Comfort and midfoot mobility rather than orthosis hardness or contouring influence their immediate effects on lower limb function in patients with anterior knee pain

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Abstract

Background: Despite evidence for use of foot orthoses in the treatment of anterior knee pain, there is a paucity of research into their mechanisms of action. This study (i) determined the immediate lower limb kinematics and muscle activity adaptations, and (ii) evaluated the effect of individual’s comfort and foot mobility.

Methods: Forty individuals diagnosed with anterior knee pain were measured for lower limb kinematics and electromyographic activity (via surface electrodes) while they jogged in three prefabricated contoured orthoses (hard, medium and soft) and a soft-flat orthosis. Subjects ranked orthoses in order of comfort.

Findings: Soft orthoses were more comfortable. No immediate adaptations in kinematics and electromyographic activity were observed when orthoses were added to shoes. There were few effects of perceived comfort and foot mobility, one being a significant interaction in frontal plane hip motion (Pillai’s V = 0.089, P = 0.031) with the least comfortable orthosis producing the greatest relative adduction in those with mobile feet (0.54° (standard deviation 0.87°)). Other main effects were a significant increase in vastus lateralis activity when wearing the least comfortable orthosis (6.94%, P = 0.007) and a delay in offset of medial gastrocnemius in individuals with less mobile feet (1.51%, P = 0.045).

Interpretation: It is becoming apparent that it is important to use more comfortable foot orthoses in a condition like anterior knee pain, where there is an associated increased hip adduction and vastus lateralis activity with least comfortable orthoses. Future research is needed to determine adaptations after ongoing wearing of orthoses.

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value to the soft orthosis but was of uniform thickness (3 mm)
(Supplemental data 1): hard (Shore A 75°); medium (Shore A 60°)
tween the orthoses.

lower limb surgery (Collins et al., 2008; Crossley et al., 2002). Forty
(4) knee effusion; (5) any foot conditions that would preclude the
or indications of patella tendinopathy; (3) chronic patella instability
the hip, pelvis or lumbar spine; (2) damage to any knee structures
running, hopping, hill or stair walking, prolonged sitting or kneeling,
than 6 weeks; (3) aggravated by at least 2 of the following activities:
patellar knee pain of a non-traumatic origin with a duration of longer
websites and upon screening had to meet the following criteria to
trial through local advertisement on notice boards, newsletters and

2. Methods

We addressed the aims of the study by measuring the immediate
effects of a range of orthoses on changes in EMG and kinematics of the
lower limb in patients with AKP, with follow up analyses of the im-
mediate influence of comfort perception and foot mobility.

2.1. Participants

Participants were recruited for a randomised controlled clinical
trial through local advertisement on notice boards, newsletters and
websites and upon screening had to meet the following criteria to
be included in the study: (1) age 18 to 40 years; (2) anterior or retro-
patellar knee pain of a non-traumatic origin with a duration of longer
than 6 weeks; (3) aggravated by at least 2 of the following activities:
running, hopping, hill or stair walking, prolonged sitting or kneeling,
or squatting; and (4) pain on palpation of the patellar facet or double
leg squat. Exclusion criteria were (1) concomitant pain or injury in the
hip, pelvis or lumbar spine; (2) damage to any knee structures or indications of patella tendinopathy; (3) chronic patella instability
(4) knee effusion; (5) any foot conditions that would preclude the
use of orthoses; (6) the use of physiotherapy treatment for knee pain or foot orthoses in the previous 3 years; or (7) any previous
lower limb surgery (Collins et al., 2008; Crossley et al., 2002). Forty
people met these criteria and were recruited for the study (Table 1).
The study was approved by the Medical Research Ethics Committee
of the University of Queensland. Prior to enrolment, subjects were
familiarised with the protocol and written informed consent was
obtained.

2.2. Orthoses

All participants were fitted with prefabricated orthoses con-
structed of ethylene-vinyl acetate (EVA) with fabric covering (Vasyli
International, Labrador). Three orthoses exhibited the same contour-
ing (manufacturer’s specification) but were of different hardness
(Supplemental data 1): hard (Shore A 75°); medium (Shore A 60°)
and; soft (Shore A 52°). A fourth orthosis featured identical Shore A
value to the soft orthosis but was of uniform thickness (3 mm)
along its length (i.e. flat). Subjects were blinded to the difference be-
cen between the orthoses.

2.3. Electromyography

We measured EMG activity from 8 muscles of the symptomatic leg.
In instances where individuals reported bilateral knee pain, measures
were taken from the patient’s chosen worse knee. Circular pre-gelled
bipolar silver/silver chloride surface electrodes were used to measure
activity from tibialis anterior (TA), soleus (SOL), medial gastrocnemius
(MG), rectus femoris (RF), vastus lateralis and medialis obliquus (VL,
VMO), biceps femoris (BF) and gluteus medius (GM). Electrodes had a
10 mm diameter contact area and fixed inter-electrode distance of
20 mm (Viasys NeuroCare Inc, San Diego, USA). Skin preparation
was conducted in accordance with SENIAM guidelines (Hermens et
al., 2000) and electrode placement was referenced to recommendations
of previous literature (Chapman et al., 2006; Hermens et al., 2000;
Perotto, 1994) and innervation zones reported by Rainoldi et
al.(2004) (Supplementary Data 2). A ground electrode (3M HealthCare,
Pymble City, Australia) was placed on the proximal tibial shaft. Data
was sampled at 3000 Hz and band-pass filtered between 10 and
1000 Hz.

2.4. Kinematic data

Three dimensional motion analysis of the ankle, knee, hip and pel-
vis was conducted using a 14 camera VICON system (Oxford Metrics,
Oxford, UK) capturing at a sampling rate of 250 Hz. Retrospective
markers, 14 mm in diameter, were placed on both lower limbs
according to the Plug In Gait model (Oxford Metrics, Oxford, UK)
which was used to determine kinematic data. Joint rotations were
referred to a standing position.

2.5. Classification of foot mobility

In a recently published paper, Vicenzino et al. (2010) reported a
change of midfoot width from weight bearing to non-weight bearing
to be one of four predictors, and the only foot posture measure of
those included in the analysis, that could identify individuals with
AKP who would benefit from the use of orthoses. Therefore, partici-
pants were classified on their midfoot mobility measured with a
foot assessment platform using a previously described protocol
(McPoil et al., 2009). Twenty-seven participants demonstrated greater
than 10.96 mm change in midfoot width and were considered to
have a more mobile midfoot (McPoil et al., 2009; Vicenzino et al.,
2010) (Table 1).

2.6. Protocol

Participants jogged on a treadmill in 3-minute intervals alternating
between their usual jogging shoe and their shoe with an orthosis
inserted, until all orthoses have been trialled (8 intervals). Prior to
commencement all shoes were inspected for wear (KM) such as
torn uppers, damage to the outer sole. No instances of excessive
wear were found and all participants reported their shoes were pur-
chased within the last 9 months. Participants were requested to
self-select a jogging speed that would not provoke their pain and
could remain constant throughout the protocol. There was no restric-
tion placed on the time between intervals. The order of presentation
of the orthoses to subjects was randomised between subjects. Impor-
tantly, the orthoses were inserted into shoes out of the subjects’ visu-
Al field in order to maintain blinding.

After all the orthoses had been worn, participants were asked to
rank the orthoses in order of most comfortable to least comfortable
(i.e., 1 = most comfortable, 4 = least comfortable). As participant
were blinded to the actual orthosis that they were wearing during
any jog, the participants nominated the number of the trial. A ranking
scale was chosen as this has been shown to be the most reliable

Table 1
Means (SD) of participants. Groups defined by foot mobility.

<table>
<thead>
<tr>
<th></th>
<th>Mobile (&gt;10.96 mm)</th>
<th>Less mobile (&lt;10.96 mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>27</td>
<td>13</td>
</tr>
<tr>
<td>n of women (%)</td>
<td>19 (70)</td>
<td>10 (77)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>28.67 (6.13)</td>
<td>31.15 (4.41)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>169.58 (14.94)</td>
<td>171.2 (8.41)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>71.03 (11.97)</td>
<td>71.15 (11.22)</td>
</tr>
<tr>
<td>Jogging speed (km/h)</td>
<td>8.11 (1.67)</td>
<td>8.31 (2.10)</td>
</tr>
</tbody>
</table>

Please cite this article as: Mills, K., et al., Comfort and midfoot mobility rather than orthosis hardness or contouring influence their immediate
measure of footwear comfort (Mills et al., 2010b). They were permitted to make notes throughout the protocol to assist in their decision.

2.7. Data management

Ten consecutive strides were detected from the final minute of each trial. A stride was defined as foot contact to subsequent ipsilateral foot contact. The trajectory of the heel marker was used to detect gait events (foot contact and foot off) using a previously validated method (Zeni et al., 2008). Low-frequency movement artefact from all marker trajectories was removed using a generalised cross-validatory spline filter (Woltring, 1986). For EMG data, recordings were adjusted for DC offset, full-wave rectified and band-pass filtered using a 4th order Butterworth filter between 15 and 400 Hz. Kinematic and EMG data were then time normalised to 100 points for each stride. EMG data were amplitude normalised to subject’s maximum voluntary contraction (MVC), obtained using standard procedure (Konrad, 2005).

2.8. Data analysis

Individual variance and repeatability of EMG and kinematic data across the 10 strides was calculated using root mean square error (RMSE) and coefficient of multiple correlations (CMC). The 10 strides were then averaged to form a single representative stride for each condition. The entire stride was assessed for kinematic and EMG changes. The maximum, minimum and total excursion of the knee, hip and pelvis in each plane and ankle in sagittal and transverse planes were derived from kinematic data. Thus derived motions were (negative-positive): pelvic posterior–anterior tilt, medio-lateral tilt and external–internal rotation; hip extension–flexion, abduction–adduction and external–internal rotation; knee extension–flexion, valgus–varus and external–internal rotation; and ankle planter–dorsiflexion and abduction–adduction. Frontal plane measures are not reported for the ankle as the foot coordinate system is based on only 2 points using the Plug-in-Gait model (Kadaba et al., 1990). Peak amplitude of muscle activity and temporal (onset, offset and time to peak) derivatives were identified from EMG data. Peak activity was defined as the maximum amplitude. A muscle was considered active when amplitude rose above 15% of the peak for greater than 10% of the stride. Offsets were defined as amplitude falling below the 15% threshold for greater than 10% of the stride (Supplementary Data 3). Temporal data was visually identified as this method has been found to be most appropriate (Chapman et al., 2006).

2.9. Statistical analysis

The distribution of comfort ranking for each orthosis was assessed using Friedman’s analysis of variance.

In order to address the first aim of this study, one-way multivariate analyses of variance (MANOVA) with the orthoses grouped together (shoe v orthoses) as single factor of interest and EMG and kinematic data as the dependent variables. Results are presented as the test statistic (Wilk’s Lambda A), multivariate F-statistic, and significance level (P-value).

For the second aim, orthoses were grouped based on their ranked comfort, regardless of their hardness or contouring. Participants were grouped according to their midfoot mobility defined as mobile (≥10.96 mm) and less mobile (<10.96 mm). The difference in EMG activity and kinematics between the orthoses and the directly preceding shod condition for each comfort rank was calculated. This resulted in a change indicating the magnitude of neuromotor or kinematic adaptation.

The amount of change between the shoe and orthoses kinematic and EMG variables was analysed using two-way MANOVA for the main effects of comfort rank and midfoot mobility. Due to the unequal number of subjects between groups, Pillai’s V was used as the test statistic in both analyses and is reported with the multivariate F-statistic. When multivariate tests were significant (P<0.05), dependent variables were considered separately with Bonferroni corrections. Univariate tests are reported as the F-score, degrees of freedom and significance level (P-value). Point estimates of effect are reported as the mean difference and 95% confidence interval (CI) as well as the standardised mean difference (SMD = mean difference/pooled standard deviation). Confidence intervals of mean differences that contained a ‘0’ indicated a null effect and SMD is referenced to the Hopkins system (Hopkins, 2007) as trivial (<0.2), small (0.2 to 0.6), moderate (0.61 to 1.2) and large (>1.2).

All analyses were conducted in SPSS version 16 (SPSS Inc, Chicago, IL USA).

3. Results

3.1. Comfort rankings

Friedman’s ANOVA found that the orthoses were equally distributed over the 4 possible comfort rankings (P=0.451), though inspection of Table 2 shows that if we discount contouring and consider the soft flat and soft contoured orthoses together then orthoses constructed of the softest material are rated most comfortable (Absolute Risk Reduction 15% (95% CI: 0.15 to 27.8); Chi-square(1)=4.033, P=0.0446).

3.2. Repeatability and variance

There were very high levels of repeatability for all kinematic variables (CMC>0.88) and high levels for all EMG variables (CMC>0.71). Error measurements of kinematic variables ranged from RMSE 0.66° (SD 0.19) to 1.99° (SD 0.87) and EMG from 11.71% (SD 3.31) to 19.44% (SD 4.19) of MVC with the TA and BF producing the greatest variability across 10 strides. The high CMC and low RMSE indicate high repeatability of both kinematic and EMG data (Chapman et al., 2009).

3.3. Comparison between shoe and orthoses (Aim 1)

The one-way MANOVA revealed no significant differences in EMG activity or kinematics between the shod and orthoses conditions (Table 3).

3.4. Neuromotor and kinematic adaptations (Aim 2)

3.4.1. Kinematics

Multivariate tests on adaptation for the kinematic variables found a significant interaction of orthosis comfort and midfoot mobility for frontal plane motion of the hip, Pillai’s V=0.089,F(6, 304)=2.35, P=0.031 (Table 4). Follow up univariate tests revealed the significant interaction occurred in regard to the amount of relative addition F (3, 152)=2.895, P=0.037 (Supplementary Data 4). An inspection of the interaction plot indicates that when participants rated the

<table>
<thead>
<tr>
<th>Rank</th>
<th>Orthosis</th>
<th>Hard</th>
<th>Medium</th>
<th>Soft</th>
<th>Soft-flat</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>7</td>
<td>7</td>
<td>12</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>10</td>
<td>12</td>
<td>12</td>
<td>6</td>
<td></td>
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<td>3</td>
<td>13</td>
<td>9</td>
<td>10</td>
<td>8</td>
<td></td>
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<tr>
<td>4</td>
<td>10</td>
<td>12</td>
<td>6</td>
<td>12</td>
<td></td>
</tr>
</tbody>
</table>
orthosis as least comfortable there was a greater increase in frontal plane motion for a mobile midfoot and the opposite for a non-mobile foot, whereas for the middle two categories between least and most comfortable exhibiting the opposite trend (Fig. 1). The pairwise comparison of change scores for least comfortable orthosis was significantly larger neuromotor change than when wearing the most comfortable (6.94% MVC (1.58 to 12.31) SMD 0.78; P = 0.004). This was due to an increase in peak activity from baseline and compared with those with a mobile midfoot (1.51% stride (0.52 to 2.51) SMD 0.33). Regarding VL peak activity, when wearing the orthosis that was perceived as least comfortable, participants experienced a significantly larger neuromotor change than when wearing the most comfortable (6.94% MVC (1.58 to 12.31) SMD 0.78; P = 0.004). This was due to an increase in peak activity from baseline and compared with all other orthoses. There was a tendency for the least comfortable orthosis to produce a greater change (an increase in VL activity) than those produced by orthoses ranked 2 and 3 (5.18% (0.08 to 1.75); P = 0.032, SMD = 0.61).

### 3.4.2. Electromyography

<table>
<thead>
<tr>
<th>Joint (plane)/muscle</th>
<th>Wilks’ A</th>
<th>F score (df)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ankle (sagittal)</td>
<td>0.997</td>
<td>0.435 (2, 317)</td>
<td>0.648</td>
</tr>
<tr>
<td>Ankle (transverse)</td>
<td>1.0</td>
<td>0.001 (2, 317)</td>
<td>0.999</td>
</tr>
<tr>
<td>Knee (sagittal)</td>
<td>1.0</td>
<td>0.44 (2, 317)</td>
<td>0.957</td>
</tr>
<tr>
<td>Knee (frontal)</td>
<td>0.998</td>
<td>0.363 (2, 317)</td>
<td>0.696</td>
</tr>
<tr>
<td>Knee (transverse)</td>
<td>1.0</td>
<td>0.029 (2, 317)</td>
<td>0.972</td>
</tr>
<tr>
<td>Hip (sagittal)</td>
<td>0.999</td>
<td>0.118 (2, 317)</td>
<td>0.889</td>
</tr>
<tr>
<td>Hip (frontal)</td>
<td>1.0</td>
<td>0.001 (2, 317)</td>
<td>0.999</td>
</tr>
<tr>
<td>Hip (transverse)</td>
<td>0.999</td>
<td>0.093 (2, 317)</td>
<td>0.911</td>
</tr>
<tr>
<td>Pelvis (sagittal)</td>
<td>0.996</td>
<td>0.568 (2, 317)</td>
<td>0.567</td>
</tr>
<tr>
<td>Pelvis (frontal)</td>
<td>0.996</td>
<td>0.618 (2, 317)</td>
<td>0.540</td>
</tr>
<tr>
<td>Pelvis (transverse)</td>
<td>0.997</td>
<td>0.503 (2, 317)</td>
<td>0.605</td>
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<tr>
<td>TA</td>
<td>0.999</td>
<td>0.095 (4, 303)</td>
<td>0.984</td>
</tr>
<tr>
<td>MG</td>
<td>0.996</td>
<td>0.354 (4, 314)</td>
<td>0.841</td>
</tr>
<tr>
<td>SOL</td>
<td>0.998</td>
<td>0.127 (4, 315)</td>
<td>0.973</td>
</tr>
<tr>
<td>RF (stride)</td>
<td>0.996</td>
<td>0.342 (4, 308)</td>
<td>0.849</td>
</tr>
<tr>
<td>RF (swing)</td>
<td>0.946</td>
<td>0.735 (4, 53)</td>
<td>0.561</td>
</tr>
<tr>
<td>VMO</td>
<td>0.997</td>
<td>0.241 (4, 315)</td>
<td>0.915</td>
</tr>
<tr>
<td>VL</td>
<td>0.999</td>
<td>0.05 (4, 315)</td>
<td>0.995</td>
</tr>
<tr>
<td>BF (stride)</td>
<td>0.997</td>
<td>0.236 (4, 302)</td>
<td>0.918</td>
</tr>
<tr>
<td>BF (swing)</td>
<td>0.945</td>
<td>0.801 (4, 55)</td>
<td>0.53</td>
</tr>
<tr>
<td>GM (stride)</td>
<td>0.996</td>
<td>0.3 (4, 300)</td>
<td>0.878</td>
</tr>
<tr>
<td>GM (swing)</td>
<td>0.94</td>
<td>0.174 (4, 11)</td>
<td>0.947</td>
</tr>
</tbody>
</table>

The two-way MANOVAs revealed no significant interactions between foot mobility and perceived comfort. Significant effects were found for midfoot mobility for MG (Pillai’s V = 0.083; F(4, 148) = 2.51, P = 0.045) and orthosis comfort for VL (Pillai’s V = 0.175; F(12, 453) = 2.334, P = 0.007) (Table 5). When the univariate main effects were examined, significant differences were found in the offset of MG between midfoot mobility types (F(1, 151) = 8.977, P = 0.003) and peak amplitude of VL between orthoses comfort levels (F(7, 152) = 2.859, P = 0.008). Inspection of the means (Supplementary Data 5) with respect to MG offset, indicated participants with less midfoot mobility (i.e. < 10.96 mm) experienced a later offset of MG compared with those with a mobile midfoot (1.51% stride (0.52 to 2.51) SMD 0.33). Regarding VL peak activity, when wearing the orthosis that was perceived as least comfortable, participants experienced a significantly larger neuromotor change than when wearing the most comfortable (6.94% MVC (1.58 to 12.31) SMD 0.78; P = 0.004). This was due to an increase in peak activity from baseline and compared with all other orthoses. There was a tendency for the least comfortable orthosis to produce a greater change (an increase in VL activity) than those produced by orthoses ranked 2 and 3 (5.18% (–0.18 to

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have found significant interaction with regard to frontal plane motion of the hip. Previous literature identified hip adduction combined with knee extension enhances VMO activity when weight-bearing (Cerny, 1995; Earl et al., 2001; Miller et al., 1997). Participants with a mobile midfoot exhibited an increase in relative adduction wearing their least comfortable orthosis. It is possible that this was a compensation strategy to preserve VMO:VL ratio in response to the significant increase in VL peak activity, also observed in the least comfortable orthosis. A second possibility is that this is an example of weakness around the hip. Robinson and Nee (2007) and Cichanowski et al. (2007) found people with patellofemoral pain exhibit global hip weakness, specifically significant hip abductor weakness. The resulting increase in hip adduction can increase the dynamic Q angle at the knee and increase lateral patellar contact pressure thus contributing to AKP (Cichanowski et al., 2007). It is important to remember that since we did not measure rearfoot frontal plane motion, we cannot comment whether it was changes in rearfoot eversion or some other mediator that resulted in changes in adduction of the hip.

There was a moderate, significant difference in peak amplitude for VL between the most and least comfortable orthosis regardless of midfoot mobility. The least comfortable orthosis produced the greatest increase in peak amplitude from the baseline condition. This has important implications as it has been identified that excessive activity of VL, relative to VMO, can lead to lateral tracking of the patella and increase the risk of AKP (Besier et al., 2009; Cowan et al., 2001; Hertel et al., 2004; Neptune et al., 2000; Van Tiggelen et al., 2009; Wong, 2009). Taken in conjunction with our findings that (a) the least comfortable orthosis was associated with increases in hip adduction and (b) the harder orthoses seem to be least comfortable, it would seem that harder orthoses should be avoided in this condition.

There was a small significant effect of midfoot mobility on the offset of MG. There was a greater delay in the offset of MG activity for the orthoses (regardless of perceived comfort) in those with a less mobile midfoot. Previous studies into the effect of foot mobility on EMG variables during gait have found MG activity was not affected by differences in foot posture (Murley et al., 2009a, 2009b, 2010), though their samples were not symptomatic. Keenan et al. (1991) found that those individuals diagnosed with rheumatoid arthritis who had valgus foot alignment had decreased MG activity compared with controls. This suggests that symptomatic and asymptomatic populations may respond differently.

There are limitations to this study that should be considered in interpreting its findings. Firstly, we only examined immediate neuro-motor effects in a selected musculoskeletal condition. Previous research of involving patients with a range of conditions has shown neuromotor adaptations may take several weeks to become apparent. Future research should focus on adaptations after ongoing use of foot orthoses in more homogeneous patient groups. Second, we used a ranking scale to determine the relative comfort between orthoses as this has been found to be the most reliable comfort scale for measuring footwear comfort (Mills et al., 2010b). In doing so we were unable to ascertain how much comfort differed between the orthoses. Previous literature has reported little change in kinematics and EMG between orthoses of similar comfort levels (Davis et al., 2008; Mundermann et al., 2003; Murley et al., 2010), so it might be possible that if we had utilised orthoses with greater differences in comfort rating we may have observed greater differences between devices. It is also important to note that the kinematic differences, though statistically significant and outside the error of measurement, are small and their clinical meaning requires follow up. Nawoczenski et al.
(1995) state that small kinematic changes in response to orthoses may have a cumulative effect that is clinically meaningful in the treatment of overuse syndromes. Finally, we utilised a protocol that purposefully did not provoke the participants’ pain during testing and so we are unable to comment on any interaction between pain and kinematics or EMG.

5. Conclusions

This study examined the acute neuromotor and kinetic effects of orthoses in people with AKP and considered the impact of an individual’s perception of comfort and mobility of the midfoot. Overall, we found that the addition of orthoses did not result in immediate changes to EMG activity or kinematics of the lower limb, but that comfort perception and foot mobility showed some impact. Orthoses perceived as least comfortable resulted in an increase in relative ad- 
duction of the hip in people with mobile feet and an increase in VL peak activity regardless of foot type. Due to the potential contribu-
tions of both of these observations to AKP, comfort is an essential con-
sideration when prescribing foot orthoses.

Supplementary materials related to this article can be found online at doi:10.1016/j.clinbiomech.2011.08.011.

Conflict of interest statement

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