Orthotic prescription process for the diabetic foot

William Munro

ARTICLE POINTS

1. A matrix of possibilities can be established to guide efforts to optimise treatment.

2. There are three main options for shoes: stock shoes, modular shoes and bespoke shoes.

3. A harmonious combination of foot orthoses and footwear will ensure optimised treatment.

4. There is a considerable variety of healing footwear available for both forefoot and hind foot relief.

5. A rational approach to the prescription of orthoses and shoes for the diabetic foot is essential.

KEY WORDS
- Prescription
- Footwear
- Orthoses
- Rockers

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Introduction

To be effective, orthoses intended for the prevention and treatment of diabetic foot lesions require multidisciplinary considerations of the prescription process. In the author's experience, generic approaches to prescription are unlikely to be adequate when presented with the broad spectrum of challenges that surround the diabetic foot. This article will set out a rational approach to the use of orthoses in prophylaxis, treatment and the maintenance of at-risk neuropathic and neuroischaemic lesions. It will also outline footwear options and the use of forefoot and hind foot orthoses in the treatment plan.

Footwear should be provided on the basis of verified clinical need. A matrix of possibilities can be established to guide efforts to optimise treatment. This matrix should be constructed using the following criteria.

1) Deformity

Deformity can be classified as 'significant' or 'non-significant'. The author's definition of significant deformity is related to the mechanical alignment of the foot with the heel, ball and toe aspects of a normal shoe. If the foot does not line up within these shoe parameters there will be potential friction, shear and pressure implications – and the deformity will be 'significant'.

An example of a significant deformity is shown in *Figure 1*. Rigid Pes Cavus, with an obvious retraction of the toes, creates a situation in which the forefoot from the ball to toe end is not in balance. Consequently, when the individual walks, the author has observed that inadequate toe depth in the toe-off phase of gait will result in an increase in plantar pressure on the metatarsal heads. It may also lead to dorsal pressure from twisting in the upper material of the shoe.

'Non-significant' deformity relates to a foot that has mechanical alignment with the heel, ball and toe end of the shoe, but which has hammer toes, hallux valgus or other manageable biomechanical anomalies.

2) Ambulatory status

It is important to assess the magnitude and type of ambulatory ability. This has been observed to range from an occupationally active level to one of sedentary disability. The durability and effectiveness of footwear and foot orthoses will depend on the wear during activity.

3) Biomechanical analysis

The extent of deformity is very often linked to the adverse biomechanics found at the talo-crural, sub-talar and mid-tarsal joints. The concept of what is hoped to be achieved can be conveyed with an intuitive biomechanical analysis, as detailed below.

In the author's opinion, it is important to recognise the relationship between the hind foot and forefoot in the three main phases of the gait cycle. The foot complex can be likened to a stable three-peg milking stool in mid-stance, where the sub-talar joint is neutral and the mid-tarsal joint is maximally pronated (*Figure 2*). Any deviation from this will result in an unstable mechanical foot structure. If the forefoot is hypermobile through excess of pronation, it is necessary to realign the foot to allow the plantar plane of the forefoot to be parallel with the plantar plane of the hind foot. This can be achieved orthotically through posting.

If the forefoot is supinated and rigidity is a factor, the orthotic accommodation is

Figure 1. An example of a deformity judged as significant: Rigid Pes Cavus.

required in the form of a cradle. By returning the foot to a stable, mechanical state, pressure redistribution is optimised, thereby reducing pressure and shear.

4) Neuropathic status

The extent of neuropathy is normally determined at an annual screening. This screening may use different methods to quantify the outcome; however, the main factor is the loss of protective sensation, as assessed using a 10 g monofilament and a Neurotip (Owen Mumford, Woodstock). The loss of protective sensation considerably increases the risk of breakdown from friction and shear force between foot and shoe and must be taken into account when formulating a prescription.

5) Ischaemic status

The vascular status is also determined at the annual screening, and this too has a bearing on risk of breakdown and tissue viability (Chantelau et al, 1990; Edmonds and Foster, 2005). Capillary refill time and the status of dorsalis pedis and the posterior tibial pulse are the main clinical indicators here.

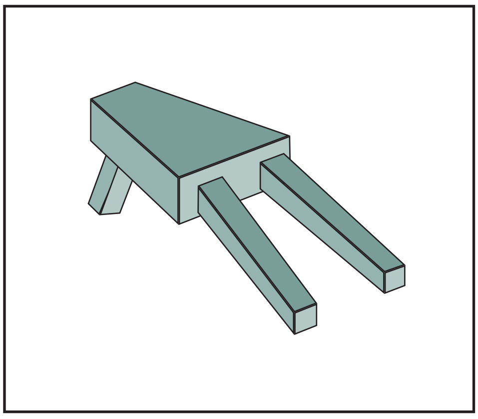

Figure 2. A 'milking stool' model of parts of the foot complex (adapted from Rose, 1986).

6) Environment

Consideration of the foot's environment covers a number of potential areas of concern. As a result of leather production processes, an allergy to chrome tanning may be an issue and should be dealt with by the use of vegetable tanning. The use of latex and rubber solutions may also pose some difficulties and avoiding these would require the hand sewing of the sole to the upper during shoe manufacture.

In addition, the prevailing elements that the patients are exposed to in terms of climate and terrain must be considered in view of fitness to purpose and durability.

Using a matrix of these factors allows for individual patients' circumstances to be taken into account and optimises the rationale for prescription of the most suitable form of footwear.

Options for shoes

There are three main options to choose from:

- stock shoes
- modular shoes
- bespoke shoes.

Stock shoes

Stock shoes currently account for some 70% of prescribed shoes (Audit Commission, 2000) and can offer a mechanically viable solution as well as being cosmetically acceptable.

The important features of stock shoes are the correct width, depth and lengths as set out by the individual manufacturers, as well as the design features of materials and pattern shapes. Foot orthoses should be manufactured with shoe compatibility in mind to ensure optimised function. Model styles should avoid rims and seams at vulnerable areas, such as the medial aspect of the first metatarsal phalangeal joint.

In some designs of stock shoes the weight or thickness of the leather used can sometimes be too light for the task it has to perform. This results in an over-torquing of the upper on the sole that then gives rise to a badly misshapen shoe that may result in trauma to the foot.

Modular shoes

Modular shoes offer a mid-way point

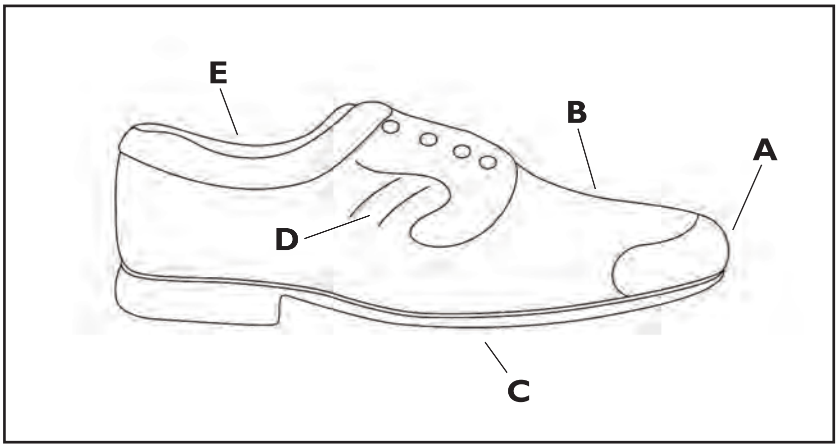

Figure 3. Features of a shoe (A = rim toe puff; B = vamp; C = lateral edge; D = nylon strip; E = padded collar).

between stock shoes and bespoke shoes. This is usually achieved by using a stock last and style, and then adding extra features such as build-ups over joints, width variances at joints and heels, and specific toe depth build-ups. These extra features may also be added at a 'rough fitting' stage to facilitate more intimate fit solutions.

Bespoke shoes

Up until the mid-1980s, bespoke was the only way that footwear was produced for patients. The technique for measurement and production was based on a standard (BS 5943) of the British Standards Institution (1980). Manufacturing was, and still is, largely centred on the hand skills of craftsmen. In the author's experience, only recently have computer-aided design and manufacturing systems started to play a greater role in footwear production and design (whereby a foot is scanned, the scan is analysed and the result is downloaded onto the machine for manufacture).

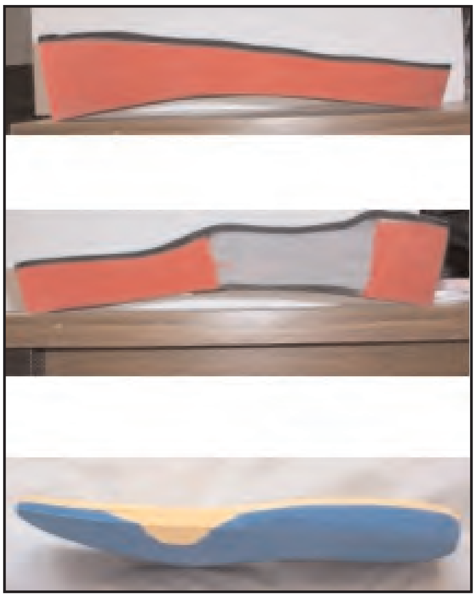

Figure 4. Examples of foot orthoses.

The greatest challenge in producing bespoke footwear is how to transfer complicated foot shapes from a two-dimensional set of measurements to a three-dimensional shoe form in a cosmetically and functionally acceptable way. Careful, methodical measurement is a fundamental prerequisite for accurate manufacture and a functionally satisfactory fit.

It is believed that this is where most of the challenges that create criticism of bespoke shoes will arise from. Inappropriate facilities for measurement and consultation, coupled with inadequate consultation times, exacerbate the need for the extreme concentration required to produce what is a precise technical specification. The measurements taken should be to the standard that would be expected of a surveyor.

The use of computer-based scanners may help produce more accurate measurements over time. However, the hand skills required to judge, for example, the density or pliability of a fatty heel pad and the extent that it might distort to produce shear can only be done by someone who has the experience, skill and knowledge to do so.

The benefit of bespoke shoes should be their ability to optimise treatment options in a way that ensures maximum protection for an at-risk foot. This means that every aspect of shoe design can be taken into account and accuracy of placement of features such as windows, rockers and tab points can be considered. (Windows are holes cut in the core material of the cradle or functional device; rockers are explained in more detail below; and tab points are the points where eyelets or velcro straps are attached.)

In the bespoke shoe, the weight and density of the upper can be more closely controlled, and the durability of sole materials and their construction can be tuned to suit the data collected from subsequent reviews.

In the author's opinion – whether stock, modular or bespoke footwear is indicated – consensus over the years has dictated certain features (e.g. Tovey and Moss,

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1 Although cosmesis is important and recent manufacturing approaches have improved the range of design possibilities, function is still the primary driver of shoe design.

2 Certain features such as rocker soles will be required for some patients when indicated by the prescription matrix, but it is not a fundamental requirement for all diabetic shoes to have a rocker sole.

3 A harmonious combination of foot orthoses and footwear will ensure optimised treatment whether the device is for prophylaxis or for maintenance of a previously ulcerated foot.

4 Appropriate material choice is vital.

1984), and the basis for a good diabetic shoe should have the following features (*Figure 3*):

- rim toe puff (A)
- upper and lining weight over vamp (B) of between 4 and 8 μm
- lateral edge (C) that is straighter from waist to toe end
- tabs that have a nylon strip (D) between the lining and the upper to facilitate a gap between the tabs of approximately 1.5 cm
- properly padded collars (E) to protect the distal aspects of the malleoli and Achilles tendon
- leather or plush linings, and not synthetic linings that may fray and become brittle.

From these factors, appropriate prescription of footwear will follow a logical sequence and allow for recognition of a spectrum of activity that will match the patient's clinical need.

Assessment of individuals points to their place on the prescription matrix and therefore indicates the functional requirements for foot orthoses and particular adaptations. The functional requirements, in turn, point to the style and design possibilities. Although cosmesis is important and recent manufacturing approaches have improved the range of design possibilities, function is still the primary driver of shoe design.

Certain features such as rocker soles will be required for some patients when indicated by the prescription matrix, but it is not a fundamental requirement for all diabetic shoes to have a rocker sole. Patients who have neuropathy with minimal biomechanical anomaly and who are at risk do not require footwear with the same design features as patients who have plantar ulceration and significant deformity.

Figure 5. Forefoot Relief shoe (left) and Heel Relief shoe (right; IPOS, Kennesaw, GA).

Foot orthoses

The challenge for footwear and foot orthoses is a mechanical one that requires the management of several factors: the interfaces between ground, shoe sole, foot orthoses, skin and then bone (Pratt and Tollafield, 1997). A harmonious combination of foot orthoses and footwear will then ensure optimised treatment, whether the device is for prophylaxis or for maintenance of a previously ulcerated foot. It is therefore vital that, in the first instance, the interface between the foot and the shoe is designed to meet the needs of not only the foot but the vehicle that carries it.

The manufacture of foot orthoses, too, is related to the function of the individual feet that are being examined. Material choices are centred on supportive function, stabilisation or accommodation of deformities, relief of excessive plantar pressure, reduction of pressure and shear, and the possible limitation of range of motion. Examples of foot orthoses are shown in *Figure 4*.

To facilitate the accurate manufacture of the orthoses it is necessary to have a repeatable patient casting procedure that allows for control or manipulation of the lower limb complex and optimises the biomechanical evaluations (Janisse, 1993).

Appropriate material choice is vital. By applying Newtonian mechanics to the design principles initially outlined by Tovey (1983) for use in Hansen's disease, changing the core material from high-density plastazote to medium-density EVA prevented the structural distortion that was often a problem after a short period of use. Consequently, Nora (Algeos, Liverpool) rubber shoe components are a good substitute for EVA; however, the patient's mass and biomechanics will ultimately be the deciding factor.

Top cover materials such as Poron (Rogers Corporation, Woodstock, CT) may be adopted, while Diabet bedding material (Algeos, Liverpool) can be used depending on the skin viability or the density of neuropathy. The author believes that Poron

Figure 6. A pressure-relieving ankle foot orthosis (PRAFO).

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1 The base principle of rockers is the shortening of the lever arm that allows for the change in the timing, magnitude and direction, with respect to the foot, of the ground reaction force over time.

2 The relationship between the shoe and the foot will need to be specified unambiguously if the impact of the rocker is to be recorded in a controllable way.

3 There is a considerable variety of healing footwear available for both forefoot and hind foot relief.

4 Where feet are dressed and bandaged and lesions are on the margins or dorsal aspect, a trauma shoe with a standard heel height and pitch should be used.

94 makes a very good substance for pressure relief windows, superseding injected silicone or Dunlopillow (Algeos, Liverpool).

Rockers

It is the author's opinion that rockers (*Figure 5*), where required, should be constructed as part of foot orthoses – a follow-through rocker using carbon fibre may be added to the outer sole to maintain the harmonisation of the required mechanical effect. It allows for a more cosmetic effect on the footwear, especially when combined with a through sole, which gives a wedge look to the shoe. It also acts as a torque converter to the sole.

Much has been written about rockers and their effectiveness (e.g. Schaff and Cavanagh, 1990). The base principle is the shortening of the lever arm that allows for the change in the timing, magnitude and direction, with respect to the foot, of the ground reaction force over time. During the normal gait cycle, the ground reaction force has a point of theoretical application close to the heel at initial contact of the limb in stance phase. This point of application, often termed the 'centre of pressure', moves forward on the foot as the gait cycle progresses.

The position and magnitude of a rocker will have influence from mid-stance onwards to toe-off on the stance limb. Moving the position of the rocker posteriorly will shorten the stance phase and not allow the centre of pressure to advance beyond the rocker. This will have a protective effect if the metatarsal heads or areas of the foot at risk are anterior to the rocker. The relative height of the rocker will also influence the effective timing and duration of the stance phase of gait.

It is important to remember that modifications such as a rocker are made to the shoe, and the relationship between the shoe and the foot will need to be specified unambiguously if the impact of the rocker is to be recorded in a controllable way.

This has to be achieved, the author believes, on an individual basis, taking into account the size and biomechanics of the individual foot and the magnitude of the rocker required. Plantar pressures change according to how far behind the metatarsal heads the rocker is placed and what the effective distance of the metatarsal heads is from the fulcrum of the rocker.

The author has found that if 10° of rocker helps to heal a forefoot plantar ulcer, then it is good to build this amount of rocker into the foot orthoses of the footwear made to maintain the foot after healing. The upper limit for a rocker would be 30°, as this, in practice, means an unsightly and somewhat unstable level to maintain that would also require a compensatory raise on the contra-lateral side.

The heel height and pitch of a shoe are very important as well, because a shoe with a heel height in excess of 2.5 cm and a pitch angle of over 30° will result in an increase in weight on the metatarsal heads. This, in turn, will have a negative influence on the actions of the foot orthoses.

Additional orthoses that aid prevention and healing

There is a considerable variety of healing footwear available for both forefoot and hind foot relief. Where feet are dressed and bandaged and lesions are on the margins or dorsal aspect, a trauma shoe with a standard heel height and pitch should be used. On too many occasions, the author has found, secondary trauma is initiated by the incorrect use of fracture cast shoes that are rockered in the mid-foot and subsequently transfer pressure to an inappropriate place.

Forefoot relief shoes come in varieties with no forefoot plantar protection and those with a follow-through sole. The advantage of the exposed forefoot is that there is no plantar pressure on the wound site; however, the patient has to be very careful not to traumatise the exposed area further. All of these shoes have a rocker to 10°, and, as previously stated, this degree of rocker should form the basis of any device once healing has been achieved. It is also possible to customise a foot orthosis to a shoe with a full sole to facilitate optimised pressure redistribution. Hind foot relief shoes should be used in conjunction with a pressure-relieving ankle foot orthosis (PRAFO) at the rehabilitation phase of treatment as daytime off-loading is nullified if recumbent relief is not used.

PRAFOs (*Figure 6*) should be used in the

Figure 7. An Aircast walker.

Conflict of interest

The author, along with Dr Derek Jones, was responsible for bringing pressure-relieving ankle foot orthoses (PRAFOs) into use in the UK, and is now associated with the marketing of PRAFOs for the company Anatomical Concepts (UK) Ltd.

prevention and treatment of distal posterior border lesions of the heel and for lesions on the medial and lateral aspects of the hind foot and the malleoli.

To maximise the treatment potential it is important to use the device in both recumbent and ambulatory modalities. The configuration and design of these devices is paramount to the safety and efficacy of their use.

In a retrospective study of three major heel wound outcomes (Munro et al, 2005). it was found that maintaining the foot in a dorsiflexed position with a stable metal upright that resisted plantar flexion, in addition to the wound site being totally pressure-relieved, was a major benefit to healing. The ability to walk with no pressure on the wound and have a heel strike enhanced the secondary calf-pump mechanism and allowed an optimum physiological state to be maintained.

In the author's opinion, the PRAFOs APU and Dual Action (Anatomical Concepts, Clydebank) have the versatility and durability to allow these functions to be performed. Devices that are made of preformed contoured polypropylene are useful only in recumbent situations and great care should be taken to monitor deterioration of the plastic, which can lead to plantar flexion of the foot with resultant increases in forefoot plantar pressure.

The use of Aircast walkers (Aircast, Summit, NJ; *Figure 7*) is now widespread and not without some controversy (based on the author's experience of a recent conference). The author believes that it is an extremely useful device if customised to the individual patient and that it can satisfy the need for immediate immobilisation of an early-stage Charcot foot. The ability to use the air cells for graduated compression allows oedema control to take place safely with little chance of tissue damage. The use of a customised foot bed further enhances the plantar pressure relief role. However, it must be stressed that a high degree of patient educational input is the key to successful safe use, and in the early stages of use frequent follow-up and counselling is desirable.

Bespoke plastic or carbon fibre devices can also achieve axial off-loading; these may also be described as a Charcot Restraint Orthotic Walker (CROW; Edmonds et al, 2004). The design and fit is specific to the needs of the patient, although these devices should always have a full foot plate and be suitably padded to protect tissue viability.

Conclusions

A rational approach to the prescription of orthoses and shoes for the diabetic foot is essential. A matrix of treatment strategies has been presented. Use of this allows patient need and level of risk to be orthotically matched to ensure optimised prevention or healing.

Shoe design and manufacture and orthoses need to be considered both individually and collectively. A harmonious combination of foot orthosis and shoe is required both for function and cosmetics.

Education and counselling is also very important. The clinical and psychological expectations of patients and the clinic team have to be met. ■

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