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First contact - orthotic insoles

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Hidden from view and often ignored, the humble insole is in fact the main footwear component through which load is passed from the ground to the body and helps ensure our first contact with it is safe and comfortable. As such, insole shape and material properties can strongly influence how feet are affected by pressures from the ground, comfort and the biomechanics of walking and running. Insoles are now known by many names including orthotics, orthoses and footbeds.

Whereas an insole in shoemaking terms is the foundation around which most shoe constructions are built, orthotics do far more and can qualify as medical devices. Unlike standard insoles, they are specifically designed in shape and material to manipulate where load is applied under the foot.

This is useful for all sorts of clinical and comfort reasons such as deflecting pressure away from vulnerable areas and helping to change how the foot copes with variations in athletic tasks. In many cases health professionals are involved in their use (podiatrists, etc.) and may customise each pair for the individual concerned. There are, however, equally useful design features that can also offer benefits for mass market use.

KEY FEATURE

A key feature of a foot orthosis is a close fit between foot shape and orthotic surface. With intimate contact comes the ability to increase or decrease pressure wherever necessary. This is achieved with a high sided heel cup and suitably high and

supportive arch profiles on both medial and lateral sides of the midfoot area, tapered down toward a flat surface under the ball of the foot as illustrated above. Additional raised areas can help off-load the ball of the foot or alter its position during walking and running.

It is the need for this intimate fit that drives many people to use customised orthoses. However, the way in which the foot shape is captured to produce these only provides one 'snap shot' of foot shape, whereas the foot is constantly changing shape as we walk. At Salford University, we have been trying to address this using the 4D shape of the foot or, in other words, the shapes the foot adopts at different times during walking. We can use these multiple shapes to design orthoses targeted at specific walking

events. For feet free of significant deformity an average shape of orthotic will often make good contact with the foot during walking and running. One way to take this further is to use foot orthoses that are foot size specific rather than simply small, medium and large sizes.

Creating a controlled, comfortable collision between the sole of the foot and the orthotic also depends on the materials used. The same shape of orthotic produces very different effects if made from two different materials. This also undermines the idea that custom orthoses are a must, since it is not all about foot and orthotic shape. It is the dynamic shape and properties of the orthosis, i.e. the shape/properties it has when walked on, that ultimately defines how it affects the foot and lower limb.

WHO BENEFITS?

The single most common trigger to providing someone with a special orthotic insole is foot or lower limb pain. Pain at the bottom of the heel, sometimes called plantar fasciitis (although this is often not technically the problem), is very common and may be relieved by using a suitable orthotic. A heel cup and supporting the arch can help unload the bottom of the heel and, by occupying space under the arch, the insole can reduce elongation of the foot that happens when we walk (*Figure 1*). This reduces the stretching of tissues that attach to the base of the heel bone, right where the pain originates. Other musculoskeletal conditions including arthritis, Achilles and other tendon injuries can often also be improved.

The group who perhaps have the most to benefit from appropriate insoles are people with diabetes and loss of sensation in their feet. Foot numbness or neuropathy, can be common in diabetics and leads to specific areas under the foot being overloaded. Under some circumstances this can lead to ulceration and become a serious medical issue. Diabetic foot ulcers are the leading cause of lower limb amputation worldwide. We have been developing mass market and customised orthotic insoles specifically designed using data on the effects of diabetes on feet and



Figure 1 – Heel cups and arch supports help reduce elongation of the foot as we walk.



Figure 2 – Combining different material densities and thickness offers both support and comfort.

focusing on prevention of foot complications such as ulceration.

More simplified insoles can also assist in protecting vulnerable feet in older people. As we age the fatty protective tissue under the ball of the foot is lost, becomes stiffer and might move because toe deformities push it out of the way. A soft cushioning material can often help redistribute loads more evenly and reduce metatarsal head pain at the ball of the foot. This can help keep older people comfortable when walking and improve their confidence to keep themselves mobile.

HOW ARE ORTHOTIC INSOLES MADE?

Like most plastic, foam and rubber products, orthotic insoles are made using techniques such as injection moulding, compression moulding and CNC milling. We have helped in the design of insoles made through injection moulding of highly durable thermoplastic elastomers. This allows a single piece product with no seams or layers bonded together, that is flexible under bending to provide comfort, but stiff and resistant to compression in areas where joints need support (*Figure 1*). It is also

washable at very high temperatures and uniquely indestructible as far as the insole market is concerned, with a lifetime in excess of anything up to 10 years.

EVA orthotics are far more common and are typically made by compression between aluminium moulds. Combining different densities of material and adjusting material thickness prior to the moulding process can produce insoles with supportive rear and midfoot sections and yet offer comfortable, compressible forefoot areas as well (*Figure 2*).

For custom orthoses, most people agree that a digital design and manufacturing process is required in order to meet appropriate quality standards. The process is driven by a digital cloud of points that map the 3D contours of the foot. This is used to modify a template insole from a design library and additional changes in geometry can be made according to a clinician's prescription. The final design is then CNC milled from EVA, PPE (polypropylene) or PU (*Figure 3*) after which it can be finished and covered.

Several groups have experimented and then brought to market 3D printed insoles. It can be done of course, but



Figure 3 – Custom made orthoses can be designed to meet specific patient requirements.

we have yet to see products that have a performance or effect on the foot that justifies the extra expense. While it is more than a gimmick, it is far from a proven technology at present. One difficulty is that traditional materials such as EVA and foams are very adaptable and we have had several decades to become good at using them to full effect and at sensible prices. It will take something very innovative to dislodge them.

HOW DO THEY WORK?

There are many theories and stories about how foot orthoses have their effect on feet. Orthotic insoles change the distribution of forces that are applied to the sole of the foot. This in turn affects the forces acting on the foot and, in some cases, lower limb joints. This has the important effect of changing the task of the muscles in the lower limb and modifying control of those muscles by the brain (the so called motor control system). The result is that the movements that feet display will change. Changing pressure distribution also alters sensory inputs to the foot. We do not as yet know how this affects muscle control and the eventual effect on the lower limb, but it is clear that orthoses do have a neuro-biomechanical effect.

Most orthotic insoles are designed to reduce the movement taking place in feet and this has led to the term anti pronation becoming popular. In truth, however, whilst pronation is reduced, that is not how they work, but is just the change that is easiest to see and is a relatively easy idea to communicate. Over pronation is another over used term and, again, is an unfounded concept. There is no evidence that pronation is a problem and thus over pronation has been largely discredited as the root cause of foot and lower

limb problems.

However, there are special circumstances where you might want to increase foot movement if it reduces stress on specific muscles or tendons that are inflamed. Professor Richard Jones, at the University of Salford, has been using orthotic insoles that would tend to increase foot pronation in order to reduce the forces that lead to and accelerate the development of knee arthritis. This has led to clinically important reductions in knee pain in several clinical trials. Patients subsequently undertake more physical activity and stay more mobile.

One issue often ignored is that the effect of an orthotic insole is very sensitive to the shoe it is used in. Put the same orthotic in two different shoes and you will get different effects. This is because three of the four surfaces of the orthotic contact the shoe: at the top of the sole and the medial and lateral sides of the upper. The upper therefore forms a sideways buttress to the foot and orthotic and a soft shoe sole will allow the orthotic to roll sideways inside it unless held firmly by the upper.

WHAT IS COMING NEXT?

Orthotic insoles are traditionally an area of low innovation. We have been using the same materials and processes for a long time. This has led to a commercial landscape that is very marketing led, rather than being driven by improvements in product performance and innovation. A key innovation on the horizon is the exciting range of materials that could be used in the future. Some of these will come through additive manufacturing technologies and the ability to print complex structures such that product behaviour varies in new

ways. This might enable products to be responsive to changes in walking speed, activity and foot shape.

We can also expect further integration of sensors and active components into orthotic insoles. There are already systems to measure temperature and pressure under feet, but only a few of these have made it to the mass market. They tend to be the result of a technology push rather than a user pull and often the technology works well but does not meet a well defined user need. A related question is how to use data describing foot behaviour over extended periods of time to monitor foot health, provide more timely replacement of insoles or advise on physical activity via your smartphone?

Active elements in orthotics include the delivery of sensory stimulation such as vibration or electrical signals. During different tasks, pressure is placed under the foot at different times and locations, and this sensory and mechanical input is detected by nerve endings in the foot. This information is used to control balance and calculate the appropriate movement strategies. There is already evidence that under the right circumstances vibratory stimulation can affect our ability to control balance, though we are not yet sure why.

There could equally be a case for stimulation of feet creating a distraction for the systems that control balance and posing a risk for older people in the form of falls. More work is therefore needed to both identify the right stimulation, where to deliver it on the foot and when to stimulate during different tasks. We are currently working with people who have suffered a stroke to understand their experiences of losing foot sensation and balance control and the possible advantages foot stimulation might have for them. 

Professor Nester leads foot and ankle research in the School of Health Sciences at the University of Salford. He is also Director of a University spin-off company that designs and manufactures orthotic insoles.