Is There Proof in the Evidence-Based Literature that Custom Orthoses Work?

PhotoDisc

Peer-reviewed studies in a number of disciplines establish the effectiveness of these devices.

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Today, practitioners and insurance carriers demand relevant data that demonstrates the degree of effectiveness, in an unprejudiced manner, as new protocols and techniques for diagnosis and treatment are developed. This effort is commonly referred to as either evidenced-based or clinical outcome data. The purpose of this article is to analyze the peer-reviewed literature related to the success and efficacy of custom foot orthoses in the treatment of foot and ankle pathology. Although most of the methods and techniques for orthotic therapy originated from the profession of podiatric medicine, the majority of evidence is from other medical professions. Research done across a number of disciplines helps remove bias and pre-determined expectations, strengthening the conclusions that can be drawn from a literature review.

This article will review the evidence-based literature for the seven most common foot pathologies and deformities that are known to have mechanical origins, and evaluate the effectiveness of orthotic therapy. The pathologies are plantar fasciitis, metatarsalgia, hallux limitus, adult-acquired flatfoot, rheumatoid arthritis feet, tarsal tunnel syndrome, and lateral ankle instability.

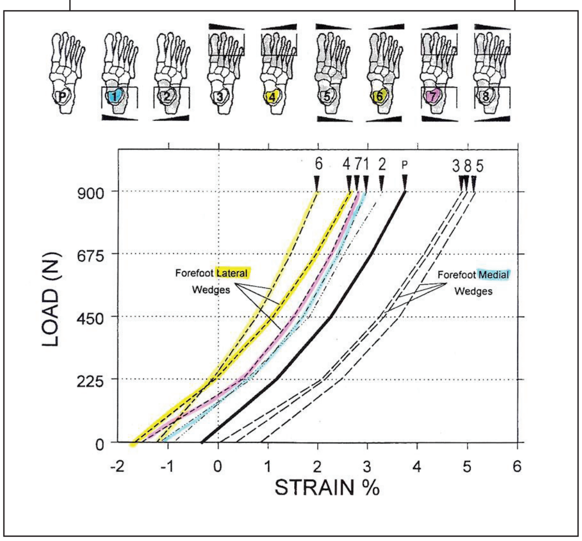

Figure 1: Kogler demonstrated that a wedge under the lateral aspect of the forefoot significantly reduced the strain on the plantar aponeurosis. This may be effective for treatment of plantar fasciitis.

Plantar Fasciitis

Plantar fasciitis is the common vernacular for mechanically-induced subcalcaneal pain, presenting as pain and tenderness at the medial tubercle of the calcaneal tuberosity as a result of abnormal foot mechanics.[1] Foot orthoses are an accepted mechanical treatment for this pathology; however, the numerous variations in foot orthoses make it difficult to determine which variable is responsible for the change. One study showed that treatment with custom orthoses designed to prevent midtarsal joint collapse during gait resulted in 89% of subjects getting relief from their symptoms.[2]

Kogler demonstrated that a wedge under the lateral aspect of the forefoot significantly reduced the strain on the plantar aponeurosis, and suggested that this may be effective for the treatment of plantar fasciitis (Figure 1).[3] The following outcome studies provide additional evidence to support treatment with custom and pre-fabricated orthotics for plantar fasciitis.

The first study by Pfeffer[4] (1999) was a well-publicized study that compared the effectiveness of stretching alone to stretching in combination with one of four different shoe inserts in the treatment of plan-

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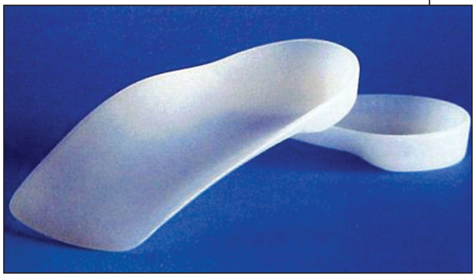

Figure 2: Studies show that custom orthoses are an effective treatment for plantar fasciitis.

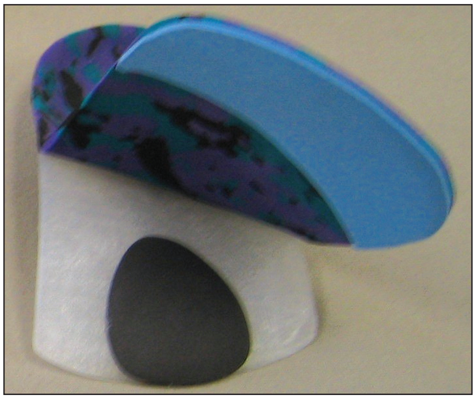

Figure 3: Orthoses control metatarsalgia symptoms by lowering peak plantar pressures in the forefoot. Two excellent studies confirm that metatarsal pads added to custom orthoses can dramatically improve the clinical outcome.

tar fasciitis (n=236). Shoe inserts included three pre-fabricated pads (silicone heel pad, 3/4-length felt pad, rubber heel cup), and custom foot orthoses. Though the conclusion states that pre-fabs along with stretching "is more effective than custom orthoses," an analysis of the statistics shows that all five treatment groups had an improvement in both pain scales, with no significant difference among the groups in the reduction of overall pain scores after eight weeks of treatment when controlled for covariates. This misleading conclusion prompted a deeper look into the study details to determine why the authors would have made a statement that was not supported by their data.

A retrospective analysis shows that the device type was not consistent. Forty-five percent of the custom orthoses were rigid polypropylene (normal width, 14-16 mm. heel cup, no posts or top covers). Another 38% were identical except that the flexibility was semi-rigid. The flexibility variance was not evaluated in this study, nor mentioned as a variable that could affect outcomes. The remainder of the orthoses (17%) varied dramatically. Variables other than shell flexibility that were altered included: heel cup depth (range 8 mm.–18 mm.), width (narrow–wide), use of a rear foot post, and use of a topcover.

The authors noted that patients were encouraged not to change their regular shoe wear. Did the authors believe that a narrow device with an 8 mm. heel cup was equivalent to a wide device with an 18 mm. heel cup for a patient with plantar fasciitis, or were they accommodating the patient's shoe choice as limited by their protocol? Improper footwear has been identified as a contributing factor in plantar fasciitis.[6]

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Another variable with the orthoses used involves the negative cast. Custom orthotic studies generally allow only a single experienced practitioner to cast each patient, minimizing any effect of the casting process on orthotic outcomes. It appears that thirteen different practitioners cast the 42 subjects, with these practitioners learning to cast by watching a video. Considering the number of uncontrolled variables in the custom orthoses group, it is unclear how the authors drew any conclusions about the efficacy of custom orthoses in the treatment of plantar fasciitis, or justified a comparison to the other treatment groups. Fortunately, there have been other outcome studies in the treatment of plantar fasciitis.

Another positive evaluation of orthotic therapy for plantar fasciitis by Lynch[7] (1998) evaluated the effect of three widely accepted treatments: anti-inflammatory (injected and oral NSAIDs), accommodative (viscose heel cup and acetaminophen), and mechanical (low-Dye strapping followed by custom foot orthoses). This randomized prospective study (n=103) found that 70% of the patients in the mechanical therapy group had improvements in pain and function, significantly better than the accommodative (30%) or the anti-inflammatory (33%) groups. Only 4% of the mechanical group had treatment failure, as opposed to 42% for the accommodative group and 23% for the anti-inflammatory group. The authors concluded that mechanical control with custom orthoses is more effective than anti-inflammatory therapy or accommodative therapy used in this study.

Martin[8] (2001) published a prospective randomized study (n=255) that evaluated the effectiveness of three different mechanical modalities used in the treatment of plantar fasciitis (over-the-counter arch supports, rigid custom-made orthoses with a heel post, and night splints). Though all three devices were effective as initial treatments for plantar fasciitis (after 12 weeks of use), "there was a statistically significant difference among the three groups with respect to early patient withdrawal from the study due to continued severe pain, noncompliance, or inability to tolerate the device. Patient compliance was greatest with the use of custom-made orthoses."

Langdorf[9] (2006) conducted a randomized trial (n=136) that evaluated the short-term (three months) and long-term (12 months) effectiveness of foot orthoses in the treatment of plantar fasciitis. The three treatment arms were: "sham" orthosis (soft, thin EVA foam molded over unmodified plaster cast), pre-fabricated foot orthosis (3/4-length retail mold, firm density polyethylene foam), and customized foot orthosis (semi-rigid polypropylene with a heel post). Both the pre-fabricated orthoses and the customized orthoses produced statistically significant improvements in function at three months. The authors noted that more participants in the sham group and the pre-fabricated group

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broke protocol than in the custom group.

Recently, Roos[10] (2006) evaluated the effect of custom-fitted foot orthoses and night splints, alone or combined, in treating plantar fasciitis in a prospective randomized trial (n=43) with one-year follow-up. The authors concluded that custom foot orthoses and anterior night splints were effective both short-term and long-term in treating pain from plantar fasciitis with all groups improving significantly in all outcomes evaluated across all times. "Parallel improvements in function, foot-related quality of life, and a better compliance suggest that a foot orthosis is the best choice for initial treatment of plantar fasciitis."

Although, at first glance, the data on the efficacy of orthotic therapy for plantar fasciitis appears conflicting, every study supports the use of custom orthotics. Each study leaves little doubt that plantar fasciitis is mechanical in origin and effective treatment is accomplished through mechanical control by custom orthoses (Figure 2). Future research may shed light on which modifications of custom orthoses may be most effective in controlling the mid-tarsal joint motion to prevent stretching of the plantar fascia.

Metatarsalgia

The diagnosis of metatarsalgia includes the symptom of pain under the metatarsal heads. Although the most common differential diagnoses for metatarsal pain includes Morton's neuroma, 2nd metatarsal stress syndrome, distal plantar fasciitis, stress fracture, arthritis, and neuritis, most cases also have a component of mechanical overload. Traditionally, the biomechanical intervention for metatarsalgia has incorporated some form of off-loading through the use of forefoot padding, metatarsal pads, and orthoses.

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In 1994, Chang[11] examined the effect of metatarsal pads on plantar pressures and loading rates. Ten symptomatic males each walked 400 steps with a metatarsal pad in place. The pressure and loading rates were measured at eight different sites on the plantar foot. The study demonstrated a decrease in pressure-time integrals in metatarsal heads[11-14] and a decrease in peak pressures at metatarsal heads.[11-12] The study concluded that the redistribution was influenced by a multitude of factors, including pad size, foot size, foot shape and pad location.

Postema's[12] study (1998) examined the effect of custom orthotics on peak pressures and metatarsal pain. Forty-two (42) symptomatic patients used either a pre-fabricated insole, custom orthotics alone, or a custom orthotic with a rocker bar added to the sole of the shoe. The results revealed that a custom orthotic alone and a custom

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orthotic with a rocker bar were both effective at lowering peak plantar pressures, but the pain scores were significantly lower with the use of the custom orthotic alone.

Hsi[13] (2005) focused on the optimum metatarsal pad position for plantar pressure relief. Ten symptomatic subjects wore a metatarsal pad in multiple locations. A sensor mat was used to determine pressure changes. The greatest decrease in peak pressure occurred when the metatarsal pad was placed slightly proximal to the metatarsal head.

Kang[14] (2006) examined the relationship of metatarsal pad location and pain relief. A group of 18 symptomatic patients wore a metatarsal pad, placed just proximal to the metatarsal head for a period of two weeks. The study found that peak pressure relief was directly correlated with plantar metatarsal pain relief, confirming that mechanical interventions are effective in treating metatarsal pain.

Every study published on the mechanical control of metatarsalgia documents a positive clinical outcome without any negative complications.

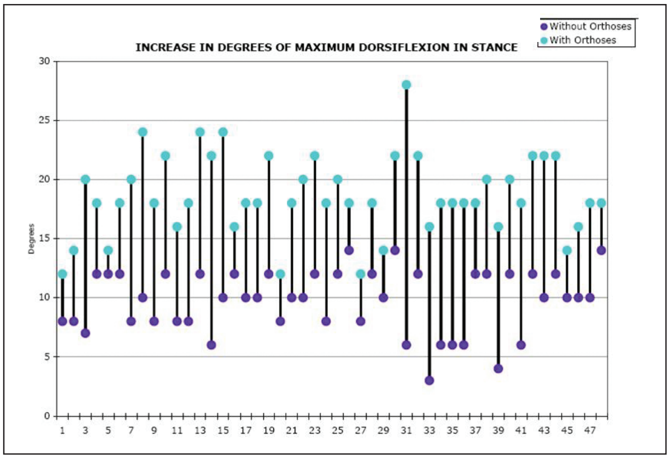

Figure 4: When custom functional orthoses were used in stance, hallux dorsiflexion increased in 100% of the subjects (mean = 8.81°).

All the evidence confirms that orthoses control metatarsalgia symptoms by lowering peak plantar pressures in the forefoot, and two excellent studies confirm that metatarsal pads (Figure 3) added to custom orthoses can dramatically improve the clinical outcome.

Functional Hallux Limitus

Functional hallux limitus is defined as twelve degrees or less of restricted hallux dorsiflexion in closed kinetic chain, and fifty degrees or greater in open kinetic chain examination. Functional hallux limitus is suspected to be the pathology behind the development of hallux abducto-valgus, hallux rigidus, hallux pinch callus, and subhallux ulcerations.[15] This section will review functional hallux limitus (FHL) only, and not structural hallux limitus (SHL),

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since treatment of the latter with orthoses is seldom mentioned in the literature and is suspected to be ineffective.

Whitaker[16] established a definitive relationship between foot position and hallux dorsi-flexion. This study used low-Dye strapping for mechanical control and evaluated its effect in 22 subjects. The study demonstrated that the mean range-of-motion (ROM) before application was 24.77° and 31.81° after application ($p<0.028$), showing statistical significance. This provided quantifiable data demonstrating that changing the foot mechanics can reverse the joint restriction found in hallux limitus.

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Grady's (2002) retrospective analysis (n=772) evaluated patients with functional hallux limitus treated with various surgical and nonsurgical modalities.[17] Hallux limitus was defined as less than ten degrees of hallux dorsi-flexion. Forty-seven percent (362) of patients with symptomatic hallux limitus were successfully treated with orthoses alone (Root functional devices or Schaffer-modified UCBL).

The most recent evidence of the effect of orthoses on functional hallux limitus was published in 2006.[1] This study evaluated the effect of a Root orthosis (made from a negative cast with the first ray plantar-flexed) on hallux dorsi-flexion in patients with functional hallux limitus of twelve degrees or less. Forty-eight (48) feet of 27 subjects were tested both in stance and in gait, with and without orthoses. The results demonstrated an increase in hallux dorsi-flexion with orthoses in 100% of the subjects, both in stance (Figure 4) and in gait (Figure 5). When the orthoses were used in stance, hallux dorsi-flexion showed a mean increase of 8.81° or 90% ($p< 0.001$). The gait evaluation methodology used a reduction in sub-hallux pressure following heel lift as a determinant of increased hallux dorsi-flexion. The functional orthoses resulted in a mean reduction in subhallux pressure of 14.8% ($p< 0.001$). This study proved that in all subjects, orthoses reversed the joint restriction found in hallux limitus.

The mechanical origins of hallux limitus and hallux valgus have been debated for years, including the possibilities of genetic or shoe-related origins. We now have ample proof that the joint restriction is due to abnormal foot position and, most impor-

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tantly, this limitation can be reversed by custom orthoses.

Adult-Acquired Flatfoot

Posterior tibial tendon dysfunction (PTTD) is currently referred to as adult-acquired flatfoot (AAF) to acknowledge that "a rupture or attenuation of the posterior tibial tendon cannot itself lead to the deformity and disability that one sees in many older adults with progressive flatfoot deformity."[18] Adult-acquired flatfoot deformity involves not only the tibialis posterior tendon, but is also associated with changes in the spring ligament, superficial deltoid ligament, plantar fascia, and the long and short plantar ligaments.[18,19] This lower extremity phenomenon tends to start with simple weakness of the tibialis posterior, progresses to ligamentous lengthening or disruption, and finally results in rearfoot subluxation.[20]

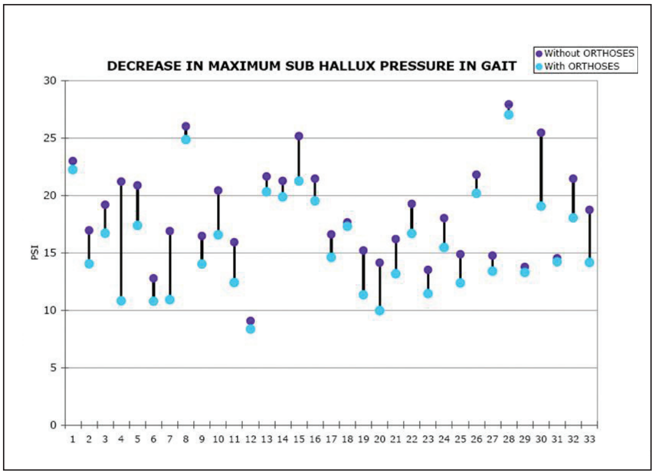

Figure 5: Custom functional orthoses used in gait resulted in decreased subhallux pressure in 100% of the subjects.

Classification of AAF is essential in determining appropriate treatment. In 1989, Johnson and Strom[4] provided the first classification system for PTTD, with Myerson[19] (1996) and Richie[18] (2004) updating the classification for AAF. The purpose of nonsurgical treatment is to maintain the initial deformity and prevent further progression. Early nonsurgical intervention with orthoses does not correct the pathology; however, it does seem to slow the progression of the pathology, reduce the symptoms, and reverse the disability.[22] Non-operative treatment with orthoses can also be particularly useful for elderly patients with relatively sedentary lifestyles, or patients at high surgical risk due to concurrent medical problems.[23]

Imhauser[24] quantified and compared the ability of various ankle braces and in-shoe custom orthoses to stabilize the medial longitudinal arch and hindfoot. They used a cadaveric model that simulated the early stage of flexible flatfoot deformity. Three conditions were tested: intact-unbraced, flatfoot-unbraced, and flatfoot-braced. The custom functional orthosis was the only device that provided superior restoration of both

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arch and hindfoot toward their non-pathologic values. They emphasize that it is very important that orthoses are accurately fitted to the desired shape of the arch. The gauntlet-type orthosis completely restored arch height and navicular height; however, it did not restore talar or calcaneal height. The ankle braces did not provide any significant restoration of medial longitudinal arch nor the hindfoot position.

A second cadaver study was performed in 2005 by Havenhill.[25] Pressure imprints were taken to determine contact area, contact pressure, and peak contact pressure within the ankle joint. A weight-bearing load simulating the midstance phase of gait was evaluated in four conditions: intact limb, flatfoot (surgically-induced severe flatfoot deformity), flatfoot realigned with custom rigid functional orthosis, and flatfoot realigned with a calcaneal osteotomy. Their results showed that the custom functional orthoses' realignment of the midfoot, in addition to the hindfoot, "surpasses the corrective capacity of the osteotomy to normalize the tibiotalar contact characteristics in the flatfoot."

Augustin[26] (2003) reported a prospective evaluation of the effectiveness of the gauntlet-type orthosis in the non-operative treatment of posterior tibial tendon dysfunction. Twenty-one subjects attempted at least one trial of bracing before considering any surgery. "All patients who had stage I or stage II disease showed pain relief that was referable to the brace and demonstrated an improvement in all three clinical measurement instruments."

Sixty percent of the stage III patients had relief of symptoms referable to the brace. The authors concluded that a well-fitted, custom molded leather and polypropylene (gauntlet-type) orthosis can be effective at relieving symptoms and either obviating or delaying any surgical intervention (Figure 6).

Muscle transfer and joint fusion surgery have been marginally effective in treating Stage I and II AAF. We now have evidence that using custom gauntlet braces to control the subtalar and midtarsal joints is a very effective treatment option in controlling pain from AAF, and can provide pain relief and even delay the need for surgical intervention in stage III AAF.

Rheumatoid Arthritis

With more than 2.1 million Americans affected by rheumatoid arthritis,[27] foot pathology related to this disease is common and often strikes early in life. Studies have shown that the foot is the initial presentation site in up to 36% of RA patients. Management of foot pathology in these patients is complex. Since the disease is progressive, many stages of intervention may be necessary throughout a patient's lifetime, depending on pain, disability and functional limitation. Numerous studies have been published that evaluate orthotic therapy in RA from various perspectives including: pain relief, device

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type, accommodation type, functional improvement, joint deformity and gait changes.[2] This discussion will be limited to articles which influence orthotic decisions for RA patients.

Chalmers[29] (2000) examined the effect of shoes and orthoses on forefoot pain. Twenty-four (24) RA patients used three different types of ambulatory intervention: shoes alone, soft orthoses, and custom semi-rigid orthoses. They found that the custom orthoses were the most effective at providing metatarsal pain relief in this group of rheumatoid patients.

Woodburn[30] (2002) evaluated the impact of custom-molded semi-rigid orthoses on pain and functional limitations in RA patients with rear foot valgus deformity and pain (n=98). The study found that there was a reduction in foot pain of 19.1%, a reduction of foot disability by 30.8%, and decrease in functional limitation by 13.5% over a 30-month period.

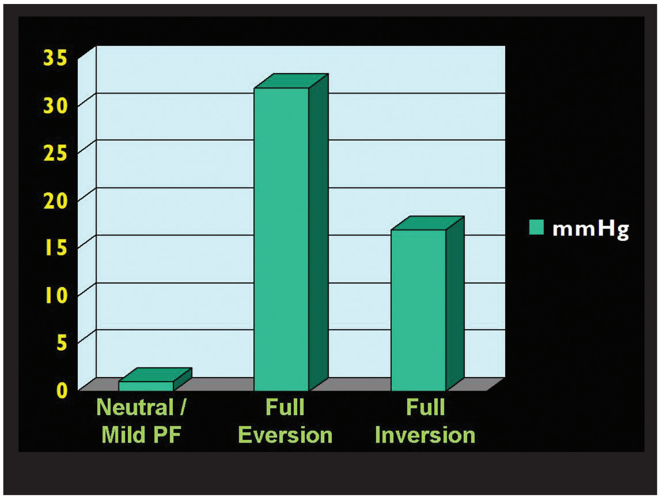

Figure 6: A well-fitted, custom-molded gauntlet orthosis can be effective at relieving symptoms and either obviating or delaying any surgical intervention in AAF patients.

Woodburn[30] (2003) also used 3-D kinematics to determine if semi-rigid orthoses could control STJ motion and increase ankle joint stability. The results showed that not only did the rigid orthoses maintain STJ position, but with continued use, the patients showed improvement in the cumulative STJ position and improvement in the STJ/ankle joint coupling.

A recent study by Powell (2005)[32] showed dramatic results by treating juvenile RA patients with orthoses. Forty (40) patients were given a shoe alone, a flat neoprene insole, or a custom semi-rigid orthosis. The results showed that custom orthoses significantly improved pain and speed of ambulation.

How could we possibly treat juvenile rheumatoid patients without custom orthoses when we have evidence that clearly shows that symptoms of pain and speed of ambulation would improve for these patients? This data documents that controlling the foot with custom functional orthoses is far more effective than the often-used accommodative orthoses.

Tarsal Tunnel Syndrome

Keck (1962)[33] first described tarsal tunnel syndrome (TTS) as pain in the proximal medial arch, and paresthesia along the lateral and medial plantar nerves. He noted that the foot was often excessively pronated at the subtalar joint in TTS. The etiology was hypothesized to be traction on the tibial nerve and compression of that nerve by the flexor retinaculum or compression of the medial plantar nerve as it perforates the fascia. No clinical outcome studies document orthotic effectiveness for TTS; however, three recent studies on the pathomechanics of TTS indicate why foot orthotic therapy would decrease symptoms.

Trepman[34] (2000) measured the tarsal tunnel pressure with the foot in various positions. The positions measured in this cadaveric study were: neutral heel position with mild plantar-flexion, everted heel position with mild dorsi-flexion, and inverted heel position with mild dorsi-flexion. They found increased pressure in the tarsal tunnel when the STJ was pronated, and reduced pressure in the tarsal tunnel when the STJ was supinated and mildly plantar-flexed (Figure 7).

Labib[35] (2002) evaluated 286 patients with heel pain over a three-year period. The authors identified 14 patients who were diagnosed with the triad of plantar fasciitis, posterior tibial tendinitis and tarsal tunnel syndrome (heel pain triad). The authors believe that the triad may be a stage of breakdown of the longitudinal arch, and that failure of the static arch (plantar fascia) and dynamic arch (PTT) may result in a variable degree of arch collapse

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leading to TTS. They also postulated that the "lack of muscular support of the longitudinal arch produces traction injury to the tibial nerve and results in tarsal tunnel syndrome."

Kinoshita[36] (2002) developed a diagnostic test for TTS that sheds light on its etiology and treatment. The foot was passively held in maximal dorsiflexion and eversion for 5-10 seconds (with all metatarsophalangeal joints maximally dorsiflexed) to create non-weightbearing STJ pronation. Patients diagnosed with TTS were tested pre-operatively and post-operatively, with results compared to a control group. No symptoms were induced in the control group with this test. Pre-operatively, 97.7% of patients with TTS had an increase in local tenderness, while 95.3% had an increase in Tinel's sign. The study confirms that this test is an excellent diagnostic tool for TTS, and provides evidence that holding the foot in a non-everted position with an orthosis may improve symptoms.

Figure 7: Tarsal tunnel pressure can be significantly reduced with a neutral STJ position.

This evidence shows, without a doubt, that tarsal tunnel syndrome is of mechanical origin. The origin starts with eversion of the rear foot and lowering of the longitudinal arch, increasing the pressure in the tarsal tunnel. Custom functional orthoses are designed to reverse this mechanism by increasing the longitudinal arch and preventing rear foot eversion.

Lateral Ankle Instability

Lateral ankle instability is defined as an unstable ankle due to disruption of the lateral ankle ligaments. It has been proposed that foot orthoses may be effective in lateral ankle instability as a result of their effect on postural control.[37,38] Postural control is the ability to maintain the body's center of mass over the supportive foot.[2] A deficit in postural control (or balance) is frequently found in patients with chronic instability and is used in studies to demonstrate the effectiveness of custom foot orthoses in treating lateral ankle instability.[39]

Orteza[40] (1992) evaluated patients, with and without history of acute ankle sprain, on a tilt board with a molded orthosis, a flat orthosis, and no orthosis. The molded orthotic device was molded directly to the patient's foot in a neutral subtalar position. The study demonstrated that patients with a history of ankle injury had improved stability with the molded orthosis, while patients with no history of injury saw no change in stability.

Guskiewicz[41] (1996) also measured the effect of a custom functionally-corrected orthoses on postural sway in patients with and without a history of lateral ankle sprain. Again, the injured group showed significantly more postural sway without orthosis, but significant improvement in postural stability with the orthosis.

Other studies[37,43-4] have also demonstrated the positive effects of custom foot orthoses on postural control in patients with histories of lateral ankle instability; however, the mechanism is still unclear. Current theories hypothesize that orthoses may be effective because they: (a) improve foot alignment, (b) stabilize the ankle and/or subtalar joints, (c) improve tactile sensation, and/or (d) improve muscular function.[44-45]

Munn[44] proposes that a custom foot orthosis should be prescribed to allow some subtalar joint pronation to occur, giving the body time to compensate for lateral sway. In other words, an orthosis should help keep the subtalar joint away from its end range-of-motion. If a patient with lateral ankle instability has a more pronated foot, a logical approach using Munn's theory would be to prevent excessive pronation. A deep heel cup, minimum cast fill and a medial heel skive (Figure 8) would help achieve this goal.

Another hypothesis of the cause of lateral ankle instability, and its treatment with orthoses, is the Rotational Equilibrium Theory of Foot Function by Kirby.[45] If a lateral ankle instability patient presents with a more supinated foot, Kirby's rotational equilibrium theory would indicate that the orthotic goal is to reduce the supinated position of the foot by applying a pronatory torque. Orthotic modifications that increase pronatory torque include lateral heel skive and forefoot valgus extensions.

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Postural stability has become a significant research topic, simply because of the medical costs resulting from the loss of postural stability. The research tells us that custom orthoses reduce postural sway and improve stability, and researchers postulate that this may prevent or reduce injury by holding the foot in a more stable position.

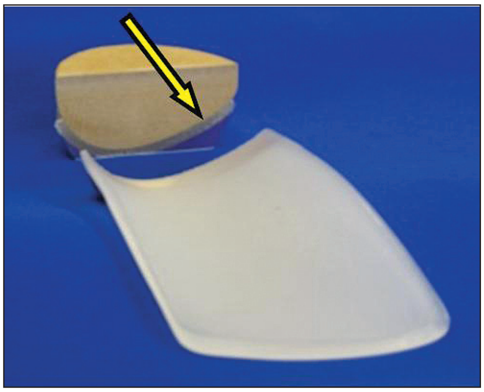

Figure 8: An orthosis with a medial heel skive.

Conclusion

Anecdotal evidence has always existed to support the effectiveness of custom foot orthoses in reducing foot pain. Now, there is peer-reviewed scientific evidence to confirm our speculations that custom orthoses are effective in treating plantar fasciitis, metatarsalgia, hallux limitus, adult acquired flat foot, rheumatoid arthritis foot, tarsal tunnel syndrome and lateral ankle instability. As orthotic therapy becomes more pathology-specific, additional research will surely demonstrate the importance of accurate prescription writing and quality manufacturing standards to further enhance the positive clinical outcomes produced from custom foot orthoses. ■

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