Efficacy of Foot Orthoses

What Does the Literature Tell Us?

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This paper reviews the literature relating to foot orthoses, in particular foot orthoses that attempt to alter biomechanical function. Whilst few well-controlled studies have been performed, the findings from the available literature are generally positive. The authors provide an overview of this literature and then summarise the findings. The literature is categorised into six research outcome areas: (i) patient satisfaction, (ii) pain and deformity, (iii) plantar pressures, (iv) position and motion, (v) muscle activity, and (vi) oxygen consumption. In addition, the difficulties associated with researching foot orthoses are discussed. (Australas J Podiatr Med 32(3): 105-113, 1998) (J Am Podiatr Med Assoc 90(3): 149-158, 2000)

Introduction

Foot orthoses (FOs) have been used for many years with the intention of alleviating symptoms, preventing deformity and enhancing performance. However, most reasoning for their use is anecdotal, with a lack of scientific evidence to support the claims many practitioners make. This lack of evidence will be one of the fundamental issues to confront foot science and the podiatric profession in the coming years. In future, government and other funding agencies will rapidly move towards policies that support modalities backed up by evidence—in reality, this process has already begun. Without this evidence, rebates and support for FOs, particularly more expensive forms of FOs, will be challenged and may be withdrawn, as occurred a few years ago in Western Australia (Personal communication: C Kippen, 5th March, 1998).

To date, there has been a significant volume of literature published relating to FOs. Much of this literature supports their use, however there is a considerable amount that is either inconclusive or refutes their effect. Whilst this is confusing, the results can be directly attributed to the different methodologies used by the authors and the varying quality of the research. To counter this situation two steps need to be taken. Firstly, it is essential that there is further well-controlled research which evaluates orthoses under specific conditions—this is stating the obvious. Secondly, systematic and critical reviews of the literature relating to FOs are also required to assist practitioners and decision-makers in understanding and assimilating the available findings.

It is the intention of this article to review the available literature and summarise the findings. As there are few well-controlled studies available on the efficacy of FOs, this review contains those articles that have met the following criteria: (i) they have researched FOs that have attempted to alter the biomechanical function of the foot, (ii) they have attempted to use an established research protocol, appropriate with the time of the study, (iii) they have been published in a peer-reviewed journal, or for earlier studies been subjected to some type of editorial process, and (iv) they have been published in the English language. However, before beginning this review, it is important to discuss the difficulties associated with researching the effects of FOs.

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Difficulties in Researching the Effects of Foot Orthoses

Due to the nature of orthotic therapy, literature evaluating its effectiveness has often been dismissed as inappropriate due to its lack of methodological rigour. Criticisms include the variable nature of the patient profile; the orthotic prescription; the manufacture of the device; and the measured outcomes. It is tempting to use these criticisms to either accept or reject findings depending on the reader's particular philosophy. Further, it is easy to dismiss a study's findings as not valid due to differences between the protocol in the study versus the clinical situation. This is a consistent criticism of clinically based research and offers a good example of the conflicting nature of research outcomes versus clinical outcomes. It is necessary in clinical research to attempt to control all variables to allow appropriate inferences to be made at the conclusion of the study. Without this safeguard, findings from the research will always be questionable.

A key point to evaluate any research is to not only evaluate its strengths and weaknesses, but, more importantly, its contribution to the knowledge on that particular topic. Most research, if carefully planned, will contribute in some way to what we know about a given topic. If the greater body of research literature is suggesting a certain finding, then it can usually be accepted that the finding bears consideration. It is short-sighted to denounce single research articles because they have small flaws in their protocol, when the research, taken as a whole, is suggesting something different.

How Are Foot Orthoses Evaluated?

Evaluation of FOs can be undertaken using several different methodologies. Whatever methodology is used is generally dependent on the philosophies of the investigators. The methodology used by a podiatrist may be different from an orthotist or biomechanist, for example.

One aspect of the methodology used in research is the outcomes that are measured. The following outcomes have been used previously in foot orthotic research:

(i) *patient satisfaction*
(ii) *pain and deformity*
(iii) *plantar pressure*
(iv) *position and motion*
(v) *muscle activity*
(vi) *oxygen consumption*

Critical evaluation of this research is necessary to establish the role of FOs in patient management. Each one of the above outcome areas will now be reviewed.

(i) Patient Satisfaction

There have been four patient satisfaction surveys conducted on FOs. Blake and Denton (1985) in a retrospective survey of 180 people with athletic injuries found that 70% indicated their orthoses had "definitely helped". In addition, 78% "felt that their posture had improved by wearing orthotic devices". Donatelli et al. (1988) surveyed 81 people retrospectively, finding that 91% of patients were satisfied with their orthoses. Ninety-four percent of patients were still wearing their FOs at the time of the survey and 52% indicated they "would not leave home without them". Gross et al. (1991) surveyed 500 long-distance runners who had been prescribed "orthotic shoe inserts". They found 76% reported complete resolution or great improvement of their symptoms, and that 90% continued to use their orthoses even after their symptoms had disappeared.

More recently, Moraros and Hodge (1993) conducted a prospective survey on 523 people receiving FOs with 83% indicating they were satisfied with their orthoses. Further, at 14 weeks post-issue, 95% reported their problem to be completely resolved or partially resolved (63% completely resolved).

Although these results are promising, there are certain methodological issues that are liable to be criticised. For example, the first three studies were retrospective surveys, and none controlled for the use of other modalities (eg. ice, physical therapy) or randomised groups to compare the effectiveness of orthoses relative to other modalities. However, in summary it can be concluded that from these studies patients are generally very satisfied with their orthoses.

(ii) Pain and Deformity

Assessing pain reduction or limitation of deformity are obvious outcomes to measure with FOs, however there have been few well-controlled trials to date. The studies performed so far have shown variable findings, with some indicating FOs to be beneficial in certain conditions, whilst others suggest they are not. Much of this research has been conducted on specific conditions, with no one area receiving great attention.

More broadly, however, the effect FOs have on pain has been assessed in a number of projects. In a descriptive study, "custom-fitted" FOs with metatarsal padding were shown to relieve sesamoid pain in 8 out of 10 patients (Axe and Ray, 1988). A further study assessed 40 patients complaining of plantar fasciitis/heel spur syndrome (Ferguson et al., 1991). The authors found that 34 out of the 40 felt their symptoms improved with FOs. Again, both these studies did not control for the concomitant use of other modalities, nor did they compare FOs to other forms of treatment. However, a recent well-controlled study assessing the effects of "functional" FOs on plantar fasciitis did compare treatments (Lynch et al., 1998). In this randomised prospective study, functional FOs were found to be more effective than anti-inflammatories (corticosteroid injection plus NSAIDs) or a viscoelastic heel cup in decreasing pain and impact on lifestyle.

In addition, two other studies have compared FOs to other treatments. Firstly, Thompson et al. (1992) surveyed 64 people with pedal osteoarthritis and found FOs "made by prescription" provided a significantly longer period of pain relief than nonsteroidal anti-inflammatory drugs alone. Secondly, Saggini et al. (1996) assessed the effect of heel lifts versus "dynamic insoles" on myofascial trigger points in the peroneus longus muscle in patients with an anatomical leg length discrepancy. The group that received "dynamic insoles" experienced a marked, significant reduction in pain after 7 days, with complete resolution of pain at 30 days. Although the number of participants in this study was small (6 per group), the authors concluded that correction of foot biomechanics with "dynamic insoles" was a far more important factor than correcting the anatomical leg length discrepancy.

There has also been a long association with FOs and knee pain. In a recent retrospective study on 102 patients it was found that "semiflexible functional" FOs were significant in reducing symptoms associated with patellofemoral pain syndrome (Saxena and Haddad, 1998). However, again, the authors did not control for use of other treatment modalities. In addition, as there was no control group it is difficult to make strong inferences as the patients may have improved with no treatment at all. This is a flaw with much of the early clinical research relating to FOs—research that contains a control group which does not receive the treatment in question is far more credible. In addition, a double-blind protocol, where the participant and the assessor are unaware of the true nature of the treatment, further aids the credibility of the findings. Although this is problematic when dealing with FOs as it is difficult 'blinding' the patient as to whether or not they have devices in their shoes.

There have been a few exceptions that have used control groups. These have included the effects of FOs on skin lesions in people with diabetes and leprosy, and the effects on pain and deformity in rheumatoid arthritis. Colagiuri et al. (1995) assessed the effects of "functional" FOs on callus size in people with diabetes. They found the FOs used in their study significantly decreased plantar callus in people with diabetes. Similarly, Cross et al. (1995) found that "podiatric" FOs significantly improved the healing rate of plantar ulcers in people with leprosy. Although primarily palliative orthoses, the devices included a "filler pad incorporating a valgus dome" under the talonavicular area and forefoot wedging to accommodate participants with a forefoot valgus deformity.

By far the most well designed study, however, looked at the effect of FOs on pain and disability in people with rheumatoid arthritis (Conrad et al., 1996). This study used a randomised, double blind methodology—the placebo was a thin Naugahyde shoe insert. It found that "functional posted foot orthoses" had no benefit over placebos in modifying pain and disability in the participants. Interestingly, patients who used their orthoses for the most time (both functional and placebo) experienced less pain and disability.

Of equal importance, however, is that further research by these authors (Budiman-Mak et al., 1995) found that "functional foot orthoses" can prevent or slow the progression of hallux valgus deformity in rheumatoid arthritis. In contrast to this positive outcome, a similar well-controlled trial found that "biomechanical" FOs significantly increased the rate of hallux valgus progression in children (Kilmartin et al., 1994). This particular study has created much debate in the podiatric profession.

Other areas that FOs have been assessed include stress fractures and balance. Simkin et al. (1989) assessed the effects of FOs on stress fractures in military recruits. They found the "Langer military stress orthotic" significantly reduced the incidence of metatarsal stress fractures in low-arched feet and femoral stress fractures in high-arched feet. Orteza et al. (1992) assessed the effects of "molded and unmolded" FOs on pain and balance in people with and without acute ankle sprains. They found that molded FOs significantly decreased pain during jogging, as well as improving balance, in the injured group. In contrast, the unmolded FOs had no effect on pain or balance.

Whilst most of this research has assessed the effects of 'functional' or 'custom-moulded' orthoses, more research is needed to compare less expensive devices to 'functional' or 'custom-moulded' FOs (less expensive devices include simple wedging and prefabricated insoles). It may be that less expensive devices have similar outcomes to more expensive FOs. To ensure clinicians are providing maximum benefit to patients at the minimum cost, these comparisons are needed.

Limited studies have already been performed using less expensive devices. For example, Sasaki and Yasuda (1987) assessed the effectiveness of a wedged insole (lateral heel/valgus wedge) in reducing symptoms in patients with osteoarthritis of the medial knee joint. For those patients with mild osteoarthritis, the wedged insole significantly reduced pain compared to a control group. The authors felt the insole was an excellent means of conservative treatment for mild osteoarthritis of the medial knee. Whilst not assessing orthoses made from a cast of the foot, this study highlights the effect of simple wedging on reducing pain in the lower limb.

In contrast to this finding of a reduction of pain in mild knee arthritis, a more recent study assessed the effect of wedging on neuroma pain (Kilmartin and Wallace, 1994). Using hard, compressed felt, the foot was either pronated or supinated to assess the effect of foot position on neuroma pain. There was no significant difference in pain between pronating and supinating the foot. In addition, pronating the foot caused no significant development of other lower limb symptoms. The results from this study suggest that aspects of FOs other than changing frontal plane position of the rearfoot, may decrease neuroma pain.

Therefore, simple inexpensive orthoses may have a role in reducing pain in certain conditions (eg. mild knee arthritis) but not in others (eg. neuroma pain). As previously mentioned, this raises the question of the effectiveness of expensive FOs versus less expensive methods of reducing symptoms, such as simple wedging or cheaper prefabricated devices.

McCourt (1990) has also assessed this issue by comparing the effectiveness of FOs made from a cast of the foot and those that were not. He found that there was no significant difference in reducing symptoms between a group that received casted FOs and those that received FOs not made from a cast. Both groups had orthoses made from 6mm polyethylene. The overall results showed that 96% of the patients studied indicated that their symptoms had totally or substantially improved. However, as there was no statistical difference between the groups, the cost and time associated with casted orthoses, compared to non-casted orthoses, needs to be questioned. Although the group sizes were too small to make major inferences from this study the results suggest further research is warranted. This issue of cost effectiveness is not new with Sperryn and Restan in 1983 raising similar questions. They noted in their series of 50 athletes, that although two thirds benefited from FOs, only half of the participants continued long-term use of the devices.

In summary, it is clear that FOs generally have a positive impact on pain and deformity in the feet. It would appear that general musculoskeletal disorders respond well to orthoses, particularly when pain reduction is assessed. There are a few exceptions, however, where FOs have been shown in the research so far to either have no significant effect (on pain and disability in rheumatoid arthritis) or a detrimental effect (on hallux valgus in children). Whilst there has been a great deal of research in this area, very little of the research has been well-controlled, therefore the findings need to be viewed with some caution. Finally, further research is needed to compare treatments, particularly expensive versus less expensive FOs, such as prefabricated insoles and simple wedging. In future, outcomes research will play a key role in determining the cost benefit of FOs.

(iii) Plantar Pressure

In the past ten years the use of sophisticated machinery to measure plantar pressures, as well as centre-of-pressure, have become popular. Instruments such as the F-Scan, emed/pedar, Musgrave, Electrodynogram (EDG) and Kistler force platform are now widely used in the assessment of foot function.

Changes in centre-of-pressure (COP) have been measured in a number of studies. Firstly, McPoil et al. (1989) assessed the effects of FOs on the COP in 18 females with forefoot deformities (nine with forefoot varus and nine with forefoot valgus). Orthoses used in this study were described as “rigid, semi-rigid and soft”. The results indicated that in the varus group, only the shoes significantly reduced the COP area. Whereas in the valgus group, the shoes only, and all three types of orthoses reduced the COP area compared to the barefoot condition, however there was no significant difference between the different types of orthoses. Based on the COP data, the authors suggest that orthoses have no benefit over footwear with good rearfoot stability for women with a forefoot varus deformity. In contrast, those women with a forefoot valgus deformity would benefit from orthoses as well as stable footwear.

Scherer and Sobiesk (1994) also assessed the effects of ‘functional’ FOs on the COP in 18 participants. They found the COP shifted laterally in 92% of participants whose COP index (area lateral to the COP divided by the area medial to the COP) was initially medially displaced. However, the method to determine the COP index in this study may be quite error prone—the method involved printing the footprint with the COP marked onto paper then cutting the footprint along the COP line and weighing the medial and lateral sections of paper. A further study found a similar lateral shift in the "instant centre of force" with "medial arch supports", however testing was only performed on five participants (Scranton et al., 1982). In contrast, Miller et al. (1996) found no change in the COP, although they did find "functional" FOs reduced both vertical and anteroposterior ground reaction forces in the early stages of the stance phase of gait. Analysing the effect of FOs on COP still appears to be in the experimental stages as the clinical meaning of COP is yet to be determined. However, there is the possibility that once the normal COP has been determined, and if it is deemed important, then FOs may be used to move an abnormal COP towards a normal COP.

Other than COP changes, the effect of FOs on temporal parameters and peak pressures has also been studied. Bennett et al. (1996) assessed the effect of FOs on 22 participants. Using "Root-type" FOs they found the lateral border of the foot reached maximum peak pressure 5% to 7% earlier in the stance phase of gait, and conversely the medial border reaches maximum peak pressure later. In contrast to these findings, Cornwall and McPoil (1997) assessed the effect of FOs on the initiation of plantar surface loading in 10 healthy volunteers. They used two different types of orthoses: a "rigid" style and an "accommodative" style. The rigid device was a prefabricated orthosis that was modified using a heat gun so as to be comfortable, then forefoot and rearfoot wedges were applied. They found the medial forefoot was loaded significantly earlier with the rigid orthosis compared to the other conditions of shoe only, and soft orthosis. Unfortunately, Cornwall and McPoil made no reference to the study by Bennett et al. (1996). The differences may be accounted for by the fact that Cornwall and McPoil divided the foot into seven distinct areas to assess plantar pressures. In addition, they used relatively "normal" participants, whereas Bennett et al. used participants with a previous history of foot and leg problems.

A further study also found that FOs ("Root" and "Blake inverted" style) significantly affect temporal parameters of gait (Reed et al., 1996). Midstance was shortened by 6-8% and the propulsive phase was lengthened by 6%. The orthoses also shortened the duration of pressure loading beneath the heel and forefoot. Interestingly, the 'Blake inverted' orthoses demonstrated a significantly longer duration of loading under the medial heel and the fifth metatarsal compared to the Root style orthosis.

Aside from temporal parameters, four recent studies have assessed the reduction in plantar pressure of different orthotic designs. Novick et al. (1993) demonstrated a significant reduction in plantar pressures using a "rigid relief orthosis", suggesting this style of orthosis could be used for the insensate foot. In addition, Albert and Rinoie (1994) specifically studied the effects of "custom" FOs on people with pronated feet and diabetes. Similarly, they found a significant decrease in plantar pressure under the first metatarsal head, suggesting this type of orthosis would be beneficial for insensate feet. Further, Hodge et al. (1997) demonstrated a "custom" FO with a metatarsal dome was the most effective at reducing forefoot plantar pressures in 12 people with rheumatoid arthritis and metatarsalgia. In addition, this style of orthosis also reduced pain most effectively. Finally, Postema et al. (1998) found that "custom moulded insoles" reduced the force impulse by 10.1% and the peak pressure by 18.2% in the central distal forefoot in participants with metatarsalgia. An interesting finding, however, was that a "rockerbar" had a similar effect.

Two single subject experimental design studies have also been performed assessing the effect of FOs on plantar pressures. As acknowledged by the authors, it is difficult to make generalisations from a single subject design. McPoil and Cornwall (1991) assessed the effect of soft FOs on forefoot and rearfoot forces. They found the orthoses significantly reduced vertical force during both running and walking. The second study found that the force-time integral was reduced by using FOs (Cornwall and McPoil, 1992). However they also tested orthoses with and without rearfoot varus wedging, finding the wedging had no significant effect on forefoot plantar pressures.

Finally, the effects of orthoses following surgery have also been studied. Stuck et al. (1988) assessed the effects of "functionally posted foot orthoses" on hallux pressures following surgical treatment for hallux rigidus. Although only six patients were tested, it was found that orthoses returned the duration of pressure under the hallux to a more normal level (as a percentage of the stance phase). This, the authors suggest, indicates the hallux was purchasing the ground more effectively following the surgery.

Although research in this area is relatively new, the amount of studies using this equipment is growing rapidly. When the parameters measured by this type of equipment, such as changes to the COP, are more fully understood, the effects FOs have will also become easier to understand. However, it is quite clear from the research so far that FOs have a significant impact on plantar pressures.

(iv) Position and Motion

The area of research relating to alteration of position or motion with FOs has received by far the most attention. This, more than likely, has occurred as the majority of research has been conducted by orthopaedists, biomechanists, podiatrists and physical therapists who generally place great importance on these measures. Most of these studies involve use of radiographic measurement or kinematic data, such as 2-dimensional motion analysis.

Radiographic assessment of static foot position received attention in the 1970's and 1980's. Mereday et al. (1972) found that although the UC-BL device decreased pain and improved gait in children, they did not achieve lasting structural changes. Further, Penneau et al. (1982) assessed the immediate effect of different types of FOs and demonstrated no significant change in x-ray appearance of feet in children with flexible pes planus. In contrast, Bordelon (1980) found that a 'custom-molded insert' (UC-BL type) corrected the talometatarsal angle in children at a rate of approximately 5 degrees per year. However, although this result conflicts with the previous two studies, the findings from a more recent prospective study may be far more important (Wenger et al., 1989). In this study, children with flexible flatfeet were assigned to one of the following experimental conditions: (i) no treatment/control group, (ii) treatment with corrective orthopaedic shoes, (iii) treatment with a Helfet heel-cup, and (iv) treatment with a "custom-molded plastic insert". The results from radiographic assessment indicated there was no significant difference between the groups—all groups demonstrated improvement in the radiographic measurements, even the control group. Therefore, with regard to influencing growth of the child's foot, it may not matter what type of treatment is employed, or if any treatment is employed at all. This is a highly contentious issue and one that requires further research.

Apart from a few studies, which will be dealt with later in this section, most other research has generally used 2-dimensional motion analysis. Kilmartin et al. (1991) demonstrated "modified Root orthoses" restricted 1st metatarsophalangeal joint dorsiflexion, thereby suggesting they could be useful to decrease pain in hallux limitus. On the other hand, if this restriction was to be avoided, he suggested a cut-out underneath the 1st ray. This would allow the 1st ray to plantarflex and therefore encourage increased 1st metatarsophalangeal joint dorsiflexion in the case of a normal joint or one that was experiencing functional hallux limitus. This aspect of orthotic therapy has also been discussed by Anthony (1991), Dananberg (1993a; 1993b) and Root (1994).

'Functional' FOs have also been shown to significantly reduce the amount and rate of pronation in walking (Novick and Kelley, 1990; McCulloch et al., 1993) and running (Bates et al., 1979; Smith et al., 1986; Baitch et al., 1991; Novick et al., 1992), although Rodgers and Leveau (1982) contradict these results, suggesting they have questionable effects in running. In addition to decreasing rearfoot pronation, certain FOs have also been shown to decrease internal tibial rotation (Cornwall and McPoil, 1995; Nawoczenski et al., 1995). This is not surprising given the coupling effect of the subtalar joint between the lower leg and the foot, and is an important finding in relation to the patellofemoral joint. For many years now a link has been suggested between abnormal subtalar joint movement and patellofemoral joint function.

Due to this, the effect of FOs on the patellofemoral joint has begun to receive attention. Eng and Pierrynowski (1994) demonstrated "soft orthotics" with wedging could change the transverse and frontal plane motion of the foot and knee during running and walking. In addition, a recent study found that semirigid rearfoot posting significantly changed patella alignment (with the patella moving medially) in participants with excessive rearfoot pronation (Klingman et al., 1997).

The effects of external forefoot and rearfoot posting of FOs has also been investigated, with most authors agreeing that posting has a limited effect on foot position. Johanson et al. (1994) found that both posted and unposted FOs decreased maximum pronation. However, if posting was to be used there was no difference in a combination of forefoot and rearfoot posting compared to rearfoot posting alone. In addition, Blake and Ferguson (1993) found that while rearfoot posts are valuable in decreasing initial pronation velocity, they felt these posts have a limited effect on rearfoot and tibial position. Furthermore, Tollafield and Pratt (1990) suggest externally posting the rearfoot more than four degrees may actually increase pronation as the foot rotates on the device.

Finally, the effect of different FOs on the plantar fascia has also been studied (Kogler et al., 1996). Using cadavers, this study found that the UC-BL and two other "custom-moulded" orthoses reduced strain in the plantar fascia, while the "functional foot orthosis" did not reduce strain. In addition, a further in vitro study by Kogler et al. (1998) found that lateral forefoot wedges decrease strain in the plantar fascia, whilst medial forefoot wedges increase strain. This research by Kogler and colleagues obviously needs to be viewed in the context of the dead 'participants', however it has already challenged previous held beliefs and may provide some answers for future directions of orthotic therapy.

In summary, FOs have been shown to have an effect on position and motion in the foot and lower extremity, particularly the amount and rate of pronation. However, the research on more static measures, such as x-ray angles, is less convincing. With the recent advent of 3-dimensional motion analysis, further research on the effects of FOs on position and motion will continue. It is important to note, though, views on the mechanism of action of FOs may need to be altered in the future as more information becomes available that challenges traditional held beliefs.

(v) Muscle Activity

There has only been one study to date on the effects of FOs on electromyographic (EMG) activity of muscles in the leg (Tomaro and Burdett, 1993). This study specifically assessed the change in EMG activity (using surface EMG) with and without FOs in the tibialis anterior, peroneus longus and gastrocnemius muscles. There was a statistically significant increase in the duration of tibialis anterior activity following heel strike in the orthotic condition, and no change in the other two muscles tested. Although EMG output is difficult to interpret, this study suggests further research using this tool is warranted. In particular, it would be interesting to examine the effect of FOs on the tibialis posterior, although this muscle is difficult to access with EMG.

(vi) Oxygen Consumption

There have been a number of studies performed on the effect FOs have on oxygen consumption (oxygen consumption is one measure of metabolic efficiency). An early study by Hennacy (1973) tested oxygen consumption whilst walking in 10 students who experienced foot problems. He found only 3 out of 10 showed an improvement in oxygen consumption with the FOs. In all participants there was an initial increase in oxygen consumption, indicating the orthoses were having a negative effect, however after 3 months the consumption fell back to or below normal in the 3 cases that showed improvement. Further studies by Hayes et al. (1983) and Burkett et al. (1985) demonstrated significant increases in oxygen consumption in runners using FOs, suggesting FOs have a negative effect on oxygen consumption.

In contrast to these negative results, Berg and Sady (1985) studied 15 healthy male students, who had been running at least 25 miles per week for the past 6 months. They found no significant difference in oxygen consumption between the FOs condition and the no FOs condition. However, rather than using "functional" FOs, this study used Sorbothane insoles. Further to this, a positive effect was found by Otman et al. (1988) who measured a decrease in oxygen consumption in people with flat feet when they walked with "arch supports".

Further research has been conducted on cyclists. Hice et al. (1985) demonstrated oxygen consumption reduced when participants used "functional" FOs whilst cycling. Whilst Anderson and Sockler (1990) found no significant difference when using similar FOs. Differences in protocol can explain the differing results (Hice et al. did not use toe clips in their study).

Although most of these studies show a negative effect when walking or running, they generally confer with research on limb mass and footwear, which show an increase in the weight of a limb causes an increase in oxygen consumption (Myers and Steudel, 1985). This suggests the improvement in biomechanical efficiency with the FOs in these studies was outweighed by the negative effect of the weight of the FOs. It would therefore appear from the research to date, that FOs have a limited role in improving oxygen consumption in walking, running and cycling. Further research is needed in this area, particularly with larger numbers of participants and comparing some of the newer, lighter materials used in fabricating FOs that have been developed more recently.

Summary

Many studies have been published which attempt to evaluate orthotic therapy. Whilst these papers have included results which are generally quite supportive of FOs, some have found either inconclusive or negative results. This review of the current literature, therefore, highlights the inherent difficulty in establishing the broad use of orthotic therapy in clinical practice. Much of the research to date could be improved upon, and from this perspective it is clear that further randomised controlled trials assessing outcomes for specific clinical conditions are necessary.

It is essential that those involved in foot science are aware of these current research findings, as well as the problems associated with researching in this area. By being aware, podiatrists will be able to negotiate with relevant stakeholders, such as health insurance companies, from an informed perspective. Most importantly, however, podiatrists who are up-to-date with current research will enhance their management of patients who may require orthotic therapy.

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Additional References

Editor's Note: The following references have been appended to the article by the authors for publication in conjunction with this reprint. Some of these references appeared only after the original publication of the article. The authors intend this list to update the reader on available sources of information on the topics discussed in the article.

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Comment

Editor's Note: Following the original publication of this article, one of the authors (K.B.L.) had personal communication with Dr. Timothy E. Kilmartin regarding one of his studies referenced in the article. The following comment was subsequently commissioned from Dr. Kilmartin for publication in conjunction with this reprint.

To the Editor:

I congratulate Karl Landorf on presenting such a comprehensive review of the efficacy of in-shoe orthoses. I note that he states in the article that in a controlled trial carried out by Kilmartin et al[1] on children with juvenile hallux valgus, the orthoses significantly increased the rate of hallux valgus progression. This is not quite accurate, and I would like to clarify my findings in that study.

Over the 3- to 4-year period of the study in question, hallux valgus worsened significantly in both the control group and the group treated with custom-made foot orthoses. The deterioration in the treatment group was not significantly greater than that in the control group. It is probably more accurate to state that, on the basis of this study, custom-made foot orthoses do not appear to prevent the progression of hallux valgus in children.

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