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Medial arch supports do not significantly alter the knee adduction moment

in people with knee osteoarthritis

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Running title: Medial arch supports for knee OA
ABSTRACT

Objective: This study aimed to evaluate the immediate effects of medial arch supports on indices of medial knee joint load (the peak external knee adduction moment (KAM) and knee adduction angular (KAA) impulse) and knee pain during walking in people with medial knee OA.

Design: Twenty one people with medial compartment OA underwent gait analysis in standardised athletic shoes wearing i) no medial arch supports and ii) prefabricated medial arch supports, in random order. Outcomes were the first and second peaks in the external KAM, the KAA impulse and severity of knee pain during testing. Outcomes were compared across conditions using paired t tests (gait data) and Wilcoxon Signed Ranks test (pain data).

Results: There were no significant changes in either first or second peak KAM, or in the KAA impulse, with the addition of medial arch supports (all p>0.05). Considerable individual variation in response to the arch supports was observed across participants. There was no immediate change in knee pain during walking when medial arch supports were worn (p=0.56).

Conclusions: This study showed no mean change in any of the measured indices of medial knee load with medial arch supports. No immediate changes in knee pain were evident.

Keywords: osteoarthritis, knee, orthotics, orthoses, biomechanics, load, adduction moment
INTRODUCTION

Knee osteoarthritis (OA) is a prevalent musculoskeletal condition worldwide and is a leading cause of knee pain and disability amongst elderly people. Of the three knee joint compartments, knee OA is most commonly observed in the medial tibiofemoral joint. This is most likely due to the greater loads applied to this compartment (relative to the lateral) during walking. Furthermore, excessive medial knee load is also believed to contribute to the progression of structural disease in people once the disease is established. Research has shown that an increased external knee adduction moment (KAM, an indirect biomechanical marker of compressive medial knee joint load) significantly increases the risk of medial tibiofemoral OA structural deterioration over time.

As there is no cure for OA and arthroplasty is the only treatment for end-stage disease, it is important to prevent or minimise the rate of structural deterioration in the knee joints of afflicted individuals as much as possible in order to reduce the personal and societal burden of disease.

During walking, the foot and the knee are linked within a closed kinetic chain, thus foot position and motion may influence load at the knee joint. Accordingly, shoe insoles can potentially increase or decrease knee load depending on their specific design features. It is thus recommended in clinical guidelines that every patient with knee OA receive advice concerning appropriate footwear.

Compared to other non-drug interventions for managing knee OA (such as exercise), there is little evidence from randomised controlled trials available to guide clinical practice regarding which shoes and shoe insoles are optimal for people with medial knee OA (and conversely, which should be avoided).
However biomechanical evaluations suggest that “minimalist” flexible lightweight footwear may be most suitable\textsuperscript{8}, and that high-heeled shoes are best avoided\textsuperscript{9-11}. Regarding insoles, most research has focussed on laterally wedged insoles, and although these can reduce medial knee load\textsuperscript{6}, they have not been shown to have any significant effect on symptoms or joint structure\textsuperscript{12-14}.

Medial arch supports are foot orthoses that provide support to the medial longitudinal arch of the foot, with the aim of realigning skeletal structures and altering lower limb movement patterns during walking. They are readily available in pre-fabricated non-customised form. Retailers and manufacturers frequently promote medial arch supports as being beneficial for shock absorption and increased foot stability\textsuperscript{15}. Importantly, given that patients with medial knee OA have a greater prevalence of pronated feet compared to asymptomatic age-matched controls\textsuperscript{16}, and that recent cross-sectional data has linked the pronated foot type to increased frequency of knee pain and medial tibiofemoral cartilage damage in older people\textsuperscript{17}, health care clinicians frequently prescribe these orthoses to patients with knee OA. Significantly, many people with musculoskeletal conditions (such as OA) also self-administer medial arch supports without consulting a healthcare professional given they are readily available for purchase over the counter in retail outlets, irrespective of whether such orthoses may be indicated or not for their condition. Given that the causal relationship between pronated foot posture and knee pain and cartilage damage in people with knee OA is yet to be established, it cannot be assumed that treating pronated feet with medial arch supports will necessarily be beneficial for people with knee OA.
In fact, because of the focus of support to the medial longitudinal arch of the foot, it is possible that medial arch supports may cause a medial shift in the centre of pressure, thereby increasing the distance between the ground reaction force and the knee centre and thus increasing the KAM during gait. Using a novel foot-worn biomechanical device that permits controlled manipulation of the centre of ‘pressure’ location (centre of force as measured by a force platform), Haim et al\textsuperscript{18} showed that a medial shift in the centre of pressure (from neutral) significantly increased the peak knee adduction moment by approximately 6%. Previous research has shown that a varus (medial) wedge orthosis results in a medial shift of the centre of pressure in young healthy people\textsuperscript{19}. Further indirect support for this argument comes from biomechanical research on laterally wedged insoles, which provide a laterally-directed (eversion) bias to the foot (ie the opposite to medial arch supports). Lateral wedges shift the centre of ‘pressure’ (centre of force as measured by a force platform) laterally and lower the KAM\textsuperscript{20-22}, which is why these types of insoles have been advocated on biomechanical grounds as beneficial for people with knee OA. Cross-sectionally, people with medial knee OA naturally demonstrate a lateral shift in centre of pressure compared to healthy controls\textsuperscript{23}, the reasons for which are unknown which but could theoretically reflect an adaptive response in an attempt to lower the increased knee loads associated with the disease.

Presently, there is very little research into the biomechanical effects of medial arch supports in people with knee OA. In a study of healthy young people,
prefabricated medial arch supports inserted into standardised athletic shoes increased the peak KAM in late stance during walking by 6%, and in early stance during running by 4%\(^2\). In another study of healthy people\(^2\), flat orthoses with a medial arch support did not significantly alter the KAM, however these were attached directly to the sole of the foot with tape and the participants did not wear shoes during testing, limiting the external validity of this study. In the only study of people with knee OA\(^2\), a modified orthotic that comprised both a medial arch support and lateral wedging was used. Given the use of a combination orthotic, and a control condition that also included medial arch supports, no conclusions about the independent biomechanical effects of medial arch supports can be drawn from this study.

The primary aim of this study was to evaluate the immediate effects of medial arch supports on indices of medial knee joint load (the two peaks in external KAM and the knee adduction angular (KAA) impulse) during walking in people with medial knee OA. A secondary aim was to evaluate the immediate effects of medial arch supports on knee pain during walking, given that some research has demonstrated a positive relationship between pain and the KAM\(^4,27,28\). It was hypothesised that medial arch supports would increase both the first and second peak KAM and KAA impulse, and in doing so would increase knee pain.

**PATIENTS AND METHODS**

**Participants**

Participants in this study were recruited from amongst those taking part in another gait study conducted concurrently at the Centre for Health, Exercise and
Twenty one people, recruited from the community by advertisements, participated in the present study. Participants were included if they were aged over 50 years, reported knee pain on most days of the previous month and demonstrated medial tibiofemoral osteophytes on x-ray\textsuperscript{29}. Other inclusion criteria were an average knee pain ≥3 in the past month on an 11-point numeric rating scale when walking. Exclusion criteria included valgus knee alignment >185° on a standardised semi-flexed knee x-ray (corresponding to a mechanical axis of > 181.3°)\textsuperscript{30}; systemic arthritic or neurological condition; any other condition (other than knee OA) causing lower limb pain; use of a gait aid; body mass index ≥ 35 kg/m\textsuperscript{2}; hip or knee joint replacement or; knee surgery or injection (past 6 months).

In this study, only the symptomatic knee was evaluated. In the case of participants with bilateral eligible knees, the more symptomatic was deemed the study limb. The University of Melbourne Human Research Ethics Committee approved the study and all participants provided written informed consent.

**Sample size**

The study aimed to detect a minimum 7.5% increase in the peak KAM with the addition of medial arch supports, equating to an absolute change of approximately 0.3 %BW*Ht according to data obtained previously in our laboratory\textsuperscript{31,32}. Assuming a standard deviation of approximately 0.4 %BW*Ht, sample size calculations revealed that 21 participants would be required to detect a 0.3 %BW*Ht change with 90% statistical power.
Medial arch supports
Participants underwent gait analysis with and without a pair of prefabricated non-customised medial arch supports (Vasyli Howard Dananberg orthoses) inserted inside standardised (Nike Air Pegasus) athletic shoes that were provided to all participants. These shoes contain an easily compressible removable standard insole/sock liner (uncompressed height of 6 mm, Shore A durometer reading approximating 30) that has no substantial medial arch support. For the medial arch support walking condition, these insoles/sock liners of the shoes were removed to permit a comfortable fit once the medial arch supports were inserted. For the control walking condition (ie without medial arch supports), the standard insoles/sock linings of the shoes remained in situ. Testing occurred in randomised order. The medial arch supports were full-length commercial inserts (Figure 2.1) of tricompound construction (moulded polyurethane, moulded ethylene vinyl acetate and sorbon) with a thickness of 4 mm and an uncompressed arch support height of 26 mm and a Shore A durometer reading approximating 70, rendering them relatively incompressible.

Gait analysis
A Vicon motion analysis system with eight MX cameras operating at 120 Hz (Vicon, Oxford, UK) was used to measure lower limb kinematics and kinetics. The standard Plug-in-Gait marker set was used (anterior superior iliac spine, posterior superior iliac spine, mid-lateral thigh, lateral femoral epicondyle, lateral shank, lateral malleolus, on the shoe over the second metatarsal head and over the posterior calcaneus). Additional medial femoral epicondyle and malleolus markers were used during the single static standing trial to assist in
determining the knee and ankle joint flexion-extension axes, halfway along which the respective joint centers were placed.

Ground reaction forces were measured by two OR6-6-2000 force plates (Advanced Mechanical Technology Inc., Watertown, MA) embedded in the floor at the midpoint of a 10m walkway at 1080 Hz, in synchrony with the cameras. Participants walked at their usual comfortable pace and data were collected from 5 successful trials for each test condition. Participants were not informed about the embedded force plates to prevent them ‘targeting’ the plates and thus altering their gait pattern. Several practice trials ensured that participants walked naturally and landed the whole foot of the test limb on the force plate. Walking speed was monitored by two photoelectric beams and verbal feedback ensured that speed during each trial varied not more than 5% from the average speed of the first. A successful trial was that in which the participant walked naturally, landed the whole foot of the test limb on the force plate and where speed did not vary by more than 5% of the first.

Net external joint moments were calculated via inverse dynamics (Nexus v1.4, Vicon, Oxford UK). Joint moments were normalised for body weight times height and reported in %BW*Ht. The dependent variables of interest were the external peak KAM in the first half of stance (first peak) and the external peak KAM in the second half of stance (second peak). The positive KAA impulse was also calculated (%BW*Ht)(s). The value of this measure is equivalent to the positive area under the adduction moment-time graph. This measure incorporates both the mean magnitude of the (positive) moment and the time for
which it is imposed on the knee. Previous research has suggested that this measure may be a useful parameter in understanding gait patterns in OA, complementing the more traditionally used peak KAM\textsuperscript{33}. Additional kinetic variables of interest included the peak knee flexion moment and the early and late stance peak hip adduction moments. The foot progression angle at mid-stance (calculated as the angle between the foot vector and the forward laboratory axis, projected into the laboratory’s transverse (floor) plane and where negative values indicate a toe-out position) was also calculated. All variables were averaged over the 5 trials for each walking condition.

Knee pain

Average knee pain during the walking tests was rated by participants with and without arch supports using an 11-point numerical rating scale with terminal descriptors of ‘no pain’ to ‘worst possible pain’. Pain was rated immediately upon completion of the walking trials for each condition.

Descriptive measures

Several measures were used to describe the severity of knee OA within the cohort. Radiographic disease severity was assessed using the Kellgren and Lawrence system\textsuperscript{34}. The Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index\textsuperscript{35} was used to assess symptomatic severity. Specifically, the pain subscale (score range 0-20, higher scores indicating worse pain), stiffness subscale (score range 0-8, higher scores indicating more stiffness) and the physical function subscale (score range 0-68, higher scores indicating poorer function) were used.
Statistical analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences (version 17, Norusis/SPSS Inc. Chicago, Illinois, USA) with an alpha level of 0.05. Data were checked for normality, via Shapiro-Wilks tests, prior to analysis. The effects of medial arch supports on gait parameters were evaluated using paired t tests, and by calculating mean differences with associated 95% confidence intervals (CIs). Comparison of pain ratings between test conditions was done with a Wilcoxon matched-pairs Signed Ranks test.

RESULTS

Characteristics of the study cohort are presented in Table 1. On average, participants were aged in their late sixties and just over half the cohort was female. Participants were generally overweight. Radiographic disease severity was mild to moderate in most cases, with only three people having severe (Grade 4) knee OA. Average scores for WOMAC indicated generally mild to moderate symptomatic severity in the cohort as a whole.

The effect of medial arch supports on measures of knee and hip load is summarised in Table 2. There were no significant changes in either first or second peak KAM or in the KAA impulse with the addition of medial arch supports. Similarly, there were no significant changes in the peak knee flexion moment or in either peak of the hip adduction moment. Walking speed was not significantly different across test conditions (mean (SD) 1.26 (0.18) m/s with and without arch supports). The foot progression angle was also similar with
and without medial arch supports (mean (SD) -7.00 (4.54) and -6.95 (4.82)
degrees respectively, p=0.89).

There was considerable individual variation in response to medial arch supports.
Individual changes in measures of knee load with medial arch supports are
depicted in Figure 2. Changes in the first peak KAM with medial arch supports
ranged from a 14% decrease in the moment to a 19% increase. Nearly half (9/21)
of the participants demonstrated an increased first peak KAM of greater than
5%, and of these, four had an increase above 10%. Similar variability was
evident in the second peak KAM. Ten (48%) participants demonstrated a
reduction in the second peak with medial arch supports, while 10 (48%)
participants demonstrated an increase. The majority of participants demonstrated
an increase in the KAA impulse with arch supports (14, 67%), with only 7
(33%) demonstrating a reduction.

A median (interquartile range) pain score of 1 (0-3) was recorded by participants
when walking without arch supports, compared to a score of 1 (1-4) when
walking with arch supports. This was not significantly different across test
conditions (p=0.56).

**DISCUSSION**

This study evaluated the immediate effects of prefabricated medial arch supports
on parameters of knee load in people with medial knee OA. Contrary to our
hypothesis, the findings from our study revealed no significant mean changes in
either the KAM peaks or the KAA impulse when medial arch supports were
inserted inside standardised athletic shoes. We also evaluated whether the addition of medial arch supports could immediately change the severity of knee pain experienced during walking. Our results showed no effect of medial arch supports on knee pain associated with OA.

In the present study, addition of medial arch supports to standardised athletic shoes resulted in small mean increases in knee load (2.2% increase in the first peak KAM, 2.5% increase in the KAA impulse and 0.5% increase in second peak KAM), that were not statistically significant. Our results partially agree with studies of healthy young people reported in the literature\textsuperscript{24,25}. Nakajima et al\textsuperscript{25} tested a flat orthotic with an attached medial arch support that was taped to the sole of the foot. The comparison condition was a flat orthotic (with no arch support) also taped to the sole of the foot. In 20 healthy volunteers, no significant change in either the peak external KAM, or in the stance phase KAM averaged over either the entire stance phase, or the early, middle or late stance phases, was observed. Franz et al\textsuperscript{24} used a more conventional prefabricated medial arch support that was inserted into standardised athletic shoes, similar to our study protocol. In their study of 22 healthy young people, no significant change in the first peak KAM during walking was observed. However, they noted a significant increase in the second peak KAM (late stance) during walking by 6%, as well as a significant 4% increase in the peak KAM during running, with medial arch supports. It is unclear why we did not observe a significant increase in late stance knee load with arch supports, given that we used a similar prefabricated medial arch support with respect to length, flexibility and physical dimensions. It is likely that the healthy young
participants in the study by Franz et al\textsuperscript{24} walked at a faster pace than our older osteoarthritic participants, which may have amplified the effects of the medial arch supports on KAM indices.

Although not statistically significant, we observed a mean increase in the first peak KAM of 2.2\% with medial arch supports. However, given that the study was powered to detect a 7.5\% difference in the first peak KAM, it is not surprising that the results were not statistically significant. A 7.5\% difference was chosen a priori as a change of this magnitude could reduce the risk of structural disease progression by approximately two-fold\textsuperscript{4}. Thus, it is possible that a real but small effect on KAM parameters with medial arch supports was not detected because of the sample size. Other reasons which may explain our lack of demonstrated effect of the medial arch supports may be related to our study sample. We did not select people on the basis of having flattened feet, nor did we measure foot posture as part of our study. Whilst our sample can be assumed to be representative of people with symptomatic medial knee OA living in the community, it is unlikely to reflect those with knee OA who might specifically seek treatment for pronated feet. It is possible our sample did not contain enough people with sufficiently flattened feet to demonstrate a significant effect of medial arch supports on either indices of knee load or pain. Future research should evaluate the effects of medial arch supports in such people specifically. Finally, we standardised the type of shoe worn by our participants rather than permit them to walk in their own self-selected shoes. Given that it is possible neuromuscular adaptation may occur over time, it is possible that significant changes in KAM may be evident only after a prolonged...
period of adaptation to the shoes and inserted medial arch supports. Future research in this area is warranted.

Although we observed no mean significant increase in parameters of knee load with our arch supports, it is important to note the considerable variation in response across individuals in our study. This is consistent with previous orthotic research\textsuperscript{21,36,37}. Individual data suggest there are some people with knee OA who experience increased medial knee loading with medial arch supports. Future research should be directed towards evaluating which patient characteristics mediate the effect of medial arch supports on indices of knee load, so that clinicians can more readily identify the patients who may be more likely to adversely increase knee load with these orthoses. Factors that may be important include foot posture/arch height, foot stiffness/mobility, knee malalignment severity, presence and nature of compensatory gait strategies, severity of disease symptoms and/or comfort of the arch supports.

We did not observe any immediate significant change in pain with medial arch supports. This may be because our cohort did not find the walking task very provocative (median pain score 1 out of 10 during the control condition) and therefore there was a reduced likelihood for pain to change across test conditions. We had hypothesised that increases in knee pain would occur because of increases in knee load with use of medial arch supports. Given that the medial arch supports did not significantly increase mean knee load, it is perhaps not surprising that pain levels were similarly unaffected. It is also possible that knee pain is not as closely linked to knee loading as previously
thought. Research has demonstrated variable, and at times conflicting, relationships between knee load and symptoms\(^4,27,28,38,39\).

There are a number of strengths to our study. Our rigorous within-subject study design permitted control of important participant-related confounding factors such as gait speed, age, mass, foot posture and gait patterns. We recruited a cohort of participants representative of community-dwelling people with medial knee tibiofemoral OA and evaluated a non-customised prefabricated medial arch support that is representative of those widely available in clinical practice. There are also some limitations to our study. We only evaluated the immediate effects of medial arch supports on indices of knee load and pain. It is possible that longer durations of wear may have resulted in different findings. Whilst we used valid and reliable universally accepted surrogate measures of medial knee load, it must be acknowledged that these are not direct measures of medial joint contact forces.

In conclusion, this study aimed to evaluate the immediate effects of non-customised prefabricated medial arch supports on parameters of knee load and pain in a cohort with medial knee OA. Findings demonstrated no significant mean change in either the peak external KAM or the KAA impulse when these orthoses were worn inside standardised athletic shoes. No immediate changes in knee pain were evident with their use.

ACKNOWLEDGEMENTS
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**AUTHOR CONTRIBUTIONS**

RSH and KLB conceived of the study idea and designed the study. LB and MS collected and processed the data. LB, RSH and KLB analysed and interpreted the data. RSH drafted the manuscript. All authors revised the manuscript for intellectual content and approved of the final article prior to submission.

**ROLE OF THE FUNDING SOURCE**

The Australian Research Council played no role in the design or conduct of this study or in the writing of this manuscript.

**CONFLICT OF INTEREST**

KLB and RSH anticipate receiving royalties in the future from an osteoarthritis shoe marketed by ASICS Pty Ltd that they have been involved in designing and testing. LB and MS have no conflict of interest to declare.
REFERENCES


Table 1: Characteristics of the study participants (n=21). Data presented as mean (standard deviation) or as number (percentage).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>68.5 (10.4)</td>
</tr>
<tr>
<td>Gender</td>
<td>9 (43%) male</td>
</tr>
<tr>
<td></td>
<td>12 (57%) female</td>
</tr>
<tr>
<td>Height (m)</td>
<td>1.7 (0.9)</td>
</tr>
<tr>
<td>Body mass (kg)</td>
<td>79.2 (16.2)</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>28.3 (5.2)</td>
</tr>
<tr>
<td>Symptom duration (yrs)</td>
<td>10.7 (11.0)</td>
</tr>
<tr>
<td>Nature of symptoms</td>
<td>7 (33%) unilateral</td>
</tr>
<tr>
<td></td>
<td>14 (67%) bilateral</td>
</tr>
<tr>
<td>Radiographic severity¹</td>
<td>9 (43%) Grade 2</td>
</tr>
<tr>
<td></td>
<td>9 (43%) Grade 3</td>
</tr>
<tr>
<td></td>
<td>3 (14%) Grade 4</td>
</tr>
<tr>
<td>Mechanical knee alignment² (*)</td>
<td>180.3 (3.8)</td>
</tr>
<tr>
<td>WOMAC³ scores</td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>5 (3)</td>
</tr>
<tr>
<td>Stiffness</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Physical function</td>
<td>17 (9)</td>
</tr>
</tbody>
</table>

¹Kellgren Lawrence grade of radiographic disease severity where higher grades indicate more severe radiographic change
²Lower scores indicate more varus alignment
3WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

Higher scores indicate worse symptoms: pain scored 0-20, stiffness scored 0-8, physical function scored 0-68.
Table 2: Effects of medial arch supports on parameters of knee and hip load.

<table>
<thead>
<tr>
<th>Variable</th>
<th>No arch supports, mean (SD)</th>
<th>Arch supports, mean (SD)</th>
<th>Mean difference#</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>First peak KAM (%BW*Ht)</td>
<td>3.63 (1.22)</td>
<td>3.72 (1.23)</td>
<td>0.08</td>
<td>-0.06, 0.23</td>
<td>0.25</td>
</tr>
<tr>
<td>Second peak KAM (%BW*Ht)</td>
<td>2.05 (0.90)</td>
<td>2.06 (0.79)</td>
<td>0.01</td>
<td>-0.15, 0.09</td>
<td>0.62</td>
</tr>
<tr>
<td>KAA impulse (%BW*Ht)(*s)</td>
<td>1.19 (0.52)</td>
<td>1.22 (0.52)</td>
<td>0.03</td>
<td>-0.02, 0.07</td>
<td>0.29</td>
</tr>
<tr>
<td>Peak knee flexion moment (%BW*Ht)</td>
<td>2.81 (1.36)</td>
<td>2.94 (1.61)</td>
<td>0.13</td>
<td>-0.30, 0.04</td>
<td>0.13</td>
</tr>
<tr>
<td>Early stance peak hip adduction moment (%BW*Ht)</td>
<td>5.92 (1.05)</td>
<td>6.02 (0.97)</td>
<td>0.10</td>
<td>-0.29, 0.09</td>
<td>0.28</td>
</tr>
<tr>
<td>Late stance peak hip adduction moment (%BW*Ht)</td>
<td>4.90 (0.92)</td>
<td>4.87 (1.03)</td>
<td>0.03</td>
<td>-0.15, 0.21</td>
<td>0.72</td>
</tr>
</tbody>
</table>

#Differences are calculated as medial arch supports minus no medial arch supports; KAM =knee adduction moment; KAA impulse = knee adduction angular impulse.
Figure 1: Medial arch supports viewed from (a) medial profile (b) above.

a)  

b)
Figure 2: Percentage change in a) first peak knee adduction moment, b) second peak knee adduction moment and c) knee adduction angular impulse among individual participants when walking with medial arch supports (compared to walking without).

a)

b)

c)
Author/s:
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