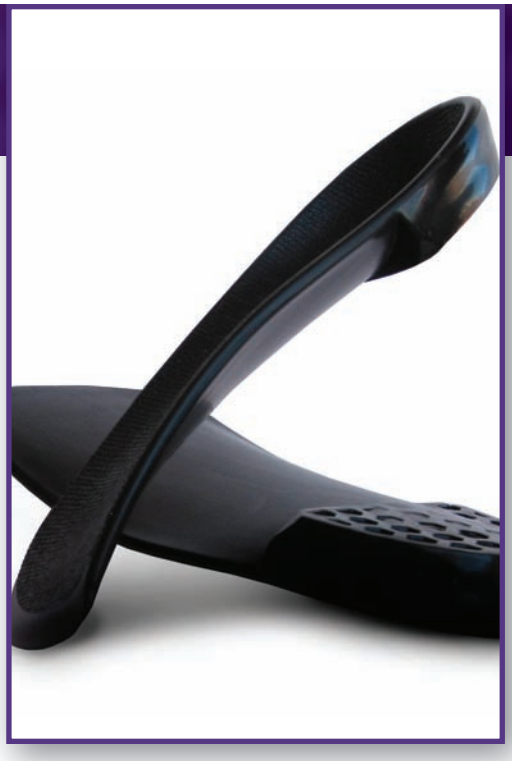
10

Prefabricated Functional Foot Orthoses: Validity and Efficacy



THE WORLD OF orthotic therapy and foot biomechanics was somewhat shaken when a randomized controlled study published in 2006[1] found that custom foot orthoses (CFO) and prefabricated foot orthoses (PFO) used in the trial had a similar effectiveness in the treatment of plantar fasciitis. There was, of course, a great deal more to that study than the one sentence, but it certainly stimulated discussion, within podiatry and orthopedic surgery, concerning the value of custom orthoses as compared to prefabricated devices.

Four relatively recent trials compare prefabricated and custom orthoses relative to plantar fasciitis.[1-4] It is quite exasperating to experience the huge difference between the successes of custom orthoses versus prefabricated ones in clinical practice and then to look at the research statistical analysis that demonstrates a minor difference between the two devices. Could it be that in plantar fasciitis it requires only the slight adjustment to foot joint motion that is offered by prefabricated orthoses to attenuate the pathomechanics? Is there a similar positive effect in pathologies such as hallux limitus, overpronation, adult acquired flatfoot, neuroma, and various sports medicine injuries?

These studies and data, comparing custom to prefabricated foot orthoses in only plantar fasciitis, are insufficient to draw any legitimate medical conclusion, particularly regarding the overall legitimacy of orthoses

A huge variety of materials, densities, sizes, shapes, flexibilities, and designs are available for prefabricated orthoses.

in other foot pathologies. The research is even more difficult to interpret due to the variety of casting, imaging, and manufacturing techniques for custom orthoses as well as the almost infinite variety of prefabricated devices that are used in these studies, which represent a large selection of materials, shapes, and flexibilities.

The purpose of this chapter is to review the literature that evaluates the effect of various prefabricated orthoses on certain foot pathologies and then try to assess the anecdotal evidence, logical deductions, and opinions that might give the clinician who use prefabricated orthoses an idea of which criteria should be used to select them. Lastly, recommendations and opinions will be made for the indications, contraindications, and desirable characteristics for PFO use, specifically for plantar fasciitis.

Defining the Orthotic Device

Discussing PFO becomes very complicated because of terminology. What is the difference between an arch support and a prefabricated foot orthosis? Is a soft prefabricated foot orthosis in the same category, and does it have the same indications as a semirigid one? How do we distinguish an accommodative prefabricated foot orthosis from a functional one?

This chapter, for the purpose of clarity, will set some parameters for the PFO discussion:

1. Soft prefabricated devices will be mostly avoided in the debate. These soft devices do have a place in patient care, especially in lowering forefoot pressure peaks, and therefore helping to avoid potential problems, as, for example, in the diabetic foot.
2. The terms "accommodative" and "functional" will be used in reference to the PFO by the intent of the device. An accommodative PFO device is designed not to change the morphology of the weight-bearing foot but rather to alter the pressure under the foot without intentionally altering the motion of the foot. A functional PFO device is designed to alter the motion *and* morphology of the foot by changing either the ground reaction force (GRF) under the foot or the progression of the center of pressure plot through the foot.
3. The term "arch support" will be avoided unless referenced in one of the cited articles and will always be assumed and classified as accommodative.

Prefabricated orthoses should be made of durable material and have sufficient rigidity to not alter shape quickly. A moderately deep heel cup, close sizing, and a rearfoot post are recommended.

There has always been the question as to whether prefabricated orthoses could actually accomplish anything significant, since their shape did not match exactly the morphology of a particular patient's foot. A 1997 cadaveric experiment attempted to report whether a prefabricated semirigid device could alter arch height or foot joint motion. The researchers established first that foot joint motions consistently moved in their apparatus as measured by a magnetic tracking device in 14 subjects when a load similar to weight-bearing was applied. When they added the orthoses and applied the same load, they discovered that the orthoses improved stability in the arch and statistically significantly decreased the motion in the direction of eversion of the subtalar joint. The devices used were nylon combined with cork and one of polyethylene. Both devices performed similarly.[5]

A study performed at the University of Teesside in England[6] compared the effectiveness and cost of accommodative prefabricated devices to functional prefabricated devices. The researchers found no significant difference in reducing pain related to the knee, ankle, heel, arch, and the first metatarsophalangeal joint between

two groups that received one or the other device. Both devices were made from 6 mm polyethylene. Ninety-six percent of the patients, when grouped together, indicated that their symptoms either substantially improved or were totally relieved when evaluated in terms of alteration to their presenting symptoms. This is a good testament to functional orthoses in itself. However, there was no statistical difference between the improvement in the prefabricated and custom groups. Does this mean that semirigid devices are effective and that it does not matter which orthosis, prefabricated or custom, is used? This conclusion must be evaluated more closely in the future.[7]

Also this article further evaluated the difference in the cost of the two devices, since the results in this particular situation seemed to indicate that both were effective. The less expensive prefabricated device, converted to about US $12, had a 69% attrition rate from the study because of possible discomfort or poor shoe fit. The more expensive custom device (US $69) had less than a third of that attrition rate. What good is an orthotic device that works if patients will not wear it? The more expensive device in this study was more efficient and, therefore, more effective.

One of the most interesting studies discussing the effect of the PFO versus the CFO was performed at Emory University in 1995.[8] The authors used definitions of accommodative versus functional orthoses, similar to those used in this text, and placed arch supports within the accommodative category. The researchers provided a thorough history and review of the literature of previous studies that compared soft accommodative orthoses to rigid or semirigid "biomechanical" orthoses. The study evaluated the effect of custom and prefabricated orthoses compared to no orthoses by evaluating three parameters: maximum pronation, calcaneal eversion, and speed of pronation.

The study design was intended to repute a previous podiatry investigation performed in 1986 that evaluated similar parameters.[9] The patients in the 1995 study, when wearing just a shoe, had the greatest maximum pronation, maximum pronation velocity, and calcaneal eversion of the three groups. The subjects were then tested with prefabricated foot orthoses and custom foot orthoses. Surprisingly, the maximum pronation velocity was lowest for the PFO, and the total degrees of pronation were less in the PFO than in the CFO. The more significant conclusion concerning custom orthoses in this study was that the time measured to get to the maximum pronation point and maximum eversion point of the heel was less in the custom orthoses, compared to a prefabricated device or just the shoe.

This conclusion was supported by another study that also measured the rearfoot kinematics of patients wearing custom and prefabricated devices.[10] The custom device significantly decreased eversion velocity, while the modified prefabricated device showed a trend toward reducing total degrees of eversion excursion. Unfortunately, we do not know which one of these parameters—speed of pronation, time to maximum pronation, or amount of eversion—is important in reducing symptoms in patients. Contemporary thought, although

never proven, is that the amount and speed of pronation are what produce the pathomechanics and symptoms. Current biomechanical thought also tells us that the amount of calcaneal eversion is directly proportionate to the forefoot symptoms and deformity.[11] This CFO/PFO comparison study has inconsistencies in the methods used to manufacture custom foot orthoses and uses only one of a large family of prefabricated devices. The two studies that compare motion control between CFO and PFO need to be repeated, this time with greater attention paid to the possible variables than those contained in these papers.

The comparison between custom and prefabricated foot orthoses remains a popular topic in the medical literature. A paper from the U.K. described an experiment in which 15 flat-footed patients between 18 and 45 years of age were again given both types of orthoses. An in-shoe measuring device was used to compare the force and force time integrals in the medial and lateral forefoot when wearing different devices. When compared to the no-orthoses situation, both devices reduced the forefoot pressure by shifting the forces to the midfoot. The customized device offered only minor benefits, which were not statistically significant, over the prefabricated device.[12]

The issue of prefabricated foot orthoses and high-heeled dress shoes has also been hotly debated among both the orthopedic and podiatric professions for the past several decades. A study group used pressure mapping in an effort to determine the value of prefabricated foot orthoses in shoes with heels ranging from 1 cm to 7.6 cm. The researchers also attempted to determine foot comfort subjectively, with and without the devices. They found that the higher the heel, the higher the impact for forefoot pressure and discomfort. They also discovered, however, that the prefabricated devices reduced medial forefoot pressure and improved comfort. The impact force on the medial forefoot was reduced significantly, by 33%, by adding the device to the shoe.[13]

Another study, performed at the University of Delaware in 2008,[14] examined the differences between PFO and CFO in rearfoot motion during walking and orthosis comfort. Two similar devices were dispensed to 19 subjects: one was a custom device fabricated from a corrected plaster cast; the other was a prefabricated device selected for size and shape by measuring the plaster cast. This is a unique technique used by one U.S. orthotic laboratory to reduce device costs. Both devices were made of the same material. A blind test was performed regarding the type of orthosis.

The subjects were tested with kinematic methods three separate times: with no device, with a custom device, and, finally, with the unique prefabricated device. The custom device showed slight but statistically significant greater rearfoot control than the prefabricated device. Additionally, the custom device was judged to be more comfortable than the prefabricated device. Comparisons of comfort were made only between the orthotic groups and not the nonorthotic group. Again, it is important to remember that even a skived felt pad in the shoe will change kinematic measurements in the rearfoot, and that these changes may have no relationship to pathology or symptoms.

So far, we know that there is a huge variability in methods and materials, which makes evaluating the difference between the CFO and PFO very difficult. We also know that at least some semirigid prefabricated devices do seem to limit pronation and calcaneal eversion almost as much as custom devices do. What we do not know is what effect this has on possibly improving the foot function to reduce pathology and control symptoms.

Some custom orthoses are designed by their cast correction technique and unique casting position to produce a higher arch and plantar flexed first metatarsal, resulting in a device that creates greater pressure in the arch. Such a device is commercially identified as a full-contact custom foot orthosis. This device was compared to a more traditional PFO made from similar semirigid materials in 42 participants and evaluated with a numeric rating scale for pain of various lower extremity symptoms. The full-contact device provided statistically significant greater pain relief than the prefabricated device, but only after just three weeks of the test.

A 2000 article from the University of Western Sydney[15] acknowledged that a systematic review of the literature concerning functional orthoses was necessary to assist practitioners in understanding and assimilating the available evidence about them. They skillfully gathered articles that (1) researched functional devices that attempted to alter the function of the foot and eliminated those articles evaluating accommodative devices; (2) used a research protocol that was appropriate at the time the study was performed; and (3) were published in a peer-reviewed journal or were subject to critical editorial review.

Many of the reviewed articles from this paper have been mentioned in this text, but there is great value for the practitioner to review this work, particularly for its completeness regarding both custom and prefabricated devices and its approach to dividing the articles into the following outcome subcategories:

Patient satisfaction
Pain and deformity
Plantar pressure
Position and motion
Muscle activity
Oxygen consumption

Contained within this article, which reviews almost four dozen reports about functional orthoses, are two that relate to noncustom devices used to alter the function of the foot. The previously described Teesside study demonstrated that a custom device might be more cost-effective and have greater patient acceptance than a prefabricated one.[7] The other study evaluated a prefabricated varus and valgus wedge producing a similar effect to a prefabricated orthosis. The patients in the study all had neuroma pain, and the authors were attempting to determine whether this pathology had mechanical origins that would benefit from biomechanical control. They found no significant effect on pain by either supinating or pronating the foot.[16]

The Western Sydney review, although of great value to the profession in understanding the wildly diverse methods and materials used to evaluate orthoses, did not

focus on prefabricated versus custom orthoses. The group did, however, emphasize several times the need to compare those two types of devices to determine whether they both have similar clinical outcomes at different costs and to encourage further research comparing the particularly expensive custom device to the less expensive prefabricated one, given that the parameters for the construction of both can be established.

It is obvious that both prefabricated and custom orthoses have an effect on the mechanics of the foot and a positive clinical outcome on some patients with foot pain. Currently, no one has conclusively quantified the difference in effectiveness of the PFO compared to the CFO. We do know that when reduction of foot pain is used as an evaluation instrument of success, both types seem to be effective to some degree.

The clinician is left with several questions after reviewing the literature. There is no debate that prefabricated foot orthoses are effective, but how effective are they compared to custom foot orthoses? If the decision is made to use the less expensive and less sophisticated orthosis, then what properties should the PFO have for the best possible clinical result? Lastly, can the careful selection of the PFO either substitute for the CFO or suggest a positive prognosis in certain pathologies?

It does seem that prefabricated devices are effective, to some degree, for knee pain.[17] Logically, this seems to make sense. Limiting rearfoot motion limits torque on the knee joint, since the subtalar joint and midtarsal joint motion create internal rotation of the tibia. The chapter on knee pain and orthoses describes a study that also used prefabricated orthoses to evaluate their effect as compared to physiotherapy when treating patellofemoral pain syndrome. This study demonstrated that both therapies were highly effective and revealed equal outcomes. When these two therapies are combined, however, there seems to be no cumulative effect suggesting that they had similar interventions. The conclusion of the study stated that general practitioners might seek to hasten recovery from patellofemoral pain by prescribing the PFO.[18]

Prefabricated devices also seem to change the heel position in children with hyperpronation as long as the device has a rearfoot varus component.[19] We do not know whether this effect is solely a visual change in the patient's stance or whether this change corrects or ameliorates pathology in the growing child. The actual trials in pediatric patients described in Chapter 5 are rather conflicting.

Several studies, previously cited, demonstrate the effectiveness of the PFO in reducing the symptomatology of plantar fasciitis and heel pain related to mechanical dysfunction of the foot. This particular clinical diagnosis has the most data-confirming efficacy but does not necessarily differentiate whether the PFO or the CFO is a better treatment.

Perhaps the value of the PFO to the clinician in heel pain therapy is diagnostic. How does the clinician know whether the presenting heel pain from plantar fasciitis is mechanical in origin or the result of other etiologies? This is a useful and cost-effective

consideration in practice. The use of the PFO is an inexpensive method to determine whether the source of the symptoms is mechanical or not. Heel pain has a large number of differential diagnoses unrelated to foot mechanics that mimic plantar fasciitis. These other diagnoses will most probably not respond to mechanical control of the foot. If symptoms are not affected after mechanical intervention with the PFO, then other diagnoses should and must be investigated.

A recent prospective study was designed to judge the effect of the "professionally fitted" PFO on the amount of hallux dorsiflexion, improved subject balance, and back, hip, knee, and foot pain in four weeks or less.[20] The devices used were prefabricated foot orthoses developed in 1969 and used commercially in a chain of shoe stores that funded the research. One orthosis was a dense foam injection-molded device that was considered "flexible" and contained hollow areas under the arch and a metatarsal pad. The second was a thin semirigid device slim enough to fit into dress shoes. The fitting of the device, by size, was performed by "an experienced fitter" in accordance with manufacturers' guidelines, which are not mentioned in the study.

Forty-one patients with foot, knee, hip, or back pain were enrolled in the study and evaluated by radiographic change in stance, balance in stance, and improvement of their symptoms. The balance or stability of the subjects was quantified by shifts in the center of pressure during stance after the patient's shoulder was pushed from behind, which the authors believed was a meaningful measure of stability as interpreted by the amount of shift in the center of pressure. The data from this part of their experiment demonstrated no significant difference in stability with and without either device as compared to barefoot. This is a predictable result, however, this device is still rather successful from a commercial perspective.

The portion of this study that evaluated hallux dorsiflexion with and without orthoses showed little effect on the joint motion with either device. This is contrary to a similar experiment that used a custom orthosis to increase hallux dorsiflexion. The custom device increased dorsiflexion in all of the subjects who were tested.[11] The evidence from these two experiments seems to suggest that when treating functional hallux limitus, in increasing hallux dorsiflexion, the custom foot orthoses are effective but the prefabricated foot orthoses are not.

When lateral static weight-bearing x-rays were taken of the patient with and without the devices, however, several angular measurements changed in stance. The arch height increased with both devices, an expected result, and there was an increase in the metatarsal declination angle. There was a slight decrease in the angle between the first and second metatarsal angle, but this result may have been due to the change in the direction of the x-ray beam for patients standing on the device more than to a reduction in the hallux valgus deformity. Possibly, the increase in declination of the first metatarsal with the device produced a perceived reduction in the intermetatarsal (IM) angle. This was an admitted flaw in the paper.

Visual analog scales were used to determine the level of back, hip, and knee pain previous to intervention and at two and four weeks of the study. The 23 patients who reported back pain had an improvement at both two and four weeks. Whether this was the result of changing the mechanics of the foot or other structures or due to the attenuation of shock or the lifting of the heel by the device is not known.

The majority of the patients in the study did, however, benefit from the devices regarding hip, knee, arch, toe, and hallux valgus pain after four weeks. There was a statistically significant reduction in their visual analog scores.

This study provides an interesting opportunity for observation of the PFO, especially before considering which qualities they should have. The devices selected, from the perspective of experienced clinicians treating foot pathology, are poor. The devices were either flexible, and therefore minimally effective in changing joint position, or extremely narrow to accommodate shoe fit, at the expense of minimal foot-to-shoe contact. The devices as viewed from the article photos had minimal heel cups, and this probably resulted in a minimal effect on heel position or rearfoot motion. There seemed to be, from the description, no varus or valgus correction of either the forefoot or rearfoot portions of the device. Even though the devices do not seem to be an appropriate selection for symptomatic patients because of their minimal characteristics, they still produced positive clinical outcomes in regard to symptoms. The clinician might wonder what positive clinical outcome a fully contacted, semirigid, deep heel cup device might have produced in this study.

Prefabricated devices also seem to have a prophylactic effect on patients without obvious foot pathology, and this information may be highly useful when considering the reduction in sports medicine injuries, particularly stress fractures. A pair of studies at Hebrew University[21,22] in Israel showed that prefabricated orthoses, when dispensed to military recruits, reduced the incidence of metatarsal and femoral stress fractures during the recruits' basic training period. The studies evaluated the effectiveness of prefabricated semirigid 3.5 mm polypropylene plastic devices with a 3° rearfoot varus post. Interestingly, the devices were effective in reducing femoral stress fractures in high-arched feet and metatarsal fractures in low-arched feet. This study is of great value because it demonstrated the effect of changing foot position during rigorous activity.

A military study performed in 2001 attempted to determine whether the PFO could reduce stress fractures and other mechanical injuries in soldiers as well as determine comfort level while wearing the devices. The stress fractures were reduced by 13%, and comfort, as compared to having no device in the shoe, was increased to a statistically significant level.[23] Although some authors attribute the reduction in stress fractures to the increased shock absorption[24] provided by orthoses, this study group speculated that orthotic shape might have played a greater role in reducing the injuries and improving comfort. If the shock absorptive mechanism of the subtalar joint could be improved by moving the joint

away from its maximally pronated position, then might this reduce the stress and strain on the osseous structures?

There do seem to be sufficient data to demonstrate the professional and ethical use of the PFO in the treatment of knee pain secondary to osteoarthritis, pediatric flatfoot, and plantar fasciitis. Data also show the validity of their use in the diagnosis of the mechanical origin of foot symptoms, particularly heel pain, and prevention of injury in the nonsymptomatic foot. Although these data are somewhat superficial because of the extremely wide variety of devices tested and the wide assortment of testing methods, an overall positive influence seems to exist.

The review of the medical literature found only one contraindication for the use of prefabricated orthoses. A single-case study describing the use of a pre-intervention study design investigated the effects of the PFO on both ankle inversion and plantar forces and pressures on the fifth metatarsal.[25] This study was specifically directed toward basketball players to see whether the devices could reduce ankle inversion injuries and the Jones fractures that are associated with this event. The study found increased plantar pressures and forces on the fifth metatarsal that the authors hypothesize may increase the risk for proximal fracture of the fifth metatarsal, a common injury in basketball.

Orthotic Goals for Prefabricated Orthoses

Now that we have established an agreement on terminology and an understanding of what the literature tells us about indications and contraindications for the PFO, which characteristics or properties should we want from the PFO? Ideally, a clinician should choose the most appropriate device, from the large variety that is available, for the specific pathology being treated.

Dividing the orthotic characteristics into shell material, design, posting, sizing, and top cover makes it easier to evaluate the various prefabricated devices on the market. The available shell material ranges from soft and flexible foams to rigid, durable, hard thermoformed plastic. Consider the foams as accommodating, and we can eliminate most of them as being incapable of changing the morphology or the function of the foot for more than the few steps it takes to alter their shape. It is very difficult to have an effect on plantar fasciitis with accommodative materials if you cannot limit, to some degree, the motion of the midtarsal joint or raise the arch and plantar flex the first metatarsal.

This leaves a group of plastics called thermosets and thermoforms, better known as graphites and polypropylene orthotics. Both materials seem to provide the semirigid flexibility desired for foot control as well as the durability necessary to withstand the stresses of walking and running. Polypropylene seems to have one advantage over polyethylene. It is less susceptible to deformation over time. Polypropylene will hold its shape longer in the shoe, which usually has higher temperature/pressure environment because of the increased activity created by most athletes and active individuals.

Next, the orthotic design could be considered the most important criterion, since

some of the literature cited earlier demonstrated that a change in GRF and a change in the center of pressure might be directly related to effectiveness. Some prefabricated devices are designed for comfort and shoe fit, not for motion control. The kinematic articles suggest that the medial skive technique,[26] sometimes known as the varus wedge effect, will create greater GRF under the medial side of the orthosis and make any orthosis more effective for the foot that requires a greater inversion moment to correct the pathomechanics. The inverted cast technique[27] has also been accepted as a method to make an orthosis more effective at controlling foot motion in the direction of inversion. These two techniques, commonly referred to as the Kirby Skive and Blake Inversion, can be found already incorporated into some prefabricated foot orthoses for the purpose of greater limit of midtarsal joint motion. Considering durability and longevity, finding a device with a skive or an inversion already incorporated might be more desirable and easier than adding customized wedges or pads to the device.

The Root-type orthotic device[27] has become a standard in the world of custom orthoses, and it always contains a rearfoot post. The purpose of this addition was to stabilize the device in the shoe and allow for a slight amount of premidstance motion necessary in gait. One paper[28] actually evaluated orthotic devices with and without rearfoot posts and found that a post increased the effectiveness of the device by slowing the medial shift of the center of pressure as compared to the same semirigid device without a post. A prefabricated device may be of much greater value to a patient if a rearfoot post exists.

Although there are no available evaluations of sizing techniques for orthoses, logic leads to the conclusion that the closer the size of the device to the size of the foot, the more comfortable and effective the device will be. Sizing choices range from the absurd "one size fits all" to selections that match U.S. or European male and female shoe sizes. Some choices split the difference and offer single devices that fit two shoe sizes. This latter type of selection often requires office modification in length and heel width to provide proper shoe and foot fit.

The selection of the top cover for the PFO is a difficult topic to cover in this chapter because of the literally hundreds of materials and densities that are available. Separate considerations on the effectiveness of top cover materials, relative to pathology, will be left to the practitioner's experience, anecdotal evidence, and preference. Little is available on this topic in the literature. Shoe gear, pathology, climate, patient weight, and dermatologic conditions must all be considered.

Considering the previous information, the following orthotic characteristics may be useful in selecting prefabricated functional orthoses.

There is good reason to select prefabricated foot orthoses that include either a medial skive or an inverted technique, and to select the PFO with a rearfoot post to improve antipronation performance. Also, a more rigid device, used for plantar fasciitis, is more effective than a flexible or soft device.

Prefabricated Orthotic Therapy Conclusions

- Semirigid functional prefabricated devices work better than soft accommodative devices
- Semirigid prefabricated devices work as well, in the short term, for plantar fasciitis as compared to custom devices
- Semirigid prefabricated functional devices do slow foot pronation and limit calcaneal eversion
- Prefabricated functional devices can reduce the eversion of rearfoot position in children with flexible flatfoot
- Prefabricated functional devices can reduce the knee pain from osteoarthritis
- Prefabricated devices are an inexpensive tool to determine whether foot symptoms are mechanical in origin
- Semirigid prefabricated devices, with rear foot posts, are an effective prophylaxis for metatarsal stress fractures in low-arched patients and femoral stress fractures in high-arched patients who are active
- Semirigid and rigid prefabricated orthoses should not be used to treat a basketball athlete

Although more research needs to be done, there is sufficient evidence to confirm that using a semirigid functional prefabricated device is professionally valid and accepted.

REFERENCES

1. Landorf KB, Keenan AM, Herbert RD. Effectiveness of foot orthoses to treat plantar fasciitis. *Arch Intern Med*. 2006;166:1305–1310.
2. Lynch DM, Goforth WP, Martin JE, et al. Conservative treatment of plantar fasciitis: a prospective study. *J Am Podiatr Med Assoc*. 1998;88(8):375–380.
3. Pfeffer G, Bacchetti P, Deland J, et al. Comparison of custom and prefabricated orthoses in the initial treatment of proximal plantar fasciitis. *Foot Ankle Int*. 1999;20(4):214–221.
4. Martin JE, Hosch JC, Goforth WP, et al. Mechanical treatment of plantar fasciitis: a prospective study. *J Am Podiatr Med Assoc*. 2001;91(2):55–62.
5. Kitaoka HB, Luo ZP, An K. Analysis of longitudinal arch supports in stabilizing the arch of the foot. *Clini Orthopaed Rel Res*. 1997;341: 250–256.
6. Rome K, Gray J, Stewart F, et al. Evaluating the clinical effectiveness and cost-effectiveness of foot orthoses in the treatment of plantar heel pain: a feasibility study. *J Am Podiatr Med Assoc*. 2004;94(3):229–238.
7. McCourt FJ. To cast or not to cast? The comparative effectiveness of casted and noncasted orthoses. *Chiropodist*. 1990;45(12): 239–243.
8. Brown GP, Donatelli R, Catlin P, Wooden M. The effect of two types of foot orthoses on rearfoot mechanics. *J Sports Phys Ther*. 1995; 21(5:)258–267.
9. Smith LS, Clarke TE, Hamill CL, Santopietro F. The effects of soft and semi-rigid orthoses upon rearfoot movement in running. *J Am Podiatr Med Assoc*. 1986;76(4):227–233.

10. Zifchock RA, Davis I. A comparison of semi-custom and custom foot orthotic devices in high and low arched individuals during walking. *Clin Biomechanics*. 2009;23(10):1287–1293.
11. Scherer PR, Sanders J, Eldredge D, et al. Effect of functional foot orthoses on first metatarsophalangeal joint dorsiflexion in stance and gait. *J Am Podiatr Med Assoc*. 2006;96(6):474–481.
12. Redmond AC, Landorf KB, Keenan AM. Contoured, prefabricated foot orthoses demonstrate comparable mechanical properties to contoured customized foot orthoses: a plantar pressure study. *J Foot Ankle Res*. 2008;16(2):20.
13. Yung-Hui L, Wei-Hsien H. Effects of shoe inserts and heel heights on foot pressure, impact force and perceived comfort during walking. *Appl Ergon*. 2005;36:355–362.
14. Davis I, Zifchock R, Deleo A. A comparison of semi-custom and custom orthoses on rearfoot control and comfort. *J Am Podiatr Med Assoc*. 2008;98(5):1–10.
15. Landorf KB, Keenan AM. Efficacy of foot orthoses: what does the literature tell us? *J Am Podiatr Med Assoc*. 2000;90(3):149–158.
16. Kilmartin TE, Wallace WA. Effect of pronation and supination orthosis on Morton's neuroma and lower extremity function. *Foot Ankle Int*. 1994:15(5):256–262.
17. Sasaki T, Yasuda K. Clinical evaluation of the treatment of osteoarthritic knees using a newly designed wedged insole. *Clin Orthopaed Rel Res*. 1987;221:181–187.
18. Collins N, Crossley K, Beller E, et al. Foot orthoses and physiotherapy in the treatment of patellofemoral pain syndrome: randomized clinical trial. *BMJ*. 2008;337:1034–1036.
19. Jay RM, Schoenhaus H, Seymour C, Gamble S. The dynamic stabilizing innersole system (DSIS): the management of hyperpronation in children. *J Foot Ankle Surg*. 1995;34(2):124–131.
20. Landsman A, DeFronzo D, Anderson J, Roukis T. Scientific assessment of over-the-counter foot orthoses to determine their effects on pain, balance and foot deformities. *J Am Podiatr Med Assoc*. 2009;99(3):206–215.
21. Milgrom C, Giladi M, Kashtan H, et al. A prospective study of the effect of a shock-absorbing orthotic device on the incidence of stress fractures in military recruits. *Foot Ankle*. 1985;6(2):101–104.
22. Milgrom C, Giladi M, Simkin A, et al. An analysis of the biomechanical mechanism of tibial stress fractures among Israeli infantry recruits. *Clin Orthop*. 1988;231:216–221.
23. Mundermann A, Stefanyshyn DJ, Nigg BM. Relationship between footwear comfort of shoe inserts and anthropometric and sensory factors. *Med Sci Sports Exer*. 2001;33(11):1939–1945.
24. Milgrom C, Finestone A, Shlamkovitch N, et al. Prevention of overuse injuries of the foot by improving shoe shock attenuation, a randomized prospective study. *Clin Orthopaed Rel Res*. 1992;281:189–192.
25. Yu B, Preston JJ, Queen RM, et al. Effects of wearing foot orthosis with medial arch support on the fifth metatarsal loading and ankle inversion angle in selected basketball tasks. *J Orthop Sports Phys Ther*. 2007;37(4):186–191.
26. Kirby KA. The medial heel skive technique: improving pronation control in foot orthoses. *J Am Podiatr Med Assoc*. 1992;82(4):177–188.
27. Blake RL, Ferguson H. The effect of extrinsic rearfoot posts on rearfoot motion. *J Am Podiatr Med Assoc*. 1993;83:202–207.
28. Paton JS, Spooner SK. Effect of extrinsic rearfoot post design on the lateral-to-medial position and velocity of the center of pressure. *J Am Podiatr Med Assoc*. 2006;96(5)383–392.