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Is your prescription of distance running shoes evidence-based?

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ABSTRACT

Objectives: To determine whether the current practice of prescribing distance running shoes featuring elevated cushioned heels and pronation control systems tailored to the individual’s foot type is evidence-based.


Review methods: English language articles were identified via keyword and medical subject headings (MeSH) searches of the above electronic databases. With these searches and the subsequent review process, controlled trials or systematic reviews were sought in which the study population included adult recreational or competitive distance runners, the exposure was distance running, the intervention evaluated was a running shoe with an elevated cushioned heel and pronation control systems individualised to the wearer’s foot type, and the outcome measures included either running injury rates, distance running performance, osteoarthritis risk, physical activity levels, or overall health and wellbeing. The quality of these studies and their findings were then evaluated.

Results: No original research that met the study criteria was identified either directly or via the findings of the six systematic reviews identified.

Conclusion: The prescription of this shoe type to distance runners is not evidence-based.

Distance runners are notorious for their high rates of minor musculoskeletal injury, with 37–56% of average recreational runners becoming injured at least once each year.¹ In recreational and competitive runners alike, running injuries almost exclusively affect the leg and are primarily due to chronic overloading rather than acute traumatic events. Our capacity to prevent such injuries is currently limited, with training advice and footwear prescription forming the mainstays.² Thus, the prescription of the correct running shoe, either alone or in concert with an orthotic, is considered a crucial and highly valued skill.

Since the 1980s, distance running shoes with elevated, heavily cushioned heels and features to control subtalar motion have been consistently recommended to footwear prescribers as the gold standard for injury prevention.² ³ Prescribed on the basis of foot type, overpronators, mild pronators and supinators are prescribed “motion control”, “stability” and “cushion” shoes respectively.² ³ In the absence of existing nomenclature to describe these shoes as a group, we propose the term “pronation control, elevated cushioned heel” (PCECH) running shoes.

Whether this approach to footwear prescription is evidence-based has traditionally been tested by examining the evidence supporting the use of each of these key features of the PCECH design.

FEATURES OF THE PRONATION CONTROL, ELEVATED CUSHIONED HEEL SHOE

Cushioning

The use of cushioning in running shoes is based on the following assumptions: (1) that impact forces while running are a significant cause of injury, (2) that running on hard surfaces is a cause of high impact forces, (3) that a cushioned shoe can reduce impact forces to a less injurious level, and (4) that the potential of the cushioning itself to cause injury is minimal.

The evidence for these assumptions is mixed. That excessive force will result in injury is self-evident.⁴ However, the evidence that running on hard surfaces causes either an increase in impact forces or an increase in injury rates is weak.⁵–¹⁰ The capacity of cushioning to reduce either impact forces or injury rates has also been called into question.⁵ Furthermore, diminished proprioception has been identified as a significant side effect of heavily cushioned shoes.¹¹ It has been argued that this diminished capacity to precisely monitor impact and foot position carries with it a significant risk of harm. The absence of data from controlled clinical trials means that the overall effect of cushioning on running injury rates remains unknown.¹²

Elevated heel

It has been suggested that an elevated heel is incorporated into the PCECH shoe to decrease Achilles tendon strain and thus Achilles tendon injury.³ ¹² It also allows placement of a substantive heel cushioning system.

Several studies have investigated the effect of progressive heel elevation on loading of the Achilles tendon, but with mixed results.¹³–¹⁵ Furthermore, it has been observed that since the introduction of the PCECH design there has actually been an increase, not a decrease in Achilles tendon injuries.¹⁶ Others have shown that heel elevation during stance places the ankle joint in a position where proprioception is inherently poor.¹⁷ The capacity of existing levels of heel elevation to increase pronation has also been noted.¹⁷ Unfortunately, the overall effect on injury rates of running in a shoe with an elevated heel remains untested in clinical trials.¹⁰
Pronation control systems
The protective effect of normalising subtalar joint motion is built on the following assumptions: (1) that overpronation and supination are causally linked to overuse injuries, (2) that promoting limited pronation reduces this risk, and (3) that PCECH shoes are an effective means of reducing injuries via this approach. Subtalar motion and foot type have not been consistently associated with injury rates in runners. Furthermore, PCECH shoes are themselves a relatively ineffective and unreliable means of altering subtalar motion, causing small and inconsistent changes in alignment. The clinical efficacy of pronation control systems remains untested, with no longitudinal trials having been reported that compare injury rates in runners wearing shoes with and without pronation control systems.

RATIONALE
It is apparent that the ongoing use of pronation control systems and elevated cushioned heels in running shoes is being challenged. We have identified several studies suggesting that these features either fail to achieve their desired purpose, or worse still, have the potential to cause harm. Also apparent is the absence of clinical data, which are required to rigorously evaluate the direct effect of each of these features on injury rates.

That this uncertainty coexists with both strong professional and consumer belief in the PCECH design means that it is more important than ever that clinicians rely on evidence rather than dogma or conjecture when making decisions for patients. Rather than examining the features of the PCECH shoe in isolation, the most definitive evidence of its effect on injury rates will come from clinical trials comparing injury rates in runners wearing PCECH shoes with those running in bare feet or in other shoe types.

Several authors have commented on the paucity of this high-level clinical evidence to support the ongoing use of PCECH running shoes, but none has reported a specific systematic review of this literature, nor broadly considered other possible effects of wearing PCECH shoes on runner’s health and performance.

METHODS
A series of clinical questions pertinent to the health and performance of competitive and recreational runners was formulated. These questions focussed on distance running performance, injury rates, osteoarthritis risk, physical activity levels, and overall health and wellbeing (table 1). The search terms used to identify evidence pertinent to each question are also shown.

These search terms were used to interrogate the following electronic databases: MEDLINE (1950–May 2007), CINAHL (1982–May 2007), EMBASE (1980–May 2007), PsychInfo (1806–May 2007), Cochrane Database of Systematic Reviews (2nd Quarter 2007), Cochrane Central Register of Controlled trials (2nd Quarter 2007), SPORTSDiscus (1925–May 2007) and AMED (1985–May 2007). Keyword and medical subject heading (MeSH) searches were performed.

Articles were included in our review if they were published in English and reported original research or a systematic review in which the study population included adult recreational or competitive runners, the exposure was distance running, the intervention being assessed was a PCECH running shoe and at least one of the outcomes listed in table 1 was measured directly. A control group who ran in non-PCECH shoes or bare feet was also required. Studies that only measured surrogate outcomes such as impact forces, rather than injury rates directly, were excluded.

The sorting of search results was undertaken by a single reviewer. During this process, articles clearly irrelevant on the basis of title and abstract were immediately excluded. Articles clearly relevant or of uncertain relevance were retained. The full texts of these articles were then retrieved and both their findings and methodology reviewed.

RESULTS
No articles were identified that reported original research addressing the capacity of PCECH shoes to prevent injury. Six systematic reviews were identified whose scope included interventions to prevent injuries in runners, or injuries common in runners. Two were outdated systematic reviews for which updated versions were identified. The details of the remaining four systematic reviews are presented in table 2.

No controlled trials were identified by these systematic reviews in which a PCECH running shoe was the intervention tested. No systematic reviews or reports of original research were found which assessed the effect of the PCECH running shoe on the enjoyment of running, on physical activity levels or on the wearer’s uptake of prescribed physical activity. No articles were found which evaluated the effectiveness of PCECH running shoes as a means of preventing the development of osteoarthritis of the leg, nor were any articles found which attempted to assess the effect of the modern athletic shoe on overall mortality, morbidity or quality of life. No studies were identified which evaluated the effect of PCECH running shoes on distance running performance.

DISCUSSION
The findings of this systematic review suggest that the true effects of PCECH running shoes on the health and performance of distance runners remain unknown. Unless convincing high-level evidence emerges to support their use, the prescription of PCECH running shoes has no place in evidence-based practice.

What weight can we give to this finding? The broad scope and the systematic manner in which this review was undertaken give us significant confidence that there are indeed no studies of relevance in the mainstream English literature. Given...
that our findings are consistent with those of other high-quality systematic reviews performed without our language restrictions, we believe that the cumulative weight of these findings cannot be ignored.\textsuperscript{10, 24, 25}

If we accept this finding, we are then faced with the realisation that we have been prescribing a treatment without proven benefit for >20 years. Worse still, these footwear prescription practices have not gone uncontested in the literature. Despite the absence of a systematic review specifically addressing the capacity of PCECH shoes to prevent injury, the lack of evidence for their use and their potential to cause injury has been raised by several authors, including leading authorities in the field.\textsuperscript{9, 17, 27, 28}

In spite of these findings, footwear prescription guidelines that unequivocally recommend the PCECH design continue to be published.\textsuperscript{4, 5} That practitioners are being encouraged to base their practice on expert opinion is not inappropriate given the lack of high-level evidence, but that such recommendations are being published without explicitly acknowledging both the lack of supporting clinical evidence and the existence of conflicting expert opinion is of concern.

Individual readers may not have the time or the training to themselves assess the quality of such recommendations and thus rely on editorial and peer review to ensure that they are evidence-based. That the peer review process has failed in these circumstances suggests that a significant subgroup of footwear researchers either remain uncommitted to genuine evidence-based practice, lack understanding of the requirements for assessing the efficacy and safety of a therapeutic intervention, or are unduly influenced by conflicts of interest such as receipt of funding from shoe manufacturers.

This suboptimal approach to evidence is mirrored by the behaviour of some of the most prominent organisations representing sports medicine professionals. It is difficult to identify a PCECH running shoe in the range by the running-shoe manufacturer ASICS that is not recommended by one or more of the International Federation of Sports Medicine (FIMS), Sports Medicine Australia (SMA) or the New Zealand Society of Podiatrists (PNZ).\textsuperscript{29} If such influential organisations are genuinely committed to evidence-based practice, then in light of our findings such recommendations cannot be credibly made.

This scenario is reminiscent of the controversy surrounding the safety of hydration guidelines endorsed by the American College of Sports Medicine while it was engaged in a commercial arrangement with Gatorade.\textsuperscript{30} It is surprising, given this recent history and the open acknowledgement by FIMS, SMA and PNZ that their footwear recommendations are made as part of sponsorship arrangements with ASICS, that these recommendations have not been questioned previously. Clearly, the fields of running-shoe research and footwear prescription have not yet matured to the point where the evidence base for such recommendations are routinely examined.

Although these broader issues regarding the use of evidence must also be addressed, the core issue remains a lack of data derived from quality clinical trials. Randomised controlled trials measuring clinically relevant outcomes such as running performance and injury rates must be used. Head-to-head trials of existing shoe constructions are urgently required to identify a gold standard distance running shoe design. Once identified, this will be the shoe against which all new designs should be evaluated until a superior alternative is confirmed. For this to occur, a systematic nomenclature for describing the structure of running shoes needs to be developed, with its use insisted upon when papers are reviewed for publication.

Once these steps have been achieved, footwear prescription guidelines can then be developed based on high-level evidence, replacing the current uncertainty as to what shoe type represents optimal care. Complementary evidence-based industry standards should also be developed and implemented in a manner similar to that of other sports protective equipment.\textsuperscript{31} This will ensure that only running shoes with proven benefit can be marketed and sold as therapeutic devices, with the remainder being clearly identifiable as fashion items.

Until these steps are achieved, clinicians will not know whether the distance running shoes they are prescribing are beneficial, harmless or harmful. Given this uncertainty, a

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study subjects</th>
<th>Study factor</th>
<th>Outcome factor</th>
<th>Result</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verhagen \textit{et al}, 2000\textsuperscript{27}</td>
<td>No restriction</td>
<td>Preventative interventions</td>
<td>Ankle sprain</td>
<td>No trials examining running shoes</td>
<td>“High quality” interventional studies published between 1980 and 1998. Language restriction undefined</td>
</tr>
<tr>
<td>Thacker \textit{et al}, 2002\textsuperscript{28}</td>
<td>No restriction</td>
<td>Preventative interventions</td>
<td>Exertional shin pain</td>
<td>No trials examining running shoes</td>
<td>Searches performed in 2000. Non-English language articles may have been excluded</td>
</tr>
<tr>
<td>Rome \textit{et al}, 2007\textsuperscript{29}</td>
<td>Adults with normal bone density</td>
<td>Preventative interventions</td>
<td>Stress fractures of bone, stress reactions of bone (not medial tibial stress syndrome)</td>
<td>No trials examining running shoes</td>
<td>Searches performed in 2004. Randomised and quasirandomised studies only</td>
</tr>
<tr>
<td>Yeung &amp; Yeung, 2007\textsuperscript{30}</td>
<td>Adolescent &amp; adult runners</td>
<td>Preventative interventions</td>
<td>Soft-tissue injury</td>
<td>No trials examining running shoes</td>
<td>Searches performed in 2000. Randomised and quasirandomised studies only</td>
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**What is already known on this topic**

The prescription of PCECH running shoes (shoes with elevated cushioned heels and pronation control features tailored to foot type) is considered best practice when prescribing shoes to distance runners. However, the findings of biomechanical and epidemiological studies continue to call into question the efficacy and safety of this approach.

**What this study adds**

This systematic review found that PCECH running shoes have never been tested in controlled clinical trials. Their effect on running injury rates, enjoyment, performance, osteoarthritis risk, physical activity levels and overall athlete health and wellbeing remain unknown. The prescription of this shoe type to distance runners is not evidence-based.
pragmatic interim approach is required. We suggest the following: (1) that all distance runners should be advised that the ideal shoe type is unknown, (2) that no change should be made to the shoe prescriptions of distance runners currently wearing PCECH shoes and experiencing no ill effects, and (3) that discontinuing the use of PCECH shoes should be considered in runners suffering repeated injuries in spite of structurally normal feet or appropriately prescribed orthotics.

When the prescription of a PCECH shoe is ceased, clinicians must then identify an alternative, again in the absence of evidence from controlled clinical trials. Evolution would suggest that a return to running in bare feet should be the first choice. However in those cases where this is considered either impractical or undesirable, prescription of a non-PCECH alternative is required. In both cases it will be essential that conservative training advice is also provided to protect the athlete from injury while adapting to the marked changes in the biomechanics involved.

**CONCLUSION**

Biomechanical and epidemiological studies have raised significant questions about the capacity of running shoes incorporating either cushioning, heel elevation or subtalar control systems to prevent injury and have identified their potential to cause harm. We identified no clinical trials that assessed the effect of the PCECH design, which incorporates all three of these features, on either running injury rates, running performance, or runners’ global health and wellbeing. Until such evidence becomes available, PCECH running shoes must be considered unproven technology with the potential to cause harm, and thus the prescription of PCECH shoes to distance runners is not evidence-based. As clinicians, researchers and footwear designers, we must now adjust our existing practice accordingly and define our future path via a renewed commitment to evidence-based practice.

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**Competing interests:** CER is a partner in the footwear design company Barefoot on Grass. PJM and RC have no competing financial interests.

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