interventions will also be evaluated.

**Study design**

The above aims will be investigated through the conduct of a pragmatic randomised single-blinded clinical trial in a community setting over a 12 month period. All participants will provide written informed consent prior to randomisation. The investigator responsible for taking the outcome measures will be blinded to participants' group allocation. In order to maintain blinding of this investigator, randomisation will be effected and controlled by an independent body, and a research assistant will perform all communication regarding group allocation. An overview of the study protocol is provided in Figure 1.

**Ethics**

Ethical approval for this study has been granted by the University of Queensland's Medical Research Ethics Committee.

**Eligibility criteria**

Volunteers will be eligible for participation in the study on the basis of the following criteria: (1) anterior or retropatellar knee pain of non-traumatic origin and greater than six weeks duration that is provoked by at least two of the following activities: prolonged sitting or kneeling, squatting, jogging or running, hopping, jumping, or stair ascending/descending; (2) the presence of pain on palpation of the patellar facets, on step down from a 25 cm step, or during a double leg squat; and (3) pain over the previous week equal to or greater than 30 mm on a 100 mm visual analogue scale. Due to the nature of the outcome measures to be used, participants will require an acceptable understanding of written and spoken English. An ability and willingness to attend all sessions required for completion of the study and comply with intervention protocols for the 12 month study period will also be an essential criterion. Volunteers will be excluded if they have any of the following: (1) concomitant injury or pathology of other knee structures (e.g. menisci, collateral and cruciate ligaments, patellar tendon, iliotibial band,
pes anserinus); (2) a history of knee surgery, patellofemoral dislocation or subluxation, Osgood-Schlatter’s disease or Sinding-Larsen-Johanssen syndrome; (3) a positive patellar apprehension test; evidence of knee joint effusion; (4) any foot condition that may preclude the use of foot orthoses; (5) pain in and/or referred from the hip or lumbar spine; or (6) a known allergy to rigid strapping tape. Prior treatment with foot orthoses will also preclude

**Figure 1**
Flow of participants through the randomised clinical trial.
volunteers from participating in order to facilitate blind- ing as to the differences between the foot orthoses and flat insoles, as will prior physiotherapy treatment for PFP within 12 months of entry into the study and current use of anti-inflammatories or corticosteroids. All participants will be required to be a minimum of 18 years of age for consent purposes, and a maximum of 40 years in order to minimise the likelihood of degenerative joint changes.

Recruitment of study participants
In order to recruit a representative sample of sufficient size, a multifaceted recruitment strategy that has been successful in past clinical trials will be used. This will target the greater Brisbane, Gold Coast and Toowoomba regions in Queensland, Australia. Paid advertisements in local and regional newspapers will be placed at regular intervals during the recruitment period, along with media releases to broaden the scope to radio and television media. These will be reinforced by regular posting of advertisements on University, gymnasium and community noticeboards within the catchment area. It is anticipated that a small number of referrals will also come from physiotherapists involved in the study, as well as general practitioners through the provision of information and advertising packages.

Volunteers who respond to advertisements will be put through a two-stage screening process to determine their suitability for inclusion in the study. Firstly, a preliminary telephone interview will be conducted to screen for major exclusion criteria. Potential participants will then be invited to attend an appointment at the University of Queensland, where they will be provided with further information about the screening process and study. A comprehensive musculoskeletal examination will then be conducted by a qualified physiotherapist to determine the volunteer's suitability for inclusion based on the eligibility criteria. At the completion of the examination, eligible volunteers will be provided with an information sheet that thoroughly explains the study protocol. They will then attend a follow-up appointment for completion of informed consent documentation and baseline outcome measures. This will be conducted by an assessor who will remain blind to group allocation and be responsible for taking outcome measures at designated follow-up times. At this appointment, the knee rated to be the most severe by participants with bilateral PFP will be selected as the knee to be studied.

Randomisation
Once informed consent has been obtained and baseline outcome measures completed, each participant will be assigned a participant number and randomly allocated to one of four intervention groups via concealed allocation. The Queensland Clinical Trial Centre, an independent off-
with the comfort level of the orthoses, the orthoses will be customised. This will first involve heat moulding as per the manufacturer’s instructions (Step 3a). This process involves mildly heating the underside of the orthosis, placing it in the intended shoe and then having the participant stand on it with the foot positioned in its neutral zone for approximately 60 seconds. If the heat moulding process alone fails to optimise comfort, the therapist will sequentially trial the addition of medial wedges of the rear and forefoot and/or a heel raise to the orthoses (Step 3b). The medial rearfoot wedges have a manufacturer specified 2° or 4° of inclination, the forefoot wedges 4° or 6° and the heel raises are 4, 6 or 8 mm thick. The foregoing underscores the primary goal of fitting of the orthoses to achieve a comfortable fit. Once comfort has been achieved, the effect of the orthoses on performance of a functional task will be evaluated. This will involve quantification of the effect of the orthoses on pain-free performance of an activity identified as pain provocative immediately prior to orthosis fitting, such as, step ups, step downs or squats. A substantial increase in the number of pain-free repetitions that can be performed will be regarded as a success. The therapist will modify the orthoses in order to improve the performance of the functional task, but with the fundamental aim of ensuring the orthoses are comfortable. This process of fitting, reviewing and adjusting the orthoses will continue over the six visits. Participants will also be given a home exercise program of foot arch-forming exercises and weight-bearing calf stretches to be performed bilaterally twice daily.

2. Flat inserts
This condition will act as a control for the application of inserts into the footwear, and will likely account for some of the potential placebo effects of prescribing an in-shoe device. The flat inserts will be identical in initial appearance to the foot orthoses described above, made from the same EVA with identical covering fabric and company logo. However, this device will be of uniform thickness along its length (3 mm) and have no inbuilt arch or varus wedging. The only modification that will be made to this insert is gentle heat moulding over the six appointments. Participants will be taught a home exercise program of minimal balance training, slowly progressing from standing on one leg while holding a rail for support, to unsupported single leg stance, moving toes up and down, and with eyes closed. The exercise program will not be reinforced as with the other interventions.

3. Physiotherapy
The physiotherapy program will consist of a combined therapy approach that represents the current Australian best practice. A recent RCT showed this program to produce a significantly greater reduction in pain and disability over six weeks compared to a placebo intervention [10]. The major components are outlined in Table 1 and illustrated in Figures 3 and 4.

4. Foot orthoses and Physiotherapy
Participants assigned to this group will receive both the foot orthoses and physiotherapy programs as described in 1 and 3 above. Due to the large volume of treatment delivered, participants in this group may undergo a seventh
visit with the physiotherapist to ensure adequate fit and comfort of the orthoses and understanding and progression of the physiotherapy exercise program.

All participants will receive an educational package at the commencement of the study, providing general information on PFP and advice on activity. In general terms, the advice on activity will entail an encouragement to participants to continue to exercise and participate in activities that do not provoke their knee pain, and to avoid aggravating activities particularly if the provoked pain persists longer than several minutes after cessation of the activity.

Outcome measures

The blinded assessor will repeat the outcome measures following completion of the 6 visits with the physiotherapist at 6 weeks, and then at 12 and 52 weeks to assess the long term outcome of the intervention.

Outcome will be assessed at each time point using measures that have been previously demonstrated as being acceptably reliable and valid indicators of change [11-16] and used in previous high-quality RCTs of PFP [10,17,18]. The primary outcome measures will be as follows.

1. Usual and worst pain Visual Analogue Scale

A 100 mm horizontal line with the descriptors 'no pain' at the 0 mm mark and 'worst pain imaginable' anchoring the 100 mm end will be used as a visual analogue scale. Participants will be required to place a vertical mark that represents their pain level on the horizontal line. They will do this twice, once to indicate their usual level of pain in the preceding week and the other to represent their worst pain.
experienced over the same time period. This will give two perceived pain severity ratings in millimetres [19]. The pain VAS has well-established reliability and validity in individuals with AKP [11,14,15,19].

2. Anterior Knee Pain Scale
This scale consists of 13 items with discrete categories related to limp, weight bearing, walking, stairs, squatting, running, jumping, prolonged sitting with flexed knees, pain, swelling, painful patellar movements, thigh muscle atrophy, and flexion deficiency. One response to each item that best describes the participant's knee pain is selected and scored on a weighted basis, with the highest representing normal and asymptomatic [20]. The 13 individual items are then summed to provide a final score where 0 represents maximal disability and 100 represents no disability. This scale has been shown to have high test-retest reliability [15,16], moderate responsiveness to clinical change [16], and a demonstrated ability to discriminate between individuals with and without AKP [20].

3. Functional Index Questionnaire
The Functional Index Questionnaire comprises eight questions pertaining to whether activities that are commonly problematic in PFP can be performed with or without difficulty [14,19]. The activities, including prolonged sitting, squatting and stair climbing, are each rated on a three point scale, where 0 = unable to do, 1 = can do with problem, and 2 = no problem. The sum of the scores for each of the eight activities provides an overall score, with 0 indicating maximal disability and 16 representing no disability. Studies have shown the FIQ to have fair to substantial test-retest reliability [11,14,15,19], and to be a valid measure for detection of clinical change [14].

4. Patient Perceived Treatment Effect Score and Perceived Global Effect Visual Analogue Scale
Participants' perceived level of recovery will be rated on two scales at the 6, 12 and 52 week follow-up visits. Perceived Treatment Effect will be measured using a 5 point Likert scale with the following categories: (1) marked worsening, (2) moderate worsening, (3) same, (4) moderate improvement, and (5) marked improvement. For the purpose of analysis, this scale will then be dichotomised according to success, where 'success' is defined as marked or moderate improvement on this scale [10]. We will also conduct a sensitivity analysis on this dichotomisation. Perceived Global Effect Visual Analogue Scale will be piloted. Participants will rate their recovery by placing a vertical mark on a 200 mm VAS with 'same' in the middle to represent no change (0 mm), 'much worse' at the far left end (-100 mm) and 'completely better' as the right hand anchor (+100 mm). A positive score will represent improvement, while a negative score will indicate worsening of the condition.

Figure 4
Hip external rotation retraining.
Secondary outcome measures that will be taken include the following:

1. Lower Extremity Functional Scale
The Lower Extremity Functional Scale is used to evaluate any difficulty experienced during daily activities as a result of the specific lower limb condition, such as PFP, and has been shown to be reliable, valid and sensitive to change in AKP participants [16] and those with general lower limb conditions [12]. Twenty items are rated individually on a 5 point scale indicating the degree of difficulty associated with performing that activity on the current day, ranging from 0 (extreme difficulty or unable to perform the activity) to 4 (no difficulty). Scores from each activity are summed to give an overall indication of functional difficulty, where 0 indicates maximal difficulty and 80 indicates no difficulty.

2. Patient-Specific Functional Scale
The Patient Specific Functional Scale assesses individual disabilities in a short, efficient format, and was designed to complement generic or condition-specific measures [13]. It has been shown to have excellent test-retest reliability and sensitivity, and good validity in individuals with knee dysfunction [13]. Participants are asked to nominate up to 5 functional activities that they are experiencing difficulty with. The current level of difficulty associated with each activity due to the specified condition is then rated on an 11-point scale, where 0 is “unable to perform the activity” and 10 is “able to perform activity at same level as before injury or problem”, and the average score across all activities is calculated.

3. McGill Pain Questionnaire
The most commonly used multidimensional pain measure, the McGill Pain Questionnaire provides a description of the participant’s pain experience, and has been utilised as a primary outcome measure in previous knee pain studies [21,22]. The first component involves descriptors of pain categorised as sensory, affective, evaluative and miscellaneous. Twenty groups of words are presented, with the participant required to select one word from each group that best describes their pain. The word chosen is scored by its rank order within the group, with the first word scoring 1, the second word scoring 2, and so forth. If no words are applicable a score of zero is recorded for that group. The Pain Rating Index is the sum of the scores across the 20 groups (range 0–78). The Number of Words Chosen is the number of groups for which a word was selected (out of 20). The second component is the Present Pain Index, a six point scale of severity ranging from no pain (0) to excruciating (5). For the final component, the participant selects one of three groups of words that best describes the pattern of their knee pain, or how pain changes with time, and leaves the question blank if there is no pain.

4. Medical Outcomes Study 36-Item Short-Form Health Survey
This questionnaire is a widely-used generic measure of health-related quality of life [23], and has been previously used in PFP populations [10]. Thirty-six items are used to calculate eight multi-item scores: physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality (energy/fatigue), social functioning, role limitations due to emotional problems, and mental health.

5. Hospital Anxiety and Depression Scale
This 14-item scale will be used to investigate whether there is an association between PFP and emotional state, and has been found to be a reliable instrument for detection of anxiety and depression in an outpatient setting and a valid indicator of severity [24], and has been used in a previous study of physiotherapy in PFP [17]. Participants are required to select the best of 4 responses to questions pertaining to either anxiety or depression (7 questions each), which are scored from 0 to 3. The scores for the anxiety and depression questions are summed separately to give total scores for each component, where 0–7 represents no anxiety or depression, 8–10 is borderline, and 11–21 indicates the presence of an anxious or depressive state.

6. Physical Activity Level in the Previous Week
Participants’ physical activity levels will be quantified using a physical activity questionnaire by which occupational, household and leisure activities of varying intensities can be accurately and reliably measured [25]. This questionnaire involves calculation of the time spent in each of these activity types at moderate, hard and very hard intensities over the preceding 7 days. The total time in hours for each intensity of activity is then multiplied by the metabolic equivalents of the activities (METs, kcal/kg/hour), and summed to give an overall caloric output for the week, and divided by seven to give an average daily output. This can then be standardised to body weight to provide an index that can be compared between and within individuals across time [25]. This questionnaire has been shown to have moderate to high reliability on test-retest, especially with moderate and vigorous intensities of activity [25], and has been used previously in a PFP population [10].

7. Step up, step down and squat tests
Three activities that typically provoke PFP will be used as a physical measure of function [10]. Step up and step down tests will be performed on a 25 cm step in a stepping order that continually loads the study knee, while squats will be of full excursion to the point where the fin-
gers touch the floor. A metronome set at 96 beats per minute will be used to standardise the rate of testing. The repetition number on which the first onset of pain occurs, or the first increase in pain where a constant background ache is present, will be recorded, up to a maximum of 25 repetitions.

8. Pressure Pain Threshold (PPT)
Pressure algometry, which has demonstrated reliability [26], will be used to measure PPT at four sites at the knee: (1) the proximal third of the medial border of the tibia; (2) the mid-point of the patella; (3) the distal portion of the rectus femoris muscle, 5 cm superior to the proximal border of the patella; (4) the most palpably tender point around the knee. A digital pressure algometer (Somedic AB, Farsta, Sweden) will measure the pressure applied at a rate of 40 kPa/s to the test site by a rubber-tipped probe (area 1 cm²) positioned perpendicular to the skin. The participant will activate a button at the precise moment that the pressure sensation changes to one of pressure and pain, which will signal cessation of pressure application and freeze the pressure reading onscreen for manual recording. Three measures will be taken at each site and the average calculated to represent the final value.

A further questionnaire regarding any adverse reactions to the intervention and whether any other treatment was sought will be completed at 12 months.

All participants will be required to maintain a daily diary over the 12 month period, recording activity levels, problems with the intervention, analgesia requirements and compliance with the home exercise program. Visual analogue scales for usual and worst pain over a week period, recording. Three measures will be taken at each site and the average calculated to represent the final value.

Sample size considerations
Sample size calculations for this study are based on the 100 mm visual analogue scale for usual pain over the past week. The mean difference between baseline and final score for each group will be compared to measure the effectiveness of each intervention. In order to detect a minimal clinically important difference of 15 mm [15,27], assuming a standard deviation of 20 mm [10], a power of 0.80 and alpha level of 0.01, a sample size of 40 participants per group will be required. To account for dropouts, particularly considering the long duration of the study [28], a group size of 44 will be recruited, with a total sample size of 176.

Planned statistical analysis
Statistical analysis will be conducted on a blinded, intention to treat basis, with all participants who were initially randomised into the study included where data is available for each measurement time. SPSS software (Version 15.0) will be used for statistical procedures. The four groups will be examined for baseline comparability with respect to demographic data such as age, gender, body mass index and duration of knee pain, as well as baseline values of outcome measures. Continuous outcome measures taken at 6, 12 and 52 weeks will be analysed using univariate analysis of variance, where the baseline value of the outcome measure will be used as a covariate and group allocation as a fixed factor. Continuous data will also be expressed as area under the curve in order to compare the overall effectiveness of each intervention over the entire 12 month period. Participant demographics will also be included in the models as covariates to assess their impact on outcome. The dichotomous measure of success will be analysed using relative risk, risk reduction and numbers needed to treat in order to facilitate clinical interpretation of findings and future guidelines. Cost effectiveness analysis will evaluate the effectiveness of the intervention measured using Perceived Treatment Effect against resource usage (e.g. physiotherapist fees, equipment, medications, etc.), through calculation of the marginal cost effectiveness of treatment in terms of dollars per 1-point improvement in outcome. To accommodate for the possibility of inflated Type I error rate resulting from multiple comparisons, significance will be set at 0.01 (i.e., 99% confidence intervals).

Discussion
In order to determine the clinical efficacy and cost-effectiveness of foot orthoses in the management of PFP, a pragmatic randomised clinical trial is to be conducted. Based on the Delphi List of criteria for quality assessment of RCTs [29], particular methodological factors have been incorporated into the study design to minimise bias and optimise the rigor of the RCT. Firstly, participants will be randomly allocated to intervention groups via concealed allocation. Poor allocation concealment has been shown to be associated with bias in RCTs [30]. Secondly, the investigator responsible for assessment of outcome at each time point will remain blind to participants’ group allocation. Although it could be argued that the use of self-reported primary outcome measures may itself reduce bias associated with an unblinded assessor, blinded of outcome assessors is still an important component due to the potential for transfer of attitudes regarding an intervention from the assessor to the participant [31]. In this study, blindness of participants and the physiotherapists administering treatment is not possible due to the nature of the interventions used. However, as it has been recommended that greater credence should be placed in results where at least the investigators have been blinded to group allocation [31], the single-blind nature of this study is not deemed to be a methodological flaw. Thirdly, the investigators responsible for statistical analysis will be blind to the treatment group allocation, thereby minimis-
ing the likelihood of bias associated with their anticipated outcomes. Fourthly, the data analysis will proceed on an intention-to-treat basis, which amongst other things, maintains randomisation, conservatively manages inflation of type I error rate and imitates real life in which it is somewhat likely that not all patients will receive the ideal or intended treatment that has been prescribed.

As recommended by the CONSORT group [6], the RCT design has endeavoured to utilise outcome measures that have established reliability and validity and, where possible, have been used previously in PFP participants. This not only enhances the quality of the measurement and outcomes, but also facilitates direct comparisons with other studies that have investigated interventions for PFP and possible meta-analyses in the future. Furthermore, the selection of clinically applicable primary outcome measures that are easily administered in a clinical setting improves the clinical relevance of study findings.

The foot orthoses chosen for use in the RCT are a range of prefabricated devices that are widely used in Australian clinical practice. These orthoses were chosen over a custom moulded device on the basis of clinical time restraints, the higher direct cost of custom moulded orthoses, and findings from a recent meta-analysis of similar benefits for both types of devices in the management of lower limb overuse conditions [32]. In fitting the orthoses, we will adopt an approach based on a key synoptic paper by Nigg et al [33]. On the basis of evidence that does not support the traditional concept that inserts and orthoses are used to align the skeleton, they proposed a new concept for the function and fitting of shoes and shoe inserts. This new concept includes the following: (a) the skeleton has a preferred path for a given movement task; (b) if an intervention (shoe and/or insert) supports this preferred path, muscle activity can be reduced; (c) an optimal shoe and/or insert feels comfortable because it reduces muscle activity and the resulting fatigue; and (d) performance should increase with an optimal shoe and/or insert since muscle activity is minimised and thus energy expenditure is reduced. Therefore, the participants’ perception of comfort will be used as the key guide for the selection and fitting of the appropriate orthoses. Although the orthoses are prefabricated, they do allow for a degree of modification in order to achieve best comfort fit. Once comfort has been achieved, using the steps outlined in Figure 2, if required, the device will be further modified to improve pain-free performance of a pain provocative functional task whilst still being comfortable. This is based on the proposition that the orthoses should minimise the patient’s pain during function [34].

A particular feature of this study is the inclusion of flat inserts as an experimental control. This assumes that the shaped contoured form of the rear and mid-section of a moulded orthosis is its active constituent in controlling foot motion, especially excessive pronation. It is the control of motion that has traditionally been viewed by practitioners, and indeed intuitively by patients, as a major function of orthoses [35-37]. To the extent that the contoured form of an orthosis is conceptualised to be its active constituent, the control flat insert may then be regarded as a placebo. However, it has not been conclusively proven that orthoses do control motion, with some studies indicating no systematic effect on motion [38,39] and others to the contrary [40-42]. An alternative view is that foot orthoses simply serve as space fillers, with their shaped form facilitating full plantar contact [43], which is regarded by some to be clinically beneficial [44,45]. We contend that the inclusion of a flat insert as an experimental control condition is especially important due to the inconsistencies in findings and viewpoints surrounding foot orthoses.

In summary, the RCT to be conducted will utilise high-quality methodologies in accordance with CONSORT guidelines. It is anticipated that findings from this study will contribute to the limited knowledge base regarding the clinical efficacy of foot orthoses in the management of PFP, and provide clinicians with high-quality evidence upon which to base clinical decision making.

**Competing interests**

In the past five years BV has received presenter fees from Vasyli International for the purpose of presenting seminars in the prescription and fitting of orthoses. The involvement in this project by Vasyli International is limited to the donation of the orthoses and inserts. Although BV conceptualised and has obtained funding from the NHMRC for the project and will act as overall co-ordinator of the project, he will be blinded to group allocation and he will not conduct the statistical analyses. As overall co-ordinator he will deal with all adverse events, in which case he will be unblinded for that individual so as to best manage and report the adverse event.

All other authors declare that they have no competing interests.

**Authors’ contributions**

NC and BV were responsible for writing this manuscript. BV is the sole chief investigator on the NHMRC grant #301037, which he conceived and wrote. TM, KC, EB and RD assisted in the study design. All authors have reviewed and approved this final manuscript.

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Vasyli International will donate the orthoses and flat inserts.

Ausmedic and Access Health will supply concessions on the purchase of tape and EMG biofeedback machines, respectively, to be used in the physiotherapy interventions.

References


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Foot orthoses and physiotherapy in the treatment of patellofemoral pain syndrome: randomised clinical trial

Natalie Collins, PhD candidate,1 Kay Crossley, principal research fellow,2 Elaine Beller, director, biostatistics,3 Ross Darnell, statistician,1 Thomas McPoil, regents professor,4 Bill Vicenzino, head of division, physiotherapy1

ABSTRACT
Objective To compare the clinical efficacy of foot orthoses in the management of patellofemoral pain syndrome with flat inserts or physiotherapy, and to investigate the effectiveness of foot orthoses plus physiotherapy.
Design Prospective, single blind, randomised clinical trial.
Setting Single centre trial within a community setting in Brisbane, Australia.
Participants 179 participants (100 women) aged 18 to 40 years, with a clinical diagnosis of patellofemoral pain syndrome of greater than six weeks’ duration, who had no previous treatment with foot orthoses or physiotherapy in the preceding 12 months.
Interventions Six weeks of physiotherapist intervention with off the shelf foot orthoses, flat inserts, multimodal physiotherapy (patellofemoral joint mobilisation, patellar taping, quadriceps muscle retraining, and education), or foot orthoses plus physiotherapy.
Main outcome measures Global improvement, severity of usual and worst pain over the preceding week, anterior knee pain scale, and functional index questionnaire measured at 6, 12, and 52 weeks.
Results Foot orthoses produced improvement beyond that of flat inserts in the short term, notably at six weeks (relative risk reduction 0.66, 99% confidence interval 0.05 to 1.17; NNT 4 (99% confidence interval 2 to 51). No significant differences were found between foot orthoses and physiotherapy, or between physiotherapy and physiotherapy plus orthoses. All groups showed clinically meaningful improvements in primary outcomes over 52 weeks.
Conclusion While foot orthoses are superior to flat inserts according to participants’ overall perception, they are similar to physiotherapy and do not improve outcomes when added to physiotherapy in the short term management of patellofemoral pain. Given the long term improvement observed in all treatment groups, general practitioners may seek to hasten recovery by prescribing prefabricated orthoses.
Trial registration Australian Clinical Trials Registry ACTRN012605000463673 and ClinicalTrials.gov NCT00118521.

INTRODUCTION
Patellofemoral pain syndrome, or idiopathic pain arising from the anterior knee,1 is one of the most common musculoskeletal presentations to general practice2 and sports medicine clinics.3-8 In a retrospective survey of 2002 runners presenting to a sports medicine centre, patellofemoral pain syndrome accounted for 19% of running injuries,9 whereas a two year prospective cohort study reported onset of the syndrome in 9% of 282 students of physical education aged 17-21.10 The pain is characteristically provoked by activities such as squatting, stair walking, and running, and hence impacts on many aspects of daily life, including the ability to perform pain free exercise or work related activities. Patellofemoral pain syndrome can result in repeat visits to a doctor given its tendency towards chronicity, with 94% of patients continuing to experience pain up to four years after initial presentation and 25% reporting significant symptoms up to 20 years later.11

Despite the prevalence, chronicity, and impact of patellofemoral pain syndrome, several systematic reviews of interventions attest to a dearth of high quality research on management.12-17 One study concluded that the available evidence at that time would lead the practitioner to implement a programme of education, stretching, and strengthening of the thigh muscles, and possibly foot orthoses.15 Subsequently a high quality randomised controlled trial found that a multimodal physiotherapy programme for six weeks18 was more effective than sham treatment: relative risk of noticeable improvement 3.39 (95% confidence interval 1.69 to 6.80).19 That study did not, however, compare physiotherapy with the control sham intervention beyond six weeks.

As an alternative or adjunct to physiotherapy, foot orthoses are commonly used to treat active people with patellofemoral pain syndrome. Recently, a systematic review of the clinical efficacy of foot orthoses identified two small clinical trials in people with patellofemoral pain syndrome.20 These studies suggest that foot orthoses may be of benefit.21,22 No high quality randomised controlled trials have evaluated the use of foot orthoses for treating patellofemoral pain syndrome.
syndrome in the short or long term. Evidence to guide the use of foot orthoses for this common clinical condition is imperative considering the widespread use of foot orthoses and the lack of consensus and controversy surrounding their prescription.²³²⁴

We evaluated the short and long term clinical efficacy of prefabricated foot orthoses in the treatment of patellofemoral pain syndrome compared with flat inserts or physiotherapy alone, and evaluated whether orthoses improved the effects of physiotherapy. We hypothesised that foot orthoses would be superior to flat inserts and equivalent to physiotherapy and that the combination of foot orthoses and physiotherapy would be superior to physiotherapy alone.

**METHODS**

We carried out a pragmatic, single blind, randomised clinical trial in a community setting for 12 months. The methods have been described in detail previously.²⁵

Volunteers from the greater Brisbane, Gold Coast, and Toowoomba regions of Queensland, Australia responded to advertisements in print media, radio and television media releases, noticeboards, and referrals from practitioners. Eligibility criteria were based on a previous clinical trial:19 age 18-40 years; insidious onset of anterior knee or retropatellar pain of greater than six weeks’ duration and provoked by at least two of prolonged sitting or kneeling, squatting, running, hopping, or stair walking; tenderness on palpation of the patella, or pain with step down or double leg squat; and worst pain over the previous week of at least 30 mm on a 100 mm visual analogue scale. Exclusion criteria were concomitant injury or pain from the hip, lumbar spine, or other knee structures; previous knee surgery; patellofemoral instability; knee joint effusion; any foot condition that precluded use of foot orthoses; allergy to strapping tape; use of physiotherapy or foot orthoses within the previous year; or use of anti-inflammatory drugs.

**Protocol**

To facilitate concealment of allocation, a blinded assessor not involved in the randomisation process determined eligibility. The randomisation sequence was drawn up and kept off site by an independent body, using a random number generator in blocks of eight with no stratification. Participants gave written informed consent and, after we had obtained baseline measures, were randomly assigned to receive one of four treatments: foot orthoses, flat inserts, physiotherapy, or foot orthoses plus physiotherapy. A research assistant communicated with the randomisation centre, participants, and project physiotherapists throughout the trial, thus ensuring that the assessor responsible for outcome measurement and data analysis remained blind to group allocation.

**Interventions**

Interventions were administered by one of 17 registered physiotherapists who underwent training for each treatment protocol. Participants attended six appointments of 20-60 minutes’ duration over six weeks, after which they were encouraged to continue with a self management programme.

The intervention programmes have been detailed previously.²⁵ In brief, participants assigned to foot orthoses received prefabricated, commercially available orthoses (Vasyli International), which were fitted previously. Participants assigned to flat inserts, manufactured from the same material (ethylenevinyl acetate) with identical covering fabric, were able orthoses (Vasyli International), which were fitted previously. Participants assigned to physiotherapy, or foot orthoses plus physiotherapy. A research assistant communicated with the randomisation centre, participants, and project physiotherapists throughout the trial, thus ensuring that the assessor responsible for outcome measurement and data analysis remained blind to group allocation.

**Follow-up**

The intervention programmes have been detailed previously. In brief, participants assigned to foot orthoses received prefabricated, commercially available orthoses (Vasyli International), which were fitted to their shoes with comfort as a primary goal. These orthoses are customisable to some degree to optimise comfort through heat moulding and by adding wedge or heel raises. As a control for these orthoses we used flat inserts, manufactured from the same material (ethylenevinyl acetate) with identical covering fabric. These were of uniform thickness, with no inbuilt arch or wedging. Physiotherapy consisted of a combined
therapy approach that has proved efficacious in patellofemoral pain syndrome and included patellar mobilisation, patellar taping, a progressive programme of vasti muscle retraining exercises with electromyographic biofeedback, hamstring and anterior hip stretches, hip external rotator retraining, and a home exercise programme. Participants assigned to orthoses plus physiotherapy received both interventions as described and had an extra appointment with the physiotherapist if more time was required for adequate delivery of all treatment components.

The participants were encouraged to continue exercise and activities that did not provoke their pain. The use of non-study interventions was discouraged throughout the trial, although over the counter drugs were permitted. Any cointerventions used for symptoms of patellofemoral pain syndrome, as well as any adverse effects arising from intervention, were recorded in diaries, reported to the research assistant, or detailed in an exit questionnaire.

Outcomes
The blinded assessor carried out reliable and valid outcome measures before randomisation (baseline) and at 6, 12, and 52 weeks after randomisation. The primary outcome measures were global improvement, severity of usual and worst pain over the preceding week, the anterior knee pain scale, and the functional index questionnaire. We measured global improvement on a five point Likert scale (“marked improvement” to “marked worsening”) and visual analogue scale (0 = worst pain imaginable, 100 = no pain). We reduced categorical data to success equating marked or moderate improvement.

Sample size
We based the sample size calculations on a clinically meaningful improvement of 15 mm on a 100 mm pain visual analogue scale for usual pain. Assuming a standard deviation of 20 mm, a power of 0.80, and an α level of 0.01, we required 40 participants in each group. We increased the sample size by 10%, to 176 (44 in each group), to allow for loss to follow-up.

Statistical analysis
Statistical analysis was done on a blinded, intention to treat basis using SPSS software (version 15.0). We chose the primary end points of 6, 12, and 52 weeks, as six weeks (immediately after the treatment period) could be considered to be the time of greatest effect, 12 weeks is a standard follow-up time in studies of patellofemoral pain syndrome, and the long term (52 weeks) efficacy of foot orthoses or this specific physiotherapy programme has not been investigated. The dichotomous measure of success was expressed as relative risk reduction and numbers needed to treat.

RESULTS
From May 2004 to May 2006, 1530 volunteers were screened and 179 enrolled in the study (fig 1). The trial was completed in June 2007, with 164 participants (92%) followed up at six weeks, 161 (90%) at 12 weeks, and 171 (96%) at 52 weeks. With the exception of duration, all groups were well matched at baseline (table 1). Including baseline data as covariates did not significantly influence outcomes.

Significant effects favoured foot orthoses over flat inserts at six weeks, with differences of 19.8 mm (99%
Table 2 | Absolute event rates of success of global effect and comparisons between groups for dichotomous measure of success expressed as relative risk reductions and numbers needed to treat (NNT)

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>No (%) moderately or markedly improved*</th>
<th>Between group differences (99% CI)†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Foot orthoses</td>
<td>Flat inserts</td>
</tr>
<tr>
<td>6 weeks</td>
<td>35/41 (85)</td>
<td>23/40 (58)</td>
</tr>
<tr>
<td>12 weeks</td>
<td>34/42 (81)</td>
<td>30/38 (79)</td>
</tr>
<tr>
<td>52 weeks</td>
<td>38/45 (84)</td>
<td>30/41 (73)</td>
</tr>
</tbody>
</table>

*Participants rated improvement on five point Likert scale of global effect.
†Positive point estimate favours first listed condition.
‡Significant at P<0.01.

confidence interval 4.0 to 35.6) on the continuous scale of global improvement, a number needed to treat of 4 (2 to 51) on the categorical scale (success equating marked and moderate improvement), and success rates of 85% (35/41) for foot orthoses and 58% (23/40) for flat inserts (fig 2, tables 2 and 3). These trends were mirrored when the categorical data on global improvement were collapsed to success equating marked improvement at six and 12 weeks. At six and 12 weeks no significant differences were found in global improvement between physiotherapy and foot orthoses, or between physiotherapy and combined physiotherapy and orthoses (tables 2 and 3). For each of the three a priori pairwise comparisons no significant differences were found between the groups on other outcome measures (table 3).

Over 52 weeks all groups had clinically meaningful improvements in worst pain severity (>20 mm on pain visual analogue scale), anterior knee pain scale (>10 points), and functional index questionnaire (>2 points; tables 1 and 3).26 Three of the four groups (foot orthoses, physiotherapy, foot orthoses plus physiotherapy) also had clinically meaningful improvements in usual pain severity, whereas the improvement in usual pain for the group receiving flat inserts was slightly less than 20 mm. No significant differences were found between groups on any primary measure at 52 weeks.

Coinerventions

Table 4 outlines the participants’ use of coinerventions. No significant differences were found in reported rates of use between foot orthoses and flat inserts (14/40, 35% v 15/39, 38%; relative risk reduction 0.09, 99% confidence interval –0.6 to 0.76), physiotherapy and foot orthoses [16/43, 37% v 14/40, 36%; –0.06, –0.78 to 0.68], or foot orthoses plus physiotherapy and physiotherapy alone [9/40, 23% v 16/43, 37%; 0.4, –0.3 to 1.01]. Two participants assigned to flat inserts crossed over to foot orthoses after 12 weeks.

Side effects

A greater proportion of participants reported mild side effects with the foot orthoses (foot orthoses 31/43, 72%; foot orthoses plus physiotherapy 20/41, 49%) than with the flat inserts (15/39, 38%; relative risk reduction –0.58, 99% confidence interval –1.01 to –0.09). These consisted of rubbing and blistering, discomfort, and pain in the toes, feet, and ankles, which on the whole responded to increasing wear and minor adjustments to the orthoses (for example, heat moulding and additions) and did not prevent wearing of the orthoses or inserts. Thirty four participants (physiotherapy 18/44, 41%; foot orthoses plus physiotherapy 16/41, 39%; relative risk reduction 0.05, –0.59 to 0.67) reported a reaction to daily patellar taping (for example, skin irritation, blistering). Two participants (physiotherapy group and foot orthoses group) experienced low back pain that required additional physiotherapy.

DISCUSSION

Foot orthoses produced short term improvements beyond that of flat inserts, with the number needed to treat indicating that four patients would need to be treated with orthoses to have one additional patient experience improvement in patellofemoral pain. Foot

Fig 2 | Percentage of participants rating perceived improvement across categories from marked improvement to marked worsening
orthoses were similar in effect to physiotherapy, and combining foot orthoses with physiotherapy did not provide additional improvement beyond physiotherapy alone. In the long term, clinically meaningful improvements occurred in pain and function for all interventions but no differences were found between interventions. The overall pattern of effect implies that foot orthoses and physiotherapy each hasten resolution of the condition, which is an important benefit for a common, chronic condition.

Treatment costs are a further consideration for practitioners and their patients. Assuming recommended retail pricing, in addition to consultation fees (usually between two to four consultations), the orthoses (three pairs, including additions) would cost $A174 (£79; €110) compared with $A45 for three flat inserts. This would seem to be a reasonable alternative to physiotherapy (six sessions at around $A495, including tape). A cost benefit analysis is required to investigate this further.

The interventions used in this trial, including the flat inserts, produced only mild side effects in the early phase of treatment. Despite the orthoses having relatively more minor side effects than the flat inserts, they showed a greater improvement in the first six weeks, suggesting that these side effects did not adversely influence treatment outcomes. About 40% of participants who received the physiotherapy intervention (with or without foot orthoses) experienced skin reactions with daily taping of the patella, despite exclusion of participants with known allergies to tape. It is difficult to know whether this is abnormally high due to inadequate reporting in previous trials, but should be considered in clinical application.

The prescription of foot orthoses for musculoskeletal pain is characterised by a lack of evidence from high quality clinical trials.15 20 Our study provided level II evidence for the use of foot orthoses in patellofemoral pain syndrome. Our data corroborate findings from a smaller study of 20 adolescent females aged 13 to 17, which found statistically significant improvements in pain during gait, sitting, and squatting after eight weeks of treatment.21 The authors did not supply point estimates of effect. Furthermore, the magnitude of the effect of physiotherapy that we observed on primary outcome measures at six weeks was comparable with that of another study.19

Some authors contend that the contoured form of foot orthoses is critical for controlling foot motion, usually excessive pronation.34-36 This exists despite three key issues, all of which impinge on the conduct of a randomised controlled trial. Firstly, research shows generally equivocal and non-systematic effects of the ability of foot orthoses to control motion.37-39 Secondly, alternative means may be available by which foot orthoses exert clinical effects, such as by serving as space fillers to facilitate full plantar contact,40 which some regard to be clinically beneficial.41 42 Thirdly, previous research has failed to show that people with patellofemoral pain syndrome have excessive foot

### Table 3

Mean (SD) scores and mean difference (99% confidence intervals) between groups for continuous primary outcome measures at 6, 12, and 52 weeks (adjusted for baseline), according to intervention for patellofemoral pain syndrome

<table>
<thead>
<tr>
<th>Variables</th>
<th>Foot orthoses</th>
<th>Flat inserts</th>
<th>Physiotherapy</th>
<th>Foot orthoses plus physiotherapy</th>
<th>Foot orthoses v flat inserts</th>
<th>Physiotherapy v foot orthoses</th>
<th>Foot orthoses plus physiotherapy v physiotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Global improvement (–100–100)</strong>:</td>
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<tr>
<td>6 weeks †</td>
<td>37.6 (27.2)</td>
<td>17.8 (27.2)</td>
<td>45.6 (27.2)</td>
<td>48.7 (27.2)</td>
<td>19.8 (4.0 to 35.6)</td>
<td>7.8 (–7.8 to 23.5)</td>
<td>3.2 (–12.3 to 18.8)</td>
</tr>
<tr>
<td>12 weeks</td>
<td>46.7 (32.8)</td>
<td>30.6 (32.8)</td>
<td>53.4 (32.8)</td>
<td>61.8 (32.8)</td>
<td>16.1 (–3.0 to 35.3)</td>
<td>6.7 (–12.1 to 25.5)</td>
<td>4.6 (–10.7 to 27.4)</td>
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<tr>
<td>52 weeks</td>
<td>52.3 (39.8)</td>
<td>49.9 (39.8)</td>
<td>54.7 (39.8)</td>
<td>55.2 (39.8)</td>
<td>2.4 (–20.0 to 24.8)</td>
<td>2.4 (–19.9 to 24.7)</td>
<td>0.5 (–22.0 to 23.0)</td>
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<tr>
<td><strong>Usual pain (0–100 mm)</strong>:</td>
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<tr>
<td>6 weeks †</td>
<td>25.4 (17.4)</td>
<td>33.4 (17.5)</td>
<td>21.2 (17.3)</td>
<td>19.4 (17.4)</td>
<td>–8 (–18.1 to 2.1)</td>
<td>–4.2 (–14.2 to 5.8)</td>
<td>–1.8 (–11.8 to 8.2)</td>
</tr>
<tr>
<td>12 weeks</td>
<td>22.1 (17.8)</td>
<td>24.5 (18.1)</td>
<td>20.1 (17.8)</td>
<td>16.4 (17.9)</td>
<td>–2.4 (–12.9 to 8.1)</td>
<td>–2 (–12.2 to 8.2)</td>
<td>–3.7 (–14.1 to 6.6)</td>
</tr>
<tr>
<td>52 weeks</td>
<td>16.2 (18.5)</td>
<td>17.9 (18.6)</td>
<td>13.9 (18.5)</td>
<td>14.4 (18.6)</td>
<td>–1.7 (–12.2 to 8.8)</td>
<td>–2.2 (–12.6 to 8.1)</td>
<td>0.4 (–10.1 to 10.9)</td>
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<tr>
<td><strong>Worst pain (0–100 mm)</strong>:</td>
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<tr>
<td>6 weeks †</td>
<td>39.8 (21.7)</td>
<td>48.2 (21.8)</td>
<td>32.2 (21.6)</td>
<td>28.5 (21.9)</td>
<td>–8.1 (–20.7 to 4.4)</td>
<td>–7.7 (–20.2 to 4.8)</td>
<td>–3.6 (–16.0 to 8.8)</td>
</tr>
<tr>
<td>12 weeks</td>
<td>33.3 (22.2)</td>
<td>35.2 (22.4)</td>
<td>26.8 (22.2)</td>
<td>26.5 (22.3)</td>
<td>–1.7 (–14.7 to 11.3)</td>
<td>–6.5 (–19.2 to 6.2)</td>
<td>–0.2 (–13.1 to 12.7)</td>
</tr>
<tr>
<td>52 weeks</td>
<td>27.6 (23.7)</td>
<td>26.1 (23.9)</td>
<td>22.2 (23.7)</td>
<td>18.8 (23.9)</td>
<td>1.5 (–11.9 to 15.0)</td>
<td>–5.5 (–18.8 to 7.9)</td>
<td>–3.3 (–16.8 to 10.1)</td>
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<tr>
<td><strong>Anterior knee pain scale (0–100)</strong>:</td>
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<tr>
<td>6 weeks †</td>
<td>79.7 (9.1)</td>
<td>74.8 (9.1)</td>
<td>83.4 (9.1)</td>
<td>83.6 (9.1)</td>
<td>4.9 (–0.4 to 10.2)</td>
<td>3.7 (–1.6 to 9.0)</td>
<td>0.2 (–5.0 to 5.5)</td>
</tr>
<tr>
<td>12 weeks</td>
<td>81.8 (9.9)</td>
<td>80.9 (9.9)</td>
<td>84.9 (9.9)</td>
<td>86.7 (9.9)</td>
<td>0.9 (&lt;4.9 to 6.6)</td>
<td>3.1 (&lt;2.5 to 8.8)</td>
<td>1.8 (&lt;4.0 to 7.5)</td>
</tr>
<tr>
<td>52 weeks</td>
<td>85.5 (8.7)</td>
<td>86.9 (9.7)</td>
<td>87.9 (9.7)</td>
<td>91.5 (9.7)</td>
<td>–1.5 (&lt;7.3 to 4.4)</td>
<td>2.5 (&lt;3.3 to 8.2)</td>
<td>3.6 (&lt;2.5 to 9.7)</td>
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<td><strong>Functional index questionnaire (0–16)</strong>:</td>
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<tr>
<td>6 weeks †</td>
<td>11.8 (2.3)</td>
<td>11.1 (2.3)</td>
<td>12.9 (2.3)</td>
<td>13.3 (2.3)</td>
<td>0.7 (&lt;0.6 to 2.0)</td>
<td>1.0 (&lt;0.3 to 2.3)</td>
<td>0.5 (&lt;0.8 to 1.8)</td>
</tr>
<tr>
<td>12 weeks</td>
<td>12.3 (2.3)</td>
<td>12.0 (2.3)</td>
<td>13.3 (2.3)</td>
<td>13.9 (2.3)</td>
<td>0.2 (&lt;1.1 to 1.6)</td>
<td>1.0 (&lt;0.3 to 2.4)</td>
<td>0.6 (&lt;0.8 to 1.9)</td>
</tr>
<tr>
<td>52 weeks</td>
<td>13.0 (2.6)</td>
<td>13.4 (2.6)</td>
<td>14.2 (2.6)</td>
<td>13.8 (2.6)</td>
<td>–0.5 (&lt;1.9 to 1.0)</td>
<td>1.3 (&lt;0.2 to 2.7)</td>
<td>–0.5 (&lt;1.9 to 1.0)</td>
</tr>
</tbody>
</table>

*Positive score favours reference group (first group listed in comparison).
†Significant at P=0.01.
‡Negative score favours reference group.
pronation compared with controls. On the basis of these issues, we included in our randomised controlled trial a flat shoe insert to evaluate the clinical efficacy of the contoured form of foot orthoses. Our findings of a clinically beneficial effect in favour of the contoured orthoses provides a solid foundation on which to consider the mechanisms of action of foot orthoses and plan future research.

Point estimates of effect between foot orthoses and flat inserts were detected by using measures of global improvement, but not by using measures of pain or physical function, even though these measures were sensitive to change over time within each group. This reflects the moderate correlations between global improvement rating scales and these measures of pain and function reported by researchers in their evaluation of outcome measures used in their randomised controlled trial. They recommended that clinical trials of patellofemoral pain syndrome incorporate a measure of perceived global response to treatment, largely on the basis that this scale feasibly encompasses many dimensions of patellofemoral pain syndrome that are meaningful to the patient (for example, pain, function, disability, participation, psychosocial factors). It is likely that a rating of global improvement captures more comprehensively the patient experience, a notion that requires further improvement that captures more comprehensively the psychosocial factors. It is likely that a rating of global improvement, but not by using measures of pain or physical function, even though these measures were sensitive to change over time within each group. This reflects the moderate correlations between global improvement rating scales and these measures of pain and function reported by researchers in their evaluation of outcome measures used in their randomised controlled trial. They recommended that clinical trials of patellofemoral pain syndrome incorporate a measure of perceived global response to treatment, largely on the basis that this scale feasibly encompasses many dimensions of patellofemoral pain syndrome that are meaningful to the patient (for example, pain, function, disability, participation, psychosocial factors). It is likely that a rating of global improvement captures more comprehensively the patient experience, a notion that requires further improvement that captures more comprehensively the psychosocial factors.

### Strengths and limitations

The prescription of foot orthoses for musculoskeletal pain is characterised by a lack of solid evidence from quality clinical trials. We studied the long term efficacy of foot orthoses in the management of patellofemoral pain syndrome. This is a clinically important issue as the condition is highly prevalent and foot orthoses are prescribed worldwide. We incorporated the recommendations from the consolidated standards of reporting trials into the methodological design, which further strengthens the validity of findings. Importantly, the attrition rate was low, with 8% of primary outcome data missing at six weeks, 10% at 12 weeks, and 4% at 52 weeks.

Unlike other clinical trials, we did not select those treated with foot orthoses on the basis of foot posture (for example, excessive pronation), largely because no valid method currently exists to identify a priori those who may benefit from foot orthoses. It is possible that participants fitted with orthoses in our trial were (randomly) heterogeneous for foot posture, yet we still found small but beneficial effects of prescribing foot orthoses compared with flat inserts. Conceivably, if the classification of patients becomes possible, then the point estimates of effect we report are likely to be an underestimate.

The characteristics of the participants in our trial were similar to those reported by others for age, height, sex, proportion with bilateral patellofemoral pain syndrome, duration of condition, severity of pain, anterior knee pain scale, and functional index questionnaire. Feasibly this represents the broader population of patients with patellofemoral pain syndrome who visit general medical practices and strengthens the external validity of the findings of our study. Further reinforcing the external validity of our findings we used physiotherapists from primary care practices in the community, and with only a short duration of training in the protocol (about 1.5 days) they were able to successfully implement an effective foot orthosis intervention, which had a similar effect to the multimodal physiotherapy programme.

A limitation of this study is the number of comparisons between groups. Although we used 99% confidence limit to assist in control of type I errors, it is possible that the significant finding between foot orthoses and flat inserts was due to chance. Notwithstanding this, a number needed to treat of 4 could be regarded as a clinically meaningful effect and in part counters the possibility of a type I error in the comparison of orthoses with flat inserts at six weeks.

A further limitation was that we did not include a control group for clinical course so we cannot...
WHAT IS ALREADY KNOWN ON THIS TOPIC

Patellofemoral pain syndrome is highly prevalent in sports medicine and presents often to general practices.

Foot orthoses are often prescribed despite a lack of evidence highlighted by systematic reviews.

WHAT THIS STUDY ADDS

Foot orthoses produce earlier and larger improvements in patellofemoral pain syndrome than flat inserts.

Adding foot orthoses to physiotherapy does not improve physiotherapy outcomes decisively conclude that foot orthoses or physiotherapy were better than no treatment over 52 weeks. Nevertheless, a case may be made for intervening with foot orthoses or physiotherapy as over 80% of participants in our study were improved at 52 weeks, compared with 50% of participants followed up at four years in a prospective long term study of the clinical course of patellofemoral pain syndrome.11

Conclusions

Prefabricated foot orthoses are superior to flat inserts in the short term management of patellofemoral pain syndrome, implying that their contoured shape is therapeutic. We found no differences between the effects of foot orthoses and physiotherapy, nor was there any benefit of adding foot orthoses to physiotherapy. Considering that all treatment groups showed clinically meaningful long term improvements, general practitioners may seek to hasten recovery by prescribing foot orthoses.

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Contributors: NC recruited and screened the participants, carried out the baseline and follow-up outcome measures and data entry and analysis, and prepared the manuscript. KC was involved in the methodological design and preparation of the manuscript. EB assisted in the trial design and carried out the randomisation procedures. RD advised on the statistical design of the trial and data analysis and interpretation. TM was involved in the National Health and Medical Research Council grant application and trial design and reviewed the manuscript. BV, in his capacity as sole chief investigator on the National Health and Medical Research Council grant, supervised the conduct of the trial, the suitability of included participants, data analysis, and preparation of the manuscript, and is guarantor.

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Patellofemoral pain syndrome

Usually resolves over time, and intervention offers only limited benefit

Patellofemoral pain syndrome is defined as pain behind or around the patella caused by stress in the patellofemoral joint. Symptoms are usually provoked by climbing stairs, squatting, and sitting with flexed knees for long periods of time. It is a common presentation in general practice and can have a big effect on patients’ ability to work. Physiotherapy and foot orthoses available without prescription are often used in the management of patellofemoral pain syndrome. In the linked randomised controlled trial (doi:10.1136/bmj.a1735), Collins and colleagues assess the effectiveness of foot orthoses, flat insoles, multimodal physiotherapy (patellofemoral joint mobilisation, patellar taping, quadriceps muscle retraining, and education), or a combination of foot orthoses and physiotherapy in people with this syndrome.

The rationale for treatment is to correct unbalanced tracking of the patella. Knee braces, knee taping, knee sleeves, and knee straps all aim to alter the patella’s tracking pattern. Some studies have shown that these strategies improve knee symptoms, although others show no significant difference compared with physiotherapy. The most commonly recommended treatment is strengthening of the quadriceps along with avoidance of painful activities. Straight leg raises are recommended to isometrically strengthen the quadriceps. One cohort study found that increasing hip muscle strength and flexibility has also been successful. In this cohort study, after six weeks of hip exercises, improvement of hip muscle function was associated with good results in patellofemoral pain syndrome.

In patients with a flat foot deformity, the foot is pronated causing a compensatory internal rotation of the lower extremity that can disturb the patellofemoral mechanism. In this situation custom made foot orthoses are used to support the medial arch and restore normal leg alignment. Foot orthoses, in addition to an exercise programme, can be effective for people with patellofemoral pain syndrome. On the other hand, a recent randomised trial showed no difference in outcome between eight weeks of treatment with functional foot orthoses, exercises, or orthoses combined with exercises. Follow-up beyond eight weeks was not available in either of these studies, which limits their value, because patellofemoral pain syndrome tends to become a chronic problem.

The linked study by Collins and colleagues randomised 179 patients with patellofemoral pain syndrome to four interventions of six weeks’ duration. The flat insole group can be regarded as a control for the foot orthoses. Global improvement, severity of usual and worst pain over the preceding week, the anterior knee pain scale, and the functional index questionnaire were measured at six, 12, and 52 weeks. Foot orthoses significantly improved outcomes at six weeks compared with flat inserts (relative risk 0.66, 99% confidence interval 0.05 to 1.17; number needed to treat 4, 2 to 51). At six weeks patients using foot orthoses or those who performed a supervised exercise programme showed significant improvement compared with those using flat insoles. This study confirms the good results seen for exercise and foot orthoses in the short term. At one year follow-up, all groups, including the one using flat insoles, showed a clinically meaningful improvement.

A systematic review found that exercise programmes consisting of either closed chain exercises (where the foot is in contact with a surface) or open chain exercises (where the foot is not in contact with a surface) are equally effective. So far, the role of foot orthoses has not been clear. A recent systematic review found no evidence to support the use of any
orthotic devices in the treatment of patellofemoral pain syndrome.\textsuperscript{4} Collins and colleagues' study suggests that foot orthoses can be useful in the short term. They may even be cost effective compared with physiotherapy.

The study also found that all groups, including the placebo group (flat insoles) made a clinically relevant improvement over time. This probably reflects the benign natural history of this syndrome, and raises the question of whether we should interfere at all. High quality randomised controlled trials are needed to answer this question. These should compare the results of knee orthoses, foot orthoses, physiotherapy, and patients without treatment; follow-up should be for at least a year. The limited evidence for the effectiveness of orthotic devices for patellofemoral pain syndrome along with the current results should encourage future researchers to use a control group not receiving any treatment.

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\textbf{References}


Relevant Article

Foot orthoses and physiotherapy in the treatment of patellofemoral pain syndrome: randomised clinical trial
Natalie Collins, Kay Crossley, Elaine Beller, Ross Darnell, Thomas McPoil, and Bill Vicenzino
BMJ 2008 337: a1735. [Abstract] [Full Text] [PDF]
Rapid Responses published:

**Patellofemoral Pain Syndrome: Important Considerations**
Bill Vicenzino, Natalie Collins, Kay Crossley, Thomas McPoil  (31 October 2008)

Professors van Dijk and van der Tempel[1] have written a good overview of the topic area, our clinical trial[2] and the need for future work to incorporate a no-treatment control group. We would like to comment on a few of the points they raise in their editorial.

1. The relationship between flat foot deformity and patellofemoral pain syndrome is a widely held clinical notion/observation that is not strongly supported by research (e.g., [3,4]). As such, we were careful not to endorse this association in our write-up, and encourage readers to exercise care when taking this point on board. Aside from there being little concrete evidence of the link between flat feet and patellofemoral pain syndrome, there is also the issue of a lack of consistent and solid evidence underpinning the notion that orthoses support the arch and control excessive pronation (flat feet) and thus alignment of the lower limb and patella. Our clinical trial shows that foot orthoses with inbuilt arch support and inversion (supination/varus) wedging/posting are superior to flat shoe inserts made of the same material. We feel that this provides evidence that there is some therapeutic property in the shape and contouring of the orthoses. This requires further evaluation, so that the
therapeutic characteristics and underlying mechanisms of action of foot orthoses become more evidence-based.

2. We have recently published a follow up study that may provide some support for the notion that the orthoses are likely to be more effective in specific individuals[5]. In this study we detail a clinical prediction rule in which 3 of the following 4 patient characteristics can be used to improve the likelihood of marked improvement at 12 weeks from 40% to 85%: (i) age > 25 years, (ii) height < 165cm, (iii) pain severity < 53mm on 100 mm VAS, and (iv) mid-foot width difference from non weight bearing to weight bearing > 11mm. The mid-foot width difference of > 11mm, which can be easily measured with a vernier caliper[6], identifies those who have greater mobility of the foot when it is loaded in weight bearing, which is a component of excessive foot pronation. This may provide some support to the notion enunciated in 1 above.

3. The need for future studies to include a group which follows a ‘wait and see policy’, as in previous randomised clinical trials (RCTs) of musculoskeletal pain[7,8], is a valid point and one we support in principle. Enacting such arms of RCTs is often perceived to be an impediment to recruitment and gaining ethical approval, and may compromise the trial’s successful completion. Notwithstanding this, it is important to understand that the natural history of many musculoskeletal pain states (or time course of resolution of acute bouts of pain) are largely not described and so it is difficult to know if some minimal attempt at intervention (e.g. flat insert) is better than just waiting for resolution. If we assume that flat inserts provide some placebo effect, beyond natural resolution in the short term, then the use of foot orthoses is likely to speed up resolution beyond that of natural recovery. Many of our patients present to clinics with patellofemoral pain that has not resolved, often after a period of waiting and seeing, and for which they are seeking a speedy resolution of their pain and subsequent return to pain-free function. In this regard, the findings of this study, and previous studies that show physiotherapy to be more effective than placebo in the short term, provides solid direction to both the patient and practitioner in their quest to return as soon as possible to pain-free participation.
in life.

4. The editorial makes two pertinent statements, that patellofemoral pain “usually resolves over time” and “tends to become a chronic problem”. The literature tends to support the latter of these rather than the former. A prospective longitudinal study found that 94% of 63 adolescent females had ongoing pain two to four years after initial presentation, while one in four had significant symptoms up to 20 years later[9]. Cross-sectional studies report mean patellofemoral pain durations of 43 months (range 6 to 108) [10] and 8 years (range 1 to 25). The median duration of knee pain of our RCT cohort reflected this chronic tendency (28 months (interquartile range 12 to 84))[2]. Our finding that individuals with patellofemoral pain have considerable symptom duration suggests that the condition does not spontaneously resolve

5. There are a few minor points that we feel should be further clarified for the reader:

(a) The study by Wiener-Ogilvie & Jones [11] was a pilot trial that was substantially underpowered to detect any between-group differences. Hence, to summarise their data as evidence of no effect is problematic as there is a high likelihood of a type II error (that is, accepting that there is no effect when in truth/fact there is an effect).

(b) The editorial makes a summarising statement that our trial confirms the good results of exercises and orthoses in the short term and cites Crossley et al[12], presumably in support of that statement. It is erroneous to do such, as Crossley and colleagues evaluated a multi-modal physiotherapy treatment that included exercise and tape, but not foot orthoses. Our study was the first adequately powered, high quality RCT to provide point estimates of effect that favoured orthoses over flat inserts in the short term.

(c) We note a reference to orthoses being used without prescription in the opening paragraph that may be misinterpreted by the reader as to mean that the orthoses used were applied by a lay person, possibly bought across the counter of a retail outlet. This would be misleading as we used qualified
physiotherapists who received additional training to fit and modify the orthoses following a predetermined algorithm (see [13,14] for more information). In brief, the orthoses were prescribed on the basis of fit and comfort in the first instance and then modified to improve pain-free performance of a previously painful task. We propose that fitting of orthoses in this way is likely best performed by a physiotherapist, podiatrist or athletic trainer, but medical practitioners with a predilection to using physical therapies should also be able to effectively fit orthoses.

(d) The authors cite a recent systematic review that they state found no evidence to support the use of any orthotic devices in patellofemoral pain[15]. This conclusion is misleading, as all five included studies evaluated knee orthotic devices, not foot orthoses. We performed a systematic review and meta-analysis[16] of more recent publications, which identified two small RCTs for foot orthoses in patellofemoral pain, one of which was underpowered to detect between-group differences [11]. Although the other study did not provide point estimates of effect for calculation of effect sizes, the authors reported a significantly greater reduction in patellofemoral pain in those treated with foot orthoses than the group that received flat inserts [17]. This study was not included in the review by D'Hondt et al[15] due to a lack of statistical data.

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