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Br. J. Sports Med. published online 18 Apr 2008;
doi:10.1136/bjsem.2008.046680

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Is your prescription of distance running shoes evidence based?

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Keywords: running, shoes, athletic injuries, prevention and control, systematic review

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.

Data sources: 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 (1985-May 2007) and AMED (1985-May 2007)

Review methods: English language articles were identified via keyword and MeSH searches of the above electronic databases. Via these searches and the subsequent review process, controlled trials or systematic reviews were sought where 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 wearers foot type and the outcomes measured 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 was identified either directly or via the findings of the six systematic reviews identified which met the study criteria.

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

BACKGROUND

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 lower limb 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] As such, the prescription of the right 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 sub-talar motion have been consistently recommended to footwear prescribers as the gold standard for injury prevention.[2-6] Prescribed on the basis of foot type, over-pronators, mild pronators and supinators are prescribed 'motion control', 'stability' and 'cushion' shoes respectively.[4,6] In the absence of existing nomenclature to describe these shoes as a group, we propose the term 'Pronation control, Elevated Cushioned Heel' (PECH) 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 PECH design.

Cushioning

The use of cushioning in running shoes is based on the following assumptions: 1) that impact forces whilst 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 to itself cause injury is minimal.

The evidence for these assumptions is mixed. That excessive force will result in injury is self-evident.[7] However, the evidence that running on hard surfaces causes either an increase in impact forces or an increase in injury rates is weak.[8-10] The capacity of cushioning to reduce either impact forces or injury rates is also being called into question.[9] 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.[10]

Elevated heel

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

A number of studies have investigated the impact of progressive heel elevation on loading of the Achilles tendon, but with mixed results.[13,14] Furthermore, it has been observed that since the introduction of the PECH design there has actually been an increase, not a decrease in Achilles tendon injuries.[15] Others have demonstrated that heel elevation during stance places the ankle joint in a position where proprioception is inherently poor.[16] The capacity of existing levels of heel elevation to increase pronation has also been noted.[17] Unfortunately, the overall impact 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 sub-talar joint motion is built on the following assumptions: 1) that over-pronation and supination are causally linked to overuse injuries, 2) that promoting limited pronation reduces this risk, and 3) that PECH shoes are an effective means of reducing injuries via this approach.

Sub-talar motion and foot type have not been consistently associated with injury rates in runners.[7,10,18,19] Furthermore, PECH shoes are themselves a relatively ineffective and unreliable means of altering sub-talar motion, causing small and inconsistent changes in alignment.[20] The clinical efficacy of pronation control systems remains untested, with no longitudinal trials having been reported which compare injury rates in runners wearing shoes with and without pronation control systems.[10]

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 a number of studies which suggest 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 is required to rigorously evaluate the direct impact of each of these features on injury rates.

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

A number of authors have commented on the paucity of this high level clinical evidence to support the ongoing use of PECH running shoes.[17,20] However, none have reported a specific systematic review of this literature, nor broadly considered other possible impacts of wearing PECH shoes on runner's health and performance.

METHOD

A series of clinical questions pertinent to the health and performance of competitive and recreational runners were formulated. These questions focus on distance running performance, injury rates, osteoarthritis risk, physical activity levels and overall health and wellbeing and are described in Table 1. The search terms utilised to identify evidence pertinent to each question are also described in Table 1.

Table 1. Review questions and search strategies employed

<i>Review Question</i>	<i>Search terms</i>
Does wearing PECH running shoes improve distance running performance?	Running + shoes + (performance or speed or acceleration or endurance or time or distance)
Does wearing PECH running shoes decrease musculoskeletal injury rates in runners?	Running + shoes + injury + (prevention or etiology)
Does wearing PECH running shoes decrease osteoarthritis rates in runners and ex-runners?	Running + shoes + osteoarthritis + prevention
Does wearing PECH running shoes affect the enjoyment of running?	Running + shoes + enjoyment
Does wearing PECH running shoes improve compliance with prescribed physical activity?	Running + shoes + (exercise prescription or exercise therapy)
Does wearing PECH running shoes improve total physical activity levels?	Running + shoes + (physical activity or physical fitness or motor activity)
What is the overall impact of wearing PECH shoes during running on health & wellbeing?	Running + shoes + (quality of life or mortality or morbidity)

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 (1985-May 2007) and AMED (1985-May 2007). Key word 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 was adult

recreational or competitive runners, the exposure was distance running, the intervention being assessed was a PECH running shoe and at least one of the outcomes listed in Table 1 was measured directly. A control group who ran in non-PECH 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 PECH shoes to prevent injury. Six systematic reviews were identified whose scope included interventions to prevent injuries in runners, or injuries common in runners.[21-26] Two were outdated systematic reviews for which updated versions were identified.[21,26] The details of the remaining four systematic reviews are presented in Table 2.

Table 2. Systematic reviews of interventions to prevent running injury

<i>Reference</i>	<i>Study subjects</i>	<i>Study factor</i>	<i>Outcome factor</i>	<i>Result</i>	<i>Limitations</i>
Verhagen, van Mechelen & de Vente, 2000[22]	No restriction	Preventative interventions	Ankle sprain	No trials examining running shoes	'High quality' interventional studies published between 1980 and 1998. Language restriction undefined.
Thacker et al, 2002[23]	No restriction	Preventative interventions	Exertional shin pain	No trials examining running shoes	Searches performed in year 2000. Non-English language articles may have been excluded.
Rome, Handoll & Ashford, 2007[24]	Adults with normal bone density	Preventative interventions	Stress fractures of bone. Stress reactions of bone (not medial tibial stress syndrome)	No trials examining running shoes	Searches performed 2004. Randomised and quasi-randomised studies only.
Yeung & Yeung 2007[25]	Adolescent & adult runners	Preventative interventions	Soft-tissue injury	No trials examining running shoes	Searches performed in 2000. Randomised and quasi-randomised studies only.

No controlled trials were identified by these systematic reviews in which a PECH running shoe was the intervention tested.

No systematic reviews or reports of original research were found which assessed the impact of the PECH 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 PECH running shoes as a means of preventing the development of osteoarthritis of the lower limb. Nor were any articles found which attempted to assess the impact of the modern athletic shoe on overall mortality, morbidity or quality of life. No studies were identified which evaluated the impact of PECH running shoes on distance running performance.

DISCUSSION

The findings of this systematic review suggest that the true effects of PECH 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 PECH 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.[10,24,25]

If we accept this finding, we are then faced with the realisation that we have been prescribing a therapy without proven benefit for over twenty 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 PECH shoes to prevent injury, the lack of evidence for their use and their potential to cause injury has been raised by a number of authors, including leading authorities in the field.[9,17,27,28]

In spite of these findings, footwear prescription guidelines continue to be published which unequivocally recommend the PECH design.[4,6] That practitioners are being encouraged to base their practice on expert opinion is not inappropriate given the lack of high level evidence. However, 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 sub-group 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 sub-optimal 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 PECH running shoe in the ASICS range 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).[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 which surrounds the safety of hydration guidelines endorsed by the American College of Sports Medicine whilst engaged in a commercial arrangement with Gatorade.[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.

Whilst 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 outcome such as running performance and injury rates must be utilised. Head to head trials of existing shoe constructions are urgently required to identify a gold standard distance running shoe design. Once identified, this is the shoe against which all new designs should be evaluated until a superior alternative is demonstrated. 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.[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 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 PECH shoes and suffering no ill effects, and 3) that discontinuing the use of PECH shoes should be considered in runners suffering repeated injuries in spite of structurally normal feet, or appropriately prescribed orthotics.

When the prescription of a PECH 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.[32] However in those cases where this is considered either impractical or undesirable, prescription of a non-PECH alternative is required. In both cases it will be essential that conservative training advice is also provided to protect the athlete from injury whilst adapting to the significant changes in biomechanics involved.[28]

CONCLUSION

Biomechanical and epidemiological studies have raised significant questions about the capacity of running shoes incorporating either cushioning, heel elevation or sub-talar

control systems to prevent injury and have identified their potential to cause harm. We identified no clinical trials which assessed the impact of the PECH design, which incorporates all three of these features, on either running injury rates, running performance or runner's global health and wellbeing. Until such evidence becomes available, PECH running shoes must be considered unproven technology with the potential to cause harm. As such, the prescription of PECH 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.

WHAT IS ALREADY KNOWN ON THIS TOPIC?

The prescription of PECH 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 PECH 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.

ACKNOWLEDGEMENTS

We wish to acknowledge the support and encouragement provided by all members of the Discipline of General Practice, University of Newcastle, with special thanks owed to Ms Susan Goode.

COMPETING INTERESTS

Dr Richards is a partner in the footwear design company *Barefoot on Grass*. Drs Magin and Callister have no competing financial interests.

FUNDING

Funding for this paper was provided in the form of income support for the first author by the Australian Government, via the Primary Health Care Research Evaluation Development Program.

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