Foot Orthoses

Many have suggested that over-the-counter (OTC) foot orthoses are “just as good” as custom foot orthoses (CFO) for treating most common ailments of the foot and lower extremity. What are the advantages and disadvantages of OTC and custom foot orthoses (CFO)?

Kirby: Both OTC and CFO have their own inherent advantages and disadvantages. OTC orthoses are less expensive, come in a number of arch heights, arch stiffnesses, cushioning materials, and are available for immediate purchase either from the office of the clinician or from a retail store. However, CFO, most typically made of polypropylene, will have much greater durability (5-15 years) versus the average OTC orthosis (3-9 months). Because of their increased durability, thermoplastic CFO will also demonstrate less alteration in shape and stiffness over time which allows the shape and stiffness of prescription variables that are built with CFO to remain relatively constant when compared with OTC orthoses.

In addition, CFOs have the distinct advantage of being made over a 3-dimensional (3D) model of the plantar foot versus the OTC orthosis, which is rather made on a “one shape fits all” principle. By using a 3D model, rather than a “one shape fits all” model, CFOs are able to effectively incorporate all of the geometric parameters that constitute the inter-individual variation within the plantar surface topography of the human foot. As a result, the CFOs have the best chance of achieving more close geometric surface congruency between the plantar foot and dorsal orthosis plate, which can effectively reduce the magnitudes of pressures acting on the plantar foot.1

The improvement in custom fit with CFO, OTC orthoses should not be underestimated due to the simple fact that the magnitude of ground reaction force acting on the plantar foot that is present in bipedal standing (0.5 × body weight [BW]), walking (1.0 × BW) and running (2.5-3.0 × BW) is the largest external force experienced by any region of the human body. Due to these relatively large magnitudes of peak ground reaction force, especially in sporting activities, even small variations in stiffness and 3D morphology of the arch, heel cup, and plantar metatarsal head regions of the foot orthosis all have the potential to produce significant alterations in the magnitude, temporal patterns, and locations of plantar pressures.

Scientific research that has been conducted over the past 2 decades has clearly shown that foot orthoses can positively affect the kinetics and kinematics of gait function and significantly alter the external and internal loading patterns acting on the structural components of the foot and lower extremity during all weight-bearing activities.2,3 The significant differences in gait kinetics, kinematics, and external and internal loading forces that are seen with appropriately constructed foot orthoses is the likely reason why experienced clinicians most commonly choose CFOs for their patients with more difficult-to-treat pathologies that require more exacting conformity and more substantial corrective modifications, and choose OTC orthoses rather as an initial treatment for more easy-to-treat pathologies.
Scherer: The value of CFO compared with prefabricated devices has yet to be determined conclusively primarily because of 2 almost insurmountable issues. First of all, there is a very wide variety of each of these vague categories concerning materials, designed purpose, flexibility, size, and additions. No one has determined in research application exactly what is a (CFO) and what is an OTC orthoses. Second, few researchers have tried a defined CFO and OTC orthoses on specific pathologies.

Without setting criteria for orthotic research, as we do with surgical procedures, we wind up with confusing and dubious results. The way some orthotic research is performed currently is like doing a surgical project comparing Austin, Lapidus and Keller bunionectomies on patients without considering the subjects met primus adductus, hallux valgus and articular set angles but expecting all three procedures to yield similar positive results. Which foot type are we applying an orthotic therapy to? What imaging technique was used? Which modifications and materials are used in the fabrication? The only criteria we seem to be concerned with, in today’s research, is that each subject has the same symptoms regardless of foot position, restrictions of motion or shoe gear. We must set stricter descriptive criteria for both patients and devices to produce more reliable data, which can be hopefully related to superior and more consistent clinical outcomes.

Until we do establish standard criteria for research on CFO versus OTC orthoses, we have to deal with logic and anecdotal evidence. Custom orthoses made from a model of the foot has to be more comfortable for the patient for the obvious reason that it will fit better if made correctly than the prefabricated that was created from a generic model of a human foot. If the device is uncomfortable and not worn by the patient it surely will not help the symptoms.

Spoonser: Let us first consider why they might be “just as good” as one another. Biomechanically, we may consider that each of the body’s tissues has a zone of optimal stress (ZOOS). In order for the tissue to remain in a healthy state, the loading applied to the tissue must be within the range of the ZOOS. From a biomechanical perspective, tissue dysfunction could be said to occur when

1. the load is excessive in relation to the mechanical properties of the tissue,
2. the biomechanical properties of the tissues have decreased in relation to a “normal load,” and
3. both 1 and 2 occur together.

Foot orthoses are generally inert pieces of shaped plastic. They “work” either psychologically, that is, via placebo effect, or mechanically by altering the reaction forces at the foot–orthosis interface. Mechanically, they can only alter kinetics at the foot–orthosis interface by virtue of 3 design variables:

• their superior surface geometry,
• their load/ deformation characteristics, and
• their frictional characteristics.

If we are presented with a dysfunctional tissue that is being subjected to loading outside of its ZOOS then the aim of foot orthoses therapy should be to manipulate the reaction forces acting at the foot–orthosis interface such that the loading applied to the target tissue falls back within its ZOOS. If we place the loading of a tissue that was previously outside of its ZOOS somewhere within its ZOOS via our foot orthoses, allowing the tissue to heal, then that foot orthosis might be assumed to be successful for treating that problem, in that patient. The body really doesn’t care whether the kinetic changes at the foot’s interface comes from custom or OTC foot orthoses, only that the reaction forces generated at the foot–orthosis interface maintain the tissues loading within their ZOOS and in a healthy state. Thus, in each patient, for each dysfunctional tissue, the key is to provide a foot orthosis that modifies the loading that the tissue experiences to be within an optimal zone. Both CFO and OTC foot orthoses should be capable of achieving this, and therefore may be seen to be “just as good” as one another in certain situations.

In terms of specific advantages and disadvantages, OTC foot orthoses are relatively cheaper than CFO. OTC devices do not require a negative model acquisition whereas CFO do; OTC devices can be dispensed instantly whereas there is usually a time delay between prescription and dispensation of CFO; both OTC and CFO are available in a range of materials and are adaptable to the patient, but ultimately CFO can be more highly tailored to a patients requirements.

What foot and lower extremity pathologies do you believe can be treated effectively with an OTC foot orthosis and what pathologies are best treated with CFO?

Kirby: In my practice, I will commonly use OTC orthoses as an initial treatment that I subsequently modify in my office to produce changes in the orthosis morphology and stiffness that are necessary to reduce the pathologic loading forces on the injured structural components of the foot and/or lower extremity. I commonly use OTC orthoses, which I subsequently modify, for initial treatment of proximal and distal plantar fasciitis, plantar plate dysfunction, metatarsalgia, posterior tibial tendinitis/dysfunction, peroneal tendinopathy, Achilles tendinopathy, chronic inversion ankle sprains, patellofemoral syndrome, iliotibial band syndrome, medial tibial stress syndrome, and other less common foot and/or lower extremity pathologies.

However, if the patient does not initially respond well to OTC orthosis therapy, needs more “tight control” of his or her abnormal gait biomechanics to alleviate their symptoms, and/or wants a more permanent in-shoe medical device to more effectively treat their condition, CFO orthosis therapy is then recommended. The skilled clinician who has the technical ability and appropriate equipment and materials in their clinics to modify orthoses (ie, grinder, glue, Korex/EVA,
topcover materials) should be able to not only easily make appropriate OTC orthosis modifications to “customize” these devices for their patients but also should be able to make modifications to existing CFO in order to make them work even better for their patients.

Spooners: As long as the foot orthosis is capable of placing the loading on the target tissue within its ZOOS without placing the loading of other tissues outside of their ZOOS, then theoretically any biomechanically related pathology that can be successfully treated with a CFO could also be treated efficaciously with an OTC foot orthosis. Provided that both types of devices deliver the desired geometry, load/deformation, and/or frictional characteristics at the foot-orthosis interface, they both will have the ability to influence the kinetics in a positive fashion. It’s important to realize that both OTC foot orthosis and CFO “work” in the same way: They modify the reaction forces at the foot-orthosis interface by virtue of the 3 design variables—superior surface geometry, load/deformation characteristics, and frictional characteristics. CFOs don’t have any mechanical qualities, or psychological qualities that OTC devices can’t have.

It is probably of limited value to attempt to think in terms of which specific pathologies are best treated with CFO as opposed to which can be treated effectively with OTC foot orthosis. Rather, it should be more helpful to identify the individual characteristics of the patient and their “version” of the named pathology that may lead to one form of foot orthoses being more successful than another within that specific individual, at that specific time. If we take 2 patients with the same named pathology, experience dictates that one of them might be treated effectively with OTC foot orthoses, while the other may require CFO to achieve a positive outcome, despite them both having the same named pathology. Thus, it’s ultimately not the type of pathology that should determine the use of custom versus OTC foot orthoses, but rather the requirements of the individual patient. Don’t try to pigeonhole patients by pathology, nor by “foot-type.” Instead, treat each as an individual with individual requirements in terms of their foot orthoses.

When a foot orthosis is prescribed and the patient’s symptoms do improve, we may assume that we have modified the target tissue’s loading such that it is back within its ZOOS. However, we don’t know exactly where the loading of the tissue lies within its ZOOS as a result of the orthotic intervention; it could be smack bang in the middle of the range, or right on the border of its upper or lower limit; yet all of these situations can result in positive outcomes. All we know is that the orthosis has placed the loading on the tissue somewhere within its ZOOS (or not, if we don’t achieve a positive outcome). If the orthosis places the loading on the tissue somewhere near the middle of its ZOOS, we can probably change the orthosis prescription variables, for example, posting the rear foot by a few degrees more or less, and the patients symptoms will still improve since the reaction forces generated at the foot-orthosis interface will still load the tissue somewhere within its ZOOS. However, if the orthosis puts the loading on the tissue only just within its ZOOS, then small changes in the prescription might just tip the tissue loading outside of its ZOOS and result in therapeutic failure. Thus, for each dysfunctional tissue within a patient there may be a range of “positive orthoses solution sets” that are a function of the 3 orthoses design variables listed above, rather than just one highly specific prescription.

The ZOOS for each tissue is a dynamic variable and is dependent on the level of tissue “health.” When a tissue is dysfunctional, the range of its ZOOS may become narrower with the division between its upper and lower limits being reduced as a function of the severity of the dysfunction. When the ZOOS are relatively wide, a number of orthoses designs may yield positive clinical outcomes. In this situation, a clinician might observe that OTC foot orthoses are “just as good” as CFOs since a wide variety of orthoses designs will still modify the loading placed on the target tissue such that the tissue can function some-where within its ZOOS because the loading tolerances of the ZOOS are relatively broad. As the level of tissue dysfunction increases and the range of the ZOOS becomes narrower, then the number of “positive orthoses solution sets” will likely decrease too. The tolerances in the 3 orthoses design variables that will yield a positive outcome become smaller and the prescription required to obtain a positive outcome should need to be more precise.

Clearly, if the tissue dysfunction is of sufficient severity then the ZOOS could be zero in that the tissue cannot develop any strain within it at all in relation to the stress applied, for example, a complete rupture of the Achilles tendon. In this situation, until there is some healing, the ZOOS could be zero. Any form of foot orthosis may be ineffective at this stage and total rest and/or surgical repair should be required to restore the ZOOS. As a tissue heals, the range of its ZOOS increases and the number of “positive orthoses solutions” that may assist with the healing of the tissue increases too.

The skilled clinician is capable of identifying the dysfunctional tissue and the severity of injury to it; they understand the biomechanical function of the tissue during various activities of daily living; and comprehend the manner in which each of the 3 foot orthoses design variables interact with one another and ultimately their kinetic influence on the foot. This knowledge allows the clinician to provide the patient with a foot orthosis that modifies the reaction forces in such a manner that the load on the target tissue falls back within its ZOOS. If an OTC device is capable of modifying kinetics at the foot-orthosis interface in a similar manner to a well-designed CFO, then there is no reason whatsoever why it should not be equally efficacious. However, while the range of OTC foot orthoses available to the clinician is constantly increasing, there will always be certain situations in which the design characteristics of the available OTC devices do not meet the demands of the patient in question. This will commonly be in a situation in which there is marked structural deformity of the foot such that an OTC
with a suitable superior surface geometry cannot be matched to the foot and/or when the range of the ZOOS is significantly narrowed due to the severity of tissue dysfunction. In these situations the almost infinite design permutations available to the clinician when employing CFO probably provides for a better chance of obtaining a positive clinical outcome than with an OTC device, simply because the custom device can be more closely tailored in terms of the 3 design variables, in order to manipulate the reaction forces at the foot-orthosis interface in the desired manner.

Does the obvious cost differential between OTC and CFO create the potential for overutilization of CFO or do you feel that CFO are underutilized by the medical profession as a whole for the effective treatment of many foot and lower extremity pathologies?

Kirby: That is a difficult question to answer since I believe there are significant regional variances within the United States and also internationally as to how podiatrists, orthopaedic surgeons, and other clinicians use OTC and CFO within their practices. In California, podiatrists use OTC orthoses quite frequently for initial treatment of less difficult-to-treat pathologies and recommend CFO when a more durable, long-lasting orthosis is needed and/or when more difficult-to-treat pathologies are encountered. This is also probably the case within the podiatric profession in other states as well, but one must realize that there may be significant regional variances in OTC and CFO usage throughout the United States.

There may also be some clinicians who recommend either OTC or CFO based solely on the cost differential between the 2 types of orthoses. Some clinicians may overutilize OTC orthoses, attempting to reduce the cost of treatment for their patients but also potentially restricting their patients’ access to a more cost-effective method of therapeutic foot orthoses for their complaints. Of course, the skilled and ethical medical professional does not consider their profit margin for a given medical service when recommending a specific treatment for a patient. Rather, the skilled and ethical medical professional offers a range of the most therapeutic treatment options to their patient, along with each treatment’s pros and cons, in order to allow their patients to make the most informed choices regarding their treatment.

In this regard, considering all the patients that I have treated in my 27 years of private practice, many of whom have been referred to me specifically for my expertise in biomechanics and foot orthosis therapy, I have seen literally hundreds, if not thousands, of patients who have been told by their primary care physicians or other medical specialists that either only surgery is available or that no effective treatment is available to treat their pathologies. These patients have been told, quite literally, that they will need to “learn to live with their pain” that is due to their mechanically based foot and/or lower extremity pathologies, basically relegating these individuals to living the rest of their lives with pain and disability.

However, when these same individuals, who have been told to “learn to live with their pain,” are instead provided with appropriate conservative care, including modified OTC orthoses, CFOs, physical therapy, and/or appropriate shoe modifications and advice, they will not only commonly find full relief from their foot and/or lower extremity pain but they will also experience improvements in their endurance and function in their everyday weight-bearing activities.

The physical relief of chronic weight-bearing pain using these safe, time-tested, and efficacious in-shoe mechanical therapies can also produce significant psychological benefits for patients. The positive psychological benefits that result from reducing or eliminating chronic pain during weight-bearing activities are not only underestimated by the medical profession as a whole but are also not appreciated by many within the podiatric and orthopedic professions. Certainly, quantifying the potential psychological benefits of foot orthosis therapy still remains a large and virtually untapped field of study for scientific research in the future.
Pronation is not even pathology! In some situations, off-the-shelf (library) orthoses shells, with or without customization are sold to the patient as true CFO. Unfortunately, I believe this lack of registration and training requirement has led to the wide-scale abuse of foot orthoses and denigration of their clinical value and worth. I think that demonstrable knowledge and registration should be a legal requirement before someone is allowed to dispense foot orthoses.

**There is an increase in alternative theories on foot and lower extremity biomechanics and foot orthosis therapy over the past 2 decades. Why do you believe these newer theories have evolved and which theories do you believe currently show the most promise?**

**Kirby:** As a podiatry student and Biomechanics Fellow at the California College of Podiatric Medicine in the early 1980s, I was exclusively trained in Neutral Position (NP) Theory as advocated by Merton Root, DPM, and his colleagues. In the last year of my training, I began to notice that many of the measurements advocated as being important in NP Theory, had little to no correlation as to how the foot functioned during gait, on what specific foot and/or lower extremity pathologies the patient developed and on how best to prescribe the most therapeutic foot orthoses.

During my Biomechanics Fellowship and in my early years of private practice, I also began to measure the plantar projection of the subtalar joint (STJ) axis on the feet of my students and my patients and began to see a very significant correlation between the function of the foot, the types of foot and/or lower extremity pathologies that they developed, and how specific orthosis modifications made that foot mechanically respond during gait. I then used that information to create orthosis modifications that were based more on the internal and external forces and moments acting within the joints of the foot and lower extremity, rather than being based on measurements of “foot and lower extremity deformities” as proposed by NP Theory. As a result of my investigation of the mechanical significance of STJ axis location relative to the plantar foot, I soon realized that many of the principles of NP Theory were flawed and inconsistent with both my clinical observations and with Newtonian mechanics.

Likewise, many others involved in foot and ankle research over the past quarter century have started to openly question the validity of prescribing foot orthoses based on the measurement of “foot and lower extremity deformities,” as suggested by NP Theory. A growing number of researchers and clinicians have instead suggested that foot orthosis treatment should rather be directed toward reducing the magnitude of pathological stress acting on the tissues of the patient, rather than “posting the orthosis to the patient’s foot and/or lower extremity deformity” as taught by the NP Theory advocates.

The result of this “paradigm shift” is now known as Tissue Stress Theory and, over the past 17 years that Tissue Stress Theory has been developed and discussed, it has continued to grow in popularity, while NP Theory is undergoing a slow and steady decline in popularity. Certainly, further research will be necessary to support or refute Tissue Stress Theory and NP Theory and the other, less popular, theories of foot orthosis function. However, my belief is that Tissue Stress Theory will be the predominant theory of foot orthosis prescription for at least the next 3 decades.

**Spooners:** Casual observation followed by systematic and careful study allows the development of theories and models of foot and lower limb biomechanics and foot orthoses therapy. However, sometimes when we test each element of that model or theory for validity, in a wide range of situations we see that elements of the theory fail. As technical advances are made, and our ability to measure the biomechanics of the lower limb improve, we develop more advanced conceptual scientific frameworks and these may expose further deficiencies in the theory.
If the deficiencies in an existing theory are shown to be significant through experimental observation, then the theory may be rewritten and modified. If the deficiencies in the existing model are shown to be too great, then a whole new model may be required and in this situation a “paradigm shift” may occur. The introduction of new models stimulates further research and so the cycle begins again. This is the nature of the scientific method. Craig Payne discussed these ideas in his 1998 article, “The Past, Present, and Future of Podiatric Biomechanics.”

If new theories have evolved in podiatric biomechanics, it is hopefully because deficiencies in the existing theories have been exposed through scientific study. This is a healthy state for our profession and shows that the scientific method is being applied. However, there also seems to be an element of podiatrists who are attempting to develop their own theories of podiatric biomechanics in order to patent examination techniques, “foot-typing” systems and orthoses designs. Such systems are, in my opinion, often reductionist and retrograde steps within the evolution of podiatric biomechanics and moreover, are frequently driven by motives relating to the financial aspirations of the individuals concerned, rather than the enhancement of podiatric biomechanics.

By definition, biomechanics is the study of the mechanical laws related to the structure and movement of living organisms, so any emerging theory has to apply and obey the laws of mechanics. Moreover, it has to be theoretically coherent, biological plausible and consistent with the evidence base. Kirby’s STJ axis location and rotational equilibrium theory of foot function provides an excellent framework for the way in which modern foot and lower limb biomechanics should be studied. While Kirby focused on the STJ within this article, the concepts discussed in this work are applicable to the other structural elements of the foot and lower limb. Fuller has also provided insight into the way in which mechanical modeling of the forces acting on a structure can be applied to the foot and lower limb in order to provide predictions of stress levels within individual tissues. Combining these and similar techniques of mechanical modeling with the “tissue stress approach” first described by McPoil and Hunt and later refined by Mueller and Maluf provides for the model of biomechanical clinical practice that seems to demonstrate the greatest theoretical coherence, biological plausibility, and consistency with the evidence base at this current time.

In the United States, there seems to have been a growing disinterest in biomechanics and a growing interest in surgery over recent years. Why do you believe that is the case and is this also the case in other countries as well? How do you think that this relative lack of interest and education in biomechanics affects the methods by which our patients are treated for mechanically based foot and lower extremity pathologies?

Kirby: I have seen a definite decline in knowledge in biomechanics and foot orthosis techniques within graduating podiatry students, podiatric residents, and podiatric physicians over the past 27 years that I have been teaching theory and practical skills in biomechanics and foot orthosis therapy. I believe that this is largely due to the US podiatric medical schools all emphasizing surgery and reducing the emphasis on increasing knowledge and clinical skills in biomechanics and foot orthosis therapy.

For example, by the time I had graduated as a podiatry student in 1983, I had personally fabricated at least 100 pairs of CF orthoses. Currently, however, most podiatric students, by the time of their graduation, will have made, on average, only 1 to 2 pairs of CF orthoses. This reduction in “hands-on” clinical skills with foot orthoses and other biomechanical therapies, in combination with 3-year surgical residency programs where very little teaching of practical skills in biomechanics, foot orthoses, and sports medicine occurs, has created a new generation of 3-year trained podiatric surgical residents who can neither effectively prescribe nor modify CFO for their patients. Unless this alarming trend where podiatry students and residents are trained mostly to do surgery, with little training in effectively treating mechanically based injuries conservatively, the US podiatry profession will gradually see patients moving toward other health professionals, who have a keener interest in biomechanics and foot orthosis therapy, for conservative care of their mechanically based foot and lower extremity pathologies.

On the other hand, over the past 2 decades, I have also had the wonderful opportunity of lecturing internationally, on numerous occasions, on foot and lower extremity biomechanics, foot orthosis therapy, and effective treatment of sports injuries. During that time of teaching and interacting with the international podiatric medical community, I have noted that the podiatrists in the United Kingdom, Ireland, Canada, New Zealand, Australia, Spain, Portugal, and Belgium are very eager and interested in learning about the latest ideas in biomechanics and foot orthosis therapy, as opposed to their US counterparts who seem to have little interest in these subjects.

It is my opinion that this difference in level of interest in biomechanics and foot orthosis therapy between US podiatrists and their international colleagues is due to the fact that most non-US podiatrists are nonsurgical specialists. On the other hand, US podiatrists, the majority of whom consider themselves surgical specialists, seem to be increasingly becoming surgically oriented, with little regard for learning the latest theories and treatment methods in foot orthosis therapy and biomechanics.

Certainly, the most intelligent foot and ankle surgeons fully realize that better surgical outcomes will be produced by the surgeon that more fully understands the mechanical function of the body parts that they surgically modify. However, the trend currently occurring in the US podiatry schools and postgraduate programs is still very disturbing where...
biomechanics and nonsurgical treatments are underemphasized. My gloomy prediction is that this shift in emphasis toward becoming primarily surgical specialists who have a limited scope of practice, rather than becoming well-rounded and versatile foot and ankle health specialists, will decrease the overall clinical effectiveness of the new generation of podiatrists in providing their patients with the best in both conservative and surgical care for their patients’ foot and lower extremity pathologies.

**Spooners** How can one perform foot surgery without an in-depth knowledge of, or even an “interest” in, foot and lower limb biomechanics? The biomechanical consequences of the surgery being performed should be thought out and planned for, long before the surgery is even undertaken. Its monitoring should be continued following the surgery. If a podiatric surgeon was “disinterested” and didn’t have a sound comprehension of biomechanics, I wouldn’t let them anywhere near my feet! Surgery is the ultimate tool for altering lower limb biomechanics since it physically alters the structure of the foot. You cannot alter foot structure without it having consequences upon the kinetics. And if you don’t understand nor have an “interest” in what the consequences of those kinetic changes might be upon the health of the individual, you probably shouldn’t be performing foot surgery in the first place, in my opinion.

Although I have been invited to speak at a number of conferences in the United States, I don’t work in the United States regularly, so it’s difficult for me to give a truly insightful answer as to why American podiatrists are becoming “disinterested in biomechanics” or that biomechanics may be seen as being somehow disconnected from surgery in the United States; it’s not, end of story. My experiences in the United States over the years suggest to me that some American podiatrists relate “biomechanics” to beginning and ending with “foot orthoses.” Biomechanics does not equal foot orthoses. Indeed, foot orthoses have mechanical properties, not biomechanical. I’d guess this comes down to education. Specifically, exactly how are these subjects are being taught within the US podiatry education system? If biomechanics is seen to equal foot orthoses by some of those leaving US podiatry schools, then the curriculums may well lack integration and this needs to be addressed. If too little time is devoted to teaching biomechanics, then the newly qualified podiatrists will lack the foundational knowledge on which to build during their professional careers.

One of my other observations from lecturing in the United Kingdom and central Europe versus the United States is that there appears to be much greater and widespread critical engagement with the contemporary theories of biomechanics within European podiatrists, while the formulaic Root based model of practice described in the 1970s seems to remain the mainstream for the majority of podiatrists within the United States. In the United Kingdom, this model has largely been rejected now due to its questionable reliability and validity and is mostly taught simply to provide an historical perspective. Perhaps, the content of the biomechanics curriculums need to be reexamined and brought up to date in the United States, with critical engagement being encouraged as oppose to dogmatic adherence to the theories at its core! In the United Kingdom and Europe where this approach has been adopted, the interest in biomechanics seems to be healthy and growing.

Or, does it just come down to the fact that a clinician can charge more for a surgical procedure than from physical therapies and foot orthoses? Is the problem due to insurance companies being willing to pay out for surgical procedures, but not for foot orthoses in the United States? Financial reward may be a driving factor in how therapies are selected by some clinicians, with the highest income generator taking preference. Here in the United Kingdom, where surgery is less widely performed, the interest in biomechanics and foot orthoses seems great, but perhaps this is only because foot orthoses are the best source of income generation for those podiatrists who cannot perform foot surgery? Regardless, financial reward for the clinician is probably not the best approach to deciding on treatment strategies within ethical patient care.

In the long term, focusing on one element of clinical practice at the detriment of others can only lead to de-skilling. If all you’ve got is a hammer, everything suddenly looks like a nail; if all you’ve got are surgical skills, everyone starts to look like a suitable case for surgery. But to reiterate, if surgery is being performed on a foot without an “interest in biomechanics,” this doesn’t bode well for the future of the patient, nor for the profession at large.

**Even though foot orthoses have been studied by scientific methods such as force plates, pressure mats, 3D motion analysis, and computer modeling techniques such as inverse dynamics and finite element analysis, the ability to place any sort of “placebo” device into the shoe of a research subject that not only has no mechanical effect on the foot but is also indistinguishable by the subject from a foot orthosis is nearly impossible. What type of scientific research studies need to be done in the near future to give us better insight as to how well foot orthoses work at healing injuries, how foot orthoses mechanically function to produce their therapeutic effects, and as to what orthosis modifications work best for each pathologic condition?**

**Kirby:** There has been a large increase in meaningful foot orthosis research within the past few decades that has given us much more solid research evidence as to how foot orthoses work. This research clearly shows that foot orthoses can not only can be therapeutic but can also change the kinetics and kinematics of walking and running gait. In addition, inverse dynamics studies point to the fact that foot orthoses alter the magnitudes and temporal loading patterns on the internal structural components of
the foot and lower extremity, which supports the idea that foot orthoses produce much of their therapeutic effects by altering the forces and moments on internal structures of the foot and lower extremity. Likewise, pressure mat/insole studies show significant reductions in plantar pressures with foot orthoses showing that foot orthoses also have a large effect on the external forces acting on the foot.

However, part of the problem with understanding how foot orthoses function during weight-bearing activities is that the methods used to currently detect changes in foot joint motion, using skin markers to measure bone motion, are only crude approximations of the actual translational and rotational motions of the osseous components of the foot skeleton. It is likely that once bone pin research is done showing the changes in motion at the talonavicular joint and other midfoot joints with foot orthoses, which are the joints most mechanically affected by a properly constructed CFOs, we will only then better appreciate how foot orthoses work to produce their mechanical effects on the foot and lower extremity.

Scherer: The newest technology still does not allow us to unequivocally “prove” that orthoses work in all pathologies. We need to recognize that all therapies do not need level one research. There is no level one research on the effectiveness of a parachute! Right now we need to continue the research that is being done as perspective and randomized clinical outcome studies on orthotic therapy but also standardize the type of CFOs we are using in the studies. There are almost 400 articles in peer-reviewed educational journals concerning pathomechanics and orthotic therapy and I doubt a tenth of the profession is aware of their findings. Most of the research is pretty convincing and far beyond anecdotal. Reduction of symptoms in children decreased morbidity in arthritides and decreased sports injuries. It’s all there. It just needs to be read by the clinician.

Sponser: The problem is this: Foot orthoses “work” by changing the kinetics at the foot’s interface. So, anything put into the shoe has the potential to alter the kinetics at the foot’s interface with it. This was one of my criticisms of Karl Landorf’s study of foot orthoses in the treatment of plantar fasciitis. Within this study, so-called “sham” orthoses were employed as a control. These were manufactured from 6-mm thick “soft” EVA foam and were custom molded to a cast of the patient’s foot and ground to shape. The authors assumed that this would have minimal kinetic effect on the foot, but did not actually go so far as to measure the kinetic effects that this had on the feet of the subjects it was issued to within the trial.

The solution would seem to be to measure the kinetic effect that all of the types of foot orthoses have on the feet of the subjects within a study. The problem with this is that, we should likely find the kinetic effect of all of the foot orthoses employed within a study to be unique to each subject, regardless of whether the devices employed were custom made or OTC foot orthoses. In other words, if we accept that foot orthoses “work” by altering the kinetics at the foot–orthosis interface, at present, each subject within the published trials is likely to be receiving a different kinetic “dose.” This is analogous to performing a drug trial in which each of the participants receives a different, unknown dose of the drug.

To resolve this issue, it might be better to standardize the influence that the foot orthoses employed within a trial have on a specific kinetic variable. For example, Craig Payne in some unpublished data from 2002 suggested that the kinetic variable “supination resistance” is a predictor of posterior tibial tendinitis, with subjects displaying posterior tibial dysfunction having significantly higher supination resistance (328 ± 21 newtons; n = 14) than a reference group (138 ± 46 newtons; n = 142). It may be hypothesized then that foot orthoses that are specifically designed to lower the supination resistance should have a more efficacious effect on the symptoms of posterior tibial dysfunction than foot orthoses that don’t lower the supination resistance. This observation seems theoretical coherent, biological plausible and consistent with the evidence base at this current time.

It should be possible to design foot orthoses such that the magnitude of the effect that the foot orthoses have on the supination resistance variable can be standardized within each participant in a trial. Note that this would mean that the orthoses each received would be tailored to each subject, but that the kinetic effect that the foot orthoses were having on the supination resistance variable would be identical in all subjects. Thus, we could provide one group of subjects with foot orthoses that have a very small influence on supination resistance, for example, less than 1% change and another group of subjects could be provided with foot orthoses that decrease their supination resistance by 50%, for example. At least in this respect all the subjects would be receiving a known, standardized “kinetic dose” in relation to the variable of interest within the trial. Obviously, this approach cannot control for all other influences, nor all other variables, but it should be an improvement on the current state in which we are really only performing a series of uncontrolled single case studies.

In many respects, the problem with foot orthoses research is that we have attempted to “run before we really know how to walk.” We have attempted to perform the perceived “gold standard” research of placebo controlled randomized trials, before we actually have a full appreciation of how the design characteristics of the foot orthoses influence the kinetics at the foot–orthosis interface. In this regard, we might do better to take a step back and actually get a firm handle on the science of foot orthoses design first. This should best be explored through the use of finite element modeling. A limited number of workers have already applied finite element analysis to foot orthoses, myself included, but it really hasn’t been exploited broadly enough yet. With such modeling the orthoses superior surface geometry, the load/deformation characteristics and the frictional characteristics can be manipulated. The influence of various orthoses designs can be “virtually” tried and the effect that these designs have on the “virtual” tissue stress and strain can...
be explored within the safety of a computer environment. Thus, through this approach we should be able to provide a greater understanding of the exact design variables required to give us the best chance of modifying the loading on a given target tissue. Yet the models will still require validation. In the first instance, this might be achieved with the help of dynamic cadaver gait simulators with strain gauges attached to the tissues of interest. Ultimately though, we have to test the orthoses designs in vivo.

What do you see as future directions for foot orthosis technologies, including the 3D imaging of the foot, manufacturing methods of the orthoses, and possible new foot orthosis technologies that we may be seeing within the next few decades?

**Kirby:** The most interesting new technology that is just now being developed to produce viable foot orthosis products is 3D printing or additive manufacturing technology, where foot orthoses are manufactured by adding tiny bits of material, layer by layer, until an orthosis is constructed, “from the ground up.” This technology will make possible foot orthosis designs that would have been thought impractical or even impossible just a decade ago. Newer topcover technologies that significantly reduce shearing forces are also now available, which may help reduce blistering and plantar ulcers. In addition, in the near future, miniature electronic componentry will allow foot orthoses to give instant wireless feedback to the clinician and/or patient as to how their foot orthosis is moving under their foot and/or how their foot is moving inside the shoe. The future looks very promising for CFO therapy.

**Scherer:** There has been a large increase in new types of orthosis technology, including scanning and manufacturing techniques, but I personally think much of it is pseudoscientific nonsense provided by opportunists and amateurs. The true 3D scanners do allow a much more accurate representation of the foot to be delivered to the orthotic lab, but it still lies in the hands of the physician to position the foot in a manner that can be used to create an orthotic that reduces clinical outcomes. The creators of some of the manufacturing systems have no idea how an orthoses should limit midtarsal joint motion or increase the supinatory moment of the subtalar joint. There is now a high disparity between the focus on efficiency and cost of the manufacturing systems and the focus on performance of the device. This disparity has already tainted the reputation of the efficacy of orthoses. The clinician must be educated and cautious at this moment of technological change and ask about clinical performance not just office efficiency.

**Spooner:** It will probably be possible to carry out good-quality 3D scanning of the foot as a form of negative model acquisition for foot orthoses manufacture using a smart phone or tablet computer within the next few years. There are already “apps” that scan objects that are available for smart phones at the cost of about $1, although the quality of the scans is not yet quite good enough for manufacturing foot orthoses. But it won’t be too long before they are capable of capturing models of sufficient standard. In essence if the phone/tablet computer manufacturers included a second camera, or better yet—one in each corner, I’m pretty sure we’d all be doing this tomorrow. Maybe not to scan feet, but to post the scan of something on Facebook!

I believe that in the next few decades, negative model acquisition will also be carried out using a combination of 4D (dynamic) scanning and force plate data; such that a model of the foot can be captured at any point in time within the gait cycle with knowledge of the kinetics occurring within the foot and lower limb at that time. This sounds a little “Star Trek” but actually dynamic scanners already exist, as do force plates, so it’s only really a case of merging these 2 technologies in an affordable package. I’m sure somebody somewhere is already working on this.

I think far more attention will be given to manipulating the load/deformation characteristics of the foot orthoses in order to influence the kinetics at the foot–orthosis interface by virtue of combining materials within the orthoses and by manipulating the shell thickness and design characteristics, particularly on the shells inferior surface. The use of direct milling and 3D printing makes this process much easier. Combining this with finite element modeling allows the manner in which the orthoses deforms under load and thus the reaction forces at the foot–orthosis interface to be better controlled for during the design process and the orthoses to effectively be “calibrated” for the individual in terms of its load/deformation characteristics.

Foot orthoses will probably include “smart material” elements such as non-Newtonian polymers that will adapt their stiffness in response to the rate of the loading applied. Such materials are already being used in certain brands of athletic footwear. Within the next few decades, we may even see the use of magneto-rheological fluids controlled by a microprocessor that is capable of managing the foot orthoses load/deformation characteristics on a step-by-step basis based on input data obtained from force measuring transducers at the base of the foot orthoses. High-end cars currently use similar technology within their suspension systems.

In terms of the materials from which orthoses are constructed, we could also see a need for foot orthoses to be manufactured from “green plastics” such as poly-lactic acid that are derived from renewable resources such as corn starch, within the next few decades. Certainly, the use of such materials may enable more widespread use of foot orthoses within developing nations.

For the manufacturing process itself, I fully expect fast, affordable 3D printing to be the pervasive technology for constructing foot orthoses within the next few decades. Such technology will be capable of printing in multiple materials and will be based in the clinician’s office. Again, such technology already exists. It is quiet and clean and it’s only a matter of time before this technology becomes fast enough and affordable to become the common place in our offices and homes.
One of the biggest changes I foresee is in the model of delivery of foot orthoses laboratory services. Presently, the clinician either casts the foot or scans it, and so on, in order to obtain a negative model and this, along with a prescription is sent to the lab for manufacture of the orthoses. The finished orthoses are then shipped back to the clinician for dispensation. In the near future, I expect to see all negative models being sent to the lab digitally, the lab then generating a digital model of the foot orthoses, which is then sent to the clinician’s office for in-house 3D printing. Thus, the lab’s role will purely be in designing the orthoses, not the manufacture per se. The labs will probably lease the 3D printers to the clinician or provide them under a click-fee/contract scheme and sell the materials to the clinician to print the orthoses.

References