The importance of effective offloading and footwear for the diabetic foot

Chronic non-healing foot ulcers are a common problem associated with diabetes mellitus. Diabetic foot ulcers (DFUs) frequently occur on the plantar aspect of the foot at sites of high shear and pressure, primarily due to repetitive injury during daily activities. One of the mainstays of foot ulcer management is, therefore, effective redistribution and relief of pressure in order to prevent further tissue trauma and facilitate the healing process. This article highlights the importance of appropriate footwear for the primary and secondary prevention of foot ulcers while introducing the reader to a range of offloading devices that aim to facilitate the healing of established foot ulceration.

Diabetes-related foot ulceration is a serious complication of diabetes mellitus. Foot ulcers are associated with significant financial costs to health services and personal costs to those affected. Approximately 8% of all diabetes-related deaths are directly attributable to foot ulcers. Furthermore, diabetic foot ulcers (DFUs) are frequently associated with adverse outcomes, including limb and/or life threatening infection and lower extremity amputation (Bergin et al, 2013).

Clinical signs of neuropathy in the diabetic foot

The International Working Group on the Diabetic Foot (IWGDF, 2014) has reported that as many as 50% of people with diabetes will have significant peripheral neuropathy and 'at-risk' feet. The IWGDF defines diabetes-related peripheral neuropathy as: "The presence of signs or symptoms of peripheral nerve dysfunction in people with diabetes after exclusion of other causes" (IWGDF, 2014). Nerve dysfunction in diabetes can affect three different types of nerves in the lower legs and feet, namely the sensory nerves, motor nerves and autonomic nerves. This can give rise to a range of clinical signs and symptoms as discussed within *Table 1*.

Sensory neuropathy (loss of sensation) is a major risk factor for developing DFUs; approximately 45–60% of all DFUs are due to sensory neuropathy (Frykberg et al, 2006). Sensory neuropathy results in loss of protective sensation which can increase the risk of unnoticed trauma or injury to the foot from ill-fitting or inappropriate footwear. In fact, trauma from pressure, shear and/or friction from footwear is a leading cause of DFUs (Bergin, et al, 2013).

Approximately 50% of all DFUs occur on the plantar surface (sole)

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of the foot (Bus et al, 2011). *Figure 1* illustrates neuropathic foot ulceration on the plantar surface of the foot.

Motor neuropathy can give rise to significant foot deformities and increased levels of mechanical foot pressure which can contribute to tissue breakdown and foot ulceration. *Figure 2* shows an asymmetric presentation of deformity to the right foot. This patient had a history of ulceration and osteomyelitis (bone infection) which had contributed to the deformities presenting in his right foot.

A combination of autonomic neuropathy and sensory neuropathy is known to contribute to Charcot foot. Charcot foot has been described as the worst of the diabetic foot deformities (Lázaro-Martínez et al, 2014). It is a condition that can affect the bones, joints and soft tissues of the foot. In the initial stages, the foot becomes very inflamed and as the condition progresses, Charcot foot is characterised by bone destruction, dislocation and severe deformities of the foot (Rogers et al, 2011). *Figure 3* shows a Charcot foot presenting with severe deformity and plantar ulceration.

Plantar pressures

High plantar pressures in association with neuropathy have long been known to increase the risk of foot ulceration (Armstrong et al, 2001). Excessive pressure on the skin can lead to the development of hyperkeratosis, commonly called calluses (Lázaro-Martínez et al, 2014). The presence of calluses on the plantar aspect of the foot increases the risk of tissue breakdown and ulceration. In the insensate foot, elevated plantar pressure is a common cause of foot ulceration (Arts et al, 2012). *Figure 4* shows a computerised scan of the foot with the red areas highlighting sites of high plantar pressure.

Why offload?

Elevated plantar pressures are known to contribute to the development of foot ulceration. Furthermore, in the presence of an established foot ulcer, high plantar pressures can significantly delay healing. The central goal of any treatment programme designed to prevent primary and secondary episodes of foot ulceration, and heal active foot ulceration is effective pressure reduction (Armstrong et al, 2003).

When to prescribe footwear or offloading devices

When considering the prescription of therapeutic footwear and/or offloading devices, it is important to take into account the primary objective. A key question is: 'is the purpose for primary or secondary prevention or is the purpose to facilitate the healing of an established foot ulcer?'

Primary prevention

In primary prevention, the focus is on the prevention of foot problems. Primary prevention involves:

- Educating patients with regard to possible foot problems that can develop with diabetes. Also, education designed to empower individuals to look after their own feet, such as daily self-inspection and monitoring of any changes, is crucial in the prevention of problems
- Annual reviews by qualified healthcare professionals to include screening for peripheral neuropathy (nerve dysfunction) and peripheral arterial disease (poor blood supply to the legs and feet), and assessment for foot deformities (National Institute of Clinical Excellence [NICE], 2004)
- Footwear assessment and advice to prevent problems arising from ill-fitting or inappropriate footwear
- Advice on purchasing appropriate footwear (if appropriate)
- Appropriate footwear and insole prescription, if required, to protect and accommodate deformity as well as reduce dangerous peak plantar pressures. This is key to preventing future deformity (Rogers et al, 2011).

All healthcare professionals involved in the care of the diabetic foot can play a role in assessing footwear. *Table 2* outlines a simple checklist

Table 1. Signs and symptoms of diabetes-related peripheral neuropathy.

Type of neuropathy	Clinical signs	Clinical implications
Sensory neuropathy	Loss of sensation to light touch, pain and temperature.	Loss of pain significantly increases the risk of unnoticed injury or trauma that can lead to tissue breakdown and foot ulceration.
Motor neuropathy	Poor nerve supply to the muscles in the leg and the foot can cause foot deformities.	Foot deformities cause the foot to function abnormally. This can result in high areas of pressure on the foot that can lead to foot ulceration.
Autonomic neuropathy	Absence of sweating (anhidrosis) in the foot can cause dry skin.	Anhidrosis can lead to callus formation and skin fissures (cracks in the skin), which can increase the risk of infection and ulceration in the diabetic foot.

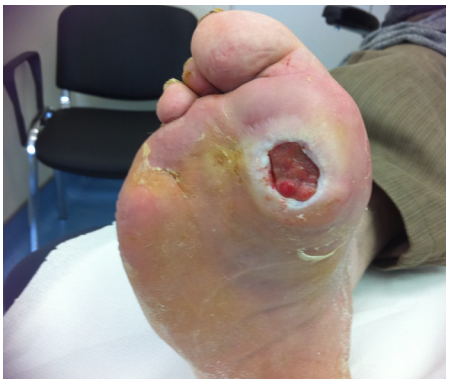


Figure 1. ***A neuropathic foot ulcer on the plantar surface of the foot.***

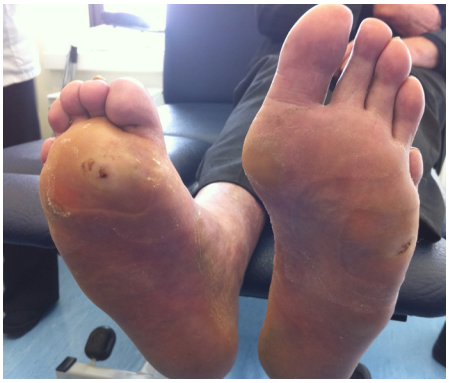


Figure 2. ***An asymmetric presentation of deformity to the right foot in a male with diabetes.***

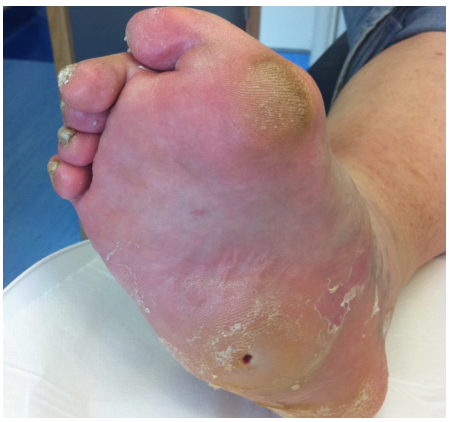


Figure 3. ***Charcot foot showing severe deformity and plantar***

for healthcare professionals, based on the principles of ask, look and feel. When any of the criteria listed within *Table 2* are not fully acceptable then a referral should be made to the podiatrist/specialist team for further assessment.

The acute foot

Managing the acute foot involves the care of people with foot care emergencies and foot ulcers. NICE (2004) defines a foot care emergency as new ulceration, swelling or discolouration. In these instances, a referral must be made to the multidisciplinary foot care team within 24 hours.

NICE guidelines expect that the multidisciplinary team, as a minimum, will:

- Investigate and treat vascular insufficiency
- Initiate and supervise wound management
- Use dressings and debridement as indicated
- Manage infection appropriately
- Ensure an effective means of distributing foot pressures, including specialist footwear, orthotics and casts
- Try to achieve optimal glucose levels and control of risk factors for cardiovascular disease.

Within its guidelines, NICE (2004) advocates assessment of the foot by a specialist team. Offloading devices that reduce peak plantar pressure and redistribute pressure from the site of the ulceration are critical to positive patient outcomes and wound healing in patients with acute foot problems.

Secondary prevention

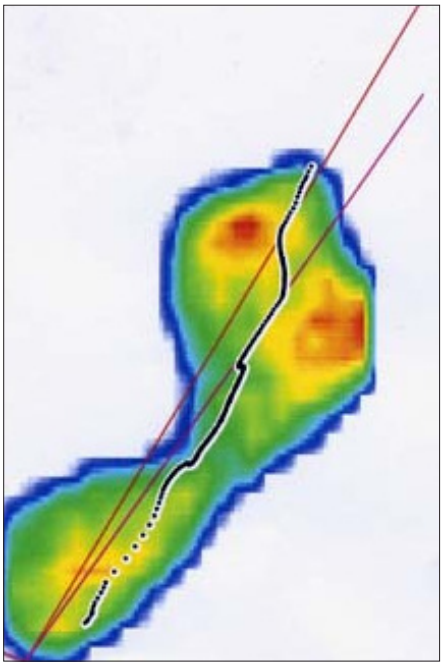
Once healing is achieved, the focus of secondary prevention is to prevent further episodes of tissue breakdown and foot ulceration. Unfortunately, the rate of recurrence in patients with a history of DFUs is high (Peters et al, 2007). Patients with a history of foot ulceration should, therefore, be considered at high risk of future foot complications and management plans should be implemented that focus on the prevention of further problems (NICE, 2004). Such plans should include ongoing foot health education, regular podiatry assessment and intervention, as appropriate, as well as footwear advice and assessment.

Therapeutic footwear for primary and secondary prevention

Therapeutic footwear has been shown to have a beneficial effect in the primary and secondary prevention of DFUs (Maciejewski et al, 2004). Furthermore, patients who routinely wear therapeutic footwear and orthoses are less likely to develop ulcer recurrence. Indeed, Tyrell and Carter (2008) reported the findings of a study that found that diabetic patients who wore their therapeutic footwear for more than 60% of the daytime reduced ulcer recurrence by more than 50%.

Therapeutic footwear aims to redistribute plantar pressures across the foot, thus reducing high pressures in at-risk areas (Owings et al, 2009). Effective therapeutic footwear has many benefits for the individual including improved mobility, comfort and protection, and an improved quality of life and sense of wellbeing (Tyrell

Figure 4. ***A scan of the foot illustrating high areas of pressure in red.***



and Carter, 2008). However, clinical effectiveness is heavily dependent on acceptability and actual use of the therapeutic footwear (Boulton and Jude, 2004).

Assessment for therapeutic footwear

Individuals presenting with foot complications associated with diabetes require rapid access to specialist multidisciplinary diabetes teams. This will enable the team to undertake appropriate assessments and initiate timely management strategies. Podiatrists and orthotists, as part of the specialist multidisciplinary team, will routinely assess the foot for the presence of deformities or structural anomalies, and assess the patient's need for therapeutic footwear.

Tyrell and Carter (2008) described three different types of therapeutic footwear:

- Stock orthopaedic — off the shelf
- Modular orthopaedic — minor modifications to stock orthopaedic shoes. Specific footwear modifications can be prescribed by the orthotist or podiatrist to prevent unwanted movements of the foot and ankle
- Full bespoke — made specifically for the patient. Bespoke footwear is generally prescribed to individuals with unusual foot shapes/severe deformities, for instance, in the case of Charcot foot.

Ultimately, regardless of the specific type, therapeutic footwear should:

- Protect the foot from injury to the skin that can result from the absence of protective sensation
- Protect the foot from deformity (or from further deformity), particularly for those with Charcot changes
- Protect the foot from external damage. Toes must always be enclosed and the sole should be firm enough to stop foreign bodies piercing it.

Table 2. Checklist for healthcare professionals involved in the assessment of footwear.

Ask	Is the footwear being used? Is the footwear comfortable? It is important to appreciate that in the presence of sensory neuropathy, the patient may not be able to feel discomfort or pain. Is the footwear easy to get on and off independently?
Look	**Observe the feet. Are there any:** Signs of pressure? Signs of damage? Signs of deformity? Signs of change over time? Signs of poor hygiene? **Assess the footwear:** Is there wear on the sole (especially on the lateral [outside border] heel) as this can wedge or tip the foot? Does it accommodate any foot deformity? Is there less than expected wear? This is a sign of poor compliance Does it provide a firm, snug fit? Can fastenings be donned firmly to prevent foot sliding?
Feel	**Feel inside the shoe. Check for:** Foreign bodies Excessive moisture Soft lining — is it intact throughout with seams flat and hidden? **Check the outside of the shoe:** Is there appropriate width and depth at the toes, metatarsal heads (ball of the foot), mid foot and heel? Is it an appropriate length? Check by palpating toes in standing.

The overall mechanical function of therapeutic footwear is to reduce plantar pressure over at risk/vulnerable sites, or previously ulcerated sites, on the foot by transferring the load across the foot. For instance, significant reductions in pressure over the forefoot can be achieved with shoes that have a modified sole known as rocker bottom sole and with footwear that include orthoses (Bus et al, 2008).

Offloading devices for acute foot problems

DFUs are frequently located on weight bearing areas of the foot. Hence, relieving pressure (offloading) on the ulcerated area is absolutely crucial in the treatment of a DFU. Treatment strategies for DFUs must, therefore, include adequate offloading of the affected area of the foot (Bus et al, 2009). Achieving adequate pressure relief will prevent further trauma and facilitate wound healing (Frykberg et al, 2006). There are a number of offloading modalities available for the management of DFUs ranging from simple insoles and orthotic devices through to total contact casts (TCCs). Offloading devices for DFU should aim to reduce pressure at the area of the wound by redistributing pressure across other areas of the foot (within safe limits).

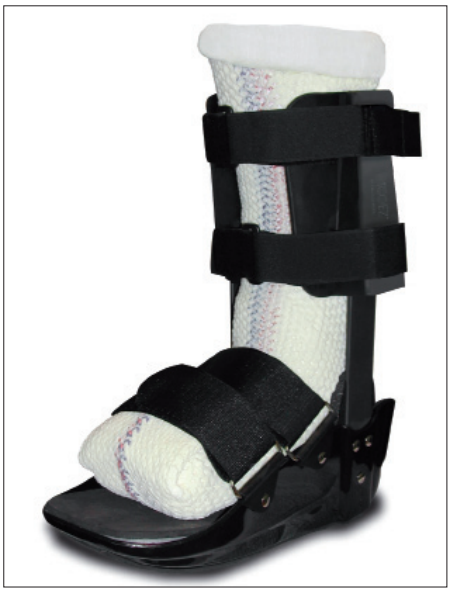


Figure 5. ***TCC-EZ® (Derma Sciences)***

The initial assessment for, and application of, offloading devices must be conducted by a skilled practitioner, for instance, a podiatrist or an orthotist. If pressure is transferred inappropriately, and above safe limits, this could give rise to further tissue damage and new episodes of ulceration.

Offloading devices range from irremovable devices, such as the TCC, to a range of removable devices that can be applied and removed at home.

Irremovable and removable devices

The TCC is an irremovable plaster or fibreglass cast that can be applied by a specialist team. TCCs are considered to be the gold standard in offloading DFUs after randomised control trials found 84–92% pressure reduction at the site of ulceration (Armstrong et al, 2005). An example would be the TCC-EZ® (Derma Sciences), which offers a one-piece, roll-on woven device that simplifies the application process while reducing the potential for causing additional tissue damage (*Figure 5*).

However, because these devices are irremovable their use is contraindicated in the presence of infection or vascular compromise (NICE, 2004) and alternative strategies that allow regular visual examination of a DFU should be considered. Furthermore, casting requires a skilled practitioner specifically trained in the technique and can be costly and time intensive in terms of application, removal and reapplications (Bus et al, 2009).

There are a number of removable devices that are available to offload DFUs (as detailed in *Table 3*).

Selection and use of an appropriate offloading device

Ideally, podiatrists and orthotists should work together to identify the most appropriate device. Offloading must be achieved in a timely way to facilitate wound healing. Other members of the multidisciplinary team have a role to play supporting compliance and reinforcing education about correct application and use.

Patient-centred care and concordance

Tyrell and Carter (2008) highlighted that dissatisfaction with the cosmetic appearance of therapeutic footwear is a constant theme in the literature. Knowles and Boulton (1996) reported poor patient concordance with therapeutic footwear in a diabetic population with only 22% of patients admitting they regularly wore the prescribed footwear. It is, therefore, important to implement a patient-centred approach when considering therapeutic footwear as a management strategy.

A key aspect that must be addressed is patients' choice of footwear, their perceptions of specific types of footwear, and criteria that are significant specifically to them. Without this there will be limited success in finding footwear to meet the needs of the patient in terms of acceptability and style (Tyrell and Carter, 2008). There is limited benefit in referring a patient for a

Table 3. Examples of removable offloading devices.

Examples of removable walkers	Examples of temporary shoes
Pneumatic walker/air cast boot An example of a Controlled Ankle Motion (CAM) walker; the air cast boot consists of inflatable sections in the inner aspect of the boot that hold the foot and ankle in position hence immobilising movement. There is total contact with the plantar aspect of the foot and a rocker bottom sole, thus the boot works by reducing areas of high pressure and redistributing pressure across the foot.	**Temporary footwear with offloading insole** Temporary footwear can be employed as a short term measure to manage DFUs. The insole is a useful layered insole that allows a clinician to remove plugs of material for targeted offloading. The advantage with such a device is that it can be rapidly tailored to the patient at the chair side.
Pressure Relieving Ankle Foot Orthosis (PRAFO) The PRAFO is a device that relives unwanted pressure from the heel area in ambulation (walking) or on lying down. Essentially, the design of the PRAFO removes all pressure from the heel and redistributes pressure across the rest of the foot. This device is ideal for ulcers located on the heel.	**Wedge shoe** Wedge shoes can be employed as a temporary measure to facilitate wound healing. Wedge shoes can be used to offload the forefoot by preventing the forefoot from making contact with the ground, thus transferring pressure across to the rearfoot.

footwear assessment, or prescribing therapeutic footwear if they will not be worn.

Poor patient concordance is also an issue with regards to offloading devices. The main disadvantage of removable devices is that they can be removed by the patient. Armstrong et al (2003) explored activity patterns of patients with DFUs and found that patients prescribed removable devices used these devices for fewer steps each day when compared to irremovable devices. In devices that are irremovable, such as the TCC, this is not an issue and this probably explains why the TCC has been found to be more effective than other offloading strategies.

Conclusion

Effective therapeutic footwear can play a significant role in the primary and secondary prevention of DFU, particularly in patients with sensory neuropathy. Therapeutic footwear can have many positive effects; for the individual this can include better mobility and an improved quality of life and sense of wellbeing. However, the clinical effectiveness of therapeutic footwear is dependent on acceptability by the patient and actual use of the footwear.

In the acute foot, offloading devices are crucial to facilitate wound healing, but again, concordance with these devices can be an issue. The multidisciplinary team must adopt a patient-centred approach towards therapeutic footwear and offloading devices to increase the likelihood of patient concordance and ultimately improve patient outcomes. WE

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