CONSENSUSDOCUMENT

REDEFINING AND DEMYSTIFYING OFFLOADING FOR DIABETES FOOT CARE

The Diabetic Foot Journal

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Foreword

Foot ulcers associated with diabetes are complex wounds and have a major long-term impact on the morbidity, mortality and quality of patients' lives (Brownrigg et al, 2012). Foot ulcers in people with diabetes are also associated with a high risk of hospitalisation and resource utilisation that is at least equivalent to other major chronic diseases such as heart disease, stroke, and cancer (Skrepnek et al, 2017). In the UK, it is estimated that 17% of patients with diabetes will have at least one amputation within 12 months from initial presentation with a foot ulcer (Guest et al, 2018).

Therefore, foot ulceration among people with diabetes urgently needs to be addressed, to limit the associated social and economic costs, as well as the personal cost to the patient. Principles of diabetic foot ulcer management include wound debridement, offloading, revascularisation, and in the presence of infection, antibiotic therapy. Alongside the control of underlying comorbidities, offloading is a key element of the management and prevention of foot ulcers among people with diabetes (NICE, 2019). However, offloading is poorly utilised, and it is estimated that only 5% of patients receive a load redistribution device (Guest et al, 2018).

The International Working Group on the Diabetic Foot (IWGDF) recommend that in a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer, a non-removable knee-high offloading device with an appropriate foot-device interface is the first-choice of offloading treatment to promote healing of the ulcer (Bus et al, 2019). This may be either a total contact cast (TCC) or a non-removable knee-high walker, with the choice dependent on the resources available, technical skills, patient preferences and extent of foot deformity present (Bus et al, 2019).

Resources, technical skill and availability of therapeutic load redistribution devices vary across the UK. This Consensus Document was commissioned and initiated by the Scottish Diabetes Foot Action Group. The document is for healthcare professionals involved in the care of people with diabetes and a foot ulcer who require offloading. The aims of the document are not only to demystify offloading and encourage the uptake of suitable load redistribution devices, but also to ensure the correct strategy is implemented to suit the individual patient's needs, clinical resources and geographical location.

Glossary

Adherence: The degree to which patients follow medical advice.

Axial offloading: The axial load in the foot is the force down the leg, perpendicular to the plane of the foot. Axial offloading is the reduction of the axial load.

Bivalved cast: A cast made from synthetic material that is cut into two halves. A bivalved cast may be required for patients who required frequent inspection of the limb or wound.

Bony prominence: Any point on the body where the bone is immediately below the skin surface, such as areas with limited fatty padding or subcutaneous tissue, such as the heels, the iliac crests and the sacrum.

Charcot neuroarthropathy: The interaction of several component factors (diabetes, sensory-motor neuropathy, autonomic neuropathy, trauma, and metabolic abnormalities of bone) results in an acute localised inflammatory condition that may lead to varying degrees and patterns of bone destruction, dislocation and deformity (Rogers et al, 2011). It is also known as Charcot foot.

Deflection: The approach to reduce or redistribute pressure and friction from one anatomical area to another.

Load: A generic term that covers all forces, including pressure and shear, applied to the skin and subcutaneous tissues (Oomens et al, 2015). Also known as mechanical load.

Load sharing: The principle whereby load is shared. In the case of offloading limbs for people with foot ulcers, load is transferred to the tibia. This is achieved by below-the-knee casts or irremovable below-the-knee devices, and not by the use of footwear and ankle-level devices.

Load redistribution: The principle whereby the plantar pressure, friction or shear forces are decreased by increasing the weightbearing surface area over which the load is distributed.

Minimally invasive surgery (MIS): A procedure or strategy that can be adopted and utilised to prevent primary or recurrent ulceration and is performed through tiny incisions instead of a large opening. Procedures that might be relevant to address biomechanical abnormalities and reduce the risk of ulceration include lengthening the Achilles tendon and plantar fascia release to allow the forefoot to be brought to a mechanically neutral position; release of the extensor hallucis and digitorum tendon; a medial head of gastrocnemius release; and repositioning of the metatarsal heads with distal minimally invasive metatarsal osteotomies (DMMO).

Modified casting: A custom-made load sharing/redistribution cast with additional padding using synthetic cast tape. This may be circumferentially intact or bivalved (based on Bus et al, 2019).

Neuropathy: Damage to one or more nerves that typically results in numbness (sensory neuropathy), tingling, muscle weakness (motor neuropathy) and pain in the affected area. Autonomic neuropathy (damage to nerves that are part of the autonomic nervous system) can lead to symptoms such as dizziness, night sweats and constipation. Peripheral neuropathy (damage to peripheral nerves) increases the risk of ulceration through loss of protective sensation, foot deformities and its common association with dry skin, which can cause cracking, fissures and calluses.

Offloading: The relief of mechanical load (i.e. pressure, stress and shear) from a specific region of the foot (Schaper et al, 2020).

Orthopaedic practitioner: An orthopaedic practitioner often works in trauma and orthopaedic clinics and applies casts and splints to keep limbs and joints in the optimum position while they heal. The orthopaedic practitioner is increasingly becoming more integrated into the multidisciplinary diabetes foot team where knowledge and expertise can be shared.

Orthosis (orthoses): An externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal system to enable patients to mobilise and can prevent reulceration. Orthoses include splints, braces and special footwear.

Orthotist: An orthotist provides a range of externally applied devices, known as orthoses. Orthotists treat patients with a wide range of conditions, including diabetes, arthritis, cerebral palsy, stroke, spina bifida and scoliosis.

Osteomyelitis: An infection of the bone. Symptoms may include pain in a specific bone with overlying redness, fever and weakness. Osteomyelitis is diagnosed by imaging and can be resolved with early use of antibiotics, but surgical intervention can also be required. People are at increased risk of osteomyelitis if bone is exposed, if they have an ulcer that is located over a bony prominence, or if the ulcer is very deep.

Subtalar joint (STJ): The talus bone forms part of the STJ and shares this articulation with the calcaneus.

Podiatrist: A podiatrist prevents, diagnoses and treats conditions of the feet and lower limbs. They also prevent, diagnose and manage deformity, skin and nail disorders, and injuries and infections due to sport or other activities.

Pressure: Results from the application of a force perpendicular (i.e. at right angles) to the surface of the skin. The pressure compresses the tissues and can distort or deform the skin, subcutaneous tissues and muscle (Oomens et al, 2015).

Pronation: The term pronation typically describes an inward complex rotation of the foot and ankle (Nigg et al, 2019). It is not possible to quantify pronation in terms of a value, so there is no value for 'normal pronation'. Therefore, terms like 'over/under/hyper/hypo-pronation' are being abandoned by clinicians.

Proprioception: The body's ability to sense its location, movements and actions. Loss of proprioception impairs the body's ability to move freely without consciously thinking about the environment.

Shear: Causes layers of body tissues to move relative to each other and may occur superficially (e.g. as a result of a force applied parallel to the surface of the skin) or more deeply (as the result of deformation of skin and muscle when pressure is applied over a bony prominence; Oomens et al, 2015).

Supination: The term supination typically describes an outward complex rotation of the foot and ankle (Nigg et al, 2019). It is not possible to quantify supination in terms of a value, so there is no value for 'normal supination'. Therefore, terms like 'over/under/hyper/hypo-supination' are being abandoned by clinicians.

Therapeutic footwear: Generic term for footwear designed to have some therapeutic effect that cannot be provided by a conventional shoe, such as custom-made shoes or sandals, custom-made insoles, extra-depth shoes, and custom-made or prefabricated medical grade footwear (Bus et al, 2019).

Total Contact Cast (TCC): Custom-made, well-moulded, minimally padded, below-knee cast made of either a combination of plaster of Paris (POP) and synthetic materials or synthetic materials only, which maintains total contact with the entire plantar surface (sole of the foot) and lower leg. TCC can be created using a range of casting techniques. How the cast finishes at the distal end should be aligned to the specific requirements of the patient. If the cast is weightbearing, a sole or shoe should be fitted to facilitate standing and walking (Bus et al, 2019).

The foot

ANATOMY OF THE FOOT

The foot consists of the forefoot, midfoot and hindfoot (Figure 1):

- **The forefoot:** Five toes (phalanges) and the five longer bones (metatarsals).
- **The midfoot:** A pyramid-like collection of five tarsal bones (three cuneiform, cuboid and navicular bones) that form the arch of the foot.
- **The hindfoot:** The heel (comprises of the calcaneus and the talus bones) and ankle.

The foot functions as a rigid structure for weightbearing, as well as a flexible structure to allow movement and articulation. The foot moves through elastic mechanisms (e.g. Achilles tendon, plantar fascia), viscoelastic mechanisms (e.g. heel pad), or by active muscle contractions (Takahashi et al, 2017).

Joints connect the bones in the foot and ankle to allow movement and articulation:

- **Talocrural joint** (ankle joint) connects the distal ends of the tibia and fibula with the proximal end of the talus.
- **Intertarsal joints** are the five joints of the tarsal bones in the foot. The **talocalcaneal joint** (subtalar joint [STJ]) connects the talus and the calcaneus. The **mid-tarsal joint** is the articulation of the calcaneus with the cuboid (the calcaneocuboid joint).
- **Tarsometatarsal joints** connects the first, second and third cuneiform bones, the cuboid bone and the metatarsal bones.
- **Metatarsophalangeal joints** connect the distal ends of the metatarsal bones with the proximal ends of the phalangeal bones.

IMPACT OF DIABETES ON FOOT ULCERATION RISK

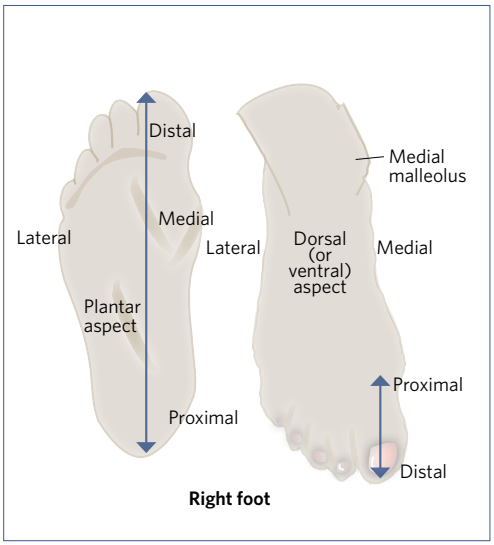
The most significant impact of persistent hyperglycaemia on foot ulceration risk are diabetic neuropathy, peripheral arterial disease and biomechanical abnormalities. Nerve damage in diabetes affects the motor, sensory and autonomic fibres:

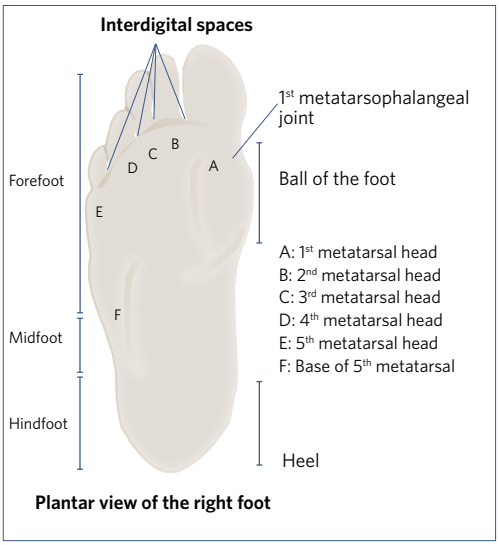
- Motor neuropathy leads to muscle weakness, atrophy and paresis.
- Sensory neuropathy leads to the loss of the protective sensation of pain, pressure and heat.
- Autonomic dysfunction causes vasodilation and decreased sweating (Brem et al, 2004), which results in a loss of skin integrity which makes the skin vulnerable to microbial infection (Bowering, 2001).

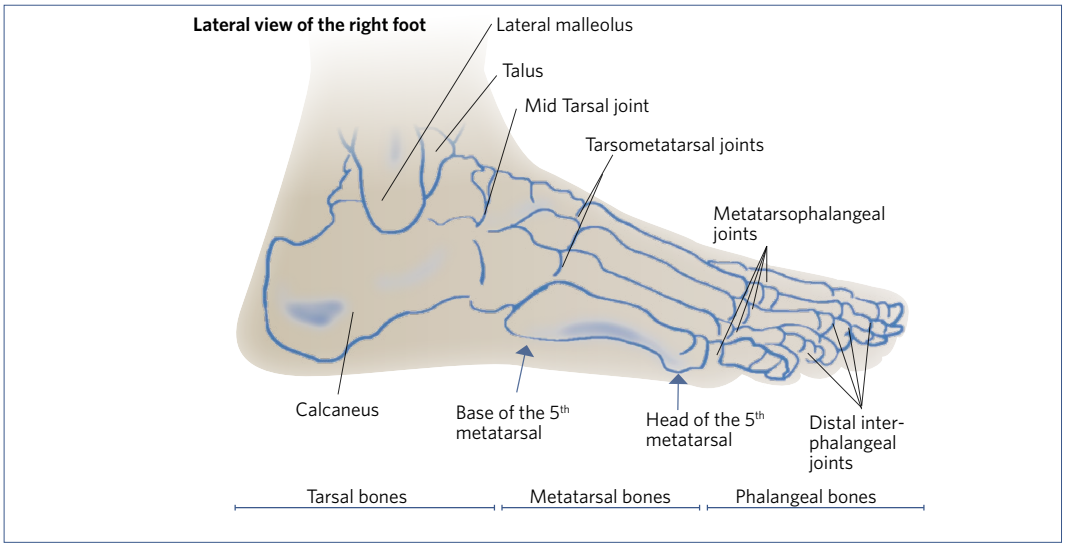
In patients with peripheral diabetic neuropathy, loss of sensation increases the risk of repetitive minor injuries, that, if undetected, may lead to foot ulceration.

Structural foot deformities and abnormalities, such as flatfoot, hallux valgus, claw toes, Charcot neuroarthropathy and hammer foot, play an important role in the pathway of diabetes foot ulcers since they contribute to abnormal plantar pressures. Deformities are caused by the impact of diabetes on the soft tissues, particularly tendons, muscle and fat. For example, thickening of plantar fascia and Achilles tendon in people with diabetes, which is more evident in the presence of neuropathy, concurs to develop a rigid foot. This results in abnormal loading under the forefoot (Gioacomozzi et al, 2005), which is exacerbated by muscle atrophy and loss of fat. Deformities to the foot alter the spatial location of the STJ axis and change the effect of external and internal forces on the structural components of the foot. Failure to address these biomechanical abnormalities result in ulceration.

The foot







Management of the STJ axis rotational equilibrium is a key aim of offloading in the management of the diabetic foot.

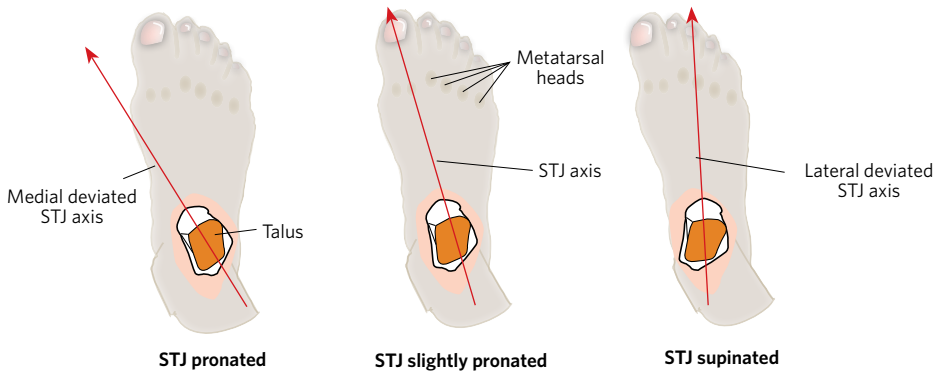


Figure 1. Anatomy of the foot (Kirby, 2001; Wounds UK, 2017).

IMPACT OF MECHANICAL LOAD IN THE FOOT OF A PERSON WITH DIABETES

Application of a mechanical load to the skin, subcutaneous tissues and muscle during weightbearing activities can lead to increased pressure, damage and ulceration (Fernando et al, 2014; Bus et al, 2016a; Armstrong et al, 2017; Lazzarini et al, 2019). **Figure 2** explains how mechanical load has the potential to cause tissue damage and cell death via deformation of tissue cells and ischaemia.

Loss of sensation increases the risk of mechanical breakdown of the skin, but this is secondary to the altered biomechanics of a person with diabetes. **Figure 3** illustrates the areas of the foot that are at risk of ulceration due to increased plantar pressure and structural deformity. Load redistribution facilitates the healing of these ulcers.

A combination of the following increases the risk of a person with diabetes developing a foot ulcer: a) reduction in or loss of protective sensation; b) altered biomechanics; and c) reduced tissue perfusion caused by microvascular damage.

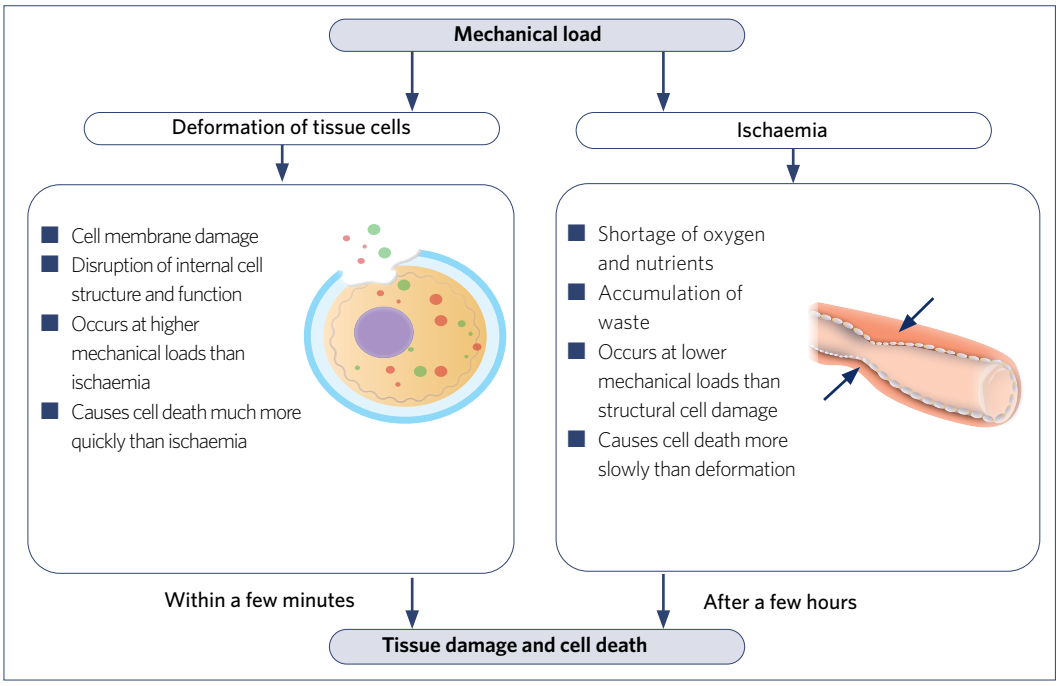


Figure 2: Main mechanisms of tissue damage and cell death due to mechanical loading (adapted from Oomens et al, 2015).

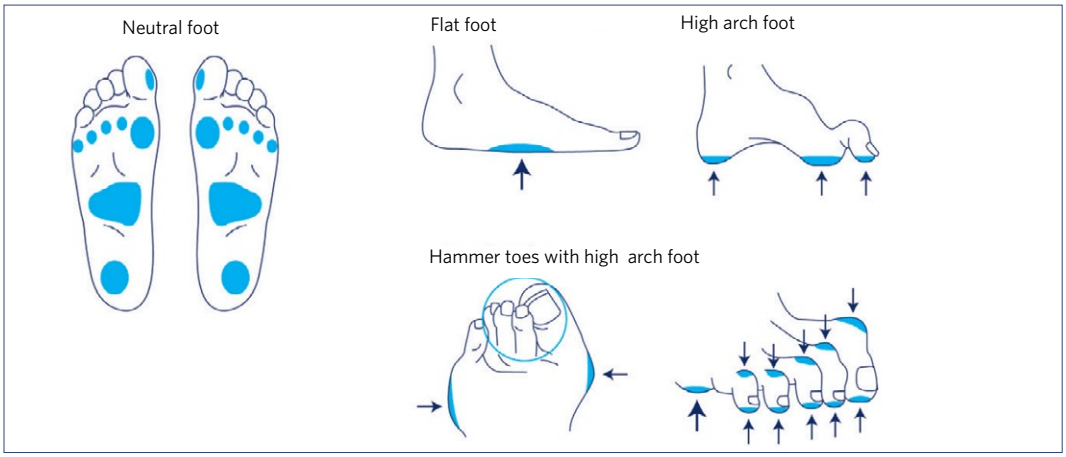


Figure 3. Areas at risk of ulceration due to increased plantar pressure depending on foot deformity (adapted from Bakker et al, 2012; Wounds International, 2013).

Holistic assessment

Assessment of the patient, the limb and the wound(s) identifies the factors associated with foot ulceration and directs the most appropriate care for the patient.

PATIENT ASSESSMENT

Patient assessment encompasses a full patient history (previous ulcer/lower-extremity amputation, claudication), vascular status, glycaemic status, skin health, current medication, ability to self-care, nutritional status, allergies, weight management and psychological wellbeing (Schaper et al, 2020). Wearing ill-fitting shoes and walking barefoot are practices that frequently lead to foot ulceration, so the patient's shoes and footwear behaviour should be examined closely (Schaper et al, 2020).

LIMB AND FOOT ASSESSMENT

Assessment of neuropathy: The IWGDF recommend that a Semmes-Weinstein 10-g monofilament is used to assess for pressure perception, and that a standard 128-Hz tuning fork is used to assess vibration perception (Schaper et al, 2020). If a monofilament or tuning fork is not available, test tactile sensation by lightly touching the tips of the toes of the patient with the tip of your index finger for 1 to 2 seconds (Rayman et al, 2011; Schaper et al, 2020).

Assessment of peripheral arterial disease/blood supply: The IWGDF recommend palpation of pedal pulses to assess vascular status (Schaper et al, 2020). If pulses are non-palpable, a range of non-invasive vascular diagnostic assessments for suspected peripheral arterial disease should be carried out, including clinical history, Doppler insonation of posterior tibial, anterior tibial, peroneal and popliteal pulses, ankle brachial pressure indexes and toe pressures.

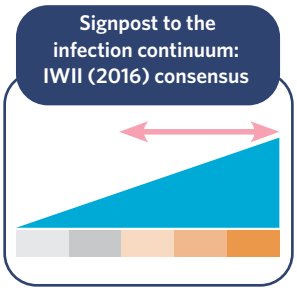
Assessment of musculoskeletal function: The IWGDF recommend the feet are checked for deformities, abnormally large bony prominences and limited joint mobility. Deformities may be caused by previous trauma, congenital conditions, ill-fitting shoes, neuromuscular conditions and prolonged soft tissue stress throughout the patient's lifetime. The feet should be examined when the patient is lying down, standing up and during movement (Khan and Armstrong, 2018; Schaper et al, 2020).

- **The physical exam** evaluates the appearance of the foot and ankle, muscle strength and the range of motion of the joints of the foot and ankle.
- **The standing exam** evaluates the foot and ankle for the presence of deformity on weightbearing loads.
- **The gait and balance exam** evaluates the foot and ankle in movement. The gait can be assessed as the patient walks into the clinic, as well as part of a formal gait assessment.

WOUND ASSESSMENT

Healthcare professionals should follow a standardised and consistent strategy for assessing and evaluating a foot ulcer, as this will guide further evaluation and therapy (Schaper et al, 2019). The diabetes-related foot ulcer should be classified as neuropathic, neuroischaemic or ischaemic. Wound assessment requires a detailed examination of the cause and duration of the ulcer, size and shape of the wound, tissue types, amount and type of exudate, and level of pain. Previous treatments, including the outcomes of treatment, and current footwear or load redistribution devices should also be reviewed. A diabetes-related foot ulcer classification system should be used to classify the wound and assist in consistent documentation and communication between staff, e.g. SINBAD (Ince et al, 2008), the University of TEXAS classification (Lavery et al, 1996a) and PEDIS (Chuan et al, 2015).

Holistic assessment



A considerable proportion of patients presenting with an non-infected foot ulcer will develop an infection prior to healing; therefore, it is important that all clinicians understand the signs and symptoms of infection (**Table 1**) and the more subtle 'secondary' signs of infection (Edmonds et al, 2004), such as level and consistency of exudate, malodour, wound undermining and friable granulation tissue.

Rapid assessment at the earliest opportunity of presentation provides practitioners the opportunity to stop the progression from mild infection to systemic infection (see the International Wound Infection Institute [IWII, 2016] infection continuum), which may lead to amputation.

Table 1. Clinical criteria of diabetic foot infections (Lipsky et al, 2012; NICE, 2019)

Clinical criteria
Local diabetic foot infection is defined by the presence of at least 2 of the following: ■ Local swelling or induration ■ Erythema ■ Local tenderness or pain ■ Local warmth ■ Purulent discharge.
Mild diabetic foot infection is defined by the presence of at least 2 of the above plus: ■ Local infection involving only the skin and subcutaneous tissue ■ Erythema >0.5cm but >2cm around the ulcer around the ulcer (exclude other causes of inflammatory response, such as trauma, gout, acute Charcot neuroarthropathy, fracture, thrombosis and venous stasis).
Moderate diabetic foot infection is defined by the presence of at least 2 of the above plus: ■ Local infection plus erythema >2cm around the ulcer ■ Infection involving structures beneath the skin/subcutaneous tissues (e.g. deep abscess, lymphangitis, osteomyelitis, septic arthritis or fasciitis) ■ No systemic inflammatory response (see severe diabetic foot infection)
Severe diabetic foot infection is defined by the presence of local infection plus two of the following signs of systemic infection: ■ Temperature >38°C or <36°C ■ Pulse >90bpm ■ Respiratory rate >20 breaths/min ■ $PaCO_2$ <32mmHg ■ White cell count 12,000mm^3 or <4,000mm^3 ■ 10% immature leukocytes

Patient suitability for offloading

Tools such as the Skellen Tool (Torbay and South Devon NHS Foundation Trust) can be used for assessing suitability for offloading in people with diabetes. The 'Skellen Tool' assesses a patient on two aspects of their foot profile, firstly their biomechanical structure and mobility, and secondly their ulceration risk factors. A sum of these factors is then calculated as the 'Skellen Score'. The higher the score the greater the assumed risk of ulceration and suitability for offloading (Ellin and Spicer, 2018).

The multidisciplinary footcare team

An ideal MDFT comprises:

- Diabetes specialist nurses
- Diabetologists
- Dietitians
- GPs with a specialist interest in diabetes
- Infection specialists
- Orthopaedic practitioners
- Orthopaedic surgeons
- Orthotists
- Patients and their family and/or carers
- Pharmacists
- Podiatrists
- Psychologists
- Social workers
- Vascular surgeons
- Wound care-trained nurses

THE IDEAL MULTIDISCIPLINARY FOOTCARE TEAM

A multidisciplinary footcare team (MDFT) approach is required when managing people with diabetes-related foot ulcers due to the association between diabetes management, vascular management, wound management, foot deformity and other comorbidities (WUWHS, 2016).

The ideal MDFT puts the patient at the centre of care and includes the full set of skills that the person with a foot ulcer requires. The ideal MDFT should be driven by a coordinator (or gatekeeper) to ensure that appropriate referrals are made and that care is integrated. The podiatrist or podiatry team are well placed to coordinate the MDFT supported by healthcare professionals with skills in the following areas: diabetology, biomechanics, orthoses, casting and wound care (NICE, 2019). Local resources will govern the availability and scope of the MDFT; it is hoped that there will be consistently greater integration between the diabetes team and the plaster room across the UK to support access to casting.

REFERRAL TO THE MDFT

For the non-specialist practitioner, a key skill is knowing when and how to refer a person with a diabetes-related foot ulcer to the MDFT. People with diabetes and a foot ulcer should be referred to the foot service within 24 hours of the initial examination or sooner in the presence of severe infection (SIGN, 2010; NICE, 2019; Short-life Working Group, 2019). Box 1 provides key action points on what to do at first presentation of a person with diabetes and a new foot ulcer.

Box 1. What to do at first presentation of a person with diabetes and a new foot ulcer (NICE, 2019)

- Refer the individual to your local podiatry-led MDFT within 24 hours of the initial examination of the person's feet or sooner in the presence of severe infection.
- Advise the individual to stay off the foot and rest.
- Do not put the individual's ulcerated foot into a closed shoe. If there are no load redistribution devices available, crutches, a wheelchair or felt padding can be used as a temporary measure until a load redistribution device is available (Baker and Osman, 2016).

If you or your service cannot provide access to a load redistribution device, the patient should be referred to a podiatry-led MDFT.

Question: Do you know how, when and where to refer people with diabetes-related foot ulcers in your area?

ROLE OF SURGERY

Surgery is often indicated to address the biomechanical abnormalities. Concerns regarding high infection rates following open surgery can mean there is caution or reluctance to offer surgical intervention to people with diabetes. Minimally invasive surgery (MIS) has prompted a resurgence in surgical consideration as it results in a more rapid and predictable post-operative recovery (Botezatu and Laptoiu, 2016).

All patients with at elevated risk or ulceration should be assessed for mechanical abnormalities that could be addressed with MIS. Patients with recurrent ulceration who have neuropathy should be discussed early with the orthopaedic team to determine if MIS would be feasible, which in turn would minimise recurrent ulcer and, therefore, amputation rates.

Offloading explained

The term 'offloading' is widely used when describing ways to support the healing of foot ulcers in people with diabetes, but the term may not provide a full understanding of the mechanics of therapeutic devices. The terms 'load redistribution', 'load sharing' and 'axial offloading' may better convey the mechanics of therapeutic devices that can be employed.

Load redistribution describes the principle whereby an increase in the weightbearing surface area over which the force is applied reduces the plantar pressure – this is sometimes referred to as the 'snowshoe principle' (Brand, 1966; Jahss, 1991; Munro, 2018). Load redistribution is assisted through load sharing and axial offloading by the mechanism of deflection. Figure 4 illustrates load redistribution, load sharing and axial offloading in regards to the foot.

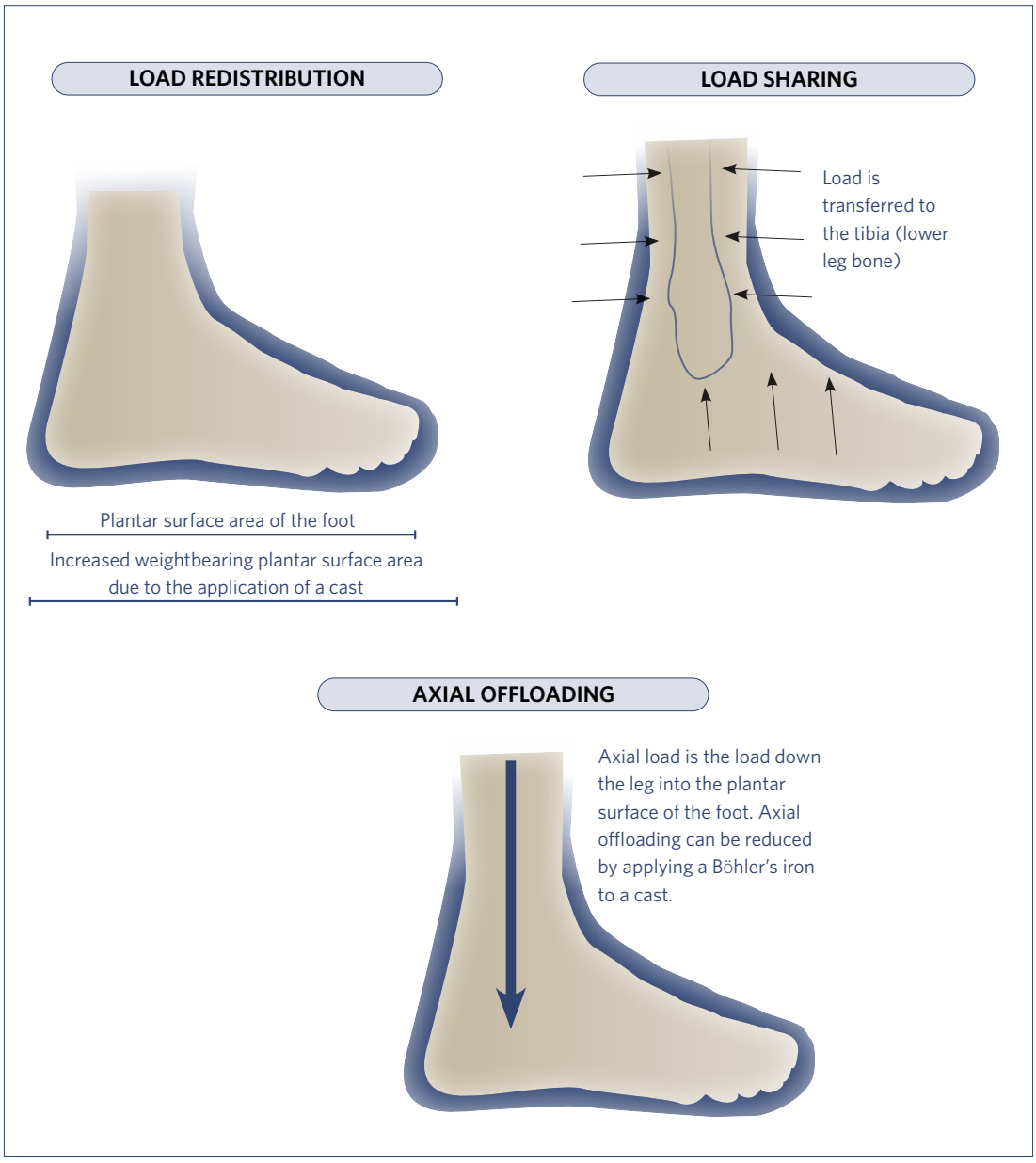


Figure 4. Load redistribution, load sharing and axial offloading of the foot. Blue shading indicate the effect of a therapeutic device.

Load redistribution and load share devices

In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer, the IWGDF recommend that a non-removable knee-high offloading device with an appropriate foot–device interface is the first choice of offloading treatment to promote healing of the ulcer (Bus et al, 2019). Non-removable, knee-high offloading devices consist of total contact casts (TCCs) and modified non-removable casts. Both devices provide load redistribution and load share. Table 2 includes the main features of TCC and modified cast.

- A TCC is a custom-made, minimally padded, knee-high non-removable cast that distributes pressure evenly over the entire plantar surface of the foot.
- A modified, non-removable cast is a pre-fabricated, knee-high, removable walker that has been made irremovable by applying a layer of cast or synthetic tape around the device (Bus et al, 2019). Other names include a non-removable walker or an 'instant TCC'.

A TCC or a non-removable knee-high modified cast is recommended as the first choice offloading device for people with diabetes and a foot ulcer (Bus et al, 2019).

Table 2. Features of a total contact cast (TCC) and modified non-removable cast relevant for the healing and management of diabetes foot ulcers (Munro and Abdul Hadi, 2017)

Features	TCC	Modified non-removable cast
Composition	Made from either a combination of POP and synthetic materials or synthetic materials only	Made from synthetic material
Padding	Very limited padding	Padding varies from centre to centre
Biomechanical consideration	Management of the STJ axis and mid-tarsal joints allows the optimal load distribution across the medial beam, lateral beam and hindfoot	May reduce the axial offloading in below-knee casts due to lack of circumferential containment because of increased padding
Weight	Dependent on materials used and application technique	
Application	A TCC for diabetes foot ulcer management is generally regarded to maintain contact with the entire plantar aspect of the foot and lower leg to offer the highest level of load redistribution and load sharing, but the cast can also be applied as a slipper or boot. How the cast finishes at the distal end should be aligned to the specific requirements of the patient (Bus et al, 2019).	A modified non-removable cast for diabetes foot ulcer management is generally recommended as a below-the-knee device to offer the highest level of load redistribution and load sharing, but the cast can also be applied as a slipper or boot. How the cast finishes at the distal end should be aligned to the specific requirements of the patient (Bus et al, 2019).
Drying time	20–30 minutes for synthetic material, up to 48 hours for POP to fully cure	20–30 minutes
Adjunct attachments	Knee-high casts can incorporate any adjunct attachments (e.g. Böhler's iron whereby the lower limb is suspended from the fibular head through circumferential containment to a similar pattern end)	
Considerations	Minor complications can be expected, particularly in the early stages of introducing casting. The majority of complications are minor, including dermal abrasions, and there is a small increased risk of maceration and fungal infections (Wukick and Motko, 2004). To reduce complications: • Consider any limb length discrepancy • Consider neuropathic pain as symptoms may be exacerbated by applying a cast.	

STJ: Subtalar joint; POP: Plaster of Paris.

Load redistribution and load share devices

There is a high level of evidence that supports the use of TCC in the healing of non-infected plantar ulcers, and that it reduces healing times by around 6 weeks (Lavery et al, 1996b; Armstrong et al, 2001; SIGN, 2010). However, the duration of treatment may vary depending on the ulcer complexity, type, size, classification and location.

Forms of TCC offer the highest level of plantar pressure relief (Cavanagh and Bus, 2010), but the application of TCC in the UK is inconsistent. In Europe, only 35% of plantar ulcers were treated using casting in specialist centres, with only half using TCC (Prompers et al, 2008). The reasons for the relatively low use of TCC are three-fold:

- **Service factors:** Casting should be conducted by appropriately trained and competent professionals to ensure all patients receive the highest standard of care. Trust board and healthcare service must recognise and respond to the changes in demand for casting services.
- **Clinician factors:** Clinicians require training, confidence and competence to efficiently apply all forms of load redistribution and load sharing devices and understand their mode of action.
- **Patient factors:** Positive verbal and body language should be used to emphasise the importance of casting, to address the patient's concerns and to manage their expectations. Patients should always receive the optimum treatment based on the resources, individual patient circumstances and prescription requirements.

If it is not possible to apply a TCC on the day of ulcer presentation, an alternative load redistribution device should be provided (NICE, 2019) to reduce plantar pressure, such as other types of knee-high modified casts, walkers or custom-made footwear. Table 3 summarise the key benefits, considerations and contraindications of load redistribution and load sharing devices.

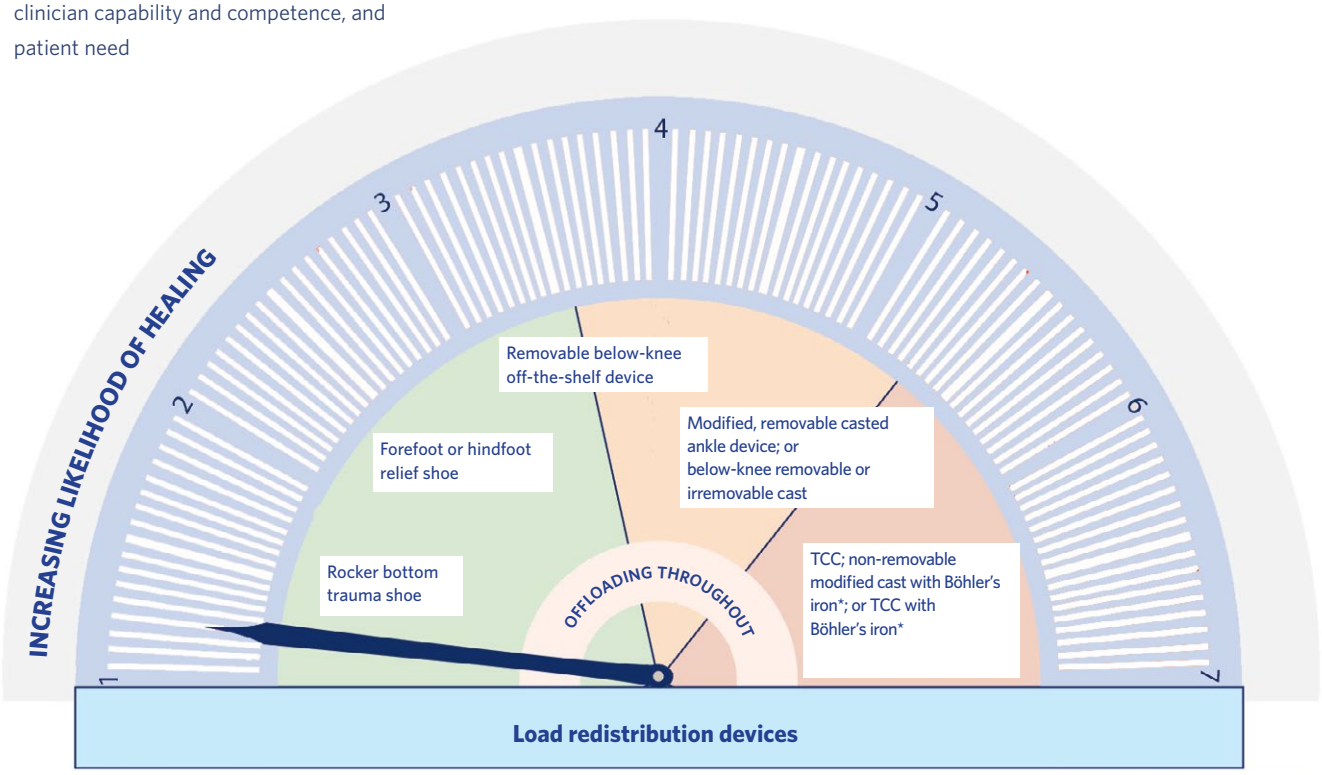
Table 3. Benefits, considerations and contraindications of load redistribution and load share devices (Lavery et al, 1996b; Armstrong et al, 2001)

Benefits	Considerations	Contraindications
■ Encourage and promote ulcer healing ■ Reduces oedema ■ Increases patient adherence ■ Decreases ambulation ■ Constantly reminds the patient of the foot ulceration ■ Raises awareness of family and friends of the seriousness of the condition	■ May restrict mobility and activities of daily living (e.g. driving, work) ■ Hindfoot ulcers at the margins of the calcaneum or the distal posterior border of the heel may not respond well (Munro, 2018) ■ Lone practitioners should refer in to an NHS multidisciplinary foot team in their locality	■ Deep foot ulcers where abscess, osteomyelitis or other deep or tracking infection is present ■ Critical limb ischaemia ■ Acute osteomyelitis ■ Presence of peripheral arterial disease, infection and oedema

REV COUNTER

The 'Rev counter' (Figure 5) illustrates the increasing likelihood of healing of different load redistribution modalities. The selection of device should be made after considering the availability, access to services and resources, clinician capability and competence, and patient need. The clinician applying and monitoring the load redistribution device should have the relevant level of capability and competence. Table 4 includes further details and examples of available load distribution devices. **Note:** The Rev counter is not intended to suggest that the patient is at first prescribed a removable rocker bottom trauma shoe and over time is progressed to a TCC.

Elements for consideration during load redistribution device selection: Availability of devices, access to services and resources, clinician capability and competence, and patient need



*The addition of a Böhler's iron provides axial offloading and significantly reduced weight transfer through the foot compared with a Sarmiento cast or standard below-knee cast among healthy volunteers (Berwin et al, 2015).

Figure 5. 'Rev counter' to illustrate the increased likelihood of healing of load redistribution devices.

Examples of load redistribution, load share and axial offloading devices

Table 4. Types of load redistribution devices (Registered Nurses' Association of Ontario, 2013; Munro, 2018)

Device	Mode of action and considerations
Load redistribution and load share devices: Total contact cast (TCC), non-removable modified cast, modified cast, load distribution cast	
Ankle Scotch-Cast boot   Cast sandal	■ Well-padded fibreglass boot, extending from just below the toes to the ankle. ■ Can be made removable or non-removable to allow frequent inspection of complex wounds. ■ The boot can be worn with a cast sandal to increase patient mobility. ■ For patients who are unsuitable for full casts.
TCC  Synthetic materials  POP	■ Custom-made, well-moulded, minimally padded, below-knee cast, made of either a combination of plaster of Paris (POP) and synthetic materials or synthetic materials only, which maintains total contact with the entire plantar surface and the lower leg. ■ TCC can be created using a range of casting techniques (Bus et al, 2019), e.g. focused rigidity casting and soft/soft combi technique. ■ Non-removable by the patient. ■ A rubber walking heel is attached to the bottom of the cast to enable weightbearing, or an off-the-shelf cast shoe can be used (Dhalla et al, 2003). ■ Reduces plantar pressure by 84–92% (Lavery et al, 1996b). ■ The healing rates of plantar ulceration treated with TCC range from 73–100% (Armstrong et al, 2001).
Non-removable modified cast e.g. TCC-EZ™ 	■ A custom-made load sharing/redistribution cast with additional padding using synthetic cast tape. ■ Non-removable by the patient. ■ Off-the-shelf cast shoes can be utilised for weightbearing.
Modified cast e.g. Delta-Cast® Conformable (patented synthetic cast tape that provides conformability, greatly reducing the need to tuck and fold during application)	■ A custom-made load sharing/redistribution cast with additional padding using synthetic cast tape. This may be circumferentially intact or bivalved to allow for dressing change. ■ Non-removable by the patient. ■ Off-the-shelf cast shoes are primarily used for weightbearing (Dhalla et al, 2003).
Load distribution cast e.g. Patella tendon-bearing orthosis or Sarmiento cast 	■ Offers the same mode of action as TCC but via different methods (e.g. materials, adjuncts, application processes or cast designs) ■ Non-removable by the patient ■ Bespoke to the patient

Examples of load redistribution, load share and axial offloading devices

Table 4 cont. Types of load redistribution devices (Registered Nurses' Association of Ontario, 2013; Munro, 2018)	
Device	**Mode of action and considerations**
Load redistribution and load share devices: Off-the-shelf walkers (also known as removable cast walkers/instant TCC)	
Air cast boot e.g. Rebound® Air Walker 	■ Offloads weightbearing pressure from the foot. ■ Available in a range of rigidities and costs. ■ Patient can remain ambulatory. ■ Removable by the patient, but can be made irremovable. ■ No clinical data to support the efficacy compared to TCC.
Vacuum cast (VACOcast® Diabetic) 	■ Suitable for patients with neuropathy, arterial diseases, highly exuding wounds and infected wounds. ■ Not suitable for patients with leg deformities or chronic Charcot foot. ■ Non-removable by the patient. The device can be locked and unlocked with a key by authorised personnel, such as community health professionals for wound dressing change. ■ Available in three sizes and comes as a complete set, including replacement liner and sole. ■ Provides total contact offloading comparable to TCC (Götz et al, 2017) with no pressure applied.
Load redistribution footwear: forefoot-relief shoes, hindfoot-relief shoes, trauma shoes, ankle-height modified casts	
Forefoot-relief shoes 	■ Offloads weightbearing pressure from the forefoot to promote healing of forefoot ulcers. ■ Removable and easy to apply. ■ More visually discreet than a cast. ■ May have a place in the early management of wounds classified as Texas A (not an ulcer), 1 and possibly 2 (Munro, 2018) ■ Relatively inexpensive. ■ Can hamper gait.
Heel-/hindfoot relief shoes e.g. Multicast Post-Operative Heel Relief Shoe 	■ Offloads weightbearing pressure from the hindfoot to promote healing of the heel. ■ Removable and easy to apply. ■ Maintains the foot in a stable configuration that promotes pressure relief and dorsiflexion at heel strike if the patient is ambulant.
Bespoke ankle-height modified casts e.g. Pressure relief ankle foot orthosis (PRAFO®)  	■ Creates an air space around the back of the heel, alleviating pressure and preventing heel ulcers. ■ The metal posterior upright component is adjustable to the patient's gait and, therefore, gait can be tuned accordingly. ■ Removable by the patient.

Table 4 cont. Types of load redistribution devices (Registered Nurses' Association of Ontario, 2013; Munro, 2018)	
Device	**Mode of action and considerations**
Rocker trauma shoe 	■ Replaces the lost function of a joint and reduce pressure on the sole of the foot so can be helpful when walking or standing for long periods. ■ Removable by the patient. ■ Care should be taken regarding the position of the rocker shoe (optimal position is behind the metatarsal heads for forefoot ulcers).
Axial offloading devices: Load distribution cast with Böhler's iron	
Load distribution cast with Böhler's iron e.g. Beagle Böhler's iron with open-toed TCC 	■ Addition of Böhler's iron to a below-knee TCC or non-removable modified cast provides axial offloading and can permit weightbearing and maintenance of functional activity. ■ A Böhler iron applied to a below-knee cast significantly reduced weight transfer through the foot compared with a Sarmiento cast or standard below-knee cast (Berwin et al, 2015). ■ Cast and iron attachment is non-removable by the patient.
Felted foam Bilayered felted foam over the plantar surface with opening for the wound	■ Inexpensive and accessible. ■ Can increase pressure and shear at wound edges if not properly applied and monitored. ■ Frequent changes required. ■ Few low-grade studies to suggest its efficacy in offloading.
Prescription footwear with foot orthoses	■ Beneficial in preventing recurrence of ulceration and there is some evidence to suggest prevention of primary ulceration. ■ Not recommended in the healing stage of ulceration.

Offloading considerations

Selecting the appropriate load redistribution device is based on the following considerations (adapted from Registered Nurses' Association of Ontario, 2013):

- Characteristics of the patient, limb, foot and ulcer(s).
- The skills of the individual applying the load redistribution device. The individual should be a properly trained healthcare professional, who — according to the latest national or regional standards — has the competency, confidence and capabilities necessary to manage patients with a DFU (based on Bus et al, 2019).
- Ability of the device to redistribute plantar pressures and offload bony prominences, which will remain at risk of ulceration.
- Availability of load redistribution device (i.e. custom-made or off-the-shelf).
- Cost-effectiveness of the device.

KEY PATIENT CONSIDERATIONS WHEN CHOOSING A LOAD REDISTRIBUTION DEVICE

Gait and balance: All load redistribution devices will alter a person's gait, so it is important to take special consideration of spinal or balance issues when selecting an load redistribution device, e.g. such as the load applied to a knee, hip or spine with osteoarthritis, or if the patient has had a previous stroke or is blind (Baker and Osman, 2016).

The patient may require an appropriate gait aid and gait training to ensure the risk of any injury or loss of balance is minimised. If the patient has a cast, a cast shoe may be required to allow mobility. Several cast shoe designs are available with different sole characteristics (e.g. flat or rocker sole). Devices are also available to place on the opposite shoe in order to correct any leg length discrepancy that often occurs with the application of a cast or other offloading shoes (Registered Nurses' Association of Ontario, 2013).

Deep vein thrombosis (DVT): While published evidence suggests there is an increase risk of DVT in post-surgical foot and ankle patients, there are only anecdotal reports for the risk of DVT in diabetic foot disease. TCC has not been shown to increase the risk of DVT in ambulatory patients. Further prospective studies specifically addressing the question are urgently needed (Voukali et al, 2016).

Wound infection: The use of load redistribution devices may improve the initial response to antibiotics prescribed for acute infection (Baker and Osman, 2016), but an acutely infected wound should not be placed into a non-removable cast device. Removable casts can be used with careful, frequent observation when infection is under control (Baker and Osman, 2016). To dress the wound, consider selecting an antimicrobial dressing to reduce wound bioburden and manage exudate.

Wound exudate: Effective offloading of the ulcer will enhance healing of the wound, thereby reducing exudate levels and risk of infection. Ensure that the surrounding skin of the wound is protected from maceration and a dressing that controls moisture is selected. Frequent dressing changes may be required, which may impact on the choice of load redistribution device.

Wound location: The location of the wound will direct the choice of load redistribution device:

- **Heel:** The heel can be one of the more difficult areas to offload, heal and prevent relapse. The approach to heel offloading is one of total load reduction by patient rest, either with the foot on the floor or lying in bed.
  - ☐ When weightbearing, Pressure Relief Ankle Foot Orthoses (see Table 4) may be used in conjunction with a hindfoot relief shoe and crutches or a walking frame.
  - ☐ For non-weightbearing, especially during prolonged episodes in bed, commercially available removable boots (e.g. FootSafe), devices fitted to bed (e.g. HeelSafe) or pressure-redistributing mattresses with

a specific heel zone can be used following assessment. This follows the Check, Protect, Refer (CPR) system adopted and implemented nationally in Scotland (Health Improvement Scotland, 2020). The heel can prove a challenge for effective offloading when patients are in hospital or the community setting and following a strategy, such as CPR, has proven to be beneficial for prevention and treatment.

- **Mid-foot:** This area of the foot is best supported by the use of a non-removable cast, such as a TCC. The base of the cast needs to be a flat surface if the cast is to be weightbearing, this can be achieved by building up the plantar surface of the cast.
- **Forefoot:** Any device that prevents forefoot loading should be used if there is a forefoot ulcer. A half shoe may be useful, but a lower-limb or boot cast is the most effective method for offloading (Bus et al, 2015).
- **Toes:** Shoe rub is the main reason for toe ulceration so shoe uppers should not touch the toes, while at the same time, the shoe fastenings must be sufficient to prevent the foot from moving within the shoe. If casts are applied and toes are exposed, great care must be taken to protect the toes from trauma.

Factors that will determine the type of load redistribution device that is suitable for the patient, include the patient's gait and balance, status of wound infection and exudate and wound location.

IN REMISSION — THE JOURNEY IS NOT OVER

The patient's journey is not over once the ulcer heals, and prevention of ulcer recurrence in the at-risk population should be a priority. Guidance should be given to patients on how to check their feet for damage, how to select socks without ridges/prominent stitching around the toes or heel, which may lead to rubbing, and how to check their footwear for the presence of any debris/materials that may cause foot trauma. People with diabetes who are at risk of ulceration or reulceration should protect their feet regardless of whether they are inside or outside:

- Avoid walking barefoot.
- Avoid wearing only socks or thin-soled standard slippers.
- Avoid exposing their feet to heat (e.g. resting on a hot water bottle).
- Wear properly fitting footwear or therapeutic footwear. Therapeutic footwear has a demonstrated plantar pressure-relieving effect during walking (Bus et al, 2016).

Prophylactic devices such as pre-fabricated or bespoke insoles; ankle, foot and in-sole orthoses; and prescription footwear can also be helpful. Post-cast footwear and orthoses need to be considered while casting is still being used by the patient to ensure application when the cast is removed. Physiotherapy may be necessary if there has been significant muscle wasting and it is available in the locality.

Listening to the patient's concerns about receiving a cast and communicating the realistic expectations of casting with the patient can help to encourage acceptance and adherence to treatment (Table 5).

Table 5: Concerns and patient expectations relating to casting.

Patient concern	Example responses from clinician
Can I work?	"It is important that you rest your leg, so, if your place of work can allow you to sit down, work from home, or negotiate your duties while you are wearing the cast, that would be beneficial. If you are unable to work, I can provide a letter of support/sick note."
Can I drive?	"Depending on the affected foot, you will need to contact your insurer to check whether you can drive. If you have an automatic car or adapted hand control car, your insurance may allow you to drive, but check first."
Will I be able to carry on being as active as before?	"A cast is designed to slow down your lifestyle so your foot can heal. We usually change a cast within a week, and it will need changing more at the start due to increased oedema. You may experience some muscle wasting while wearing a cast. If there is significant muscle wasting in the first 2 to 4 weeks, we may need to change the cast to improve fit. If muscle wastage is significant once the cast is removed, physiotherapy can help to rebuild muscle." *Note: The level of activity is very individualised to the patient: some patients are very active in a cast, while others struggle, and the device should be adapted to fit the person.*
How can I be intimate with my partner?	"Try having an open, honest discussion with your partner." *Note: Physiotherapy may be able to assist, as they often offer support and handouts for people who have had hip replacements for example.*
How can I sleep with this thing on?	"I understand it is uncomfortable, but in the long-term it will help to heal your ulcer. While you sleep, it's important to protect the opposite leg to avoid scratches or rubbing. Tights or long socks over the cast, and pillows between the leg can make sleeping more comfortable."
Will the cast smell?	"Frequent cast changes normally mean that the cast itself will not smell. However, If there is an increase in foul smell from the ulcer and it is accompanied by an increase in pain, warmth or inflammation, seek medical attention as it could indicate there is an infection."
What if my leg gets itchy under the cast?	"It is rare that you will experience itching; however, if you do experience some itching under the cast and it is not improving, you need to contact the service who applied it immediately to check there is no underlying deterioration to the skin integrity. Do not attempt to scratch the skin to relieve the itching with knitting needles or similarly sharp objects, as this could break your skin."
How can I shower or bathe with a cast?	"To try to keep the cast dry, use a waterproof cover (e.g. LimbO® Waterproof Protector, Seal-Tight Cast/Dressing Protector) that you can apply over the cast while you bathe or shower. " *Note: Discuss their bathroom set-up. Is it a bath they have to step into? If so, and they have poor balance, it might be pertinent to refer to occupational therapy to arrange a shower chair or other assisting equipment.*

Reduce practice variation

Reducing practice variation among people with diabetes and foot ulcers requires effective holistic assessment, accurate diagnosis and management. To achieve this, several interlinking steps are required: improved clinical skills, supported/shared care and evidence-based practice (Figure 6).

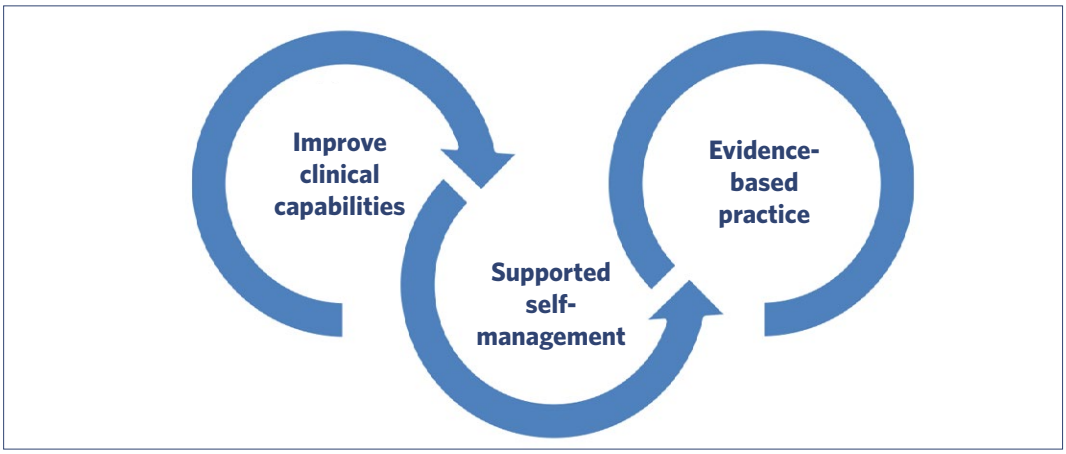


Figure 6. To reduce practice variation requires a three-pronged approach.

IMPROVE THE CAPABILITIES OF ALL HEALTHCARE PROFESSIONALS WHO MAY ENCOUNTER PEOPLE WITH DIABETES AND FOOT ULCERS

The Lower Limb Capability Framework assesses a clinician's capabilities to care for people with diabetes who have foot ulcers (Short-life Working Group, 2019). It comprises 16 dimensions on lower-limb care and is relevant for all clinicians in the MDFT. The dimensions are divided into Levels A–F, which reflect increasing complexity of care (i.e. Level A: Healthcare Technician, to Level F: Consultant Clinician). No single clinician needs to possess all of the capabilities to the highest level, rather these capabilities should be reflected across the team or service responsible for delivering local diabetic foot care (Short-life Working Group, 2019). Chapter 15 refers specifically to the capabilities required for "Load distribution, load sharing and axial offloading in an active diabetic foot".

A nationally agreed set of principles for the management of people with diabetes-related foot ulcers and Charcot neuroarthropathy is required. Clinical training and patient education already exist, and these should be harnessed and managed to deliver sustainable, quality-assured services nationally (Munro et al, 2018). This could take the shape of an accredited university course on casting for allied healthcare professionals, which would also strengthen links with orthopaedic practitioners in the MDFT.

SUPPORTED SELF-MANAGEMENT

Supported self-management with the patient should be approached with a critical eye to ascertain the patient's willingness and ability to engage in their own care. All patients should be provided with the relevant information (in plain language) and have access to the resources they need. The National Wound Care Strategy Programme (2020) has developed a tool to assess whether shared care is appropriate: https://www.ahsnnetwork.com/wp-content/uploads/2020/04/Shared-Care-for-Wounds-30.03.20.pdf

IMPLEMENT RESEARCH INTO EVIDENCE-BASED BEST PRACTICE BY FOLLOWING PATHWAYS TO SUPPORT STANDARDISED PATIENT CARE

High-quality, head-to-head studies continue to provide insights into the link between intervention and outcomes. The diabetes foot community requires standard definitions of basic parameters, such as wound healing and remission because without a standard vocabulary it is impossible to accurately evaluate and synthesise the studies that are available.

In the future, there will be analysis of the cost-effectiveness of diabetes foot care. Despite the continuing pressure of healthcare cost, there has been little attention in studies on footwear and offloading (Bus et al, 2016b). Another area of research under way is investigating the ability to monitor circulation under casting, with the potential to safely provide casting to more people who may be at high risk of ulceration.

TAKE-HOME MESSAGES

- For the non-specialist practitioner, the key skill required is to know when and how to refer a person with a diabetes-related foot ulcer to the MDFT.
- Identifying the cause and type of the load distribution anomaly through an holistic wound, limb and patient assessment will guide selection of the most appropriate care and therapeutic device for the patient.
- When selecting the load redistribution device, the following must be considered: wound location, level of exudate, presence of wound infection, and how offloading will affect the person's gait and balance.
- Wound infection is very common; many people with diabetes will initially present with non-infected ulcers, which will become infected. It is important to be aware of the signs and symptoms of infection to ensure rapid intervention.
- Reducing practice variation requires accurate and thorough holistic assessment, appropriate diagnosis and the adoption of evidence-based methods of practice. This requires three elements: improved clinical capabilities, encouragement of supported self-management with the patient and implementation of evidence-based practice.

OVER TO YOU — NEXT STEPS

Now consider the following questions about the availability of MDFT services in your locality and load redistribution devices:

- Do you have training, knowledge and experience to apply:
  - ☐ TCC?
  - ☐ Non-removable walkers?
  - ☐ Bespoke casting?
  - ☐ Modified pre-fabricated casts?
  - ☐ Therapeutic footwear?
  - ☐ If not, do you know who to refer to?
- Is there a MDFT in your organisation?
  - If so, do they follow existing pathways and guidance, such as NICE, SIGN?
- Do you know the MDFT referral waiting time for individual's first presentation of ulceration?

If any of the answers are no, find out how you can implement pathways to improve patient care in your area.

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