

Evidence-Based Medicine (EBM) and Orthotic Therapy



EBM supports orthosis modifications and troubleshooting.

By Lawrence Huppín, DPM

Orthotic therapy has changed considerably in the past decade as new studies have provided evidence on the efficacy of foot orthoses in treating many of the most common pathologies seen in podiatric clinics. Research has not only shown efficacy but has also indicated how orthotic prescriptions should be written in order to achieve optimum clinical outcomes for specific pathologies.

Unfortunately, many podiatrists—and orthotic laboratories—have not kept abreast of recent literature and continue to practice less than optimum orthotic therapy.

This leads to a “chicken or the egg” scenario where the following occurs:

- Doctors do not practice evidence-based treatment when prescribing orthoses, resulting in ➡
- Poor clinical outcomes, resulting in ➡
- Doctor frustration with orthotic therapy, resulting in ➡
- Doctors ignoring research and education that can help them achieve better clinical outcomes.

EBM

Evidence-based medicine (EBM) shows that orthoses do work to treat many of the common problems seen in podiatric clinics. But practicing EBM also may require

that doctors alter how they approach orthotic therapy. This includes ensuring that negative casting follows what the literature demonstrates are the most effective methods, orthotic prescriptions that follow EBM tenets, and choosing orthotic labs that are able to fill these prescriptions accurately.

In addition, podiatrists who follow EBM must often upgrade their orthotic troubleshooting skills. Those practitioners who practice evidence-based orthotic therapy by capturing EBM based images of the foot, writing EBM prescriptions, using labs that can fill EBM prescriptions and have excellent or-

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thotic troubleshooting skills will be the most successful at providing relief to their patients and building a successful orthotic therapy practice.

Evidence-Based Orthotic Prescriptions

Evidence in the literature indicates what the most effective orthotic prescriptions are for specific pathologies. For example, a number of studies have shown that orthoses that conform very close to the arch of the foot are more effective for many of the pathologies most commonly treated with custom orthoses. Let's look at a few examples of those pathologies and their associated studies.

Metatarsalgia

Researchers out of George Washington University studied the effect of a total contact insert (TCI) and a metatarsal pad (MP) on metatarsal head peak plantar pressures and pressure-time integrals. Their conclusion was that the total contact insert and a metatarsal pad caused substantial and additive reductions of pressures under the metatarsal heads. The TCI reduces excessive pressures at the metatarsal heads by increasing the contact area of weight-bearing forces. The MP acts by compressing the soft tissues proximal to the metatarsal heads and relieving compression at the metatarsal heads.¹

A 2000 study by Chalmers compared the effects of semi-rigid and soft orthoses worn in supportive shoes, and supportive shoes worn alone, on metatarsal phalangeal joint pain in patients with rheumatoid arthritis. Their results showed that semi-rigid orthoses had significant effect on pain. Soft orthoses did not show a significant effect on pain, nor did shoes alone,



Figure 1: For many of the pathologies most commonly treated with orthoses, studies indicate that orthoses that conform closer to the arch of the foot are more effective than those that gap from the arch. This orthosis is gapping from the arch of the foot.

showing that semi-rigid orthoses worn in supportive shoes were an effective treatment for metatarsalgia. Supportive shoes worn alone or worn with soft orthoses did not provide pain relief for metatarsalgia.²

Plantar Fasciitis

A 1996 cadaveric study by Kogler demonstrated in 1996 that orthoses which conform closely to the arch of the foot more effectively reduce plantar fascia tension.³ A follow-up study in 1999 found that valgus forefoot wedging decreased tension on the plantar fascia, while varus wedging increased tension. This study showed that the most effective way to decrease strain on the plantar fascia is to use orthoses that conform close to the arch of the foot and to evert the forefoot.⁴

Hallux Limitus

Roukis, et al. found that prevention of first ray plantarflexion resulted in decreased first metatarsophalangeal joint (MPJ) dorsiflexion (hallux limitus). Subsequently, they also found that when the first ray was allowed to plantarflex, there was an increase in available first MPJ dorsiflexion.⁵ This is indicative that orthoses that prevent first ray dorsiflexion (orthoses that conform close to the arch when the first ray is dorsiflexed) enhance windlass function. In a 2000 study, Harradine found that increasing eversion of the heel, which acts to dorsiflex the first ray as the medial forefoot is jammed into the supporting surface, decreased available dorsiflexion of the first MPJ.⁶ These studies indicate that orthoses which prevent first ray dorsiflexion (orthoses that



Figure 2: This "total contact orthosis" conforms tightly to the arch of the foot.

conform close to the arch when the first ray is plantarflexed during casting) enhance windlass function.⁶

Other pathologies with peer-reviewed evidence of the efficacy of foot orthoses include adult-acquired flat foot, rheumatoid arthritis foot, pes cavus, patella-femoral dysfunction, osteoarthritis of the medial knee, tarsal tunnel syndrome, and lateral ankle instability.

Evidenced-Based Orthotic Prescriptions May Change Your Orthoses

One of the common factors found in writing orthotic prescriptions is that, for many pathologies, studies indicate that orthoses that conform closer to the arch of the foot (Figure 1) are likely to provide better clinical outcomes than those that gap from the arch (Figure 2). It is critical that podiatrists be aware of this as many custom orthoses prescribed by podiatrists are made in such a way that the orthotic shell does not conform closely to the arch of the foot. There are several situations that can lead to an orthosis that does not adequately conform to the arch of the foot. These include:

- **Using foam box casting technique:** McPoil, et al. compared non-weight-bearing (NWB) vs. semi-weight-bearing (SWB) casting of the feet (plaster negative suspension casts vs. foam impression casts). The authors found that NWB plaster casting was superior to foam box SWB casting since the SWB casting resulted in artificial varus in the forefoot.⁷ Laughton and McClay-Davis did a similar study com-

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paring two casting techniques, NWB plaster vs. SWB foam impressions.⁸ They found that NWB casting had good agreement with the clinically measured forefoot-to-rear-foot relationship. SWB foam impressions had poor forefoot-to-rear-foot agreement and the SWB foot resulted in an artificial increase in varus, likely resulting from first ray dorsiflexion due to weight-bearing. This study recommended NWB foot imaging as the most reliable and valid technique.

- **Improper Prescriptions:** For an orthosis to conform closely to the arch of the foot, the doctor should prescribe a minimum fill. Any medial arch fill greater than minimum will lead to a device that gaps from the arch.

- **Overfill of the medial arch by the lab:** Maintaining close contour also requires that the orthotic lab not overfill the medial arch. To achieve this, practitioners must carefully evaluate the work of their lab to ensure that their prescription is followed. (Figure 3) Labs may sometimes overfill the arch in reaction to demands from their customers. Podiatrists who lack skill or desire to troubleshoot orthoses demand that their labs manufacture a “no adjustment necessary” orthosis. Labs respond by overfilling the medial arch of the positive cast to make orthoses that have lower arches. The result is a device that rarely causes arch irritation but also rarely provides optimum clinical outcomes.

Close arch contour can be achieved with an orthosis prescription that includes minimum cast fill and mild inversion.

Podiatrists who do not capture an image or cast of the foot that follows EBM criteria, who do not write prescriptions with minimum cast fill, or use orthotic labs which routinely overfill the medial arch will supply their patients with orthoses that do not conform well to the arch of the foot and provide less than optimum clinical outcomes for many of the most common pathologies treated with foot orthoses.

Orthoses that conform closer to the arch, are wider or have deeper heel cups, or have additions such as metatarsal pads are also more likely

to require occasional adjustments and troubleshooting. It becomes imperative that in order to provide the best possible outcomes with orthotic therapy, practitioners must not only write prescriptions that follow best practices but also have troubleshooting skills and optimally be able to make orthotic adjustments in their clinics.

In summary, practitioners who write orthotic prescriptions based on evidence in the literature and only use labs that will fill their prescription as written are likely to see:

- Improved clinical outcomes
- Orthoses that tend to have higher arches, wider widths, deeper heel cups, and require more modifications.

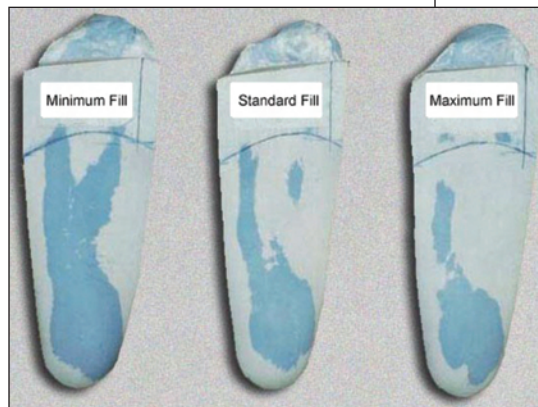


Figure 3: An orthosis made from a cast with minimum fill will conform closer to the arch of the foot than one made from a positive cast with standard or maximum fill. (photo courtesy of LER, *Recent Advances in Orthotic Therapy*, 2011)

- Orthoses that will occasionally have need for adjustment.

Podiatrists' Options for Orthosis Troubleshooting

If a podiatrist is going to practice EBM orthotic therapy, certain basic proficiencies are required. Orthotic prescriptions must be written to treat the pathology, not to eliminate any need for orthotic adjustment. Occasional troubleshooting and adjustment of orthoses will be necessary for those practitioners who follow EBM when prescribing orthoses. When deciding whether to follow EBM in their orthotic therapy and whether to make orthotic adjustments in their offices, podiatrists can choose one of the following scenarios:

- 1) **Prescribe orthoses that rarely, if ever, require adjustment.** These tend to be orthoses with arch-

es that don't conform well to the arch of the foot, and thus do not adequately address the pathology. This occurs when practitioners write orthotic prescriptions with standard or maximum arch fill or when orthotic labs overfill the medial arch. In effect, this choice is to ignore EBM and prescribe a less effective orthosis. This choice is a disservice to your patients and to the profession.

- 2) **Follow EBM and prescribe better orthoses but ship the orthoses back to the lab when adjustments are necessary.** This is workable, but a time-consuming, inconvenient, and expensive option. On an online heel pain forum, one patient, whose feelings likely represent those of most patients, had this to say about her podiatrist who followed this scenario:

“My custom orthotics are still uncomfortable after four weeks.... I still feel like I have two golf balls shoved up under my arches. I made an appointment with the podiatrist who made the mold. If there are any adjustments that need to be made, the nurse said they will need to be shipped back to the lab where the orthotics were made; the podiatrist

is not going to make them. YIKES! I am already perpetually in a state of ‘waiting’ for relief. The turnaround will be at least two weeks. My question is... can I bring my orthotics to a local pedorthist and have modifications made, or do they only work on their own fabrications? I am feeling a little panicky because I am a teacher, and I am hoping to get this plantar fasciitis under control before school starts. The idea of sending off my orthotic doesn't sound like a quick procedure.”

- 3) **Follow EBM, prescribe better orthoses, and develop orthotic troubleshooting and adjustment skills.**

- 4) **Refer orthotic therapy to colleagues who will follow EBM and prescribe more effective orthoses**

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Figure 4: A grinder is an essential tool for orthotic practitioners. Among other uses, it can be used to thin the arch of the orthosis to increase flex and reduce reactive force applied to the plantar aspect of the foot.

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and have the ability to modify these devices in their offices.

Prescribing for Modifying

The most common patient complaint when prescribing EBM orthoses is an arch that feels too high. With some simple adjustments to your prescription, this is an exceedingly easy problem to troubleshoot effectively in the office. These simple changes to your prescriptions can make these adjustments easy to perform:

- **Prescribe Polypropylene orthoses for a majority of your devices.** Polypropylene is the easiest material to adjust—especially when arch irritation is present. Simply use a grinder to thin the planter surface of the arch of the orthosis (Figure 4) This increases the flex of the device and reduces orthotic reactive force on the arch. It is a quick and easy adjustment. A video demonstrating this technique can be seen at www.tinyurl.OrthoticArch. The arches on carbon fiber devices can also be adjusted but require heating the device and lowering the arch. This is not only more time-consuming, but you run a significant chance of altering the shape of the orthosis.

- **Prescribe wider orthoses.** Wider devices act to spread force over a larger surface area, thus decreasing the force applied per square inch and decreasing the likelihood of arch irritation (Figure 5). In addition, wider orthoses tend to offer greater control over excessive pronation and arch collapse. The downside is that shoe fit may be

more of an issue, but adjusting for size by grinding the orthosis narrower or the heel cup shallower are some of the easier orthosis modifications.

- **Ask your lab to glue your covers “posterior only”.** (Figure 6) This allows for easy adjustments to the distal portion of the orthosis, including the addition of modifications such as metatarsal pads.

- **Do not prescribe bottom covers.** Bottom covers make modifications much more difficult to perform and can be easily added to the orthoses at a later date, once you and the patient are sure the orthosis is working as it should.

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Patient Education

When prescribing more effective orthoses that are not made from positive casts with excessive medial arch fill, it is critical that patients understand ahead of time that some adjustment may be necessary. When it is explained correctly, you will find that not only do they understand, but they appreciate that you are making a superior orthosis for them. Let’s use metatarsalgia as an example. As noted earlier, a number of recent studies have demonstrated that very specific orthotic modifications reduce pressure under the metatarsal heads.¹⁻⁷ These include total contact orthoses (orthoses that conform very close to the arch of the foot), metatarsal pads, and cushioning under the met heads. A very effective method to explain the benefits of orthotic therapy, how your orthotics work better, and what problems patients might experience and how you will deal with them is to explain the effects of pressure on their feet. An explanation on orthotic choices for a patient with metatarsalgia might go like this:

“In order to relieve your pain, a

number of studies have shown that we have to reduce the pressure under the ball of your foot. We do this by putting an orthotic inside your shoe that will transfer the pressure off of the ball of your foot and onto the arch. These studies show that the tighter an orthotic hugs your arch, and the wider it is through the arch, the more pressure it takes off the ball of your foot.”

Because of this, I need to advise

you that in a small number of cases, patients may initially feel the arch of the orthotic pushing too hard on their arch or they may have some problems with shoe fit. If this occurs, it takes just a couple of minutes to make an adjustment for you here in the office, and we always guarantee you will be comfortable in your orthotics. If I were to go the other direction and err toward orthotics that were too low or too narrow, they may never have a chance to bother you, but they are also unlikely to provide you the best pain relief.

In addition, you’ll notice that when you first get your orthotics, the cover may not be

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Figure 5: Wider orthoses spread weight over a larger surface area and are less likely to cause arch irritation. This orthosis is the full width of the foot.



Figure 6: Prescribing an orthosis with the cover glued “posterior only” will make it easy to add metatarsal pads and make other adjustments to the anterior portion of the orthosis. (photo courtesy of LER, *Recent Advances in Orthotic Therapy*, 2011)

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glued down on the front. This is to allow me to easily make adjustments to your orthotics. Once you are sure they are working as they should we'll glue the cover down, and put vinyl on the bottom so that they slide easily in and out of shoes."

Orthotic Troubleshooting 101

Unfortunately, most podiatric medical schools and podiatric residency programs spend little time teaching orthotic troubleshooting techniques. In addition, orthotic therapy, in general, and orthotic troubleshooting, in particular, are poorly addressed at most podiatric continuing education programs. It therefore can be problematic for a practitioner to gain the training necessary to become expert in orthosis modifications. There are, however, at least a few good methods to acquire this information:

- 1) Visit the offices of podiatrists who are experts at orthotic modifications and troubleshooting.
- 2) Use orthotic labs which offer expert consultation, including instruction on orthotic modifications and troubleshooting.
- 3) Attend seminars that incorporate strong orthotic therapy component.

Basic Troubleshooting Skills

At a minimum, every orthotic practitioner who follows evidence-based orthotic therapy should be able to perform the following orthotic modifications:

- Adjust for arch height/rigidity
- Adjust for shoe fit, including orthotic width and heel cup height
- Add covers
- Add metatarsal pads, metatarsal bars, forefoot cushion, apertures, Morton's extensions, reverse Morton's extensions, and varus/valgus wedges.

Materials and Equipment

In order to perform these basic adjustments, some standard equipment and materials are needed. These include:

- Grinder
- Ticro Polishing cone (to polish polypropylene after grinding)
- Hood or fume filter (Figure 7)
- Solvent to remove covers

(Non-toxic solvents such as Orange-Sol™ are very effective and safe to use)

- Korex to use for Morton's/reverse Morton's extensions, varus/valgus extensions, aperture
- Poron to use for cushion
- Self stick metatarsal pads
- Self stick wedges

Podiatric medical supply houses and orthotic labs can help you find necessary equipment, materials and supplies.

Conclusion

Anecdotal evidence has always existed to support the effectiveness of



Figure 7: When working with glues, a hood or fume filter, such as this "Fume Buster" brand, are essential equipment. It functions as both a work surface and a fume filter.

custom foot orthoses in reducing foot pain. Now, there is peer-reviewed scientific evidence to confirm not only the efficacy of orthotic therapy but also how orthotic prescriptions should be written to best treat specific pathologies. Studies demonstrating the effectiveness of specific orthotic prescriptions are available for many pathologies including plantar fasciitis, metatarsalgia, hallux limitus, adult acquired flat foot, rheumatoid arthritis foot, tarsal tunnel syndrome, and lateral ankle instability.

For individual podiatrists and the profession of podiatric medicine to maintain a reputation as experts and leaders in providing orthotic therapy, podiatrists must provide their patients with evidence-based orthotic therapy. To

do so means that certain basic proficiencies must be met. This includes critical evaluation of foot image capture, whether by traditional plaster methods or via optical scanning; following evidence-based protocol in writing orthotic prescriptions and developing in-office troubleshooting skills that will allow practitioners to alter orthoses to improve function and comfort. To ignore any of these proficiencies is to choose to provide patients with orthoses that do not optimally address their pathology. ■

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