Why Custom Orthotic inserts don't work

A critical look at the orthotic devices we prescribe.

David Hallowell Podiatrist and Orthotist

As a Lab owner and clinician of some 25 years, it's always been of interest to me how many patients attend our clinics with previously prescribed orthoses which have either been clinically unsuccessful or which were never worn due to the discomfort they caused. These patients are understandably sceptical about orthoses and given that many of them have parted with a great deal of money, they may also be somewhat distrusting of our profession. Some may ultimately end up on orthopaedic waiting lists due to the failure of their devices, so the stakes are high. Orthopaedic surgeons are not trained in assessing the quality and function of an orthotic so when faced with a patient who is in pain and who has been unsuccessfully issued with orthoses their options may be somewhat limited. So, it's quite possible that some patients may have surgical procedures which could have been avoided had their orthoses been successful. These unsuccessful outcomes are occurring against a backdrop of technological advances like dynamic foot pressure systems, video gait analysis, and 3D foot scanning. Technical advances have facilitated greater understanding of the foots movements and have led to ever more complex biomechanical theories and concepts emerging. One could be forgiven for thinking that these advancements in biomechanical technology would lead to a concomitant improvement in orthotic management outcomes but this does not appear to be the case. If not, it begs the question "where might we be going wrong"? The science of Podiatry biomechanics has become incredibly complex and at times completely baffling. We have seen many biomechanical gurus emerge over the years. I well remember one such guru being slightly embarrassed when one of our more pragmatic college lecturing staff asked him "could subtalar joint pronation be prevented by rolling a handkerchief up and placing it in the medial arch area of the shoe". Has Podiatry as a profession created a science of biomechanics that is at best confusing, at worst self-serving and which has become divorced from the devices we ultimately ask patients to wear? Biomechanical concepts regarding foot function have become ever more complex. Here are just a few of the concepts which quite often stimulate debate on one of the more popular Podiatry discussion sites.

- Neutral calcaneal stance
- Criteria for Normalcy
- The Root classification scheme
- Planal dominance preferred movement pathway theory
- Joint axis location & rotational equilibrium theory
- Tissue stress theory
- Sagittal plain facilitation theory
- Beam theory

During my 20 years working with the Ministry of Defence being under pressure to see large numbers of patients and to produce consistent results I gradually started to dispense with many of the biomechanical concepts which had been taught in college. These had been taught as if they were carved in stone and handed down from above. The first thing to go was subtalar joint neutral, others included drawing lines on soft tissues to represent bone alignment and measuring inversion and eversion of the calcaneum. The most valueless idea I left behind was the notion that taking a non-weight bearing cast/image is the only and best means of producing an effective orthotic. As many of the service personnel brought in orthoses which had been made at different locations around the world it was easy to see which orthoses worked well and why. This impacted not only on my biomechanical approach but also on our manufacture methods. Much of our approach today actually relates more closely to orthopaedic work by people like G. K Rose in the 1950's than to the theory's put forward by Roote, Weed and Orion. These became the foundation of Podiatric biomechanics and despite being superseded by more recent concepts they still permeate much of Podiatry orthotic control theory. Although this article mainly focuses on why custom orthoses don't work for patients it is also clear that the term "custom foot orthoses" doesn't work for Podiatry as a profession. This is because the term custom orthotic itself has become almost meaningless. Ask any group of Podiatrists for a functional definition of what a custom orthotic is and you may be surprised at the variety of responses you get. Laboratories are using different methods and systems to manufacture their devices so that if you send a cast to 5 different labs you may get back 5 completely different shaped devices depending on the method/system being used and the technician involved in designing them. Again, a look at the Podiatry discussion sites reveals much debate regarding what a custom foot orthotic is or should be and how it should be designed. I remember reading an article by a Podiatrist who said that there was no evidence that custom devices produced better results than "off the shelf orthoses". When I asked about the custom orthoses he was referring to, it became clear that he'd been buying computer manufactured library shapes which he thought were custom "presumably because a cast was taken". So, we as a profession clearly need a more functional definition of what a custom orthotic is, as without it the term "Custom Orthotic" can at best be misleading.

Regarding poor patient outcomes, there are 7 reasons why in my opinion custom orthoses don't work for the patients we treat. So, let's look at those reasons, lets as a friend of mine used to say "kick the tyres" of custom orthoses.

1. Rearfoot Posting - By far the greatest number of the custom orthoses being issued today are provided to reduce the effects of abnormal subtalor joint pronation. When we studied biomechanics at college we were told that custom orthoses must never be referred to as arch supports. The reason for this we were told was that a custom orthotic is designed to control calcaneal eversion and thus control abnormal pronation. A curious thing happens when you try to use an orthotic purely in this way, firstly the patient finds the upward force applied by the device in a relatively small area of the foot (anterior/medial aspect of the calcaneum) uncomfortable and secondly the correction simply does not work. Another flaw in this method becomes clear when we realise that to control the relationship between any two bodies (in this case the calcaneus and the talus) which are moving in relation to each other it is necessary to control both. By applying force to the calcaneus only, we do not control the talus and its tendency to slip medially and downward. This is analogous to trying to stabilise a fractured limb by applying plaster bandage to the distal fragment only. Or attempting to control the knee joint by applying a brace to only the lower leg. This in my opinion is the reason why one of the most common modifications made to dysfunctional orthoses is the addition of a D medial arch filler.
2. Posting Circles - Rearfoot posting we were taught was one of the keys to successful prescription outcomes. However, if we take a cross section through the heel cup of most modern custom orthoses we will find that many of them are circular in shape. What this means is that no matter how much rearfoot posting is written on the prescription the heel cup never actually changes shape and its face angle (that part of the device which is meant to alter with different rearfoot posting measurements) remains identical Fig1 and 2.

Fig 1

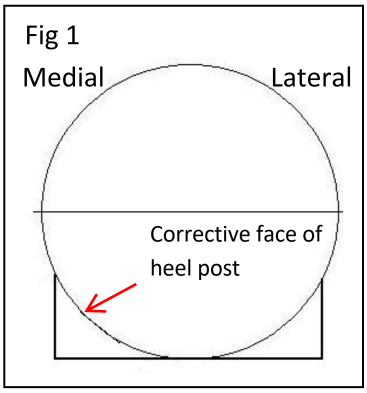
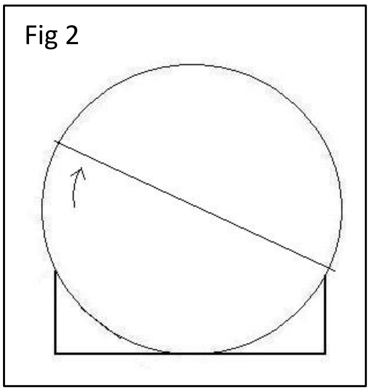


Fig 2



Why then is it that most orthoses are circular in cross section? The simple answer is that most labs are now using some degree of automated design and experience has shown that these systems like regular shapes i.e. circles. The non-changing of the face angle has given rise to the now common use of medial skives Fig 3. which are a means to increase function around the medial aspect of the calcaneum by increasing invertory Ground reactive force (GRF). I personally don't question this for those who believe in calcaneal inversion as a means of correcting ST joint mechanics but I do question the reasons why it has become necessary. It's a strange paradox given how apparently important this rearfoot posting angle is that many practitioners tick the box for "labs discretion" for rearfoot posting on their prescription forms.

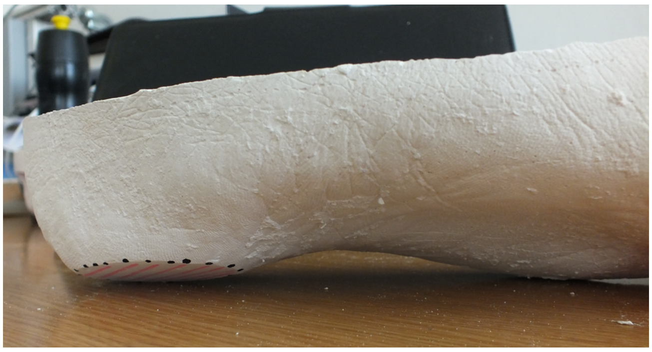


Fig 3 Medial skive a flattened area on the anterior medial aspect of the calcaneus designed to increase GRF.

3. <u>Arch Contact Angle</u> - The main area where movement takes place in patients with abnormal ST joint pronation is the talo/navicular joint with in many cases little eversion of the calcaneum. This again explains the repeated use of D filler arch pads to improve dysfunctional orthoses. So, all the emphasis on taking calcaneal ROM measurements and completing calculations to identify Podiatry's Holy Grail of subtalar joint neutral can be seen to be of very questionable value particularly in the light of what's been said about the resultant rearfoot posting. If most of the movement in an over-pronating foot takes place at the talo/navicular joint it seems reasonable that this is the best place to effect change? *It's interesting to note that the main antipronatory muscle groups attach in this area*. To reduce a movement itself or counter a force acting in a particular direction a force must be applied in the opposite direction. The further from perpendicular the face angle of the orthotic is to the force or movement, the less correction is created. When looking at the talo/navicular joint what we see is a downward and medial movement due to the displacement of the Talus. These are known as talo/navicular drop and drift respectively. The degree of drop and drift varies for each individual patient depending on the axial relationships of the relevant joints. These two movements resolve into a single downward and medial movement. Fig 4. It is in this area that in my opinion many orthoses fail. Most devices either have a face angle which is not perpendicular to the motion or force they are trying to counter or they are not in contact with the foot in this vital area.

Fig 4. Sectioned cast. Horizontal line Talo/nav drift and vertical line Talo/nav drop. Diagonal line is the resultant angular movement which must be opposed by the orthotic devices face angle (red line).

It is clear then that the more medial drift the more vertical the side wall of any corrective orthotic needs to be. This gives rise to a fabrication problem as many of the new milling systems don't like vertical surfaces. They are extremely difficult to mill from a solid piece of material and the systems often default to a different shape rather than attempt to mill a near vertical surface. They also have limitations in the depth of material they can mill and this prevents extremely high flanges like those in Fig 5. The orthotic in Fig 5 illustrates this with an extreme case were the patient had a rupture of her tibialis posterior and wanted an alternative to an ankle foot brace. The device was almost 60mm deep in the medial arch and was almost vertical at the talo/navicular joint.

Fig 5a and b showing high vertical flange used as a buttress to control tal/nav drift

4. <u>Arch curvature</u> - In order that the pressure across the arch area of the device be spread as evenly as possible, the 3 dimensional curvature of the arch profile should be as close as possible to that of the corrected arch itself. While this statement seems self-evident it is strange that many orthoses have a cross sectional curvature which actually curves away from the foot Fig 7b. This has 2 effects a) It means that the correction through the medial aspect of the device is completely lost and b) It increases the load or force created by other areas of the device and therefore creates areas of low pressure and non-function, as well as areas of disproportionately high pressure (Hot spots) and discomfort Fig6.

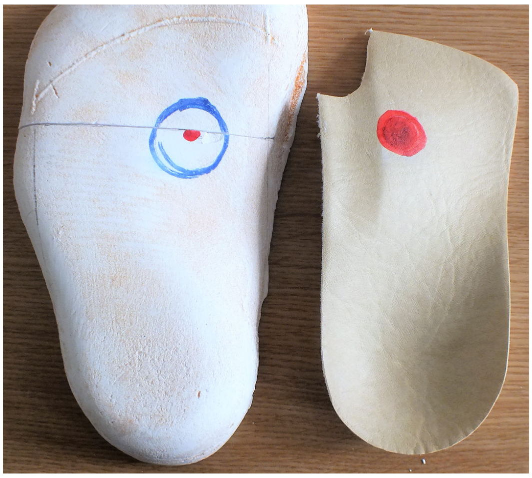


Fig 6. Hotspot due uneven pressure across the orthotic, Patient had severe pain under 2nd met shaft.

Fig 7a Showing good contact through Talonavicular area of orthotic and even pressure across the device.

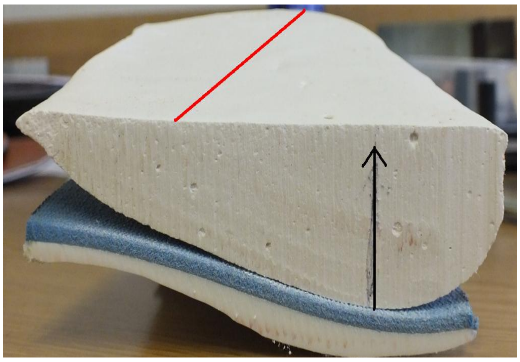


Fig 7b Showing pronatory imbalance due to lack of contact through talo/nav joint and concomitantly increased GRF lateral to the ST joint axis (Red line)

5. <u>The lateral border</u> – This aspect of orthoses often gets ignored during discussions and yet it is one of the most misunderstood parts of the device. Even in poorly fitting orthoses the lateral border usually fits reasonably well as it is normally fairly straight in most feet. Notice in Fig 7b that the vertical line of GRF on the orthotic is lateral to the ST joint axis (drawn in the transverse plane). It is therefore creating a pronatory force which is not counterbalanced by the poorly fitting medial aspect of the orthotic. This creates an orthotic which increases pronatory force rather than reducing it. Almost all the orthoses that I see where the outcomes have been unsatisfactory have these two aspects in common, a reasonably close fitting lateral border and a poor fitting medial arch, what's known as "pronatory imbalance" (PI). It is essential if an orthotic is to function properly and produce a balance of GRF that it fits evenly across its entire surface Fig 7a.
6. <u>Restoring movement</u> - Much of the abnormal pronation we see is due to a lack of normal movement somewhere within the kinetic chain either due to soft tissue tightness, muscle dysfunction or joint damage. If orthoses are to be successful it is important that all issues both functional and structural be addressed. It is therefore essential that the issuing clinician takes the time to find the underlying cause of the reduced movement and attempt to rectify it to whatever degree possible. This is an area to which Podiatrists can sometimes be accused of paying lip service. Not fully dealing with the underlying cause of pronation has 3 main effects. a) It reduces the possibility of a successful outcome for the patient. b) By not reducing the pronatory impulse/force caused by the underling dysfunction the foot hits against the orthotic with greater force than it would if the underlying cause had been ameliorated. In severe cases the pronatory force causes the foot to be

battered against the orthotic like a ship dashing against rocks. This is greatly magnified in devices which have a pronatory imbalance Fig 7b. In the long term this can cause a complete breakdown of the structural integrity of the foot to a point where in many cases surgical intervention may be required.
c) It creates a situation where orthoses are seen as a treatment in and of themselves and not as a part of a much broader co-ordinated approach to the patient's management. In my own experience restoration of proper function is almost always better if approached with the co-operation of a Physiotherapist.

7. Automation - I've mentioned automated design and manufacture (CAD-CAM) several times in this article and I guess I must be in a small minority of those who believe that it is not currently the best way to design and manufacture custom orthoses. The reasons for this are many and varied. a) CAD-CAM systems are in my opinion being developed and used not to make better orthoses but to reduce the labour intensity of the process. This inevitably leads to compromises in quality as the main selling points of the systems are price and ease of use. b) To date I have seen few systems which do not use some aspect of preformed generic library shape/profile technology. It's interesting to note that some labs have moved away from the term "custom" to the conveniently ambiguous term "prescription" which infers their devices are custom without saying it. c) Any CAD-CAM system runs on a set of parameters outside of which it can never operate and which limit the amount of different shapes which can be produced as opposed to plaster which as a liquid can be poured into an infinite variety of shapes. The following photographs Fig8 and Fig9 show a cast of foot which had completely collapsed and which had a large medial talo/navicular bulge. The first orthotic from a CAD-CAM system was unable to deal with the unusual shape of the particular foot and defaulted to a standard medial arch profile while the plaster cast with a vacuum formed device fits closely. Even the system that my own company purchased while not using library shapes still limits the shapes of plaster additions we can produce. For this reason, we have largely moved back to more traditional manufacture methods.

Fig 8 Pronatory imbalance due to software defaulting to a lower arch setting.

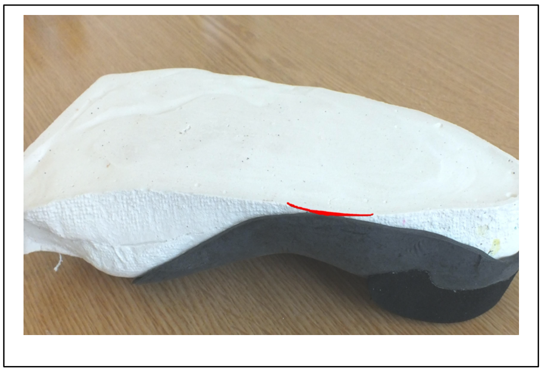


Fig 9 Red line shows area of talo/nav control

d) Barriers to entry - In the early days of orthotic therapy a great many Podiatrists made their own orthoses, this meant they had to review trouble shoot, and modify their devices necessitating a sound knowledge of the orthoses they prescribed. When commercial Podiatric manufacture labs started to operate most had a high degree of specialist knowledge as they were either owned by a Podiatrist or they had a Podiatrist or an Orthotist as the technical manager. This situation has steadily changed with the increasing availability of CAD-CAM systems. Today you're just as likely to find a computer programmer or an entrepreneur running a lab without anyone from a specialist background being involved. As one salesman for a well-known CAD-CAM system said to me recently “we can train someone to operate our system in about 2 days” this has removed all the restrictions to entering the orthotic market and made the running costs much lower. After the initial investment, the system can be run by anyone with a basic knowledge of computers. The role of lab owners has been reduced to one of keeping up sales volumes and reducing costs to a minimum. I first saw this trend in 1996 when we were buying our first 3D foot scanner. I didn’t want to direct mill in the UK so we went to a company in the USA run by a larger than life character who owned an orthopaedic shoe shop. He had bought a library shape system and employed a few student computer boffins to run it. He then simply undercut the whole market by offering direct milled orthoses at $40 pair and captured a huge chunk of the American Orthotic market in a very short period of time. He laughed at the idea of hiring a Podiatrist to oversee things. “All I need is someone who can press buttons and a few glue guys for finishing”. I vividly remember watching a staff member scanning hundreds of slipper casts for hours on end, if the casts didn’t fit into the scanner aperture he cheerfully hammered them flat with his fist. On questioning this process, I was told “the system only needs the basic dimensions of the cast and then it does the rest”.
e) In Podiatry education, changes in orthotic manufacture have come about at a time when Podiatry schools which once had their own labs where students could learn and hone their skills are now buying orthoses. The main reasons for this are that it becomes financially difficult to justify in-house labs and the increasing academic load has meant that many where underutilized. Podiatry as a profession has also moved away from hands on manufacture in favour of prescription, so the gulf between the lab and the end user has never been wider. When I recently asked a newly qualified Podiatrist about orthoses they told me that all orthoses that have a plaster cast taken are custom and that CAD-CAM manufacture must be the most accurate way of making orthoses.

Another said that his company's orthoses were not custom made but were custom fitted. With this degree of sophistication, it's hardly surprising that the issuing of orthosis is now being undertaken by Physiotherapist's Chiropractors and others and in many cases with as much success as Podiatry can claim. This lack of real technical and practical sophistication in my opinion has been a great loss to our profession. At a foot and ankle conference I attended recently one of the guest speakers who was a Podiatrist and apparently specialised in biomechanics was unable to clearly answer a basic question put forward about the casting method, production and function of a particular type of orthotic. Luckily a physiotherapist who knows the subject and who has spent years perfecting her knowledge of biomechanics and orthotics and who has spent time physically making and modifying orthoses was able to answer the question with a clarity that would be the envy of many Podiatrists.

Conclusion

Having given this article the title "why custom orthoses don't work" it is probably best to put that statement in context. As a manufacturer, prescriber and designer of orthoses for the past 25 years I firmly believe that custom orthoses are of enormous benefit to those who need them if three essential criteria /conditions are observed. Firstly, that they are used as a part of a treatment plan and are not used in isolation as a treatment in and of themselves. Secondly that they are designed and manufactured in such a way that they closely fit across their entire surface when the foot is positioned in the optimum alignment for the individual patient. Finally, they are made from a suitably ridged material to allow them to resist the pathomechanical forces being generated. If these three criteria are not met then we will be doing ourselves, our profession and most importantly our patients a great disservice. The fact that failure may often mean surgical intervention should spur us on to demanding only the very best fitting orthoses for our patients.